

## LOW VISION

# The Implantable Miniature Telescope, Part One: The Device and the Surgery

BY ANNIE STUART, CONTRIBUTING WRITER

Patients who have lost central vision due to end-stage, age-related macular degeneration may soon have hope for some restoration of their visual field with the Implantable Miniature Telescope (IMT). Developed by VisionCare Ophthalmic Technologies, the 4-mm implantable telescope replaces the lens in one eye and redirects central vision images onto undamaged parts of the retina surrounding the macula, using either 2.2x or 3x magnification. The untreated eye provides peripheral vision for mobility and orientation. VisionCare has filed for FDA approval.

While there are no similar devices now on the U.S. market, some ophthalmologists may be aware of other telescopic devices, including the “IOL-VIP” (Intraocular Lens for Visually Impaired People) system, developed by an Italian company and distributed in the United Kingdom and Ireland by Veni Vidi. It consists of two intraocular lenses implanted in the eye—one highly concave, one highly convex—with the space between functioning as a Galilean telescope. Its shortcoming is that, when inside the eye, the telescope’s fluid doesn’t allow much

*This is the first installment of a two-part story in which EyeNet takes a look at a promising investigational implantable telescope for end-stage age-related macular degeneration. Part two will examine steps for streamlining the surgical experience and enhancing the postop results for patients.*

magnification, a problem solved by the IMT’s air-filled cylinder, said Baruch D. Kuppermann, MD, PhD, professor of ophthalmology and chief of the retina service at the University of California, Irvine.

Following is a look at the status and potential promise of the IMT.

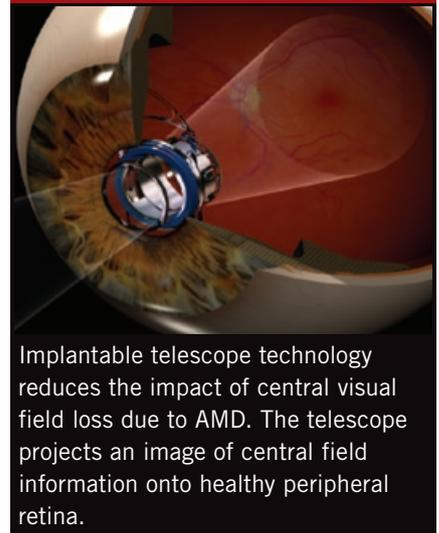
### Promising Clinical Trial Results

Two-year results from a prospective, multicenter phase 1 and 2 trial of 217 patients were published in November 2008.

AMD patients with moderate to profound bilateral impairment of their central vision received the third generation of the telescope implant, with integrated wide-angle micro-optics, and it greatly improved visual acuity and patient satisfaction rates, said Henry L. Hudson, MD, lead author for the study and a retina specialist in private practice in Tucson, Ariz. The wide-angle feature doubled the field of view when compared with the earlier midstudy results.<sup>1</sup>

Two years after implantation, 60 percent of telescope-implanted study eyes gained three lines or more of visual acuity, compared with 10 percent of fellow eye controls. The 3x model produced even greater improvement—an average of 3.6 lines.<sup>2</sup> Median visual acuity improvement was more than three lines better in telescope-implanted eyes than fellow eyes undergoing cataract surgery and IOL implantation. These results answered, in part, a question raised early on by the FDA: Had

### Re-Refracting the Light

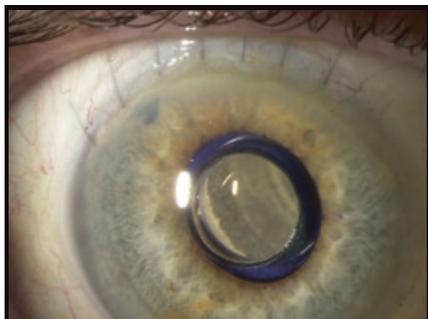


Implantable telescope technology reduces the impact of central visual field loss due to AMD. The telescope projects an image of central field information onto healthy peripheral retina.

results been inadvertently enhanced by concurrent procedures? In other words, how much was vision improvement simply due to removal of a cataract rather than from the telescope itself?

Dr. Kuppermann said that patients with end-stage AMD who have cataract surgery gain mostly peripheral vision, whereas, in this study, the benefits were to central vision. And he believes the telescopic device is responsible for this effect.

“This is a group of patients with very limited visual potential who now can improve their vision three or sometimes four lines or more,” said Stephen S. Lane, MD, a medical monitor for the trial and an adjunct professor of ophthalmology at the University of Minnesota in Minneapolis. “For



The telescope implant is virtually unnoticeable in this six-week postop eye. The device is secured in the capsular bag after large-incision phacoemulsification lens removal.

someone who is essentially blind, that's a big change in vision."

And, although it's not a cure, it's exciting to provide an option for patients who, other than vision rehabilitation, may have no other recourse, said Kristin Carter, MD, a comprehensive ophthalmologist in private practice in Tucson, Ariz. Dr. Carter was one of the investigators for the IMT study.

In March 2009, the FDA Ophthalmic Devices Advisory Panel recommended, with certain conditions, approval of the premarket application for the IMT.<sup>3</sup>

"We're working closely with the FDA to complete the regulatory process," said Allen W. Hill, president and CEO of VisionCare, who noted that the telescopic device has regulatory approval in Europe.

### Challenges of the Procedure

"The IMT is functionally a Galileian telescope," said Dr. Kuppermann, who was an author of the phase 1 trial report.<sup>4</sup> Unlike a foldable intraocular lens that's injected through a very small incision during cataract surgery, the telescope procedure is unique. It utilizes phaco removal of the crystalline lens, but with specific wound and capsular bag preparation. The surgeon first coats the telescope implant with viscoelastic, then carefully lifts the cornea to avoid IMT contact with the endothelium during insertion. The telescope is implanted into the bag, and the surgeon sutures the incision closed, removing the viscoelastic prior

to placing the last suture. "A cylinder on a haptic plate, the IMT can be seen protruding, sometimes coming to the edge of the pupil or beyond," said Dr. Kuppermann.

### A Tiny Giant in the Chamber?

Dr. Hudson initially had concerns about the size of the implant. "At first, I had doubts," he said. "I was concerned that the height of the device and its protrusion into the anterior chamber would cause frequent cases of corneal decompensation. I'm glad this did not occur." After seeing the results with his first implant, in a man who'd been told for 15 years that nothing more could be done, Dr. Hudson said he became excited about the prospects for other patients.

### This device needs skilled hands.

Although an outpatient procedure done under local anesthesia, the surgery does require special skills and takes about an hour to complete. That's mainly because of the telescope's large size, said Dr. Carter. "It's like putting four lens implants in at once. The implantation and suturing takes a lot longer than with a phaco, and the implantation is more challenging due to the thickness of the IMT."

For this and other reasons, training is critical, said Dr. Hudson.

### Endothelial Cell Loss

Although the IMT clinical trials exceeded expectations in some respects, Dr. Lane said he was not content with the level of endothelial cell loss, which was 27 percent two years after surgery.<sup>2</sup> However, he added, this complication was mainly due to surgical trauma; therefore, steps to minimize trauma could also limit cell loss.

**Big device needs big incision.** Due to the bulk of the device, incision size is a big consideration, said Dr. Lane. "We found that you need to have a larger incision than we were using in the earlier study. Initially, we were trying to do things through a smaller incision—maybe 9 or 10 mm. You really need to make sure it's 12 mm."

Another surgical challenge has to do with space, said Dr. Lane. "It's a

very big prosthetic device so you need a lot of room to put it in. You're talking about a telescope that is 4 mm in height compared with a standard lens implant that is a fraction of a millimeter in thickness."

Any extra pressure from behind can make it very difficult to put the lens in, he added.

**More ways to save cells.** Dr. Lane described other steps taken in the subsequent trials to minimize endothelial cell loss.

One involved thorough coating of the device with viscoelastic. The potential postapproval surgical protocol, based on the March Advisory Panel recommendation, might involve FDA labeling to mandate specific selection of patients with adequate cell counts. "You want to start with someone who has a healthy endothelial cell layer to make sure there is an adequate number of cells," he said.

### Weighing Trade-Offs

Aside from concerns about endothelial cell loss, the telescope implant presents a few, mostly manageable, trade-offs. "Once a person has the implantable telescope, it's relatively hard to evaluate the macula because the view through the cylinder is challenging," said Dr. Kuppermann. Although administering injections of VEGF is easy, knowing whether they're needed is another matter due to this minified view, he said.

Dr. Kuppermann added that the IMT procedure sacrifices peripheral vision in the treated eye because the telescope implant renders the central field on this area. However, patients maintain peripheral vision in the untreated eye. And since the device is inside the eye, patients can scan the entire field in front of them with the telescope eye using natural eye movements.<sup>5</sup>

Lylas G. Mogk, MD, director of the Visual Rehabilitation and Research Centers at the Henry Ford Health System in Detroit, described some other factors to consider when comparing the pre- and postop visual function of these patients:

**Images are larger, not clearer.**

True, the IMT improves vision as tested one letter at a time, monocularly, said Dr. Mogk, but it does this by making print three times bigger so the patient can see three lines smaller. “This is not the same experience as having vision become more acute,” she said. “And it requires the individual to switch back and forth from one eye to the other. Because vision in one eye is three times bigger, the procedure also eliminates binocular depth perception.”

**Contrast sensitivity is compromised.**

“Contrast sensitivity is reduced in macular degeneration already,” said Dr. Mogk, “and although contrast sensitivity was not specifically studied in the trials, the telescope implant probably does diminish it even more, reducing the ability to distinguish between objects of similar tone to their background, including faces and shapes that blend with their backgrounds.”

**Scotoma pattern may matter.** The third factor affecting function for any person with AMD is scotoma pattern, she said. “When you put it all together—size of images, contrast, scotoma pattern—how much will IMT do for you beyond just holding an external telescope?” she asked. “For carefully selected patients, it may allow more flexibility than external devices, but anyone considering an IMT should be exposed to the range of alternatives in vision rehabilitation, as there are devices that are easier to use and more suitable for many senior patients.”

1 Hudson, H. L. et al. *Ophthalmology* 2006;113:1987–2001.

2 Hudson H. L. et al. *Am J Ophthalmol* 2008;146:664–673.

3 [www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OphthalmicDevicesPanel/ucm128172.htm](http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OphthalmicDevicesPanel/ucm128172.htm).

4 Lane, S. S. et al. *Am J Ophthalmol* 2004;137:993–1001.

5 Peli, E. *Optom Vis Sci* 2002;79:225–33.

*Drs. Hudson, Lane and Mogk are paid consultants to VisionCare but have no financial interests in the IMT. Drs. Carter and Kupperman served as clinical investigators in the IMT trial.*



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