

Implantable Miniature Telescope

The first-ever technology approved for end-stage age-related macular degeneration.

BY TIFFANY L. CHAN, OD

Age-related macular degeneration (AMD) is a progressive retinal condition and is the leading cause of legal blindness in individuals over the age of 60 years. In the United States, approximately 1.75 million people suffer from AMD, and the number is expected to increase to 3 million by 2020.¹ It is estimated that approximately 30% of adults older than 75 have some signs of AMD, and approximately 10% of them demonstrate advanced or late stages of the disease.²

Progression of AMD can lead to a decline in the ability to see fine detail and a loss of central vision in one or both eyes (Figure 1). As AMD worsens, patients will frequently develop irreversible retinal damage, including large areas of atrophy or scarring in the macula. For patients with advanced AMD, this loss of central vision can have a significant impact on their ability to perform activities of daily living, including reading, recognizing faces, and driving. The Beaver Dam Eye Study showed that poor visual acuity, poor contrast sensitivity, and a discrepancy in vision between the two eyes were positively correlated with the risk of falling.³ The study also found that vision impairment is an independent risk factor of mortality with a hazard ratio of 1.24.⁴

Until now, there have been no medical treatment options to offer patients with end-stage AMD. Therapies targeting vascular endothelial growth factor have greatly improved outcomes for neovascular or “wet” AMD.⁵ If fibrosis or scarring occurs, however, the sight-threatening damage is irreversible. Similarly, no medical interventions are available to reverse retinal damage seen in patients with advanced atrophic or “dry” macular degeneration. To maximize the remaining vision, low-vision rehabilitation and visually assistive equipment should be implemented to help patients with managing tasks and to enhance independence and functioning with their daily activities.

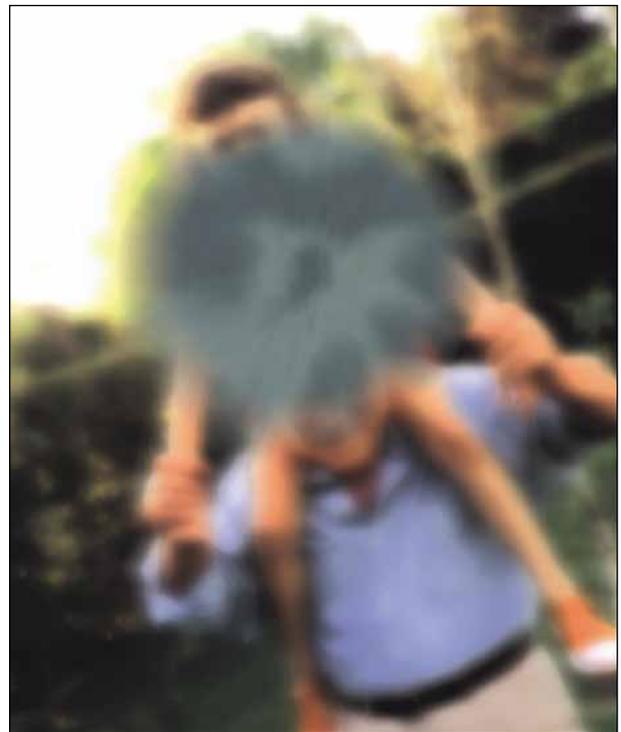


Figure 1. End-stage AMD is the leading cause of blindness in the United States. The disease creates a permanent central vision blind spot making it difficult or impossible to recognize even close family or friends.

THE IMPLANTABLE MINIATURE TELESCOPE

The Implantable Miniature Telescope (IMT, VisionCare Ophthalmic Technologies) is the first surgical intervention approved for patients with end-stage AMD (Figure 2). It was approved by the US Food and Drug Administration in July 2010. The telescope implant is an intraocular visual prosthetic device, which is inserted into the lens capsule during cataract extraction in lieu of a traditional IOL (Figure 3). The power of

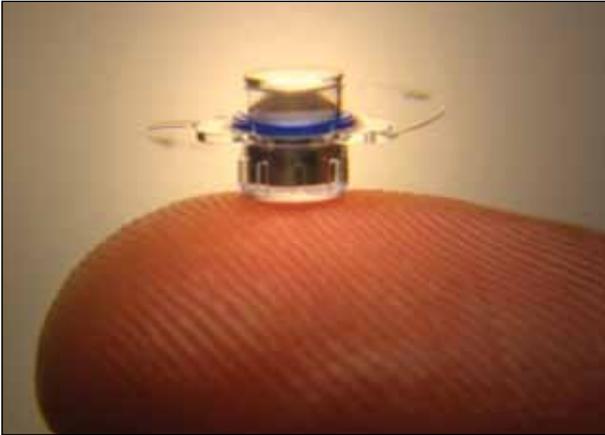


Figure 2. Smaller than a pea, the telescope implant uses wide-angle micro-optics to improve vision for patients with end-stage AMD, the most advanced form of macular degeneration.

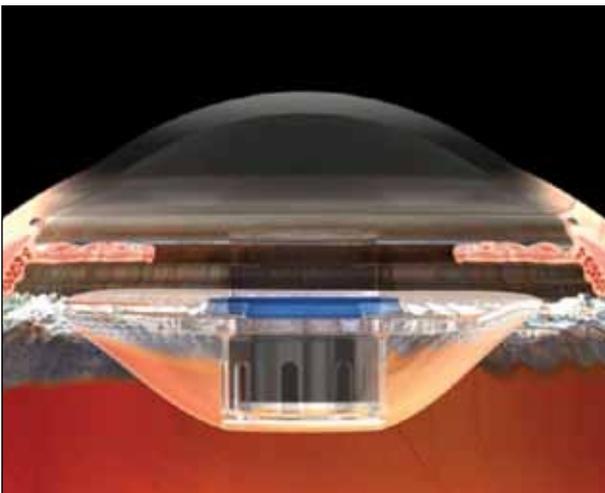


Figure 3. The tiny telescope is implanted in place of the eye's lens to help improve vision in patients with end-stage AMD.

the miniature telescope helps to magnify images two to three times their original size with the goal of improving the central vision in one eye of patients with moderate to profound visual impairment (Figure 4).

Patient selection for the telescope prosthesis is critical, and there is an extensive screening process involved (Table). It is approved for patients 75 years or older with stable, bilateral, end-stage AMD with either geographic atrophy or disciform scarring involving the fovea. Visual acuity criteria include a BCVA of 20/160 to 20/800 in the better-seeing eye. The telescope implant is implanted into one eye and, at this time, candidates cannot have had prior cataract surgery in that eye. Many ocular comorbidities, which may increase

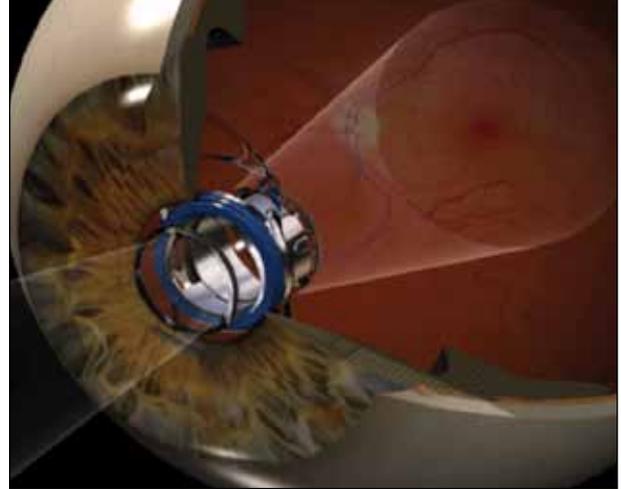


Figure 4. CentraSight's implantable telescope technology reduces the impact of the central vision blind spot due to end-stage AMD. The telescope implant projects the objects the patient is looking at onto the healthy area of the light-sensing retina not degenerated by the disease.

the likelihood of complications, are criteria for exclusion such as pseudoexfoliation, corneal dystrophies, optic nerve disorders, or pathology that compromises peripheral vision in the fellow eye.

PRE- AND POSTOPERATIVE CONSIDERATIONS

Both before and after surgery, patients work closely with low-vision specialists and occupational therapists to ensure that they will be able to utilize the device fully. An external telescope simulator helps to demonstrate the telescopic power prior to surgery. With this simulator, the patient is able to appreciate the visual enhancements made with the telescope, but also importantly, understand the limitations of the device. Like any telescope, the image is larger, but the field of view is reduced. The telescope implant has a field of view of approximately 20°. As stated previously, the telescope is implanted into one eye. The implanted eye will be responsible for detailed vision, and the fellow or nonsurgical eye will be responsible for peripheral vision tasks, including ambulation.

Although the telescope implant can provide approximately two to three times magnification, a person with end-stage AMD will still require glasses and visually assistive equipment after the procedure. This is an important aspect that patients need to be educated about. Additionally, driving is contraindicated, even if the individual meets the vision requirements in his or her state. From a practical standpoint,

TABLE. ELIGIBILITY REQUIREMENTS

Summary of patient eligibility criteria for the implantable miniature telescope:

1. At least 75 years of age
2. Bilateral, stable end-stage AMD with retinal findings of geographic atrophy or disciform scar with foveal involvement
3. BCVA of 20/160 to 20/800 in the better-seeing eye
4. Evidence of a cataract in the eye considered for the implantable telescope
5. Be willing to undergo preoperative screening and postoperative training with a low-vision specialist and/or occupational therapist

(Courtesy of James Gilman)

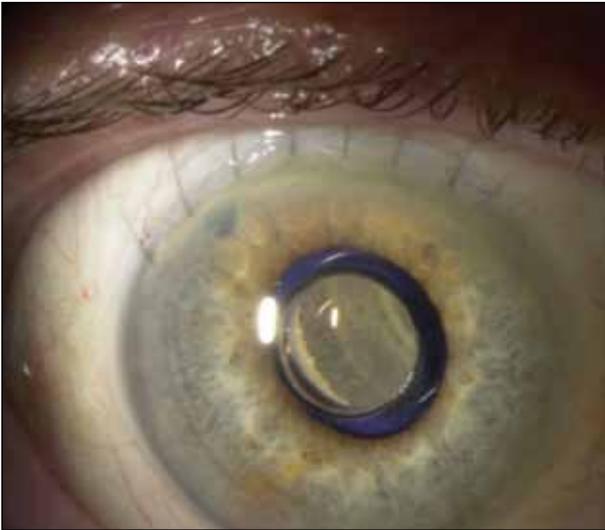


Figure 5. The implantable telescope technology helps improve vision in patients with the most advanced form of macular degeneration, end-stage AMD, while being virtually unnoticeable in the eye.

this makes sense, because the image will be two to three times larger in the implanted eye compared with the fellow eye. Depth perception will also be affected. Prior to the surgery, much of the comprehensive evaluations are spent educating patients about enhancements and limitations of the device to help manage patient expectations.

A cornea/cataract specialist performs the surgery to implant the telescope prosthesis. The procedure involves removing the eye's natural lens, as in cataract surgery, and replacing it with the implantable telescope (Figure 3). Patients are prescribed a standard postsurgical regimen of eye drops with the addition of atropine dilating drops for 1 month. Due to the dilation and

“Early studies demonstrate a statistically significant improvement of vision in eyes with the implanted telescope compared with control eyes.”

corneal edema, the initial postoperative vision may be poor and underestimate the final visual outcome. Postsurgical sessions with low-vision specialists will focus on assisting the patient to appreciate and stabilize the telescopic image.

A potential risk related to the procedure is corneal endothelial cell loss that can affect overall corneal health. The most common complication of the implantable telescope procedure was inflammatory deposits.⁶

CONCLUSION

Early studies demonstrate a statistically significant improvement of vision in eyes with the implanted telescope compared with control eyes. Approximately 90% of patients demonstrated 2 or more lines of improvement on the ETDRS (Early Treatment of Diabetic Retinopathy Study) visual acuity chart, and 67% of patients were able to see 3 or more lines on the eye chart after the surgery compared with before the surgery.⁶ Most patients are able to appreciate improved facial recognition. Although it is not a cure for the disease, the implantable telescope has the potential to make a positive difference in the lives of some people with end-stage AMD (Figure 5). ■

Tiffany L. Chan, OD, is an instructor of ophthalmology at Wilmer Eye Institute, Johns Hopkins University, Baltimore. She has no financial interest in the product and company mentioned herein. Dr. Chan may be reached at tchan25@jhmi.edu.

1. Chappelov AV, Kaiser PK. Neovascular age-related macular degeneration: potential therapies. *Drugs*. 2008;68:1029-1036.
2. Friedman DS, O'Colmain BJ, Munoz B, et al. Prevalence of age-related macular degeneration in the United States. *Archives of Ophthalmology*. 2004;122(4):564-572.
3. Knudtson MD, Klein BE, Klein R. Biomarkers of aging and falling: the Beaver Dam eye study. *Arch Gerontol Geriatr*. 2009;49(1):22-26.
4. Knudtson MD, Klein BE, Klein R. Age-related eye disease, visual impairment, and survival: the Beaver Dam eye study. *Arch Gerontol Geriatr*. 2006;124:243-249.
5. Freund KB, Mrejen S, Gallege-Pinazo R. An update on the pharmacotherapy of neovascular age-related macular degeneration. *Expert Opin Pharmacother*. 2013. doi:10.1517/14656566.2013.787410
6. Implantable Miniature Telescope Professional Use Information, FDA-approved product labeling. Available from: <http://www.centrasight.com/pdf/ProfessionalUse2010.pdf>. Accessed April 4, 2013.