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 years 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.

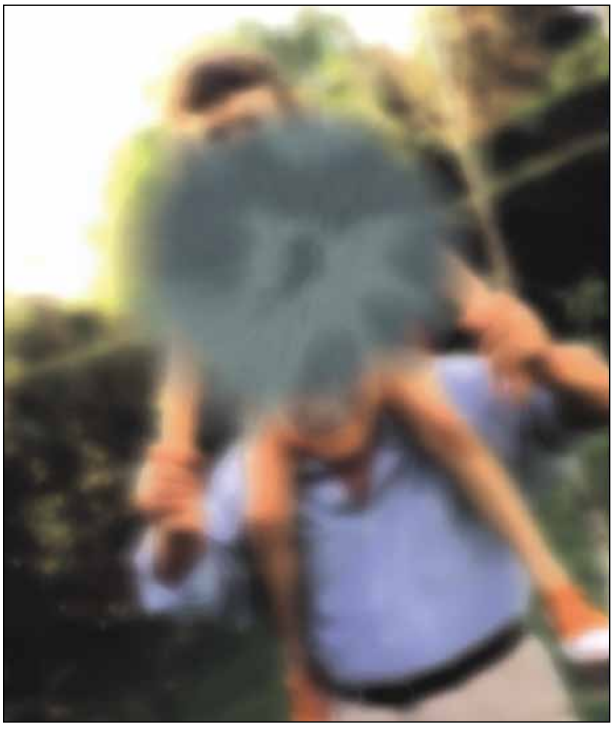

Figure 1. End-stage AMD is the leading cause of blindness in the United States. The disease creates a permanent central vision blind spot, making it difficult or impossible for the patient to recognize even close family or friends.

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 FDA in July 2010. The telescope implant is an intraocular

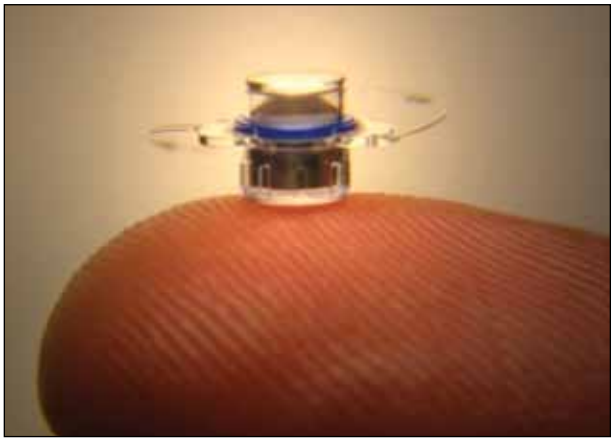

Figure 2. Smaller than a pea, the IMT uses wide-angle micro-optics to improve vision for patients with end-stage AMD.

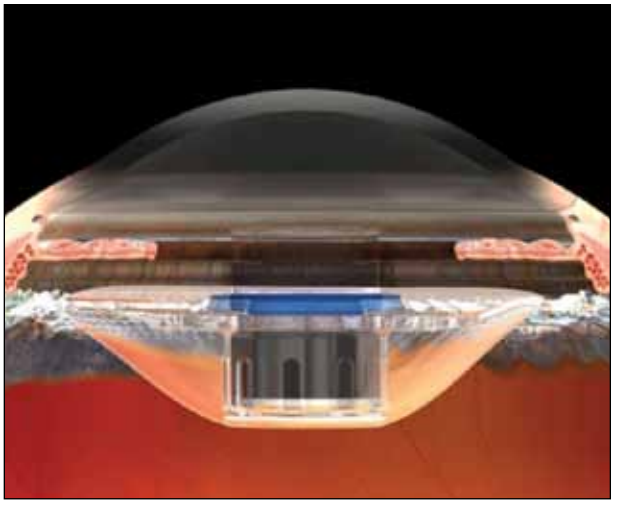

Figure 3. The IMT is implanted in place of the eye's lens to help improve vision.

visual prosthetic device, which is inserted into the lens capsule during cataract extraction in lieu of a traditional IOL (Figure 3). The power of 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 (see *Eligibility Requirements*). It is approved for patients 75 years of age 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 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 with 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 require-

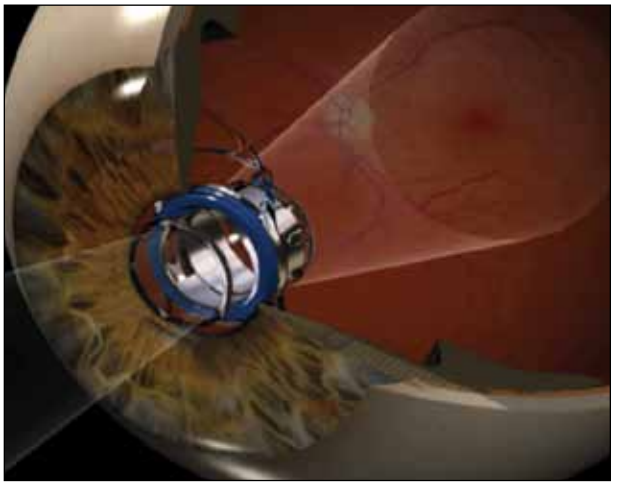

Figure 4. The IMT technology reduces the impact of the central vision blind spot due to end-stage AMD. The telescope implant projects images of the objects the patient is looking at onto the healthy area of the light-sensing retina.

ELIGIBILITY REQUIREMENTS

Summary of patient eligibility criteria for the Implantable Miniature Telescope (VisionCare Opthalmic Technologies):

- at least 75 years of age
- bilateral, stable end-stage age-related macular degeneration with retinal findings of geographic atrophy or disciform scar with foveal involvement
- BCVA of 20/160 to 20/800 in the better-seeing eye
- evidence of a cataract in the eye considered for the implantable telescope
- willingness to undergo preoperative screening and postoperative training with a low vision specialist and/or occupational therapist

ments in his or her state. From a practical standpoint, 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 patients' 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 corneal edema, their 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.

(Courtesy of James Gilman.)

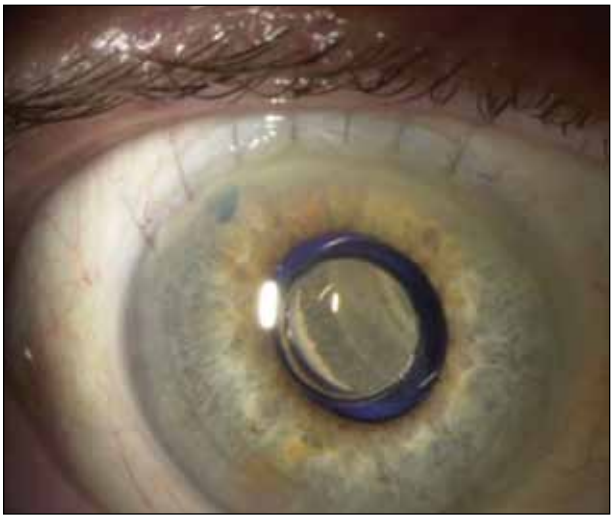

Figure 5. The IMT helps improve vision in patients with the most advanced form of macular degeneration, while being virtually unnoticeable in the eye.

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

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). ■

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