A New Kind of Vision: The Telescope Implant for Advanced AMD

An implantable telescope offers patients with late-stage AMD an option for elevating quality of life.

By Sunil Gupta, MD

Although AMD treatments have improved dramatically during the past 10 years with the addition of new drugs, anti-VEGF therapies, and laser therapies, some patients inevitably progress to a point at which conventional treatment proves ineffective. Retina specialists will be confronted by patients and their loved ones asking, "What's next?" as vision deteriorates to the point that patients can no longer recognize faces and may even feel self-conscious about participating in activities they used to enjoy. For some of these patients, an implantable telescope may offer a chance at regaining the quality of life they formerly enjoyed.

The Implantable Miniature Telescope (by Dr. Isaac Lipshitz; IMT), developed by VisionCare Ophthalmic Technologies, is approved by the US Food and Drug Administration for use in patients 65 years and older with stable, bilateral, end-stage AMD with either geographic atrophy (GA) or disciform scarring involving the fovea. A recent ruling by the Centers for Medicare and Medicaid Services permits surgeons to perform the IMT surgery in the setting of an ambulatory surgery center.

RECOGNIZING YOUR TELESCOPE IMPLANT PATIENT

Because the IMT is integrated into the patient's visual system, it is more functional than handheld or mounted external vision appliances. The device is implanted into 1 eye, and the patient views and scans the environment with natural eye movements, which affords a normal vestibular reflex. As a result, patients can participate in real-world activities rather than only simple stationary tasks. The IMT allows, with the aid of conventional glasses, the implanted eye to see both near and far.

Success with the IMT is heavily dependent on careful patient selection. CentraSight, VisionCare's comprehensive treatment program, helps patients navigate surgical evaluation, implantation, and postoperative care.

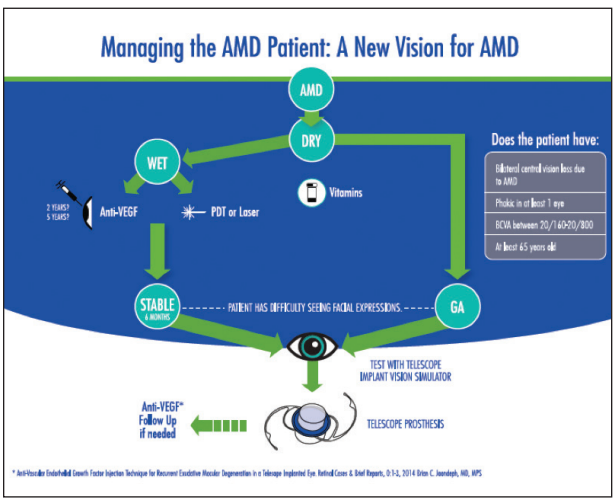

Figure 1. Deciding when a patient is a candidate for the telescope implant is nuanced. Doctors must consider whether they have wet or dry AMD and whether conventional therapies still appear effective over time.

Eligibility criteria

Candidates are not eligible for the device if they have had previous cataract surgery in the eye designated for implantation, as the procedure requires the natural lens to be removed and the capsular bag to be intact for implant placement. It is also notable that studies show that cataract removal in the end-stage AMD patient does not provide as much visual benefit as the telescope implant.[1] Ocular comorbidities that are criteria for exclusion include pseudoexfoliation, corneal dystrophies, optic nerve disorders, or pathology that compromises peripheral vision in the fellow eye (Figure 1).

Patients who have stable AMD after previous treatment of wet AMD are candidates for the device, as are patients

with underlying GA as the primary cause of central scotomas. Those who may have failed treatment with anti-VEGF or other therapies for neovascular AMD and now have disciform scars may also be considered. Patients with active choroidal neovascularization during the prior 6 months are not candidates per the FDA indications. Stargardt maculopathy is considered a contraindication.

During the surgical evaluation process, a patient meets with low-vision specialists who analyze the patient's motivations for surgery and postsurgical expectations. An evaluation includes simulations with a specialized external telescope that mimics the qualities of the telescope implant. While working with the external telescope, patients also gauge whether postsurgical visual improvement will be meaningful.

EVALUATION AND TREATMENT

There is a team of clinical experts involved with each implant case, and each member is responsible for different aspects of the overall treatment program. There are 4 steps to the evaluation and treatment process:

- Diagnosis by a retina specialist.
- Vision evaluation, including external telescope simulations by a low-vision specialist.
- Implantation by a cornea-trained cataract surgeon.
- Postimplantation visual rehabilitation by low-vision and occupational therapy specialists.

The telescope is implanted into 1 eye and the other is left as is to preserve peripheral vision, which is reduced in the eye undergoing surgery. The American Medical Association CPT Panel granted this procedure (which is a hybrid cornea and cataract procedure) a unique CPT code: 0308T "Insertion of ocular telescope prosthesis including removal of crystalline lens."

INTRAOCULAR MAGNIFICATION

The telescope implant technology is based on wide-angle micro-optics that, in combination with the optics of the cornea, create a telephoto system that magnifies objects in view. Secured into the capsular bag after lens extraction and held in position by haptic loops, the telescope implant renders a retinal image approximately 2.7 times larger than the natural lens provides. This allows central images to be seen by viable perimacular retina around the areas of central scotoma (Figure 2). Essentially, what patients see in their central vision is made larger, minimizing the apparent size of the scotoma in their straight-ahead vision.

In a clinical trial, 67% of implanted eyes achieved a 3-line or more improvement in best corrected distance visual acuity (BCDVA) compared with 13% of fellow eye controls.[2] More important, though, patients also reported improved quality of life, as assessed by the National Institutes of Health Visual Functioning Questionnaire 25.

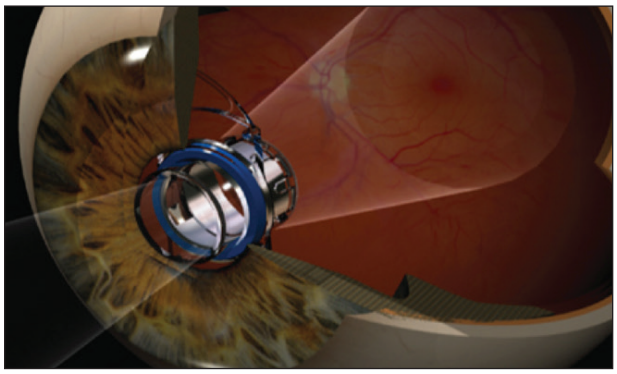

Figure 2. The IMT is implanted in the place of the natural lens, projecting objects on to the healthy perimacular retina not degenerated by the disease.

The FDA's expanded indication, which lowered the age of eligibility from 75 years to 65 years, was based on data from the safety and efficacy study IMT-002 and the long-term studies IMT-002-LTM and IMT-002-LTME, which followed patients for 5 and 8 years, respectively.

In those studies, the telescope implant performed as well in patients 65 to 75 years old as it did in those more than 75 years old.[3] Long-term results showed substantial retention of BCDVA improvement in both groups. In the younger cohort, BCDVA improvement was 2.4 lines 60 months after telescope surgery in the study population, decreasing by only 4 letters (0.7 lines) in telescope-implanted eyes from 24 to 60 months. The most common significant surgery-related ocular complications in the study population were corneal edema at fewer than 30 days after surgery (6.5%), iris prolapse (8.6%) in the younger patient cohort, and corneal edema (7.9%) in the older cohort.

POSTIMPLANTATION PATIENT MANAGEMENT

After surgery, the cornea specialist follows the patient for postsurgical care before returning him or her to the referring ophthalmologist for long-term management. Patients are prescribed a standard postsurgical regimen of eye drops in addition to atropine dilating drops for 1 month. Due to the dilation and corneal edema, patients' initial postoperative vision may be poor, and patients may underestimate the final visual outcome during this time. Therefore, it is critical to the procedure's success that patients undergo visual rehabilitation to adapt to their new way of seeing. Low vision specialists are an integral part of the team because they teach patients exercises related to static and dynamic movement.

Anti-VEGF therapy is currently the standard of care for recurrent choroidal neovascularization. In a patient with the IMT, optical coherence tomography can be used through the implant to monitor the fundus. Injecting anti-VEGF agents behind the IMT is similar to injecting into a phakic eye.[4]

(Continued on page 19)

(Continued from page 15)

CASE STUDY: VISUAL ACUITY AND QUALITY OF LIFE

Recently, in my own practice, an 82-year-old patient, whose preoperative BCVA was evaluated at 20/800, relayed her postoperative goals as the ability to recognize faces, watch TV, and read labels and prices while shopping. Four months following implantation and occupational therapy, each of the patient's goals were met or exceeded. Her BCDVA was 20/80, and she reported excellent functionality. She could now apply makeup and assume more responsibility for cooking and her finances (because she could see her checkbook again). Also, she now reads large print and is back to enjoying crossword puzzles. Her experience mirrors findings from the clinical trials.

A NEW STANDARD FOR END-STAGE AMD

In a large-scale study, patients reported less difficulty in performing activities of daily living and improvement in vision-targeted psychosocial domains.[2] On the National Eye Institute Visual Functioning Questionnaire, patients were less dependent on others, less worried or frustrated with their visual acuity, less limited in their activities, and better able to recognize facial expressions following implantation of the IMT. Often, additional external magnification (ie, glasses) may be required for patients to read small text, such as the print on a prescription label.

Fifteen million Americans live with some form of AMD, the leading form of blindness in adults 60 years and older, and it is estimated that 2 million of these Americans have progressed to end-stage disease,[5] which is also associated with increased stress and depression as vision diminishes.[6]

The CentraSight program offers a new treatment standard for end-stage AMD, because it has been shown to improve visual acuity and quality of life. Many patients with long-standing bilateral disease may become depressed, withdrawn, or stressed as their vision worsens. Retina specialists have a unique role in the ophthalmic community, as they may serve as a first link in educating their patients about the IMT as a possible treatment option for this disease. ■

Sunil Gupta, MD, is the founder of Retina Specialty Institute in Pensacola, Florida. He did not indicate a financial relationship with the products or companies mentioned herein. Dr. Gupta may be reached at sgupta@retinaspecialty.com.

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