

Telescope Implant—Changing Visual Expectations and Evolving the Standard of Care for End-stage Age-related Macular Degeneration Patients

Charles C Wykoff, MD, PhD, FACS^{1,2}

Clinical Assistant Professor of Ophthalmology, Retina Consultants of Houston, Blanton Eye Center, Weill Cornell Medical College, Houston Methodist Hospital, Houston, Texas, US

Abstract

End-stage age-related macular degeneration (AMD) affects approximately 1.8 million Americans and limits older adults' ability to perform activities of daily living. No current pharmaceutical options exist for visual improvement in these patients. The telescope implant is the only Food and Drug Administration approved intraocular device for visual rehabilitation in end-stage AMD patients, with either bilateral geographic atrophy or disciform scarring, who are phakic (in at least one eye) with best spectacle-corrected visual acuity of 20/160–20/800 or worse in both eyes.

Keywords

Telescope implant, end-stage AMD, five-year outcomes

Disclosure: Charles C Wykoff, MD, PhD, FACS, does not have any disclosures or conflicts of interest to report relevant to VisionCare Ophthalmic Technologies, Inc. The opinions expressed in this paper are his own and supported by existing evidence. No funding was received in the publication of this article.

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Received: July 29, 2015 **Published:** October 16, 2015 **Citation:** *US Ophthalmic Review*, 2015;8(2):116–117 DOI: <http://doi.org/10.17925/USOR.2015.08.02.116>

Correspondence: Charles C Wykoff, MD, PhD, FACS, Retina Consultants of Houston, Blanton Eye Center, Houston, Texas, US. E: ccwmd@houstonretina.com

End-stage AMD—Clinical Challenge with New Option for Visual Rehabilitation

Age-related macular degeneration (AMD) is a leading cause of vision loss with approximately 200,000 new diagnoses of its neovascular form each year in the US alone.¹ Fortunately, many of these patients benefit from anti-vascular endothelial growth factor (anti-VEGF) pharmaceutical treatments, and such management has changed the epidemiology of blindness in many countries.^{2–5} However, many patients have advanced dry AMD manifest as geographic atrophy or end-stage neovascular AMD associated with macular fibrosis and disciform scarring. The characteristic central scotoma of end-stage AMD, affecting approximately 1.8 million Americans,⁶ can significantly limit older adults' ability to perform activities of daily living and engage in social interaction, negatively affecting their quality of life, and increasing rates of depression and dependency on caregivers.^{7,8} In these frustrating clinical situations, where no current pharmaceutical option exists for visual improvement, one may consider refractive visual rehabilitation with implantation of an intraocular telescope.

The Implantable Miniature Telescope (IMT or “telescope implant,” VisionCare Ophthalmic Technologies, Saratoga, CA) is the only Food and Drug Administration (FDA) approved intraocular telescopic implant for visual rehabilitation in end-stage AMD from geographic atrophy or disciform scarring. The telescope implant is indicated for such bilateral, phakic (in at least one eye) patients with best spectacle-corrected visual acuity (BSCVA) of 20/160–20/800 or worse in both eyes.^{9–11}

The telescope implant is a fixed-focus, unilaterally implanted device that produces a telephoto effect and enlarges objects in the patient's central visual field by about threefold. Approximately 20–24° of external field of view is projected onto approximately 55° of retina, and therefore, the peripheral field of the implanted eye is reduced.¹¹ Given the permanent monovision-like situation created with one eye serving central function and the other peripheral function, patient education both before and after surgery is critical to success. To facilitate this, there are more than 120 dedicated CentraSight teams in the US and Europe, which utilize structured steps for patient screening and postimplantation rehabilitation for optimal device utilization and maximization of visual function.¹²

Originally approved in 2010, in the fourth quarter of 2014, the FDA expanded the telescope implant label to include patients who are 65 years and older, significantly increasing its potential reach within our aging population.^{9–11} The device is implanted into the capsular bag by a qualified anterior segment surgeon at the time of cataract surgery through an enlarged wound. The device has a 4.4 mm anterior–posterior length and protrudes through the pupil by approximately 0.1–0.5 mm, allowing clearance of approximately 2.5 mm between the device and the corneal endothelium.

Five-year Outcomes Following Telescope Implantation—Sustained Visual Improvement

Two years following implantation in the IMT-002 prospective clinical study that led to the initial approval of FDA, mean BSCVA improved more

than three lines¹⁰—an impressive gain, which has been correlated with functionally meaningful improvements in near and distance activities, social functioning, mental health, and dependency.¹¹

More recently, 5-year efficacy and safety outcomes following implantation have been reported by Boyer and colleagues¹² with an emphasis on comparing patients who are 65–74 years old with those of patients who are 75 years old and above. Of the 217 patients enrolled in IMT-002, 63 (29 %) completed 5 years of follow-up, though data were also available at 36 months (n=64) and 48 months (n=84). Overall mean visual gains were largely maintained, with mean BSCVA improvement of 2.4 lines from baseline; 62 % of patients maintained two lines BSCVA improvement at 5 years. Retention of the highest levels of BSCVA gain was reportedly greater in younger patients when compared with those of older patients, with 58 versus 38 %, respectively, maintaining three lines or more improvement at 5 years. Vision loss of two lines or more was reported in 9.4 % of study eyes in the older cohort at 5 years compared with 28.1 % of fellow eyes over the same time period—consistent with the progressive natural history of AMD.

The most notable reported adverse event was loss of corneal endothelial cell density (ECD). Surgical implantation led to an acute mean ECD loss of approximately 20 %—consistent with that reported following large incision cataract surgery.¹³ Subsequently, the reported annual mean ECD loss of 3 % is greater than the reported 0.6 % ECD loss expected annually in healthy eyes but similar to the 2.8 % ECD loss annually reported following large incision conventional cataract surgery and intraocular lens implantation.^{14,15} Nevertheless, <3 % of patients reportedly underwent corneal transplantation and surgical explantation was infrequent (5.8 % of implants were removed, primarily due to patient dissatisfaction).

Retinal Imaging and Intravitreal Injecting Following Implantation—Standard Techniques Employed

Following telescope implantation, visualization of the retina is more challenging than through a standard pseudophakic lens. Approximately 0.5 % of eyes may develop active choroidal neovascularization within 2 years of telescope implantation.¹³ Optical coherence tomography can be performed through the implant.¹⁶ Furthermore, if new or recurrent exudative disease activity is identified, pharmaceutical agents including anti-VEGF medications can be readily administered intravitreally in standard fashion, entering the sclera approximately 3.5 mm posterior to the corneal–scleral limbus and aiming posteriorly toward the optic nerve.¹⁴ Finally, focal macular laser can be performed through the implant.¹⁷

Telescope Implant—Future Potential Indications

When the FDA expanded the telescope implant indication to include younger patients, it increased access to this potentially life-improving technology. But recent reports indicate that the device may also be effective following scleral fixation, potentially allowing pseudophakic patients access to the device through lens exchange—more prospective data are required.

Conclusion—Telescope Implant Offers Improved Vision, Sooner

In the 2015 Preferred Practice Pattern Guidelines for AMD, the American Academy of Ophthalmology describes the telescope implant as an option for motivated, end-stage AMD patients.¹⁸ The telescope implant brings hope to a segment of our patients with end-stage AMD, and long-term data indicate that the telescope implant is safe, effective, and capable of improving the visual lives of many patients. ■

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