IMPROVING THE QUALITY OF LIFE OF PATIENTS WITH LATE-STAGE AMD



A clinical evaluation of an intraocular telescope implanted in the capsular bag during cataract surgery.

BY STANISLAO RIZZO, MD; ALFONSO SAVASTANO, MD; AND PAOLA SASSO, MD

A meta-analysis published in *The Lancet* found that 8.7% of the global population is affected by age-related macular degeneration (AMD).[1] Current treatments, including injections, laser therapy, and supplements, can slow the progression of AMD-related scarring that leads to central field vision loss. External low vision aids, such as magnifiers and spectacles, can help manage existing vision loss, but these devices can be costly and have limited efficacy.

AMD is the leading cause of vision loss in individuals 50 years of age and older, and it is the primary cause of blindness in people 65 years of age and older.[2,3] As the population ages, the number of people with AMD is projected to rise from approximately 196 million in 2020 to 288 million by 2040.[1] Late-stage AMD is characterized by progressive macular atrophy and central scotomas. Treatment options for these patients are extremely limited, creating a significant unmet need.

A SURGICAL TREATMENT FOR LATE-STAGE AMD

The smaller-incision new-generation implantable miniature telescope (SING IMT; Samsara Vision) is the first approved surgical treatment for bilateral central vision loss due to late-stage AMD. The device has the CE Mark for adults 55 years of age and older, and it is under clinical investigation in the United States for adults 65 years of age and older.[4]

Utilizing a Galilean optical concept, the SING IMT is indicated for monocular implantation in the capsular bag. Although not a cure, the device provides 2.7 times magnification of the central visual field. The magnified and enhanced images fall on healthy parts of the retina, reducing the impact of the central vision scotoma and potentially allowing the patient to view the image with the healthier perimacular retina.

Compared to other external optical devices, the SING IMT has a relatively large field of view at 20°, but this can limit the eye's peripheral vision. Monocular implantation of the device allows the other eye to help compensate for this limitation. Compared to external magnifiers, the implant allows more natural eye movements and usually does not cause dizziness or disturb the patient's vision. The SING IMT is easier to implant and has a better safety profile than the first-generation intraocular telescope approved in the United States in 2010, which was implanted in more than 600 patients with late-stage AMD (www.samsaravision.com).

COLLABORATIVE APPROACH TO PROMOTE BEST OUTCOMES

Patient Evaluation and Education

To determine a patient's eligibility for the SING IMT, an interdisciplinary team evaluates the individual's vision and provides education about the outpatient surgery experience. The device is placed during cataract surgery, so a history of cataract surgery is a contraindication for the SING IMT. The team also assesses the patient's motivation to participate in postoperative low vision rehabilitation to learn how to use their new vision.

Surgical Procedure and Rehabilitation

In the hands of an experienced surgeon, the SING IMT procedure takes about 30 minutes. Training a patient to use their new vision in static situations, visual tasks requiring hand-eye coordination, and ambulation takes longer. For the best possible functional results, patients must commit to the rehabilitation process—typically six to eight sessions over the course of 3 to 4 months.

Three recent postmarket studies in the European Union evaluated and reported patients' corrected distance visual acuity (CDVA) outcomes at 3 months. In a study of 11 Italian patients, Savastano et al reported gains of 11.64 and 10.91 letters at 1 and 3 months postoperatively, both statistically significant results ($P < .001$).[5] In terms of reading vision, most participants were unable to perform a baseline measurement. At 1 and 3 months after surgery, their corrected near visual acuity had

improved to 50.91 (±15.2) letters and 59.09 (±11.6) letters, respectively. The difference from baseline was statistically significant ($P < .001$). Endothelial cell loss was less than with the first-generation device.[5-7]

READING PERFORMANCE PREDICTS VISION-RELATED QUALITY OF LIFE

One of the best predictors of vision-related quality of life (QOL) is reading performance or the ability to read quickly and accurately.[7,8] Across seven sessions over a 24-week training period, we evaluated the effect of SING IMT implantation followed by rehabilitation training on the functional visual performance of patients with late-stage AMD. The required rehabilitation program following SING IMT implantation involves individual exercises that align with the patient's personal goals, such as reading, recognizing faces, or resuming hobbies. Spectacles are worn to bring each of these functional tasks into focus with the SING IMT. The rehabilitation program serves to keep patients engaged and promote the best possible outcomes.

Before our recent study, a survey of our patient population revealed which activities of daily living mattered the most to them: reading (36%), writing (21%), watching TV (29%), and face recognition (14%).

Our study included 11 Italian patients (men, n = 8; women, n = 3; mean age, 77.5 ±8 years) who received a SING IMT in one eye and then participated in seven biweekly rehabilitation sessions focused on reading speed (RS), reading acuity (RA), and fixation stability (FS). We selected these benchmarks because RS quantifies the efficiency of reading, RA identifies the smallest legible print size at a standardized reading distance, and FS indicates the stability of gaze during reading.[8,9]

Training related to the prioritized skills was conducted during at least seven 90-minute sessions (with a 15-minute break) every 2 weeks over a period of 6 months. Participants' RS, RA, FS, and CDVA were assessed at 6, 8, 10, 12, 14, 16, and 24 weeks. They entered the rehabilitation phase of the SING IMT program when the dilation drop regimen (related to the healing process) ceased because dilation can interfere with patients' functional vision.

We found that patients' RS nearly doubled, with mean RS improving from the second program session (16.9 ±11.4 words per minute) to the last session (30.9 ±17.6 words per minute [$P = .0057$] between the first and second-to-last sessions). After the first session of the rehabilitation program (6 weeks postoperatively), participants' mean RA was 0.64 ±0.26 LogMAR. After the last session (24 weeks postoperatively), their mean RA was 0.45 ±0.19 LogMAR, a statistically significant improvement. Every patient achieved their maximal RA value by the final rehabilitation session.

The majority (55%, n = 6) of patients required only two sessions to achieve 15 seconds or more of FS. All reached this goal by their last rehabilitation session. Participants' CDVA significantly improved between the first and last rehabilitation sessions ($P = .0125$). From baseline to the last follow-up visit, 82% of patients (n = 9) achieved an improvement of 10 letters, and more than half (54.5%, n = 6) experienced an improvement of 15 letters. One patient's CDVA improved by 25 letters.

FUNCTIONAL VISION IMPROVES QOL

The SING IMT, through a deliberately integrated program that combines a novel intraocular telescope with comprehensive vision training, can help patients regain central vision once it has been lost to late-stage AMD. The potential benefits of the device are improved vision and QOL, but these benefits can be achieved only when patients work postoperatively with a team of professionals, such as an optometrist and an occupational therapist trained in low vision, through the rehabilitation program.

To our knowledge, this is the first study of functional outcomes following SING IMT implantation. Although many earlier studies confirmed that patients' CDVA improved, visual acuity and clarity do not reveal enough about how people actually use their vision to perform daily activities. This study confirmed that the SING IMT program improved participants' functional vision, which is vital to gaining vision-based QOL outcomes. ■

1. Wong WL, Su X, Li X, et al. Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. *Lancet Glob Health*. 2014;2(2):e106-e116.
2. Foroughian F, Agrón E, Clemons TE, Ferris FL 3rd, Chew EY; Age-Related Eye Disease Study Research Group. Visual acuity outcomes after cataract surgery in patients with age-related macular degeneration: age-related eye disease study report no. 27. *Ophthalmology*. 2009;116(11):2093-2100.
3. Jager RD, Mieler WF, Miller JW. Age-related macular degeneration [published correction appears in *N Engl J Med*. 2008;359(16): 1736]. *N Engl J Med*. 2008;358(24):2606-2617.
4. OraConnects. Concerto: study for late-stage age-related macular degeneration. Accessed June 6, 2024. https://www.oraconnects.com/find-a-trial-amd-old
5. Savastano A, Ferrara S, Sasso P, et al. Smaller-incision new-generation implantable miniature telescope: three-months follow-up study. *Eur J Ophthalmol*. Published online November 3, 2023. doi:10.1177/11206721231212545
6. Toro MD, Vidal-Aroca F, Montemagni M, Xompero C, Fioretto G, Costagliola C. Three-month safety and efficacy outcomes for the smaller-incision new-generation implantable miniature telescope (SING IMT). *J Clin Med*. 2023;12(2):518.
7. Mastropasqua R, Gironi M, D'Aloisio R, et al. Intraoperative iridectomy in femto-laser assisted smaller-incision new generation implantable miniature telescope. *J Clin Med*. 2023;13(1):76.
8. Mitchell J, Wolffsohn J, Woodcock A, et al. The MacDQoL individualized measure of the impact of macular degeneration on quality of life: reliability and responsiveness. *Am J Ophthalmol*. 2008;146(3):447-454.
9. Sasso P, Savastano A, Vidal-Aroca F, et al. Enhancing the functional performance of patients with late-stage age-related macular degeneration implanted with a miniature telescope using rehabilitation training [published correction appears in *Ophthalmol Ther*. 2024;13(3):709]. *Ophthalmol Ther*. 2024;13(3):697-707.

STANISLAO RIZZO, MD
- Ophthalmology Unit, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome; Università Cattolica del Sacro Cuore, Rome; and Consiglio Nazionale delle Ricerche, Istituto di Neuroscienze, Pisa, Italy
- stanislao.rizzo@policlinicogemelli.it
- Financial disclosure: None

PAOLA SASSO, MD
- Ophthalmology Unit, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome
- paoladottsasso@gmail.com
- Financial disclosure: None

ALFONSO SAVASTANO, MD
- Ophthalmology Unit, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome
- alfonso.savastano@policlinicogemelli.it
- Financial disclosure: None