



Surgical Technique

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SING-IMT Removal for Unsatisfied Patients: Step-by-Step Surgery for a Safe Explant

Purpose: To report three cases of Smaller-Incision New-Generation Implantable Miniature Telescope (SING-IMG) explantation and three-piece acrylic intraocular lens (IOL) implantation in patients affected by late-stage dry age-related macular degeneration.

Methods: This is a single-center cohort study. Three patients with stable dry age-related macular degeneration previously implanted with SING-IMT failed to adapt to the device requesting its explantation. Surgical procedures were performed under peribulbar anesthesia, with careful removal of the SING-IMT telescope through a sclerocorneal tunnel of 8 mm and implantation of a three-piece acrylic IOL. Patients underwent pre- and postoperative assessments, including visual acuity measurements, endothelial cell count, and intraocular pressure. Patients were followed postoperatively for at least 6 months, with particular attention to IOL stability and posterior capsule integrity.

Results: Postoperative assessments demonstrated positive outcomes, revealing no IOL dislocation or posterior capsular opacification after 6 months. Endothelial cell count diminished. Best-corrected visual acuity returned to values before SING-IMT implantation.

Conclusion: In our small cohort, SING-IMT explantation appeared to be a safe option. Despite promising visual outcomes, some patients might not adapt to SING-IMT. Further studies are needed to evaluate criteria to predict telescope adaptation.

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Age-related macular degeneration (AMD) is a major cause of severe vision loss in people older than 55 years in the developed world. A 2014 meta-analysis of pooled global population-based studies estimated the prevalence of any AMD in individuals aged 45 to 85 years as 8.69%. The prevalence of early AMD was 8.01%, whereas late AMD was 0.37%. Projec-

tions indicate that by 2040, this prevalence is anticipated to increase to 288 million people.¹

Classically, we distinguish two types of AMD, the “dry” and “wet” forms. Dry AMD is a chronic condition typically resulting in varying degrees of visual impairment and, in some cases, advancing to severe blindness over time. Conversely, wet AMD, affecting only 10% to 15% of AMD cases, manifests suddenly and accelerates swiftly toward blindness if not promptly treated.²

Two potential therapeutic approaches for dry AMD include pharmacological and surgical interventions.

The pharmacological interventions being investigated to reduce the rate of disease progression include 1) drugs with antioxidative properties, 2) inhibitors of the complement cascade, 3) neuroprotective agents, 4) visual cycle inhibitors, 5) gene therapy, and 6) cell-based therapies.³

Regarding surgical approaches, several types of intraocular implants are being studied as potential treatments for advanced AMD.⁴

A Galilean telescope is the commonest system used in IMT lenses, the IOL-VIP System, and iolAMD. IMT lenses can achieve greater magnification compared with

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the IOL-VIP System and iolAMD because the positive and negative lenses are positioned within air.⁵

The Implantable Miniature Telescope, IMT (developed by Dr. Isaac Lipshitz at VisionCare Ophthalmic Technologies in Saratoga, CA), is a type of visual prosthetic device intended to enhance central vision for individuals with moderate to severe vision impairment due to bilateral late-stage AMD. The device is implanted within the capsular bag following cataractous lens extraction.

IMT aims to diminish the relative size of the scotoma by magnifying central visual field images by threefold, covering both the central and peripheral retina.^{6,7}

In 2020, approval was granted for the utilization of the smaller-incision new-generation implantable miniature telescope (SING IMT) within the European Union, marking the introduction of the second generation of this implant. Unlike its predecessor, the SING IMT provides enhanced magnification along with simplified and less-invasive implantation procedures.^{8,9}

Unfortunately, some patients, even after completing rehabilitation sessions and regaining visual acuity both for near and distance (average of improvement 15 letters ETDRS)^{10,11} struggled to adapt to the new vision provided by the device. The symptoms complained by patients were so unbearable that the SING IMT removal became necessary.

Intervention

Herein, we describe the surgical technique used to remove the SING-IMT in three of our patients and implanting them with a standard three pieces monofocal foldable intraocular lens. The study was conducted following the tenets of the Declaration of Helsinki, and written informed consent was obtained from all participants. This research was approved by the Catholic University of the Sacred Heart Ethical Committee in Rome, Italy.

In all the cases, the SING IMT removal was not performed before 6 to 8 months to be sure that the patient was not able to tolerate and adapt to it. All the explanted eyes had a follow-up of 6 months at least.

Surgical Technique

Before surgery, the patients underwent peribulbar anesthesia using 0.5 mL of ropivacaine and 0.5 mL of mepivacaine. Two side service keratocentesis (1.2 mm) were performed at the 9- and 3-o'clock positions. Sclerocorneal tunnel of 8 mm at 12-o'clock position was made by the surgeon after the opening of conjunctiva and Tenon capsule. Adhesive viscoelastic was injected into anterior chamber to protect corneal

endothelium. Then, the haptics of the SING IMT were, in first instance, gently dislocated from the capsular bag. Once they were pulled out the capsular bag, they were cut using Vannas scissors. The device was rotated to free it from adhesions with the posterior capsule and, eventually, removed using anatomical forceps. Fortunately, we did not observe vitreous tissue prolapse, and anterior capsulorhexis was circular and continuous. Therefore, the decision was to implant a three-piece IOL in the ciliary sulcus after the injection of cohesive viscoelastic. Sclerocorneal tunnel was secured with 8-0 Vicryl sutures, and viscoelastic was removed from the anterior chamber. Surgeon checked the integrity of keratocentesis and sutures. Conjunctiva was sutured with 8-0 Vicryl sutures (see **Video, Supplemental Digital Content 1**, <http://links.lww.com/IAE/C338>, which clearly shows the procedure).

Results

We performed the removal of SING-IMT and implantation of standard three-piece acrylic foldable intraocular lens in three of our patients.

At 6 months, no dislocation of the IOL implanted had been observed. Furthermore, the posterior capsule did not present an opacification under the SING-IMT telescope. The rate of endothelial loss was approximately 7% from an average of 2,430 cells per cubic millimeter before explantation to an average of 2,260 cells per cubic millimeter after the explantation.

In the first patient, IOP measurements before and after surgery remained the same. Instead, in the second and third patients, the IOP increased from 12 mmHg to 16 mmHg and from 10 mmHg to 20 mmHg, respectively.

The distance and near best-corrected visual acuity after surgery returned to values comparable to those measured before the SING-IMT implantation.

Discussion

SING-IMT is showing promising results in terms of visual acuity recovery and safety profile.^{10,11} Unfortunately, a portion of patients fail to adapt to the device despite completing the rehabilitation correctly.

These patients report double vision, difficulty walking, doing everyday life simple tasks, and the presence of an unbearable fog in the visual field. Even in the absence of postoperative complications (elevated IOP, lens tilting, endothelial damage), the high level of discomfort and the resulting reduction in the quality of life have required the removal of the device.

Surgery in this case is not without risks. The large size of the SING-IMT requires the creation of an 8-

mm corneal tunnel. Freeing the lens from the capsular bag is very challenging because there is a risk of vitreous prolapse into the anterior chamber, necessitating vitrectomy and subsequent risk of retinal tears. In the presence of intact anterior capsulorhexis, we opted for the implantation of a three-piece IOL in the ciliary sulcus, thus avoiding the need for scleral-fixated lens implant. In the postoperative follow-up, we did not encounter complications resulting from surgery (increase/reduction in IOP, corneal decompensation, retinal tears/detachment, choroidal elevations).

Patients were visited the day after the surgery, at one week, and at one month. The symptoms reported were a sensation of a foreign body, burning of the eyes, and mild eye pain. All symptoms improved during the follow-up period. In all cases, the symptoms that had led to the removal of the lens completely resolved after surgery.

The cloudy vision complained by all our patients did not match with the opacification of the posterior capsule that was observed to be clear in all our cases (Figure 1). We speculated that probably the square edge of the telescope and its voluminous shape contrasted the posterior capsule opacification development.

However, we were not able to understand where that complaint of cloudy vision came from. We postulated that even if the patient complained about cloudy vision, what affected them was their visual field loss. Despite the best-corrected visual acuity loss for near and far after SING IMT removal, patients referred to be satisfied as they gain their visual field again.

Conclusion

Although SING-IMTs are showing promising results in patients with moderate/severe dry AMD, some

of them, even in the absence of exclusion criteria for device implantation, presented an impossibility to adapt to the new type of vision. Further studies are needed to define predictive characteristics of adaptation failure to the device and to establish inclusion criteria with greater accuracy even if the SING IMT explant resulted to be a complex but safe surgical possibility.

Key words: age-related macular degeneration, low vision visual prosthesis, implantable miniature telescope, SING IMT, surgical technique.

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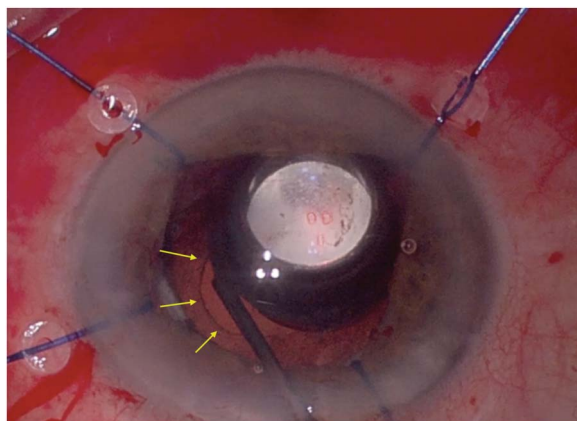


Fig. 1. Checking of the posterior capsule integrity before SING IMT removal. Yellow arrows show the edge where the posterior portion of the telescope was inserted. Despite the opacification of the capsule in the periphery (yellow arrows), the posterior capsule was always clear and neat in the central just below the SING IMT.