



In Vivo Evaluation of SING IMT™ Alignment for Late-Stage Age-Related Macular Degeneration Using Anterior Segment OCT

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ABSTRACT

Introduction: This study aimed to assess the in vivo positioning, tilt, and decentration of the second-generation implantable miniature telescope (SING-IMT™; Samsara Vision, Inc., Far Hills, NJ, USA) using swept-source anterior segment optical coherence tomography (AS-OCT). **Methods:** This was a multicentric retrospective observational study conducted at two tertiary referral centers (Palagi Hospital, Florence, Italy, and Royal Victoria Infirmary Hospital, Newcastle upon Tyne, UK). Eleven eyes from 11 patients with end-stage age-related macular degeneration

(AMD) underwent secondary SING IMT™ implantation at these two tertiary centers. Using high-resolution AS-OCT (CASIA2 system [Tomey, Nagoya, Japan] and Anterior system [Heidelberg Engineering, Heidelberg, Germany]), telescope alignment was assessed after 12 months. Decentration and tilt were calculated and reported in both Cartesian and polar coordinates. Telescope configuration relative to the iris plane and corneal-telescope (C-T) distance and endothelial cell count was also evaluated.

Results: The mean (\pm standard deviation) follow-up was 15.7 ± 2.8 months. The mean decentration was 0.33 ± 0.12 mm, with a predominant

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superior and nasal displacement. Mean tilt was $3.28 \pm 1.31^\circ$, oriented mainly in the supero-temporal direction. Three positional configurations were observed: anterior to the iris plane (36.4%), at the iris plane (36.4%), and posterior to the iris plane (27.3%). The mean C–T distance was 2.71 ± 0.48 mm. Mean endothelial cell loss at 12 months was $13.21\% \pm 3.57\%$.

Conclusions: After 12 months of follow-up, the SING-IMT™ maintained stable in-the-bag fixation, with tilt and decentration values within the ranges previously reported for conventional in-the-bag intraocular lenses.

Keywords: Second-generation implantable miniature telescope; Age-related macular degeneration; Anterior segment optical coherence tomography

Key Summary Points

Why carry out this study?

Late-stage age-related macular degeneration leads to irreversible central vision loss and disability. The first-generation implantable miniature telescope (IMT) improved vision but had surgical and safety limitations.

The newer second generation IMT (SING-IMT™) offers improved design but evidence on in vivo alignment remains limited.

What was learned from the study?

This study provides the first detailed in vivo evaluation of the SING-IMT™ positioning using swept-source anterior segment optical coherence tomography.

After 12 months of follow-up, the SING-IMT™ maintained stable in-the-bag fixation, with tilt and decentration values consistent with reports for standard in-the-bag intraocular lenses.

These novel findings support the long-term safety and effectiveness of the SING-IMT™ in clinical practice.

INTRODUCTION

Age-related macular degeneration (AMD) is the leading cause of irreversible visual impairment in industrialized countries, affecting approximately 200 million individuals worldwide, a figure expected to rise due to global population aging [1]. In its advanced stages, both the neovascular (wet) and geographic atrophy (dry) forms of AMD result in central vision loss, severely impacting patients' quality of life and independence [2].

To address the visual disability associated with late-stage AMD, intraocular vision-enhancing devices, such as the implantable miniature telescope (IMT) have been developed. The first-generation IMT demonstrated significant visual gains [3]; however, its widespread adoption has been limited by surgical complexity, including the need for a large corneal incision, and concerns regarding postoperative endothelial cell loss.

In 2020, the second-generation device, termed the Smaller-Incision New-Generation Implantable Miniature Telescope (SING-IMT™; Samsara Vision, Inc., Far Hills, NJ, USA), was introduced and received regulatory approval for clinical use in Europe [4]. While retaining the Galilean fixed-focus optical design of its predecessor, it offers a smaller overall diameter and flexible silicone haptics, enabling implantation through a smaller incision. Early evidence supports the short-term safety and effectiveness of the SING-IMT™; however, these findings are based on studies with limited sample sizes and short follow-up periods [4, 5].

Although the SING-IMT™ has been introduced into clinical practice, its positioning has not been systematically investigated using anterior segment optical coherence tomography (AS-OCT). Differences in geometry and material properties compared to the earlier model may affect both alignment and long-term stability. Furthermore, critical parameters such as endothelial distance, tilt, and decentration—which are known to influence intraocular lens (IOL) performance and safety—remain insufficiently characterized. The present study provides

an in vivo assessment of SING-IMT™ positioning AS-OCT.

METHODS

The study was a multicenter retrospective observational study conducted at Palagi Hospital A.S.L. Toscana Centro (Florence, Italy) and the Royal Victoria Infirmary Hospital (Newcastle upon Tyne, UK). It was a case series that included all patients who underwent secondary SING-IMT™ implantation for late-stage AMD between May 2022 and January 2024. The study adhered to the principles of the Declaration of Helsinki, and the study protocol received approval from the ethics committee of Palagi Hospital, Azienda USL Toscana Centro (Florence, Italy) and from the local ethics committee of the Royal Victoria Infirmary Hospital (Newcastle upon Tyne, UK). The study also complied with Good Clinical Practice standards. All patients provided written informed consent for both the surgical procedure and for the use of their clinical data for research purposes.

Patient Selection

Inclusion criteria for SING-IMT™ implantation were defined according to the manufacturer's guidelines and aligned with established ophthalmologic and functional parameters. Eligible patients were ≥ 55 years of age and exhibited bilateral end-stage AMD with central vision loss secondary to fovea-involving geographic atrophy or fibrotic scarring with corrected distance visual acuity (CDVA) between 20/80 and 20/800 (0.6–1.6 logMAR) on the ETDRS chart. Additional requirements included an anterior chamber depth (ACD) ≥ 2.5 mm to allow adequate space for in-the-bag implantation, an endothelial cell density (ECD) > 1600 cells/mm², and an intraocular pressure (IOP) < 22 mmHg. Exclusion criteria included active choroidal neovascularization (CNV) or CNV treatment within the previous 6 months, a history of intraocular surgery,

corneal dystrophies, myopia greater than -6.0 D or hyperopia greater than $+4.0$ D, and a history of steroid-induced ocular hypertension or glaucoma. A minimum follow-up duration of 12 months was required for study inclusion.

SING-IMT™ Specifications

The SING-IMT™ is an implantable visual prosthetic designed to improve near, mid, and distance visual acuity in patients with bilateral end-stage AMD. Compared to the first-generation IMT™, it offers higher magnification (up to $2.7\times$ of the central visual field) and is easier to implant. The device consists of a glass telescope housed in a silicone haptic carrier, forming a telephoto optical system in combination with the cornea. It weighs 121 mg in air and 63 mg in aqueous humor, with a haptic diameter of 10.8 mm, optic diameter of 3.6 mm, and axial length of 4.4 mm. Following standard phacoemulsification, the preloaded device is implanted into the capsular bag using a Tsert SI cartridge (Samsara Vision, Inc.) through a 6.5- to 8.0-mm sclero-corneal incision, where it is stabilized by foldable silicone haptics. The SING-IMT implant was performed by three different expert surgeons (FB, SDS, LD), using the surgical technique previously described [6, 7].

Anterior Segment OCT Evaluation

Anterior segment OCT evaluation was conducted using two swept-source (SS) AS-OCT systems: the CASIA2 AS-OCT system (Tomey, Nagoya, Japan) was used for six eyes from the Florence cohort, and the Anterior AS-OCT system (Heidelberg Engineering, Heidelberg, Germany) was used for five eyes from the Newcastle cohort.

In accordance with the AS-OCT images, three configurations of the telescope position relative to the plane passing through the scleral spurs were identified. In the first configuration, the telescope was located posterior to the iris plane, partially covered by the iris. In the second configuration, the telescope was aligned with the iris plane but did not extend beyond the scleral spur plane. In the third configuration, the

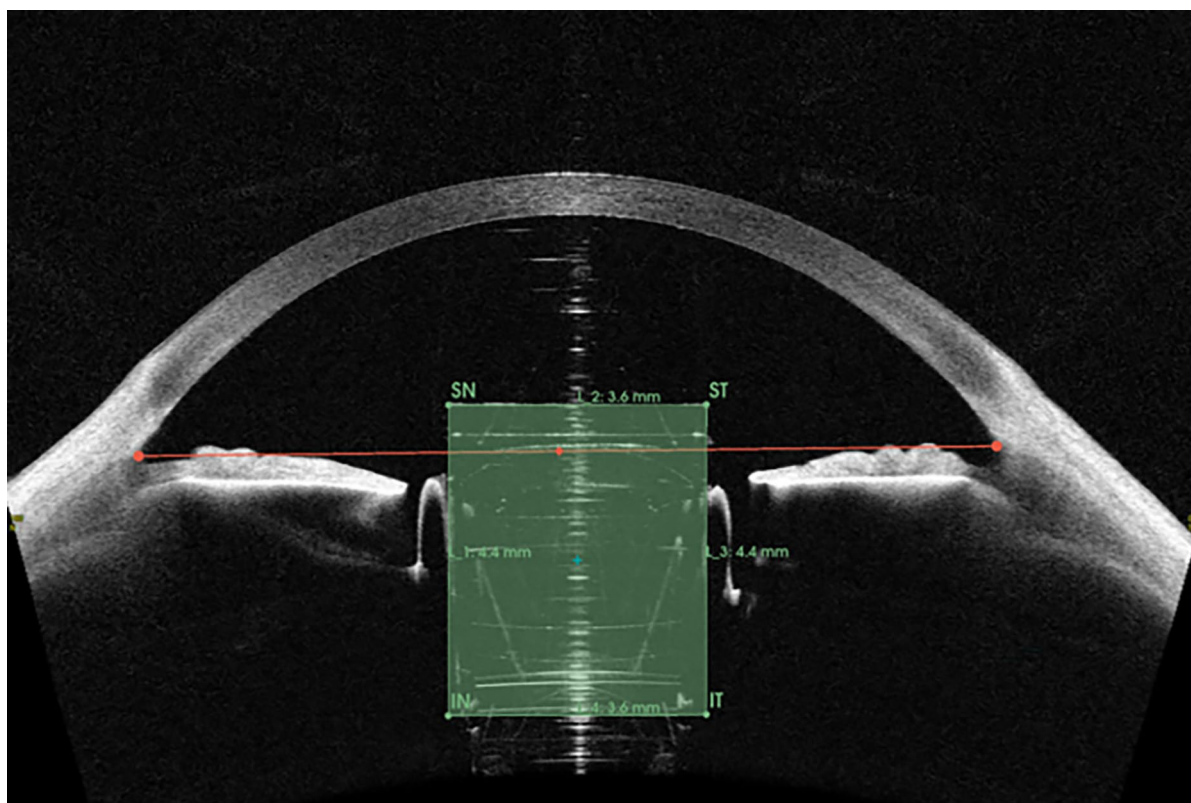


Fig. 1 Swept-source anterior segment OCT image showing the segmentation process performed using 3D Slicer software. The scleral spurs (filled red circles) were identified and connected to define the reference axis. The margins of the implanted telescope are highlighted in green,

and the blue cross indicates the geometric centroid of the telescope. *AS-OCT* Anterior segment optical coherence tomography, *IN* inferior-nasal, *IT* inferior-temporal, *SN* superior-nasal, *ST* superior-temporal,

telescope was positioned anterior to the iris plane, protruding beyond the plane defined by the scleral spurs.

Additionally, the corneal–telescope (C-T) distance was defined as the distance from the central corneal endothelium to the anterior surface of the telescope; this measurement was used to evaluate the spatial relationship between the implant and the corneal endothelium.

All AS-OCT evaluations were conducted at the 12-month postoperative visit.

Decentration and Tilt Measurement

For each subject, six radial scans were captured at 30° intervals and grouped into three orthogonal meridional planes. In each image, the scleral

spurs were identified, either automatically by the device software or manually annotated, and connected to define a reference axis. The boundaries of the SING-IMT™ were manually

Table 1 Patient characteristics

Patient characteristics	Value
Number of eyes	11
Sex (man/ woman)	4/7
Mean (\pm SD) age (years)	80.1 \pm 5.36
Diagnosis (geographic atrophy/disciform scars)	9/2
Mean follow-up (months)	15.7 \pm 2.8
<i>SD</i> Standard deviation	

segmented using 3D Slicer software (version 5.8.0) by placing four fiducial points: superior-nasal (SN), superior-temporal (ST), inferior-nasal (IN), and inferior-temporal (IT). The SN and ST points were placed directly on the clearly visible anterior corners of the telescope. Due to posterior shadowing and reflections, the inferior corners (IN and IT) were often obscured; in these cases, they were geometrically reconstructed by translating SN and ST exactly at 4.40 mm posteriorly along the local optical axis, defined as the line orthogonal to the anterior contour (SN-ST) in each B-scan. The geometric center (centroid) of these four points was computed automatically using the 3D Slicer software (Fig. 1). For each scan, the distance between the center of the scleral spur axis and the telescope centroid was measured. Additionally, the tilt angle was calculated between the scleral spur plane and the telescope axis, defined as the line orthogonal to the anterior surface of the telescope. Each orthogonal scan pair was combined to determine the three-dimensional spatial relationship between the telescope and the ocular reference system. Decentration and tilt were reported in both polar and Cartesian coordinates.

To manage potential discrepancies between the CASIA2 and Anterior AS-OCT systems, image scaling was carefully calibrated using the integrated reference scales provided by each device, ensuring consistent pixel-to-millimeter conversions across all analyses.

All image acquisitions and processing were performed independently by two experienced ophthalmologists (LDA and RR), and interobserver agreement for decentration and tilt measurements was assessed using the intraclass correlation coefficient (ICC).

Endothelial Cell Assessment

Endothelial cell density was evaluated preoperatively and at 12 months postoperatively using specular microscopy. In the Florence cohort, measurements were obtained using the PERSEUS Endothelial Microscope (CSO, Florence, Italy), and in the Newcastle cohort, the CEM-530 Specular Microscope (Nidek Co., Ltd., Japan), was used.

Statistical Analysis

Descriptive statistics were expressed as mean \pm standard deviation (SD) for continuous variables and as absolute and relative frequencies for categorical variables. Normality of data distribution was assessed using the Shapiro–Wilk test. Paired comparisons were performed using the Wilcoxon signed-rank test. Interobserver agreement was evaluated with the ICC. All analyses were performed using IBM SPSS Statistics (version 29.0; IBM Corp., Armonk, NY), and a p -value < 0.05 was considered to be statistically significant.

RESULTS

Eleven eyes of 11 patients (4 men, 7 women) were included in the study. The mean (\pm SD) age at the time of SING-IMT implantation was 80.1 ± 5.36 (range 75–89) years. The mean follow-up was 15.7 ± 2.8 (range 12–19) months. Nine patients presented with geographic atrophy, and two patients had disciform scars. The demographic characteristics are summarized in Table 1.

The mean (\pm SD) preoperative axial length (AL) was 23.37 ± 0.74 mm, and the mean preoperative anterior chamber depth (ACD) was 3.01 ± 0.35 mm. Mean CDVA was 14.73 ± 6.02 ETDRS letters before surgery and significantly improved to 26.82 ± 8.96 at the last follow-up ($p < 0.01$). The mean preoperative ECD was 2413 ± 422 cells/mm² and decreased to 2092 ± 416 cells/mm² at 12 months postoperatively ($p < 0.01$). This corresponded to a mean endothelial cell loss (ECL) of $13.21\% \pm 3.57\%$.

Postoperative complications included transient IOP elevation in three patients (27.3%), which required IOP-lowering eye-drop, anterior fibrin chamber reaction in one patient (9.1%) [8], which required subtenon injection of triamcinolone acetonide, and transient corneal oedema in two patients (9.2%) that was successfully resolved through a regimen of topical steroids and hypertonic eye drops.

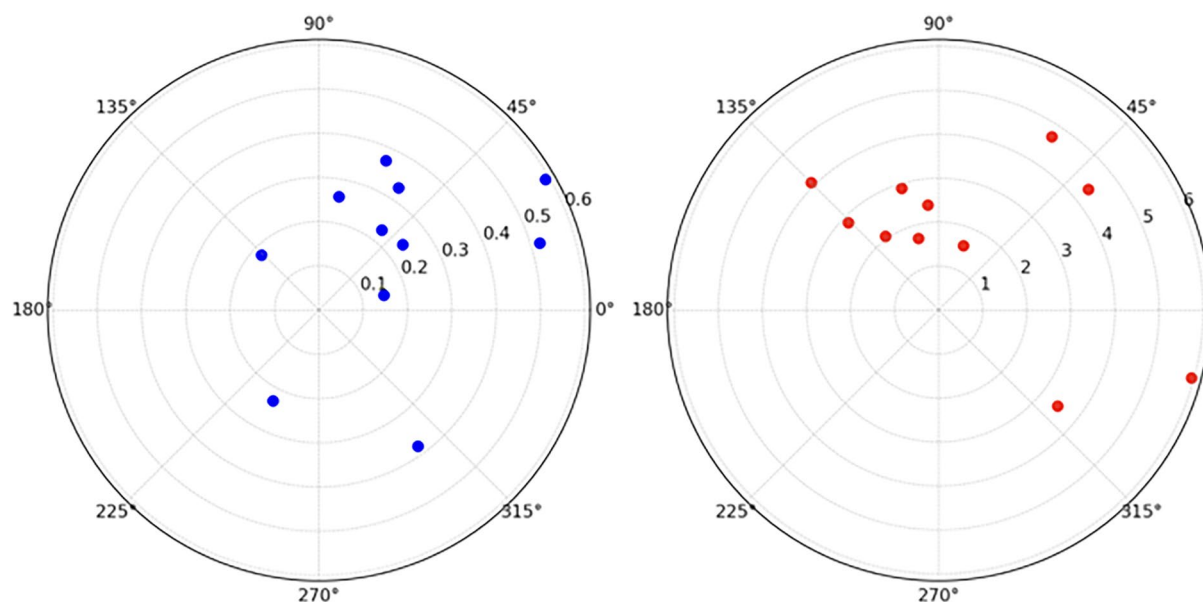


Fig. 2 Schematic representation of the three telescope configurations relative to the plane passing through the scleral spurs. **a** Posterior configuration: the telescope is positioned behind the iris plane and partially covered by the iris. **b** Intermediate configuration: the telescope is

aligned with the iris plane but does not exceed the scleral spur plane. **c** Anterior configuration: the telescope protrudes anteriorly beyond the scleral spur plane and the iris plane

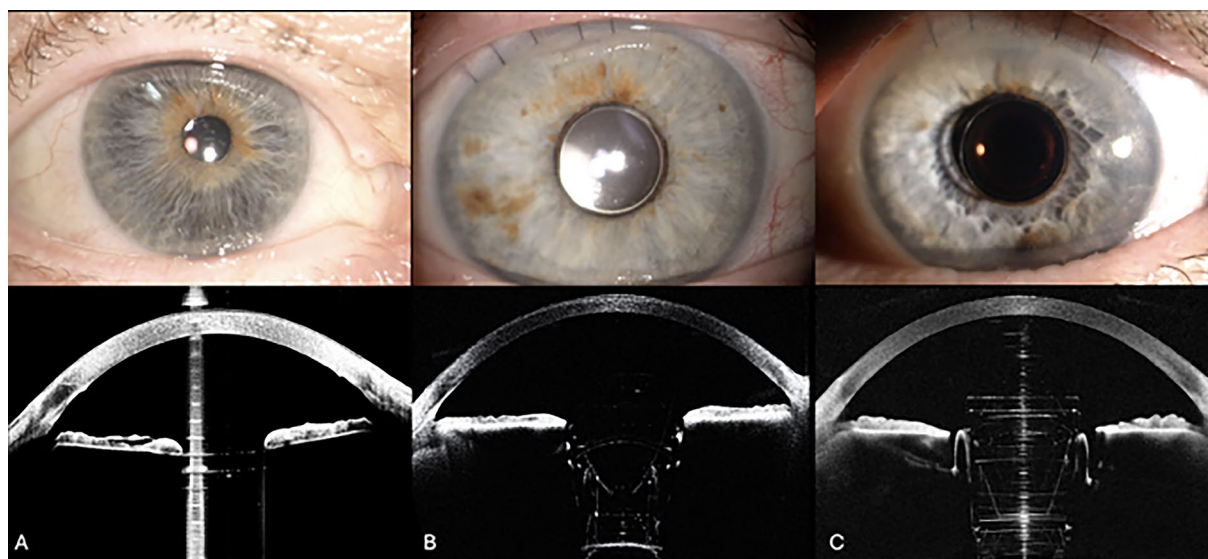


Fig. 3 The polar plot illustrates the distribution of the SING-IMT™ across various angles (left panel). Tilt degrees are shown as the distance from the center of the axis (right panel)

Table 2 Summary of biometrics, anterior segment optical coherence tomography parameters, decentration, and tilt in the 11 eyes assessed in this study

Parameters	Mean \pm SD	95% CI
Preoperative ETDRS (letters)	14.73 \pm 6.02	10.68–18.77
Postoperative ETDRS (letters)	25.82 \pm 8.96	19.80–31.84
Preoperative axial length (mm)	23.37 \pm 0.74	22.87–23.87
Preoperative ACD (mm)	3.01 \pm 0.35	2.77–3.25
Preoperative ECD (cells/mm ²)	2413 \pm 422	2129–2696
Postoperative ECD (cells/mm ²)	2092 \pm 416	1812–2371
Mean ECL (%)	13.21 \pm 3.57	10.81–15.61
Mean C-T distance (mm)	2.71 \pm 0.48	2.39–3.03
Mean decentration radius (mm)	0.33 \pm 0.12	0.25–0.41
<i>x</i> (mm)	0.17 \pm 0.19	0.04–0.30
<i>y</i> (mm)	0.12 \pm 0.19	–0.01 to 0.25
Mean tilt (°)	3.28 \pm 1.31	2.40–4.16

ACD Anterior chamber depth, *AS-OCT* anterior segment optical coherence tomography, *CI* confidence Interval, *C-T* cornea–telescope, *ECD* endothelial cell density, *ECL* endothelial cell loss, *ETDRS* Early Treatment Diabetic Retinopathy Study, *SD* standard deviation, *SING-ITM* Smaller-Incision New-Generation Implantable Miniature Telescope

AS-OCT Evaluation

Four telescopes (36.4%) were at the iris plane, three telescopes (27.3%) were below the iris plane, and four telescopes (36.4%) were above the iris plane (Fig. 2). The mean (\pm SD) C-T distance was 2.71 \pm 0.48 mm.

Figure 3 shows the radius of decentration and tilt in a polar plot; the mean (\pm SD) radius of decentration was 0.33 \pm 0.12 mm. Regarding horizontal decentration, the mean displacement of the telescope was 0.17 \pm 0.19 mm nasally; for vertical decentration, the telescope was observed on average to be positioned superiorly by 0.12 \pm 0.19 mm. The mean tilt of 3.28 \pm 1.31° relative to the scleral spur plane was toward the supero-temporal direction. The ICC was 0.83 (95% confidence interval [CI] 0.21–0.76) for decentration and 0.88 (95% CI 0.19–0.77) for tilt. All parameters are summarized in Table 2.

DISCUSSION

We conducted an in vivo analysis of patients 12 months following implantation with SING-ITM™, using AS-OCT to address the characteristics of the device; to our knowledge, this is the first in vivo investigation of the device's stability with this imaging approach. There are numerous factors influencing biomechanical stability inside the capsular bag, including surgical techniques [9], IOL material properties [10], haptic design [11], as well as the inherent patient's variability of the capsular bag and wound healing.

The second generation of the IMT™ implant incorporates a redesigned shape that enables in-the-bag implantation through a smaller incision (7.5–8 mm) compared to the incisions needed for the first-generation device (12.5–13 mm). This advancement is made possible by the silicone haptics of the SING-ITM™, which are foldable, thereby allowing for loading into the T-vert injector. As a result, the surgical procedure is both simpler and safer, with reduced endothelial cell loss.

The methodology used to calculate decentration and tilt has previously been applied to spherical and aspherical IOLs of various designs [12, 13]. However, the SING-ITM™ optic has a different shape, appearing as a rectangular structure on OCT images. While the anterior edges of the telescope are clearly visible, the posterior edge cannot be visualized—even with the two SS AS-OCT devices used in this study, which typically provide good tissue

penetration—due to imaging artifacts. Therefore, using the known dimensions of the telescope, we manually segmented its visible edges in the cross-sectional images to estimate its center and assess decentration and tilt relative to the axis passing through the scleral spur. We selected the scleral spur plane as the reference, as the topographic axis may be altered by the surgical procedure and unstable fixation.

The degree of tilt and decentration observed after 12 months was comparable to that of both C-loop [13] and plate [14] IOLs reported in the literature using AS-OCT-based methodologies, in populations of elderly cataract patients without significant ocular comorbidities. Notably, there was a tendency for superior and nasal displacement, observed in both right and left eyes. Furthermore, the evaluation of lens position after a minimum of 12 months suggests sustained stability, despite the device being heavier than a conventional IOL. This stability can also be attributed to the strict eligibility criteria for implantation, which excluded myopic eyes with an axial length > 25 mm, as well as cases of pseudoexfoliation from the surgical procedure.

The SING-IMT™ demonstrates aberration characteristics similar to those of conventional monofocal IOLs [15], suggesting a potential tolerance to small misalignments that is comparable to standard IOLs [16]. However, its telescopic design introduces unique optical considerations that may affect this tolerance; further specific investigations are essential to validate its tolerance to tilt and decentration in clinical practice. Notably, explantation cases due to blurry or hazy vision have been reported [17, 18], in which optical misalignment may represent a contributing factor.

While earlier reports on the first-generation intraocular telescope described a near-constant protrusion of the device through the pupil (ranging from 0.1 to 0.5 mm) [19], our study identified three distinct configurations of device positioning: anterior to the pupillary plane, at the pupillary plane, and posterior to the pupillary plane. This variability may reflect the interplay of several mechanisms. In vitro investigations have indicated that SING-IMT™ implantation

can induce a capsular bag distension of approximately 2–3 mm [20], although the magnitude of this effect is likely reduced compared with that of the first-generation device, given the smaller diameter of its foldable silicone haptics (10.8 mm vs 13.5 mm for the rigid PMMA loops). In addition, postoperative capsular contraction, which could otherwise accentuate anterior displacement, may be attenuated by the flexibility of the silicone haptics. These factors might account for the absence of a uniform anterior protrusion and the wider range of device positions observed at 12 months.

The mean (\pm SD) C-T distance was 2.71 ± 0.48 mm; to the best of our knowledge, this is the first study to report this critical parameter with a 12-month follow-up; additionally, the mean distance in our cohort was greater than previously reported for the first-generation IMT [19]; this may contribute to the favorable profile of ECL observed in both our series and aligns with recently published findings on the SING-IMT™.

At 12 months, the mean (\pm SD) ECL in our cohort was $13.21\% \pm 3.57\%$, consistent with previously reported short-term outcomes for the SING-IMT™ [4, 5, 21]. In our study, endothelial assessment was limited to baseline and the 12-month follow-up, preventing a clear distinction between acute postoperative loss—presumably linked to surgical trauma—and any delayed loss potentially related to long-term proximity of the implant to the endothelium.

Our study does have some limitations. First, the retrospective nature of the study and the limited sample size rendered our statistical analyses less robust, and the manual measurement techniques used to assess tilt and decentration could also introduce potential inaccuracies. Although two different SS AS-OCT devices were employed for image acquisition—an aspect that could theoretically introduce inter-device measurement bias—previous validation studies have demonstrated a high level of agreement between these platforms in quantifying anterior segment parameters [22]. In addition, the lack of a control group restricts causal inference, and the tertiary nature of the hospital may further

limit the generalizability of the results. A further limitation concerns the effect of SING IMT™ weight on stability with changes in head position, which was not evaluated and may warrant future investigation.

CONCLUSION

In conclusion, the SING-IMT™ exhibited tilt and decentration values comparable to those of standard in-the-bag IOLs, despite its distinct material composition and geometric design. In addition, the device appeared largely confined to the pupillary plane, while maintaining adequate clearance from the corneal endothelium. Prospective multicentric studies are needed to confirm these results and define the long-term outcomes of the SING-IMT™.

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Data Availability. Data are available upon reasonable request to the corresponding author.

Declarations

Conflicts of Interest. Lorenzo De Angelis, Mario Galasso, Raffaele Raimondi, Sandro Di Simplicio, Mario Romano, Mario Damiano Toro, Stanislao Rizzo and Francesco Barca declare that they have no conflicts of interest related to this work. Faustino Vidal-Aroca reports also being an employee of Samsara Vision during this study.

Ethical Approval. The study adhered to the principles of the Declaration of Helsinki, and the study protocol received approval from the ethics committee of Palagi Hospital, Azienda USL Toscana Centro (Florence, Italy) and from the local ethics committee of the Royal Victoria Infirmary Hospital (Newcastle upon Tyne, UK). The study also complied with Good Clinical Practice standards. All patients provided written informed consent for both the surgical procedure and for the use of their clinical data for research purposes.

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