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Research article

Smaller-incision new-generation implantable miniature telescope in late-stage age-related macular degeneration: 6 month outcomes

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ABSTRACT

Purpose: To evaluate the intermediate-term visual and safety outcomes of the small-incision second-generation implantable miniature telescope (SING IMT) in patients with late-stage age-related macular degeneration (AMD) at 6 months post-surgery.
Design: Retrospective cohort study.
Methods: Medical records of patients implanted with the SING IMT at two sites in Italy were reviewed. Outcomes evaluated up to 6 months post-surgery included best-corrected distance (BCDVA) and distance-corrected near (DCNVA) visual acuity, intraocular pressure (IOP), anterior chamber depth (ACD), corneal endothelial cell density (ECD), and adverse events.
Results: The study involved 35 patients (mean age: 77.4 years). At 6 months post-surgery, the mean ± standard deviation (SD) change in BCDVA from baseline was −0.29 ± 0.142, and at least 1-, 2-, and 3-line gains in BCDVA were achieved in 97.1 %, 68.6 % and 51.4 %, of operated eyes, respectively. The percentage of patients able to read at near distance increased from 28.6 % at baseline to 97.1 % at 6 months post-surgery with a mean improvement of −0.57 ± 0.206. No clinically meaningful change from baseline was observed in terms of IOP or ACD. The mean (SD) change from baseline in ECD at 6 months in operated eyes was −280.7 (315.9) cells/mm^2 (−11.4 %). The most frequent adverse event was corneal edema, and all cases were resolved with topical medications.
Conclusions: This intermediate-term assessment confirms that SING IMT implantation improved distance and near vision, with a low impact on the corneal endothelium and an acceptable and manageable rate of complications and adverse effects.

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1. Introduction

Age-macular degeneration (AMD) is an eye condition involving a progressive accumulation of drusen on the macula and/or pigmentary abnormalities, which ultimately damages the retina and results to irreversible central vision loss [1]. The late (also called advanced) form of AMD is usually associated with disciform scar (DS) (advanced wet AMD) and/or any geographic atrophy (GA) [1], and represents the most frequent cause of severe visual loss in older adults in developed countries [2]. Today, around 67 million people in Europe and around 20 million people in the US are affected by AMD, and this numbers are expected to increase over time due to population ageing [3,4]. Between 0.5 and 1 % of the patients are affected by late AMD in the developed world [3,4]. AMD negatively impacts the quality of life of patients as well as daily tasks including mobility, face recognition, computer use, watching TV, reading, and in some cases, self-care [5].

The treatment options currently available for patients with late wet AMD include anti-VEGF therapies [6]. Pegcetacoplan and avacincaptad pegol represent the first treatments approved by health authorities for GA, and have shown to reduce growth of GA only up to 20 % [7,8]. However, no clear data are currently available to know if these treatments can help restoring the vision. A non-surgical alternative to improve the vision of these patients and thus, their quality of life, is the use of low vision aids, such as spectacles, magnifiers or telescopes. However, these external devices are usually bulky and can require the occupation of one or both hands [9]. Internal aids are devices designed to be intraocularly implanted in patients. Compared to external aids, these devices are more discreet, and most importantly, improve head motion and vestibular effects [10].

The small-incision second-generation implantable miniature telescope (SING IMT) has been specifically developed to improve the visual performance of patients with central vision loss due to late AMD. Compared with the previous generations of the device, SING IMT is preloaded and presents several benefits including lower invasiveness and faster procedure and recovery times [11,12]. This device has received CE marking, indicating compliance with European health, safety, and environmental protection standards and aims to increase the magnification of the visual field in one eye based on a similar optical principle than the Galilean telescope (Fig. 1).

Two separated retrospective studies assessing the performance and safety outcomes after SING IMT implantation have been conducted in two different centers in Italy. The 3-month outcomes reveals promising progress, demonstrating an improvement of at least 3 lines for the majority of patients across both centers [12,13] The aim of this report is to present the intermediate-term (6-months) outcomes of these studies including visual acuities, intraocular pressure (IOP), anterior chamber depth (ACD), corneal endothelial cell density (ECD) and occurrence of complications, adverse events and device deficiencies.

2. Material and methods

2.1. Study design

This retrospective study included 35 patients with late-stage AMD treated at two different sites in Italy, the University Federico II in Naples and the Policlinico Gemelli hospital in Rome. The study was conducted in accordance with the tenets of the Declaration of Helsinki and approved by the Ethics Committee of the University of Naples Federico II and the Policlinico Gemelli hospital (protocol n° EC-19/2022 & protocol n° 4634, respectively). Written informed consent for the processing of personal data was obtained from all patients. Patients older than 55 years old, with stable central VA loss caused by untreatable bilateral late-stage AMD (geographic atrophy, disciform scar, or both), with a diagnosis of cataract in the study eye, and have good peripheral vision in the fellow eye (i.e.,

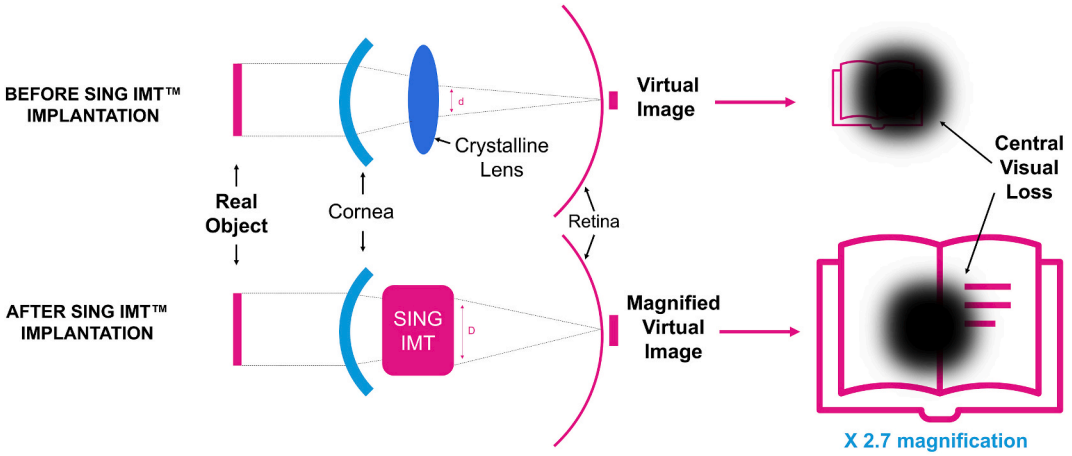

Fig. 1. Optical principle of the SING IMT™. The light diverging from a real object (i.e., a book) is focused by the cornea and the crystalline lens on the retina which forms the virtual image. In case of late-stage AMD, the central retina can be damaged, resulting in a central vision loss where the object cannot be imaged. Based on a Galilean-like optical principle, SING IMT™ is composed of micro-optics that can increase the diameter (D > d) of the focused light inside the eye, resulting into a ~2.7×-magnification of the virtual image. The virtual image is then larger than the visual central loss and can be imaged by the peripheral retina.

no other retinal diseases) an anterior chamber depth over 2.5 mm, endothelial cell density exceeding 1600 cells/mm^2, and baseline visual acuity (CDVA) between 20/80 and 20/800. Only patients achieving a five-letter improvement on the ETDRS scale with the ETS (external telescope simulator) were considered suitable for implantation. The full list of inclusion and exclusion criteria are detailed in the previous studies [11–13].

2.2. Surgical procedure and postoperative care

The surgical procedure and postoperative care have also been described in previous studies [11,12]. Briefly, standard cataract surgery was performed via a continuous manual circular anterior capsulorhexis with a diameter of at least 5.5–6.0 mm and a phacoemulsification. Then, the SING IMT preloaded in a delivery system was inserted into the anterior chamber through a sclerocorneal incision enlarged at 7.5–8.0 mm at 12 o'clock position. The telescope was then positioned into the capsular bag with two haptics inferiorly and one superiorly. Finally, the sclerocorneal incision was sutured and an iridectomy was performed. Following SING IMT implantation, patients received topical medications including antibiotic and anti-inflammatory eyedrops for one month, mydriatic and cycloplegic agents for at least 2 weeks and hypertonic medications for 2 weeks in case of corneal edema.

2.3. Rehabilitation program

To optimize the visual outcomes, patients implanted with SING IMT implantation followed a rehabilitation program aiming to improve the collaboration between the implanted eye and the fellow eye. Patients started this program 6 weeks following surgery, the time required for corneal healing and clear vision. All patients included in this study attended 8 sessions of 1 h and a half each (with a 15-min break) every 2–3 weeks over a period of 6 months. The program covered different skills such as visual abilities, reading, writing, visual motor integration, and mobility [14].

2.4. Baseline and postoperative outcomes

All baseline and postoperative outcomes were obtained from the electronic medical records. Patients underwent a clinical examination at baseline and at different follow-up visits following SING IMT implantation (1 day, 2 weeks, 1 month, 3 months and 6 months). This examination included slit lamp biomicroscopy, gonioscopy, dilated fundus examination, and measurements of BCDVA, DCNVA, IOP, ACD and ECD, as reported in the 3-month follow-up studies [12,13]. Distance and near VAs were measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart or Jaeger levels, respectively, and then converted to LogMAR. Optical biometry was used to determine the axial length as well as the ACD. Corneal ECD was measured using specular microscopy, and IOP using Goldmann applanation tonometry. Finally, the rate of adverse events and complications were recorded.

2.5. Statistical analysis

Continuous variables were expressed as arithmetic mean ± standard deviation (SD), median, minimum, and maximum. Paired *t*-test was used to compare the different outcomes at the postoperative timepoints versus baseline, as well as the implanted eye versus the fellow eye. Statistical significance was set at $p < 0.05$. All data were analyzed using SAS v. 9.4 (SAS Institute, Cary, NC, USA).

3. Results

3.1. Baseline demographics

Overall, 35 patients across both sites were included in this study. Mean patient age was 77.4 ± 6.89, and 45.7 % (16/35) of the

Table 1
Baseline characteristics of patients.

Parameter	Patients (N = 35)
Mean age, years (SD)	77.4 (6.89)
Range	59–91
Gender, n (%)	
Male	19 (54.3)
Female	16 (45.7)
Ethnicity, n (%)	
Caucasian	35 (100)
Diagnosis, n (%)	
Geographic atrophy	30 (85.7)
Disciform scar	5 (14.3)
Implanted eye, n (%)	
Right (OD)	23 (65.7)
Left (OS)	12 (34.3)

OD, right eye; OS, left eye; SD, standard deviation.

patients were female (Table 1). Moreover, all patients included were white. GA was diagnosed in 85.7 % (30/35) of the patients were, and disciform scar in 14.3 % (5/35). Finally, the SING IMT was mostly implanted in right eyes (65.7 %, 23/35) (Table 1).

3.2. Visual outcomes

Mean (±SD) baseline LogMAR BCDVA was 1.52 ± 0.142, corresponding to ~20/640 in Snellen. Following SING IMT implantation, mean BCDVA were found improved for all patients with a mean change from baseline of −0.14, −0.27 and −0.29 at 1-, 3-, and 6-months timepoints, respectively ($p < 0.001$ between baseline and all timepoints) (Fig. 2A). At 6 months follow-up, mean LogMAR BCDVA was 1.24 ± 0.197, corresponding to ~20/360 in Snellen. At the 3- and 6-month follow-up visits, a BCDVA improvement was measured in all treated eyes. A loss in BCDVA between 3-month and 6-month timepoints was found in one patient due to an implant dislocation. Overall, most patients (51.4 %, 18/35) had an improvement of 3 lines or better at the 6-month follow-up visit (Fig. 2B).

At baseline, only 28.6 % (10/35) of patients were able to read at near distance (Fig. 3A). This percentage significantly after SING IMT implantation to achieve 97.1 % (34/35) at 6-months post-surgery. Only one patient was still not able to read at near due to an implant dislocation. Among the patients able to read, mean ± SD LogMAR DCNVA was 0.82 ± 0.155, corresponding to ~20/125 in Snellen, and significantly decreased at all postoperative timepoints ($p < 0.0001$) (Fig. 3B). At 6 months follow-up, mean ± SD LogMAR DCNVA was 0.49 ± 0.230, corresponding to ~20/63 in Snellen, and a 3-line improvement compared to baseline.

3.3. IOP and ACD

Mean baseline IOP was 14.5 ± 2.91 mmHg for the eye receiving the implant and 14.4 ± 2.20 mmHg for the fellow eye. IOP was found to be slightly decreased at different postoperative timepoints in both eyes (Fig. 4A). At 6 months follow-up, change in IOP was less than 1 mmHg in both eyes compared to baseline. Mean baseline ACD was 3.111 ± 0.5305 mm and 3.442 ± 0.9315 mm for the eye receiving the implant and the fellow eye, respectively. At 6 months post-surgery, mean ACD was found slightly higher than baseline only in the fellow eye, with a mean change of 0.399 ± 0.9311 ($p = 0.0469$). However, this difference does not appear clinically meaningful. No change was observed in the implanted eye.

3.4. Endothelial cell density

At baseline, the ECD was 2468.2 ± 344.49 cells/mm^2 for the eye that would be implanted with SING IMT, and 2330.5 ± 399.71 cells/mm^2 for the fellow eye. In the implanted eye, the loss in ECD was −205.0 at 1-month, −245.3 at 3-month and −280.7 cells/mm^2 at 6-month timepoints, corresponding to a change from baseline of 8.3 %, 9.9 % and 11.4 %, respectively (Fig. 5). In comparison, the loss in ECD in the fellow eye was −34.2 at 1-month, −40.7 at 3-month and −58.0 cells/mm^2 at 6-month timepoints, corresponding to a change from baseline of 1.5 %, 1.7 % and 2.5 %, respectively (Fig. 5). The ECD loss between the implanted eye and the fellow eye was found significantly different at each timepoint ($p < 0.05$).

3.5. Rates of complications and adverse events

Corneal edema (that continued after 30 days post-surgery) was found to be the most common complications and occurred in 22.9 % of patients following SING IMT implantation (Table 2). Other complications and adverse events included iris atrophy still present at 7 days post-surgery, transient hyphema for more than 30 days, iris incarceration, distorted pupil, inflammatory deposits on device,

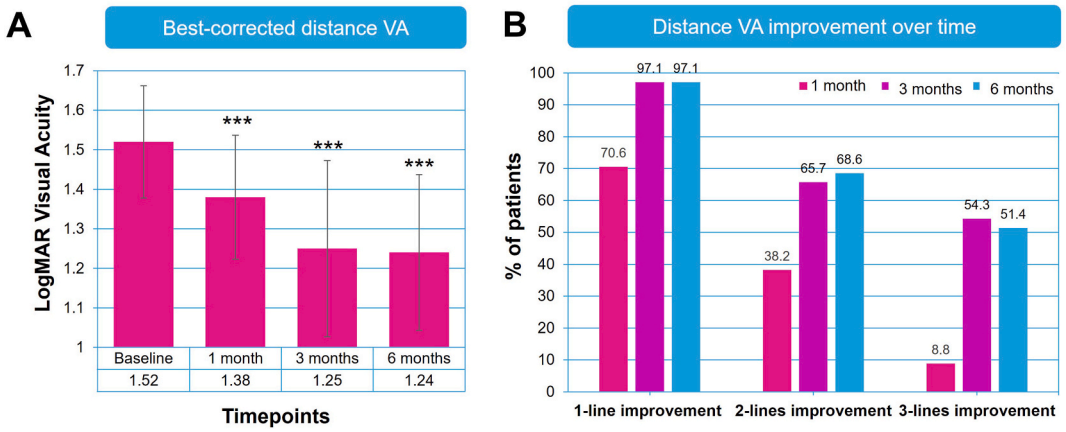

Fig. 2. Improvement of distance visual acuity following SING IMT implantation. (A) Mean ± SD LogMAR BCDVA at baseline and at different postoperative follow-up timepoints. (B) Percentage of patients who achieved at least 1-, 2-, or 3-line improvement in LogMAR BCDVA at different timepoints compared to baseline. BCDVA, best-corrected distance visual acuity; SD, standard deviation. ***$p < 0.001$.

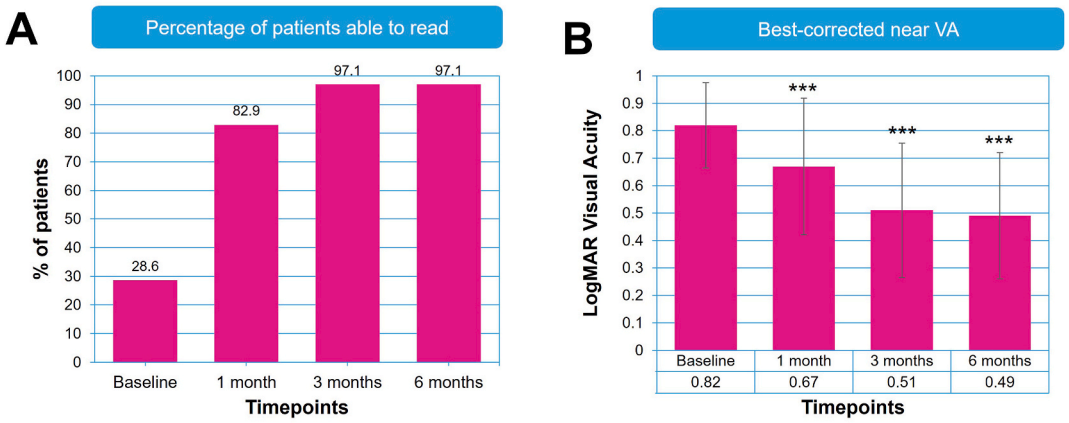

Fig. 3. Improvement of near visual acuity following SING IMT implantation. (A) Percentage of patients who were able to read at near distance at baseline and at different postoperative timepoints, (B) Mean ± SD LogMAR DCNVA at baseline and at different postoperative timepoints. (B). DCNVA, distance-corrected near visual acuity; SD, standard deviation. ***p < 0.001.

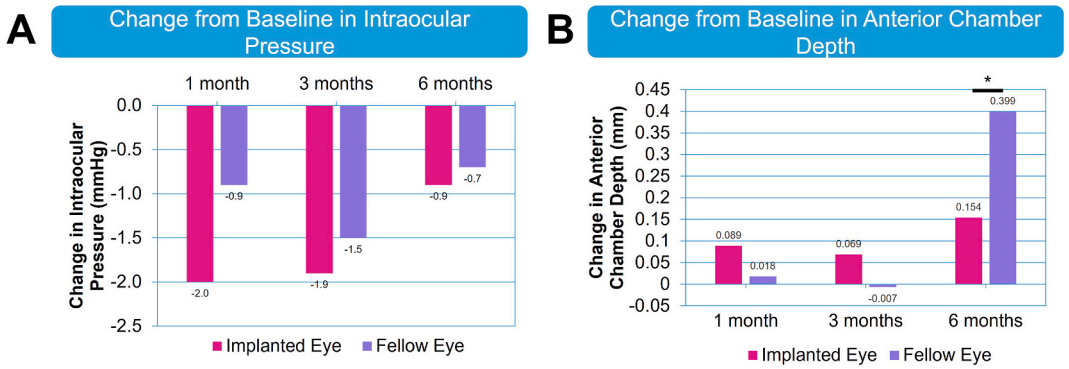

Fig. 4. Mean change *from baseline at different postoperative timepoints between the implanted eye and the fellow eye of (A) intraocular pressure and (B) anterior chamber depth.* *p < 0.05.

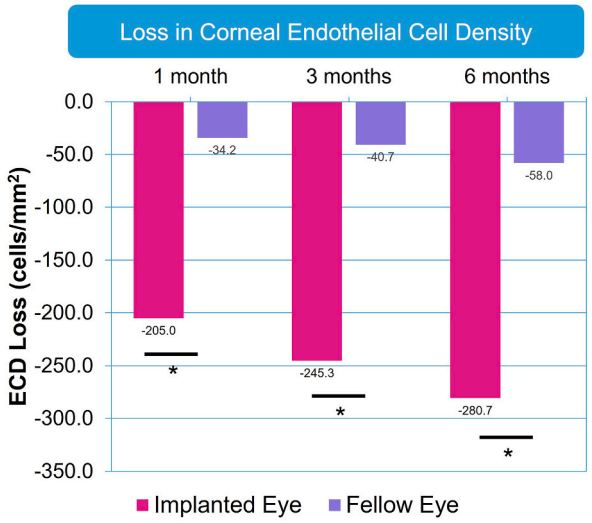

Fig. 5. *Mean loss in corneal endothelial cell density from baseline at different postoperative timepoints between the implanted eye and the fellow eye.* *p < 0.05.

increasing IOP within 7 days requiring treatment, choroidal neovascularization, pigment deposits on device, iris damage, implant dislocation and iris prolapse. Overall, 80 % of these complications and adverse events were able to be managed by different types of treatment and were found to be resolved at the 6-month follow-up visit. Only 4 cases of iris atrophy, 2 cases of pigment deposits on device and 1 case of iris damage were not possible to resolve.

4. Discussion

The short-term outcomes of SING IMT were described in two 3-months follow-up studies conducted in two different centers [12,13]. In this study, we combined the 6-month follow-up data of these two centers in order to assess the performance and safety outcomes on a larger population size.

Results of this study showed that the distance visual performance of implanted patients was found to be significantly improved by 3-line or more in 51.4 % at 6 months post-surgery, which confirmed the data reported in the previous studies [11–15]. In addition to distance vision, we also showed in this report that DCNVA was also significantly improved by ~3 lines at 6 months post-surgery. Similar VA improvements were reported with a previous generation of the device at 6-month follow-up [16,17]. All these results demonstrate that SING IMT implantation can be highly beneficial to improve visual performance in case of advanced central visual loss.

At 3-month follow-up, the endothelial cell loss following SING IMT implantation ranged from 8.3 % to 10.4 % [12,13]. This study showed that the cell loss slightly increased at 6-month follow up to achieve 11.4 %, which represents a similar rate compared to the loss induced by cataract surgery alone reported in the literature [18]. Interestingly, the endothelial cell loss is substantially reduced compared to the previous generation of the device at a similar postoperative follow-up timepoints [17]. However, data from our study support the view that regular ECD monitoring is essential in patients receiving the SING IMT implant.

No new complications or adverse events occurrent between the 3-month and 6-month follow-up timepoints [12,13]. The majority of complications and adverse events (80 %), and all cases of the most common one (corneal edema), were resolved at the 6-month follow-up visit. The other events (iris damage/atrophy, pigment deposits on the device) were not possible to solve because they were probably related to the device and not to inflammation. In addition, no reactivation of choroidal neovascularization were observed between the 6-month and 3-month follow-up [12,13]. Finally, no significant changes in terms of IOP or ACD were observed. Overall, these data suggest an acceptable safety profile of the SING IMT implantation.

This study presents some limitations, especially its retrospective design and the relatively low number of participants. Another limitation could be the fact that the effect on the visual outcomes of the cataract surgery alone has not been compared with SING IMT implantation. However, a study showed that the visual improvement due to cataract surgery is rather limited for patients with advanced AMD, such as wet AMD, with 7 ETDRS letters improvement [19], compared to 14 letters improvement measured in this study. Therefore, the improvement in visual acuity demonstrated in this study is due to the SING IMT implantation, and not only the phacoemulsification.

5. Conclusion

The analysis of 6-month follow-up data from diverse clinical centers reaffirmed the prior evidence concerning the efficacy and safety of SING IMT implantation. This study reasserted the substantial enhancement in distance visual acuity, consistent with earlier reports, and notably demonstrated significant improvement in distance-corrected near visual acuity (DCNVA). Addressing concerns regarding endothelial cell loss post-implantation, this study noted a marginal increase at the 6-month interval thereby providing reassurance regarding the safety profile of the intervention. Importantly, the observed reduction in endothelial cell loss compared to prior device iterations at similar postoperative periods indicates potential advancements in minimizing this concern. The absence of new complications or adverse events during the follow-up period, coupled with the resolution of a majority of complications, underscores the manageable nature of associated adverse effects. Acknowledging inherent limitations in the retrospective design and limited participant cohort, future comparative analyses with the sole impact of cataract surgery could provide valuable insights. In essence, this 6-month study reinforces the pivotal role of SING IMT in significantly visual outcomes for late-stage AMD patients, showing safety profiles amidst manageable adverse events. While this retrospective design precludes functional assessments, future prospective studies could incorporate measures such as visual function questionnaires to gain further insights into patient quality of life and activities of daily living. Ongoing clinical studies in the United States and Europe (NCT05438732 and NCT04796545, respectively) stand as pivotal endeavors to corroborate the presented data, paving the way for broader clinical adoption and continual refinement of this surgical approach.

CRediT authorship contribution statement

Mario Damiano Toro: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Project administration, Data curation, Conceptualization. **Alfonso Savastano:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Data curation, Conceptualization. **Faustino Vidal Aroca:** Writing – review & editing, Validation, Supervision, Project administration, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Paola Sasso:** Writing – review & editing, Visualization, Validation, Resources, Methodology. **Giuseppe Francione:** Supervision, Methodology, Investigation, Formal analysis, Data curation. **Gaetano Fioretto:** Visualization, Methodology, Investigation, Data curation. **Marina Montemagni:** Visualization, Software, Resources, Investigation. **Claudio Xompero:** Visualization, Software, Resources, Investigation. **Nicola**

Table 2
Rates of complications and adverse events which occurred in patients following SING IMT implantation, treatment used to manage the event, and if the event has been resolved at 6 months post-surgery.

Complications and adverse events	Proportion, % (n)	Treatment performed	Resolved?
Corneal edema, from 30 days after surgery	22.9 (8)	Topical medications	Yes
Iris atrophy, from 7 days after surgery	11.4 (4)	N/A	No
Transient hyphema for more than 30 days	8.6 (3)	BSS rinse	Yes
Iris incarceration	8.6 (3)	Surgical repositioning	Yes
Distorted pupil	8.6 (3)	Iridoplasty	Yes
Inflammatory deposits on device	8.6 (3)	Topical medications	Yes
Increasing IOP within 7 days requiring treatment	5.7 (2)	Topical medications	Yes
Choroidal neovascularization	5.7 (2)	Anti-VEGF injection	Yes
Pigment deposits on device	5.7 (2)	N/A	No
Iris damage	2.9 (1)	N/A	No
Implant dislocation	2.9 (1)	Surgical repositioning	Yes
Iris prolapse	2.9 (1)	Surgical repositioning	Yes
Iritis, from 30 days after surgery	2.9 (1)	Topical medications	Yes
Uveitis	2.9 (1)	Topical medications	Yes

IOP, intraocular pressure; N/A, non applicable.

Claudio D'Onofrio: Visualization, Software, Methodology, Investigation, Data curation. **Ciro Costagliola:** Supervision, Methodology, Formal analysis, Conceptualization. **Stanislao Rizzo:** Writing – review & editing, Validation, Supervision, Investigation, Conceptualization.

Ethics statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the University of Naples Federico II (protocol n° EC-19/2022 of December 1, 2022 & protocol n° 4634 of July 28, 2022, respectively). Informed Consent Statement: Written informed consent was obtained from all subjects involved in the study.

Data availability statement

Data are available upon reasonable request to the corresponding author.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Faustino Vidal Aroca reports a relationship with Samsara Vision that includes: employment. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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