A Prospective Multicenter Clinical Trial to Evaluate the Safety and Effectiveness of the Implantable Miniature Telescope

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• PURPOSE: **To evaluate the safety and preliminary efficacy of a novel visual prosthetic device, the Implantable Miniature Telescope, IMT (by Dr Isaac Lipshitz) (IMT), in a phase I trial in patients with significant bilateral central vision impairment from late-stage age-related macular degeneration (AMD). The IMT is designed to reduce the relative size of the scotoma by rendering enlarged (threefold) central visual field images over the central and peripheral retina.**

• DESIGN: **Prospective, multicenter, open-label clinical trial.**

• METHODS: **In this prospective, multicenter phase I trial, 14 patients aged 60 or older with bilateral geographic atrophy or disciform scar AMD, cataract, and best-corrected visual acuity (BCVA) between 20/80 and 20/400 had an IMT implanted in one eye. Distance and near BCVA, endothelial cell density, and quality of life, measured as activities of daily life (ADL), were evaluated preoperatively and postoperatively.**

• RESULTS: **At 12 months, 10 (77%) of 13 patients gained 2 more lines of either distance or near BCVA, and eight (62%) of 13 patients gained 3 or more lines in either distance or near BCVA. Mean endothelial cell density decreased by 13%. All adverse events resolved without sequelae. ADL scores improved in the majority of patients.**

• CONCLUSION: **The results of this phase I trial support further evaluation of the IMT in a larger study population with late-stage AMD. A phase II/III trial is in progress. (Am J Ophthalmol 2004;137:993–1001.**

IN THE UNITED STATES, MORE THAN 1.6 MILLION INDIVIDUALS have late-stage age-related macular degeneration (AMD) defined as choroidal neovascularization or geographic atrophy,[1] and more than 500,000 new cases are diagnosed each year.[2] Approximately 45% to 55% of these individuals have bilateral disease.[3] These individuals experience irreversible moderate to severe central vision impairment in one or both eyes, negatively impacting central vision tasks such as recognizing facial features, driving, watching television, and reading. The impact on quality of life can be profound, leading to loss of independence, chronic depression, and increased risk of accidents.[4]

Patients presenting with central field loss from advanced AMD generally respond well to magnification for distance and near vision, and external vision appliances such as handheld and spectacle-mounted telescopes may be prescribed. However, available devices are cumbersome to use, and clinically measured visual fields are small. Patients are often self-conscious of their appearance, and they may experience nausea when using these devices because of a vestibular ocular reflex conflict caused by the need to scan using head movement rather than natural eye movement. In addition to these limitations, these devices also do not provide a permanent solution to debilitating central vision loss.

A visual prosthetic device that provides the eye with an enlarged retinal image of the central visual field has been developed with the goal of improving central vision in patients with moderate to severe vision impairment from bilateral, untreatable late-stage AMD. The Implantable Miniature Telescope, IMT® (by Dr Isaac Lipshitz), (IMT;

Biosketch and/or additional material at www.ajo.com.

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This study was supported by the sponsor, VisionCare Ophthalmic Technologies, Inc, Saratoga, California. The device being investigated, the Implantable Miniature Telescope, is proprietary to them. The sponsor paid for the conduct of the study. Dr. Lane is a paid consultant to VisionCare, the study sponsor. The IMT (by Dr. Isaac Lipshitz) was invented by VisionCare founders Yossi Gross and Dr. Isaac Lipshitz.

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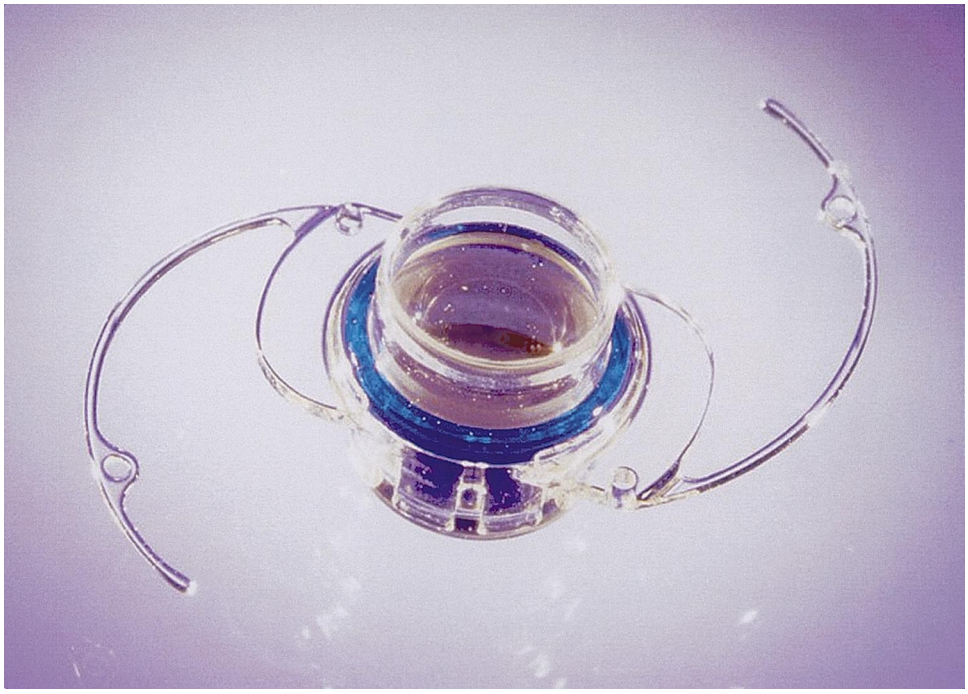

FIGURE 1. The Implantable Miniature Telescope (IMT by Dr Isaac Lipshitz), view of anterior aspect. The central glass optical cylinder of this visual prosthetic device houses high-plus and high-minus microlenses. The optic is centered in a clear polymethylmethacrylate (PMMA) carrier plate with modified C-loops. The blue PMMA ring serves as a light restrictor, designed to prevent glare.

VisionCare Ophthalmic Technologies, Saratoga, California) is designed for placement in the posterior chamber of the anterior segment of the eye during an outpatient surgical procedure.[5] The IMT is composed of an optical apparatus supported by a polymethylmethacrylate (PMMA) carrier with two continuous haptics (Figure 1). The optical component is a compound lens system composed of an anteriorly positioned positive lens and a posteriorly positioned negative lens sealed in a glass tube with clear window end caps. In conjunction with the cornea, the device functions as a telephoto system with an optimal focusing distance of 0.5 m. The overall refractive power of the optic is provided by both microlenses and the air spaces contained in the glass tube. The air spaces also add buoyancy to the device, decreasing its weight in aqueous. The device weighs approximately 46 mg in aqueous and 96 mg in air, about four to five times heavier than an intraocular lens. During an outpatient procedure, the IMT is implanted within the capsular bag in the posterior chamber, after the cataractous crystalline lens has been removed, and is secured by the haptic loops to inhibit tilt or movement. No intraocular lens is used in conjunction with this device.

The IMT optic is approximately 4.6 mm in length and 3.0 mm in diameter, spanning the distal portion of the posterior chamber to the distal portion of the anterior chamber. Positioned in the capsular bag, the IMT marginally protrudes through the pupil by approximately 0.1 mm to 0.5 mm, allowing for a clearance of approximately 2.0 mm from the anterior window of the IMT to the corneal endothelium (Figures 2 and 3).

The IMT optics and configuration are designed for a standard eye. Once implanted, the IMT together with the cornea functions as a telephoto system, producing an image on the retina that is three times larger than the image normally projected by the cornea and crystalline lens. Postoperatively, standard prescription spectacle lenses are dispensed for distance and near vision, fine-tuning the focus of the enlarged retinal image. The optical design of the device provides it a large depth of field, much larger than the normal eye with an intraocular lens. The optic is also made to produce an image on the spherical retina so that curvature of field is minimized.

In contrast with previous attempts that projected images specifically onto the preferred retinal location,[6] the IMT renders a high-resolution enlarged image onto 36 degrees of the retina (with a 12-degree field of view) to provide the patient with the ability to recognize images that were either difficult or impossible to see because of maculopathy. If needed, higher magnification can be achieved by bringing reading material and near vision activities closer to the eye and using low-power plus spectacles to maintain focus.

The IMT is designed for monocular use in patients with central field loss and intact peripheral vision. The implanted eye provides central vision, while the fellow eye

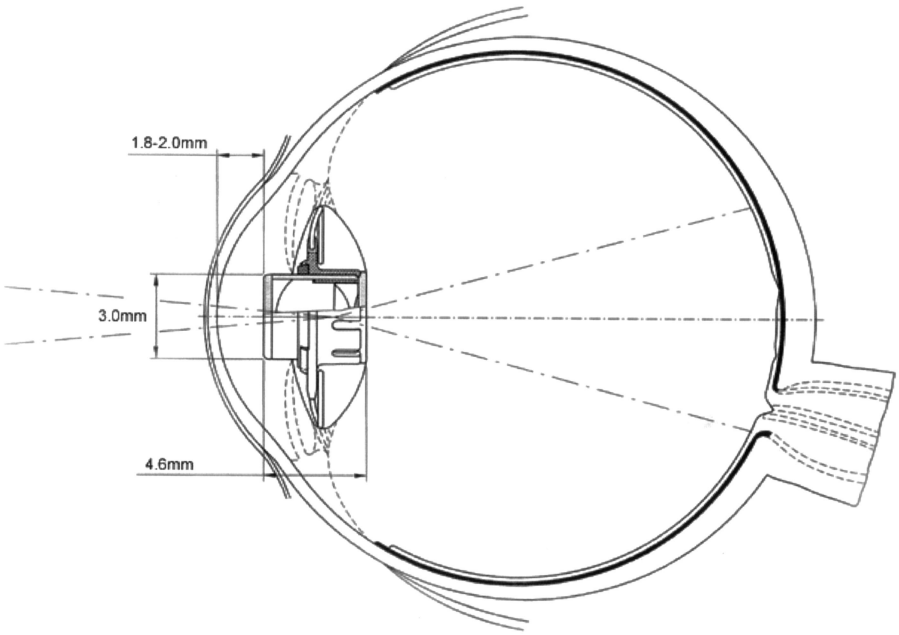

FIGURE 2. A cross-section schematic of the Implantable Miniature Telescope device positioned in the posterior chamber with haptics in the capsular bag. Note that the device marginally protrudes through the pupil, generally allowing for a 2-mm clearance to the corneal endothelium.

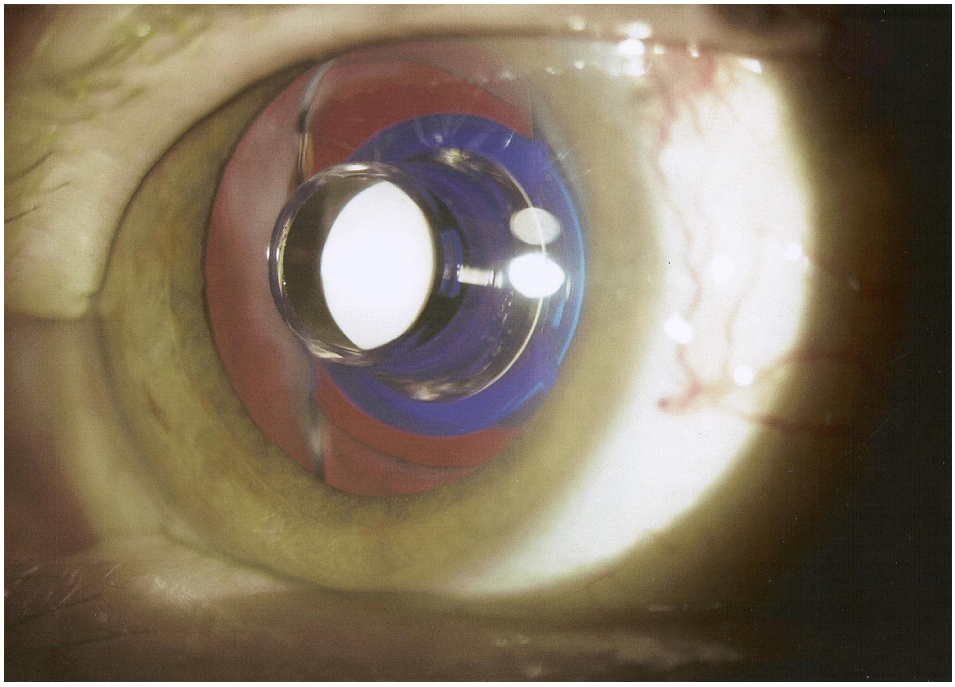

FIGURE 3. The Implantable Miniature Telescope device shown 6 months postimplantation. The capsular bag has fibrosed around the carrier plate and haptics. The convex surface of the high-plus microlens is seen illuminated behind the front window of the telescope. (Photograph by David A. Peroceschi.)

provides peripheral vision for orientation and mobility tasks.

A functional advantage of the IMT is avoidance of patient symptoms precipitated by vestibular ocular reflex conflict, which can occur with head-mounted image-enlargement devices. Despite its threefold image enlargement, the unique intraocular placement of the IMT allows the vestibular ocular reflex to occur without disparity

between head movements and compensatory eye movements.[7] The capability afforded by the device of scanning distant or near images using natural eye scanning movements, rather than head scanning movements, can provide comfortable, functional use in daily visual activities. Cosmetically, natural appearance is maintained.

A phase I multicenter trial of the IMT in patients with stable, untreatable AMD was conducted with the goal of evaluating the safety and effectiveness of this novel device.

DESIGN

THIS STUDY WAS A PROSPECTIVE, MULTICENTER, OPEN-label clinical trial.

METHODS

A PHASE I CLINICAL TRIAL OF THIS VISUAL PROSTHETIC device was conducted at four centers in the United States; 15 patients with stable advanced AMD with bilateral macular scars were enrolled. All investigational centers obtained institutional review board approval before initiating the study. This study was conducted under an investigation device exemption granted by the US Food and Drug Administration.

Patients who were candidates for enrollment in this study presented with bilateral, stable atrophic or disciform scar AMD and cataract and were referred to or recruited from the physician's regular practice. Patients were required to be 60 years or older, with best-corrected visual acuity (BCVA) between 20/80 and 20/400 in both eyes and improved visual acuity with an external telescope in the planned operative eye. Only the eye with worse visual acuity was eligible to be enrolled in the study, and only if visual acuity with the external telescope was equal to or better than the BCVA of the fellow eye without the external telescope. External telescope visual acuity assessment was performed with a plano Galilean telescope (Designs for Vision, Inc) with 3× magnification and an 8-degree visual field. Other eligibility criteria included a requirement for adequate mental capacity to allow conduct of the extensive visual examination necessary for the study and for informed consent. Patients were also screened for their ability and willingness to return for scheduled follow-up examinations for a period of 1 year after surgery. Patients with significant corneal disease, endothelial cell density (ECD) $<$1,500 cells/mm,^{2} myopia or hyperopia $>$6.0 diopters, previous intraocular or refractive surgery, glaucoma or ocular hypertension under treatment, zonular weakness, lens pseudoexfoliation, diabetic retinopathy, retinal vascular disease, vitreous in anterior chamber, optic nerve disease, history of retinal detachment, retinitis pigmentosa, and previous laser surgery or treatment other than laser for macular degeneration and retinal tear were excluded from enrollment.

Patients meeting the inclusion criteria underwent a preoperative evaluation, including a comprehensive ophthalmic examination, which included slit-lamp examination, fundus photography of the macular lesion, cataract evaluation, A-scan, corneal pachymetry and topography, fluorescein angiography, measurement of intraocular pressure and visual acuity, and specular microscopy. Best-corrected (with and without telescope) distance acuities were measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart light box. A trial frame refraction was performed by a vision specialist or technician at a distance of 2 m. Patients reading less than 15 letters correctly at 2 m were retested at 1 m. Before testing at 1 m, a +0.50 diopter was added to the 2-m correction already in the trial frame to compensate for the closer testing distance. The manifest refraction that was recorded was corrected to a standard 6-m test distance by deducting the "test distance" power (+0.50 diopter for a 2-m test distance; +1.00 diopter for a 1-m test distance). Near visual acuity was measured with the Near ETDRS Modified Vision Chart using M-unit equivalents for each line of acuity measured. This evaluation was performed at 13 inches by adding the appropriate plus power (+4.00 diopters) to the distance-corrected manifest refraction. Potential visual acuity was measured with either a potential acuity meter or retinometer.

An IMT providing threefold retinal image enlargement (VisionCare Ophthalmic Technologies, Saratoga, California) was used for all patients. The IMT is biocompatible, with PMMA and quartz glass composing the external surfaces of the device that contact the aqueous and intraocular structures. Devices were sterilized by ethylene oxide, similar to the process used for intraocular lens sterilization. Surgical implantation of the IMT was performed through either a limbal incision, as described by Lipshitz and associates,[8] or a scleral tunnel approach after phacoemulsification cataract extraction. In the limbal insertion technique, a 10-mm (120 to 160 degrees) peritomy was used to accommodate the length of the IMT. If the scleral tunnel approach was used, a 10-mm-long incision was made 2.5 to 3 mm from the limbus. Both techniques required a large continuous curvilinear capsulorrhexis of at least 6.5 mm to ensure an adequate opening for IMT insertion into the bag. During insertion, handling of the central glass optic and touch of the corneal endothelium were to be avoided. Before suturing of the incision was completed, the IMT carrier loops were rotated in the capsular bag to the 12:6 o'clock position, which is necessary for stability. A peripheral iridectomy was also performed to prevent potential pupillary block.

Viscoelastic use was limited to a list of commercially available materials identified in the study protocol, with selection of the specific viscoelastic made by each site. Intraoperative medications, as well as postoperative med-

ications (topical corticosteroid and antibiotic), of the surgeon's choice were used. At the discretion of the study investigators, topical corticosteroids were used either beginning immediately after surgery or following the first postoperative week (for patients who received an intraoperative sub-Tenon injection of betamethasone) and were then tapered at the discretion of the study investigator.

Patients were examined postoperatively on days 1 and 7 and at 1, 3, 6, and 12 months. Endothelial cell density measurements were performed at 3, 6, and 12 months. Patients participated in vision training sessions at weeks 1, 2, 4, 6, 10, and 12 to help adapt to the device. Quality of life was evaluated by administration of the Activities of Daily Life (ADL) scale, a modified version of the Activities of Daily Vision Scale (ADVS),[9] preoperatively and at 3, 6, and 12 months. The ADL scale was created from the ADVS by eliminating driving-related questions and modifying other questions to make it more applicable to this patient population with central field loss from advanced AMD.

RESULTS

• **STUDY POPULATION:** The IMT was implanted in 14 of the 15 study eyes enrolled. In one eye implantation was not successful because of an inadequate capsulorrhexis associated with capsular tear during removal of the cataract, which was further complicated by vitreous loss and choroidal hemorrhage. As a result of these intraoperative complications, the surgical procedure was aborted. Since implantation of the IMT was aborted, this patient has been excluded from the analysis, resulting in a study cohort of 14 eyes of 14 patients.

The study cohort was composed of eyes from patients with a mean age of 80 years (range, 74 to 89 years). All of the patients were white and 64% were female. At baseline, all patients had normal slit-lamp examination, other than the presence of cataract, and normal intraocular pressures. All 14 patients completed the 3- and 6-month examinations, and 13 patients returned for the 12-month examination. One patient died before the 12-month visit. The death was not related to the study device. None of the patients presented with observable worsening of AMD or capsular clouding behind the IMT during the course of the study.

• **DISTANCE VISUAL ACUITY:** Best-corrected distance visual acuities are summarized in Table 1. At 3 and 6 months, seven (50%) of the 14 patients experienced an improvement of 2 or more lines in distance BCVA, and this improvement in best-corrected distance acuity remained stable in the study population through 12 months. One patient experienced a loss of 1 line of distance BCVA, from 20/100 to 20/163, at 3 months; however, near BCVA improved from 20/533 (20/266 at 6 inches) to 20/60 during the same period. At 6 and 12 months, distance BCVA for this eye improved to 20/100 and 20/80, respectively.

TABLE 1. Best-Corrected Distance Visual Acuity at 3, 6, and 12 Months

Distance Visual Acuity (ETDRS)	3 Months (N = 14)		6 Months (N = 14)		12 Months (N = 13)	
	N	(%)	N	(%)	N	(%)
Gained ≥2 lines from baseline	7	(50.0)	7	(50.0)	7	(53.8)
Gained 1 line from baseline	1	(7.1)	3	(21.4)	5	(38.5)
<1 complete line change from baseline (no change)	5	(35.7)	4	(28.6)	1	(7.7)
Lost 1 line from baseline	1	(7.1)	0	(0)	0	(0)
Lost ≥2 lines from baseline	0	(0)	0	(0)	0	(0)
Total	14	100	14	100	13	100

ETDRS = Early Treatment Diabetic Retinopathy Study.

TABLE 2. Best-Corrected Near Visual Acuity at 3, 6, and 12 Months

Near Visual Acuity (Near ETDRS Modified Vision Chart)	3 Months (N = 14)		6 Months (N = 14)		12 Months (N = 13)	
	N	(%)	N	(%)	N	(%)
Gained ≥2 lines from baseline	8	(57.1)	6	(42.9)	6	(46.1)
Gained 1 line from baseline	2	(14.3)	2	(14.3)	2	(15.4)
<1 complete line change from baseline (no change)	1	(7.1)	2	(14.3)	4	(30.8)
Lost 1 line from baseline	2	(14.3)	2	(14.3)	1	(7.7)
Lost ≥2 lines from baseline	1	(7.1)	2	(14.3)	0	0
Total	14	100	14	100	13	100

ETDRS = Early Treatment Diabetic Retinopathy Study.

• **NEAR VISUAL ACUITY:** Best-corrected near visual acuities for the study cohort are shown in Table 2. Of the 14 patients, an improvement of 2 or more lines was reported for eight eyes (57.1%) at 3 months and for six eyes (42.9%) at 6 months. At 12 months, six (46.1%) of the 13 eyes experienced an improvement of 2 or more lines of near BCVA.

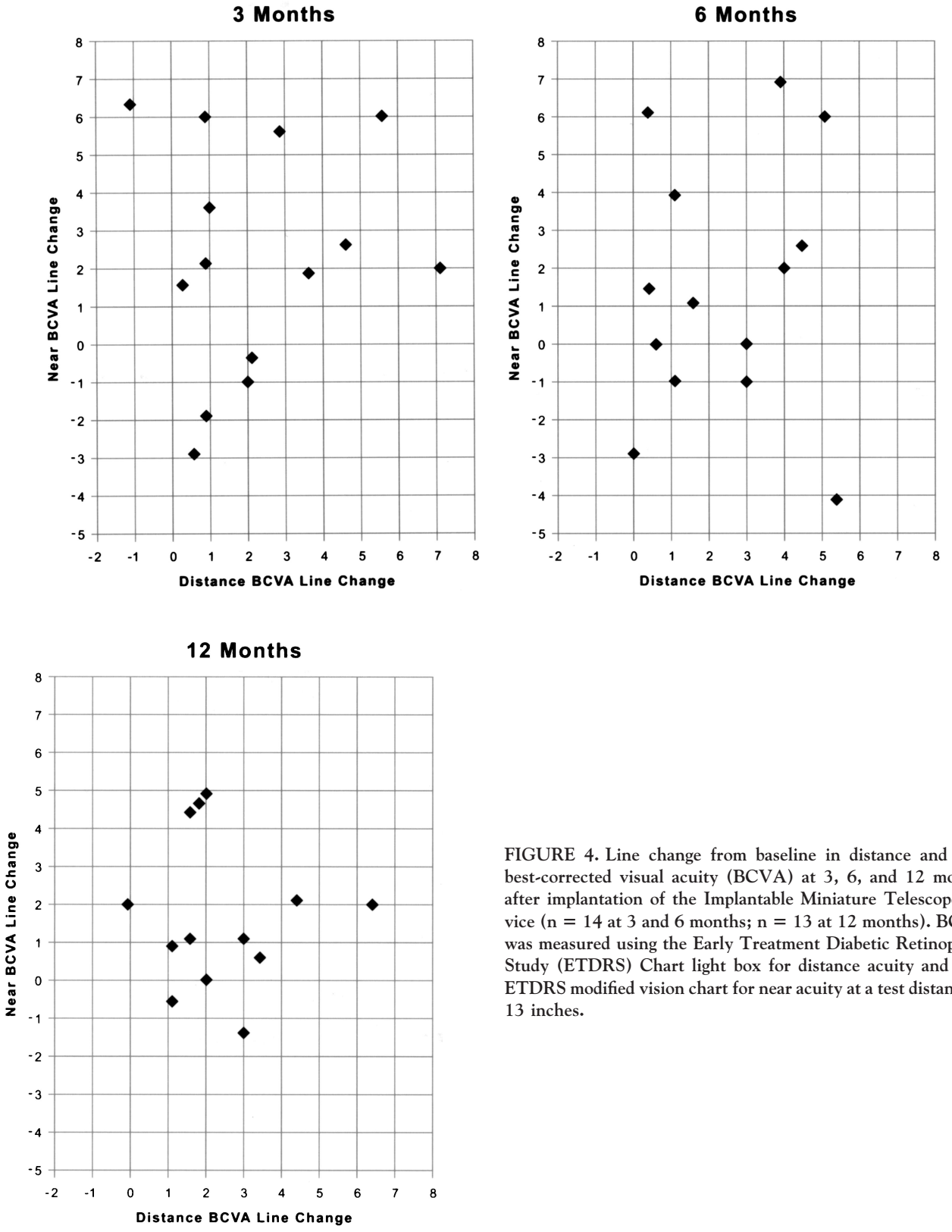

FIGURE 4. Line change from baseline in distance and near best-corrected visual acuity (BCVA) at 3, 6, and 12 months after implantation of the Implantable Miniature Telescope device (n = 14 at 3 and 6 months; n = 13 at 12 months). BCVA was measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) Chart light box for distance acuity and near ETDRS modified vision chart for near acuity at a test distance of 13 inches.

TABLE 3. Endothelial Cell Density and Percentage Change From Baseline

	Baseline	3 Months (N = 14)	6 Months (N = 14)	12 Months (N = 13)
Endothelial cell count				
Mean	2,247.6	2,085.6	1,935.5	1,934.2
SD	314.6	425.1	292.4	354.7
Range	1,733 to 2,916	1,300 to 2,710	1,300 to 2,406	1,086 to 2,300
% Change in endothelial cell count from baseline				
Mean		−6.7%	−13.0%	−13.2%
SD		16.4%	13.6%	17.3%
Range		−45.8% to 15.3%	−45.8% to 14.7%	−45.8% to 15.4%

• **IMPROVEMENT IN LINES OF EITHER DISTANCE OR NEAR BCVA:** The number of lines of improvement in either distance or near BCVA is shown graphically in Figure 4. At 3 months, an improvement of 2 lines or greater in either distance or near acuity was reported for 11 (78.6%) of 14 patients. At 12 months, 10 (76.9%) of 13 patients experienced an improvement of 2 lines or greater, and eight (61.5%) of 13 patients experienced an improvement of 3 lines or greater in either distance or near BCVA. Thus, the majority of eyes had a 2-line or more improvement in either near or distance BCVA over the course of the study, as shown graphically.

• **ENDOTHELIAL CELL DENSITY:** Mean ECD and change in ECD from baseline to 3, 6, and 12 months is shown in Table 3. Baseline endothelial cell counts ranged from 1,733 to 2,916 cells/mm^2 with a mean of 2,247.6 cells/mm^2 (SD, 314.6 cells/mm^2). Mean endothelial cell loss was 6.7% (SD, 16.4%) at 3 months, 13.0% (SD, 13.6%) at 6 months, and 13.2% (SD, 17.3%) at 12 months. ECD was below 1,500 cells/mm^2 in two eyes enrolled in the study. In one eye, ECD decreased from 2,400 cells/mm^2 preoperatively to 1,300 cells/mm^2 at 3 months, and then remained unchanged at 6 and 12 months. In the second eye, ECD was 1,733 cells/mm^2 at baseline, 2,562 cells/mm^2 at 3 months, 1,485 cells/mm^2 at 6 months, and 1,086 cells/mm^2 at 12 months.

• **QUALITY OF LIFE:** Quality of life was evaluated by administration of the ADL questionnaire, a modified version of the ADVS. Those patients with greater improvement in BCVA tended to score higher in ADL at 12 months, as compared with baseline. Specifically, patients who gained 3 lines or more of distance or near BCVA (8/13) averaged a 55% improvement on ADL, and patients who gained 2 or more lines (10/13) averaged a 29% improvement. Those patients who achieved an improvement in BCVA of less than 2 lines averaged a 12% improvement on ADL.

• **COMPLICATIONS AND ADVERSE EVENTS:** The complications reported during the course of this study were largely related to acute inflammatory reaction, consisting of anterior chamber cell and flare. There were several reports of inflammatory deposits on the IMT, as well as posterior synechiae. Additionally, two nonocular events were reported: the death of one study patient 10 months after implantation of the IMT, and surgical removal of a kidney stone approximately 30 days following implantation of the IMT.

The most notable complication following IMT implantation, reported in six of the 14 eyes, consisted of late intraocular inflammation observed 1 month or more postoperatively, with varying clinical signs, including anterior chamber cells, fibrin, conjunctival injection, iritis, and anterior uveitis. All cases resolved with appropriate corticosteroid treatment. Interestingly four of these patients were treated at a single investigational center and had not received a sub-Tenon or subconjunctival corticosteroid injection at the end of surgery, but rather the standard course of very limited anti-inflammatory treatment used for patients undergoing clear corneal cataract surgery.

In contrast, all other study patients received an intraoperative corticosteroid injection followed by a fairly lengthy period of topical corticosteroid administration tapering over time, with the exception of a single patient enrolled at the beginning of the study. In this patient, the intraoperative corticosteroid injection was inadvertently omitted, with a resulting intense inflammatory reaction that was controlled with rigorous topical corticosteroid administration, tapering over time. Analogous to this situation, one of the four eyes with an adverse event report of inflammation experienced intense ocular inflammation following sudden discontinuation of topical corticosteroid administration by a nonstudy ophthalmologist who examined the patient. As in the patient with immediate postoperative inflammation resulting from omission of a corticosteroid injection, the latter eye responded rapidly to frequent administration of topical corticosteroid solution, with complete resolution of the ocular inflammation.

In addition to the absence of a corticosteroid injection at the end of surgery, the four eyes with delayed ocular inflammation had a considerably shorter topical corticosteroid regimen than other study patients, with corticosteroid tapering over a shorter time than at other sites. A longer regimen of topical corticosteroid treatment was used by the other clinical centers on the basis of the larger incision (10 mm to 12 mm) required for IMT implantation, the larger dimensions and weight (46 mg in aqueous) of the device, as compared with an intraocular lens, and the fact that the IMT protrudes through the pupil, potentially touching the iris, serving as a possible source of transient inflammation until the IMT stabilizes in the eye as the capsular bag fibroses around the device. All ocular adverse events resolved with corticosteroid treatment without sequelae. One eye required a longer duration of topical corticosteroids before resolving after the 12-month visit.

DISCUSSION

THE DATA FROM THE PHASE I STUDY OF THE IMT PROVIDES evidence of the clinical utility of this device in patients with otherwise untreatable, bilateral stable scar-stage AMD. The majority of patients in this trial experienced an improvement of 2 or more lines of best-corrected distance or near visual acuity, or both. Loss of best-corrected distance acuity was reported for only a single study eye at the 3-month examination, and acuity in this eye improved significantly at the 6- and 12-month examinations. Loss of lines of best-corrected near visual acuity was reported for six of the implanted eyes. However, a concurrent improvement in best-corrected distance acuity was reported for five of these six eyes; distance BCVA remained unchanged in the sixth eye. The majority of patients showed improvement in activities of daily living (ADL), and those with greater improvement in BCVA tended to score better on the ADL scale. At less than 7% loss at 3 months, 13% loss at 6 months, and 13% loss at 12 months, mean endothelial cell loss, an important safety parameter for this device, is within the range reported for large-incision cataract surgery.[10–12] All ocular adverse events resolved with appropriate corticosteroid treatment.

Visual acuity outcomes in this study also show some patients gaining unequal lines of best-corrected distance and near visual acuity, and even some subjects losing lines of distance and gaining lines of near visual acuity, and vice versa. In this small sample, the reason for these outcomes is unclear and is most likely multifactorial. In a normal, nondiseased eye capable of 20/20 visual acuity, any increase (or decrease) in distance vision would be expected to be equally reflected by a change in near vision. This is the basis of visual acuity testing that is routinely performed by eye care specialists. However, these corresponding changes are representative of refractive changes, not changes from retinal pathology.

Factors that could explain the difference between best-corrected distance and near vision in this study population include patient age and experience with the testing methods, study site experience with the testing methods, and accurate distance and near refraction. Although great care was taken to limit the effects of these factors, it is possible that they had some bearing on the final study results. However, the similarity of 3-month and 12-month data would seem to downgrade the influence of "learning curve" issues.

Proper implantation of the IMT was most likely not a factor in the varying intrapatient acuities. With proper positioning of both haptics in either the capsular bag or sulcus, any possibility of decentration or tilt is minimized. Up to 0.5 mm decentration of the device is tolerable without significant impact on image quality. Tilting of the device would cause a shift in image position, but with minimal degradation in image quality. An axial deviation of up to 1.1 mm from the nominal position can also be tolerated. Furthermore, proper postoperative refraction corrects for any degradation from axial position in the eye, allowing optical performance to be maintained.

Scotoma size is a factor that likely has a bearing on the disparity between distance and near acuities. A study subject with a rather small scotoma would be more likely to show acuities more like a normal eye. The larger and denser a scotoma is, the greater the disparity that might be seen between distance and near acuities. Scotoma size was not mapped in this study and is a subject of investigation for a larger follow-up study.

Interestingly, the one factor common to all study subjects is also the most difficult to define: the psychophysics of visual impairment. Psychophysics is the study of the relation between stimulus and sensation. Though not well understood, it is well accepted by vision specialists that, even under ideal testing conditions, distance and near visual acuity for a single patient may vary by 2 lines or more. Simple physics tells us this cannot be the case: a letter that subtends a specific visual angle should be visible to the patient regardless of the test distance. Although research is ongoing, at this time there is no clear explanation of this anomaly. Scotoma mapping in future studies may help provide insights.

Given the absence of treatment alternatives for this patient population, the improvement in visual acuity, and the positive impact of improvement of visual acuity on quality of life, the benefits associated with implantation of the IMT appear to outweigh the risks to the patient. On the basis of results of the initial phase of clinical evaluation, a multicenter phase II/III trial has been initiated with the objective of evaluating two IMT models that provide 2.2× and 3× retinal image enlargement and which are designed to have a wider field of view than the device studied in the phase I trial described in this report. A wider field of view may be important to maximize the functional benefit for patients implanted with the IMT. Furthermore, increased attention to surgical and pharmacologic mea-

sures that can control potential inflammation associated with the IMT procedure is advised.

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