Injectable intraocular telescope: Pilot study

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PURPOSE: To assess the feasibility of a new injectable telescopic intraocular lens (IOL).

SETTING: London Eye Hospital, London, United Kingdom.

DESIGN: Prospective interventional pilot study.

METHOD: Eyes with bilateral, intermediate, or advanced dry age-related macular degeneration (AMD); preoperative decimal corrected distance visual acuity (CDVA) of 0.25 or less; and improvement with extraocular simulation of the intervention had implantation of 2 IOLs designed for use together in a Galilean telescope configuration (ioIAMD). Patients were followed for 4 months. Safety was assessed by monitoring visual acuity, intraocular pressure, specular microscopy, and anterior segment and macular optical coherence tomographies. Fixation stability and macular sensitivity were determined using microperimetry in some eyes.

RESULTS: There were no significant intraoperative or postoperative complications. In 1 eye, an anterior sulcus IOL was replaced; there were no sequelae. The mean endothelial cell density was reduced by 18%. The mean decimal CDVA improved from 0.12 preoperatively to 0.20 at 4 months, a 67% gain. The mean change in spherical equivalent after implantation was −1.5 diopters (D) with 0.5 D of induced astigmatism. Microperimetric testing indicated a magnification effect and a deviation of the retinal image by up to 5 degrees, with improved fixation stability.

CONCLUSIONS: This injectable intraocular miniature telescope appears safe in the short to medium term and capable of improving visual function. No significant issues were encountered regarding candidate eye selection or patient retention and cooperation. Further work is needed to evaluate the safety and efficacy of the device, particularly with respect to daily-living activities and the range of indications.

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Online Video

Age-related macular degeneration (AMD) is the major cause of vision loss in individuals 50 years or older in developed countries and affects nearly 10% of people over 65 years of age.[1] In the United States alone, more than 8 million people have intermediate AMD and nearly 2 million have advanced AMD—numbers that are expected to increase 50% by 2020.[2] Consequently, even with the benefits of improved medical therapies for choroidal neovascularization (CNV) (the less prevalent form of AMD) and nutritional supplementation, it is expected that the socioeconomic burden from AMD will remain considerable over the coming decades.

At present there is no medical therapy for geographic atrophy, and patients with advanced AMD and other forms of maculopathy rely largely on supportive measures to maintain daily-living activities. These include external magnifiers, handheld telescopes, and video-magnifiers, all of which might improve visual function but have disadvantages primarily related to limited portability, a reduced field of view, and the need to increase head and hand

movements to use them effectively. Patients might also benefit from eccentric viewing training to use a retinal locus that maximizes their functional capacity; however, this requires multiple clinic visits and a suitably motivated patient and in many cases might not be achievable.[3] The surgical options for managing AMD are limited. Macular translocation surgery is complex and has a high complication rate, and benefits from retinal pigment epithelium–choroidal grafts have been shown to be transient.[4,5]

There is a need for more efficient and effective devices for improving the vision and quality of life of patients with AMD. Several miniature ocular implants were designed to meet this need, including the Implantable Miniature Telescope (IMT) (Visioncare Ophthalmic Technologies, Inc.)[6] and the Intraocular Lens for Visually Impaired People (IOL-VIP, Lenspecial).[7] The IMT is U.S. Food and Drug Administration–approved and is a fixed-focus telescopic device designed for monocular implantation that has been shown to improve visual function with a magnification (and consequent reduction in visual field) of ×2.2 to ×3.0.[6] The IOL-VIP[7] uses a Galilean-telescope configuration with a high-minus IOL in the capsular bag and a high-plus IOL in the anterior chamber to achieve a theoretical magnification of ×1.3, combined with a prismatic effect that permits targeting of the preferred retinal locus or an alternative locus to maximize the patient's visual capability.

Since their introduction, these devices have been used in relatively few specialist surgical centers, perhaps explaining the limited evidence of their benefit. This poor uptake might be partly due to the devices' costs, which are considerable, but more likely is a consequence of the surgical complexity involved in their implantation. Of 217 eyes enrolled in 1 study[6] that examined use of the IMT, which requires a 12.0 mm limbal incision for implantation, 11 surgeries were aborted because of complications such as posterior capsule rupture, choroidal hemorrhage, and zonular dehiscence. Similarly, the siting of a high-plus anterior chamber IOL accounts for many of those complications encountered in the use of the IOL-VIP which, again, requires a large incision and capsulorhexis for its implantation and is associated with high levels of hyperopic shift.[8]

Age-related cataract affects more than 22 million people in the U.S., most over 60 years of age, and the prevalence of AMD in the U.S. population is 6.5%. From this, it might be inferred that a substantial proportion of individuals having cataract surgery, not just in the U.S. but worldwide, could benefit from intraocular telescopes.[9,10] To significantly benefit those with moderate-to-severe vision loss, such devices will have to be cost-effective and easily, quickly, and safely implanted.

We present the results of a pilot study with the iolAMD (London Eye Hospital Pharma), a new intraocular Galilean telescope that is composed of 2 soft acrylic IOLs that are injected into the capsular bag and sulcus through a small incision to provide a theoretical magnification of ×1.25 to ×1.3 with or without a prismatic effect.

PATIENTS AND METHODS

Patients

Local ethics approval was obtained from the London Eye Hospital Ethics Committee for an interventional noncomparative prospective single-center pilot study. Patients were recruited and provided valid consent with particular attention to the risks for aniseikonia, visual field reduction, endothelial cell loss, and the possibility of needing IOL explantation. Inclusion criteria included bilateral intermediate or advanced dry AMD with central scotomata; minimal cataract (≤1+) or pseudophakia; Snellen corrected distance visual acuity (CDVA) of less than 0.25, improvement on simulation with the new injectable telescopic IOL (CDVA or subjective improvement); and agreement to have preoperative and postoperative assessments. Exclusion criteria included active CNV treated within 6 months of recruitment; active diagnosis of phacodonesis or corneal guttata; an axial length (AL) of over 24.5 mm or under 20.5 mm; a history of angle closure or pigment dispersion syndrome, retinal detachment, retinitis pigmentosa, optic neuropathy, or uncontrolled glaucoma; and intraocular surgery within 6 months of recruitment.

Patient Assessment

At baseline and 1 week, 1 month, and 4 months postoperatively, examinations included assessment of full subjective refraction, CDVA (Snellen), near acuity (N-point at 40 cm), intraocular pressure (IOP) (Goldmann applanation tonometry), fundus photography (Visucam, Carl Zeiss Meditec), biometry (IOLMaster, Carl Zeiss Meditec AG), optical coherence tomography (OCT) (Stratus, Carl Zeiss Meditec AG), specular microscopy (Nidek CEM-530, Nidek Co. Ltd.) (3 acceptable images derived from the central cornea), and clinical examination (including clinical grading of any lenticular opacity). Preoperative simulation of the intervention was carried out using a handheld extraocular magnifier

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with a built-in prism (IOL-VIP system, Soleko SPA). The CDVA was recorded with the simulator in place and with any orientation preference (and therefore prismatic correction) and the results were cross-checked against the location of the preferred retinal loci as determined by microperimetry testing (where performed). The positions of the implants were recorded postoperatively using anterior segment OCT (AS-OCT) without pupillary mydriasis (Visante, Carl Zeiss Meditec AG). Microperimetry was performed preoperatively and postoperatively in 3 eyes of 3 patients using the Macular Integrity Assessment (MAIA, Ellex Medical Lasers Ltd.) at baseline and 4 months under mesopic conditions with no mydriasis. The "expert" algorithm was used to assess the macular threshold sensitivity and fixation stability (37 points tested in a 10-degree area centered on the preferred retinal locus; 4-2 strategy; stimulus size Goldmann III with duration 200 ms). To avoid confounding the effect of the intervention, no patient had preoperative or postoperative visual rehabilitation by training for eccentric viewing, steady eye strategy, or any other method as part of the study.

Interventional Device

The iolAMD is an implantable device approved for use in the European Economic Area that is composed of 2 soft hydrophobic acrylic IOLs (1 high-minus and 1 high-plus) arranged in a Galilean-telescope configuration to provide ×1.25 to ×1.3 theoretical magnification (Figure 1). After crystalline lens extraction (or existing IOL explantation), the IOLs are injected separately into the eye through a 3.0 mm corneal incision. The high-minus IOL is shaped for siting in the capsular bag, and the high-plus IOL (available in 11.75 mm and 12.00 mm diameters) is shaped for positioning in the ciliary sulcus. Details of the optic design of the telescope were published previously.[11,A] To reduce the optic aberrations associated with high-powered IOLs and increase the tolerance of the system to variations in IOL separation that might arise from anatomic differences between individual eyes, some surfaces of the new intraocular Galilean telescope are rendered hyperaspheric with unique wavefront characteristics (eg, the conic constant of the posterior surface of the posterior IOL is set at −10.0). In the prismatic version, the optic of the IOL in the sulcus is displaced relative to that of the IOL in the capsular bag using an asymmetric haptic configuration that allows deviation of a retinal image by up to 3 degrees of retinal eccentricity from fixation in the direction of the shorter of the 2 haptics. The system permits free rotation of the anterior IOL relative to the posterior IOL and its replacement, if necessary. These features ensure that the path of light can be further modified by subsequent rotation or replacement of the anterior IOL, should macular disease progress, and the foldable nature of the implants allows for relative ease of explantation of both IOLs in the event of an unsatisfactory functional outcome. Implantation of each IOL takes the same amount of time as for a standard monofocal IOL.

Surgical Technique

Surgery was performed by the same surgeon (M.A.Q.) using standard techniques. Topical mydriatic agents were used for pupil dilation, and anesthesia was induced by sub-Tenon delivery. A 5.0 mm curvilinear capsulotomy and crystalline lens fragmentation were performed using a femtosecond laser surgery platform (Lensx, Alcon Surgical, Inc.), and lens extraction was completed using the Whitestar Signature

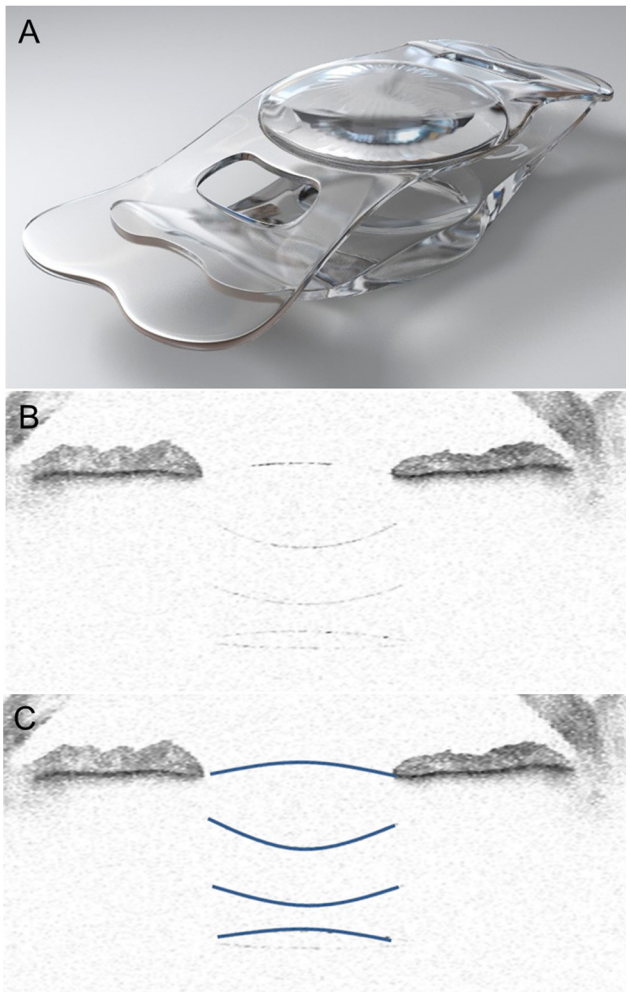

Figure 1. Artistic rendering of the injectable telescopic IOL (*A*) and its appearance on AS-OCT after implantation in the eye of patient 5 (*B*) with optic surfaces highlighted (*C*).

phacoemulsification system (Abbott Medical Optics, Inc.) with a standard 2.8 mm corneal incision sited at 100 degrees. The capsular bag was filled with a cohesive ophthalmic viscosurgical device (OVD), and the high-minus injectable telescopic IOL was loaded in the injector cartridge, injected in the capsular bag through the main wound, and centered (Video 1, available at http://jcrsjournal.org). To target a preferred retinal locus located directly superior to the area of geographic atrophy (ie, with the scotoma superior to fixation in the patient's visual field [most cases]), the injectable telescopic high-plus IOL was loaded in the injector cartridge with the short haptic trailing; then it was injected into the eye with the long leading haptic positioned in the sulcus before the trailing haptic was dialed into position and the OVD aspirated. To target other preferred retinal loci, usually sited to the right of the scotoma, the high-plus IOL was rotated into position in the anterior chamber and the trailing haptic then dialed into the sulcus. Application of force to the IOL in a vector aligned with the haptics was avoided to minimize the risk for trauma to the zonular fibers. As a precaution against pupil block, a superior peripheral iridectomy was performed during the initial group of surgeries, although this subsequently was determined to be unnecessary and

omitted from later surgeries. After careful preoperative counseling and assessment, 1 patient had explantation of monofocal IOLs (by viscodissection without cutting the haptics) before implantation of the new intraocular Galilean telescope in each eye. In both of these instances, the capsular bag was preserved; however, in 1 eye (patient eye 5), in which capsular fibrosis prevented siting the high-minus IOL in the bag, both injectable telescopic IOLs were sited in the sulcus with the haptics aligned. All patients received intracameral antibiotics and were subjected to a standard post-phacoemulsification regimen of a topical steroid and antibiotic for 1 month.

RESULTS

All visual acuity values are given in decimal notation. All 18 eyes of 12 patients (4 men and 8 women) completed the study. The mean patient age was 77 years (range 65 to 85 years). Table 1 shows the preoperative characteristics of the operated eyes and the postoperative refractive outcomes. Table 2 gives the preoperative and postoperative spherical equivalent (SE), astigmatism correction, CDVA (including simulated), and corrected near visual acuity (CNVA) values. Based on World Health Organization definitions of visual impairment, preoperatively 8 study eyes had moderate visual impairment (CDVA 0.290 to 0.130), 7 had severe visual impairment (CDVA 0.100 to 0.050), and 3 had profound visual impairment (CDVA <0.050).

Safety

All surgeries were uneventful except in 1 eye (patient 11) in which the high-plus IOL was vaulting anteriorly, causing a reduction in the quality of vision. This high-plus IOL was replaced with a smaller-diameter IOL, after which there were no short- to medium-term sequelae. There were no reported problems with aniseikonia after monocular implantation. Six patients had implantation of the injectable telescopic IOLs in the fellow eye approximately 6 weeks after the first-eye surgery, with no complications. A precautionary intraoperative peripheral iridectomy was performed in 9 eyes (including the eye of patient 11 in which the high-plus IOL was replaced). In 8 eyes, a single 10-0 nylon suture was used to secure the wound as a precaution; the suture was removed 1 month after surgery.

One week postoperatively, the operated eyes showed signs consistent with recent phacoemulsification and IOL implantation, with 1 to 2+ cells in the anterior chamber and with 2 eyes having mild levels of corneal edema. There was no difference between the mean preoperative and postoperative IOPs (18.0

Table 1. Clinical characteristics of operated eyes.

				Refraction					
				Preoperative			Postoperative		
Eye	Axial Length (mm)	Lenticular Opacity	PRL Location	Sphere (D)	Cylinder (D)	Axis°	Sphere (D)	Cylinder (D)	Axis°
1	23.46	+	S	−2.00	−0.50	105	−4.50	0.00	0
2	24.20	+	S	1.50	−1.00	90	−3.00	−1.00	90
3	23.53	+	S	1.50	−0.75	100	−2.00	−2.00	95
4	24.39	IOL	R	−2.00	0.00	0	−3.00	0.00	0
5	23.36	±	I	−3.50	−1.50	140	−5.00	−2.00	130
6	23.17	+	S	1.00	0.00	0	1.00	−1.75	115
7	22.90	±	S	0.00	−2.00	90	2.50	−2.25	90
8	24.33	IOL	R	0.00	0.00	0	−3.00	0.00	0
9	22.57	+	S	1.25	−1.25	100	4.00	−2.00	90
10	24.06	±	S	0.00	−0.25	109	1.00	−2.00	110
11	24.14	+	S	0.00	−1.25	0	1.75	−1.75	120
12	23.38	±	R	0.75	−0.75	107	0.00	0.00	0
13	22.52	+	S	1.00	−0.50	100	1.00	0.00	0
14	23.45	±	L	0.50	−0.50	90	−2.75	−1.25	90
15	20.83	±	R	8.00	−1.00	60	2.00	−1.25	80
16	23.90	±	S	0.50	−1.00	40	−1.50	−2.00	90
17	23.81	±	S	−0.50	0.00	0	−3.50	−1.00	145
18	23.87	±	I	−3.50	−0.75	70	−3.00	−1.50	90
All (mean)	23.44	—	—	0.25	−0.72	67	−1.00	−1.21	74

I = PRL inferior to area of atrophy; IOL = intraocular lens; L = PRL to the left of the area of atrophy; PRL = preferred retinal locus; R = PRL to the right of the area of atrophy; S = PRL superior to area of atrophy

Table 2. Preoperative and postoperative parameters.

					Corrected Distance Visual Acuity				
	Spherical Equivalent (D)		Cylinder (D)		Near (Decimalized Snellen Equivalent)		Distance (Decimalized Snellen)		
Eye	Preop	Postop	Preop	Postop	Preop	Postop	Preop	Simulated	Postop
1	−2.25	−4.50	−0.50	0.00	<0.080	0.125	0.040	0.060	0.060
2	1.00	−3.50	−1.00	−1.00	0.125	0.220	0.100	0.125	0.125
3	1.15	−3.00	−0.75	−2.00	0.125	0.250	0.125	0.160	0.250
4	−2.00	−3.00	0.00	0.00	<0.080	0.180	0.040	0.050	0.063
5	−4.25	−6.00	−1.50	−2.00	<0.080	0.080	0.100	0.200	0.080
6	1.00	0.00	0.00	−1.75	<0.080	0.220	0.100	0.200	0.320
7	−1.00	1.50	−2.00	−2.25	0.250	0.180	0.200	0.200	0.400
8	0.00	−3.00	0.00	0.00	<0.080	<0.080	0.050	0.050	0.010
9	0.75	3.00	−1.25	−2.00	0.090	0.125	0.060	0.080	0.100
10	0.00	0.00	−0.25	−2.00	<0.080	0.090	0.080	0.130	0.130
11	−0.75	1.00	−1.25	−1.75	0.250	0.250	0.160	0.320	0.250
12	0.40	0.00	−0.75	0.00	<0.080	0.180	0.010	0.063	0.100
13	0.75	1.00	−0.50	0.00	0.125	0.180	0.063	0.080	0.160
14	0.25	−3.25	−0.50	−1.25	0.180	0.400	0.250	0.500	0.400
15	7.50	1.50	−1.00	−1.25	0.220	0.500	0.250	0.400	0.320
16	0.00	−2.50	−1.00	−2.00	0.125	0.180	0.125	0.125	0.160
17	−0.50	−4.00	0.00	−1.00	0.330	0.330	0.250	0.400	0.400
18	−3.85	−3.75	−0.75	−1.50	<0.080	0.180	0.200	0.250	0.320
All (mean)	−0.10	−1.58	−0.72	−1.21	<0.140	0.210	0.120	0.190	0.200

mm Hg ± 4.9 [SD] and 16.0 ± 3.3 mm Hg, respectively). In 1 eye (patient 8), the IOP rose from 14 mm Hg at baseline to 22 mm Hg 4 months postoperatively; this eye was treated with a neodymium:YAG (Nd:YAG) laser to widen a peripheral iridotomy as a precaution, although there was no evidence of iridocorneal angle closure or pupillary block on clinical examination or AS-OCT. A mean reduction of 18% in the endothelial cell count was recorded at 4 months (2119 ± 502 cells/mm^2 versus 1729 ± 508 cells/mm^2) (Figure 2), with no cases of clinical corneal decompensation. There were no signs of cystoid macular edema or active CNV on the preoperative or postoperative macular OCTs. The data acquired from AS-OCT indicated no gross deviation from the expected positions of the IOLs in the patients' eyes.

The mean CDVA increased from 0.12 ± 0.08 to 0.20 ± 0.13 (Figure 3, *A*) and a similar increase in CNVA, from less than 0.14 ± 0.08 to 0.21 ± 0.11 was also observed (Figure 3, *B*). In 2 eyes the CDVA lowered slightly from baseline, 1 (patient 5) decreasing from 0.1 to 0.08 and 1 (patient 8) decreasing from 0.05 to 0.01. It is unclear why the eye of patient 5 failed to meet the simulated outcome; however, a strong subjective improvement in vision was reported and the IOLs appeared well-positioned on AS-OCT. The eye of patient 8 was recovering from an Nd:YAG laser peripheral iridotomy when the final CDVA was recorded but also had explantation of a monofocal IOL before implantation of the injectable telescopic IOL; hence, suboptimum positioning of the IOL implanted in the capsular bag might account for its failure to meet the simulated postoperative visual acuity. This eye also had monofocal explantation and then implantation of the injectable telescopic IOL in the fellow eye, in this case with both IOLs positioned in the sulcus, and the CDVA was better than the

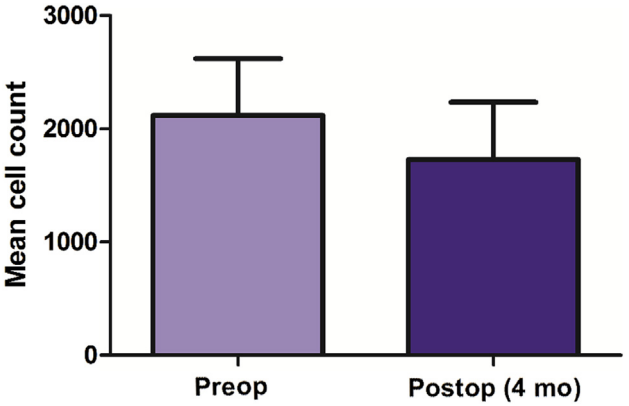

Figure 2. The mean preoperative and postoperative endothelial cell density (cells/mm^2) in the operated eyes.

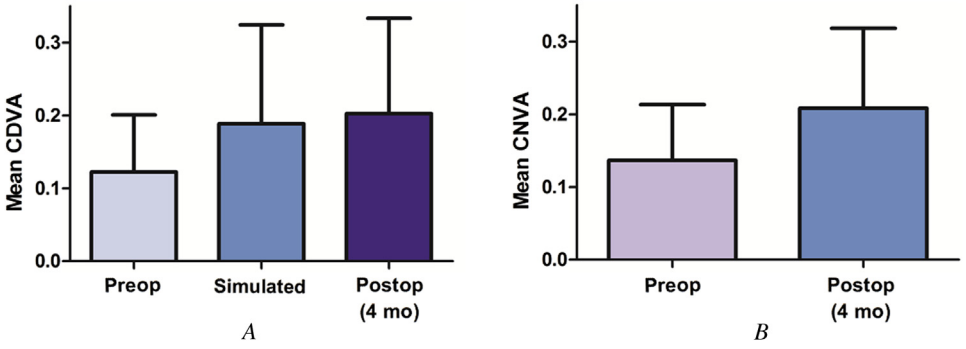

Figure 3. Preoperative, simulated, and postoperative mean CDVA (*A*) and preoperative and postoperative mean CNVA (*B*) (CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity).

simulated postoperative outcome 4 months after implantation.

A moderate postoperative hyperopic shift in refraction was noted in 3 eyes; the ALs were slightly shorter than the cohort mean in 2 of these cases (patients 7 and 8), and patient 11 had the previous replacement of the anterior IOL (Tables 1 and 2). Overall, the mean SE showed a myopic shift from −0.10 diopter (D) at baseline (range +7.50 to −4.25 D) to −1.60 D 4 months after implantation (range +3.00 to −4.50 D) (Figure 4, *A*). The mean cylinder increased from −0.7 to −1.2 D (Figure 4, *B*).

Efficacy

The mean CDVA increased 67% overall from baseline at the final postoperative review, and the mean CNVA improved more than 50%. The increase in mean CDVA exceeded the increase predicted by preoperative simulation and the level of acuity expected with a theoretical ×1.25 to ×1.3 magnification (Figure 3, *A*). There was a mean improvement in CDVA of 60% in eyes with moderate visual impairment and of 67% in eyes with severe visual impairment. One patient with profound vision loss (patient 12) was observed to have a 10-fold improvement in CDVA although improvements were more modest in the other 2 patients with this level of visual acuity. These results were reflected in the preoperative to postoperative reclassification of visual impairment in 11 eyes after implantation of the injectable telescopic IOL: 5 eyes improved from moderate visual impairment to mild visual impairment, 3 improved from severe to moderate, 1 improved from severe to mild, and 1 improved from profound to severe. One eye (patient 8) moved from severe to profound visual impairment, while the rest remained unchanged in terms of classification.

The MAIA microperimeter testing in eyes of patients 16, 17, and 18 at baseline and 4 months after implantation showed the mean percentage of fixation points within a 4-degree circle increased from 71.8 to 77.0 and within a 2-degree circle increased from 34.9 to 39.7. (Patient 18 did not complete the postoperative microperimetry testing because of fatigue.) The mean threshold improved from 7.7 dB to 16.4 dB.

Figure 5 shows representative microperimetry images obtained at baseline and 4 months for patient 16. On simulation, this patient noted a preferred retinal locus located superior to the area of geographic atrophy; this locus was targeted in the implantation of the injectable telescopic IOL. The red-free image after implantation (Figure 5, *A* and *B*, zoom images 5, *C* and *D*) showed a wider field of view of the fundus than the baseline image, which is suggestive of a telescopic effect (like when an image is minimized when

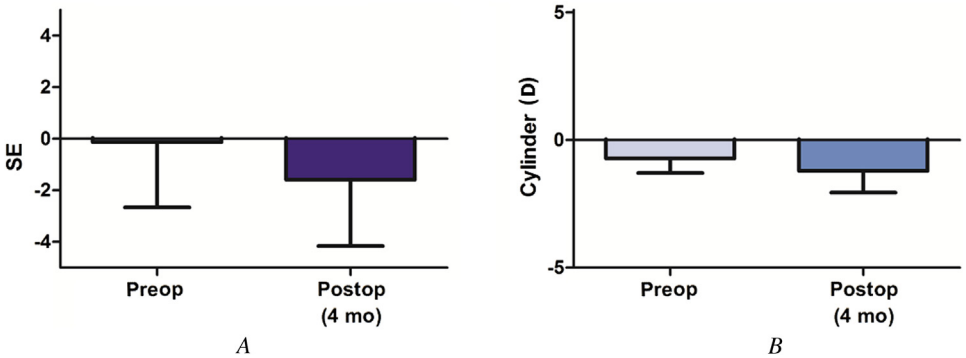

Figure 4. The mean preoperative and postoperative SE (*A*) and astigmatic correction (*B*) in operated eyes (SE = spherical equivalent).

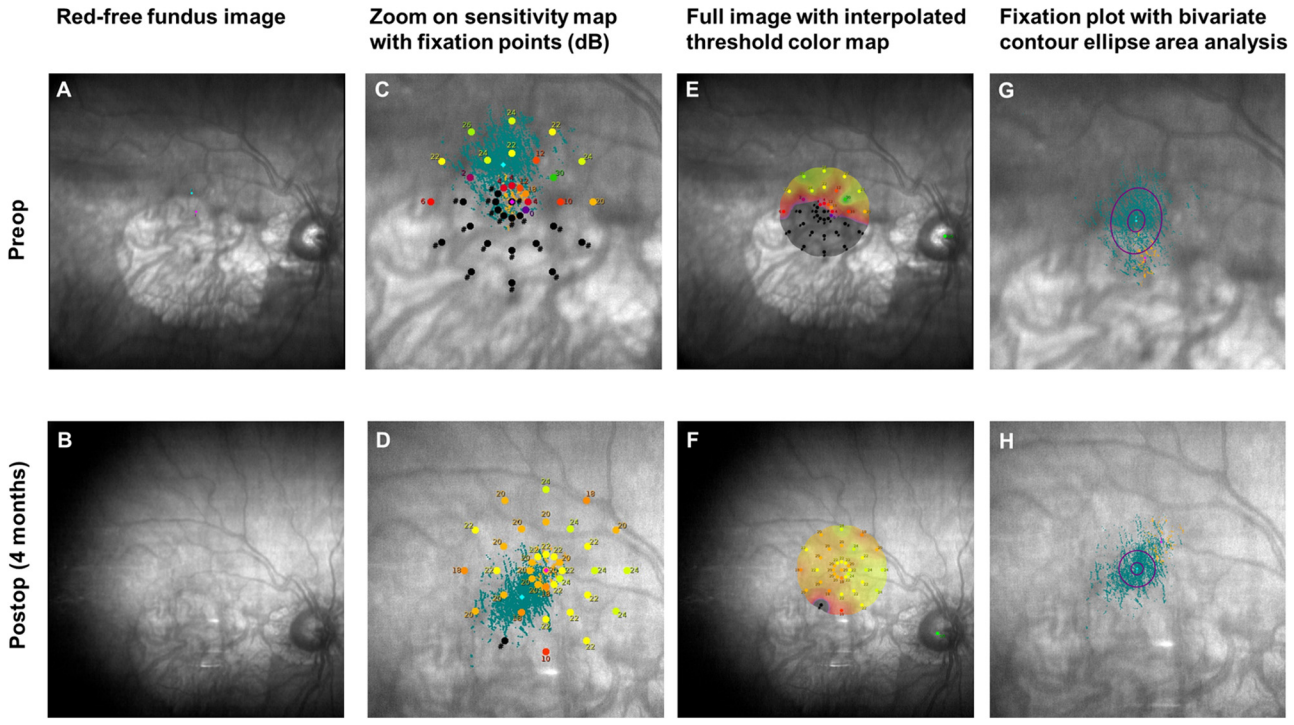

Figure 5. Representative microperimetry images obtained at baseline and 4 months after implantation from the eye of patient 16. The orange fixation dots represent points used in the first 10 seconds of the test.

observed through the wrong end of a telescope). The baseline fixation points (Figure 5, *C* [*blue dots*]) are at the superior border of an area of geographic atrophy, with approximately one half of stimuli unseen (*black spots on the sensitivity map*) (Figure 4, *C*).

After implantation, the preferred retinal locus was shifted superiorly by approximately 5 degrees (Figure 5, *D*), with each stimulus separated by 2.5 degrees and with 1 stimulus point left unseen; the average threshold sensitivity improved from 7.2 dB to 20.2 dB. The baseline and post-implantation interpolated sensitivity maps showed the changes by representing the sensitivity at each point of the retina using information from nearby stimuli (Figure 5, *E* and *F*). These changes are associated with a more tightly focused cluster of fixation points after implantation and a gravitational center being shifted slightly superiorly, as indicated by the bivariate contour ellipse area analysis (the smaller ellipse contains 63% of all fixation points, and the larger ellipse contains 95% of all fixation points). At baseline, there was an elliptical spread of fixation points, with 31% of points within a 2-degree circle and 74% within a 4-degree circle, while after implantation the spread of fixation points becomes more regular and the number of points within 2-degree and 4-degree circles increased to 48% and 88%, respectively (Figure 5, *G* and *H*). The CDVA in this eye improved from 0.125 at baseline to 0.160 after implantation.

DISCUSSION

This small-scale preliminary pilot study was undertaken to evaluate the feasibility of a new injectable telescopic IOL–the iolAMD—and to make initial assessments regarding its short- to medium-term safety and efficacy.

The high-plus and high-minus IOLs of the injectable telescope were relatively simple to load and inject into the study eyes, and no intraoperative or immediate postoperative complications were encountered. An intraoperative peripheral iridectomy was performed as a precaution in 10 of the study eyes; however, patients were monitored closely and in 8 eyes no iridectomy was performed and the postoperative phase was uneventful. Any pigment deposition on the anterior surfaces of the IOLs did not appear to be progressive and was not associated with a rise in IOP; however, given these changes, the recording of preoperative and postoperative gonioscopic examinations with or without ultrasound biomicroscopy should be considered in future studies. The postoperative reduction in endothelial cell density was comparable with other published data but higher than might be

expected given the techniques used and the degree of cataract in the study cohort; this is most likely due to test–retest variability; however, further investigation is needed to confirm this.[12]

The IOLs appeared stable in all eyes; however, the explantation of 1 sulcus-implanted IOL and its substitution with a smaller version, even though performed with ease, reflects the difficulty of accurately assessing the sulcus dimensions preoperatively. The white-to-white dimensions and other ocular parameters, such as iridocorneal angle, are poor predictors of sulcus diameter. Consequently, it is worth considering direct measurement of the ciliary sulcus preoperatively to determine the appropriate size of the IOL for sulcus implantation.[13] The anterior high-plus IOL plate haptic conformation is based on preexisting designs for sulcus-implanted IOLs, with available diameters of 11.75 mm and 12.00 mm. We found no evidence of rotational instability in the sulcus-implanted IOL, but this was not assessed objectively, and a rotational shift that is likely to produce subjective changes in a normally sighted individual might go unnoticed in an eye with AMD. Even so, the visual acuities remained stable in the study cohort, and the risks for oversizing a sulcus-implanted IOL in this context (angle closure, iris chafing, anterior vaulting, and suboptimum separation of the IOLs) outweigh the risks typically associated with undersizing, which would normally include inducing cataract in a phakic eye.

We noted a mean postoperative improvement in CDVA of 67% and refractive outcomes that were relatively predictable, with a mean shift in SE of −1.5 D and induced astigmatism of 0.5 D. Although we acknowledge the limitations of Snellen visual acuity testing in this context, these data are comparable with published data for the IOL-VIP, in which similar levels of improvement were obtained in a comparable subgroup with severe vision loss and minimal cataract preoperatively.[7] However, improvements in vision with the IOL-VIP are associated with a strong tendency toward hyperopia (as much as +16.0 D in some instances), which combined with rehabilitation training might account for a significant proportion of an increase in CDVA associated with its use.[8] This hyperopic shift has prompted suggestions that IOL-VIP implantation should be restricted to eyes with ALs longer than 23.0 mm. In contrast, we observed an improvement in visual acuity in patients with the injectable telescopic IOL without any hyperopic shift. This improvement in visual function therefore might be attributable directly to the magnification and prismatic effect afforded by this device.

We observed no clear association between the AL and the refractive outcome in our patients; 2 eyes with a postoperative hyperopic refractive shift were slightly shorter than the mean in the cohort. The study eye with the shortest AL (patient 15) experienced a large myopic shift. It is very likely that the increased depth of focus afforded by the injectable telescopic IOL tempers any subjective refractive shift, although the need for revised optics in eyes with extreme ALs cannot be discounted.[11,A] This increased depth of focus might also account for the observed improvement in the mean CNVA with the iolAMD. We did not assess reading capacity in this study, but we note that the effect on near vision with the IOL-VIP, which uses standard spherical optics, has been varied, with 1 study reporting an increase in reading distance and another suggesting no effect on reading capacity.[7,8]

The optics of the injectable telescopic IOL are also designed to increase the tolerance for a range of separations of the 2 IOLs in the eye. We did not measure postoperative IOL separation, but the visual outcomes in our patient cohort suggest that the device performs well in this regard. Similarly, the degree of magnification it affords requires further investigation but is highly likely to vary between individuals in line with the amount of IOL separation. In a longer eye, more separation between the 2 injectable telescopic IOL optics would be expected and consequently, so would greater magnification; however, more than ×1.3 magnification would most likely result in further diminution of the visual field, which would otherwise be reduced by approximately 30%.

The effect of the device on the visual field was not explored in the present study, but this is an aspect of visual function that might affect improvement in activities of daily living. A reduction in the peripheral visual field, for example, has been associated with an increased risk for falls[14] and for involvement in car accidents.[15] For individuals already at increased risk for such events, any loss of visual field would have to be balanced with predicted improvement in visual acuity or reading ability. There were no reported cases of aniseikonia in our cohort, so it might be reasonable to perform injectable telescopic IOL implantation only in the better-seeing eye in some individuals to retain a full peripheral field in the eye with worse central vision.

The effects of intraocular telescopes on activities of daily living remain an underexplored area of study. A clinical trial evaluating the safety and efficacy of the IMT intraocular telescope[6] found improvements in functional vision and quality of life; however, the IMT is intended for use in eyes with moderate to profound vision loss, whereas the full range of patients who could benefit from the injectable telescopic IOL is not yet determined. Our results suggest that the iolAMD injectable telescopic IOL might be more effective in eyes with moderate to severe visual

impairment, although for safety reasons the study only included eyes with moderate to profound visual impairment (CDVA $\leq$0.25). Even so, in many instances, distance visual acuities in our patients exceeded the simulated outcome (as would be expected with the superior optics associated with intraocular implantation), and the mean improvement in CDVA of 67% is greater than might be expected with a theoretical magnification of $\times$1.25 to $\times$1.3. This level of performance might be partly accounted for by preexisting lenticular opacity (even if minimal) but also might be related to improved fixation in the operated eyes, as suggested by the limited data acquired using microperimetry. Fixation instability is a feature of central visual field loss and probably arises from a tendency for patients to use a preferred retinal locus at the border of an area of atrophy (where the residual cone density is the greatest), such that a visual target will move in and out of the scotoma with greater frequency and amplitude.[16] The effect of fixation instability is thought to account for reduced reading rates in patients with central vision loss compared with normally sighted individuals using the same retinal eccentricities. If reproducible, our data would constitute the first objective evidence for improved fixation stability and threshold sensitivity associated with the implantation of an intraocular telescope combining magnification and a prismatic effect. In the eye of patient 16, we confirmed a magnification effect and determined a possible shift in the preferred retinal locus superior to a large area of geographic atrophy that was associated with improvements in threshold sensitivity, fixation stability, and visual acuity. Because these patients had longstanding geographic atrophy and therefore had established preferred retinal loci, the question arises as to why prismatic shifting of the retinal image toward the preferred retinal locus confers any benefit. The best comparison for this is the evidence base for eccentric viewing training. A recent review of the literature in this field[3] concluded that the quality of evidence showing that eccentric viewing training improves near visual acuity and reading speed is moderate, with less robust data supporting its effect on distance visual acuity and daily-living activities. One study in particular[17] reported greater improvement in near visual acuity from eccentric viewing training combined with use of a magnifier than from eccentric viewing training or the use of a magnifier alone. Another study[18] suggested eccentric viewing training might even reduce reading speed, particularly when a patient is conscious of using a trained retinal locus. Overall, there is a general lack of high-quality evidence of the effectiveness of eccentric viewing training, and there is even less information available about its cost-effectiveness, given the necessity for multiple clinic visits and highly motivated patients. Consequently, there might be a role for an implant such as the injectable telescopic IOL in facilitating the cost-effective rehabilitation of patients with central vision loss. Whether the improvements in visual acuity identified in the present study translate into improved ability to perform daily-living activities such as reading ability remains a key question. However, if implantation of the injectable telescopic IOL is simple and safe, its outcomes can be measured against those of eccentric viewing training and magnifiers in the context of randomized clinical trials.

The prismatic shift afforded by the iolAMD is theoretically limited to 3 degrees from the visual axis, although this can vary somewhat between individuals. The effect of such a shift is either to move the image to an area of the retina that is far enough away from the boundary of geographic atrophy to allow greater acuity and fixation stability or to relieve some pressure on the oculomotor system to control eccentric fixation. However, beyond 5 degrees, the density of the cone photoreceptors drops off considerably at the macula, which limits the benefits of targeting healthier retina at such eccentricities. Even so, our results suggest that patients with very large areas of geographic atrophy might benefit from the device; there also is evidence that visual acuity is poorly predicted by the eccentricity of the preferred retinal locus.[19] Most patients reported a preference for a prismatic shifting of the image to a retinal locus superior to the area of atrophy. This is in keeping with published data[18,20,21] indicating that patients tend either to favor this area for reading because the scotoma is above fixation in their visual field and thus tends not to interfere as much with the process of reading or to favor an area to the right of the geographic atrophy (ie, with fixation to the left of the scotoma in their visual field) because this also benefits patients who read from left to right.

Evidence suggests that most patients with geographic atrophy exhibit the same pattern of fixation in both eyes and that the preferred retinal locus remains stable for more than 4 years—both of which are relevant factors for patients having implantation of a device such as the injectable telescopic IOL.[21] However, some patients with central vision loss use more than 1 preferred retinal locus, each for different purposes, and it is possible that a prismatic device will disrupt the fixation pattern that works best for them.[18] Furthermore, evidence suggests that patients with CNV tend to establish a repeatable preferred retinal locus within 6 months of developing a central scotoma, which would have to be considered if use of the injectable telescopic IOL were extended to this

category of patients.[18] Beyond this, conceivably the injectable telescopic IOL could be used to rehabilitate vision in patients with a wide range of macular pathology (eg, macular holes and diabetic macular edema).

In summary, this pilot study provides evidence that the iolAMD injectable telescopic IOL is safe to use in the short to medium term and can significantly improve distance and near visual acuities. Its ease of implantation and the rapid postoperative recovery associated with its use make it suitable for wider investigation. In particular, clinical trials to confirm the level of efficacy suggested by this study are warranted, with particular attention to the effects of the device on the visual field, reading ability, and activities of daily living.

WHAT WAS KNOWN

- Implantation of telescopic IOLs is associated with high rates of complications and with greatly reduced visual fields or high hyperopic shifts.

WHAT THIS PAPER ADDS

- Improvements in visual acuity were achieved in patients with severe to profound dry AMD using a new injectable telescopic IOL with minimum changes to refraction.
- Implantation of the injectable telescopic IOL appears safe and was easy to perform.
- It is possible to target a patient's preferred retinal locus using the prismatic correction afforded by the injectable telescopic IOL. This was associated with improved fixation stability that might provide additional improvements to visual function.

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