I.

APPENDIX 12

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

II. GENERAL INFORMATION

Device Generic Name:	AMD Telescope Prosthesis
Device Trade Name:	Implantable Miniature Telescope IMT™(by Dr. Isaac Lipshitz)
Applicant's Name and Address:	VisionCare Ophthalmic Technologies, Inc. 14395 Saratoga Ave., Suite 150 Saratoga, CA 95070 (408) 872-9393 (phone) (408) 872-9395 (fax)
Date(s) of Panel Recommendation:	TBD
PMA Number:	P050034
Date of Good Manufacturing Practice Inspection:	TBD
Date of Notice of Approval to Applicant:	TBD

III. INDICATIONS FOR USE

The AMD telescope prosthesis is indicated for monocular implant in patients ≥ 65 years of age with stable moderate (distance BCVA of 20/80 or poorer) to profound (distance BCVA of 20/800 or better) vision impairment caused by bilateral central scotomas associated with end-stage age-related macular degeneration. Patients must have:

- retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography
- evidence of cataract
- at least a five-letter improvement on the ETDRS chart with an external telescope
- adequate peripheral vision in the eye not scheduled for surgery
- willingness to participate in a post-operative training program in use of the AMD telescope prosthesis.

IV. CONTRAINDICATIONS

Implantation of the AMD telescope prosthesis is contraindicated in patients:

- with evidence of cornea guttata
- with anterior chamber depth <3.0 mm
- who do not meet the minimum age and endothelial cell density, as shown in the grid below:

ENDOTHELIAL CELL DENSITY

Age Range	65-69		70-74		75-79		80-84		85-89		90 or Greater	
Gender	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Minimum Cell Density	2460	2755	2000	2325	2000	2000	2000	2000	1800	1800	1800	1800

The endothelial cell density (ECD) table indicates the minimum ECD per age group at the time of implantation based on mean cell loss of 24.6% at 12 months, an estimated annual ECD loss rate of 5.5% for eyes without guttata and with anterior chamber depth of 3.0mm or greater (upper 90% confidence interval for annual loss estimated by the biexponential model utilizing 4-year data), and a minimum ECD as a function of age that should result in at least 750 cells/mm^2 at end of the average life span based on the National Vital Statistics Reports (Vol 53, No. 3, November, 2004).

The device is also contraindicated in patients:

- who have evidence of active CNV on fluorescein angiography or treatment for CNV within the past six months
- with any ophthalmic pathology that compromises the patient's peripheral vision in the fellow eye
- with previous intraocular or cornea surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes
- who have prior or expected ophthalmic related surgery within 30 days preceding AMD telescope prosthesis surgery
- with a history of steroid-responsive rise in intraocular pressure, uncontrolled glaucoma, or preoperative IOP >22 mm Hg, while on maximum medication
- with known sensitivity to post-operative medications

- in whom the planned operative eye has:
  - Myopia > 6.0 D
  - Hyperopia > 4.0 D
  - An axial length < 21 mm
  - A narrow angle, i.e., < Schaffer grade 2
  - Cornea stromal or endothelial dystrophies, including guttata
  - Inflammatory ocular disease
  - Zonular weakness/instability of crystalline lens, or pseudoexfoliation
  - Diabetic retinopathy
  - Untreated retinal tears
  - Retinal vascular disease
  - Optic nerve disease
  - A history of retinal detachment
  - Intraocular tumor
  - Retinitis pigmentosa
  - An ocular condition that predisposes the patient to eye rubbing.

V. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the device labeling.

VI. DEVICE DESCRIPTION

VisionCare's Implantable Miniature Telescope, IMT™(by Dr. Isaac Lipshitz) (also referred to as "AMD telescope prosthesis") is a visual prosthetic device which, when combined with the optics of the cornea, constitutes a telephoto system for improvement of visual acuity in patients with bilateral, end-stage macular degeneration. The AMD telescope prosthesis is surgically implanted in the capsular bag of the eye after removal of the eye's lens, and is held in position by haptic loops.

The AMD telescope prosthesis' optical component, which contains two micro lenses, enlarges the retinal images of objects in the central visual field, allowing the patient to recognize and identify objects that could not otherwise be seen at both near and far distances. The AMD telescope prosthesis is available in two models: Wide Angle (WA) 2.2X, and Wide Angle (WA) 3X, which provide nominal magnification of 2.2x and 2.7x, respectively.

Both models are set for intermediate to far vision (increasing the ability to view objects several feet away from the patient). The addition of conventional spectacles provides correction for near (e.g., for reading) and distance activities.

The AMD telescope prosthesis is implanted in one eye only. The implanted eye provides central vision, while the fellow eye continues to be used for peripheral vision.

The AMD telescope prosthesis is composed of three primary components; a fused silica capsule that contains the optical elements, a clear polymethylmethacrylate (PMMA) carrier, and a blue PMMA light restrictor. The optical component is snap-fitted into the carrier. All materials are biocompatible for long-term ocular implantation per ISO 10993. The telescope prosthesis has been determined to be MR-Conditional (will not present any additional hazard or risk to a patient undergoing an MRI procedure using a scanner operating with a static magnetic field of 3-Tesla or less).

The AMD telescope prosthesis is assembled and packaged in a controlled environment and is sterilized by ethylene oxide. Table 1 compares the finished product specifications of the two device models. More detailed information regarding the AMD telescope prosthesis is provided in the device labeling.

TABLE 1
PRODUCT SPECIFICATIONS OF THE AMD TELESCOPE PROSTHESIS

FEATURE	MODEL WA 2.2X	MODEL WA 3X
MAGNIFICATION	2.2x ± 10%	2.7x ± 10%
DEPTH OF FIELD	1.5 to 10 m	1.5 to 10 m
OPTIMAL FOCUSING DISTANCE	3 m	3 m
FIELD OF VIEW	Full field: 24° (Nominal), 52.8° on the retina Center (High Resolution): 9°, 20° on the retina	Full field: 20° (Nominal), 54° on the retina Center (High Resolution): 6°, 16.2° on the retina
DIMENSIONS		
Overall Diameter	13.5 mm	13.5 mm
Clear Aperture	3.2 mm	3.2 mm
Telescope Diameter	3.6 mm	3.6 mm
Axial Length	4.4 mm	4.4 mm
Haptic Angulation	12.7°	12.7°
WEIGHT		
Air	115 mg + 10%	115 mg + 10%
Aqueous	60 mg + 10%	60 mg + 10%

VII. ALTERNATIVE PRACTICES OR PROCEDURES

Alternative, corrective interventions currently available are vision aids such as special spectacles and head-mounted or hand-held telescopes, which magnify images onto the retina.

VIII. MARKETING HISTORY

The VisionCare AMD telescope prosthesis device has not been marketed within the United States. The device has received marketing approval in the European Union. The device has not been withdrawn from marketing for any reason relating to the safety or effectiveness of the device.

IX. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse events associated with AMD telescope prosthesis implantation include:

- Choroidal detachment
- Cornea decompensation
- Cornea edema
- Cornea transplant
- Cyclitic membrane
- Decentered AMD telescope prosthesis
- Dislocation of AMD telescope prosthesis
- Distorted pupil
- Endophthalmitis
- Flat anterior chamber
- Hyphema
- Hypopyon
- Increased IOP requiring treatment
- Inflammatory deposits on the telescope prosthesis
- Intraocular inflammation
- Iris atrophy
- Iris transillumination defects
- Iritis
- Pigment deposits on the AMD telescope prosthesis
- Posterior capsular opacification
- Posterior synechiae
- Pupillary block
- Removal of the AMD telescope prosthesis
- Repeat iridectomy
- Repositioning of the AMD telescope prosthesis
- Retinal detachment
- Tilted AMD telescope prosthesis
- Uveitis/Vitritis
- Vitrectomy/vitreous aspiration
- Vitreous in anterior chamber
- Vitreous incarceration in incision
- Wound leak

Surgical techniques that may lead to increased ocular complications or cornea endothelial cell loss include, but are not limited to:

- Forcing the telescope prosthesis into the anterior chamber through an incision that is too small
- Cornea endothelium touch with surgical instruments, the AMD telescope prosthesis, or other intraocular matter
- Excessive stretching (e.g., 'tenting') of the cornea
- Inadequate intra-operative anterior chamber space management or peri-operative wound management leading to shallow chamber
- Placing one or both carrier haptics outside of capsular bag (i.e., sulcus)
- Inadequate use of ocular viscoelastic devices.

X. SUMMARY OF PRECLINICAL STUDIES

Preclinical studies performed on the AMD telescope prosthesis were consistent with the FDA draft guidance document for refractive implants dated August 1, 2000. VisionCare conducted a battery of *in vivo* and *in vitro* acute and chronic toxicity tests that establish the biocompatibility of the AMD telescope prosthesis materials. These studies, combined with data from chemistry and engineering analyses, demonstrate the suitability of the materials and overall device design for use as an intraocular implant. The adequacy of the manufacturing processes, including

sterilization, was established through review of the manufacturing information in the PMA as well as through on-site inspection. Preclinical testing demonstrates safety and effectiveness of the AMD telescope prosthesis from the microbiology, toxicology, engineering, and manufacturing perspectives.

XI. SUMMARY OF CLINICAL STUDIES

This report summarizes data for the pivotal (IMT-002) and Long-Term Monitoring (IMT-002-LTM) trials.

A. OBJECTIVES

The objective of the IMT-002 pivotal study was to demonstrate the safety and effectiveness of the AMD telescope prosthesis for the improvement of visual acuity in patients with bilateral moderate to profound central vision impairment due to untreatable, end-stage age-related macular degeneration (AMD). The primary objective of the IMT-002-LTM study was to collect and report long-term safety of the AMD telescope prosthesis.

B. STUDY DESIGN

The prospective, multicenter IMT-002 study required data collection through 2 years. Primary clinical endpoints were one year for safety and efficacy, and the second-year visits were scheduled for safety follow up. The IMT-002-LTM trial was designed as a 5-year follow-up post-approval surveillance study (additional 3 years after IMT-002 study completion), and was implemented before PMA approval. The study population is those subjects previously enrolled in the IMT-002 trial who agreed and consented to enroll in the 5-year follow-up study. A total of 217 subjects were enrolled and available for analysis at 28 clinical sites for the IMT-002 study. The IMT-002-LTM study enrolled 129 subjects from the IMT-002 study population. Data through 4-year visits after telescope implantation is available in this document.

C. INCLUSION AND EXCLUSION CRITERIA

In order to be enrolled in the IMT-002 study, subjects needed to have met these conditions: bilateral, stable, untreatable central vision disorders (untreatable AMD or Stargaardt's macular dystrophy) as determined by fluorescein angiography, and cataract; distance best-corrected visual acuity (BCVA) between 20/80 and 20/800, and adequate peripheral vision in one eye (the non-targeted eye) to allow navigation; achievement of at least a five-letter improvement on the ETDRS chart in the eye scheduled for surgery, with an external telescope; anterior chamber depth of ≥ 2.5mm in the operative eye; be available for the study duration of approximately 24 months and willing to return for all visits for training and evaluation; be alert, mentally competent, and able to understand and comply with the requirements of the clinical trial, and personally motivated to abide by the requirements and restrictions of the clinical trial; at least 55 years of age; and provide written informed consent.

Subjects not meeting the above inclusion criteria were excluded from the study. In addition, subjects who exhibited any of the following conditions were excluded: evidence of active CNV on fluorescein angiography or treatment for CNV within the past six months; anticipated need

for cataract extraction and intraocular lens implantation during the first 12 months following AMD telescope prosthesis implantation in the fellow eye (if cataract extraction was anticipated, this procedure had to be performed at least 30 days prior to enrollment in the clinical study); ophthalmic related surgery within the 30 days preceding implantation of the AMD telescope prosthesis; any of the following conditions in the operative eye: myopia > 6.0 D, hyperopia > 4.0 D, axial length < 21 mm, endothelial cell density < 1600 cells/mm^2, narrow angle (i.e., less than Schaffer grade 2), cornea stromal or endothelial dystrophies or disorders, inflammatory ocular disease, zonular weakness/instability of crystalline lens, pseudoexfoliation, diabetic retinopathy, untreated retinal tears, retinal vascular disease, optic nerve disease, history of retinal detachment, retinitis pigmentosa or any intraocular tumor and medical or ophthalmic condition that in the opinion of the study Investigator rendered the subject unsuitable for participation in the trial; any ophthalmic pathology that compromised the subject's peripheral vision in the fellow eye; any ocular condition that predisposed the subject to eye rubbing; significant communication impairments or severe neurological disorders that prevented or interfered with the study requirements; previous intraocular or cornea surgery of any kind in the operative eye(s), including any type of surgery for either refractive or therapeutic purposes; history of steroid-responsive rise in intraocular pressure, uncontrolled glaucoma, or preoperative IOP >22 mm Hg; known sensitivity to planned study concomitant medications; and participation in any other ophthalmic drug or device clinical trial during the time of this clinical investigation.

Subjects enrolled in the IMT-002 study were eligible to enroll in the IMT-002-LTM study upon completion and exit from the IMT-002 study.

D. STUDY PLAN, PATIENT ASSESSMENTS, AND EFFICACY CRITERIA

All subjects were expected to return for IMT-002 follow-up examinations at 1 day, 1 week, 1 month, and 3, 6, 9, 12, 18 and 24 months postoperatively. In addition, subjects were required to return for vision training at week 1, 2, 4, 6, 10 and 12.

Preoperatively, the subjects' medical and ocular histories were recorded. The clinical parameters measured during the study included: distance BCVA (BCDVA) and near BCVA (BCNVA; 8 and 16 inches), manifest refraction, intraocular pressure, slit lamp examination, fundus examination, endothelial cell count, activities of daily life questionnaire, and VFQ-25.

The primary efficacy criterion for this study was an improvement of 2 lines or greater in either BCDVA or BCNVA in 50% of the implanted eyes at 12 months post-implantation. Quality of Life questionnaires were used as secondary measurements of procedure success.

Safety outcomes included preservation BCVA (i.e., no more than 10% of implanted eyes were to experience a loss of more than 2 lines in either near or distance BCVA without a corresponding improvement [gain of 2 or more lines] in the other BCVA), endothelial cell loss of 17% at 12 months, and the occurrence of adverse events and complications.

Under Protocol IMT-002-LTM, patients were scheduled for examination at 30, 36, 42, 48, 54, and 60 months after surgery. Examinations at each study visit consisted of slit lamp exam, measurement of intraocular pressure, BCDVA, endothelial cell density, pachymetry, complications, and adverse events.

E. STUDY PERIOD AND INVESTIGATIONAL SITES

Subjects were implanted with the AMD telescope prosthesis between December 2002 and November 2003 at 28 US clinical sites. The IMT-002 database for this PMA reflects all data collected through study completion. The IMT-002-LTM database reflects all data gathered on study participants following IMT-002 completion and includes 48-month follow-up

F. IMT-002 DATA ANALYSIS AND RESULTS

DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Presented in Table 2 are the demographic characteristics at baseline for all operated subjects in IMT-002. As anticipated, this is an elderly study population (mean age at surgery was 75.6 years [S.D. 7.3, range 55 – 93 years]). The cohort consists primarily of Caucasians. At baseline, mean BCDVA was 20/312.

TABLE 2
DEMOGRAPHIC AND BASELINE CHARACTERISTICS
OPERATED SUBJECTS (N=217) IMT-002

217 Eyes of 217 Operated Subjects		
	Number	**Percentage**
Gender		
Female	103	47.5%
Male	114	52.5%
Race		
Caucasian	208	95.9%
Black	3	1.4%
Hispanic	5	2.3%
Asian	1	0.5%
Age (In Years)		
Mean (SD)	75.6 (7.3)	
Minimum	55	
Maximum	93	
Anterior Chamber Depth		
Mean (SD)	3.15 (0.38)	
Minimum	2.48	
Maximum	4.74	
Type of AMD		
Geographic atrophy (GA)	85	39.2%
Disciform scar	93	42.9%
GA & Drusen	11	5.1%
GA & Disciform scar	8	3.7%
Drusen & Disciform scar	13	6.0%
GA & Drusen & Disciform scar	7	3.2%
Best-corrected Visual Acuity		
Mean BCDVA	20/312	
(Range)	(20/873, 20/80)	
Mean BCNVA @8"	20/315	
(Range)	(20/1262, 20/50)	
Mean BCNVA @16"	20/260	
(Range)	(20/632, 20/63)	

IMT-002 POST-OPERATIVE CHARACTERISTICS AND RESULTS

ACCOUNTABILITY

Accountability for all implanted subjects at the time of database closure across the study visit schedule is presented in Table 3A for IMT-002 and Table 3B for IMT-002-LTM.

TABLE 3A
AVAILABILITY AND ACCOUNTABILITY
OPERATED SUBJECTS (N = 217)
IMT-002

Total Subjects (N) = 217		1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
Available for Analysis	n/N (%)	217/217 (100.0%)	207/217 (95.4%)	204/217 (94.0%)	196/217 (90.3%)	196/217 (90.3%)	180/217 (82.9%)	174/217 (80.2%)
Discontinued	n/N (%)	0/217 (0.0%)	7/217 (3.2%)	11/217 (5.1%)	13/217 (6.0%)	16/217 (7.4%)	20/217 (9.2%)	29/217 (13.4%)
Deceased		0/217 (0.0%)	1/217 (0.5%)	3/217 (1.4%)	3/217 (1.4%)	5/217 (2.3%)	7/217 (3.2%)	10/217 (4.6%)
IMT removed postoperatively		0/217 (0.0%)	1/217 (0.5%)	1/217 (0.5%)	1/217 (0.5%)	2/217 (0.9%)	2/217 (0.9%)	8/217 (3.7%)
Lost to Follow-up	n/N (%)	0/217 (0.0%)	0/217 (0.0%)	0/217 (0.0%)	1/217 (0.5%)	2/217 (0.9%)	8/217 (3.7%)	13/217 (6.0%)
Missed Visit	n/N (%)	0/217 (0.0%)	3/217 (1.4%)	2/217 (0.9%)	7/217 (3.2%)	3/217 (1.4%)	9/217 (4.1%)	1/217 (0.5%)
% Accountability = Available for Analysis ÷ (Enrolled - Discontinued)		217/217 (100.0%)	207/210 (98.6%)	204/206 (99.0%)	196/204 (96.1%)	196/201 (97.5%)	180/197 (91.4%)	174/188 (92.6%)

TABLE 3B
AVAILABILITY AND ACCOUNTABILITY
IMT-002-LTM

	30 Months	36 Months	42 Months	48 Months
Available for analysis	3/3 (100%)	84/85 (99%)	113/125 (90%)	106/129 (82%)
Discontinued (cumulative)			4/125 (3%)	6/129 (5%)
Deceased			3/125 (2%)	5/129 (3%)
IMT removed postoperatively			1/125 (1%)	1/129 (1%)
Lost to Follow-up			3/125 (2%)	10/129 (8%)
Missed Visit		1 /85 (1%)	5/125 (4%)	7/129 (5%)
% Accountability = Available for Analysis / (Enrolled - Discontinued)	3/3 100%	84/85 99%	113/121 93%	106/123 86%

Table 3C shows the data for operated eyes without telescope prosthesis placement. Surgical complications (described below) led to 11 subjects not being implanted with the device, leaving a cohort of 206 telescope-implanted subjects. Of the 206 eyes, 115 eyes were implanted with the WA 2.2X model device and 91 eyes were implanted with the WA 3X model device.

Of the 11 subjects not successfully implanted, in 5 eyes the AMD telescope prosthesis was not implanted because of surgical complications and in 6 eyes telescope implantation was attempted but the device was removed at the time of surgery, also as a result of surgical complications. An intraocular lens was placed in these 11 eyes rather than the telescope prosthesis.

TABLE 3C
OPERATED EYES WITHOUT AMD TELESCOPE PROSTHESIS PLACEMENT
IMT-002

Number of Eyes	Surgical Complication
Cases with Intraoperative Contraindications for IMT Implantation	
3	Posterior Capsule Tear
2	Choroidal Detachment
Cases with IMT Placed and Removed Intraoperatively	
4	Posterior Capsular Tear
1	Zonular Dehiscence
1	Choroidal Hemorrhage

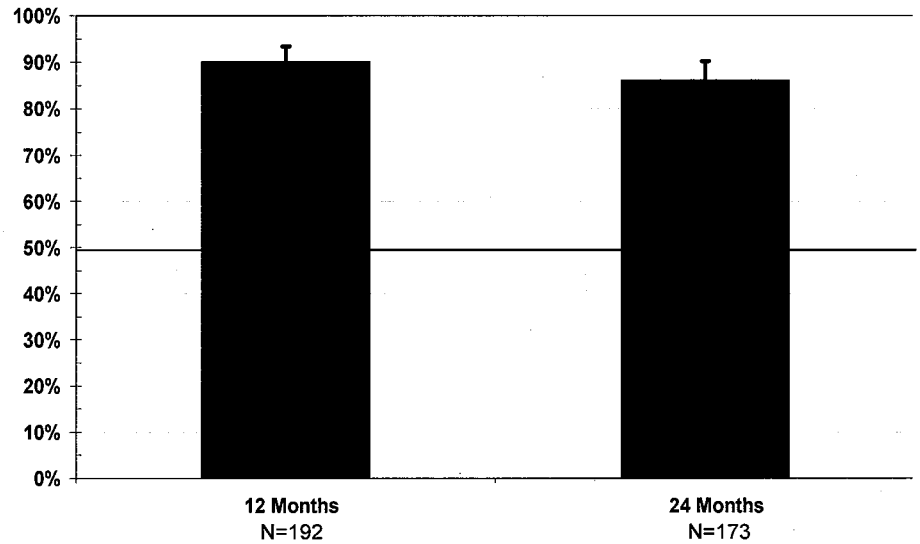
EFFECTIVENESS

The AMD telescope prosthesis improved visual acuity and quality of life in subjects with end-stage AMD. The primary effectiveness endpoint, a 2-line or greater gain in either distance or near BCVA at 12 months in at least 50% of study subjects, was met and exceeded. The secondary effectiveness endpoint, improvement in quality of life, was also achieved. The WA 3X device provided somewhat superior results as compared to the WA 2.2X, an outcome that would be expected given the higher magnification of this model.

VISUAL ACUITY PRIMARY ENDPOINT

Ninety percent of telescope-implanted eyes achieved at least a 2-line or greater gain in either distance or near BCVA at 12 months, thus exceeding the 50% criterion specified for the primary endpoint. This improvement was maintained at 24 months. (Figure 1)

FIGURE 1
IMT-002 PRIMARY EFFECTIVENESS ENDPOINT
ALL AMD TELESCOPE PROSTHESIS IMPLANTED EYES
(≥ 2 LINES IMPROVED FROM BASELINE IN DISTANCE OR NEAR BEST-CORRECTED VISUAL ACUITY)



CUMULATIVE AND MEAN VISUAL ACUITY CHANGE AT 12 AND 24 MONTHS

Mean line change exceeded a 3-line improvement from baseline at both one and two years. Cumulative change in lines of BCVA from baseline is shown in Table 4. Approximately 2% of patients lost 2 lines or more of distance BCVA.

TABLE 4
CUMULATIVE BCDVA CHANGE FROM BASELINE
ALL AMD TELESCOPE-IMPLANTED EYES (IMT-002)

	12 Months	24 Months
	n (%)	n (%)
N	193	173
Gain ≥ 6 lines	21 (10.9%)	16 (9.2%)
Gain ≥ 5 lines	49 (25.4%)	33 (19.1%)
Gain ≥ 4 lines	87 (45.1%)	74 (42.8%)
Gain ≥ 3 lines	128 (66.3%)	103 (59.5%)
Gain ≥ 2 lines	155 (80.3%)	129 (74.6%)
Gain ≥ 1 lines	170 (88.1%)	146 (84.4%)
No change	19 (9.8%)	24 (13.9%)
Loss of >2 lines	4 (2.1%)	3 (1.7%)
Mean Line Change (SD)	3.43 lines (SD 2.31)	3.15 lines (SD 2.19)

Mean BCDVA improved from 20/312 at baseline to 20/141 at 12 months and to 20/149 at 24 months (Table 5). Mean BCNVA at 8 inches improved from 20/315 at baseline to 20/181 at 12 months and to 20/190 at 24 months. Mean BCNVA at 16 inches improved from 20/262 at baseline to 20/149 at 12 months and to 20/157 at 24 months.

TABLE 5
MEAN BCVA AT BASELINE, 12 MONTHS AND 24 MONTHS
AMD TELESCOPE-IMPLANTED EYES (IMT-002)

	Baseline		12 Months		24 Months	
	N	Mean	N	Mean	N	Mean
Mean BCDVA **95% CI**	206	**20/312** (20/334, 20/291)	193	**20/141** (20/152, 20/131)	173	**20/149** (20/161, 20/138)
Mean BCNVA at 8" **95% CI**	206	**20/315** (20/341, 20/291)	192	**20/181** (20/196, 20/167)	173	**20/190** (20/207, 20/174)
Mean BCNVA at 16" **95% CI**	206	**20/262** (20/282, 20/244)	192	**20/149** (20/161, 20/138)	173	**20/157** (20/170, 20/145)

VISUAL ACUITY BY DEVICE MODEL

Improvements in BCDVA and BCNVA were achieved with both the WA 2.2X and WA 3X device models. A summary of improvement in visual acuity in terms of the primary effectiveness endpoint and % of patients achieving a 3-line change are shown in Table 6.

TABLE 6
SUMMARY OF IMPROVEMENT IN VISUAL ACUITY
STRATIFIED BY AMD TELESCOPE-IMPLANTED MODEL (IMT-002)

IMPROVEMENT IN VISUAL ACUITY	12 MONTHS		24 MONTHS	
	WA 2.2X	WA 3X	WA 2.2X	WA 3X
	% (n)	% (n)	% (n)	% (n)
≥2 LINES GAIN OF BCDVA *OR* BCNVA	89.0% (97)	91.6% (76)	84.5% (82)	88.2% (67)
BCDVA LINES GAINED				
≥3 LINES GAIN OF BCDVA	60.0% (66)	74.7% (62)	52.6% (51)	68.4% (52)
BCNVA LINES GAINED (8 OR 16 INCHES)				
≥3 LINES GAIN OF BCNVA	64.2% (70)	72.3% (60)	58.8% (57)	68.4% (52)

LONG-TERM VISUAL ACUITY

Long-term follow up data from the IMT-002-LTM study demonstrates mean BCDVA improvements were generally retained at 36 and 48 months in telescope-implanted eyes. There was a slight decline in BCDVA at 48 months. (Table 7)

TABLE 7
MEAN BCDVA AT BASELINE, 36 MONTHS AND 48 MONTHS
AMD TELESCOPE-IMPLANTED EYES
(IMT-002 AND IMT-002-LTM)

BCDVA	Baseline	36 Months	48 Months
IMT-Implanted Eyes			
N	206	74	96
Mean 95% CI	**20/312** (20/334, 20/291)	**20/156** (20/175, 20/139)	**20/171** (20/191, 20/152)

QUALITY OF LIFE

Quality of life, as assessed by the National Eye Institute's Visual Function Questionnaire-25 (VFQ-25), was a secondary outcome measure. The VFQ-25 is a validated version of the National Eye Institute Visual Function Questionnaire (VFQ) which measures vision-targeted health status for persons with chronic eye diseases including macular degeneration. A five (5) point difference in subscale and/or composite scores may be interpreted as clinically significant. The VFQ-25 survey was administered at baseline and postoperatively. As shown below, implantation with the AMD telescope prosthesis improved quality of life in this study population (subjects with end-stage AMD and significant bilateral vision impairment).

VFQ-25 RESULTS

Outcomes for all subscales of the VFQ-25 and the composite score are summarized in Table 8. At 12 months, the mean VFQ-25 composite score increased by a clinically significant amount (an increase of 6 points at 12 months). Overall, seven of the VFQ-25 subscales improved by clinically significant levels (general vision, near activities, distance activities, social functioning, mental health, role difficulties, and dependency). In subscales where no improvement or a decline in performance was expected (color vision, driving, and peripheral vision), performance was stable or declined. Also, the mean score of the general health subscale declined by 5 points, likely reflecting the impact of other health-related events on the general health of the elderly study population.

TABLE 8
MEAN SCORE CHANGE AT 12 MONTHS
NEI 25-ITEM VISUAL FUNCTION QUESTIONNAIRE (VFQ-25)
IMT-002

VFQ-25 Subscale	Preop Mean Score (95%CI) N = 206	12 Months Mean Score (95%CI) N = 193	Change from Preop Mean Score (95%CI) N = 193	P-value
General Vision	35.3 (33.2, 37.4)	50.3 (47.5, 53.1)	14.1 (11.0, 17.2)	<.0001
Near Activities	25.5 (23.6, 27.5)	37.3 (34.6, 40.0)	11.2 (8.4, 13.9)	<.0001
Distance Activities	34.3 (31.7, 36.8)	42.4 (39.1, 45.7)	7.9 (4.4, 11.4)	<.0001
Color Vision	63.9 (60.1, 67.8)	67.7 (63.9, 71.5)	3.4 (-0.2, 6.9)	NS
Social Functioning	49.3 (46.0, 52.7)	58.3 (55.1, 61.4)	8.6 (4.8, 12.4)	<.0001
Mental Health	39.8 (36.5, 43.1)	49.3 (45.5, 53.0)	9.3 (6.1, 12.5)	<.0001
Role Difficulties	37.4 (34.2, 40.7)	44.8 (41.0, 48.5)	7.3 (3.5, 11.0)	0.0002
Dependency	37.7 (34.0, 41.4)	48.3 (44.4, 52.2)	10.0 (6.1, 13.9)	<.0001
Ocular Pain	88.2 (86.0, 90.4)	88.5 (86.1, 90.9)	0.6 (-2.1, 3.3)	NS
Driving	2.3 (1.0, 3.6)	1.9 (0.6, 3.2)	-0.5 (-1.6, 0.5)	NS
Peripheral Vision	67.6 (63.9, 71.3)	62.9 (59.7, 66.1)	-5.9 (-10.4, -1.5)	0.0091
Overall Composite	44.0 (42.1, 45.8)	50.3 (48.2, 52.4)	6.0 (4.0, 8.1)	<.0001
General Health	64.0 (60.8, 67.1)	59.7 (56.4, 63.0)	-5.1 (-8.1, -2.0)	0.0015

VFQ-25 scores on a scale of 0 (low) to 100 (maximum).
95%CI = 95% Confidence Interval.
General Health not included in Overall Composite per NEI VFQ-25 scoring guidelines.

SAFETY

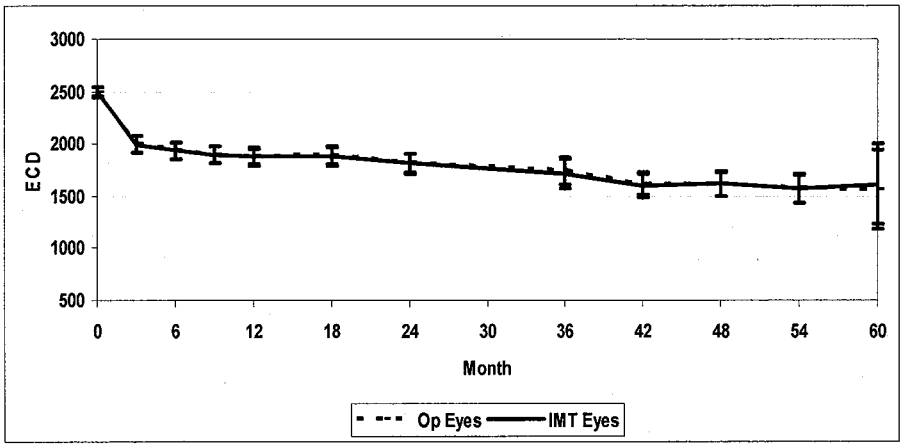
Data from both IMT-002 and IMT-002-LTM are provided below to describe safety parameters for the AMD telescope prosthesis. The IMT-002 protocol identified three safety outcomes which are described below: 1) preservation of visual acuity, 2) corneal endothelial cell density loss at 12 months, and 3) complications and adverse events, including corneal edema, corneal decompensation and device explantation. Other safety considerations (clearance from the cornea to the device, intraocular pressure, and posterior capsular opacification) are also detailed in this section. An ECD grid is provided to determine patient candidacy in terms of baseline corneal health, anterior chamber depth, and age.

CORNEAL ENDOTHELIAL CELL DENSITY

The endpoint for endothelial cell loss associated with the implantation procedure for the IMT-002 study specified ECD loss was not to exceed 17% one year after implantation; actual ECD loss exceeded this target at 12 months and was 25%. The most significant loss of corneal endothelial cells occurred from baseline to 3 months and from baseline to 6 months. This acute ECD loss results primarily from the 11 to 12 mm surgical incision required for insertion of the AMD telescope prosthesis, as well as the manipulation of the device during implantation. From 6 and 12 months through 48 months, the rate of endothelial cell loss was relatively stable (3% per year). (Figures 2 and 3)

FIGURE 2

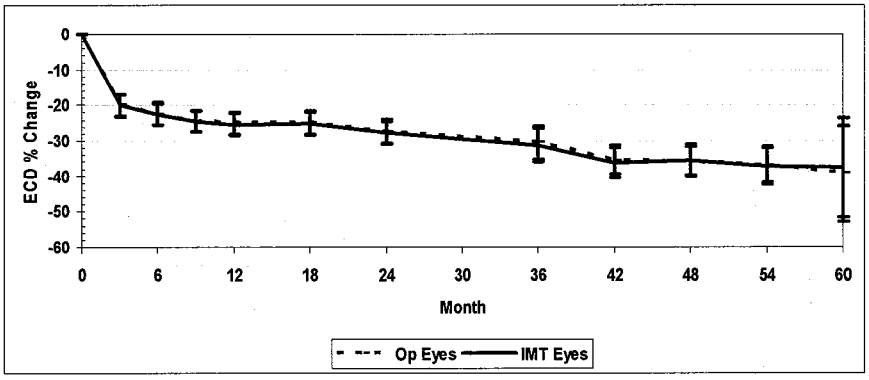
ECD
Operated Eyes Versus IMT-Implanted Eyes
IMT-002 and IMT-002-LTM



		Preop	1-3 Months	4-6 Months	7-9 Months	10-12 Months	13-18 Months	19-24 Months	25-30 Months	31-36 Months	37-48 Months	49-54 Months	55-60 Months
Op Eyes	Mean	2498	2001	1936	1891	1881	1887	1813	1736	1612	1611	1572	1563
	95%CI	2451, 2546	1919, 2082	1855, 2016	1809, 1973	1795, 1967	1796, 1978	1723, 1903	1610, 1863	1505, 1720	1495, 1727	1439, 1706	1181, 1945
	N	216	198	200	190	190	182	173	79	110	94	65	18
	ECD<750	0 (0%)	6 (3%)	8 (4%)	9 (5%)	9 (5%)	13 (7%)	12 (7%)	3 (4%)	9 (8%)	7 (7%)	5 (8%)	3 (17%)
IMT Eyes	Mean	2496	1995	1937	1891	1871	1878	1808	1713	1595	1620	1572	1616
	95%CI	2447, 2545	1912, 2078	1856, 2018	1809, 1973	1786, 1957	1787, 1969	1718, 1898	1576, 1850	1481, 1709	1499, 1741	1431, 1713	1227, 2005
	N	206	193	198	190	186	180	171	70	101	88	60	17
	ECD<750	0 (0%)	6 (3%)	8 (4%)	9 (5%)	9 (5%)	13 (7%)	12 (7%)	3 (4%)	9 (9%)	7 (8%)	5 (8%)	2 (12%)

FIGURE 3

ECD % Change from Baseline,
Operated Eyes Versus IMT-Implanted Eyes
IMT-002 and IMT-002-LTM



		Preop	1-3 Months	4-6 Months	7-9 Months	10-12 Months	13-18 Months	19-24 Months	25-30 Months	31-36 Months	37-48 Months	49-54 Months	55-60 Months
Op Eyes	Mean	0%	-20%	-22%	-24%	-25%	-25%	-27%	-30%	-35%	-36%	-37%	-39%
	95%CI		-23%, -17%	-25%, -20%	-27%, -21%	-28%, -22%	-28%, -21%	-31%, -24%	-35%, -26%	-40%, -31%	-40%, -32%	-42%, -32%	-53%, -26%
	N	216	198	200	190	190	182	173	79	110	94	65	18
IMT Eyes	Mean	0%	-20%	-22%	-24%	-25%	-25%	-28%	-31%	-36%	-35%	-37%	-38%
	95%CI		-23%, -17%	-25%, -19%	-27%, -21%	-28%, -22%	-28%, -22%	-31%, -24%	-36%, -26%	-40%, -32%	-40%, -31%	-43%, -32%	-51%, -24%
	N	206	193	198	190	186	180	171	70	101	88	60	17

As shown in Figure 2, mean ECD at baseline was 2496 cells/mm^2. At 3 and 6 months after implantation, ECD was 1995 cells/mm^2 and 1936 cells/mm^2 respectively (Figure 2). ECD percent loss from baseline reported at 3 and 6 months post-implantation was 20% and 22%, respectively (Figure 3).

Mean ECD at 12 months after device implantation was 1871 cells/mm^2, a 25% loss from baseline (Figures 2 and 3). Mean ECD at 24, 36 and 48 months was 1808, 1713, and 1620, respectively, with associated percent losses of 28%, 31%, and 35%, respectively. For the small number of subjects for whom data are available at 54 and 60 months, mean ECD was 1572 and 1616 cells/mm^2, respectively, a decline from baseline ECD of 37% at 54 months and 38% at 60 months.

From 6 months and 12 months through 48 months, the rate of endothelial cell loss is relatively stable. The annual rate of loss from year 1 to year 2 was 2.2%, from year 2 to year 4 was 2.8%, and from year 3 to year 4 was 2.8%. Mean ECD at 48 months post device implantation in these subjects with an average age of 80 was 1620 cells/mm2 (Figure 3).

The initial period of acute "fast loss" and, thereafter, an on-going period of "slow loss" is also observed in cataract surgery and other procedures such as penetrating keratoplasty. The rate of slow loss is higher than the rate of loss associated with aging, but much less rapid than the rapid component surgical loss.

When ECD levels fall too low (< 750mm^2), the cornea may become edematous, can thicken and lose transparency, and corneal transplantation may be needed. The endothelial cell density needed to maintain corneal transparency is uncertain. Ultimately, in the 2-year IMT-002 study there were 2 (1%) of 206 cases that resulted in corneal decompensation. There were 2 more cases of corneal decompensation in the IMT-002-LTM 4-year follow up study. Therefore, identification of risk factors for endothelial cell loss is described below.

IDENTIFICATION OF RISK FACTORS FOR ENDOTHELIAL CELL LOSS

Risk factors potentially associated with ECD loss – presence of guttata in the eye, surgical specialty, learning curve, and anterior chamber depth – were evaluated and are described below. ECD loss data associated with the risk factors are presented in Table 9. These and other contraindications, precautions, and warning issues are discussed in the device labeling.

TABLE 9
ENDOTHELIAL CELL DENSITY LOSS ASSOCIATED WITH IDENTIFIED RISK FACTORS

Risk Factor	Variable	N	ECD loss at 3 months
Guttata	Not Present	167	19%
	Present	26	26%
Surgeon Specialty	Cornea Specialist	46	13%
	Non-Cornea Specialist	121	21%
Surgical Order	> 5 cases	46	19%
	≤ 5 cases	75	23%
Anterior Chamber Depth	≥ 3mm	102	18%
	< 3mm	65	23%

GUTTATA
Cornea guttata has been shown to be a risk factor for endothelial cell loss following cataract surgery (Bourne et al, 1994). The same effect is seen in telescope implantation surgery. As shown in Table 9, the percent ECD loss at 3 months postoperatively was lower in non-guttata eyes than in eyes with guttata. Accordingly, the presence of guttata is a contraindication to the use of the telescope prosthesis.

SURGEON SPECIALTY
ECD loss was lower for eyes operated by cornea specialists than by non-cornea specialists. ("Cornea specialist" is defined as ophthalmologists who had fellowship or other specialty training in diseases and surgery of the cornea and who were at the time of the study regularly performing cornea surgical procedures such as penetrating keratoplasty). Although the number of subjects implanted by a cornea specialist is modest, there was lower ECD loss in these subjects of physicians who are experienced in the medical management and surgical treatment of the cornea.

LEARNING CURVE
A similar but less pronounced difference in ECD loss was observed for the learning curve, i.e., the first 5 eyes operated by non-cornea specialists. For these surgeons, lower ECD loss was observed in eyes operated after the learning curve of 5 eyes, compared to the ECD loss for eyes operated during the surgeon's first 5 cases. Surgical order had no effect on ECD loss when the surgery was performed by a cornea specialist.

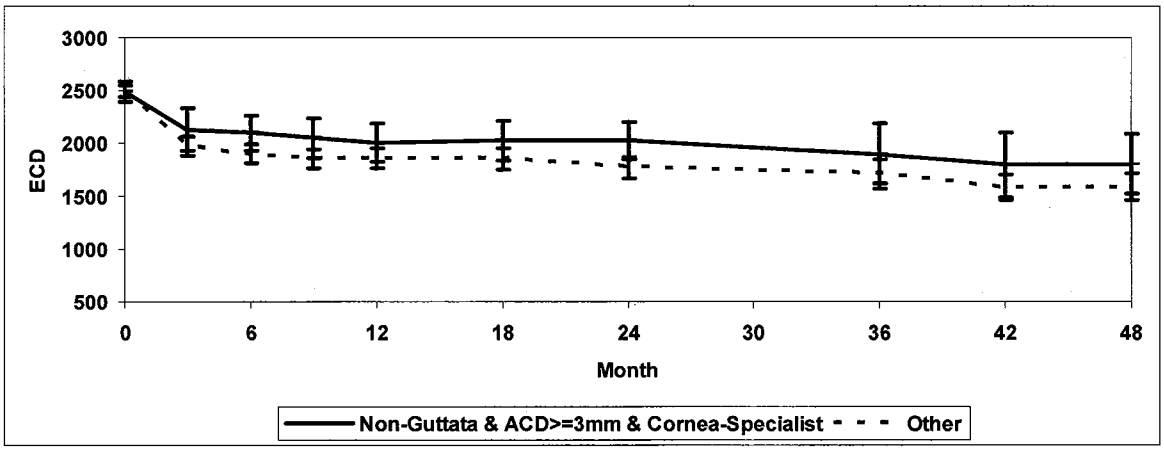
ANTERIOR CHAMBER DEPTH (ACD)
ACD ≥ 3.0 mm was associated with lower endothelial cell loss at 3 months postoperatively. The finding of greater ECD loss in shallow anterior chambers (< 3.0 mm) at 3 months is likely the result of less working space in the anterior chamber and more surgical trauma to the cornea endothelial monolayer.

RELATIONSHIP AMONG AND BETWEEN COMBINED RISK FACTORS

Acute ECD loss is less when telescope implantation is performed by cornea specialists in non-guttata eyes with ACD ≥ 3.0 mm as illustrated in Figures 4 and 5. This reduced acute surgical risk at 3 and 6 months was maintained at later study visits, i.e., through 4 years.

FIGURE 4

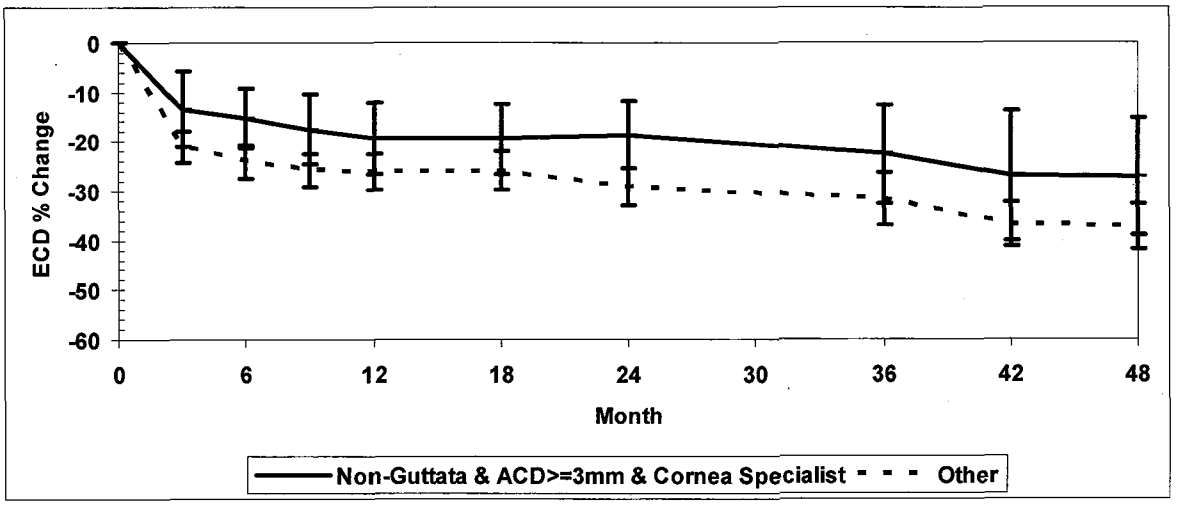
ECD
Non-Guttata Eyes with ACD ≥ 3 mm Implanted by Cornea Specialist Versus Other Eyes
IMT-002 and IMT-002-LTM



		[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Non-Guttata	Mean	2488	2128	2099	2047	2007	2024	2024	1897	1793	1803
ACD>=3mm	95%CI	2391, 2586	1926, 2330	1932, 2265	1862, 2233	1826, 2189	1834, 2214	1843, 2204	1612, 2182	1489, 2096	1520, 2086
Cornea-	N	36	31	36	32	33	31	30	10	13	13
Specialist	ECD<750	0 (0%)	1 (3%)	1 (3%)	1 (3%)	1 (3%)	1 (3%)	0 (0%)	0 (0%)	1 (8%)	1 (8%)
Other	Mean	2500	1977	1900	1859	1855	1859	1768	1710	1581	1580
	95%CI	2447, 2554	1887, 2067	1809, 1991	1768, 1950	1758, 1952	1756, 1961	1667, 1870	1568, 1852	1464, 1698	1453, 1708
	N	180	167	164	158	157	151	143	68	96	81
	ECD<750	0 (0%)	5 (3%)	7 (4%)	8 (5%)	8 (5%)	12 (8%)	12 (8%)	3 (4%)	8 (8%)	6 (7%)

FIGURE 5

ECD % Change from Baseline
Non-Guttata Eyes with ACD ≥ 3 mm Implanted by Cornea Specialist Versus Other Eyes
IMT-002 and IMT-002-LTM



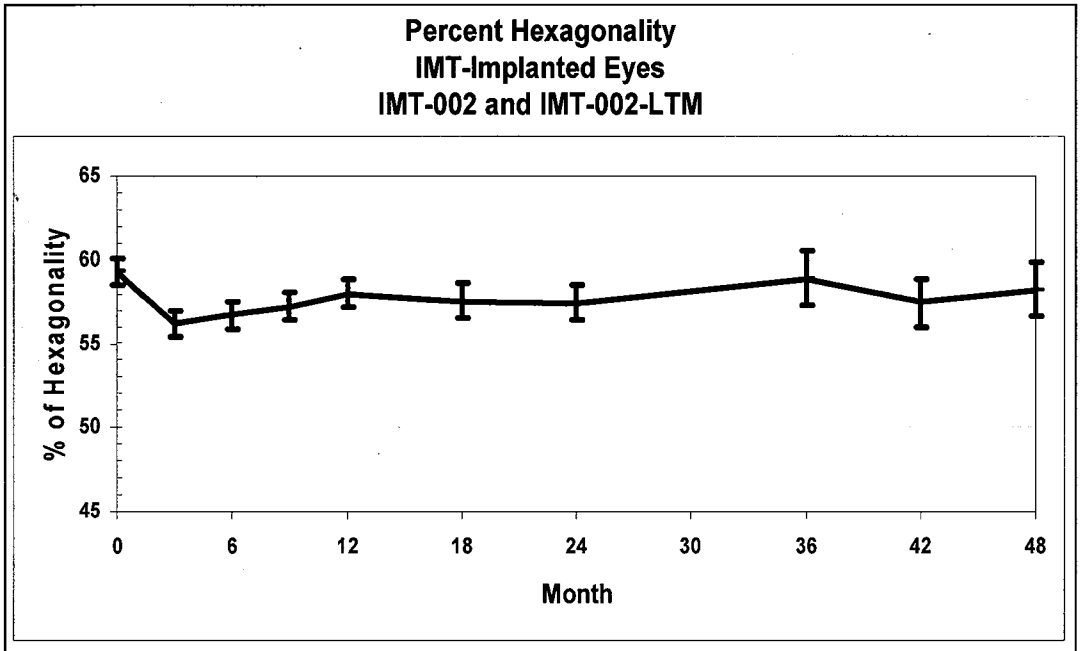
		Pre-op	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	30 Months	36 Months	48 Months
Non-Guttata	Mean	0%	-14%	-15%	-17%	-19%	-19%	-19%	-23%	-27%	-27%
ACD>=3mm	95%CI		-21%, -6%	-21%, -9%	-25%, -10%	-26%, -12%	-26%, -12%	-26%, -12%	-33%, -13%	-40%, -14%	-39%, -15%
Cornea-trained	N	36	31	36	32	33	31	30	10	13	13
Other	Mean	0%	-21%	-24%	-26%	-26%	-26%	-29%	-32%	-37%	-37%
	95%CI		-24%, -18%	-27%, -21%	-29%, -23%	-30%, -22%	-30%, -22%	-33%, -25%	-37%, -26%	-41%, -32%	-42%, -33%
	N	180	167	164	158	157	151	143	68	96	81

ENDOTHELIAL MORPHOLOGY (% HEXAGONALITY) AND MORPHOMETRY (COEFFICIENT OF VARIATION)

Analyses of cornea endothelial shape and variation in size (pleomorphism and polymegathism) are reported to be sensitive indicators of endothelial function and endothelial cell damage and recovery (Glasser et al, 1985).

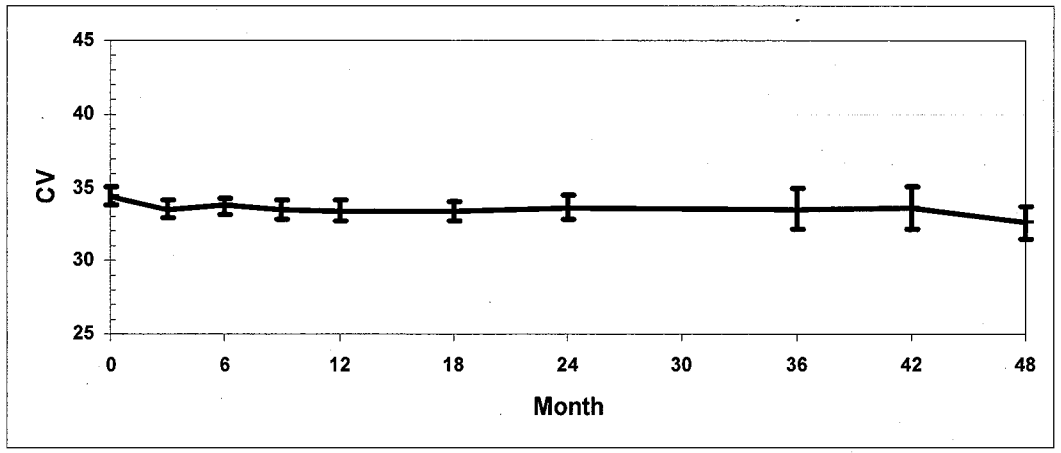
A decrease in % Hexagonality and stable CV at 3 months were observed in the telescope-implanted eyes. This decrease in % Hexagonality, indicative of the stress induced by surgical trauma, began to reverse itself shortly after 3 months, returning to near baseline levels (Figure 6). Changes in CV (Figure 7) were small throughout the 24-month IMT-002 study and for the 36-month and 48-month visits under the IMT-002-LTM study. These findings suggest the cornea endothelial cell monolayer returned to normal % Hex and CV values after surgery and remained stable at 48 months.

FIGURE 6



	Pre-Op	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
Mean	59	56	57	57	58	58	57	59	57	58
95%CI	58, 60	55, 57	56, 57	56, 58	57, 59	57, 59	56, 58	57, 60	56, 59	57, 60
N	206	193	198	190	186	180	171	69	101	88

FIGURE 7



	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
Mean	34	34	34	33	33	33	34	34	34	33
95%CI	34, 35	33, 34	33, 34	33, 34	33, 34	33, 34	33, 34	32, 35	32, 35	32, 34
N	205	193	198	190	186	180	171	70	101	88

CORNEA PACHYMETRY

Because an increase in cornea thickness may indicate cornea edema and inadequate function, cornea thickness was assessed by ultrasonic pachymetry in the IMT-002 and IMT-002-LTM studies. Cornea thickness generally remained within normal limits of 550-570 microns.

USE OF A GRID TO ALLOW PHYSICIANS AND PATIENTS TO ASSESS LIKELIHOOD THAT PATIENTS WILL RETAIN SUFFICIENT ENDOTHELIAL CELL DENSITY OVER THE PATIENT'S LIFE SPAN

An 'ECD grid' allows physicians and patients to calculate the minimum ECD needed before telescope prosthesis implantation, such that the patient would be able to obtain the benefits of improved visual acuity from implantation of the device without an undue risk of ECD loss to a level potentially leading to cornea decompensation and requiring cornea transplant.

The grid below (also in CONTRAINDICATIONS) for telescope prosthesis implantation is similar to the FDA CDRH phakic IOL grid. The grid uses an ECD of 750 cells/mm^2 as a target ECD, actuarial data on life expectancy data (National Vital Statistics Reports, Vol. 53, No. 6, November 10, 2004), and a biexponential model utilizing IMT-002 and IMT-002-LTM ECD data providing predicted annual ECD percent loss. ECD data utilized in the biexponential model is consistent with the labeling - excluding subjects with guttata and anterior chamber depths <3.0 mm. The model utilizes a conservative approach of using ECD data from both cornea specialists and non-cornea specialists.

Applying the biexponential model to the data described from IMT-002 and IMT-002-LTM through 4 years, the mean ECD at 12 months (to incorporate the full effect of surgical loss) was 1954 cells/mm^2, and the mean annual loss thereafter was 3.8%. To make the grid more conservative (i.e., to increase the likelihood that patients will have sufficient ECD to preserve corneal transparency through their life spans), the lower 90% confidence interval for the 1 year mean ECD and the upper 90% confidence interval for annual ECD percent loss are utilized in constructing the grid. To summarize, the following assumptions were used to develop the grid of baseline ECD:

- ECD data from the IMT-002 and IMT-002-LTM studies through 48 months, for eyes without corneal guttata and with anterior chamber depth ≥3.0 mm
- 12-month ECD loss of 24.6%, the lower 90% confidence interval for 12-month ECD, 1911 cells/mm^2, estimated by the biexponential model, and
- Annual ECD loss of 5.5%, the upper 90% confidence interval for annual loss estimated by the biexponential model, utilizing 48 month data.

The resulting ECD grid, shown in Table 10, sets minimum ECD criteria as a function of age that should result in at least 750 cells/mm^2 at end of average life span.

If a patient lacks sufficient ECD at baseline to predict ECD of at least 750 cells/mm^2 at the end of their life span, implantation of the AMD telescope prosthesis is contraindicated.

TABLE 10
GRID OF PREOPERATIVE ECD REQUIRED FOR AMD TELESCOPE IMPLANTATION
(BASED ON IMPLANTED EYES WITHOUT GUTTATA AND WITH ACD ≥ 3.0 MM)

Age Range		65-69		70-74		75-79		80-84		85-89		90 or Greater	
Gender		Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Avg. Life Span		16.0	19.5	10.2	15.8	10.3	12.4	7.8	9.4	5.7	6.9	4.2	5.0
Minimum Cell Density		**2460**	**2755**	**2000**	**2325**	**2000**	**2000**	**2000**	**2000**	**1800**	**1800**	**1800**	**1800**
ECD at year	1	1855	2077	1508	1753	1508	1508	1508	1508	1357	1357	1357	1357
	2	1753	1963	1425	1657	1425	1425	1425	1425	1283	1283	1283	1283
	3	1657	1855	1347	1566	1347	1347	1347	1347	1212	1212	1212	1212
	4	1565	1753	1273	1480	1273	1273	1273	1273	1145	1145	1145	1145
	5	1479	1657	1203	1398	1203	1203	1203	1203	1082	1082	1082	1082
	6	1398	1566	1137	1321	1137	1137	1137	1137	1023	1023	1023	1023
	7	1321	1480	1074	1249	1074	1074	1074	1074	967	967	967	967
	8	1248	1398	1015	1180	1015	1015	1015	1015	913	913	913	913
	9	1180	1321	959	1115	959	959	959	959	863	863	863	863
	10	1115	1249	906	1054	906	906	906	906	816	816	816	816
	11	1054	1180	857	996	857	857	857	857	771	771	771	771
	12	996	1115	809	941	809	809	809	809	728	728	728	728
	13	941	1054	765	889	765	765	765	765	688	688	688	688
	14	889	996	723	840	723	723	723	723	651	651	651	651
	15	840	941	683	794	683	683	683	683	615	615	615	615
	16	794	889	646	750	646	646	646	646	581	581	581	581
	17	750	840	610	709	610	610	610	610	549	549	549	549
	18	709	794	576	670	576	576	576	576	519	519	519	519
	19	670	750	545	633	545	545	545	545				
	20	633	709	515	598	515	515	515	515				
	21	598	670		566								
	22	565	633		534								
	23	534	598		505								
	24	505	566										
	25		534										
	26		505										

Life expectancy -- National Vital Statistics Reports, Vol. 53, No. 6, November 10, 2004

Cell density at end of life

Years post implant when cell density reaches 500 cell per mm^2

PRESERVATION OF VISUAL ACUITY

Protocol IMT-002 specified that preservation of visual acuity was to be assessed in terms of whether more than 10% of telescope-implanted study eyes lost >2 lines of either BCDVA or BCNVA without a corresponding improvement in the other. This endpoint was met. At 12 months, 5% of eyes incurred such losses, and at 24 months, 6% of eyes incurred such losses.

Loss of more than 2 lines of BCDVA was higher in fellow eyes than in telescope-implanted eyes at all visits in the IMT-002 study. Three telescope-implanted eyes (2%) lost more than 2 lines of BCDVA at 24 months versus 16 (9%) of fellow eyes.

COMPLICATIONS AND ADVERSE EVENTS

A total of 217 subjects were evaluated in the IMT-002 clinical trial. A total of 206 eyes were implanted with the AMD telescope prosthesis and followed for 24 months. 129 patients were enrolled in the IMT-002-LTM long-term monitoring trial for which 4-year data was available. Safety data below includes all patients available from baseline through 4 years postoperative.

Ocular complications were defined as events directly related to the surgical procedure for telescope implantation, whether successful or not, occurring in the operative and immediate postoperative period. Events occurring after the immediate postoperative period were classified not as ocular complications but as adverse events. All ocular complications and ocular adverse events and rate per 100 person-year for both IMT-002 and IMT-002 LTM studies are shown in Tables 11 – 14 below.

The AMD telescope prosthesis was placed but removed intraoperatively in 6 eyes because of surgical complications (posterior capsule tear, zonular dehiscence, choroidal detachment). A standard intraocular lens was placed in these eyes. The most common ocular complication was increased IOP requiring treatment ≤ 7 days (N = 59; 27.2%). (Increased IOP reported beyond 7 days and requiring treatment was classified as an adverse event, not as an ocular complication). Increased IOP classified as an ocular complication was likely associated with the liberal use of high molecular weight viscoelastic material (Healon V) in the eye.

Other common (occurring at a rate of 5% or greater) ocular complications were: corneal edema, iris prolapse, and corneal abrasions. Fourteen (14) cases (6.5%) of corneal edema occurred within 30 days of surgery; all 14 cases were first reported on postoperative Day 1 and three of these cases of corneal edema were still noted at the 1 month visit. Iris prolapse was observed in 12 eyes (5.5%) and 11 eyes (5.1%) had corneal abrasions. In general, the ocular complications were transient.

Adverse events occurring at 5% or greater in the IMT-002 study were inflammatory deposits (N=51; 23.5%), pigment deposits (N=23 eyes; 10.6%), guttae (N=16; 7.4%), posterior synechiae (N=15; 6.9%), iritis (N=12; 5.5%), and iris transillumination defects (N=12; 5.5%). In the majority of eyes, deposits resolved over the course of patient follow-up; neither the inflammatory deposits nor the pigment deposits on the telescope prosthesis affected

visual acuity. Pigment and inflammatory deposits were managed medically with a standardized course of anti-inflammatory agents, starting with a sub-Tenon's injection of betamethasone depot administered at the end of surgery followed by topical administration of prednisolone acetate 1% or equivalent tapering over 2-3 months. All remaining adverse events in study IMT-002 were reported at a frequency of less than 5.0%. There were no cases of endophthalmitis, retinal detachment, or retinal tear.

TABLE 11
OCULAR COMPLICATIONS DENSITY
OPERATED EYES (N=217), IMT-002

Complications	Total Number of Eyes with Reports	Total Person-Year[1]	Rate per 100 Person-year (Density)[2]
Aborted surgery	5	337.1	1.48
Anterior chamber hemorrhage	1	338.2	0.30
Anterior segment neovascularization	1	339.6	0.29
Anterior synechiae	3	337.3	0.89
Bleb	1	339.5	0.29
Blepharitis	7	335.6	2.09
Blurred vision	1	340.0	0.29
Chalazion	2	339.2	0.59
Choroidal detachment	2	338.8	0.59
Choroidal hemorrhage	1	339.4	0.29
Conjunctival injection	4	336.1	1.19
Corneal abrasion	11	323.1	3.40
Corneal edema ≤ 30 days	14	315.9	4.43
Corneal endothelial touch	3	335.0	0.90
Cortical remnants	2	338.0	0.59
Cyclitic membrane ≤ 7 days	1	338.3	0.30
Cyclodialysis cleft	1	338.3	0.30
Descemet's membrane separation	3	336.3	0.89
Ectropion	2	338.7	0.59
Endothelial folds	2	338.9	0.59
Flat anterior chamber ≤ 21 days	2	336.7	0.59
Folds in corneal graft	1	339.3	0.29
Glaucoma	1	339.3	0.29
Haze	2	336.5	0.59
Hyphema	10	324.2	3.08
Hypotony	2	337.6	0.59
IMT dislocation (intraoperative)	1	339.9	0.29
IMT removal (intraoperative)	6	339.0	1.77
IMT replacement (interoperative)	1	338.1	0.30
Increased IOP requiring treatment ≤ 7 days	59	248.7	23.72
Increased IOP ≤ 15 days	3	337.3	0.89
Iridotomy ≤ 7 days	3	334.6	0.90
Iris atrophy ≤ 7 days	4	333.7	1.20
Iris damage	8	328.7	2.43
Iris incarceration	3	336.7	0.89
Iris prolapse	12	321.0	3.74
Iris transillumination defects ≤ 21 days	8	329.1	2.43
Iritis ≤ 30 days	2	338.6	0.59
Ophthalmic migraine	1	339.1	0.29
Peribulbar hemorrhage	1	339.5	0.29
Peripapillary hemorrhage	1	338.2	0.30
Phthisis	1	339.6	0.29
Posterior capsular rupture	10	334.0	2.99
Posterior capsule opacification	8	333.4	2.40
Increased IOP requiring treatment ≤ 7 days	59	248.7	23.72
Increased IOP ≤ 15 days	3	337.3	0.89
Iridotomy ≤ 7 days	3	334.6	0.90

TABLE 11 *(CONTINUED)*
OCULAR COMPLICATIONS DENSITY
OPERATED EYES (N=217), IMT-002

Complications	Total Number of Eyes with Reports	Total Person-Year[1]	Rate per 100 Person-year (Density)[2]
Increased IOP requiring treatment ≤ 7 days	59	248.7	23.72
Increased IOP ≤ 15 days	3	337.3	0.89
Iridotomy ≤ 7 days	3	334.6	0.90
Iris atrophy ≤ 7 days	4	333.7	1.20
Iris damage	8	328.7	2.43
Iris incarceration	3	336.7	0.89
Iris prolapse	12	321.0	3.74
Iris transillumination defects ≤ 21 days	8	329.1	2.43
Iritis ≤ 30 days	2	338.6	0.59
Ophthalmic migraine	1	339.1	0.29
Peribulbar hemorrhage	1	339.5	0.29
Peripapillary hemorrhage	1	338.2	0.30
Phthisis	1	339.6	0.29
Posterior capsular rupture	10	334.0	2.99
Posterior capsule opacification	8	333.4	2.40
Significant anterior chamber bleeding	3	335.0	0.90
Strabismus surgery	1	339.5	0.29
Surgical mydriasis	1	339.0	0.29
Suture rupture	4	336.3	1.19
Uveitis	1	339.3	0.29
Vitreous bulge	1	339.4	0.29
Vitreous hemorrhage ≤ 7 days	1	339.4	0.29
Vitreous in anterior chamber ≤ 7 days	3	335.0	0.90
Vitreous loss	3	337.8	0.89
Vitreous loss - vitrectomy required	7	336.5	2.08
Watery eyes	3	338.6	0.89
Worsening of subretinal scarring	1	339.6	0.29
Wound leak	3	337.6	0.89
Zonular dehiscence ≤ 7 days	1	339.8	0.29

TABLE 12
OCULAR COMPLICATIONS DENSITY
OPERATED EYES (N = 129), IMT-002-LTM

Complications	Total Number of Eyes with Reports	Total Person-Year[1]	Rate per 100 Person-year (Density)[2]
Aborted surgery	3	380.3	0.79
Afferent pupil defect	1	386.1	0.26
Alternating exotropia	1	385.7	0.26
Anterior synechiae	3	380.1	0.79
Asthenopia	1	384.0	0.26
Blepharitis	6	374.5	1.60
Chalazion	1	384.3	0.26
Choroidal detachment	1	384.5	0.26
Choroidal hemorrhage	1	384.7	0.26
Conjunctival injection	2	380.0	0.53
Corneal abrasion	10	357.8	2.79
Corneal edema ≤ 30 days	10	355.0	2.82
Corneal endothelial touch	2	380.7	0.53
Corneal neovascularization	1	385.5	0.26
Descemet's membrane separation	1	383.2	0.26
Ecchymoses on eyelid	1	386.6	0.26
Ectropion	1	386.6	0.26
Endothelial folds	2	382.9	0.52
Epithelial basement membrane dystrophy	1	386.6	0.26
Esotropia	1	387.1	0.26
Flashes	1	383.7	0.26
Flat anterior chamber ≤ 21 days	1	383.7	0.26
Folds in corneal graft	1	384.6	0.26
Glare	1	385.6	0.26
Glaucoma	1	384.5	0.26
Haze	2	382.3	0.52
Hyphema	3	376.4	0.80
IMT dislocation (intraoperative)	1	385.0	0.26
IMT posteriorly positioned	1	386.6	0.26
IMT removal (intraoperative)	3	381.6	0.79
IMT removal (intraoperative)	3	381.6	0.79
Increased IOP requiring treatment ≤ 7 days	31	294.0	10.54
Increased IOP ≤ 15 days	1	384.1	0.26
Iris atrophy ≤ 7 days	2	381.8	0.52
Iris damage	6	372.0	1.61
Iris incarceration	2	380.8	0.53
Iris prolapse	5	372.7	1.34
Iris transillumination defects ≤ 21 days	2	381.8	0.52
Meibomian gland dysfunction	1	386.6	0.26
Ophthalmic migraine	1	384.1	0.26
Peripapillary hemorrhage	1	384.6	0.26
Posterior capsular rupture	5	376.8	1.33
Posterior capsule opacification	11	366.7	3.00
Significant anterior chamber bleeding	2	381.1	0.52
Strabismus	1	386.6	0.26
Strabismus surgery	1	385.0	0.26
Superficial punctate keratitis	1	385.8	0.26
Surgical mydriasis	1	384.3	0.26

Complications	Total Number of Eyes with Reports	Total Person-Year[1]	Rate per 100 Person-year (Density)[2]
Suture rupture	1	384.6	0.26
Treatment of PCO	1	385.6	0.26
Uveitis	1	384.5	0.26
Uveitis/vitritis	1	386.6	0.26
Vitreous hemorrhage ≤ 7 days	1	384.7	0.26
Vitreous in anterior chamber ≤ 7 days	3	378.4	0.79
Vitreous loss	1	383.8	0.26
Vitreous loss - vitrectomy required	3	380.3	0.79
Watery eyes	2	382.6	0.52
Wound leak	1	385.1	0.26
Zonular dehiscence ≤ 7 days	1	385.1	0.26

TABLE 13
OCULAR ADVERSE EVENTS DENSITY
OPERATED EYES (N=217), IMT-002

Adverse Events	Total Number of Eyes with Reports	Total Person-Year[1]	Rate per 100 Person-year (Density)[2]
Anterior chamber inflammation > 30 days	6	333.2	1.80
Anterior ischemic optic neuropathy	1	339.4	0.29
Choroidal neovascularization	1	339.8	0.29
Conjunctivitis	5	335.9	1.49
Cornea decompensation > 7 days	2	338.4	0.59
Cornea edema > 30 days	6	337.4	1.78
Cyclitic membrane > 7 days	1	338.3	0.30
Cystoid macular edema	1	338.5	0.30
Decrease in visual acuity	4	334.8	1.19
Device failure	2	339.1	0.59
Diplopia	3	335.6	0.89
Distorted pupil	9	330.1	2.73
Dry eye	10	331.5	3.02
Entropion	2	336.3	0.59
Exposed suture	3	336.2	0.89
Eye pain	3	337.1	0.89
Flat anterior chamber > 21 days	1	339.0	0.30
Floaters	3	337.2	0.89
Focal striae	1	338.4	0.30
Foreign body sensation	9	330.4	2.72
Guttae	16	326.0	4.91
IMT dislocation	2	337.0	0.59
IMT removal	8	336.0	2.38
Increased IOP requiring treatment > 7 days	7	333.8	2.10
Inflammatory deposits on IMT	51	283.0	18.02
Inflammatory membrane	1	338.6	0.30
Iridotomy > 7 days	3	336.6	0.89
Iris atrophy > 7 days	8	331.9	2.41
Iris transillumination defects > 21 days	12	326.8	3.67
Iritis > 30 days	12	329.5	3.64
Keratic precipitates on IMT > 30 days	3	338.1	0.89
Obstructed iridectomy	1	338.7	0.30
Ocular allergy	1	338.2	0.30
Pigment deposits on IMT	23	320.0	7.19
Pigment epithelium around the peripheral iridectomy > 30 days	1	339.1	0.29
Posterior synechiae	15	323.2	4.64
Ptosis	4	336.3	1.19
Secondary glaucoma	2	336.8	0.59
Subconjunctival hemorrhage	9	329.5	2.73
Subretinal hemorrhage	3	338.8	0.89
Synechiae	1	338.8	0.30
Tearing	1	338.4	0.30
Visual disturbance	1	338.1	0.30
Vitreous flare	1	338.3	0.30
Vitreous hemorrhage > 7 days	3	337.1	0.89
Vitreous in anterior chamber > 7 days	4	334.4	1.20
Zonular dehiscence > 7 days	1	340.0	0.29

TABLE 14
OCULAR ADVERSE EVENTS DENSITY
OPERATED EYES (N = 129), IMT-002-LTM

Adverse Events	Total Number of Eyes with Reports	Total Person-Year[1]	Rate per 100 Person-year (Density)[2]
Anterior chamber inflammation > 30 days	4	376.7	1.06
Choroidal neovascularization	3	385.2	0.78
Conjunctivitis	5	378.0	1.32
Cornea decompensation > 7 days	4	381.8	1.05
Cornea edema > 30 days	13	371.4	3.50
Cornea transplant	2	385.4	0.52
Decrease in visual acuity	1	384.0	0.26
Diplopia	3	380.3	0.79
Distorted pupil	6	373.3	1.61
Dry eye	6	373.3	1.61
Entropion	1	382.9	0.26
Exposed suture	2	380.7	0.53
Eye pain	2	380.9	0.53
Flat anterior chamber > 21 days	1	384.5	0.26
Floaters	2	380.6	0.53
Focal striae	2	383.4	0.52
Foreign body sensation	5	373.0	1.34
Guttae	16	356.5	4.49
IMT dislocation	4	378.8	1.06
IMT removal	7	375.8	1.86
Increased IOP requiring treatment > 7 days	4	378.0	1.06
Iridotomy > 7 days	2	381.4	0.52
Iris atrophy > 7 days	6	376.1	1.60
Iris transillumination defects > 21 days	5	376.1	1.33
Iritis > 30 days	9	366.3	2.46
Ocular allergy	1	384.2	0.26
Posterior synechiae	15	358.3	4.19
Precipitates or deposits on IMT	49	267.4	18.32
Ptosis	2	385.7	0.52
Secondary glaucoma	1	383.4	0.26
Subconjunctival hemorrhage	8	364.4	2.20
Subretinal hemorrhage	3	383.5	0.78
Visual disturbance	1	383.0	0.26
Vitreous flare	1	383.1	0.26
Vitreous in anterior chamber > 7 days	4	378.6	1.06
Zonular dehiscence > 7 days	1	385.2	0.26

Significant adverse events included choroidal neovascularization (CNV), corneal edema, device removal during the course of the study, and corneal decompensation leading to penetrating keratoplasty.

CHOROIDAL NEOVASCULARIZATION

CNV was identified in one (1) eye in the IMT-002 study for an incidence of 0.5%, a rate consistent with that reported by Sunness et al., 1999. An additional 3 cases of CNV were observed during the IMT-002-LTM study. These cases of CNV were successfully treated

with thermal laser photocoagulation (Garfinkel et al, 2006), photodynamic therapy or intravitreal injection of anti-VEGF therapeutic agents.

CORNEAL EDEMA

The proportion of eyes with corneal edema at each study visit is shown in Table 15.

TABLE 15
CORNEAL EDEMA
AMD TELESCOPE-IMPLANTED EYES, IMT-002 & IMT-002-LTM

Visit	Number of Available Eyes	Number of Eyes with Corneal Edema	% of Eyes with Corneal Edema
Day 1	206	14	6.8%
Day 7	205	7	3.4%
1 Month	206	3	1.5%
3 Months	201	1	0.5%
6 Months	202	1	0.5%
9 Months	196	1	0.5%
12 Months	194	0	0.0%
18 Months	180	0	0.0%
24 Months	174	3	1.7%
30 Months	3	0	0.0%
36 Months	79	3	3.8%
42 Months	110	6	5.5%
48 Months	102	2	2.0%
54 Months	35	1	2.9%
60 Months	6	0	0.0%

CORNEA DECOMPENSATION AND TRANSPLANTATATION

Four study eyes have undergone cornea transplantation to date in the IMT-002 and IMT-002-LTM studies (i.e., through 4 years follow-up). All 4 cases involved surgical complications at the time of device implantation. In 2 of the 4 cases of cornea decompensation, the AMD telescope prosthesis was removed during cornea transplantation procedure and replaced with an IOL. Visual acuity returned to baseline levels in these 2 patients. The AMD telescope prosthesis was left in place in the other 2 cases of cornea transplantation. Visual acuity returned to pre-transplant levels.

POSTERIOR CAPSULE OPACIFICATION

There were 8 reports of posterior capsule opacification (PCO) during the 24-month clinical trial (Protocol IMT-002). Six of these were graded minimal, 2 were graded moderate and none was reported as vision-impairing. PCO was reported in an additional eye during Protocol IMT-002-LTM, and surgical capsulotomy was successfully performed.

INTRAOCULAR PRESSURE

Intraocular pressure (IOP) and change in IOP from baseline for eyes implanted with the AMD telescope prosthesis is displayed in Table 16. Mean IOP was 15.7 mm Hg at baseline, increased to 22.1 mm Hg at Day 1, then returned to within 1 mm of baseline and was generally stable for the remainder of the study.

TABLE 16
INTRAOCULAR PRESSURE (IOP) AND CHANGE IN IOP FROM BASELINE
IMT-002 AND IMT-002-LTM

IOP	Baseline n (%)	1 Day n (%)	7 Day n (%)	1 Month n (%)	3 Months n (%)	6 Months n (%)	9 Months n (%)	12 Months n (%)
N	206	206	205	203	199	198	195	194
Mean	16	22	16	16	15	14	14	14
95% CI	15, 16	21, 23	15, 17	15, 16	14, 15	14, 15	14, 15	14, 14
Change from Baseline								
N		206	205	203	199	198	195	194
Mean		6	0	-0	-1	-1	-1	-2
95% CI		5, 8	-0, 1	-1, 0	-2, -1	-2, -1	-2, -1	-2, -1
Decrease > 10 mm Hg		1 (0%)	6 (3%)	1 (0%)	0 (0%)	0 (0%)	1 (1%)	1 (1%)
Decrease 6 - 10 mm Hg		11 (5%)	22 (11%)	15 (7%)	23 (12%)	26 (13%)	21 (11%)	30 (15%)
Decrease 1 - 5 mm Hg		39 (19%)	67 (33%)	76 (37%)	95 (48%)	96 (48%)	100 (51%)	86 (44%)
No Change		12 (6%)	19 (9%)	25 (12%)	14 (7%)	21 (11%)	14 (7%)	23 (12%)
Increase 1 - 5 mmHg		49 (24%)	56 (27%)	73 (36%)	58 (29%)	49 (25%)	55 (28%)	50 (26%)
Increase 6 - 10 mm Hg		33 (16%)	24 (12%)	11 (5%)	8 (4%)	6 (3%)	4 (2%)	4 (2%)
Increase > 10 mm Hg		61 (30%)	11 (5%)	2 (1%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)

TABLE 16 (CONTINUED)
INTRAOCULAR PRESSURE (IOP) AND CHANGE IN IOP FROM BASELINE
IMT-002 AND IMT-002-LTM

IOP	18 Months n (%)	24 Months n (%)	36 Months n (%)	42 Months n (%)	48 Months n (%)	54 Months n (%)	60 Months n (%)
N	179	174	74	104	96	34	6
Mean	15	15	14	16	15	14	17
95% CI	14, 15	14, 15	14, 15	15, 16	15, 16	13, 15	13, 20
Change from Baseline							
N	179	174	74	104	96	34	6
Mean	-1	-1	-1	-0	-1	-1	2
95% CI	-1, -0	-1, -0	-2, -0	-1, 0	-1, 0	-2, 0	-2, 5
Decrease > 10 mm Hg	1 (1%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Decrease 6 - 10 mm Hg	14 (8%)	17 (10%)	6 (8%)	5 (5%)	4 (4%)	2 (6%)	0 (0%)
Decrease 1 - 5 mm Hg	78 (44%)	77 (44%)	36 (49%)	54 (52%)	43 (45%)	19 (56%)	2 (33%)
No Change	27 (15%)	25 (14%)	10 (14%)	6 (6%)	17 (18%)	2 (6%)	1 (17%)
Increase 1 - 5 mmHg	51 (28%)	49 (28%)	17 (23%)	33 (32%)	29 (30%)	10 (29%)	1 (17%)
Increase 6 - 10 mm Hg	7 (4%)	5 (3%)	4 (5%)	5 (5%)	3 (3%)	1 (3%)	2 (33%)
Increase > 10 mm Hg	1 (1%)	1 (1%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)

POSTOPERATIVE ANTERIOR CHAMBER DEPTH

Ultrasound biomicroscopic (UBM) or anterior segment ocular coherence tomographic (AC OCT) images were obtained for 45 telescope-implanted eyes.

A standard means of measuring left peripheral clearance, right peripheral clearance and cornea-to-iris distance was utilized.

Mean clearance for the total cohort of 45 eyes with UBM or AC OCT imaging was 2.51 mm (SD 0.33), with a median of 2.53 mm (Table 17).

TABLE 17
CENTRAL CLEARANCE FROM ANTERIOR SURFACE OF AMD TELESCOPE PROSTHESIS TO THE CORNEAL ENDOTHELIUM
ALL EYES WITH IMAGES VS EYES GROUPED BY BASELINE ACD

	Distance from IMT to Cornea All Eyes (N=45)	Distance from IMT to Cornea ACD <3.0 mm (N=15)	Distance from IMT to Cornea ACD ≥3.0 mm to 3.5 mm (N=24)	Distance from IMT to Cornea ACD >3.5 mm (N=6)
Mean	2.51	2.48	2.53	2.53
SD	0.33	0.35	0.31	0.38
Median	2.53	2.45	2.55	2.66

Mean peripheral clearance for left corneal measurements for 45 eyes with images was 2.17 mm (Table 18). Clearance for the left cornea increased from 2.13 mm for eyes with ACD <3.0 mm, 2.16 mm for ACD >3.0 to 3.5 mm, and 2.31 mm for eyes with ACD >3.5 mm. Mean clearance for the right peripheral cornea was 2.21 mm.

TABLE 18
PERIPHERAL CLEARANCE FROM ANTERIOR SURFACE OF AMD TELESCOPE PROSTHESIS TO THE CORNEAL ENDOTHELIUM
ALL EYES WITH IMAGES VS EYES GROUPED BY BASELINE ACD

	All Eyes Peripheral Clearance Left	Clearance Left ACD <3.0 mm	Clearance Left ACD ≥3.0 to 3.5 mm	Clearance Left ACD >3.5 mm		All Eyes Peripheral Clearance Right	Clearance Right ACD <3.0 mm	Clearance Right ACD ≥3.0 to 3.5 mm	Clearance Right ACD >3.5 mm
N	40	13	22	5		39	13	22	4
Mean	2.17	2.13	2.16	2.31		2.21	2.17	2.21	2.38
SD	0.29	0.32	0.30	0.12		0.35	0.34	2.22	0.26
Median	2.18	2.15	2.16	2.27		2.24	2.22	2.25	2.49

The AMD telescope prosthesis is not an anterior chamber device, but does protrude slightly into the anterior chamber. The minimum clearance of 1.00 mm required for anterior chamber intraocular lenses per ISO 11979-3 is significantly exceeded.

DEVICE FAILURES AND REPLACEMENTS

Four device failures were reported in the IMT-002 study. Two of the device failures occurred during surgery and involved a broken haptic; one occurred before implantation and the device was not used, and one occurred during implantation, necessitating intraoperative replacement. Two involved condensation in the telescope portion of the device occurring one month postoperatively, resulting in device removal. No device failures were reported in the IMT-002-LTM study through 4 years.

The AMD telescope prosthesis was removed from 8 eyes postoperatively after the initial implantation procedure in the IMT-002 trial. Four subjects requested removal of the AMD telescope prosthesis because they were dissatisfied with the device. As noted above, the AMD telescope prosthesis was also removed from two eyes due to device failures and in two eyes that underwent cornea transplantation.

After IMT-002 trial completion, the telescope prosthesis was removed from an additional 4 eyes per subject request due to dissatisfaction.

OTHER SECONDARY SURGICAL INTERVENTIONS

Seven secondary surgical interventions not involving telescope prosthesis removal were performed during the IMT-002 study and none has been reported to date in the IMT-002-LTM. These procedures consisted of one YAG laser treatment of the anterior surface of the telescope prosthesis to eliminate pigment deposits; 4 YAG laser peripheral iridotomies; one surgical repair of a distorted pupil; and one removal of a cortical fragment resulting from inadequate cataract removal.

XII. CONCLUSIONS DRAWN FROM THE STUDIES

RISK/BENEFIT ANALYSIS

The VisionCare AMD telescope prosthesis is surgically implanted into one eye of patients with end-stage age-related macular degeneration to improve central vision. Efficacy outcomes include clinically meaningful improvements in visual acuity and quality of life. Risks associated with eye surgery and the AMD telescope prosthesis include: intraocular inflammation, iritis, uveitis, raised intraocular pressure, and cornea decompensation (typically related to endothelial cell loss). The data in this application provides reasonable assurance that the benefits of use of the AMD telescope outweigh the risk of illness or injury when used in accordance with the directions for use.

SAFETY

AMD telescope prosthesis implantation complication rates were comparable to large incision intraocular anterior segment surgery. Although a significant amount of endothelial cell loss was associated with surgery, 20% cell loss at 3 months postoperative, the rate of loss stabilized over time, with 25%, 28%, 31%, and 35% cell loss at postoperative years 1, 2, 3, and 4, respectively. Annualized rate of endothelial cell loss from 2 to 4 years was 2.8%. If excessive endothelial cell loss occurs causing ECD to reach < 750 cells/mm^2, the patient may require a cornea transplant. Thus, it is important to follow risk reduction parameters detailed in this document and periodically monitor the health of the patient's cornea.

EFFECTIVENESS

The VisionCare AMD telescope prosthesis exceeded the target effectiveness criteria (BCVA) and demonstrated clinically significant improvement in quality of life (National Eye Institute Visual Function Questionnaire).

XIII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was referred to the Ophthalmic Device Panel, and FDA advisory committee, for review of valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the AMD telescope prosthesis under the prescribed indications for use.

XIV. CDRH DECISION

CDRH issued an approval order on _____, 2009. The applicant's manufacturing facility was inspected on _____, 2005 and was found to be in compliance with the medical device Quality System Regulation.

XV. APPROVAL SPECIFICATIONS

Directions for Use: See Device Labeling.
Hazards to health from use of the device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.
Post-approval requirements and restrictions: See Approval Order.