

APPENDIX 3

EYES NOT SUCCESSFULLY IMPLANTED WITH THE IMT

N = 11

EXCERPTED FROM P050034 AMENDMENT 007

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5.1 EYES NOT SUCCESSFULLY IMPLANTED WITH IMT DUE TO INTRAOPERATIVE COMPLICATIONS (N=11)

The cohort of 11 eyes not successfully implanted with the IMT consisted of 7 cases of posterior capsular rupture, 2 eyes identified as having choroidal detachment, one eye with choroidal hemorrhage, and an eye with loss of zonular support. With regard to the two cases identified on the study case report forms as choroidal detachment, the medical monitor for posterior segment issues during the study, J. Heier, M.D., spoke to both of the surgeons who reported choroidal detachment, and while the event was specifically documented as choroidal detachment, in both eyes there was positive posterior pressure and chamber shallowing, but no sign of choroidal detachment was verified either intra- or postoperatively. One case of choroidal hemorrhage occurred in association with a particularly long surgery.

5.1.1 BEST CORRECTED DISTANCE VISUAL ACUITY

Although these eyes did not undergo implantation, for eyes with follow-up available, at 1 month postoperative, there was no visual loss from baseline, as shown in Table 96. One eye (ID [REDACTED]) had an improvement in BCDVA at 1 month, but vision returned to the baseline level at 3 months, and then decreased slightly between 3 and 6 months. Otherwise, postoperative BCDVA was generally stable from baseline through the last available visit.

This finding is confirmed in the analysis of cumulative change in BCDVA (Table 97), which shows that the mean change in visual acuity from baseline was less than 1 line for this cohort of eyes.

TABLE 96
BCDVA BY VISIT
11 NON-IMPLANTED EYES

Patient ID	Preop	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
	20/138							
	20/348	20/174	20/320	20/438				
	20/400	20/400	20/381			20/400		
	20/182	20/138	20/125	20/115				
	20/182	20/166						
	20/381							
	20/264	20/289						
	20/438	20/438						
	20/500	20/458						
	20/551	20/526	20/526			20/418		
	20/400	20/320	20/289					

TABLE 97
CUMULATIVE BCDVA CHANGE FROM BASELINE
11 NON-IMPLANTED EYES
(INCLUDING BCDVA AFTER IMT REMOVAL & IOL IMPLANT)

	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	Last Available
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
N	9	5	2	0	2	0	9
Gain ≥ 6 lines	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)		0 (0.0%)
Gain ≥ 5 lines	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)		0 (0.0%)
Gain ≥ 4 lines	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)		0 (0.0%)
Gain ≥ 3 lines	1 (11.1%)	0 (0.0%)	0 (0.0%)		0 (0.0%)		0 (0.0%)
Gain ≥ 2 lines	1 (11.1%)	0 (0.0%)	1 (50.0%)		0 (0.0%)		1 (11.1%)
Gain ≥ 1 lines	3 (33.3%)	2 (40.0%)	1 (50.0%)		1 (50.0%)		3 (33.3%)
No change	6 (66.7%)	3 (60.0%)	1 (50.0%)		1 (50.0%)		6 (66.7%)
Loss of >2 lines	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)		0 (0.0%)
Mean Line Change (SD)	0.64 lines (1.01 lines)	0.76 lines (0.68 lines)	0.50 lines (2.12 lines)		0.60 lines (0.85 lines)		0.44 lines (0.94 lines)

N = number of non-missing BCDVA change from baseline. No 24-month BCDVA data were available.

5.1.2 ENDOTHELIAL CELL DENSITY

Table 98 provides the available endothelial cell density (ECD) for the eyes that were not implanted with an IMT due to intraoperative complications. In general, ECD was stable in this cohort of eyes, however, one eye (ID: [REDACTED]), which did not undergo IMT implantation due to posterior capsular rupture showed a loss of > 1,000 cells/mm² from baseline at 6 months. In this case, vitreous loss occurred subsequent to rupture of the posterior capsule, requiring a vitrectomy. This unexpected additional surgical trauma likely contributed to the greater endothelial cell loss observed in this eye.

TABLE 98
ENDOTHELIAL CELL DENSITY
11 NON-IMPLANTED EYES

Patient ID	Preop	3 Months	6 Months	12 Months
	2891.3	NA	NA	NA
	2457.3	NA	1905.7	NA
	2913.0	2690.7	NA	2849.3
	2721.5	1452.7	1707.3	NA
	NA	NA	NA	NA
	2613.0	2307.0	NA	NA
	2600.0	NA	NA	NA
	2068.3	NA	NA	NA
	2161.0	NA	NA	NA
	2850.0	2468.7	NA	2288.7
	2183.0	2245.3	NA	NA

5.1.3 OCULAR COMPLICATIONS AND ADVERSE EVENTS

The ocular complications reported for the 11 eyes not successfully implanted with the IMT are summarized in Table 99. The most prevalent ocular complication was posterior capsular rupture (n=7), followed by vitreous loss requiring vitrectomy (n=6); this would be anticipated since posterior capsular rupture was the most common reason for the IMT not to be implanted.

TABLE 99
OCULAR COMPLICATIONS
11 NON-IMPLANTED EYES

Event	Operative (N=11)	Day 1 (N=11)	Day 7 (N=10)	Interim (N=4)	Cumulative (N=11)
	n	n	n	n	n
Aborted surgery (IMT placement not attempted)	5				5
Choroidal detachment	2				2
Choroidal hemorrhage	1				1
Cortical remnants	1				1
Increased IOP requiring treatment ≤ 7 days		1		1	2
Iris damage	1				1
Iris transillumination defects ≤ 21 days		1			1
Iritis ≤ 30 days			1		1
Posterior capsular rupture	7				7
Vitreous hemorrhage		1			1
Vitreous loss	2				2
Vitreous loss – vitrectomy required	6				6
Wound leak		1			1
Zonular dehiscence ≤ 7 days	1				1

Ocular adverse events reported postoperatively, i.e., in the absence of the IMT in the eye, are summarized in Table 100. A distorted pupil was observed in two eyes. Floaters, iris atrophy, iris transillumination defects, subretinal hemorrhage and zonular dehiscence were each observed in one eye. It should be noted that in some cases the same adverse event was reported at multiple visits for the same subject at multiple visits, if the event was not resolved.

TABLE 100
OCULAR ADVERSE EVENTS
11 NON-IMPLANTED EYES

Event	Operative (N=11)	Day 1 (N=11)	Day 7 (N=10)	1 Month (N=11)	3 Months (N=6)	12 Months (N=2)	Cumulative (N=11)
Distorted pupil		2	1	1			2
Floaters		1	1	1			1
Intraoperative IMT insertion & removal	6						6
Iris atrophy > 7 days						1	1
Iris transillumination defects > 21 days						1	1
Subretinal hemorrhage				1	1		1
Zonular dehiscence > 7 days				1			1

% = n/N x 100.

The same adverse event could have been reported for a subject at multiple visits.

5.1.4 CASE SUMMARIES FOR EYES WITHOUT SUCCESSFUL IMT IMPLANTATION

Subjects without successful IMT implant have been divided into aborted surgery (n=5), in which the IMT was not inserted into the eye as a result of an unrelated surgical complication, and intraoperative IMT removal (n=6).

5.1.4.1 ABORTED SURGERIES (N=5)

Patient [REDACTED]

IMT implantation was aborted in an 86-year-old female due to choroidal detachment. An IOL was successfully implanted 12 days after the attempted IMT implantation. Distance visual acuity assessed at 12 month did not change from the preoperative distance visual acuity.

Patient [REDACTED]

Surgery to implant the IMT was aborted in an 89-year-old male due to posterior capsular rupture. Subsequent vitreous loss required a vitrectomy and cortical remnants were left in the capsular bag. A gain of 2 lines of BCDVA from baseline (0.96 logMAR or 20/182) was reported at the last available assessment at 6 months (0.76 logMAR or 20/116), thus there was no visual acuity loss.

Patient [REDACTED]

As a result of intraoperative choroidal detachment, IMT implantation was aborted in an 87-year-old male. The event resolved without sequelae. The subject exited the study approximately 4 months postoperatively and no other adverse events or complications were reported.

Patient [REDACTED]

IMT implantation was aborted in a 79-year-old male due to posterior capsular rupture. Subsequent vitreous loss required a vitrectomy. An IOL was successfully implanted. At the 1 month visit, mild subretinal hemorrhage was observed which resolved without sequelae. At the last available assessment at 12 months, unresolved iris atrophy and iris transillumination defects were noted. However, none of these events had an untoward effect on vision, since a gain of 1.2 lines of BCDVA from baseline (1.44 logMAR or 20/551 to 1.32 logMAR or 20/418) was reported at that time.

Patient [REDACTED]

IMT implantation was aborted in an 86-year-old male due to posterior capsular rupture. Because of the lack of posterior capsular support for the IMT, an IOL was inserted. No other adverse events or complications were reported for this subject. A gain of 1.4 lines of BCDVA from baseline (1.3 logMAR or 20/400) was reported at the last available assessment at 3 months (1.16 logMAR or 20/289).

5.1.4.2 INTRAOPERATIVE IMT REMOVAL (N=6)

Patient [REDACTED]

Intraoperative IMT removal was performed in a 67-year-old female. As the surgeon began to close the wound, the IMT was no longer in place, but appeared to be free floating in the posterior segment. The surgeon immediately opened the wound and attempted, unsuccessfully, to retrieve the device. A retina specialist was called in to assist with the procedure and the IMT was successfully retrieved. The postoperative course was without sequelae and the subject exited from the study 1 month postoperatively. No postoperative specular images were obtained for this patient, thus, the effect of the IMT removal on the corneal endothelium is unknown.

Patient [REDACTED]

Intraoperative IMT removal was performed in a 79-year-old male due to choroidal hemorrhage. After uneventful IMT implantation, during closing of the surgical wound, anterior displacement of the device and iris followed by loss of the red reflex were noted. The IMT was removed, and the choroidal hemorrhage was visualized by the surgeon. A limited vitrectomy was performed, and the wound was closed immediately. No other adverse events were reported for this subject. At the exit examination, 6 months post-

operatively, a loss of less than 1 line BCDVA was reported (from 1.24 logMAR or 20/348 to 1.34 logMAR or 20/438).

Patient [REDACTED]

Intraoperative WA 2.2X IMT removal was performed in a 57-year-old female. As the IMT was being placed in the eye and the inferior haptic was in the capsular bag, posterior capsular rupture was noted. The device was removed, an anterior vitrectomy was performed and residual vitreous was cleared from the anterior chamber. A sulcus fixated IOL was subsequently inserted. This subject also experienced transient distorted pupil, transient increased IOP requiring treatment and iris transillumination defects that resolved with sequelae. The subject exited the study approximately 1 month post-operatively and no change in BCDVA (from 0.96 logMAR or 20/182 to 0.92 logMAR or 20/166, gain of 0.4 lines) was reported at that time.

Patient [REDACTED]

As a result of zonular dehiscence, intraoperative WA 2.2X IMT removal was performed in a 73-year-old female. Upon placement of the device in the anterior chamber of the eye, it was noted that the leading haptic was in the sulcus rather than in the capsular bag. As the surgeon attempted to remove and reposition the haptic, the leading haptic engaged the ciliary zonules, causing loss of superior zonular support. The device was removed from the eye and the vitreous face remained intact. A posterior chamber IOL was placed in the ciliary sulcus. The subject experienced (unresolved) iris damage. In addition, transient wound leak and increased IOP requiring treatment without sequelae were reported. The subject exited the study approximately 6 weeks post-operatively and no change in BCDVA (from 1.12 logMAR or 20/264 to 1.16 logMAR or 20/289, loss of 0.4 lines) was reported at that time.

Patient [REDACTED]

Intraoperative IMT removal was performed in a 76-year-old female due to posterior capsular rupture. Vitreous was observed in the anterior chamber and the pupil was distorted. Distance visual acuity at 1 month was the same as at baseline. The patient was exited from the study one month postoperatively.

Patient [REDACTED]

Posterior capsule rupture and subsequent vitreous loss requiring vitrectomy resulted in the removal intraoperatively of an IMT in a 79-year-old male. A standard IOL was placed in the sulcus, and postoperative follow-up was uneventful except for mild, transient iritis. Distance visual acuity at 1 month was the same as at baseline (from 1.40 logMAR or 20/500 to 1.36 logMAR or 20/458). The patient was exited from the study one month post-operatively.

EYES MISSING THE 24-MONTH VISIT
N = 13
EXCERPTED FROM P050034 AMENDMENT 007

5.2 EYES MISSING THE 24-MONTH VISIT

A total of 13 eyes did not return for the final study examination at 24 months. The reasons for missing this visit included patient hospitalizations and surgeries (open heart surgery, back surgery), kidney cancer, and stroke. Several patients were bed ridden, several patients refused to return for further examination, and only a single patient was lost to follow-up, with no response to certified letters mailed by VisionCare to the patient.

5.2.1 BEST CORRECTED DISTANCE VISUAL ACUITY

A line listing of all available visual acuity data for the 13 eyes missing the 24-month visit is provided in Table 107, and the cumulative change in BCDVA for this cohort of eyes is summarized in Table 108.

As shown in the line listing in Table 107, all but a single eye (patient [REDACTED]) in this cohort experienced a substantial improvement in best corrected distance acuity. Patient [REDACTED] experienced a decrease in BCDVA from baseline through 9 months as a result of anterior ischemic optic neuropathy. On average, mean change in BCDVA for this 13-eye cohort was approximately 3 lines, confirming that the patients in this cohort did not discontinue participation in the study as a result of poor visual acuity outcomes.

TABLE 107
BCDVA BY VISIT
13 EYES MISSING 24-MONTH FOLLOW-UP

Patient ID	Preop	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
	20/182	20/125	20/121	20/125	20/110	20/110		
	20/264	20/526	20/577	20/693	20/800			
	20/209	20/115	20/83	20/73	20/87	20/76	20/87	
	20/145	20/87	20/96	20/76	20/121	20/100		
	20/418	20/240	20/121	20/125	20/125	20/115	20/115	
	20/630	20/182	20/200	20/152	20/145	20/138	20/121	
	20/693	20/289	20/174	20/289	20/400	20/348	20/364	
	20/191	20/96	20/96	20/91	20/83	20/91	20/105	
	20/200	20/105	20/80	20/83	20/76	20/91	20/91	
	20/551	20/219	20/200	20/219		20/230		
	20/348	20/200	20/145	20/182	20/115	20/152		
	20/630	20/526	20/200	20/240	20/230	20/174		
	20/276	20/174		20/145				

TABLE 108
CUMULATIVE BCDVA CHANGE FROM BASELINE
13 EYES MISSING 24-MONTH FOLLOW-UP

	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	Last Available
	n (%)						
N	13	12	13	11	11	6	13
Gain ≥ 6 lines	0 (0.0%)	1 (8.3%)	1 (7.7%)	1 (9.1%)	1 (9.1%)	1 (16.7%)	1 (7.7%)
Gain ≥ 5 lines	1 (7.7%)	4 (33.3%)	2 (15.4%)	2 (18.2%)	3 (27.3%)	2 (33.3%)	3 (23.1%)
Gain ≥ 4 lines	2 (15.4%)	7 (58.3%)	5 (38.5%)	5 (45.5%)	4 (36.4%)	2 (33.3%)	3 (23.1%)
Gain ≥ 3 lines	4 (30.8%)	9 (75.0%)	8 (61.5%)	7 (63.6%)	9 (81.8%)	4 (66.7%)	7 (53.8%)
Gain ≥ 2 lines	10 (76.9%)	9 (75.0%)	11 (84.6%)	9 (81.8%)	10 (90.9%)	6 (100.0%)	11 (84.6%)
Gain ≥ 1 lines	11 (84.6%)	11 (91.7%)	12 (92.3%)	9 (81.8%)	11 (100.0%)	6 (100.0%)	12 (92.3%)
No change	1 (7.7%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Loss of >2 lines	1 (7.7%)	1 (8.3%)	1 (7.7%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
Mean Line Change (SD)	2.31 lines (1.97 lines)	3.40 lines (2.51 lines)	3.14 lines (2.50 lines)	3.00 lines (3.01 lines)	3.91 lines (1.52 lines)	4.23 lines (1.80 lines)	3.09 lines (2.84 lines)

N = number of non-missing BCDVA change from baseline. No 24-month BCDVA data were available.

5.2.2 ENDOTHELIAL CELL DENSITY

Table 109 summarizes ECD for the eyes that missed the 24-month visit. ECD remained stable in the majority of eyes after the initial surgical loss observed at 3 months, however several eyes (IDs: [REDACTED], [REDACTED], and [REDACTED]) had a more substantial loss of ECD. With the exception of patient [REDACTED] in which iris prolapse occurred intraoperatively, surgery and follow-up in the other eyes was unremarkable.

TABLE 109
ENDOTHELIAL CELL DENSITY
13 EYES MISSING 24-MONTH FOLLOW-UP

Patient ID	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
	2639.7	2170.3	2014.3	2171.3	2243.7	NA	NA
	2649.7	3125.7	2856.7	3008.0	NA	NA	NA
	2276.7	2000.7	1962.0	1941.0	1935.7	1930.0	NA
	2860.3	2694.3	2737.3	2815.7	2434.3	NA	NA
	1821.3	1606.0	1672.7	1296.7	1214.3	736.0	NA
	3100.0	2976.3	2482.7	2718.0	2853.7	2900.0	NA
	2910.3	2871.0	2500.3	2707.3	2413.7	2633.3	NA
	2529.7	2478.7	2345.7	2556.0	2418.0	2392.3	NA
	2282.7	1605.7	1680.0	1613.7	1526.7	1621.0	NA
	2429.0	1322.3	1274.0	NA	1325.0	NA	NA
	2643.7	2189.7	2214.7	2443.3	2203.0	NA	NA
	1875.3	1227.3	1238.0	1446.7	1411.0	NA	NA
	1983.0	NA	1842.7	NA	NA	NA	NA

Table 110 summarizes the ocular complications for the 13 eyes that missed the 24-month visit. The most prevalent ocular complication in this subset was increased IOP requiring treatment (n=4), followed by iris prolapse (n=2). One eye had posterior capsule opacification, however, this was not visually significant

TABLE 110
OCULAR COMPLICATIONS
13 EYES MISSING 24-MONTH FOLLOW-UP

Event	Operative (N=13)	Day 1 (N=13)	Day 7 (N=13)	1 Month (N=13)	9 Months (N=11)	12 Months (N=11)	18 Months (N=6)	Cumulative (N=13)
	n	n	n	n	n	n	n	n
Corneal edema ≤ 30 days		1						1
HypHEMA			1					1
Increased IOP requiring treatment ≤ 7 days		4						4
Iris prolapse	1		1					2
Iris transillumination defects ≤ 21 days		1	1					1
Iritis ≤ 30 days				1				1
Posterior capsule opacification					1	1	1	1
Suture rupture			1					1

Table 111 summarizes the ocular adverse events for the 13 eyes that missed the 24-month visit. In this subset, the most prevalent ocular adverse event was represented by inflammatory deposits on the IMT (n=3). The remaining ocular adverse events occurred in a single eye each.

TABLE 111
OCULAR ADVERSE EVENTS
13 EYES MISSING 24-MONTH FOLLOW-UP

Event	1 Month (N=13)	3 Months (N=12)	6 Months (N=13)	9 Months (N=11)	12 Months (N=11)	18 Months (N=6)	Interim (N=8)	Cumulative (N=13)
	n	n	n	n	n	n	n	n
Anterior chamber inflammation > 30 days						1		1
Anterior ischemic optic neuropathy		1	1	1			1	1
Conjunctivitis							1	1
Corneal edema > 30 days							1	1
Dry eye				1	1			1
Guttae					1			1
Inflammatory deposits on IMT			1	1	2	2		3
Iris transillumination defects > 21 days	1	1	1	1	1	1		1
Iritis > 30 days				1			1	1
Synechiae		1	1	1	1	1		1

CASE SUMMARIES

Patient [REDACTED]

Successful IMT implantation was performed in an 85-year-old female. The subject was lost to follow-up approximately 12 months postoperatively due to poor health. No adverse events or complications were reported for this subject. At the last available assessment, distance visual acuity showed a gain in 2.2 lines from the preoperative distance visual acuity (from 0.96 logMAR or 20/182 to 0.74 logMAR or 20/110), and near visual acuity showed a gain of 4 lines and 5 lines from baseline respectively at 8" (from 20/320 to 20/125) and 16" (from 20/250 to 20/80).

Patient [REDACTED]

IMT implantation was performed in a 78 year-old-male. The subject was last seen approximately 9 months postoperatively, after which he moved out of state. Two ocular adverse events were reported for this subject. Anterior ischemic optic neuropathy (AION) was reported at 3 months, and resolved with loss of BCDVA, and inflammatory deposits on the IMT were observed at the 6 month visit. At the last available assessment, i.e., the 9 month visit, distance visual acuity showed a loss of approximately 5 lines from the preoperative distance visual acuity (from 1.12 logMAR or 20/264 to 1.60 logMAR or 20/800).

Patient [REDACTED]

Successful IMT implantation was performed in a 71 year-old-male. The subject was last seen approximately 18 months postoperatively; he was unable to return for the 24 month visit due open heart surgery requiring cardiac rehabilitation. Only one complication was reported for this subject, i.e., transient increased IOP requiring treatment in the immediate postoperative period. At the last available assessment, BCDVA showed a gain of almost 4 lines from the preoperative distance visual acuity (from 1.02 logMAR or 20/209 to 0.64 logMAR or 20/87), while BCNVA at 8" and 16" showed a gain of 2 lines (from 20/200 to 20/125) and 3 lines (from 20/200 to 20/100), respectively, from preoperative BCNVA.

Patient [REDACTED]

Successful IMT implantation was performed in an 85-year-old female. The subject was last seen 12 months postoperatively; she was unable to return for the 18 month visit since she was recuperating from back surgery, and she was unable to travel at the 24 month visit due to leg problems. Two transient adverse events, corneal edema and iritis, were observed at approximately 7 months post implantation; both events resolved without sequelae. At the last available assessment, BCDVA showed a gain of 1.6 lines from the preoperative BCDVA (from 0.86 logMAR or 20/145 to 0.70 logMAR or 20/100), while no change was noted in BCNVA at 8" (20/125) and a gain of 4 lines was observed in BCNVA at 16" (from 20/200 to 20/80) from preoperative near visual acuity.

Patient [REDACTED]

Successful IMT implantation was performed in a 78-year-old male. The subject was last seen 18 months postoperatively but was then hospitalized with pneumonia and therefore missed the 24-month visits. On Day 1 post-implantation, iris transillumination defects were observed, and 1 week post implantation, moderate hyphema which resolved without sequelae was noted. At the last available assessment, BCDVA showed a gain of 5.6 lines from the preoperative BCDVA (from 1.32 logMAR or 20/418 to 0.76 logMAR or 20/115), while a gain of 1 line in BCNVA at 8" (from 20/250 to 20/200) and a gain of 2 lines in BCNVA at 16" (from 20/400 to 20/250) from preoperative near visual acuity were described.

Patient [REDACTED]

Successful IMT implantation was performed in a 77-year-old female. The subject was last seen 18 months postoperatively; she was non compliant at 24 months and was considered lost to follow-up. No adverse events and complications were reported for this subject. At the last available assessment, BCDVA showed a gain of 7.2 lines from the preoperative BCDVA (from 1.50 logMAR or 20/630 to 0.78 logMAR or 20/121), while a gain of 4 lines in BCNVA at 8" (from 20/800 to 20/320) and 16" (from 20/630 to 20/250) from preoperative near visual acuity were noted.

Patient [REDACTED]

Successful IMT implantation was performed in an 86-year-old female. The subject was last seen 18 months postoperatively; she experienced a stroke approximately three months following the 18 month visit which required hospitalization and admittance to a nursing home precluding follow-up at 24 months. Only one ocular complication was reported for this subject, specifically mild, transient increased IOP requiring treatment in the peri-operative period. At the last available assessment, BCDVA showed a gain of 2.8 lines from the preoperative BCDVA (from 1.54 logMAR or 20/693 to 1.26 logMAR or 20/364), while a gain of 4 lines in BCNVA at 8" (from 20/400 to 20/160) and a gain of 3 lines in BCNVA at 16" (from 20/400 to 20/200) from preoperative near visual acuity were described.

Patient [REDACTED]

Successful IMT implantation was performed in a 65-year-old male. The subject was last seen 18 months postoperatively and was considered lost-to-follow-up at 24 months. One week post implant, iris prolapse was observed which required the repair of a suture rupture. One month post implant, mild iritis which resolved without sequelae was noted. Three unresolved adverse events were reported, i.e., synechiae at 3 months, inflammatory deposits on the IMT at 12 months, and trace cells in the anterior chamber at 18 months. BCDVA showed a gain of 2.6 lines from the preoperative distance visual acuity (from 0.98 logMAR or 20/191 to 0.72 logMAR or 20/105), while a gain of 3 and 2 lines respectively at 8" (from 20/200 to 20/100) and 16" (from 20/200 to 20/125) from preoperative near visual acuity were observed at the 18 month visit.

Patient [REDACTED]

Successful IMT implantation was performed in a 78-year-old male. The subject was last seen 18 months postoperatively; he was unable to return for the 24 month visit since he moved to Canada. Only one ocular complication was reported for this subject, specifically moderate, inflammatory deposits on the IMT were noted at the 12 month visit. At the last available assessment, BCDVA showed a gain of 3.4 lines from the preoperative BCDVA (from 1.00 logMAR or 20/200 to 0.66 logMAR or 20/91), while a gain of 2 lines in BCNVA at 8" (from 20/200 to 20/125) and a gain of 1 line in BCNVA at 16" (from 20/160 to 20/125) from preoperative near visual acuity were described.

Patient [REDACTED]

Successful IMT implantation was performed in an 88-year-old female. The subject was last seen 12 months postoperatively and refused to travel for additional office visits. Peri-operatively, corneal edema and increased IOP requiring treatment were observed; both complications resolved without sequelae. BCDVA showed a gain of 3.8 lines from the preoperative distance visual acuity (from 1.46 logMAR or 20/551 to 1.04 logMAR or 20/219), while a gain of 4 and 6 lines respectively at 8" (from 20/500 to 20/200) and 16" (from 20/500 to 20/250) from preoperative near visual acuity were observed at the 12 month visit.

Patient [REDACTED]

Successful IMT implantation was performed in an 80-year-old male. The subject was last seen 12 months postoperatively; he was unable to return for the 18 and 24 month visits since he was undergoing rehabilitation due to renal cancer. Only one ocular adverse event was reported for this subject, specifically mild, dry eyes OU were reported at the 12 month visit. At the last available assessment, BCDVA showed a gain of 3.6 lines from the preoperative BCDVA (from 1.24 logMAR or 20/348 to 0.88 logMAR or 20/152), while a gain of 3 lines in BCNVA at 8" (from 20/320 to 20/160) and a gain of 2 lines in BCNVA at 16" (from 20/320 to 20/200) from preoperative near visual acuity were observed.

Patient [REDACTED]

Successful IMT implantation was performed in a 70-year-old male. During IMT implantation, iris prolapse occurred which resolved without sequelae. Furthermore, transient increased IOP requiring treatment was reported in the peri-operative period. BCDVA showed a gain of 5.6 lines from the preoperative distance visual acuity (from 1.50 logMAR or 20/630 to 0.94 logMAR or 20/174), while a gain of 5 and 2 lines respectively at 8" (from 20/630 to 20/200) and 16" (from 20/400 to 20/250) from preoperative near visual acuity were observed at the 12 month visit.

Patient [REDACTED]

Successful IMT implantation was performed in a 76-year-old female. The subject was last seen 6 months postoperatively; illness prevented additional follow-up beyond 6 months. Only one ocular adverse event was reported for this subject; specifically mild conjunctivitis which resolved without sequelae was reported at approx. 1 month post implant. At the last available assessment, BCDVA showed a gain of 2.8 lines from the preoperative BCDVA (from 1.14 logMAR or 20/276 to 0.86 logMAR or 20/145), while a gain of 2 lines in BCNVA at 8" (from 20/160 to 20/250) and no change in BCNVA at 16" (20/200) from preoperative near visual acuity were observed.