

ATTACHMENT 1

IN TEXT AND ADDITIONAL TABLES

**(INCLUDES ALL TABLES FOUND IN AMENDMENT 13 AND
ADDITIONAL TABLES NOT SHOWN IN THE NARRATIVE)**

P050034 AMENDMENT 013
VISIONCARE OPHTHALMIC TECHNOLOGIES
IMPLANTABLE MINIATURE TELESCOPE™ (IMT)

~ LIST OF IN-TEXT AND ADDITIONAL TABLES ~
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TABLE 1
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)	

TABLE 2
OPERATED EYES WITHOUT IMT 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

TABLE 3
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 4
AVAILABILITY AND ACCOUNTABILITY
OPERATED SUBJECTS
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 5.1
MEAN BCVA AT BASELINE, 12 MONTHS AND 24 MONTHS
IMT-IMPLANTED EYES
IMT-002

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

TABLE 5.2
VISUAL ACUITY EFFECTIVENESS ENDPOINT
IMT-002

BCVA Endpoints	12 Months		24 Months	
	Operated Eyes	IMT Eyes	Operated Eyes	IMT Eyes
Effectiveness (N=)	194	192	175	173
Overall Effectiveness Endpoint	171 (88.1%)	173 (90.1%)	150 (85.7%)	149 (86.1%)
≥2 lines gain of BCDVA or BCNVA	83.6%, 91.8%	85.8%, 93.4%	80.6%, 89.9%	81.0%, 90.2%
Binomial exact p-value for H_a: success rate > 50%	<.0001	<.0001	<.0001	<.0001
≥2 lines gain of BCDVA and BCNVA	141 (72.7%) 66.9%, 77.9%	141 (73.4%) 67.7%, 78.6%	115 (65.7%) 59.4%, 71.7%	114 (65.9%) 59.5%, 71.9%

TABLE 6
SUMMARY OF IMPROVEMENT IN VISUAL ACUITY
IMT-IMPLANTED EYES
IMT-002

IMPROVEMENT IN VISUAL ACUITY	12 MONTHS % (n)	24 MONTHS % (n)
≥ 2 LINES GAIN OF BCDVA OR BCNVA	90.1% (173)	86.1% (149)
≥ 2 LINES GAIN OF BCDVA AND BCNVA	73.4% (141)	65.9% (114)
≥ 3 LINES GAIN OF BCDVA AND BCNVA	53.1% (102)	49.1% (85)
BCDVA LINES GAINED		
≥ 2 LINES GAIN OF BCDVA	80.3% (155)	74.6% (129)
≥ 3 LINES GAIN OF BCDVA	66.3% (128)	59.5% (103)
≥ 4 LINES GAIN OF BCDVA	45.1% (87)	42.8% (74)
≥ 5 LINES GAIN OF BCDVA	25.4% (49)	19.1% (33)
BCNVA LINES GAINED (8" OR 16")		
≥ 2 LINES GAIN OF BCNVA	82.8% (159)	77.5% (134)
≥ 3 LINES GAIN OF BCNVA	67.7% (130)	63.0% (109)
≥ 4 LINES GAIN OF BCNVA	49.0% (94)	43.9% (76)
≥ 5 LINES GAIN OF BCNVA	28.6% (55)	24.3% (42)

TABLE 7.1
SUMMARY OF IMPROVEMENT IN VISUAL ACUITY
IMT-IMPLANTED EYES
STRATIFIED BY PREOPERATIVE BCDVA
IMT-002

IMPROVEMENT IN VISUAL ACUITY	12 MONTHS			24 MONTHS		
	Baseline BCDVA 20/80 to 20/160+	Baseline BCDVA 20/160 to 20/400	Baseline BCDVA Worse than 20/400	Baseline BCDVA 20/80 to 20/160+	Baseline BCDVA 20/160 to 20/400	Baseline BCDVA Worse than 20/400
	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)
≥2 LINES GAIN OF BCDVA OR BCNVA	86.7% (13)	86.1% (99)	98.4% (61)	71.4% (10)	83.7% (87)	94.5% (52)
≥2 LINES GAIN OF BCDVA AND BCNVA	46.7% (7)	69.6% (80)	87.1% (54)	35.7% (5)	65.4% (68)	74.5% (41)
≥3 LINES GAIN OF BCDVA AND BCNVA	13.3% (2)	47.0% (54)	74.2% (46)	21.4% (3)	43.3% (45)	67.3% (37)
BCDVA LINES GAINED						
≥2 LINES GAIN OF BCDVA	53.3% (8)	74.8% (86)	96.8% (61)	42.9% (6)	71.2% (74)	89.1% (49)
≥3 LINES GAIN OF BCDVA	13.3% (2)	60.9% (70)	88.9% (56)	21.4% (3)	54.8% (57)	78.2% (43)
≥4 LINES GAIN OF BCDVA	0.0% (0)	39.1% (45)	66.7% (42)	7.1% (1)	37.5% (39)	61.8% (34)
≥5 LINES GAIN OF BCDVA	0.0% (0)	13.9% (16)	52.4% (33)	0.0% (0)	13.5% (14)	34.5% (19)
BCNVA LINES GAINED 8" OR 16"						
≥2 LINES GAIN OF BCNVA	80.0% (12)	80.9% (93)	87.1% (54)	64.3% (9)	77.9% (81)	80.0% (44)
≥3 LINES GAIN OF BCNVA	60.0% (9)	64.3% (74)	75.8% (47)	50.0% (7)	58.7% (61)	74.5% (41)
≥4 LINES GAIN OF BCNVA	40.0% (6)	43.5% (50)	61.3% (38)	28.6% (4)	41.3% (43)	52.7% (29)
≥5 LINES GAIN OF BCNVA	26.7% (4)	23.5% (27)	38.7% (24)	14.3% (2)	21.2% (22)	32.7% (18)

TABLE 7.2
SUMMARY OF IMPROVEMENT IN BCDVA
IMT-IMPLANTED EYES
STRATIFIED BY PREOP BCDVA
IMT-002-LTM

IMPROVEMENT IN BCDVA	36 MONTHS			48 MONTHS		
	Baseline BCDVA 20/80 to 20/160+	Baseline BCDVA 20/160 to 20/400	Baseline BCDVA Worse than 20/400	Baseline BCDVA 20/80 to 20/160+	Baseline BCDVA 20/160 to 20/400	Baseline BCDVA Worse than 20/400
	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)
≥2 LINES GAIN OF BCDVA	37.5% (3)	66.0% (31)	89.5% (17)	40.0% (4)	65.5% (38)	82.1% (23)
≥3 LINES GAIN OF BCDVA	12.5% (1)	46.8% (22)	84.2% (16)	10.0% (1)	51.7% (30)	53.6% (15)
≥4 LINES GAIN OF BCDVA	12.5% (1)	31.9% (15)	52.6% (10)	10.0% (1)	25.9% (15)	39.3% (11)
≥5 LINES GAIN OF BCDVA	0.0% (0)	12.8% (6)	26.3% (5)	0.0% (0)	5.2% (3)	21.4% (6)
MEAN BCDVA	20/96	20/146	20/225	20/126	20/152	20/240
95% CI	(20/128, 20/72)	(20/167, 20/127)	(20/279, 20/181)	(20/199, 20/79)	(20/174, 20/134)	(20/292, 20/197)

Data after IMT explant was excluded.

TABLE 7.3
BCDVA STRATIFIED BY PREOP BCDVA
IMT-IMPLANTED EYES
IMT-002-LTM

	Baseline BCDVA 20/80 to 20/160+ Mean (95% CI)	Baseline BCDVA 20/160 to 20/400 Mean (95% CI)	Baseline BCDVA Worse than 20/400 Mean (95% CI)	Overall Mean (95% CI)
36-Month Cohort	N = 8	N = 47	N = 19	N = 74
Preop BCDVA	20/122 (20/148, 20/101)	20/264 (20/286, 20/243)	20/551 (20/602, 20/504)	20/293 (20/330, 20/261)
36-Month BCDVA	20/96 (20/128, 20/72)	20/146 (20/167, 20/127)	20/225 (20/279, 20/181)	20/156 (20/175, 20/139)
48-Month Cohort	N = 10	N = 58	N = 28	N = 96
Preop BCDVA	20/123 (20/143, 20/107)	20/266 (20/286, 20/247)	20/542 (20/579, 20/507)	20/302 (20/334, 20/273)
48-Month BCDVA	20/126 (20/199, 20/79)	20/152 (20/174, 20/134)	20/240 (20/292, 20/197)	20/171 (20/191, 20/152)

Data after IMT explant was excluded.

TABLE 8
SUMMARY OF IMPROVEMENT IN VISUAL ACUITY
IMT-IMPLANTED EYES
STRATIFIED BY IMT MODEL
IMT-002

IMPROVEMENT IN VISUAL ACUITY	12 MONTHS		24 MONTHS	
	WA 2.2X	WA 3.0X	WA 2.2X	WA 3.0X
	% (n)	% (n)	% (n)	% (n)
≥2 LINES GAIN OF BCDVA OR BCNVA	89.0% (97)	91.6% (76)	84.5% (82)	88.2% (67)
≥2 LINES GAIN OF BCDVA AND BCNVA	67.0% (73)	81.9% (68)	60.8% (59)	72.4% (55)
≥3 LINES GAIN OF BCDVA AND BCNVA	46.8% (51)	61.4% (51)	40.2% (39)	60.5% (46)
BCDVA LINES GAINED				
≥2 LINES GAIN OF BCDVA	74.5% (82)	88.0% (73)	69.1% (67)	81.6% (62)
≥3 LINES GAIN OF BCDVA	60.0% (66)	74.7% (62)	52.6% (51)	68.4% (52)
≥4 LINES GAIN OF BCDVA	36.4% (40)	56.6% (47)	36.1% (35)	51.3% (39)
≥5 LINES GAIN OF BCDVA	16.4% (18)	37.3% (31)	14.4% (14)	25.0% (19)
BCNVA LINES GAINED 8" OR 16"				
≥2 LINES GAIN OF BCNVA	80.7% (88)	85.5% (71)	76.3% (74)	78.9% (60)
≥3 LINES GAIN OF BCNVA	64.2% (70)	72.3% (60)	58.8% (57)	68.4% (52)
≥4 LINES GAIN OF BCNVA	43.1% (47)	56.6% (47)	41.2% (40)	47.4% (36)
≥5 LINES GAIN OF BCNVA	28.4% (31)	28.9% (24)	20.6% (20)	28.9% (22)

TABLE 9.1
CUMULATIVE BCDVA IMPROVEMENT FROM BASELINE
IMT-IMPLANTED EYES
IMT-002-LTM

	36 Months	48 Months
	n (%)	n (%)
N	74	96
Gain ≥ 3 lines	39 (53%)	46 (48%)
Gain ≥ 2 lines	51 (69%)	65 (68%)
Gain ≥ 1 lines	63 (85%)	75 (78%)

Records after IMT explant excluded

TABLE 9.2
MEAN BCDVA AT BASELINE, 36 MONTHS AND 48 MONTHS
IMT-IMPLANTED EYES
IMT-002 AND IMT-002-LTM

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

Records after IMT explant excluded

TABLE 9.3
BEST CORRECTED DISTANCE VISUAL ACUITY (BCDVA)
IMT-IMPLANTED SUBJECTS INCLUDING AVAILABLE PARTIAL DATA FOR
54 AND 60 MONTHS
IMT-002 AND IMT-002-LTM

	Baseline		12 Months		24 Months		36 Months		42 Months		48 Months		54 Months		60 Months	
	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean
IMT-Implanted Eyes																
Mean BCDVA (SD logMAR)	206	20/312 (0.214)	193	20/141 (0.228)	173	20/149 (0.225)	74	20/156 (0.221)	104	20/174 (0.275)	96	20/171 (0.244)	34	20/171 (0.254)	6	20/103 (0.328)
Median		20/317		20/138		20/152		20/145		20/159		20/174		20/166		20/87

N = number of eyes returned for the visit with non-missing BCDVA.

TABLE 10
CHANGE IN BCDVA FROM BASELINE
FOLLOWING CATARACT REMOVAL AND IOL IMPLANTATION

	All Eyes with Cataract Removal and IOL Implantation				IMT-Implanted Eyes at 12 Months
	Fellow Eyes of Subjects with Cataract Surgery During Study	IMT Eyes with Aborted IMT Implant & with IOL Implant	IMT Eyes with IMT Removal Postoperatively & with IOL Implant	Overall	
N	22	9	6	37	193
Mean Lines Change in BCDVA (95% CI)	0.35 (-0.60, 1.29)	0.38 (-0.32, 1.07)	-0.20 (-2.24, 1.84)	0.26 (-0.35, 0.88)	3.43 (3.10, 3.76)

TABLE 11
CHANGE IN BCDVA FROM PRE-IOL IMPLANT
IMT EYES WITH IMT REMOVAL POSTOPERATIVELY & WITH IOL IMPLANT

	Change from Pre-IOL Implant
N	6
Mean Lines Change in BCDVA (95% CI)	-2.2 (-3.30, -1.10)

TABLE 12.1
BCDVA INCREASE ≥ 2 OR ≥ 3 LINES
FELLOW EYES WITH CATARACT SURGERY AND IOL IMPLANT DURING STUDY
AND CORRESPONDING IMT-IMPLANTED EYES

BCDVA Increase	IMT Eyes N = 22 n (%)	Fellow Eyes N = 22 n (%)	McNemar P-value
≥ 2 Lines	20 (90.9%)	6 (27.3%)	0.0001
≥ 3 Lines	16 (72.7%)	2 (9.1%)	0.0005

BCDVA Change in Fellow Eyes = Change from study baseline to the last available BCDVA
BCDVA Change in IMT Eyes = Change from study baseline BCDVA to 12-Month BCDVA

TABLE 12.2
BCDVA LINE CHANGE FROM BASELINE
EXTERNAL TELESCOPE AND IMT EYES AT 12-MONTHS
IMT-002

	N	Mean	95% CI	Median	Wilcoxon P-value for Comparing to Theoretical Change	Wilcoxon P-value for Comparing External Telescope vs 12-Month IMT
2.2X						
2.2X External Telescope	110	2.9 Lines	2.7 Lines, 3.1 Lines	2.8 Lines	<.0001	
12-Month 2.2X IMT	110	3.0 Lines	2.5 Lines, 3.5 Lines	3.4 Lines	0.1984	
Paired Difference	110	0.1 Lines	-0.4 Lines, 0.5 Lines	0.4 Lines		0.2142
3.0X						
3.0X External Telescope	83	3.6 Lines	3.3 Lines, 3.8 Lines	3.4 Lines	<.0001	
12-Month 3.0X IMT	83	4.0 Lines	3.6 Lines, 4.4 Lines	4.4 Lines	0.3727	
Paired Difference	83	0.5 Lines	0.1 Lines, 0.9 Lines	0.6 Lines		0.0055

N = number of eyes with 12-month data.

TABLE 13.1
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 ¹
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 ²	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.

1 P-value for testing that mean VFQ change = 0.

2 General Health not included in Overall Composite per NEI VFQ-25 scoring guidelines.

TABLE 13.2
VFQ-25 SCORE PERCENT OF PATIENTS ACHIEVING
A CLINICALLY MEANINGFUL 5 POINT CHANGE IN COMPOSITE SCORE
IMT-IMPLANTED EYES
IMT-002

Change in VFQ-25 Composite Score	12 Months (N = 193)	
	%	n/N
Subjects with increase \geq 5 points	51.8%	100/193
Subjects with decrease \geq 5 points	22.3%	43/193

TABLE 13.3
CHANGE IN VFQ-25 COMPOSITE SCORE FROM BASELINE AT 12 MONTHS
STRATIFIED BY AGE
IMT-002

Change in VFQ-25	Age			
	< 71	71 to 75	76 to 80	> 80
N	42	49	56	46
Mean (SD)	10.5	6.5	3.3	4.7
95% confidence interval for mean ¹	5.7, 15.3	2.4, 10.6	-0.4, 7.0	0.7, 8.8
Median	9.6	4.7	4.4	1.3
Range	-13.9, 45.1	-17.4, 58.3	-31.3, 48.5	-15.2, 56.3
Comparing VFQ Change from Baseline Among Sub-groups				
P-value of Kruskal-Wallis Test	0.1364			
n & % of eyes with increase ≥5 points	27/42 (64%)	24/49 (49%)	27/56 (48%)	22/46 (48%)
95% confidence interval for % ¹	48%, 78%	34%, 64%	35%, 62%	33%, 63%
Comparing %s Among Sub-groups				
Fisher's Exact p-value	0.3415			

N = number of treated eyes returned for the 12-month visit with a non-missing change in VFQ-25 assessment and age at implant. Records after IMT removal were excluded and reported separately.

¹ Normal distribution approach was used for mean. CI for % was calculated based on Clopper Pearson method.

TABLE 13.4
CHANGE IN VFQ-25 COMPOSITE SCORE FROM BASELINE AT 12 MONTHS
STRATIFIED BY GENDER
IMT-002

Change in VFQ-25	Gender	
	Female	Male
N	93	100
Mean (SD)	8.4	3.8
95% confidence interval for mean ¹	5.4, 11.5	1.1, 6.5
Median	6.9	3.2
Range	-22.5, 56.3	-31.3, 58.3
Comparing VFQ Change from Baseline Between Sub-groups		
P-value of Wilcoxon Test	0.0267	
n & % of eyes with increase ≥5 points	53/93 (57%)	47/100 (47%)
95% confidence interval for % ¹	46%, 67%	37%, 57%
Comparing Percentages Between Sub-groups		
Fisher's Exact p-value	0.1950	

N = number of treated eyes returned for the 12-month visit with a non-missing change in VFQ-25 assessment and gender. Records after IMT removal were excluded and reported separately.

¹ Normal distribution approach was used for mean. CI for % was calculated based on Clopper Pearson method.

TABLE 13.5
CHANGE IN VFQ-25 COMPOSITE SCORE FROM BASELINE AT 12 MONTHS
STRATIFIED BY IMT MODEL
IMT-002

Change in VFQ-25	IMT Model	
	WA 2.2X	WA 3.0X
N	110	83
Mean (SD)	5.2	7.1
95% confidence interval for mean ¹	2.8, 7.6	3.6, 10.7
Median	4.7	5.6
Range	-22.5, 56.3	-31.3, 58.3
Comparing VFQ Change from Baseline Between Sub-groups		
P-value of Wilcoxon Test	0.5288	
n & % of eyes with increase ≥5 points	55/110 (50%)	45/83 (54%)
95% confidence interval for % ¹	40%, 60%	43%, 65%
Comparing Percentages Between Sub-groups		
Fisher's Exact p-value	0.6626	

N = number of treated eyes returned for the 12-month visit with a non-missing change in VFQ-25 assessment and IMT Model Records after IMT removal were excluded and reported separately.

¹ Normal distribution approach was used for mean. CI for % was calculated based on Clopper Pearson method.

TABLE 13.6
CHANGE IN VFQ-25 COMPOSITE SCORE FROM BASELINE AT 12 MONTHS
STRATIFIED BY PREOPERATIVE BCDVA
IMT-002

Change in VFQ-25	Preoperative BCDVA		
	Moderate Impairment (20/80 to 20/160)	Severe Impairment (20/161 to 20/400)	Profound Impairment (Worse than 20/400)
N	20	110	63
Mean (SD)	1.3	7.9	4.3
95% confidence interval for mean ¹	-4.5, 7.0	4.8, 10.9	1.7, 7.0
Median	-0.9	5.4	7.0
Range	-22.5, 26.9	-17.6, 58.3	-31.3, 19.9
Comparing VFQ Change from Baseline Among Sub-groups			
P-value of Kruskal-Wallis Test	0.2514		
n & % of eyes with increase ≥5 points	7/20 (35%)	57/110 (52%)	36/63 (57%)
95% confidence interval for % ¹	15%, 59%	42%, 61%	44%, 70%
Comparing %s Among Sub-groups			
Fisher's Exact p-value	0.2383		

N = number of treated eyes returned for the 12-month visit with a non-missing change in VFQ-25 assessment and preoperative BCDVA Records after IMT removal were excluded and reported separately.

¹ Normal distribution approach was used for mean. CI for % was calculated based on Clopper Pearson method.

TABLE 13.7
CHANGE IN VFQ-25 COMPOSITE SCORE FROM BASELINE AT 12 MONTHS
STRATIFIED BY 12-MONTH VISUAL ACUITY IMPROVEMENT
IMT-002

Change in VFQ-25	12-Month Visual Acuity Improvement		
	Gain \geq 2 lines of both BCDVA & BCNVA	Gain \geq 2 lines of either BCDVA or BCNVA, but not both	Other
N	141	32	20
Mean (SD)	6.7	6.0	1.5
95% confidence interval for mean ¹	4.2, 9.1	1.6, 10.4	-5.1, 8.2
Median	6.6	5.6	-0.5
Range	-31.3, 58.3	-14.2, 43.1	-17.6, 35.4
Comparing VFQ Change from Baseline Among Sub-groups			
P-value of Kruskal-Wallis Test	0.2677		
n & % of eyes with increase \geq 5 points	77/141 (55%)	17/32 (53%)	6/20 (30%)
95% confidence interval for % ¹	46%, 63%	35%, 71%	12%, 54%
Comparing %s Among Sub-groups			
Fisher's Exact p-value	0.1242		

N = number of treated eyes returned for the 12-month visit with a non-missing change in VFQ-25 assessment and 12-Month visual acuity Records after IMT removal were excluded and reported separately.

¹ Normal distribution approach was used for mean. CI for % was calculated based on Clopper Pearson method.

TABLE 14
CHANGE FROM PREOPERATIVE IN ADL SCORES
IMT-IMPLANTED EYES
IMT-002

ADL 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-value¹
Mobility	53.8 (51.1, 56.4)	66.0 (63.1, 68.9)	12.0 (8.7, 15.2)	<.0001
Distance Activities	43.7 (41.6, 45.8)	57.3 (54.4, 60.2)	13.4 (10.4, 16.3)	<.0001
Near Activities	30.9 (28.3, 33.5)	48.5 (45.3, 51.7)	17.0 (13.8, 20.2)	<.0001
Total	41.4 (39.2, 43.5)	55.9 (53.1, 58.6)	14.2 (11.4, 16.9)	<.0001

95%CI = 95% Confidence Interval.

¹ P-value for testing that mean ADL change = 0.

TABLE 15
PRESERVATION OF BCVA
OPERATED EYES (N = 217)
IMT-002

	1 Month n (%) % CI	3 Months n (%) % CI	6 Months n (%) % CI	9 Months n (%) % CI	12 Months n (%) % CI	18 Months n (%) % CI	24 Months n (%) % CI
N=	211	206	204	195	194	181	175
Overall Safety Rate >2 lines loss of BCDVA and no change/loss of BCNVA or >2 lines loss of BCNVA and no change/loss of BCDVA	17 (8.1%) 5.2%, 11.8%	6 (2.9%) 1.3%, 5.7%	10 (4.9%) 2.7%, 8.2%	9 (4.6%) 2.4%, 7.9%	10 (5.2%) 2.8%, 8.6%	9 (5.0%) 2.6%, 8.5%	11 (6.3%) 3.6%, 10.2%
Binomial exact p- value for Ha: safety rate < 10%	0.2071	<.0001	0.0064	0.0048	0.0114	0.0111	0.0587
>2 lines loss of BCDVA and BCNVA	6 (2.8%) 1.2%, 5.5%	2 (1.0%) 0.2%, 3.0%	2 (1.0%) 0.2%, 3.1%	4 (2.1%) 0.7%, 4.6%	2 (1.0%) 0.2%, 3.2%	2 (1.1%) 0.2%, 3.4%	3 (1.7%) 0.5%, 4.4%
>2 lines loss of BCDVA and no change of BCNVA	2 (0.9%) 0.2%, 3.0%	0 (0.0%) 0.0%, 1.4%	1 (0.5%) 0.0%, 2.3%	2 (1.0%) 0.2%, 3.2%	0 (0.0%) 0.0%, 1.5%	1 (0.6%) 0.0%, 2.6%	0 (0.0%) 0.0%, 1.7%
>2 lines loss of BCNVA and no change of BCDVA	9 (4.3%) 2.2%, 7.3%	4 (1.9%) 0.7%, 4.4%	7 (3.4%) 1.6%, 6.3%	3 (1.5%) 0.4%, 3.9%	8 (4.1%) 2.1%, 7.3%	6 (3.3%) 1.5%, 6.4%	8 (4.6%) 2.3%, 8.1%

Table 16.1
LOSS OF BEST CORRECTED DISTANCE VISUAL ACUITY (BCDVA)
IMT-IMPLANTED EYES
IMT-002

BCDVA	6 Months		9 Months		12 Months		18 Months		24 Months	
	n	%	N	%	n	%	n	%	n	%
Loss > 2 lines	3	1.5%	6	3.1%	4	2.1%	4	2.2%	3	1.7%
One-sided upper 95% CL ¹	3.8%		6.0%		4.7%		5.0%		4.4%	
N ²	201		195		193		179		173	

- 1 CL = exact confidence limit calculated based on Clopper PEarson method.
2 N = number of eyes with available data.

Table 16.2
LOSS OF BEST CORRECTED DISTANCE VISUAL ACUITY (BCDVA)
FELLOW EYES OF IMT-IMPLANTED EYES
IMT-002

BCDVA	6 Months		9 Months		12 Months		18 Months		24 Months	
	n	%	n	%	n	%	n	%	n	%
Loss > 2 lines	14	7.0%	14	7.2%	15	7.8%	18	10.0%	16	9.2%
One-sided upper 95% CL ¹	10.7%		11.0%		11.7%		14.5%		13.6%	
N ²	200		195		193		180		174	

1 CL = exact confidence limit calculated based on Clopper PEarson method.

2 N = number of eyes with available data.

Table 17.1
LOSS OF BEST CORRECTED DISTANCE VISUAL ACUITY (BCDVA)
IMT-IMPLANTED EYES
IMT-002-LTM

BCDVA	36 Months		42 Months		48 Months		54 Months		60 Months	
	n	%	n	%	n	%	n	%	n	%
Loss > 2 lines	2	2.7%	9	8.7%	4	4.2%	2	5.9%	0	0.0%
One-sided upper 95% CL¹	8.3%		14.6%		9.3%		17.4%		39.3%	
N²	74		104		96		34		6	

1 CL = exact confidence limit calculated based on Clopper PEarson method.

2 N = number of eyes with available data.

Table 17.2
LOSS OF BEST CORRECTED DISTANCE VISUAL ACUITY (BCDVA)
FELLOW EYES OF IMT-IMPLANTED EYES
IMT-002-LTM

BCDVA	36 Months		42 Months		48 Months		54 Months		60 Months	
	n	%	n	%	n	%	n	%	n	%
Loss > 2 lines	10	13.5%	14	13.6%	11	11.5%	5	14.7%	1	16.7%
One-sided upper 95% CL ¹	21.8%		20.4%		18.3%		28.5%		58.2%	
N ²	74		103		96		34		6	

1 CL = exact confidence limit calculated based on Clopper Pearson method.

2 N = number of eyes with available data.

TABLE 18.1
ECD, PERCENT CHANGE IN ECD, AND ANNUALIZED PERCENT CHANGE IN ECD
IMT-IMPLANTED EYES
IMT-002 AND IMT-002-LTM

	Preop	6 Months	12 Months	24 Months	36 Months	48 Months
ECD						
N	206	198	186	171	70	88
Mean	2496	1937	1871	1808	1713	1620
95% CI	2447, 2545	1856, 2018	1786, 1957	1718, 1898	1576, 1850	1499, 1741
Percent Change in ECD (Between Two Visits 1-Year Apart)						
		Preop to 12 Months	12 to 24 Months	24 to 36 Months	36 to 48 Months	
N		186	169	65	51	
Mean		-25%	-2%	-7%	-2%	
95% CI		-28%, -22%	-4%, 1%	-12%, -2%	-6%, 1%	
Percent Change in ECD						
	Preop to 6 Months	6 to 48 Months	12 to 48 Months	24 to 48 Months	36 to 48 Months	
N	198	85	88	86	51	
Mean	-22%	-12%	-7%	-6%	-2%	
95% CI	-25%, -19%	-17%, -7%	-12%, -2%	-10%, -2%	-6%, 1%	
Annualized Percent Change in ECD						
		Annualized 6 to 48 Months	Annualized 12 to 48 Months	Annualized 24 to 48 Months	Annualized 36 to 48 Months	
N		85	88	86	51	
Mean		-3%	-2%	-3%	-3%	
95% CI		-5%, -2%	-4%, -1%	-5%, -1%	-7%, 1%	

N = number of eyes with non-missing data.

Annualized: For each eye, ECD at the end of the interval minus ECD at the beginning of interval, divided by number of months between the interval, and multiplied by 12.

TABLE 18.2
ECD, PERCENT CHANGE IN ECD, AND PERCENT CHANGE IN ECD BETWEEN CONSECUTIVE VISITS
IMT-IMPLANTED EYES
IMT-002 AND IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months	54 Months	60 Months
ECD												
N	206	193	198	190	186	180	171	70	101	88	60	17
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
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%)
Percent Change in ECD												
N		193	198	190	186	180	171	70	101	88	60	17
Mean		-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%
Percent Change in ECD Between Consecutive Visit												
		Preop to 3 Months	3 to 6 Months	6 to 9 Months	9 to 12 Months	12 to 18 Months	18 to 24 Months	24 to 36 Months	36 to 42 Months	42 to 48 Months	48 to 54 Months	54 to 60 Months
N		193	188	188	179	176	168	65	60	82	56	15
Mean		-20%	-3%	-2%	-1%	2%	-3%	-7%	-1%	4%	-5%	1%
95% CI		-23%, -17%	-5%, -1%	-5%, -0%	-4%, 1%	-1%, 5%	-5%, -1%	-12%, -2%	-6%, 5%	-1%, 9%	-8%, -2%	-6%, 7%
Percent Change in ECD Between 12 Months Intervals (12-month ECD Loss)												
						6 to 18 Months	12 to 24 Months	24 to 36 Months	30 to 42 Months	36 to 48 Months	42 to 54 Months	48 to 60 Months
N						177	169	65	NA	51	58	16
Mean						-4%	-2%	-7%	NA	-2%	-2%	-2%
95% CI						-7%, -1%	-4%, 1%	-12%, -2%	NA	-6%, 1%	-5%, 2%	-8%, 4%

N = number of eyes with non-missing data.

TABLE 18.3
ECD AND PERCENT CHANGE IN ECD
OPERATED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	216	198	200	190	190	182	173
ECD							
Mean	2498	2001	1936	1891	1881	1887	1813
95% CI	2451, 2546	1919, 2082	1855, 2016	1809, 1973	1795, 1967	1796, 1978	1723, 1903
Percent Change in ECD							
Mean		-20%	-22%	-24%	-25%	-25%	-27%
95% CI		-23%, -17%	-25%, -20%	-27%, -21%	-28%, -22%	-28%, -21%	-31%, -24%
ECD < 750	0 (0%)	6 (3%)	8 (4%)	9 (5%)	9 (5%)	13 (7%)	12 (7%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.4
ECD AND PERCENT CHANGE IN ECD
24-MONTH CONSISTENT COHORT
OPERATED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	154	154	154	154	154	154	154
ECD							
Mean	2501	2015	1940	1888	1849	1864	1801
95% CI	2443, 2558	1927, 2103	1851, 2029	1798, 1977	1757, 1941	1768, 1959	1706, 1895
Percent Change in ECD							
Mean		-19%	-22%	-24%	-26%	-25%	-28%
95% CI		-22%, -16%	-25%, -19%	-28%, -21%	-29%, -22%	-29%, -22%	-31%, -24%
ECD < 750							
	0 (0%)	3 (2%)	5 (3%)	8 (5%)	8 (5%)	11 (7%)	11 (7%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.5
ECD AND PERCENT CHANGE IN ECD
OPERATED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	129	119	121	119	122	119	116	79	110	94
ECD										
Mean	2507	1950	1865	1868	1810	1814	1766	1736	1612	1611
95% CI	2443, 2570	1842, 2059	1756, 1975	1760, 1976	1699, 1920	1700, 1927	1652, 1881	1610, 1863	1505, 1720	1495, 1727
Percent Change in ECD										
Mean		-22%	-25%	-25%	-28%	-27%	-29%	-30%	-35%	-36%
95% CI		-26%, -18%	-29%, -21%	-29%, -22%	-32%, -23%	-32%, -23%	-34%, -25%	-35%, -26%	-40%, -31%	-40%, -32%
ECD < 750	0 (0%)	4 (3%)	8 (7%)	7 (6%)	8 (7%)	11 (9%)	11 (9%)	3 (4%)	9 (8%)	7 (7%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.6
ECD AND PERCENT CHANGE IN ECD
48-MONTH CONSISTENT COHORT
OPERATED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	43	43	43	43	43	43	43	43	43	43
ECD										
Mean	2525	2073	1993	1952	1866	1906	1900	1758	1702	1710
95% CI	2407, 2644	1900, 2246	1811, 2175	1777, 2127	1698, 2035	1743, 2069	1730, 2070	1584, 1933	1526, 1879	1532, 1887
Percent Change in ECD										
Mean		-18%	-21%	-23%	-26%	-24%	-24%	-30%	-33%	-32%
95% CI		-24%, -11%	-27%, -15%	-29%, -17%	-32%, -20%	-30%, -19%	-31%, -18%	-36%, -24%	-39%, -26%	-39%, -26%
ECD < 750	0 (0%)	1 (2%)	3 (7%)	3 (7%)	3 (7%)	2 (5%)	3 (7%)	1 (2%)	3 (7%)	4 (9%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.7
ECD AND PERCENT CHANGE IN ECD
IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	206	193	198	190	186	180	171
ECD							
Mean	2496	1995	1937	1891	1871	1878	1808
95% CI	2447, 2545	1912, 2078	1856, 2018	1809, 1973	1786, 1957	1787, 1969	1718, 1898
Percent Change in ECD							
Mean		-20%	-22%	-24%	-25%	-25%	-28%
95% CI		-23%, -17%	-25%, -19%	-27%, -21%	-28%, -22%	-28%, -22%	-31%, -24%
ECD < 750							
	0 (0%)	6 (3%)	8 (4%)	9 (5%)	9 (5%)	13 (7%)	12 (7%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.8
ECD AND PERCENT CHANGE IN ECD
24-MONTH CONSISTENT COHORT
IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	154	154	154	154	154	154	154
ECD							
Mean	2501	2015	1940	1888	1849	1864	1801
95% CI	2443, 2558	1927, 2103	1851, 2029	1798, 1977	1757, 1941	1768, 1959	1706, 1895
Percent Change in ECD							
Mean		-19%	-22%	-24%	-26%	-25%	-28%
95% CI		-22%, -16%	-25%, -19%	-28%, -21%	-29%, -22%	-29%, -22%	-31%, -24%
ECD < 750							
	0 (0%)	3 (2%)	5 (3%)	8 (5%)	8 (5%)	11 (7%)	11 (7%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.9
ECD AND PERCENT CHANGE IN ECD
IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	123	116	120	119	119	118	114	70	101	88
ECD										
Mean	2500	1937	1865	1868	1786	1802	1758	1713	1595	1620
95% CI	2434, 2566	1827, 2047	1754, 1975	1760, 1976	1677, 1895	1690, 1915	1644, 1873	1576, 1850	1481, 1709	1499, 1741
Percent Change in ECD										
Mean		-22%	-25%	-25%	-29%	-28%	-30%	-31%	-36%	-35%
95% CI		-26%, -18%	-29%, -21%	-29%, -22%	-33%, -24%	-32%, -24%	-34%, -25%	-36%, -26%	-40%, -32%	-40%, -31%
ECD < 750										
ECD < 750	0 (0%)	4 (3%)	8 (7%)	7 (6%)	8 (7%)	11 (9%)	11 (10%)	3 (4%)	9 (9%)	7 (8%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.10
ECD AND PERCENT CHANGE IN ECD
48-MONTH CONSISTENT COHORT
IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	43	43	43	43	43	43	43	43	43	43
ECD										
Mean	2525	2073	1993	1952	1866	1906	1900	1758	1702	1710
95% CI	2407, 2644	1900, 2246	1811, 2175	1777, 2127	1698, 2035	1743, 2069	1730, 2070	1584, 1933	1526, 1879	1532, 1887
Percent Change in ECD										
Mean		-18%	-21%	-23%	-26%	-24%	-24%	-30%	-33%	-32%
95% CI		-24%, -11%	-27%, -15%	-29%, -17%	-32%, -20%	-30%, -19%	-31%, -18%	-36%, -24%	-39%, -26%	-39%, -26%
ECD < 750	0 (0%)	1 (2%)	3 (7%)	3 (7%)	3 (7%)	2 (5%)	3 (7%)	1 (2%)	3 (7%)	4 (9%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.11
ECD STRATIFIED BY GUTTATA
IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
Guttata Eyes							
N	26	26	26	25	24	22	21
Mean	2419	1788	1719	1651	1652	1630	1523
95% CI	2242, 2596	1520, 2056	1476, 1963	1398, 1904	1365, 1938	1328, 1931	1248, 1798
ECD < 750	0 (0%)	1 (4%)	1 (4%)	2 (8%)	2 (8%)	2 (9%)	2 (10%)
Non-Guttata Eyes							
N	180	167	172	165	162	158	150
Mean	2507	2027	1970	1927	1904	1913	1848
95% CI	2457, 2557	1940, 2114	1884, 2056	1841, 2013	1815, 1993	1818, 2007	1753, 1942
ECD < 750	0 (0%)	5 (3%)	7 (4%)	7 (4%)	7 (4%)	11 (7%)	10 (7%)

N = number of eyes returned for the visit with non-missing data.

TABLE 18.12
PERCENT CHANGE IN ECD STRATIFIED BY GUTTATA
IMT-IMPLANTED EYES
IMT-002

	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
Guttata Eyes						
N	26	26	25	24	22	21
Mean	-26%	-29%	-32%	-32%	-33%	-36%
95% CI	-36%, -16%	-38%, -20%	-41%, -23%	-42%, -22%	-44%, -23%	-47%, -25%
Non-Guttata Eyes						
N	167	172	165	162	158	150
Mean	-19%	-21%	-23%	-24%	-24%	-26%
95% CI	-22%, -16%	-24%, -18%	-26%, -20%	-28%, -21%	-28%, -21%	-30%, -23%

N = number of eyes returned for the visit with non-missing data.

TABLE 18.13
ECD STRATIFIED BY GUTTATA
IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
Guttata Eyes										
N	16	16	16	16	16	15	15	7	14	12
Mean	2415	1672	1678	1607	1535	1450	1464	1583	1285	1303
95% CI	2169, 2660	1322, 2023	1342, 2014	1270, 1943	1192, 1879	1110, 1790	1111, 1817	1166, 2001	959, 1610	947, 1659
ECD < 750	0 (0%)	1 (6%)	1 (6%)	1 (6%)	2 (13%)	2 (13%)	2 (13%)	0 (0%)	2 (14%)	1 (8%)
Non-Guttata Eyes										
N	107	100	104	103	103	103	99	63	87	76
Mean	2513	1979	1894	1909	1825	1854	1803	1728	1645	1670
95% CI	2445, 2580	1864, 2094	1776, 2011	1795, 2022	1710, 1940	1736, 1971	1682, 1923	1580, 1875	1524, 1766	1542, 1798
ECD < 750	0 (0%)	3 (3%)	7 (7%)	6 (6%)	6 (6%)	9 (9%)	9 (9%)	3 (5%)	7 (8%)	6 (8%)

N = number of eyes returned for the visit with non-missing data.

TABLE 18.14
PERCENT CHANGE IN ECD STRATIFIED BY GUTTATA
IMT-IMPLANTED EYES
IMT-002-LTM

	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
Guttata Eyes									
N	16	16	16	16	15	15	7	14	12
Mean	-30%	-30%	-33%	-36%	-39%	-38%	-34%	-47%	-44%
95% CI	-44%, -15%	-43%, -16%	-46%, -21%	-49%, -23%	-52%, -26%	-52%, -23%	-47%, -20%	-60%, -34%	-57%, -31%
Non-Guttata Eyes									
N	100	104	103	103	103	99	63	87	76
Mean	-21%	-25%	-24%	-27%	-26%	-28%	-31%	-34%	-34%
95% CI	-25%, -17%	-29%, -20%	-28%, -20%	-32%, -23%	-31%, -22%	-33%, -24%	-36%, -26%	-39%, -30%	-39%, -29%

N = number of eyes returned for the visit with non-missing data.

TABLE 18.15
ECD AND PERCENT CHANGE IN ECD
48-MONTH CONSISTENT COHORT OF NON-GUTTATA IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	39	39	39	39	39	39	39	39	39	39
ECD										
Mean	2556	2100	2015	1975	1889	1933	1918	1788	1738	1740
95% CI	2444, 2667	1911, 2289	1815, 2214	1785, 2165	1705, 2073	1757, 2108	1733, 2104	1600, 1976	1553, 1923	1552, 1928
Percent Change in ECD										
Mean		-18%	-21%	-23%	-26%	-24%	-25%	-30%	-32%	-32%
95% CI		-24%, -11%	-28%, -15%	-30%, -16%	-33%, -19%	-31%, -18%	-32%, -18%	-37%, -23%	-39%, -25%	-39%, -25%
ECD < 750	0 (0%)	1 (3%)	3 (8%)	3 (8%)	3 (8%)	2 (5%)	3 (8%)	1 (3%)	3 (8%)	4 (10%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.16
ECD STRATIFIED BY ACD
NON-GUTTATA IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
ACD < 3.0 mm							
N	68	65	65	62	59	58	55
Mean	2463	1944	1844	1859	1849	1874	1745
95% CI	2376, 2549	1801, 2088	1690, 1999	1708, 2011	1682, 2017	1699, 2049	1572, 1917
ECD < 750	0 (0%)	3 (5%)	5 (8%)	3 (5%)	3 (5%)	6 (10%)	7 (13%)
ACD ≥ 3.0 mm							
N	112	102	107	103	103	100	95
Mean	2534	2080	2046	1968	1935	1935	1907
95% CI	2473, 2596	1970, 2189	1945, 2146	1864, 2072	1831, 2039	1823, 2048	1795, 2019
ECD < 750	0 (0%)	2 (2%)	2 (2%)	4 (4%)	4 (4%)	5 (5%)	3 (3%)

N = number of eyes returned for the visit with non-missing data.

TABLE 18.17
PERCENT CHANGE IN ECD STRATIFIED BY ACD
NON-GUTTATA IMT-IMPLANTED EYES
IMT-002

	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
ACD < 3.0 mm						
N	65	65	62	59	58	55
Mean	-22%	-25%	-25%	-25%	-25%	-29%
95% CI	-26%, -17%	-31%, -20%	-30%, -20%	-31%, -20%	-31%, -19%	-35%, -23%
ACD ≥ 3.0 mm						
N	102	107	103	103	100	95
Mean	-18%	-19%	-22%	-24%	-24%	-25%
95% CI	-22%, -14%	-23%, -15%	-26%, -18%	-28%, -20%	-28%, -20%	-29%, -21%

N = number of eyes returned for the visit with non-missing data.

TABLE 18.18
ECD STRATIFIED BY ACD
NON-GUTTATA IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
ACD < 3.0 mm										
N	44	41	42	42	42	41	41	27	37	31
Mean	2421	1896	1706	1766	1701	1679	1590	1573	1477	1621
95% CI	2300, 2542	1711, 2081	1504, 1908	1571, 1960	1496, 1907	1475, 1883	1389, 1791	1329, 1817	1290, 1664	1400, 1843
ECD < 750	0 (0%)	2 (5%)	5 (12%)	3 (7%)	3 (7%)	6 (15%)	7 (17%)	2 (7%)	4 (11%)	2 (6%)
ACD ≥ 3.0 mm										
N	63	59	62	61	61	62	58	36	50	45
Mean	2577	2037	2020	2007	1910	1969	1953	1843	1769	1704
95% CI	2500, 2653	1887, 2187	1882, 2158	1871, 2142	1776, 2044	1831, 2107	1812, 2094	1659, 2027	1614, 1925	1544, 1864
ECD < 750	0 (0%)	1 (2%)	2 (3%)	3 (5%)	3 (5%)	3 (5%)	2 (3%)	1 (3%)	3 (6%)	4 (9%)

N = number of eyes returned for the visit with non-missing data.

TABLE 18.19
PERCENT CHANGE IN ECD STRATIFIED BY ACD
NON-GUTTATA IMT-IMPLANTED EYES
IMT-002-LTM

	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
ACD < 3.0 mm									
N	41	42	42	42	41	41	27	37	31
Mean	-22%	-30%	-28%	-30%	-31%	-34%	-34%	-40%	-35%
95% CI	-29%, -16%	-37%, -23%	-34%, -21%	-38%, -23%	-38%, -24%	-42%, -27%	-43%, -25%	-47%, -34%	-43%, -27%
ACD ≥ 3.0 mm									
N	59	62	61	61	62	58	36	50	45
Mean	-21%	-21%	-22%	-25%	-23%	-24%	-28%	-30%	-33%
95% CI	-26%, -15%	-26%, -16%	-27%, -17%	-31%, -20%	-29%, -18%	-30%, -19%	-35%, -22%	-36%, -24%	-39%, -27%

N = number of eyes returned for the visit with non-missing data.

TABLE 18.20
ECD AND PERCENT CHANGE IN ECD
48-MONTH CONSISTENT COHORT OF NON-GUTTATA IMT-IMPLANTED EYES
WITH ACD ≥ 3.00 MM
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	22	22	22	22	22	22	22	22	22	22
ECD										
Mean	2622	2191	2110	2030	1903	1964	1997	1877	1830	1803
95% CI	2484, 2760	1959, 2423	1857, 2364	1781, 2280	1673, 2133	1727, 2202	1735, 2259	1616, 2139	1561, 2098	1534, 2072
Percent Change in ECD										
Mean		-16%	-20%	-23%	-27%	-25%	-24%	-28%	-30%	-31%
95% CI		-25%, -8%	-29%, -11%	-32%, -13%	-36%, -19%	-34%, -16%	-34%, -14%	-38%, -19%	-40%, -20%	-41%, -22%
ECD < 750	0 (0%)	0 (0%)	1 (5%)	2 (9%)	2 (9%)	1 (5%)	2 (9%)	1 (5%)	2 (9%)	3 (14%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 18.21
ECD STRATIFIED BY SURGEON SPECIALTY
NON-GUTTATA IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
Non-Cornea Specialist							
N	127	121	119	119	115	113	109
Mean	2530	1986	1942	1895	1869	1884	1808
95% CI	2470, 2590	1881, 2091	1835, 2049	1789, 2001	1759, 1979	1766, 2002	1692, 1923
ECD < 750	0 (0%)	4 (3%)	5 (4%)	6 (5%)	6 (5%)	10 (9%)	9 (8%)
Cornea Specialist							
N	53	46	53	46	47	45	41
Mean	2452	2135	2033	2010	1989	1984	1954
95% CI	2360, 2544	1983, 2288	1887, 2178	1865, 2156	1838, 2139	1828, 2141	1791, 2117
ECD < 750	0 (0%)	1 (2%)	2 (4%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)

N = number of eyes returned for the visit with non-missing data.

TABLE 18.22
PERCENT CHANGE IN ECD STRATIFIED BY SURGEON SPECIALTY
NON-GUTTATA IMT-IMPLANTED EYES
IMT-002

	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
Non-Cornea Specialist						
N	121	119	119	115	113	109
Mean	-21%	-23%	-25%	-26%	-26%	-29%
95% CI	-25%, -18%	-27%, -19%	-29%, -22%	-30%, -23%	-30%, -21%	-33%, -25%
Cornea Specialist						
N	46	53	46	47	45	41
Mean	-13%	-17%	-18%	-19%	-20%	-20%
95% CI	-18%, -7%	-22%, -12%	-23%, -13%	-25%, -13%	-25%, -15%	-26%, -14%

N = number of eyes returned for the visit with non-missing data.

TABLE 18.23
ECD STRATIFIED BY SURGEON SPECIALTY
NON-GUTTATA IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
Non-Cornea Specialist										
N	79	77	76	77	77	77	74	48	69	57
Mean	2551	1971	1902	1893	1821	1841	1778	1713	1621	1638
95% CI	2475, 2627	1836, 2105	1761, 2044	1757, 2030	1684, 1959	1699, 1983	1635, 1922	1529, 1897	1478, 1763	1481, 1794
ECD < 750	0 (0%)	2 (3%)	5 (7%)	5 (6%)	5 (6%)	8 (10%)	8 (11%)	3 (6%)	6 (9%)	5 (9%)
Cornea Specialist										
N	28	23	28	26	26	26	25	15	18	19
Mean	2404	2006	1870	1953	1836	1891	1876	1775	1738	1769
95% CI	2261, 2548	1766, 2247	1646, 2094	1749, 2158	1615, 2056	1678, 2105	1645, 2107	1543, 2007	1508, 1969	1548, 1990
ECD < 750	0 (0%)	1 (4%)	2 (7%)	1 (4%)	1 (4%)	1 (4%)	1 (4%)	0 (0%)	1 (6%)	1 (5%)

N = number of eyes returned for the visit with non-missing data.

TABLE 18.24
PERCENT CHANGE IN ECD STRATIFIED BY SURGEON SPECIALTY
NON-GUTTATA IMT-IMPLANTED EYES
IMT-002-LTM

	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
Non-Cornea Specialist									
N	77	76	77	77	77	74	48	69	57
Mean	-23%	-26%	-26%	-29%	-28%	-30%	-33%	-36%	-37%
95% CI	-27%, -18%	-31%, -21%	-31%, -21%	-34%, -24%	-33%, -23%	-36%, -25%	-39%, -26%	-41%, -31%	-43%, -32%
Cornea Specialist									
N	23	28	26	26	26	25	15	18	19
Mean	-16%	-22%	-19%	-23%	-22%	-22%	-24%	-27%	-25%
95% CI	-26%, -7%	-30%, -13%	-27%, -11%	-32%, -14%	-29%, -14%	-31%, -13%	-32%, -16%	-37%, -17%	-34%, -16%

N = number of eyes returned for the visit with non-missing data.

TABLE 18.25
ECD AND PERCENT CHANGE IN ECD
48-MONTH NON-GUTTATA CONSISTENT COHORT OF IMT-IMPLANTED EYES IMPLANTED BY CORNEA SPECIALIST
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	9	9	9	9	9	9	9	9	9	9
ECD										
Mean	2370	2015	1993	2045	1973	1974	2048	1857	1764	1949
95% CI	2147, 2592	1637, 2394	1730, 2255	1778, 2311	1690, 2255	1711, 2237	1657, 2440	1576, 2138	1481, 2048	1667, 2231
Percent Change in ECD										
Mean		-14%	-15%	-13%	-16%	-16%	-13%	-21%	-25%	-17%
95% CI		-30%, 2%	-26%, -5%	-23%, -4%	-28%, -4%	-26%, -6%	-30%, 4%	-32%, -10%	-36%, -14%	-28%, -6%
ECD < 750										
ECD < 750	0 (0%)									

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 19.1
PAIRED ANALYSIS BETWEEN 12 TO 48 MONTHS FOR THE
DIFFERENCE IN ECD AND PERCENT CHANGE IN ECD BETWEEN
IMT-IMPLANTED EYES AND FELLOW EYES
IMT-002 AND IMT-002-LTM

	IMT-Implanted Eyes	Fellow Eyes	Difference Between IMT-Implanted and Fellow Eyes
ECD Change from 12 to 48 Months			
N	87	87	87
Mean	-158	-58	99
95% CI	-233, -82	-121, 5	4, 195
Percent Change in ECD from 12 to 48 Months			
Mean	-6%	-3%	3%
95% CI	-11%, -1%	-6%, 0%	-2%, 9%

Difference = Fellow Eye - IMT-implanted Eye.
 Subjects without ECD at 12 months or 48 Months were excluded.

TABLE 19.2
PAIRED ANALYSIS BETWEEN 12 TO 48 MONTHS FOR THE
DIFFERENCE IN ECD AND PERCENT CHANGE IN ECD BETWEEN
IMT-IMPLANTED EYES AND PHAKIC FELLOW EYES
IMT-002 AND IMT-002-LTM

	IMT-Implanted Eyes	Phakic Fellow Eyes	Difference Between IMT-Implanted and Fellow Eyes
ECD Change from 12 to 48 Months			
N	56	56	56
Mean	-171	-9	162
95% CI	-259, -82	-58, 41	58, 265
Percent Change in ECD from 12 to 48 Months			
Mean	-6%	-1%	5%
95% CI	-13%, 0%	-3%, 2%	-2%, 12%

Difference = Fellow Eye - IMT-implanted Eye.

Subjects without ECD at 12 months or 48 Months were excluded.

Phakic Fellow Eyes = Fellow eyes without IOL implants at the beginning of study or during the study.

TABLE 19.3
PAIRED ANALYSIS BETWEEN 12 TO 48 MONTHS FOR THE
DIFFERENCE IN ECD AND PERCENT CHANGE IN ECD BETWEEN
IMT-IMPLANTED EYES AND PSEUDOPHAKIC FELLOW EYES
IMT-002 AND IMT-002-LTM

	IMT-Implanted Eyes	Pseudophakic Fellow Eyes	Difference Between IMT-Implanted and Fellow Eyes
ECD Change from 12 to 48 Months			
N	31	31	31
Mean	-134	-148	-14
95% CI	-281, 13	-302, 5	-208, 181
Percent Change in ECD from 12 to 48 Months			
Mean	-7%	-7%	0%
95% CI	-15%, 1%	-14%, 1%	-9%, 10%

Difference = Fellow Eye - IMT-implanted Eye.

Subjects without ECD at 12 months or 48 Months were excluded.

Pseudophakic Fellow Eyes = Fellow eyes with IOL implants at the beginning of study or during the study.

TABLE 19.4
ECD AND PERCENT CHANGE IN ECD
FELLOW EYES OF OPERATED EYES
IMT-002 AND IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	214	194	198	191	191	183	175	80	110	97
ECD										
Mean	2436	2410	2404	2386	2386	2390	2358	2314	2283	2298
95% CI	2377, 2494	2350, 2471	2345, 2462	2322, 2449	2322, 2449	2320, 2460	2284, 2431	2204, 2425	2177, 2390	2189, 2407
Percent Change in ECD										
Mean		-1%	-1%	-2%	-2%	-2%	-3%	-6%	-6%	-6%
95% CI		-2%, 0%	-2%, 0%	-3%, -1%	-3%, -0%	-3%, 0%	-5%, -1%	-8%, -3%	-9%, -3%	-9%, -3%
ECD < 750	1 (0%)	1 (1%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2%)	2 (2%)

TABLE 19.5
ECD AND PERCENT CHANGE IN ECD
PHAKIC FELLOW EYES
IMT-002 AND IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	151	136	138	133	130	124	119	56	73	65
ECD										
Mean	2498	2481	2469	2460	2475	2486	2468	2393	2426	2452
95% CI	2439, 2557	2420, 2542	2409, 2528	2397, 2523	2413, 2538	2417, 2555	2399, 2537	2269, 2518	2321, 2530	2342, 2562
Percent Change in ECD										
Mean		-0%	-1%	-1%	-1%	-1%	-1%	-4%	-2%	-2%
95% CI		-2%, 1%	-2%, 0%	-3%, -0%	-2%, 0%	-3%, 0%	-3%, 1%	-6%, -2%	-5%, 0%	-5%, 1%
ECD < 750	0 (0%)	1 (1%)	0 (0%)							

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

Phakic Fellow Eyes = Fellow eyes without IOL implants at the beginning of study or during the study.

TABLE 19.6
ECD AND PERCENT CHANGE IN ECD
PSEUDOPHAKIC FELLOW EYES
IMT-002 AND IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	63	58	60	58	61	59	56	24	37	32
ECD										
Mean	2286	2244	2254	2215	2195	2186	2124	2130	2002	1986
95% CI	2152, 2421	2108, 2380	2122, 2386	2071, 2359	2058, 2332	2034, 2338	1960, 2288	1907, 2352	1782, 2222	1773, 2200
Percent Change in ECD										
Mean		-1%	-2%	-4%	-4%	-3%	-8%	-10%	-12%	-14%
95% CI		-3%, 1%	-4%, 1%	-6%, -1%	-7%, -0%	-7%, 2%	-12%, -4%	-16%, -4%	-18%, -6%	-20%, -8%
ECD < 750										
	1 (2%)	1 (2%)	0 (0%)	1 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)	2 (6%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

Phakic Fellow Eyes = Fellow eyes without IOL implants at the beginning of study or during the study.

TABLE 20.1
INCIDENCE OF RISK FACTORS IN EYES WITH MEAN ECD < 750 CELLS/MM²
IMT-IMPLANTED EYES
(WITHIN-EYE MEAN FROM 6 TO 48 MONTHS)
IMT-002 AND IMT-002-LTM

Presence of Guttata	1/10 (10.0%)
Learning Curve (First 5 Eyes of Any Surgeon)	7/10 (70.0%)
ACD < 3.0 mm	6/10 (60.0%)
Surgeon Specialty (Non-cornea Specialist)	8/10 (80.0%)

TABLE 20.2
COMBINATION OF RISK FACTORS IN EYES WITH MEAN ECD < 750 CELLS/MM²
IMT-IMPLANTED EYES
(WITHIN-EYE MEAN FROM 6 TO 48 MONTHS)
IMT-002 AND IMT-002-LTM

No Risk Factors	1/10 (10.0%)
One Risk factor	0/10 (0.0%)
Two Risk Factors	6/10 (60.0%)
Three Risk Factors	2/10 (20.0%)
Four Risk Factors	1/10 (10.0%)

TABLE 20.3
WITHIN-EYE MEAN ECD FOR 6 TO 48 MONTHS
PREDICTED PROBABILITY OF ECD < 750 CELLS/MM²
IMT-IMPLANTED EYES
IMT-002 AND IMT-002-LTM

Subset	Total Number of Eyes	Mean (SD) of Within-Eye Mean ECD cells/mm²	Number of Eyes with Within-Eye Mean ECD < 750 cells/mm²	% of Eyes with Within-Eye Mean ECD < 750 cells/mm²	95% Conf Interval¹ on % of Eyes with Within-Eye Mean ECD < 750 cells/mm²
IMT Eyes	201	1830.6 (571.7)	10	5.0%	(2.4%, 9.0%)
Non-Guttata Eyes	175	1861.9 (562.3)	9	5.1%	(2.4%, 9.5%)
Non-Guttata Eyes with Surgical Order >5	72	1902.1 (545.1)	3	4.2%	(0.9%, 11.7%)
Non-Guttata Eyes with ACD ≥3	108	1924.9 (513.3)	4	3.7%	(1.0%, 9.2%)
Non-Guttata Eyes Implanted by Cornea Specialists	53	1963.4 (524.8)	2	3.8%	(0.5%, 13.0%)
Non-Guttata Eyes ACD ≥3 Implanted by Cornea Specialists	36	2008.5 (484.5)	1	2.8%	(0.1%, 14.5%)

¹ Exact confidence interval per Clopper-Pearson method.

TABLE 20.4
WITHIN-EYE MEAN ECD FOR 6 TO 48 MONTHS
PREDICTED PROBABILITY OF ECD < 1000 CELLS/MM²
IMT-IMPLANTED EYES
IMT-002 AND IMT-002-LTM

Subset	Total Number of Eyes	Mean (SD) of Within-Eye Mean ECD cells/mm²	Number of Eyes with Within-Eye Mean ECD < 1000 cells/mm²	% of Eyes with Within-Eye Mean ECD < 1000 cells/mm²	95% Conf Interval¹ on % of Eyes with Within-Eye Mean ECD < 1000 cells/mm²
IMT Eyes	201	1830.6 (571.7)	22	10.9%	(7.0%, 16.1%)
Non-Guttata Eyes	175	1861.9 (562.3)	18	10.3%	(6.2%, 15.8%)
Non-Guttata Eyes with Surgical Order >5	72	1902.1 (545.1)	5	6.9%	(2.3%, 15.5%)
Non-Guttata Eyes with ACD ≥3	108	1924.9 (513.3)	7	6.5%	(2.6%, 12.9%)
Non-Guttata Eyes Implanted by Cornea Specialists	53	1963.4 (524.8)	3	5.7%	(1.2%, 15.7%)
Non-Guttata Eyes ACD ≥3 Implanted by Cornea Specialists	36	2008.5 (484.5)	1	2.8%	(0.1%, 14.5%)

¹ Exact confidence interval per Clopper-Pearson method.

TABLE 20.5A
PERCENT OF HEXAGONALITY
IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	206	193	198	190	186	180	171
Mean	59.3	56.2	56.7	57.2	58.0	57.5	57.4
95% CI	58.5, 60.1	55.4, 57.0	55.8, 57.5	56.4, 58.1	57.2, 58.9	56.5, 58.6	56.4, 58.5
%Hex < 45 (stress)	4 (2%)	7 (4%)	5 (3%)	4 (2%)	4 (2%)	5 (3%)	7 (4%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5B
PERCENT OF HEXAGONALITY
IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	123	116	120	119	119	118	114	69	101	88
Mean	59.4	56.4	56.2	57.8	58.0	57.5	57.4	58.9	57.5	58.2
95% CI	58.3, 60.5	55.3, 57.4	55.2, 57.3	56.6, 59.0	56.8, 59.1	56.2, 58.9	56.2, 58.5	57.3, 60.5	56.0, 58.9	56.6, 59.9
%Hex < 45 (stress)	3 (2%)	6 (5%)	3 (3%)	4 (3%)	3 (3%)	4 (3%)	3 (3%)	1 (1%)	5 (5%)	4 (5%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5C
PERCENT OF HEXAGONALITY
48-MONTH CONSISTENT COHORT
IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	43	43	43	43	43	43	43	43	43	43
Mean	59.6	58.9	56.4	58.2	59.2	58.9	57.4	59.3	58.0	58.4
95% CI	57.8, 61.4	57.7, 60.0	54.7, 58.0	56.6, 59.8	57.3, 61.0	56.6, 61.3	55.7, 59.0	57.5, 61.1	56.0, 60.0	55.6, 61.1
%Hex < 45 (stress)	1 (2%)	0 (0%)	1 (2%)	0 (0%)	1 (2%)	1 (2%)	0 (0%)	0 (0%)	2 (5%)	2 (5%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5D
PERCENT OF HEXAGONALITY
FELLOW EYES OF IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	204	191	196	191	188	181	173
Mean	59.5	59.5	59.7	59.8	60.0	60.0	59.1
95% CI	58.7, 60.3	58.8, 60.3	59.0, 60.5	59.0, 60.6	59.2, 60.7	59.1, 60.8	58.2, 59.9
%Hex < 45 (stress)	3 (1%)	0 (0%)	2 (1%)	0 (0%)	1 (1%)	3 (2%)	2 (1%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5E
PERCENT OF HEXAGONALITY
FELLOW EYES OF IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	121	116	118	119	120	118	115	71	101	90
Mean	59.5	59.7	60.1	60.0	60.0	60.1	59.1	59.0	59.5	59.7
95% CI	58.4, 60.5	58.7, 60.7	59.0, 61.2	58.9, 61.0	59.0, 61.0	59.0, 61.2	58.0, 60.2	57.6, 60.4	58.4, 60.6	58.5, 60.9
%Hex < 45 (stress)	2 (2%)	0 (0%)	2 (2%)	0 (0%)	0 (0%)	3 (3%)	1 (1%)	1 (1%)	0 (0%)	0 (0%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5F
COEFFICIENT OF VARIATION
IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	205	193	198	190	186	180	171
Mean	34.4	33.5	33.8	33.5	33.4	33.4	33.6
95% CI	33.8, 35.1	32.9, 34.2	33.2, 34.3	32.8, 34.2	32.7, 34.2	32.7, 34.1	32.8, 34.5
CV > 45 (stress)	8 (4%)	5 (3%)	2 (1%)	3 (2%)	5 (3%)	3 (2%)	3 (2%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5G
COEFFICIENT OF VARIATION
IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	122	116	120	119	119	118	114	70	101	88
Mean	34.0	33.2	33.6	33.0	33.1	33.3	33.6	33.5	33.6	32.6
95% CI	33.2, 34.9	32.3, 34.0	32.8, 34.4	32.0, 33.9	32.1, 34.0	32.4, 34.2	32.5, 34.7	32.1, 35.0	32.2, 35.1	31.5, 33.7
CV > 45 (stress)	3 (2%)	3 (3%)	1 (1%)	2 (2%)	4 (3%)	2 (2%)	3 (3%)	2 (3%)	7 (7%)	1 (1%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5H
COEFFICIENT OF VARIATION
48-MONTH CONSISTENT COHORT
IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	42	42	42	42	42	42	42	42	42	42
Mean	33.8	32.6	33.4	32.7	32.2	33.3	33.9	33.8	33.6	32.9
95% CI	32.6, 35.1	31.4, 33.8	32.1, 34.6	31.0, 34.3	31.0, 33.5	32.0, 34.6	32.5, 35.2	32.3, 35.3	31.4, 35.7	31.2, 34.7
CV > 45 (stress)	0 (0%)	4 (10%)	1 (2%)							

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5I
COEFFICIENT OF VARIATION
FELLOW EYES OF IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	203	191	196	191	188	181	173
Mean	34.3	35.0	35.1	34.8	35.0	34.8	35.3
95% CI	33.7, 34.9	34.3, 35.6	34.6, 35.7	34.2, 35.5	34.3, 35.7	34.2, 35.5	34.6, 35.9
CV > 45 (stress)	5 (2%)	7 (4%)	4 (2%)	5 (3%)	8 (4%)	8 (4%)	6 (3%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5J
COEFFICIENT OF VARIATION
FELLOW EYES OF IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	120	116	118	119	120	118	115	71	101	90
Mean	34.2	34.7	34.8	34.6	34.6	34.5	35.1	34.9	34.8	34.5
95% CI	33.4, 35.0	33.9, 35.6	34.1, 35.5	33.8, 35.4	33.8, 35.5	33.7, 35.3	34.2, 36.0	34.1, 35.8	34.0, 35.7	33.6, 35.3
CV > 45 (stress)	2 (2%)	3 (3%)	2 (2%)	2 (2%)	4 (3%)	3 (3%)	6 (5%)	1 (1%)	2 (2%)	0 (0%)

N = number of eyes returned for the visit with non-missing data. Only 3 eyes had the 30-month records and they were not included in the analyses.

TABLE 20.5K
CORNEA THICKNESS
IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	206	198	200	191	192	177	172
Mean	553	552	556	554	558	554	561
95% CI	548, 559	546, 558	550, 563	547, 561	549, 567	547, 562	553, 568

N = number of eyes returned for the visit with non-missing data.

TABLE 20.5L
CORNEA THICKNESS
IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	123	121	122	120	122	116	115	43	82	84
Mean	556	553	559	558	562	557	565	565	568	562
95% CI	549, 563	545, 561	550, 568	549, 567	549, 575	547, 566	556, 575	548, 581	554, 582	548, 577

N = number of eyes returned for the visit with non-missing data. The 30-month records were excluded in the analyses due to very small sample size.

TABLE 20.5M
CORNEA THICKNESS
48-MONTH CONSISTENT COHORT
IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	26	26	26	26	26	26	26	26	26	26
Mean	554	543	545	546	566	560	560	565	571	554
95% CI	537, 572	528, 558	529, 562	527, 565	537, 594	535, 585	537, 582	545, 586	545, 597	532, 577

TABLE 20.5N
CORNEA THICKNESS
FELLOW EYES OF IMT-IMPLANTED EYES
IMT-002

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	206	195	200	192	193	178	173
Mean	554	553	553	552	554	555	553
95% CI	549, 560	548, 559	548, 559	547, 558	548, 560	549, 561	547, 559

N = number of eyes returned for the visit with non-missing data. The 30-month records were excluded in the analyses due to very small sample size.

TABLE 20.50
CORNEA THICKNESS
FELLOW EYES OF IMT-IMPLANTED EYES
IMT-002-LTM

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months	42 Months	48 Months
N	123	120	122	120	122	116	115	43	81	84
Mean	557	557	557	556	558	557	556	557	557	553
95% CI	550, 564	551, 564	550, 565	549, 563	550, 565	550, 565	549, 563	543, 571	549, 566	544, 561

N = number of eyes returned for the visit with non-missing data. The 30-month records were excluded in the analyses due to very small sample size.

TABLE 21.1
BI-EXPONENTIAL MODEL FOR ECD
 $ECD_{\text{month}} = p \times e^{-a \times \text{month}} + q \times e^{-b \times \text{month}} + \varepsilon$
NON-GUTTATA IMT-IMPLANTED EYES WITH ACD ≥ 3 MM
BASED ON DATA FROM BASELINE TO 48 MONTHS
IMT-002 AND IMT-002-LTM

Parameter	Estimate	Approx Std Error	95% Lower	95% Upper	t-value	Approx Pr > t
p	506.7	65.5	378.1	635.3	7.7	<.001
a	0.5	0.2	0.1	1.0	2.5	0.012
q	2029.7	45.0	1941.4	2118.0	45.1	<.001
b	0.003	0.001	0.001	0.005	3.5	<.001

Annual ECD % Loss (90% CI) based on the slow exponential rate: 3.8% (2.0%, 5.5%).

TABLE 21.2
PREDICTED MEAN ECD BASED ON BI-EXPONENTIAL MODEL FOR
NON-GUTTATA IMT-IMPLANTED EYES WITH ACD \geq 3 MM
BASED ON DATA FROM BASELINE TO 48 MONTHS
IMT-002 AND IMT-002-LTM

Time	Mean ECD	90% Confidence Intervals
3 Months	2109.2	2029.4, 2189.0
12 Months	1954.0	1911.0, 1997.1
24 Months	1879.7	1842.2, 1917.3
36 Months	1808.9	1753.7, 1864.1
48 Months	1740.8	1660.4, 1821.2
60 Months	1675.2	1569.3, 1781.1

TABLE 21.3
PREDICTED PROBABILITY OF ECD LESS THAN THRESHOLD BASED ON
BI-EXPONENTIAL MODEL FOR
NON-GUTTATA IMT-IMPLANTED EYES WITH ACD \geq 3 MM
BASED ON DATA FROM BASELINE TO 48 MONTHS
IMT-002 AND IMT-002-LTM
(EXCLUDING PREOP RESIDUALS)

Probability of ECD			
Time	<1000	<750	< 500
3 Months	5.0	1.6	0.1
12 Months	7.1	3.2	0.9
24 Months	8.5	4.3	1.3
36 Months	8.9	6.1	1.9
48 Months	9.8	6.9	2.6
60 Months	10.5	7.7	3.5

The empirical frequency of residuals was used to estimate these probabilities.

TABLE 22.1
BI-EXPONENTIAL MODEL FOR ECD
 $ECD_{\text{month}} = p \times e^{-a \times \text{month}} + q \times e^{-b \times \text{month}} + \varepsilon$
IMT-IMPLANTED EYES
BASED ON DATA FROM BASELINE TO 48 MONTHS
IMT-002 AND IMT-002-LTM

Parameter	Estimate	Approx Std Error	95% Lower	95% Upper	t-value	Approx Pr > t
p	530.0	51.4	429.1	630.9	10.3	<.001
a	0.6	0.2	0.2	1.1	3.0	0.003
q	1967.1	34.2	1900.0	2034.3	57.5	<.001
b	0.004	0.001	0.003	0.006	5.6	<.001

Annual ECD % Loss (90% CI) based on the slow exponential rate: 4.8% (3.4%, 6.2%).

TABLE 22.2
PREDICTED MEAN ECD BASED ON BI-EXPONENTIAL MODEL FOR
IMT-IMPLANTED EYES
BASED ON DATA FROM BASELINE TO 48 MONTHS
IMT-002 AND IMT-002-LTM

Time	Mean ECD	90% Confidence Intervals
3 Months	2019.7	1955.5, 2083.9
12 Months	1872.2	1838.8, 1905.6
24 Months	1781.4	1752.0, 1810.9
36 Months	1695.3	1652.1, 1738.4
48 Months	1613.3	1551.8, 1674.8
60 Months	1535.3	1455.7, 1614.9

TABLE 22.3
PREDICTED PROBABILITY OF ECD LESS THAN THRESHOLD
BASED ON BI-EXPONENTIAL MODEL FOR IMT-IMPLANTED EYES DATA
BASED ON DATA FROM BASELINE TO 48 MONTHS
IMT-002 AND IMT-002-LTM
(EXCLUDING PREOP RESIDUALS)

Time	Probability of ECD		
	< 1000	< 750	< 500
3 Months	7.2	2.8	0.3
12 Months	9.4	5.0	1.4
24 Months	11.4	6.7	2.6
36 Months	13.1	8.2	3.9
48 Months	15.4	9.6	5.1
60 Months	17.4	11.4	6.7

The empirical frequency of residuals was used to estimate these probabilities.

TABLE 22.4
BI-EXPONENTIAL MODEL FOR ECD
 $ECD_{\text{month}} = p \times e^{-a \times \text{month}} + q \times e^{-b \times \text{month}} + \varepsilon$
IMT-IMPLANTED EYES
BASED ON DATA FROM BASELINE TO 54 MONTHS
IMT-002 AND IMT-002-LTM

Parameter	Estimate	Approx Std Error	95% Lower	95% Upper	t-value	Approx Pr > t
p	530.5	50.3	431.8	629.3	10.5	<.001
a	0.6	0.2	0.2	1.1	3.0	0.003
q	1966.5	32.6	1902.7	2030.4	60.4	<.001
b	0.004	0.001	0.003	0.005	6.3	<.001

Annual ECD % Loss (90% CI) based on the slow exponential rate: 4.8% (3.6%, 6.0%).

TABLE 22.5
PREDICTED MEAN ECD BASED ON BI-EXPONENTIAL MODEL
IMT-IMPLANTED EYES
BASED ON DATA FROM BASELINE TO 54 MONTHS
IMT-002 AND IMT-002-LTM

Time	Mean ECD	90% Confidence Intervals
3 Months	2019.7	1955.6, 2083.8
12 Months	1872.0	1838.7, 1905.3
24 Months	1781.5	1753.7, 1809.4
36 Months	1695.7	1658.1, 1733.2
48 Months	1614.0	1561.2, 1666.7
60 Months	1536.2	1467.9, 1604.4

TABLE 22.6
PREDICTED PROBABILITY OF ECD LESS THAN THRESHOLD BASED ON
BI-EXPONENTIAL MODEL
IMT-IMPLANTED EYES
BASED ON DATA FROM BASELINE TO 54 MONTHS
(EXCLUDING PREOP RESIDUALS)
IMT-002 AND IMT-002-LTM

Probability of ECD			
Time	< 1000	< 750	< 500
3 Months	7.2	2.7	0.3
12 Months	9.4	4.9	1.4
24 Months	11.3	6.6	2.5
36 Months	13.1	8.1	3.7
48 Months	15.3	9.6	4.9
60 Months	17.4	11.3	6.5

The empirical frequency of residuals was used to estimate these probabilities.

TABLE 23
OCULAR COMPLICATIONS OPERATED EYES
IMT-002

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Complications	Operative	Day 1	Day 7	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	Interim	Cumulative
	N = 217	N = 217	N = 215	N = 217	N = 207	N = 204	N = 196	N = 196	N = 180	N = 174	N = 114	N = 217
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Aborted surgery	5 (2.3%)	1 (0.5%)	0 (0.0%)	5 (2.3%)								
Anterior chamber hemorrhage	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Anterior segment neovascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.5%)
Anterior synechiae	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	2 (1.0%)	2 (1.0%)	2 (1.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	3 (1.4%)
Bleb	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Blepharitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.0%)	1 (0.5%)	3 (1.5%)	2 (1.1%)	3 (1.7%)	2 (1.8%)	7 (3.2%)
Blurred vision	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Chalazion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	2 (0.9%)
Choroidal detachment	2 (0.9%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	2 (0.9%)							
Choroidal hemorrhage	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Conjunctival injection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.4%)	1 (0.5%)	2 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	4 (1.8%)
Corneal abrasion	0 (0.0%)	3 (1.4%)	4 (1.9%)	4 (1.8%)	0 (0.0%)	2 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.6%)	11 (5.1%)
Corneal edema ≤ 30 days	0 (0.0%)	14 (6.5%)	7 (3.3%)	3 (1.4%)	0 (0.0%)	14 (6.5%)						
Corneal endothelial touch	2 (0.9%)	2 (0.9%)	0 (0.0%)	3 (1.4%)								
Cortical remnants	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	2 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (0.9%)
Cyclitic membrane ≤ 7 days	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.5%)							
Cyclodialysis cleft	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.6%)	1 (0.6%)	1 (0.9%)	1 (0.5%)
Descemet's membrane separation	3 (1.4%)	1 (0.5%)	0 (0.0%)	3 (1.4%)								

% = n/N × 100.

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

TABLE 23 (CONTINUED)
OCULAR COMPLICATIONS
OPERATED EYES
IMT-002

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Complications	Operative	Day 1	Day 7	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	Interim	Cumulative
	N = 217	N = 217	N = 215	N = 217	N = 207	N = 204	N = 196	N = 196	N = 180	N = 174	N = 114	N = 217
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Ectropion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (0.9%)
Endothelial folds	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.9%)	2 (0.9%)
Flat anterior chamber ≤ 21 days	2 (0.9%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	2 (0.9%)							
Folds in corneal graft	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Glaucoma	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	1 (0.9%)	1 (0.5%)
Haze	0 (0.0%)	1 (0.5%)	2 (0.9%)	2 (0.9%)	2 (1.0%)	2 (1.0%)	2 (1.0%)	2 (1.0%)	1 (0.6%)	2 (1.1%)	2 (1.8%)	2 (0.9%)
HypHEMA	0 (0.0%)	8 (3.7%)	3 (1.4%)	0 (0.0%)	1 (0.9%)	10 (4.6%)						
Hypotony	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	1 (0.5%)	1 (0.6%)	1 (0.6%)	2 (1.8%)	2 (0.9%)
IMT dislocation (intraoperative)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
IMT removal (intraoperative)	6 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (2.8%)
IMT replacement (interoperative)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Increased IOP requiring treatment ≤ 7 days	0 (0.0%)	51 (23.5%)	14 (6.5%)	0 (0.0%)	2 (1.8%)	59 (27.2%)						
Increased IOP ≤ 15 days	0 (0.0%)	2 (0.9%)	2 (0.9%)	0 (0.0%)	3 (1.4%)							
Iridotomy ≤ 7 days	2 (0.9%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.4%)
Iris atrophy ≤ 7 days	0 (0.0%)	3 (1.4%)	2 (0.9%)	0 (0.0%)	4 (1.8%)							
Iris damage	8 (3.7%)	6 (2.8%)	6 (2.8%)	6 (2.8%)	5 (2.4%)	5 (2.5%)	5 (2.6%)	4 (2.0%)	4 (2.2%)	4 (2.3%)	2 (1.8%)	8 (3.7%)
Iris incarceration	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.6%)	2 (1.1%)	0 (0.0%)	3 (1.4%)
Iris prolapse	6 (2.8%)	3 (1.4%)	3 (1.4%)	0 (0.0%)	2 (1.8%)	12 (5.5%)						

% = n/N × 100.

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

TABLE 23 (CONTINUED)
OCULAR COMPLICATIONS
OPERATED EYES
IMT-002

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Complications	Operative N = 217	Day 1 N = 217	Day 7 N = 215	1 Month N = 217	3 Months N = 207	6 Months N = 204	9 Months N = 196	12 Months N = 196	18 Months N = 180	24 Months N = 174	Interim N = 114	Cumulative N = 217
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Iris transillumination defects ≤ 21 days	0 (0.0%)	5 (2.3%)	6 (2.8%)	2 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (3.7%)
Iritis ≤ 30 days	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)
Ophthalmic migraine	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Peribulbar hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Peripapillary hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Phthisis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.5%)
Posterior capsular rupture	9 (4.1%)	2 (0.9%)	2 (0.9%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.8%)	10 (4.6%)
Posterior capsule opacification	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	6 (3.1%)	6 (3.1%)	8 (4.4%)	7 (4.0%)	1 (0.9%)	8 (3.7%)
Significant anterior chamber bleeding	3 (1.4%)	2 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.4%)
Strabismus surgery	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Surgical mydriasis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Suture rupture	0 (0.0%)	0 (0.0%)	2 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.8%)	4 (1.8%)
Uveitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Vitreous bulge	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Vitreous hemorrhage ≤ 7 days	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Vitreous in anterior chamber ≤ 7 days	0 (0.0%)	0 (0.0%)	3 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.4%)
Vitreous loss	3 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.4%)
Vitreous loss - vitrectomy required	7 (3.2%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (3.2%)

% = n/N × 100.

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

TABLE 23 (CONTINUED)
OCULAR COMPLICATIONS
OPERATED EYES ENROLLED
IMT-002

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Complications	Operative	Day 1	Day 7	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	Interim	Cumulative
	N = 217	N = 217	N = 215	N = 217	N = 207	N = 204	N = 196	N = 196	N = 180	N = 174	N = 114	N = 217
	n (%)											
Watery eyes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	2 (1.1%)	3 (1.7%)	1 (0.9%)	3 (1.4%)
Worsening of subretinal scarring	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)							
Wound leak	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	1 (0.9%)	3 (1.4%)						
Zonular dehiscence ≤ 7 days	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	1 (0.9%)	1 (0.5%)						

% = n/N × 100.

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

TABLE 24
OCULAR COMPLICATIONS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Aborted surgery	3 (2.3%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Afferent pupil defect	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Alternating exotropia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Anterior synechiae	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	1 (0.9%)
Asthenopia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Blepharitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	3 (2.4%)	2 (1.7%)
Chalazion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.9%)
Choroidal detachment	1 (0.8%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Choroidal hemorrhage	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Conjunctival injection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)							
Aborted surgery	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)
Afferent pupil defect	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Alternating exotropia	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.9%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Anterior synechiae	1 (0.9%)	1 (1.2%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)
Asthenopia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Blepharitis	3 (2.6%)	2 (2.4%)	3 (2.7%)	3 (2.8%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	6 (4.7%)
Chalazion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Choroidal detachment	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Choroidal hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Conjunctival injection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = $n/N \times 100$.

The same event could have been reported for a subject at multiple visits. "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 24 (CONTINUED)
OCULAR COMPLICATIONS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Corneal abrasion	0 (0.0%)	3 (2.3%)	4 (3.1%)	4 (3.1%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Corneal edema ≤ 30 days	0 (0.0%)	10 (7.8%)	6 (4.7%)	3 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Corneal endothelial touch	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Corneal neovascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Descemet's membrane separation	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ecchymoses on eyelid	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ectropion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Endothelial folds	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
Epithelial basement membrane dystrophy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Esotropia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)							
Corneal abrasion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (3.9%)	10 (7.8%)
Corneal edema ≤ 30 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (7.8%)
Corneal endothelial touch	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)
Corneal neovascularization	0 (0.0%)	1 (1.2%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Descemet's membrane separation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Ecchymoses on eyelid	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Ectropion	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Endothelial folds	1 (0.9%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)
Epithelial basement membrane dystrophy	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Esotropia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N × 100.

The same event could have been reported for a subject at multiple visits. "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 24 (CONTINUED)
OCULAR COMPLICATIONS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Flashes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Flat anterior chamber ≤ 21 days	1 (0.8%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Folds in corneal graft	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Glare	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Glaucoma	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)
Haze	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.9%)
Hyphema	0 (0.0%)	3 (2.3%)	2 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
IMT dislocation (intraoperative)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
IMT posteriorly positioned	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
IMT removal (intraoperative)	3 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)							
Flashes	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.9%)	1 (2.8%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Flat anterior chamber ≤ 21 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Folds in corneal graft	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Glare	0 (0.0%)	1 (1.2%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Glaucoma	1 (0.9%)	1 (1.2%)	1 (0.9%)	1 (0.9%)	1 (2.8%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Haze	1 (0.9%)	1 (1.2%)	2 (1.8%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)
Hyphema	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)
IMT dislocation (intraoperative)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
IMT posteriorly positioned	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
IMT removal (intraoperative)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N × 100.

The same event could have been reported for a subject at multiple visits. "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 24 (CONTINUED)
OCULAR COMPLICATIONS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N=129	N=129	N=128	N=129	N=125	N=124	N=122	N=124	N=117
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Increased IOP requiring treatment ≤ 7 days	0 (0.0%)	25 (19.4%)	9 (7.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increased IOP ≤ 15 days	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Iris atrophy ≤ 7 days	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Iris damage	5 (3.9%)	3 (2.3%)	3 (2.3%)	3 (2.3%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	2 (1.7%)
Iris incarceration	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.9%)
Iris prolapse	2 (1.6%)	2 (1.6%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Iris transillumination defects ≤ 21 days	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Meibomian gland dysfunction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ophthalmic migraine	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Peripapillary hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N=116	N=84	N=113	N=106	N=36	N=6	N=77	N=129
	n (%)	n (%)	n (%)					
Increased IOP requiring treatment ≤ 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	31 (24.0%)
Increased IOP ≤ 15 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Iris atrophy ≤ 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)
Iris damage	2 (1.7%)	2 (2.4%)	3 (2.7%)	4 (3.8%)	1 (2.8%)	1 (16.7%)	2 (2.6%)	6 (4.7%)
Iris incarceration	1 (0.9%)	1 (1.2%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)
Iris prolapse	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (3.9%)
Iris transillumination defects ≤ 21 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)
Meibomian gland dysfunction	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Ophthalmic migraine	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Peripapillary hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N × 100.

The same event could have been reported for a subject at multiple visits. "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 24 (CONTINUED)
OCULAR COMPLICATIONS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Posterior capsular rupture	5 (3.9%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Posterior capsule opacification	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	5 (4.1%)	5 (4.0%)	7 (6.0%)
Significant anterior chamber bleeding	2 (1.6%)	2 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Strabismus	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Strabismus surgery	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Superficial punctate keratitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Surgical mydriasis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	0 (0.0%)
Suture rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Treatment of PCO	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Uveitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)							
Posterior capsular rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (3.9%)
Posterior capsule opacification	8 (6.9%)	4 (4.8%)	8 (7.1%)	6 (5.7%)	3 (8.3%)	0 (0.0%)	1 (1.3%)	11 (8.5%)
Significant anterior chamber bleeding	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)
Strabismus	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Strabismus surgery	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Superficial punctate keratitis	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Surgical mydriasis	0 (0.0%)	1 (1.2%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Suture rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Treatment of PCO	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Uveitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = $n/N \times 100$.

The same event could have been reported for a subject at multiple visits. Posterior capsule opacification = at least two PCO reports from Slit Lamp findings at or after 9 months. "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 24 (CONTINUED)
OCULAR COMPLICATIONS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Uveitis/vitritis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vitreous hemorrhage ≤ 7 days	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vitreous in anterior chamber ≤ 7 days	0 (0.0%)	0 (0.0%)	3 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vitreous loss	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vitreous loss - vitrectomy required	3 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Watery eyes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	2 (1.7%)
Wound leak	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Zonular dehiscence ≤ 7 days	1 (0.8%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)							
Uveitis/vitritis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Vitreous hemorrhage ≤ 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Vitreous in anterior chamber ≤ 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)
Vitreous loss	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Vitreous loss - vitrectomy required	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)
Watery eyes	2 (1.7%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)
Wound leak	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Zonular dehiscence ≤ 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N × 100.

The same event could have been reported for a subject at multiple visits. "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 25
OCULAR COMPLICATIONS DENSITY
OPERATED EYES (N=217)
IMT-002

Page 1 of 2

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

TABLE 25 (CONTINUED)
OCULAR COMPLICATIONS DENSITY

OPERATED EYES (N=217)

IMT-002

Page 2 of 2

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

¹ Total Person-Year = Sum of follow-up days for subjects without the corresponding event and the follow-up days up to the date of the reported event for the subjects reported with the corresponding event, divided by 365.25. The follow-up day for each subject = last available visit date (or event reported date) - surgical date + 1. The "+ 1" was to consider the event reported at the surgical day.

² Density = Total Number of Eyes with Reports ÷ Total Person-Year × 100.

TABLE 26
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

TABLE 26 (CONTINUED)
OCULAR COMPLICATIONS DENSITY
OPERATED EYES (N = 129)
IMT-002-LTM

Page 2 of 2

Complications	Total Number of Eyes with Reports	Total Person-Year ¹	Rate per 100 Person-year (Density) ²
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
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

¹ Total Person-Year = Sum of follow-up days for subjects without the corresponding event and the follow-up days up to the date of the reported event for the subjects reported with the corresponding event, divided by 365.25. The follow-up day for each subject = last available visit date (or event reported date) - surgical date + 1. The "+ 1" was to consider the event reported at the surgical day.

² Density = Total Number of Eyes with Reports ÷ Total Person-Year × 100.

TABLE 27
OCULAR COMPLICATIONS

EYES WITH IMT NOT IMPLANTED (N=11)

Complications	Operative N = 11	Day 1 N = 11	Day 7 N = 10	1-Month N = 11	3 Months N = 6	6 Months N = 2	9 Months N = 0	12 Months N = 2	18 Months N = 0	24 Months N = 0	Interim N = 4	Cumulative N = 11
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Aborted surgery	5 (45.5%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			0 (0.0%)	5 (45.5%)
Choroidal detachment	2 (18.2%)	1 (9.1%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			0 (0.0%)	2 (18.2%)
Choroidal hemorrhage	1 (9.1%)	1 (9.1%)	1 (10.0%)	1 (9.1%)	1 (16.7%)	0 (0.0%)		0 (0.0%)			1 (25.0%)	1 (9.1%)
Cortical remnants	1 (9.1%)	1 (9.1%)	1 (10.0%)	1 (9.1%)	1 (16.7%)	0 (0.0%)		0 (0.0%)			1 (25.0%)	1 (9.1%)
Increased IOP requiring treatment ≤ 7 days	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			1 (25.0%)	2 (18.2%)
Iris damage	1 (9.1%)	1 (9.1%)	1 (10.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			1 (25.0%)	1 (9.1%)
Iritis ≤ 30 days	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			0 (0.0%)	1 (9.1%)
Posterior capsular rupture	7 (63.6%)	2 (18.2%)	2 (20.0%)	1 (9.1%)	1 (16.7%)	1 (50.0%)		0 (0.0%)			1 (25.0%)	7 (63.6%)
Vitreous hemorrhage ≤ 7 days	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			0 (0.0%)	1 (9.1%)
Vitreous loss	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			0 (0.0%)	2 (18.2%)
Vitreous loss - vitrectomy required	6 (54.5%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			0 (0.0%)	6 (54.5%)
Wound leak	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			0 (0.0%)	1 (9.1%)
Zonular dehiscence ≤ 7 days	1 (9.1%)	1 (9.1%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)			1 (25.0%)	1 (9.1%)

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

TABLE 28
OCULAR ADVERSE EVENTS
OPERATED EYES IMT-002

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Adverse Events	Operative	Day 1	Day 7	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	Interim	Cumulative
	N=217	N=217	N=215	N=217	N=207	N=204	N=196	N=196	N=180	N=174	N=114	N=217
	n (%)											
Anterior chamber inflammation > 30 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.4%)	2 (1.0%)	2 (1.0%)	2 (1.0%)	3 (1.7%)	0 (0.0%)	3 (2.6%)	6 (2.8%)
Anterior ischemic optic neuropathy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Choroidal neovascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Conjunctivitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (3.5%)	5 (2.3%)
Corneal decompensation > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.0%)	2 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)
Corneal edema > 30 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	3 (1.7%)	3 (2.6%)	6 (2.8%)
Cyclitic membrane > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Cystoid macular edema	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.5%)						
Decrease in visual acuity	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	2 (1.0%)	2 (1.0%)	2 (1.0%)	2 (1.0%)	2 (1.1%)	3 (1.7%)	2 (1.8%)	4 (1.8%)
Device failure	1 (0.5%)	2 (0.9%)	2 (0.9%)	0 (0.0%)	2 (0.9%)							
Diplopia	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	2 (1.0%)	2 (1.0%)	2 (1.0%)	2 (1.0%)	1 (0.6%)	2 (1.1%)	2 (1.8%)	3 (1.4%)
Distorted pupil	0 (0.0%)	3 (1.4%)	4 (1.9%)	4 (1.8%)	3 (1.4%)	5 (2.5%)	4 (2.0%)	4 (2.0%)	4 (2.2%)	4 (2.3%)	3 (2.6%)	9 (4.1%)
Dry eye	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	2 (1.0%)	2 (1.0%)	6 (3.1%)	4 (2.0%)	4 (2.2%)	4 (2.3%)	4 (3.5%)	10 (4.6%)
Entropion	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (0.9%)
Exposed suture	0 (0.0%)	3 (2.6%)	3 (1.4%)									
Eye pain	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.0%)	2 (1.0%)	1 (0.6%)	1 (0.6%)	3 (2.6%)	3 (1.4%)
Flat anterior chamber > 21 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.5%)
Floaters	0 (0.0%)	1 (0.5%)	1 (0.5%)	2 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.6%)	1 (0.6%)	1 (0.9%)	3 (1.4%)

% = n/N x100.

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

TABLE 28 (CONTINUED)
OCULAR ADVERSE EVENTS
OPERATED EYES
IMT-002

Page 2 of 3

Adverse Events	Operative	Day 1	Day 7	1-Month	3-Months	6 Months	9 Months	12-Months	18-Months	24-Months	Interim	Cumulative
	N=217 n (%)	N=217 n (%)	N=215 n (%)	N=217 n (%)	N=207 n (%)	N=204 n (%)	N=196 n (%)	N=196 n (%)	N=180 n (%)	N=174 n (%)	N=114 n (%)	N=217 n (%)
Focal striae	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	1 (0.5%)							
Foreign body sensation	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	2 (1.0%)	4 (2.0%)	4 (2.0%)	4 (2.0%)	4 (2.2%)	3 (1.7%)	7 (6.1%)	9 (4.1%)
Guttae	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	7 (3.4%)	8 (4.1%)	13 (6.6%)	11 (6.1%)	11 (6.3%)	3 (2.6%)	16 (7.4%)
IMT dislocation	0 (0.0%)	0 (0.0%)	2 (0.9%)	2 (0.9%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (0.9%)
IMT removal	0 (0.0%)	8 (7.0%)	8 (3.7%)									
Increased IOP requiring treatment > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (2.3%)	2 (1.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.6%)	2 (1.1%)	3 (2.6%)	7 (3.2%)
Inflammatory deposits on IMT	0 (0.0%)	2 (0.9%)	9 (4.2%)	2 (0.9%)	5 (2.4%)	18 (8.8%)	21 (10.7%)	25 (12.8%)	24 (13.3%)	13 (7.5%)	6 (5.3%)	51 (23.5%)
Inflammatory membrane	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	1 (0.5%)	1 (0.6%)	1 (0.6%)	1 (0.9%)	1 (0.5%)
Iridotomy > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.9%)	3 (1.4%)
Iris atrophy > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.8%)	4 (1.9%)	4 (2.0%)	3 (1.5%)	7 (3.6%)	7 (3.9%)	7 (4.0%)	2 (1.8%)	8 (3.7%)
Iris transillumination defects > 21 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (2.3%)	9 (4.3%)	9 (4.4%)	9 (4.6%)	9 (4.6%)	8 (4.4%)	8 (4.6%)	2 (1.8%)	12 (5.5%)
Iritis > 30 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.4%)	2 (1.0%)	1 (0.5%)	0 (0.0%)	4 (2.2%)	1 (0.6%)	7 (6.1%)	12 (5.5%)
Keratic precipitates on IMT > 30 days	0 (0.0%)	1 (0.6%)	2 (1.8%)	3 (1.4%)								
Obstructed iridectomy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Ocular allergy	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Pigment deposits on IMT	0 (0.0%)	1 (0.5%)	2 (0.9%)	1 (0.5%)	3 (1.4%)	4 (2.0%)	12 (6.1%)	12 (6.1%)	14 (7.8%)	8 (4.6%)	4 (3.5%)	23 (10.6%)
Pigment epithelium around the peripheral iridectomy > 30 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Posterior synechiae	0 (0.0%)	0 (0.0%)	4 (1.9%)	4 (1.8%)	7 (3.4%)	9 (4.4%)	8 (4.1%)	8 (4.1%)	7 (3.9%)	6 (3.4%)	4 (3.5%)	15 (6.9%)

% = n/N x 100.

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

TABLE 28 (CONTINUED)
OCULAR ADVERSE EVENTS
OPERATED EYES
IMT-002

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Adverse Events	Operative N = 217	Day 1 N = 217	Day 7 N = 215	1 Month N = 217	3 Months N = 207	6 Months N = 204	9 Months N = 196	12 Months N = 196	18 Months N = 180	24 Months N = 174	Interim N = 114	Cumulative N = 217
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Ptosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.6%)	2 (1.1%)	2 (1.8%)	4 (1.8%)
Secondary glaucoma	0 (0.0%)	0 (0.0%)	2 (0.9%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)
Subconjunctival hemorrhage	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (5.3%)	9 (4.1%)
Subretinal hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	3 (1.4%)
Synechiae	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Tearing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Visual disturbance	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Vitreous flare	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Vitreous hemorrhage > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.8%)	3 (1.4%)
Vitreous in anterior chamber > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.4%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	4 (1.8%)
Zonular dehiscence > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)

% = n/N × 100.

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

TABLE 29
OCULAR ADVERSE EVENTS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Anterior chamber inflammation > 30 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	2 (1.7%)
Choroidal neovascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Conjunctivitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Corneal decompensation > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)	2 (1.6%)	0 (0.0%)
Corneal edema > 30 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
Corneal transplant	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Decrease in visual acuity	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.9%)
Diplopia	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	2 (1.6%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.9%)
Distorted pupil	0 (0.0%)	1 (0.8%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	3 (2.4%)	2 (1.6%)	2 (1.6%)	2 (1.7%)
Dry eye	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	3 (2.5%)	3 (2.4%)	3 (2.6%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)							
Anterior chamber inflammation > 30 days	0 (0.0%)	1 (1.2%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (5.2%)	4 (3.1%)
Choroidal neovascularization	0 (0.0%)	1 (1.2%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	3 (2.3%)
Conjunctivitis	0 (0.0%)	1 (1.2%)	2 (1.8%)	1 (0.9%)	1 (2.8%)	0 (0.0%)	3 (3.9%)	5 (3.9%)
Corneal decompensation > 7 days	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	4 (3.1%)
Corneal edema > 30 days	3 (2.6%)	4 (4.8%)	7 (6.2%)	3 (2.8%)	1 (2.8%)	0 (0.0%)	6 (7.8%)	13 (10.1%)
Corneal transplant	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)
Decrease in visual acuity	1 (0.9%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Diplopia	1 (0.9%)	1 (1.2%)	2 (1.8%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	3 (2.3%)
Distorted pupil	2 (1.7%)	4 (4.8%)	4 (3.5%)	4 (3.8%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	6 (4.7%)
Dry eye	3 (2.6%)	3 (3.6%)	2 (1.8%)	2 (1.9%)	1 (2.8%)	0 (0.0%)	2 (2.6%)	6 (4.7%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = $n/N \times 100$.

The same event could have been reported for a subject at multiple visits. "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 29 (CONTINUED)
OCULAR ADVERSE EVENTS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Entropion	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Exposed suture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Eye pain	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.9%)
Flat anterior chamber > 21 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.9%)
Floaters	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.9%)
Focal striae	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Foreign body sensation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	2 (1.7%)
Guttae	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	4 (3.2%)	6 (4.9%)	9 (7.3%)	8 (6.8%)
IMT dislocation	0 (0.0%)	0 (0.0%)	2 (1.6%)	2 (1.6%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	0 (0.0%)
IMT removal	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Entropion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Exposed suture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	2 (1.6%)
Eye pain	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	2 (1.6%)
Flat anterior chamber > 21 days	1 (0.9%)	1 (1.2%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Floaters	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)
Focal striae	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)
Foreign body sensation	1 (0.9%)	1 (1.2%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	5 (6.5%)	5 (3.9%)
Guttae	8 (6.9%)	6 (7.1%)	13 (11.5%)	12 (11.3%)	3 (8.3%)	0 (0.0%)	3 (3.9%)	16 (12.4%)
IMT dislocation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (3.9%)	4 (3.1%)
IMT removal	0 (0.0%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (9.1%)	7 (5.4%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N x 100.

The same event could have been reported for a subject at multiple visits. "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 29 (CONTINUED)
OCULAR ADVERSE EVENTS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)	n (%)	n (%)	n (%)					
Increased IOP requiring treatment > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.9%)
Iridotomy > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.9%)
Iris atrophy > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	2 (1.6%)	5 (4.0%)	4 (3.4%)
Iris transillumination defects > 21 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	4 (3.2%)	4 (3.2%)	4 (3.3%)	5 (4.0%)	4 (3.4%)
Iritis > 30 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	4 (3.4%)
Ocular allergy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Posterior synechiae	0 (0.0%)	0 (0.0%)	3 (2.3%)	3 (2.3%)	5 (4.0%)	4 (3.2%)	4 (3.3%)	5 (4.0%)	5 (4.3%)
Precipitates or deposits on IMT	0 (0.0%)	2 (1.6%)	6 (4.7%)	2 (1.6%)	4 (3.2%)	14 (11.3%)	22 (18.0%)	28 (22.6%)	30 (25.6%)
Ptosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Secondary glaucoma	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Increased IOP requiring treatment > 7 days	2 (1.7%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	4 (3.1%)
Iridotomy > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)
Iris atrophy > 7 days	4 (3.4%)	4 (4.8%)	4 (3.5%)	4 (3.8%)	1 (2.8%)	1 (16.7%)	2 (2.6%)	6 (4.7%)
Iris transillumination defects > 21 days	4 (3.4%)	5 (6.0%)	4 (3.5%)	2 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (3.9%)
Iritis > 30 days	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (6.5%)	9 (7.0%)
Ocular allergy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Posterior synechiae	4 (3.4%)	3 (3.6%)	7 (6.2%)	4 (3.8%)	1 (2.8%)	1 (16.7%)	3 (3.9%)	15 (11.6%)
Precipitates or deposits on IMT	19 (16.4%)	11 (13.1%)	16 (14.2%)	19 (17.9%)	5 (13.9%)	1 (16.7%)	12 (15.6%)	49 (38.0%)
Ptosis	1 (0.9%)	1 (1.2%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)
Secondary glaucoma	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N x 100.

The same event could have been reported for a subject at multiple visits. "Inflammatory deposits on IMT", "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 29 (CONTINUED)
OCULAR ADVERSE EVENTS
OPERATED EYES
IMT-002-LTM

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Subconjunctival hemorrhage	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
Subretinal hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Visual disturbance	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vitreous flare	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vitreous hemorrhage > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vitreous in anterior chamber > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Zonular dehiscence > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)							
Subconjunctival hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (6.5%)	8 (6.2%)
Subretinal hemorrhage	0 (0.0%)	1 (1.2%)	2 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	3 (2.3%)
Visual disturbance	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Vitreous flare	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Vitreous hemorrhage > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Vitreous in anterior chamber > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (3.1%)
Zonular dehiscence > 7 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = $n/N \times 100$.

The same event could have been reported for a subject at multiple visits. "Pigment deposits on IMT", and "Keratic precipitates on IMT" were combined to "Precipitates or deposits on IMT".

TABLE 30
OCULAR ADVERSE EVENTS DENSITY
OPERATED EYES (N=217)
IMT-002

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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
Corneal decompensation > 7 days	2	338.4	0.59
Corneal 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

¹ Total Person-Year = Sum of follow-up days for subjects without the corresponding event and the follow-up days up to the date of the reported event for the subjects reported with the corresponding event, divided by 365.25. The follow-up day for each subject = last available visit date (or event reported date) - surgical date + 1. The "+ 1" was to consider the event reported at the surgical day.

² Density = Total Number of Eyes with Reports ÷ Total Person-Year × 100.

TABLE 30 (CONTINUED)
OCULAR ADVERSE EVENTS DENSITY
OPERATED EYES (N=217)
IMT-002

Page 2 of 2

Adverse Events	Total Number of Eyes with Reports	Total Person-Year ¹	Rate per 100 Person-year (Density) ²
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

¹ Total Person-Year = Sum of follow-up days for subjects without the corresponding event and the follow-up days up to the date of the reported event for the subjects reported with the corresponding event, divided by 365.25. The follow-up day for each subject = last available visit date (or event reported date) - surgical date + 1. The "+ 1" was to consider the event reported at the surgical day.

² Density = Total Number of Eyes with Reports ÷ Total Person-Year × 100.

TABLE 31
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
Corneal decompensation > 7 days	4	381.8	1.05
Corneal edema > 30 days	13	371.4	3.50
Corneal 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

¹ Total Person-Year = Sum of follow-up days for subjects without the corresponding event and the follow-up days up to the date of the reported event for the subjects reported with the corresponding event, divided by 365.25. The follow-up day for each subject = last available visit date (or event reported date) - surgical date + 1. The "+ 1" was to consider the event reported at the surgical day.

² Density = Total Number of Eyes with Reports ÷ Total Person-Year × 100.

TABLE 31 (CONTINUED)
OCULAR ADVERSE EVENTS DENSITY
OPERATED EYES (N = 129)
IMT-002-LTM

Page 2 of 2

Adverse Events	Total Number of Eyes with Reports	Total Person-Year ¹	Rate per 100 Person-year (Density) ²
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

¹ Total Person-Year = Sum of follow-up days for subjects without the corresponding event and the follow-up days up to the date of the reported event for the subjects reported with the corresponding event, divided by 365.25. The follow-up day for each subject = last available visit date (or event reported date) - surgical date + 1. The "+ 1" was to consider the event reported at the surgical day.

² Density = Total Number of Eyes with Reports ÷ Total Person-Year × 100.

TABLE 32.1
OCCURRENCES OF LATE CORNEAL EDEMA WITH (EARLY) ECD LOSS (N = 12)

Page 1 of 3

Patient ID	Time of Late Corneal Edema Observation	ECD (cells/mm ²)		Corneal Thickness (microns)		Surgical Order	Complication & Relevant Perioperative Findings
		Preop		Preop			
001-202 (IMT-002-LTM)	42 Months	Preop	2642	Preop	546	≥ 4 Cases	3+Edema at D1 1+Edema at 42M 1+Edema at 48M 1+Edema at 52M Increased IOP requiring treatment ≤ 7 days
		6M	2274	3M	574		
		9M	2326	6M	561		
		12M	1855	9M	578		
		18M	1929	12M	569		
		24M	1011	18M	586		
		42M	508	24M	597		
		48M	660	48M	656		
		52M	556	52M	642		
60M	505						
001-208 (IMT-002-LTM)	36 Months	Preop	2908	Preop	607	≥ 4 Cases	1+Edema at D7 1+Edema at 3M 1+Edema at 9M 1+Edema at 12M 1+Edema at 18M 2+Edema at 24M 4+Edema at 36M 3+Edema at 42M 4+Edema at 48M Increased IOP requiring treatment ≤ 7 days
		3M	432	3M	621		
		6M	452	6M	677		
		9M	397	9M	601		
		12M	361	12M	694		
		18M	351	18M	700		
				24M	771		
				42M	771		
				48M	920		
003-201 (IMT-002)	24 Months	Preop	2763	Preop	516	First 1-3 Cases	2+Edema at D1 1+Edema at D7 2+Edema at 24M 3+Edema at 42M Iris damage
		3M	1684	3M	528		
		6M	1380	6M	508		
		9M	1070	9M	516		
		12M	845	12M	499		
		18M	604	18M	569		
		24M	529	24M	580		
				48M	550		
		52M	558				
		60M	602				
008-211 (IMT-002-LTM)	36 Months	Preop	2457	Preop	524	≥ 4 Cases	2+Edema at D1 1+Edema at 1M 1+Edema at 36M 1+Edema at 42M 1+Edema at 48M Choroidal hemorrhage, vitreous hemorrhage ≤ 7 days, intraop. IMT removal
		6M	1906	3M	546		
		Post IMT R	1354	6M	546		
		Post IMT R	1861				
		Post IMT R	1106				
		Post IMT R	1480				

TABLE 32.1 (CONTINUED)

OCCURRENCES OF LATE CORNEAL EDEMA WITH (EARLY) ECD LOSS (N = 12)

Patient ID	Time of Late Corneal Edema Observation	ECD (cells/mm ²)		Corneal Thickness (microns)		Surgical Order	Complication & Relevant Perioperative Findings
012-212 (IMT-002)	24 Months	Preop	2455	Preop	546	≥ 4 Cases	1+Edema at D1 1+Edema at 24M 1+Edema at 42M Precipitates or Deposits on IMT
		3M	2211	3M	542		
		6M	1074	6M	559		
		9M	1048	9M	567		
		12M	955	12M	633		
		18M	553	18M	662		
		24M	519	24M	716		
		42M	618	36M	658		
		48M	719	42M	724		
				48M	633		
013-209 (IMT-002)	9 Months	Preop	1909	Preop	553	≥ 4 Cases	2+Edema at D1 2+Edema at D7 2+Edema at 9M 2+Edema at 12M Anterior synechiae, flat anterior chamber
		3M	633	3M	565		
		6M	463	6M	635		
		Post CT	3442	9M	730		
		Post CT	3133	12M	155		
		Post CT	2984	42M	533		
		Post CT	3128	48M	532		
		Post CT	2483				
		Post CT	1987				
		Post CT	1529				
Post CT	1264						
022-203 (IMT-002-LTM)	48 Months	Preop	2465	Preop	551	First 1-3 Cases	1+Edema at 48M
		3M	782	3M	590		
		6M	431	6M	626		
		9M	309	9M	708		
		12M	311	12M	736		
		18M	664	18M	641		
		24M	503	24M	611		
		36M	823	42M	706		
		42M	594	48M	741		
48M	501						
022-205 (IMT-002-LTM)	36 Months	Preop	2774	Preop	565	≥ 4 Cases	3+Edema at 36M 3+Edema at 42M Increased IOP requiring treatment ≤ 7 days
		6M	2566	3M	585		
		9M	2814	6M	590		
		12M	2959	9M	596		
		18M	2748	12M	599		
		24M	2860	18M	605		
		36M	2444	24M	640		
		42M	841	36M	655		
		48M	2153	42M	770		
		52M	1405	48M	534		

Post IMT R = Post IMT Removal. Post CT=Post corneal transplant.

TABLE 32.1 (CONTINUED)
OCCURRENCES OF LATE CORNEAL EDEMA WITH (EARLY) ECD LOSS (N = 12)

Page 3 of 3

Patient ID	Time of Late Corneal Edema Observation	ECD (cells/mm ²)		Corneal Thickness (microns)		Surgical Order	Complication & Relevant Perioperative Findings
026-202 (IMT-002)	24 Months	Preop	2738	Preop	557	First 1-3 Cases	1+Edema at D1 1+Edema at D7 1+Edema at 24M 1+Edema at 42M
		3M	1315	3M	519		
		6M	846	6M	619		
		9M	656	9M	646		
		12M	446	12M	604		
		18M	628	24M	715		
		24M	676	48M	598		
		42M	983				
026-209 (IMT-002-LTM)	55 Months	Preop	2463	Preop	599	≥ 4 Cases	1+Edema at D1 Increased IOP requiring treatment ≤ 7 days Vitreous in anterior chamber ≤ 7 days
		3M	1901	3M	536		
		6M	1554	6M	559		
		9M	1170	9M	658		
		12M	901	12M	588		
		18M	638	18M	534		
		24M	544	24M	640		
		36M	386	42M	553		
026-212 (IMT-002-LTM)	36 Months	Preop	1769	Preop	600	≥ 4 Cases	3+Edema at 36M 2+Edema at 42M
		3M	916	3M	576		
		6M	646	6M	705		
		9M	531	9M	433		
		12M	519	12M	570		
		18M	457	18M	589		
		24M	505	24M	631		
		36M	324	42M	712		
031-203 (IMT-002)	3 Months	Preop	2118	Preop	607	First 1-3 Cases	3+Edema at D1 2+Edema at D7 1+Edema at 1M 1+Edema at 3M 1+Edema at 6M 3+Edema at 9M IMT dislocation, Increased IOP requiring treatment ≤ 7 days, iris atrophy ≤ 7 days
		6M	385	3M	706		
		Post CT	1857	6M	742		
				12M	955		
				36M	641		
				42M	622		
				48M	622		

Post IMT R = Post IMT Removal. Post CT=Post corneal transplant.

TABLE 32.2
OCCURRENCES OF LATE CORNEAL EDEMA WITH NO ECD LOSS
FOLLOWING IMT IMPLANTATION
(N = 1)

Patient ID	Time of Late Corneal Edema Observation	ECD (cells/mm ²)		Corneal Thickness (microns)		Surgical Order	Complication & Relevant Perioperative Findings
011-203 (IMT-002)	7 Months	Preop	2860	Preop	610	First 1-3 Cases	Corneal edema (no grade) and iritis reported at 7 months. Corneal edema not observed at 12 and 36 months.
		3M	2694	3M	602		
		6M	2737	6M	607		
		9M	2816	9M	592		
		12M	2434	12M	595		
		36M	2336	36M	593		

TABLE 33
PREOPERATIVE AND LAST AVAILABLE BCDVA
EYES THAT UNDERWENT POSTOPERATIVE IMT REMOVAL (N = 12)

Page 1 of 2

Patient ID	Explant Date (Months from Date of Implant)	Preop BCDVA (LogMAR)	Last Available BCDVA (LogMAR) Post Explant	ECD Prior to Explant	ECD Most Recent Visit Post Explant	Comments
Subject Dissatisfaction						
001-209	03/29/2006 (31 Months)	20/604 (1.48)	20/399 (1.30)	2544	1926	Patient was dissatisfied with IMT.
001-213	05/03/2006 (31 Months)	20/551 (1.44)	20/726 (1.56)	1675	1454	Patient was dissatisfied with IMT.
004-203	02/24/2005 (22 Months)	20/502 (1.40)	20/276 (1.14)	1772	666	Patient was dissatisfied with IMT.
008-207	04/19/2004 (10 Months)	20/317 (1.20)	20/289 (1.16)	1625	1100	Patient was dissatisfied with IMT.
008-208	06/30/2004 (12 Months)	20/219 (1.04)	20/240 (1.08)	2891	2199	Patient was dissatisfied with IMT.
010-206	08/16/2004 (12 Months)	20/381 (1.28)	NAV	1858	NAV	Patient was dissatisfied with IMT. No BCDVA reported post IMT removal.
012-210	02/08/2005 (19 Months)	20/276 (1.14)	20/166 (0.92)	2408	1389	Patient was dissatisfied with IMT.
020-210	03/08/2007 (41 Months)	20/200 (1.00)	NAV	2258	NAV	Patient was dissatisfied with IMT. No BCDVA reported post IMT removal
Device Failure or Corneal Decompensation						
013-202	03/24/2003 (1 Month)	20/348 (1.24)	NAV	2316	NAV	Postoperative IMT removal due to device failure (condensation). No BCDVA reported post IMT removal.
023-217	11/18/2003 (1 Month)	20/348 (1.24)	20/458 (1.36)	2529	1234	Postoperative IMT removal due to device failure (condensation).

NAV = not available.

TABLE 33 (CONTINUED)
PREOPERATIVE AND LAST AVAILABLE BCDVA
EYES THAT UNDERWENT POSTOPERATIVE IMT REMOVAL (N = 12)

Page 2 of 2

Patient ID	Explant Date (Months from Date of Implant)	Preop BCDVA (LogMAR)	Last Available BCDVA (LogMAR) Post-Explant	ECD Prior to Explant	ECD Most Recent Visit Post Explant	Comments
013-209	09/01/2004 (12 Months)	20/303 (1.18)	20/348 (1.24)	463	1264	Postoperative IMT removal due to corneal decompensation, PKP
031-203	08/10/2004 (10 Months)	20/551 (1.44)	20/1002 (1.70)	385	1857	Postoperative IMT removal due to corneal decompensation, PKP. Last available BCDVA was reported 8 days post IMT removal

NAV = not available.

TABLE 34
SECONDARY SURGICAL INTERVENTIONS IN IMT-IMPLANTED EYES

SUBJECT ID	ADVERSE EVENT	SEVERITY	INTERVENTION	OUTCOME
001-209	Pigment deposits on IMT	Moderate	YAG laser to anterior surface of IMT	Event resolved with no sequelae
004-204	Iridotomy > 7 days	Mild	Re-open PI with YAG laser	Event resolved with no sequelae
005-201	Iridotomy > 7 days	Mild	Re-open PI with YAG laser	Event resolved with no sequelae
005-202	Iritis > 30 days	Mild	Re-open PI with YAG laser	Event resolved with no sequelae
005-203	Pigment epithelium around the peripheral iridectomy > 30 days	Mild	Re-open PI with YAG laser	Event resolved with no sequelae
014-202	Decrease in visual acuity	Moderate	Cortical fragment removed	Event resolved with no sequelae, ie, visual acuity improved after cortical fragment removal
026-203	Distorted pupil	Moderate	Surgery to repair	Event resolved with no sequelae

TABLE 35
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002 STUDY

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	Operative N=217	Day 1 N=217	Day 7 N=215	1 Month N=217	3 Months N=207	6 Months N=204	9 Months N=196	12 Months N=196	18 Months N=180	24 Months N=174	Interim N=114	Cumulative N=217
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abdominal problems	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Angiography-3 stents	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Arrhythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.1%)	0 (0.0%)	1 (0.9%)	5 (2.3%)
Blood in stool	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Bradycardia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Bronchitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	2 (1.1%)	0 (0.0%)	4 (1.8%)
CVA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
CVA-TIA	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (1.8%)	4 (1.8%)
Cancer	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	2 (1.1%)	1 (0.6%)	5 (4.4%)	12 (5.5%)
Cardiac arrest	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Carotid surgery	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Chest pain	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Cholecystectomy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Confusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Congestive heart failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.9%)	2 (0.9%)
Contusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (8.8%)	10 (4.6%)
Decreased mobility	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)

% = n/N x 100.

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

TABLE 35 (CONTINUED)
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002 STUDY

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	Operative	Day 1	Day 7	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	Interim	Cumulative
	N=217	N=217	N=215	N=217	N=207	N=204	N=196	N=196	N=180	N=174	N=114	N=217
	n (%)											
Depression	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	2 (1.8%)	2 (0.9%)
Diabetes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)
Facial nerve paralysis	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Fractured femur	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Fractured heel bone	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Fractured hip	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.5%)								
Fractured toe	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Fractured wrist	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Headache	0 (0.0%)	2 (1.8%)	2 (0.9%)									
Hearing loss	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Hematuria	0 (0.0%)	1 (0.6%)	1 (0.9%)	1 (0.5%)								
Hip replacement	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Hospitalization	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Hypercholesterolemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Hypertension	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (1.8%)	4 (1.8%)
Hypotension	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (0.9%)
Incontinence	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (0.5%)	1 (0.6%)	1 (0.6%)	2 (1.8%)	6 (2.8%)

% = n/N x 100.

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

TABLE 35 (CONTINUED)
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002 STUDY

Page 3 of 4

	Operative	Day 1	Day 7	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	Interim	Cumulative
	N=217	N=217	N=215	N=217	N=207	N=204	N=196	N=196	N=180	N=174	N=114	N=217
	n (%)	n (%)										
Inguinal hernia	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)						
Kidney stones	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Knee replacement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.8%)	3 (1.4%)
Leg pain	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	4 (1.8%)
Other*	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.5%)	3 (1.5%)	2 (1.1%)	4 (2.3%)	10 (8.8%)	20 (9.2%)
Oxycontin overdose	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Pacemaker insertion	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.5%)								
Pansinusitis	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Parkinson's disease	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (0.9%)						
Periorbital bruising	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Pneumonia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (4.4%)	6 (2.8%)
Renal failure	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (0.9%)						
Ruptured pseudoaneurysm	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Scalp hematoma	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Sepsis	0 (0.0%)	1 (0.9%)	1 (0.5%)									
Shingles	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Shortness of breath	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.5%)								

% = n/N x 100.

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

* Including abdominal aorta stent placed, acute diverticulitis, bad reaction to Advil, benign prostate hypertrophy, bone transplant lower gum, carpal tunnel surgery in right hand, combined prostate & bladder surgical procedure & hospitalization, enlarged prostate, gallstones - pain, hernia surgery, hospitalization: unknown etiology fever, hospitalized for chest pain, hospitalized for chest pain; ischemic heart disease w/ angina, irritable bowel syndrome, open heart surgery, osteoporosis, peripheral vascular disease, pinched nerve in back, pulled back muscle, rupture of varicose vein upper lip, screw removal from elbow post fracture, septal deviation, and sexually assault.

TABLE 35 (CONTINUED)
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002 STUDY

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	Operative N=217	Day 1 N=217	Day 7 N=215	1 Month N=217	3 Months N=207	6 Months N=204	9 Months N=196	12 Months N=196	18 Months N=180	24 Months N=174	Interim N=114	Cumulative N=217
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Sinusitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.9%)	1 (0.5%)
Spinal stenosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Syncope	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Trauma due to fall	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.8%)	3 (1.4%)
UTI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)
Ulcer	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	3 (1.4%)

% = n/N x 100.

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

TABLE 36
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002-LTM STUDY

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Anemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Arrhythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Basal cell carcinoma	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Bradycardia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Brain hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Bronchitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
CVA-TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)
Cancer	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)
Cellulitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chest pain	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)							
Anemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Arrhythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)	0 (0.0%)	2 (2.6%)	4 (3.1%)
Basal cell carcinoma	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Bradycardia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Brain hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Bronchitis	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)
CVA-TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)
Cancer	1 (0.9%)	0 (0.0%)	2 (1.8%)	2 (1.9%)	1 (2.8%)	0 (0.0%)	5 (6.5%)	10 (7.8%)
Cellulitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Chest pain	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N x 100.

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

TABLE 36 (CONTINUED)
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002-LTM STUDY

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N=129	N=129	N=128	N=129	N=125	N=124	N=122	N=124	N=117
	n (%)								
Colon polyp	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Congestive heart failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)
Contusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)
Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dehydration	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Depression	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diabetes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
Emphysema	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Facial nerve paralysis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Focal nasal atrophy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N=116	N=84	N=113	N=106	N=36	N=6	N=77	N=129
	n (%)							
Colon polyp	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Congestive heart failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Contusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (6.5%)	5 (3.9%)
Dehydration	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Depression	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Diabetes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)
Emphysema	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Facial nerve paralysis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Focal nasal atrophy	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N × 100.

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

TABLE 36 (CONTINUED)
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002-LTM STUDY

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Events	OP	DI	D7	1M	3M	6M	9M	12M	18M
	N=129	N=129	N=128	N=129	N=125	N=124	N=122	N=124	N=117
	n (%)								
Fractured heel bone	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fractured hip	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fractured toe	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Headache	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hematuria	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hernia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hip fracture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hospitalization	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hypercholesterolemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hypertension	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N=116	N=84	N=113	N=106	N=36	N=6	N=77	N=129
	n (%)							
Fractured heel bone	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Fractured hip	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Fractured toe	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Headache	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Hematuria	1 (0.9%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Hernia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Hip fracture	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)
Hospitalization	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Hypercholesterolemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Hypertension	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N × 100.

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

TABLE 36 (CONTINUED)
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002-LTM STUDY

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N=129	N=129	N=128	N=129	N=125	N=124	N=122	N=124	N=117
	n (%)								
Hyponatremia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hypotension	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.9%)
Kidney failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Knee replacement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Open heart surgery	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Osteoarthritis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)	3 (2.4%)	1 (0.9%)
Pansinusitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N=116	N=84	N=113	N=106	N=36	N=6	N=77	N=129
	n (%)							
Hyponatremia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Hypotension	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Infection	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	4 (3.1%)
Kidney failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	2 (1.6%)
Knee replacement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.6%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	4 (3.1%)
Open heart surgery	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Osteoarthritis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Other	4 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (9.1%)	15 (11.6%)
Pansinusitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = $n/N \times 100$.

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

Other: Including abdominal aorta stent placed, acute diverticulitis, bad reaction to Advil, benign prostate hypertrophy, bone transplant lower gum, combined prostate & bladder surgical procedure & hospitalization, gallstones - pain, hospitalization: unknown etiology fever, hospitalized for chest pain, hospitalized for chest pain; ischemic heart disease w/ angina, osteoporosis, peripheral vascular disease, pinched nerve in back, pulled back muscle, rupture of varicose vein upper lip, screw removal from elbow post fracture, septal deviation, and sexually assault.

TABLE 36 (CONTINUED)
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002-LTM STUDY

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Parkinson's disease	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Periorbital bruising	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pinched nerve	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pneumonia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pubic fracture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Renal failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Scalp hematoma	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Shingles	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Shortness of breath	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus bradycardia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)							
Parkinson's disease	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Periorbital bruising	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Pinched nerve	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Pneumonia	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	3 (2.3%)
Pubic fracture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Renal failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Scalp hematoma	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Shingles	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Shortness of breath	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Sinus bradycardia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N x 100.

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

Other: Including abdominal aorta stent placed, acute diverticulitis, bad reaction to Advil, benign prostate hypertrophy, bone transplant lower gum, combined prostate & bladder surgical procedure & hospitalization, gallstones - pain, hospitalization: unknown etiology fever, hospitalized for chest pain, hospitalized for chest pain; ischemic heart disease w/ angina, osteoporosis, peripheral vascular disease, pinched nerve in back, pulled back muscle, rupture of varicose vein upper lip, screw removal from elbow post fracture, septal deviation, and sexually assault.

TABLE 36 (CONTINUED)
REPORTED NON-OCULAR ADVERSE EVENTS
OPERATED EYES ENROLLED IN IMT-002-LTM STUDY

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Events	OP	D1	D7	1M	3M	6M	9M	12M	18M
	N = 129	N = 129	N = 128	N = 129	N = 125	N = 124	N = 122	N = 124	N = 117
	n (%)								
Sinusitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Spinal stenosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
Stroke	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Torn meniscus	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
UTI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ulcer	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.6%)	0 (0.0%)
Ulcerative colitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Events	24M	36M	42M	48M	54M	60M	Uns	Cum
	N = 116	N = 84	N = 113	N = 106	N = 36	N = 6	N = 77	N = 129
	n (%)	n (%)	n (%)					
Sinusitis	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
Spinal stenosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Stroke	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	2 (1.6%)
TIA	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Torn meniscus	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.8%)
UTI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	2 (1.6%)
Ulcer	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	3 (2.3%)
Ulcerative colitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (0.8%)

Uns=Unscheduled Visits. Cum=Cumulative (number of eyes reported with the AE from IMT-002 to IMT-002-LTM).

% = n/N × 100.

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

Other: Including abdominal aorta stent placed, acute diverticulitis, bad reaction to Advil, benign prostate hypertrophy, bone transplant lower gum, combined prostate & bladder surgical procedure & hospitalization, gallstones - pain, hospitalization: unknown etiology fever, hospitalized for chest pain, hospitalized for chest pain; ischemic heart disease w/ angina, osteoporosis, peripheral vascular disease, pinched nerve in back, pulled back muscle, rupture of varicose vein upper lip, screw removal from elbow post fracture, septal deviation, and sexually assault.

TABLE 37.1
DISTRIBUTION OF EYES IMAGED BY PREOPERATIVE ACD

Preoperative ACD Category	Distribution of All IMT-Implanted Eyes by Baseline ACD (N=206)	Number of Eyes Imaged (N=45)
<3.0 mm (Mean 2.8 mm)	80 (39%)	15 (33%)
3.0 mm to 3.5 mm (Mean 3.2 mm)	92 (45%)	24 (53%)
>3.5 mm (Mean 3.6mm)	34 (16%)	6 (13%)

TABLE 37.2
CENTRAL CLEARANCE FROM ANTERIOR SURFACE OF IMT
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

TABLE 37.3
PERIPHERAL CLEARANCE FROM ANTERIOR SURFACE OF IMT
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

TABLE 37.4
COMPARISON OF ACD IN IMT-IMPLANTED EYES AND
IOL-IMPLANTED FELLOW EYES AT ENTRY INTO PROTOCOL IMT-002

Baseline ACD (mm) in IMT vs Fellow Eyes with IOL N=13		Baseline ACD (mm) in IMT vs Phakic Fellow Eyes (without IOL) N=32	
IMT-Implanted Eyes	IOL-Implanted Fellow Eyes	IMT-Implanted Eyes	Phakic Fellow Eyes
3.21	3.79	3.12	3.26

TABLE 38
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 38 (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%)

TABLE 39
CURRENT VERSUS PREVIOUS PROPOSED LABELING ELEMENTS

CURRENT	PREVIOUS
<p>Proposed indication</p> <p>The Implantable Miniature Telescope (IMT^{by Dr. Isaac Lipshitz}) is indicated to improve vision by monocular implantation in patients 65 or older with stable moderate (distance BCVA of $\leq 20/80$) to profound (distance BCVA $\geq 20/800$) vision impairment caused by <i>bilateral central scotomous</i> associated with end-stage age-related macular degeneration. Patients must have:</p>	<p>Proposed indication</p> <p>The Implantable Miniature Telescope (IMT^{by Dr. Isaac Lipshitz}) is indicated for monocular implantation in patients ≥ 55 years of age with:</p>
<ul style="list-style-type: none"> • retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography, 	<ul style="list-style-type: none"> • bilateral, stable, untreatable moderate to profound central vision disorders resulting from age-related macular degeneration as determined by fluorescein angiography,
<ul style="list-style-type: none"> • evidence of cataract, 	<ul style="list-style-type: none"> • evidence of cataract
<ul style="list-style-type: none"> • at least a five-letter improvement on the ETDRS chart with an external telescope, 	<ul style="list-style-type: none"> • who achieve a five-letter improvement on the ETDRS chart in the eye scheduled for surgery using an external telescope,
<ul style="list-style-type: none"> • <i>adequate peripheral vision in the eye not scheduled for surgery</i> 	
	<ul style="list-style-type: none"> • anterior chamber depth < 2.5 mm
<ul style="list-style-type: none"> • <i>willingness</i> to participate in a postoperative visual training/rehabilitation program. 	<ul style="list-style-type: none"> • who show interest in participating in postoperative visual rehabilitation program.

TABLE 39 (CONTINUED)
CURRENT VERSUS PREVIOUS PROPOSED LABELING ELEMENTS

CONTRAINDICATIONS		CONTRAINDICATIONS										
<ul style="list-style-type: none"> evidence of corneal guttata 		<ul style="list-style-type: none"> corneal endothelial dystrophies contraindicated 										
<ul style="list-style-type: none"> anterior chamber depth <3.0 mm 												
<ul style="list-style-type: none"> The IMT is contraindicated in patients who do not meet the minimum age and endothelial cell density, as shown in the grid below: 		<ul style="list-style-type: none"> The IMT is contraindicated in patients with endothelial cell density less than 1,600 cell/mm² 										
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	16.6	19.5	13.2	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
WARNINGS AND OTHER RELEVANT LABELING INFORMATION						WARNINGS AND OTHER RELEVANT LABELING INFORMATION						
<p><i>Surgery to implant the IMT should be performed only by cornea specialists.</i></p>						Not specified						
<p><i>This device is restricted to use only by physicians who have participated in the training provided by Vision Care</i></p>						Not specified						
<p>Precaution <i>Patients should be advised of the potential risk of loss of endothelial cell density, and further advised that additional ECD may be lost over time. They should also be told that sufficiently large loss of endothelial cell density could cause corneal edema leading to cornea decompensation possibly requiring corneal transplantation. Patients should be advised that it is important to have a pre-operative assessment of their corneal endothelium. Patients should be given sufficient information about the benefits and risks, including ECD loss, of the procedure to make a judgment together with their physician about whether to undergo the procedure.</i></p>						Not specified						

TABLE 40.1
DEMOGRAPHIC INFORMATION
SUBJECTS ENROLLED IN IMT-002-LTM VERSUS
SUBJECTS NOT ENROLLED IN IMT-002-LTM
OPERATED EYES

		129 Operated Eyes Enrolled in LTM		88 Operated Eyes Not Enrolled in LTM		P-value ¹
		Number	Percentage	Number	Percentage	
Gender	Female	64	49.6%	39	44.3%	0.4898
	Male	65	50.4%	49	55.7%	
Race	Caucasian	122	94.6%	86	97.7%	0.9103
	Black	2	1.6%	1	1.1%	
	Hispanic	4	3.1%	1	1.1%	
	Asian	1	0.8%	0	0.0%	
	Other	0	0.0%	0	0.0%	
Eye Implanted	Right	60	46.5%	45	51.1%	0.5803
	Left	69	53.5%	43	48.9%	
Age (In Years)	Mean	74.7		76.8		0.0402
	Standard Deviation	7.3		7.4		
	Minimum	57		55		
	Maximum	89		93		

¹ Fisher's Exact test for gender, race, and eye, and t-test for age.

TABLE 40.2
RISK FACTORS ON ECD
GUTTATA, ACD, SURGEON TRAINING, AND SURGICAL ORDER
ENROLLED IN IMT-002-LTM VERSUS NOT ENROLLED IN IMT-002-LTM
IMT-IMPLANTED EYES

	123 IMT-Implanted Eyes Enrolled in LTM	83 IMT-Implanted Eyes Not Enrolled in LTM	P-value ¹
With Guttata	16/123 (13.0%)	10/83 (12.0%)	1.0000
ACD < 3 mm	52/123 (42.3%)	32/83 (38.6%)	0.6651
Non-Cornea Specialist	91/123 (74.0%)	57/83 (68.7%)	0.4325
Surgical Order ≤ 5	66/123 (53.7%)	55/83 (66.3%)	0.0839
0 Risk Factor	13/123 (10.6%)	4/83 (4.8%)	0.5224
1 Risk Factor	30/123 (24.4%)	26/83 (31.3%)	
2 Risk Factors	50/123 (40.7%)	35/83 (42.2%)	
3 Risk Factors	25/123 (20.3%)	14/83 (16.9%)	
4 Risk Factors	5/123 (4.1%)	4/83 (4.8%)	

¹ Fisher's Exact test.

5 of 11 subjects without a successful IMT implant were enrolled in the LTM study. Subjects without a successful IMT implant were not included in this table.

TABLE 40.3
SUMMARY OF VISUAL ACUITY EFFECTIVENESS AND SAFETY ENDPOINTS
ENROLLED IN IMT-002-LTM VERSUS NOT ENROLLED IN IMT-002-LTM
IMT-IMPLANTED EYES

BCVA Endpoints	12 Months		24 Months	
	Enrolled in LTM	Not Enrolled in LTM	Enrolled in LTM	Not Enrolled in LTM
Effectiveness (N=)	121	71	116	57
Overall Effectiveness Endpoint ≥2 lines gain of BCDVA or BCNVA	110 (90.9%) 85.4%, 94.8%	63 (88.7%) 80.6%, 94.3%	103 (88.8%) 82.8%, 93.2%	46 (80.7%) 70.1%, 88.8%
Binomial exact p-value for Ha: success rate > 50%	<.0001	<.0001	<.0001	<.0001
≥2 lines gain of BCDVA and BCNVA	94 (77.7%) 70.6%, 83.8%	47 (66.2%) 55.9%, 75.5%	82 (70.7%) 63.0%, 77.6%	32 (56.1%) 44.4%, 67.4%
Not reported	1	1	0	1
Total	122	72	116	58
Safety (N=)	122	71	116	57
Overall Safety Rate >2 lines loss of BCDVA and no change/loss of BCNVA or >2 lines loss of BCNVA and no change/loss of BCDVA	6 (4.9%) 2.2%, 9.5%	4 (5.6%) 1.9%, 12.4%	6 (5.2%) 2.3%, 10.0%	5 (8.8%) 3.5%, 17.6%
Binomial exact p-value for Ha: safety rate < 10%	0.0339	0.1500	0.0484	0.4888
>2 lines loss of BCDVA and BCNVA	1 (0.8%) 0.0%, 3.8%	1 (1.4%) 0.1%, 6.5%	2 (1.7%) 0.3%, 5.3%	1 (1.8%) 0.1%, 8.1%
>2 lines loss of BCDVA and no change of BCNVA	1 (0.8%) 0.0%, 3.8%	0 (0.0%) 0.0%, 4.1%	0 (0.0%) 0.0%, 2.5%	0 (0.0%) 0.0%, 5.1%
>2 lines loss of BCNVA and no change of BCDVA	4 (3.3%) 1.1%, 7.3%	3 (4.2%) 1.2%, 10.6%	4 (3.4%) 1.2%, 7.7%	4 (7.0%) 2.4%, 15.3%
Not reported	0	1	0	1
Total	122	72	116	58

TABLE 40.4
ECD STRATIFIED BY IMT-002-LTM ENROLLMENT
ENROLLED IN IMT-002-LTM VERSUS NOT ENROLLED IN IMT-002-LTM
IMT-IMPLANTED EYES

	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
Enrolled in IMT-002-LTM Study							
N	123	116	120	119	119	118	114
Mean	2500	1937	1865	1868	1786	1802	1758
95% CI	2434, 2566	1827, 2047	1754, 1975	1760, 1976	1677, 1895	1690, 1915	1644, 1873
ECD < 750	0 (0%)	4 (3%)	8 (7%)	7 (6%)	8 (7%)	11 (9%)	11 (10%)
Not Enrolled in IMT-002-LTM Study							
N	83	77	78	71	67	62	57
Mean	2491	2082	2048	1929	2023	2022	1907
95% CI	2417, 2564	1956, 2208	1932, 2163	1802, 2057	1890, 2156	1869, 2175	1763, 2051
ECD < 750	0 (0%)	2 (3%)	0 (0%)	2 (3%)	1 (1%)	2 (3%)	1 (2%)
P-values							
Wilcoxon Test	0.6065	0.1019	0.0699	0.5376	0.0106	0.0192	0.1535
Fisher's Exact for ECD<750		1.0000	0.0233	0.4878	0.1599	0.2241	0.0633

N = number of eyes returned for the visit with non-missing data.

TABLE 40.5
PERCENT CHANGE IN ECD STRATIFIED BY IMT-002-LTM ENROLLMENT
ENROLLED IN IMT-002-LTM VERSUS NOT ENROLLED IN IMT-002-LTM
IMT-IMPLANTED EYES

	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
Enrolled in IMT-002-LTM Study						
N	116	120	119	119	118	114
Mean	-22%	-25%	-25%	-29%	-28%	-30%
95% CI	-26%, -18%	-29%, -21%	-29%, -22%	-33%, -24%	-32%, -24%	-34%, -25%
Not Enrolled in IMT-002-LTM Study						
N	77	78	71	67	62	57
Mean	-16%	-18%	-23%	-19%	-20%	-24%
95% CI	-21%, -12%	-22%, -14%	-27%, -18%	-24%, -15%	-25%, -15%	-29%, -19%
P-values						
Wilcoxon Test	0.0741	0.0765	0.5620	0.0085	0.0204	0.1602

N = number of eyes returned for the visit with non-missing data.