



October 14, 2008

PMA Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

RE: P050034 – Amendment 15
VisionCare Ophthalmic Technologies Implantable Miniature Telescope
IMT (by Dr. Isaac Lipshitz)TM

Dear Sir or Madam,

Please find enclosed six (6) copies of Amendment 15 to P050034, for the Implantable Miniature Telescope (IMT).

This amendment provides responses to three information requests by the Division of Ophthalmic and ENT Devices (DOENTD). These requests for information were submitted via email to Gene Hilmantel, O.D., M.S. on October 14, 2008:

Item 1: Response to email dated October 1, 2008

Item 2: Response to email dated October 3, 2008

Item 3: Response to email dated October 6, 2008

Each original email request is followed by VisionCare's response, with the requested information.

Thank you for your consideration of this PMA P050034 as amended. If you have any questions or need any additional information during your review, please contact me at (949) 715-0609 (phone), or by fax at (949) 715-0610, or by email at judy@clinregconsulting.com.

Sincerely,

Judy F. Gordon, D.V.M.
Regulatory Consultant to VisionCare Ophthalmic Technologies, Inc.



P050034
AMENDMENT 015
VISIONCARE OPHTHALMIC TECHNOLOGIES
IMPLANTABLE MINIATURE TELESCOPE™ (IMT BY DR. ISAAC LIPSHITZ)

OCTOBER 14, 2008

APPLICANT

VisionCare Ophthalmic Technologies, Inc.
14395 Saratoga Ave., Suite 150
Saratoga, CA 95070

CORRESPONDENT

Judy Gordon D.V.M.
ClinReg Consulting Services, Inc.
Tel: (949) 715-0609
Fax: (949) 715-0610
e-mail: judy@clinregconsulting.com

P050034 AMENDMENT 015
VISIONCARE OPHTHALMIC TECHNOLOGIES
IMPLANTABLE MINIATURE TELESCOPE

- ITEM 1. RESPONSE TO EMAIL DATED OCTOBER 1, 2008**
- ITEM 2. RESPONSE TO EMAIL DATED OCTOBER 3, 2008**
- ITEM 3. RESPONSE TO EMAIL DATED OCTOBER 6, 2008**

ITEM 1. RESPONSE TO E-MAIL DATED OCTOBER 1, 2008

- 1. For the following two separate groups:**
 - a. All IMT-implanted eyes that had both the 2-year and the 4-year visits**
 - b. All IMT-implanted eyes that had both the 3-year and the 4-year visits**

Please provide:

- i. The mean ECD for the 2- and 4-year (or 3- and 4-year) visits, along with the number of eyes and the percent change in the mean.**
- ii. The mean, standard deviation, maximum and minimum of the individual eye percent loss of ECD**
- iii. A graph showing the distribution of the individual eye changes (cells/mm²) in ECD**
- iv. A graph showing the distribution of the individual % changes in ECD.**

VisionCare Response:

Mean ECD for the 2-year and 4-year visits, and for the 3-year and 4-year visits are shown in Tables 1 and 2. Percent change in ECD, standard deviation, 95% confidence interval, range for the individual eye ECD percent loss and percent change in mean ECD are shown in these tables.

For the 86 eyes with 2-year and 4-year visits, mean ECD was 1756 cells/mm² at 2 years and 1616 cells/mm² at 4 years. The individual eye percent change in ECD from 24 to 48 months was -6% (S.D. 19%), with a range from -53% to +68%.

For the 51 eyes with 3-year and 4-year visits, mean ECD was 1752 cells/mm² at 3 years and 1705 cells/mm² at 4 years. The mean percent change in ECD from 3 years to 4 years was -2% (S.D. 13%), with a range from -39% to +29%.

The distribution of individual eye changes and percent changes in ECD are displayed in Figures 1 and 2 for eyes with 2-year and 4-year visits, and in Figures 3 and 4 for eyes with 3-year and 4-year visits.

Please note that percent change in ECD between visits was previously submitted to FDA in Amendment 13 (September 2, 2008), Volume 1, page 140, Table 18.1. This table is provided here as well, to facilitate review.

TABLE 1
MEAN ECD, PERCENT CHANGE IN ECD, AND
PERCENT CHANGE IN MEAN ECD
IMT-IMPLANTED EYES WITH ECD AT BOTH 24 AND 48 MONTHS (MATCHED PAIRS)

N	86	86
Mean (SD)	1756 (581)	1616 (571)
N		86
Mean (SD)		-6% (19%)
95% CI		-10%, -2%
Min, Max		-53%, 68%
Percent Change in Mean (from 24 to 48 Months) (1616 - 1756) ÷ 1756 × 100%		-8.0%

N = number of eyes with non-missing data.

TABLE 2
MEAN ECD, PERCENT CHANGE IN ECD, AND
PERCENT CHANGE IN MEAN ECD
IMT-IMPLANTED EYES WITH ECD AT BOTH 36 AND 48 MONTHS (MATCHED PAIRS)

N	51	51
Mean (SD)	1752 (550)	1705 (558)
N		51
Mean (SD)		-2% (13%)
95% CI		-6%, 1%
Min, Max		-39%, 29%
Percent Change in Mean (from 36 to 48 Months) (1705 - 1752) ÷ 1752 × 100%		-2.7%

N = number of eyes with non-missing data.

AMENDMENT 013 (SEPTEMBER 2, 2008)

TABLE 18.1

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

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
N		186	169	65	51	
Mean		-25%	-2%	-7%	-2%	
95% CI		-28%, -22%	-4%, 1%	-12%, -2%	-6%, 1%	
N	198	85	88	86	51	
Mean	-22%	-12%	-7%	-6%	-2%	
95% CI	-25%, -19%	-17%, -7%	-12%, -2%	-10%, -2%	-6%, 1%	
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.

FIGURE 1
ECD CHANGE FROM 24 TO 48 MONTHS
IMT-IMPLANTED EYES WITH ECD AT 24 AND 48 MONTHS (MATCHED PAIRS)
N = 86

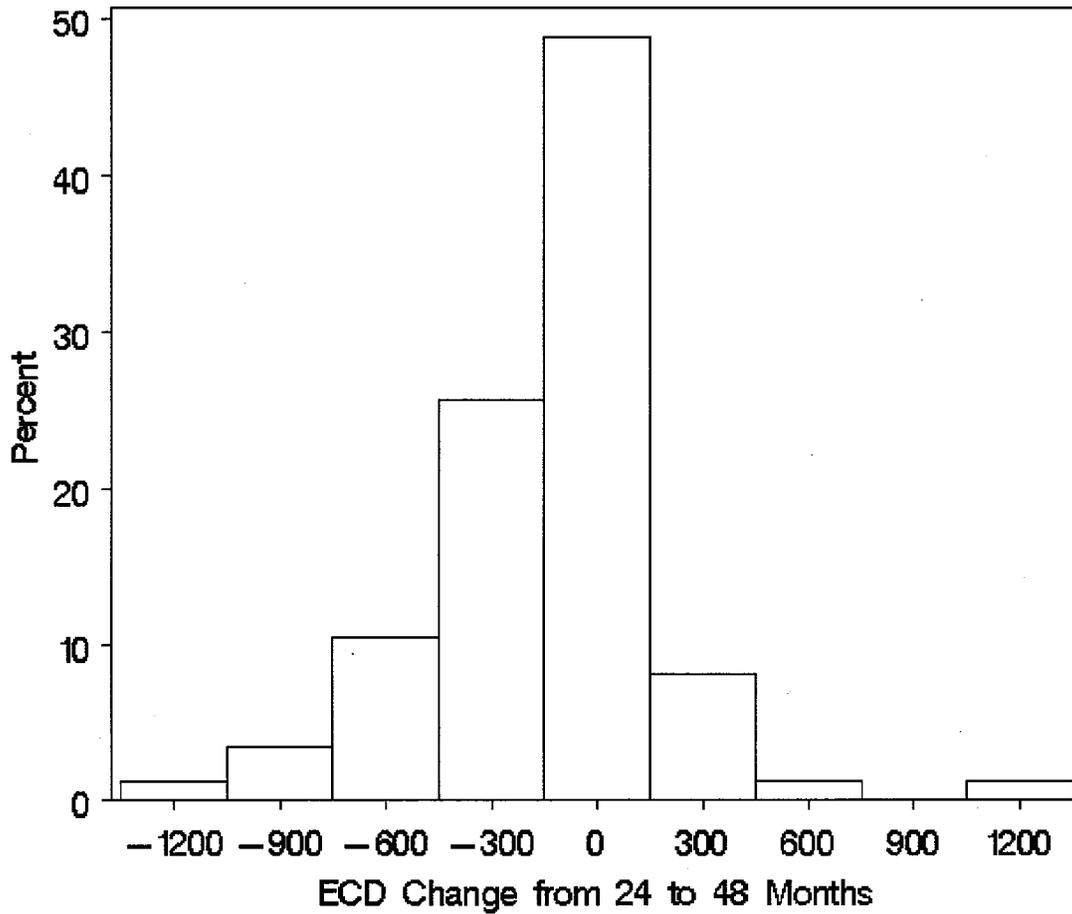


FIGURE 2
ECD % CHANGE FROM 24 TO 48 MONTHS
IMT-IMPLANTED EYES WITH ECD AT 24 AND 48 MONTHS (MATCHED PAIRS)
N = 86

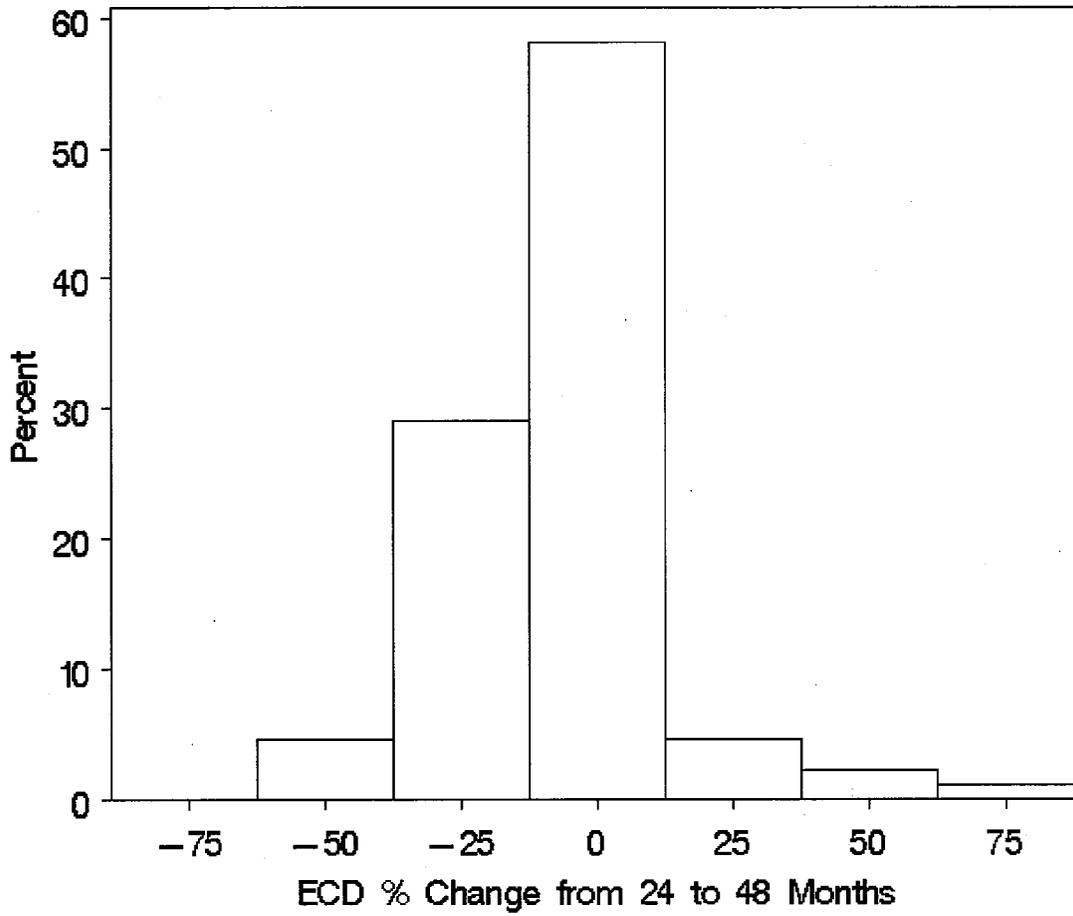


FIGURE 3
ECD CHANGE FROM 36 TO 48 MONTHS
IMT-IMPLANTED EYES WITH ECD AT 36 AND 48 MONTHS (MATCHED PAIRS)
N = 51

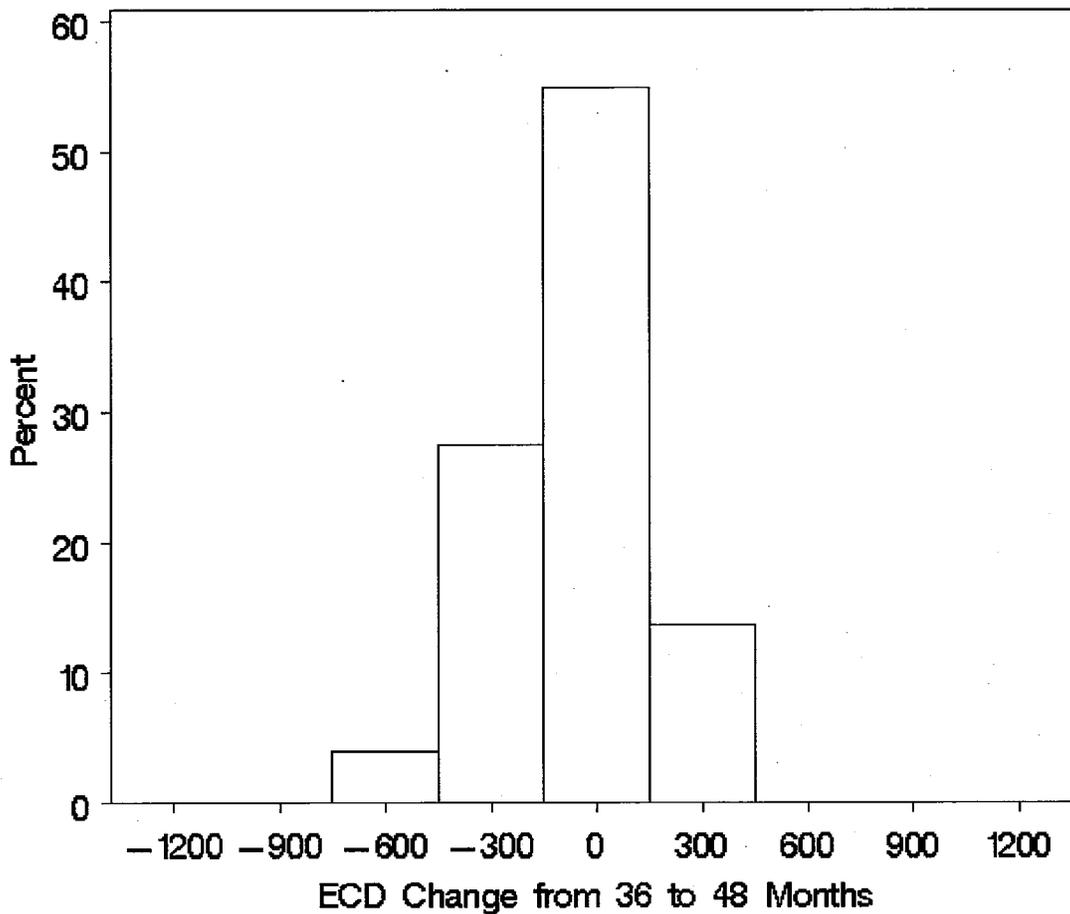
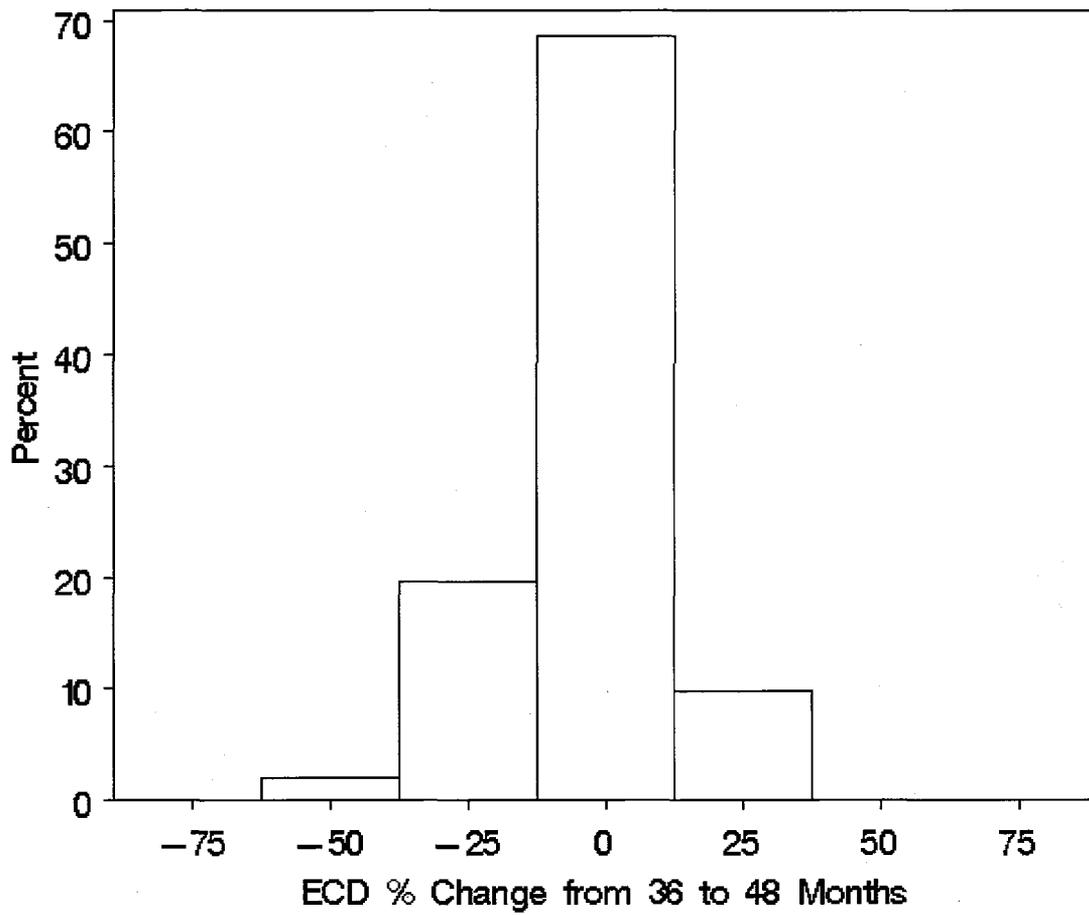


FIGURE 4
ECD % CHANGE FROM 36 TO 48 MONTHS
IMT-IMPLANTED EYES WITH ECD AT 36 AND 48 MONTHS (MATCHED PAIRS)
N = 51



2. For the following two separate groups:
 - a. All IMT-implanted eyes that had both the preop and the 4-year visits
 - b. All IMT-implanted eyes that had both the preop and the 2-year visits

Please provide:

- i. The mean and standard deviations of the central corneal thickness (CCT) for the preop and 4 year (or preop and 2 year) visits, along with the number of eyes and the percent change in the mean.
- ii. The mean, standard deviation, maximum, and minimum of the individual eye percent change in CCT;
- iii. A graph showing the distribution of the individual eye changes (microns) in CCT.
- iv. A graph showing the distribution of the individual % changes in CCT.

VisionCare Response:

Mean and percent change in central corneal thickness (CCT), with standard deviation and range, for eyes with baseline and 2-year or baseline and 4-year visits are displayed in Tables 3 and 4.

In the 172 eyes with baseline and 2-year CCT measurements, mean CCT changed from 554 (S.D. 40) microns at baseline to 561 (S.D. 50) microns over the 24 month period. The percent change in CCT from baseline to 2 years for this cohort of eyes was 1% (S.D. 6%), with a range of -25% to +31%.

A similarly change in mean CCT was observed from in the 84 eyes with measurements at baseline and 4 years, from 555 (S.D. 41) microns to 563 (S.D. 68) microns over 48 months. The percent change from baseline to 4 years was 1% (S.D. 9%), with a range of -23% to +52%.

The distribution of individual eye changes and percent changes in CCT are displayed in Figures 5 and 6 for eyes with baseline and 2-year visits, and in Figures 7 and 8 for eyes with baseline and 4-year visits.

TABLE 3
MEAN CENTRAL CORNEAL THICKNESS (CCT), PERCENT CHANGE IN CCT, AND
PERCENT CHANGE IN MEAN CCT
IMT-IMPLANTED EYES WITH CCT AT BOTH PREOP AND 24 MONTHS
(MATCHED PAIRS)

N	172	172
Mean (SD)	554 (40)	561 (50)
N		172
Mean (SD)		1% (6%)
95% CI		0%, 2%
Min, Max		-25%, 31%
Percent Change in Mean (from Preop to 24 Months) (561 - 554) ÷ 554 × 100%		1.2%

N = number of eyes with non-missing data.

TABLE 4
MEAN CENTRAL CORNEAL THICKNESS (CCT), PERCENT CHANGE IN CCT, AND
PERCENT CHANGE IN MEAN CCT
IMT-IMPLANTED EYES WITH CCT AT BOTH PREOP AND 48 MONTHS
(MATCHED PAIRS)

N	84	84
Mean (SD)	555 (41)	563 (68)
N		84
Mean (SD)		1% (9%)
95% CI		-1%, 3%
Min, Max		-23%, 52%
Percent Change in Mean (from Preop to 48 Months) (563 - 555) ÷ 555 × 100%		1.4%

N = number of eyes with non-missing data.

FIGURE 5
CCT CHANGE FROM PREOP TO 24 MONTHS
IMT-IMPLANTED EYES WITH CCT AT BASELINE AND 24 MONTHS (MATCHED PAIRS)
N = 172

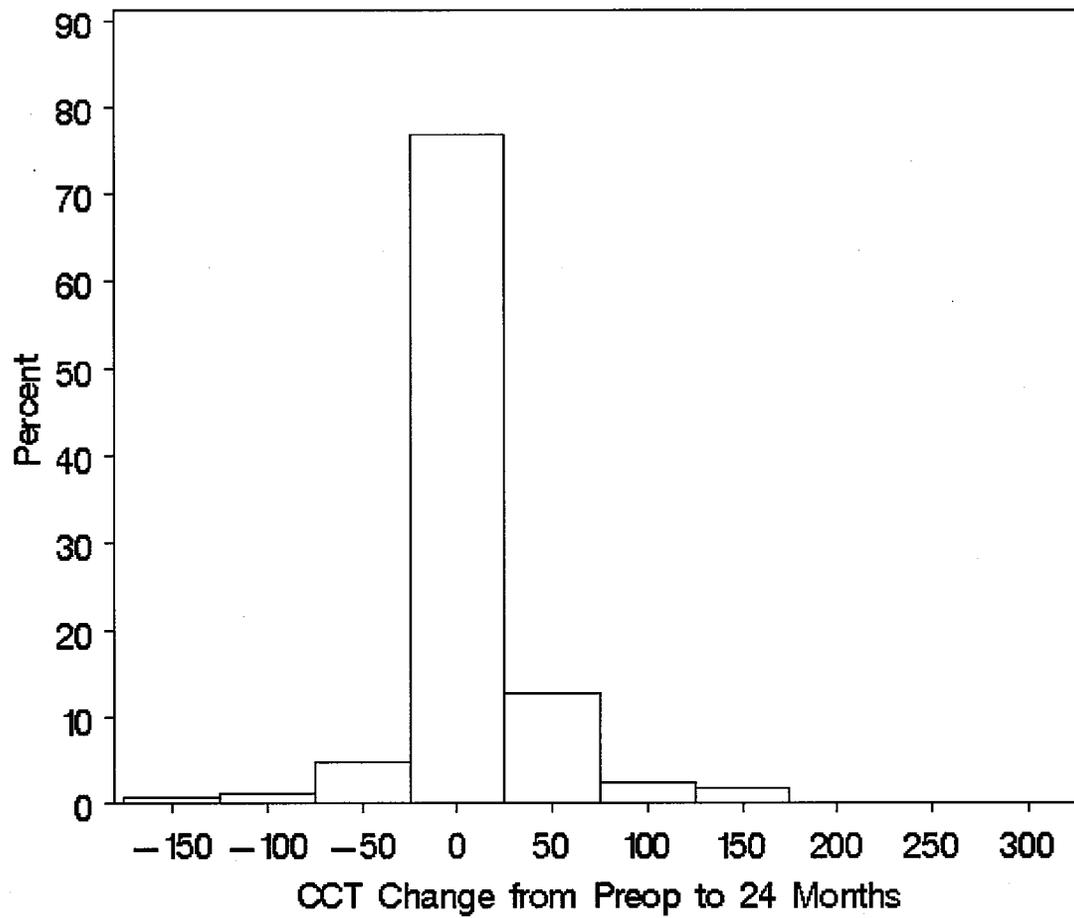


FIGURE 6
CCT % CHANGE FROM PREOP TO 24 MONTHS
IMT-IMPLANTED EYES WITH CCT AT BASELINE AND 24 MONTHS (MATCHED PAIRS)
N = 172

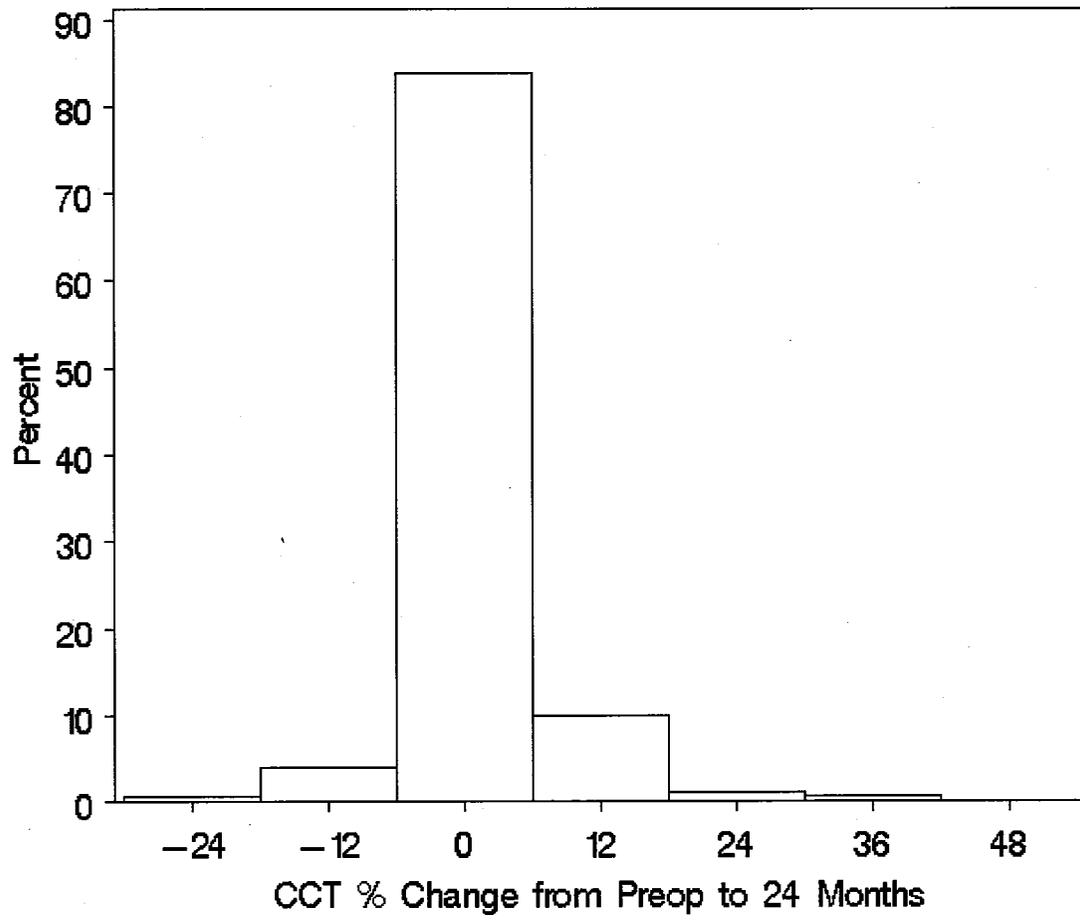


FIGURE 7
CCT CHANGE FROM PREOP TO 48 MONTHS
IMT-IMPLANTED EYES WITH CCT AT BASELINE AND 48 MONTHS (MATCHED PAIRS)
N = 84

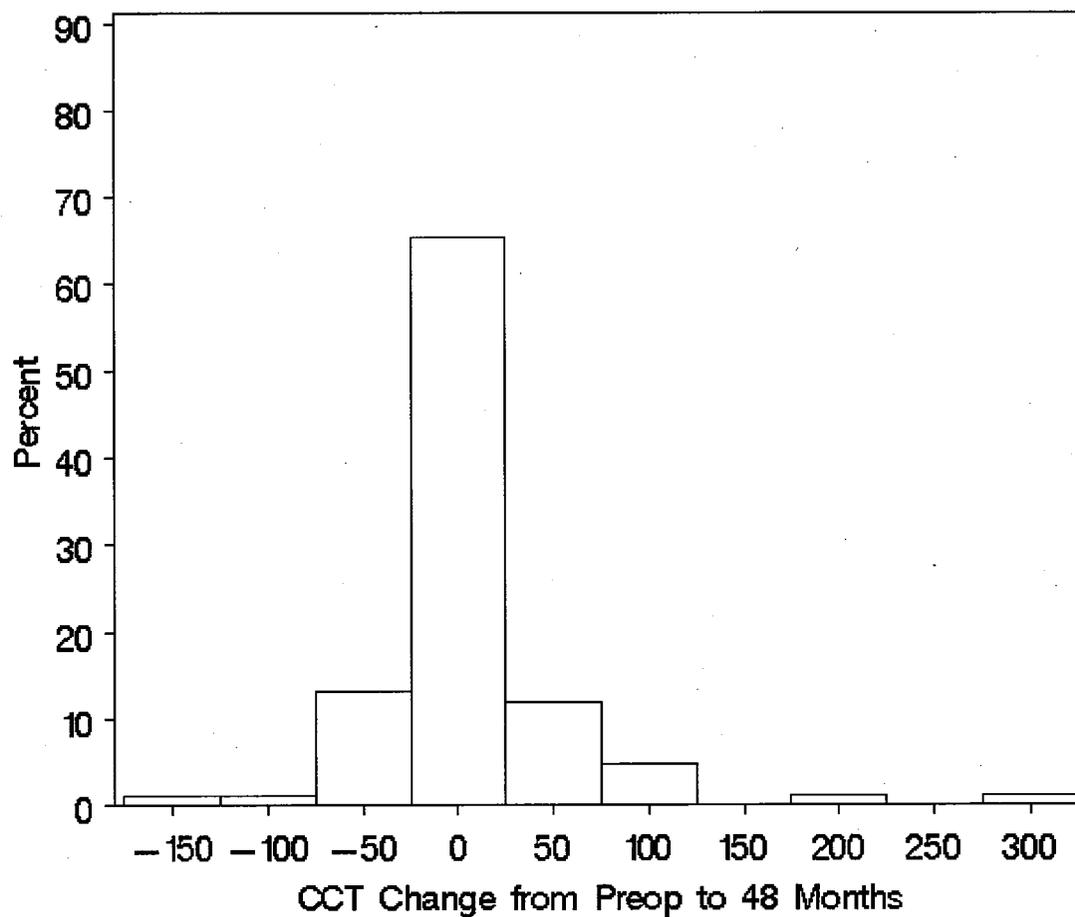
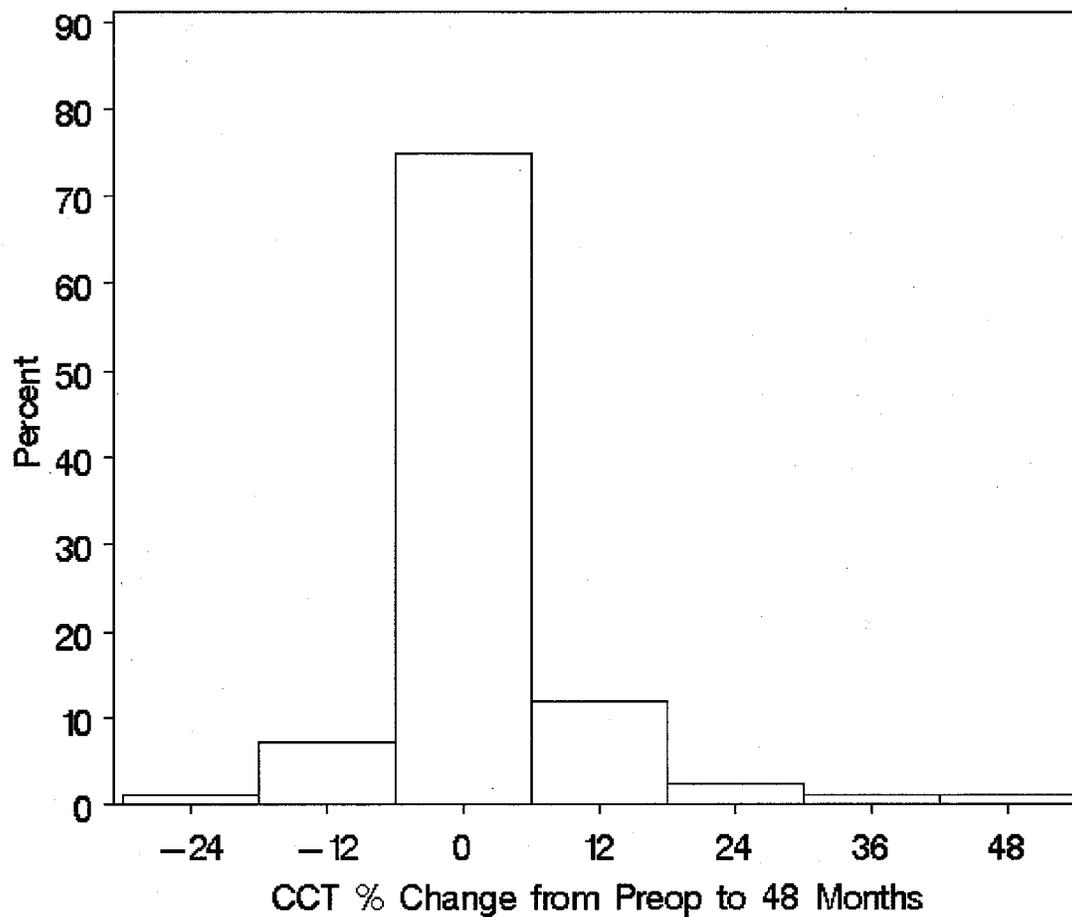


FIGURE 8
CCT % CHANGE FROM PREOP TO 48 MONTHS
IMT-IMPLANTED EYES WITH CCT AT BASELINE AND 48 MONTHS (MATCHED PAIRS)
N = 84



ITEM 2. RESPONSE TO EMAIL DATED OCTOBER 3, 2008

Please provide the following analyses (for eyes in the IMT-implanted cohort) to help clarify our understanding of late corneal edema in your device.

- 1. For each scheduled visit, provide the number of cases of corneal edema and the percentage of available eyes that have corneal edema.**
- 2. Please provide a line listing for each eye that had corneal edema at > 3 months postop. These should include ECD, %hexagonality, coefficient of variation, central corneal thickness (pachymetry), times from surgery at which edema was noted, and dates at which edema was noted. Cases with corneal decompensation and/or transplantation should be noted. Brief descriptions of any treatment for the edema should be noted. Graphs that show the three specular microscopy parameters and central corneal thickness as a function of time should be provided for each of these eyes.**

VisionCare Response:

The proportion of available eyes with corneal edema at each scheduled visit is shown in Table 5.

An examination of the data line listing provided in Table 6 shows that a total of 12 eyes of 12 study subjects were reported to have corneal edema at greater than 3 months postoperatively.

Specular microscopy parameters and central corneal thickness are displayed graphically in Figures 9 through 12.

**TABLE 5
CORNEAL EDEMA
IMT-IMPLANTED EYES**

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

The following 3 IMT-implanted eyes were reported with corneal edema at unscheduled visits without being reported at the scheduled visits: [REDACTED] at 211 days; [REDACTED] at 1445 days, 1470 days and 1563 days; [REDACTED] at 1662 days.

TABLE 6
DATA LISTING FOR IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT > 3 MONTHS
N = 12
Page 1 of 5

	1st Report of Corneal Edema: 08/08/06 (1224 days).						
	02/21/03	PREOP	-40	2642	59.7	35.3	546
	06/20/03	3M	79				574
	08/26/03	6M	146	2274	52.0	36.3	561
	01/16/04	9M	289	2326	63.3	37.0	578
	03/19/04	12M	352	1855	49.3	36.0	569
	09/14/04	18M	531	1929	56.0	35.0	586
	03/08/05	24M	706	1011	58.7	32.3	597
	08/08/06	42M	1224	508	33.0	28.7	
	03/06/07	48M	1434	660	61.0	25.3	656
	08/28/07	54M	1609	556	50.0	46.0	642
	02/26/08	ECD only (60 Months for ECD)	1791	505	33.0	17.5	
	1st Report of Corneal Edema: 05/15/06 (971 days).						
	Reported with Corneal Decompensation on 02/02/07 (1234 days).						
	08/06/03	PREOP	-42	2908	59.0	31.0	607
	12/12/03	3M	86	432	52.7	35.3	621
	03/16/04	6M	181	452	49.7	27.0	677
	05/18/04	9M	244	397	38.3	42.3	601
	08/24/04	12M	342	361	67.0	33.5	694
	01/11/05	18M	482	351	54.3	33.7	700
	05/10/05	24M	601				771
	02/02/07	42M	1234				771
	09/04/07	48M	1448				920
	1st Report of Corneal Edema: 01/18/05 (692 days).						
	Reported with Corneal Transplant on 12/06/06 (1379 days).						
	01/17/03	PREOP	-40				516
	01/23/03	ECD only (Preop for ECD)	-34	2763	67.3	28.0	
	05/22/03	3M	85	1684	60.3	34.0	528
	08/12/03	6M	167	1380	51.7	32.3	508
	12/04/03	9M	281	1070	64.0	31.0	516
	02/12/04	12M	351	845	52.0	27.0	499
	06/10/04	18M	470	604	20.0	21.0	569
	01/08/05	ECD only (24 Months for ECD)	682	529	56.3	23.7	
	01/18/05	24M	692				580
	03/20/07	48M	1483				550
	07/24/07	54M	1609				558
	02/26/08	60M	1826				602

TABLE 6 (CONTINUED)
DATA LISTING FOR IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT > 3 MONTHS
N = 12
 Page 2 of 5

1st Report of Corneal Edema: 04/09/04 (211 days).						
08/01/03	PREOP	-41	2860	57.3	33.7	610
12/01/03	3M	81	2694	55.0	35.7	602
02/02/04	6M	144	2737	60.3	32.0	607
04/09/04	INTERIM	211				721
05/03/04	9M	235				592
05/04/04	ECD only (9 Months for ECD)	236	2816	54.3	35.7	
07/19/04	12M	312	2434	37.0	30.3	595
11/06/06	36M	1152	2336	59.0	32.0	593
1st Report of Corneal Edema: 04/15/05 (644 days).						
06/30/03	PREOP	-11	2455	55.0	36.3	546
10/10/03	3M	91	2211	54.3	35.0	542
01/14/04	6M	187	1074	48.0	37.7	559
04/05/04	9M	269	1048	48.3	32.7	567
07/14/04	12M	369	955	62.0	29.7	633
01/07/05	18M	546	553	45.0	26.3	662
04/15/05	24M	644				716
06/20/05	INTERIM	710	519	46.0	21.7	548
08/21/06	36M	1137				658
01/03/07	42M	1272	618	56.3	30.7	724
06/11/07	48M	1431	719	40.0	30.0	633
1st Report of Corneal Edema: 06/25/04 (277 days). Reported with Corneal Decompensation on 06/25/04 (277 days). Reported with Corneal Transplant on 09/01/04 (345 days).						
08/29/03	PREOP	-24	1909	61.0	32.7	553
01/14/04	3M	114	633	58.3	22.0	565
04/27/04	6M	218	463	59.0	31.3	635
06/25/04	9M	277				730
08/17/04	12M	330				155
09/09/04	INTERIM (excluded from primary ECD analyses)	353	3128	58.0	37.3	629
10/07/04	INTERIM (excluded from primary ECD analyses)	381	3442	55.3	34.3	581
01/18/05	INTERIM (excluded from primary ECD analyses)	484	3133	50.3	42.0	549
05/11/05	INTERIM (excluded from primary ECD analyses)	597	2984	51.3	35.3	546

TABLE 6 (CONTINUED)
DATA LISTING FOR IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT > 3 MONTHS
N = 12 Page 3 of 5

(Cont'd)	07/18/06	36M (excluded from primary ECD analyses)	1030	2483	49.7	36.0	
	04/11/07	42M (excluded from primary ECD analyses)	1297	1987	57.3	38.0	533
	10/02/07	48M (excluded from primary ECD analyses)	1471	1529	61.3	30.3	532
	03/11/08	ECD only (excluded from primary ECD analyses)	1632	1264	61.0	28.0	
1st Report of Corneal Edema: 06/28/07 (1445 days). Reported with Corneal Decompensation on 10/24/07 (1563 days).							
	06/05/03	PREOP	-39	2465	66.0	29.7	551
	10/14/03	3M	92				590
	10/27/03	ECD only (3 Months for ECD)	105	782	57.0	25.3	
	02/03/04	6M	204	431	42.7	28.0	626
	04/27/04	9M	288	309	50.0	14.7	708
	07/14/04	12M	366	311	39.0	26.0	736
	12/15/04	18M	520	664	26.0	33.3	641
	04/19/05	ECD only (24 Months for ECD)	645	503	49.0	28.0	
	04/20/05	24M	646				611
	09/19/06	36M	1163	823	61.3	41.3	
	02/14/07	42M	1311	594	58.0	20.0	706
	06/12/07	48M	1429	501	25.0	37.0	741
1st Report of Corneal Edema: 10/25/06 (1101 days). Reported with Corneal Transplant on 08/15/07 (1395 days).							
	09/26/03	PREOP	-24				565
	10/06/03	ECD only (Preop for ECD)	-14	2774	58.0	40.0	
	01/07/04	3M	79				585
	04/27/04	6M	190	2566	45.0	28.5	590
	06/09/04	9M	233	2814	57.3	42.7	596
	08/25/04	12M	310	2959	51.0	45.3	599
	02/08/05	ECD only (18 Months for ECD)	477	2748	51.0	41.3	
	02/09/05	18M	478				605
	06/07/05	ECD only (24 Months for ECD)	596	2860	58.7	39.7	
	06/08/05	24M	597				640
	10/25/06	36M	1101	2444	53.3	39.0	
	12/04/06	CCT only (36 Months for CCT)	1141				655
	05/07/07	42M	1295	841	53.3	34.7	770
	10/25/07	48M	1466	2153	58.3	32.0	534
	04/22/08	ECD only (54 Months for ECD)	1646	1405	53.0	32.0	

TABLE 6 (CONTINUED)
DATA LISTING FOR IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT > 3 MONTHS
N = 12
Page 4 of 5

	1st Report of Corneal Edema: 03/09/05 (644 days).						
	04/30/03	PREOP	-35	2738	62.0	31.7	557
	08/12/03	3M	69	1315	57.7	34.7	519
	12/18/03	6M	197	846	68.7	30.0	619
	03/10/04	9M	280	656	46.0	23.3	646
	06/30/04	12M	392	446	64.3	30.7	604
	12/08/04	INTERIM	553	628	60.0	25.0	645
	03/09/05	24M	644	676	50.0	14.0	715
	09/20/06	42M	1204	983	56.7	44.0	
	07/18/07	48M	1505	851	48.3	32.3	598
	1st Report of Corneal Edema: 04/17/08 (1662 days).						
	07/15/03	PREOP	-76				599
	08/26/03	ECD only (Preop for ECD)	-34	2463	66.3	29.7	
	01/21/04	3M	114	1901	59.0	27.3	536
	03/23/04	6M	176	1554	55.3	31.0	559
	05/11/04	9M	225	1170	59.0	32.0	658
	08/19/04	12M	325	901	70.7	22.3	588
	01/28/05	18M	487	638	56.0	22.3	534
	05/10/05	24M	589	544	57.3	25.0	640
	08/14/06	36M	1050	386	55.7	30.3	
	02/19/07	42M	1239	393	50.0	9.5	553
	08/27/07	48M	1428				612
	1st Report of Corneal Edema: 09/06/06 (1043 days).						
	09/25/03	PREOP	-34	1769	67.0	27.7	600
	01/07/04	3M	70	916	55.7	31.7	576
	04/29/04	6M	183	646	67.0	24.0	705
	07/08/04	9M	253	531	67.0	19.7	433
	09/14/04	12M	321	519	53.3	28.0	570
	02/01/05	18M	461	457	60.7	29.7	589
	06/14/05	24M	594	505	51.3	37.0	631
	09/06/06	36M	1043	324		8.0	
	04/18/07	42M	1267	709	47.0	32.0	712

TABLE 6 (CONTINUED)
DATA LISTING FOR IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT > 3 MONTHS
N = 12
Page 5 of 5

	1st Report of Corneal Edema: 12/18/03 (72 days). Reported with Corneal Decompensation on 06/17/04 (254 days). Reported with Corneal Transplant on 08/10/04 (308 days).						
	08/20/03	PREOP	-48	2118	61.3	31.3	607
	12/18/03	3M	72				706
	03/04/04	6M	149	385	46.0	30.5	742
	08/05/04	12M	303				955
	10/16/06	36M	1105				641
	04/03/07	42M (excluded from primary ECD analyses)	1274	1857	60.3	35.3	622
	10/25/07	48M	1479				622

FIGURE 9
ECD
IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT >3 MONTHS
N = 12

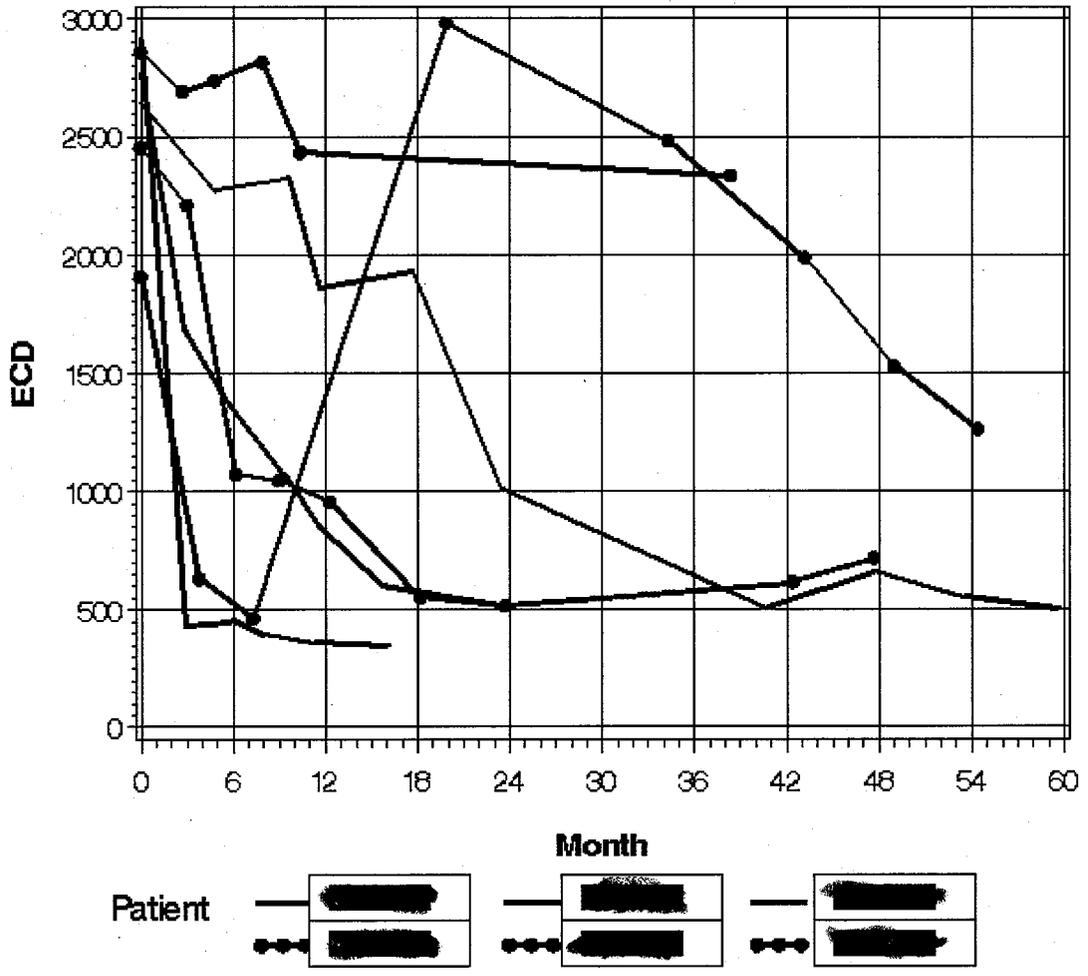


FIGURE 9 (CONTINUED)
ECD
IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT >3 MONTHS
N = 12

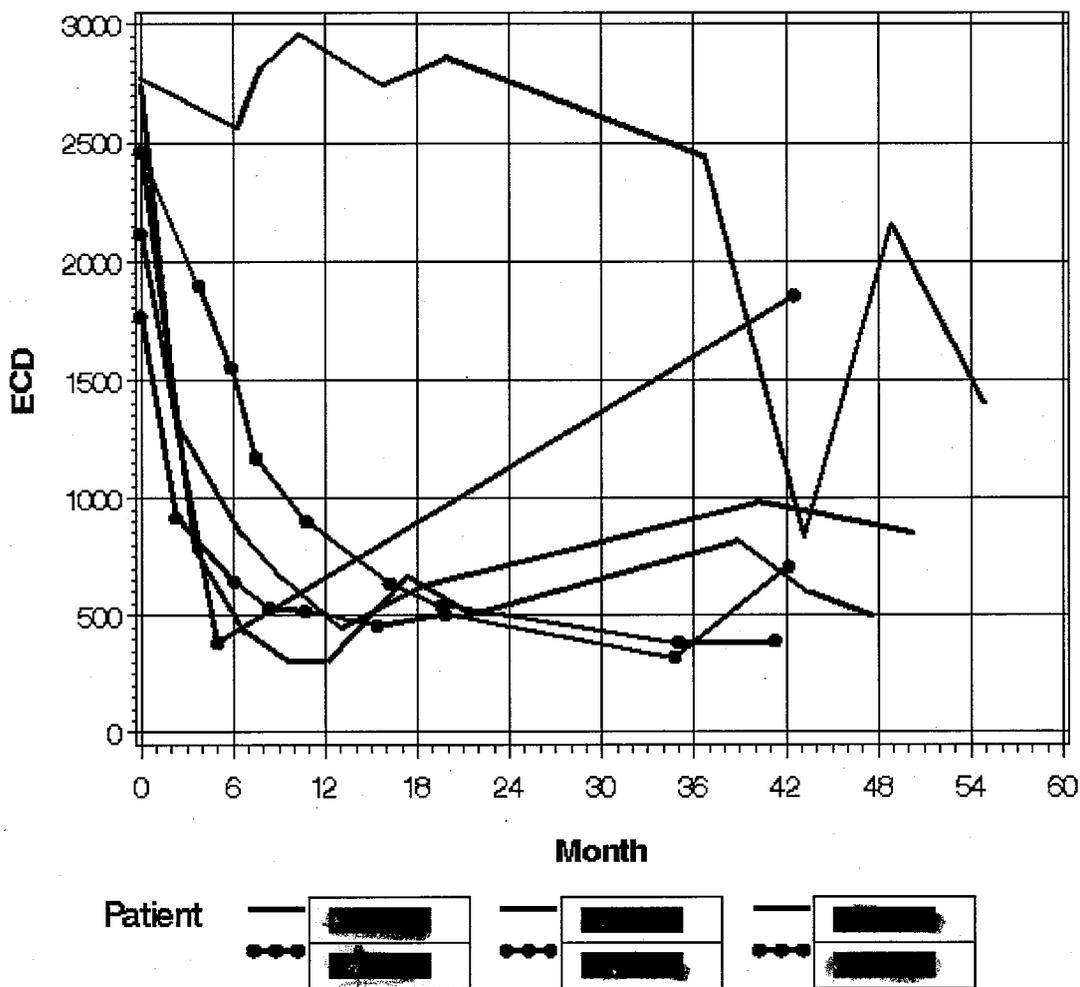


FIGURE 10
% HEXAGONALITY
IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT >3 MONTHS
N = 12

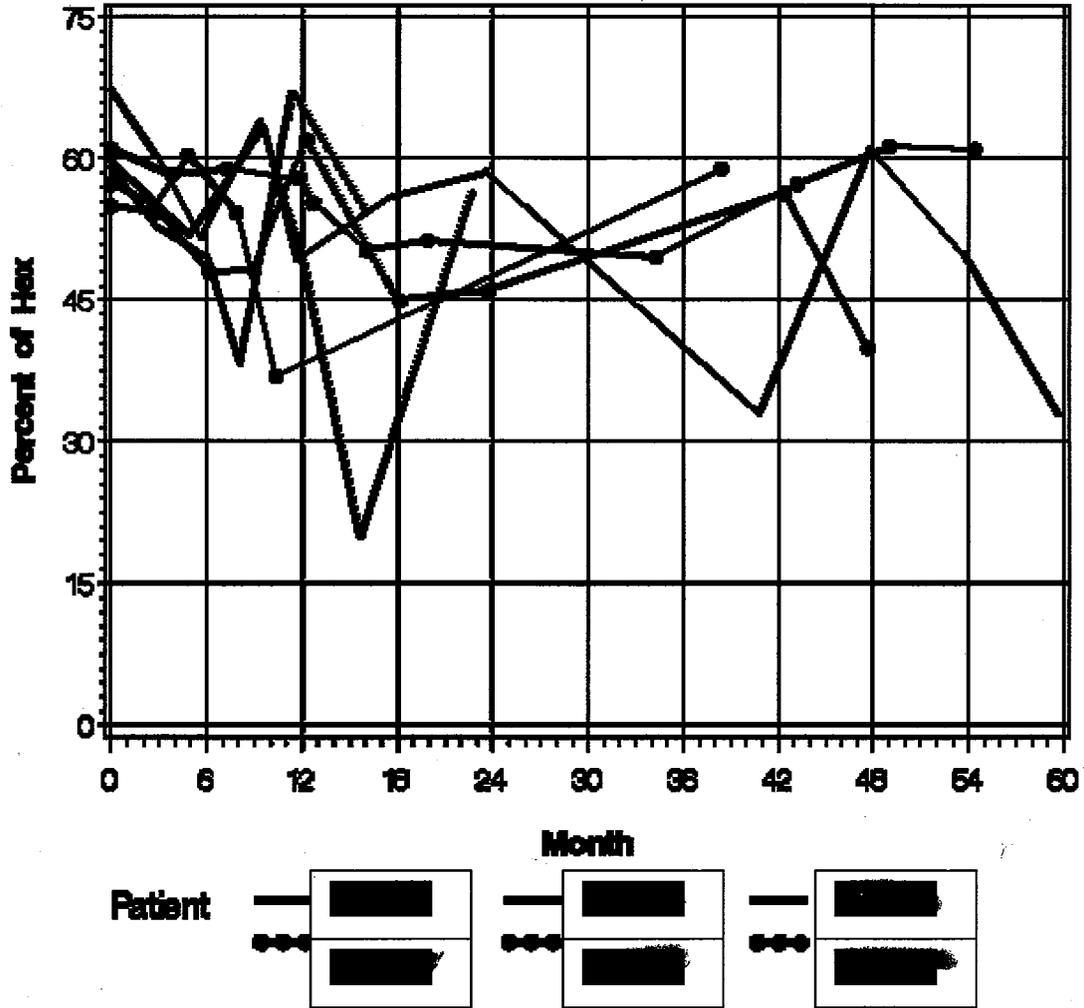


FIGURE 10 (CONTINUED)
% HEXAGONALITY
IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT >3 MONTHS
N = 12

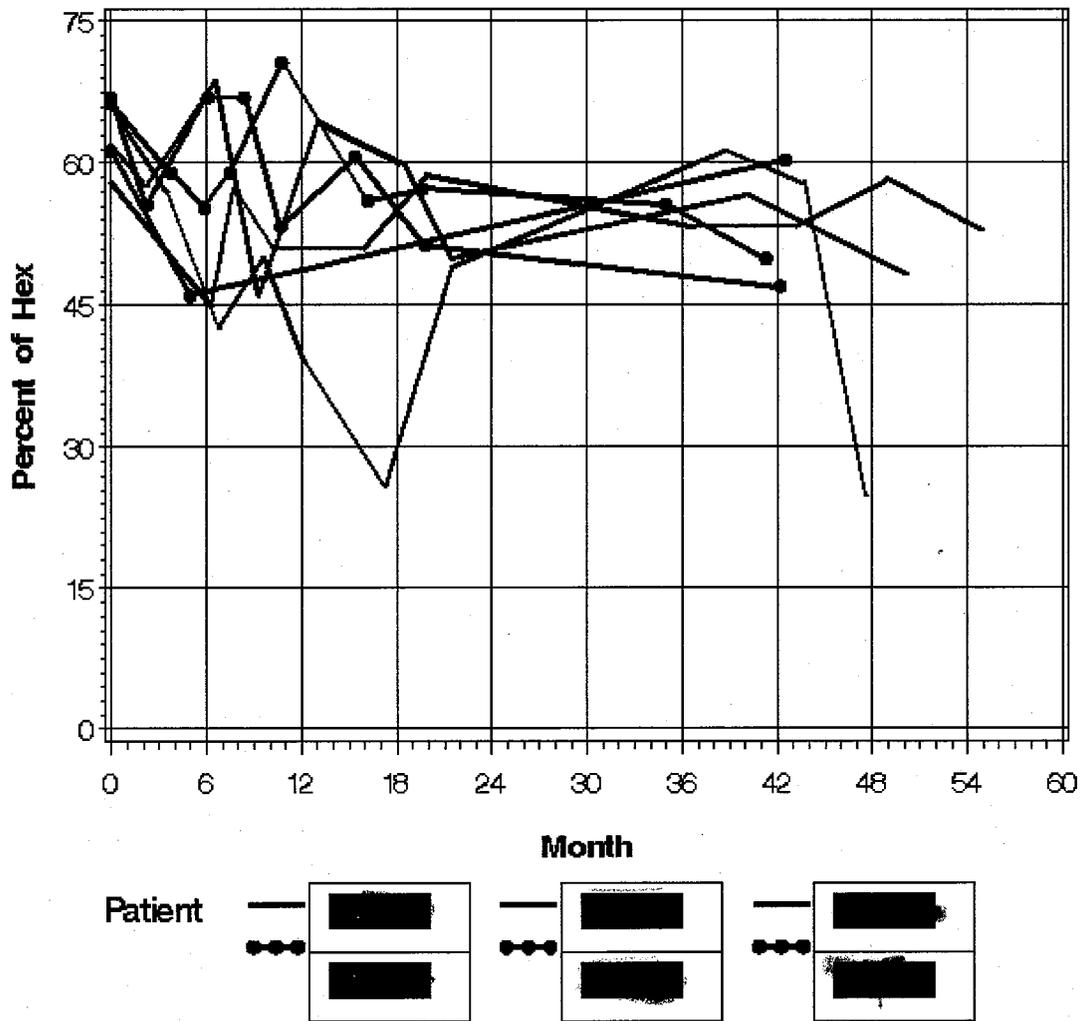


FIGURE 11
COEFFICIENT OF VARIATION
IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT >3 MONTHS
N = 12

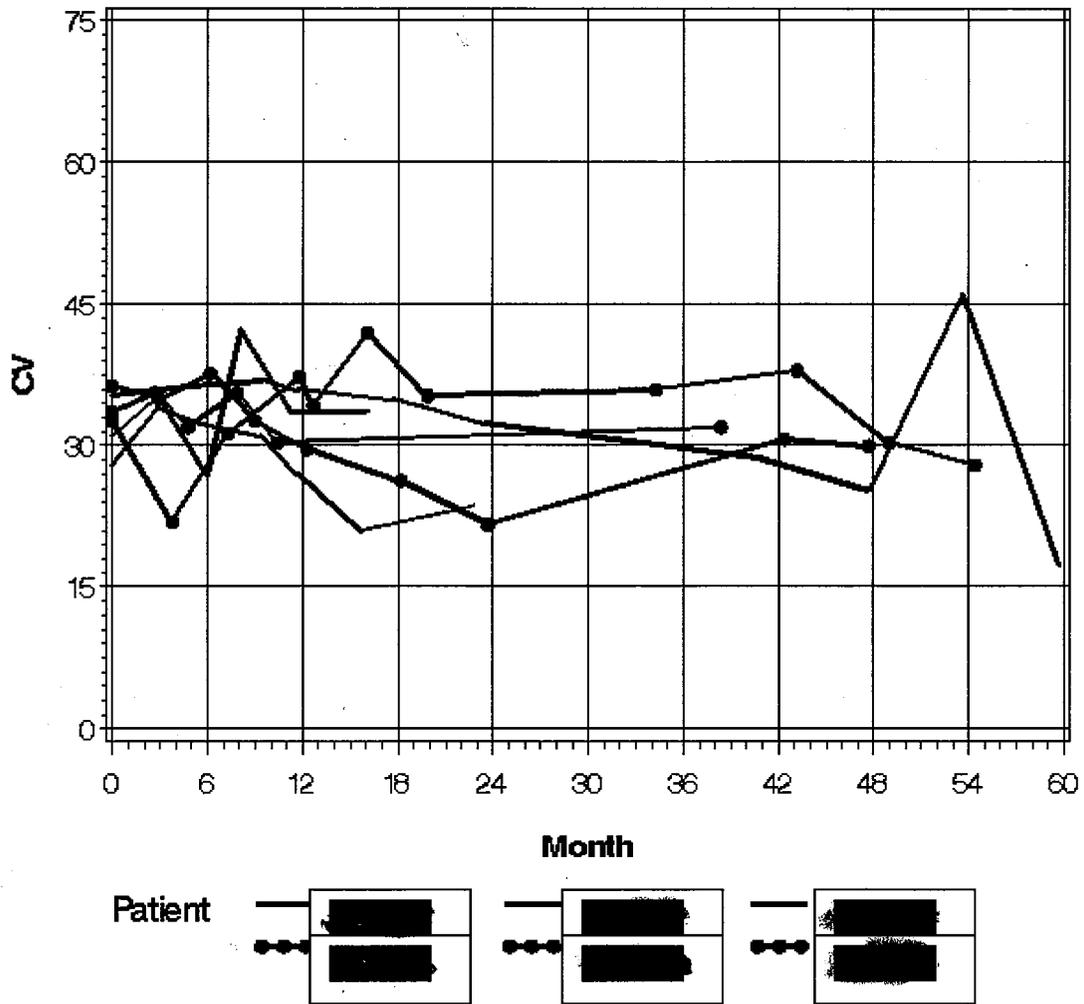


FIGURE 11 (CONTINUED)
COEFFICIENT OF VARIATION
IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT >3 MONTHS
N = 12

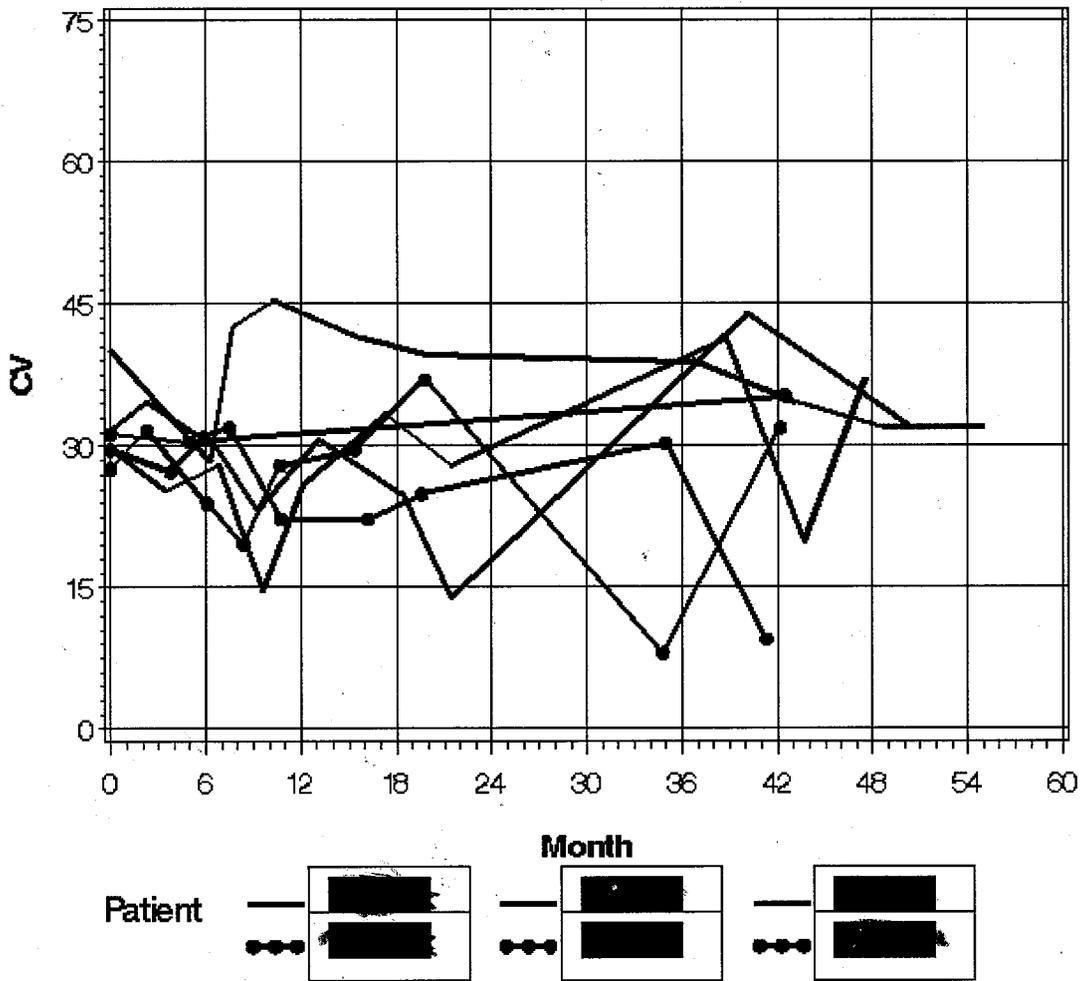


FIGURE 12)
CENTRAL CORNEAL THICKNESS
IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT >3 MONTHS
N = 12

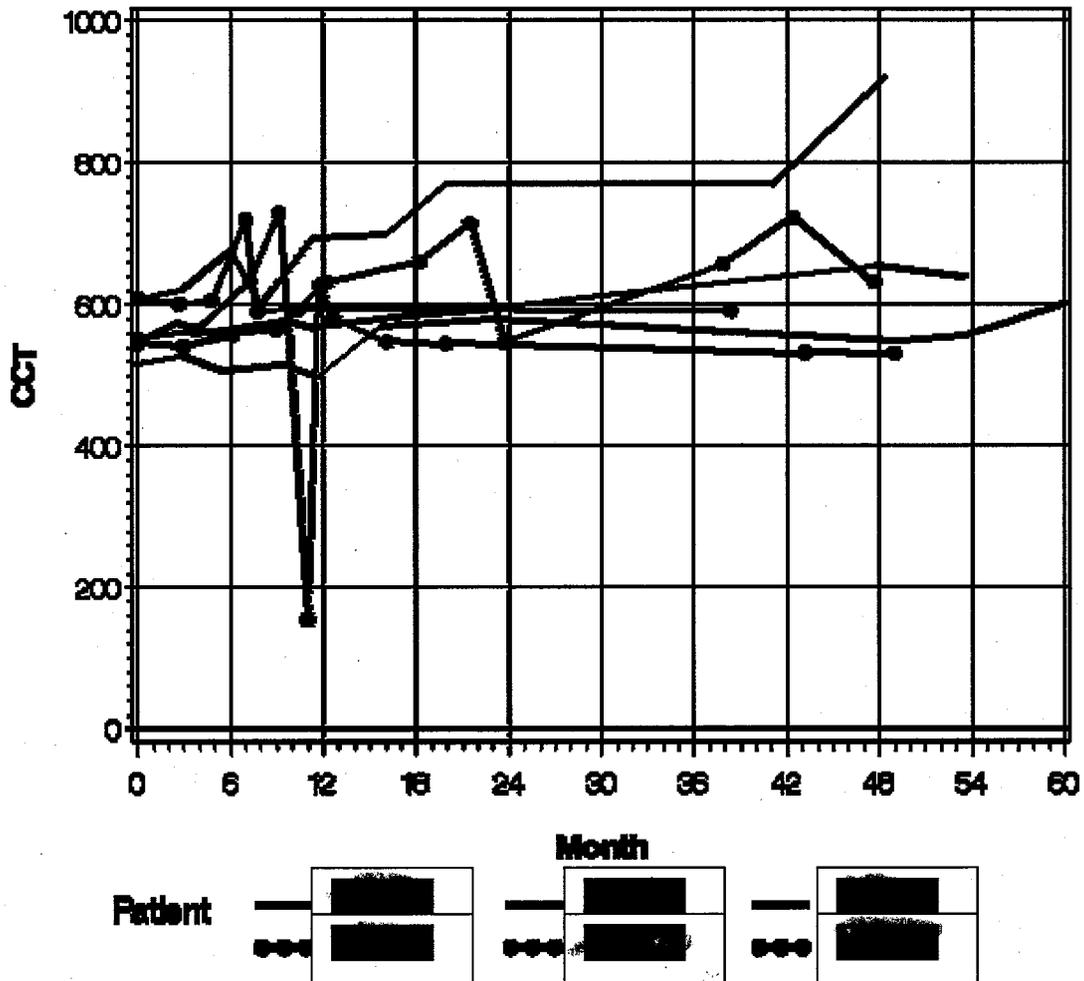
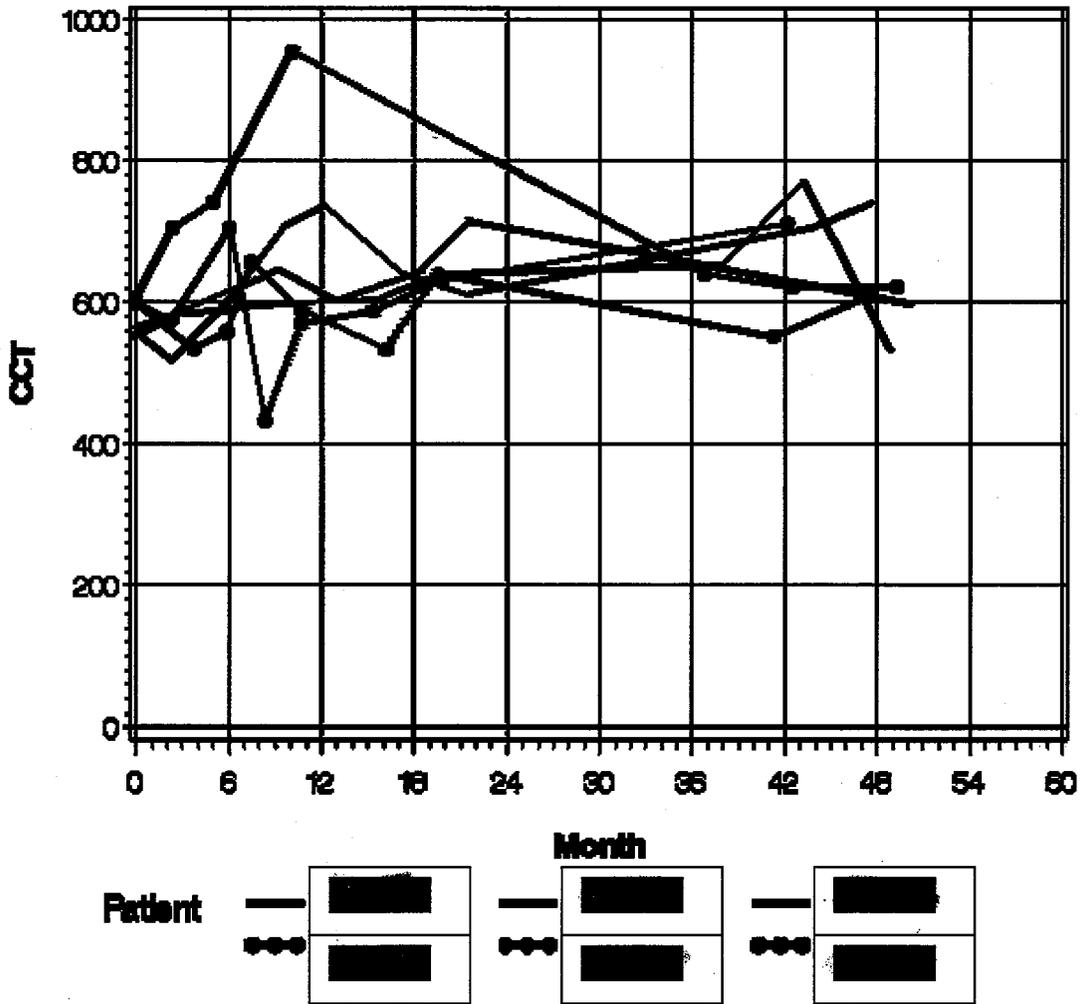


FIGURE 12 (CONTINUED)
CENTRAL CORNEAL THICKNESS
IMT-IMPLANTED EYES WITH CORNEAL EDEMA AT >3 MONTHS
N = 12



ITEM 3. RESPONSE TO EMAIL DATED OCTOBER 6, 2008

On page 58 of Volume 1 (p58), you state:

As shown in Figure 21, corneal thickness [CCT] did increase somewhat after IMT implantation, but the thickness was generally within normal limits of 550-570 microns.

You have provided mean CCTs, but no information concerning the spread of the data. For each scheduled visit (including pre-op) for all IMT-implanted eyes, please provide a table showing, along with the mean CCT and number of patients measured, the standard deviation of the CCTs; the minimum and maximum; the number and percent of patients with measurements above 600 microns; and the 50th, 75th, 90th, and 95th percentiles. Please provide a similar table for the fellow eyes.

Similarly, please provide a table showing the "difference in CCT between the two eyes" at each visit (including pre-op), for each IMT-implanted patient. This should include "n;" mean difference; standard deviation of the differences; 50th, 75th, 90th and 95th percentiles for the difference.

Please provide a similar table for the increase in CCT from pre-op. Include: "n," mean increase (microns) from baseline, standard deviation of the increase, 50th, 75th, 90th, 95th, 100th percentile for the increase.

VisionCare Response:

Mean CCT and change in CCT, with standard deviation and range, the number and percent of eyes with mean CCT >600 microns, and the 50th, 75th, 90th, 95th and 100th percentile are displayed in Tables 7 and 8 for IMT-implanted eyes, fellow eyes and the between-eye difference.

Between eye difference in mean CCT and change in mean CCT were small ranging from -1 micron at baseline to 10 microns at 48 months postoperatively (Table 7). CCT increased 7 microns from baseline to 24 months and 8 microns from baseline to 48 months (Table 8).

**TABLE 7
CENTRAL CORNEAL THICKNESS (CCT)
IMT-IMPLANTED SUBJECTS**

N	206	198	200	191	192	177	172	43	82	84
Mean	553	552	556	554	558	554	561	565	568	563
95% CI	548, 559	546, 558	550, 563	547, 561	549, 567	547, 562	553, 568	548, 581	554, 582	548, 577
SD	40	43	47	48	63	49	50	53	63	68
Min	440	441	423	421	155	417	435	430	457	423
Max	671	706	742	730	955	700	771	667	771	920
50th Percentile	553	551	556	551	557	556	562	565	554	562
75th Percentile	581	576	584	584	587	586	591	593	602	596
90th Percentile	604	603	609	614	611	611	616	644	638	627
95th Percentile	619	624	629	640	635	635	638	658	706	656
% of CCT > 600	23 (11.2%)	23 (11.6%)	28 (14.0%)	25 (13.1%)	32 (16.7%)	28 (15.8%)	31 (18.0%)	8 (18.6%)	22 (26.8%)	16 (19.0%)
N	206	195	200	192	193	178	173	43	81	84
Mean	554	553	553	552	554	555	553	557	557	553
95% CI	549, 560	548, 559	548, 559	547, 558	548, 560	549, 561	547, 559	543, 571	549, 566	544, 561
SD	39	39	40	38	40	40	39	46	39	39
Min	447	447	455	466	451	464	468	484	471	464
Max	690	703	670	657	656	665	682	708	638	630
50th Percentile	555	553	553	552	552	555	554	552	556	554
75th Percentile	580	579	580	581	580	584	578	585	593	584
90th Percentile	602	601	603	599	608	602	602	606	601	604
95th Percentile	617	614	617	619	621	623	612	630	621	612
% of CCT > 600	22 (10.7%)	21 (10.8%)	26 (13.0%)	19 (9.9%)	29 (15.0%)	21 (11.8%)	20 (11.6%)	6 (14.0%)	9 (11.1%)	10 (11.9%)
N	206	194	200	191	192	177	172	43	81	84
Mean	-1	-1	3	1	4	-0	7	8	11	10
95% CI	-3, 2	-6, 3	-2, 7	-4, 7	-4, 11	-6, 5	2, 13	-4, 20	1, 22	-1, 21
SD	18	33	32	38	50	39	37	39	47	52
Min	-120	-149	-155	-173	-386	-231	-167	-109	-96	-109
Max	72	136	216	173	351	127	174	128	185	337
50th Percentile	-1	-3	1	0	2	2	3	6	4	4
75th Percentile	8	13	13	11	15	16	17	22	22	19
90th Percentile	18	32	28	34	35	33	42	57	47	46
95th Percentile	24	49	50	60	48	43	70	70	117	83

N = number of eyes with non-missing data.

TABLE 8
CHANGE IN CENTRAL CORNEAL THICKNESS (CCT) FROM BASELINE
IMT-IMPLANTED SUBJECTS

N	198	200	191	192	177	172	43	82	84
Mean	-1	3	1	4	0	7	9	10	8
95% CI	(-6, 3)	(-2, 8)	(-5, 6)	(-4, 11)	(-6, 6)	(1, 12)	(-4, 22)	(-1, 22)	(-4, 19)
SD	34	37	40	53	40	36	42	51	54
Min	-132	-98	-167	-398	-174	-142	-106	-157	-138
Max	164	217	177	347	144	170	113	206	313
50th Percentile	-4	0	-1	2	1	2	9	0	1
75th Percentile	10	15	12	16	13	17	24	20	20
90th Percentile	28	32	29	35	38	41	75	54	59
95th Percentile	50	66	68	55	54	64	79	112	88
N	195	200	192	193	178	173	43	81	84
Mean	-1	-1	-2	-1	-1	-2	0	-2	-3
95% CI	(-4, 1)	(-4, 3)	(-5, 1)	(-5, 2)	(-5, 2)	(-5, 1)	(-8, 8)	(-6, 2)	(-7, 1)
SD	17	24	21	23	21	21	27	19	20
Min	-60	-64	-72	-107	-88	-105	-55	-57	-60
Max	103	159	107	105	95	113	108	61	102
50th Percentile	-1	-1	-3	0	-2	-1	-3	-2	-1
75th Percentile	7	7	7	9	7	7	10	9	6
90th Percentile	18	15	16	22	19	15	27	21	15
95th Percentile	23	27	23	28	24	26	38	30	20
N	194	200	191	192	177	172	43	81	84
Mean	-0	4	3	5	2	8	9	12	11
95% CI	(-5, 5)	(-1, 9)	(-3, 9)	(-2, 13)	(-5, 8)	(3, 14)	(-4, 22)	(1, 24)	(-1, 22)
SD	37	36	43	53	45	37	43	51	55
Min	-149	-148	-175	-386	-249	-136	-127	-118	-100
Max	174	218	173	336	153	182	136	193	334
50th Percentile	-2	2	1	4	3	4	10	6	3
75th Percentile	12	14	12	17	18	19	23	22	22
90th Percentile	36	35	35	35	39	39	73	49	55
95th Percentile	59	60	74	78	56	64	74	115	85

N = number of eyes with non-missing data.