

Clinical Studies Summary

Tables 1 To 8: All Eye Data (N=138)

**Tables 10 To 14: Bilateral Series Cohort –
Both eyes examined (N=42 patients)**

Appendix C. 1: Bilateral Series Cohort Clinical Results Tables

Appendix C. 2: Monocular Series Cohort Clinical Results Tables

Lenstec™ TetraFlex™ Accommodating Posterior Chamber IOL - Prior Clinical Study Summary

As part of an ongoing study of the Lenstec™ TetraFlex™ Accommodating Posterior Chamber IOL, 2 users in England, (Dr. Deepak Chitkara, Manchester, England, and Dr. Sunil Shah, Birmingham, England) have implanted a total of 205 IOLs; 138 have been followed up for a minimum of 6 months postoperatively.

The majority of these IOL's were implanted between February 2003 and July 2004. A comparable surgical technique was followed at both centers and standardized clinical outcome parameters were collected. The surgical technique used in this study is identical to the proposed technique in the IDE study in that equivalent lens implantation instructions were followed.

All eyes in the prospective study were implanted with IOL's identical to the device proposed in the IDE study. Patients recruited were all above 18 years of age; the mean age was 57.33 years, ranging from 23 to 88 years old with a standard deviation of 13.24 years. In this patient series, 40.3% were male and 59.7% were female (9 not reported).

This series includes 40 monocularly implanted cases and 98 eyes of 49 patients implanted bilaterally. The bilateral series is not divided into primary and second eyes because in all but 6 cases, the IOLs were implanted in both eyes on the same day. The results from all eyes will be reviewed as part of a safety cohort, and overall efficacy will be reported as well for the monocular series cohort and bilateral series cohort (individual eyes). A subset of 42 bilaterally implanted patients was examined with both eyes open during the efficacy examination. Efficacy will be reported separately for this latter cohort.

Four cases (2.9%) of the 138 eyes that underwent TetraFlex IOL implantation were diagnosed with amblyopia preoperatively.

All Eyes (N = 138)

Safety Assessment

Best Spectacle Corrected Visual Acuity

Table 1 presents the BSCVA over time in the 138 cases receiving the TetraFlex IOL. At 6 months or later, 96.8% of the 94 cases seen during that period had 20/40 or better BSCVA.

Table 2 demonstrates the change in BSCVA over time, compared to preoperatively. No patient lost ≥ 2 lines at 6 months or later.

Postoperative Complications

Table 3 summarizes the postoperative findings/observations. There were no operative or postoperative complications attributable to the TetraFlex IOL. Astigmatic keratotomy (AK) incisions were performed in 8 cases at the time of the IOL surgery and in 1 case at 3 months postoperatively. In 2 cases where astigmatic keratotomy (AK) incisions were performed there was a wound gape and an associated iris prolapse at the wound at 1 day postoperatively that required repair. In 4 eyes of 4 separate cases with large AK's performed, there was also significant early inflammatory response with fibrin seen in the anterior chamber. These cleared rapidly with steroid drops.

Some degree of posterior capsular opacification was seen in 4 eyes of separate patients at 6 months or before with one case requiring a Nd:YAG posterior capsulotomy. None of the 4 cases lost lines of BSCVA or had any other symptoms/complications.

Efficacy Assessment

Uncorrected Visual Acuity

Table 4 presents the uncorrected distance vision over time. At 6 months or later, 75 of the 81 reported cases (92.6%) had 20/40 or better vision, and 74.1% had 20/25 or better.

At 6 months or later, no reported cases demonstrated a UCDVA worse than 20/80, in comparison to preoperative UCDVA where 61.1% of cases were worse than 20/80.

Unaided near vision is presented in **Table 5**; at 6 months or later, 36 of the 81 reported cases (44.4%) had 20/40 or better vision, in comparison to 7.1% preoperatively.

Distance Corrected Near Vision

The distance corrected near vision over time is provided in **Table 6**. Of the 80 reported cases at 6 months or later, 48 (60%) had 20/40 or better distance corrected near vision.

Manifest Refraction

The TetraFlex IOL effectively caused 94.7% of the 94 reported cases to be within ± 1.0 D of emmetropia (manifest refraction spherical equivalent) (**Table 7**), and 70.2% of cases were within ± 0.5 D, at 6 months or later. Comparatively, the preoperative data showed that only 10.7% of cases were within ± 1.0 D of emmetropia. Target refractions ranged between emmetropia to 0.25 D.

Accommodative Amplitude

Table 8 shows that 95.6% of the 91 reported cases had an accommodative amplitude of > 1.0 D, 69.2% could accommodate > 2.0 D, and 19.8% more than 3.0 D.

Similar tables are presented for the bilateral series cohort (N = 98) in Appendix 1, and the monocular series cohort (N = 40) in Appendix 2. As presented in Table 9 below, the results were similar in the two cohorts.

Table 9: Safety and Efficacy Variables of Different Study Cohorts

| Parameter at 6 Months or later post IOL implantation | All Eyes N=138 % (n/N) | Bilateral Cohort N=98 % (n/N) | Monocular Cohort N=40 % (n/N) |
|--|------------------------------|-------------------------------------|-------------------------------------|
| BSCVA 20/40 or better | 96.8 (91/94) | 98.5 (64/65) | 93.1 (27/29) |
| BSCVA Loss \geq 2 lines | 0 (0/94) | 0 (0/65) | 0 (0/29) |
| UCVA 20/40 or better | 92.6 (75/81) | 93.3 (56/60) | 90.5 (19/21) |
| MRSE \pm 1.0 D | 94.7 (89/94) | 93.8 (61/65) | 96.5 (28/29) |
| Accommodative Amplitude > 2.0 D | 69.2 (63/91) | 67.2 (43/64) | 74.1 (20/27) |
| Accommodative Amplitude > 3.0 D | 19.8 (18/91) | 17.2 (11/64) | 25.9 (7/27) |

Bilateral Series Subset - Examined with both eyes open (N = 42 patients)

Efficacy Assessment

Best Spectacle Corrected Visual Acuity

Six months or later after TetraFlex IOL implantation, all examined patients experienced a BSCVA of 20/32 or better; additionally 96.7% were 20/25 or better (Table 10).

Uncorrected Visual Acuity

Table 11 presents the uncorrected distance visual acuity over time. At 6 months or later, all of the 30 reported cases had 20/40 or better vision, and all but one patient had a UCVA of 20/25 or better. Unaided near visual acuity at 6 months or later was 20/40 or better in 70% of the reported cases (**Table 12**).

Distance Corrected Near Vision

Table 13 presents the distance corrected near vision over time. Of the 30 examined patients at 6 months or later, 27 (90%) had 20/40 or better distance corrected near vision.

Accommodative Amplitude

Six months or later after TetraFlex IOL implantation, 96.6% of the 29 examined patients had accommodative amplitude of more than 2.0 D, and 48.3% could accommodate more than 3.0 D (**Table 14**).

Conclusions

The Study Sponsor believes that the results of these Pre IDE clinical cases support the safety of the Lenstec™ TetraFlex™ Accommodating Posterior Chamber IOL to sufficiently allow continuous enrollment of cases in a Phase III protocol from the onset of the IDE clinical investigation. The Study Sponsor also believes that the demonstrated safety of the KH 3500 IOL in the bilateral series cohort supports the enrollment of the second eye of bilateral cases as early as the first eye 1 month postoperative time interval, per discussions with the FDA on October 19th, 2004.

The preliminary effectiveness outcomes reported during these Pre IDE clinical cases substantiates the feasibility of the investigational lens to provide improvements in both near and distance uncorrected visual acuity.

Based on these outcomes, the enclosed IDE Clinical Investigational Protocol incorporates these study features: a single-phase (Phase III) study cohort where fellow eyes may be treated one month after the primary eye lens implantation.

TABLES 1 to 8
“ALL EYE DATA (N=138)”

TABLE 1 - BEST CORRECTED DISTANCE VISUAL ACUITY with TIME
All Eyes

| | Preop n/N (%) | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|-------------------|-------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| 20/15 or better | 49 / 138 (35.5%) | 1 / 5 (20%) | 44 / 109 (40.4%) | 50 / 125 (40%) | 52 / 99 (52.5%) | 45 / 94 (47.9%) |
| 20/20 or better | 74 / 138 (53.6%) | 3 / 5 (60%) | 81 / 109 (74.3%) | 92 / 125 (73.6%) | 81 / 99 (81.8%) | 75 / 94 (79.8%) |
| 20/25 or better | 99 / 138 (71.7%) | 4 / 5 (80%) | 102 / 109 (93.6%) | 116 / 125 (92.8%) | 92 / 99 (92.9%) | 83 / 94 (88.3%) |
| 20/32 or better | 104 / 138 (75.4%) | 4 / 5 (80%) | 106 / 109 (97.2%) | 119 / 125 (95.2%) | 95 / 99 (96%) | 89 / 94 (94.7%) |
| 20/40 or better | 117 / 138 (84.8%) | 5 / 5 (100%) | 107 / 109 (98.2%) | 121 / 125 (96.8%) | 97 / 99 (98%) | 91 / 94 (96.8%) |
| 20/80 or better | 132 / 138 (95.7%) | 5 / 5 (100%) | 109 / 109 (100%) | 124 / 125 (99.2%) | 99 / 99 (100%) | 94 / 94 (100%) |
| 20/200 or better | 138 / 138 (100%) | 5 / 5 (100%) | 109 / 109 (100%) | 125 / 125 (100%) | 99 / 99 (100%) | 94 / 94 (100%) |
| Worse than 20/200 | 0 / 138 (0%) | 0 / 5 (0%) | 0 / 109 (0%) | 0 / 125 (0%) | 0 / 99 (0%) | 0 / 94 (0%) |
| Not Reported | 0 | 93 | 1 | 1 | 0 | 0 |
| TOTAL | 138 | 98 | 110 | 126 | 99 | 94 |

TABLE 2 - CHANGE IN BEST CORRECTED DISTANCE VISUAL ACUITY
All Eyes

| | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|--------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| Decrease > 2 Lines | 0 / 5 (0%) | 0 / 109 (0%) | 1 / 125 (0.8%) | 0 / 99 (0%) | 0 / 94 (0%) |
| Decrease 2 Lines | 1 / 5 (20%) | 3 / 109 (2.8%) | 4 / 125 (3.2%) | 4 / 99 (4%) | 0 / 94 (0%) |
| Decrease 1 Line | 2 / 5 (40%) | 26 / 109 (23.9%) | 20 / 125 (16%) | 16 / 99 (16.2%) | 13 / 94 (13.8%) |
| No Change | 2 / 5 (40%) | 52 / 109 (47.7%) | 53 / 125 (42.4%) | 46 / 99 (46.5%) | 46 / 94 (48.9%) |
| Increase 1 Line | 0 / 5 (0%) | 15 / 109 (13.8%) | 13 / 125 (10.4%) | 18 / 99 (18.2%) | 14 / 94 (14.9%) |
| Increase 2 Lines | 0 / 5 (0%) | 9 / 109 (8.3%) | 17 / 125 (13.6%) | 11 / 99 (11.1%) | 8 / 94 (8.5%) |
| Increase > 2 Lines | 0 / 5 (0%) | 4 / 109 (3.7%) | 17 / 125 (13.6%) | 4 / 99 (4%) | 13 / 94 (13.8%) |
| Not Reported | 93 | 1 | 1 | 0 | 0 |
| TOTAL | 98 | 110 | 126 | 99 | 94 |

TABLE 3 - POSTOPERATIVE FINDINGS/OBSERVATIONS
All Eyes

| | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|--|------------------|-------------------|--------------------|---------------------|------------------------------|
| LASIK | 0 / 98 (0%) | 0 / 110 (0%) | 0 / 126 (0%) | 2 / 99 (2%) | 0 / 94 (0%) |
| Posterior Capsule Opacification | 0 / 98 (0%) | 0 / 110 (0%) | 0 / 126 (0%) | 2 / 99 (2%) | 2 / 94 (2.1%) |
| Nd:YAG for PCO | 0 / 98 (0%) | 0 / 110 (0%) | 0 / 126 (0%) | 1 / 99 (1%) | 0 / 94 (0%) |
| Fibrinoid Reaction secondary to large AK incision | 0 / 98 (0%) | 4 / 110 (3.6%) | 0 / 126 (0%) | 0 / 99 (0%) | 0 / 94 (0%) |
| AK | 8 / 98 (8.2%) | 0 / 110 (0%) | 0 / 126 (0%) | 1 / 99 (1%) | 0 / 94 (0%) |
| Iris Prolapse repaired 1 day postop secondary to large AK incision | 2 / 98 (2%) | 0 / 110 (0%) | 0 / 126 (0%) | 0 / 99 (0%) | 0 / 94 (0%) |
| Sutured too large AK incision | 0 / 98 (0%) | 0 / 110 (0%) | 1 / 126 (0.8%) | 0 / 99 (0%) | 0 / 94 (0%) |

**TABLE 4 - UNCORRECTED DISTANCE VISUAL ACUITY with Time
All Eyes**

| | Preop n/N (%) | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|-------------------|------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| 20/15 or better | 0 / 113 (0%) | 9 / 98 (9.2%) | 17 / 108 (15.7%) | 16 / 123 (13%) | 15 / 99 (15.2%) | 21 / 81 (25.9%) |
| 20/20 or better | 2 / 113 (1.8%) | 37 / 98 (37.8%) | 43 / 108 (39.8%) | 40 / 123 (32.5%) | 37 / 99 (37.4%) | 44 / 81 (54.3%) |
| 20/25 or better | 11 / 113 (9.7%) | 57 / 98 (58.2%) | 72 / 108 (66.7%) | 79 / 123 (64.2%) | 70 / 99 (70.7%) | 60 / 81 (74.1%) |
| 20/32 or better | 21 / 113 (18.6%) | 77 / 98 (78.6%) | 85 / 108 (78.7%) | 96 / 123 (78%) | 82 / 99 (82.8%) | 68 / 81 (84%) |
| 20/40 or better | 27 / 113 (23.9%) | 90 / 98 (91.8%) | 93 / 108 (86.1%) | 103 / 123 (83.7%) | 88 / 99 (88.9%) | 75 / 81 (92.6%) |
| 20/80 or better | 44 / 113 (38.9%) | 95 / 98 (96.9%) | 104 / 108 (96.3%) | 120 / 123 (97.6%) | 99 / 99 (100%) | 81 / 81 (100%) |
| 20/200 or better | 76 / 113 (67.3%) | 98 / 98 (100%) | 108 / 108 (100%) | 123 / 123 (100%) | 99 / 99 (100%) | 81 / 81 (100%) |
| Worse than 20/200 | 37 / 113 (32.7%) | 0 / 98 (0%) | 0 / 108 (0%) | 0 / 123 (0%) | 0 / 99 (0%) | 0 / 81 (0%) |
| Not Reported | 25 | 0 | 2 | 3 | 0 | 13 |
| TOTAL | 138 | 98 | 110 | 126 | 99 | 94 |

**TABLE 5 - UNCORRECTED NEAR VISUAL ACUITY with Time
All Eyes**

| | Preop n/N (%) | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|-------------------|------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| 20/15 or better | 0 / 98 (0%) | 0 / 29 (0%) | 0 / 104 (0%) | 0 / 104 (0%) | 0 / 99 (0%) | 0 / 81 (0%) |
| 20/20 or better | 0 / 98 (0%) | 1 / 29 (3.4%) | 8 / 104 (7.7%) | 7 / 104 (6.7%) | 3 / 99 (3%) | 2 / 81 (2.5%) |
| 20/25 or better | 1 / 98 (1%) | 8 / 29 (27.6%) | 17 / 104 (16.3%) | 19 / 104 (18.3%) | 11 / 99 (11.1%) | 7 / 81 (8.6%) |
| 20/32 or better | 3 / 98 (3.1%) | 17 / 29 (58.6%) | 32 / 104 (30.8%) | 32 / 104 (30.8%) | 24 / 99 (24.2%) | 17 / 81 (21%) |
| 20/40 or better | 7 / 98 (7.1%) | 24 / 29 (82.8%) | 55 / 104 (52.9%) | 45 / 104 (43.3%) | 44 / 99 (44.4%) | 36 / 81 (44.4%) |
| 20/80 or better | 8 / 98 (8.2%) | 26 / 29 (89.7%) | 76 / 104 (73.1%) | 72 / 104 (69.2%) | 70 / 99 (70.7%) | 55 / 81 (67.9%) |
| 20/200 or better | 12 / 98 (12.2%) | 28 / 29 (96.6%) | 88 / 104 (84.6%) | 86 / 104 (82.7%) | 81 / 99 (81.8%) | 70 / 81 (86.4%) |
| Worse than 20/200 | 86 / 98 (87.8%) | 1 / 29 (3.4%) | 16 / 104 (15.4%) | 18 / 104 (17.3%) | 18 / 99 (18.2%) | 11 / 81 (13.6%) |
| Not Reported | 40 | 69 | 6 | 22 | 0 | 13 |
| TOTAL | 138 | 98 | 110 | 126 | 99 | 94 |

**TABLE 6 - DISTANCE CORRECTED NEAR VISION with TIME
All Eyes**

| | Preop n/N (%) | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|-------------------|------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| 20/15 or better | 0 / 19 (0%) | 0 / 2 (0%) | 0 / 95 (0%) | 0 / 101 (0%) | 0 / 97 (0%) | 0 / 80 (0%) |
| 20/20 or better | 2 / 19 (10.5%) | 0 / 2 (0%) | 2 / 95 (2.1%) | 1 / 101 (1%) | 1 / 97 (1%) | 2 / 80 (2.5%) |
| 20/25 or better | 9 / 19 (47.4%) | 0 / 2 (0%) | 18 / 95 (18.9%) | 8 / 101 (7.9%) | 6 / 97 (6.2%) | 9 / 80 (11.3%) |
| 20/32 or better | 10 / 19 (52.6%) | 1 / 2 (50%) | 33 / 95 (34.7%) | 17 / 101 (16.8%) | 23 / 97 (23.7%) | 19 / 80 (23.8%) |
| 20/40 or better | 12 / 19 (63.2%) | 2 / 2 (100%) | 52 / 95 (54.7%) | 41 / 101 (40.6%) | 50 / 97 (51.5%) | 48 / 80 (60%) |
| 20/80 or better | 13 / 19 (68.4%) | 2 / 2 (100%) | 77 / 95 (81.1%) | 66 / 101 (65.3%) | 71 / 97 (73.2%) | 69 / 80 (86.3%) |
| 20/200 or better | 15 / 19 (78.9%) | 2 / 2 (100%) | 87 / 95 (91.6%) | 84 / 101 (83.2%) | 83 / 97 (85.6%) | 78 / 80 (97.5%) |
| Worse than 20/200 | 4 / 19 (21.1%) | 0 / 2 (0%) | 8 / 95 (8.4%) | 17 / 101 (16.8%) | 14 / 97 (14.4%) | 2 / 80 (2.5%) |
| Not Reported | 119 | 96 | 15 | 25 | 2 | 14 |
| TOTAL | 138 | 98 | 110 | 126 | 99 | 94 |

TABLE 7 - MANIFEST REFRACTION SPHERICAL EQUIVALENT with TIME
All Eyes

| | Preop n/N (%) | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|-------------------|------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| More than +2.00 D | 52 / 113 (46%) | 0 / 4 (0%) | 1 / 108 (0.9%) | 0 / 126 (0%) | 0 / 99 (0%) | 0 / 94 (0%) |
| +1.51 to +2.00 D | 11 / 113 (9.7%) | 0 / 4 (0%) | 0 / 108 (0%) | 1 / 126 (0.8%) | 0 / 99 (0%) | 1 / 94 (1.1%) |
| +1.01 to +1.50 D | 11 / 113 (9.7%) | 0 / 4 (0%) | 2 / 108 (1.9%) | 3 / 126 (2.4%) | 3 / 99 (3%) | 3 / 94 (3.2%) |
| +0.51 to +1.00 D | 2 / 113 (1.8%) | 1 / 4 (25%) | 12 / 108 (11.1%) | 16 / 126 (12.7%) | 14 / 99 (14.1%) | 12 / 94 (12.8%) |
| -0.50 to +0.50 D | 7 / 113 (6.2%) | 0 / 4 (0%) | 77 / 108 (71.3%) | 77 / 126 (61.1%) | 70 / 99 (70.7%) | 66 / 94 (70.2%) |
| -0.51 to -1.00 D | 3 / 113 (2.7%) | 2 / 4 (50%) | 9 / 108 (8.3%) | 18 / 126 (14.3%) | 9 / 99 (9.1%) | 11 / 94 (11.7%) |
| -1.01 to -1.50 D | 0 / 113 (0%) | 1 / 4 (25%) | 5 / 108 (4.6%) | 8 / 126 (6.3%) | 3 / 99 (3%) | 1 / 94 (1.1%) |
| -1.51 to -2.00 D | 2 / 113 (1.8%) | 0 / 4 (0%) | 2 / 108 (1.9%) | 3 / 126 (2.4%) | 0 / 99 (0%) | 0 / 94 (0%) |
| -2.00 to -2.50 D | 1 / 113 (0.9%) | 0 / 4 (0%) | 0 / 108 (0%) | 0 / 126 (0%) | 0 / 99 (0%) | 0 / 94 (0%) |
| Less than -2.00 D | 14 / 113 (12.4%) | 0 / 4 (0%) | 0 / 108 (0%) | 0 / 126 (0%) | 0 / 99 (0%) | 0 / 94 (0%) |
| Not Reported | 25 | 94 | 2 | 0 | 0 | 0 |
| TOTAL | 138 | 98 | 110 | 126 | 99 | 94 |

TABLE 8 - ACCOMMODATIVE AMPLITUDE with TIME
All Eyes

| | Preop n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|--------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| >0.0 | 7 / 7 (100%) | 92 / 92 (100%) | 112 / 112 (100%) | 96 / 96 (100%) | 91 / 91 (100%) |
| >1.0 | 7 / 7 (100%) | 92 / 92 (100%) | 109 / 112 (97.3%) | 96 / 96 (100%) | 87 / 91 (95.6%) |
| >2.0 | 6 / 7 (85.7%) | 68 / 92 (73.9%) | 81 / 112 (72.3%) | 73 / 96 (76%) | 63 / 91 (69.2%) |
| >3.0 | 0 / 7 (0%) | 28 / 92 (30.4%) | 32 / 112 (28.6%) | 23 / 96 (24%) | 18 / 91 (19.8%) |
| >4.0 | 0 / 7 (0%) | 12 / 92 (13%) | 17 / 112 (15.2%) | 6 / 96 (6.3%) | 3 / 91 (3.3%) |
| >5.0 | 0 / 7 (0%) | 7 / 92 (7.6%) | 9 / 112 (8%) | 0 / 96 (0%) | 0 / 91 (0%) |
| >6.0 | 0 / 7 (0%) | 6 / 92 (6.5%) | 5 / 112 (4.5%) | 0 / 96 (0%) | 0 / 91 (0%) |
| >7.0 | 0 / 7 (0%) | 2 / 92 (2.2%) | 3 / 112 (2.7%) | 0 / 96 (0%) | 0 / 91 (0%) |
| Mean | 2.29 | 3.39 | 3.08 | 2.81 | 2.69 |
| Not Reported | 131 | 18 | 14 | 3 | 3 |
| TOTAL | 138 | 110 | 126 | 99 | 94 |

TABLES 10 to 14

**“BILATERAL SERIES COHORT – BOTH EYES EXAMINED (N=42
PATIENTS)”**

TABLE 10 - BEST CORRECTED DISTANCE VISUAL ACUITY with TIME
Exams on Both Eyes

| | Preop n/N (%) | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|-------------------|------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| 20/15 or better | 23 / 40 (57.5%) | 0 / 1 (0%) | 24 / 41 (58.5%) | 27 / 42 (64.3%) | 29 / 38 (76.3%) | 23 / 30 (76.7%) |
| 20/20 or better | 32 / 40 (80%) | 0 / 1 (0%) | 35 / 41 (85.4%) | 39 / 42 (92.9%) | 37 / 38 (97.4%) | 29 / 30 (96.7%) |
| 20/25 or better | 39 / 40 (97.5%) | 1 / 1 (100%) | 40 / 41 (97.6%) | 42 / 42 (100%) | 38 / 38 (100%) | 29 / 30 (96.7%) |
| 20/32 or better | 39 / 40 (97.5%) | 1 / 1 (100%) | 41 / 41 (100%) | 42 / 42 (100%) | 38 / 38 (100%) | 30 / 30 (100%) |
| 20/40 or better | 40 / 40 (100%) | 1 / 1 (100%) | 41 / 41 (100%) | 42 / 42 (100%) | 38 / 38 (100%) | 30 / 30 (100%) |
| 20/80 or better | 40 / 40 (100%) | 1 / 1 (100%) | 41 / 41 (100%) | 42 / 42 (100%) | 38 / 38 (100%) | 30 / 30 (100%) |
| 20/200 or better | 40 / 40 (100%) | 1 / 1 (100%) | 41 / 41 (100%) | 42 / 42 (100%) | 38 / 38 (100%) | 30 / 30 (100%) |
| Worse than 20/200 | 0 / 40 (0%) | 0 / 1 (0%) | 0 / 41 (0%) | 0 / 42 (0%) | 0 / 38 (0%) | 0 / 30 (0%) |
| Not Reported | 0 | 34 | 2 | 0 | 0 | 0 |
| TOTAL | 40 | 35 | 43 | 42 | 38 | 30 |

**TABLE 11 - UNCORRECTED DISTANCE VISUAL ACUITY with Time
Exams on Both Eyes**

| | Preop n/N (%) | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|-------------------|------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| 20/15 or better | 0 / 42 (0%) | 5 / 35 (14.3%) | 15 / 42 (35.7%) | 15 / 42 (35.7%) | 13 / 38 (34.2%) | 14 / 30 (46.7%) |
| 20/20 or better | 1 / 42 (2.4%) | 18 / 35 (51.4%) | 28 / 42 (66.7%) | 26 / 42 (61.9%) | 27 / 38 (71.1%) | 25 / 30 (83.3%) |
| 20/25 or better | 6 / 42 (14.3%) | 26 / 35 (74.3%) | 37 / 42 (88.1%) | 35 / 42 (83.3%) | 33 / 38 (86.8%) | 29 / 30 (96.7%) |
| 20/32 or better | 10 / 42 (23.8%) | 34 / 35 (97.1%) | 38 / 42 (90.5%) | 39 / 42 (92.9%) | 35 / 38 (92.1%) | 29 / 30 (96.7%) |
| 20/40 or better | 11 / 42 (26.2%) | 35 / 35 (100%) | 41 / 42 (97.6%) | 40 / 42 (95.2%) | 36 / 38 (94.7%) | 30 / 30 (100%) |
| 20/80 or better | 18 / 42 (42.9%) | 35 / 35 (100%) | 42 / 42 (100%) | 42 / 42 (100%) | 38 / 38 (100%) | 30 / 30 (100%) |
| 20/200 or better | 28 / 42 (66.7%) | 35 / 35 (100%) | 42 / 42 (100%) | 42 / 42 (100%) | 38 / 38 (100%) | 30 / 30 (100%) |
| Worse than 20/200 | 14 / 42 (33.3%) | 0 / 35 (0%) | 0 / 42 (0%) | 0 / 42 (0%) | 0 / 38 (0%) | 0 / 30 (0%) |
| Not Reported | 2 | 0 | 1 | 0 | 0 | 0 |
| TOTAL | 44 | 35 | 43 | 42 | 38 | 30 |

**TABLE 12 - UNCORRECTED NEAR VISUAL ACUITY with Time
Exams on Both Eyes**

| | Preop n/N (%) | 1 Day n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|-------------------|------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| 20/15 or better | 0 / 36 (0%) | 0 / 9 (0%) | 0 / 41 (0%) | 0 / 41 (0%) | 0 / 38 (0%) | 0 / 30 (0%) |
| 20/20 or better | 0 / 36 (0%) | 0 / 9 (0%) | 7 / 41 (17.1%) | 6 / 41 (14.6%) | 2 / 38 (5.3%) | 4 / 30 (13.3%) |
| 20/25 or better | 1 / 36 (2.8%) | 3 / 9 (33.3%) | 19 / 41 (46.3%) | 16 / 41 (39%) | 11 / 38 (28.9%) | 9 / 30 (30%) |
| 20/32 or better | 2 / 36 (5.6%) | 6 / 9 (66.7%) | 26 / 41 (63.4%) | 22 / 41 (53.7%) | 19 / 38 (50%) | 18 / 30 (60%) |
| 20/40 or better | 4 / 36 (11.1%) | 6 / 9 (66.7%) | 30 / 41 (73.2%) | 27 / 41 (65.9%) | 27 / 38 (71.1%) | 21 / 30 (70%) |
| 20/80 or better | 4 / 36 (11.1%) | 7 / 9 (77.8%) | 35 / 41 (85.4%) | 33 / 41 (80.5%) | 33 / 38 (86.8%) | 25 / 30 (83.3%) |
| 20/200 or better | 4 / 36 (11.1%) | 9 / 9 (100%) | 37 / 41 (90.2%) | 37 / 41 (90.2%) | 35 / 38 (92.1%) | 29 / 30 (96.7%) |
| Worse than 20/200 | 32 / 36 (88.9%) | 0 / 9 (0%) | 4 / 41 (9.8%) | 4 / 41 (9.8%) | 3 / 38 (7.9%) | 1 / 30 (3.3%) |
| Not Reported | 8 | 26 | 2 | 1 | 0 | 0 |
| TOTAL | 44 | 35 | 43 | 42 | 38 | 30 |

TABLE 13 - DISTANCE CORRECTED NEAR VISION with TIME
Exams on Both Eyes

| | Preop n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|-------------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| 20/15 or better | 0 / 7 (0%) | 0 / 38 (0%) | 0 / 40 (0%) | 0 / 38 (0%) | 0 / 30 (0%) |
| 20/20 or better | 2 / 7 (28.6%) | 5 / 38 (13.2%) | 1 / 40 (2.5%) | 2 / 38 (5.3%) | 3 / 30 (10%) |
| 20/25 or better | 4 / 7 (57.1%) | 15 / 38 (39.5%) | 3 / 40 (7.5%) | 7 / 38 (18.4%) | 10 / 30 (33.3%) |
| 20/32 or better | 4 / 7 (57.1%) | 19 / 38 (50%) | 10 / 40 (25%) | 15 / 38 (39.5%) | 19 / 30 (63.3%) |
| 20/40 or better | 5 / 7 (71.4%) | 26 / 38 (68.4%) | 23 / 40 (57.5%) | 27 / 38 (71.1%) | 27 / 30 (90%) |
| 20/80 or better | 5 / 7 (71.4%) | 33 / 38 (86.8%) | 31 / 40 (77.5%) | 32 / 38 (84.2%) | 29 / 30 (96.7%) |
| 20/200 or better | 5 / 7 (71.4%) | 36 / 38 (94.7%) | 36 / 40 (90%) | 36 / 38 (94.7%) | 30 / 30 (100%) |
| Worse than 20/200 | 2 / 7 (28.6%) | 2 / 38 (5.3%) | 4 / 40 (10%) | 2 / 38 (5.3%) | 0 / 30 (0%) |
| Not Reported | 37 | 5 | 2 | 0 | 0 |
| TOTAL | 44 | 43 | 42 | 38 | 30 |

TABLE 14 - ACCOMMODATIVE AMPLITUDE with TIME
Exams on Both Eyes

| | Preop n/N (%) | 1 Week n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months or Later n/N (%) |
|--------------|------------------|-------------------|--------------------|---------------------|------------------------------|
| >0.0 | 3 / 3 (100%) | 39 / 39 (100%) | 35 / 35 (100%) | 38 / 38 (100%) | 29 / 29 (100%) |
| >1.0 | 3 / 3 (100%) | 39 / 39 (100%) | 35 / 35 (100%) | 38 / 38 (100%) | 29 / 29 (100%) |
| >2.0 | 3 / 3 (100%) | 33 / 39 (84.6%) | 30 / 35 (85.7%) | 36 / 38 (94.7%) | 28 / 29 (96.6%) |
| >3.0 | 0 / 3 (0%) | 20 / 39 (51.3%) | 12 / 35 (34.3%) | 16 / 38 (42.1%) | 14 / 29 (48.3%) |
| >4.0 | 0 / 3 (0%) | 14 / 39 (35.9%) | 5 / 35 (14.3%) | 7 / 38 (18.4%) | 3 / 29 (10.3%) |
| >5.0 | 0 / 3 (0%) | 6 / 39 (15.4%) | 2 / 35 (5.7%) | 1 / 38 (2.6%) | 1 / 29 (3.4%) |
| >6.0 | 0 / 3 (0%) | 6 / 39 (15.4%) | 2 / 35 (5.7%) | 0 / 38 (0%) | 0 / 29 (0%) |
| >7.0 | 0 / 3 (0%) | 2 / 39 (5.1%) | 2 / 35 (5.7%) | 0 / 38 (0%) | 0 / 29 (0%) |
| Mean | 2.33 | 4.56 | 3.69 | 3.30 | 3.25 |
| Not Reported | 41 | 4 | 7 | 0 | 1 |
| TOTAL | 44 | 43 | 42 | 38 | 30 |

APPENDIX C. 1

Bilateral Series Cohort Clinical Results

Data Tables:

Accommodative Amplitude

BSCVA over Time

Change in BSCVA

DCNV over Time

Manifest Refraction Spherical Equivalent (MRSE)

Postoperative Findings

UCDV over Time

UCNV over Time

APPENDIX C. 2

Monocular Series Cohort Clinical Results

Data Tables:

Accommodative Amplitude

BSCVA over Time

Change in BSCVA

DCNV over Time

Manifest Refraction Spherical Equivalent (MRSE)

Postoperative Findings

UCDV over Time

UCNV over Time