Light-adjustable lens complication

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Correction of Myopia after Cataract Surgery with a Light-Adjustable Lens

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Purpose: To determine whether residual myopia could be corrected postoperatively using the light-adjustable lens (LAL) technology in patients undergoing cataract surgery and LAL implantation.

Design: A prospective clinical study was conducted at Codet Vision Institute in Tijuana, Mexico. The LALs were implanted that would purposely result in myopic errors of up to −1.5 D (diopter). The LAL was treated with a spatial intensity profile delivered by a digital light delivery device to induce a targeted myopic refractive change. Once the desirable myopic correction was achieved, the LAL was treated again to lock-in the lens power.

Participants: Fourteen eyes of 14 patients were studied.

Methods: The manifest refraction, uncorrected visual acuity (UCVA), and best- or spectacle-corrected visual acuity (BCVA), were measured with follow up time of 1 to 9 months to determine the achieved refractive corrections and their stability.

Main Outcome Measures: We measured UCVA and BCVA, achieved versus targeted refractive outcome, and refractive stability with follow up time of 1 to 9 months.

Results: Of 14 eyes, 13 eyes (92.9%) achieved 0.25 D of the target refraction at 1 day post lock-in with 100% of the eyes achieving the targeted refractive adjustment within 0.5 D or better with up to 9 months postoperative follow-up. All eyes treated show no change in manifest spherical refraction >0.25 D between 1 day post lock-in, and 3, 6, and 9 months postoperative visits. The data demonstrate the stability of the achieved refractive change after the adjustment and lock-in procedures. The mean rate of change was 0.006 D per month, which is 6 times more stable than that of laser corneal refractive procedures.

Conclusions: Residual myopia errors up to −1.5 D were successfully corrected with precision and significant improvement in UCVA and without compromising BCVA using the LAL technology.

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with LAL implantation. Based on preoperative biometry, LALs were implanted that would purposely result in myopic refractive errors of up to −1.5 diopters. In this fashion, we were able to adjust lens power and test whether myopic refractive error could be corrected in the postoperative period. We intentionally targeted a myopic refractive outcome because extensive preclinical data (in vitro and in vivo in an animal model) confirmed the ability to adjust postoperative myopic refractive errors precisely. Furthermore, if we had targeted patients for emmetropia, then large numbers of patients would have to be enrolled to detect those with substantial postoperative refractive errors. This would expose excessive numbers of subjects to an investigational device.

Methods

The clinical study was initiated after Institutional Review Board approval at Codet Vision Institute under the direction of Dr Arturo Chayet. Subjects who required cataract extraction and IOL implantation and volunteered for this study were screened for eligibility. Informed consent was signed by individually eligible patients. Preoperative biometry was performed using an immersion biometry unit (Axis II Ophthalmic Echograph, Quantel Medical, Boze-man, MT) and LAL power was selected to result in a postoperative refractive error of up to −1.5 diopters of myopia. All patients underwent phacoemulsification using a topical anesthetic, clear corneal incision (3.0–3.5 mm) and anterior capsulorhexis. The LAL of the appropriate power was implanted in the capsular bag using the Nichamin II Foldable Lens Insertion Forceps. No suture was used to close the incision. The operative eye was patched after surgery as our standard of practice. The patch was removed the following day, and patients were instructed to wear Calhoun Vision supplied UV-blocking photochromic spectacles at all times when indoors and outdoors until the adjustment and lock-in procedures were completed.

The LAL was adjusted and locked in using a digital light delivery (DLD) system engineered by Carl Zeiss-Meditec (Jena, Germany). The DLD uses a mercury (Hg) arc lamp with a narrow bandpass interference filter producing a beam at 365 nm (± 4 nm full width half maximum). The DLD generates and projects a spatial light modulator formed monolithically on a silicon substrate. The surgeon centers and focuses the treatment beam on the LAL using an alignment reticle while patient alignment is achieved using a fixation target paracentral to the delivery beam.

At 10 days to 3 weeks post-implantation, visual acuity (BCVA and UCVA) and residual myopic refractive error were measured. The DLD was then used to adjust LAL power to correct the myopic error. Refractive power adjustments are defined at the accuracy of the achieved sphere to the targeted refractive correction. This adjustment time frame was selected because refractive power after implantation has substantially stabilized. Data reported in literature revealed that >80% of the refractive power change owing to anterior chamber depth shift for 3-piece IOLs as a result of wound healing occurred at 1 day to 1 week postoperatively.5–8 A second irradiation treatment was given a minimum of 20 hours after adjustment to lock-in the lens. The following study endpoints were evaluated:

- Attempted versus achieved lens power change (manifest refraction).
- Stability of adjusted lens power (manifest refraction).
- Visual acuity (UCVA and BCVA).
- Complications and adverse events.

Results

A total of 14 patients were treated for refractive adjustments in the range of 0.0 to −1.50 D and followed for 1 to 9 months postoperatively. Of the 14 patients included in this study, 11 were male and 3 were female. The patients ranged in age from 46 to 83 years old with a mean of 67 years. All eyes were accounted for at the 1-, 3-, 6-, and 9-month postoperative visits in Table 1. There were no missed visits or any patients lost to follow-up during the study period. The distribution of refractive adjustments attempted can be found in Table 2.

Target versus Achieved Myopic Corrections

The accuracy of the achieved sphere to the targeted refractive adjustment is demonstrated in the bar graph presented in Figure 1.
and data in Table 3. Thirteen of the 14 eyes (92.9%) treated were within 0.25 D of the target refraction at 1 day after the lock-in visit with 100% of the eyes achieving 0.50 D of the targeted refractive adjustment at 1 day after lock-in, and at the 3-, 6-, and 9-month postoperative visits.

### Stability of Refractive Adjustment

All 14 eyes (100%) were stable within 0.25 D with 13 eyes showing no change at a period up to 9 months postoperatively as compared with refraction at 1 day after lock-in treatment (Table 4). The mean rate of change was 0.006 D per month, which is approximately 6 times more stable than that of laser corneal refractive procedures (0.04 D/month).9 These data demonstrate stability of the achieved refractive change after lock-in.

### Uncorrected Visual Acuity

All 14 eyes demonstrated stability of UCVA after lock-in. The UCVA bar graph before and after the myopic corrections can be found in Figure 2. Ten of the 14 eyes achieved UCVA of 20/25 or better. All eyes achieved UCVA of 20/30 or better except one. In this 1 eye, UCVA improved from 20/100 before adjustment to 20/50 after adjustment. This eye was noted to have posterior capsular opacification immediately after the surgery. The BCVA of this eye was 20/40. Significant improvement in UCVA was observed in 71% (10/14) of eyes and UCVA was stable for a follow-up period up to 9 months.

### Best-Corrected Visual Acuity

The BCVA before and after refractive adjustments are displayed in Figure 3. All 14 eyes were stable after refractive adjustment and lock-in treatments with a follow-up period of 9 months. The BCVA before and after refractive adjustments and lock-in were maintained at 20/25 for all patients throughout the follow-up period except one. This eye was noted to have posterior capsular opacification immediately after surgery. The BCVA was maintained at 20/40 with a 3-month follow-up period.

### Complications

There were no adverse events or complications detected.

### Discussion

In a pilot study correcting for 0.0 to −1.5 diopters of myopia in the LAL, we demonstrate that 13 of 14 (93%) adjustments were within 0.25 diopters of the intended refraction and the remaining eye was within 0.5 diopters. More than 70% of eyes had improved UCVA, and BCVA was maintained at 20/25 or better throughout a follow-up period up to 9 months except 1 patient (posterior capsular opacification noted after surgery). Although this study was limited to correction of up to 1.5 diopters, we have corrected >2.0 diopters of myopia in vitro. Further in vitro studies demonstrate the ability to correct up to 3.5 diopters of myopia with 2 adjustments separated by ≈24 hours (Calhoun Vision, Inc, unpublished data, July 2004).

The ability to adjust LAL power precisely in patients with postoperative myopia has several applications. First, as demonstrated in this study, adjustment could be used to improve UCVA. Second, if a patient desired to be left with some degree of myopia for uncorrected intermediate or near acuity initially, but found monovision not tolerable later, the LAL could be adjusted and corrected for emmetropia. Unlike patients undergoing corneal refractive surgery to create

![Figure 2](image_url)

**Figure 2.** Bar graph of uncorrected visual acuity (UCVA) before and after myopic corrections (20/20 = 1.0; 20/40 = 0.5; 20/100 = 0.2). Significant improvement in UCVA was observed in 71% of eyes. Of 14 eyes, 10 (71%) eyes achieved UCVA of ≥20/25. All eyes were ≥20/30 and stable for a follow-up period up to 9 months except one. Posterior capsular opacification was noted on the 1 eye immediately after surgery. ■, Before; □, after.
monovision who can be tested preoperatively with a contact lens trial, it is difficult to determine monovision tolerance in patients with cataracts because of media opacity. Some patients do not tolerate monovision owing to reduced contrast sensitivity and stereoacuity, as well as esophoric shifts.\(^{10,11}\) During the time that the patient implanted with an LAL acclimated to monovision, he or she would have to wear protective UV glasses so the lens would not develop undesired optical changes from outside ambient light exposure.

Although we demonstrated the potential to reverse moderate myopia in the postoperative period, optimal UCVA can only be obtained by correcting astigmatic error as well. We are currently refining nomograms for correction of toric refractive error.

**Footnotes and Financial Disclosures**

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