Light-adjustable lens complication

HAFEZI, Farhad, SEILER, Theo, ISELI, Hans Peter


DOI : 10.1016/j.ophtha.2009.12.019
PMID : 20346825

Available at:
http://archive-ouverte.unige.ch/unige:22460

Disclaimer: layout of this document may differ from the published version.
Correction of Myopia after Cataract Surgery with a Light-Adjustable Lens

Arturo Chayet, MD,1 Chris Sandstedt, PhD,2 Shiao Chang, PhD,2 Paul Rhee, OD,3 Barbara Tsuchiyama, BS,2 Robert Grubbs, PhD,4 Dan Schwartz, MD5

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.

Financial Disclosure(s): Proprietary or commercial disclosure may be found after the references. Ophthalmology 2009;116:1432–1435 © 2009 by the American Academy of Ophthalmology.

Biometric errors and wound healing introduce varying levels of imprecision into spherical refractive outcomes after cataract surgery. Although residual myopia after cataract surgery is preferable to hyperopia, it still limits uncorrected visual acuity (UCVA). This effect is most pronounced in patients undergoing surgery with intraocular lenses (IOLs) designed to treat presbyopia who wish to optimize UCVA at both near and distance. In a recent study of the Crystalens (Eyeonics, Inc, Aliso Viejo, CA), 60% of patients had UCVA of 20/20 if final refractive error was within 0.5 diopters of plano, whereas only 6.8% saw as well, if residual myopia was >0.5 diopters (manifest refraction spherical equivalent).1 However, intentional residual myopia is used to provide monovision after cataract surgery. In this case, refractive precision is equally important to maximize near visual acuity. If undesired levels of myopia occur after cataract surgery, postoperative adjustment of IOL power is not possible with conventional IOLs, and patients sometimes require additional corneal refractive surgery to optimize refractive outcomes. A light-adjustable lens (LAL) has been recently described, which enables noninvasive correction of residual refractive error.2–4

The LAL contains photosensitive silicone macromers dispersed within the ultraviolet (UV)-absorbing silicone lens matrix that enable postoperative, noninvasive adjustment of refractive power using UV light. The LAL formulation has been described previously2 and is based on the principles of photochemistry and diffusion. The application of the appropriate wavelength of light through a defined spatial irradiance profile onto the LAL polymerizes the macromer in the exposed region, thereby producing a difference in the chemical potential between the irradiated and nonirradiated regions. To reestablish thermodynamic equilibrium, macromers from the unirradiated portion of the lens diffuse along the concentration gradient into the photopolymerized portion of the lens, producing a change in shape and concomitant predictable power change.

By controlling the irradiation dose (i.e., beam irradiance and duration) and spatial irradiance profile, the refractive power of the LAL is modified to add or subtract spherical power, eliminate astigmatic error, and correct higher order aberrations. One day after LAL adjustment, the entire lens is irradiated to polymerize remaining photosensitive macromer and prevent additional change in lens power. This second irradiation procedure is referred to as “lock-in.”

To determine whether residual myopic refractive error could be corrected postoperatively using the LAL, we performed a pilot study in patients undergoing cataract surgery...
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, Bozeman, 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 spectacle plane. No attempt was made to correct coexisting astigmatism. This adjustment time frame was selected because refractive error could be corrected in the postoperative period. The accuracy of the achieved sphere to the targeted refraction in the range of 0.0 to −1.5 diopters as a result of wound healing occurred at 1 day to 1 week postoperatively. 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.

**Table 1. Number of Patients and Postoperative Follow-up Time**

<table>
<thead>
<tr>
<th>No. of Patients (Total = 14)</th>
<th>Postoperative Time (mos)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>9</td>
</tr>
</tbody>
</table>

**Table 2. Distribution of Refractive Adjustments Attempted**

<table>
<thead>
<tr>
<th>Attempted Sphere, Diopters</th>
<th>n</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>−1.25 to −1.5</td>
<td>4</td>
<td>14</td>
<td>28.6</td>
</tr>
<tr>
<td>−0.75 to −1.0</td>
<td>5</td>
<td>14</td>
<td>35.7</td>
</tr>
<tr>
<td>−0.25 to 0</td>
<td>1</td>
<td>14</td>
<td>7.1</td>
</tr>
<tr>
<td>0</td>
<td>4</td>
<td>14</td>
<td>28.6</td>
</tr>
<tr>
<td>Total</td>
<td>14</td>
<td>14</td>
<td>100.0</td>
</tr>
</tbody>
</table>

\(n=\) number of eyes at each attempted sphere; \(N=\) total number of eyes.

**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). 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.

<table>
<thead>
<tr>
<th>Change of Refraction (diopters)</th>
<th>No. of Eyes (N = 14)</th>
<th>Follow-up Time (mos)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>13</td>
<td>1–9</td>
</tr>
<tr>
<td>0.25</td>
<td>1</td>
<td>1–3</td>
</tr>
</tbody>
</table>

Table 4. Stability of Refractive Adjustment

**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 (Cahoun 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. 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.](image-url)
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. 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.

References


Footnotes and Financial Disclosures

Originally received: May 30, 2008.
Final revision: January 14, 2009.
Accepted: February 11, 2009.

1 Codet Vision Institute, Tijuana, Mexico.
2 Calhoun Vision, Inc., Pasadena, California.
3 Lake Forest, California.
4 California Institute of Technology, Pasadena, California.
5 University of California at San Francisco, San Francisco, California.

Financial Disclosure(s):
The authors (CS, SC, BT) are Calhoun Vision employees. PR is a former Calhoun Vision employee. AC is the clinical investigator for Calhoun Vision, compensated only for his typical surgery fee for each patient, with no financial interest. DS and RG are both Founding Scientists and a Board Member of Calhoun Vision with financial interest.

Supported by SBIR grant EY12181-02.

Correspondence:
Arturo Chayet, MD. Ave. Padre Kino No. 10159, Tijuana, Mexico 22320.
E-mail: arturo.chayet@codetvision.com.