Clinical Evaluation of an Ultraviolet Light Adjustable Intraocular Lens Implanted after Cataract Removal

Eighteen Months Follow-up

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Purpose: To determine the effectiveness of a light-adjustable intraocular lens (LAL) that can be adjusted postoperatively using ultraviolet (UV) irradiation.

Design: A prospective, nonrandomized clinical trial was conducted at Center for Vision Science, Ruhr University Eye Clinic, in Bochum, Germany.

Participants: We included 122 eyes of 91 patients with significant cataract.

Methods: All patients had a visually significant cataract and were willing to volunteer for the trial. Participants underwent small-incision phacoemulsification followed by implantation of a LAL and were treated with a spatially profiled UV light delivered by a digital light delivery device to induce a targeted spherical and cylindrical refractive change postoperatively. Once the desired correction was achieved, the LAL was treated again to lock in the lens power. Distance visual acuity and manifest refraction was determined with follow-up time to determine the achieved refractive corrections and their stability.

Main Outcome Measures: We measured uncorrected visual acuity and best corrected visual acuity achieved versus targeted refractive outcome and refractive stability with a follow-up time of 18 months.

Results: Residual postoperative refractive errors of 0.96 ± 0.85 diopters (D) in sphere and −0.98 ± 0.50 D in cylinder were corrected and stable over a follow-up time of 18 months. Final refraction achieved was 0.03 ± 0.17 D in spherical equivalent refraction.

Conclusions: Residual spherocylindrical errors up to 2.25 D in sphere and −2.75D in cylinder were successfully corrected with precision. The LAL technology has the potential individually to correct postoperative refractive errors precisely. The achieved refractive corrections are stable for up to 18 months.

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The concept of an intraocular lens (IOL) that can be adjusted in vivo has been hypothesized and studied since phacoemulsification became the standard of care in cataract surgery. The first published report of a multicomponent IOL that could be adjusted after implantation was in 1996.[1] A 2003 concept developed at the University of Missouri-Rolla involved the use of samarium and cobalt magnets placed inside an IOL optic to create an adjustable IOL.[2,3] In 2005, German researchers reported on animal and human eye results of an IOL developed by Acri.Tec (now Carl Zeiss Meditech, Jena, Germany) that could be reversibly adjusted after implantation.[4,5]

The first presentation of the light-adjustable IOL (LAL; Calhoun Vision, Pasadena, CA) used in this study took place in 2003. It described the development of a photoreactive silicone material that could be adjusted noninvasively after implantation using a light delivery device (Chang SH, et al. New material for adjustable IOL. Association of Research and Vision in Ophthalmology, 2003 Annual Meeting, Fort Lauderdale, FL). Published papers have explored in vitro and in vivo results in animal eyes, as well as first human eye results.[6–10] Prospective studies on residual myopic[11,12] and hyperopic corrections[13,14] were only recently published. The feasibility to correct astigmatism was first demonstrated in 5 patients with a follow-up of 9 months.[15] The first publication of combined sphere and astigmatism correction using the LAL in 21 patients was published in early 2011.[12]

Although correction of astigmatism has been demonstrated in a small number of subjects, it is desirable to determine whether residual spherocylindrical refractive errors could be corrected postoperatively using the LAL in a larger number of patients.

Patients and Methods

This was a prospective nonrandomized clinical trial involving 122 eyes (91 patients). The study received ethical committee approval and all aspects of the Helsinki Declaration were observed. All

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Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Subjects must sign a written informed consent form.	Study eye with zonular laxity, dehiscence or with pseudoexfoliation.
Study eye has preoperative regular corneal astigmatism ≤2.25 diopters by corneal topography or keratometry.	Subjects taking systemic medication that may increase sensitivity to ultraviolet light.
Subjects must be adults between the ages of 40 and 80 inclusive with visually significant cataracts.	Study eye with age-related macular degeneration involving the presence of geographic atrophy or soft drusen.
Study eye has BCVA projected (by clinical estimate based upon past ocular history and retinal examination) to be ≥20/25 after cataract removal and intraocular lens implantation.	Study eyes with hard drusen are permitted if the density of drusen is such that impairment of acuity >20/25 is not expected.
Study eye has clear intraocular media other than cataract.	Study eye with retinal degenerative disorder (other than macular degeneration) that is expected to cause future vision loss.
Subject's fellow eye either has BCVA of ≥20/40, or the decrease in BCVA is due at least in part to cataract, and successful cataract surgery is expected to yield BCVA of ≥20/40.	Subjects with diabetes and evidence of retinopathy. Diabetics without retinopathy are permitted.
Subject is willing and able to comply with the schedule for power adjustment/lock-in treatments, the schedule for follow-up visits, and to wear ultraviolet-protective eyewear at all times before the second lock-in.	Study eyes with glaucomatous optic neuropathy by visual field examination. Eyes under treatment for glaucoma or glaucoma suspect eyes are permitted if the visual field is normal.
Study eye has fully dilated pupil diameter of ≥7.0 mm.	Study eye with a history of uveitis.
	Study eye with significant anterior segment pathology, such as rubeosis iridis, aniridia, or iris coloboma.
	Study eye with corneal pathology that is either progressive or sufficient to reduce BCVA to ≤20/25.
	Study eye with keratoconus or pellucid marginal degeneration.
	Study eye with any corneal dystrophy, including basement membrane dystrophy.
	Study eye with keratoconjunctivitis sicca associated with corneal changes, such as superficial punctuate keratopathy, sufficient to reduce BCVA to ≤20/25.
	Study eye that has undergone previous corneal or intraocular surgery, except that eyes with previous pterygium excision are permitted as long as the pterygium did not extend >2 mm onto the cornea from the limbus.
	Subjects with complications during cataract surgery, including posterior capsule rupture, zonular rupture, radial capsulorhexis tear, vitreous loss, iris trauma, corneal complications, or any intraoperative abnormality that may affect the postoperative pupillary dilation, or the centration or tilt of the intraocular lens.

BCVA = best corrected visual acuity.

patients had a visually significant cataract, dilated pupil of ≥7.0 mm and were willing to volunteer for the study with a signed informed consent. The exclusion criteria are pathologies of the retina or cornea, glaucoma, or history of uveitis (Table 1).

Preoperatively, all enrolled patients underwent a full clinical examination including manifest refraction, Snellen best spectacle-corrected visual acuity (BCVA), corneal topography and anterior segment imaging (Pentacam HR, Oculus, Wetzlar, Germany),[16] and keratometry. The implant power was selected based on standard ocular biometry data from noncontact partial coherence laser interferometry (IOL Master, Carl Zeiss Meditech), the surgeons' personal A constant, and a modified IOL power calculation formula.[17,18] The LAL is supplied in a range of +10 diopters (D) to +30 D, of +17 to +24 D in 0.5-D increments. It can undergo both spherical and cylindrical power adjustments in the range of ±0.25 to 2 D using a controlled application of spatially profiled ultraviolet (UV) light (365 nm) delivered by a digital light delivery device (DLDD, Carl Zeiss Meditec). The LAL with DLDD as a system has received CE Mark.

Participants underwent small incision phacoemulsification (performed by F.H.H.) followed by implantation of a 3-piece, silicone LAL in the posterior chamber using standard surgical techniques. All patients were instructed to wear UV-blocking photochromic spectacles (7EYE, Pleasanton, CA) at all times when indoors and outdoors after cataract surgery and until the final lock-in treatment was completed.

After a period of postoperative refractive stabilization, typically 14 to 21 days, the subject returns for examination and refraction by the surgeon to determine whether adjustment in spherical and/or cylindrical power is required. All eyes received either a combined spherical and cylindrical adjustment according to the myopic or hyperopic shift intended to correct residual refractive errors or a power-neutral adjustment if the eyes did not require a refractive power adjustment. The irradiation procedure is performed with the pupil fully dilated and the subject positioned in the chin and head rests of the DLDD. During the commencement of LAL irradiation, the subject is required to fixate on an alignment target. The irradiation treatment exposures are delivered in a continuous dose. After irradiation, the adjusted lens power stabilizes within a minimum of 48 hours postadjustment.

If necessary, additional adjustments can be performed 2 to 8 days after the initial adjustment to fine tune the refractive power change. After the desired refractive outcome is achieved, the entire lens is irradiated to stabilize the lens power. This final irradiation procedure is referred to as "lock-in." The lock-in treatment is typically performed 2 to 3 days after the final adjustment and comprised of 2 procedures administered 2 to 4 days apart.

Table 2. Demographics

Variable	Value
Patients	
Total	91
Eyes	
Total	122
Females	70 eyes (58.2%)
Males	52 eyes (41.7%)
Right	62 (50.8%)
Left	60 (49.2%)
Age, yrs	
Mean	76
Range	51 to 88
Median	77
Refraction (mean in diopters)	
SEQ	0.36 ± 2.78 (−9.53 to 5.75)
SEQ sphere	0.82 ± 2.74 (−9.00 to 6.50)
SEQ cylinder	−0.92 ± 0.66 (−3.25 to 0.00)
Axial length (mm)	24.66 ± 2.74 (21.65 to 28.56)
Follow-up examinations	121 of 122 eyes (99.2%) (122 of 122 eyes until 12 months follow-up)

SEQ = spherical equivalent.

The treatment wavelength is 365 nm with a beam diameter of 5.3 mm, duration ranges from 60 to 130 seconds for adjustment, and up to 144 seconds for lock-in. Irradiance power for adjustment and lock-in is 14.5 and 240 mW/cm^2, respectively.

We evaluated (1) attempted versus achieved lens power change (manifest refraction); (2) BCVA and uncorrected visual acuity (UCVA); (3) stability of adjusted lens power (manifest refraction); and (4) complications and adverse events.

Statistical Analysis

For statistical analysis, the logarithm of the minimum angle of resolution values of visual acuity were converted in decimal notation and vice versa, as described by Westheimer.[19] All statistical evaluations were performed using Datagraph-med 4.00 (Pieger and Moerschbacher, Wendelstein, Germany) following guidelines of reporting refractive surgical data.

Results

The average age of the study group was 76 years (range, 51–88; median, 77), with a gender ratio of 58.2% female (70 eyes) to 41.8% male (52 eyes). The LAL was implanted in 62 right eyes and 60 left eyes. Preoperatively, the mean refraction in spherical equivalent (SEQ) was 0.36 ± 2.78 D (range, −9.53 to 5.75), the mean sphere was 0.82 ± 2.74 D (range, −9.00 to 6.50), and the mean cylinder was −0.92 ± 0.66 D (range, −3.25 to 0.00; Table 2). Sixty-seven percent of eyes had a preoperative UCVA of ≤20/50. No preoperative refractive spherical error criterion was used to enroll patients.

All 122 eyes received an initial adjustment of the LAL, 56 received a second treatment, and 7 a third adjustment. No patients showed increased refractive errors of sphere or cylinder after adjustment or lock-in procedures.

At the 18-month post lock-in visit, 99.2% of eyes (121 of 122 eyes) were available for follow-up. The mean SEQ refraction achieved was 0.03 ± 0.17 D (range, −0.62 to 0.47) with a mean residual sphere of 0.10 ± 0.22 D (range, −0.50 to 0.05) and a mean residual cylinder of −0.25 ± 0.22 D (range, −0.75 to 0.00). Table 3 summarizes the change of refraction from preoperative to 18 months after lock-in. The achieved SEQ as a function of time is presented in Figure 1 (available online at http://aaojournal.org) where the average refraction is annotated at each time point and plotted as the solid line with dotted lines as ±1 standard deviation. The standard deviation is greatly reduced at 18 months post lock-in compared with that before the surgery. All eyes showed excellent refractive stability over time after the final lock-in.

Figure 2 displays a scattergram of attempted versus achieved SEQ at 18 months after lock-in. The solid line indicates the attempted equals to the achieved SEQ, and the dotted line represents ±1.0 D from the attempted refraction. The results showed that 98% of eyes were within ±0.50 D of the targeted refractive outcome, with 97% within ±0.25 D and 100% within ±1.00 D of the intended outcome as presented by the bar graph in Figure 3. The UCVA improved from 0.86 before adjustment to 1.02 (20/20) ±0.13 one month after lock-in procedure and is stable with follow-up time up to 18 months as shown in Figure 4.

The bar graph in Figure 5 demonstrates significant improvements in UCVA at 18 months post lock-in follow-up visit where 100% achieved UCVA of ≥20/25, 88% achieved ≥20/20, and 25% achieved 20/16. Only 22% of eyes achieved ≥20/25 before adjustment. The postoperative safety results showed that all eyes gained lines of UCVA with 93% gaining >2 lines of vision and

Table 3. Change of Manifest Refraction over the 18-month Period

Refraction (Time/Treatment)	Number of Eyes	SEQ (D)	Sphere (D)	Cylinder (D)
Preoperative	122	0.36 ± 2.78 (−9.53 to 5.75)	0.82 ± 2.74 (−9.00 to 6.50)	−0.92 ± 0.66 (−3.25 to 0.00)
Postoperative, before first adjustment	122	0.55 ± 0.77 (−1.38 to 1.75)	0.96 ± 0.85 (−0.75 to 2.25)	−0.98 ± 0.50 (−2.75 to 0.00)
Postoperative, before second adjustment	56	−0.02 ± 0.65 (−1.38 to 1.68)	0.34 ± 0.76 (−1.00 to 1.25)	−0.74 ± 0.52 (−1.50 to 0.00)
Postoperative, before third adjustment	7	0.15 ± 0.38 (−0.88 to 1.00)	0.38 ± 0.41 (−0.50 to 1.50)	−0.46 ± 0.31 (−1.25 to 0.00)
Postoperative, before lock-in	122	0.22 ± 0.47 (−0.50 to 0.71)	0.41 ± 0.30 (−0.50 to 0.25)	−0.37 ± 0.36 (−0.5 to 0.00)
Postoperative, 1 month after lock-in	122	−0.02 ± 0.29 (−0.75 to 0.63)	0.21 ± 0.32 (−0.50 to 0.05)	−0.44 ± 0.27 (−0.50 to 0.00)
Postoperative, 3 months after lock-in	122	0.03 ± 0.28 (−0.75 to 0.50)	0.17 ± 0.32 (−0.50 to 0.50)	−0.20 ± 0.25 (−0.50 to 0.00)
Postoperative, 6 months after lock-in	122	0.01 ± 0.22 (−0.75 to 0.50)	0.15 ± 0.27 (−0.50 to 0.50)	−0.27 ± 0.25 (−0.50 to 0.00)
Postoperative, 12 months after lock-in	122	−0.03 ± 0.19 (−0.63 to 0.48)	0.11 ± 0.23 (−0.50 to 0.50)	−0.26 ± 0.23 (−0.50 to 0.00)
Postoperative, 18 months after lock-in	121	−0.03 ± 0.17 (−0.62 to 0.47)	0.10 ± 0.22 (−0.50 to 0.50)	−0.25 ± 0.22 (−0.75 to 0.00)

SEQ = spherical equivalent of refraction.
Values are presented as means ± standard deviation and range (minimum to maximum value) in diopters (D).

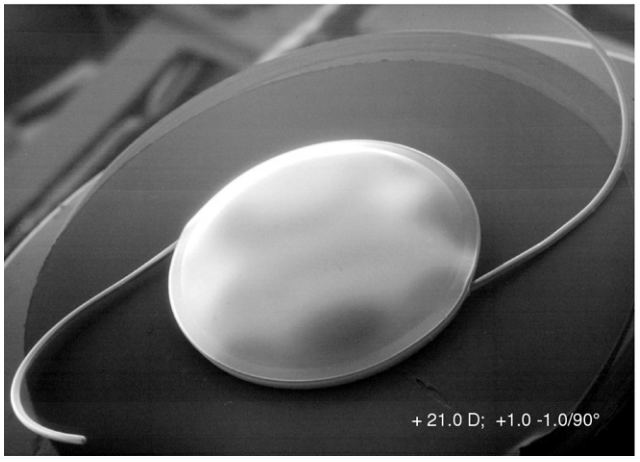

Figure 2. Electron microscopic image of a light-adjustable intraocular lens of +21.0 diopters (D) after a combined adjustment of +1.0 D in sphere −1.0/90° D in cylinder/axis.

7% gaining ≥2 lines of vision compared with preoperative BCVA (Fig 6).

The efficacy results found that the patients had after lock-in procedure an UCVA of 1.02 (20/20) ±0.13 (Fig 7). After cataract surgery, UCVA increased in comparison with preoperative BCVA. The bar graph in Figure 8 demonstrates significant improvement in UCVA at 18-months post lock-in follow-up visit. 100% achieved UCVA of ≥20/25, 88% achieved ≥20/20, and 25% achieved 25/20. The UCVA is stable for a follow-up period up to 18 months.

Complications

Any adverse events or complications were recorded. In addition to typical adverse events associated with IOLs, we looked carefully for evidence of macular edema, uveitis, UV keratopathy, IOL dislocation, elevated intraocular pressure, posterior capsular opacity, glare, and halos. There were no reported intraoperative adverse events in this patient series. Postoperatively, 2 eyes experienced transient corneal edema, which resolved completely after 1 week. Immediately after surgery, 3 patients experienced increased intraocular pressure, which normalized without the need for local therapy after <3 days. Two patients suffered from dry eye syndrome (moderate keratoconjunctivitis sicca) and had refractive changes of 0.38 D and 0.5 D in SEQ refraction over 18 months of follow-up. We do not know whether this phenomenon is related to the UV light treatments, because all corneas have been protected by a special contact lens provided from the manufacturer for safe irradiations.

Discussion

As cataract surgery has evolved and small incision phacoemulsification has become the dominant procedure, surgeons have been on a continual quest to provide patients with an emmetropic visual outcome. Since the inception of IOLs, surgeons have been working to refine formulas to determine the most accurate method for IOL power calculations. In fact, the number of articles published on the subject of accuracy of IOL power calculations was >20 in the past 2 years alone (2007–2009).[20–25]

With current methods of IOL power determination, the vast majority of patients achieve a UCVA of ≥20/40. A much smaller percentage achieves optimal vision without spectacle correction. Nearly all patients are within 2 D of emmetropia. In a study of 1676 patients, 1569 (93.6%) patients were within 2 D of the intended refractive outcome.[26] In 1320 cataract extractions on patients without ocular comorbidity, Murphy et al[27] found that 858 (65%) had UCVA ≥20/40.[27] A 2007 survey of cataract surgeons reported that incorrect IOL power remains a primary indication for foldable IOL explantation or exchange.[26,28]

In addition to imprecise IOL power determinations, postoperative UCVA is most often limited by preexisting astigmatism. Staar Surgical (Monrovia, CA) and Alcon Laboratories (Fort Worth, TX) both market a toric IOL that corrects preexisting astigmatic errors. These IOLs are available in only 2 to 3 toric powers (2.0, 3.5 D and 1.50, 2.25 and 3.0 D, respectively at the IOL plane) and the axis must be precisely aligned at surgery. Other than surgical repositioning, there is no option to adjust the IOL's axis that may shift postoperatively.[29] Furthermore, individualized correction of astigmatism is limited by the unavailability of multiple toric powers.

An additional problem associated with using preimplantation corneal astigmatic errors to gauge the required axis and power of a toric IOL is the unpredictable effects of surgical wound healing on the final refractive error. After the refractive effect of the cataract wound stabilizes, there is often a shift in both magnitude and axis of astigmatism, off-setting the corrective effect of a toric IOL. Therefore, a means to postoperatively adjust (correct) astigmatic refractive errors after lens implantation and surgical wound healing is very desirable for a toric IOL. Although limbal relaxing incision is a widely accepted technique for treating corneal astigmatism, the procedure is typically performed during cataract surgery and therefore does not address the effect of postimplantation wound healing.

Eyes undergoing corneal refractive procedures (approximately 1.0 million/year in the United States alone) that subsequently develop cataracts are challenging with respect

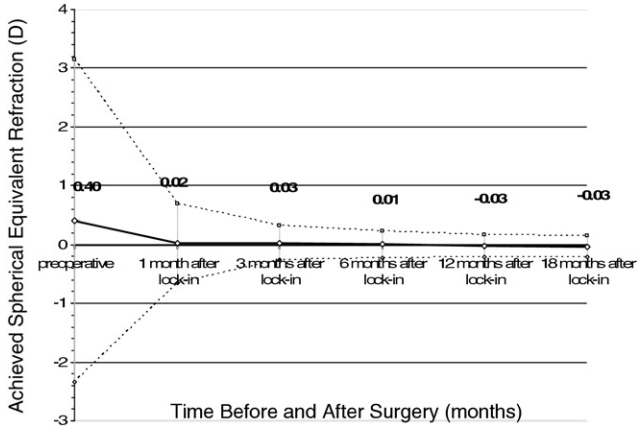

Figure 3. Stability of spherical equivalent refraction (SEQ). All 119 eyes were stable within ±0.25 diopters (D) compared with the SEQ at 1 month after lock-in treatment. Three eyes changed 0.38 to 0.50 D owing to an increase in anterior chamber depth (1 eye) and keratoconjunctivitis sicca (2 eyes).

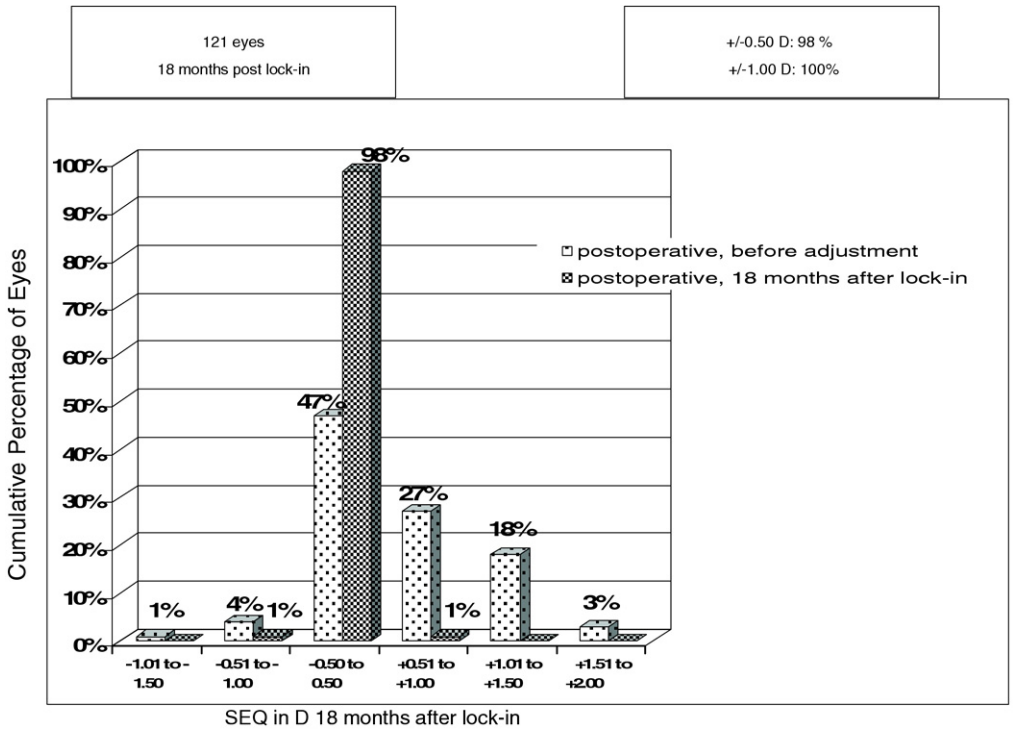

Figure 4. Accuracy of spherical equivalent refraction (SEQ). Of treated eyes, 98% were within 0.5 diopters (D) and 96% within 0.25 D of the target refraction. All eyes achieved 1.0 D of the targeted refractive adjustment at 18 months post lock-in.

to IOL power determination. Corneal topographic alterations induced by refractive surgery reduce the accuracy of keratometric measurements, often leading to significant postoperative ametropia.[30–37] Recent studies of patients who have had corneal refractive surgery (photorefractive keratectomy, laser in situ keratomileusis, radial keratotomy) and subsequently required cataract surgery frequently demonstrate refractive "surprises" postoperatively. As the refractive surgery population ages and develops cataracts, appropriate selection of IOL power for these patients has become an increasingly challenging clinical problem. The ability to address this problem with an adjustable IOL is valuable to patients seeking optimal distance vision after cataract surgery.

Our results found that the Calhoun LAL demonstrated excellent refractive stability over time, as well as signifi-

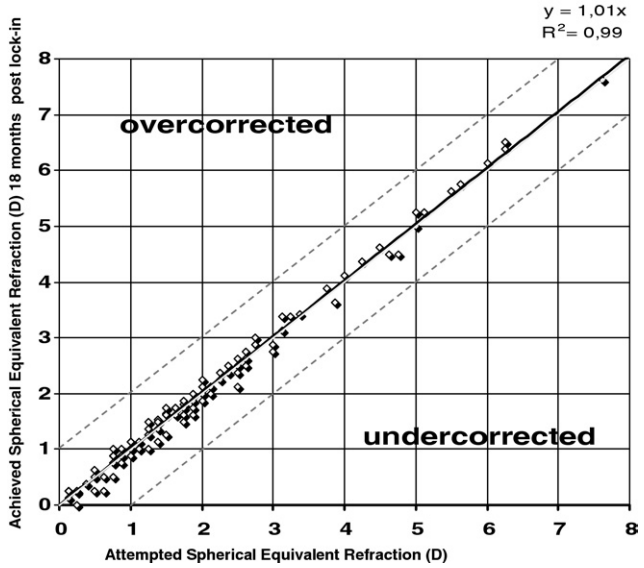

Figure 5. Attempted versus achieved spherical equivalent refraction (SEQ). The solid line indicates attempted equals to achieved refraction; the dash lines are 1.0 diopters from the attempted refraction.

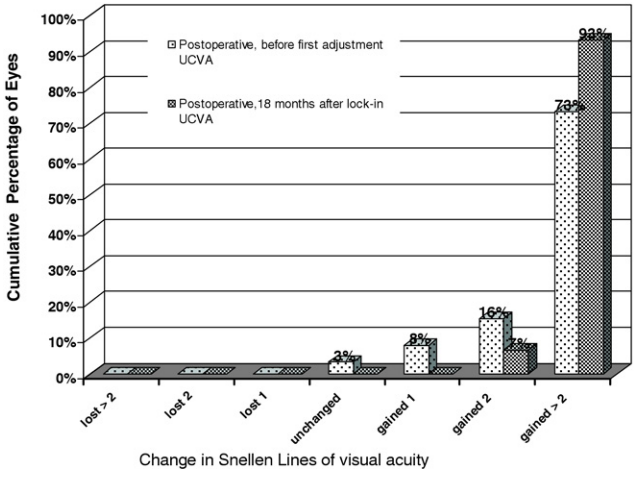

Figure 6. Change in distance visual acuity. All 121 eyes gained ≥2 lines 18 months after lock-in, before first adjustment 3% were unchanged, 9% gained 1 line, and 88% two lines or more in comparison with best-corrected visual acuity (BCVA) preoperatively.

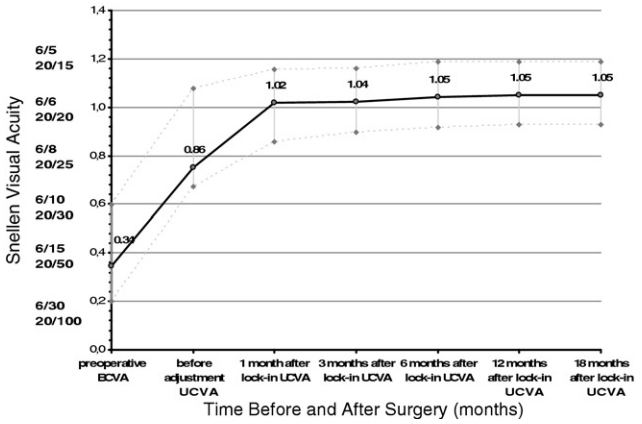

Figure 7. Snellen visual acuity over time. Before surgery, best-corrected visual acuity (BCVA) was in mean <20/50; 1 month after lock-in, uncorrected visual acuity (UCVA) achieved in mean >20/20.

cantly improved visual outcomes in all patients enrolled in the study. The vast majority of patients (98%) were within ±0.50 D of the intended correction, with 79% of eyes having 0 D of residual sphere. The postoperative residual SEQ refractive error was 0.55 ± 0.77 D (range, −1.38 to 1.75) using the optimized surgeons' A-constant (Table 3). The residual SEQ was significantly improved to −0.03 ± 0.17 D (range, −0.62 to 0. D) at 18 months after lock-in.

One of the keys to success with the Calhoun LAL is the patient compliance to wear UV-protective spectacles until lock-in is performed. Without the UV-protective spectacles, there is a risk for unintended photopolymerization of LAL by ambient UV light leading to unpredictable optical changes of the implanted lens. Therefore, patients must wear the provided UV-blocking sunglasses at all times until lock-in is completed. After lock-in, no UV protection is necessary.

Although this trial demonstrates precise adjustment of sphere up to 2.0 D and cylinder up to −2.0 D in 1 step, approximately half of the eyes (56/122) required a second adjustment to individually fine tune residual refractive errors before lock-in. Chemical analysis of light-adjustable lenses reveals that photoreactive macromer is available to undergo multiple photopolymerization leading to additional refractive changes as long as the lens is not locked-in. In vitro studies, a +3.5-D power change was achieved in LALs with secondary adjustments.[9] The nomograms (power, duration, and beam size) of secondary adjustments are identical to those of first adjustments. The light adjustable lens and DLDD provide surgeons a means to fine tune refractive power in the postoperative period. As long as the patient is compliant and willing to wear the provided UV-protecting spectacles, a delay of adjustments or lock-in procedures will not affect the lens or patients' health. In this trial, all patients were compliant and there were no issues.

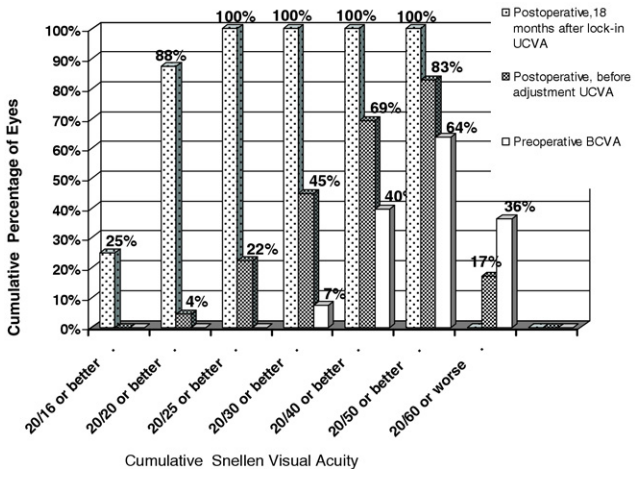

Figure 8. Cumulative Snellen visual acuity. All eyes achieved uncorrected visual acuity (UCVA) of ≥20/25; 89% achieved 20/20, and 25% 25/20.

Retina safety of the irradiation delivered to the LAL by DLDD was demonstrated in a rabbit model where no signs of retina toxicity were observed after near UV light exposure up to 5 times the expected maximum lock-in dosage.[38] In our study, 100% of the eyes met ≥20/40 BCVA safety criteria.

In our series of patients treated for residual spherical and cylindrical refractive errors, adjustments were precise and the achieved refractive outcome was stable for up to 29 months of follow-up. This technology may provide surgeons with a greater confidence in final refractive outcome as increasing numbers of patients expecting better UVCA develop cataracts. We are currently considering ways to evolve new adjustment profiles to optimize near vision and multifocal targeted outcomes.

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