Light-Adjustable Lens Technology a Potential “Game Changer” for Cataract Patients

New technology currently in clinical trials at UCLA’s Stein Eye Institute and more than a dozen other centers across the country promises to dramatically reduce spherical and astigmatic refractive errors and improve unaided visual acuity after cataract surgery, according to the Stein Eye Institute cataract and refractive surgeon who heads the Phase 3 clinical trial at UCLA.

The unique chemistry of the light-adjustable lens (LAL) material—allowing for movement of molecules in an otherwise finished product—enables ophthalmologists to adjust the power of the implanted lens after the surgery through the noninvasive application of light before “locking in” the changes, explains Kevin M. Miller, MD, Kolokotrones Professor of Clinical Ophthalmology and chief of the Stein Eye Institute’s Comprehensive Ophthalmology Division. Dr. Miller notes that with conventional lenses, for a variety of reasons, at least half of patients do not experience 20/20 vision after cataract surgery—requiring them to wear glasses or contact lenses, or to pursue LASIK or other refractive operations.

“This technology will enable cataract patients to have the types of refractive outcomes previously experienced only by patients who have LASIK,” says Dr. Miller. “The odds of achieving 20/20 or better uncorrected visual acuity after cataract surgery will go up dramatically. That’s very exciting.”

Strabismus Impairs Vision Even for Patients Who Do Not See Double

Findings from a UCLA Stein Eye Institute-led study, “Functional burden of strabismus: decreased binocular summation and binocular inhibition,” suggest that strabismus impairs visual function to a greater extent than was previously appreciated, particularly in its impact on binocular vision and summation.

Although many people with strabismus experience double vision, more than half of strabismus patients—typically those who had childhood onset of the disorder—do not have double vision. Yet, many of these patients complain that they have difficulty navigating situations involving a large number of visual cues, such as supermarkets or shopping malls. Often, these individuals choose to close one eye to achieve their best vision.

Cataract surgery is one of the most common surgical procedures in the world. In the United States, an estimated 3 million cataract operations are done each year—a number that is expected to increase significantly as the U.S.
population ages. Dr. Miller notes that in the hands of the best surgeons, only about half of patients come out of the surgery with 20/20 uncorrected vision; for the average surgeon, the proportion is far lower. “There are lots of unknowns in cataract surgery,” Dr. Miller explains. “We don’t know how the incision is going to heal and what effect that is going to have on the astigmatism. It is difficult to obtain precisely accurate axial length measurements in some eyes. And the biggest unknown is where the lens is going to sit inside the eye. We do our best calculations, but it doesn’t always turn out perfectly.”

For the many patients who end up with significant refractive errors following surgery, the only options for seeing clearly have been glasses, contact lenses, or pursuing refractive surgery. Moreover, it has not been possible for cataract surgeons to predict which patients will be left with refractive errors. “With the light-adjustable lens, we wait until the eye is completely healed and then we adjust,” Dr. Miller explains. “It means we just have to be close, not perfect, in the original procedure. This is a complete game-changer.”

The Calhoun Vision Light Adjustable Lens currently being tested in Phase 3 clinical trials is made of silicone and shaped like any other lens implant, but it is not “finished” when shipped. Part of the lens includes small molecules that can move throughout the silicone matrix, while other molecules within the implant are photo-initiators. When ultraviolet (UV) light is focused onto the material via a light-delivery device, these photosensitive molecules attach to the bound silicone; once the entire lens has been treated, the movable molecules within the lens are locked in place.

That means that after a lens is implanted, if the power turns out to be slightly off kilter—preventing the patient from experiencing 20/20 uncorrected vision—the cataract surgeon can irradiate the lens with a precise pattern of UV light. (The back of the lens has a UV filter, preventing the ultraviolet light from reaching and potentially damaging the retina.) Crosslinking the photosensitive molecules in the region of the lens that was UV-treated creates a disequilibrium that causes the unbound molecules to flow down their concentration gradient, changing the shape and adjusting the power of the lens accordingly. This can be done multiple times, if necessary, until the power is optimal, before the lens is locked into its final form. Patients are instructed to wear special glasses that block ambient UV rays until the adjustments and lock-ins are completed.

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The Stein Eye Institute is participating in a national Phase 3 FDA trial of the Calhoun Vision LAL, the final test before the lens—currently available in Europe—is approved for the U.S. market. Preliminary data indicate that on average, patients with light-adjustable lens implants are experiencing better than 20/20 uncorrected vision. “That just doesn’t happen in other cataract trials,” Dr. Miller notes.

He points out that the technology promises to only improve with time. While the current lens is monofocal, the next step after FDA approval would be to add multifocality to the platform. Currently, the technology allows for adjustment of both the sphere and the cylinder dimensions, which account for about 97 percent of refractive errors of the human eye; eventually, LAL could be used to compensate for higher-order aberrations such as wavefront corrections, which glasses are unable to address. In addition, future generations of the technology, currently in the research pipeline, may allow for continuous adjustment, ensuring that patients can remain glasses-free for the rest of their lives.

“The potential for the light-adjustable lens is enormous,” says Dr. Miller. “There are incremental technologies and there are disruptive technologies. This is disruptive—it has the ability to change everything.”

For more information about the Calhoun Vision Light Adjustable Lens clinical trial or to attend an informational seminar, contact: LALstudy@jsei.ucla.edu.
Mean Binocular Summation Scores

<table>
<thead>
<tr>
<th></th>
<th>High contrast visual acuity (ETDRS) ± SD</th>
<th>2.5% Low Contrast Sloan Acuity ± SD</th>
<th>1.25% Low Contrast Sloan Acuity ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strabismus (n=60)</td>
<td>1.01 ± 0.07</td>
<td>1.0 ± 0.3</td>
<td>0.9 ± 0.4</td>
</tr>
<tr>
<td>Controls (n=80)</td>
<td>1.02 ± 0.05</td>
<td>1.3 ± 0.4</td>
<td>1.5 ± 1.0</td>
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<tr>
<td>P-value²</td>
<td>0.9</td>
<td>0.0053</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

This table shows the difference in binocular summation ratio score (binocular score/better eye score). There was significantly less binocular summation in strabismic patients and at the lowest contrast level (1.25%), the strabismic patients had a score of <1, which means that they saw worse with both eyes open than with one eye open.

² Binocular summation score calculated as a ratio between the binocular letter score and the better eye letter score (binocular score/better eye score)

“Many patients with strabismus who don’t experience double vision have nondescript complaints about their vision,” says Stacy L. Pineles, MD, assistant professor of ophthalmology and lead author of the study. “Some of them will have eye surgery to improve their alignment and then will report seeing better, even though the surgery wasn’t to improve their vision. Clinicians were unsure why this was the case, so we decided to try to measure what was occurring.”

For their study, published in the November 2013 issue of JAMA Ophthalmology, Dr. Pineles and colleagues enrolled patients who were about to undergo strabismus surgery and compared their performance with normal subjects on tests involving binocular vision and binocular summation—the difference between viewing something with both eyes together vs. with one eye alone. “Binocular summation is the combination of visual signals from the two eyes that occurs in the brain,” Dr. Pineles explains. “During this process, the vision is enhanced by viewing with the two eyes together, especially in low-contrast situations such as on a rainy, foggy day. To our knowledge, binocular summation has not been well studied as a functional measure of binocularity in strabismus.”

Dr. Pineles’ group found that while the control group tested better when viewing with both eyes together, as expected, the strabismus patients performed no better on the tests with both eyes open than when viewing with one eye alone—and for the low-contrast eye charts, they had lower scores when viewing with two eyes than with one alone. “Many of the strabismus patients had binocular inhibition, meaning the strabismus was somehow causing them to see worse with both eyes open on the low-contrast eye charts,” Dr. Pineles says. Although the reason is not clear, one possible explanation is that in the misaligned eye, the image being viewed is not reaching the fovea—the area of the retina required for central vision—distracting from the image being taken in by the other eye.

The findings go a long way toward explaining why strabismus patients who do not experience double vision still have functional vision complaints. “Prior to this study, we assumed these patients’ vision was whatever it was in their better eye—that their second eye wasn’t contributing to depth perception, but also wasn’t hurting their vision,” Dr. Pineles says. “With this study, we see that when both of their eyes are open, which is how people go about their lives, they actually might see worse than if they closed one eye—or, perhaps, if the strabismus were corrected.”

Whether strabismus surgery might improve vision for these patients is a question Dr. Pineles and colleagues are now investigating. They are currently conducting a longitudinal study of the same patients after their strabismus surgery to determine whether aligning their eyes improves their binocular vision in low-contrast situations. The patients are being tested at two months, six months, and a year after the surgery to measure binocular summation and overall visual symptoms, as well as their vision-related quality of life. “It’s quite possible that more patients could benefit visually from strabismus surgery. We will know more after we analyze data from this study,” Dr. Pineles says.

“Many doctors, patients, and insurance companies have assumed that strabismus surgery in adults is a cosmetic procedure,” Dr. Pineles concludes. “Our study indicates that strabismus actually is a functional cause of decreased vision. It is not just a psychosocial issue, but it affects patients’ ability to use their two eyes together. We hope that strabismus surgery will prove beneficial in addressing this problem.”
AARP The Magazine ranks the Stein Eye Institute as No. 3 in the country for complex eye-care referrals.

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Stein and Doheny Affiliation Broaden Access to Eye Care

The greater Los Angeles region and Orange County are reaping immediate benefits from the historic alliance of the UCLA Stein Eye Institute and the Doheny Eye Institute: Two Doheny Eye Center UCLA locations—one in Arcadia and the other in Orange County—are now open and seeing patients, and a third Doheny Eye Center UCLA is set to open this summer in Pasadena.

For referring physicians, the opening of the three Doheny Eye Center UCLA locations means that Doheny ophthalmologists—now members of the UCLA Department of Ophthalmology—remain a trusted resource in the community, providing comprehensive and subspecialty eye care at a nearby locale. Like UCLA’s Stein Eye Institute in Westwood and the Stein Eye Center UCLA–Santa Monica, the Doheny Eye Center UCLA provides the finest in clinical care, diagnostic equipment, and treatment.

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Arcadia
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Doheny Eye Center UCLA
Orange County
Orange Coast Memorial Medical Center
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Phone: (714) 963-1444

Doheny Eye Center UCLA
Pasadena
Huntington Pavilion
625 S. Fair Oaks Blvd., 2nd Floor
Pasadena, CA 91105
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