

News in Review

COMMENTARY AND PERSPECTIVES

As AAO 2014 approaches, *EyeNet* brings you a preview of some papers to be presented there. Each was chosen by its session chair because it either constitutes important news in the field or is illustrative of a trend. Although only four subspecialties are represented below, paper sessions will also be held in the following areas: cornea, external disease; intraocular inflammation, uveitis; ocular tumors and pathology; orbit, lacrimal, plastic surgery; and pediatric ophthalmology, strabismus. Look for a complete list of papers in the *Final Program* (pages 145-163), *Meeting Guide* (pages 105-109), or Mobile Meeting Guide (www.aao.org/mobile).

Retina Paper

Implanted Microchip Helps RP Patients

A German company's subfoveal "retina on a chip" appears to be a safe and effective device for giving patients who were blind from retinitis pigmentosa (RP) sufficient vision to distinguish objects in their environment, detect motion, and navigate independently, according to a vitreoretinal surgeon who has worked for two decades to develop the implantation protocol.

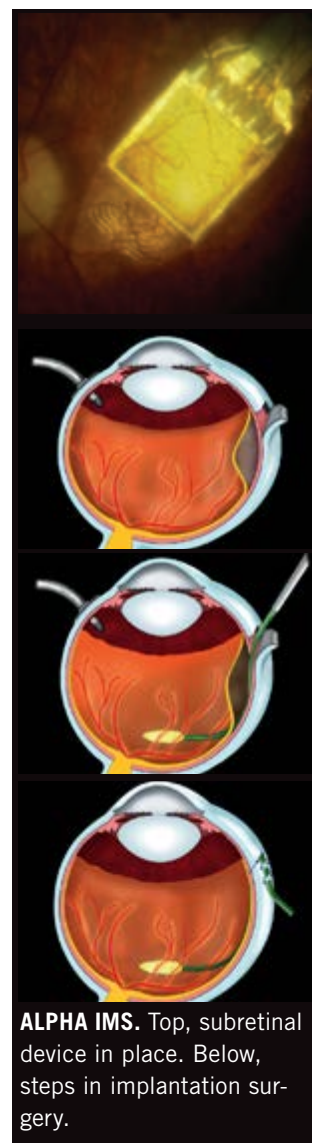
Implanted transchoroi-

dally under the retina, the Alpha IMS microchip (Retina Implant), measuring 3 × 3 mm, contains an array of 1,500 microphotodiode-amplifier-electrode elements that convert light entering the eye into electrical signals. The signals stimulate the healthy bipolar cells and, after reaching the visual cortex, enable patients to perceive blurry, black-and-white images of the world around them. A handheld

battery pack, connected to a subdermal coil behind the ear, provides power for the implant and signal modulation.¹

Visual results. In his paper at AAO 2104, Helmut Sachs, MD, chief physician in the department of ophthalmology at Klinikum Dresden Friedrichstadt, in Germany, presents the latest data on 26 patients implanted with the Alpha IMS retinal prosthesis (from clinical trials involving 40 patients). Visual function tests were performed at a computer monitor to assess light perception, light localization, motion detection, grating acuity, and visual acuity measured with Landolt C.

Among these implant re-



ALPHA IMS. Top, subretinal device in place. Below, steps in implantation surgery.

ipients, 85 percent had light perception, 58 had light localization, and 23 percent had motion detection, Dr. Sachs said. With regard to acuity, 54 percent achieved measurable grating acuity, and 18 percent had measurable Snellen visual acuity (the best being 20/546).

The Alpha IMS received the CE mark for commercial use in Europe in July 2013. In August 2014 it was approved for reimbursement by the German public health insurance system.

“We are out of the trial phase now, but there’s an enormous amount of re-

search still to be done,” said Dr. Sachs. “There are still some patients in whom we do not get visual sensations with the device—cases where we do not understand what is going on. But these are very unusual.”

Safety. Adverse events also have been infrequent. Two ocular adverse events were reported during the study: One patient had an intraocular pressure spike up to 46 mmHg that was successfully treated. Another patient had a retinal detachment immediately after planned explantation of the device. Surgical treat-

ment was successful, but local retinal fibrotic changes were observed.

Regarding potential operative complications, Dr. Sachs said, “There was the fear that going through the choroid would cause enormous bleeding, but this has not happened in more than 40 patients. So, obviously, we have a safe surgical strategy. Forty surgeries in a row cannot go well if there were a great problem.”

Although in the earliest cases, the implantation surgery took six to eight hours,¹ Dr. Sachs said he has found that the surgical time decreases with experience. “You have an extraocular part, which can be reduced to, say, one hour, and the retinal part, which will be one and a half to two hours.

And so, in an optimal case, you may take three hours, which is about the duration of a macular translocation surgery,” he said.

The only retinal prosthesis system currently approved for use in the United States is the Argus II (Second Sight), which also has a CE mark. This epiretinally implanted device has 60 electrodes, compared with 1,500 in the Alpha IMS, and its images come from an external camera, rather than from light rays at the fovea.

—Linda Roach

■ **Subretinal Implantation and Functional Results of the Alpha IMS Chip to Restore Vision in 26 Blind Retinitis Pigmentosa Patients.** *When: Tuesday, Oct. 21, 12:14-12:21 p.m., during the retina, vitreous paper session (8:30 a.m.-12:45 p.m.). Where: Room S405. Access: Free.*

1 Stingl K et al. *Proc Biol Sci.* 2013;280(1757):20130077. doi: 10.1098/rspb.2013.0077.

Dr. Sachs is a consultant to, and has equity interest in, Retina Implant AG.

Cataract Paper

Second-Eye Surgery: Major QoL Benefits

A study of the impact of second-eye cataract surgery among Veterans Affairs (VA) patients yielded a surprise: In several patient-reported outcomes, the increase in quality of life (QoL) after surgery on the second eye was as great as that achieved after the first surgery.

According to lead author, Nakul Shekhawat, MD, MPH, “The veterans

we studied appreciated the benefits from the second surgery as much as from the first. I myself was expecting an incremental improvement from the second surgery, but not such a magnitude of improvement that matched that of the first surgery.” When he began the study four years ago, Dr. Shekhawat was a medical student at Vanderbilt University; he is now an incom-

ing resident at Kellogg Eye Center at the University of Michigan in Ann Arbor.

Study background. Dr. Shekhawat said that this multicenter study was part of a larger national initiative—the Ophthalmic Surgery Outcome Database pilot project—to improve quality of cataract surgery in the Veterans Health Administration.

The study included 432 patients, ranging in age from their 40s to 90s, who had both of their cataract surgeries performed at VA hospitals in Nashville, Boston, Philadelphia, St. Louis, and Houston. Each of these facilities was associated with a major research university in the area.

Details and findings. All participants completed the National Eye Institute’s Visual Functioning Question-

naire—25 (VFQ-25) before and after first- and second-eye surgeries. Not surprisingly, QoL was higher after second-eye surgery than first-eye surgery for all subscales and composite score ($p < .05$ for all). However, for certain subscales—general vision, near activity, mental health, role difficulties, dependence, and driving ability—there were no significant differences in incremental benefits gained between first- and second-eye surgeries ($p > .05$ for all).

Patient-centered approach. Dr. Shekhawat commented that although there have been prior second-eye studies measuring stereopsis and functional capacity, “Those were not patient-centered studies, they were not asking the patients how they felt, how they

■ **Impact of First Eye vs. Second Eye Cataract Surgery on Quality of Life.** *When: Sunday, Oct. 19, 10:30-10:37 a.m., during the cataract paper session (10:30 a.m.-noon). Where: Room S405. Access: Free.*

Refractive Surgery Paper

Presbyopia Prospects: Kamra vs. IOLs

In a recent retrospective study, the Kamra corneal inlay (AcuFocus) surpassed the overall performance of three multifocal or accommodating intraocular lenses (IOLs) with respect to binocular mesopic contrast sensitivity and range of continuous functional vision at varying vergences.

The study compared previously published data¹ on 25 Crystalens AO accommodative IOL patients, 25 AcrySof ReSTOR +3.0 D multifocal IOL patients, and

functioned on a day-to-day basis. Those were clinical assessments made in a very controlled setting—not in a real-world setting.” He noted that in this study, the nurse-coordinators phoned patients before and after surgery to ask them how they felt about performing specific tasks, such as waking up in the morning, sorting their clothes, walking down stairs, socializing, and driving their car.

Although there might have been some selection bias, said Dr. Shekhawat, “The distribution of the scores for the second surgery provided strong evidence that there was a significant benefit matching that of the first surgery.”

—Peggy Denny

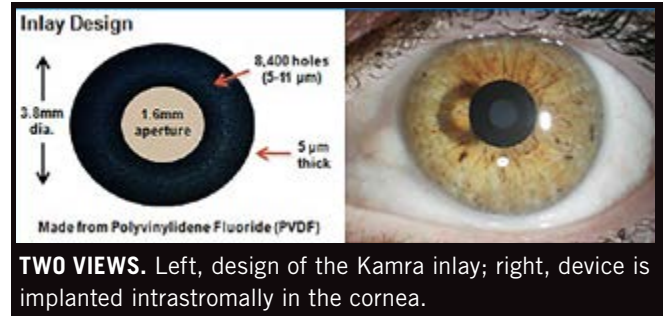
Dr. Shekhawat reports no related financial interests.

22 Tecnis multifocal IOL patients against a subgroup of 327 Kamra patients enrolled in the U.S. Kamra clinical trial at 18 clinical sites. It’s important to note that these recent Kamra data were compared retrospectively against earlier results from the IOLs, and the patients were not randomized.

Currently available outside the United States, the 4- to 6- μ m thick Kamra is implanted intracorneally in the nondominant eye. The inlay’s small central aperture increases depth of focus by blocking unfocused light rays, and thousands of laser-drilled pores are arranged to minimize diffraction problems at night.

Real-world results? To more closely mimic patients’ real-world experiences, the researchers measured acuity at different vergences in a controlled-light environment using a high-contrast chart, as well as contrast sensitivity under mesopic conditions, with and without glare. Mesopic vision requires seeing at an intermediate range of light levels between cone threshold and rod saturation.

“The whole world isn’t black on white with 100 percent contrast,” said Jay Stuart Pepose, MD, PhD, lead author and professor of clinical ophthalmology at Washington University School of Medicine in St.



Louis. “We live in environments where illumination, wavelengths, and contrast all vary. And with increasing use of computers, cell phones, and GPS, for example, intermediate vision is becoming more and more important.”

Better overall. “The inlay’s binocular mesopic contrast sensitivity was significantly better at all spatial frequencies than that of the premium lens implants,” said Dr. Pepose. “In fact, the Kamra patients achieved both better contrast sensitivity—with and without glare—and a broader continuous range of vision than the patients with IOLs.”

Crystalens and Kamra inlay patients had continuous functional vision of 20/40 or better over a range of 3 D and 4 D, respectively, whereas ReSTOR and Tecnis multifocal patients had noncontinuous functional vision over a 4.5 D range.

Although the Crystalens surpassed the Kamra inlay in binocular uncorrected intermediate vision, the inlay’s intermediate vision was significantly better than that of the two multifocals,

while having minimal impact on distance vision. In addition, the Kamra came out ahead of the Crystalens in uncorrected near vision when they were tested monocularly, but there were no significant differences when tested binocularly.

However, both the ReSTOR and the Tecnis yielded better uncorrected near vision than either the Kamra or Crystalens when tested binocularly.

A menu of options. Despite the inlay’s strong overall performance—as well as its ease of removal, if needed—no perfect presbyopia solution yet exists, said Dr. Pepose. Surgeons can’t take a one-size-fits-all approach because patients have unique needs, and each option has its own strengths and weaknesses, he said. “One purpose of the study was to help surgeons and patients better understand what they may be gaining and giving up with each solution.” —Annie Stuart

1 Pepose JS et al. *Am J Ophthalmol.* 2014;158(3):436-446.e1.

Dr. Pepose is a consultant to AcuFocus.

■ **Comparison of Depth of Focus and Mesopic Contrast Sensitivity in Small-Aperture Corneal Inlay, Accommodating IOL, and Multifocal IOL Patients.** When: Tuesday, Oct. 21, 9:54-10:01 a.m., during the refractive surgery paper session (8:30-10:15 a.m.). Where: Room S404. Access: Free.

Glaucoma Paper

Prognostic Clues From the Lamina Cribrosa

If the eye has a crystal ball, it may be the lamina cribrosa (LC)—at least when it comes to predicting glaucoma progression. “The effect of lamina cribrosa characteristics on the rate of progression is substantial,” said Eun Ji Lee, MD, PhD, assistant professor, Seoul National University Bundang Hospital, Korea.

Two factors: thickness and depth. In a study that measured LC thickness and LC depth in 110 open-angle glaucoma patients, Dr. Lee found that those LC characteristics serve as important prognostic factors for glaucoma progression. Specifically, thinner LC and greater LC displacement influence the rate of retinal nerve fiber layer (RNFL) thinning. Overall, the annual rate of RNFL thinning was $-0.87 \mu\text{m}$. For every $100 \mu\text{m}$ of LC thinning and greater depth, the RNFL additionally thinned by 0.35 and $0.85 \mu\text{m}/\text{year}$, respectively.

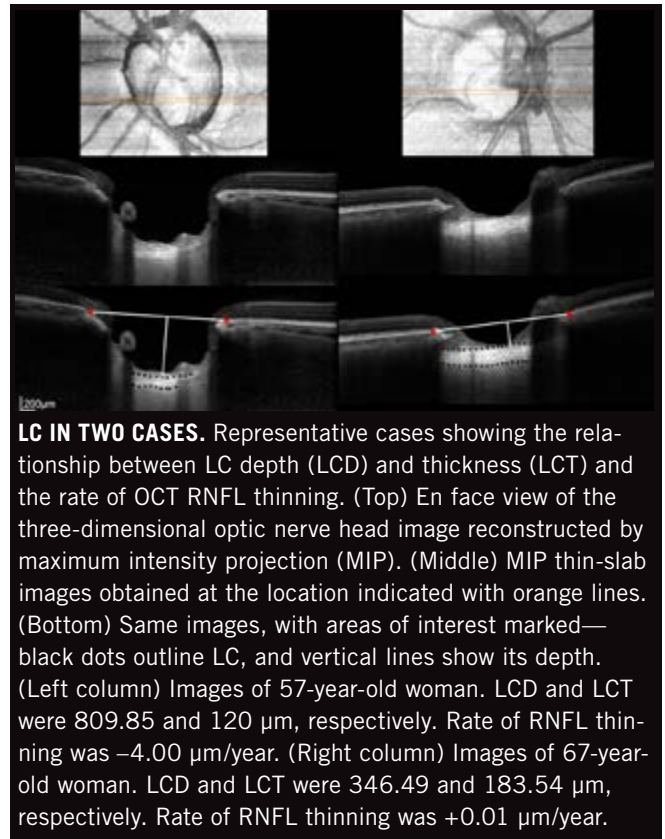
The study was inspired by earlier findings that LC displacement or compression is the primary event causing subsequent axonal damage. Also, thinner LC may increase the trans-laminar pressure gradient, which in turn may hamper

the axonal flow within the optic nerve axons. At the same time, Dr. Lee had noted great variability of LC depth and thickness among patients. “It was reasonable to postulate that a larger LC depth or smaller LC thickness can expedite the disease progression,” she said.

Technology adds to predictive power. The optic nerve scans were captured by spectral-domain optical coherence tomography, using the enhanced depth imaging technique. Before the advent of this technology, the LC could only be examined after enucleation of the eye.

“Measuring LC thickness and depth is not mandatory in the management of glaucoma patients, but it does add valuable information in predicting the disease prognosis,” Dr. Lee said. She advised clinicians to consider the possibility of progression in eyes with a deeply excavated optic disc or a thin LC. “Those eyes should be monitored more carefully by frequent structural and functional tests. If progression is noted, target IOP can be set to an even lower level.”

These findings may help explain why the rate of pro-



LC IN TWO CASES. Representative cases showing the relationship between LC depth (LCD) and thickness (LCT) and the rate of OCT RNFL thinning. (Top) En face view of the three-dimensional optic nerve head image reconstructed by maximum intensity projection (MIP). (Middle) MIP thin-slab images obtained at the location indicated with orange lines. (Bottom) Same images, with areas of interest marked—black dots outline LC, and vertical lines show its depth. (Left column) Images of 57-year-old woman. LCD and LCT were 809.85 and $120 \mu\text{m}$, respectively. Rate of RNFL thinning was $-4.00 \mu\text{m}/\text{year}$. (Right column) Images of 67-year-old woman. LCD and LCT were 346.49 and $183.54 \mu\text{m}$, respectively. Rate of RNFL thinning was $+0.01 \mu\text{m}/\text{year}$.

gression varies substantially among glaucoma patients. Knowing that certain factors are associated with a faster rate of progression may help individualize treatment and follow-up, Dr. Lee said.

—Miriam Karmel

Dr. Lee reports no related financial interests.

RELATED READING

Lee EJ, Kim TW, Weinreb RN, et al. Reversal of lamina cribrosa displacement after intraocular

pressure reduction in open-angle glaucoma. *Ophthalmology*. 2013;120(3):553-559.

Lee EJ, Kim TW, Weinreb RN. Reversal of lamina cribrosa displacement and thickness after trabeculectomy in glaucoma. *Ophthalmology*. 2012;119(7):1359-1366.

Lee EJ, Kim TW, Weinreb RN, et al. Three-dimensional evaluation of the lamina cribrosa using spectral-domain optical coherence tomography in glaucoma. *Invest Ophthalmol Vis Sci*. 2012;53(1):198-204.

■ **Influence of Lamina Cribrosa Thickness and Depth on the Rate of Progressive Retinal Nerve Fiber Layer Thinning.** When: Monday, Oct. 20, 2:24-2:31 p.m., during the glaucoma paper session (2:00-5:30 p.m.). Where: Room S404. Access: Free.

About the Best Papers of 2014

At the end of each paper session at AAO 2014, the expert panel members will select one paper that they consider the best of that group. Watch for announcements of these Best Papers in the daily *Academy Live* e-newsletters, reported onsite from the meeting.

