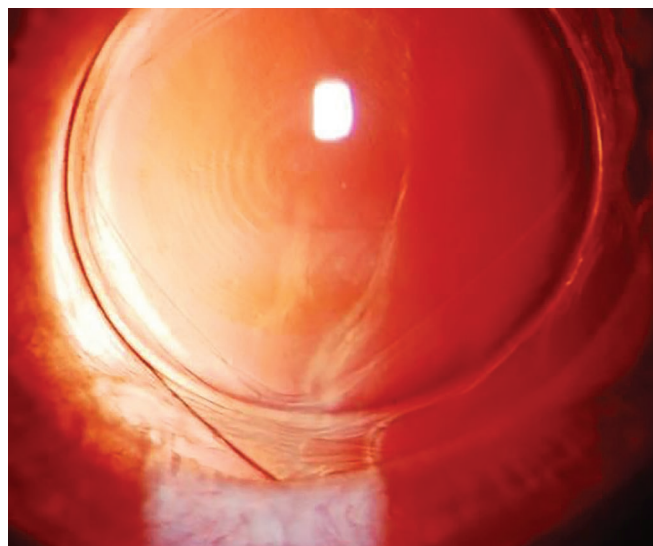


News in Review

COMMENTARY AND PERSPECTIVE

THIS MONTH, NEWS IN REVIEW HIGHLIGHTS SELECTED papers from the original papers sessions at AAO 2017. Each was chosen by the session chair because it presents important news or illustrates a trend in the field. Only 4 subspecialties are included here; papers sessions will also be held in 6 other fields. See the Meeting Program, which you'll find in your meeting bag, or the Mobile Meeting Guide (aao.org/mobile) for more information.



CATARACT PAPER

Femtosecond Laser Corrects Power of Implanted IOL

A METHOD FOR USING A FEMTOSECOND laser to change the refractive power of an already implanted intraocular lens (IOL) appears to be biocompatible, with no evidence of postoperative inflammation or toxicity, a preclinical study has found.

In the technique, a specialized, low-power femtosecond laser (Perfector, Perfect Lens) alters the lens power by making specific parts of a hydrophobic acrylic lens more hydrophilic, said Nick Mamalis, MD, at the University of Utah in Salt Lake City.

“The reason why this technology is so interesting is that it allows the change of power of an IOL that is already inside the eye. This doesn’t require a special lens to be placed to begin with,” said Dr. Mamalis.

Precise femtosecond laser nomograms for different types of corrections—including spherical power, astigmatism, and multifocal adjust-

ments—were developed previously *ex vivo*, Dr. Mamalis said. This study was designed to test the safety and effectiveness of such treatments in pseudophakic, living eyes, Dr. Mamalis said.

Study details. In the study, 6 rabbits had a standard hydrophobic acrylic IOL implanted in both eyes (with the fellow eyes as controls), followed by a 2-week healing period. Then the laser treatments were performed in 1 eye.

“We followed the rabbits for an additional 4 weeks, to look for signs of inflammation or toxicity from the laser treatment,” Dr. Mamalis said. “We then sacrificed the animals and examined the enucleated eyes grossly and histopathologically.”

No inflammation. In slit-lamp examinations, the researchers found “no postoperative inflammation or toxicity in the treated eyes,” he said. “More importantly, when we looked at them in terms of a careful histopathologic examination, there was no sign of un-

TREATED LENS. This slit-lamp image is of an IOL in a rabbit eye. What looks like a multifocal pattern—visible individual zones in the IOL—is a refractive change. This is done with a phase wrapping algorithm and allows higher diopter changes.

toward inflammation, toxicity, or any kind of a reaction in the eyes that had the laser adjustment done, compared to the control eyes.”

Adjustments on target. The researchers then explanted the IOLs in order to assess the degree to which they had been adjusted. “What we found is that the treatments were incredibly precise and that the changes in power were really consistent, within 0.1 D of target,” Dr. Mamalis said.

Clinical implications. If this technology eventually is proved safe and effective in humans, it would help cataract surgeons optimize patients’ postoperative visual acuity, Dr. Mamalis

Evaluation of the Biocompatibility of IOL Power Adjustment Using a Femtosecond Laser. *When:* Tuesday, Nov. 14, 10:00-10:07 a.m., during the second cataract original papers session (10:00 a.m.-noon). *Where:* Room 271. *Access:* Free.

said. “Oftentimes we calculate everything correctly and still have a refractive surprise, especially in patients who have had previous refractive surgeries. This would allow us to correct those [cases],” he said. —Linda Roach

Relevant financial disclosures—Dr. Mamalis: Alcon: S; Anew Optics: C,S; Calhoun Vision: S; ClarVista Medical: S; Cord: S; LensGen: S; Medicutur: S; Omega: S; Perfect Lens: S; PowerVision: S; Shifamed: S; Zeiss: S.

CORNEA PAPER

Novel Device Proves Effective for Dry Eye

A HANDHELD DEVICE THAT DELIVERS tiny electrical pulses inside the nose is proving to be effective for stimulating tear production in dry eye patients.

Edward J. Holland, MD, at the Cincinnati Eye Institute in Ohio, was the medical monitor for the 2 clinical trials of the TrueTear intranasal tear neurostimulator (Allergan). Positive outcomes in the trials led to FDA marketing approval for the device in April.

How it works. Designed to be used daily, the device has 2 soft-tipped prongs that the patient inserts into the superior nasal cavities, slightly anterior, which stimulates tear production, Dr. Holland said. The prongs, which are held in the nose for several seconds, stimulate an ophthalmic branch of afferent trigeminal nerve fibers in the nasal cavity up to 60 times per second with micropulses of 0.7 to 5 milli-Amperes (mA).

Results. “This is a quite effective therapy,” Dr. Holland said. “In both trials, we showed statistically significant increases in Schirmer [scores] both at 1 day and at 180 days.”

The first study was a 1-day randomized crossover trial. Schirmer test scores (mean \pm standard deviation) were significantly greater ($p < .0001$) with

active intranasal stimulation than with sham treatment applications (25.3 ± 10.7 mm vs. 9.2 ± 7.3 mm, respectively).

In the second study, an open-label trial, Schirmer scores after 180 days of use also were significantly greater ($p < .0001$) with intranasal stimulation: 17.3 ± 12.0 mm, compared to 7.9 ± 6.4 mm without stimulation.

No significant adverse events were observed in either study.

Patient satisfaction. “I think a lot of ophthalmologists when they hear about this treatment think that it sounds unusual and the patients won’t use it,” Dr. Holland said. “But patient satisfaction was very, very high. Patients didn’t want to give the device back at the end of the trial.”

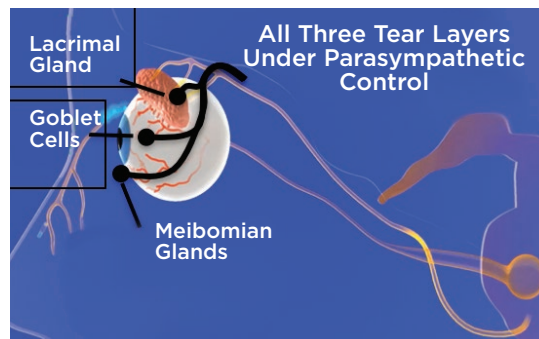
Methods of action. Although aqueous tear deficiency is the sole FDA indication for the prescription-only tear stimulator, other studies have shown that it has additional positive effects, Dr. Holland said.

Researchers have found that the device stimulates all 3 layers of the tear film, Dr. Holland said. “The device stimulates the aqueous layer, and you’ll feel your eyes water. But it also triggers the goblet cells in the conjunctiva to release mucin, and it stimulates the meibomian glands to release meibum,” he said. “You basically improve all 3 layers of the tear film with 1 stimulation, so in theory this could be used for patients with dry eye no matter the etiology.”

Furthermore, in the longer-term trial, patients reported that they needed to use the device less over time, he said. “The longer you’re using the device, the less you [need to] use it, because your ocular surface recovers,” he said.

—Linda Roach

Relevant financial disclosures—Dr. Holland: Allergan: C,S.



METHOD OF ACTION. By targeting the nasolacrimal reflex, the device stimulates all 3 tear layers, Dr. Holland said.

GLAUCOMA PAPER

Lamina Cribrosa May Warn of VF Loss

THE LAMINA CRIBROSA IS REGARDED as the primary site of pathogenesis in glaucoma. Now there’s evidence that the lamina cribrosa (LC) may also be the site of an early warning system for subsequent visual field (VF) loss.

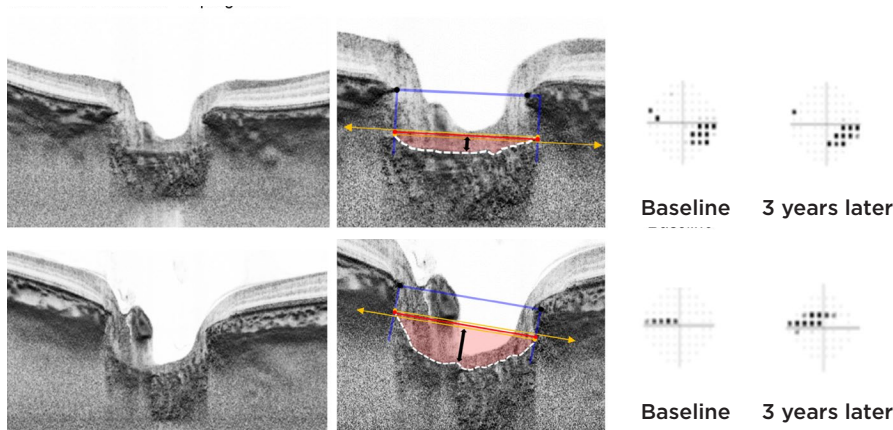
Study rationale. LC deformation has been noted to occur primarily in early glaucoma stages, and biomechanical changes to the LC appear to be closely associated with glaucomatous change. “This study was undertaken to investigate the association between the extent of baseline LC deformation and subsequent glaucoma progression,” said Ahnul Ha, MD, who is at Seoul National University Hospital in South Korea.

The researchers evaluated 101 eyes with early-stage primary open-angle glaucoma (POAG). All eyes had been followed longer than 3.5 years, had undergone more than 5 reliable standard automated perimetry tests, and had well-controlled intraocular pressure (IOP) during follow-up.

Using swept-source optical coherence tomography (SS-OCT), the researchers took baseline LC images and then calculated manually what they call the lamina cribrosa curvature index (LCCI) at 12 radial lines.

Faster progression. Baseline LCCI showed a significant correlation with the rate of subsequent VF progression. Eyes with greater LCCI values (eyes

Intranasal Tear Neurostimulation for Subjects With Dry Eye Disease: Results From 2 Pivotal Clinical Trials. *When:* Sunday, Nov. 12, 2:24-2:31 p.m., during the first cornea original papers session (2:00-3:30 p.m.). *Where:* Room 255. *Access:* Free.



PROGRESSION. The researchers used SS-OCT to calculate the LCCI (lamina cribrosa curvature index) at baseline and compared that to later visual field changes.

with greater LC deformation) at early stages of glaucoma showed a significantly faster rate of VF progression, even in cases with well-controlled IOP.

Higher risk in younger patients. A separate analysis by age group revealed significantly faster VF progression, with LCCI changes occurring more rapidly in the relatively younger age group (< 68 years). Dr. Ha speculated this could be due to the more pliant LC microstructure of younger individuals, which may cause “more kinking and pinching of the axons in the laminar pores,” inducing faster progression.

Clinical implications. The findings suggest that axons of retinal ganglion cells might be more vulnerable to further glaucomatous injury in POAG eyes with greater posterior bowing of the LC. And while the results suggest that greater LCCI value can be regarded as a risk factor for further progression in POAG, Dr. Ha stressed that the LCCI value is only a single parameter of the LC’s deformation and is not a direct index of glaucoma progression.

The bottom line, she said: “In vivo assessment of the LC by SS-OCT is becoming more important, so that these eyes can be monitored more carefully for subsequent VF deterioration.”

—Miriam Karmel

Relevant financial disclosures—Dr. Ha: None.

RETINA PAPERS

IRIS Registry Mined for Insights

THE IRIS REGISTRY, THE NATION’S only comprehensive database of ophthalmic outcomes, currently includes real-world data from 41.2 million patients. For the following separate studies, researchers mined the data to shed light on treatment patterns.

Study 1: DME treatment patterns. Researchers identified a large cohort of 13,410 newly diagnosed patients with diabetic macular edema (DME) and their initial treatment. They found that only 5,316 patients (39.6%) received any type of treatment during the first year after diagnosis. Among those who were treated during the first year, 59.3% received anti-vascular endothelial growth factor (VEGF) drugs, 34.6% were treated with laser, and 4.5% received steroids as the initial treatment.

Dangers of inaction. “Although some patients’ DME may not be urgently vision threatening—prompting physicians to observe, rather than to treat during the first year—a large proportion of patients may not be receiving the treatment they need and are at risk for vision loss,” said coauthor Jeffrey R. Willis, MD, who practices in Sacramento, California. This may be

occurring for a range of reasons, he said, from transportation and insurance issues to poor awareness about the importance of timely treatment.

Building on these findings, said Dr. Willis, future studies should investigate barriers that limit patients’ access to DME treatment. In addition, developing longer-acting drugs could be an avenue for addressing logistical challenges around current DME care.

A powerful research tool. “The IRIS Registry can be a powerful tool to help clinical researchers and health policy makers understand unmet needs in ophthalmic care,” Dr. Willis commented. “We are in the very beginning stages of understanding the utility of large datasets in ophthalmology. As more people utilize the registry, the more capable we will become in applying it to promote better health outcomes.”

Study 2: Return to the OR after macular surgery. Capitalizing on its data from a wide range of practices, D. Wilkin Parke III, MD, turned to the IRIS Registry to retrospectively assess the rate of return to the operating room within a year of macular surgery.

Rate of return. Among 11,472 eyes that had undergone vitrectomy to treat macular hole, 2,095 had a second surgery, with 851 (7.4%) returning for surgery unrelated to cataract. Among 20,291 eyes that had undergone vitrectomy for epiretinal membrane, 3,354 had a second surgery and 1,252 (6.2%) were unrelated to cataract. Most non-cataract second surgeries after macular hole surgery involved a second macular hole repair. Membrane stripping was the procedure conducted most often in second surgeries after an initial epiretinal membrane surgery.

Small-gauge better? “I pursued this

POSTERS AT THE MEETING

For a look at cutting-edge research, check the Scientific Poster Theatre Hall. New this year: Tours are being replaced by moderated discussions. **When:** For times, check the Mobile Meeting Guide at aao.org/mobile. **Where:** Hall C. **Access:** Free.

Baseline Lamina Cribrosa Curvature Index and Prediction of Glaucoma Progression. **When:** Monday, Nov. 13, 2:48-2:55 p.m., during the glaucoma original papers session (2:00-5:00 p.m.). **Where:** Room 271. **Access:** Free.



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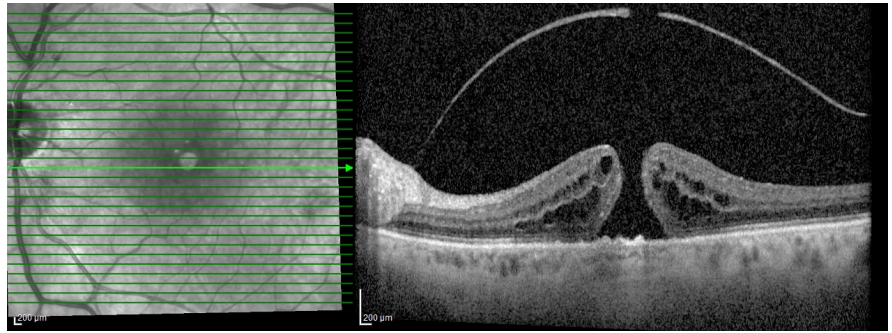
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BACK TO THE OR? OCT of a full-thickness macular hole.

research because I wanted accurate data for conducting surgical evaluations,” said Dr. Parke, who practices in Minneapolis. “But what interested me most was whether the transition from 20-gauge to small-gauge surgery had translated into a lower rate of postoperative retinal detachments (RDs).” In the study, about 2% of eyes undergoing surgery for either a macular hole or epiretinal membrane required RD repair—low, but not as low as previous small series had indicated, he said.

During the study time frame (from January 2013 through June 30, 2015), the IRIS Registry lacked the capacity to extract data such as surgical techniques being used, said Dr. Parke. However, this period could serve as a proxy for small-gauge surgeries, given that most retina surgeons were conducting them during this time, he said.

Visual results. Overall, eyes requiring second surgeries had worse visual outcomes. When a second noncataract surgery wasn't needed, the last best-corrected visual acuity (BCVA) was 20/72 for macular hole and macular pucker surgeries. When a noncataract second surgery was needed, the BCVA was 20/155.

Lessons learned. Because clinical registries depend upon real-world physicians, said Dr. Parke, the data will

always be less clean than with a curated prospective study. For this reason, miscoding or erroneous charting—as well as patients moving to practices that were not participating in the registry—may have affected the data.

“But the hope is that the power is great enough to minimize or render that concern irrelevant,” said Dr. Parke. “I think we can now tell our patients that there is approximately a 5%-6% chance they will need a second retina surgery and a 2% chance that a serious complication will occur after surgery.” Said another way, macular surgeries have a 94% success rate. “And considering prior studies and the fact that this was real-world data, that is better than I thought it would be.” —Annie Stuart

Relevant financial disclosures—Drs. Parke and Willis: None.

AAO 2017
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MORE AT THE MEETING

Want to access big data for research?

Learn more at **Research to Prevent Blindness-AAO IRIS Registry Grant Program** (Spe25). **When:** Monday, Nov. 13, 10:15-11:15 a.m. **Where:** Room 338. **Access:** Free.

Treatment Patterns for DME in the United States: Analysis of the IRIS Registry.

When: Sunday, Nov. 12, 11:39-11:46 a.m., during the first retina, vitreous original papers session (10:00 a.m.-12:15 p.m.). **Where:** Room 255. **Access:** Free.

Return to the OR After Macular Surgery: IRIS Registry Analysis. **When:** Tuesday, Nov. 14, 11:15-11:22 a.m., during the second retina, vitreous original papers session (10:15 a.m.-12:30 p.m.) **Where:** Room 255. **Access:** Free.

For the financial disclosure key, see page 12. For full disclosures, including category descriptions, view this News in Review at aao.org/eyenet.