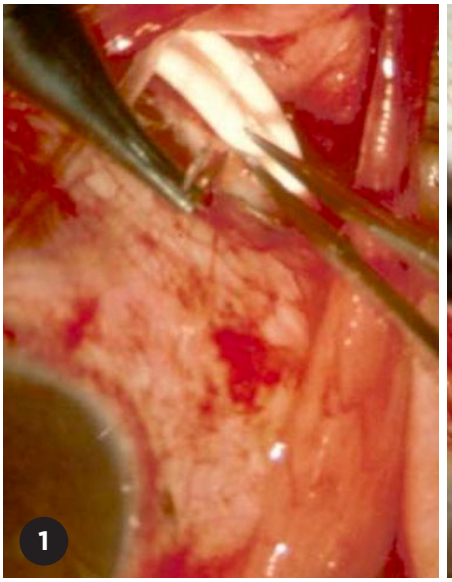
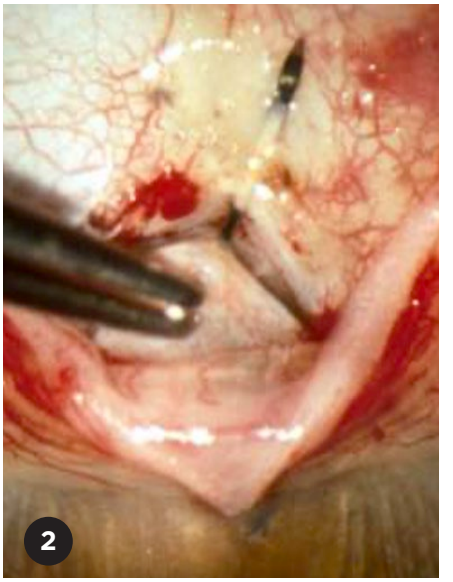
News in Review

COMMENTARY AND PERSPECTIVE

THIS MONTH, NEWS IN REVIEW highlights selected papers from the original papers sessions at AAO 2021. Each was chosen by the session chairs because it presents important news or illustrates a trend in the field. Only four subspecialties are included here; papers sessions also will be held in five other fields. For up-to-date information, check the Mobile Meeting Guide (aao.org/mobile).





NO CLEAR WINNER. *Although results were similar for tube shunt surgery (1) and trabeculectomy (2), nuances from the PTVT Study may influence treatment decisions for selected patients.*

GLAUCOMA

Surgical Choices: Outcomes of PTVT Study at Five Years

WHAT'S THE BEST SURGICAL STRATEGY for managing medically uncontrolled glaucoma in patients who have not previously undergone incisional ocular surgery? According to the five-year findings of the Primary Tube Versus Trabeculectomy (PTVT) Study, both tube shunts and trabeculectomy with mitomycin C (MMC) are viable surgical options.

Same—but different? "The PTVT Study does not demonstrate clear superiority of one glaucoma operation over the other," said Steven J. Gedde, MD, at Bascom Palmer Eye Institute in Miami and a study chairman.

Even so, the data suggest that the choice is more than a flip of the coin for some patients. For instance, those patients with lower preoperative IOP appear to benefit most from primary trabeculectomy with MMC, while those with higher pre-op IOP may benefit more from primary tube shunt surgery. "Before seeing the results of the PTVT Study, I was unaware of the importance of preoperative IOP when selecting a traditional glaucoma procedure," Dr. Gedde said.

In addition, the results for trabeculectomy with MMC were achieved with significantly fewer glaucoma medications, a finding that could influence treatment decisions.

Study specifics. For this multicenter randomized clinical trial, patients with medically uncontrolled glaucoma were randomly assigned to treatment with a 350-mm^2 Baerveldt shunt (Johnson & Johnson) or trabeculectomy with MMC (0.4 mg/mL for two minutes). Primary outcome measures included rate of surgical failure defined as IOP >21 mm Hg or reduced <20% below baseline; IOP≤ 5 mm Hg; repeat glaucoma surgery; or loss of light perception vision.

Outcomes. At the five-year follow-up, mean IOP was similar for both procedures (13.4 mm Hg for the tube group vs. 13.0 mm Hg for trabeculectomy; p = 0.52). What's more, the cumulative probability of failure was not significantly different between the tube and trabeculectomy cohorts (42% vs. 35%, respectively; p = 0.21).

With regard to the need for supplemental medications, the rate of complete success without additional medications was higher for patients in the trabeculectomy plus MMC group (34%) than for those who received the shunt (9%; p < .001).

A surprise finding. At the one-year follow-up, the surgical failure rate was significantly higher in the tube group (17%) than in those who underwent trabeculectomy (8%). But by the end of

Treatment Outcomes in the Primary Tube Versus Trabeculectomy Study After 5 Years of Follow-Up. Presented during the first glaucoma original papers session. **When:** Saturday, Nov. 13, at 8:48 a.m. **Where:** Room 255-257.

Steven J. Gedde, MD

five years, the difference was no longer statistically significant.

A risk factor analysis found lower preoperative IOP to be significantly associated with failure. Specifically, the rate of tube shunt failure was strongly influenced—and trabeculectomy failure was less influenced—by pre-op IOP, Dr. Gedde said.

Bottom line. While both procedures are viable surgical options for managing refractory glaucoma, the findings suggest that trabeculectomy with MMC is the preferred surgical procedure in the subgroup of patients who either are nonadherent or are poorly tolerant of glaucoma therapy, said Dr. Gedde. He added, "Surgical skill and experience with each operation are important additional considerations that were not evaluated in this study."

—Miriam Karmel

Relevant financial disclosures—Dr. Gedde: None.

RETINA

Port Delivery System for AMD

THERE'S MORE GOOD NEWS ON THE Port Delivery System (PDS), which has the potential to reduce the burden of anti-VEGF treatment for patients with neovascular age-related macular degeneration (AMD). In an experimental study, the implant was found to effectively deliver ranibizumab over a six-month period.

PDS specifics. The PDS (Roche) is a permanent refillable implant roughly the size of a small pellet. It is surgically implanted into the vitreous and continuously delivers a customized formulation of ranibizumab over a period of months. In preliminary results from the phase 3 Archway study, 98.4% of those who received the PDS did not require supplemental treatment before the first refill-exchange at 24 weeks.[1]

Study specifics. For this in vitro study, implants were filled with ranibizumab 10, 40, or 100 mg/mL. Drug concentrations were measured via automated sample preparation, and concentration data were used to calculate a mean daily ranibizumab release rate during an initial fill and at three refill exchanges.

Main outcomes included the release rate of ranibizumab, the active release rate (measured in grams per day), and the amount of drug retained in the implant at the end of the study.

Drug release. Approximately 70% of ranibizumab 100 mg/mL was released from the implant during the six months, said Mark R. Wieland, MD, at Northern California Retina Vitreous Associates in San Jose.

The mean active release rate was 3.95 g/day at the initial fill and 3.99, 3.85, and 4.0 g/day at the first, sec-

CATARACT

Update on the Synergy IOL

IN A SIX-MONTH STUDY, THE TECNIS SYNERGY IOL PRO- vided extensive range of vision and spectacle independence in the vast majority of patients with presbyopia.

The Synergy is a hybrid model that combines both multifocal and extended-depth-of-focus (EDOF) technologies. It provides excellent near vision and a wide range of continuous vision, said Daniel H. Chang, MD, at Empire Eye & Laser Center in Bakersfield, California.

Clinical trial. Dr. Chang was a principal investigator for the prospective study, which compared the Tecnis Synergy (model ZFR00V) and a monofocal control (model ZCB00) in 272 patients at 15 sites. Johnson & Johnson Surgical Vision developed both lens models.

In the study, the Synergy maintained a range of about 3.5 D, which was 2.3 D greater than the monofocal control lens. "Patients achieved good quality of vision from near to far, and they did not have to search for a 'sweet spot' to hold reading material," said Dr. Chang.

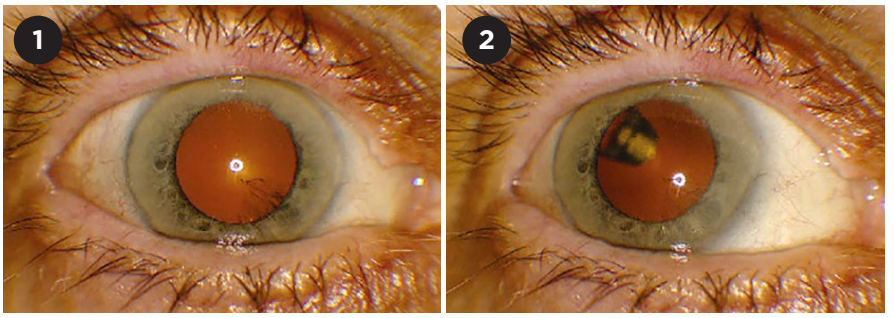
Spectacle wear. At six months, nearly 88% of the Synergy subjects reported needing spectacles "none of the time" on a 5-point scale at all queried distances (far, intermediate, near, and overall). This was an 85%-point difference in spectacle independence at all distances compared to the control lens. On a 2-point scale, at least 91% of the Synergy subjects reported "no need for glasses" for distance, intermediate, and near vision.

Challenges and trade-offs. The challenge of presbyopia-correcting lenses is the need to balance visual quality, depth of field, and dyphotopsias, said Dr. Chang. Given the depth of field provided by the Synergy lens, it is understandable that a small percentage of patients had early complaints about uncorrected distance vision, he said. Many of these complaints were related to refractive error and improved with time, but this stresses the importance of hitting the refractive target. "Unlike an EDOF lens like the Tecnis Symfony, which provides some tolerance to refractive error, you really need to nail the refractive target with the Tecnis Synergy," said Dr. Chang. "If you do miss, it is actually better to be slightly hyperopic than myopic."

In low light, he said, Synergy recipients may get more halos and starbursts compared to lenses that provide less depth of field. However, Johnson & Johnson incorporated both a violet light filter and new high-definition lathing technology to help mitigate these symptoms, Dr. Chang said. And, of course, counseling patients ahead of time can go a long way toward improving patient satisfaction, he added. *—Annie Stuart*

Relevant financial disclosures—Dr. Chang: Johnson & Johnson Surgical Vision: C,L,S.

Clinical Evidence Supporting the Range of Vision With a New Presbyopia-Correcting IOL With Hybrid Technologies. Presented during the cataract original papers session. **When:** Saturday, Nov. 13, at 2:24 p.m. **Where:** Room 255-257.



IN PLACE. *A patient with the PDS in place. The implant cannot be seen when the eye is in the primary position (1) but is visible when the patient looks up (2).*

ond, and third drug refill exchanges, respectively. Changing the initial concentration of ranibizumab from 10 to 100 mg/mL increased the initial drug release rates from 2 to 17 g/day.

Drug retention. During refill-exchange, approximately 98% of the previous implant contents were replaced with fresh drug during one 100-mg/mL refill.

Conclusion and next steps. The results indicate that the PDS can continuously and reproducibly deliver ranibizumab over a period of months while maintaining potency, Dr. Wieland said.

Next up: regulatory review. This summer, Roche submitted an application to the FDA. The implant is also under review by the European Medicines Agency. *—Jean Shaw*

1 Awh CC et al. Primary analysis results of the phase 3 Archway trial of the Port Delivery System with ranibizumab for patients with neovascular AMD. Paper presented at: Retina Society 2020 Virtual; July 26, 2020.

Relevant financial disclosures—Dr. Wieland: Roche: C.

The Port Delivery System With Ranibizumab: A New Paradigm for Long-Acting Retinal Drug Delivery. Presented during the third retina original papers session. **When:** Monday, Nov. 15, at 11:54 a.m. **Where:** Room 255-257.

CORNEA

Smartphone Used to Assess Health of Endothelium

WITH A SMARTPHONE, A SLIT LAMP, and artificial intelligence (AI)–generated software, researchers have developed a tool for assessing corneal endothelium (CE) function. The novel system promises to enable mobile field screening for endothelial health, which would be particularly useful in low-resource regions.

Potential. The smartphone-based system was developed to be portable, reliable, not dependent on internet connection, and fast. In a preliminary study published earlier this year, a $500 smartphone, coupled with a slit lamp, performed comparably to a $30,000 specular microscope.[1]

The system "will empower general ophthalmologists to identify and detect CE changes at a very affordable price, making it accessible to many more patients," said Madhu Uddaraju, MBBS, MS, at the Srikiran Institute of Ophthalmology in Andhra Pradesh, India.

Testing. The system was tested on 30 eyes (15 patients) without ocular disease who underwent a routine eye exam at the Srikiran Institute, a referral eye hospital, in January 2020.

Image capture and AI. First, researchers captured images of the central cornea of both eyes using the Tomey EM-4000 specular microscope. Next, using the specular reflection technique, they imaged the same set of eyes with a OnePlus 7 Pro smartphone that was attached to a Topcon SL-D701 slit-lamp ocular. A technician performed all imaging.

An AI-based algorithm was used to analyze the images for three clinically relevant parameters of endothelial health: endothelial cell density (ECD), percentage of hexagonal cells (HEX), and coefficient of variation (CV). The analysis can be run in under five seconds on a mobile phone without internet connection, with total capture and analysis taking two to four minutes for both eyes, similar to the speed of specular microscopy.

Outcomes. The findings revealed no significant difference in mean ECD or mean HEX computed by either the specular microscope or the smartphone: Mean ECD was 2,799 ± 156 cells/mm^2 when computed by the microscope, versus 2,799 ± 166 cells/mm^2 when computed by the smartphone. Similarly, mean HEX was 52 ± 6% when computed by microscope and 53 ± 6% when computed by smartphone.

There was, however, a difference in CV as computed by the two devices, with a mean difference of 3.8%.

Next steps. The researchers are now comparing the device with conventional specular microscopes in patients with Fuchs dystrophy. Also, for more robust results, they are gradually increasing the number of study patients, which may help explain the CV disparity, Dr. Uddaraju said. "Once we have larger study results and make the system simpler and more user friendly, we will make it available to our colleagues."

—Miriam Karmel

1 Mantena S et al. *Transl Vis Sci Technol.* 2021; 10(4):4.

Relevant financial disclosures—Dr. Uddaraju: None.

Low-Cost, Smartphone-Based Specular Imaging and Automated Analysis of the Corneal Endothelium. Presented during the cornea original papers session. **When:** Sunday, Nov. 14, at 8:24 a.m. **Where:** Room 255-257.

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