

EYE INSERT RELEASES GLAUCOMA MEDICATION OVER 6 MONTHS

Studies show that many patients do not use glaucoma eye drops as directed and that up to half of them stop administering their medication after a year. Researchers are tackling the challenge of medication adherence with new drug delivery methods such as a silicone ring treated with bimatoprost that rests on the surface of the eye. An ophthalmologist fits the patient with the ring, which releases medication slowly over 6 months.

In a phase 2 clinical trial, ophthalmologists at 10 sites nationwide tested the ring on patients with glaucoma or ocular hypertension. In the study, 64 patients received the topical ocular insert containing bimatoprost. They were also supplied with artificial tears. The control group of 66 patients wore an insert treated with no drug but used 0.5% timolol drops, the regulatory benchmark for glaucoma drugs. IOP in the bimatoprost group fell 3.2 to 6.4 mm Hg over 6 months compared with 4.2 to 6.4 mm Hg in the timolol group. Overall, IOP decreased in the group wearing the bimatoprost ring by about 20% from the initial measurements over 6 months. The device was well tolerated and safe, with a retention rate of 89% for both groups at 6 months. The ring became dislodged in 15 patients but was replaced each time, allowing therapy to continue. A phase 3 study of a larger group of patients is expected to begin later this year.

Iridex's MicroPulse P3 Shown to Reduce IOP

Iridex's MicroPulse P3 significantly reduces mean IOP and allows for retreatment, if necessary, according to data presented at the annual meetings of the Association for Research in Vision and Ophthalmology and the American Society of Cataract and Refractive Surgery.

MicroPulse is a tissue-sparing laser delivery therapy that electronically "chops" the laser emission into trains of micro-second pulses. Per a company press release, this strategy allows the physician to more precisely control the laser's effects on target tissues, offering the potential for ocular treatment with less collateral damage than conventional laser treatments.

A study population of 45 glaucoma patients (45 eyes) with a mean preoperative IOP of 28.1 mm Hg underwent micro-pulse transscleral cyclophotocoagulation with the MicroPulse P3 probe at 2 W, with a total duration of 140 to 180 seconds at a 31.3% duty cycle. According to the company press release, the investigators reported a mean IOP reduction among the study population of 42% (an average of 16.4 mm Hg). Ten of the 45 patients needed retreatment with the Cyclo G6 (Iridex) to achieve the target IOP, and all of these patients responded to repeat treatment with MicroPulse.

Alex Huang, MD, PhD, Receives Heidelberg Research Award

Alex Huang, MD, PhD, is the winner of the Heidelberg Engineering Xtreme Research Award 2016 for his research on aqueous angiography and structural analysis of outflow pathways using optical coherence tomography. He received the award in a ceremony during the annual meeting of the Association for Research in Vision and Ophthalmology in Seattle.

Dr. Huang is a glaucoma clinician scientist at the Doheny Eye Institute and with the Department of Ophthalmology of the David Geffen School of Medicine at UCLA. According to Heidelberg, Dr. Huang presented the highlights of his current research in a lecture entitled, "To See and Touch Aqueous Humor Outflow."

With the annual Xtreme Research Award, Heidelberg Engineering says it intends to honor the most cutting-edge research for the advancement of ophthalmic care. This year, the award recognized Dr. Huang's latest research initiative on structure and function of the anterior segment consisting of a novel method referred to as *aqueous angiography*. The technique involves dye-based angiography of the anterior chamber and optical coherence tomography of the outflow pathways using a multimodal imaging platform.

Although this research is still in its early stages, the goal is to improve angle-based glaucoma procedures by guiding placement according to the individual anatomy of each eye. For example, stent location in microinvasive glaucoma surgery is believed to have an influence on the outcome of the procedure. If this hypothesis proves true, then positioning the stent according to the characteristics of each eye could improve surgical outcomes.

"We are genuinely excited about future possibilities and potential clinical impact that structural and functional anterior segment imaging such as aqueous angiography may have on glaucoma and ophthalmology," Dr. Huang stated in the press release. "With these tools, one day we may start tailoring glaucoma care to an individual patient's anatomy or patterns of aqueous humor outflow."

"Looking ahead, we would like to provide a diagnostic imaging platform to perform dye-based angiography of the anterior segment pre- or intraoperatively and for this reason, we are enthusiastic about Dr. Huang's research project," Dr. Kester Nahen, managing director of Heidelberg Engineering, stated in the press release. "Such novel applications of anterior segment research could provide clinically valuable information about aqueous humor flow and flow patterns leading to more effective glaucoma treatment."

Envisia Therapeutics Announces Interim Results of Low-Dose ENV515 Analysis

Envisia Therapeutics reported positive results from an interim 3-month analysis of an ongoing safety and efficacy evaluation of the low-dosage form of ENV515 XR, an extended-release formulation of travoprost that could offer a sustained reduction in IOP for more than 6 months after a single dose.

In the interim analysis, the low-dosage form of ENV515 reportedly demonstrated a favorable safety profile and a sustained, clinically meaningful reduction in IOP over the entire 3 months. Previously, a 28-day evaluation of the low-dosage form of the drug demonstrated a reduction in IOP comparable to that achieved with topical timolol, while the high-dosage form demonstrated results comparable to that of topical once-daily Travatan Z (travoprost ophthalmic solution; Alcon).

This second cohort of the ongoing phase 2 trial was a 12-month safety and efficacy evaluation of the low-dosage drug that was designed as an open-label trial that enrolled five glaucoma patients. The study drug produced a decrease of 7.1 mm Hg or 27% from baseline that was comparable to that achieved with topical timolol 0.5% twice daily (7.4 mm Hg or 28%) administered to the nonstudy eye.

ENV515 was well tolerated, and there were no serious adverse events; no changes in corneal endothelial cell counts, as evaluated by an independent reading center; and no changes in corneal thickness. The most common adverse event was early-onset

transient hyperemia related to the dosing procedure.

"These results enable us to move forward with the dose escalation study later this year, evaluating the high-dosage form of ENV515 that has been formulated with the goal of achieving efficacy comparable to Travatan Z with a duration greater than 6 months," said Benjamin Yerxa, Envisia's president, in a press release.

BrightFocus Foundation Awards Grants to Glaucoma Researchers

BrightFocus Foundation has awarded grants to five scientists in the fields of glaucoma and macular degeneration research.

Meredith Gregory-Ksander, PhD, of the Schepens Eye Research Institute, Massachusetts Eye and Ear Infirmary, received the Thomas R. Lee Award for Glaucoma Research to test whether inhibiting an important new regulator of inflammation in the optic nerve head will stop the development of glaucoma and vision loss.

Yvonne Ou, MD, of the University of California, San Francisco, received the Dr. Douglas H. Johnson Award for Glaucoma Research to better understand the progression from optic nerve cell injury to loss of nerve cell connections to cell death in glaucoma, information that could ultimately lead to treatments before irreversible cell death occurs.

These researchers are among a group of 32 scientists who will collectively receive nearly \$5 million in vision research grants this year from BrightFocus.

Icare Releases New ic100 Tonometer

Icare USA has released the FDA-approved Icare ic100 tonometer. The product uses the same rebound technology as its successor, the Icare TA01i, but has added features to make it easier for professionals to obtain consistent, repeatable IOP measurements, according to a company press release.

Upgrades include improved ergonomics, a new user interface, a built-in intelligent position assistant that uses colored lights to help operators guide the tonometer into the correct position, and an automated measuring sequence that takes a series of six measurements with a single touch of a button. The unit requires no calibration and is suitable for all types of patients in nearly any setting. Using the instrument demands no drops or specialized skills.

Call for Nominations for Champion for Children's Vision Award

The National Center for Children's Vision and Eye Health (NCCVEH) at Prevent Blindness has issued a call

for nominations for the second annual Bonnie Strickland Champion for Children's Vision Award. Nominees may include individuals (such as a parent advocate, legislator, or professional) or a group composed of diverse stakeholders, including family and community leaders, who are implementing changes to improve children's vision and eye health in the United States. Nominees should demonstrate an impact in one or more areas of a public health system supporting children's vision.

The deadline for submission is June 17, 2016. The award will be presented to the recipient at the NCCVEH annual meeting on August 6, 2016, in Alexandria, Virginia. The award consists of a commemorative plaque, recognition, an opportunity to present at the annual meeting, and round-trip economy airfare for one to Alexandria, along with one night of lodging. The award recipient will be featured on NCCVEH's website with an overview of the winner's program.

For more information or to submit a nomination, visit <http://bit.ly/1sevW6G>, or contact Kira Baldonado at (800) 331-2020 or kbaldonado@preventblindness.org.

12-Month Data Highlight the Safety and Efficacy of Ab Interno Canaloplasty in Primary Open-Angle Glaucoma

According to Ellex Medical Lasers, a 12-month case series review of 228 patients with primary open-angle glaucoma showed that ab interno canaloplasty (ABiC) helps to reduce IOP and medication dependence with minimal complications.

ABiC is an FDA-approved, bleb-free procedure that uses Ellex's proprietary iTrack 250- μ m microcatheter to circumferentially viscodilate Schlemm canal and restore natural aqueous outflow. The intervention does not require a tensioning suture to maintain the IOP reduction, and the procedure spares conjunctival manipulation for future procedures, if required. ABiC can be performed as standalone procedure and in combination with cataract surgery.

The case series study included 228 eyes with mild to moderate primary open-angle glaucoma that underwent ABiC either alone or in combination with cataract surgery. Data for the entire patient cohort showed that, 12 months postoperatively, there was a total average decrease of 30% in IOP and a 50% reduction in medications. In 127 patients who underwent the procedure combined with phacoemulsification, there was a mean decrease of 23.39% in IOP and a 50% reduction in medications. Data in 98 patients who underwent ABiC showed a total average decrease of 36.74% in IOP and 66.66% in medications. Findings also reportedly showed a total average decrease of 38.88% in IOP and 50% in medications in patients with uncontrolled glaucoma (IOP $\geq$ 16 mm Hg, n=161), while patients with controlled glaucoma (IOP $\leq$ 15 mm Hg, n=67) benefited from a 50% reduction in medication use. There were no complications or safety issues. ■