

STUDY SHOWS SIGNIFICANT ADVANTAGES OF CO₂ LASER-ASSISTED SCLERECTOMY SURGERY

Three-year follow-up data from a study of patients undergoing CO₂ laser-assisted sclerectomy surgery with IOptima's IOptimate CO₂ laser system demonstrated a decrease in IOP from baseline of 45.1% at 1 year, 46.8% at 2 years, and 42.5% at 3 years.¹ Patients also used significantly fewer medications after surgery, IOptima reported in a press release.

The multicenter study included 111 eyes in 111 subjects. Inclusion criteria were uncontrolled glaucoma under maximally tolerated hypotensive medical treatment, a baseline IOP higher than 18 mm Hg, and no prior ocular surgery or laser treatment except clear corneal incision cataract surgery. Exclusion criteria were previous ocular surgery (other than cataract), ocular media opacity preventing proper evaluation of the optic nerve, extremely small pupil size, and poor vision in the fellow eye.

Complete success was defined as a 20% IOP reduction and an IOP between 5 and 18 mm Hg. Complete success rates after 12, 24, and 36 months were 60.2%, 57.9%, and 47.8%, respectively. Qualified success was defined as similar IOP requirements achieved with hypotensive medications. Qualified success rates after 12, 24, and 36 months were 79.6%, 91.2%, and 84.8%, respectively. Complications were reduced by more than 35% compared to trabeculectomy (based on treatment outcomes in the Tube Versus Trabeculectomy [TVT] study).²

The preoperative IOP of 25.8 ± 5.4 mm Hg (mean ± standard deviation) dropped to 13.5 ± 3.8 mm Hg at 6 months, 13.5 ± 4.1 mm Hg at 12 months, 13.0 ± 3.1 mm Hg at 24 months, and 14.2 ± 2.9 mm Hg at 36 months. The number of medications dropped from 2.39 ± 1.24 to 0.47 ± 0.84 at 12 months, 0.53 ± 0.75 at 24 months, and 0.71 ± 0.89 at 36 months. No technical device malfunctions occurred during the study at any of the sites.

1. Geffen N, Mimouni M, Sherwood M, Assia E. Mid-term clinical results of CO₂ laser-assisted sclerectomy surgery (CLASS) for open-angle glaucoma treatment. *J Glaucoma*. 2016;25(12):946-951.

2. Gedde SJ, Schiffman JC, Feuer WJ, et al. Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up. *Am J Ophthalmol*. 2012; 153:789-803.

Inotek's Trabodенoson Fails Phase 3 Trial

Inotek's MATrX-1 trial of trabodенoson did not achieve its primary endpoint of superiority in IOP reduction compared with placebo at all 12 time points tested (four times per day on days 28, 42, and 84), the company reported.

The 8 AM time point did not achieve statistical separation with any trabodенoson dose, primarily due to an unexpectedly high placebo response compared to that observed in phase 2, Inotek reported. The 6%/2,000-µg daily dose of trabodенoson was statistically superior to placebo at days 84, 42, and 14, and marginally superior at day 28. The daily IOP reduction from diurnal baseline at 3 months for this dose was 4.25 mm Hg compared to 2.38 mm Hg for placebo and 5.29 mm Hg for the timolol 0.5% twice-daily control arm. No significant safety or tolerability events were reported. The safety profile of trabodенoson was comparable to that of placebo. There was minimal drug-related hyperemia, and four subjects (2.2%) discontinued the trial due to treatment-related adverse events.

iStent Studied as Standalone Procedure

A study showed that a single iStent Trabecular Micro-Bypass Stent (Glaukos) significantly reduced IOP when implanted as a standalone procedure in pseudophakic eyes with open-angle glaucoma, Glaukos reported in a press release. Researchers evaluated iStent procedure outcomes in 42 pseudophakic eyes with a mean preoperative IOP of 20.26 mm Hg.¹ In 21 eyes followed for 2 years, mean medicated IOP decreased 6.64 mm Hg to 13.62 mm Hg (33%). In total, 96% of study patients with a preoperative medicated IOP of at least 19 mm Hg achieved an IOP reduction at their last collected follow-up. With a low rate of postoperative IOP spikes and only one patient requiring additional glaucoma surgery, the safety profile was favorable. Study researchers enrolled patients with primary open-angle glaucoma, normal-tension glaucoma, and ocular hypertension.

1. Ferguson TJ, Berdahl JP, Schweitzer JA, Sudhagoni R. Evaluation of a trabecular micro-bypass stent in pseudophakic patients with open-angle glaucoma. *J Glaucoma*. 2016;25(11):896-900.

Rhopressa Inspection Pushed Back to February

Aerie Pharmaceuticals has been notified by its third-party manufacturing vendor that the Rhopressa manufacturing line in Tampa, Florida, will not be ready for the FDA pre-approval inspection until the end of February, according to a press release. The manufacturer had previously advised Aerie and the FDA that it expected to be prepared for inspection in January. In October 2016, the Rhopressa new drug application was withdrawn, because the manufacturer was not prepared for preapproval inspection by the FDA. Aerie expects to resubmit the Rhopressa new drug application near the end of the first quarter of 2017.

Zika and Glaucoma Linked for First Time

A team of researchers in Brazil and at the Yale School of Public Health, New Haven, Connecticut, has published the first report demonstrating that the Zika virus can cause glaucoma in infants who were exposed to the virus during gestation, according to a news release.

“We identified the first case where Zika virus appears to have affected the development of the anterior chamber or front portion of the eye during gestation and caused glaucoma after birth,” said Albert Icksang Ko, MD, professor at the Yale School of Public Health and coauthor of the study published in the journal *Ophthalmology*.¹ The researchers identified a 3-month-old boy who was exposed to Zika virus during gestation. Although no signs of glaucoma were present at the time of birth, the infant developed swelling, pain, and tearing in the right eye. The research team diagnosed glaucoma and performed a trabeculectomy, which successfully alleviated the pressure within the eye.

1. de Paula Freitas B, Ko AI, Khouri R. Glaucoma and congenital Zika syndrome [published online ahead of print November 18, 2016]. *Ophthalmology*. doi:10.1016/j.ophtha.2016.10.004.

Cynthia A. Bradford, MD, Begins Term as President of AAO

Cynthia A. Bradford, MD, began her term as the 120th president of the American Academy of Ophthalmology on January 1. She was elected by the Academy’s community of ophthalmologists in recognition of her long-standing commitment to quality patient care. Dr. Bradford’s clinical focus is cataract and IOL implant surgery. She is a professor of ophthalmology at the Dean McGee Eye Institute at the University of Oklahoma College of Medicine, Oklahoma City.

Student Diversity, Mentoring Initiative Launched

The American Academy of Ophthalmology and the Association of University Professors in Ophthalmology launched a minority ophthalmology mentoring program intended to attract underrepresented minorities into ophthalmology. This year, 18 medical students were selected to participate in Student Engagement Day at the annual meeting. They learned about the importance of eye care for disadvantaged patients at risk of glaucoma and diabetic retinopathy, global health issues, and the subspecialties. Students were matched with mentors with whom they will have a relationship for several years.

Gerhard Zinser, PhD, Receives Founders’ Award

Gerhard Zinser, PhD, cofounder and managing director of Heidelberg Engineering, received the Founders’ Award from the Optometric Glaucoma Society. In his laudatory speech, John Flanagan, OD, PhD, one of the founders of the Optometric Glaucoma Society, emphasized Dr. Zinser’s significant and long-standing contribution to diagnostic imaging in eye care with innovative and reliable devices.

Call for Applications for Joanne Angle Investigator Award

Prevent Blindness is inviting applications for its 2017 Joanne Angle Investigator Award, a grant that provides funding for research investigating public health related to eye health and safety. Applications will be accepted in the following priority areas in adult vision, children’s vision, and eye injury: the societal burden and economic aspects of eye disease and vision loss, best practices to integrate vision screening and follow-up care, and vision program effectiveness and evaluation. Basic laboratory science research will not be supported under this program. This year, preference will be given to public health research that relates to glaucoma or age-related macular degeneration.

The deadline for entry is March 6 CDT at noon. Grants are for a 1-year period, provide up to \$25,000, and commence on July 1. Applications are reviewed by a panel of experts. For more information or to submit an application for the 2017 Joanne Angle Investigator Award, visit www.preventblindness.org/investigator-awards, or call Prevent Blindness at (800) 331-2020. ■