Redefining glaucoma
A two-pressure disease

Growing evidence supports relationship between IOP, cerebrospinal fluid pressure

By Fred Gebhart;
Reviewed by John P. Berdahl, MD

SIoux Falls, SD

Most Ophthalmologists learned that glaucoma is a disease of elevated IOP. There is a good possibility it is something else entirely.

“We know that IOP matters in glaucoma, but perhaps the pressure differential across the cornea—which is what we measure in IOP—is only a surrogate for the pressure differential that really matters,” said John P. Berdahl, MD.

“What matters is the pressure across the optic nerve head, the pressure gradient between the eye and the cerebrospinal fluid (CSF) 500 μm across the lamina cribrosa,” said Dr. Berdahl, of Vance Thompson Vision, Sioux Falls, SD. “There is growing evidence to support the idea that glaucoma is not a one-pressure disease, IOP, but a two-pressure disease, the difference between IOP and CSF pressure.”

The idea that CSF pressure contributes to glaucoma was first presented in 2008. Eight years later, a growing body of retrospective and prospective data supports the two-pressure model, Dr. Berdahl noted.

Intracranial pressure (ICP) is already recognized as a factor in optic nerve dysfunction. Intracranial hypertension causes the optic nerve to bow outward. The pressure differential impedes axonal transport at the lamina cribrosa, depriving the optic nerve of nutrition. If the metabolic needs of the optic nerve are not met for a sufficiently long period, the nerve withers and vision suffers.

Dr. Berdahl suggested that glaucoma is the
Up to 7.1 mm Hg additional IOP reduction from baseline when added to a PGA

<table>
<thead>
<tr>
<th>Treatment Arm</th>
<th>8 AM</th>
<th>10 AM</th>
<th>3 PM</th>
<th>5 PM</th>
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<tbody>
<tr>
<td>PGA + SIMBRINZA® Suspension (N=88)</td>
<td>24.5</td>
<td>22.9</td>
<td>21.7</td>
<td>21.6</td>
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<tr>
<td>PGA + Vehicle (N=94)</td>
<td>24.3</td>
<td>22.6</td>
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5.6 mm Hg* additional mean diurnal IOP lowering observed from baseline when added to a PGA

<table>
<thead>
<tr>
<th>Treatment Arm</th>
<th>Baseline</th>
<th>22.7</th>
<th>Week 6</th>
<th>17.1</th>
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<tr>
<td>PGA + SIMBRINZA® Suspension (N=83)</td>
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<td>PGA + Vehicle (N=92)</td>
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Study Design: A prospective, randomized, multicenter, double-blind, parallel-group study of 189 patients with open-angle glaucoma and/or ocular hypertension receiving treatment with a PGA. PGA treatment consisted of either travoprost, latanoprost, or bimatoprost. Patients in the study were randomized to adjunctive treatment with SIMBRINZA® Suspension.

Aim for Target IOP
Consider Adding SIMBRINZA® Suspension to a PGA
SIMBRINZA® Suspension should be taken at least five (5) minutes apart from other topical ophthalmic drugs.

24-hour IOP-lowering coverage, including the night — nocturnal efficacy established through an 8 AM time point

INDICATIONS AND USAGE
SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% is a fixed combination indicated in the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration
The recommended dose is one drop of SIMBRINZA® Suspension in the affected eye(s) three times daily. Shake well before use. SIMBRINZA® Suspension may be used concomitantly with other topical ophthalmic drug products to lower intracocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

IMPORTANT SAFETY INFORMATION

Contraindications
SIMBRINZA® Suspension is contraindicated in patients who are hypersensitive to an ingredient of this product and neonates and infants under the age of 2 years.

Warnings and Precautions
Sulfonamide Hypersensitivity Reactions—Brinzolamide is a sulfonamide, and although administered topically, is absorbed systemically. Sulfonamide attributable adverse reactions may occur. Fatalities have occurred due to severe reactions to sulfonamides. Sensitization may recur when a sulfonamide is readministered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

Corneal Endothelium—There is an increased potential for developing corneal edema in patients with low endothelial cell counts.

Severe Hepatic or Renal Impairment (CrCl <30 mL/min)—SIMBRINZA® Suspension has not been specifically studied in these patients and is not recommended.


Learn more at myalcon.com/simbrinza
For additional information about SIMBRINZA® Suspension, please refer to the brief summary of the full Prescribing Information on the following page.
BRIEF SUMMARY OF PRESCRIBING INFORMATION

RADIATIONS AND IONIZATION

SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% is a fixed combination of a carbonic anhydrase inhibitor and an alpha 2 adrenergic receptor agonist intended for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

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This combination (brinzolamide/brimonidine) is indicated for the treatment of open-angle glaucoma and ocular hypertension. SIMBRINZA should not be used to treat ocular pharmacodynamic effects such as hypertension. Caution is advised in patients being taken MAO inhibitors which can affect the reduction of intraocular pressure.

DOSAGE FORMS AND STRENGTHS

SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% contains 2 mg/mL brinzolamide in a 10 mg/mL brimonidine tartrate solution.

CONTRAINDICATIONS

Simbrinza® Suspension is contraindicated in patients who are hypersensitive to sulfonamides, sulfites, benzoic acid, or any of the ingredients in SIMBRINZA® Suspension. SIMBRINZA® Suspension is contraindicated in neonates and infants (under the age of 2 years).

Sulfonamide Reactions

Patients receiving SIMBRINZA® Suspension should be advised of the potential for sulfonamide reactions. SIMBRINZA® Suspension contains sulfates, sulfites, benzoic acid, and other sulfonamides. Sulfonamide hypersensitivity reactions may occur with topical administration of sulfonamide, and although administered topically is absorbed systemically. Therefore, the same types of reactions may be anticipated that occur with oral administration of sulfonamide.

Clinical Studies Experience

- In two clinical trials of 3 months duration, 435 patients were treated with SIMBRINZA® Suspension as single therapy and 103 patients were treated concomitantly with other topical ophthalmic medications. Five patients receiving SIMBRINZA® Suspension as single therapy reported reactions that may have been due to SIMBRINZA® Suspension. Three of these reactions were reported as serious and reversible, two were mild and resolved.

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Overdosage

- No overall differences in safety or effectiveness have been observed between elderly and younger individuals over 12 years of age.

- In a study of brinzolamide in lactating rats, decreases in body weight gain in offspring and a decrease in plasma drug concentration were observed in nursing female rats. However, no adverse effects of brinzolamide on the nursing male rats were observed.

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Special Report

Sulfonamide Reactions

- Advise patients that if the solution becomes cloudy, they should discontinue its use and consult their physician.

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Surgery

- No overall differences in safety or effectiveness have been observed between elderly and younger individuals over 12 years of age.

Ocular Pressure Lowering Treatments

- No overall differences in safety or effectiveness have been observed between elderly and younger individuals over 12 years of age.

Endophthalmitis Prophylaxis

- No overall differences in safety or effectiveness have been observed between elderly and younger individuals over 12 years of age.

Keratitis Phototoxicity

- No overall differences in safety or effectiveness have been observed between elderly and younger individuals over 12 years of age.

Clinical Diagnosis

- No overall differences in safety or effectiveness have been observed between elderly and younger individuals over 12 years of age.

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In This Issue

- 6 EDITORIAL
- 9 FOCAL POINTS
- 18 MARKETPLACE
- 46 AFTER-HOURS
THE RECENT EXPERIENCES of Peter J. McDonnell, MD, of having to endure “pop science” lessons from community leaders, though lamentable, are neither rare nor recent phenomena. (“Unpopular science,” Ophthalmology Times, July 1, 2016; http://bit.ly/2awi8Bq)

C.P. Snow was a physicist/mathematician who delivered a lecture at Cambridge in 1959 which led to a publication entitled “The Two Cultures and the Scientific Revolution.” He highlights the same deficiencies. Snow’s rapier wit lays bare the smug emptiness of pseudointellectual erudition of his day with passages such as this:

A good many times I have been present at gatherings of people who, by the standards of the traditional culture, are thought highly educated and who have with considerable gusto been expressing their incredulity at the illiteracy of scientists. Once or twice I have been provoked and have asked the company how many of them could describe the Second Law of Thermodynamics. The response was cold: it was also negative. Yet I was asking something which is the scientific equivalent of: Have you read a work of Shakespeare’s?[5]

I now believe that if I had asked an even simpler question—such as, What do you mean by mass, or acceleration, which is the scientific equivalent of saying, Can you read?—not more than one in ten of the highly educated would have felt that I was speaking the same language. So the great edifice of modern physics goes up, and the majority of the cleverest people in the western world have about as much insight into it as their neolithic ancestors would have had.[5]

Unfortunately, we are likely to see more divergence between the two cultures which can roughly be defined, on one hand, as the right-brained, hard science adherents and the left-brained, social scientist, and artist classes on the other. Colleges and universities no longer provide a classical education with curricula mandating a grasp of sciences, history, mathematics, literature, and languages.

Now a student can receive a diploma from even a prestigious school without ever having taken biology, physics, or chemistry. Furthermore, the notion that everyone needs and is entitled to a college education has taken hold of modern America. When masses of marginal, easily triggered snowflake students, who need safe spaces, show up to campus (or online), you can be sure that they are not going to test their collective mettle in biochemistry or quantum mechanics, because these fields have correct and incorrect conclusions. Along the way to finding the correct conclusions, there is much trial and error (read failures), and these fragile souls are not able to suffer such indignities.

No, these types of students gravitate to courses with no objective conclusions where they can display their “feelings” in essays and art to like-minded professors who liberally bestow grade-inflated As and cause entire graduating classes to garner Latin honors.

Even if we can keep this scourge of scientific illiteracy from infecting future medical school classes, we still have to deal with a population of patients who have been steeped in a medieval education has taken hold of modern America. On the bright side, perhaps counseling and informed consent will become less time consuming when we need only to discuss imbalances of blood, phlegm, black bile, and mucus. Thus concludes my attempt at evil humour.

—Paul Berner, MD
Fort Harrison, MT

REGARDING DR. MCDONNELL’S RECENT editorial, “Unpopular Science,” I thought about a member of the teaching faculty to which I belong who once wrote that people who apply to medical schools would be better prepared for a medical career if they came from a humanities background than a science background.

As a graduate of an engineering school, I understand what motivated the position, but I don’t agree with it. In school we used to say that if every detail of the bridge wasn’t calculated with utmost precision it would collapse.

But if you had an opinion in the world of philosophy, literature, history, or politics, you could endlessly debate it without any definite conclusions being made. We called this, somewhat derisively, “hand waving.”

That’s why we called these fields, “soft science,” whereas our domain was “hard science.” I’m guessing that the folks who deny climate change must invariably be humanities graduates and the folks at the Paris conference were hard scientists.

If someone is fixing my retinal detachment I want him/her to be thoroughly grounded in the physics, chemistry, and biology of what climate change must invariably be humanities graduates and the folks at the Paris conference were hard scientists.

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—Benjamin H. Bloom, MD
Philadelphia

Letters to the Editor may be submitted to mdlugoss@advanstar.com. Letters may be edited for clarity and length.

What’s Trending
See what the ophthalmic community is reading on OphthalmologyTimes.com

1 7 common mistakes in managing uveitic glaucoma

2 Treat presbyopia with eye drop?

3 What books are your fellow ophthalmologists reading?

Video
To watch step-by-step best practices in ABIC procedures, go to http://bit.ly/2alhaWR (Video courtesy of Mark Gallardo, MD)

Correction

The statement should read: “The source of the data is the DRCR.net, but the analyses, content, and conclusion presented herein are solely the responsibility of the authors and have not been reviewed or approved by DRCR.net.”

Ophthalmology Times regrets the error.
The iStent® Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L) is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

**CONTRAINDICATIONS.** The iStent® is contraindicated in eyes with primary or secondary angle closure glaucoma, including neovascular glaucoma, as well as in patients with retrolental tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. **WARNINGS.** Gonioscopy should be performed prior to surgery to exclude PAS, rubeosis, and other angle abnormalities or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. The iStent® is MR-Conditional meaning that the device is safe for use in a specified MR environment under specified conditions, please see label for details. **PRECAUTIONS.** The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the iStent® has not been established as an alternative to the primary treatment of glaucoma with medications in children, in eyes with significant prior trauma, chronic inflammation, or an abnormal anterior segment, in pseudophakic patients with glaucoma, in patients with pseudoxvivial glaucoma, pigmentary, and exudative glaucoma, in patients with unmedicated IOP less than 22 mmHg or greater than 36 mmHg after “washout” of medications, or in patients with prior glaucoma surgery of any type including argon laser trabeculoplasty, for implantation of more than a single stent, after complications during cataract surgery, and when implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract. **ADVERSE EVENTS.** The most common post-operative adverse events reported in the randomized pivotal trial included early post-operative corneal edema (8%), BCVA loss of ≥1 line at or after the 3 month visit (7%), posterior capsular opacification (6%), stent obstruction (4%), early post-operative anterior chamber cells (3%), and early post-operative corneal abrasion (3%). Please refer to Directions for Use for additional adverse event information. **CAUTION:** Federal law restricts this device to sale by, or on the order of, a physician. Please reference the Directions for Use labeling for a complete list of contraindications, warnings, precautions, and adverse events.
Ophthalmology and poison

Ophthalmic substances have long history as murder instruments

By Peter J. McDonnell, MD

director of the Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, and chief medical editor of Ophthalmology Times.

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IN ANCIENT ROME, death by poison was common. Emperors poisoned potential rivals. Aspirants to the throne poisoned emperors. Mothers poisoned the other potential male heirs of the emperor so that their own sons would be next in line to “wear the purple.” Poisoning people you didn’t like was the thing to do.

My view is that murdering people with poison is a terrible thing, even if the victim is an annoying parent, mother-in-law, or department chairman. I consider it inexcusable for ophthalmologists to be party to such a thing. It’s morally wrong, plus the penalty would likely be severe (suspended operating privileges or tenure).

Yet, ophthalmologists certainly have the means to go around poisoning folks. Agatha Christie wrote a murder mystery in which eye drops are the instrument of death. According to The New Yorker, one of her readers probably copied the crime in real life:

“Indeed, Christie’s attention to detail left her open to the accusation that she offered a handbook for would-be murderers. [Kathryn] Harkup recounts a 1977 case in France, in which Roland Roussel, a fifty-eight-year-old office worker, murdered his aunt using atropine eye drops. The gardener who found a copy of the Miss Marple mystery “The Tuesday Club Murders” in Roussel’s apartment reportedly declared, “I’m not saying Roussel was inspired by the book, but we found it in his apartment with the relevant passages on poison underlined.’’

The use of alkaloids in modern and Roman times is described in The Poisons of Agatha Christie:

All ophthalmologists know that a nonselective beta blocker, such as timolol, can cause death in an individual with asthma or cardiac conduction abnormalities. Squirted under the tongue, large amounts of this eye drop could be systemically absorbed with fatal consequences.

I also mention the Tom Clancy novel, The Teeth of the Tiger. Colamine and atropine (both anti-cholinergic anti-muscarinic in action) and hyoscyamine (an isomer of atropine). Both the Empelancy describes the assassination of bad guys by members of a super-secret nongovernmental agency that exactly revenge.

The instrument of death is the injection of succinylcholine, causing prompt paralysis, and the victim is believed to have died of a heart attack. Making this relevant is the wrinkle that an ophthalmologist friend and loyal Ophthalmology Times reader suggested the succinylcholine angle to Clancy. Does my friend need to take a remedial ophthalmic ethics course?

I point these scenarios out to you, my fellow ophthalmologists, only so that you won’t imitate those Romans or the English people in Agatha Christie novels and make the mistake of poisoning anyone. Not even your mother-in-law. Despite how mean she may be, it would be wrong to poison her with agents readily available to ophthalmologists. Very, very wrong.

References
• http://www.newyorker.com/books/page-turner/agatha-christie-and-the-golden-age-of-poisons
• http://hubpages.com/education/The-Poisons-of-Agatha-Chrste

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The Poisons of Agatha Christie

Belladonna (also known as Deadly Nightshade, Devil’s Berries, or Death Berries) features in The Caribbean Mystery and The Big Four. Foliage and berries are toxic, containing a mixture of alkaloids including hyoscine (scopor Augustus and Agrippina used bella- donna to poison contemporaries. Symptoms include dilated pupils, blurred vision, tachycardia, dry mouth, slurred speech, urinary retention, confusion, and hallucinations.”

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Ophthalmology Times’ vision is to be the leading content resource for ophthalmologists.

Through its multifaceted content channels, Ophthalmology Times will assist physicians with the tools and knowledge necessary to provide advanced quality patient care in the global world of medicine.
ARVO ushers new president, releases special OCT issue

Clinicians, researchers also gearing up for biannual ARVO-Asia, annual meeting in 2017

ARVO View By Katrina Norfleet

M embers of the Association for Research in Vision and Ophthalmology (ARVO) welcomed Emily Y. Chew, MD, FARVO, of the National Eye Institute/National Institutes of Health (NEI/NIH) as the organization’s new president following its 2016 annual meeting.

Dr. Chew serves as deputy director of the Division of Epidemiology and Clinical Applications, deputy clinical director, and the chief of the clinical trials branch at NEI/NIH.

An ARVO member in the Clinical/Epidemiological Research (CL) Section since 1983, Dr. Chew has served as the CL Section of the NEI/NIH. He has served as chairman of the CL Section of the Annual Meeting Program Committee, chairman of the Awards Committee and an editorial board member of ARVO’s Investigative Ophthalmology & Vision Science (IOVS).

IOVS RELEASES

SPECIAL ISSUE ON OCT
Did you know it has been 25 years since vision researchers developed optical coherence tomography (OCT)?

To commemorate this milestone, ARVO has released a special issue of IOVS—publishing more than 70 papers from authors on five continents in the online-only, open-access, peer-review journal. The special issue, released in July, covers a range of topics of interest to clinicians, such as OCT technology and methods, cornea/anterior, retina, age-related macular degeneration (AMD), diabetic retinopathy, and glaucoma.

“OCT has transformed the practice of retina and glaucoma clinicians,” says OCT co-inventor and guest editor David Huang, MD, PhD, of Oregon Health and Science University. “This is also a time when two new exciting trends in OCT have taken off: OCT angiography and intraoperative OCT.”

Anchoring the issue are seven invited review articles from pioneering research groups in their respective fields, including:

- “Clinical Utility of OCT in Glaucoma,” by researchers in the lab of Joel Schuman, MD, of New York University
- “Optical Coherence Tomography and the Development of Anti-Angiogenic Therapies in Neovascular Age-related Macular Degeneration,” by Philip J Rosenfeld, MD, PhD, at the University of Miami
- “Optical Coherence Tomography Angiography,” by researchers in the lab of David Huang, MD, PhD, OHSU
- “Optical coherence tomography for retinal surgery: perioperative analysis to real-time four-dimensional image-guided surgery,” by researchers in the labs of Joseph Izatt, PhD, and Cynthia Toth, MD, at Duke University

To read the IOVS special issue on OCT, visit http://bit.ly/29Gmgd2

NEI/FDA WORKSHOP
NEI and FDA will hold a 1-day public workshop on Nov. 9, 2016, to review clinical trial design considerations for AMD and inherited retinal diseases. This is an opportunity to partner with peers in developing strategies for clinically meaningful surrogate or interim endpoints.

The meeting is being managed by ARVO, and it will take place at the NIH Campus in Bethesda, MD. To register, visit www.arvo.org/Endpoints2016

ARVO-ASIA 2017
More than 1,000 clinicians and researchers will gather for the biannual ARVO-Asia meeting, Feb. 5 to 8, 2017, under the theme, “Bridging disciplines and disparities: Connecting eye research with health outcomes.”

Participants will discuss how collaborations across disciplines, among countries, and between the laboratory and the clinic can ensure discoveries translate into effective prevention, diagnosis, and treatments for patients with eye disease across the globe.

The four-day meeting will include plenary lectures, symposia, workshops, papers, and posters, as well as highlight the role of public health issues and infectious diseases in eye related conditions.

The program also will feature keynote speakers Malvina B. Eydelman, MD, and Hugh R. Taylor, AC, MD, FRANZCO.

Dr. Eydelman, a board-certified ophthalmologist, is director of the FDA Division of Ophthalmic and Ear, Nose, and Throat Devices. Dr. Eydelman has been actively involved in the standardization of ophthalmic devices for more than 20 years and spearheaded numerous initiatives designed to improve their safety and effectiveness.

Dr. Taylor, a Melbourne Laureate, is the Harold Mitchell Chair of Indigenous Eye Health at the University of Melbourne and president of the International Council of Ophthalmology. His work focuses on the provision of eye care, improving access to services, and the elimination of trachoma in indigenous communities.

Note these important deadlines:
- Abstract submission – Sept. 20
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KATRINA NORFLEET is director of communications with the Association for Research in Vision and Ophthalmology. Readers may contact her at 240/221-2924 or knorfleet@arvo.org.
Intracameral antibiotics: Best endophthalmitis prophylaxis?

By Cheryl Guttman Krader; Reviewed by Harry W. Flynn Jr., MD, and Nidhi Relhan, MD

Postoperative endophthalmitis remains a potentially devastating complication of cataract surgery. However, good visual outcomes are possible if the infection is recognized early and treated appropriately, according to Harry W. Flynn Jr., MD.

He provided an overview of the classification, manifestations, etiology, prophylaxis, and management of post-cataract surgery endophthalmitis.

Endophthalmitis after cataract surgery is divided into acute- and delayed-onset cases, based on whether the event occurs within 6 weeks of the procedure or later, said Dr. Flynn, professor of ophthalmology and The J. Donald M. Gass Distinguished Chair in Ophthalmology, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine.

Acute-onset endophthalmitis presents with ocular redness, pain, hypopyon, and fibrin in the anterior chamber, and is most often due to Gram-positive bacteria, with coagulase negative Staphylococci being the most common pathogen.

Patient- and surgery-related features that increase the risk of acute-onset endophthalmitis include significant blepharitis or lid abnormalities, relative immune compromise (e.g., diabetes, older age), incision leak, intraoperative vitreous loss, application of lidocaine gel prior to povidone-iodine preparation of the ocular surface, and contaminated solutions introduced into the anterior chamber.

Delayed-onset endophthalmitis usually follows an indolent course in which inflammation gradually progresses, leading to vitritis and infiltrates in the vitreous cavity. Hypopyon is less common with delayed-onset endophthalmitis compared with acute-onset endophthalmitis, but infection in the capsular bag manifested by the appearance of white plaques is seen more often with delayed-onset endophthalmitis.

Continues on page 13: Endophthalmitis
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The safety of lifitegrast was evaluated in 5 clinical studies. 1401 patients received at least one dose of lifitegrast (1287 of which received Xiidra). The most common adverse reactions (5-25%) were instillation site irritation, dysgeusia, and reduced visual acuity.
**Indication**
Xiidra™ (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

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In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

For additional safety information, see accompanying Brief Summary of Safety Information on the following page and Full Prescribing Information on Xiidra-ECP.com.
BRIEF SUMMARY: Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE
Xiidra™ (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

DOSEAGE AND ADMINISTRATION
Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single use container. Discard the single use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25 % of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

USE IN SPECIFIC POPULATIONS
Pregnancy
There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear.

Animal Data
Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg/kg/day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg/kg/day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

Lactation
There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

Pediatric Use
Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Geriatric Use
No overall differences in safety or effectiveness have been observed between elderly and younger adult patients.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast. Mutagenesis: Lifitegrast was not mutagenic in the in vitro Ames assay. Lifitegrast was not clastogenic in the in vivo mouse micronucleus assay. In an in vitro chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation. Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD] of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.

For more information, go to www.Xiidra.com or call 1-800-828-2088.

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US Patents: 8367701; 9353088; 7314938; 7745460; 7790743; 7928122; 9216174; 8168655; 8080407; 8592450; 9085553 and pending patent applications.
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ENDOPHTHALMITIS

Intracameral antibiotic injection is another approach used available in the United States, and the need for compounding the solution for injection introduces risks of dilution errors, contamination, and toxic anterior segment syndrome.5-8 Vancomycin is also being used intracamerally for endophthalmitis prophylaxis. This practice is concerning after recent reports associating it with the development of hemorrhagic occlusive retinal vasculitis9 and considering the potential to promote bacterial resistance to vancomycin.10

With regard to the latter issue, Dr. Flynn cited the Centers for Disease Control Hospital Infection Control Practices Advisory Committee Recommendations for Preventing the Spread of Vancomycin Resistance.11 Its list of situations in which vancomycin use should be discouraged include both routine surgical prophylaxis and topical application or irrigation. We are living in an era of antibiotic stewardship12 where more and more, we are being scrutinized by the government and other health-care agencies as to antibiotics we utilize during our surgery, Dr. Flynn said. We must keep in mind the risks, benefits, costs, and antibiotic stewardship in deciding whether or not to utilize intracameral antibiotics.13

Dropless cataract surgery in which triamcinolone plus moxifloxacin with or without vancomycin is injected into the anterior vitreous via a transzonular approach using a long, 27- or 30-gauge cannula represents a novel approach during cataract surgery.14

Discussing the potential downsides of this method, Dr. Flynn listed concerns about bacterial resistance, compounding errors, steroid-induced glaucoma, lens subluxation and dislocation, and patient complaints of blurred vision for one or more weeks following surgery.

References

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This article was adapted from Dr. Flynn’s presentation at the 2015 meeting of the American Academy of Ophthalmology. Dr. Flynn and Dr. Reihan have no relevant financial interests to disclose.
Photoactivation has promise for keratitis treatment

Subjecting bacteria to blue light with antibiotic agents may be common treatment in future

By Laird Harrison

he same photoactivation process used in collagen cross-linking for keratoconus can kill bacteria without the need for the oxygen responsible for the biomechanical effects, potentially pointing toward better treatments for keratitis, according to Olivier Richoz, MD, PhD, a corneal and anterior segment fellow at Belfast Royal Victory Hospital, Belfast, United Kingdom.

When using collagen cross-linking to treat keratoconus, clinicians anesthetize the patients’ cornea, apply 0.1% riboflavin, and expose the cornea to 365 nm ultraviolet light. Free radicals created by this irradiation create new covalent bonds, which strengthen the cornea.

The treatment also kills pathogens and has been used in infectious keratitis since 2008, Dr. Richoz said.

Some pathogens causing the disease, such as Fusarium solani, can be resistant to common anti-fungal medications.

About 60,000 people in the United States and 2 million people in India get keratitis every year, he said.

Having shown in previous research that the biomechanical effects of collagen cross-linking depend on oxygen, Dr. Richoz wanted to know whether the same was true of the anti-bacterial effects of the treatment.

The question proved difficult to answer because photoactivation has a strong effect on only the first 100 to 150 µm of the cornea. That means if you want to analyze the killing rate of bacteria, you need to create an experimental setting that uses extremely small slides of cornea, Dr. Richoz said.

After a year of experimenting, he created conditions in which the hypothesis could be tested. After incubating the Staphylococcus aureus and Pseudomonas aeruginosa with riboflavin for 30 minutes, he put the bacteria on discs of cornea 150 µm in thickness and 10 mm in diameter.

He treated some of the cornea discs for 5 minutes at 18 mW/cm² of ultraviolet light in the presence of oxygen, and others in an oxygen-free environment. He did not treat some of the cornea discs at all. Then he put the cornea discs in a 0.9% solution of sodium chloride for 60 minutes.

Next, he plated the solution on Mueller-Hinton agar, incubated it for 24 hours, and counted the number of colony-forming units.

Compared with the control discs, the irradiated discs had only 1% of the S. aureus and 2% of the P. aeruginosa when the irradiation took place in the presence of oxygen. In the oxygen-free environment, 5% of the S. aureus and 50% of the P. aeruginosa survived.

From this, Dr. Richoz concluded that free radicals are only partially responsible for the death of bacteria when riboflavin is photoactivated. He theorizes that the interaction of riboflavin with DNA in the bacteria may be a more important effect.

We know that the riboflavin can react with the DNA, he said. But we don’t know if the killing rate is only due to the effect of the riboflavin on the DNA, or maybe the riboflavin can interact with something else in the bacteria. If the process can work with riboflavin, perhaps it will work with other molecules such as antibiotics. The idea is to choose a molecule in the future that is specific to the bacteria and to photoactivate that molecule, he said.

This would avoid the risk of damage to the patients’ healthy tissue. He has already used software to predict the reactivity of molecules in various antibiotics.

Damage to healthy cornea from photoactivated riboflavin is not a significant risk because stromal cells regenerate within a year of treatment, Dr. Richoz said.

But making the photoactivation more selective to pathogens could be important in other types of infections or in cancer, he said. Dr. Richoz has conducted small experiments in animals with skin infections caused by antibiotic-resistant bacteria. In these experiments, he used blue light rather than ultraviolet light since blue light is non-ionizing and does not damage healthy skin cells.

The experiments were successful. If we inject the antibiotics to which the bacteria is resistant, and we subject the bacteria to a specific pattern of blue light, the bacteria becomes sensitive again, Dr. Richoz said. It was very exciting.

Dr. Richoz has a patent on this technology and also on the use of slit lamps which could be used to inexpensively to generate the necessary radiation, an approach that could be particularly useful in developing countries where more sophisticated equipment is not available, he said.

For now, he is focusing on the use of scleral cross-linking, which he believes could be used to treat progressive myopia.

The idea is to use a similar technology as corneal cross-linking, but in this case to cross-link the sclera in the back of the eye, he said. It’s extremely difficult. You need a miniaturized device to access the posterior part of the eye.

Photoactivation has promise for keratitis treatment.
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ABiC targets all sites of outflow resistance
Reductions in IOP, daily medication among benefits of minimally invasive technique

By Cheryl Guttman Krader; Reviewed by Mark Gallardo, MD

Growing experience with ab-interno canaloplasty (ABiC) shows the minimally invasive glaucoma surgery (MIGS) is very safe and provides significant and sustained reduction of IOP and medication use, according to Mark Gallardo, MD.

Performed through a 1.8-mm, temporal clear-corneal incision and using an illuminated microcatheter (iTrack 250A, Ellex) that provides continual transscleral visualization, ABiC lowers IOP by restoring the natural pathway of aqueous outflow. Based on its outcomes and benefits, Dr. Gallardo now considers ABiC as a first-line option for patients with mild-to-moderate glaucoma whose IOP is uncontrolled on maximum tolerated medical therapy. Because of its potential to reduce or eliminate medication burden, he also sees ABiC as a useful adjunct when performing cataract surgery in patients with mild-to-moderate glaucoma controlled on medications.

Dr. Gallardo is in private practice, El Paso Eye Surgeons, El Paso, TX, and an adjunct clinical faculty member in the department of ophthalmology at University of Texas Health Science Center, San Antonio, and Texas Tech Health Sciences Center, Lubbock.

With passage of the microcatheter through the ostomy in the trabecular meshwork, ABiC uniquely accesses, catheterizes, and viscodilates all sites controlling aqueous outflow. It has been associated with an average IOP reduction of about 35%, and with follow-up available to 18 months in some patients, its benefit is largely maintained, he noted.

“What I love most about ABiC, however, is that it is truly an atraumatic procedure,” Dr. Gallardo said.

“With the exception of the small ostomy created in the trabecular meshwork, there is no disruption of tissue throughout the aqueous drainage system,” he said. “Therefore, ABiC has an excellent safety profile—no sight-threatening complications have been associated with its use, and other surgical options remain available if ABiC is not successful or fails over time.”

The idea for ABiC stems from evidence that good IOP lowering was still achieved in eyes that underwent traditional canaloplasty without placement of the tensioning suture.

“I have a number of patients who had traditional canaloplasty in one eye and then ABiC in the other whose IOP and need for medication is similar in their fellow eyes,” he said. ABiC can achieve the same outcome as traditional canaloplasty, but is a much simpler and faster surgery because it eliminates the major incisional steps of the ab externo approach and placement of a tensioning suture, he noted.

OUTCOMES
Dr. Gallardo has analyzed results for his patients who have up to 12 months of follow-up. Mean IOP in this cohort was reduced from 18.6 ± 6.4 mm Hg preoperatively (n = 122) to 14.1 ± 3.7 mm Hg at 6 months (n = 65) and to 12.9 ±2.0 mm Hg at 12 months (n = 28). Mean number of medications used daily was reduced by half from 2.0 to 1.0.

About 50% of the patients in his series underwent ABiC alone. In that subgroup, mean IOP
The same premise applies to glaucoma surgery, he noted.

"Trying to rejuvenate the natural drainage system in appropriately selected patients is a minimally invasive procedure that can be very successful but leaves the opportunity to perform a procedure that bypasses the natural drainage system if it is unsuccessful," Dr. Gallardo said.

Mark Gallardo, MD
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Dr. Gallardo is a paid consultant, speaker, and principal investigator of ABC for Ilux.
CO₂ laser-assisted procedure showing long-term efficacy, safety
Simplified filtration procedure has short learning curve; reduced need for medical devices

By Cheryl Gutman Krader; Reviewed by Noa Geffen, MD, and Michael Mimoun, MD

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which is the more challenging step in the standard non-penetrating deep sclerectomy procedures. "The CO\textsubscript{2} laser was chosen for this procedure because its wavelength effectively ablates dry tissue, but is highly absorbed by water," Dr. Mimouni said. "The laser is used to ablate the deeper scleral layer until percolation is achieved, without perforation."

**STUDY RESULTS**


Patients were eligible for study participation if they had primary open-angle glaucoma or primary exfoliation glaucoma with an IOP >18 mm Hg despite maximum tolerated medical therapy, Shaffer angle >grade 2, no ocular disorders other than cataract, and no surgical intervention in the study eye other than clear corneal cataract surgery. About three-fourths of the study participants had primary open-angle glaucoma.

Mitomycin-C was used in 89% of procedures. During the first year after the laser treatment, there were 12 needling procedures and 18 gonipunctures.

Efficacy results analyzed data from 100 eyes, of which 81 were seen at 1 year, 41 at 3 years, and 21 at 5 years. Mean IOP was 25.8 ± 5.4 mm Hg at baseline, 7.7 ± 9.5 mm Hg on the first day after surgery and averaged 13.5 ± 4.1, 14.2 ± 2.9, and 14.3 ± 2.6 mm Hg at 1, 3, and 5 years, respectively.

Prior to CLASS, patients were on an average of 2.4 ± 1.2 medications daily, and the average number was reduced significantly to 0.5 ± 0.8, 0.7 ± 0.9, and 0.8 ± 0.8 at 1, 3, and 5 years, respectively.

Complete success, defined as IOP between 5 and 18 mm Hg with a ≥20% reduction from baseline on no medications, was achieved in 59.1% of eyes seen at 1 year, 43.5% at 3 years, and in 40.9% of eyes followed to 5 years.

Qualified success, which was defined using the same IOP criteria but with or without medication, was achieved at rates of 78.5%, 84.8%, and 86.4% at 1, 3, and 5 years, respectively.

Complications were mostly mild without any significant sequelae. The most common procedure-related complications were early wound leak (8.3%), shallow anterior chamber (5.6%), and hypophema (4.6%).

"Although some of the patients experienced complications during follow-up, most were transient and mild," Dr. Mimouni said. "In addition, they compared favorably with trabeculectomy if we consider the trabeculectomy arm of the Tube versus Trabeculectomy Study in which 87% of eyes developed at least one complication by 5 years."

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**take-home**

- CO\textsubscript{2} laser-assisted sclerectomy performed with a proprietary laser system is a simplified filtration procedure that is showing good IOP-lowering efficacy and safety in eyes followed to 5 years.

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**NNOA GEEFEN, MD**

**MICHAEL MIMOUNI, MD**

This article was adapted from a poster presentation by Dr. Mimouni and colleagues at the 12th European Glaucoma Society Congress. The study was supported in part by IOPtima. Dr. Geffen and Dr. Mimouni have no financial conflict of interest to report.
end result of the same situation in reverse. Pressure inside the eye is higher than intracranial pressure, which results in the posterior cupping that is seen in glaucoma. Axonal transport is impeded at the lamina cribrosa and the optic nerve, its metabolic needs unmet, eventually withers and vision is lost.

“This represents a potential redefinition of glaucoma,” he said. “This concept opens up entirely new therapeutic modalities and options for patients and physicians. And it explains physiology and pathophysiology that don’t fit the traditional one-pressure model.”

Elevated IOP might explain primary open-angle glaucoma, he continued. But elevated IOP cannot account for normotension glaucoma. Nor can clinicians explain why elevated IOP may not lead to glaucoma in ocular hypertensives. The two-pressure model does.

In individuals without glaucoma, the pressure differential between IOP and intracranial pressure is about 4 mm Hg. In individuals with glaucoma, the pressure gradient across the lamina cribrosa is greater, in the range of 13 mm Hg and higher.

“What causes cupping visual field loss in glaucoma? The cupping is caused by posteriorly directed forces generated when IOP is greater than ICP,” Dr. Berdahl continued.

He sees the same mechanism at work in normotension glaucoma. These individuals have normal IOP but a low ICP. The pressure gradient across the lamina cribrosa is high enough to impede axonal transport and eventually cause damage to the ocular nerve and increasing loss of vision.

OCULAR HYPERTENSION
The two-pressure model also explains ocular hypertension without glaucoma. These individuals have elevated IOP with a similarly elevated ICP that protects the optic nerve. Even though the absolute pressure on both sides of the lamina cribrosa is high, the normal pressure gradient allows for normal axonal transport.

Testing the two-pressure model at the clinical level is difficult. Ophthalmologists and other vision specialists routinely measure IOP at the cornea. But the only currently available method to measure ICP is an invasive lumbar puncture.

Multiple research groups are working with animal models to develop noninvasive or less invasive methods to measure ICP. Dr. Berdahl founded Equinox LLC to develop special goggles (Balance Goggles). The goggles use physics to counteract the increased ICP of weightlessness by increasing the external pressure on the eye, which raises IOP to restore the normal pressure gradient at the lamina cribrosa.

“The goggles have a good shot at controlling eye pressure very precisely to counteract ICP,” Dr. Berdahl said.

“The same concept can be applied to glaucoma by reducing the atmospheric pressure on the eye which reduces IOP and reduces the pressure gradient at the optic nerve,” he said. “Redefining glaucoma as a two-pressure pathology opens a lot of physical and pharmacologic pathways to diagnose, treat, and even prevent glaucoma.”

Dr. Berdahl is taking a different approach. About one-half of visitors to the International Space Station suffer from vision impairment and intracranial pressure (VIIP). In a normal environment, gravity pulls fluid into the lumbar column and slightly reduces ICP, he explained.

WEIGHTLESS ENVIRONMENT
In a weightless or microgravity environment, such as the space station, CSF redistributes evenly throughout the cerebrospinal space, increasing ICP. In some astronauts, this increased ICP causes flattening of the eye, hyperopic shift, choroidal folds, optic disk edema, and impaired vision.

OCT LEARN HOW the concept for the goggles was inspired by John P. Berdahl, MD, while on a scuba diving trip.
Go to http://bit.ly/2aGZaFJ

Dr. Berdahl founded Equinox LLC to develop special goggles (Balance Goggles). The goggles use physics to counteract the increased ICP of weightlessness by increasing the external pressure on the eye, which raises IOP to restore the normal pressure gradient at the lamina cribrosa.

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JOHN P. BERDAHL, MD
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This article was adapted from Dr. Berdahl’s presentation at the 2016 meeting of the American Society of Cataract and Refractive Surgery. Dr. Berdahl has financial interests with Equinox.
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The American Academy of Ophthalmology is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.
Dual blade helps surgeons lower IOP
Instrument performs goniometry through trabecular meshwork for increased aqueous outflow

By Vanessa Caceres; Reviewed by Leonard K. Seibold, MD

AURORA, CO ::
A NEW TRABECULAR meshwork excision blade is yet another option for glaucoma surgeons in their quest to lower their patients’ IOP.

The dual blade (Kahook Dual Blade, New World Medical) is engineered for angle anatomy and incises the trabecular meshwork through paired incisions to allow for tissue removal, said Leonard K. Seibold, MD, assistant professor and co-director, Glaucoma Fellowship, University of Colorado School of Medicine, Aurora, CO.

Use of the blade can be paired with cataract surgery or as a stand-alone procedure. The blade is one of several new minimally invasive surgery options within glaucoma.

“The dual blade performs a goniometry through the trabecular meshwork to allow increased aqueous outflow, thereby lowering IOP,” Dr. Seibold said.

UNIQUE DESIGN FEATURES
Four unique design features of the blade, according to Dr. Seibold, include its sharp tip, which can pierce through the trabecular meshwork; a ramp that elevates and stretches the trabecular meshwork; a dual blade that helps to incise and results in a free strip of meshwork; and a footplate that fits atraumatically in Schlemm’s canal.

The single-use, disposable blade is used via an ab interno approach through a clear-corneal incision. It is placed in the anterior chamber and the tip of the blade is pierced across the trabecular meshwork, then the dual blades create two incisions as the blade is advanced, Dr. Seibold said.

A free strip of trabecular meshwork is created and removed. Surgeons can treat about 90° to 150° of the angle.

USE WITH CATARACT SURGERY
If use of the dual blade is combined with cataract surgery, the postoperative regimen is similar to that of standard cataract surgery. Patients use a nonsteroidal inflammatory drug and a topical steroid tapered over 3 to 4 weeks. Pilocarpine is added to keep the cleft open for 4 weeks; patients restart their glaucoma drops as needed.

Clinical data from eight surgeons and 122 patients who mostly had moderate or severe open-angle glaucoma revealed that in 93% of cases, trabecular meshwork was removed from the anterior chamber, Dr. Seibold said.

The average extent of removal was 114°; in 98% of cases, surgeons said that use of the blade was easy and straightforward.

An analysis of postoperative outcomes at 3 months found a 33% reduction in IOP, from 17.5 mm Hg preoperatively to 11.8 mm Hg postoperatively. Sixty-nine percent of patients were able to stop using at least one of their glaucoma medications after surgery.

The strip of free tissue that is removed with the blade offers potential for future analysis, which researchers at the University of Colorado are currently considering.

“We’ve never been able to take live trabecular meshwork samples of this size in glaucoma patients and study them,” Dr. Seibold said. “We can look for ultrastructural changes that may give us insight into its

‘We’re just on the cusp of diving in to see where this opportunity will lead us.’
— Leonard K. Seibold, MD
pathogenesis. There is also the potential for genetic analysis. We’re just on the cusp of diving in to see where this opportunity will lead us.”

Looking at adverse events, about 40% of patients experienced hyphema intraoperatively, but that percentage dwindled to 9% at postoperative day 1.

That percentage is more favorable compared with other trabecular meshwork-focused procedures, Dr. Seibold said.

One patient needed additional surgery for uncontrolled IOP.

Although other IOP-lowering procedures are also effective, Dr. Seibold said that use of the blade is the only one that can bypass the trabecular meshwork without an implant, has no moving parts or additional equipment to acquire, and leaves no large remnants of trabecular meshwork behind.

Still, head-to-head trials and longer-term outcomes are needed, he added.

In 98% of cases, surgeons said use of the blade was easy and straightforward.
SAVANNAH, GA ::

**CYCLOPHOTOCOAGULATION** (CPC) had once been considered as a last-resort treatment for patients with glaucoma. However, with new treatment paradigms, this is no longer the case.

A form of cycloablative, CPC is used to treat glaucoma through the destruction of ciliary body epithelium and stroma, resulting in aqueous secretion reduction and lower IOP.

Newer treatments with contact transscleral (TSCPC) methods using an 810-nm, continuous-wave diode laser have proven safer and more efficacious in the treatment of various forms of glaucoma than traditional cyclotherapy, which carries more risks.

Safer still is a more recent paradigm (Cyclo G6 Laser System using MicroPulse Transscleral Cyclophotocoagulation [mTSCPC]) with the MicroPulse P3 probe (Iridex).

The technology breaks up the traditional continuous-wave laser into short bursts that allow the tissue to cool within the intervals between bursts. This minimizes collateral damage and has excellent safety and efficacy rates with most cases experiencing no incidence of visually significant hypotony or other complications, and superior rates of IOP reduction.

Inflammation is always a risk which can be reduced with the use of a topical steroid. I prescribe prednisolone acetate ophthalmic suspension (Pred Forte Allergan), however, this only needs to be administered for 4 or 5 days instead of weeks or longer as with past treatments.

Many patients present with uncontrolled pressures after numerous treatment paradigms have failed, including rigorous medication regimens and multiple selective laser trabeculoplasty (SLT) treatments.

With the MicroPulse P3, I have seen excellent pressure lowering and minimal recovery for patients other than a few hours of patching post-procedure. Visual acuity is unchanged and the treatment is repeatable if necessary. The primary goal is to control patients’ pressure and reduce or eliminate medications. To that end, I titrate the treatment based on patients’ response.

### Case Studies

**CASE ONE:** A 78-year-old white female suffering with pseudoexfoliation glaucoma since 2005 presented as a referral for uncontrolled IOP in her right eye. She has no other concerning pathologies. She is pseudophakic, and upon presentation her visual acuity was 20/25 with a cup-to-disc ratio of 0.6. This patient was subject to an arduous medication regimen including:

- Brimonidine (2%) three times daily.
- Recently begun oral acetazolamide (Diamox) at 250 mg four times a day.

The patient had undergone prior SLT procedures in 2008, 2012, and 2014. Despite the medication regimen and previous procedures, her pressure upon presentation was 31 mm Hg. As the previous SLT procedures failed, I moved to the new modality, utilizing the laser system with the probe. The patient was given 4 ccs of 2% lidocaine retrobulbar with topical proparacaine prior to the procedure. Treatment parameters were 80 seconds superiorly and 80 seconds inferiorly at a power level of 2,000 mW.

The patient required a second treatment and parameters changed to 160 seconds inferiorly and 100 seconds superiorly with the power level remaining at 2,000 mW. Post-procedure, the patient was removed from oral acetazolamide, and began prednisolone acetate three times a day for 5 days. The patient’s pressure was significantly reduced after each procedure (Table 1).

While it was necessary to repeat the treatment, her pressure is currently stable at 2 mm Hg at 2 months post-initial procedure. At 2 months post-procedure, this patient is holding stable at a pressure of 10 mm Hg and has ceased brimonidine treatment.

**CASE TWO:** A 68-year-old white male presented with primary open-angle glaucoma (POAG) in the left eye. His medication regimen included:

- Brinzolamide (Azopt, Alcon Laboratories) three times a day;
- Brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5% (Combigan, Allergan) twice a day;
- Bimatoprost (Lumigan 0.01%, Allergan) once a day at bedtime;
- Dorzolamide/timolol combination twice a day;
- Bimatoprost ophthalmic solution (Lumigan 0.01%, Allergan) once a day at bedtime;
- Brinzolamide (Azopt, Alcon Laboratories) three times daily;

**Table 1: Case One Outcomes**

<table>
<thead>
<tr>
<th>PRESSURE</th>
<th>VISUAL ACUITY</th>
<th>INFLAMMATION PRESENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>At presentation</td>
<td>31 mm Hg</td>
<td>20/25</td>
</tr>
<tr>
<td>Week 1</td>
<td>17 mm Hg</td>
<td>20/25</td>
</tr>
<tr>
<td>Week 4</td>
<td>10 mm Hg</td>
<td>20/25</td>
</tr>
<tr>
<td>Week 8</td>
<td>Stable at 17 mm Hg</td>
<td>20/25</td>
</tr>
</tbody>
</table>

**Table 2: Case Two Outcomes**

<table>
<thead>
<tr>
<th>PRESSURE</th>
<th>VISUAL ACUITY</th>
<th>INFLAMMATION PRESENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>At presentation</td>
<td>31 mm Hg</td>
<td>20/25</td>
</tr>
<tr>
<td>Week 1</td>
<td>17 mm Hg</td>
<td>20/25</td>
</tr>
<tr>
<td>Week 4</td>
<td>Stable at 17 mm Hg</td>
<td>20/25</td>
</tr>
</tbody>
</table>

### Take-Home:

- Charles L. Harris, MD, reviews safety and efficacy rates in a glaucoma case series after adding a proprietary laser system with probe to the surgical armamentarium.

Continues on page 30: Case series
CASE SERIES

(Continued from page 29)

He is pseudophakic with a posterior chamber IOL and had undergone prior SLT procedures in 2006, 2008, and 2014. Upon presentation, his cup-to-disc ratio was 0.8 to 0.9. Visual acuity was 20/25. His pressure was 31 mm Hg. This briefly decreased to 23 mm Hg with oral acetazolamide, however, that was a temporizing measure.

As with the previous case, this patient was treated with the laser system and probe, with 4 ccs of 2% lidocaine retrobulbar and topical proparacaine pre-procedure. He was treated for 100 seconds superiorly and 160 seconds inferiorly at a power level of 2,000 mW. He was also placed on prednisolone acetate for 5 days. At week 1 post-procedure, his pressure had decreased to 17 mm Hg and has remained stable through 1-month follow-up (Table 2 on Page 29).

CASE THREE: This case has been especially challenging. A 77-year-old pseudophakic female presented with advanced pseudoxfoliation open-angle glaucoma. She had a cup-to-disc ratio of 0.9 and visual acuity of 20/30. Her pretreatment pressures were 15 mm Hg. She has had undergone SLT on several occasions. One of these procedures resulted in a corneal abrasion, obtained while checking for pressure spikes. This patient was treated with the laser system and probe at 80 seconds both superiorly and inferiorly. Due to her history, this patient has been followed very closely.

The procedure was repeated to obtain a more permanent drop in pressure. While some patients may opt for a trabeculectomy or shunt at this point, this patient preferred to continue the MicroPulse procedures as they have a much better safety profile.

At week 6, she experienced a rise in pressure and a MicroPulse laser trabeculectomy (MLT) procedure was performed. At 1-month post-procedure, her pressure again spiked and a second MP3 procedure was scheduled.

However, when the patient presented for the treatment, her pressure had stabilized and the treatment was no longer required. At more than 3 months post-initial procedure, her pressure is stable at 14 mm Hg (Table 3). She remains on her medications and her corneal surface disease is stable from the anterior basement dystrophy (map dot fingerprint disease).

Though this modality is new to my practice, the excellent results thus far confirm confidence in its safety and efficacy and make this treatment a welcome tool in the armamentarium.

Table 3: Case Three Outcomes

<table>
<thead>
<tr>
<th></th>
<th>PRESSURE</th>
<th>VISUAL ACUITY</th>
<th>INFLAMMATION</th>
<th>OTHER TREATMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Presentation</td>
<td>22 mm Hg</td>
<td>20/30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td>16 mm Hg</td>
<td>20/30</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>16 mm Hg</td>
<td>20/30</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Week 4</td>
<td>18 mm Hg</td>
<td>20/30</td>
<td>No</td>
<td>Optic nerve scan; noted</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>retinal fibroid layer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>improvement</td>
</tr>
<tr>
<td>Week 6</td>
<td>21 mm Hg</td>
<td>20/30</td>
<td>No</td>
<td>MLT performed</td>
</tr>
<tr>
<td>Post MLT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 days</td>
<td>14 mm Hg</td>
<td>20/30</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2 weeks later</td>
<td>17 mm Hg</td>
<td>20/30</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>22 mm Hg</td>
<td>20/30</td>
<td>No</td>
<td>MP3 scheduled</td>
</tr>
<tr>
<td>Week 14</td>
<td>14 mm Hg</td>
<td>20/30</td>
<td>No</td>
<td>MP3 not needed</td>
</tr>
</tbody>
</table>

(Tables courtesy of Charles L. Harris, MD)

References

Bimatoprost sustained-release device mitigates glaucoma adherence issue

Improved compliance with IOP-lowering ability among benefits of novel implant

By Lynda Charters; Reviewed by Thomas R. Walters, MD

AUSTIN, TX ::

THE BIMATOPROST SUSTAINED-release implant (bimatoprost SR, Allergan) offers a major advantage for patients, namely, improved adherence for those with problematic compliance with topical IOP-lowering glaucoma drugs. Almost three-quarters of study patients experienced IOP control over the first 6 months of the phase I/II safety and efficacy trial.

The implant is a biodegradable device especially developed to make sure the drug gets to its target location in order to best control glaucoma. The implant is placed intracamerally in the eye using a prefilled, single-use applicator system that releases bimatoprost over an extended period, explained Thomas R. Walters, MD.

PHASE I/II TRIAL

This is a prospective, 24-month, dose-ranging, controlled clinical trial in patients with open-angle glaucoma to evaluate the IOP-lowering effect and safety of bimatoprost sustained-release in patients with glaucoma. After a washout period, one eye (termed the study eye) of 75 patients was injected intracamerally with an implant containing one of four doses, i.e., 6, 10, 15, or 20 μg, of bimatoprost.

The fellow eye was treated with topical bimatoprost 0.03% once daily. Re-treatment was permitted with the implant containing the three lower drug doses (6, 10, or 15 μg) beginning at 16 weeks after the start of the study until month 12. Topical IOP rescue drugs also could be administered to either eye of the patients. The primary outcome measures were the changes in the IOP compared with baseline and the development of any adverse events.

All study patients were older than 18 years and had open-angle glaucoma in the eye that received the implant. All had an IOP ranging from 22 to 36 mm Hg after the washout period.

Patients were excluded if they had a history of narrow- or closed-angle glaucoma or had undergone a surgery to removed cataract in which a posterior capsular tear occurred. In addition, they also were excluded if the central endothelial cell count was less than 2,000 cells/mm².

The mean patient age was 63.1 years, and the patients were evenly divided by gender. The mean baseline IOP in the study eye was 25.2 mm Hg and that in the fellow eye was 24.5 mm Hg.

The IOP decreases in the study eyes achieved with topical bimatoprost 0.03% in 12 weeks and were comparable to those achieved with topical bimatoprost 0.03% in overall IOP reduction through week 16. In most patients, the implant successfully controlled the IOP for up to 6 months after implantation, and the second treatment in those patients who needed it showed similar efficacy.

The investigators believe that the interim results of the phase I/II trial support further clinical development of the glaucoma implant.

The implant is a biodegradable device especially developed to make sure the drug gets to its target location in order to best control glaucoma.

IOP CHANGES

“The IOP decreased significantly compared with baseline with all doses of the drug in the implant,” Dr. Walters said. Specifically, the mean overall IOP reductions from baseline through week 16 after the first implantation of the bimatoprost sustained-release device were 7.2, 7.4, 8.1, and 9.5 mm Hg with the 6-, 10-, 15-, and 20-μg doses compared with an 8.4 mm Hg decrease in the pooled fellow eyes treated with topical bimatoprost. The IOP decreases in the study eyes reached significance (p ≤ 0.001).

The investigators commented that 92% and 72% of the study eyes did not need rescue or re-treatment by week 16 and month 6, respectively. The most common adverse event was transient conjunctival hyperemia (median duration of 5 days), which developed within 2 days after the implant was injected.

In 24 eyes that did require another treatment to control IOP, the overall mean IOP reduction from the baseline IOP was 8 mm Hg through 16 weeks after the repeat bimatoprost sustained-release treatment. In those eyes, the IOP had to decrease by less than 20% compared with baseline after the first injection of the bimatoprost device at consecutive visits that were 1 or more weeks apart.

In addition, these eyes could not have received previous rescue therapy with a topical IOP-lowering medication and the safety level was adequate with the first implant, according to Dr. Walters.

The study investigators concluded based on their findings that the four doses of bimatoprost sustained-release were well tolerated and the decreases in IOP were comparable to those achieved with topical bimatoprost 0.03% in overall IOP reduction through week 16.

IOP changes significantly compared with baseline with all doses of the drug in the implant. The IOP decreases in the study eyes achieved with topical bimatoprost 0.03% in 12 weeks and were comparable to those achieved with topical bimatoprost 0.03% in overall IOP reduction through week 16. In most patients, the implant successfully controlled the IOP for up to 6 months after implantation, and the second treatment in those patients who needed it showed similar efficacy. Most of the adverse effects were transient and associated with the actual injection process. The investigators believe that the interim results of the phase I/II trial support further clinical development of the glaucoma implant.
Multiple next-generation stent use may lead to better IOP control

Patients with mild-to-moderate, open-angle glaucoma had IOP reduction of 20% or more

By Vanessa Caceres; Reviewed by Richard L. Lindstrom, MD

MINNEAPOLIS ::

IMPLANTATION OF TWO second-generation stents as a stand-alone procedure helped a group of patients with glaucoma reduce IOP to 15 mm Hg or less, said Richard L. Lindstrom, MD.

This IOP reduction occurred without the use of postoperative medications for 18 months. Patients had open-angle glaucoma (OAG) and a mean IOP of 19 mm Hg on one preoperative medication, said Dr. Lindstrom, MD, adjunct professor emeritus, University of Minnesota, Minneapolis.

ABOUT THE STUDY

Dr. Lindstrom was one of a large group of physicians from around the globe who took part in the study, based at a study center in Armenia. The prospective, single-arm, open-label study included 57 patients with mild-to-moderate OAG with a medicated IOP of 18 to 30 mm Hg and an unmedicated IOP of 22 to 38 mm Hg. Patients had best-corrected visual acuity (BCVA) of 20/100 or better.

Study investigators aimed to measure at month 12 the number of patients with an IOP that was reduced by 20% or more compared with their baseline IOP without medication. A secondary outcome was an IOP of 18 mm Hg or less without medication, Dr. Lindstrom said. Investigators also evaluated safety.

The device used in the study (iStent Inject Trabecular Micro-Bypass Stent System) is a second-generation device not yet approved by the FDA, although it has a CE Mark in Europe. The device uses natural physiologic outflow pathway to Schlemm’s canal via micro-bypass through trabecular meshwork.

<i>FIGURE 1</i> IOP reduced to ≤15 mm Hg on 0 medication; sustained through 18 months. “BL” indicates IOP after patients stopped using their medications.

<i>FIGURE 2</i> Two stents are preloaded in a single-use, sterile inserter. (Figures courtesy of Richard L. Lindstrom, MD)

Mean IOP Through Month 18

<table>
<thead>
<tr>
<th>Month</th>
<th>Mean ± SD IOP (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRE</td>
<td>[VALUE] ± 1.9</td>
</tr>
<tr>
<td>BL</td>
<td>[VALUE] ± 1.9</td>
</tr>
<tr>
<td>M1</td>
<td>[VALUE] ± 1.9</td>
</tr>
<tr>
<td>M3</td>
<td>[VALUE] ± 2.3</td>
</tr>
<tr>
<td>M6</td>
<td>[VALUE] ± 2.1</td>
</tr>
<tr>
<td>M12</td>
<td>[VALUE] ± 1.9</td>
</tr>
<tr>
<td>M18</td>
<td>20</td>
</tr>
</tbody>
</table>

41% decrease from preop unmedicated IOP

Second-generation, single-piece, titanium microbypass stent

Implanted ab internally through a temporal corneal incision

Uses natural physiologic outflow pathway to Schlemm’s canal via micro-bypass through trabecular meshwork

The use of multiple second-generation stent systems led to a 20% or higher reduction in IOP in a group of patients with mild-to-moderate, open-angle glaucoma.

take-home

The use of multiple second-generation stent systems led to a 20% or higher reduction in IOP in a group of patients with mild-to-moderate, open-angle glaucoma.

by month 12, 100% of patients had a 20% or greater decrease in their preoperative unmedicated IOP, Dr. Lindstrom said.

Seventy-five percent had a 20% or greater decrease in their IOP with medication at month 18.

Of the 57 patients, 27 were women, and all were white. The mean age was 65.3 years. Patients used an average of one medication before the procedure, and the mean IOP with medication was 19.5 mm Hg. The unmedicated IOP was 24.4 mm Hg. The most common type of medication used was a prostaglandin analogue.

Around the world, physicians have found that the placement of two or three stents gives a greater effect than what’s approved in the United States,” Dr. Lindstrom said. “Also, the next-generation product is a simpler stent to place.”
decrease compared with preoperative medicated IOP. Without medication, 100% had an IOP of 18 mm Hg or lower, and 67% had an IOP of 15 mm Hg or lower.

An analysis of the mean IOP through month 18 reveals the IOP-lowering trends, Dr. Lindstrom said.

Although the mean IOP increased to 24.4 mm Hg right after the washout period—when patients stopped using their medications—it dropped down to 14.3 mm Hg at month 1 and then ended at 14.4 mm Hg at month 18.

“That was a 41% decrease from the preoperative unmedicated IOP,” Dr. Lindstrom said.

There were no major safety issues in the study; one patient had a loss of BCVA because of a cataract progression. At month 18, 93% of patients had BCVA of 20/40 or better.

The study did have some limitations, Dr. Lindstrom said. It was open label, there was no control group, and all patients were white. Additionally, the qualifying IOP was not measured on multiple days. However, the study showed overall good outcomes and safety, Dr. Lindstrom said.

He added that although the second-generation device is not yet available in the United States, it should be eventually approved and used here.

RICHARD L. LINDSTROM, MD
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This article was adapted from Dr. Lindstrom’s presentation at the 2016 meeting of the American Society of Cataract and Refractive Surgery. Dr. Lindstrom is a consultant for and equity owner in Glaukos.

Sight Sciences receives IDE approval for comparative trial

MENLO PARK, CA ::

SIGHT SCIENCES announced it received full Investigational Device Exemption (IDE) approval from the FDA to initiate a trial comparing ab interno canaloplasty with selective laser trabeculoplasty (SLT).

The VISCO360 versus SLT Glaucoma Trial is a multicenter, prospective, randomized, controlled clinical evaluation that will study the safety and effectiveness of the company’s viscosurgical system (VISCO360) in canaloplasty versus SLT in the reduction of IOP in primary open-angle glaucoma (POAG).

The fully integrated, single-handed, single-use device combines a custom-access cannula, a soft and flexible microcatheter with an atraumatic tip, an internal infusion pump and viscoelastic reservoir, and a control wheel that advances and retracts the microcatheter.

“We are extremely excited to begin this pivotal clinical trial investigating the use of our [device] for this specific indication,” said Paul Badawi, co-founder and chief executive officer, Sight Sciences. “We believe there is a huge unmet need for an effective ab interno glaucoma procedure that is not performed in conjunction with cataract removal and we look forward to working with all of our clinical partners in the execution of this large, robust FDA clinical study.”

“I believe [surgeons] will find this familiar ab interno approach to canaloplasty extremely useful,” said Steven Sarkisian, MD, professor of ophthalmology, Dean McGee Eye Institute, University of Oklahoma, Oklahoma City, and a principal investigator in the VISCO360 Study.
LOS ANGELES ::

NEW RESULTS ON STAND-ALONE implantation of a gel stent for glaucoma underscored existing data on combination glaucoma-plus-cataract surgery.

The latest data from a multicenter European study of the gelatin stent (Xen 45) showed a mean reduction in IOP of 42% 12 months after implantation. The stent was developed by AqueSys, which was acquired by Allergan in 2015, and is widely available outside the United States. It remains an investigational device in the United States.

“This gel stent is simply the most exciting approach we have had for the surgical treatment of glaucoma for a long, long time,” said Rohit Varma, MD, MPH, interim dean of the Keck School of Medicine, the Grace and Emery Beardsley Professor and Chair of Ophthalmology and director, Roski Eye Institute, University of Southern California. “Once the pressure drops after implanting the stent, it stays low for a number of years.”

Dr. Varma presented unpublished topline data from 12 months of follow up on 103 patients treated by 11 different surgeons across seven European countries.

Mean IOP, IOP change, medication reduction, safety studied through 12 months

BY FRED GEBHART

Most prior data on the stent has come from combination procedures, Dr. Varma noted. This is one of the largest studies of stand-alone implantation in reducing IOP and medication use in patients with primary open-angle glaucoma and no prior incisional surgery, he added.

Before implantation, patients had a mean best-medicated IOP of 22.8 mm Hg. The mean best-medicated IOP 12 months after implantation was 13.3 mm Hg, a 42% reduction. Patients in the trial were taking a mean of 3.3 IOP-lowering eye drops before implantation and 1.1 drops 12 months post-implantation, a 66% reduction in medication use.

“The problem is that glaucoma is a long-term disease and we are treating patients over a lifetime,” Dr. Varma said. “All we have at this point is drops, then laser, which is not particularly effective, then invasive surgery, trabeculectomy, and tubes. There is a need for a treatment that is more effective than drops, is minimally invasive like laser, and produces clinically significant and consistent reduction in IOP over the long term. That’s where [this device] comes in.”

The stent is placed ab interno using a preshaped hydrogel cylinder guided by hand through a clear-corneal incision about 1.6 mm in length. Once in place, the device hydrates and swells, adapting to the shape of the surrounding tissue to connect the anterior chamber directly with the subconjunctival space.

Once implanted, 1 mm of the stent remains in the anterior segment, 3 mm are interscleral, and 2 mm extend into the subconjunctival space. The direct channel between the anterior chamber and the subconjunctival space avoids blockages in the physiologic drainage system, but sock-like scarring can block the tube tip in 10% to 30% of patients.

An application of mitomycin C at the time in insertion can prevent scarring or the scar can be needled in a follow-up office procedure if needed.

Other adverse events include minor bleb leak at the time of insertion in fewer than 2% of cases and perforation of the conjunctiva. Erosion of the conjunctiva has been a very rare occurrence in the several hundred implantations that have been performed to date, Dr. Varma said.

“Because the [stent] is soft, it conforms to the shape of the tissue and is much less likely to erode compared with conventional stents,” he said. “And because the tube is soft, it avoids one of the major complications with harder silicone tubes, which can injure corneal epithelial cells, leading to corneal edema. We are not seeing corneal edema with [this] stent.”

The stent has CE Mark for both stand-alone placement and in combination with cataract surgery. Allergan recently completed a U.S. trial and is preparing data submission to the FDA for 510(k) marketing clearance.

Device designers used Poiseuille’s law of laminar flow to exploit the known relationship between length and lumen to regulate outflow volume and avoid hypotony.

‘We are not seeing corneal edema with [this] stent.’

— Rohit Varma, MD, MPH

Special Report ) CONTEMPORARY SURGICAL & CLINICAL STRATEGIES IN GLAUCOMA

Novel gelatin stent implant appears effective as stand-alone procedure

Mean IOP, IOP change, medication reduction, safety studied through 12 months

By Fred Gebhart

HOW IT WORKS

The stent is a 6-mm hydrophilic cylinder made of cross-linked porcine gelatin with a 45-μm lumen. With a 210-μm outer diameter, three stents can fit inside the lumen of a Baerveldt tube. A smaller and narrower device allows for ab interno placement that is less prone to hypotony and other complications than conventional tube stents. Because the device drains directly into the subconjunctival space, it can lower IOP as effectively as more invasive trabeculectomy.

About one-half of the transplants for the device done outside the United States have been stand-alone procedures and half done in conjunction with cataract surgery, Dr. Varma added. Three different models have been developed with lumens of 45, 63, and 140 μm. Testing outside the United States suggests the 45-μm model provides the optimal combination of improved IOP lowering and low rates of adverse events for most patients.

Device designers used Poiseuille’s law of laminar flow to exploit the known relationship between length and lumen to regulate outflow volume and avoid hypotony.

DEVICE IMPLANTATION

The stent is placed ab interno using a preloaded injector with a 27-gauge needle that is

take-home

- One-year results are reviewed for use of a novel ab-interno gelatin stent as a stand-alone procedure for patients with mild-to-moderate, primary open-angle glaucoma.

ROHIT VARMA, MD, MPH

rvarma@usc.edu

This article was adapted from Dr. Varma’s presentation at the 2016 meeting of the American Society of Cataract and Refractive Surgery. He is a consultant for AqueSys.
Branded vs. Generics: You Make the Call

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Pharmacologic pipeline brimming with glaucoma agents on horizon

Continued research into novel mechanisms of action driving drug development

By Fred Gebhart

THE PACE OF new glaucoma drug development continues, fueled by continuing research into novel mechanisms of action. Three companies—Aerie Pharmaceuticals, Bausch + Lomb, and Inotek Pharmaceuticals—shared their latest results during “New Horizons in Glaucoma Pharmaceuticals” at the 2016 Glaucoma 360 meeting.

AERIE PHARMACEUTICALS

Aerie Pharmaceuticals is staking its future on glaucoma, said Tom Mitro, president and chief operation officer. Two products, Rhopressa and Roclatan, are moving toward FDA submission. “Rhopressa will be positioned as an additive to prostaglandin therapy,” Mitro said. “That market is 16 million to 17 million prescriptions annually in the United States alone. The current market is made up of products 20 to 30 years old that require two or more times daily dosing and can have some serious systemic side effects.”

Rhopressa is a once-daily eye drop that inhibits Rho kinase (ROCK) and norepinephrine transporter (NET). Both are novel targets for the lowering of IOP and combine three distinct mechanisms of action.

ROCK inhibition increases fluid outflow through the trabecular meshwork and reduces episcleral venous pressure, while NET inhibition reduces production of aqueous. The NET inhibition effect makes Rhopressa helpful in patients with extremely high IOP, Mitro said.

Two phase III registration trials showed Rhopressa used once daily is not inferior to timolol used twice daily in patients with an IOP of less than 25 mm Hg. The company expects a New Drug Application in the third quarter of 2016.

Roclatan is a fixed-dose combination of Rhopressa plus latanoprost. Phase IIB results suggest that Roclatan has the potential to become the most efficacious, IOP-lowering agent in the market, Mitro said.

Roclatan also showed strong effects in patients who had used a prostaglandin prior to clinical trials. After a washout period at the beginning of trials, patients who had previously used a prostaglandin showed the greatest IOP-lower effect compared with all other subgroups. One of two planned U.S. phase III trials is currently enrolling and a second began enrolling during the second quarter. An E.U.-based phase III trial is scheduled to begin during the second quarter of 2017.

BAUSCH + LOMB

Bausch + Lomb has completed phase III trials of latanoprostene bunod (LBN), its novel prostaglandin analogue plus nitric oxide donating moiety (See related article, Page 39). The compound is metabolized into latanoprost-free acid and nitric oxide. Latanoprost-free acid increases uveoscleral outflow to reduce IOP, while nitric oxide donors have been shown to lead to relaxation of the trabecular meshwork to increase outflow and reduce IOP.

Phase II VOYAGER dose-ranging studies versus latanoprost in patients with open-angle glaucoma or ocular hypertension showed a statistically significant reduction in mean diurnal IOP at both 0.024% and 0.040% doses (p ≤ 0.009), said Megan Cavet, PhD, manager of medical affairs. The 0.024% dose had the largest proportion of patients with a mean diurnal IOP of 18 mm Hg or less at all time points during the 28-day study. Ocular treatment-emergent adverse events were mild to moderate in severity and were similar in both LBN and latanoprost patients.

The more recent phase III APOLLO trial compared LBN against timolol in a 3-month efficacy study that was followed by a 9-month safety extension. LBN showed both a statistically and a clinically significant improvement in IOP at all time points during the efficacy study. The IOP-lowering effect was maintained out to 1 year during the safety extension.

“We have seen LBN can result in a statistically significant IOP lowering compared with both timolol and latanoprost,” Dr. Cavet said. “LBN also showed 24-hour, IOP control over a range of baseline IOPs and there were no significant treatment-associated adverse events.”

INOTEK PHARMACEUTICALS

The company completed a successful phase II meeting with FDA at the end of 2015 for trabodenoson, an agent which appears to treat both the pathophysiology of elevated IOP and the neural damage that can result for excessive IOP.

“We have the opportunity to treat glaucoma in two synergistic ways, the plumbing and electrical pathways,” said Cadmus Rich, MD, vice president of medical affairs and clinical development. “On the plumbing side, we treat the loss of normal IOP regulation at the trabecular meshwork resulting in an increase in IOP. On the electrical side, we treat the pathology common to all glaucoma patients, the neuropathy that disrupts the relaying of the visual signal.”

A trabodenoson-monotherapy program is in phase III with top-line data expected toward the end of 2016. A fixed-dose combination of trabodenoson plus latanoprost is in phase II with top line data expected during the first half of 2017.

Efficacy increases with both dose and time, Dr. Rich said. Trials have not shown any dose-limiting toxicity. The maximum tolerated dose has not yet been determined and there have been no treatment-related dropouts in any clinical trials.
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Aqueous drainage tube provides trabeculectomy-like efficacy
IOP-lowering benefit accompanied by reduced need for pressure-lowering medication

By Cheryl Guttman Krader; Reviewed by Juan F. Batlle, MD

SANTO DOMINGO, DOMINICAN REPUBLIC ::

**IMPLANTATION OF** the transcleral micro-lumen aqueous drainage tube (InnFocus MicroShunt, InnFocus) by itself, or in combination with phacoemulsification, is safe and provides significant and durable IOP-lowering, said Juan F. Batlle, MD.

In most patients, IOP is lowered into the range of 10 to 13 mm Hg and remains stable at that level with follow-up to 3 years, said Dr. Batlle, director, Centro Laser, and director, Elias Santana Charity Hospital, Santo Domingo, Dominican Republic.

“This level of IOP falls within the zone identified in the Advanced Glaucoma Intervention Study as being optimal for preventing vision loss, and matches what can be achieved with trabeculectomy,” he said.

However, the microshunt has a more favorable safety profile than filtering surgery, as so far it is avoiding hypotony-related and late bleb complications that can necessitate surgical intervention, Dr. Batlle noted.

The device received CE Mark in January 2012, but is still investigational in the United States.

**MEASURE OF SUCCESS**

He also analyzed success rates and reported that it was 95% at 3 years using a definition based on a stringent IOP cutoff of ≤14 mm Hg plus additional criteria requiring at least a 20% decrease from baseline, no additional glaucoma surgery requiring an operating room setting, no loss of light perception vision, and no chronic hypotony, or use of glaucoma medication.

The only failure occurred in one patient at 27 months who developed an encapsulated bleb. In that individual, a second microshunt was inserted without explantation of the first device and resulted in lowering of IOP into the low teens.

“The only other postoperative intervention performed in this series of 23 eyes was a single case of a bleb needling procedure,” he said.

The most common complications encountered in the study, hypotony (13%) and choroidal effusion (8.7%), occurred early after surgery, were transient, and resolved without any intervention. No serious adverse events occurred during longer follow-up, and there have been no cases of bleb infection or leaks nor any issues with device migration or erosion.

Implantation is performed in an ab externo procedure that Dr. Batlle describes as relatively simple because it avoids the need for scleral dissection sclerostomy, iridotomy, and tensioning sutures. It is also relatively quick, taking less than 12 minutes to complete once surgeons complete the learning curve.

The device is inserted through a 3-mm scleral tract formed under the limbus with a 25-gauge needle. Dr. Batlle was originally creating the tract with a 27-gauge needle, but shifted to using the larger needle that has made insertion of the device easier and faster without causing periannular leakage.

**ABOUT THE STUDY**

Dr. Batlle has published his experience with the microshunt [J Glaucoma. 2016;25(2):e58-65] in a study enrolling 23 eyes that would be considered candidates for trabeculectomy or a tube procedure. All had glaucoma inadequately controlled on maximum tolerated glaucoma medication and an IOP between 18 and 40 mm Hg.

In 14 eyes, the transcleral aqueous drainage tube was implanted as a stand-alone procedure, while the remaining 9 eyes also underwent phacoemulsification with IOL implantation.

In all cases, mitomycin-C (MMC) 0.4 mg/mL was applied intraoperatively for 3 minutes. All eyes were evaluable for follow-up at 1 year, and 22 eyes were seen at 2- and 3-year visits.

Mean IOP at baseline was 23.8 ± 5.3 mm Hg at baseline and measured 10.7 ± 2.8 mm Hg at 1 year. 11.9 ± 3.7 mm Hg at 2 years, and 10.7 ± 3.5 mm Hg at 3 years, with the latter value representing a 55% reduction from baseline.

Results were similar in subgroup analyses of eyes undergoing microshunt implantation alone or as a combined procedure.

The IOP-lowering benefit was accompanied by a significant reduction in need for IOP-lowering medication. Mean number of medications used per patient was 2.4 preoperatively and was only 0.3 at 1 year, 0.4 at 2 years, and 0.7 at 3 years. At last follow-up, two-thirds of the patients were on no medications.
Second trial confirms IOP-lowering efficacy of first-in-class agent

Latanoprostene bunod demonstrates superiority to timolol in primary, secondary endpoints

By Cheryl Guttman Krader; Reviewed by Felipe A. Medeiros, MD, PhD

SAN DIEGO ::

ONCE-DAILY TREATMENT with latanoprostene bunod (LBN) 0.024% ophthalmic solution (Bausch + Lomb) is safe, effective, and well tolerated for lowering IOP in patients with open-angle glaucoma and ocular hypertension. That’s the affirmation from published results of a second phase III clinical trial, said Felipe A. Medeiros, MD, PhD.

Data from the LUNAR study investigating the novel nitric oxide-donating prostaglandin F2α analogue were published online in the American Journal of Ophthalmology on May 19, 2016, and are consistent with findings from the phase III APOLLO study that appeared online ahead of print in Ophthalmology in February 2016.

Dr. Medeiros is professor of ophthalmology, University of California, San Diego, and lead author of the published paper reporting results of the LUNAR study.

Both double-masked trials randomly assigned adults with open-angle glaucoma or ocular hypertension 2:1 to treatment with LBN in the evening plus vehicle in the morning or twice daily treatment with timolol maleate 0.5%.

Follow-up visits were scheduled after 2 weeks, 6 weeks, and 3 months, and IOP measurements were obtained at 8 a.m., 12 p.m., 4 p.m. at each visit.

The primary objective of the studies was to demonstrate the non-inferiority of the mean IOP-lowering effect of LBN to timolol over the 3-month treatment period. If that endpoint was met, statistical superiority of LBN to timolol was evaluated as a secondary objective.

LBN met the primary and secondary objectives in both studies, and the review of adverse event data and vital sign measurements showed no unexpected safety concerns associated with its use. LBN is thought to increase aqueous humor outflow through a dual mechanism, Dr. Medeiros said.

“It is rapidly metabolized upon instillation in the eye to latanoprost acid, a prostaglandin analogue that increases uveoscleral outflow, and nitric oxide, an important physiological signaling molecule that regulates aqueous humor outflow through the trabecular meshwork/Schlemm’s canal pathway,” he said.

“If approved, LBN would be the first nitric oxide-donating prostaglandin analogue on the market and would be a welcome addition for offering a new therapeutic alternative for ophthalmologists and their patients with open-angle glaucoma or ocular hypertension,” he said.

THE LUNAR STUDY

A total of 420 patients were randomly assigned for LUNAR. The two study groups were well matched in their demographic and baseline ocular characteristics. Mean diurnal IOP was 26.6 mm Hg in the LBN group and 26.4 mm Hg in the timolol-treated patients.

Mean IOP reduction and mean IOP were analyzed as primary efficacy outcome measures. Across the nine time points assessed, LBN was associated with mean IOP reductions of 29.1% to 32.1% versus 25.2% to 28.7% for timolol. There were statistically significant differences favoring LBN over timolol in the analysis of mean IOP at all time points except at the 8 a.m. measurement at week 2.

Prespecified secondary efficacy outcome measures considered the proportions of patients that consistently achieved two IOP-lowering targets: ≥25% reduction from baseline and IOP ≤18 mm Hg.

The difference between LBN and timolol was statistically significant for the proportion of patients achieving a ≥25% reduction from baseline IOP (31.0% versus 18.5%; p = 0.007).

The proportion of eyes achieving an IOP ≤18 mm Hg was consistently numerically greater in the LBN group compared with timolol at all nine timepoints, but the difference in the overall proportion of patients achieving this target did not quite reach statistical significance (17.7% versus 11.1%; p = 0.084).

LBN was safe and tolerated well. The most common treatment-emergent adverse events in LBN-treated eyes in both phase 3 trials were conjunctival hyperemia, eye irritation, eye pain, and instillation site pain.

LBN is thought to increase aqueous humor outflow through a dual mechanism.

LBN VERSUS LATANOPROST

Data comparing LBN with latanoprost 0.005% (Xalatan, Pfizer) are available from the phase IIb VOYAGER study [Weinreb RN, et al. Br J Ophthalmol. 2015;99:738-745], a dose-ranging study that included more than 400 patients.

In VOYAGER, diurnal IOP reduction was greater in patients treated with LBN 0.024% compared with the latanoprost group at the primary endpoint on day 28, Dr. Medeiros noted.

“The benefit of LBN exceeded 1 mm Hg, and in VOYAGER there was also a statistically significant difference favoring LBN over latanoprost in an analysis of the proportion of patients who achieved a mean diurnal IOP ≤18 mm Hg at day 28,” he said. “This commonly used therapeutic target for patients with glaucoma was achieved by 68.7% of patients treated with LBN 0.024% versus only 47.5% of those treated with latanoprost.”

FELIPE A. MEDEIROS, MD, PHD

Dr. Medeiros has received institutional grant money from Allon Laboratories, Allergan, Bausch + Lomb, Merck, and the National Eye Institute, and has served as a paid consultant for Allon and Alcon.
A newly introduced high-definition imaging device for evaluation of meibomian glands (LipiScan, TearScience) measures lipid layer thickness and evaluates blink dynamics with an efficient, easy-to-use device for clinical practices, said Preeya K. Gupta, MD, assistant professor of ophthalmology, Duke University, Durham, NC.

“Despite being smaller and easier to accommodate in a clinic, it still takes very high-resolution meibomian gland images,” Dr. Gupta said. “I use it as a screening tool in my office to help identify patients who might have meibomian gland dysfunction (MGD) or who may have been misdiagnosed or underdiagnosed in the past.”

She also uses it to screen both refractive surgery and cataract surgery candidates to identify co-existing MGD that can lead to dry eye.

Before the development of imaging devices specifically for evaluation of the meibomian glands, it was difficult to determine if a patient had gland atrophy and other signs of gland dysfunction, such as dilation or tortuosity, Dr. Gupta said.

“Now you can identify anatomically whether or not there is gland dysfunction or atrophy,” she said. “As a clinician it has provided a lot of information about the meibomian glands that we really didn’t have access to in the past.”

It is not only helpful for making a diagnosis, but also for framing treatment expectations in discussions with patients, she added. For example, if the images showed very severe gland atrophy, she could explain that the treatment goal is to preserve the few remaining glands, and that it could be an uphill battle. But if the patient had relatively minor gland atrophy accompanied by symptomatic dry eye or MGD, she could outline the specific treatment steps likely to produce improvement.

The device uses a patented technique that takes high-definition images of the glands using a transilluminator and near-infrared technology, said Joseph Boorady, OD, president and chief executive officer of TearScience.

The device and its predecessor (LipiView, TearScience) have a transilluminator, which everts the eyelid and uses a proprietary infrared light source to image the lid. The infrared light allows the camera on the lid to take very high-quality, high-definition images of the glands, he said.

“In order to accurately diagnose MGD, which still today is vastly misunderstood and underdiagnosed, you need to look at two things: structure and function,” Dr. Boorady said. “Look at the structure of the meibomian glands and [whether they are] secreting lipid or not.”

Traditionally, physicians would transilluminate the eyelid and use a slit lamp to evaluate the meibomian glands when they wanted to look at the structure.

However, the imaging technology developed by the company provides a high-resolution view of the glands in under 10 seconds per lid, Dr. Boorady said. Function can then be assessed using the slit lamp along with the company’s handheld meibomian gland evaluator or by manual expression.

Until relatively recently, tools for evaluating the meibomian gland had largely been found in research settings and tended to be more sophisticated and complex than was necessary for the typical clinical practice, Dr. Boorady said. The new product was developed as a less-expensive alternative to traditional methods.
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The University is especially interested in candidates who can contribute to the diversity and excellence of the academic community through their research, teaching, and/or service. Applicants are requested to include in their cover letter information about how they will further this goal. The University of Vermont is an Affirmative Action/Equal Opportunity Employer. Applications from women, veterans and people of diverse racial, ethnic and cultural backgrounds are encouraged. Applications will be accepted until the position is filled.

Interested individuals should apply online at https://www.uvmjobs.com/postings/20419 (position number 00024181). Inquiries may be directed to Dr. Brian Kim c/o Emily Nuse at Emily.Nuse@uvmhealth.org.

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developed in response to demand for a dedicated, smaller, and less-expensive device that produced high-quality images.

“It’s been an easy instrument to integrate into clinical practice because it’s not invasive and it’s easy for technicians to use and become familiar with,” Dr. Gupta said. “As a clinician, what I’m focused on is whether a device going to give me good images, and also [whether] it easy for my staff to use. I would say this device definitely captures excellent images . . . but it’s much more portable and compact and easier to integrate, especially into higher-volume practices and busy clinics.”

Dr. Gupta noted that the device is less expensive than one of the company’s previous developments (LipiView II), and clinicians could purchase multiple devices for different office locations or more than one in a large clinic. The device’s small footprint also makes it unlikely to disrupt patient flow, regardless of the practice size and number of devices on site.

“I believe [physicians] are looking for an easy and cost-effective way to get images so that they can screen a lot more patients in their offices,” Dr. Boorady said. “We believe we’ve filled that niche. More screening and more identification of MGD will lead to more treatment, which is why we want to help [physicians] identify this dysfunction.”

PREEYA K. GUPTA, MD

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Dr. Gupta is a consultant to TearScience.

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Techie-turned ophthalmologist tinkers through fellowship
MERGING CODING SKILLSET WITH MEDICINE

Sabin Dang, MD, didn’t have as clear cut of a journey to the ophthalmic world as many might expect. While today he spends his working hours improving visual outcomes of patients, a few years ago one would have found him creating coding software in his IT consulting company to help businesses grow.

“There’s not many people who make that switch,” Dr. Dang said. “I don’t know many people who have.”

That was absolutely the wrong direction I wanted to go in,” he said. “I was helping businesses, but I wasn’t helping people.”

That was one of many factors that played into Dr. Dang’s decision to make a transition to medicine, where he felt he could make a tangible difference in people’s lives. And for him, it was clear as to which medical field he would choose.

“I’m a big techie. I don’t think there’s any field that’s more high-tech than what we do. The sheer number of new equipment and cutting-edge technology, surgery, and imaging equipment... for me it ended up being a no-brainer,” he explained. “I get all the cool toys and I get to do what I love!”

He attended medical school at the Charles R. Drew/UCLA Medical Education program, and is currently in his last year of fellowship at Tufts New England Eye Center/Ophthalmic Consultants of Boston.

Integrating his skills
One of the innovative ways Dr. Dang has merged his medical and technological skillsets is in creating his own EHR. Many EHRs have their main goal of most accurate billing or best compliance, however, they all seem to be missing the bigger picture, Dr. Dang said.

“There’s been a disconnect between the software vendors and what we’re actually doing in clinic,” he said. “There are ways to hit compliance and all the coding, but still at the core of it make the primary focus the physician-patient interaction.”

Rather than marketing his program, (which allows clinicians to use dictation), Dr. Dang uses it as a proof-of-concept and talking point for the direction that technology can move in by focusing on the physician-patient interaction.

“I want to make clinic more efficient and I want physicians to have more time with the patient,” he said. “I think technology can get us back to that as opposed to what it’s doing more recently, which is taking us away from that.”

Still tinkering
Despite his busy schedule, Dr. Dang makes it a point to continue tinkering in his spare time. One of his favorite ways to incorporate his love for technology and programming with his family is with Lego Mindstorms.

“I still love to tinker with technology,” he said. “It’s a creative outlet for me, but long gone are those days of 12-hour programming sessions!”

Upon completing his fellowship, Dr. Dang will practice at The Retina Institute in St. Louis.
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