Ophthalmology Times®

CUTTING-EDGE ADVANCEMENTS

October 15, 2014 VOL. 39, NO. 19

CLINICAL DIAGNOSIS | SURGERY | DRUG THERAPY

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Technology

ROUND-THE-CLOCK IOP MONITORING

Presbyopia-correcting implant extends range of vision

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ReSTOR®
MULTIFOCAL IOL

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CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS: The AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

WARNING/PRECAUTION: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery.

Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. Clinical studies with the AcrySof® ReSTOR® lens indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ ReSTOR® IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

ATTENTION: Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

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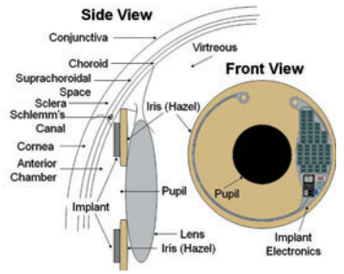
ROUND-THE-CLOCK IOP MONITORING CLOSER TO REALITY



PHILADELPHIA :: **AN ONGOING** conundrum for glaucoma specialists has been an inability to monitor patients' IOP measurements throughout a 24-hour period in real-world clinical settings. About a decade ago, investigators started looking beyond the office readings and found that pressure increased at night during patients' sleep cycle. "That was quite a paradigm shift, as we used to believe that the pressure increased early in the morning when cortisol levels rose," explained Marlene Moster, MD.

*(See story on page 42 : **IOP monitoring**)*

Focal Points

GLAUCOMA 360° UNITES INDUSTRY, R&D, PHILANTHROPY

SAN FRANCISCO :: **ORGANIZERS** for Glaucoma 360° are promising the fourth installment of this meeting—set for Feb. 5 to 7, 2015—will be even better than those held in the past 3 years. "This meeting has come of age," said Tom Brunner, president and chief executive officer of the Glaucoma Research Foundation. "It is now the most widely known glaucoma meeting of its type and has become the meeting to attend."

*(See story on page 10 : **Glaucoma**)*

Presbyopia-correcting implant extends range of vision

Lens technology provides full range of continuous, high-quality vision; minimizes dysphotopsias

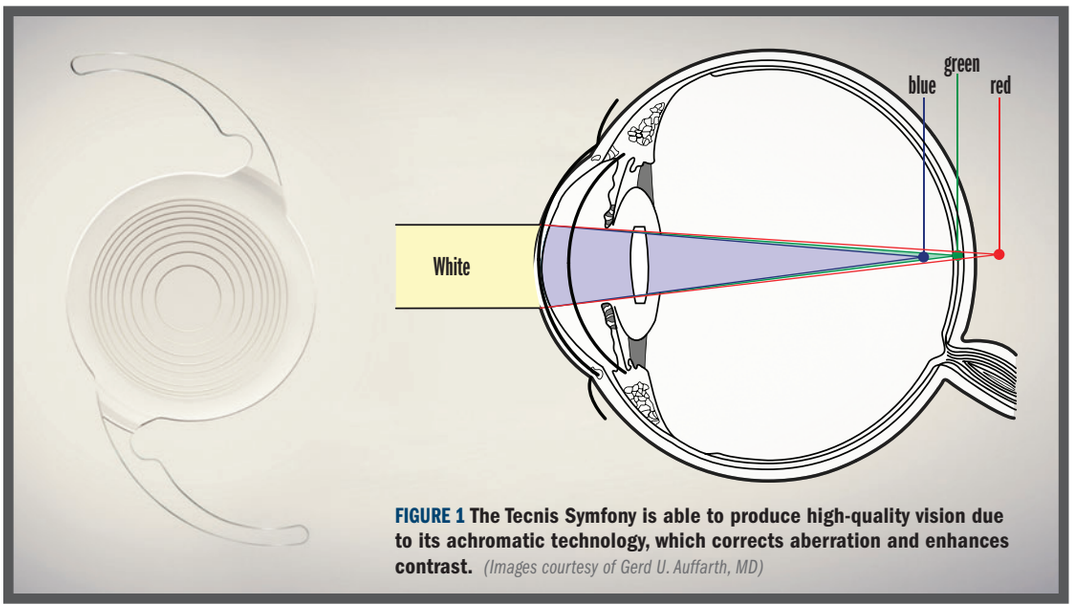


FIGURE 1 The Tecnis Symfony is able to produce high-quality vision due to its achromatic technology, which corrects aberration and enhances contrast. *(Images courtesy of Gerd U. Auffarth, MD)*

By Cheryl Guttman Krader;
Reviewed by Gerd U. Auffarth, MD

FINDINGS FROM STUDIES evaluating the performance of a new presbyopia-correcting IOL (Model ZXR00; Tecnis Symfony Extended Range of Vision IOL, Abbott Medical Optics) indicate that it provides a full range of continuous, high-quality vision and successfully addresses the limitations accompanying multifocal IOL technology.

The novel IOL possesses innovative surface design features that result in 50% less light loss than traditional diffractive technologies, such as multifocal or trifocal IOLs, enhanced depth of focus, crisp image quality, and very low rates of visual symptoms. The Symfony Extended Range of Vision IOL has received the CE Mark, is available in Europe, and is being studied in a pivotal trial in the United States.

"Recent strategies for enhancing multifocal IOL technology have focused on ways to improve intermediate vision, and this has been accomplished with the introduction of trifocal designs and lenses with a lower add. However, because a multifocal optic distributes light to different foci, all multifocal IOLs suffer from problems with contrast sensitivity loss and dysphotopsias," said Gerd U. Auffarth, MD, professor and chairman, Department of Ophthalmology, Ruprecht-Karls University of Heidelberg, Germany.

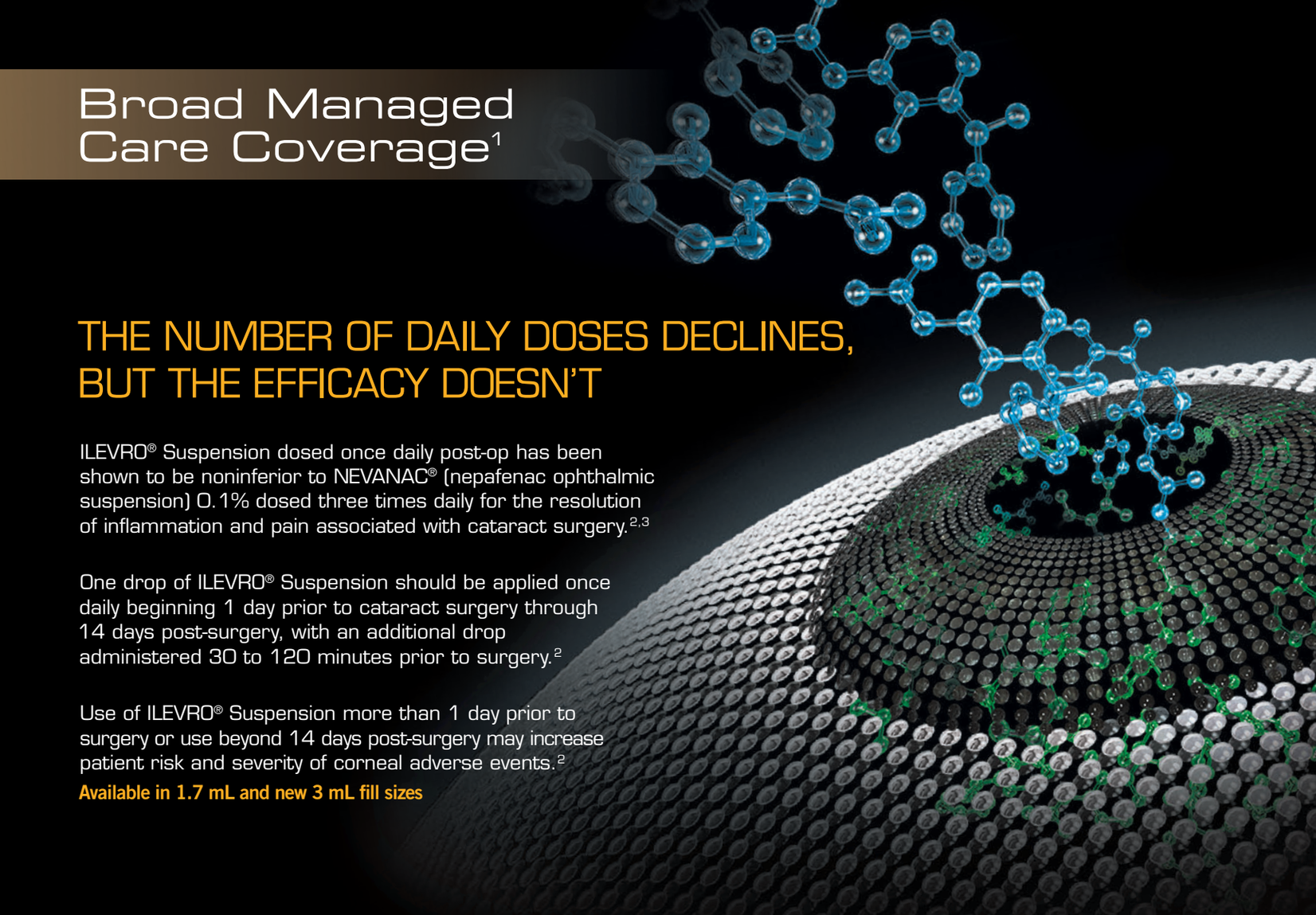
"This extended-range-of-vision IOL represents an entirely new design concept that allows for an extended range of crisp vision and a high rate of spectacle independence while minimizing photic issues, such as halos and glare, to levels similar to those occurring with a monofocal IOL," he said

Discussing the design of the new lens, Leonard Borrmann, PharmD, divisional vice president, research and development, Abbott Medical Optics, Santa Ana, CA, explained it combines two complementary diffractive technologies.

The first technology uses a modification of the height and the profile of the diffractive echelette to elongate the focus, as compared with the diffrac-

*(Continues on page 24 : **Extended range**)*

Broad Managed Care Coverage[1]



THE NUMBER OF DAILY DOSES DECLINES, BUT THE EFFICACY DOESN'T

ILEVRO® Suspension dosed once daily post-op has been shown to be noninferior to NEVANAC® (nepafenac ophthalmic suspension) 0.1% dosed three times daily for the resolution of inflammation and pain associated with cataract surgery.[2,3]

One drop of ILEVRO® Suspension should be applied once daily beginning 1 day prior to cataract surgery through 14 days post-surgery, with an additional drop administered 30 to 120 minutes prior to surgery.[2]

Use of ILEVRO® Suspension more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events.[2]

Available in 1.7 mL and new 3 mL fill sizes

INDICATIONS AND USAGE

ILEVRO® Suspension is a nonsteroidal, anti-inflammatory prodrug indicated for the treatment of pain and inflammation associated with cataract surgery.

IMPORTANT SAFETY INFORMATION

Contraindications

ILEVRO® Suspension is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other NSAIDs.

Warnings and Precautions

- Increased Bleeding Time – With some nonsteroidal anti-inflammatory drugs including ILEVRO® Suspension there exists the potential for increased bleeding time. Ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery.
- Delayed Healing – Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including ILEVRO® Suspension may slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- Corneal Effects – Use of topical NSAIDs may result in keratitis. In some patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use.

  Patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

  Use more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events.
- Contact Lens Wear – ILEVRO® Suspension should not be administered while using contact lenses.

Adverse Reactions

The most frequently reported ocular adverse reactions following cataract surgery occurring in approximately 5 to 10% of patients were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation.

For additional information about ILEVRO® Suspension, please refer to the brief summary of prescribing information on adjacent page.

References: 1. Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, June 2014. **2.** ILEVRO® Suspension prescribing information. **3.** NEVANAC® Suspension prescribing information.

For more resources for eye care professionals, visit MYALCON.COM/ILEVRO

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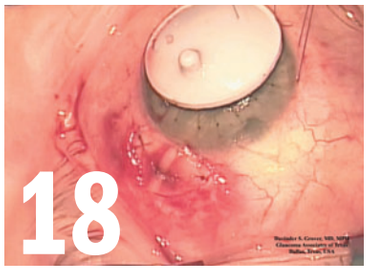

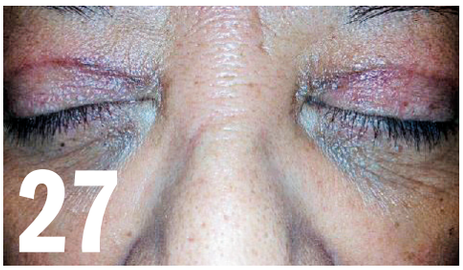

Surgery

Clinical Diagnosis

Drug Therapy

Technology

InDispensable

In Every Issue

An attack on elite education

Do wealthier parents maximize children's chances of acceptance?

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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THE DEFINITIONS OF zombie include:

1. A corpse said to be revived by witchcraft, especially in certain African and Caribbean religions.

2. A person who is or appears lifeless, apathetic, or completely unresponsive to the surroundings.

3. A computer controlled by another person without the owner's knowledge and used for sending spam or other illegal or illicit activities.

4. A tall, mixed drink consisting of several kinds of rum, liqueur, and fruit juice.

Of these, the last one most appeals to me. But it is definition number two, I fear, that is contemplated by author William Deresiewicz, PhD, in a recent article in *The New Republic*. The article excoriates the admissions criteria and educational experience of our most prestigious centers of higher learning.

The author, a former professor at Yale University, asserts that wealthier parents—by providing their children with more opportunities for activities and better schooling and tutoring—maximize their children's chances of acceptance.

FEW PASSIONATE STUDENTS

These children of privilege, we are told, are "content to color within the lines that their education had marked out for them. Few were passionate about ideas. Beneath a faced of seamless, well adjustment, . . . are toxic levels of fear, anxiety, and depression, of emptiness and aimlessness and isolation. The prospect of not being successful terrifies them."

Professors, we are told, hand out good grades to all students because they "are regarded by the institution as 'customers,' people to be pandered to instead of challenged." Students are focused on getting the grades they need, and not on reflecting upon what they are learning.

Prof. Deresiewicz thinks that the Ivy League functions to preserve an elitist system. He reports that 75% of freshmen at the 100-plus most selective colleges come from households in the upper quarter of the income distribution, while only 3% are from the bottom quarter.

DISMANTLE THE SYSTEM

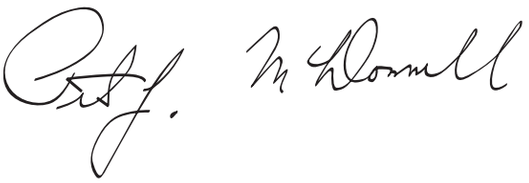
Not one to offer minor adjustments, the author's proposed solution is "dismantling the entire system," and creating a free system of public education that would be funded by taxes on the wealthiest 10% of Americans. As noted in this column recently, among that 10% is the vast majority of ophthalmologists.

As a tenured professor at one of the selective colleges that the author pillories, it is perhaps not surprising that I am a big believer in the importance and value of higher education. All the data I have seen point to education being a key determinant of future income and wealth, so I personally am in favor of addressing wealth inequality by strengthening education standards in our country and around the world. But when it comes to thinking of my former college schoolmates as zombies, with the exception of Eric (an ophthalmologist in Long Island), I'm not sure I see it.

P.S. For a good zombie, try the following:

1/2 oz Bacardi 151 rum; 1 oz pineapple juice; 1 oz orange juice; 1/2 oz apricot brandy; 1 tsp sugar; 2 oz light rum; 1 oz dark rum; 1 oz lime juice.

Blend all ingredients with ice, except Bacardi 151 rum. Pour into a Tom Collins glass. Float Bacardi 151 rum on top. Garnish with a fruit slice, sprig of mint and a cherry. (Find it at *http://bit.ly/1vOE1u7*) ■



Reference

- *http://www.newrepublic.com/article/118747/ivy-league-schools-are-overrated-send-your-kids-elsewhere*

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LETTER TO EDITOR

Axing R&D funding alarming

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

Like so many, I have followed Valeant's hostile takeover bid for Allergan. I read with interest the recent comments by Scott Whitcup, MD, and Cal Roberts, MD, in *Ophthalmology Times* (See *"Focus on efficient R&D pays dividends for physicians, patients" [http://bit.ly/1saXYMM]* and *"Future of ophthalmic innovation is through R&D partnerships," [http://bit.ly/1oOh720]* July 15, 2014, pages 6-7), both individuals who I consider friends and in whom I have great respect, regarding the contrasting philosophies of these two companies.

I hope, by this letter, to add a different perspective that may add some insight to this dialogue. While we in the field of ophthalmology may not have much clout in this knock-down, drag-out struggle between two large companies, I do feel we have a stake in the outcome.

By way of clarification, I am professor, chairman, and CEO of the John A. Moran Eye Center/University of Utah School of Medicine, Salt Lake City. What I express here is solely my own opinion. While I have been a consultant for Allergan in the past, I have no direct financial interest in Allergan or Bausch + Lomb (B+L), nor have I been a consultant since January 2010.

PARTNERSHIP IN RESEARCH

What I have helped to develop recently is a partnership between Allergan and our Center for Translational Medicine under the able guidance of Gregory Hageman, PhD. The focus of this partnership is the identification of pathways and targets for age-related macular degeneration (AMD), a leading cause of irreversible vision loss worldwide.

We recruited Dr. Hagemen in 2009 because of his expertise in the field of causal biological processes that lead to the development of AMD. The driving desire on both our parts was to come up with a more efficient and economical model of getting scientific breakthroughs into the marketplace.

Dr. Hageman had just finished a disappointing experience with a start-up company that had raised a lot of venture capital (VC), and is aware of the shortcomings of university scientists trying to innovate using the "start-up company model."

This common failure has been called "The Valley of Death," and the purpose of this letter is not to detail the reasons why this process is so inefficient and ineffective. Suffice it to say, Dr. Hageman and I felt that an approach more driven by the science in the early phase and then partnering with expertise at the appropriate time to seamlessly work toward approved treatments was worth a new look.

PERFECT PARTNERSHIP

Dr. Hageman came to us with a large National Institute of Health (NIH) R-24 grant that provided money to specifically translate his AMD research toward the development of treatment modalities. We built a large team, used great advisors, and ran with all resources we could muster to locate and protect novel pathways at the core of genetic risk for AMD.

> 'This loss of (research) expertise . . . is an international tragedy of epic proportions.'
>
> — Randall J. Olson, MD

When we felt the process was mature enough, we looked at multiple potential partners in both the VC and pharmaceutical company arenas. It soon was clear to us that the perfect partner was Allergan because of its willingness to invest in, and work collaboratively with, our outstanding research team.

The contracting was not easy because we wanted a seamless arrangement based on milestones and pre-arranged royalties, so that all in the partnership were all in, and no one had a reason to hold their cards to their chest. This partnership was signed at the end of 2013 and the result has been an absolute wonder to behold.

Because of our access to abundant and rigorously characterized patient and tissue samples, and other robust resources, we can contribute to the discovery process in ways that the pharmaceutical industry typically cannot. When it comes to selecting an appropriate druggable target, then perfecting and developing the best therapeutic modality for that target, it is clear the Allergan team has the resources and expertise to run circles around us, and have shown this definitively to be the case in the few months we have worked together. What a fantastic partnership!

We are excited for the future development of novel treatments for this devastating disease that will likely derive from this partnership. Moreover, we feel a strong case will be made in the future, if we succeed, that our decisions have created a much more efficient and less costly approach to drug development.

What I can say further is that the retinal research team at Allergan is the finest such group in industry in the world today! Sadly, they have no illusions that if Valeant were successful in their takeover bid that all of their jobs are most certainly at risk.

In fact by Valeant's own claims, over 80% of the Allergan research budget would be eliminated and what would be left would largely be expertise in late-stage clinical trials. This is an elimination of research dollars larger than the entire budget of the National Eye Institute! This loss of expertise to the field of ophthalmology and the long-term loss to all those individuals losing vision, should Valeant be successful, is an international tragedy of epic proportions, in my opinion.

WHERE'S THE EXPERTISE?

Even if Valeant choses to maintain our partnership, where would the expertise be that is the very basis of our dynamic and productive partnership? Clearly not likely to be a component of the Valeant model, where most of the research budget will be converted to debt financing.

While no one can predict the future, I personally know when Valeant took over B+L, I was told that Valeant was interested in re-

Continues on page 8 : **R&D funding**

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CATALYS® Precision Laser System
INDICATIONS: The CATALYS® System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single-plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

CONTRAINDICATIONS: Should not be used in patients with corneal ring and/or inlay implants, severe corneal opacities, corneal abnormalities, significant corneal edema or diminished aqueous clarity that obscures OCT imaging of the anterior lens capsule, patients younger than 22 years of age, descemetocele with impending corneal rupture, and any contraindications to cataract surgery. **ADVERSE EFFECTS:** Complications include mild Petechiae and subconjunctival hemorrhage due to vacuum pressure of the LIQUID OPTICS Interface suction ring. Potential complications and adverse events include those generally associated with the performance of capsulotomy and lens fragmentation, or creation of a partial-thickness or full-thickness cut or incision of the cornea. **CAUTION:** Should be used only by qualified physicians who have extensive knowledge of the use of this device and have been trained and certified by Abbott Medical Optics/OptiMedica.

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INDICATIONS: The WHITESTAR SIGNATURE® System incorporating FUSION® Fluidics is a modular ophthalmic microsurgical system that facilitates anterior segment (cataract) ophthalmic surgery. The modular design allows the users to configure the system to meet their surgical requirements. **WARNINGS:** Risks and complications of cataract surgery may include broken ocular capsule or corneal burn. This device is only to be used by a trained licensed physician.

1. Conrad-Hengerer et al. *J Cat Refract Surg.* 2012; Conrad-Hengerer et al, JCRS 2012; 38(11): 1888-94.
2. Fabian E et al. New Phaco Fluidics Control: Case to Prevent Surge. Presented at ESCRS, Sept 2006, London, U.K.

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R&D FUNDING

(Continued from page 6)

search with an 18-month approval window, which by definition would be after FDA phase II clinical trials. Is there roughly a billion dollars of VC money ready to fill this gap (the amount of research dollars Valeant has said they would cut in its acquisition of Allergan)?

In fact, VCs are increasingly less interested in drug development in a world where software and device development is so much easier and more lucrative. With the overall NIH budget down 20% in inflation-adjusted dollars, the NIH grant success level at historic lows, and industry increasingly taking the short-term view of the need to invest in product development, as exemplified by Valeant's approach to research, I see a dismal future for vision scientists and for patients suffering with vision loss if these trends continue.

Sadly, all indications are that they are only getting worse. So, is this an atmosphere where the best and brightest are willing to start a career either in academic or industry basic bioscience?

I get it, that from a short-term view, industry has a hard time showing that investment in core research discovery enhances quarterly earnings. Allergan has been a refreshing exception. Just read Allergan CEO David Pyott's letter to shareholders in its annual report last spring, just before Valeant's takeover bid.

LONG-TERM VIEWPOINT

Pyott vowed to increase the investment in R&D in both absolute terms and as a percentage of company revenue because he knows Allergan's success with so many of its top products, as well as its deep portfolio, is the result of this long-term view.

Sadly, this investment is the reason Allergan has become such a tempting takeover target. It is ironic that the very willingness to take this approach may be the very reason that an incredibly talented research and development team could be wiped out.

My father's first job after receiving his doctorate degree was with a basic research think tank at Shell Oil Co. in Emeryville, CA. At that time, Shell, Bell, and GE labs were among the most prestigious places to work in science in the world. These operations are all gone today!

We, as a country, have dramatically decreased the percentage of our gross national product invested in basic research and it is naive to think we will not pay the price down the road.

While Valeant's hostile takeover bid of Allergan is but one example of this trend, all of us in the vision community have a personal stake in its outcome, in my estimation.

I view the alarming trend of short-term thinking on the part of Wall Street and our federal government as a major concern for our country's fiscal health and for our patient's well-being.

Respectfully submitted,
Randall J. Olson, MD

What's Trending

See what the ophthalmic community is reading on *OphthalmologyTimes.com*

1. **We [ophthalmologists] are the 99%!**
   http://bit.ly/1v1nndN
2. **Promoting ophthalmic practice through social media made easy**
   http://bit.ly/1mZrZOT
3. **Is MRSA testing and prophylaxis a worthwhile approach?**
   http://bit.ly/1nS520X
4. **Earlier glaucoma detection: Study finds progress, but at very slow rate**
   http://bit.ly/1x31713

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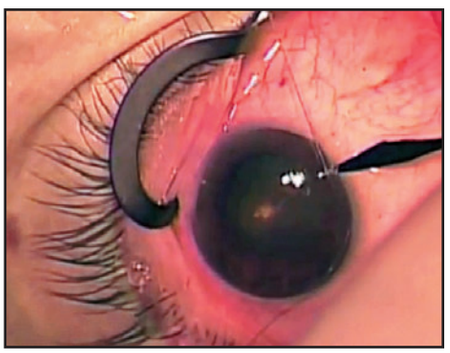

The ab interno procedure is demonstrated. Go to **http://bit.ly/1psspl9**

(Video courtesy of Davinder S. Grover, MD)

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Survey Recap

Ophthalmology Times asked: When deciding upon which product to use or prescribe in your practice, upon which source of information do you most rely?

- 48% Peer-reviewed literature
- 24% Presentations at scientific CME meetings
- 0% Information presented at company-sponsored speaker's bureau events
- 14% Experience of colleagues
- 5% Information provided by local sales representatives
- 10% Other

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Glaucoma 360° unites philanthropy, industry, CME

All-encompassing meeting focuses on latest research and therapies for this eye disease

By Beth Thomas Hertz

SAN FRANCISCO ::

The organizers for Glaucoma 360° here are promising that the fourth installment of this meeting, set for Feb. 5 to 7, 2015, will be even better than those held in the past 3 years.

"This meeting has come of age," said Tom Brunner, president and chief executive officer of the Glaucoma Research Foundation, which is overseeing the meeting. *Ophthalmology Times* is a sponsor of the event.


Dr. Iwach

"It is now the most widely known glaucoma meeting of its type and has become the meeting to attend," Brunner added.

Andrew Iwach, MD, a glaucoma practitioner in the San Francisco area and chairman of the Board of the Glaucoma Research Foundation who co-founded and co-chairs the event with Adrienne Graves, PhD, explained that the meeting is called Glaucoma 360° because it is all-encompassing.

"It combines a philanthropic gala, an event about the latest that is going on in industry, and a half-day of CME," he said. "It really is a one-of-a-kind event."

GLAUCOMA RESEARCH FOUNDATION
GLAUCOMA 360

FOR MORE DETAILS
about Glaucoma 360° visit
http://www.glaucoma360.org.

ANNUAL GALA

The meeting begins Thursday, Feb. 5, with the Glaucoma 360° Annual Gala. The annual fundraising benefit supports the Glaucoma Research Foundation's mission to fund innovative research and provide education and support for glaucoma patients and their caregivers. Individual tickets are $395 for this black-tie-preferred event at the Palace Hotel in downtown San Francisco.


Dr. Graves

This is the 9th year the Gala has been held. At the Gala, Dr. Graves will be honored with the Catalyst Award for her many contributions to ophthalmology. Attendees typically include philanthropists, scientists, industry leaders, and others, Brunner said. "Everyone who has an interest in preventing vision loss from glaucoma will be there."

Dr. Iwach called it a fun, relaxing evening.

"It's a great opportunity to reflect on the challenges of caring for glaucoma as well as to celebrate how far we've come, and to raise money for more research," he said.

NEW HORIZONS FORUM

The "New Horizons Forum," set for Friday, Feb. 6, will be a full day of presentations, panels and discussions featuring CEOs from start-up companies, industry executives, ophthalmic leaders, venture capitalists, and the FDA.

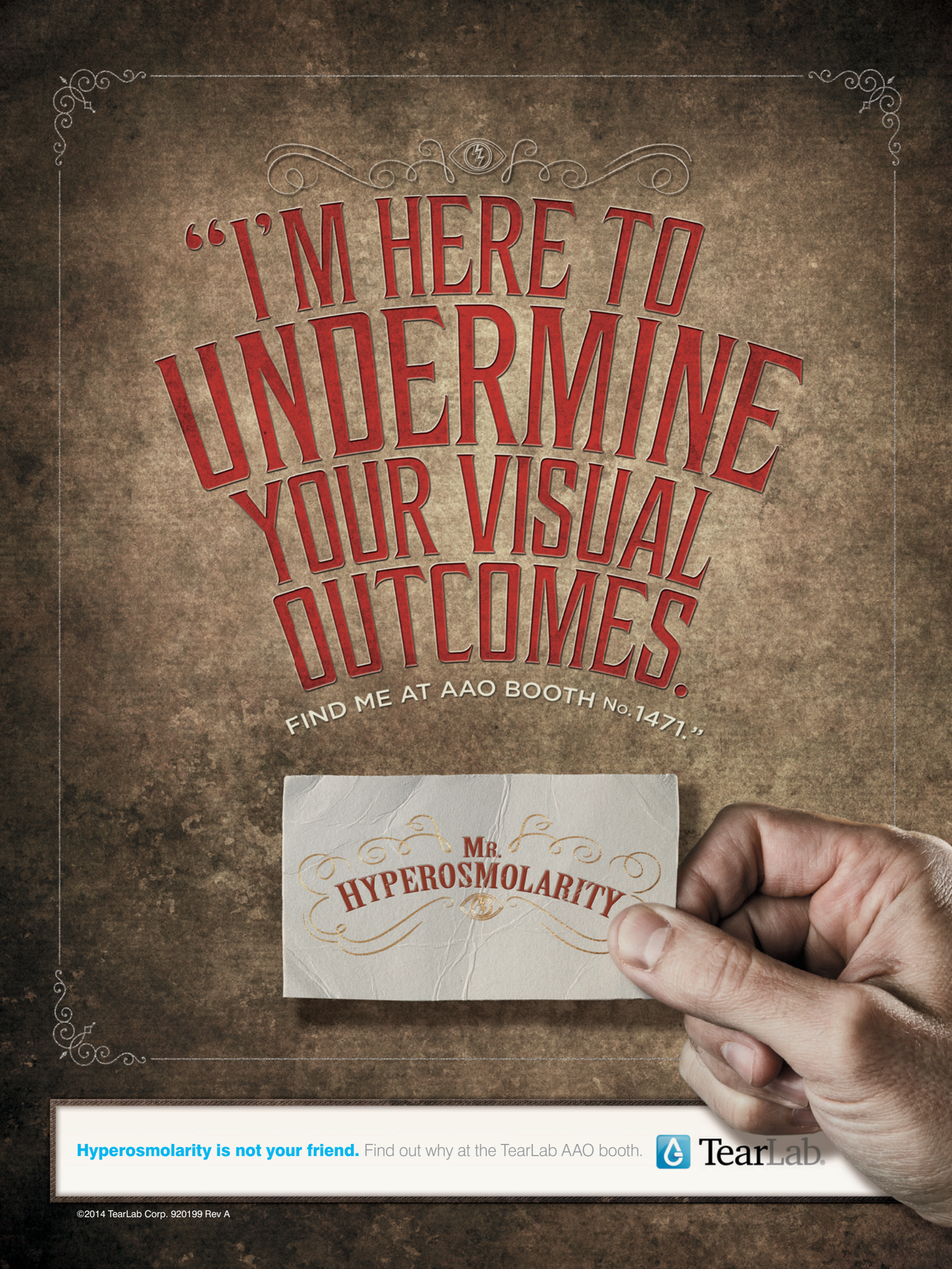
This gathering unites these leaders with the goal of speeding the translation of new ideas to improved therapies for glaucoma patients, Dr. Iwach said.

"It lets ophthalmologists see what is in the pipeline and what new ideas are out there," he said. "It also exposes people with ideas to companies that need study sites and participants. It can help clinicians get into clinical research."

Brunner calls this day "the centerpiece of Glaucoma 360°."

"We are so excited that this meeting has become well-enough known that we couldn't invite all the companies that wanted to present," he said. "This speaks to the

Continues on page 12 : **Glaucoma 360°**



Poll: Attitudinal survey of minority populations on eye and vision health

Many Americans rate losing eyesight as having greatest impact; underscore funding research

By Kathryn Foxhall

WASHINGTON, DC ::

UPON LEARNING the federal government spends on average $2.10 annually per person on eye and vision research, many Americans said this amount of spending is not enough, according to a recent public opinion poll.

Of non-Hispanic White Americans, 47% said this monetary amount is not enough; 25% said it is enough; and a full 23% were not sure. Among African-Americans, 51% said it is not enough. Fifty percent of Hispanics and 35% of Asians agreed.

The poll—conducted online in August 2014 for Research!America and the Alliance for Eye and Vision Research (AEVR) and supported by Research to Prevent Blindness—also showed about one-half of Americans said that on a scale of one to 10 losing their eyesight would rate a 10 in terms of impact on their lives.

AEVR Executive Director James Jorkasky said the study is the most rigorous to date that reflects minority populations and their attitudes about vision and vision loss.

Neil Bressler, MD, chief of the Retina Division, Wilmer Eye Institute, Johns Hopkins University of Medicine, Baltimore, said the results were striking because they show the high value that people place on their sight extends across ethnic groups.

TAKE-HOME

- ***A recent national public opinion poll reflects racial and ethnic populations and their attitudes about vision and vision loss.***

CHALLENGES WITH FUNDING RESTRAINTS

The groups presented the research at a Washington, DC press conference in hope of getting federal funding increases this year for the National Eye Institute (NEI). But on the same day Congress finished a "Continuing Resolution" that flat funds most government functions at least through Dec. 11. The fiscal year 2015 began Oct. 1 and a new annual budget was supposed to be in place by then.

AEVR's Jorkasky said because the continuing resolution mandates new funding for Ebola that amount must be taken from other efforts.

"This translates to an annualized cut of $370,000 to the National Eye Institute's (NEI) FY2014 operating budget of $673.5 million, which is about the current $400,000 value of one investigator-initiated grant (R01)," he said.

The National Alliance for Eye and Vision Research gave written testimony in the Congressional appropriations hearings this year, saying: "NEI has lost 25% of its purchasing power since FY2003. The FY2013 sequester cut has already resulted in NEI awarding 30 fewer grants…."

In comparison, he estimated that private funding for eye and vision research is about $50 to $60 million per year, aside from funding raised by ophthalmology departments and

Continues on page 14 : **National poll**

GLAUCOMA 360°

(Continued from page 10)

fact that there is a lot going on in this field and the right people are at this meeting."

Plans for Friday's event include the Opening Keynote Address, "Opportunities and Challenges for Innovation in Glaucoma," by Paul P. Lee, MD, JD, director of the W.K. Kellogg Eye Center, University of Michigan. Many presentations and discussions about new drugs and devices will follow, as well as sessions on IOP monitoring, funding, and regulatory updates

"People like that this meeting is small enough that you can really talk with the experts who are there," Brunner said. "With several breaks, a luncheon, and a reception, networking is a key part."

HALF DAY OF CME

On Saturday, Feb. 7, the Glaucoma Symposium CME event will be held. In its 19th year, this symposium for clinicians highlights the latest advances in glaucoma management, medications, and surgical technique. The target audience is practicing ophthalmologists, ophthalmology residents, and fellows.

Dr. Iwach noted that more than 400 ophthalmologists attended this day last year.

"The content is very clinically based and the faculty is truly stellar. We ask all speakers to give the audience clinical pearls that they can put into practice next week in their office, and they deliver," he said. "We know time is so precious for doctors and we are committed to quickly giving them ideas that are useful."

Dr. Lee also will be the keynote speaker on Saturday. His topic will be "Improving Patient Outcomes: Combining Science and Art."

Others topics to be covered include Glaucoma: Managing the Odds; Complexities Encountered with Cataract Surgery in Glaucoma Patients; Glaucoma Neuroprotection; New Surgical Devices and Procedures; and Stem Cells and Glaucoma: Fact or Fiction?

The Glaucoma Symposium CME is complimentary but advance registration is required.

WORTH ATTENDING

Dr. Iwach said that all three events are worth attending, but encouraged ophthalmologists to come, even if they can't stay the whole time.

"There is a lot going on, plus it's a beautiful time to be in San Francisco," he said. "We have left Saturday afternoon free, so they can go explore the wine country at a time of year when it is not so crowded, or visit any of the other great museums or activities in the Bay Area. ■

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NATIONAL POLL

(Continued from page 12)

schools or colleges of optometry—the amount for which would be difficult to estimate, he said.

Paul Sieving, MD, PhD, NEI director, said, "The outcome of federal and private philanthropy in investing in research over the past half century have produced real results," a message the vision community needs to get out to the nation.

James Tsai, MD, president of the New York Eye and Ear Infirmary of Mount Sinai, argued that with advances including the human genome project and new information from neurosciences, "now is not the time to reduce the investment, but to increase the investment to really take advantage of the hard work that has already been done."

The funding restraints are happening while the burden of vision problems is growing larger, due in great part to the aging of the baby boomers, AEVR said.

Many people are not aware of that, according to the poll. Asked how much health-care costs from eye disorders will change by the year 2050, the proportion of respondents who say they will "increase significantly" ranged from 20% to 32% across ethnic groups.

Meantime, the poll also showed that large majorities of Americans in various ethnic groups—79% to 83%—say they feel it's very important or somewhat important that the nation support research on prevention and treatment for eye and vision disorders.

KNOWLEDGE GAPS

The poll also shows significant gaps in knowledge about eye diseases and sizable differences in that knowledge among ethnic groups. When asked about cataract, glaucoma, diabetic retinopathy or diabetic eye disease, and age-related macular degeneration (AMD), 22% to 35% of people in the different ethnic groups said they had heard of none of these conditions.

Fifty-nine percent of non-Hispanic Whites had heard of AMD, but that proportion ranged from 33% to 37% for Asian, Hispanic, and African-American people.

Of those four conditions, the least recognized was diabetic retinopathy or diabetic eye disease. Knowledge of it ranged from 27% to 41% across the ethnic groups.

IDENTIFYING RISK FACTORS

Large majorities of 70% to 80% strongly agreed or somewhat agreed with the idea that exposure to excessive sunlight or ultraviolet radiation is associated with greater risk of eye disease.

In addition, 42% to 57% of people strongly or somewhat agreed that obesity is a risk factor for eye disease and 48% to 62% recognized smoking as a risk, according to the poll.

Other findings showed that about half of respondents said they had health insurance for routine eye exams or glasses. But 34% to 42% said they never had eye exams or had them less often than they would like because they lacked coverage.

About half of people in all ethnic groups said they would be very likely or somewhat likely to participate in a clinical trial if their healthcare provider recommended it. ■

Sniffing up the wrong tree

Intranasal abuse of dexmethylphenidate can lead to neurotrophic keratopathy

By Bradley L. Shoss, MD, *Special to* Ophthalmology Times

Editor's Note: Ophthalmology Times *is pleased to announce Bradley Shoss, MD, of Washington University in St. Louis, as the winner of the publication's 2014 Resident Writer's Award Program, sponsored by Allergan. Dr. Shoss' winning submission is featured here.*

The Ophthalmology Times *Resident Writer's Award Program is a unique recognition opportunity designed to promote excellence in Ocular Surface Disease education. It was created to acknowledge outstanding case identification and written presentation skills in ophthalmology residents.*

The second place winner is Seanna Grob, MD, of the Massachusetts Eye and Ear Infirmary at Harvard University with her entry, "A Pharmacological Approach to Dry Eye Syndrome in a Case of Graft-Versus-Host Disease (GVHD)."

The third place winner is Evan Warner, MD, of the University of Wisconsin, with his entry, "Not Just Dry Eyes."

To read all of the case study submissions in this year's Ophthalmology Times *Resident Writer's Award Program, visit* ***http://bit.ly/1tAgVVy.***

A 37-YEAR-OLD Caucasian male was referred from an outside provider for severe bilateral dry eye disease and a new corneal ulcer in the left eye.

On initial exam at Washington University, best-corrected visual acuity (BCVA) measured 20/50 in the right eye and 20/60 in the left eye. Biomicroscopic exam revealed marked diffuse superficial keratopathy in both eyes accompanied by multiple areas of concern for ulceration.

Ocular surface cultures were obtained and the patient's antibiotic regimen was adjusted to hourly dosing of topical moxifloxacin. The etiology of the keratopathy remained unclear, although there was suspicion that it might be related to a Vitamin A deficiency given this patient's history of celiac disease and alcohol abuse. Subsequent workup for this proved to be negative.

At a later office visit, however, the patient revealed regular intranasal dexmethylphenidate (Focalin) abuse for many years. Based on the presentation of his neurotrophic ulcer combined with this social history, the diagnosis of a pharmacologic-induced neurotrophic keratopathy was made.

HISTORY

The patient presented initially to an outside provider where he was diagnosed with filamentary keratitis and dry eye syndrome.

In addition to bandage contact lenses, the patient was treated with a combination of a topical antihistamine medication, two different antibiotic and steroid combination medications, as well as preservative-free artificial tears.

After 5 weeks of aggressive therapy, the patient returned with worsening of his blurry vision, tearing, and photophobia.

Repeat exam showed new corneal ulceration in the left eye. At that time, the patient was urgently referred to the ophthalmology service at Washington University in St. Louis, MO. His past ocular history was only significant for dry eye syndrome, first noted about 2.5 years ago. His past medical history included bipolar disorder, alcohol and substance abuse, attention deficit hyperactivity disorder, and celiac disease.

EXAMINATION, MICROBIOLOGY

On initial examination, BCVA was 20/50 in the right eye and 20/60 in the left eye. There was bilateral diffuse lid edema with periocular erythema, and moderate injection of the conjunctival vessels bilaterally.

Severe epithelial keratopathy was seen bilaterally with multiple foci of stromal infiltrates accompanied by overlying epithelial defects. The largest epithelial defect was found near 10 o'clock in the peripheral cornea of the left eye, measuring 2.8 mm horizontally by 2.0 mm vertically. This particular ulcer was oval-shaped with rolled edges and had a dense infiltrate centrally. Mild stromal thinning was noted, with residual thickness estimated at 90% NST (normal stromal thickness).

On presentation to Washington University, several microbiology cultures were obtained via ocular swab. The bacterial culture eventually demonstrated a rare growth of vancomycin-resistant enterococcus. Overall, the clinical appearance seemed most consistent with a neurotrophic ulcer and secondary bacterial keratitis.

The posterior segment was normal in both eyes.

DISCUSSION AND DIAGNOSIS

A worsening bilateral keratopathy that appears refractory to medical therapy can give a confusing and complicated picture. This was especially puzzling in our patient given his relative lack of past ocular history.

This case study demonstrates how social history can make a significant role in making the correct diagnosis. While our initial differential diagnosis included atypical infectious keratitis, neurotrophic keratopathy, topical anesthetic abuse, and vitamin A deficiency, the patient's admission of chronic intranasal dexmethylphenidate (Focalin) abuse in the context of his clinical picture certainly helped to make the diagnosis. Corneal sensation testing confirmed bilateral hypesthesia, which was consistent with a neurotrophic etiology.

'This case study demonstrates how social history can make a significant role in making the correct diagnosis.'

— Bradley L. Shoss, MD

Dexmethylphenidate is a stimulant routinely used in the treatment of ADHD. It actively stimulates the noradrenergic and dopaminergic pathways. When abused intranasally, effects are similar to amphetamines and crack cocaine.

Continues on page 16 : **Resident writer**

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RESIDENT WRITER

(Continued from page 15)

In addition, dosages associated with intranasal abuse can far exceed the typical prescribing range.[1] In the cornea, prior work has demonstrated that sensory and sympathetic nerves serve an essential role in the maintenance and nourishment of the corneal epithelium. Consequently, sustained damage to the neural network impairs the neurogenic support of the cornea and promotes neural apoptosis.[2]

In methylphenidate abuse, it is suspected that these stimulants caused irreversible damage to the dopamine and serotonin receptors, leading to neurotoxicity and a subsequent neurotrophic keratopathy.

In support of this, Gozil et al. demonstrated a dose-dependent toxicity of the corneal epithelium with oral administration of methylphenidate seen in a rat model.[3]

A review of the literature found several case reports and series with keratopathy related to cocaine abuse, also termed "crack keratopathy," or "crack eye syndrome." Keratitis has also been reported in methamphetamine abusers. Interestingly, many of these were accompanied by atypical bacterial infections that did not respond to aggressive antimicrobial therapy.[4]

This patient's culture demonstrated vancomycin-resistant enterococcus with sensitivity only to linezolid and gentamicin. He was started on fortified gentamicin drops but these were discontinued after just a few days due to patient discomfort from epithelial toxicity. A temporary tarsorrhaphy was also performed to assist healing.

Eventually, his clinical picture stabilized and his epithelial defects healed.

CONCLUSIONS

In patients with atypical corneal defects or ulceration, eye care providers must remember to explore social history. Abuse of certain commonly prescribed medications, particularly with dosages higher than recommended, can result in toxic effects not usually encountered.

While this patient's initial diagnosis at time of referral was dry eye disease, a later diagnosis of pharmacologically-induced neurotrophic keratopathy was made. Establishing the most specific diagnosis can assist greatly in clinical management of these complicated patients. ■

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Positive results for dry eye therapy

By Rose Schneider; *Content Specialist,* Ophthalmology Times

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In slit lamp examinations, no subjects revealed any clinically abnormal signs of the anterior and posterior eye structures. With dosing of up to 4 drops per eye per day, no systemic levels of cyclosporin were detected after any dose or at any time point when using a highly sensitive assay with a LLOQ as low as 0.1 ng/ml. ■

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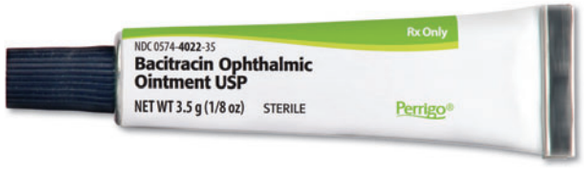

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Novel pedicle flap: Long-term solution for complex tube erosions

Technique allows for preservation of tube, IOP control; preserves adjacent quadrants of conjunctiva

By Cheryl Guttman Krader; *Reviewed by Davinder Grover, MD, MPH*

DALLAS :: Use of a forniceal conjunctival pedicle flap offers a safe and effective method to repair glaucoma drainage device tube erosions in eyes with extensively scarred conjunctiva precluding direct conjunctival closure, according to the findings of a retrospective study.

The technique was first tried with success more than a decade ago by James Merritt MD, an oculoplastic surgeon, and glaucoma specialists, Ronald L. Fellman, MD and David Godfrey, MD, in patients with severe ocular surface disease whose conjunctival defect was unrepairable using other standard techniques [Arch Ophthalmol. 2003;121:1772-1775]. They reasoned that the pedicle flap would support the viability of the tissue overlying the tube because it maintains a vascular supply at its base. Over the ensuing years, they continued to use the technique when confronted with similar challenging cases.

LONG-TERM OUTCOMES

Anticipating that the recent growth in tube surgeries will be accompanied by an increase in the number of cases of tube erosions, the group decided to review long-term outcomes using the pedicle flap repair and published their results [JAMA Ophthalmol. 2013;131:662-666].

They identified 15 eyes of 14 consecutive patients. The patients had a mean age of about 73 years and one-third had diabetes. Almost two-thirds of the patients were functionally monocular and 80% had a history of at least four prior incisional ocular surgeries.

The pedicle flap was interpolated onto a corneal patch in eight eyes while pericardium was used for the other seven repairs. With a mean follow-up of about 4 years after the repair procedure (range 3 to 156 months), all patients were free from recurrent erosions and maintained IOP control without any change in number of glaucoma medications.

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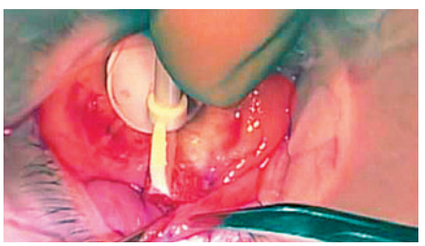

VIDEO To watch the technique, narrated by Dr. Grover, go to **http://bit.ly/1oRA3gi**

(Images/video courtesy of Davinder Grover, MD, MPH)

Dr. Grover

"Recurrent glaucoma tube erosion has been reported to occur in almost 50% of eyes after primary surgical repair," said Davinder Grover, MD, MPH, lead author of the published paper and a glaucoma specialist, Glaucoma Associates of Texas, Dallas. "The risk is even higher in eyes of patients with diabetes or uveitis, and often management of recurrent erosion necessitates removal of the drainage device.

"Our experience shows that the pedicle flap repair provides a good long-term solution," Dr. Grover said. "It allows for preservation of the tube and ongoing IOP control, and it also preserves adjacent quadrants of conjunctiva in case they become needed for a future glaucoma surgery."

The pedicle flap is dissected in a 3:1 ratio of length to width. It can be harvested from either the superior or inferior fornix, although it is sometimes necessary to split the eyelid vertically to the apex of the tarsus to achieve adequate exposure and access to the forniceal

Continues on page 21 : ***Pedicle flap***

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(phenylephrine and ketorolac injection) 1% / 0.3%

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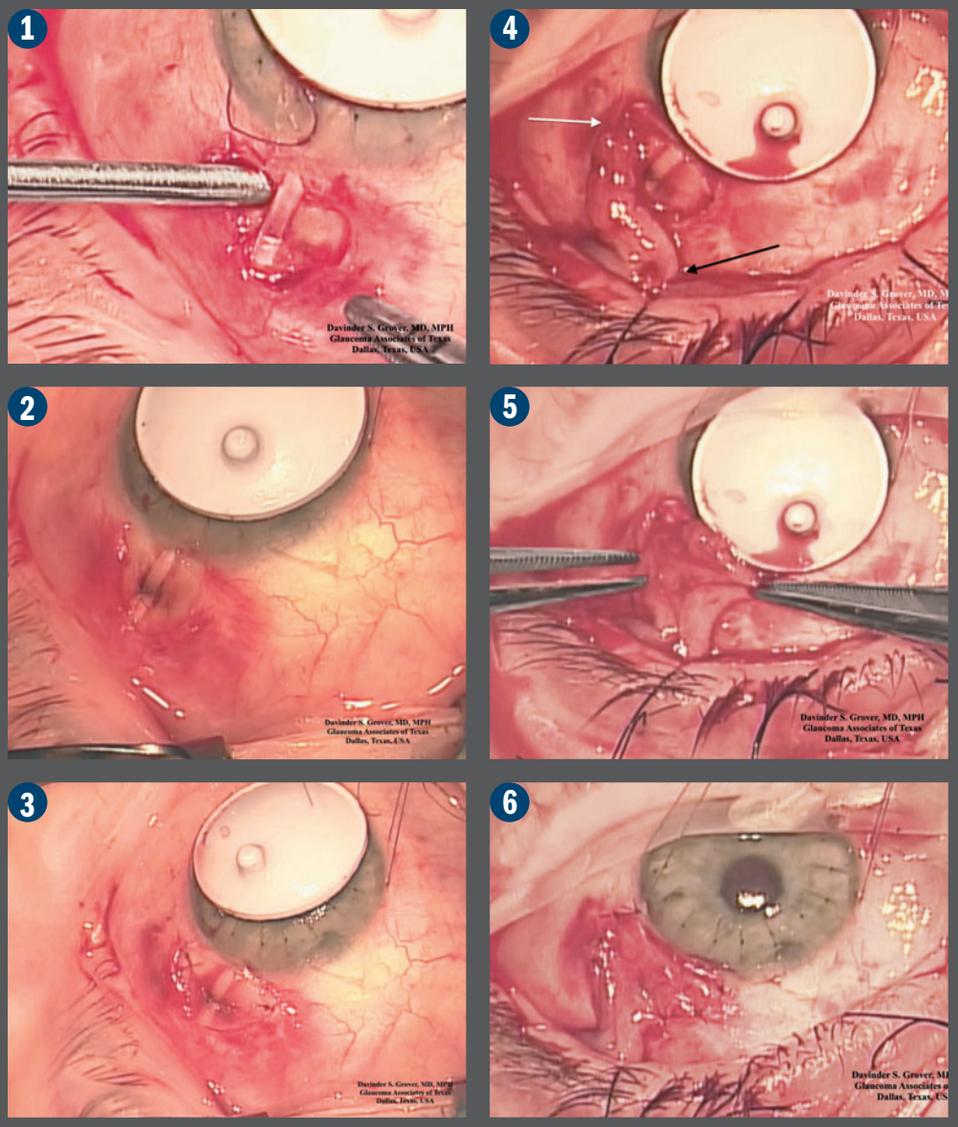
Intraoperative View of Pedicle Flap Technique



INTRAOP 1: Photo demonstrates the importance of using cautery to destroy the surrounding epithelial tissue. **INTRAOP 2:** Photo demonstrates the use of a 10.0 nylon mattress suture for stabilization of the tube to the globe. **INTRAOP 3:** Photo demonstrates a partial thickness piece of donor corneal tissue secured over the tube, protecting the tube from repeat erosion. **INTRAOP 4:** Photo demonstrates the pedicle flap after it has been created. The black arrow represents the base of the flap. The white arrow points to the distal tip of the flap, which will later be sutured into place. **INTRAOP 5:** Photo demonstrates the distal part of the flap being moved into position over the previously placed corneal patch graft. **INTRAOP 6:** Photo demonstrates the distal end of the pedicle flap sutured into position.

PREOPERATIVE

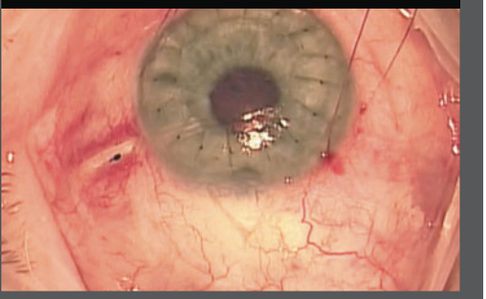
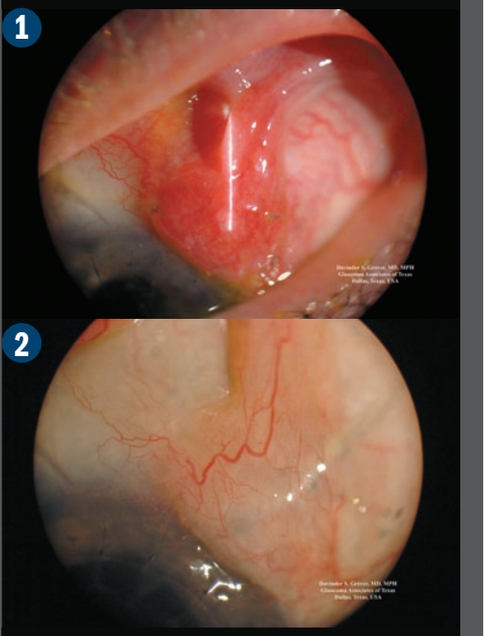


Photo demonstrates tube erosion. Note the previous scarred trabeculectomy site at 12 o'clock and the tube erosion in the superior-temporal quadrant.

POSTOPERATIVE



POSTOP 1: Slit lamp photograph of the pedicle flap on postoperative day 1. **POSTOP 2:** Slit lamp photograph of the pedicle flap on postoperative year 1. Note that the pedicle flap is flat. A symblepharon has not formed. Note the healthy vasculature that has been transfer to the area.

PEDICLE FLAP

(Continued from page 18)

conjunctiva. The need for the latter technique can be determined by performing a simple distraction test on the eyelid overlying the exposed tube.

ADDITIONAL PEARLS

"Splitting of the lid was performed in three cases in our series, and they all healed uneventfully with acceptable cosmesis," Dr. Grover said. "It is especially helpful and desirable to have an oculoplastic surgeon involved in the repair and particularly if it is necessary to perform the lid incision.

"However, some of the cases in our series were completed entirely by the glaucoma specialist when the surgeon felt the the oculoplastic surgeon was not needed," he added.

In a patient who presents with an exposed tube, Dr. Grover said surgeons should examine the eye carefully to determine the cause for the erosion and whether a simple repair is possible.

"Perhaps the tube was poorly positioned and if there is ample conjunctiva to cover it, hopefully the problem can be successfully managed by removing and redirecting the tube and then covering it with a partial thickness corneal patch and direct conjunctival closure," he said.

"However, if there is not sufficient redundancy of conjunctiva and vascular supply to the area is in question, our experience has shown a 100% success rate using the pedicle flap," Dr. Grover said. ■

DAVINDER GROVER, MD, MPH

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Dr. Grover did not indicate any proprietary interest in the subject matter.

Quest: Better patient interface design

Capsular rim morphological analyses show benefits of soft contact lens technology

By Cheryl Guttman Krader; *Reviewed by Fritz H. Hengerer, MD, PhD*

FRANKFURT, GERMANY ::

MICROSCOPIC ANALYSIS of anterior capsule specimens created during capsulotomy with a proprietary femtosecond laser system (LenSx, Alcon Laboratories) show a better profile of morphological changes using the current soft contact lens interface (SoftFit) compared with the original rigid curved contact interface, said Fritz H. Hengerer, MD, PhD.

Dr. Hengerer

In the study, 15 eyes each underwent laser capsulotomy using the two interfaces. Laser pulse-energies for the rigid and soft interface groups were 15 µJ and 5 µJ, respectively, in accordance with the manufacturer's recommended settings.

Evaluations of the anterior capsule discs with light and scanning electron microscopy showed use of the soft contact lens interface and lower pulse energy resulted in fewer tags and bridges, smoother edges, and a more regular and thinner demarcation line, explained Dr. Hengerer, assistant professor of ophthalmology, Goethe-University Frankfurt am Main, and deputy director, University Eye Clinic, Frankfurt, Germany.

"Most studies investigating use of the femtosecond laser for capsulotomy have focused on its benefits for improving predictability and precision of capsulotomy shape, size, and location or have looked at capsular bag tensile strength," he said. "Our study evaluating the microanatomical structural characteristics of the capsular specimen reveals benefits from the modification of the patient interface for the LenSx laser.

"Now, additional studies investigating the effects of changing laser pulse energy and spot size as well as information from long-term follow-up of eyes undergoing femtosecond laser capsulotomy will allow further optimization," Dr. Hengerer continued.

TAKE-HOME

- ***A morphological analysis of capsular specimens shows benefits associated with use of the current soft contact lens patient interface found on a femtosecond laser (LenSx, Alcon Laboratories).***

STUDY RESULTS

Dr. Hengerer reported that complete capsulotomy was successfully achieved in all eyes, and the mean time for the procedure was similar in the rigid and soft interface groups (2.5 and 2.7 seconds, respectively). He also noted that intraoperative visualization with the laser platform's integrated optical coherence tomography revealed visible folds in the posterior corneal surface during interface suction with the rigid interface, but not using the soft contact lens technology.

Discussing the results from the morphological analyses, Dr. Hengerer noted that tags and bridges of the capsular rim are thought to develop as a result of minor torsional movements of the eye under fixation that in turn can be affected by the design of the patient interface.

"The results of our study are consistent with a previous report by Talamo et al. that demonstrated drifting of the eye was minimized using a liquid optical immersion interface compared with a curved contact interface," he said.

Dr. Hengerer also attributed the reduction in posterior corneal folds in the soft interface group to the interface design. In addition, he noted that the folds can affect laser focusing posterior to the back of the cornea and thus raise the potential for damage to intraocular tissues. In particular, there may be a risk of iris damage in eyes with small pupils, Dr. Hengerer said.

"We still observed some straying of the laser spots using the soft contact lens interface and also a demarcation line along the cut in both groups, which we previously reported is evidence of the laser's destructive effect on surrounding tissue," he said. "However, with use of the soft interface and a lower laser pulse energy, these signs of the laser's interaction with surrounding tissue were reduced."

The study has also been published [Kohnen T, et al. *Graefes Arch Clin Exp Ophthalmol*. 2014;252:293-298]. ■

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Dr. Hengerer has no relevant financial interests to disclose.

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EXTENDED RANGE

(Continued from page 1)

tive echelletes in a multifocal that create two discrete foci.

"Typically, optics that create multiple foci or that elongate the focus suffer from some loss of image quality," Dr. Borrmann said. "However, the Symfony IOL optic compensates for that problem by incorporating a second diffractive optic technology that reduces chromatic aberration and boosts image quality."

The optics in a refractive system, including cameras, telescopes and the eye itself, all have some degree of chromatic aberration such that the focal point varies for different wavelengths of light.

For example, whereas green light focuses on the retina, the focal point is anterior to the retina for blue light and falls behind the retina for red light. Chromatic aberration causes blur that can degrade image quality and contrast, said Patricia Piers, PhD, director of IOL research and development, Abbott Medical Optics.

"The achromatic technology in the Symfony IOL corrects for the positive natural chromatic aberration of the eye by providing negative chromatic aberration just as a negative aspheric IOL design compensates for positive spherical aberration in the average cornea," Dr. Piers said.

"By correcting for the eye's positive chromatic aberration, achromatic technology enhances contrast," Dr. Piers said. "And, in combination with its aspheric optic profile, the Tecnis Symfony IOL delivers high-image quality without any effect on range of vision."

PROOF OF PERFORMANCE

An initial prospective clinical study conducted in New Zealand compared the new extended-range-of-vision IOL with the single-piece Tecnis monofocal IOL (ZCB00, Abbott Medical Optics). In that trial, 31 patients were bilaterally implanted with the new IOL and there were 10 implanted patients that received bilateral monofocal IOLs.

The results showed that binocular far UCVA was similarly excellent in the two groups. However, patients receiving the extended-range-of-vision IOL had significantly better distance-corrected intermediate (66 cm) and near (40 cm) visual acuity.

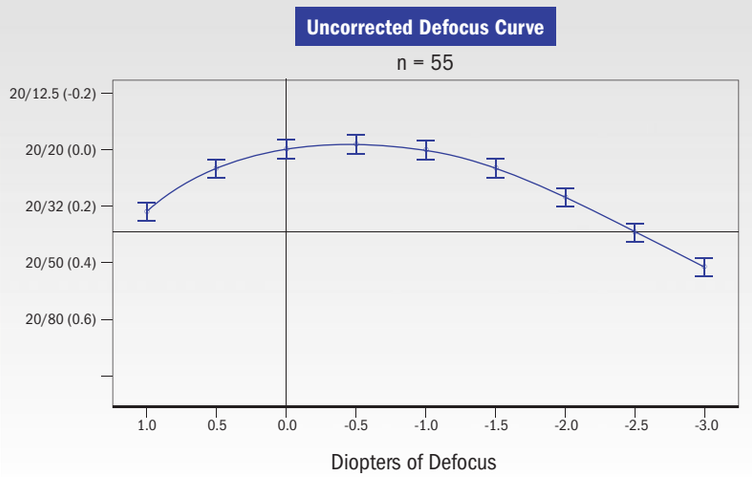
In addition, 96% of patients in the extended-range-of-vision IOL group achieved 20/25 or better intermediate UCVA compared with only 74% of controls, while 92% of patients in the new IOL group and 42% of the controls had near UCVA of 20/40 or better. The binocular defocus curve showed the new lens was associated with a statistically and clinically significant increase in depth of focus compared to the monofocal IOL.

Patients with the extended-range-of-vision IOL implanted had sustained mean visual acuity of 20/20 or better through 1.5 D of defocus and a full range of functional vision (i.e., 20/40 or better) through 2.5 D of defocus.

At the XXXII Congress of the European Society of Cataract and Refractive Surgeons (ESCRS) last month in London, Dr. Auffarth reported outcomes from an ongoing open-label prospective, multicenter trial investigating the

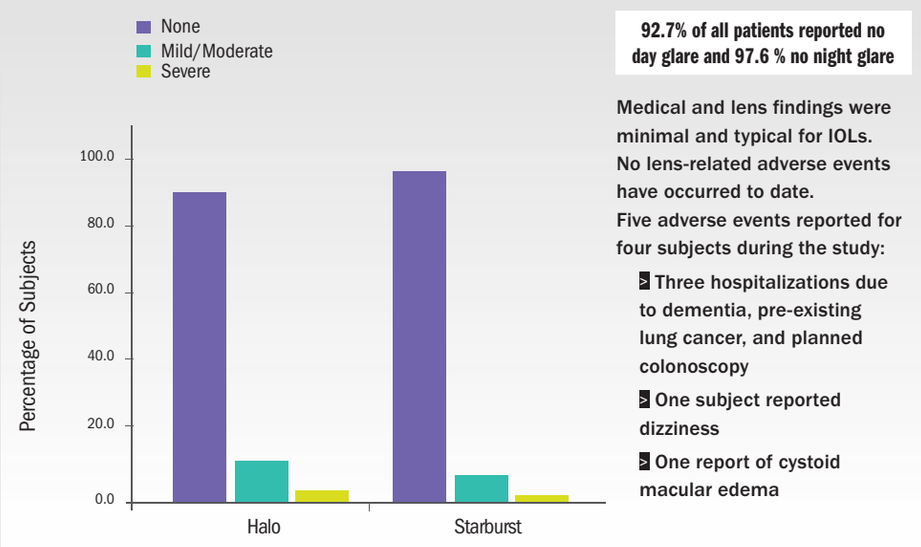
(Continues on page 26 : Outcomes)

Sustained Uncorrected Visual Acuity of 20/25 or Better over More than 1.5 D of Defocus



(FIGURE 2) Sustained uncorrected visual acuity of 20/25 or better over more than 1.5 D of defocus was achieved in a recent study.

Low Ocular Symptom Rates; No Device-Related Adverse Events



(FIGURE 3) In the study, 92.7% of all patients tested reported no day glare and 97.6% no night glare.
(Figures courtesy of Gerd U. Auffarth, MD)

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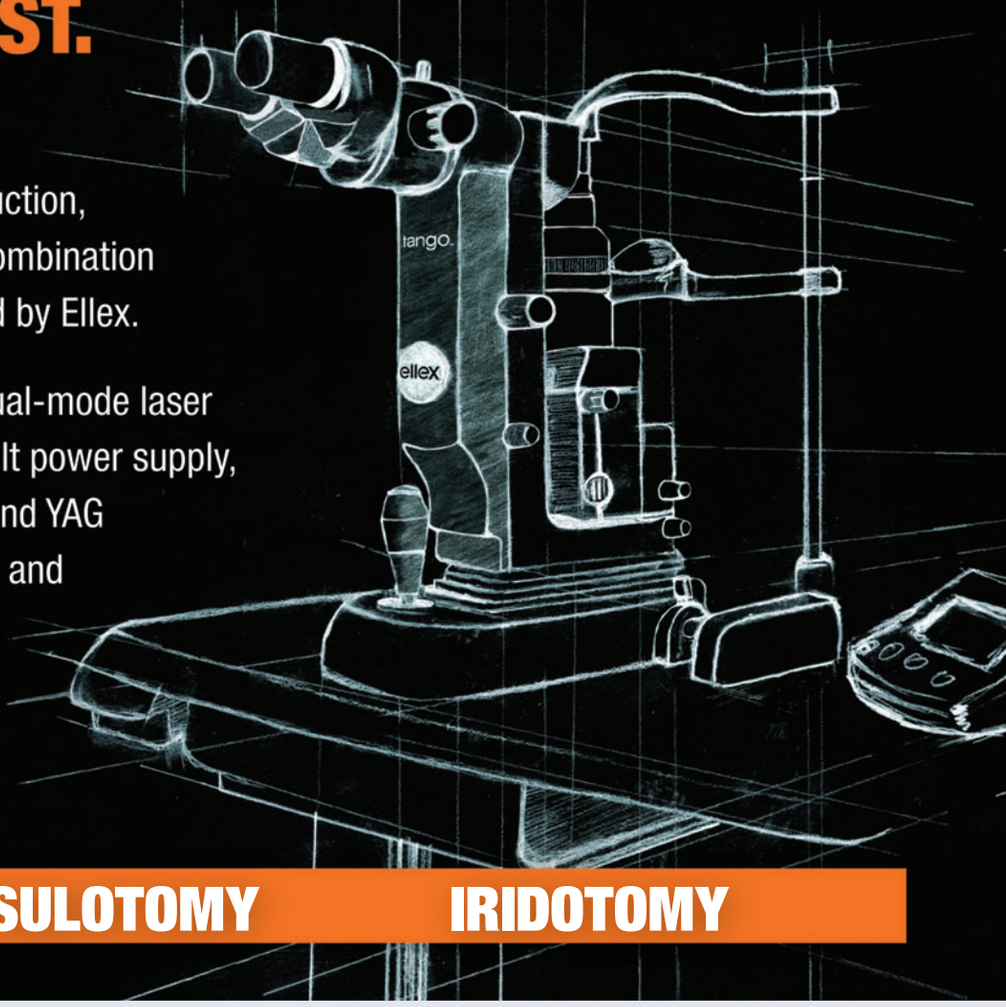

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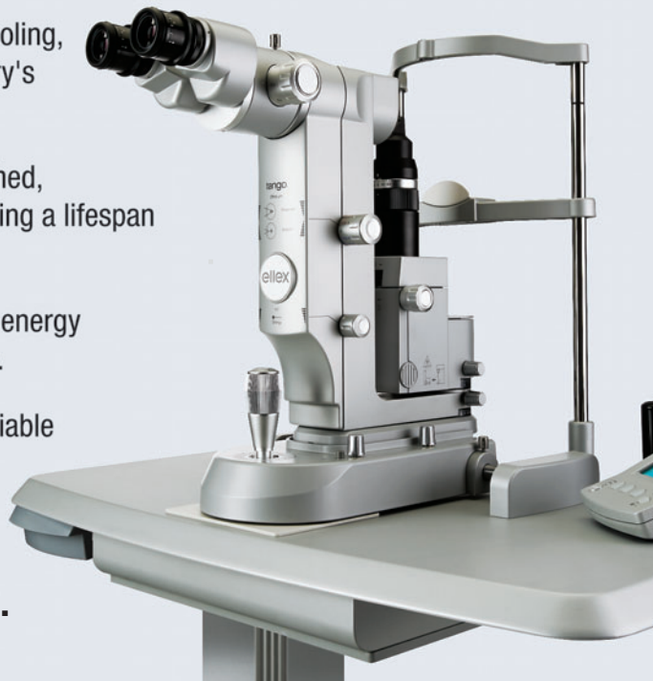

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OUTCOMES

(Continued from page 24)

extended-range-of-vision IOL. The study has a planned enrollment of 150 patients, and as of mid-September 2014, all 150 participants had been enrolled at 14 clinical sites across Europe.

The results presented by Dr. Auffarth were from 82 bilaterally implanted patients with 1-month follow-up. For the group, mean logMAR UCVA was –0.01 for far, 0.03 for intermediate, 0.18 for near (measured at 40 cm), and 0.07 for near at the patient's best distance, which was about 47 cm. The mean minimum near add for best near visual acuity at 40 cm was 1.2 D.

Overall, more than 90% of patients achieved binocular UCVA of 20/25 or better for both far and intermediate, 99% had binocular UCVA of 20/40 or better at far and intermediate, and 88% of patients were seeing at least 20/40 uncorrected at near.

Defocus curve testing highlighted the extended range of vision provided by the lens, with a sustained mean visual acuity of 20/32 or better through more than 2.0 D of defocus and of 20/40 or better through 2.5 D of defocus.

"The defocus curve established in clinical testing for this new lens is consistent with that predicted from bench data and stands in contrast to the defocus curves of traditional multifocal IOLs that feature two distinct peaks," Dr. Auffarth said.


Dr. Auffarth

"From this testing it is quite clear that the new lens provides ample uncorrected distance and intermediate visual acuity," Dr. Auffarth said.

BENEFIT OF MICRO, MONOVISION APPROACH

He noted that based on analyses of UCVA data from patients with a small interocular difference in postoperative refraction, it appears that a micromonovision approach may enhance near functional outcomes with the new lens. Patients with a refractive error ≤–0.5 D in one eye and within ±0.5 D in the fellow eye had a mean near UCVA of 20/32 and maintained excellent intermediate and far UCVA.

About 97% of patients said they were able to function comfortably without glasses for distance and intermediate vision tasks and almost three-fourths were spectacle independent for near. All but two patients said they would recommend the lens to friends and family.

Other subjective data showed the lens design met its objective for minimizing the visual disturbances associated with multifocal IOLs.

Ninety-three percent of patients reported no day glare and 98% experienced no night glare. In addition, about 90% of patients reporting experiencing no halos or starburst, and when they occurred, these symptoms were rarely severe.

These findings are consistent with data from the study in New Zealand in which the incidence and degree of difficulty with halos and glare was similar in the extended-range- of-vision IOL and monofocal IOL control groups.

"These results are very encouraging in suggesting this new lens will successfully mitigate the adverse effects associated with multifocal IOL technology," Dr. Auffarth said.

TAKE-HOME

- ***A new presbyopia-correcting IOL has a novel optic combining two complementary diffractive technologies. Results from bench and clinical testing show it provides a full range of continuous, high-quality vision, minimizes dysphotopsias, and may be more tolerant to refractive errors than multifocal IOLs.***

TOLERANCE TO REFRACTIVE ERROR

Another benefit of the new IOL is that it appears to be more tolerant than multifocal IOLs to refractive errors, both sphere and cylinder. This feature was investigated through testing in the optics laboratory of Pablo Artal, PhD, at the University of Murcia, Spain using adaptive optics vision simulation technology.

As reported by Dr. Piers at the ESCRS Congress, the study included 5 subjects and used a binocular adaptive optics vision simulator to assess high-contrast visual acuity as a function of object vergeance with SLOAN letters. The testing was done with a pupil size of 3.5 mm in white light and under monocular conditions with the subjects looking through a phase profile corresponding to the Tecnis Symfony IOL design.

The results showed that distance corrected visual acuity stayed within 1 line of peak performance over the range of vergeances from –0.5 to 1.5 D. The shape of the defocus curve was not affected by refractive errors, but rather only its position was shifted to the left or right, she reported.

"These data indicate that errors in IOL power selection of plus or minus 0.5 D at the spectacle plane will still allow for excellent distance and intermediate uncorrected visual acuity," Dr. Piers said.

"Similarly, the shape of the defocus curve was unaffected by the presence of residual astigmatism of up to 1 D, and this residual astigmatism does not significantly affect the range of object distances over which visual acuity remained within 1 line of peak performance." ■

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Dr. Auffarth is a consultant to Abbott Medical Optics and other companies that market IOLs and has received research and travel grants, lecture honoraria, and funds for research from Abbott Medical Optics and from other companies marketing IOLs.

B+L introduces handpiece for femtocataract

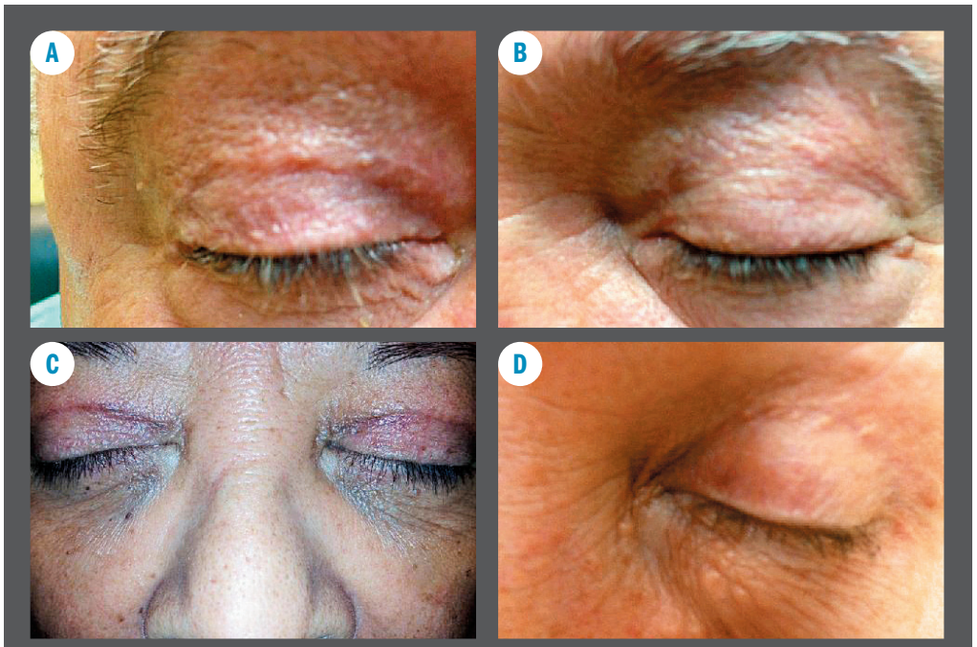
By Rose Schneider; *Content Specialist,* Ophthalmology Times

BRIDGEWATER, NJ ::
BAUSCH + LOMB has unveiled a new handpiece specifically designed for femtocataract surgery.

The disposable ZeroPhaco I/A handpiece—with either 15°or 30° bevel needle—is designed for the removal of soft cataracts following femtosecond laser fragmentation without the use of ultrasonic energy.

Pre-assembled with a standard infusion sleeve, the coaxial handpiece is designed to work with the Stellaris and Stellaris PC systems for lens removal using an I/A mode. The handpiece is used as replacement for the ultrasound phacoemulsifaction handpiece and is green-colored to avoid confusion with the I/A handpiece for cortical cleanup.

In addition to the standard incision format—for incision sizes greater than 2.4 mm—the I/A handpiece is also available for use in a MICS 2.2-mm incision as well. ■



A. Right upper eyelid, sutured, 1 month postoperative. B. Left upper eyelid, 1 month postoperative. Same patient from Figure A but with stitchless blepharoplasty using topical skin adhesive. C. Bilateral upper eyelid, stitchless blepharoplasty, 1 month postoperative. D. Left upper eyelid, sutured, 3 months postoperative. *(Images courtesy of John T. LiVecchi, MD, FACS, FSEE)*

A SURGEON'S PURSUIT OF SUTURELESS BLEPHAROPLASTY

How use of a topical skin adhesive can create a no-stitch procedure

***Plastics Pearls* By John T. LiVecchi, MD, FACS, FSEE**

Editor's note: *Ophthalmology Times is pleased to announce the return of "Plastics Pearls." The primary focus of this regularly recurring column will be on the latest innovations in oculoplastics. In this first installment, John T. LiVecchi, MD, FACS, FSEE, discusses how a stitchless blepharoplasty procedure is possible with use of a new topical skin adhesive.*

As ophthalmic surgery continues to evolve, myriad improvements have been made to small-incision cataract surgery and sutureless cataract surgery, resulting in enhanced surgical outcomes. Why not sutureless blepharoplasty?

This is the consideration I have applied to blepharoplasty and other oculoplastic procedures. If the procedure could be done faster without compromising outcomes, then why not? If the incision can be closed faster with a topical skin adhesive and also provide a microbial barrier, so much the better. Could topical skin adhesives also improve cosmesis in the ever-critical aesthetic procedure market?

These are some questions considered in a quest to improve one of the specialties' most commonly performed procedures, the blepharoplasty.

USE OF ADHESIVE

Topical skin adhesives have been around for many years, but until the advent of 2-octyl cyanoacrylate iterations, they were too brittle and exothermic for most oculoplastic procedures. That has changed with the development of a new topical skin adhesive (SurgiSeal, Adhezion Biomedical).

This adhesive is stronger, more flexible, and dries faster than other topical skin adhesives. When dry, the adhesive has the effective strength of a 5.0 suture or 10 days of healing. The adhesive also provides a waterproof microbial barrier, greatly reducing the chance of postoperative infection and eliminating the need for antibiotic ointments during the entire postoperative period. As an additional benefit of this new adhesive, the patient can shower the same day of surgery.

HISTORICAL PERSPECTIVE

Twenty years ago, I decided to use "crazy glue" in a few routine procedures performed to enhance results or aide in procedures in other ways.

For instance, when performing a dacryocystorhinostomy in conjunction with silicone intubation, there would be occasions when the patient would inadvertently and prematurely unravel or pull out the silicone stent completely from the nose. In order to prevent this, a drop of crazy glue was added to the silicone stent knot at the end of every case to solve the problem.

In another example, the glue was used as a temporary tarsorrhaphy in children who were uncooperative. The idea for this came from observing cases with children who were playing with the glue and splashed their eyelids closed. It was sometimes easier to leave the glue on the screaming kids' eyelids rather than traumatize them further—and at the same time avoid heart failure of the parents as they watched their child being pinned down by two technicians—while I was picking off the glue.

Of course, a ragged edge of the glue that may be in contact with the eye was first ruled out. I also used it on adults to save time and suturing, knowing that in about 10 days time it will be all gone on its own.

Continues on page 30 : ***Sutureless***

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SUTURELESS

(Continued from page 27)

I also liked using it for stab incisions for ptosis-sling procedures. This allowed me to be very secure and confident that the probability of an infection was close to zero with its protective barrier.

NECESSITY AS MOTHER OF INVENTION

The question arose in my mind two decades ago about whether or not to glue blepharoplasty incisions. The difference with eyelids was that they were in constant motion from blinking all day long as compared with the other sites where adhesives were used, which for the most part were relatively static.

Also, I had tried using medical grade glue that existed back then but abandoned its use for several reasons. The glue cured too lumpy from the lack of a good application process. It was too brittle and took too long to dry. In addition, the wound edges could not be seen to determine if there was proper opposition, from the thick glue lumpiness and the bleeding that occurred between the skin-glue plain.

Twenty years later, this new topical skin adhesive resolved those issues with a specific applicator unique for the use in blepharoplasty.

Upon studying the safety and efficacy claims of this adhesive, I performed an initial series of 20 sutureless blepharoplasty cases, or 40 eyes. Everything in the blepharoplasty procedure is standard procedure, until incision closure occurs.

The training required for application of the adhesive was straightforward. Though specific, it was much easier and less time consuming than suturing. It involved wound drying, wound approximation, and a two-layer application of adhesive. The first application is applied for about 30 seconds of dry time, and then the second application is applied for the final 30 seconds of dry time. In a total of about 2 minutes the closure was the equivalent of 6.0 suture or 10 days of healing.

In the initial case, two to three temporary sutures were placed at the incision site for approximation. The sutures were removed after the adhesive cured, in accordance with directions, where the temporary sutures were placed. The surgical sites were observed to have negligible wound gape and no dehiscence, resulting in sutureless blepharoplasty or no-stitch blepharoplasty.

Now, I have observed more than 100 eyes with this sutureless blepharoplasty experience and am confident in the procedure's benefit. Subsequent to the initial sutured procedure, temporary sutures have not been used as both confidence and technique have evolved. However, that it would be prudent for surgeons to use the temporary sutures until they are confident in their ability to close with this topical skin adhesive and approximate at the same time.

It is important to note that no adverse reactions or infections have been experienced, but instead good wound closure. Time is saved by using this adhesive, as opposed to placing a long running suture—with the average cost for operating room time in the $60/minute range.

With the added benefit of a microbial barrier, the chances for infection are greatly reduced.

From a patient's perspective, when asked if they had a preference of having an incision closed with surgical glue or suture, the response was almost unanimous in favor of glue. When patients are seen postoperatively the next day they have reported that they like not needing sutures removed. This adhesive comes off by itself in 5 to 10 days, as normal re-epithelialization takes place.

SUTURES A THING OF THE PAST?

In the quest for a better blepharoplasty, suture tracks are a thing of the past. Healing is probably accelerated by reducing the further inflammatory result from the insult of needles passing through with the suture and the suture itself.

Common sense is encouraged when selecting patients for stitchless blepharoplasty. Potential patient compliance and the ability to recognize early dementia-like conditions are crucial for successful outcomes.

The sutureless blepharoplasty technique involves a learning curve and some initial apprehension that is well founded. Fortunately, the adhesive had already been used on hundreds of thousands of wound-closure events—general surgery, plastic surgery, orthopedic surgery, trauma surgery, and the basic tenants for most effective wound/incision closure were well demonstrated.

It is important to note that although the blepharoplasty procedure is not changed until closure occurs, at closure the wound edges should be as dry and as blood-free as possible to ensure superior closure.

When the incision is approximated, the adhesive is applied to the length of the incision via the pen-like applicator. The surgeon goes over the incision with glue, and by virtue of the wide applicator forms a bridge of adhesive creating the bond that holds the tissue edges together. At this time the surgeon must keep the edges approximated while the adhesive cures, which is about 30 seconds for the first application.

Next, with the incision already approximated, the surgeon applies another layer of adhesive and waits about 30 seconds or when the layer of the adhesive is completed on the contralateral eyelid. At this juncture, surgical efforts are secure. Certainly, extra caution needs to be exercised regarding keeping adhesive away from eyelid margins and eyelashes, as the tissue exposed will be glued.

ATTENTION TO DETAIL

Surgeons should be conscientious that even though they have reduced time, reduced infection, and improved cosmesis, they are still performing surgery and it remains very specific. Any lack of attention to changes in a procedure can create unwanted challenges, and add time to an otherwise improved procedure.

Over the course of a 30-year ophthalmic journey and more than 25,000 oculoplastic procedures, great advances have occurred in cataract surgery, refractive surgery, and posterior segment surgery. In a quest to improve outcomes and efficiency in the oculoplastic surgery realm, it is clear that a significant advance in technique is being refined.

When selective and appropriate patients are chosen, I am confident that we have reduced the time to perform a blepharoplasty, without compromising the integrity of the incision. We have reduced the opportunity of infection, eliminated the need for antibiotic ointments postoperatively, and improved cosmesis.

Most importantly, patients are delighted with the results. ■

JOHN T. LIVECCHI, MD, FACS, FSEE, *is editor of the Plastics Pearls column and a member of Ophthalmology Times' editorial advisory board. He is assistant clinical professor of ophthalmology at Drexel University College of Medicine, Philadelphia and the University of Central Florida College of Medicine, Orlando. Dr. LiVecchi is in private practice and director of oculoplastics at the Lange Eye Institute. Dr. LiVecchi has no financial interest. Dr. LiVecchi wishes to credit Jim Simms, who helped him design the new tissue adhesive applicator.*

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Managing cases of orbital venous malformation with hybrid procedure

How endovascular operating room serves as unique setting for novel application in ophthalmology

By Lynda Charters; *Reviewed by Emmy Yuen-Mei Li, FRCS, and Hunter Kowk-lai Yuen, FCOphthHK*

HONG KONG ::

A NOVEL HYBRID procedure for treating orbital venous malformations in the endovascular operating room—requiring collaboration among a radiologist, surgeon, and ophthalmologist—seems to be safe and well controlled with real-time, high-quality surveillance to facilitate the surgical resection.

Dr. Li

Emmy Yuen-Mei Li, MD, FRCS—in describing the features in an operating theater and endovascular operating room—noted that the Queen Elizabeth Hospital in Hong Kong was established in 2011. The primary procedures performed there include diagnostic and therapeutic percutaneous vascular procedures, combined open and endovascular procedures, and abdominal aneurysmal stent grafts.

"An operating room is specifically designed and equipped with instruments for open surgery," said Dr. Li, associate consultant, Hong Kong Eye Hospital, and honorary assistant clinical professor, Department of Ophthalmology and Visual Sciences, The Chinese University of Hong Kong.

"Usually the operating room is equipped only with basic radiologic equipment, for example, a C-arm. An intervention radiology suite is specifically design for interventional radiology procedures; it may not contain instruments for open surgery and the infection control standards are not equal to those of an operating room," Dr. Li said. "However, the endovascular operating room combines the benefit of both for treating vascular lesions."

take-home

- **The management of orbital vascular lesions in the endovascular operating room appears to be safe and well controlled with real-time surveillance to facilitate the surgical resection.**

ENDOVASCULAR OPERATING ROOM BENEFITS

The endovascular operating room is a positive-pressure room in which standard sterilization procedures are followed. Available equipment includes appropriate digital subtraction fluoroscopic imaging equipment (digital subtraction angiographic system) and ultrasonography; surgical glue, guide wires, and catheters; and a full range of surgical instruments. Personnel include trained interventional radiologists, surgeons, nurses, and radiology technicians.

Using an endovascular operating room facilitates one-stop provision of diagnosis and treatment of vascular lesion, e.g., identification of outflow draining vessels; real-time controlled injection of glue or a sclerosant; subsequent immediate open surgical lesion removal if necessary with no patient transfers needed; open exposure of lesions for direct puncture; and complications of the endovascular procedure (residual stenosis, occlusion, bleeding) can be treated with immediate surgery, according to Dr. Li.

Digital subtraction angiography allows simultaneous biplane imaging with better three-dimensional visualization. Digital subtraction images are possible; a lower radiation dose can be used and there is less interference from bone shadows. Roadmapping allows safer canalization of the vascular lesions.

MANAGING ORBITAL VASCULAR LESIONS

Dr. Li recounted the experience at her institution in managing orbital vascular lesions. All patients underwent digital subtraction fluoroscopic venography to confirm the extent of the lesion and the draining pattern of the vascular lesions, especially that of any intracranial communication, she said.

For small lesions for which surgical excision was unnecessary, fluoroscopic-guided sclerotherapy with 5% ethanolamine was performed. For larger lesions, a histoacryl glue/lipiodol mixture was injected to solidify the lesion, followed by surgical resection (transconjunctival or transcutaneous) performed by oculoplastic surgeons.

In six patients (4 women, 2 men; mean age, 32 years) with a venous malformation in the periocular and orbital regions, the mean follow-up was 19.5 months (range, 14 to 24 months). Four lesions were in the left upper lid, one in the left lower lid, and one in the right upper lid. The mean surgical time was 186 minutes (range, 91 to 324 minutes).

In four of the six patients, the surgery achieved complete lesion removal clinically and radiologically. The disfigurement was corrected in all patients, and there were no lesion recurrences.

No intraoperative complications—such as intracranial spilling of sclerosant/tissue glue, cerebrovascular event, or excessive bleeding—were observed.

Postoperatively, none suffered from visual loss from the surgery. One patient with a massive lesion had mild limitation in extraocular movement after surgery. No other adverse events—such as wound infection, secondary hemorrhage, tissue necrosis, and unsightly scar—were noted.

NOVEL APPLICATION

Based on their experience, the investigators cited the advantages of performing the hybrid procedure in an endovascular operating room. The surgery affords more controlled hemostasis, easier removal of solidified lesion, better assessment of draining vessels, is more likely to achieve complete resection of multiloculated lesions, and decreased risk of spillage of sclerosant/glue—thus, a overall higher degree of safety, better outcome, and fewer hospital admissions with shorter hospital stays, they noted.

"The hybrid procedure for treating orbital venous malformation in the endovascular operating room is a novel application in ophthalmology," Dr. Li said.

"It facilitates a safer, well-controlled orbital venous malformations resection with real-time, high-quality biplane digital subtraction angiography system surveillance," she concluded. "Its success requires collaboration among interventional radiologist, surgeon, and ophthalmologist." ■

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This article was adapted from Dr. Li's presentation at the 2013 meeting of the American Academy of Ophthalmology. Dr. Li has no financial interest in the subject matter.

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Cultures in evaluating donor corneal tissue for transplant

Findings could lead to greater availability of donor tissue if confirmed in larger sample size

By Nancy Groves; *Reviewed by Peter Krall, MD*

VISTA, CA ::

Current screening practices for donor corneal tissue include donor nasal and sputum cultures. However, a recent study suggests that automatically excluding samples with certain pathogens, such as *Pseudomonas*, or obtaining medical consultation for clearance, may be unnecessary, said Peter Krall, MD, one of the investigators.

No growth was found in any bacteria or fungus rim culture from donors with positive sputum cultures prior to death either during standard 5 to 7 day incubation times or an extended period of up to 3 weeks.

Dr. Krall

If these findings are confirmed in larger studies, they could prompt re-examination of eye bank infectious screening policies and more efficient use of scarce donor tissue, said Dr. Krall, in private practice, Vista, CA.

At the time the study was conducted, he was a cornea fellow in the Department of Ophthalmology at the University of Florida and conducted the research with colleagues there as well as with the Lions Eye Institute for Transplant and Research in Tampa. Dr. Krall's mentor, Anup Kubal, MD, was the lead researcher on the project.

Both organizations were looking for new research projects and became interested in screening practices for sputum cultures after being unable to locate any studies showing a correlation between positive sputum culture and increased contamination of corneal grafts, Dr. Krall said.

IMPLICATIONS OF RESEARCH

Medical directors of eye banks are likely to reject donor tissue with certain isolates to reduce the risk of contamination, no matter how small that risk may be. If it could be shown that a positive sputum culture had no correlation with a subsequent positive graft culture, then the transplant culture could benefit.

"If we can save as much tissue and rule in as much as possible, that means more tissue for more procedures around the world," he said.

The researchers provided background data on the frequency of isolates from 2,000 sputum cultures. Yeasts were present in 7.0%, normal flora in 6.1%, S. aureus in 4.3%, Klebsiella in 2.5%, Acinetobacter in 2.0%, Streptococcus and E. coli each in 1.5%, and several others in less than 1% of samples. This suggests that a low level of pathogens is not uncommon.

For their study, the researchers obtained corneoscleral rims that had already been excluded from transplant due to low endothelial cell counts; rims from individuals with sputum cultures positive for methicillin-resistant Staphylococcus aureus (MRSA) were automatically excluded. The sputum isolates included a variety of microorganisms, such as Candida spp. and Pseudomonas spp.

The researchers sampled 18 rims, obtaining samples for bacteria and fungus from each. The cultures were developed for 5 days for bacterial cultures and 7 days for fungal cultures before being scored on a scale of 1 to 4. The score was 0 following both the normal and extended incubation periods.

TAKE-HOME

- ***A small study of donor corneal tissues has shown that positive sputum cultures prior to death are not correlated with positive graft cultures after preparation. Despite the presence of low levels of various pathogens, no growth was found in any bacteria or fungus rim cultures.***

Culture Project Raw Data

SAMPLE	ISOLATE	CULTURE RESULT
2013-10-5821	Klebsiella & Pseudomonas	0 - No growth
2013-10-5822	Klebsiella & Pseudomonas	0 - No growth
2013-10-5781	Heavy Klebsiella Pneumoniae	0 - No growth
2013-10-5782	Heavy Klebsiella Pneumoniae	0 - No growth
2013-10-5779	Oral Pharyngeal Flora	0 - No growth
2013-10-5780	Oral Pharyngeal Flora	0 - No growth
2013-10-5729	Candida species	0 - No growth
2013-10-5861	Normal flora	0 - No growth
2013-10-5862	Normal flora	0 - No growth
2013-11-5929	Enterobacter cloacae	0 - No growth
2013-11-5930	Enterobacter cloacae	0 - No growth
2013-11-5943	Moderate E. coli	0 - No growth
2013-11-5944	Moderate E. coli	0 - No growth
2013-11-5947	Mod. yeast, E. coli, S. aureus	0 - No growth
2013-11-6127	Enterobacter aerogenes	0 - No growth
2013-11-6128	Enterobacter aerogenes	0 - No growth
2013-11-6169	1+ normal resp flora	0 - No growth

Source: Peter Krall, MD

FUTURE STUDY

"It is definitely a small sample size, but is in line with other research that shows there's no correlation between a positive sputum culture and that particular bacteria showing up in the corneoscleral rim culture," Dr. Krall said. Larger studies would be needed to confirm the findings and lead to changes in eye bank procedures.

"The implications are pretty big . . . if we can definitely prove that there isn't a correlation between any sort of sputum culture and the corneal grafts being contaminated. That's the main point of the project," he added. ■

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This article was adapted from a poster presented at the 2014 meeting of the Association for Research in Vision and Ophthalmology. Dr. Krall has no relevant commercial disclosures.

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Managing retinal vaso-occlusive diseases

Examining the role of ranibizumab therapy for macular edema secondary to BRVO

by Nancy Groves; *Reviewed by Ivan J. Suñer, MD*

TAMPA, FL ::

A SMALL, proof-of-principle, pilot study has shown that therapy consisting of injections of ranibizumab plus peripheral scatter laser therapy guided by ultra-widefield fluorescein angiography (UWFA, Optos P200Tx) is effective in patients with macular edema secondary to branch retinal vein occlusion (BRVO) associated with peripheral nonperfusion, according to Ivan J. Suñer, MD.

Dr. Suñer

While the trial enrolled just 12 patients, the results were dramatic, said Dr. Suñer, trial investigator and Retina Associates of Florida, P.A., Tampa.

No patients receiving the experimental therapy experienced recurrence of macular edema (one had a recurrence due to macular ischemia) versus 100% recurrence in the control group (p <0.001). A larger, multicenter study will be necessary to obtain more evidence on this new treatment protocol, he said.

"We have the combination of new imaging technologies and new treatments so that we can now be more specific and guided in our therapy to try to block the underlying pathobiology in the long term as well as in the short term," Dr. Suñer said.

FURTHER EXAMINATION

The BRAVO Study demonstrated the effectiveness of ranibizumab (Lucentis, Genentech) therapy for macular edema secondary to BRVO.

However, patients often need additional injections to maintain visual acuity gains or treat recurrences. Dr. Suñer and colleagues theorized that peripheral nonperfusion is responsible for the ongoing production of VEGF and subsequent recurrence of macular edema. While ranibizumab therapy blocks VEGF and allows for resolution of macular edema, it does not reverse the underlying pathobiology.

To explore this hypothesis, investigators enrolled 12 patients and randomly assigned them equally to the experimental protocol or the BRAVO protocol used in studies leading to approval of ranibizumab for the treatment of BRVO.

Patients in the experimental arm of the study, dubbed Revolutionary (REtinal Vein OccLUsion Treatment with Scatter Laser guided by Ultra-widefield angIOgraphy in combiNAtion with Ranibizumab StudY), were treated with peripheral scatter laser to nonperfused areas on UWFA at baseline and 6 monthly injections plus additional therapy as needed for recurrence of macular edema in the subsequent 6 months.

Patients in the control group duplicated the BRAVO treatment regimen by receiving 6 monthly injections plus further therapy as needed for recurrences in the subsequent 6 months, but no laser therapy. The re-treatment criteria were a decrease in best-corrected vision by ≥5 letters on the ETDRS chart or increase in optical coherence tomography thickness by ≥50 µm.

At 6 months, the mean visual gain for patients in the Revolutionary treatment group was 17 letters compared to 15 in the control group. At 12 months, the respective gains were 19 and 15 letters. The OCT change at 6 months was -207 µm in the Revolutionary treatment group and -241 in the controls. At 12 months, the changes were nearly identical: -282 µm in the experimental treatment group and -282 in the controls.

TAKE-HOME

- ***A new treatment strategy evaluated in a pilot study shows promise for treatment of macular edema secondary to branch retinal vein occlusion associated with peripheral nonperfusion.***

ANALYSIS OF STUDY FINDINGS

"In the end, all the patients had good vision. However, patients in the group that received laser treatment required no further injections in the subsequent 6 months. In the control group, all of the patients required further treatment in the subsequent 6 months of observation. On average they required 2.2 treatments," Dr. Suñer said.

"The results showed proof of principle," he continued. "We think that treatment impacted the underlying pathobiology that resulted in VEGF production and macular edema. We showed that if you can identify these patients at baseline and treat them with peripheral laser, you have a better chance of getting good vision with stability of the condition as opposed to requiring long-term, chronic therapy with ranibizumab or any other anti-VEGF agent."

According to Dr. Suñer, it was difficult until a few years ago to reliably capture the majority of the peripheral retina with existing angiography devices. Capturing multiple fields of view of the peripheral retina required very cooperative patients, well-dilated pupils, as well as proficient photographers.

Furthermore, capturing these images did not allow evaluation of the dynamics of the early and late portions of the angiogram throughout the retina.

With the Optos noncontact UWFA system, capturing the images of the majority of the retina is more reliable and reproducible. The platform can image well through small pupils and has a wide depth of field, which virtually eliminates limitations due to patient and/or photographer factors, Dr. Suñer said.

"The reality is now we have a way to study these patients and look at what's happening physiologically. We have the marriage of the imaging technology—the ultra-widefield angiography as well as the high resolution optical coherence tomography—with many therapeutic options—pharmacologic and surgical—to help better target our treatment strategies and then also monitor response to therapy in the follow up," Dr. Suñer said.

"In macular edema secondary to BRVO, peripheral laser and the anti-VEGF agents can work well in concert," he said. "The laser is reversing the underlying biologic drive that's causing the macular edema, and in the meantime, the anti-VEGF agent is blocking the VEGF that's available in the vitreous until the laser can kick in and stabilize the condition in the longer term." ■

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Dr. Suñer is a consultant for Genentech, Regeneron, and ThromboGenics and has received grant support from these companies.

Sustained delivery: A new frontier in ocular therapeutics

Controlling patients' drug administration increases likelihood for improved response to treatment

By Steven T. Simmons, MD,
Special to Ophthalmology Times

ALBANY, NY ::

For decades physicians have been searching for a solution to the traditional method of delivering medication to the eye in order to treat ocular disorders—such as inflammation, allergy, dry eye, and probably the most important, glaucoma. Many therapeutic agents are available that—when prescribed and used appropriately—handle the majority of patient issues without incident.

However, the problem lies in the phrase "used appropriately."

We, as physicians, know how difficult it is to take medications appropriately over time. Compliance is critical to any successful medical treatment—especially in chronic, asymptomatic diseases like glaucoma.

PATIENT ADHERENCE

Because of physician reliance on patient compliance for a successful therapeutic effect from eye drops, numerous efforts are being directed toward the development of sustained-release platforms using eye medications that have previously been approved. These medications are effective when used appropriately.

However, we all know that more than half of patients fail to comply with the dosing regimens they are prescribed. Thus, one of the goals of sustained, ocular drug delivery is to remove patient compliance in order to achieve the therapeutic effect.

Ideally if we, as physicians, can control patients' drug administration—whether for glaucoma or other diseases—there is a much higher likelihood of improved outcomes in response to treatments.

Essentially, two approaches exist for sustained-release systems:

1) Invasive—such as the injection of an insert through the cornea into the anterior chamber or surgical placement of a delivery device under the conjunctiva.

2) Non-invasive—such as the placement of a device in the tear duct or on the ocular surface.

Invasive systems have the advantage of being placed closer to the targeted site of action, but have the disadvantage of causing repeated tissue trauma and exposure to infection and rejection which could be concerning with chronic diseases like glaucoma.

Another concern using invasive approaches is in the situation where the insert or implant must be removed. This will pose additional surgical risk to the patient and add significant cost to the health-care system.

NON-INVASIVE SYSTEMS

Non-invasive delivery systems overcome these disadvantages.

Continues on page 38 : ***Sustained***

SUSTAINED

(Continued from page 37)

They are easily placed without tissue damage, easily removed when needed, and will likely result in lower infection and complication rates.

There are two main locations for the placement of a non-invasive sustained release system on the ocular surface or in the tear duct. One of the most promising sustained-release programs—known as the punctal plug delivery system (PPDS)—is being developed by Mati Therapeutics Inc.

Punctal plugs have been available for decades in ophthalmology, and even though they have improved over the years they still come with considerable drawbacks.

Three areas of most concern are retention rate, patient comfort, and ease of insertion. For use in dry eye conditions, the newest plugs have addressed the issues of patient comfort and ease of insertion fairly well.

Retention rates still tend to be low, which is manageable with dry eye patients since their symptoms tend to return if the plug is dislodged, and there is a low risk of disease progression in the short term until the patient's next visit.

When considering a therapeutic delivery plug, retention rates are critical and had to be improved to treat patients with glaucoma successfully.

OVERCOMING PRIOR HURDLES

The sustained-delivery platform developed by Mati Therapeutics Inc. has seen more than $100 million invested in its development, and this investment has helped the PPDS platform (Evolute) to overcome many of the historical hurdles limiting ocular sustained delivery devices in the past.

Some of the main obstacles historically have been long-term efficacy, controlled delivery of medication, and retention rates of a long term non-surgical device.

In order to meet these needs, the company has developed more than 100 iterations of the sustained-release platform and treated more than 1,000 patients to ensure the correct development path.

All of this research ended up in the creation of the sustained-delivery platform which overcomes each of these barriers by combining a silicone punctal plug with a sustained-release, drug-eluting core.

The advantage of using a silicone plug—which is non-bioerodable, non-biodegradable, or non-bioabsorbable—to anchor the drug core is that retention features do not change over time. This has resulted in a consistent, predicable retention rate of 92% for the system over 90 days, according to the latest, multicenter phase II trial.

The other advantage is removal of the system is not complicated, because it is readily identifiable and easily removed.

ELUTION PROFILE

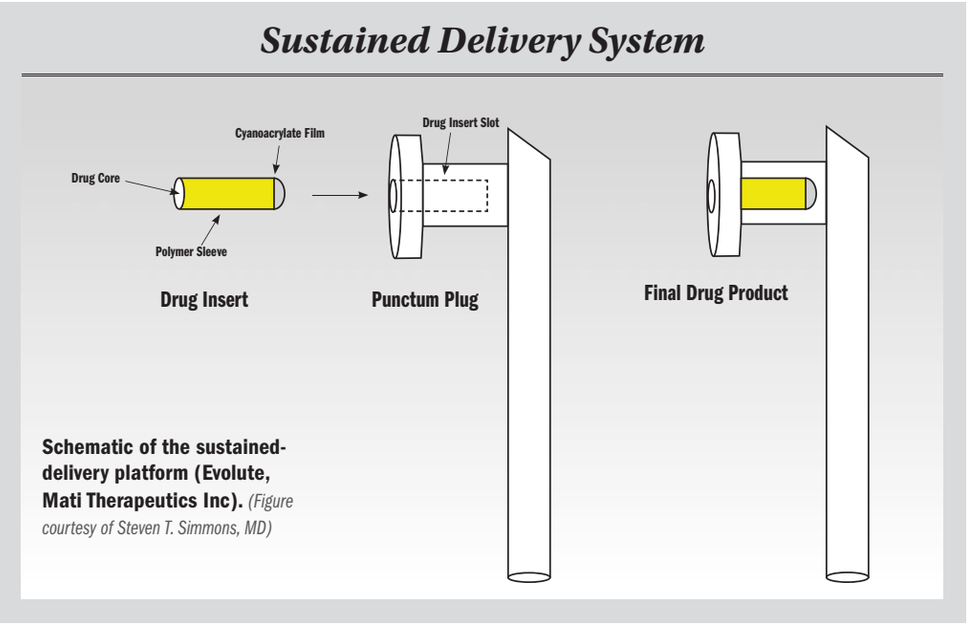
The sustained-release drug core is also composed of non-bioerodable, non-biodegradable, or non-bioabsorbable components. This results in a robust and predictable, long-term elution profile as the system is primarily governed by the rate of diffusion of the active drug into the tear film from the core.

Other sustained-release systems use biodegradation of the matrix to release active drug, and this can be variable based on the subject's tear composition and production rate.

These variables do not affect the Mati system and will not cause an alteration to the elution rate. Biodegradable systems or other systems that change shape over time also suffer from the disadvantage that these changes may result in the loss of the core from the device—adversely effecting efficacy.

TAKE-HOME

- ***The development of sustained, ocular drug delivery aims to remove patient compliance in order to achieve the therapeutic effect.***



Schematic of the sustained-delivery platform (Evolute, Mati Therapeutics Inc). *(Figure courtesy of Steven T. Simmons, MD)*

MOVING FORWARD

The first product being developed incorporates latanoprost into the sustained-delivery platform for glaucoma. Through extensive formulation development, the Evolute latanoprost drug core was developed to minimize any large burst of medication, reducing local and systemic side effects.

The elution rate has delivered a consistent 5 to 6 mm Hg IOP reduction from untreated baseline over 12 weeks.

Also, the platform is preservative-free. Benzalkonium chloride and other preservatives are suspected of causing ocular surface issues, such as conjunctival inflammation, tear film instability, corneal toxicity, anterior chamber inflammation, and allergic reactions.

BENEFITS FOR PHYSICIAN, PATIENT

In clinical studies, the vast majority of patients preferred the sustained-delivery platform to eye drops. The patient no longer has to adhere to time-sensitive daily regimens once the device has been inserted.

This may prove to be a huge benefit for ophthalmologists and their patients by ensuring better adherence and more consistent administration of the therapeutic agent—potentially leading to improved outcomes. ■

STEVEN T. SIMMONS, MD, *is co-director of Glaucoma Consultants, Albany, NY, and associate clinical professor of ophthalmology, Albany Medical Center. Dr. Simmon's research interests in the field of glaucoma include new pharmaceutical development, adjunctive use of glaucoma medications, and primary surgery for the treatment of glaucoma.*

Dropless cataract surgery: Technique and tips

Procedure helps reduces cost, hassle, and compliance issues for patients, families, staff

By James C. Loden, MD *Special to* Ophthalmology Times

EFFICACY AND COST were the two major reasons that I began investigating transzonular delivery of antibiotics and steroids for my patients. Even generic ophthalmic antibiotic and steroid drops have risen dramatically in price, and a rate of 1 in 500 for post-cataract endophthalmitis in the United States seemed too high to me.[1]

My investigations for other options led me to the transzonular delivery of sterile injectable compounded triamcinolone acetonide and moxifloxacin hydrochloride (Tri-Moxi, Imprimis Pharmaceuticals) during cataract surgery.

Triamcinolone acetonide and moxifloxacin hydrochloride has eliminated many of the nuisances associated with cataract surgery including: extra cost, confusion about correct drugs, and compliance issues.

TAKE-HOME

- ***James C. Loden, MD, describes his surgical technique and tips for performing dropless cataract surgery.***

TECHNIQUE

I use a transzonular approach to inject triamcinolone acetonide and moxifloxacin hydrochloride into the anterior vitreous following placement of the intraocular lens.

It is first necessary to ensure that the anterior chamber is filled with a cohesive viscoelastic to create the space for the cannula to pass through. Air bubbles or balanced saline solution filling the anterior chamber will not provide the stability needed for the injection.

I also inject a small amount of viscoelastic between the anterior capsule and the iris to ensure that I have created a space into which I can easily insert the cannula.

I recommend a fine, 27- or 30-gauge cannula, and one that is sufficiently long with an appropriate angle.

The proper technique involves reaching up under the iris to the equator of the lens capsule and then sliding posteriorly through the zonules; a short cannula will not be effective at reaching the correct zone.

In addition, a thicker cannula with a larger distal tip will encounter greater resistance. Careful visualization throughout this process will help you ensure that you are in the correct position.

If the cannula is pressing into the equator of the capsule rather than passing through the zonules, it will cause the anterior capsule to distort and bend outward. The correction is to insert the cannula farther into the periphery before turning posterior.

The entire maneuver should be performed decisively and confidently by the surgeon, as timid insertion will not get the cannula where it needs to be.

During the initial learning curve, surgeons will miss on occasion and insert the triamcinolone acetonide and moxifloxacin hydrochloride into the anterior chamber.

On the occasions this occurs, I, withdraw the cannula, add additional viscoelastic, if necessary, and repeat the injection. The medication will also sometimes migrate from the vitreous to the anterior chamber. In these cases, I will inject an additional 0.1cc of triamcinolone acetonide and moxifloxacin hydrochloride into the vitreous to ensure that the patient receives the full dose and no breakthrough inflammation occurs.

Once complete, I patch the eye for the first 24 hours post-surgery. I have found that this minimizes complaints about cloudy vision or floaters by getting patients past the initial period of side effects from the injection, which they are instructed

Continues on page 41 : ***Dropless***

Exploring pressure-lowering effect of novel drug in dose-escalation trial

Effect of ONO-9054 sustained up to 33 hours after final dose in 10- and 30-µg/mL dose groups

By Nancy Groves; *Reviewed by Alon Harris, MD, PhD, FARVO*

INDIANAPOLIS ::

POST HOC ANALYSIS of results of a small, randomized, double-masked, placebo controlled clinical trial of a drug being developed for the treatment of ocular hypertension (OHT) and primary open-angle glaucoma (POAG) (ONO-9054, Ono Pharmaceuticals) showed that all subjects who received the active medication experienced a reduction in IOP to 18 mm Hg or less after 14 days of dosing.

At higher doses of the drug, IOPs of 16 mm Hg or less were more frequent.

"It's a unique drug in terms of looking for new avenues in lowing IOP because of the potential pathways that it uses," said Alon Harris, MD, PhD, FARVO, professor of ophthalmology, Indiana University School of Medicine, Indianapolis. He is also director of clinical research at the Eugene and Marilyn Glick Eye Institute and professor of cellular physiology.

Dr. Harris explained that ONO-9054 is a dual FP/EP3 prostaglandin receptor agonist and an isopropyl ester pro-drug of the free acid ONO-AG-367 with ocular hypertensive activity.

TAKE-HOME

- ***A drug being developed for the treatment of ocular hypertension and primary open-angle glaucoma (ONO-9054) showed promising results in a small, randomized trial.***

EXAMINING THE STUDY

The dose-escalation trial enrolled 48 subjects with bilateral OHT or early POAG. The subjects were randomly assigned 1:3 to receive placebo or ONO-9054 in doses of 3, 10, 20, or 30 µg/mL. The study drug was administered once daily in both eyes on day 1 and on days 5 to 18. IOP measurements were performed at baseline and on days 18 and 19. The post hoc analysis evaluated the magnitude of IOP and proportion of subjects who reached targets by measuring the mean and standard deviation of IOP on days 18 and 19.

"IOP was sustained at a minimum of 25% below baseline in all groups, and IOP was sustained up to 33 hours post-dose in the 10- and 30-µg/mL dose groups, so the 10 and 30 µg/mL seem to be very potent dosages for lowering the IOP," Dr. Harris said. "The analysis showed that in doses above 10 µg/mL, approximately 80% to 90% of the IOP measurements were 18 mm Hg or lower.

"That's a very important cutoff, and yet at 14 days, we're talking about 16 mm Hg," he continued. "Over 75% of the subjects in the 10 µg/mL dose group reached pressures of ≤16 mm Hg, and it was sustained for more than 12 hours."

At baseline, mean IOP ranged from 23.3±0.6 to 25.2±2±5 mm Hg. After treatment, 78% to 89% of the pressures measured were 18 mm Hg or lower among subjects who had been randomized to doses above 10 µg/mL.

All patients receiving the drug experienced a reduction in IOP to 18 mm Hg or less after 14 days of dosing. More than half of the responses ranged lower than 18 mm Hg at all time points in the doses above 10 µg/mL. In the 10 µg/mL dose group, more than 50% of the responses ranged lower than 16 mm Hg, or 67.5% lower than baseline, at all time points. Further, 20% of all subjects receiving doses of 10, 20, and 30 µg/mL had IOP measurements of 15 mm Hg or lower at some point in the study.

MORE ANALYSIS

The analysis also showed that at 8 a.m. after 14 days of dosing, the numbers of patients who had IOP measurements of no more than 16 mm Hg were higher in the cohorts receiving doses above 10 µg/mL. The numbers were 0/12 in the placebo group; 1/9 (11.1%) in 3 µg/mL; 7/9 (77.8%) in 10 µg/mL; 4/9 (44.4%) in 20 µg/mL; and 6/9 (66.7%) in the 30 µg/mL cohort. On day 18, after 14 days of consecutive dosing, all the subjects in the placebo group had an IOP of 18 mm Hg or higher.

ONO-9054 is promising, Dr. Harris noted, while acknowledging the trials process is still in early stages. A report on its hypotensive effect was given at the 2013 meeting of the American Academy of Ophthalmology by Serle et al. ■

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This article was adapted from a poster presentation at the 2014 meeting of the Association for Research in Vision and Ophthalmology. Dr. Harris is a consultant for Ono Pharmaceuticals.

Corneal CXL NDA resent to FDA

By Rose Schneider

WALTHAM, MA ::

AVEDRO HAS resubmitted its new arug application (NDA) for riboflavin ophthalmic solution/KXL System to the FDA.

According to the company, Avedro anticipates an application action date in March 2015. The resubmission is a comprehensive reply to the FDA's March complete response letter.

"We have been working closely with the FDA to address the issues raised in the complete response letter," said David Muller, PhD, chief executive officer of Avedro.

The proposed indications of treatment of progressive keratoconus or corneal ectasia following refractive surgery were both granted orphan drug status by the FDA in 2011. If approved, the ophthalmic solution would be the first FDA approved therapeutic treatment for these orphan indications, and entitle Avedro to 7 years of U.S. market exclusivity, the company said. ■

DROPLESS

(Continued from page 39)

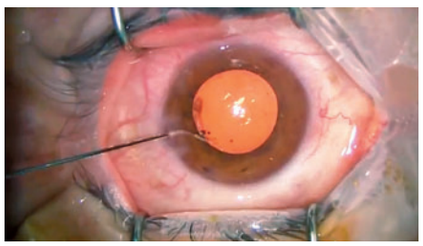
to expect during the first week post-surgery. While the transzonular delivery of antibiotics and steroids is preferable for most patients, there are a few patients with whom I personally avoid this approach—glaucoma patients or suspects, known steroid responders, and patients receiving a toric IOL.

EXCEPTIONS

Due to the delicacy of toric IOL placement, I do not like to risk rotation of the lens with the injection of viscoelastic or triamcinolone acetonide and moxifloxacin hydrochloride following confirmed placement, and provide these patients with intracameral Vigamox (moxifloxin HCl 0.5%) and sub-Tenon kenalog. If I am performing arcuate incisions, I supplement triamcinolone acetonide and moxifloxacin hydrochloride with a topical antibiotic for three days postoperatively to prevent keratitis.[2]

Without a doubt, eliminating the need for postoperative drops has been one of the greatest changes to my cataract procedure, reducing cost, hassle, and compliance issues for my patients, their families, and my staff. ■

DROPLESS CATARACT SURGERY



VIDEO To watch the technique being performed, go to **http://bit.ly/1rXr80d**

(Video courtesy of James S. Lewis, MD)

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JAMES C. LODEN, MD, *is president of Loden Vision Centers in Nashville, TN. He acknowledged no financial interest in the products or companies he mentioned. Dr. Loden may be reached at 615/859-3937; lodenmd@lodenvision.com.*

FDA approves revised indication for Allergan DME treatment

By Rose Schneider

IRVINE, CA ::

THE FDA HAS approved Allergan's dexamethasone intravitreal implant 0.7 mg (Ozurdex), a sustained-release biodegradable steroid implant, for the treatment of diabetic macular edema (DME).

The implant was originally approved in June as a treatment for DME in adult patients who have an artificial lens implant (pseudophakic) or who are scheduled for cataract surgery (phakic). Based on ongoing review of clinical data demonstrating efficacy and safety, the FDA has now approved the implant for use in the general DME patient population.

"We are pleased that the updated indication supports the use of (the implant) to help improve vision for more patients with DME," said Scott M. Whitcup, MD, executive vice president, research and development and chief scientific officer, Allergan.

The FDA approval of the implant is based on the MEAD (Macular Edema: Assessment of Implantable Dexamethasone in Diabetes) study where it has demonstrated long-term efficacy in the treatment of DME without the need for monthly injections. The most common adverse events in the studies included cataracts and elevated IOP. An increase in mean IOP was seen with each treatment cycle, and the mean IOP generally returned to baseline between treatment cycles.

The implant is also indicated for the treatment of macular edema following branch retinal vein occlusion or central retinal vein occlusion, and for the treatment of non-infectious uveitis affecting the posterior segment of the eye. ■

Round-the-clock IOP measure closer to technologic reality

Device for continuous, long-term monitoring of patients based on wireless communication

By Michelle Dalton, ELS; *Reviewed by Marlene Moster, MD*

PHILADELPHIA ::

An ongoing conundrum for glaucoma specialists has been an inability to monitor patients throughout a 24-hour period in real-world clinical settings. About a decade ago, investigators started looking beyond the office readings and found IOP increased at night during sleep.

"That was quite a paradigm shift, as we used to believe that the pressure increased early in the morning when cortisol levels rose," said Marlene Moster, MD, professor of ophthalmology, Thomas Jefferson University School of Medicine, Philadelphia. What diurnal studies on patients with glaucoma went on to find is that extrapolating IOP from one eye to the other is ineffective, as each eye operates independently.

Dr. Moster

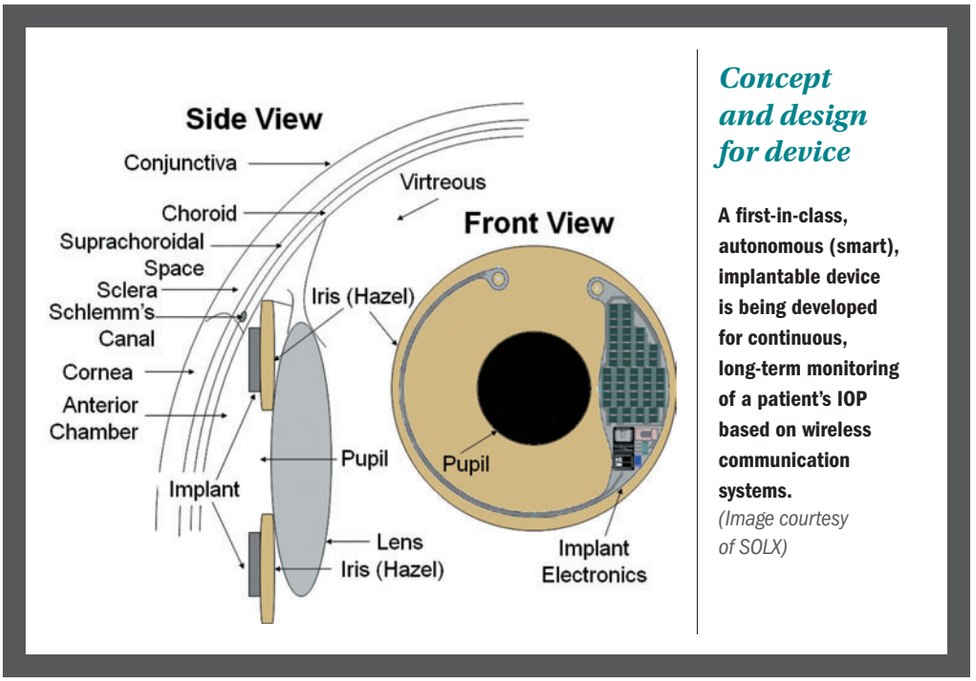
"When the pressure rises in one eye, it may rise in the other but not as much," Dr. Moster said. "Even a diurnal pressure curve in patients with primary open-angle glaucoma poorly describes IOP fluctuations. Therefore, it is almost impossible to predict the IOP variability moving forward in time."

MUCH KNOWLEDGE TO BE GAINED

Glaucoma specialists and researchers alike agree there is a substantial amount that is just not yet known about IOP—how heavy exercise may affect it, how inversion positions in yoga (or any position where the head is below the heart) may affect pressure, or how the pressure varies when new drops or therapies are introduced.

Therapy is determined based on a fleeting moment's worth of data, and may not be reflective of the dynamic nature of IOP in daily life.

What if glaucoma specialists could monitor a patient 24/7? What if physical contact with the eye was not needed to get an accurate measurement? What if all that could be accomplished without office visits?



Concept and design for device

A first-in-class, autonomous (smart), implantable device is being developed for continuous, long-term monitoring of a patient's IOP based on wireless communication systems. *(Image courtesy of SOLX)*

ENVISIONING THE POSSIBILITIES

"The potential to have 24-hour IOP measurements for us is like having an A1C reading for diabetic patients," Dr. Moster said.

To that end, SOLX is developing a first-in-class, autonomous (smart), implantable monitoring device for continuous long-term patient monitoring based on wireless communication systems (similar to Bluetooth or WiFi).

In the most simplistic of descriptions, the technology would be implanted in the eye and could interact with a patient's nearby smartphone or tablet (or a base station for those without phone/tablet access) to relay the information to the glaucoma specialist's office.

The ability to monitor continuously was initially problematic from an engineering standpoint, said Doug Adams, founder, president, and chief executive officer of SOLX.

The earliest iterations needed a battery to function, and "that didn't work, as there wasn't enough power to work the electronics in the device and keep it small enough to be implanted," Adams said.

But transforming the device into one that "slept" until it was within range of a wireless recharging unit "turned out to require very little power," he said.

While SOLX is not the only company working on 24-hour monitoring devices, it is the only one that can do so autonomously, without direct patient interaction, and can take measurements without external control signals. SOLX funded grants for PhD-candidates from Purdue University to develop an ultra-low-power miniature implantable wireless pressure sensing system.

Eric Chow, PhD, based his thesis on the electromagnetic/wireless and integrated circuit design aspects of the technology, Adams

Continues on page 44 : ***24 hour***

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24 HOUR

(Continued from page 42)

said, quipping that physicians will need to learn a "host of new engineering terms" when these devices come to market.

A high-frequency transmitter integrated circuit was created, achieving "sufficient efficiency to draw minimal power from the limited onboard storage array while outputting a sufficiently large signal to overcome tissue-induced attenuation," Dr. Chow and others wrote.[1] They created two versions of the system—one using a low-temperature co-fired ceramic material for the substrate and the other used silicon for the substrate.

The prototype developed in Dr. Chow's work was implanted in rabbits between the sclera and choroid layers in the suprachoroidal space.[1] The entire system combines the implant and the onboard microelectromechanical system.

"When you think about compliance and the difficulty older patients have, we wanted to create a device that the patient would only need to occasionally pass, within about 3 feet of a base unit," Adams said. "This device captures data all day with no external user input."

Other companies' devices require active patient interaction, although the devices themselves are inactive, he noted.

Dr. Moster believes the data can be distilled into a simple analysis to make it easier to remotely monitor patients.

"We'll be able to monitor their therapies and ensure the drugs are truly effective," she said. "We'll understand if our treatments are active over a 24-hour period and if not, either change the drug combination, or decide if glaucoma surgery is the best solution."

DEFINING THE PIECES

While SOLX engineers started formulating how to encapsulate the device, companies like Microsoft and Apple were inadvertently helping the technology along when they introduced smart phones and other communications devices.

"We challenged our engineers to do more than just measure and read IOP," Adams said. "The requirements would be very specific. I wanted programmability where the doctor could select the requirements. Physicians can take a reading as little as once per hour, or up to 2,400 times per day."

Because the device is implanted and not external, the FDA is concerned about biocompatibility, and SOLX "auditioned" several platforms, including PMMA, liquid crystal polymers (LCP), and titanium.

The LCP completely encapsulates the device, which makes it slightly larger than ideal, Adams said.

The group is still evaluating titanium and platinum to encapsulate the device. "The FDA is intently focused on safety outcomes," Adams said. "We're putting electronics inside the eye. They cannot leak, and we have to have a truly biocompatible package with significant longevity."

Although the current device measures 3 × 5 mm, smaller devices are being developed, Adams said, with a belief that within 2 years the devices will be closer to 1 × 2 mm, and within 5 years, closer to 250 µm cubed.

"I think over time, glaucoma specialists are going to deliver this device inside the eye at the slit lamp," he said.

Dr. Moster said additional studies would concentrate on best placement for the device (anterior chamber, suprachoroidal space, etc.).

"The possibilities are very broad as to how we can place these in the eye and wirelessly gather data," she said.

TAKE-HOME

- ***The development of a device for 24-hour IOP monitoring is unique in that it can do so autonomously, without direct patient interaction, and can take measurements without external control signals.***

EARLY RESULTS, POTENTIAL APPLICATIONS

Another potential advantage for physicians is if the patient is away—out of town for a weekend, for instance—the device continues to store the readings and downloads the next time it's in range of the home base unit, Adams said.

"We're making this technology work without any interaction on the part of the patient," he said. "The device can also function through a smart phone or other mobile device."

"This sensor technology can be applied to anywhere in the body where pressure needs to be measured—ophthalmology, cardiology, neurology, urology," Adams said. "Over time, we'll be able to network the devices so they can 'talk' to each other."

Physicians in all specialties will have a greater understanding of how diseases interact and function inside the body, he noted.

SOLX has investigated the device in animal studies, in eyes, arteries, and will be investigating its potential in the spine to measure cerebrospinal fluid (CSF) pressure, Adams said. The group plans to implant three devices in one rabbit to see the interaction (if any) exists between the pressure levels.

Ideally, researchers would be able to determine the relationship between blood pressure and IOP, or between IOP and CSF, he said.

Human trials could start as early as next year, Adams said.

In animal studies, the device has been incredibly accurate, and "we think we can be within 0.5 mm Hg," he said.

ADVANCEMENTS FOR THE FUTURE

The device is not yet perfect—and drift is an issue for sensors. Over the course of several months, drift may contribute 1 mm Hg to 5 mm Hg.

"That's a huge difference that we need to overcome," he said, but believes current developments will overcome overcome the issue altogether.

Dr. Moster said implantation in the future may be through 30-gauge needles (or smaller), and when injected into the anterior chamber, "it can fall into the bottom of the angle where we can see it easily with gonioscopy at the slit lamp."

The casing will need to be non-reactive, so as not to incite any biologic issues once human studies are fully enrolled.

She also hopes the more information gathered about how IOP fluctuates throughout the day—and maybe in even smaller increments such as hours or minutes—the more clinicians will learn about the pathophysiology of glaucoma.

"We don't know if normal tension or angle closure glaucomas are affected similarly throughout a 24-hour span as open-angle," she said. "This technology has the potential to be our Holy Grail." ■

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MARLENE MOSTER, MD

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Dr. Moster did not indicate a proprietary interest in the subject matter.

Announcing the Winners of the 2014 Resident Writer's Award Program

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Evan Warner, MD

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Smart lens technology: The next big breakthrough for ocular medicine?

What physicians need to know about smart lens technology from Alcon and Google

By Rose Schneider; *Content Specialist,* Ophthalmology Times

BASEL, SWITZERLAND ::

THIS PAST SUMMER, Novartis announced that its eye-care division, Alcon Laboratories, had entered into an agreement with a division of Google Inc. to in-license its "smart lens" technology for ocular medical uses.

While Google will deliver the smart lens technology, Alcon will manufacture and deliver the contact lenses and IOLs. The technology is currently in the research and development phase. Once that phase is completed, Alcon will manufacture the final commercial product, including the technology.

But what exactly does this mean for physicians in eye care and their patients?

TAKE-HOME

- ***Alcon recently announced a partnership to in-license Google's smart lens technology, but many questions remain. What will this new product bring to eye care and will it change ocular medicine?***

NEED TO KNOW

According to Franck Leveiller—vice president of research and development of vision care for Alcon—there are two areas of interest the companies will focus its immediate attention:

- ***DIABETIC PATIENTS:*** **Leveiller said the lenses will help these patients manage their disease by providing a continuous, minimally invasive measurement of the body's glucose level via the technology, which is designed to measure tear fluid in the eye and connect wirelessly with a mobile device.**

- ***PRESBYOPIA:*** **Because patients living with this disease can longer read without glasses, Leveiller said the smart lens will potentially provide accommodative vision correction to help restore their eyes' natural autofocus on near objects in the form of an accommodative contact lens or IOL as part of their refractive cataract treatment.**

In addition to contact lenses, Leveiller said Alcon would also explore the technology—which involves non-invasive sensors, microchips, and other miniaturized electronics that are embedded within the lens—into IOLs as part of the refractive cataract treatment for presbyopia.

"Within eye care, there is still a great amount of 'white space,' which is ripe for innovation ideas to address some of its most pressing eye diseases and conditions," Leveiller said. "(For example), the possibility of an accommodating lens for presbyopia patients—whether a contact lens or an intraocular lens—would give them freedom from eyeglasses, improving their overall lifestyle."

Another 'white space' Alcon hopes to conquer in the future with the smart lens technology, Leveiller said, is glaucoma.

The companies are also keeping those who are intolerant to contact lens in mind while developing the technology, he added.

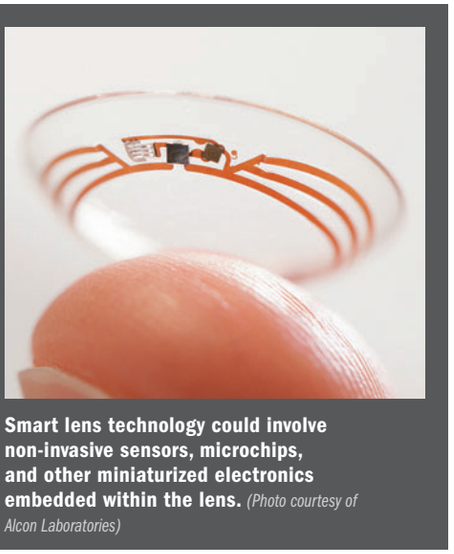
"We are currently in the very early stages of developing the smart lens technology, but our aim is to develop a lens that is comfortable and well-tolerated by patients," Leveiller explained. "This is an example of how Alcon can complement Google by providing our extensive experience and expertise in contact lens material and surface design . . . in order to improve smart lens biocompatibility and comfort performance."

FIRST IMPRESSIONS

While the companies continue work on the smart lenses, eye-care physicians are already excited for its possible capabilities for their patients.

"It's a huge opportunity for all kinds of monitoring and health-care needs," said H. Jay Wisnicki, MD, New York Eye & Ear Infirmary, Beth Israel Center, Albert Einstein Collage of Medicine, New York. "I think the movement to smart lenses is great, . . . people wear contacts anyway."

In particular, Dr. Wisnicki said he is highly anticipating the smart lens for diabetes patients, as the technology will give them the ability to have better control over monitoring blood glucose levels.



Smart lens technology could involve non-invasive sensors, microchips, and other miniaturized electronics embedded within the lens. *(Photo courtesy of Alcon Laboratories)*

"Can you imagine that instead of the old ways of finger pricks . . . it can be monitored in a non-invasive way," said Dr. Wisnicki, also a member of *Ophthalmology Times* Editorial Advisory Board and editor of the *Tech Talk* column.

While he expects technical challenges, Dr. Wisnicki said he sees huge potential for the technology in regards to improving glaucoma care as well.

"The potential benefits of that are unbelievable," he said.

However, Dr. Wisnicki said he does have doubts that the technology would work for IOP.

"(There are some) major challenges for IOP," he said. "Think of the eye as a water balloon. You've got to touch it . . . I don't see how a contact lens is going to measure IOP."

Nevertheless, Dr. Wisnicki said he would "absolutely" recommend the smart lenses to his patients, even if they were in an experimental phase.

"I am very pleased with this collaboration between Alcon and Google on these technologies," he said. "(They) are very strong companies with strong track records that can only help patients and ophthalmologists." ■

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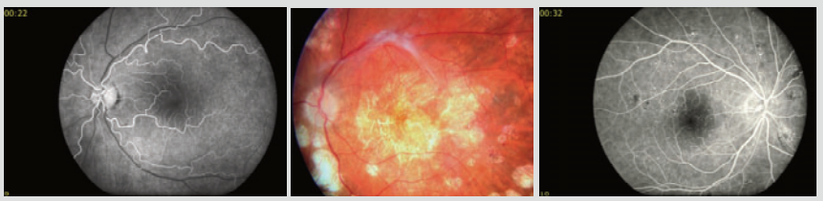

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Sustained drug-delivery technology moving toward clinical applications

By Fred Gebhart

OPHTHALMOLOGISTS HAVE terrific treatments for glaucoma and less-than-terrific treatment results. Eye-drop adherence may fall below 50% within a few months.

One solution? A large spectrum of drug-delivery technologies are moving quickly toward clinical relevance. Some companies are focusing on micro- and nano-scale particles, others on gels and solid drug depots. Some are designed for topical administration, some for injection, and others are implanted like a contact lens.

AMORPHEX THERAPEUTICS

The topical ophthalmic drug delivery device is a soft elastomer drug depot that floats atop the sclera under the eyelid. It can be inserted or removed as easily as a contact lens with none of the problems associated with soft contact lenses that dry out or collect deposits.

"We are delivering therapeutic doses of drug, but without any of the systemic exposure you get from eye drops," said Robert Thompson, president and chief executive officer (CEO), Amorphex Therapeutics. "You can deliver multiple drugs at multiple rates of release with a single device. In testing we have done on animals and human subjects, we have never seen any detectable amount of drug in the blood."

CLEARSIDE BIOMEDICAL

If current clinical programs support successful animal studies, Clearside aims to transform the choroid into a drug target and the suprachoroidal space into a reliable delivery channel.

"You can put a large amount of drug into the suprachoroidal space and it spreads very evenly across the posterior of the eye," said Daniel White, president and CEO, Clearside. Injection into the suprachoroidal space compartmentalizes drug in the choroid and the retina with minimal diffusion into other ocular tissues. Suprachoroidal delivery produces similar therapeutic results as intravitreal injection, while using just 10% of the drug concentration typically injected.

ENVISA THERAPEUTICS

Why not use miniature molds to create micro-size injectable rods that contain nano-sized drug particles?

"Our technology is gentle enough that we can formulate very sensitive substances, such as DNA, monoclonal antibodies, even cyclosporine, to create clinically useful products," said Chief Scientific Officer Benjamin Yerxa, PhD, Envisa Therapeutics. "We can very precisely create microgram doses with the precise size, shape, and physical characteristics needed to ensure optimal therapeutic activity."

Trials of extended-release prostaglandin in canines show an almost immediate response and a sustained 30% reduction in IOP over more than 120 days. Clinical trials are planned for later this year.

GRAYBUG

Sustained delivery is an idea whose time is coming, but not quite yet. Michael O'Rourke, president and CEO of GrayBug, would like to change that.

"We can tailor microparticle and nanoparticle platforms with delivery times from days to months, depending on the need," O'Rourke said. "We have seen a 30% to 50% increase in drug in target tissues compared to topical delivery for up to 115 days and very good long-term lowering of IOP in animal models."

The miniature particles are well tolerated. In rabbit tests, particle injections induced inflammation similar to saline injections and significantly less than convention PLGA particles.

KALA PHARMACEUTICALS

Kala makes nanoparticles designed to penetrate the mucus barrier protecting the eye and other tissues. The mucus-penetrating platform (MPP) uses nanoparticles smaller than the pores in the mucin mesh that protects the eye.

"Our drug particles have been coated with an engineered polymer layer to penetrate the mucin layer, like they were coated with Teflon, to reach the target tissue," said Chief Medical Officer Kim Brazzell, PhD, Kala.

When applied to the surface of the eye, particles quickly migrate to the cornea, aqueous humor, retina, choroid, and sclera but not into the aqueous humor. That migration, via the suprachoroidal space, could transform glaucoma treatment with the potential for neuroprotection with a sustained release topical agent.

OCULAR THERAPEUTIX

Ocular Therapeutix's hydrogel sealant launches in the United States this year. The same hydrogel technology is being developed for sustained-release drug delivery.

"We have an opportunity in glaucoma to do a better drug delivery," said Scott Corning, vice president of marketing and sales. Other products in development include a dexamethasone-loaded plug for inflammation and an injectable anti-VEGF depot for 6-month use in wet age-related macular degeneration and other retinal conditions.

SKS OCULAR

SKS uses micro-molds to build bioerodable polymers using gelatin hydrogels. The gels can be layered with multiple drugs released at different rates, said Barbara Wirostko, MD, chief medical officer of the glaucoma program, SKS Ocular.

"Glaucoma is our most advanced product," Dr. Wirostko said. "We have high drug-loading capabilities that can be injected with small needles for long-term sustained release. Sustained delivery is the delivery system of the future for ophthalmic care."

Other vehicles are being tested for AMD, retinal vein occlusion, diabetic macular edema, and other conditions.

ZORDERA

Zordera is an early stage university start-up. The goal is to commercialize novel thin-film polymer fabrication for glaucoma and other ophthalmic conditions.

"In glaucoma, we have great drugs and patients are using them 50% of the time, maybe less," said Co-Founder Robert Bhisitkul, MD, PhD, professor of clinical ophthalmology at the University of California, San Francisco. "We are creating tiny biodegradable films that I can inject in the office that give linear drug release over an extended period." ■

Editor's Note: *This article was adapted from a presentation at the 2014 meeting of Glaucoma 360 held in association with the Glaucoma Research Foundation and* Ophthalmology Times.

Should your practice have an optical dispensary?

A look at factors that ophthalmic practices should weigh for a new or existing optical shop

By Rose Schneider, *Content Specialist,*
Ophthalmology Times

ST. LOUIS, MO ::

The addition of an optical dispensary to an ophthalmic practice is not only beneficial for patients, but also an ideal way to increase revenue for the clinic, according to Carolyn Salvato, ABO.

For ophthalmic practices that are considering adding an optical shop or that already have one, the first question to ask is: "Do we have the potential to be a good optical?" said Salvato, director of optical consulting, BSM Consulting, St. Louis, MO.

While optical shops can increase a practice's revenue substantially, Salvato said if a clinic is not fully prepared to spend the necessary funds, hire the right staff, and put in the effort to make it a good investment, failure is easily attained.

STEPS TO ADDING A DISPENSARY

Examining the practice's space is the first step in figuring out if adding an optical shop is even possible.

"That is really important," she said. "I've had offices put them in storage closets and then wonder why they don't work."

Placing the optical shop near the front of the practice is the ideal spot—while also having staff promote the dispensary—for maximum exposure to patients, Salvato said.

"Visibility is key, because you want patients to see it when they come in," she said.

Another important aspect to keep in mind, Salvato said, is making sure the practice has a proper volume of patients who would use the dispensary.

"Do you write more than 10 to 15 scripts a day?" she asked. "That's imperative, as far as having an optical shop; it all depends on the volume that you can produce out of your own business because if you are thinking, 'I'm going to open an optical shop,' . . . and you're going to get walk-in visits, that's not typically what happens."

Additionally, informing a practice's referring opticians that the clinic is opening an optical shop is a must, Salvato said.

"You need to inform them. Don't try to hide it from the (opticians) if they're a good referral source for you," she said. "Let them know they've got nothing to worry about so they know upfront, they don't find out from the outside."

Continues on page 54 : ***Dispensary***

Getty Images/iStockphoto/360

In Brief

Increments of 0.1 mm

SYNERGEYES EXPANDS CONTACT LENS PARAMETERS

CARLSBAD, CA :: **SYNERGEYES INC.** has expanded parameters for its Duette Progressive lens. Parameters are now available in 0.1-mm increments, which will facilitate even more precise alignment fitting, creating optimal centration and clear, stable vision at all distances for even more patients.

A survey of 600 eye-care professionals verified the need for a high-performance contact lens for astigmatic presbyopes.

"The vast majority of doctors said the most positive impact on their practices would be a better contact lens for astigmatic presbyopes. Expanding parameters of the Duette Progressive lens to 0.1-mm increments will allow practitioners to optimize visual outcomes more successfully for even more patients," said SynergEyes' President and CEO James K. Kirchner, OD.

(Photo courtesy of SynergEyes)

Combining GP optics with SoftCushion comfort technology, the progressive lenses provide crisp, clear vision for astigmatic presbyopes. A patient's initial pair of lenses can be designed empirically based on a refraction and corneal curvature measurements.

Utilizing a near center aspheric add zone in combination with a distance asphere, the lenses provide a seamless progression of powers from distance to near, giving presbyopes GP vision at all distances along with soft lens comfort.

With a choice of three add powers to give the practitioner greater control over the visual outcome, the lens is a go-to lens for presbyopes with astigmatism and is also an ideal choice for moderate to advanced presbyopes who no longer get acceptable near vision from soft multifocal contact lenses, according to the company. The lens also features an 84 Dk silicone hydrogel skirt around the 130 Dk center, and includes UV-blocking materials.

Practitioners report successful outcomes with very few follow-up visits when empirically fitting the Duette Progressive lens, according to Dr. Kirchner. ■

DISPENSARY

(Continued from page 53)

If a practice's patient base is largely referrals, Salvato recommended not pursing an optical shop.

Having a complete understanding of the financial responsibility that opening an optical dispensary can be is yet another important question to ask oneself before taking action.

"Are you financially prepared for this investment? It is a big investment and depending on the volume you have available to capture, sometimes it can be a 2- to 3-year turnaround to get a return on investment," she said.

Typically, the average cost per square foot to build an optical shop is about $30 to $50, Salvato said. A standard size of an optical shop is about 400 square feet.

Nevertheless, these averages are the minimum standards, she emphasized, as some practices need bigger shops depending on how many providers there are in the optical dispensary.

There are also costs for the shop's displays, which can range from $15,000 to $80,000 or more depending on their complexity and style, Salvato said.

Equipment and tools for the dispensary are another expense, ranging about $5,000 or more depending on what the practice already has in its inventory, she said.

TAKE-HOME

- ***Examining the pros and cons of maintaining or starting an optical dispensary within an ophthalmic practice.***

TIPS FOR MAINTAINING A DISPENSARY

For ophthalmic practices that already have optical shops, the question that needs to be addressed is whether the clinic has the motivation to make it work. One of the best ways to maintain the dispensary is having the right staff, as well as making sure the optical manager is accountable for the success of the business, Salvato said.

One of the mistakes ophthalmic practices make, Salvato noted, is hiring experienced opticians and expecting them to also have an adequate business background to manage the shop.

"I'm not saying you need to avoid (opticians), but make sure they've got a business background, too, so they can . . . make it profitable," she said.

Providing staff training and continued education is a good way to ensure they're knowledgeable to make the optical shop successful.

The next step is to have a clear understanding of the practice's dispensary's competition:

- ***CORPORATION RETAIL CHAINS:*** There are more of these dispensaries than ever, Salvato said, and are typically high priced, even though they market lower prices. "They're masters at marketing, they're very, very good at what they do," she said.
- ***WHOLESALE AND DISCOUNT CHAINS:*** These optical shops offer lower prices and have strict loyalty. However, because they buy many discontinued products, Salvato said the product quality is reduced. "Your patients think it's a good idea. Unfortunately, if they break (their glasses bought at these dispensaries), they're out of luck," she said.
- ***LOCAL OPTICAL SHOPS:*** These are the most difficult with which to compete because customers and the community are extremely loyal and want to support them, Salvato said. However, the number of local optical shops throughout the United States is shrinking due to competition.

ENSURING YOUR DISPENSARY'S SUCCESS

To ensure the dispensary becomes profitable, inventory management is key.

"The offices I go to . . . this is where we lose the most money," she said. "This is your biggest investment for your optical—make sure it's managed effectively."

Putting it simply, Salvato said that in order to ensure an optical shop's success, practices need to make sure the dispensary is a priority. ■

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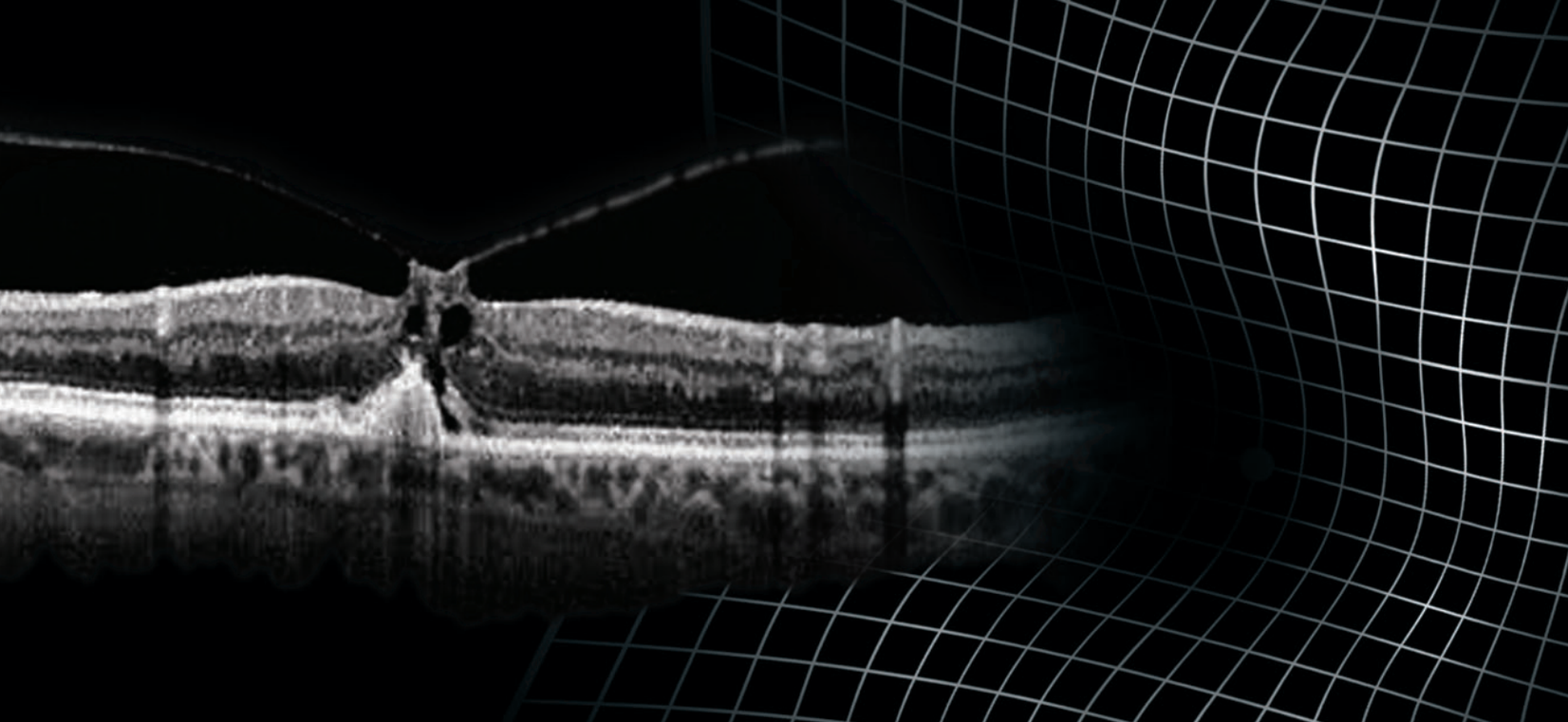

SYMPTOMATIC VITREOMACULAR ADHESION (VMA)

SYMPTOMATIC VMA MAY LEAD TO VISUAL IMPAIRMENT FOR YOUR PATIENTS[1-3]

IDENTIFY | Recognize metamorphopsia as a key sign of symptomatic VMA and utilize OCT scans to confirm vitreomacular traction.

REFER | Because symptomatic VMA is a progressive condition that may lead to a loss of vision, your partnering retina specialist can determine if treatment is necessary.[1-3]

THE STEPS YOU TAKE TODAY MAY MAKE A DIFFERENCE FOR YOUR PATIENTS TOMORROW

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