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October 1, 2014 VOL. 39, NO. 18
CLINICAL DIAGNOSIS | SURGERY | DRUG THERAPY

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Surgery

SEALANT SUPERIOR MEANS OF WOUND

MALIGNANT GLAUCOMA

Keys to recognizing the condition

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IMPORTANT SAFETY INFORMATION

CAUTION: United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

INDICATION: The LenSx® Laser 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.

RESTRICTIONS:
- Patients must be able to lie flat and motionless in a supine position.
- Patient must be able to understand and give an informed consent.
- Patients must be able to tolerate local or topical anesthesia.
- Patients with elevated IOP should use topical steroids only under close medical supervision.

Contraindications:
- Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength
- Descemetocele with impending corneal rupture
- Presence of blood or other material in the anterior chamber
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy
- Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
- Corneal thickness requirements that are beyond the range of the system
- Corneal opacity that would interfere with the laser beam
- Hypotony or the presence of a corneal implant
- Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- History of lens or zonular instability
- Any contraindication to cataract or keratoplasty
- This device is not intended for use in pediatric surgery.

WARNINGS: The LenSx® Laser System should only be operated by a physician trained in its use.
The LenSx® Laser delivery system employs one sterile disposable LenSx® Laser Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.
The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

PRECAUTIONS:
- Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser.
- Discard used Patient Interfaces as medical waste.

AES/COMPLICATIONS:
- Capsulotomy, phacofragmentation, or cut or incision decentration
- Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
- Capsular tear
- Corneal abrasion or defect
- Pain
- Infection
- Bleeding
- Damage to intraocular structures
- Anterior chamber fluid leakage, anterior chamber collapse
- Elevated pressure to the eye

ATTENTION: Refer to the LenSx® Laser Operator's Manual for a complete listing of indications, warnings and precautions.

IMPORTANT SAFETY INFORMATION FOR THE VERION™ REFERENCE UNIT AND VERION™ DIGITAL MARKER

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

INTENDED USES: The VERION™ Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient's eye in order to determine the radii and corneal curvature of steep and flat axes, limbal position and diameter, pupil position and diameter, and corneal reflex position. In addition, the VERION™ Reference Unit provides preoperative surgical planning functions that utilize the reference image and preoperative measurements to assist with planning cataract surgical procedures, including the number and location of incisions and the appropriate intraocular lens using existing formulas. The VERION™ Reference Unit also supports the export of the high-resolution reference image, preoperative measurement data, and surgical plans for use with the VERION™ Digital Marker and other compatible devices through the use of a USB memory stick.

The VERION™ Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, the planned capsulorhexis position and radius, IOL positioning, and implantation axis from the VERION™ Reference Unit surgical plan can be overlaid on a computer screen or the physician's microscope view.

CONTRAINDICATIONS: The following conditions may affect the accuracy of surgical plans prepared with the VERION™ Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements.

Only trained personnel familiar with the process of IOL power calculation and astigmatism correction planning should use the VERION™ Reference Unit. Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERION™ Reference Unit.

The following contraindications may affect the proper functioning of the VERION™ Digital Marker: changes in a patient's eye between preoperative measurement and surgery, an irregular elliptic limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

WARNINGS: Only properly trained personnel should operate the VERION™ Reference Unit and VERION™ Digital Marker.

Only use the provided medical power supplies and data communication cable. The power supplies for the VERION™ Reference Unit and the VERION™ Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on.

Only use a VERION™ USB stick to transfer data. The VERION™ USB stick should only be connected to the VERION™ Reference Unit, the VERION™ Digital Marker, and other compatible devices. Do not disconnect the VERION™ USB stick from the VERION™ Reference Unit during shutdown of the system.

The VERION™ Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

PRECAUTIONS: To ensure the accuracy of VERION™ Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION™ Digital Marker in conjunction with compatible surgical microscopes.

ATTENTION: Refer to the user manuals for the VERION™ Reference Unit and the VERION™ Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.

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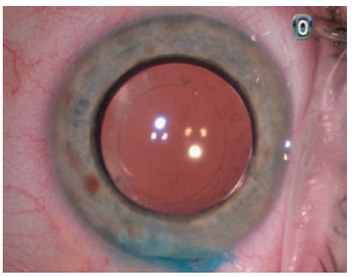
SEALANT SUPERIOR MEANS OF WOUND CLOSURE IN STUDY



MINNEAPOLIS :: **A HYDROGEL** sealant prevented fluid egress from leaking clear corneal cataract incisions more effectively than sutures and had a better safety profile in a prospective multicenter study. "Clear corneal cataract incisions commonly leak—even when well constructed—and it is important to prevent these leaks since they can result in a variety of sight-threatening events, as well as compromise refractive outcome," said Stephen S. Lane, MD.

(See story on page 16 : Closure)

Clinical Diagnosis

AT ISSUE: PREOP TESTING FOR MRSA, PROPHYLAXIS

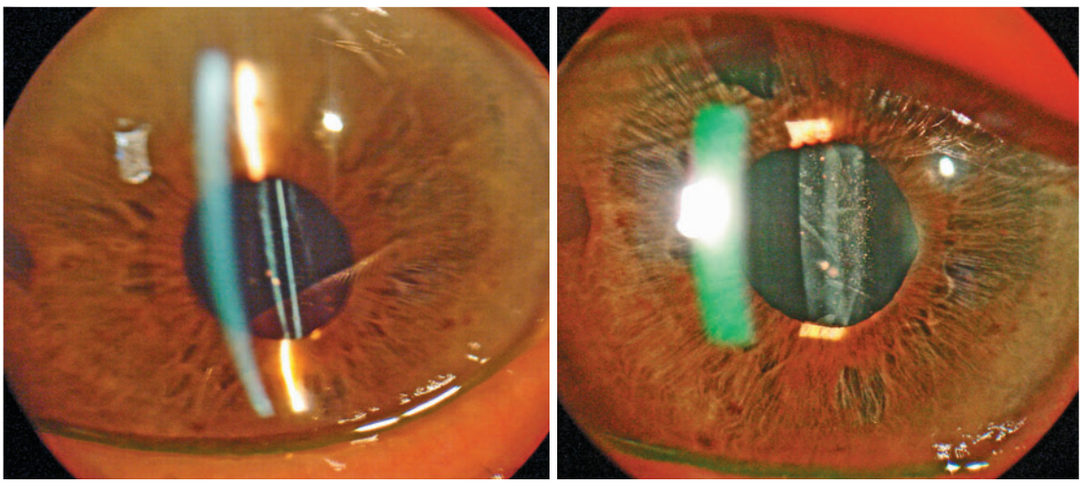
GIVEN THE INCREASE in prevalence of methicillin-resistant *Staphylococcus aureus* (MRSA) colonization and in levels of MRSA antimicrobial resistance, the question arises whether preoperative testing for MRSA to guide targeted prophylaxis should be done routinely in patients undergoing cataract surgery. Peter J. McDonnell, MD, and Stephen D. McLeod, MD, weigh the pros and cons and also discuss whether available evidence supports a selective testing approach in which patients would be screened based on certain history factors.

(See story on page 36 : MRSA)

MALIGNANT GLAUCOMA

Keys to recognizing the condition

Diagnosis and intervention guided by better understanding of the anatomy



AXIAL SHALLOWING OF ANTERIOR CHAMBER. This pseudophakic female patient developed elevated IOP with angle-closure glaucoma due to axial shallowing of the anterior chamber. Note that the PCIOL is pushed forward, toward the cornea, causing the iris to close off the angle. She was already post-iridotomy. The diagnosis of malignant glaucoma was made and her medical therapy failed.

AXIAL DEEPENING OF THE ANTERIOR CHAMBER POST SURGERY. The patient underwent an irido-zonulo-hyaloidotomy combined with pars plana vitrectomy and iridectomy. Note the axial deepening of the anterior chamber. The PCIOL is located more posteriorly, helping to open the angle. *(Figures courtesy of Ronald L. Fellman, MD)*

By Cheryl Guttman Krader;
Reviewed by Ronald L. Fellman, MD

DALLAS ::
MALIGNANT GLAUCOMA is a rare condition, and so ophthalmologists can go for decades without encountering a single case of this angle-closure glaucoma.

Or—because the condition is so uncommon—clinicians who do not maintain an index of suspicion for malignant glaucoma may overlook the diagnosis and mistake it as pupil block, according to Ronald L. Fellman, MD.

Differentiating the two conditions is important, because their treatment is different and can be easily done by careful examination at the slit lamp, said Dr. Fellman, attending surgeon and clinician at Glaucoma Associates of Texas, Dallas.

"Malignant glaucoma is angle-closure glaucoma in which there is ciliovitreal block—not pupil block—although the two may co-exist," Dr. Fellman said. "Understanding the anatomic features along with clinical suspicion of malignant glaucoma is key to both its accurate recognition and appropriate treatment."

DIAGNOSTIC CLUE

Although the pathogenic mechanism for malignant glaucoma remains unclear, there is no question that the angle closure is associated with anterior displacement of both the iris and lens.

On slit lamp examination, therefore, the giveaway diagnostic clue is axial shallowing with anterior displacement of the lens-iris diaphragm. (See Figures 1 and 2 on Page 34)

(Continues on page 34 : Malignant)

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Jeffrey Whitman, M.D.
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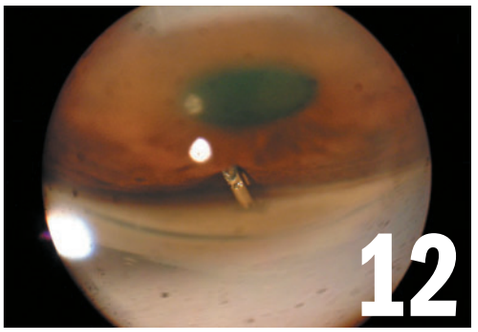

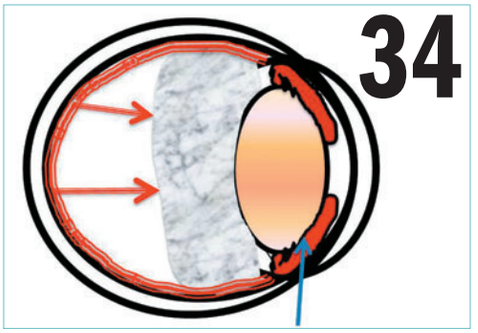

Special Report

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What's Trending

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

1. **Correcting radial keratotomy**
   http://bit.ly/1vSkpsr
2. **How YAG laser vitreolysis can be used for floater treatment**
   http://bit.ly/1udjGxH
3. **How new methodology improves accuracy for IOL power selection**
   http://bit.ly/1tyIDad
4. **Low use of herpes zoster vaccine raises concerns**
   http://bit.ly/WnWAcH

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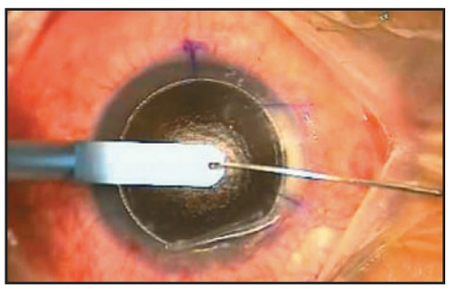
Video



To watch a procedure using the hydrogel corneal inlay. Go to **http://bit.ly/1nICYas**
(Video courtesy of Julian Theng, MD)

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Ophthalmologists are the 99%

Research suggests most physicians aren't so financially successful after all

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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DEAR LOYAL *Ophthalmology Times* reader and fellow ophthalmologist:

Like you, I chose to attend medical school with the goal of helping patients who were ill and needed curing, comforting, or both. So perhaps the financial rewards of a career in medicine have made you feel slightly embarrassed and concerned that people might be resentful or jealous. Well, here's good news: research suggests we physicians aren't so financially successful after all.

The print and television news in the United States was filled, not long ago, with stories about the Occupy Movement. This involved protests, sit-ins, and campers going to places like Wall Street, where the wealthiest 1% of Americans apparently work or generate their wealth. Much written about this 1% group was not very complimentary.

THOSE WITHIN THE 1%

Curious as to the identities of those within the 1%, I consulted the website of Professor G. William Domhoff of the Sociology Department of The University of California at Santa Cruz. Dr. Domhoff studies wealth and income distribution in the United States and correlates this with political power.

According to the website, which breaks the top 1% into subsets, "the 99 to 99.5th percentiles largely include physicians, attorneys, upper middle management, and small business people who have done well . . . The net worth for those in the lower half of the top 1% is usually achieved after decades of education, hard work, saving, and investing as a professional or small business person."

The website goes on to say that this part of the 1%—which includes a lot of physicians—doesn't exactly qualify as a group of fat cats.

"An income of $190,000 post tax or $15,800 per month will certainly be a nice lifestyle but is far from rich . . . Our poor lower half of the top 1% lives well but has some financial worries . . . Those in the 99th to 99.5th percentile lack access to power. For example, most physicians today are having their incomes reduced by HMOs, PPOs, and cost controls from Medicare and insurance companies; the legal profession is suffering from excess capacity, declining demand and global outsourcing; successful small businesses struggle with increasing regulation and taxation. I speak daily with these relative winners in the economic hierarchy and many express frustration."

> 'We, physicians, are really just worker bees. For us, the chances of joining the top 0.5% is reportedly miniscule.' – *Peter J. McDonnell, MD*

THE REST OF THE RANKS

Americans who rank in the top 99th to 99.5th, according to this analysis, are not doing so well.

"Most of those in the bottom half of the top 1% lack power . . . and are essentially well-compensated workhorses for the top 0.5%, just like the bottom 99%. In my view, the American dream of striking it rich is merely a well-marketed fantasy that keeps the bottom 99.5% hoping for better and prevents social and political instability. The odds of getting into that top 0.5% are very slim and the door is kept firmly shut by those within it."

We, physicians, are really just worker bees, even if we make into the 99% to 99.5% group. For us, the chances of joining the top 0.5% is reportedly miniscule: "membership in this elite group is likely to come from being involved in some aspect of the financial services or banking industry, real estate development . . . or government contracting. Some hard-working

Continues on page 8 : **Editorial**

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Ophthalmology Times *Mission Statement*

Ophthalmology Times is a physician-driven media brand that presents cutting-edge advancements and analysis from around the world in surgery, drug therapy, technology, and clinical diagnosis to elevate the delivery of progressive eye health from physician to patient.

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

Through its multifaceted content channels, *Ophthalmology Times* will assist physicians with the tools and knowledge necessary to provide advanced quality patient care in the global world of medicine.

Access to quality care, impact of ACA lead list of challenges

Sen. Sherrod Brown also discusses Medicare and SGR issues, pediatric concerns

***Sight Lines* By J.C. Noreika, MD, MBA**

Dr. Noreika

Editor's Note: *Welcome to the latest installment of "Sight Lines," a feature in which J.C. Noreika, MD, MBA, an ophthalmologist in Medina, OH, discusses trends in ophthalmology, medicine, and health care with key leaders in their fields. In this issue, Dr. Noreika talks with U.S. Sen. Sherrod Brown (D-OH).*

DR. NOREIKA: It is an honor to speak to you today. You represent more than 11 million people in Washington, DC, and you've been a long-time friend of medicine and ophthalmology. I would like to talk about the changes that are going on in medicine—especially in regard to accessibility to quality health care and the Affordable Care Act (ACA). Can you share your thoughts relative to these changes?

SEN. BROWN: Early in my congressional career, you invited me to your office and I watched you and learned about your practice. My dad was a general practice physician, as you know, and so I was open to these discussions. As the ACA is implemented, it is important that doctors have their say and that members of Congress understand the challenges physicians face and the interplay between the law and a physician's practice.

There are a number of very positive things in the ACA. A lot more people have insurance. In Ohio, about a half million more people have insurance today than (several) months ago. Having children with pre-existing conditions no longer disqualifies a family from getting insurance. We have seen thousands of cases already in Ohio, for instance, where a family previously denied (coverage by insurance companies) for years can no longer be denied. On the other end, when someone gets sick and becomes very expensive to care for, the insurance companies can no longer cut them off.

Also, the ACA requires that 80% to 85% of premium dollars go to actual health care. That means it goes to medicine, doctors, and hospitals, not to advertising, marketing, executive salaries, or profits.

The law also has some very important provisions for seniors in terms of preventive care. Things such as eye checkups, physicals, or screenings for osteoporosis or diabetes are covered with no co-payment and no deductible. This is particularly important for ophthalmologists, since so many of their patients are seniors.

On the other end of the age spectrum, people under 27 can be covered on their parents' health-care plan.

There have been problems, of course, but I think the ACA is a big advance for patients in general.

DR. NOREIKA: Is there anything about it you would have done differently?

SEN. BROWN: Yes. For instance, I had a provision in the bill that would have allowed people to buy into Medicare at age 55. This would have let people who lose their jobs at age 58 and can't get insurance because of their health to be in a program like Medicare, which works most of the time for most people. It needed 60 votes to pass, but it only got 59.

Certainly, I would have done the rollout differently, too. I don't really care to second-guess though. When Medicare passed in 1965, there was a lot of opposition from

Continues on page 8 : **Sen. Brown**

'As health-care reform takes hold and we see more of a plateau in health-care costs, the cost to fix the SGR will probably go down. That is not certain, but it is making it easier for Congress to fix it.'

—Sen. Sherrod Brown (D-OH)

Photo courtesy of Sen. Sherrod Brown (D-OH)

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For important safety information, please see adjacent page.

SEN. BROWN

(Continued from page 6)

doctors and insurance companies. But shortly after it passed, Vice President Hubert Humphrey began to call mayors and governors in the South and told them that if they wanted Medicare, they had to integrate their hospitals. That was the same timeframe in which voting rights and civil rights laws passed, so it was very controversial.

Social Security was controversial at the beginning. Medicare was controversial at the beginning, and the ACA is, too. But I think over 2 or 3 years, as doctors adapt and realize that their practices can prosper and we are not taking choices away from them, they will generally be satisfied with this.

DR. NOREIKA: Medicare is a great segue to the next theme. Can the sustainable growth rate (SGR)—which is important to ophthalmologists because we see so many Medicare patients—be fixed?

SEN. BROWN: It absolutely can be fixed. You and I worked together on the first SGR fix when I was in the House of Representatives. I co-sponsored it with the Republican Chairman of the Committee. It was temporary, unfortunately, and has been temporary ever since because of the cost. That's the bad news, but at least we have extended it every year.

The good news is that the Senate Finance Committee passed a repeal in December. It didn't move forward in the Senate, but I think a permanent solution is in sight. The new chairman on the Senate Finance Committee and the ranking Republican have great interest in making this permanent. As health-care reform takes hold and we see more of a plateau in health-care costs, the cost to fix the SGR will probably go down. That is not certain, but it is making it easier for Congress to fix it.

There is great interest in finding a permanent fix. It makes no sense to make doctors lobby us to fix the SGR over and over again instead of pursuing a long-term fix. We need to free up doctors to practice medicine, and let the ones who are activists lobby Congress about tobacco or other public health issues. ■

OphthalmologyTimes.com PODCAST

LISTEN TO what Sen. Sherrod Brown (D-OH) says about medical malpractice liability and the role of ophthalmologists and pediatricians with regard to examining for retinopathy of prematurity. For the complete audio interview with J.C. Noreika, MD, MBA, go to http://bit.ly/1vdoBiQ

OT

Check out Dr. Noreika's past interviews online.

▶ Peter J. McDonnell,MD
http://bit.ly/RlZnkP

▶ Samuel Masket, MD
http://bit.ly/1ttV46R

EDITORIAL

(Continued from page 4)

and clever physicians and attorneys can acquire as much as $15-20 million before retirement, but they are rare."

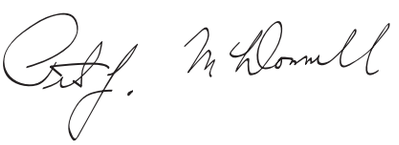
Making it to the tippy-top requires physicians to be both hard working and clever? That leaves yours truly out!

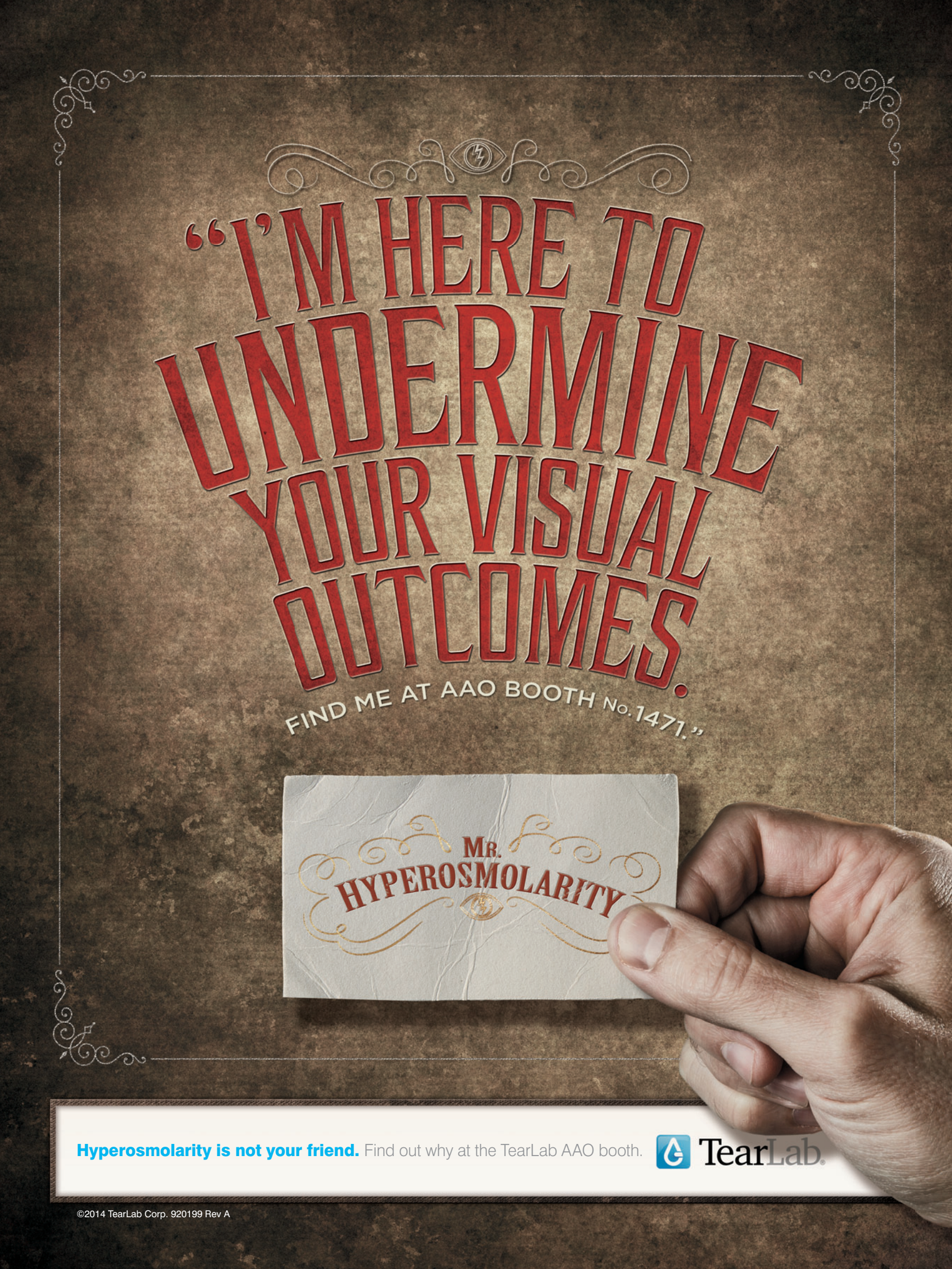
But here's the really sad part: "One might think that physicians, America's highest-paid professional group, would be largely exempt from the economic currents affecting most other Americans. This isn't so. Medscape, a key physician website, reports that as of 2013, mean income for male physicians in all specialties was $259,000; for female physicians, it was $199,000. Family practice doctors and internists earned the least, averaging around $175,000. Orthopedic surgeons earned the most, averaging around $450,000; they are *the only physician specialty falling within the top 1% by income*." (emphasis added).

It is not an issue for me that, as a physician, I am "just a high-paid workhorse" who is probably not hard working and clever enough to be among the top 0.5% financial rung of Americans. But the revelation that orthopedic surgeons are the only doctors whose average incomes earn them entry into the top 1% is a hard pill to swallow. I say we ophthalmologists occupy the American Academy of Orthopaedic Surgeons! ■

Reference

- *http:www2.ucsc.edu/whorulesamerica/power/investment_manager.html*





AAO BRINGS HOT TOPICS, 'VIEW ACROSS THE POND' TO CHICAGO

Ocular oncology, European updates among top focal points for this year's meeting

By Rose Schneider, *Content Specialist,*
Ophthalmology Times

The "Windy City" will welcome this year's meeting of the American Academy of Ophthalmology, and attendees will have the opportunity to hear the "view across the pond" in joint sessions with the European Society of Ophthalmology.

Attendees of the meeting at Chicago's McCormick Place from Oct. 17 to 21 will also notice ocular oncology's larger role, as the topic has been given its own subspecialty day and will be the focus of the Jackson Memorial Lecture.

The Governmental Affairs Program will also provide updates on key hot topics, such as:

- 2015 Medicare update
- Q&A with the FDA
- 2014 American Medical Association ophthalmology section council symposium
- Visual impact of traumatic brain injury: Lessons learned

Further updates on the AAO's IRIS Registry (Intelligent Research in Sight) will be featured, including subspecialty day presentations, such as "Big Data: How It Will Change Your Life" and "IRIS Registry: Update on What Has to Happen by When"; a technology theater piece titled "Introducing the Academy's IRIS Registry: How to Meet Regulatory Requirements for Quality Measures"; and a special session focusing on PQRS, value-based modifier, meaningful use, and sequestration.

take-home

- **The 2014 meeting of the American Academy of Ophthalmology will convene in Chicago from Oct. 17 to 21. Visit *www.aao.org* for the latest updates or to register.**

Participants will also be able to utilize the Mobile Meeting Guide—a web app that uses Wi-Fi or data to access content. The guide contains complete Subspecialty Day and AAO 2014 program information.

To locate a session, abstract, handout, or evaluation attendees may select "Search Program" and use the filter options. Once the session/course is found, handout and evaluation buttons will be visible if they are available for that respective session/course.

The guide also contains Chicago information, satellite symposia, and related group events, as well as an exhibitor search and floor plans. New this year, the guide will have a responsive design that detects attendees' type of device (mobile or desktop) and formats to that device. Also, there will be a networking feature where attendees can start or join discussion groups.

For those who cannot attend the meeting, the option of experiencing the Virtual Meeting is an important tool to utilize. Ophthalmologists from across the globe will be able to watch more than 20 hours of programming live from their computers or handheld devices free of charge. An ophthalmologist will moderate these sessions so the virtual audience can participate while watching the session.

OT **For the AAO virtual meeting schedule, go to *http://bit.ly/XLqyYG***

2014 SUBSPECIALTY DAYS

The annual meeting will be preceded by Subspecialty Days on Friday, Oct. 17, and Saturday, Oct. 18.

Attendees can choose from eight meetings that feature in-depth reviews on current clinical developments in each subspecialty area:

FRIDAY, OCT. 17:

- ***REFRACTIVE SURGERY:*** **Mission 20/20. (Note: This is a two-day meeting that will take place on both subspecialty days)**
- ***RETINA:*** **Reaching New Heights. This session will include video submissions for the first time. (Note: This is a two-day meeting that will take place on both subspecialty days)**

SATURDAY, OCT. 18:

- ***CORNEA:*** **Restocking the Toolbox: Concepts and Techniques for the Toughest Jobs**

Photos courtesy of City of Chicago

Special Report)

AAO MEETING PREVIEW

- ***GLAUCOMA:*** Integrating New Technologies and Approaches Into Your Daily Practice
- ***OCULOFACIAL PLASTIC SURGERY:*** A Global Summit
- ***PEDIATRIC OPHTHALMOLOGY:*** A Magnificent Mile of Innovations
- ***REFRACTIVE SURGERY:*** Mission 20/20
- ***RETINA:*** Reaching New Heights. This session will include video submissions for the first time
- ***UVEITIS:*** Extinguishing the Great Fire

Participants who register for one-day meetings can float between the meetings taking place that day. Two-day registrants can attend any presentation taking place on Friday or Saturday.

OPENING SESSION

The opening session will be held Sunday from 8:30 to 10 a.m. It will include the presentation of the Laureate Award to Jerry A. Shields, MD. Jonathan B. Rubenstein, MD, will give opening and concluding remarks. Han E. Grossniklaus, MD, will give the Jackson Memorial Lecture at 9:30 a.m.

LEARNING LOUNGE

For those wanting to continue the conversation with colleagues, visit the Learning Lounge to participate in informal, small group-focused discussions led by experts in the field.

HIGHLIGHTS INCLUDE:

- Advanced Power Calculations for Cataract and Refractive Surgeons, Saturday, 12 p.m.
- MIGS: Tips for the Cataract Surgeon, Saturday, 12:15 p.m.

JOINT SESSIONS

The AAO will host three joint sessions with the European Society of Ophthalmology called "View Across the Pond." The sessions will examine different perspectives on IOLs, retina, and cornea issues.

PLANNED EVENTS INCLUDE:

- ***CURRENT CATARACT AND IOL PRACTICES:*** Discussing key differences between surgeries performed in Europe and the United States, Sunday, 2 to 3 p.m.

- ***RETINA:*** Comparing and contrasting North American and European approaches to the diagnosis and management of a variety of medical and surgical disorders of the retina, Monday, 8:30 to 10 a.m.

- ***CORNEA ENIGMAS:*** Highlighting the state-of-the-art treatment of corneal and surface disorders in the United States versus Europe, Tuesday, 10:45 a.m. to 12:15 p.m.

ACADEMY CAFÉ

These popular sessions are open to all attendees. Enjoy free coffee while listening in on lively panel discussions and sending questions via text message.

THE LINEUP INCLUDES:

- Saturday: IRIS Registry, 1:15 to 2:30 p.m.; Cataract, 3:15 to 4:30 p.m.
- Sunday: Glaucoma, 10:30 to 11:45 a.m.; Cornea and External Disease, 1 to 2:15 p.m.; Retina, 2:30 to 3:45 p.m.
- Monday: Uveitis, 8:30 to 9:45 a.m.; Oculoplastics, 10:30 to 11:45 a.m.
- Tuesday: Cataract, 10:30 to 11:45 a.m.

BREAKFAST WITH THE EXPERTS

Another popular, interactive event is Breakfast with the Experts. Tickets are $30 in advance and $40 at the door. These sessions will be held Sunday through Tuesday, with several options each day.

EXHIBITION HALL

The world's largest exhibition of ophthalmic technology, products, and services will be open from 9 am. to 5 p.m. on Saturday, Sunday, and Monday, and 9 a.m. to 1 p.m. on Tuesday.

Attendees may visit the Virtual Exhibition online to plan their visit ahead of time; create a "My Expo" account by entering an e-mail address and choosing a password; search the list of exhibitors by company name, booth number, product categories, or medical specialty; as well as tag the exhibitors they plan to visit and print a personalized plan before traveling to Chicago.

Be sure to visit *Ophthalmology Times* at Booth 128.

PRACTICE MANAGEMENT COURSES

Many practice management courses being offered are especially pertinent to physicians.

SOME HIGHLIGHTS INCLUDE:

- ICD-10-CM: Simplifying the Complex, Sunday, 4:30 to 5:30 p.m.
- Keeping Your Practice Out of Legal Hot Water: An HR and Compliance Workshop, Saturday, 9 a.m. to 1 p.m.

OTHER HIGHLIGHTS

- The 2015 Medicare update will take place on Sunday from 12:15 to 1:45 p.m.

- ***THE AFFORDABLE CARE ACT:*** Present and future prospects for ophthalmology will be a platform for speakers to provide insight on how ophthalmologists should respond to the health-care reform's changes. The discussion will take place on Monday from 8:30 to 10 a.m.

- ***ACADEMY RESOURCE CENTER.*** Review and purchase clinical references, patient education, and practice management/coding products. Experience demonstrations of various online resources, such as: ONE Network, Academy online community, Academy store, EyeWiki, and state and federal Affairs.

- ***TECHNOLOGY PAVILION:*** This pavilion will serve as a central place to discuss the latest in hardware, software, social networking, and e-prescribing. Academy members and independent consultants offer user-friendly presentations in the Technology Pavilion (Booth 165), which showcases the latest technology trends that can benefit medical practices.

ORBITAL GALA

The Foundation of the AAO will host the 2014 Orbital Gala on Sunday from 6 to 10 p.m. at the Radisson Blu Aqua Hotel. The evening will start with a cocktail reception and silent auction, and be followed by a buffet dinner and dancing. The gala's theme will be the Roaring '20s.

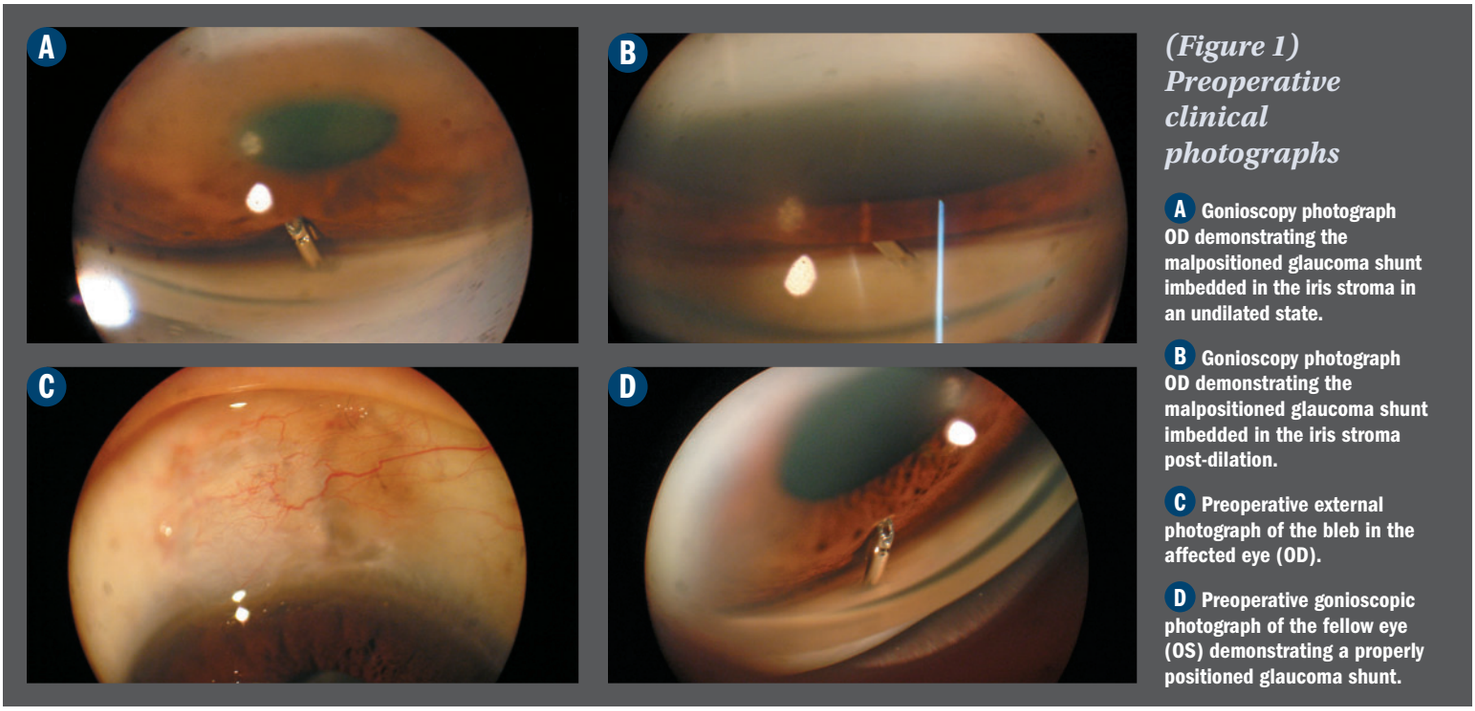
B. Thomas Hutchinson, MD, is this year's honoree. He is a past AAO president, founding chairman of EyeCare America, and past chairman of the Foundation Advisory Board. The gala supports the AAO's priority programs and projects, including educational, quality-of-care research, and service programs.

To learn more or purchase tickets, visit *www.faao.org*. Note that ticket sales end on Oct. 10 and will not be sold at the door. ■

Ab interno technique for glaucoma shunt removal

Gonioprism-assisted approach minimally invasive, less traumatic than traditional procedure

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



(Figure 1) Preoperative clinical photographs

A Gonioscopy photograph OD demonstrating the malpositioned glaucoma shunt imbedded in the iris stroma in an undilated state.

B Gonioscopy photograph OD demonstrating the malpositioned glaucoma shunt imbedded in the iris stroma post-dilation.

C Preoperative external photograph of the bleb in the affected eye (OD).

D Preoperative gonioscopic photograph of the fellow eye (OS) demonstrating a properly positioned glaucoma shunt.

DALLAS ::

A gonioprism-assisted ab interno approach for explantation of the miniature stainless steel glaucoma shunt (Ex-PRESS, Alcon Laboratories) is an efficient and minimally invasive technique with an advantage of sparing the conjunctiva, according to its innovators (Davinder S. Grover, MD, MPH, and Ronald L. Fellman, MD).


Dr. Grover

Its use in two patients—one with severe eye pain secondary to a malpositioned shunt and the other with a non-functioning device—was described in a published paper [*JAMA Ophthalmol*. 2013;131:1356-1358]. The authors believe the explantation technique is worth knowing about considering the growing popularity of the miniature shunt in the care of patients with glaucoma.

"Use of the [shunt] has been increasing among some surgeons who feel it provides a more predictable outcome with faster visual recovery and potentially a lower risk of hypotony compared [with] trabeculectomy," said Dr. Grover, lead author of the paper and a glaucoma specialist, Glaucoma Associates of Texas, Dallas.

Additionally, the device has been associated with a low risk of erosion, he noted.

"Nevertheless, as the [shunt] is used in more and more eyes, it is likely that glaucoma surgeons will be seeing more patients with device-related complications in the future," Dr. Grover said.

The traditional external approach to removing the shunt involves both conjunctival and scleral flap dissection.

With an external approach, the surgeons may encounter difficulties with closure because of the poor quality scleral and/or conjunctival tissue. The latter situation is avoided entirely using the ab interno approach, which is much less traumatic and invasive overall, he explained.

TAKE-HOME

- ***If explantation of a miniature stainless steel glaucoma shunt becomes indicated, an ab interno technique offers several advantages compared with the traditional external approach.***

TWO PATIENT CASES

The first patient in which the ab interno technique was used had undergone bilateral implantation of the miniature shunt performed at another practice. She reported developing pain in the right eye on the day after the procedure. She presented 6 months later to Glaucoma Associates of Texas with severe pain.

Examination revealed a healthy bleb, but on gonioscopy it was seen that the internal tip of the shunt was embedded in the iris.

Continues on page 14 : ***New approach***

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1. Bausch & Lomb Incorporated Study #658 - "A Prospective Multicenter Clinical Study to Evaluate the Safety and Effectiveness of a Bausch + Lomb One Piece Hydrophobic Acrylic Intraocular Lens in Subjects Undergoing Cataract Extraction." Final Clinical Study Report, dated 24 Aug 2011. **2.** Tetz MR, Werner L, Schwahn-Bendig S, Batlle JF. A prospective clinical study to quantify glistenings in a new hydrophobic acrylic IOL. Presented at: American Society of Cataract and Refractive Surgery (ASCRS) Symposium & Congress; April 3-8, 2009; San Francisco, CA. **3.** enVista™ Directions for Use. **4.** Santhiago MR, Netto MV, Barreto J Jr, et al. Wavefront analysis, contrast sensitivity, and depth of focus after cataract surgery with aspherical intraocular lens implantation. *Am J Ophthalmol*. 2010;149(3):383-389. **5.** Pepose JS, Qazi MA, Edwards KH, Sanderson JP, Sarver EJ. Comparison of contrast sensitivity, depth of field and ocular wavefront aberrations in eyes with an IOL with zero versus positive spherical aberration. *Graefe's Arch Clin Exp Ophthalmol*. 2009;247(7):965-973. **6.** Johansson B, Sundelin S, Wikberg-Matsson A, Unsbo P, Behndig A. Visual and optical performance of the Akreos® IOL Adapt Advanced Optics and Tecnis Z9000 intraocular lenses: Swedish multicenter study. *J Cataract Refract Surg*. 2007;33(9);1565-1572. **7.** Data on file. Bausch & Lomb Incorporated.

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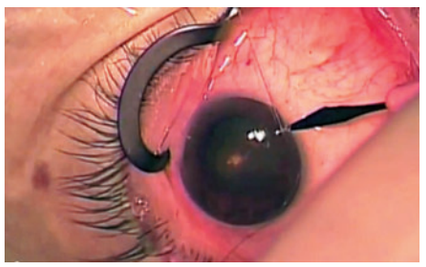
AB INTERNO SHUNT REMOVAL



VIDEO The ab interno procedure is demonstrated. Go to **http://bit.ly/1psspI9**
(Video courtesy of Davinder S. Grover, MD)

NEW APPROACH

(Continued from page 12)

Surgical intervention became indicated when medical management aiming to reduce inflammation and pain was not successful.

"We hated to disrupt the conjunctiva because the glaucoma surgery looked beautiful, and that is why we undertook an ab interno approach to remove the malpositioned shunt," Dr. Grover said. "At the same time, in order to protect against bleb failure, we enlarged the internal sclerostomy.

"The patient experienced immediate resolution of her pain, and with the ab interno conversion to a traditional filtering procedure, her IOP remains well controlled after 1.5 years of follow-up," he said.

The second case described in the paper involved removal of the shunt in a patient who developed a tenon cyst that was refractory to bleb needling with mitomycin C. An ab interno circumferential trabeculotomy was also performed at the time of shunt removal.

"Given the ease and safety of the ab interno approach for shunt removal, we believe it is in the best long-term interest of any patient to remove the shunt if it no longer serves a purpose," Dr. Grover said.

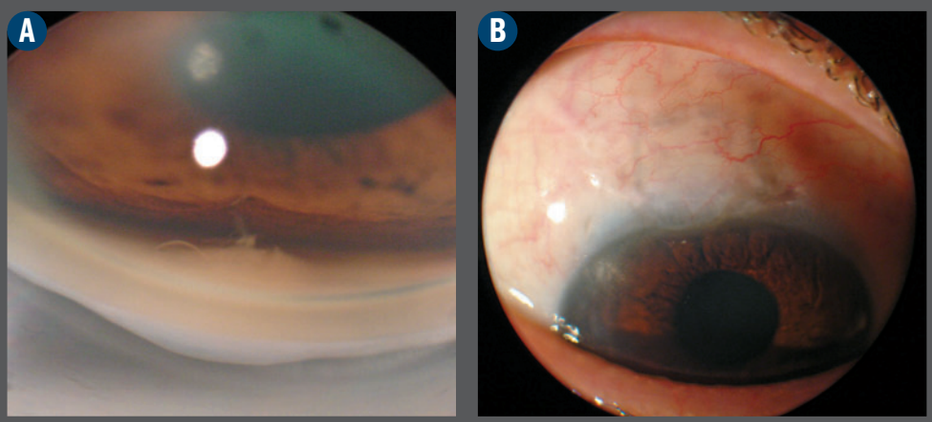
"We are not advocating taking a patient to the operating room primarily to remove the shunt," he said. "However, if an eye with [this] shunt requires an additional surgical procedure, we feel it would be prudent to remove the shunt to protect against the low risk of subsequent erosion and exposure."

PERFORMING THE PROCEDURE

The ab interno procedure involves creation of two corneal paracenteses made about 4 clock hours nasally and temporally from the shunt. After filling the anterior chamber with viscoelastic and using a gonioprism to visualize the shunt within the angle, a 25-gauge microvitreoretinal blade is introduced through the corneal incisions to dissect the scleral tissue adjacent to the shunt and then to cannulate its distal lumen.

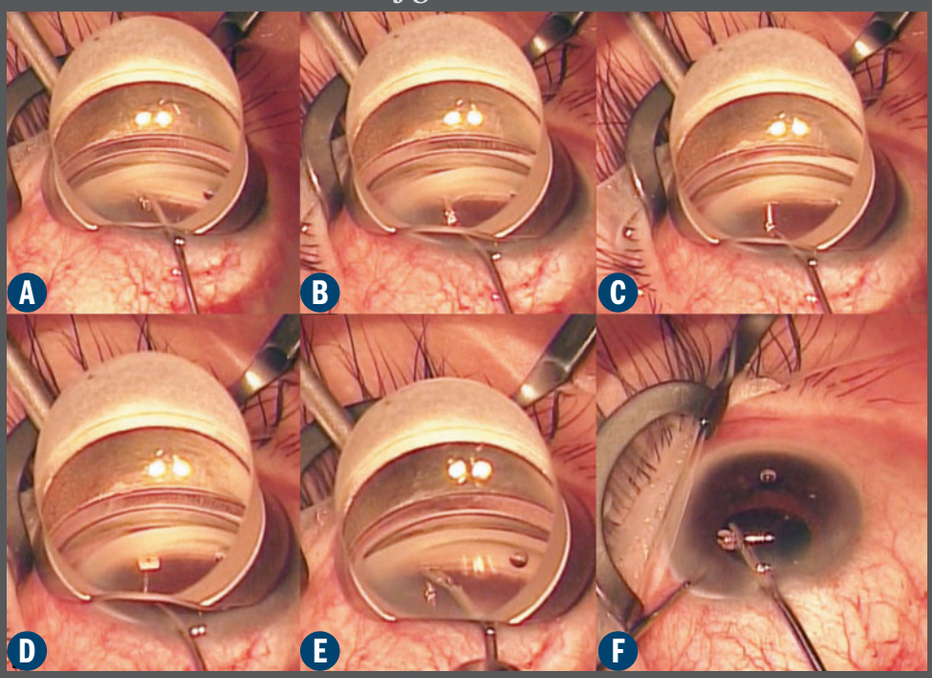
The device is then delivered into the anterior chamber, and using a microsurgical forceps for control, it is explanted through an enlarged temporal corneal incision. ■

(Figure 2) Postoperative clinical photographs



A Gonioscopy photograph OD demonstrating the post-operative appearance of the angle. Note the sclerostomy is patent and the iris stroma is indented, marking the area where the shunt was located. B Postoperative external photograph of the bleb in the affect eye (OD).

(Figure 3) Intraoperative photographs demonstrating ab interno removal of glaucoma shunt



A The scleral tissue adjacent to the shunt is incised with a 25-gauge MVR blade. B The lumen of the shunt is cannulated with the MVR blade. C D The distal tip of the shunt is directed posteriorly allowing the anterior lip of the shunt to be delivered into the anterior chamber. E F Microsurgical forceps are used to retrieve the shunt and remove the device from the anterior chamber through the corneal incisions. *(Images courtesy of Davinder S. Grover, MD)*

DAVINDER S. GROVER, MD, MPH
E: *dgrover@glaucomaassociates.com*

Drs. Grover and Fellman have no relevant financial conflicts of interest pertaining to this subject.

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Study: Sealant superior to sutures for closing cataract incisions

Results indicate sealant offers better means of wound closure sutures when using toric IOLs

By Cheryl Guttman Krader; *Reviewed by Stephen S. Lane, MD*

MINNEAPOLIS ::

A HYDROGEL SEALANT (ReSure Sealant, Ocular Therapeutix) prevented fluid egress from leaking clear corneal cataract incisions more effectively than sutures and had a better safety profile in a prospective multicenter study, said Stephen S. Lane, MD.

Dr. Lane

"Clear corneal cataract incisions commonly leak, even when well constructed, and it is important to prevent these leaks since they can result in a variety of sight-threatening events as well as compromise refractive outcome," said Dr. Lane, medical director, Associated EyeCare, and adjunct professor of ophthalmology, University of Minnesota, Minneapolis.

"Although sutures have been the gold standard for closing cataract incisions, they have a leak rate of about 24% according to various publications along with a number of other drawbacks," Dr. Lane said. "The results of this study indicate the hydrogel sealant offers a better means of wound closure sutures when using toric IOLs."

ABOUT THE RESEARCH

The study included 49 patients operated on at 11 participating centers who were followed at regular visits through 28 days after surgery. All patients had undergone uncomplicated surgery with implantation of a toric IOL (AcrySof IQ Toric, Alcon Laboratories) and had a positive Seidel test at the end of the procedure.

Incisions were tested at the conclusion of surgery, and the leaking was either spontaneous or induced by minimal provocation using a calibrated force gauge (Ocular Force Gauge, Ocular Therapeutix) to apply up to 1 ounce of force in 0.25 ounce increments at a location 0.5 mm away from the scleral side.

Patients were randomly assigned 3:2 to incision closure with the hydrogel sealant (30 eyes) or suture (19 eyes). Immediate re-testing of incision integrity showed the sealing rate was significantly higher using the hydrogel sealant group compared with sutures (96.6% versus 57.9%).

During the follow-up, 9 (47.4%) patients in the suture closure experienced a device-related adverse event, of which 6 required suture removal. Only 2 (6.7%) patients in the hydrogel sealant group experienced a device-related adverse event, and in neither case was removal of the sealant required.

Dr. Lane noted that a much larger study would be required to determine the superiority, if any, of using the hydrogel sealant versus sutures in terms of astigmatism outcomes when implanting toric IOLs.

TAKE-HOME

- ***A hydrogel sealant demonstrated significant superiority to suturing for sealing incisions that were leaking when tested immediately after small-incision phacoemulsification and toric IOL implantation.***

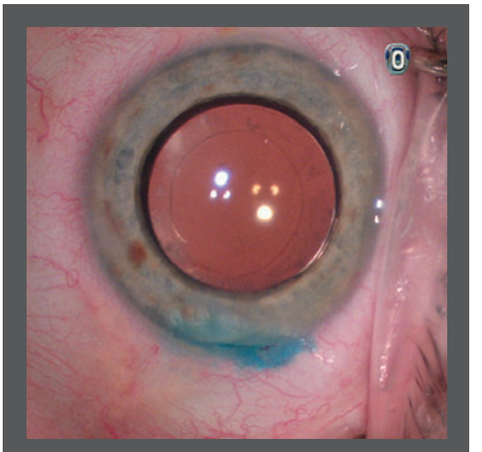
OTHER STUDY FINDINGS

Incision dimensions were similar in the two groups. Mean incision width was 2.7 mm in the suture group and 2.5 mm in the sealant group. Mean tunnel length was 2.5 mm in the suture group and 2.2 mm in the sealant group.

IOP was also monitored during the study and was increased in both groups on the first day after surgery.

Mean IOP at baseline in the suture and ocular sealant groups was 13.89 and 16.07 mm Hg, respectively, and rose to 16.21 and 19.87 mm Hg, respectively, on the first day after surgery.

The only adverse events related to use of the sealant were a single case of >2 line loss of best-corrected visual acuity that resolved and a case of corneal astigmatism >3 D.



The hydrogel sealant is shown in place covering an incision. *(Image courtesy of Stephen S. Lane, MD)*

Device-related adverse events in the suture group included one case of corneal astigmatism >3 D, five reports of discomfort/eye irritation/feeling of tightness, two subconjunctival hemorrhages, and one infection. All adverse events in the suture group resolved.

SURGEON FEEDBACK

Feedback from the surgeons participating in the study indicated the hydrogel sealant was overall easy to use. It is applied as a liquid and gels in situ within 30 seconds. Following corneal re-epithelialization, the sealant sloughs off in the tears.

"One of the disadvantages of sutures is that their use requires an additional visit for removal," Dr. Lane said. "With the sealant, there is no need to remove the device." ■

STEPHEN S. LANE, MD

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This article was adapted from Dr. Lane's presentation at the 2014 meeting of the American Society of Cataract and Refractive Surgery. Dr. Lane is a consultant with Ocular Therapeutix.

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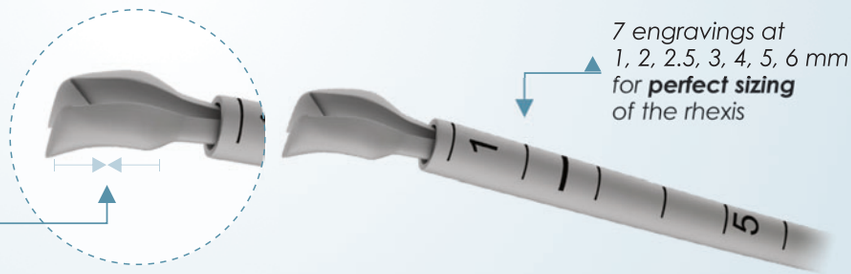

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Managing small pupils: A surgeon's step-wise approach to treatment

How a pupil expansion device helps to protect the iris during cataract surgery

By Boris Malyugin, MD, PhD, *Special to* Ophthalmology Times

MOSCOW ::

DESPITE THE DIFFERENT treatments available to protect the iris during cataract extraction, performing surgery on an eye with a small pupil remains technically challenging. This is due, in part, to the different mechanisms causing small pupils, as well as the surgeon's skill and experience in managing this condition.

Complications can occur more commonly during small-pupil phacoemulsification surgery. These include increased risk of iris damage, iris bleeding, iris prolapse from one or more wounds, anterior capsule damage, incomplete evacuation of the cortical material, and difficulties with placing and aligning the IOL in the bag.[1,2]

In my practice, a step-wise approach is used to manage small pupils, starting with an intracameral injection of phenylephrine or epinephrine and eventually working up to pupil expanders.

Various pupil expansion devices are available, such as metal or plastic hooks, iris rings, and expanding devices. One device (Malyugin Ring, MicroSurgical Technology) was developed to give surgeons a reliable device that is easy to use, expands the pupil up to 7 mm, and protects the iris from damage.

COMPLICATIONS OF SMALL-PUPIL CATARACT SURGERY

Aside from being technically challenging, working with a pupil smaller creates a greater risk for certain complications. In addition, the recommended default pupil diameter for femtosecond cataract surgery is 5 mm—thus, small pupils are typically contraindicated for this technology.[3,4]

Performing cataract surgery on an eye with a small pupil can cause iris bleeding, iris prolapse into a wound, and incomplete evacuation of any cortical material. Additionally, iris chafing can contribute to increased postoperative inflammation and iris defects that can create cosmesis concerns.

Patients with intraoperative floppy iris syndrome (IFIS) may experience progressive pupillary constriction during surgery. This greatly increases the chance of the iris prolapsing into the side port or phaco incisions, or becoming trapped in the ultrasound tip.

A small anterior capsulorhexis can also result if the surgeon is working with a small pupil. This raises the risk of anterior capsule damage from the chopper or ultrasound tip, and heightens the probability of postoperative capsular phimosis.

The surgeon may also have trouble with appropriate visualization during the procedure due to a reduced red reflex and inability to see the peripheral capsule adequately. As a result, the ophthalmologist may have trouble ensuring the lens and haptics are placed completely in the bag, and it may be difficult to see any toric markings on the IOL optics to confirm proper alignment.

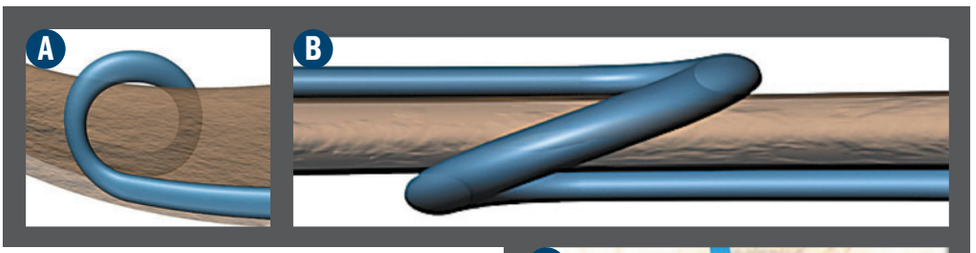
OPTIONS FOR INCREASING PUPIL SIZE

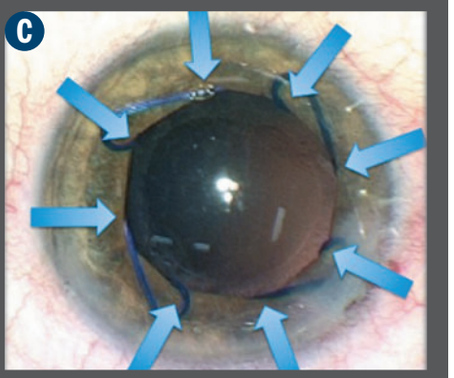
When treating a patient with a small pupil, a step-wise approach is used to increase and then maintain pupil size. This improves visibility and decreases the risk of complications, such as IFIS.

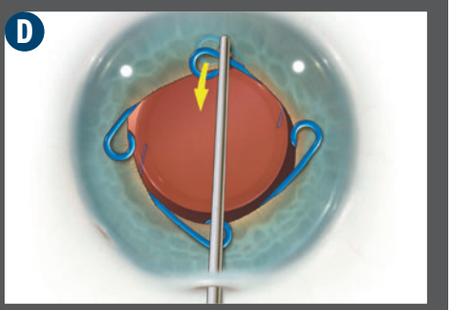
Step one is to use intracameral mydriatics. Shugarcaine[5] and epi-Shugarcaine can be used to increase mydriasis and reduce iris flaccidity; epi-Shugarcaine is preferred in patients with history of tamsulosin use.[6]

If the intracameral injection does not provide sufficient mydriasis, I proceed with viscodilatation, posterior synechiolysis, and pupil-stretching techniques, if appropriate. Small pupils that are not due to IFIS can be managed by mechanical stretching of the iris.

Continues on page 21 : ***Small pupil***







A B Rendition of one of the scrolls and how it secures the iris. Side view of a scroll and the paper-clip action (left). Top view of a scroll securing the iris margin (right).

C The Malyugin Ring gives eight points of fixation to secure the iris.

D Disengaging the distal scroll first during removal. The thin profile makes the Malyugin Ring easy and safe to manipulate during surgery.

Device insertion and removal
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Animation of device use
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(Images courtesy of Boris Malyugin, MD, PhD)

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SMALL PUPIL

(Continued from page 18)

Lysing posterior synechia will obviously improve mydriasis. Viscodilatation with gentle hydrodissection can be used to prevent iris prolapse in patients with IFIS. It is important not to overfill anterior chamber and also to avoid pressure spikes. This minimizes the chance of iris prolapse.[7]

When using a viscoadaptive OVD (for instance, Healon5, Abbott Medical Optics), the surgeon should take into account that usually this type of viscoelastic does not stay in the anterior chamber throughout the whole nucleus removal step of the procedure. Subsequently repeated injections may be needed during the course of the surgery. Decreasing fluidic parameters and aspiration/vacuum rates helps to reduce the rate of OVD aspiration and decreases the chance of iris aspiration into the phaco needle.

The final step is to use pupil expansion devices, including:

- Plastic hooks
- Metal hooks
- 5S iris ring (Morcher GmbH)
- Perfect Pupil (Milvella)
- Graether expander (Eagle Vision Inc.)
- Clarke ring
- Siepser ring
- Malyugin Ring (MicroSurgical Technology)

There are advantages and disadvantages to these devices. They all require additional steps when performing any cataract surgery—lengthening surgery time, increasing costs, and introducing additional instruments into the eye. However, preventing complications related to performing surgery in a small pupil and IFIS outweigh these disadvantages.

Metal or plastic iris hooks can be used to widen the pupil and allow better visualization. The significant advantage is that they allow the surgeon to fixate the iris and the capsule to the limbus. Disadvantages include additional paracenteses, and the possibility of overstretching the iris sphincter and creating iris defects.

Pupil expanders—such as Perfect Pupil, 5S ring, the Graether ring, and the Clarke ring—increase the pupil size, while protecting the iris margin and preventing iris sphincter overstretching. They can be inserted through the main incision so that multiple additional paracenteses are not needed.

TAKE-HOME

Boris Malyugin, MD, PhD, explains how he uses a stepwise approach to manage small pupils, starting with an intracameral injection of phenylephrine or epinephrine and eventually working up to pupil expanders.

This device offers a number of advantages over previous iris expansion devices. It is available in two sizes: 6.25- and 7-mm diameter rings.[8] This gives surgeons two options for pupil width. The 6.25-mm ring can be used for most cases. It causes less stress to the iris tissue, is easier to implant and remove, and is better for small eyes.

The 7-mm ring is designed for surgeons who need larger pupils for a specific reason, such as using an IOL with a 6.5-mm optic. Certain phaco techniques can be used easily with this ring size, including the divide-and-conquer and flip methods. It is also the preferred width in IFIS cases to minimize the risk of movement and miosis.

Since the device can be placed through a main incision that is 2.2 mm or larger, it eliminates the need for extra incisions or additional paracenteses for iris hooks. By using a wound-assisted technique for insertion and removal, the ring can be used in a microincision of 1.6 to 1.8 mm. The thin 5-0 polypropylene paper-clip scroll design gives eight points of fixation, providing the surgeon a round pupil instead of the square one that is formed with four iris hooks (Images A, B, and C).

In addition, the device maintains a wide pupil with minimal iris contact compared with other corneal rings. This reduces iris chafing and makes it less likely to damage the iris sphincter.[9]

The thin profile does not cause the iris to "tent." This minimizes the chance of viscoelastic being trapped beneath it. It is also easier for surgeons to use in shallower anterior chambers. It is thinner than the typical 1 mm thickness of other corneal rings, making it easier to manipulate inside the eye (Image D).

There is less chance of corneal contact during insertion, and it does not get in the way of instruments during the procedure, which makes it safer during surgery. The injector is disposable, unlike other iris rings. This eliminates sterile processing costs. Furthermore, the injector is also used to remove the device, so another instrument is not required.[10]

One significant advantage of the device is that it can be used in cases of small pupils with a posterior capsular rupture. The fixation of the ring is very stable and does not need any additional fixation. Nevertheless, to be even more on the safe side, Dr. Amar Agarwal suggested attaching 6-0 polyglactin vicryl suture to the leading scroll of the ring before implantation. In patients with pre-existing opening in the posterior capsule (for instance, penetrating trauma case), this technique gives extra security for the ring throughout surgery and prevents it from dropping into the vitreous cavity.[11]

CONCLUSION

With the advent of new medications and technologies, performing cataract surgery on small pupils carries less risk than in the past. Surgeons can now use a step-by-step approach to enlarge the pupil to a safe diameter.

When mydriatics, mechanical stretching, and viscodilatation do not provide a wide enough pupil—particularly in cases of IFIS—pupil expansion devices can be employed. Expanders, such as the Malyugin ring, offer good dilation and iris stabilization while minimizing pupil distortion and iris damage.

The ease of insertion and removal with the disposable delivery system makes the device an especially desirable option when treating small pupils due to IFIS. Surgeons can now be more confident in offering safe cataract surgery to patients with small pupils and those who are taking alpha 1-antagonists, such as tamsulosin. ■

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BORIS MALYUGIN, MD, PHD, *is professor of ophthalmology and deputy director general at the S. Fyodorov Eye Microsurgery State Institution, Moscow, Russia. Dr. Malyugin receives royalties from MicroSurgical Technology. Readers may contact him at boris.malyugin@gmail.com.*

Presbyopic laser vision correction: Analyzing PRK method at 1 year

Multifocal bi-aspheric ablation profile, micro-monovision approach delivers good outcomes

By Cheryl Guttman Krader; *Reviewed by Erika N. Eskina, MD*

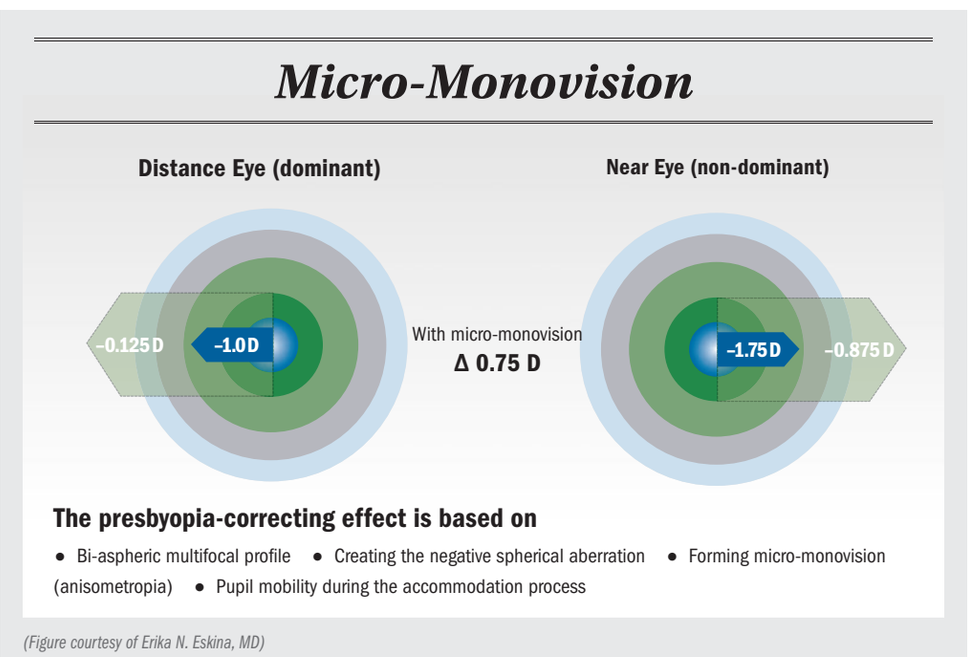
MOSCOW ::

PHOTOREFRACTIVE keratectomy (PRK) using a proprietary multifocal bi-aspheric ablation profile (PresbyMax, Schwind eye-tech solutions) and a micro-monovision-based approach is a safe and effective treatment for ametropic presbyopes, according to outcomes of patients followed for up to 1 year, said Erika N. Eskina, MD.

Dr. Eskina

"We chose to use PRK rather than LASIK because surface ablation greatly increases the possibilities of the method and expands the indications," said Dr. Eskina, professor, Department of Ophthalmology, National Medical-Surgical Center, and medical director, laser surgery clinic, "SPHERE," Moscow, Russia. "However, we recognize that some ophthalmologists still question the effectiveness and predictability of PRK.

"Our initial experience has already suggested a modification to the refractive target that we believe will be beneficial, and further study with longer follow-up is still needed to show the safety and effectiveness of corneal presbyopia correction with the use of a surface ablation technique," she said.



(Figure courtesy of Erika N. Eskina, MD)

VISUAL ACUITIES

Data collected in a cohort of 16 bilaterally treated patients showed good distance and near visual acuity associated with a high rate of spectacle independence. Contrast sensitivity was maintained within the normal range, no eyes lost more than 1 line of best-corrected visual acuity (BCVA), and patient satisfaction was high. There was a slight residual myopia in the dominant eye.

The treatments were planned using the manufacturer's custom ablation manager software and performed with its 500-Hz excimer laser (Amaris). Targets included up to 0.75 D of anisometropia, a surgical add of 1.75 D to 2.25 D, and refractions of –0.13 D in the dominant (distance) eye and –0.875 D in the non-dominant (near) eye.

"The PresbyMax principle, introduced in 2009, is based on both eyes contributing equally to providing visual acuity at all distances by actively participating in the visual process," Dr. Eskina said.

Beginning in 2012, the micro-monovision approach forms slight anisometropia, which together with an additional amount of spherical aberration enlarges the add effect in binocular vision conditions. In addition the change in target refraction with micro-monovision increases the distance uncorrected visual acuity (UCVA) of the dominant eye, Dr. Eskina explained.

Eligibility criteria for the treatment include age ≥40 years, sphere +5 to –6 D, astigmatism ≤2 D, photopic pupil size ≤3 mm, and scotopic/mesopic pupil size ≥4.50 mm. Patients with monocular vision, whose profession requires excellent visual acuity in different light conditions, and those with unrealistic expectations are excluded.

"Presbyopia correction with this procedure requires a careful preoperative exam with use of strict exclusion criteria and a detailed explanation to the patient concerning visual recovery," Dr. Eskina said.

TAKE-HOME

- ***Results from follow-up to 1 year in 16 patients treated with PRK using a multifocal bi-aspheric ablation profile show good visual acuity outcomes and patient satisfaction.***

ABOUT THE STUDY GROUP

The study group included 6 patients with myopia and 10 with hyperopia. Mean preoperative SE for those with myopia was –4.15 D in the eye treated for distance and –4.54 D in the near eye; corresponding values in the hyperopic group were +2.14 and +1.98 D, respectively. Patients had a mean near add of 1.95 D at 40 cm preoperatively and average pupil size of 2.86 mm in photopic conditions and 5.03 mm in scotopic conditions.

All patients were seen at 6 months, and at that visit, binocular near UCVA was 0.2 logRAD or better in all patients with hyperopia and 0.1 logRAD or better in all patients with

Continues on page 24 : ***Presbyopic***

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Scleral implant procedure effective in restoring near vision for presbyopia

Improvement in near visual acuity increased, maintained over 2-year clinical trial

By Lynda Charters; *Reviewed by Michael Endl, MD*

AMHERST, NY ::

A PROCEDURE USING scleral implants (Refocus Scleral Implants, Refocus Group) for the treatment of presbyopia achieved a substantial improvement in near visual acuity 2 years after surgery in a single-center study—with 96% of patients having 20/40 or better monocular vision and all patients achieving 20/40 or better binocular vision.

"In our experience, the scleral spacing procedure was effective for restoring near visual acuity in presbyopic emmetropic patients without adverse effects both objectively and subjectively," said Michael Endl, MD, who is in private practice in Amherst, NY, and principal investigator of this study. "The improvement in vision increased and has been maintained over the course of the 2-year clinical trial."

Dr. Endl highlighted a number of procedures that are available for treating presbyopia.

- **Corneal approaches include excimer laser (multifocal, monovision), femtosecond laser (intrastromal rings), conductive keratoplasty, and corneal inlays.**
- **Presbyopic correction using IOLs includes monofocal (monovision), multifocal, and accommodating approaches.**
- **Scleral surgeries include the scleral implant procedure and scleral laser incisions.**

TAKE-HOME

- ***A scleral spacing procedure for the treatment of presbyopia restored near vision in presbyopic emmetropic patients without adverse effects.***

SINGLE-CENTER EXPERIENCE

Dr. Endl and Claus Fichte, MD, evaluated the effect of the scleral implants on distance-corrected near visual acuity (DCNVA) after implantation at the center with the longest follow-up in a multicenter, prospective, IDE clinical trial.

Sixty-three eyes of 33 patients (20 men, 13 women) underwent this procedure at Fichte, Endl and Elmer Eyecare. The average patient age at surgery was 54 years (range, 50 to 60 years). The average manifest refraction spherical equivalent (MRSE) was +0.17 D (range, –0.50 to +0.875 D).

During the scleral spacing procedure, four scleral implants were circumferentially implanted intrasclerally in the oblique quadrants just posterior to the lens equator. Inclusion criteria included best-corrected distance visual acuity (BCDVA) of 20/20 in each eye, MRSE between +0.75 to –0.50 D with 1 D or less of astigmatism and DCNVA between 20/50 to 20/100. All eyes were phakic.

The primary outcome of DCNVA was obtained using standardized illumination at 40 cm at all visits. Patients with scleral thickness less than 530 µm and those who had undergone a previous ocular surgery or chronic ocular disease were excluded.

Patient enrollment and the surgeries were completed in August 2012. Two-year data are available for 25 patients.

VISUAL ACUITY OUTCOMES

By month 24 after the scleral implant procedure, 96% of patients achieved DCNVA of 20/40 or better monocularly and three lines of improvement in DCNVA compared with baseline, Dr. Endl noted.

All patients achieved DCNVA or 20/40 or better binocularly. The distribution of binocular DCNVA at 2 years was 100% 20/40; 95% 20/32; 64% 20/25, and 27% 20/20. The investigators found that visual acuity improved over the course of the 2-year follow-up period.

There were minimal adverse events postoperatively and all study-related adverse events resolved without sequelae. No patients lost BCDVA. ■

MICHAEL ENDL, MD

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The article was adapted from a presentation at the 2014 meeting of the American Society of Cataract and Refractive Surgery. Dr. Endl has no financial interest in the subject matter. Refocus Group provided research funding and travel expenses.

PRESBYOPIC

(Continued from page 22)

myopia. At 12 months, those same near UCVA levels were reached by 6 (67%) of the patients with hyperopia and 3 (50%) of the patients with myopia.

Binocular distance UCVA was 0.1 logMAR or better in all patients with hyperopia at 6 and 12 months and 0.0 logMAR or better in all patients with myopia. At both 6 and 12 months all patients had binocular BCVA of 0.0 logMAR or better.

"The majority of hyperopes gained at least 3 lines in both binocular near and distance UCVA," Dr. Eskina said. "Among the myopes, the majority gained at least 3 lines in distance UCVA and had almost no loss of lines in binocular near UCVA."

Though near vision improvement was achieved rapidly, recovery in distance acuity took up to 3 months in patients with myopia and even longer in patients with hyperopia. Analyses of refractive outcomes showed the postoperative anisometropic target of 0.75 D was achieved in both groups at 6 and 12 months, but there was a slight residual myopia in both eyes which became less within the observation period.

"Small residual myopia in the distance eye may decrease distance UCVA and influence the patient's satisfaction level," Dr. Eskina said. "In the future, we believe that slightly increasing the refractive target in the distance eye by about –0.25 D from the manifest value in the myopes and from the cycloplegic value in the hyperopes will be beneficial." ■

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This article was adapted from Dr. Eskina's presentation at the 2014 meeting of the American Society of Cataract and Refractive Surgery. Dr. Eskina has no relevant financial interests to disclose.

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Use of retinal prosthesis system helps shape vision for retinitis pigmentosa

Patient expectations and counseling facilitate integration of device into daily life

By Thiran Jayasundera, MD, FACS, *Special to* Ophthalmology Times

ANN ARBOR, MI ::

THE ADVENT OF the retinal prosthesis system (Argus II Retinal Prosthesis System, Second Sight Medical Products)—while not fully restoring vision to blind individuals—is the first FDA-approved device to offer a second chance at sight for patients with vision loss from retinitis pigmentosa. The more patients utilize the system, the more they learn to interpret their new form of vision.

The system induces visual perception in blind individuals through the electrical stimulation of the retina, partially restoring a type of vision.

To qualify as a candidate for the system, patients must have been diagnosed with retinitis pigmentosa, be at least 25 years of age, have bare light or no light perception in both eyes, have previously had some sort of useful vision, and most importantly, must be willing and able to attend the pre and postoperative follow-up and rehabilitation sessions.

TAKE-HOME

- ***The advent of a retinal prosthesis system offers a second chance at sight for patients with vision loss from retinitis pigmentosa.***

ABOUT THE SYSTEM

The system is made up of both internal and external components. The external components include a pair of glasses (onto which a camera and antenna are mounted) and a video processing unit (VPU). A cable connects the glasses to the VPU.

The internal component is an epiretinal prosthesis that is implanted in and around the eye, typically the worse-seeing eye, and includes an antenna, an electronics case, and an electrode array.

The components work together to bypass the damaged photoreceptors in the retina and stimulate the remaining retinal cells that will register the perception of patterns of light the users will learn to interpret.

This system—while not restoring full sight or curing retinitis pigmentosa—is the first device that partially restores useful vision to these patients.

PREPARING FOR IMPLANTATION

Prior to surgery, patients will need to be seen to assess eligibility for the device, which should include an eye exam—including an assessment of residual vision, anesthesiology assessment, retinal photography, and optical coherence tomography.

It is also important to do an A- and B-scan ultrasound to measure the axial length of the eye and evaluate the retina for conditions that may prevent the implant from resting well against the retina.

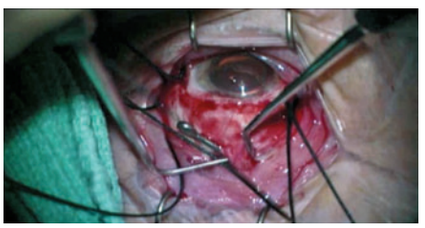
Finally, patients need to be started on an oral antibiotic—such as moxifloxacin 400 mg daily—about 2 days prior to surgery.

While the medical preparations are necessary, the most important aspect of the implantation preparation is counseling. It is crucial that patients have realistic expectations of the outcome of this procedure. Along with needing to understand all the risks and probable benefits of having the system implanted, patients must understand that post-implantation they will experience a visual perception that is different from the type of vision they had before they lost their sight. This is important in order to manage the patients' expectations.

Patients will not wake from the surgery suddenly able to see. They must first learn to interpret the images they will perceive. This involves fitting or customized programming of the device and low-vision rehabilitation.

The experiences of individuals using the system will vary. Many express joy at being able to detect light patterns and motion after years of being blind. Users have also been able to identify different sources of light, locate items in front of them on a table, detect poles and other objects in their path, follow a sidewalk or crosswalk, determine where people are located, and even sort light and dark colored laundry or read large print words. While the system will not restore normal sight, it can provide users with a form of artificial vision that can enhance their connection to their surroundings and the people in their lives.

SURGICAL PROCEDURE



VIDEO Watch a procedure using the retinal prosthesis system in a patient with retinitis pigmentosa. Go to **http://bit.ly/1t0hBTX**

(Video courtesy of Thiran Jayasundera, MD, FACS)

SURGICAL PROCEDURE OVERVIEW

Two key aspects of this surgery are to focus on the accuracy of the device placement and to ensure that the sclerotomy is well closed. Each surgical step should be done with the precision prescribed by the manufacturer so no errors are made.

Sutures should be placed only once. It is necessary to be meticulous in terms of surgical technique and ensure thorough removal of the vitreous (and membrane, if present) during the time of vitrectomy. Unlike other surgeries, errors may be more difficult to correct with this procedure.

The surgery is administered under general anesthesia and patients also need an antibiotic given intravenously during the surgery. Once it has been established that the implant is in working order, the eye that will receive the implant is prepped and draped, a 360° conjunctival peritomy is made, and the muscles are isolated.

The extraocular portion of the implant is passed around the eye, underneath the rectus muscles. Before suturing the tabs, ensure

Continues on page 28 : ***Pigmentosa***

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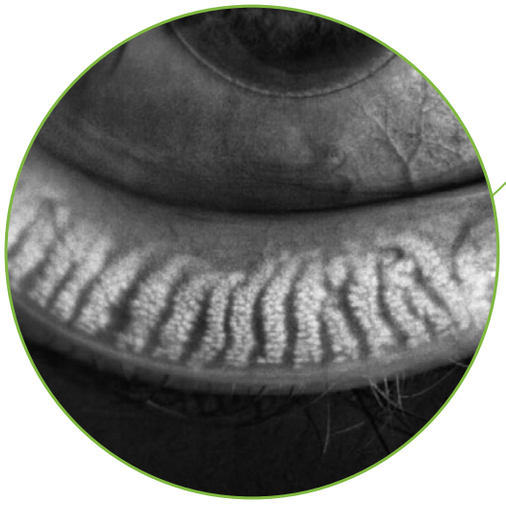
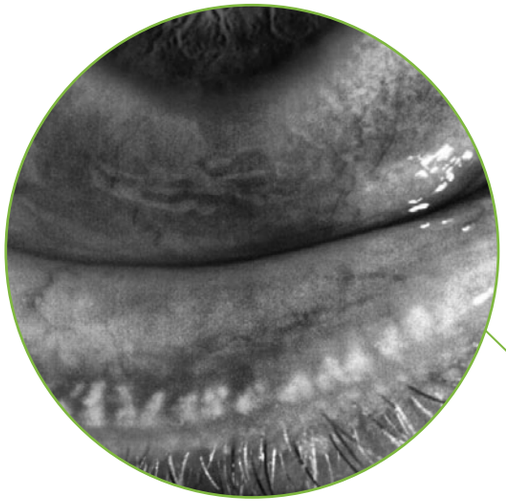


normal meibomian gland structure

structural change (duct dilation,
gland atrophy and drop out)



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PIGMENTOSA

(Continued from page 26)

that the implant is the correct distance from the limbus and that the suture tabs are in the prescribed position such that the cable falls smoothly onto the surface of the cornea. This will make placing the array over the macula much easier.

The implant is inserted through a 5-mm linear incision that is made in the superior temporal quadrant. To facilitate placement, the tip of special tack forceps can be used—without touching the retina—to move the array into position before it is tacked down. The tack injector is inserted through a 19-gauge sclerotomy and the array is tacked onto the macula. The ideal position for the array is such that it is centrally placed on the macula (Figure 1).

The sclerotomy is closed with a horizontal mattress suture, which goes underneath the cable, and a 9- × 5-mm pericardial graft placed on top of the case and the cable and sutured to the sclera. The Tenons are closed and sutured in all four quadrants and once the conjunctiva is closed, the subconjunctival dexamethasone and antibiotics are injected.

WHAT PATIENTS EXPERIENCE

Patients will need the typical drops that are given after vitrectomy surgery—which is prednisolone acetate drops four times a day, antibiotic drops four times a day, and atropine drops twice a day.

After surgery is when the real work begins. The patient generally returns the day after surgery, a few days to a week later, and again a month later for medical follow-ups, to have their new device fitted, and to begin training and rehabilitation.

Typically 1 to 2 weeks after surgery, they have what is essentially a fitting session where the device is turned on and the thresholds of the electrodes are measured. The electrodes are stimulated to see if the patient detects any perceptions of light. People usually perceive the sensation of light or a flashing light. Over time, they will learn to interpret these patterns of light as shapes and objects.

About 2 weeks to 1 month after surgery, the external equipment—including the VPU and the glasses that contain the camera—are given to the patients and they will begin low-vision rehabilitation. Low-vision therapists will teach patients how to use their device, including how they can move their heads in order to scan an object. These therapists will help patients learn to interpret what they are seeing. The number of sessions a patient requires will vary, but in general, they could require from five to 12 sessions of therapy.

At each session they learn something new. During their first session, they will learn the basics, including how to put the glasses on and change the battery. From there, they learn how best to use the device, including how to move their heads in order to use the camera on the glasses to scan the presence or absence of an object that is in front of them.

At these sessions, the patients are given many different tasks to help facilitate the integration of the system into their lives. These tasks include activities, such as sorting black-and-white shapes, determining if a light is being turned on or off, and other exercises that are designed to help the patients interpret what they are seeing. A lot of these tasks can and should be performed at home as well, and the patient is provided a take-home kit to facilitate this process.

OT After 20 years of research and development and many clinical trials, the FDA approval of the retinal prosthesis brings hope for patients with late-stage retinitis pigmentosa. **Read more about how the retinal prosthesis works at http://bit.ly/1rokVeO.**

VISUAL BENEFITS

The more patients are willing and able to practice the exercises they are given in their low-vision therapists' offices in their home environment, the faster they will learn to utilize their new sight. Those who are dedicated to practicing learn very quickly. Once patients have completed their training and learned to interpret the information provided by the system, they will be able to utilize their newfound visual functionality in their everyday lives.

Continued updates to the system hardware and software are likely to enhance their experiences going forward. While experiences will vary between patients, there is no doubt the system will continue to be a light in the darkness for those suffering from this degenerative disease. ■

THIRAN JAYASUNDERA, MD, FACS, *is assistant professor of ophthalmology and visual sciences at the University of Michigan Kellogg Eye Center of Ann Arbor, a Fellow of the American College of Surgeons, Fellow of the Royal College of Surgeons of Canada, and Fellow of the Royal Australia and New Zealand College of Ophthalmologists. Dr. Jayasundera can be reached at thiran@med.umich.edu. Dr. Jayasundera did not indicate financial interest in the subject matter.*

Alphaeon to acquire Clarion Medical

By Rose Schneider; *Content Specialist,* Ophthalmology Times

IRVINE, CA ::

ALPHAEON CORP. has entered into a definitive agreement to acquire all of the outstanding shares and assets of Clarion Medical Technologies for an undisclosed sum.

"Over the past 25 years, Clarion has shown consistent and profitable growth," said Robert E. Grant, chief executive officer of Alphaeon. "This acquisition expands (our) geographic reach and provides early market experience with leading products from around the world, including Teoxane's full-line of dermal fillers, a strong energy device platform, and multiple ophthalmic technologies that provide patients optimal outcomes.

"We also intend to launch ShoutMD, as well as our portfolio of performance, wellness, and beauty products in Canada through our unique digital selling approach," he continued. "We look forward to partnering closely with the specialty physicians in Canada to advance patient outcomes and experiences."

"Clarion prides itself on being a trusted strategic partner to Canada's leading physicians, which is why it is important for us to select a partner whose values and customer centricity aligns with ours," said Dan Webb, chief executive officer and founder of Clarion. "We truly believe that together we will be able to continue to offer innovative solutions and best-in-class service to our physicians and their patients.

"Most importantly, this transaction provides Clarion access to the ShoutMD proprietary procial (professional and social) media platform, which enables real-time peer-to-peer engagement with the leading physicians within lifestyle healthcare, around the world," Webb added. ■

Refractive surgery screening devices valuable but not necessarily equal

Study evaluates correlation of Scheimpflug and OCT relational thickness metrics

By Lynda Charters;
Reviewed by Heather Weissman, MD

ATLANTA ::

Many different technologies are commercially available for use by refractive surgeons to screen potential patients preoperatively.

"Many of these machines provide similar information and assign values to patients who are at increased risk for developing ectasia after refractive surgery," said Heather Weissman, MD, a resident at Emory Eye Center, Emory University, Atlanta. "There is overlap of some information between machines."

However, the question that currently remains unanswered is: Are these machines providing similar screening information?

RETROSPECTIVE STUDY

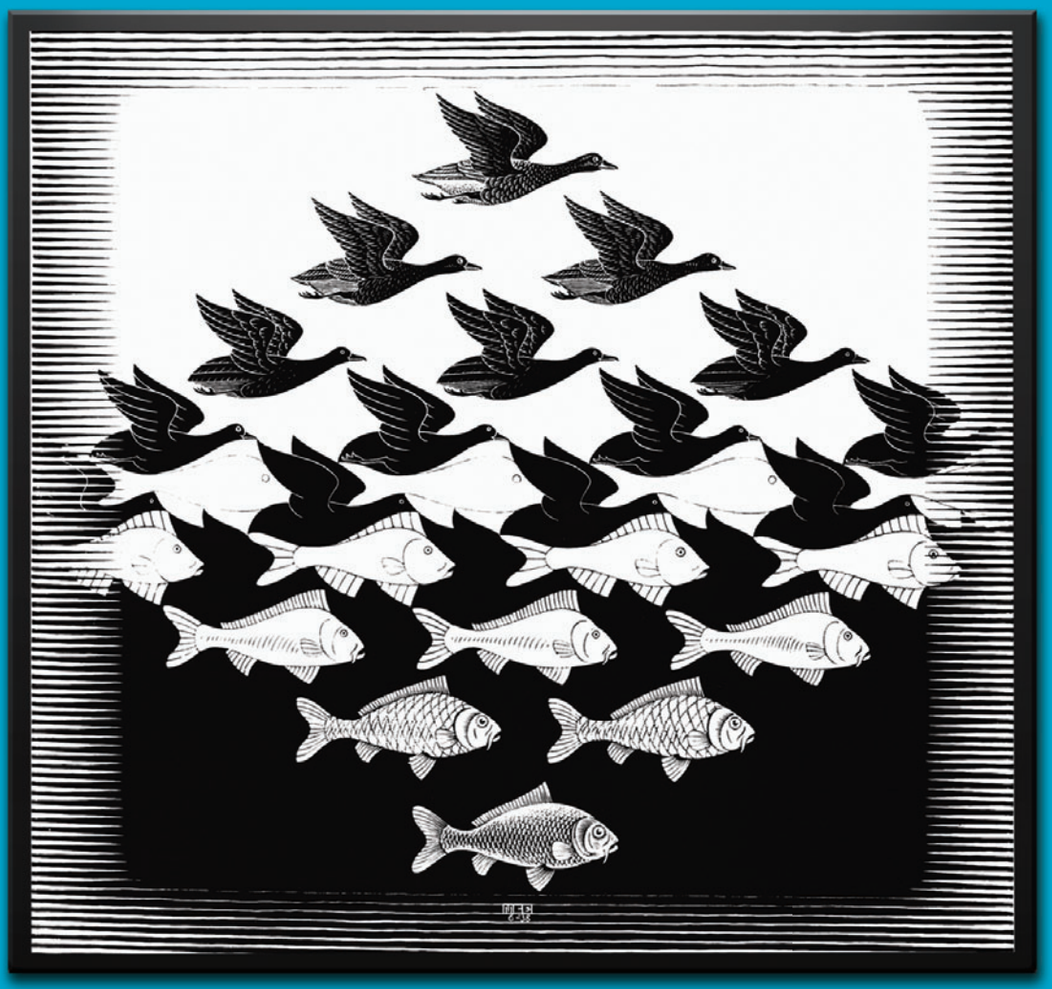
A comparison of Scheimpflug and spectral-domain optical coherence tomography (SD-OCT) values—superior-inferior (S-I) and superonasal-inferotemporal (SN-IT)—that were obtained from possible candidates for refractive surgery with suspect screening parameters showed that the values were poorly correlated and the two screening devices cannot be used interchangeably.

Dr. Weissman

Dr. Weissman and co-authors, Trey Nunnery, MD, and J. Bradley Randleman, MD, conducted a retrospective study to evaluate the correlation between the values obtained using Scheimpflug (Pentacam HR, Oculus Inc.) Ambrósio Relational Thickness (ARTMax) and SD-OCT (Optovue Inc.) when the S-I and SN-IT regions of the eye were measured.

A consecutive series of 182 eyes of 91 patients who were possible surgical candidates underwent a refractive surgical evaluation using Scheimpflug camera and SD-OCT and were found to have suspicious screening parameters with an ectasia risk score of 3. The

Continues on page 33 : ***Screening***



Indication and Usage

Diabetic Macular Edema

OZURDEX® (dexamethasone intravitreal implant) is a corticosteroid indicated for the treatment of diabetic macular edema in patients who are pseudophakic or are phakic and scheduled for cataract surgery.

Dosage and Administration

FOR OPHTHALMIC INTRAVITREAL INJECTION ONLY. The intravitreal injection procedure should be carried out under controlled aseptic conditions. Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis without delay.

IMPORTANT SAFETY INFORMATION

Contraindications

Ocular or Periocular Infections: OZURDEX® (dexamethasone intravitreal implant) is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

Advanced Glaucoma: OZURDEX® is contraindicated in patients with advanced glaucoma.

Non-intact Posterior Lens Capsule: OZURDEX® is contraindicated in patients whose posterior lens capsule is not intact.

Hypersensitivity: OZURDEX® is contraindicated in patients with known hypersensitivity to any components of this product.

Warnings and Precautions

Intravitreal Injection-related Effects: Intravitreal injections, including those with OZURDEX®, have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored regularly following the injection.

Steroid-related Effects: Use of corticosteroids including OZURDEX® may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

Corticosteroids should be used cautiously in patients with a history of ocular herpes simplex.

Risk of Implant Migration: Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

Adverse Reactions

Adverse reactions reported by greater than or equal to 1% of patients in the two combined 3-year clinical trials following injection of OZURDEX® for diabetic macular edema include: cataract (68%), intraocular pressure increased (35%), conjunctival hemorrhage (23%), visual acuity reduced (9%), conjunctivitis (6%),

Now, for DME patients who are pseudophakic or phakic and scheduled for cataract surgery...

NEW INDICATION

SEE DME *Differently.*

- **The pathophysiology**
  — An **inflammatory cascade** plays a key role[1-5]
- **The therapeutic targets**
  — Suppress multiple **inflammatory cytokines**[6]
- **The clinical results**
  — Achieve clinically significant **3-line gains** in BCVA[6,*]

IMPORTANT SAFETY INFORMATION (continued)
Adverse Reactions (continued)
vitreous floaters (5%), conjunctival edema (5%), dry eye (5%), vitreous detachment (4%), vitreous opacities (3%), retinal aneurysm (3%), foreign body sensation (2%), corneal erosion (2%), keratitis (2%), anterior chamber inflammation (2%), retinal tear (2%), eyelid ptosis (2%) and hypertension (13%).

Cataracts and Cataract Surgery: The incidence of cataract development in patients who had a phakic study eye was higher in the OZURDEX® group (68%) compared with Sham (21%). The median time of cataract being reported as an adverse event was approximately 15 months in the OZURDEX® group and 12 months in the Sham group. Among these patients, 61% of OZURDEX® subjects versus 8% of sham-controlled subjects underwent cataract surgery, generally between Month 18 and Month 39 (Median Month 21 for OZURDEX® group and Month 20 for Sham group) of the studies.

Increased Intraocular Pressure: Approximately 42% of the patients who received OZURDEX® were subsequently treated with IOP-lowering medications during the study.

In the sham control group, IOP-lowering medications were used in approximately 10% of patients.

The increase in mean IOP was seen with each treatment cycle, and the mean IOP generally returned to baseline between treatment cycles (at the end of the 6-month period).

Please see Brief Summary of full Prescribing Information on next page.

*Best-corrected visual acuity.

Ozurdex® (dexamethasone intravitreal implant) 0.7 mg

1. Jain A, Varshney N, Smith C. The evolving treatment options for diabetic macular edema. *J Inflam.* 2013:689276. **2.** Bhagat N, Grigorian RA, Tutela A, Zarbin MA. Diabetic macular edema: pathogenesis and treatment. *Surv Ophthalmol.* 2009;54(1):1-32. **3.** Ehrlich R, Harris A, Ciulla TA, Kheradiya N, Winston DM, Wirostko B. Diabetic macular oedema: physical, physiological and molecular factors contribute to this pathological process. *Acta Ophthalmologica.* 2010;88:279-291. **4.** Scholl S, Kirchhof J, Augustin AJ. Pathophysiology of macular edema. *Ophthalmologica.* 2010;224(suppl 1):8-15. **5.** Zhang W, Liu H, Al-Shabrawey M, Caldwell RW, Caldwell RB. Inflammation and diabetic retinal microvascular complications. *J Cardiovasc Dis Res.* 2011;2(2):96-103. **6.** OZURDEX® Prescribing Information.

ALLERGAN Retina

www.Ozurdex.com APC80EV14 141624

OZURDEX®

(dexamethasone intravitreal implant) 0.7 mg

Brief Summary—Please see the OZURDEX® package insert for full Prescribing Information.

INDICATIONS AND USAGE

Retinal Vein Occlusion: OZURDEX® (dexamethasone intravitreal implant) is a corticosteroid indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

Posterior Segment Uveitis: OZURDEX® is indicated for the treatment of non-infectious uveitis affecting the posterior segment of the eye.

Diabetic Macular Edema

OZURDEX® (dexamethasone intravitreal implant) is a corticosteroid indicated for the treatment of diabetic macular edema in patients who are pseudophakic or are phakic and scheduled for cataract surgery.

CONTRAINDICATIONS

Ocular or Periocular Infections: OZURDEX® (dexamethasone intravitreal implant) is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

Advanced Glaucoma: OZURDEX® is contraindicated in patients with advanced glaucoma.

Non-Intact Posterior Lens Capsule: OZURDEX® is contraindicated in patients whose posterior lens capsule is not intact.

Hypersensitivity: OZURDEX® is contraindicated in patients with known hypersensitivity to any components of this product.

WARNINGS AND PRECAUTIONS

Intravitreal Injection-related Effects: Intravitreal injections, including those with OZURDEX®, have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments.

Patients should be monitored regularly following the injection *[see Patient Counseling Information].*

Steroid-related Effects: Use of corticosteroids including OZURDEX® may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses *[see Adverse Reactions].*

Corticosteroids should be used cautiously in patients with a history of ocular herpes simplex.

Risk of Implant Migration: Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

ADVERSE REACTIONS

Clinical Studies Experience: Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Adverse reactions associated with ophthalmic steroids including OZURDEX® include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Retinal Vein Occlusion and Posterior Segment Uveitis

The following information is based on the combined clinical trial results from 3 initial, randomized, 6-month, sham-controlled studies (2 for retinal vein occlusion and 1 for posterior segment uveitis):

Adverse Reactions Reported by Greater than 2% of Patients

MedDRA Term	OZURDEX® N=497 (%)	Sham N=498 (%)
Intraocular pressure increased	125 (25%)	10 (2%)
Conjunctival hemorrhage	108 (22%)	79 (16%)
Eye pain	40 (8%)	26 (5%)
Conjunctival hyperemia	33 (7%)	27 (5%)
Ocular hypertension	23 (5%)	3 (1%)
Cataract	24 (5%)	10 (2%)
Vitreous detachment	12 (2%)	8 (2%)
Headache	19 (4%)	12 (2%)

Increased IOP with OZURDEX® peaked at approximately week 8. During the initial treatment period, 1% (3/421) of the patients who received OZURDEX® required surgical procedures for management of elevated IOP.

Following a second injection of OZURDEX® (dexamethasone intravitreal implant) in cases where a second injection was indicated, the overall incidence of cataracts was higher after 1 year.

Diabetic Macular Edema

The following information is based on the combined clinical trial results from 2 randomized, 3-year, sham-controlled studies in patients with diabetic macular edema. Discontinuation rates due to the adverse reactions listed in the table below were 3% in the OZURDEX® group and 1% in the Sham group. The most common ocular (study eye) and non-ocular adverse reactions are as follows:

Adverse Reactions Reported by ≥ 1% of Patients

MedDRA Term	OZURDEX® N=324 (%)	Sham N=328 (%)
Ocular		
Cataract[1]	166/243[2] (68%)	49/230 (21%)
Intraocular pressure increased[3]	115 (35%)	16 (5%)
Conjunctival hemorrhage	73 (23%)	44 (13%)
Visual acuity reduced	28 (9%)	13 (4%)
Conjunctivitis	19 (6%)	8 (2%)
Vitreous floaters	16 (5%)	6 (2%)
Conjunctival edema	15 (5%)	4 (1%)
Dry eye	15 (5%)	7 (2%)
Vitreous detachment	14 (4%)	8 (2%)
Vitreous opacities	11 (3%)	3 (1%)
Retinal aneurysm	10 (3%)	5 (2%)
Foreign body sensation	7 (2%)	4 (1%)
Corneal erosion	7 (2%)	3 (1%)
Keratitis	6 (2%)	3 (1%)
Anterior Chamber Inflammation	6 (2%)	0 (0%)
Retinal tear	5 (2%)	2 (1%)
Eyelid ptosis	5 (2%)	2 (1%)
Non-ocular		
Hypertension	41 (13%)	21 (6%)

[1] Includes cataract, cataract nuclear, cataract subcapsular, lenticular opacities in patients who were phakic at baseline. Among these patients, 61% of OZURDEX® subjects vs. 8% of sham-controlled subjects underwent cataract surgery.

[2] 243 of the 324 OZURDEX® subjects were phakic at baseline; 230 of 328 sham-controlled subjects were phakic at baseline.

[3] Includes IOP increased and ocular hypertension.

Cataracts and Cataract Surgery

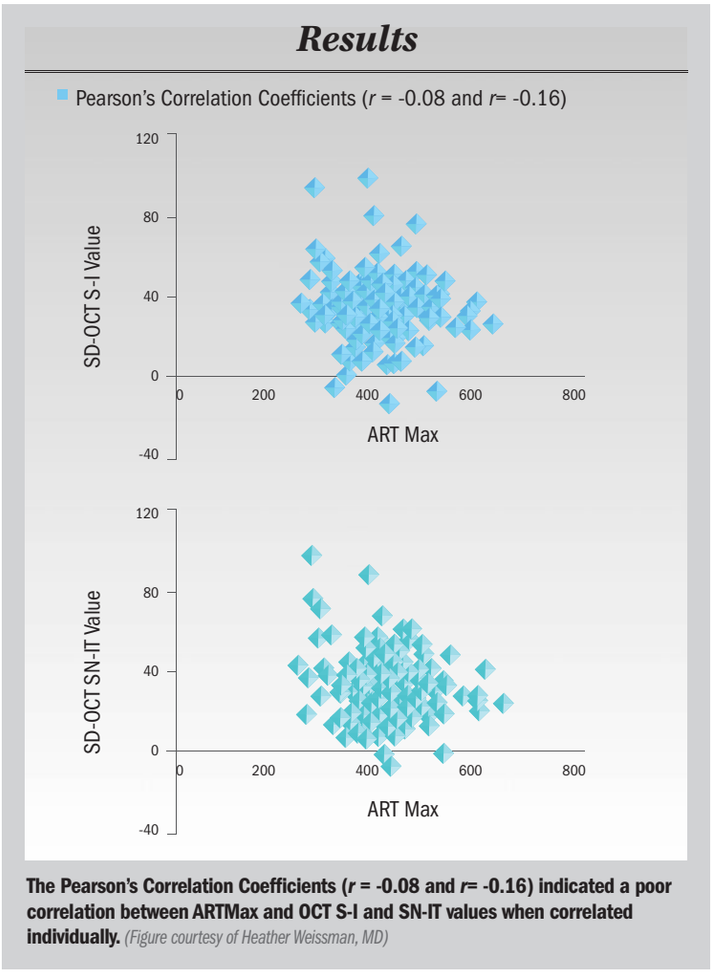
At baseline, 243 of the 324 OZURDEX® subjects were phakic; 230 of 328 sham-controlled subjects were phakic. The incidence of cataract development in patients who had a phakic study eye was higher in the OZURDEX® group (68%) compared with Sham (21%). The median time of cataract being reported as an adverse event was approximately 15 months in the OZURDEX® group and 12 months in the Sham group. Among these patients, 61% of OZURDEX® subjects vs. 8% of sham-controlled subjects underwent cataract surgery, generally between Month 18 and Month 39 (Median Month 21 for OZURDEX® group and 20 for Sham) of the studies.

Increased Intraocular Pressure

Summary of Elevated IOP Related Adverse Reactions

	Treatment: N (%)	
IOP	**OZURDEX® N=324**	**Sham N=328**
Any IOP Related AE	120 (37%)	18 (6%)
≥10 mm Hg IOP Change from Baseline at any visit	91 (28%)	13 (4%)
≥25 mm Hg IOP at any visit	106 (33%)	15 (5%)
≥35 mm Hg IOP at any visit	20 (6%)	3 (1%)
Glaucoma	4 (1.2%)	1 (0.3%)
IOP lowering procedure*	4 (1.2%)	1 (0.3%)

* OZURDEX®: 1 surgical trabeculectomy for steroid-induced IOP increase, 1 surgical trabeculectomy for iris neovascularization,1 laser iridotomy, 1 surgical iridectomy
Sham: 1 laser iridotomy



The Pearson's Correlation Coefficients (*r* = -0.08 and *r*= -0.16) indicated a poor correlation between ARTMax and OCT S-I and SN-IT values when correlated individually. *(Figure courtesy of Heather Weissman, MD)*

SCREENING

(Continued from page 29)

SD-OCT S-I and SN-IT values that were obtained were correlated individually with the ARTMax score and the SD-OCT values then were averaged and correlated with the ARTMax score using Pearson's correlation coefficient (*r*).

The Pearson's correlation coefficients (r = –0.08 and r= –0.16, respectively) showed a poor correlation between ARTMax and SD-OCT S-I and SN-IT values when correlated individually, Dr. Weissman noted.

The second analysis also showed a poor correlation (r = –0.12) between the technologies when the SD-OCT values were averaged together.

The investigators concluded that the Pentacam HR ARTMax and SD-OCT indices were correlated poorly in patients with suspicious screening parameters. These two screening metrics are not analogous or interchangeable.

The study was unable to determine the relative superiority of either device.

TAKE-HOME

- ***Metrics from refractive surgery screening devices are not interchangeable, shows a recent study.***

CLOSING THOUGHTS

"More studies need to be carried out to prove the validity and agreement among refractive surgery screening modalities," Dr. Weissman said. ■

HEATHER WEISSMAN, MD

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This article was adapted from Dr. Weissman's presentation at the 2014 meeting of the American Society of Cataract and Refractive Surgery. Dr. Weissman and colleagues have no financial interest in the subject matter.

***Figure 1:** Normally aqueous flows unobstructed into all chambers*

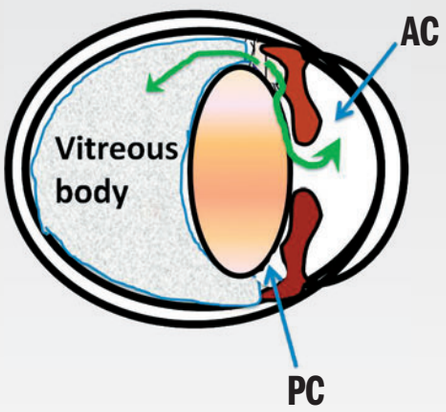
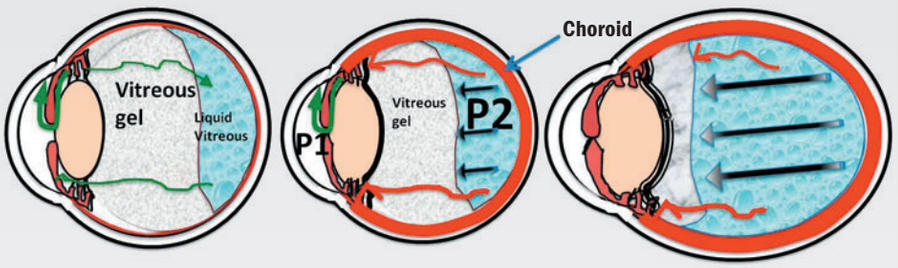


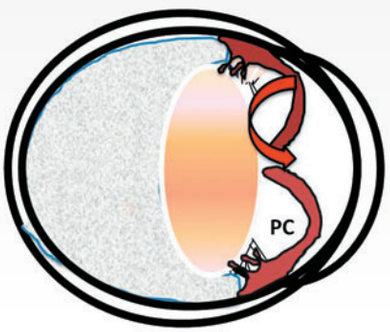
***Figure 3a:** Mechanism of ciliovitreal block*



1. Normally, there is a diffusion of aqueous through hyaloid, zonules, and vitreous
2. Choroidal expansion is stimulus, IOP increases immediately
3. There is a pressure differential across vitreous gel to exit eye, P2 to P1
4. This worsens vitreous gel fluid conductivity
5. Vitreous compresses, moves forward
6. Ciliovitreal block processes crowd lens
7. Ciliovitreal block
8. Angle closes, cycle worsens

Adapted from Quigley, 66th Jackson Memoiral Lecture, AJO 2009:657-669

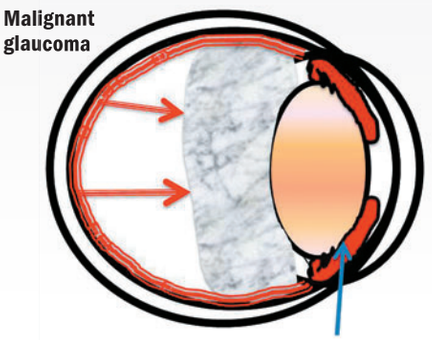
***Figure 2:** Obstruction to aqueous flow at pupil*



Pupil block

Aqueous builds up in posterior chamber (PC), closes the angle

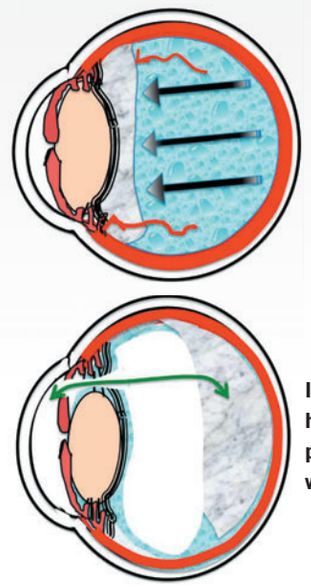
***Figure 3b:** Obstruction to aqueous flow in ciliary and vitreous bodies*



Posterior chamber obliterated, unlike pupil block

Ciliovitreal block due to expansion of choroid with loss of vitreous gel conductivity, pushes iris-lens forward, flattens AC

***Figure 4:** Surgical management*



Ciliovitreal block, angle closed

Irido-zonulo-hyaloidotomy plus vitrectomy

(Images courtesy of Ronald L. Fellman, MD)

MALIGNANT

(Continued from page 1)

In contrast, only the iris will be bowed forward toward the cornea when angle closure is due to pupil block, Dr. Fellman explained.

"Patients with malignant glaucoma may also have a history of narrow angles and pupil block, and so many of them already have a patent iridotomy," he said. "IOP may be elevated, but it may be normal."

Other findings in eyes with malignant glaucoma include a normal-appearing posterior segment—i.e., there is no suprachoroidal hemorrhage, central retinal vein occlusion, or choroidal mass to explain the axial shallowing. Typically, malignant glaucoma develops in short eyes that have a thick sclera, and often, the patient has a recent history of intraocular surgery (e.g., cataract or glaucoma surgery) that may be the precipitating event.

TAKE-HOME

- ***Malignant glaucoma is a type of angle-closure glaucoma that is uncommon and therefore rarely recognized. Ronald L. Fellman, MD, describes its diagnostic features and management considerations.***

MECHANISTIC THEORY

Various theories have been proposed to explain the development of malignant glaucoma. However, Dr. Fellman said that a concept introduced by Harry Quigley, MD, in his 2009 Edward Jackson Memorial Lecture seems to make the most sense.

According to Dr. Quigley, the triggering event is expansion of the choroid. (Figures 3a and 3b)

Subsequently, a pressure differential across the vitreous gel is created that decreases its fluid conductivity and results in increased vitreous compression. As the vitreous gel moves forward, it crowds the ciliary body and lens, aggravating a relative ciliovitreal block with further axial collapse of the anterior chamber. As the IOP increases, the cycle worsens.

MALIGNANT GLAUCOMA MANAGEMENT

Medical management should be prescribed as initial treatment for malignant glaucoma. It is effective in relieving the angle-closure attack about 50% of the time and involves a multipronged approach.

The medical regimen includes a mydriatic cycloplegic agent that decreases ciliovitreal block by multiple mechanisms that include:

- Tightening the zonules, which retracts the lens
- Widening the ciliary body diameter, which allows for better aqueous diffusion
- Pulling the ciliary body processes away from the lens equator, which also improves aqueous diffusion

Also, if the physician suspects simultaneous pupillary block, adding a sympathomimetic may further alleviate it.

In addition, an aqueous suppressant agent is used to reduce IOP, reducing the trans pressure differential across the vitreous gel, and patients are treated with a hyperosmotic agent as well that shrinks the vitreous and choroid, Dr. Fellman noted.

If medical management fails, surgery is indicated. Its goal is to create a unichambered eye, and whether the patient is phakic or pseudophakic, surgery should include irido-zonulohyaloidotomy plus pars plana vitrectomy (PPV). Phacoemulsification may be necessary in phakic eyes. (Figure 4 on Page 34)

"Timely surgical treatment breaks the ciliovitreal block and saves the angle," Dr. Fellman said.

"In the past, PPV alone was performed to treat malignant glaucoma, but it did not always relieve the ciliovitreal-hyaloid block because in malignant glaucoma, the problem does not involve the vitreous alone," he said.

Adding iridozonulohyaloidotomy to create a unichambered eye breaks the angle-closure attack because it gives aqueous access to all chambers, he noted.

ADDITIONAL CONSIDERATIONS

Dr. Fellman noted that considering the connotation of the word "malignant," ophthalmologists may consider referring to the condition as aqueous misdirection syndrome, or preferably ciliovitreal block, in their discussions with patients.

Clinicians should also recognize that patients who develop malignant glaucoma in one eye are at risk for developing the condition in the fellow eye. ■

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This article was adapted from Dr. Fellman's presentation during Glaucoma Day at the 2014 meeting of the American Society of Cataract and Refractive Surgery. Dr. Fellman has no financial conflicts with the subject matter.

At issue: Is process of MRSA testing, prophylaxis a worthwhile method?

Surgeons also weigh costs, merits, and limitations of alternative approaches

By Cheryl Gutttman Krader; *Reviewed by Peter J. McDonnell, MD, and Stephen D. McLeod, MD*

TAKE-HOME

- ***Although infections caused by methicillin-resistant Staphylococcus aureus (MRSA) are a prominent concern for cataract surgeons, leading ophthalmologists discuss the pros and cons of performing universal MRSA screening to guide targeted prophylaxis.***

GIVEN THE INCREASE in prevalence of methicillin-resistant *Staphylococcus aureus* (MRSA) colonization and in levels of MRSA antimicrobial resistance, the question arises whether preoperative testing for MRSA to guide targeted prophylaxis should be done routinely in patients undergoing cataract surgery.

Two leading ophthalmologists—Peter J. McDonnell, MD, William Holland Wilmer Professor and director, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, and Stephen D. McLeod, MD, Theresa M. and Wayne M. Caygill, MD Endowed Chair and professor, Department of Ophthalmology, University of California–San Francisco—weighed the cost-effectiveness of universal testing.

Both physicians also concluded that available evidence does not support a selective testing approach in which patients would be screened based on certain history factors.

Speaking in favor of MRSA testing and targeted prophylaxis, Dr. McLeod suggested that selective empiric prophylaxis, i.e., use of intracameral vancomycin (rather than intracameral cefuroxime) in certain individuals considered to be at particularly high risk for MRSA colonization based on history (previous history of colonization or residence in an extended-care facility) might be reasonable considering the effectiveness and relative safety of intracameral vacomycin.

Taking the opponent's position, Dr. McDonnell underscored the current low rates of postoperative endophthalmitis, the potential for topical antibiotic delivery to achieve target site concentrations exceeding MRSA minimum inhibitory concentrations, and the activity of host defense mechanisms in addition to the lack of adequate criteria for identifying carriers of methicillin-resistant organisms. Based on those considerations, Dr. McDonnell advocated for a universal precautions approach in which every patient should be considered as a potential carrier of MRSA and treated using povidone-iodine lid scrubs, topical antibiotic drops, and draping to isolate the lashes.

LIMITATIONS OF UNIVERSAL SCREENING

In reviewing the relevant evidence, Dr. McLeod first cited experience from the United Kingdom where implementation of universal screening for MRSA resulted in numerous cases of cataract surgery being withheld.

He said that in 2006, the U.K. Department of Health recommended that all elective surgical admissions undergo screening for MRSA and that anyone testing positive should be treated with a decolonization regimen.

'Selective testing and targeted prophylaxis should not be considered.'

— Stephen D. McLeod, MD

The treatment for cataract surgery patients involved nasal mupirocin and chlorhexidine baths, but it was not always effective in eradicating MRSA carriage, and in that situation, surgery was not performed, Dr. McLeod explained.

Dr. McLeod discussed the cost effectiveness of universal MRSA screening to guide targeted prophylaxis based on a model published by Sharifi et al. [*Ophthalmology*. 2009;10:1887-1896]. Assuming a Medicare reimbursement rate of $68 for preoperative MRSA testing, the researchers concluded that a change in prophylaxis indicated by testing would have to reduce infection rates by an order of 10 to be cost effect.

"However, all staphylococcal organisms constitute only about 50% of cases of culture-positive endophthalmitis cases postcataract surgery," Dr. McLeod said. "So, even if the screening and modified prophylaxis were 100% effective for all staphylococcal species, infection rates could not be reduced by more than half."

Dr. McDonnell presented calculations on the costs of universal testing that were based on the following values:

- **Annual number of cataract operations = 3 million**
- **Endophthalmitis rate = 1 in 3000**
- **Proportion of infections caused by methicillin-resistant Staphylococcus = 50%**

He also assumed a cost of $100 for preoperative culture and sensitivity testing of specimens from the lid margin and conjunctiva ($300 million total), a 40% positivity rate (1.2 million positive cultures), a cost of $100 for a 10- to 14-day course of antibiotic therapy for culture-positive patients ($120 million), and a $150 charge for a return office visit with culture to confirm efficacy of the decolonization regimen ($180 million).

Based on those figures, Dr. McDonnell said the universal screening and pre-treatment protocol would result in $600 million in additional expenditures.

"Assuming it is 100% effective (which would be an overestimate), it would eliminate 500 infections per year, translating into a cost of $1.2 million per infection," he said.

SELECTIVE SCREENING

Both Drs. McLeod and McDonnell pointed to the absence of specific and sensitive criteria for guiding selective preoperative screening for MRSA carrier status. Citing a study from London involving patients seen in a hospital emergency department, about 60% of the patients would be screened as potential MRSA carriers and 15% of those actually positive would be missed using selection criteria of hospital admission within the past year, pre-

vious MRSA colonization, or residence in a care home, Dr. McLeod said.

"Selective criteria would likely be less broad in the general cataract population, but still would be inadequately sensitive and specific," he said. "Therefore, selective testing and targeted prophylaxis should not be considered."

'A universal precautions type of approach . . . is probably the most cost effective.'

— Peter J. McDonnell, MD

Dr. McDonnell cited results from a multicenter study by Olson et al. that showed only older age predicted increased likelihood of having a preoperative eyelid or conjunctival culture positive for methicillin-resistant *S. epidermidis* (MRSE) or MRSA [*Clin Ophthalmol*. 2010;(4):1505-1514]. In that study enrolling 399 patients who were at least 50 years old, *S. epidermidis* (63%) and *S. aureus* (14%) were the most frequently isolated organisms, and about 40% of patients were positive for either MRSE or MRSA. Multivariate logistic regression analysis did not identify major risk factors other than age, and being a health-care worker or family member of a healthcare worker was specifically not a risk factor for colonization with methicillin-resistant organisms.

INTRACAMERAL ANTIBIOTIC ISSUES

As another possible scenario, Dr. McLeod discussed use of universal empiric prophylaxis in which vancomycin—not cefuroxime or moxifloxacin—would be used routinely as the intracameral antibiotic. However, he recommended against that approach considering its potential to promote bacterial resistance to vancomycin.

Addressing intracameral antibiotic use for endophthalmitis prophylaxis, Dr. McDonnell said that he suspects this practice will become increasingly prevalent in the United States considering the evidence from European studies demonstrating it reduces the likelihood of endophthalmitis.

"However, to the best of my understanding, the data show prophylaxis with an intracameral antibiotic reduces infection in all patients, not just MRSA carriers," he said. "Therefore, I still believe that a universal precautions type of approach to preventing MRSA endophthalmitis is probably the most cost effective." ■

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Dr. McDonnell is a board member of Allergan Inc. and chief medical editor of Ophthalmology Times.

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Dr. McLeod has no relevant financial interests to disclose.

Dr. McDonnell and Dr. McLeod presented these viewpoints in a session during Cornea Day at the 2014 meeting of the American Society of Cataract and Refractive Surgery.

Detecting early stages of glaucoma: Progress being made, but at slow rate

Data provide significant opportunity to audit service delivery, identify areas for improvement

By Cheryl Guttman Krader; *Reviewed by Trishal Boodhna, MSc*

LONDON ::

A STUDY FROM England analyzing visual field loss at the time of glaucoma diagnosis shows the average level of severity decreased over a recent 15-year period.

However, the annual rate of change was low, indicating a need for strategies that will improve earlier disease detection, said Trishal Boodhna, MSc.

Boodhna

"Detecting glaucoma sooner than later is important, because glaucoma-related vision loss is irreversible," said Boodhna, a PhD student in Health Economics in Professor David Crabb's Research Lab at City University London.

In addition, from a health economic perspective, the cost burden for treatment is lower for earlier versus more advanced stages of disease, he said.

"Although our study indicates we are getting better at detecting glaucoma earlier in England, the question as to whether the rate of improvement is sufficient requires further exploration," Boodhna said.

Available studies show that screening programs for glaucoma are not cost-effective. However, there has to be a middle ground between that approach and the opportunistic way glaucoma is usually detected in the United Kingdom, when people have routine eye exams with optometrists, he explained.

TAKE-HOME

- ***Analyses of visual field data collected at centers across England showed the average level of severity of vision loss at the time of glaucoma detection decreased—improved—over time. Still, the rate of improvement between 1998 and 2012 was only 0.1 dB per year.***

ANALYZING THE DATA

Trends in visual field severity at the time of glaucoma diagnosis were examined using data from Humphrey SITA visual fields recorded at four regionally different glaucoma clinics in England in the years 1998 to 2012.

Approximately 433,000 visual fields were available, but after applying selection criteria requiring a mean deviation (MD) outside 95% normative limits in at least one eye and having at least two visits to the glaucoma clinic, tests representing the worse eye in only 26,131 patients were included in the study.

Patients were categorized as to the severity of their glaucoma at the time of diagnosis using the following criteria:

- **MD 0 to –6 dB = early**
- **MD >–6 to –12 dB = moderate**
- **MD >–12 dB = severe**

During the first 5 years of the study (1998 to 2002), 43% of patients presented with early disease and 29% presented with severe disease. During the past 5 years, 50% of patients presented with early disease and 22% had severe disease at diagnosis.

"Although these positive changes were statistically significant, the data still show that during the last 5 years, 1 in 5 patients had a severely damaged visual field at the time of glaucoma diagnosis," Boodhna said. "We should be performing better."

A trend analysis was also conducted to determine the annual rate of improvement in the average level of glaucoma vision loss at presentation, and it was calculated to be 0.1 db per year or only 1.0 db per decade.

STUDY LIMITATIONS

Boodhna noted the study has several limitations. Given its retrospective nature and lack of other clinical data it is not possible to control for the effect of visual co-morbidities on the visual field (e.g., cataract) or for population variation.

However, the sheer large scale of the data used means that the estimates are likely to be representative.

In addition, there is no information on the reliability of individual visual fields. However, it is also not considered to be a significant limitation constraining the validity of the analyses given the infrequent nature of unreliable visual fields and the large dataset being analyzed.

Boodhna also noted that because the study focused on detection of glaucoma based on visual field loss, it may have excluded some patients with early glaucoma that was detected on structural testing.

"The compilation of multisite electronic visual field records provides significant opportunity to audit service delivery and to identify areas for improvement, such as in glaucoma identification found in this study," he concluded. "The fact remains that a significant proportion of patients are being diagnosed with advanced stage glaucoma when we should seek to be identifying them at the earliest stages." ■

The data still show that during the past 5 years,

1 in 5

patients had a severely damaged visual field at the time of glaucoma diagnosis.

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This article was adapted from Boodhna's presentation at the 2014 meeting of the Association for Research in Vision and Ophthalmology. Boodhna and his co-authors have no relevant financial interests to disclose.

Study: Role of fellow eye in AMD therapy

Monthly OCT monitoring necessary for early detection, prompt treatment to maximize outcomes

By Michelle Dalton, ELS; *Reviewed by Adnan Tufail, MD, FRCOphth, and Javier Zarranz-Ventura MD, PhD, FEBO*

SECOND EYES WITH neovascular age-related macular degeneration (AMD) typically start treatment with better baseline visual acuity. However, they do not show significant vision gain but maintain better mean visual acuity than first eyes at all time points for at least 3 years, making them the more important eye functionally, finds new research from the U.K. AMD Electronic Medical Records Users Group.[1]

"In the United Kingdom, patients have OCT to both eyes at each visit that may help to pick up very early second eye involvement," said Adnan Tufail, MD, FRCOphth, of the Medical Retina Service, Moorfields Eye Hospital NHS Foundation Trust, London, and principal investigator of the study. Trials do not typically enroll fellow eyes to avoid the bias that could result from using both eyes of one patient.

EXTRACTING DATA

In this analysis, study authors extracted up to 5 years of routinely collected, anonymized data from 14 centers in the U.K. National Health Service. The database included 12,951 treatment naive eyes of 11,135 patients receiving 92,976 ranibizumab injections. Baseline, change and actual visual acuity over 3 years, and the number of treatments/clinic visits were assessed.

TAKE-HOME

- ***The characteristics of second treated eyes in patients with neovascular age-related macular degeneration (AMD) treated with ranibizumab were studied in a large cohort evaluation.***

"The main finding of this report is that second eyes are detected and start treatment with better visual acuity than first eyes, then this baseline visual acuity level decline slowly for at least 3 years," said Javier Zarranz-Ventura, MD, PhD, Médico Adjunto Oftalmología at the Unidad de Vitreo-Retina, Institut Clínic d´Oftalmologia (ICOF)–Hospital Universitario Sagrat Cor–Hospital Clínic in Barcelona, Spain.

"Second eyes still maintain better visual acuity than first eyes at the end of follow-up

Continues on page 41 : ***Second eye***

Effects of astigmatism differ among multifocal and monofocal IOL use

How various magnitudes and manifestations impact optical quality, patient satisfaction

By Lynda Charters; *Reviewed by Scott M. MacRae, MD*

ROCHESTER, NY ::

THE EFFECT OF astigmatism varies with different factors, such as magnitude, manifestation, light level, and dominant or non-dominant eye.

"These factors all affect the patient satisfaction with multifocal or monofocal IOLs," said Scott M. MacRae, MD, professor of ophthalmology, and professor of visual science, University of Rochester, Rochester, NY.

HOW PUPIL SIZE PLAYS ROLE

The use of multifocal and accommodating IOLs raised a number of questions for Dr. MacRae and colleagues, Len Zheleznyak, MS, and Geunyoung Yoon, PhD. They began studying the effect of astigmatism and higher-order aberrations on visual performance and found that the size of the pupil has a great impact on astigmatic magnitudes.

Dr. MacRae

For example, when going from a 2- to 6-mm pupil, the amount of the reduction in image quality resulting from the astigmatism is about 50% as the pupil dilates, Dr. MacRae explained.

"This becomes even more profound with higher degrees of astigmatism, that is, from over 0.75 to 1.5 D. This may be mildly or very disabling for a patient who is not corrected for the astigmatic effect," he said.

These patients can function while driving in bright light, for example, but not at night in dim light, he noted.

AXIS OF ASTIGMATISM

Another factor to consider is the axis of the astigmatism. Investigators found that the neural system is highly tuned to horizontal and vertical gratings, but not as much to oblique gratings.

"We perform better in interpreting images with horizontal and vertical images than oblique images, resulting in about a 50% reduction in image quality," he said.

AGAINST-THE-RULE OR WITH-THE-RULE

Studies of myopic against-the-rule astigmatism have shown that patients can see better during near vision tasks compared with patients who have with-the-rule astigmatism, according to Dr. MacRae.

"The phenomenon that occurs is that patients tend to 'cue off' of vertical letters, such as *p*, *q*, or *t*," he said.

Dr. MacRae and colleagues found that patients who had myopic against-the-rule astigmatism obtained a better image of a poster with the word "Rochester" printed on it than those with with-the-rule astigmatism because the vertical letters stood out.

With distance tasks, the opposite is true, he noted.

Patients with with-the-rule myopic astigmatism obtained slightly better images because of the vertical letters being presented.

DOMINANT VERSUS NON-DOMINANT EYE

The effects of the astigmatism are greater in the dominant eye than the non-dominant eye, Dr. MacRae noted.

"In the non-dominant eye, for near vision tasks, patients are not affected by myopic against-the-rule astigmatism," he said.

Correction of the astigmatism in the dominant eye will result in good binocular function at distance.

The investigators found that with increasing astigmatism, the image quality decreases—especially in multifocal wearers compared with monofocal and pseudoaccommodating IOL users.

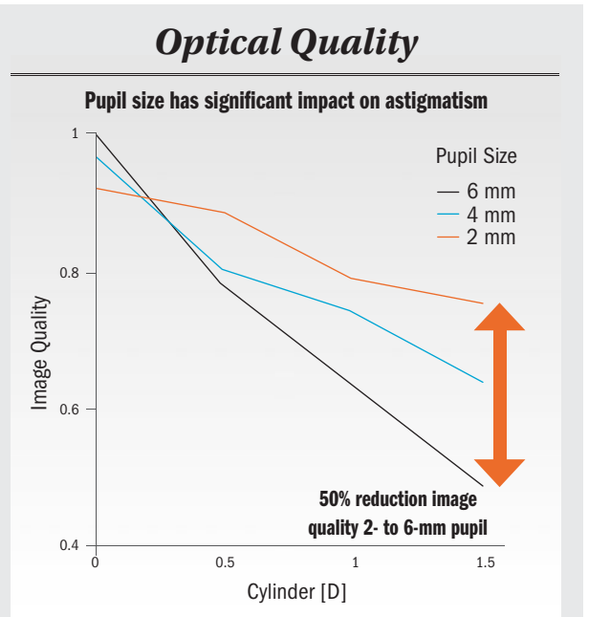
"This finding indicates that we need to be more attuned to subtle levels of astigmatism for multifocal patients," he said.

"Less than 0.5 D of astigmatism has a negligible effect on visual acuity and visual performance, while 0.75 D definitely affects the image quality," Dr. MacRae said. "The visual system is tuned to horizontal and vertical directions; there is worse visual performance with oblique astigmatism and better visual performance with horizontal and vertical astigmatism.

"Astigmatism has a greater effect on multifocal than monofocal IOLs—resulting in reduced depth of field and image quality," Dr. MacRae concluded. "Finally, astigmatism reduces the image quality more with larger pupils, with multifocal IOLs [being] particularly susceptible." ■

TAKE-HOME

- ***The effect of astigmatism varies with different factors and can affect patient satisfaction with multifocal or monofocal IOLs.***



The amount of reduction in image quality as a result of astigmatism is about 50% as the pupil dilates. *(Figure courtesy of Scott M. MacRae, MD)*

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Dr. MacRae is a consultant to AcuFocus, Bausch + Lomb, and Ziemer.

SECOND EYE

(Continued from page 39)

(that commonly show an improvement during the loading dose to decline later on)," said Dr. Zarranz-Ventura, co-lead author of the study.

STUDY DETAILS

Of the patients, 1,816 (16.3%) received treatment to the fellow eye at some point during the study. Mean (standard deviation) of baseline and final visual acuity were 0.66 (0.32) logMAR and 0.65 (0.40) logMAR for first eyes, and 0.41 (0.34) logMAR and 0.56 (0.40) logMAR for second eyes.

"The outcomes of second eye versus first eye match that of our initial analysis," Dr. Tufail said. "The primary driver for a patient's visual acuity state was the vision at initiation of treatment. Although second eyes had poor vision gain they were in a better visual acuity state, and therefore more likely to retain driving vision than first eyes."

The mean number of injections/visits was similar between the two eyes, he said.

HOW STUDIES DIFFER

In this analysis of real-world data, first treated eyes gain vision initially but by 2 years had regressed to the initial presenting visual acuity. Similarly, second treated eyes showed no initial improvement in vision, and by 2 years had lost more than 5 ETDRS letters. In other large cohort studies, such as the Comparison of Age-related Macular Degeneration Treatments Trials (CATT)[2], first treated eyes gained and maintained vision at the 2-year time point. The CATT study also had a much greater percentage of eyes that gained 15 ETDRS letters at different time points than in this analysis.

One possible explanation for the difference between findings is that patients analyzed in this study underwent 9.5 injections in the first treated eye and 9.1 injections in the second treated eye, whereas in CATT, they were closer to 12 injections. Also, this represents a true clinical setting, whereas CATT had strict inclusion, exclusion, and treatment regimens.

"Monthly OCT monitoring seems necessary for early detection and prompt treatment to maximize outcomes," Dr. Zarranz-Ventura added. ■

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Dr. Zarranz-Ventura is a grant recipient of the Spanish Retina and Vitreous Society (Sociedad Española de Retina y Vitreo), has received travel grants from Allergan and Bayer, and is a member of the Allergan´s European Retina Panel.

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Gathering comparative effectiveness data for CRVO

SCORE2 uses state-of-the-art retinal imaging techniques, provides insights on anatomic features

The Panretinal View By Barbara A. Blodi, MD

Editor's Note:
Ophthalmology Times *is pleased to announce the return of "The Panretinal View." The primary focus of this regularly recurring column will be on the latest innovations in the medical and surgical treatment of retinal disease.*

In this first installment, Barbara A. Blodi, MD, provides an update on cutting-edge research that is taking place in the SCORE2 (Study of COmparative Treatments in REtinal Vein Occlusion 2), an investigator-initiated, multicenter, randomized prospective, clinical trial. Not only is SCORE2 the first comparative effectiveness study for treatment of CRVO, but also it is the first large, multicenter study investigating the efficacy of a treat-and-extend protocol for this condition.

In addition, SCORE2 is incorporating state-of-the-art retinal imaging techniques, and so is expected to provide important insights on anatomic features of CRVO and their potential associations with visual outcomes.

For more than a decade after results from the Central Vein Occlusion Study (CVOS) were published,[1] observation remained the standard of care for patients with central retinal vein occlusion (CRVO).

However, a paradigm shift began to take place about 5 years ago as data from a series of randomized, controlled clinical trials demonstrated efficacy of intravitreal pharmacotherapy using anti-vascular endothelial growth factor (VEGF) agents and corticosteroids.[2-6]

For the past several years, retinal specialists have had three FDA-approved therapeutic options from which to choose for treatment of macular edema following CRVO—ranibizumab (Lucentis, Genentech), aflibercept (Eylea, Regeneron), and dexamethasone implant (Ozurdex, Allergan), along with two off-label therapies of bevacizumab (Avastin, Genentech) and triamcinolone acetonide—but there remains a need for more information to guide optimal use.

In 2014, it is generally agreed that anti-VEGF therapy is the most appropriate modality for initial treatment, and bevacizumab is the most widely used,[7] even though it is off-label and outcomes data are available from only case reports and small randomized trials.

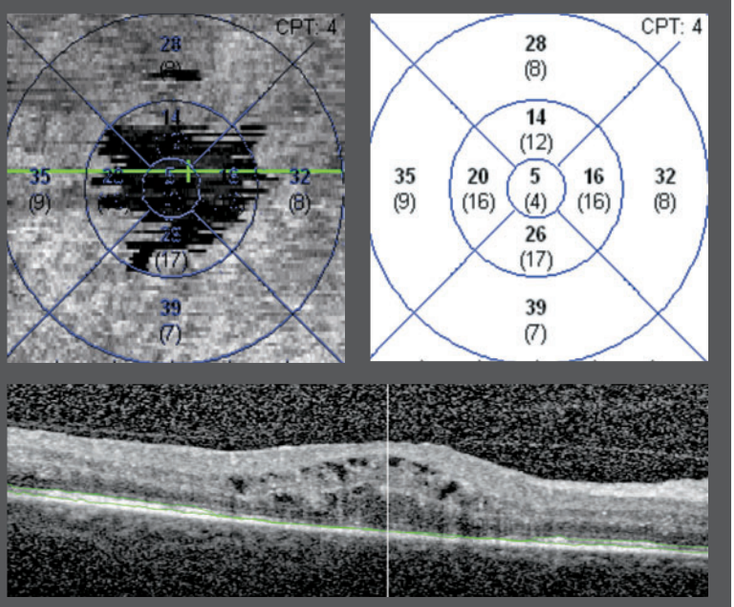
Due predominantly to their potential for elevating IOP and causing cataract, corticosteroids are generally reserved as second-line treatment, although their effectiveness in this role has not been well-established.

Recognizing the need for evidence-based data to guide clinicians in their management of patients with CRVO, the National Eye Institute (NEI) is sponsoring SCORE2 (**S**tudy of **CO**mparative Treatments in **RE**tinal Vein Occlusion 2), an investigator-initiated, multicenter, randomized prospective, clinical trial. Not only is SCORE2 the first comparative effectiveness study for treatment of CRVO, but also it is the first large, multicenter study investigating the efficacy of a treat-and-extend protocol for this condition.

In addition, SCORE2 is incorporating state-of-the-art retinal imaging techniques, and so is expected to provide important insights on anatomic features of CRVO and their potential associations with visual outcomes.

Ingrid U. Scott, MD, MPH, professor of ophthalmology and public health sciences, Penn State College of Medicine, Hershey, PA, is the study chair, Michael S. Ip, MD, associate professor of ophthalmology and visual sciences, University of Wisconsin Madison, is co-chair, and I am the principal investigator of the SCORE2 Reading Center.

Demonstrating the IS-OS defect



Area of IS-OS layer defect in central and inner subfield in eye with central retinal vein occlusion and edema. *(Images courtesy of Barbara A. Blodi, MD)*

SCORE2 DESIGN

SCORE2 is designed as a non-inferiority trial to compare aflibercept and bevacizumab as first-line therapy for decreased vision due to macular edema associated with CRVO and to investigate the effectiveness of the dexamethasone implant as rescue therapy. The study is being conducted at about 80 centers across the United States, with a target sample size of 360 patients who will initially be randomly assigned 1:1 to receive aflibercept 2 mg or bevacizumab 1.25 mg at monthly intervals.

TAKE-HOME

- ***Findings from the Study of COmparative Treatments in REtinal Vein Occlusion 2 (SCORE2) are expected to provide insights into the efficacy of various therapies for central retinal vein occlusion.***

The primary analysis for non-inferiority is being conducted at month 6 and will look at change from baseline best-corrected visual acuity (BCVA). As in the Comparison of Age-Related Macular Degeneration Treatments Trials (CATT), the non-inferiority limit is set at 5 letters.

At month 6, patients will be assessed for their therapeutic response using BCVA and spectral domain optical coherence tomography (SD-OCT) criteria and assigned to further treatment based on that categorization.

Patients will be categorized as poor/marginal responders if their visual acuity is <58 ETDRS letters or shows a ≤5 letter improvement from baseline *and* they exhibit one of the following OCT findings: SD-OCT central subfield thickness ≥300 µm or ≥320 µm [depending on device], intraretinal cystoid space, or subretinal fluid.

Otherwise, patients are categorized as good responders.

Good responders will be re-randomly assigned to continue monthly injections with their original assigned medication or to begin a treat-and-extend regimen. For treat and extend, the intervisit interval will be increased by 2-week increments to a maximum of 10 weeks as long as the response remains good.

Patients who are poor/marginal responders at month 6 will begin rescue treatment.

Patients originally randomly assigned to aflibercept will be treated with the dexamethasone implant at month 6.

Further treatment with the implant will be determined on an as-needed basis. Patients who had received bevacizumab will be switched to monthly aflibercept injections. At month 9, after 3 aflibercept injections, the latter patients will be re-evaluated for response, and those who improve to the good response category become eligible for a treat-and-extend aflibercept regimen.

At 12 months, visual acuity and SD-OCT outcomes will be analyzed to compare the monthly and treat-and-extend dosing strategies for patients who were initial good responders and to understand the efficacy of the dexamethasone implant and switching to aflibercept as second-line intervention.

PLANNING THE TRIAL

The decisions to compare bevacizumab and aflibercept as first-line agents in SCORE2 and to not include ranibizumab were based on the following considerations. In the interest of containing study cost and duration, it was decided to limit the trial to two treatment arms instead of three.

In addition, it seemed reasonable to compare either bevacizumab or ranibizumab against aflibercept since bevacizumab and ranibizumab have a similar mechanism of action in targeting only VEGF-A, whereas aflibercept has a broader mechanism of action that includes activity against VEGF-A, VEGF-B, and platelet-derived growth factor.[8,9] Ultimately, the bevacizumab versus aflibercept comparison seemed to be of greatest importance taking into account that:

1 **Head-to-head comparison trials have demonstrated the clinical equivalence of bevacizumab and ranibizumab for treatment of neovascular age-related macular degeneration.**[10-12]

Continues on page 44 : ***SCORE2***

SCORE2

(Continued from page 43)

2 **Bevacizumab, ranibizumab, and aflibercept are being compared for the treatment of diabetic macular edema in the Diabetic Retinopathy Clinical Research Network Protocol T.[13]**

3 **There has been no formal comparison between bevacizumab and aflibercept for treatment of CRVO.**

4 **Bevacizumab is less expensive and more widely used than ranibizumab.**

The dexamethasone implant was chosen as rescue therapy for the aflibercept arm to gather evidence on its efficacy as second-line treatment.

However, switching to another anti-VEGF agent is a common rescue strategy in clinical practice, and the planning committee decided that based on aflibercept's broader mechanism of action, there was a rationale to evaluate it as rescue therapy for patients with an inadequate response to bevacizumab.

IMAGING INNOVATIONS

All patients in SCORE2 will undergo monthly imaging with SD-OCT during the first 6 months of the study, and the images will be read at the Fundus Photograph Reading Center of the University of Wisconsin-Madison. In addition to standard measures of macular thickness, new proprietary segmentation analysis software (not yet commercially available) will be used that allows evaluation of the photoreceptor inner segment–outer segment (IS-OS) junction also known as the ellipsoid zone.

Extensive macular edema secondary to CRVO can disrupt the IS-OS junction, and there is some evidence to suggest that status of the IS-OS junction in eyes with CRVO may be a surrogate for predicting visual function.[14] Availability of a biomarker that could help guide clinicians in their management decisions is desirable considering that there is only a modest correlation between OCT-measured central retinal thickness and visual acuity.[15]

As another unique component of its imaging protocol, SCORE2 is including ultrawide field angiography assessments that provide a 200° view of the retina. The ultrawide field angiograms have the potential to identify leakage and ischemia outside of the macula. The images will be obtained at baseline and every 6 months in a subset of patients enrolled at centers where this technology is available (~40% of participating sites) and using the Optos imaging systems. The findings on fluorescein angiography will then be evaluated for correlations with OCT-measured retinal thickness and visual acuity.

In addition, five of the SCORE2 sites will be imaging participants with adaptive optics (AO). This imaging system decreases aberrant light and coupled with a scanning laser ophthalmoscope, allows imaging of individual rods and cones in the retina. We plan to correlate area of photoreceptor loss identified by AO imaging with visual acuity and OCT-derived central retinal thickness outcomes. The information provided by this new technology and these analyses may contribute to better understanding of the pathogenesis and prognosis of vision loss due to macular edema associated with CRVO.

In addition, five of the SCORE2 sites will be imaging participants with adaptive optics (AO). This imaging system decreases aberrant light and coupled with a scanning laser ophthalmoscope, allows imaging of individual rods and cones in the retina. We plan to correlate area of photoreceptor loss identified by AO imaging with visual acuity and OCT-derived central retinal thickness outcomes.

The information provided by this new technology and these analyses may also contribute to better understanding of the pathogenesis and prognosis of vision loss due to macular edema associated with CRVO.

GEARING UP

Members of the SCORE2 Executive Committee are very grateful to the NEI for its support, and we, together with members of the Planning Committee and all of the investigators, are very excited as the study is now getting under way. We believe the results from SCORE2 will provide valuable clinical guidance that will help optimize individualized care and have important public health and economic consequences. ■

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Dexamethasone implant shows good safety, visual outcomes in MEAD study

The 3-year clinical trial served as basis for FDA approval of corticosteroid for DME

By Michelle Dalton, ELS; *Reviewed by David S. Boyer, MD*

LOS ANGELES :: **INFLAMMATION IS NOW** considered a critical factor in diabetic retinopathy/diabetic macular edema (DME) pathogenesis,[1] and steroids are well known for their ability to reduce edema quickly.

As such, the Macular Edema: Assessment of Implantable Dexamethasone in Diabetes (MEAD) study served as the foundation for the FDA approval of dexamethasone intravitreal implant 0.7 mg (Ozurdex, Allergan) for the treatment of DME.[2]

The MEAD study evaluated both the 0.7- and 0.35-mg versions in more than 1,000 patients over 3 years.

"The mean number of injections was around 4 in each group over the course of the study," said David S. Boyer, MD, clinical professor of ophthalmology, Department of Ophthalmology, University of Southern California Keck School of Medicine, Los Angeles.

REDUCING BURDEN

The dexamethasone intravitreal implant "can reduce the number of injections that patients need and the number of times they come into the office," Dr. Boyer said. "We still have to be conscious of the fact they will need to come into the office for monitoring of their IOP."

People who come from a long distance for the injection may be able to have their IOP checked by their general ophthalmologist and treated closer to home, if necessary. It is hoped that this will decrease the treatment burden to patients and to the people who bring them to the office, he noted.

In July 2014, the FDA approved the implant for the treatment of DME, but limited its use to pseudophakic patients or in phakic patients scheduled to undergo cataract surgery.

"It's going to be most useful in patients who don't get the response we would like to see with anti-vascular endothelial growth factor (VEGF) therapies," Dr. Boyer said. Since some patients do not respond well to anti-VEGF therapies, "most would be helped with a corticosteroid, since that's a totally different mechanism of action."

STUDY DETAILS

In the MEAD study, 1,048 patients with DME, best-corrected visual acuity (BCVA) between 34 and 68 ETDRS letters, and central subfield retinal thickness (CRT) ≥300 mm by optical coherence tomography (OCT) were randomly assigned in a 1:1:1 ratio to treatment with dexamethasone implant 0.7 mg, dexamethasone implant 0.35 mg, or sham procedure.

Patients who met re-treatment eligibility criteria could be re-treated no more often than every 6 months.

The primary endpoint was achievement of ≥15-letter improvement in BCVA from baseline at study end in the intent-to-treat population with last-observation-carried-forward for missing values. Safety measures included adverse events (AEs) and IOP.

There were 22.2% of patients with ≥15-letter improvement in BCVA from baseline at study end in the 0.7-mg group, 18.4% in the 0.35-mg group and 12% in the sham group ($p \leq 0.018$). Mean average reduction in central retinal thickness from baseline during the study was greater with dexamethasone implant 0.7 mg (–111.6 mm) and dexamethasone implant 0.35 mg (–107.9 mm) than sham (–41.9 mm) ($p < 0.001$, area-under-the-curve approach).

Rates of cataract-related AEs in phakic eyes were 67.9%, 64.1%, and 20.4% in the dexamethasone implant 0.7 mg, dexamethasone implant 0.35

Continues on page 47 : ***MEAD Study***

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Ophthalmology Times
CUTTING-EDGE ADVANCEMENTS

MEAD STUDY

(Continued from page 45)

mg, and sham groups, respectively. IOP increases were usually controlled with medication or no therapy.

SAFETY CONCERNS

Phakic patients who receive multiple dexamethasone injections may lead to cataract development, Dr. Boyer noted. For young patients with a clear lens, he recommends staying with anti-VEGF therapy.

"I do feel one [dexamethasone] injection is well tolerated and will not lead to cataract formation, but multiple injections are likely to cause cataract," he said.

In the MEAD study, phakic patients who developed cataract (about 59%) had vision improvements to better than baseline after the cataract was removed and similar to pseudophakic patients, about a 6- to 7-letter gain.

As for IOP spikes, "the profile was much safer than any other steroid that has been examined," he said. "[Dexamethasone implant] is much less likely to cause permanent pressure effects."

In the MEAD study, only one patient (0.3%) needed filtration surgery to manage steroid-induced glaucoma. Differences in the pharmacologic and pharmacokinetic profiles of the various steroids may account for the differing profiles, and explain why those who received dexamethasone underwent significantly fewer incisional surgeries to treat IOP spikes.

"These are typically self-limiting curves," Dr. Boyer said. "They peak at 8 weeks and then taper over the next 6 to 8 weeks."

Dexamethasone itself is less liphophilic than triamcinolone acetonide or fluocinolone acetonide and does not accumulate to the same extent in the trabecular meshwork or lens, according to the study authors.

TAKE-HOME

- ***Dexamethasone intravitreal implant 0.7 and 0.35 mg provided statistically and clinically significant improvement in best-corrected visual acuity and reduction in central subfield retinal thickness with an average of 4 to 5 injections over 3 years.***

CO-MANAGEMENT

Dr. Boyer recommends patients with diabetes undergoing evaluation for cataract surgery have a retinal consult to at least get an optical coherence tomography.

If there are no signs of diabetic retinopathy and no signs of thickening, cataract surgeons can continue as they normally would, he noted.

"If they do have any form of diabetic retinopathy, we know it will worsen after cataract surgery," Dr. Boyer said.

Even patients with diabetes who undergo uncomplicated cataract surgery seem to have an increase in retinal thickness, regardless of current therapy.

"Having [dexamethasone] on board 2 to 3 weeks before probably will reduce chances of developing edema," Dr. Boyer said. ■

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This article was adapted from Dr. Boyer's presentation at the 2014 meeting of the Association for Research in Vision and Ophthalmology. Dr. Boyer is a consultant or advisor to Allergan, Genentech, Novartis, Regeneron, and Roche.

Nicox buys rights to anti-viral drop

SOPHIA ANTIPOLIS, FRANCE ::

NICOX S.A has agreed to acquire the Carragelose anti-viral eye drop program from Marinomed Biotechnologie GmbH of Austria. The acquisition will provide Nicox with an anti-viral ophthalmic product, expected to launch in Europe within 2 years and pending CE marking.

"The Carragelose anti-viral eye drop is an innovative approach to the management of viral conjunctivitis, and will complement our growing expertise in this area with the AdenoPlus diagnostic test," said Gavin Spencer, executive vice president, corporate development at Nicox. "We believe Carragelose has the potential to help health-care professionals manage patients with viral conjunctivitis, . . . and represents an excellent fit for our expanding portfolio of ophthalmic products." ■

Recording, viewing devices enhance surgical workflow

Image sensor technology enables capture of quality images, video from procedures

By Nancy Groves; *Reviewed by Matthew Chang, MD*

A pair of surgical recording and viewing devices (Sony Electronics Medical Division) can improve workflow during ophthalmic surgery.

Matthew Chang, MD, who is in a multispecialty ophthalmology practice in Colorado Springs, CO, said he has used the company's cameras with the surgical microscope while performing anterior segment procedures for over a decade and has been pleased with the results. After replacing an older camera with the latest generation earlier this year, the improvement in technology was apparent immediately, he noted.

"I was blown away by the clarity of the images," he said. "The quality with today's monitors is exceptional, especially for the modest price of the camera."

With the images produced by the new camera, his surgical technician can also readily know exactly where he is during a procedure and anticipate his needs. She, too, was struck by the clarity, quality, and revelation of detail attained with the new camera, Dr. Chang said. He also noted that the camera was easy to set up right out of the box.

The medical video camera (MCC-500MD) (at right) features the latest-generation, image-sensor technology with better low-light sensitivity for superb image reproduction capability. The camera can be paired with a recorder (HVO-550MD) (at left). *(Images courtesy of Sony Electronics Medical Division)*

HOW WORKFLOW ENHANCED

The company has tapped into more than a decade of experience with recording and viewing products to introduce new features that will enhance workflow, according to Evan Krachman, marketing manager and new business development manager at Sony.

The medical video camera (MCC-500MD) features the latest-generation, image sensor technology for better low-light sensitivity than traditional one-third-sized, image sensor technology for superb image reproduction capability, he noted. The technology also offers HDMI, HD-SDI (1080P), S-video, and composite connectivity options. Multiple views are possible in the operating room since all outputs are active simultaneously. The camera can be paired with a recorder (HVO-550MD)—featuring MPEG-4 recording, USB connectivity, and network recording capabilities—to capture full-HD quality surgical video.

"We've been making digital capture systems since 2001; this is the fifth-generation system introduced to the surgical marketplace," Krachman said. "We've learned a lot over the last 13 years making medical devices, listening to surgeons, having them tell us what features they want and being able to translate these features to help improve workflow."

In the surgical setting, the procedure is the top priority, while recording video is secondary, and no one on the team wants to spend time on a complicated set-up. With earlier versions of the technology, it was necessary to enter a patient ID to start the recorder.

"With this new one, you just hit record and it automatically assigns an ID. You can start working right away and not have to go into any detail to start the system," Krachman added.

"We've also learned that a lot of physicians like to be able to view the footage that they've recorded right after the case or at the end of the day," he said. "Instead of having to jump through several different menus, this new recorder has a simple playback feature. If you want to see what you recorded last, you just hit the play button on the recorder, and there's the last session that you recorded."

In addition, surgeons often like to take video with them. The ability to record on a USB jump drive or a hard drive has been available on all of the company's recorders and has been implemented into the latest model as well. The surgeon can simultaneously record on the hard drive and on a personal jump drive.

"The idea is to make it simple to record and then walk out of the room with the recording," Krachman said.

The recorder's 500GB internal hard drive will store up to 85 hours of HD video with easy access to previously recorded cases.

HAVING A BACK-UP PLAN

If a physician realizes mid-case that someone has forgotten to start the recorder, the new technology can partially remedy that due to a function that constantly records 5 seconds of video in a buffer any time the system is turned on, even if it wasn't set to record.

"That's a really nice feature to have on these units," Krachman said, noting that even the extra few seconds could capture valuable information.

The system is also designed to accommodate older technology. Many ophthalmic centers still have legacy equipment, such as older monitors that are not high definition or moni-

TAKE-HOME

- ***The combination of camera and recorder products is designed to capture and record ophthalmic procedures for an enhanced surgical workflow.***

tors in remote locations. To address that situation, the new recorder will record in HD but will output to older standard definition monitors.

"Anyone in the staff outside of the operating room can also be monitoring and anticipating the needs of the doctor and staff during the operation," Krachman said. "It's the latest technology but it also works well with some of the installed equipment that's already there. It's not necessary to replace every monitor in the facility."

COMPATIBILITY FOR END USER

The availability of a camera and video recorder from the same manufacturer is an advantage to customers, said Niall Byrne, national sales manager at Prescott's Inc., which sells reconditioned medical and surgical equipment, including audiovisual devices.

"When you have two pieces that are intended to work in conjunction with each other, coming from the same manufacturer and designed by the same people, it's obviously a benefit to us and to the end user," Byrne said, adding that subtle compatibility issues can occur with audiovisual products from different manufacturers even when the input and output connections are the same, due to differences in the software.

"You want things to be as simple as an on-off switch, and [this] is one of the few companies that is making both the recorder and the camera," Byrne added.

According to Krachman, prices for the new products are competitive.

"The new camera model that we just brought out is actually lower priced than the unit we brought out 9 years ago that was only a standard definition recorder," he said. "We wanted to offer very good value to our customers. To get higher quality, you shouldn't have to pay higher prices. We were very conscious of that with both the recorder and the camera." ■

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

Vision award honors retinal researchers

ROCKVILLE, MD ::

SEVEN MEMBERS of the Association for Research in Vision and Ophthalmology (ARVO) were named as recipients of the 2014 Champalimaud Vision Award—the highest distinction in ophthalmology and visual science—for their pioneering work to treat age-related macular degeneration and diabetic retinopathy. The prize is worth €1 million.

The laureates worked in parallel and in collaboration to identify vascular endothelial growth factor (VEGF) as the major trigger for angiogenesis in the eye.

The researchers demonstrated that blocking VEGF could suppress ocular angiogenesis.

His Excellency Aníbal António Cavaco Silva, president of Portugal, announced the recipients at a ceremony in Lisbon:

- **Napoleone Ferrara, MD, of University of California, San Diego School of Medicine and Moores Cancer Center**
- **Joan Whitten Miller, MD, FARVO, of Harvard Medical School and Massachusetts Eye and Ear Infirmary**
- **Evangelos S. Gragoudas, MD, FARVO, of Harvard Medical School and Massachusetts Eye and Ear Infirmary**
- **Patricia A. D'Amore, PhD, MBA, FARVO, of Harvard Medical School and Massachusetts Eye and Ear Infirmary**
- **Anthony P. Adamis, MD, FARVO, of Genentech/Roche, who is also affiliated with Harvard Medical School**
- **George L. King, MD, FARVO, of Joslin Diabetes Center and Harvard Medical School**
- **Lloyd Paul Aiello, MD, PhD, FARVO, of the Beetham Eye Institute, Joslin Diabetes Center in Boston, Harvard Medical School and Massachusetts Eye and Ear Infirmary**

The researchers will use the funds from the award to further their research efforts to cure blindness, according to ARVO. ■

Self-tonometry, monitoring systems provide wealth of patient care data

Technologic advances aim to enable ambulatory IOP measurement, reduce office visits

By Cheryl Guttman Krader; *Reviewed by L. Jay Katz, MD*

PHILADELPHIA ::

THE AVAILABILITY OF technologies for ambulatory IOP measurement will usher in a new era for the management of glaucoma.

"Clearly, IOP measurements are the basis for diagnosing glaucoma and evaluating therapeutic response, and we have a variety of instruments available for determining IOP in the office," said L. Jay Katz, MD, director of the glaucoma service, Wills Eye Hospital, Philadelphia. "However, access to information beyond IOP spot-checks will revolutionize patient care."

Dr. Katz said the technologies will provide better understanding of IOP and patient adherence to topical medications and to make more timely adjustments in therapy while reducing the number of office visits. In addition, these new IOP-monitoring systems will add value by increasing patient involvement in their own care.

AMBULATORY IOP MEASUREMENT

Dr. Katz reviewed several devices for ambulatory IOP measurement, none of which has FDA approval. One of the instruments is a home tonometry device developed by a Finland company, and it is commercially available in countries outside the United States (ICare ONE, icare). It operates on the principle of rebound tonometry, analyzing the motion of a deployed disposable plastic probe as it contacts the eye and bounces back. The output measurement is in mm Hg.

Results from published studies found that about 75% of patients were able to correctly perform self-tonometry with the device and that the data it generated had reasonable agreement with IOP measurements obtained using Goldmann applanation tonometry. However, the device has some drawbacks, he noted.

"The instrument is not inexpensive, the accuracy of its measurements depends on proper positioning, and it cannot be used to measure IOP while the patient is asleep," Dr. Katz added.

Other devices overcome the latter limitation. One is a contact lens-based system (Triggerfish, Sensimed) with embedded strain gauges to detect corneal curvature changes at the limbus that occur in response to changes in IOP. The device, available outside the United States, records readings for 90 seconds, every 8.5 minutes, providing up to 144 measurements in a 24-hour period. When the patient returns to the physician's office, the collected data can be transferred wirelessly to a computer via Bluetooth.

"The measurements obtained with the device are not in mm Hg and cannot be converted directly to mm Hg," said Dr. Katz. "However, studies evaluating its performance have shown that it detects changes that are consistent with circadian IOP patterns, treatment responses, and various maneuvers."

IMPLANTABLE DEVICES

Other ambulatory IOP systems being developed are implantable devices that will measure IOP and transmit the readings to external devices via telemetry.

For instance, Implandata is developing two different versions of its device—one for intraocular placement during cataract surgery (ARGOS-IO), and one for external placement into the subconjunctival or intrascleral space that is intended as a stand-alone procedure (ARGOS-EO).

The system consists of the implanted microsensor and a handheld device that transfers energy to the sensor and receives and stores its data. The system can be programmed to obtain measurements continuously or sporadically at predetermined times as well as to take readings on demand.

Testing in a lab setting using cadaver eyes showed IOP measurements obtained correlated well with manometry readings. A study in living animals showed the expected fluctuations of IOP corresponding with the cardiac cycle and with application of digital pressure to the eye. The device is now under clinical investigation.

> 'Access to information beyond IOP spot-checks will revolutionize patient care.'
>
> — L. Jay Katz, MD

AcuMEMS is also developing wireless sensor systems for direct IOP measurement with plans to introduce several models—one that is placed into the anterior chamber during glaucoma surgery (360^{AC}), and a second that would be placed into the capsular bag with the IOL at the time of cataract surgery (360^{PC}). Results from animal studies demonstrate the feasibility of the implantation procedure and the ability to obtain recordings with the different models.

Dr. Katz noted that the enormous amount of data provided by the IOP-monitoring devices is meaningless without physician review and interpretation.

"The companies developing these technologies are very aware of that aspect and are working to establish codes that will allow physicians to be reimbursed for the time they spend evaluating IOP," he added. ■

TAKE-HOME

- ***Technologies will provide better understanding of IOP and patient adherence to topical medications and allow timely adjustments in therapy while reducing the number of office visits.***

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This article was adapted from Dr. Katz's presentation during the Glaucoma 360° meeting in association with the Glaucoma Research Foundation and Ophthalmology Times. Dr. Katz did not indicate any proprietary interest in the subject matter.

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Deadline to apply for a Fellowship is June 30, 2015.
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- This position will include performing cataract surgery on patients with and without glaucoma and will not involve primary or general ophthalmology.
- Our subspecialists in anterior segment reconstruction, cataract, cornea, glaucoma, neuro, oculoplastics, refractive and retina are at the cutting edge and internationally recognized leaders in their fields. We participate in the care of very complex patients from all over the country, other parts of the world, as well as our local tri-state area.
- Interested in research? We already have a strong infrastructure in place to facilitate clinical research and participation in clinical trials.
- With the changing climate of healthcare, our large size and very strong administrative leadership team have us positioned very well for the future but continue to strive to anticipate and respond to changes ahead.
- The Cincinnati area offers big city sports and culture with a small town family feel. It's a wonderful place to work and live.

CEI is considered one of the world's premier ophthalmic treatment, research and education centers. We are one of the largest ophthalmology private practices in the United States with over 50 eye doctors practicing in 16 locations across the tri-state area. The Mission of Cincinnati Eye Institute is to enhance the quality of our patients' lives by compassionately providing the highest level of eye care.

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- This position involves primary/general ophthalmology as well as surgical opportunities.
- Our subspecialists in anterior segment reconstruction, cataract, cornea, glaucoma, neuro, oculoplastics, refractive, and retina are at the cutting edge and internationally recognized leaders in their fields. We participate in the care of very complex patients from all over the country, other parts of the world, as well as our local tri-state area.
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Wanted: Large practice seeks clinical manager

How changing times have transformed daily life in the practice of medicine

Putting It In View *By Dianna E. Graves, COMT, BS Ed*

HERE IS THE WANT AD of the future for the position of Clinical Manager:

> **Busy ophthalmology practice located in six locations throughout the metropolitan area, consisting of: (12) ophthalmologists, (4) optometrists, surgical Center, full optical department and (65 total clinical staff) seeks Clinical Manager with the following qualifications: strong information technology background with at least 4 years of experience in all aspects of EMR and MU Stages I and II and patient scheduling using three unrelated, non-integrated systems. A strong ability to be reactive on a constant basis. People skills a plus, but not required. Clinical skills a plus but not required—must be at least a COA (to ensure you can enter into CPOE). Travel between locations not required. Salaried position requiring at least 60+ hours a week and call. Salary: $45,000. Firm. Those interested please apply to _____.**

If you saw that employment ad in the Sunday newspaper, you might think to yourself: "You've got to be kidding me." You would laugh out loud and then turn the page to the crossword puzzle.

But, if you sat down and wrote the job description for your role in the clinic as it is right now, you might not be too surprised to see multiple similarities. Or should I say, the role you hired on for is not the same anymore because it has morphed into your current role as IT Coordinator.

When we began our EMR/EHR, PQRS and Escribe system-wide integration changes into the world of computerized patient records 5 years ago, we did what most groups do before embarking on a mega-dollar investment.

We investigated four or five different computer systems, and then went on a site visit to a large, compatible-sized practice to see how they were using the system we were interested in. We wanted to get their opinion on the benefits/drawbacks they had encountered. Two physicians, the business office manager, and clinical manager (me) all went for a whirlwind tour to see what this new system was all about.

The office we went to was more than accommodating. They shared how they started their adventure, how they planned and integrated it, and after 2 years, how the system had developed for them.

As sometimes occurs when you are asking someone their opinion of a product, it became obvious that they were being very politically correct with their issues/concerns that they had run across. Especially the parts where their roles that they now had were beginning to slowly and painfully morph into roles they had not anticipated, nor wanted.

Time was short during our fact-finding mission, and I needed to know the real story, not the politically laundered one.

As their clinical manager and I were walking through the clinic, visiting with technicians, and watching the system in action during patient exams, she took me toward our last stop—the diagnostic area to show me how the OCT and HVF were integrated directly into the computer. Walking down the hall, I noticed a darkened room to the left. As we neared the door, I gently pushed her into the darkened room and shut the door.

Turning the light on, I said: "Okay, it's you and me. Tech to tech, manager to manager. No one is here to listen and you can deny you ever said anything, and I can deny I ever heard it. How do you, and your technicians, really feel about this system?"

She looked like a deer in the headlights, then softly said: "Do you like your job?"

"Yes, I can actually can say that I do. I enjoy the teaching and technician interaction, as well as the everyday ebb and flow of the patient world," I said.

Then she told me her story:

"I used to like my job too, and then we had to get a computerized medical records. And now, the job I hired on for—you can't even recognize it. I spend 80% of my day working on computer issues. I no longer leave my office, and I am working weekends and nights to do the job I was hired for—trying to catch up on reviews, get classes together for continuing education, and making sure the clinics are running efficiently.

My title has been changed from Clinical Manager to Clinical Systems Director. I do everything reactively, can't make a plan and stick to it, and now have delegated all the things I used to love to my leads, who are trying to be the managers and see patients all at the same time. The doctors are mad at me because I am not patrolling the clinics, but we can't afford to get an IT service in here, so it is the managers doing it all, with the help of the doctors.

My college degree was in Business, not IT! I loved my job, and I have been here 20 years. We spent 2 years integrating this system. Our pay increases were held to augment the costs of the getting the system. They said we did a great job, but I was making about $5.25 when you broke it down with all the hours we put it. So, today is Friday. On Monday I am giving my 2-week notice. My job is gone—and I want out! Please don't tell anyone."

TAKE-HOME

- ***Job descriptions for the clinical manager in an ophthalmic practice have changed drastically over the years. Dianna E. Graves, COMT, BS Ed, laments how the focus on patient care has shifted in the practice of medicine.***

Continues on page 56 : ***Help wanted***

HELP WANTED

(Continued from page 55)

She walked out of the room, and left me there.

To say the answer I received was more than I bargained for is an understatement.

Actually, it was a premonition.

It has nothing to do with the system we purchased—it has to do with the way medicine is now being practiced. Ten years ago, when doctors stopped by my office to talk, it was about an interesting case in the operating room or a patient who had a fairly obscure disease process going on that showed up on the schedule. Maybe we would talk about a technician who needed a little extra work, or about adjusting schedules so that he/she could coach soccer with his/her kid during the summer months.

THEN AND NOW

Now, when they loom in the doorway, it is to tell me that Server 5 is very slow, or that when they hit the "Save and Send" button, it sends, but doesn't save. Or, they have found a shortcut on the desktop that will allow them to click the "ALT 6" button and it will automatically print the note, versus having to "Save, Send, Print" which is two clicks.

I will return to the tenet that the doctors—and the technicians—just want to see their patients and do quality patient care, but our roles have changed from patient care providers to technical troubleshooters.

Physicians and staff have also become part of the IT support team. You need their input to help troubleshoot, whereas in the old days, you smiled tolerantly at their computer suggestions and then ignored whatever it was that they said.

I am not condemning the EMR/EHR systems—and I will be the first one to solidly say that when we began our computer conversion, it was one of the best things that ever happened to our group as it allowed the records to be easily integrated from anywhere the doctor was. This improved consistency in patient care (especially if a doctor was on call and the chart was located six towns away), it created a safe place to store this information and allowed us to analyze information and trends, and it also allowed for inter-communicability with other areas (Labs, MRI).

What I am saddened by is what we have lost because of this good idea. Somewhere it has caused a drastic and devastating effect on the ability to focus on the patient.

FOCUS ON CARING FOR PATIENTS

Victor Hugo said: "Change your opinions, keep to your principles; change your leaves, keep intact your roots."

Where we have fallen is that this fast, quiet, tsunami-like wave has engulfed the medical world.

It has changed everything regarding the way we practice, in such a way, that our roots have been left bare, and the patient-care tree is withering and dying. We don't have time to look at a patient, or talk with the patient. We spend our time pointing, dropping down, and clicking.

Keep the changes that protected the patient and allowed us the ability to safely manage their systems. But there needs to be a way to get back to what we did so well—the ability to care for patients.

By the way, if there had been a want ad for my job written 12 years ago, it might have looked like this:

> **Busy ophthalmology practice located in six locations throughout the metropolitan area consisting of: (14) ophthalmologists, surgical center, and full optical component and (30) technicians seek clinical services manager with the following qualifications: At least 5 years' experience in a clinical managerial role. JCAHPO COT/COMT certification a must. Continuing education and advancement of clinical skills in a fast-paced, dynamic patient-care setting. Travel between clinics, and supervisory interaction with all technical staff. Advisory role to the physicians regarding technicians and the diagnostic department. Safety director and OSHA director for the group. Salaried position. Please inquire to _____.**

For a sobering view of your world, pull out your old job description and then update it with a description of your world as it is today. ■

> 'There needs to be a way to get back to what we did so well—the ability to care for patients.'
>
> — Dianna E. Graves, COMT, BS ED

DIANNA E. GRAVES, COMT, BS ED

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Promoting ophthalmic practice through social media made easy

Tips for utilizing social media marketing with minimal administrative involvement

By Rose Schneider, *Content Specialist,* Ophthalmology Times

HOUSTON ::

IN RECENT YEARS, social media has emerged as a game-changer for companies looking to promote their businesses outside of the print platform.

It is no longer enough to purchase an advertisement in a newspaper or magazine to promote a practice's LASIK discounts and expect patients to come—practices must now go directly to the customer, and social media is the ideal way to accomplish this goal, said Michael W. Malley.

Understanding the practice's target audience—current and potential future patients—is the first step in tackling a social media marketing strategy, according to Malley, president and founder of the Centre for Refractive Marketing (CRM Marketing Group), an ophthalmic consulting and advertising agency based in Houston.

AUDIENCE BREAKDOWN

According to Malley, recent research has found that women go online by way of smartphones more often than men by about 10%.

Men and women also respond to social media differently, he explained, so practices should not be discouraged if there is no immediate reaction to promotion efforts, Malley continued.

"When it comes to how men respond to social media, it's kind of how men do things in life—we want quick, easy access to things," Malley said.

> Understanding the practice's target audience is the first step in tackling a social media marketing strategy. – *Michael W. Malley*

For example, if a practice is going to promote a coupon or savings-special offer, men are more likely to make a quicker decision to purchase something or scan a QR code than women, he said.

Women, on the other hand, prefer doing research by following social trends before making a purchase.

"They will follow trends and information and see what their friends are doing from a social media standpoint," Malley said. "It takes a little time" to get women to respond to promotions.

"Just don't give up too soon when you're making those offers out there," he advised.

Women also tend to ignore ads on social media more than men, he said.

"We start off with half the audience ignoring your ads, you're already in the hole a bit, so don't expect overwhelming response from any social media that you do because you're losing about half as soon as you start," he said. "It takes time."

SOCIAL MEDIA INTERACTION

How a practice interacts with its audience on social media is also highly important, Malley explained.

"When was the last time you bought something for $4,000 or $5,000 based on a Facebook ad about something you weren't on Facebook about?" Malley posed. "That's not how this thing works. We think if we put a banner ad on Google network or our Facebook page . . . people are going to jump all over (it).

"(But), they're using social media not to have LASIK—that's the first revelation you need to realize," Malley continued. "They're not using social media for LASIK—LASIK is a part of their social media."

By becoming a part of the conversation with the practice's Facebook audience—instead of simply posting photographs or information and expecting people to find it—customers are more likely to interact.

Utilizing local media with a large social media presence is another effective tip to expand that conversation to promote the practice.

In order to accomplish this method, Malley said practices should first look at their own Facebook and Twitter followers.

Which media outlets are they following? Do any of those outlets have large social followings?

If the answer to those two questions is "yes," practices should reach out to those media targets—such as radio or television stations—and attempt a deal for them to promote campaigns through their accounts

FURTHER TIPS

"How many people are following you or are interested in you versus a super large FM radio station or a TV station?" Malley said. "Everything we (CRM Group) do now, before we negotiate any media, we say whatever we do with (radio or television stations) externally from a media standpoint, we want to hook up with (them) online, with social, with Facebook. Anything they have going on, we want that."

From these relationships, a practice's campaign that would normally only have been seen by its 700 Twitter followers would now also be viewed by the local radio station's 100,000 followers.

Furthermore, creating connections with those who are in charge of large media outlets can increase a practice's campaign visibility as well, Malley explained.

TAKE-HOME

- ***Social media is a highly effective tool for promoting practices' campaigns, but knowing several key strategies will increase success from advertising.***

Continues on page 58 : ***Social media***

SOCIAL MEDIA

(Continued from page 57)

"It never hurts to hook up with the guy that controls all the station programing," he said.

Those connections become even more valuable when they go from just a connection to a patient. For example, if a radio personality has a great LASIK experience at your practice, get them to be the face of the practice's next campaign for more visibility, Malley said.

EXPOSURE ON THE HOMEPACE

Homepage takeover is another excellent route for maximizing a promotion's exposure to target audiences.

"In one entire day you (can't) go to that station and not see our ads all over their homepage, and I think that's a pretty good investment of dollars," Malley said. "(CRM Group) actually got more out of this than we actually did on (a) radio campaign."

Nevertheless, the biggest takeaway from learning how to market through social media is that no matter how good a physician is at his or her clinic or how great a LASIK campaign is for patients, do not expect people to pay attention without active social media effort.

"As good as your doctor is or as good as you might be, people have more important things to do than follow you online and go to your Facebook page every day or tweet about you every day," Malley stressed.

"The core part of my messaging is piggyback—everybody you know—every person that you've worked with from a media standpoint," he said. ■

Advertiser Index

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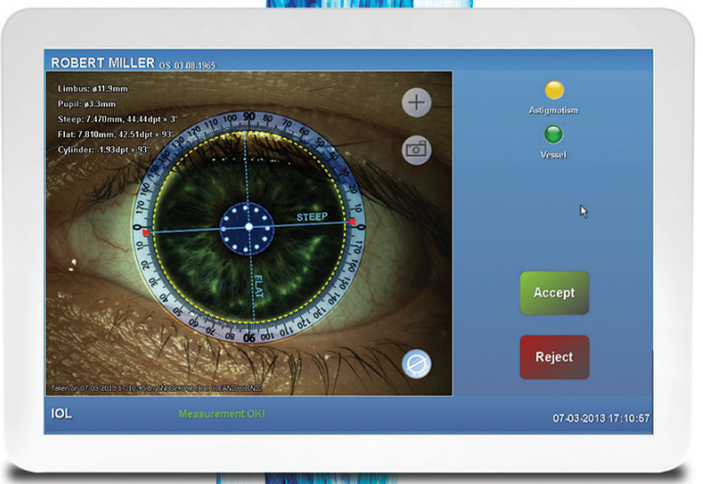

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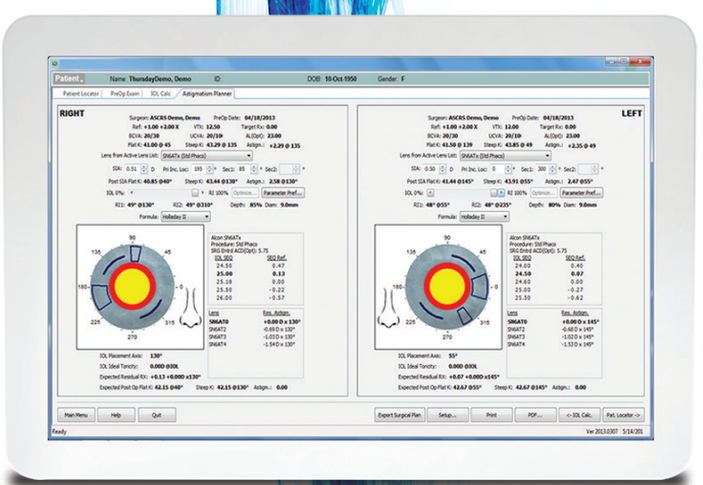

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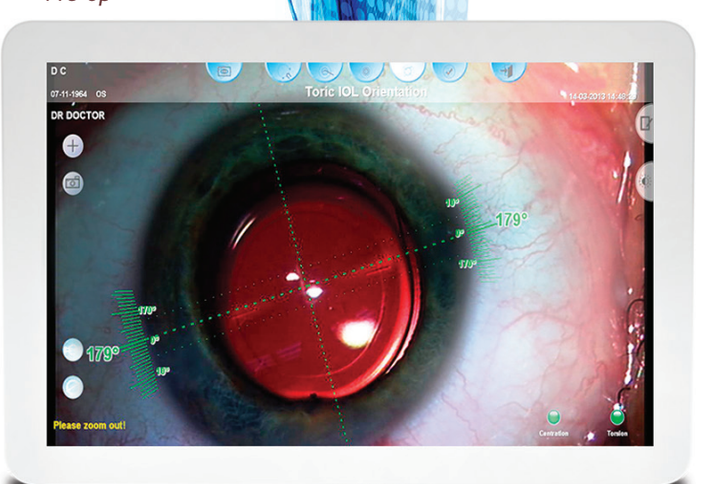

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