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In This Issue

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Cornea

EVIDENCE DOES NOT JUSTIFY CXL WITH LASIK

By Cheryl Guttman Krader

IRVINE, CA :: **COMBINING ROUTINE CORNEAL** collagen crosslinking (CXL) with primary LASIK may not be a strategy for preventing postoperative ectasia.

"An assessment of the risk:benefit ratio, based on current evidence, does not justify the routine application of CXL at the time of LASIK," explained Perry S. Binder, MS, MD, clinical professor of ophthalmology, Gavin Herbert Eye Institute, University of California, Irvine. "Furthermore, how do we justify the additional cost to patients in lieu of what is known about the risks of CXL and postLASIK ectasia and the limited peer-reviewed studies of CXL with primary LASIK?

(See story on page 9)

MIGS extending beyond glaucoma

Novel procedures enter realm of cataract and cornea

By Cheryl Guttman Krader;
Reviewed by Leon W. Herndon, MD

DURHAM, NC :: **MICROINVASIVE** glaucoma surgery (MIGS) is an emerging category that can be readily learned by cataract surgeons and corneal subspecialists.

"However, the need for close surveillance of the [patient with] glaucoma must still be kept in mind," said Leon W. Herndon, MD, associate professor of ophthalmology, Duke University Eye Center, Durham, NC. "Randomized trials are needed to determine the efficacy of the MIGS procedures compared with trabeculectomy, which remains the gold standard for incisional glaucoma surgery."

The reason why non-glaucoma specialists would be interested in learning MIGS procedures relates to data on the prevalence of comorbid cataract and glaucoma combined with the benefits of MIGS procedures.

"In the United States alone, more than 3 million cataract procedures are performed each year, and more than 650,000 [patients with] cataracts have co-existing glaucoma or ocular hypertension," Dr. Herndon said.

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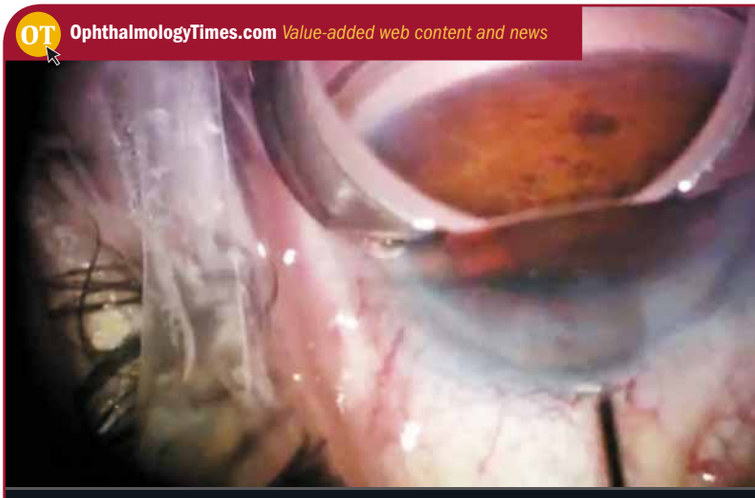

Microinvasive glaucoma surgery typically involves an ab interno approach to the filtering angle, as shown in this video clip (http://ow.ly/juUal) of surgery with a microbypass trabecular stent. *(Video courtesy of Leon W. Herndon, MD)*

Go to http://ow.ly/juUal

"Cataract surgery by itself can lower IOP, but most patients still need medication for IOP control," he said. "MIGS procedures performed with an ab interno surgical approach cause minimal tissue trauma, are associated with a better safety profile and faster recovery than traditional filtering surgery, and do not preclude the success of more aggressive surgical intervention if it is needed in the future."

MIGS OPTIONS

The MIGS procedures seek to avoid bleb formation and rely on augmentation of the physiologic outflow pathways. These techniques, which include the microbypass trabecular stent (iStent, Glaukos) and ab interno tra-

*(Continues on page 10 : **Ectasia**)*

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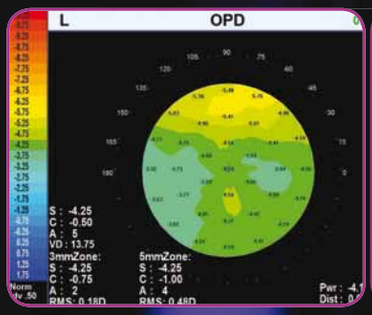

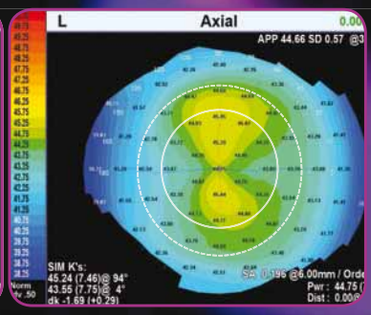

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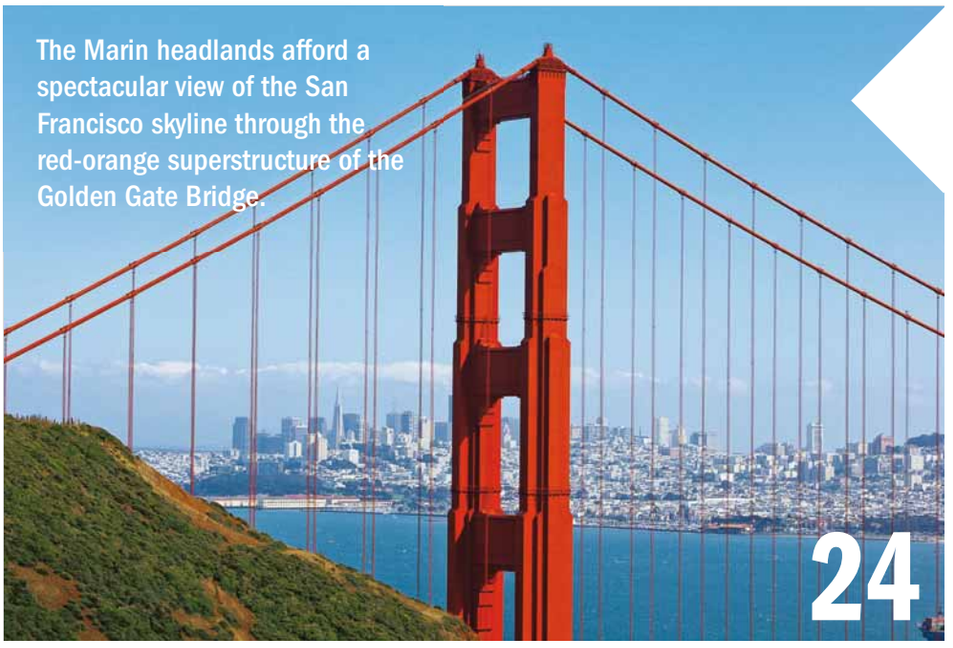

The Marin headlands afford a spectacular view of the San Francisco skyline through the red-orange superstructure of the Golden Gate Bridge.

Special Report

ASCRS MEETING PREVIEW

Cornea

Cataract

Refractive

Glaucoma

Retina

Practice Management

Playing it safe

When risk-averse behavior creates self-defeating pattern

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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THIS IS A TRUE story. I left the office a little early today in order to get my hair cut. I plopped down in the chair, facing the television showing the Winter X Games on *ESPN*. The young lady asked if I had anything special in mind this time.

"Just make me look intelligent to men and irresistible to women," I said.

"Easy," she replied, and began snipping away.

"What do you do?" she inquired.

"I'm a professional snowboarder," was my answer. I waited for the laughter that did not come.

"Cool," she replied, "but isn't that dangerous?"

"Not the way I do it," was my rejoinder. "Besides, my middle name is Risk."

"Cool," she replied. "But don't you have to pay a lot for medical insurance?"

It turns out that the issue of risk had been in the back of my mind. Normally, we Americans are noted for being entrepreneurial risk-takers. But, according to Ron Ashkenas of the Haas School of Business at the University of California, Berkeley, when the economy gets bad and unemployment rises, people start playing it safe.

According to Ashkenas, laboratory mice can be conditioned to exhibit "good" behaviors by giving them sugar pellets when they do what the scientist wants and shocks when they do the opposite. But, if the consequences are random (i.e., the same behavior is sometimes rewarded and sometimes punished), the mice become highly stressed and confused and start taking no actions at all: "They stop taking risks, which is the safest possible behavior."

OF MICE AND HUMANS

In a company faced with tough times, argues Ashkenas, the same phenomenon takes place (but with people and not mice). "I discovered that while executives genuinely wanted innovation, they simultaneously wanted to control costs and report consistent earnings. So while a few people had been recognized and rewarded for innovation, many others had been laid off. As a result, the strongest and most consistent message . . . was that people in the company, at all levels, were risk-averse. Like the mice in the lab experiment, managers and employees were anxious about the consequences of failure and felt it more prudent to continue doing what they had always done. Such behavior inevitably creates a self-defeating pattern. If the firm does not create an environment where people can take risks and occasionally fail, then innovation will be stifled."

> 'It would be a shame if ophthalmology in our country, long known for its ability to develop and rapidly adopt new technology to serve its patients better, began to play it safe.'
>
> — *Peter J. McDonnell, MD*

In today's slow-growth economy, combined with cuts in physician reimbursement and research grants, the word "company" in the paragraph above might be replaced with the word "medical practice" or "academic clinical department." It would be a shame if ophthalmology in our country, long known for its ability to develop and rapidly adopt new technology to serve its patients better, began to play it safe. Back during the Clinton years when the U.S. economy was charging along, ophthalmic

Continues on page 8 : **Editorial**

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Dr. Apple's lab endures at University of Heidelberg

Transition places Dr. Auffarth, 'Apple Korps' at core of IOL research

By Jennifer A. Webb

HEIDELBERG, GERMANY ::

The late David J. Apple, MD, spent his life investigating the successes and failures of IOLs right up until his death in 2011.

Today, his groundbreaking work continues at the University of Heidelberg, Germany, under the guidance of Apple Korps member Gerd U. Auffarth, MD, PhD, chairman of the ophthalmology department there.

With the blessing of Dr. Apple's widow, Ann, a shipping container with 300 boxes of archives and documents and more than 20,000 preserved specimens was delivered last spring to Heidelberg to launch the David J. Apple International Laboratory for Ocular Pathology there. Dr. Auffarth said he was honored to continue the work of Dr. Apple, who taught him a great deal about working with IOLs and running an international laboratory.

'[Dr. Apple] was an excellent mentor. He was like a scientific father to me.' *– Gerd U. Auffarth, MD, PhD*

"He was an excellent mentor," Dr. Auffarth said. "He was like a scientific father to me."

Dr. Apple, who died at age 69 from complications from his aggressive tongue cancer treatment, began studying IOLs in 1981 when he joined Randall J. Olson, MD, as a pathologist at the University of Utah in Salt Lake City. Together, they founded the Center for Intraocular Lens Research. In 1988, he moved the lab to the Storm Eye Institute, Medical University of South Carolina, Charleston, where he was chairman and professor of ophthalmology and pathology.

Dr. Apple had begun researching IOL pathology and related complications, refining implantation techniques, and studying materials used in their manufacture. By studying thousands of human eyes donated post-mortem, he was able to identify the best techniques and materials, and his work led to many fewer IOL-related complications in patients.

He went on to receive three major honors within ophthalmology: the American Society of Cataract and Refractive Surgery's Innovator's (Kelman) Award in 2005; the American Academy of Ophthalmology (AAO) Hall of Fame award in 2007; and the AAO's Life Achievement Honor Award.

Dr. Apple

"He was a visionary to start in a research field that no one was interested in," Dr. Auffarth said. "Without him, we wouldn't have all these premium lenses and the quality of lenses we have today . . . . A lot of companies would have a different type of product if not for him."

'APPLE KORPS'

In 1992, Dr. Auffarth joined the "Apple Korps," as Dr. Apple affectionately called his more than 200 fellows. For 2 years he worked closely with his mentor to analyze specimens that arrived, catalog them, and develop database programs. They became close friends and colleagues, visiting nearly every year in Charleston or Heidelberg, where Dr. Auffarth eventually became chairman and established a similar international laboratory.

Two years before he died, Dr. Apple—who had studied in Germany, co-authored an eye pathology textbook in German, and was elected in 2003 to the German Academy of Research in the Natural Sciences—made plans to join his former student at Heidelberg as a professor and continue his research there. However, his health declined too rapidly.

Ann said her husband of 16 years, who had moved his lab back to Salt Lake City in 2002 then returned to South Carolina in 2008, worried a great deal about who might continue his life's work. Within days of the funeral, she communicated via Skype with Dr. Auffarth and Jane Gay, Dr. Apple's assistant, to ask him to consider picking up the reins.

"I desperately wanted someone who would apply himself but also his staff and his resources to the continuation of what David had done," Ann said. "David lived many years knowing, in some bit of fear, that it was just going to come to an end when he was gone."

LEGACY CONTINUES

To Ann's relief, Dr. Auffarth was ready and willing to move the lab from the Apple home, where they had built an addition to house the lab in his later years, to Heidelberg. There, not only would Dr. Auffarth continue related research, but also he could employ the considerable depth of expertise of the German Cancer Research Center, the Center for Molecular Biology of Heidelberg University, Heidelberg University Biochemistry Center, the Max Planck Institute for Medical Research, and the European Molecular Biology laboratory.

"Gerd showed a consistent belief in the kind of work David did and attempted to do similar things," Ann said. "They talked often and e-mailed often. It was an ongoing academic, professional, and personal relationship with a great deal of respect going both ways."

Gay (Dr. Apple's assistant) along with re-

Continues on page 8 : **Apple lab**

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SM-037, Rev A, 03/01/2013

APPLE LAB

(Continued from page 6)

search assistant, Marcella Escobar, PhD, packed up the archives and specimens for delivery. They also remain the U.S. contact to receive and ship specimens destined for the Apple laboratory in Germany.

The laboratory, which will operate as a network within the university, will accept intraocular ophthalmic device samples from throughout the world for research. Dr. Auffarth, who plans to recruit several fellows, said he hopes the laboratory will once again be an international center where device manufacturers and ophthalmic surgeons will come to discover ways to improve vision care. And, expanding on his mentor's work, researchers in the lab will have access to patients in the eye department, Dr. Auffarth said.

> 'The most successful companies were those who listened to Dr. Apple, picked up his ideas, and ran with them.' – *Donald J. Munro*

IMPRINT ON MANUFACTURERS

Donald J. Munro, former chairman and managing director of Rayner Intraocular Lenses, is working with Dr. Auffarth to help lens developers work with the lab on rigorous product testing.

"There are lots of new medical device companies that I'm sure are eager to get their product into western Europe and North American countries," Munro said. "And, if their medical devices are studied at this institution, it will give credibility to their product."

Dr. Apple's scientific curiosity, deep intellectual reserves, and humility combined to help manufacturers improve their lenses, Munro said. For example, his research proved that nylon was a poor material for haptics, because it lost its shape and resulted in patient complications. Most manufacturers switched materials within a few years.

"Sometimes the results were not what you wanted to hear because it meant you had to change course and make a re-development," Munro said. "The most successful companies were those who listened to Dr. Apple, picked up his ideas, and ran with them."

Bringing the lab to the German city and the revered institution his mentor loved is one way Dr. Auffarth hopes to show his gratitude for the start Dr. Apple gave him.

He hopes to re-create the atmosphere and spirit of the Apple lab, and invites fellow Korps members to visit.

"It's a natural way to continue his legacy and keep his name alive," Dr. Auffarth said. "We will put the lab's name in every publication, and his name will really live on." ■

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THE RESEARCH GOES ON

Go to **http://ow.ly/juTYx** for a video interview with Gerd U. Auffarth, MD, PhD, chairman, Department of Ophthalmology, University of Heidelberg, Germany. He talks about the steps in place to continue the ophthalmic research lab and legacy of the late David J. Apple, MD, in this exclusive *Ophthalmology Times* video interview. *(Video courtesy of Ophthalmology Times)*

GERD U. AUFFARTH, MD, PHD

Readers may contact Dr. Auffarth via e-mail at ga@uni-hd.de to inquire about the David J. Apple International Laboratory for Ocular Pathology.

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EDITORIAL

(Continued from page 4)

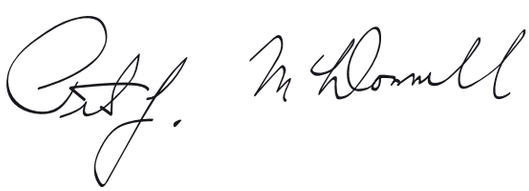
practices had the confidence and cash to acquire excimer lasers remarkably rapidly. RK changed overnight from a fairly common procedure to a historic curiosity, replaced with PRK and LASIK. A large experience and literature with the excimer rapidly developed.

EFFECT ON OPHTHALMOLOGY

Admittedly, not all new medical innovations are fantastic. But I wonder if as many of my fellow ophthalmologists today feel they can take the risk of investing major dollars into femtosecond laser technology for cataract surgery (by way of disclosure, I have no financial relationships with companies that build these devices).

What if they are prevented from charging adequate fees to cover the added costs associated with purchasing and using the laser? What if there is not a substantial increase in patients coming to the practice in response to marketing the presence of this new toy? Will a junior ophthalmologist in a group practice refrain from arguing for the investment because he/she fears the wrath of senior partners if the hoped-for-benefits fail to accrue?

This evening I found myself pondering this issue of risk-taking behavior in today's medical practice environment while sipping a cocktail. Lost in thought, I suddenly became aware of a young lady looking at me, when I heard her say, "Nice haircut!" After a quick glance in the mirror, I wondered, "Hmm, I wonder if I also look intelligent to men?" ■



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Evidence does not justify CXL with LASIK approach

Uncertainty outweighs risks, benefits of simultaneous crosslinking to prevent postLASIK ectasia

By Cheryl Guttman Krader; *Reviewed by Perry S. Binder, MS, MD*

TAKE-HOME

- ***The risk:benefit ratio for routine corneal collagen crosslinking for primary LASIK cases does not justify routine application.***

IRVINE, CA ::

COMBINING ROUTINE corneal collagen crosslinking (CXL) with primary LASIK may not be a strategy for preventing postoperative ectasia.

"An assessment of the risk:benefit ratio, based on current evidence, does not justify the routine application of CXL at the time of LASIK," explained Perry S. Binder, MS, MD, clinical professor of ophthalmology, Gavin Herbert Eye Institute, University of California, Irvine. "Furthermore, how do we justify the additional cost to patients in lieu of what is known about the risks of CXL and postLASIK ectasia and the limited peer-reviewed studies of CXL with primary LASIK?

"Instead of performing CXL with LASIK in a case where there is doubt about the risk of ectasia, surgeons can consider implanting a phakic IOL, or in some cases, performing PRK," he added.

FEAR OF THE UNKNOWN

The fear of not being able to identify patients at risk for ectasia is one reason why surgeons might consider routine CXL at the time of LASIK. However, the risk of postLASIK ectasia has been decreasing due to a variety of factors, Dr. Binder noted.

There is better awareness of the risk(s), leading to better patient selection, as well as better methods for screening. In addition, flap thickness has become more reliable with use of the femtosecond laser, and there are more ways to measure postoperative flap and residual bed thickness.

"We are now much better at detecting and eliminating eyes at risk for developing ectasia, and so the incidence of the risk of ectasia has decreased," Dr. Binder said.

On the other hand, the routine addition of CXL to LASIK introduces potential complications, including no effect, under- or over-response, corneal scarring, corneal infiltrates, delayed epithelial healing, and endothelial cell damage or loss. Moreover, there is little known about the safety and benefit of combining the two techniques.

Further compounding the uncertainties is the broad variability in the radiation and riboflavin dosages being used for CXL.

FACTORS contributing to current decrease in postLASIK ectasia

- **Better awareness of risk factors**
- **More tools for measuring postoperative flap and residual stromal bed thickness** (optical coherence tomography, high-frequency ultrasound)
- **Increased flap thickness predictability,** resulting in more predictable residual stromal bed thickness
- **Better screening tools** (new topography algorithms, biomechanical measurements, epithelial thickness measurements)

UNANSWERED QUESTIONS

Pertinent to performing CXL with LASIK, questions remain. How will the intact epithelium affect ultraviolet A penetration to the riboflavin in the interface? What would be the diffusion of riboflavin in either direction after instillation into the LASIK interface?

The safety of performing CXL at the time of LASIK is also not well characterized, due to the limited data on the combined procedure. In theory, however, adding CXL may introduce additional risks. For example, there may be increases in risk of infection due to longer operative and bed exposure time, as well as for loss of deeper stromal cells. Flap adhesion might also be affected with the potential for an increased risk of dislodgement by superficial trauma.

Also, it is unknown how simultaneous CXL will affect the refractive outcome of LASIK and the stability of the treatment effect considering that the CXL procedure might change the excimer laser ablation rate, corneal compactness, refractive index, and curvature. The possibility that CXL might have an effect on postLASIK IOL power calculations must also be considered.

Dr. Binder observed that establishing a benefit of combining CXL with primary LASIK for reducing the risk of ectasia will be a challenge, considering the low incidence of ectasia and the multiple variables that would need to be controlled.

"A study designed to detect a treatment difference for an adverse event with an incidence of 1% would require an enrollment of 300 patients," Dr. Binder said. "A study of primary CXL with LASIK would have to stratify patients based on numerous clinical parameters, including thickness of the cornea, flap, and residual stromal bed, patient age, and variables in the CXL technique.

"Considering the confounders and that the risk for postLASIK ectasia is very low, a study investigating the effect of CXL on ectasia would have to be extremely long, include a huge number of eyes, and even then, it may not provide an answer," he said.

Looking ahead, Dr. Binder called for the development of techniques and technology that would allow predictable irradiation of focal areas of the affected cornea and to determine the treatment depth. ■

PERRY S. BINDER, MS, MD

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Dr. Binder has no financial interest in the subject matter. This article is adapted from Dr. Binder's presentation during Refractive Surgery 2012 at the annual meeting of the American Academy of Ophthalmology.

ECTASIA

(Continued from page 1)

beculectomy (Trabectome, NeoMedix), are appropriate for patients with mild-to-moderate glaucoma because they achieve a modest IOP target (~15 to 16 mm Hg). Eligible patients also are limited to those with an open angle and must be able to tolerate topical medications, which will probably still be needed to some degree after surgery, Dr. Herndon said.

Describing some published results from the MIGS procedures, Dr. Herndon said that in a study of 304 patients who had concurrent cataract surgery with ab interno trabeculectomy, mean IOP decreased from 20 mm Hg at baseline to 15 mm Hg at 1 year. The medication requirement was also significantly reduced.


Dr. Herndon

"There were very few complications, but 78% of eyes developed some hyphema," he said.

In the U.S. IDE study of the microbypass trabecular stent, 240 eyes were randomly assigned to undergo cataract surgery alone or with the stent. After 1 year, the proportion of eyes achieving IOP of 21 mm Hg or less without medication was significantly higher in the combined group compared with the controls having cataract surgery alone (73% versus 50%). A significant difference in this endpoint favoring the combined group was maintained at 2 years (61% versus 50%).

Studies have also been undertaken to evaluate outcomes after implantation of multiple stent devices. In a study where patients underwent cataract surgery and received two or three stents, there was a trend for IOP to be lower in the group with two stents compared with those with three stents implanted. However, the average daily medication use was significantly lower for eyes with three stents implanted.

The Schlemm's canal scaffold (Hydrus, Ivantis [not FDA approved]), is still being evaluated in a U.S. IDE study. The device has the CE mark, and early European data show that its use results in IOPs in the mid-teens at 1 year.

Dr. Herndon also noted that compared with the above procedures, a lower IOP target (<13 mm Hg) can be achieved with a trabeculectomy-type procedure (Ex-PRESS shunt, Alcon Laboratories). This "kinder and gentler trabeculectomy" can be performed in eyes with open or narrow angles.

Based on its IOP-lowering efficacy, it might be considered appropriate to manage eyes with moderate-to-advanced glaucoma, those with progressive normal-pressure glaucoma, and for patients with intolerance to most medications, he said.

TAKE-HOME

- ***Microinvasive glaucoma surgery can achieve a modest IOP target with a good safety profile for appropriately selected patients with open-angle glaucoma.***

GEARING UP

Cornea surgeons who might be interested in performing MIGS should familiarize themselves with intraoperative gonioscopy, he said.

"After implanting the IOL, deepen the anterior chamber, tilt the patient's head about 35° away from yourself, and angle the microscope about 35° toward yourself," Dr. Herndon said. "Place a surgical gonioprism on the cornea with the non-dominant hand and use a Sinskey hook or similar instrument in the dominant hand to approach the angle and mimic the subtle wrist pronation needed for implantation." ■

LEON W. HERNDON, MD

E: *leon.herndon@duke.edu*

Dr. Herndon is a consultant and lecturer for Alcon Laboratories and Glaukos. This article is adapted from Dr. Herndon's presentation during Cornea 2012 at the annual meeting of the American Academy of Ophthalmology.

TG-PRK/CXL may benefit postLASIK ectasia

By Cheryl Guttman Krader; *Reviewed by Simon P. Holland, MD*

VANCOUVER ::

EARLY RESULTS USING two excimer laser platforms show topography-guided PRK (TG-PRK) with simultaneous corneal collagen crosslinking (CXL) has promise as an effective treatment for patients who are highly symptomatic because of postLASIK ectasia, said Simon P. Holland, MD.

Dr. Holland, clinical professor of ophthalmology, University of British Columbia, Vancouver, reviewed outcomes for a series of 24 eyes with postLASIK ectasia; the TG-PRK procedure was performed using the Allegretto Wave-Light laser (Alcon Laboratories) in 17 eyes and with the iRES laser (iVIS) in seven eyes. All of the eyes had follow-up of at least 6 months.


Dr. Holland

"All but two patients [had symptomatic improvement], two-thirds of eyes achieved uncorrected visual acuity of 20/40 or better, and close to half of the eyes gained 2 or more lines of best-corrected visual acuity [BCVA]," Dr. Holland said. "Mean astigmatism was reduced from –3.3 to –1.1 D in the Allegretto-treated eyes and from –2.5 to –1.1 D after iRES treatment.

"With follow-up to 3 years in some eyes, we have seen no progression of ectasia," he added.

Comparing the two laser subgroups, Dr. Holland observed that the iRES treatment does not induce as much myopia as the Allegretto system because the iRES ablation is more central. However, the gain in BCVA is less with the iRES treatment. While 53% of eyes in the Allegretto group gained 2 or more lines of BCVA, only 14% of the iRES-treated eyes achieved that level of improvement. No iRES-treated eyes and 1 (6%) Allegretto-treated eye lost 2 or more lines of BCVA.

CXL was performed with application of 0.1% riboflavin in dextran until aqueous staining. Hypotonic dextran was used to thicken the cornea in eyes with thickness <400 µm. The UV irradiation was with a 370-nm light source at 3 mW/cm^2. The excimer laser portion of the procedure was performed with transepithelial PRK and a custom topographical neutralization technique.

Postoperative management consisted of a bandage contact lens and a standard postPRK protocol.

"Delayed epithelialization remains the main complication of this procedure," Dr. Holland said. ■

SIMON P. HOLLAND, MD

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Dr. Holland and his collaborator, David T.C. Lin, MD, have no financial interest in the material presented. This article is adapted from Dr. Holland's presentation during Refractive Surgery 2012 at the annual meeting of the American Academy of Ophthalmology.

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'Telling It Like It Is!' sums state of cataract surgery

Third annual meeting delivers on innovative educational program

By Zaid Smith, PhD

Cataract : *In this Issue*

TAKE-HOME

- ***Challenging surgical cases, controversies, and the management of surgical complications were the focus of the third annual "Cataract Surgery: Telling It Like It Is!" meeting.***

SARASOTA, FL ::

Candid. No-holds-barred. Highly clinical. State of the art. For the third consecutive year, cataract surgeons gathered here in January for "Cataract Surgery: Telling It Like It Is!" with an agenda ready to deliver on these goals.

The extended-weekend conference was organized by Robert H. Osher, MD, professor of ophthalmology, University of Cincinnati, and medical director emeritus, Cincinnati Eye Institute. Dr. Osher established the meeting without continuing medical education units so as to be able to mention new products, drugs, and off-label advances in surgical technique.


Dr. Osher

"The goal of this meeting is to provide the best quality, useful education with total honesty and without censorship," Dr. Osher said. "We want every attendee to depart Sarasota more confident about delivering the best possible surgical care."

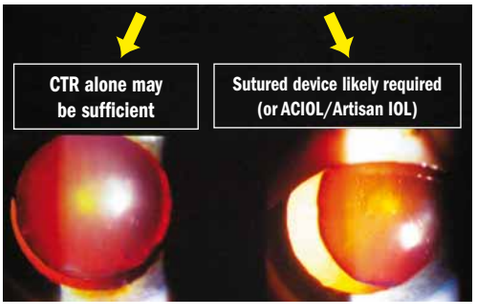
With a capacity crowd of nearly 400 attendees and 80 exhibitors, this pioneering educational approach appears to fill an unmet need in the cataract surgery community.

This year's faculty included:

- **Richard Mackool, MD, director, Mackool Eye Institute and Laser Center, Astoria, NY;**
- **Warren Hill, MD, medical director, East Valley Ophthalmology, Mesa, AZ;**
- **Ike Ahmed, MD, assistant professor of ophthalmology, University of Toronto and clinical assistant professor of ophthalmology, University of Utah, Salt Lake City;**
- **Michael Snyder, MD, voluntary assistant professor of ophthalmology, University of Cincinnati and in private practice, Cincinnati Eye Institute;**
- **Robert Cionni, MD, medical director, The Eye Institute of Utah, Salt Lake City and adjunct clinical professor of ophthalmology, University of Utah, Salt Lake City;**
- **Graham D. Barrett, MD, clinical professor, Lions Eye Institute and Sir Charles Gardner Hospital, Perth, Australia;**
- **William Fishkind, MD, clinical professor, University of Utah, Salt Lake City, clinical professor, University of Arizona, Tucson, AZ, and director, Fishkind, Bakewell & Maltzman Eye Care and Surgery Center, Tucson, AZ;**
- **Lisa B. Arbisser, MD, ophthalmologist for Eye Surgeons Associates, Iowa and Illinois Quad Cities; and adjunct associate professor, John A. Moran Eye Center, University of Utah, Salt Lake City;**
- **Robert Weinstock, MD, director, Cataract and Refractive Surgery, The Eye Institute of West Florida, Largo, FL, and assistant clinical professor of ophthalmology, University of South Florida, Tampa.**

The education unofficially began Wednesday evening with a pre-meeting movie night. Dr. Osher presented 10 video clips from the library of the *Video Journal of Cataract and Refractive Surgery* and led an interactive discussion of each.

On Thursday, the meeting opened with a new technology symposium featuring a format that Dr. Osher called "Showdowns," with side-by-side comparisons of similar technologies, as presented by physician advocates. Phacoemulsification machines, microscopes, presbyopia-correcting IOLs, toric lens alignment technology, biometry equipment, and femtosecond lasers for cataract surgery were reviewed in detail.



(FIGURE 1) **A discussion on "Rings and Things" included the use of zonular and pupil expansion devices, such as capsular tension rings (CTRs).**

RINGS AND THINGS

On Friday morning the session opened with a tutorial called "Rings and Things," in which Drs. Ahmed and Cionni discussed the use of zonular and pupil expansion devices, including capsular tension rings (CTRs), capsular tension segments (CTSs), and capsule retractors in cases of zonular dialysis or deficiency. There was some debate on the timing of CTR placement.

Dr. Cionni maintained that "the best time is after phacoemulsification, after all capsule has been cleaned and you have a good view, to be certain of being in the right place and that there's no capsular opening."

While agreeing that there were advantages to the late placement, Dr. Ahmed had a different take, preferring CTR placement prior to phacoemulsification and cortex removal in most cases.

"The time to insert a CTR is when you need it," Dr. Ahmed said, adding that Dr. Cionni's late placement timing was an acceptable alternative, though requiring much viscoelastic to keep the capsule open and structurally intact.

Dr. Cionni replied that with experience, late CTR placement becomes more comfortable. In early placement, the addition of a safety suture in the leading eyelet can both help insert the CTR

Continues on page 14 : ***Telling***

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Please see brief statement on adjacent page.

Abbott Medical Optics

TELLING

(Continued from page 12)

and rescue it, should the capsule be broken during phacoemulsification.

Both presenters agreed on the importance of the generous use of dispersive viscoelastic in the anterior chamber to prevent vitreous from coming forward into the zonular weakness, of keeping the capsule expanded with viscoelastic throughout the procedure, and of the utility of CTR injectors. With early placement of the CTR, cortex can be caught on the ring, but this annoyance can be minimized with the scalloped Henderson CTR design.

Attention then turned to videos of cases where a CTR was used to provide circumferential tension, along with a CTS (or two) providing more localized support. Devices highlighted in this setting included the Mackool and MST capsule retractors, the FCI Model MR-1G CTR, and GORE-TEX sutures for securing the capsule to the sclera. The latter, although an off-label use, were said to have less leakage and chance of breaking than other suture materials.

The next event was a symposium on complications, conducted by Dr. Osher. A wide range of videos was shown, demonstrating the management of thermal injury, iris prolapse, conjunctival ballooning, capsular tears, positive pressure, flying cannulas, bleeding, inverted IOLs, tears in Descemet's membrane and zonulae, and damaged egos.

"If you operate, you will get complications," Dr. Osher said. "You get the best outcomes when you expect and prepare for the worst. If you encounter a complication, don't deny, don't delay, and know how to manage it."

SITUATIONS AND DECISIONS

Dr. Hill presented a symposium titled "Situations and Decisions," a compilation of ways to stay out of trouble when determining IOL power calculations and making IOL selections. "One recurring problem is that most ophthalmologists are still stuck in the 1990s in terms of the use of formulas they use," Dr. Hill said.

Ophthalmologists can do much better than the older two-variable, third-generation formulas, he noted. For those physicians who take the time to track their outcomes, 74% to 82% of patients are within 0.5 D of the target refraction.

What formula is best overall? The Haigis formula uses three lens constants (a0, a1, and a2) and can be optimized to match the individual geometry of individual IOL models. This formula is available on many biometers. Visit the Haigis Users Group for Laser Interference Biometry site, originated by Wolfgang Haigis, PhD, at *www.augenklinik.uni-wuerzburg.de/ulib/c1.htm*.

Overall theoretical formulas are Holladay 2 and Olsen, but they require more measurement information. However, they offer improved accuracy. Dr. Hill himself uses the Olsen formula, although he said that the software interface can sometimes be difficult to use. Emerging engineering-based statistical models for IOL power calculations are currently being developed that promise even better results.

Dr. Hill offered several Web-based resources to help minimize refraction and astigmatism errors in IOL calculations, including *www.astimatismfix.com* to determine if a toric lens is properly placed; *www.SIA-calculator.com* for calculating how much astigmatism is created during cataract surgery; and the ASCRS calculator, which has become an indispensible tool for IOL power calculations after refractive surgery. Links to these and other resources are also found at *www.doctor-hill.com/iol-main/iol_main.htm*.

GOING 3-D

After an afternoon of vitrectomy and glaucoma procedure wet labs, participants were treated to an evening at the movies with three-dimensional (3-D) videos. Drs. Wein-

Continues on page 16 : ***Surgery***

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SURGERY

(Continued from page 14)

stock and Ahmed discussed cases using TrueVision's 3-D visualization during surgery. Effective use was made of the 3-D medium to show bimanual dissection techniques following femtosecond laser capsulorhexis in a range of challenging cases.

"One of the paramount benefits of laser technology is safer cataract surgery and faster recovery," Dr. Weinstock said.

Dr. Ahmed then showed a traumatic case of a subluxed cataract and atonic pupil, demonstrating the use of zonular techniques and CTR placement. In the 3-D presentation, the lens tilt and the complicated spatial relationships were clearly visible. In Dr. Ahmed's opinion, 3-D surgery was easy to learn.

"The first day with TrueVision, I thought I would play around with it for an hour," he said. "But it stayed on the microscope all day, and we used it for a list of complex cases."

Dr. Mackool followed with a two-part presentation, "3-D, OR and Office Pearls." In the first part, he explained, "it's never been more important to make good use of your time, since you're being paid less for it."

He offered dozens of tips and techniques for improving efficiency, including having patients fill out questionnaires at home prior to the office visit, which, in turn, allows an estimation of the time to schedule for each case. Having technicians do everything possible before the consultation shortens and improves the consultation.

"The more that's done before you get to the patient, the more data you have when you consult with the patient," Dr. Mackool said.

A wide range of appropriate handouts for patients to read while dilating patients' pupils saves explanation (and repetition) time.

In the second part, Dr. Mackool demonstrated in 3-D with his Sony system other techniques for improving operating efficiency and outcomes, including reducing the incidence of posterior capsule tear (keeping the chopper posterior to the phaco tip is one key), and decreasing the time to change instruments.

"It isn't that the steps inside the eye are done crazy fast," he said. "It's that the steps outside the eye are done superfast."

AT THE READY FOR VITRECTOMY

Saturday morning featured Drs. Arbisser and Fishkind discussing ways of preventing and managing unexpected vitrectomy in their session "Oops . . . Vitrectomy!" In a thorough and fast-paced presentation, Dr. Arbisser showed the principles for avoiding vitrectomy and various techniques for managing dangerous situations. Much attention was given to ways of elevating and retrieving descending lenses, including spearing from anterior incisions and viscolevitation, as well as pars plana approaches to anterior vitrectomy.

Both presenters stressed the importance of advance preparation, including having a vitrectomy kit set aside with all the tools needed, and having staff trained in what to do. Dr. Fishkind added that having a card in that kit with the machine settings for vitrectomy was useful—especially distinguishing between "Cut IA" and "IA Cut."

A high cutting rate is worth acquiring, in his view, since "with the newer high cutting-rate machines, the vitrectors act like ice cream scoops, allowing them to be used as surgical instruments."

He also stressed the importance of managing all the other problems before calmly proceeding with the vitrectomy.

CHALLENGING CASES

In the "Challenging Case" symposium, Drs. Snyder and Ahmed showed how they negotiated a series of difficult cases, including intumescent white cataract, very small pupils, lens iris diaphragm retropulsion, posterior polar cataract, trauma, iris prolapse, uveitis, congenital lenticonus, and "insanely dense 'catarocks'," among others.

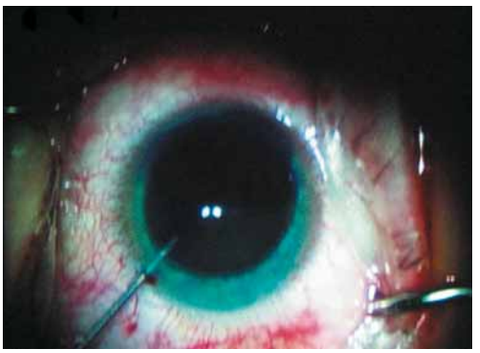
"I like to think of each case as being the roughest case of the day—until it's over," Dr. Snyder said. "And then, the next one is. When you think a case is going to be routine, you get in trouble."

Some of the devices highlighted as being particularly useful in difficult situations were GORE-TEX sutures (off-label), Malyugin rings, iris prostheses (not FDA approved), the Colvard (Oasis) and Malyugin (MST) pupil expanders, Kuglen hooks, and intraoperative gonio mirrors.

Dr. Osher presented the International Award to Dr. Barrett, "the most interesting person in the world," for his teaching, his innovations in surgery, IOL design, videography, and for his efforts on behalf of the Australasian Society of Cataract and Refractive Surgeons and the Asia-Pacific Association of Cataract and Refractive Surgeons.

PERI-OPERATIVE MEDICATIONS

The lunch symposium on "Peri-Operative Medications" featured a panel that included:



(FIGURE 2) **Surgeons showed how they negotiated "insanely dense 'catarocks'" and other difficult cases.**

- **Johnny L. Gayton, MD (Eyesight Associates, Warner Robins, GA);**
- **James Gills, MD (St. Luke's Cataract and Eye Institute, Tarpon Springs, FL);**
- **Anup K. Khatana, MD (Cincinnati Eye Institute, Cincinnati, OH);**
- **Deepinder K. Dhaliwal, MD (associate professor of ophthalmology, University of Pittsburgh).**

Dr. Osher moderated, asking a series of quick questions and eliciting quick answers (from both panel and audience) in response.

There was a range of opinion on which steroid to use, and a lively discussion of difluprednate (Durezol, Alcon), which Dr. Dhaliwal characterized as "a steroid on steroids." The acceptance of nonsteroidal anti-inflammatory drugs continues to rise, although cautions were expressed in regard to the use of generic agents.

Frustration was expressed with the current state of innovation in anti-infective agents, which was laid at the FDA's door. Dr. Gills shared his success in avoiding endophthalmitis (0/75,000 cases) using intracameral vancomycin/ceftazidime only.

"I transfer the cost and the responsibility of fighting infection from them to me, and it saves them about $400," he said.

More conventional approaches included besifloxacin (Besivance, Bausch + Lomb), moxifloxacin (Vigamox, Alcon), and polymixin B/trimethoprim (Polytrim, Allergan). Alcon's ganciclovir (Zirgan) received high praise when the discussion turned to antiviral agents. Approaches to patients with glaucoma and blepharitis rounded out the session.

After lunch, a wet lab on "Advanced Suturing" was led by Dr. Snyder, with an emphasis on iris fixation and repair using Siepser, horizontal mattress, and cow-hitch knots. Participants could work with the GORE-TEX 9-0 and 10-0 sutures, which were not off-label for use on plastic bowls and pantyhose. Additional

labs were offered, including a risk management session led by Bradley Fouraker, MD, of Brandon Cataract Center and Eye Clinic, Brandon, FL. OMIC offered a 5% to 10% discount on annual insurance premiums for the completion of the lecture.

A tutorial on "Minimally Invasive Glaucoma Surgery," was presented by Drs. Ahmed and Steven Vold, MD (Vold Vision, Fayetteville AR), and focused on the use of the iStent G1 trabecular bypass stent (Glaukos), the CyPass microstent (Transcend Medical), and the EX-PRESS glaucoma filtration device (Alcon).

Dr. Khatana then reviewed indications and techniques for trabectome (including strengthening the deltoids, better maintaining proper hand position).

TORIC IOLS

In the tutorial on "Toric IOLs," Dr. Hill discussed ways to use toric IOLs properly, in particular, determining the orientation of the steep and flat meridians and the power difference between those meridians—thinking like the calculator.

"The Ks that you used to calculate the spherical power of the IOL can be completely different [from] what you use for the toric calculators," he said. "It's helpful to keep in mind that you're not just getting a set of Ks."

Dr. Osher noted that the adaptation of the toric lens has lagged, because of a lack of confidence in the diagnostics and in nailing the target meridian. He exhorted the audience to use toric IOLs now.

"No conscientious person would do a refraction, find significant cylinder, and only prescribe the sphere," Dr. Osher said. "In the operating room, each of us must strive to be a skilled refractive cataract surgeon."

To help facilitate the goal of toric adoption, Dr. Osher shared tricks on interpreting manual K, automated K (using either the Haag-Streit LenStar or the Zeiss IOLMaster), topography (Zeiss Atlas), and aberrometry (WaveTec ORA System and Clarity Holos).

He then explained how to work with emerging technology in a practical manner with a video demonstration.

"You may not be as perfect as possible, but you'll still help the patient with a toric lens," he reassured participants.

"IOL Repositioning/Exchange" was discussed and demonstrated in alternating cases by Drs. Snyder and Mackool. Useful tools included the Snyder-Osher IOL holding forceps and serrated scissors to remove IOLs, the high-speed (at least 2,500 cuts per minute) 23-gauge vitrectomy cutter for converting capsular tears, and the ultrasound biomicroscope for measuring chamber depth.

IRIS RECONSTRUCTION

Sunday morning started with a session on "Iris Reconstruction" by Dr. Snyder. In his experience, there are three ways to repair the iris. The first approach is by stretching and re-apposition. For this, the Siepser knot is key and was carefully explained. Usually, 2.5 clock hours is the largest area that can be covered. Dr. Snyder uses 10-0 prolene with the Ethicon CTC-6 needle. Microforceps developed by Dr. Ahmed were endorsed for anterior chamber tying.

Iris sculpting is a second approach, with numerous variations, including YAG laser, scissors, and vitrector. Scissors work well on ad-

Continues on page 18 : ***Techniques***

Femtosecond laser technology up to challenge of complex cases

Ability to maneuver without entering the eye a plus in some difficult cataract surgeries

By Cheryl Guttman Krader; *Reviewed by Robert J. Cionni, MD*

SALT LAKE CITY ::

THE ADVENT OF femtosecond laser technology for cataract surgery is helping to improve the safety and efficacy outcomes in a variety of complex situations.

Robert J. Cionni, MD, presented videos to illustrate use of a proprietary femtosecond laser (LenSx, Alcon Laboratories) in two challenging cases. One eye had a white mature cataract and the second was a post-trauma case with marked zonular dialysis and a dense lens, explained Dr. Cionni, medical director, The Eye Institute of Utah, Salt Lake City.

Dr. Cionni

The femtosecond laser was used in both cases to create the capsulotomy and corneal incisions, and it was used to perform lens fragmentation in the eye with zonular dialysis. The device could not be used with the white cataract, because the laser energy does not penetrate very deeply into the opaque lens material. However, its use for capsulotomy in the latter case was an advantage, Dr. Cionni noted.

WHITE CATARACT

"Typically, when performing capsulotomy in eyes with white intumescent cataracts, the fear is that the increased intralenticular pressure will cause the capsule to splay out," Dr. Cionni said. "Using the [femtosecond] laser to open the capsule, without ever opening the eye, allows the natural anterior chamber pressure to counteract the intralenticular pressure and results in a beautiful capsulotomy without any radial tears.

"I have used the [femtosecond laser] system in this situation about a dozen times with consistently good results," he said. When treating the eye with the white cataract, trypan blue was instilled to aid visualization of the capsule as Dr. Cionni inspected the laser cut to make certain it was complete. An ultrasonic chopper (Ultrachopper, Alcon) was used to divide the nucleus into quadrants. The patient received a toric IOL with a good refractive result.

POST TRAUMA

In the post-traumatic case, the ability to use the femtosecond laser to create the capsulotomy and fragment the lens without entering the eye offered advantages. Benefits included ensuring a complete and intact capsulorhexis and allowing for the surgery case to be completed with reduced zonular stress. The video from the femtosecond laser portion of the procedure showed how the laser not only was able to cut through the anterior capsule, but also through vitreous that had prolapsed from the original trauma.

In the operating room, the vitreous was removed with a bimanual anterior vitrectomy approach. The anterior chamber was filled with viscoelastic prior to removing the cut portion of the anterior capsule. Hydrodissection was performed to free the lens successfully. Instillation of ample viscoelastic enabled forward manipulation of the nuclear pieces created by the femtosecond laser fragmentation and safe removal.

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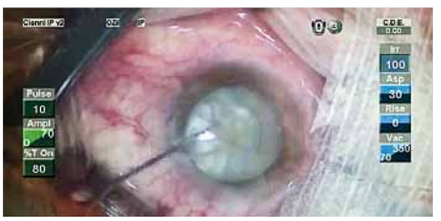

WHITE MATURE CATARACT

Go to **http://ow.ly/juU6T** for a video that shows how use of the femtosecond laser is enabling safe cataract surgery in difficult clinical situations, including eyes with white intumescent cataracts. *(Video courtesy of Robert J. Cionni, MD)*

"Notice the stability of the anterior chamber and uneventful cortex removal thanks to the use of hydro- and viscodissection," said Dr. Cionni in his narration.

The case also involved placement of a capsular tension ring and sutured capsular tension segment that afforded a stable, well-centered capsular bag and allowed successful implantation of a multifocal IOL. Pupillary mydriasis was addressed with a single modified Siepser suture. ■

ROBERT J. CIONNI, MD

Dr. Cionni is a consultant to Alcon Laboratories. This article is adapted from Dr. Cionni's presentation during the Spotlight on Cataracts session at the 2012 annual meeting of the American Academy of Ophthalmology.

TECHNIQUES

(Continued from page 17)

hesions and scarring without tissue loss. The 23- to 27-gauge vitrector can be used to reshape the pupil.

"It's like the eraser tool in Photoshop," he said. "The only problem is there's no undo button, so do it slowly."

The pupillary cerclage method of Greg Ogawa, MD, was also detailed. The MST capsulorhexis forceps developed by Barry Seibel, MD, received praise for iris work.

Finally, Dr. Snyder showed the use of iris prostheses—a problematic area, given that none are presently FDA-approved, not even for compassionate use. "But I do want to show these devices anyway, because you might want to send your patients to Canada, or Europe, or Asia, or South America," he said, before discussing Morcher and Humanoptics devices. The Humanoptics CustomFlex iris was singled out as being exciting, but cautionary tales were told of the Morcher 30-B and NuColorIris devices.

FAVORITE TOOLS

After breakfast, the seminar "My Favorite Instruments" featured Drs. Weinstock, Arbisser, Barrett, Mackool, Snyder, and Osher presenting short videos showing the use of their favorite operating room tools. Dr. Weinstock led off with the other hand as the most important tool, making a case for bimanual surgery. He then showed the

Continues on page 23 : ***Instruments***

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The VICTUS Femtosecond Laser Platform is indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea; for anterior capsulotomy during cataract surgery; and for the creation of penetrating arcuate cuts/incisions in the cornea in patients undergoing cataract surgery or other ophthalmic treatment requiring penetrating arcuate cuts/incisions in the cornea.

Attention: Please refer to the Directions for Use for complete use instructions and safety.

Summary of Contraindications: Corneal disease or pathology that precludes transmission of laser wavelength or that distorts laser light. Patients who do not give informed consent, are pregnant or nursing, have existing corneal implants, have had any previous cornea surgery, or are pediatric patients. Conditions that interfere with intent to treat such as glaucoma, retinal disorders, rheumatic diseases, epilepsy, herpes zoster or herpes simplex keratitis, and heavy vascularization of ocular tissues. Conditions that interfere with proper docking such as chemosis, nystagmus, significant loss of stability of the conjunctiva, keratoconus, and corneal diseases requiring treatment. Conditions that may interfere with capsulotomy such as poorly dilating pupils or anterior chamber depths (ACD) < 1.5 mm or > 4.8 mm. Conditions that may interfere with creation of flap such as dry eye diseases, cataract, diabetes mellitus, severe acne rosacea, severe wound-healing disorders, and immune deficiency diseases.

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See better. Live better.

Broad inclusion criteria expand femtosecond laser's reach

Large series shows increased safety, efficiency, efficacy with laser-assisted cataract surgery

By Cheryl Guttman Krader; *Reviewed by Burkhard Dick, MD*

TAKE-HOME

- ***A proprietary femtosecond laser system (Catalys Precision Laser System, OptiMedica) is being used to perform cataract surgery in all comers.***

BOCHUM, GERMANY :: **A FEMTOSECOND LASER** system is improving cataract surgery safety and enabling treatment of challenging cases with broad inclusion criteria.

A review of experience with the first 850 cases of laser-assisted cataract surgery using a proprietary femtosecond laser system (Catalys Precision Laser System, OptiMedica) shows there are advantages for using the technology in routine and challenging cases.

Dr. Dick

Key features of the image-guided device were described by Burkhard Dick, MD, professor of ophthalmology and chairman, Ruhr-University of Bochum, Bochum, Germany. He presented data demonstrating the system's reliable performance and capabilities for delivering superior outcomes compared with procedures done with conventional cataract surgery techniques.

"[The platform] allows a gentle dock, creates perfect corneal cuts, provides better vision than conventional surgery, and is bringing us close to eliminating the need for ultrasound," he said.

Dr. Dick noted that the femtosecond laser has a liquid optics interface. IOP increases only 10 mm Hg after application of the suction ring. Docking is possible for all comers, including Asian and pediatric patients and as well as patients with strabismus, plus those with previous glaucoma filtering surgery.

Complete capsulotomy was achieved in more than 99% of the 850 eyes in his series and in 93% of 27 eyes with mature, white cataracts, he noted. Results from a prospective, randomized, fellow eye-controlled, single-surgeon study showed that eyes having femtosecond laser-created capsulotomies had significantly less capsular bag shrinkage compared with eyes operated on with conventional techniques.

PRE-TREATING THE LENS

Use of the femtosecond laser for lens fragmentation resulted in significant reductions in ultrasound requirements, measured as effective phacoemulsification time (EPT) on a proprietary phacoemulsification platform (Stellaris, Bausch + Lomb), across all Lens Opacities Classification System (LOCS) III subgroups of eyes.

"For the femtosecond laser group, median EPT was 0 in grade 2 eyes, close to 0 in grade 3 eyes, and 0.19 seconds in grade 4 eyes," Dr. Dick said. "Compared with groups of eyes having conventional surgery, these values represent reductions in ultrasound usage of 100%, 98%, and 95%, respectively."

In a series of 57 eyes with grade 5 very dense cataracts, mean EPT was 2.24 seconds and <1 second in almost half of the eyes.

TECHNICAL ADVANTAGE

"Ultrasound energy is still needed to remove these brunescent to rubra lenses, but the amount of energy used is comparable to that associated with my conventional surgery for grade 3 cataracts," Dr. Dick said. "So, it is a great technical advantage to pre-treat the grade 5 lenses with the femtosecond laser."

Using a 350-µm grid pattern for the fragmentation, 40% of the first 850 cases (mean LOCS III = 3.2) were completed with no ultrasound, he noted.

"After changing my phaco tip, software settings, and instrumentation, and adopting a mental change about the need for phaco, 87 of my last 100 cases were done without ultrasound energy," Dr. Dick said.

Results from a prospective intraindividual comparison study showed eyes treated with the femtosecond laser had 19% less inflammation on postoperative day 1 relative to conventional controls, as well as superior best-corrected visual acuity outcomes at 6 hours and 3 and 7 days postoperatively.

The precision achieved using the femtosecond laser to create corneal incisions was demonstrated in an eye that was treated prior to undergoing enucleation for a malignant ocular tumor.

"The laser was programmed to create a 30° angular cut, keep the epithelium intact, and cut through Bowman's membrane to 200 µm above the endothelium," Dr. Dick said. "We were impressed with its performance in achieving all of these criteria."

Dr. Dick noted that he is continuing to discover new applications for the femtosecond laser in cataract surgery, including posterior capsulotomy, the bag-in-the-lens technique, and capsulotomy in pediatric eyes. ■

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SURGICAL EXAMPLE

Go to **http://ow.ly/jzho2** for a video showing a surgical case example of treatment on the right eye with capsulotomy, fragmentation (350 µm fragmentation grid), main incision at 180°, and intrastromal arc incisions. *(Video courtesy of Burkhard Dick, MD)*

BURKHARD DICK, MD

E: *dickburkhard@aol.com*

Dr. Dick is a consultant to Abbott Medical Optics, AcuFocus, Allergan, AqueSys, Bausch + Lomb, Bayer, Calhoun Vision, Carl Zeiss Meditec, Domilens, Geuder, Hoya, Morcher, Novartis, Oculus, Ophtec, Optical Express, OptiMedica, PowerVision, Pfizer, and Transcend Medical. This article is adapted from Dr. Dick's presentation at the 2012 annual meeting of the American Academy of Ophthalmology.

For the reduction of IOP in patients with POAG or OHTN

When it's important to consider ocular and systemic side effects...

An alternate route to IOP reduction

- Effective at lowering IOP throughout the day and over the long term[1-3]
- Excellent systemic safety profile including no deleterious effects on CV or pulmonary function in clinical studies[1]
- Established ocular side effects profile: In clinical trials comparing RESCULA and timolol,* both were generally well tolerated regarding ocular adverse events, with similar incidence of hyperemia and similar changes to eyelash length and density[1,4,5]
  - The only events seen significantly more often with RESCULA than with timolol were burning and stinging and burning/stinging upon instillation; these events were generally mild and transient[2,4]
- No labeled drug-drug interactions[1,4]

Indication

RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Important Safety Information

RESCULA is contraindicated in patients with hypersensitivity to unoprostone isopropyl or any other ingredient in this product.

RESCULA has been reported to increase pigmentation of the iris, periorbital tissues, and eyelashes. Patients should be advised about the potential for increased brown iris pigmentation which is likely to be permanent.

RESCULA should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular edema, including cystoid macular edema, has been reported. RESCULA should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

*In pooled safety analyses of pivotal trials comparing RESCULA with timolol maleate 0.5%.[4]

Please see Brief Summary on reverse and full Prescribing Information, available from your Sucampo representative.

Rescula®
(Unoprostone isopropyl
ophthalmic solution) 0.15%

Brief Summary of Prescribing Information for RESCULA.

INDICATIONS AND USAGE

Rescula (unoprostone isopropyl ophthalmic solution) 0.15% is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) twice daily.

Rescula may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If two drugs are used, they should be administered at least five (5) minutes apart.

CONTRAINDICATIONS

Rescula is contraindicated in patients with hypersensitivity to unoprostone isopropyl or any other ingredient in this product.

WARNINGS AND PRECAUTIONS

Iris Pigmentation

Unoprostone isopropyl ophthalmic solution may gradually increase the pigmentation of the iris. The pigmentation change is believed to be due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. The long term effects of increased pigmentation are not known. Iris color changes seen with administration of unoprostone isopropyl ophthalmic solution may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. Treatment with Rescula solution can be continued in patients who develop noticeably increased iris pigmentation. Patients who receive treatment with Rescula should be informed of the possibility of increased pigmentation.

Lid Pigmentation

Unoprostone isopropyl has been reported to cause pigment changes (darkening) to periorbital pigmented tissues and eyelashes. The pigmentation is expected to increase as long as unoprostone isopropyl is administered, but has been reported to be reversible upon discontinuation of unoprostone isopropyl ophthalmic solution in most patients.

Intraocular Inflammation

Rescula should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular Edema

Macular edema, including cystoid macular edema, has been reported. Rescula should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Contamination of Tip and Solution

To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use. There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.

Use with Contact Lenses

Rescula contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to application of solution and may be reinserted 15 minutes following its administration.

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.

In clinical studies, the most common ocular adverse reactions with use of Rescula were burning/stinging, burning/stinging upon drug instillation, dry eyes, itching, increased length of eyelashes, and injection. These were reported in approximately 10–25% of patients. Approximately 10–14% of patients were observed to have an increase in the length of eyelashes (≥ 1 mm) at 12 months, while 7% of patients were observed to have a decrease in the length of eyelashes.

Ocular adverse reactions occurring in approximately 5–10% of patients were abnormal vision, eyelid disorder, foreign body sensation, and lacrimation disorder.

Ocular adverse reactions occurring in approximately 1–5% of patients were blepharitis, cataract, conjunctivitis, corneal lesion, discharge from the eye, eye hemorrhage, eye pain, keratitis, irritation, photophobia, and vitreous disorder.

The most frequently reported nonocular adverse reaction associated with the use of Rescula in the clinical trials was flu-like syndrome that was observed in approximately 6% of patients. Nonocular adverse reactions reported in the 1–5% of patients were accidental injury, allergic reaction, back pain, bronchitis, increased cough, diabetes mellitus, dizziness, headache, hypertension, insomnia, pharyngitis, pain, rhinitis, and sinusitis.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Rescula. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish causal relationship to drug exposure.

Voluntary reports of adverse reactions occurring with the use of Rescula include corneal erosion.

There have been rare spontaneous reports with a different formulation of unoprostone isopropyl (0.12%) of chemosis, dry mouth, nausea, vomiting and palpitations.

USE IN SPECIFIC POPULATIONS

Pregnancy Category C - There are no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, RESCULA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pediatric Use - the safety and efficacy of RESCULA in pediatric patients have not been established.

It is not known whether RESCULA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when RESCULA is administered to a nursing woman.

No overall differences in safety or effectiveness of RESCULA have been observed between elderly and other adult populations.

CLINICAL PHARMACOLOGY

Mechanism of Action

Rescula is believed to reduce elevated intraocular pressure (IOP) by increasing the outflow of aqueous humor through the trabecular meshwork. Unoprostone isopropyl (UI) may have a local effect on BK (Big Potassium) channels and ClC-2 chloride channels, but the exact mechanism is unknown at this time.

STORAGE AND HANDLING

Store between 2°–25°C (36°–77°F).

For more detailed information please read the Prescribing Information.

Marketed by:

Sucampo Pharma Americas, LLC
Bethesda, MD 20814

Revised 01/2013

References: **1.** RESCULA [package insert]. Bethesda, MD: Sucampo Pharmaceuticals, Inc; 2012. **2.** Data on file. CSR C97-UIOS-004. Sucampo Pharmaceuticals, Inc. **3.** Data on file. CSR C97-UIOS-005. Sucampo Pharmaceuticals, Inc. **4.** Data on file. Integrated summary of clinical safety. Sucampo Pharmaceuticals, Inc. **5.** McCarey BE, Kapik BM, Kane FE; Unoprostone Monotherapy Study Group. Low incidence of iris pigmentation and eyelash changes in 2 randomized clinical trials with unoprostone isopropyl 0.15%. *Ophthalmology*. 2004;111(8):1480-1488.

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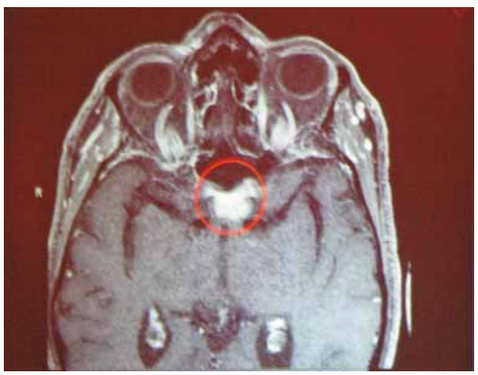
INSTRUMENTS

(Continued from page 18)

microcapsulorhexis forceps with interchangeable tips (Storz) and the 0.4-mm irrigation/aspiration (I&A) port (used with a Venturi pump).

Dr. Arbisser told about her chopper of choice (Rosen Phaco Splitter) and about nuclear spears (Epsilon) from an anterior approach for rescuing a descending nucleus.

Dr. Mackool featured the long, thin capsulorhexis forceps (Crestpoint Management), the 22-gauge hydrodissection cannula, and viscodissection, in general. The Mackool big ball chopper spatula, 0.25-mm I&A tips, and the Mackool (Jr.) titanium toric axis marker (both Crestpoint Management) rounded out his selections.



(FIGURE 3) **The immediate postoperative period is a time when everyone is paying close attention, such as in unexpected diagnoses.** *(Photos courtesy of Zaid Smith, PhD)*

Dr. Snyder highlighted the Snyder-Osher forceps and serrated scissors (Crestpoint Management) for IOL removal, the 23-gauge Seibel capsulorhexis forceps (MST), and Snyder ruler (MST), with markings up to 16 mm.

Dr. Barrett mentioned his Phaco Axe, but concentrated on the second-generation I&A cannula of his design (MST).

Dr. Osher finished the session with presentation of a magnifier (Bausch + Lomb), the Wet-Field Thermodot (Beaver-Visitec International) for orientation marking, an internal flare knife, a capsulorhexis ring (Crestpoint), a bevel-down phaco tip (Alcon), a "mature" chopper, a "double-finger" chopper, intraocular forceps and scissors (Crestpoint), a new Malyugin ring injector (MST), and 27-gauge curved cannulas for dry cortical removal (Bausch + Lomb, Crestpoint).

LESSONS LEARNED

The faculty then presented a session of "Cases that Taught Us Something." Dr. Weinstock showed a cataract surgery done entirely through 1-mm incisions, using instrumentation from MST. Dr. Arbisser discussed a trauma case with extensive free vitreous around zonules with a failed attempt to secure the bag.

Dr. Hill showed a patient whose confusing post-surgical recovery led to the fortuitous discovery of a meningioma that had coincidentally begun impinging on the optic nerve at about the same time. Luckily for the patient, the immediate postoperative period is a time when everyone is paying close attention.

Dr. Hill reminded the audience that things are not always as they may appear and referred to Hickam's dictum that commonly is stated as patients can have as many different diagnoses as they damn well please. He was given a loud round of applause.

Dr. Snyder showed a case demonstrating that "things follow pressure gradients: the number one lesson in ophthalmology. Something I think about in every case is where are the favorable and unfavorable gradients."

Dr. Barrett showed a nanophthalmos case, with the lessons learned when operating in "a small world."

Dr. Osher reviewed a case of intraoperative iris disinsertion that taught him never to sew inside the eye, but rather to use the Siepser sliding knot suture, and a case of a projectile cannula that taught him "every cannula is a potential missile. Always pinch the cannula tightly, and direct the tip perpendicular to the lateral border of the incision before injecting."

The conference ended with the session, "What the Hell Was That?" in which Dr. Mackool showed videos of bizarre phenomena and situations encountered during surgery, described with humor and insight. One of the incidents was a little piece of plastic appearing suddenly in two consecutive eyes, but only in a certain operating room. A search of the operating room trashcans revealed that the plastic phaco wrenches were being stripped on use by a new (and considerably more muscular) technician in that operating room, with the result that bits were being dispersed into the eye.

The next "Cataract Surgery: Telling It Like It Is!" conference will be held Jan. 15 to 19, 2014. ■

MEETING DEDICATED TO THE PRECISE NEEDS OF THE ANTERIOR SEGMENT SPECIALIST

The Marin headlands afford a spectacular view of the San Francisco skyline through the red-orange superstructure of the Golden Gate Bridge (left); Moscone Center exterior (below).

SAN FRANCISCO CAPTURES EYES OF ASCRS, ASOA ATTENDEES

Moscone Center at the heart of annual meeting's ophthalmic sessions, exhibition hall

From Staff Reports

take-home

- **Educational opportunities abound at this year's meeting of the American Society of Cataract and Refractive Surgery/American Society of Ophthalmic Administrators, April 19 to 23, in San Francisco.**

SAN FRANCISCO ::

This famed city by the bay has captured the hearts of many over the years. For attendees of the annual meeting of the American Society of Cataract and Refractive Surgery (ASCRS)/ American Society of Ophthalmic Administrators (ASOA), it also captures the eyes.

Meeting from April 19 to 23 at San Francisco's Moscone Center, the conference is described by event organizers as the only meeting in the United States dedicated to the precise needs of the anterior segment specialist, aligned with the most established practice management program for comprehensive ophthalmology and subspecialties.

The meeting also poses an opportunity for attendees to meet leaders in the field, experience in-depth educational programming, gather invaluable connections and professional relationships, and find the tools eye-care professionals need to stay sharp and be competitive in the profession. Among the meeting's highlights:

FRIDAY, APRIL 19

Cornea Day 2013 will be held from 8 a.m. to 4:30 p.m. The 1-day symposium will provide an overview of managing the atypical cornea in cataract surgery, challenges in refractive surgery, advances in ocular surface, and a global perspective of corneal transplantation and corneal disease. Visit *www.corneaday.org* for details. Separate registration is required.

ASCRS Glaucoma Day 2013 will address the start of the microinvasive glaucoma surgery (MIGS) era with a full program developed specifically for the anterior segment specialist. Visit *www.ascrsglaucomaday.org* for details. Separate registration is also required. This event will be held from 8:30 a.m. to 5 p.m.

Friday evening also brings the ASCRS eyePAC reception, a private event for contributors, from 6 to 8 p.m.

SATURDAY, APRIL 20

The ASCRS Resident and Fellow Program will be held from 8 a.m. to 12:45 p.m. Highlights will include "How to Avoid Being Sued: What You Can Do to Reduce the Risk of Regulatory or Malpractice Liability," given by Mark Kropiewnicki, JD, LLM, as well as presentations on evaluating employment opportunities, negotiating contracts, and demystifying the path to the podium.

The ASCRS Opening General Session will be held from 10 to 11:45 a.m. It will include speeches from David F. Chang, MD, outgoing president, and Eric D. Donnenfeld, MD, incoming president. There also will be brief comments from Honored Guests Jae Ho Kim, MD, PhD, and Harold A. Stein, MD. ASCRS Ophthalmology Hall of Fame inductees will be honored, and Richard L. Lindstrom, MD, will deliver an update on the ASCRS Foundation. Finally, the Binkhorst Lecture, "Intraocular Lens Evo-

Continues on page 26 : ***ASCRS***

Courtesy of San Francisco Travel Association/Scott Chernis (left); Courtesy of San Francisco Travel Association/Naina Ayya (right)

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ASCRS

(*Continued from page 24*)

lution: What a Long, Strange Trip It's Been," will be presented by Nick Mamalis, MD.

The Physician Symposia and Scientific Papers start on Saturday, as do physician courses and skill transfer sessions, and continue through the rest of the meeting.

SUNDAY, APRIL 21

The Combined Symposia of Cataract and Refractive Surgery Societies will be held from 8 to 9:30 a.m.

The ASCRS Lecture on Science and Medicine will be held from 10 to 11 a.m. as part of the Sunday General Session. "When Experts Disagree: A New Approach to Medical Decision Making" will be presented by Jerome Groopman, MD, and Pamela Hartzband, MD.

Networking abounds at Moscone Center.

The Government Relations General Session, with invited guest Sen. Rand Paul, MD (R-KY), ophthalmologist, will be held from 11 a.m. to noon.

The ASCRS Foundation has partnered with TearLabs to host the First ASCRS Foundation Run for Sight 5-K run and 1-mile walk on Sunday. The run will go through some of San Francisco's most beautiful neighborhoods and will support the foundation's humanitarian work in Ethiopia and China. The Run for Sight event will take place from 7 to 9 a.m. at Golden Gate Park in San Francisco. Shuttle busses will transport runners to and from the major hotels beginning at 6:30 a.m. on race day, and a light breakfast will be provided. All proceeds from the race benefit the ASCRS Foundation's cataract blindness treatment efforts.

Registration is $25 in advance and $35 on the day of the race. All registered runners will receive a race T-shirt, bib, and timing chip. Medals will be awarded to the male and female winners in each age category.

MONDAY, APRIL 22

The Innovators Session will be held from 10 to 11:30 a.m. The Charles D. Kelman Innovator's Lecture, "Humans, Happiness, and the Wonder of New," will be presented by Richard J. Mackool Sr., MD.

The 31st Annual Film Festival Reception and Awards will be held from 4:30 to 6:30 p.m. During the meeting, attendees can view more than 180 videos entries on their mobile devices and at film and poster kiosks. Entries are submitted in the following categories: Cataract Complications, Cataract/Implant Surgery, Glaucoma Surgery, In-house Productions, Instruments and Devices/IOLs, New Producer, New Techniques, Quality Teaching, Refractive/Cornea Surgery, and Special Interest. A winner and runner-up will be chosen in each category; among these finalists, three will be recognized as Best of the Best and one Grand Prize winner will be selected.

Now in its second year, the People's Choice Award is presented for the single film that receives the most votes from meeting attendees.

Beginning on Thursday, April 18, each meeting attendee can cast a vote once for their favorite film on the ASCRS website or at film and poster kiosks. Voting ends at 5 p.m. on Sunday. A team of nine panelists will judge the films based on applicability/education value, originality, scientific content/validity, clarity, cinematic quality, and artistic effects. ■

Other program highlights

The Ophthalmic Photographers Society Exhibit: **This will be held Saturday through Monday from 9 a.m. to 5 p.m. and Tuesday from 9 a.m. to 1 p.m. Winning photographs from 18 categories will be on display.**

Exhibit Hall: **The exhibition hall will be open Saturday through Monday from 9 a.m. to 5 p.m. and Tuesday from 9 a.m. to 1 p.m.**

Virtual Poster Discussion Forum: **During the meeting, virtual posters will be available on demand at kiosks throughout Moscone Center. Live discussion of posters will be available via an online forum that will enable attendees to post questions or comments about a poster, reply to a discussion thread, receive e-mail notification of replies to specific posts and threads, and set up a "buddy" list to see which of their friends are currently online.**

ASOA highlights

COE Overview, Part I; Practice Management Boot Camp; Everyday Use of Excel for the Practice Administrator, **8 a.m. to 5 p.m., Friday.**

Pinto Practice Coaching; Maximizing Leadership Skills, **8 a.m. to noon, Friday.**

ICD-10 Workshops, **8 a.m. to noon or 1 to 5 p.m., Friday.**

ASOA Welcome Reception, **5:45 to 7 p.m., Friday.**

COE Overview, Part II, **8 a.m. to 5 p.m., Saturday.**

ASOA Opening General Session: Presidential speeches followed by roundtable discussions, **8:30 to 11:30 a.m., Saturday.**

ASOA Celebration, **8 p.m. to midnight, Regency Center, Sunday.**

Courtesy of San Francisco Travel Association/Naina Ayya

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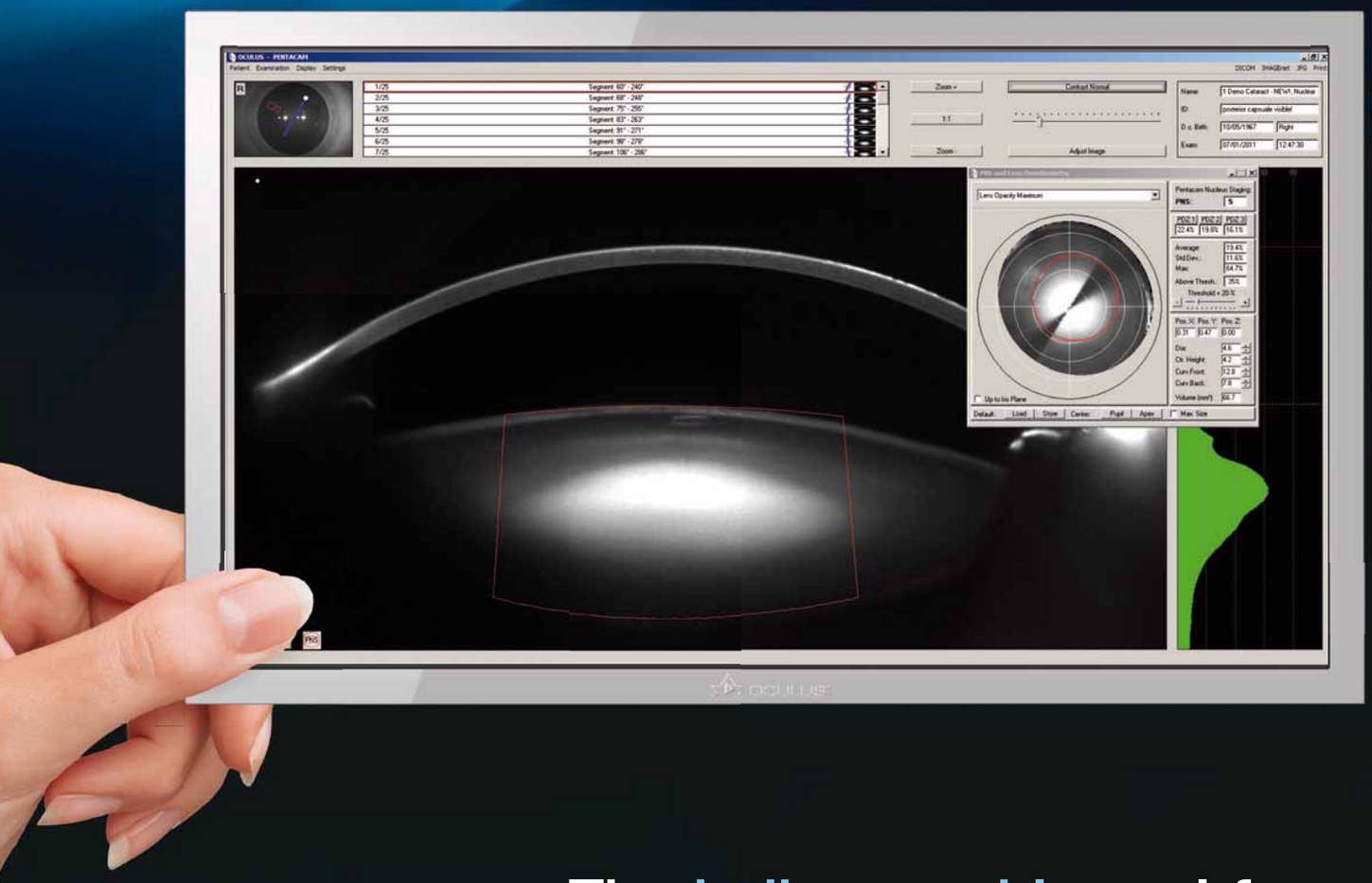

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Thermal pulsation can be effective therapy for MGD, dry eye in ophthalmologists' practices

Anterior Segment Techniques *By Ernest W. Kornmehl, MD, FACS*

How it works **A) An interferometer measures the lipid layer thickness and evaluates the ocular surface via digital images. B) The meibomian gland evaluator applies standardized pressure (0.3 psi) to five consecutive glands. C) The thermal pulsation system applies controlled warmth (up to 42.5° C) to the inner eyelid surface with intermittent pressure to the outer surface for 12 minutes.**

Dry eye is ubiquitous. Its causes are manifold and varied and include long-term contact lens wear, medications, aging, pregnancy, and meibomian gland dysfunction (MGD).

MGD is now recognized as the leading cause of dry eye.[1] MGD is commonly associated with inflammation and pouting glands, but is most often "non-obvious"[2] without any signs of inflammation noted with standard clinical evaluation techniques.

DIAGNOSING MGD

It is crucial to be able to diagnose MGD. Many patients who present with the typical complaints of dry eye will have normal tear secretion or a mixed form of dry eye with tear insufficiency and MGD.

Classic signs of MGD include pouting or inspissated meibomian glands, crossing telangiectasias, and eryrthema of the lid margins often associated with rosacea. A cotton swab often is used to express the meibomian glands in order to determine the nature and quality of the expressed secretions.

However, most patients with MGD have the non-obvious form of MGD. How do ophthalmologists make this diagnosis? One such technology (LipiView, TearScience) is available to make the diagnosis easier, along with a therapeutic device (LipiFlow Thermal Pulsation System, TearScience) designed to assist in the management of patients with MGD.

TAKE-HOME

- ***Thermal pulsation therapy assists in the diagnosis and management of meibomian gland dysfunction. Ophthalmologists, however, must conduct a careful pre-treatment evaluation and articulate likely results with patients.***

THERAPY IN ACTION

The technology features an interferometer that measures the thickness of the lipid layer and evaluates the ocular surface via digital images (Photo A). It is helpful to both patients and physicians when low readings are measured and documented in patients with non-obvious MGD.

The meibomian gland evaluator (Photo B) applies standardized pressure (0.3 psi) to five consecutive glands—allowing a controlled, reproducible method to assess gland secretions.

The thermal pulsation system (Photo C) applies controlled warmth (up to 42.5° C) to the inner eyelid surface with intermittent pressure to the outer surface for 12 minutes. The procedure is relatively painless, with patients able to return to work immediately after the treatment. Patients may have mild ocular injection for 1 to 2 hours immediately following the procedure. It is important to note that the activators applied to the lids come in one size only, and placement may be uncomfortable for patients with small palpebral fissures.

PUBLISHED DATA

The system demonstrated significant improvement in meibomian gland secretion at 2 and 4 weeks in a non-significant risk, prospective, open-label, randomized, crossover, multicenter clinical trial.[3] This same study also documented a greater reduction in dry eye symptoms compared with a warm compress system (iHeat, Advanced Vision Research), with no significant difference in the incidence of non-serious adverse events.

Greiner recently documented that a single treatment with the thermal pulsation system provides sustained improvement in meibomian gland function scores and Standard

Continues on page 31 : ***MGD***

Photos A and C courtesy of Ernest W. Kornmehl, MD, FACS; Photo B courtesy of TearScience

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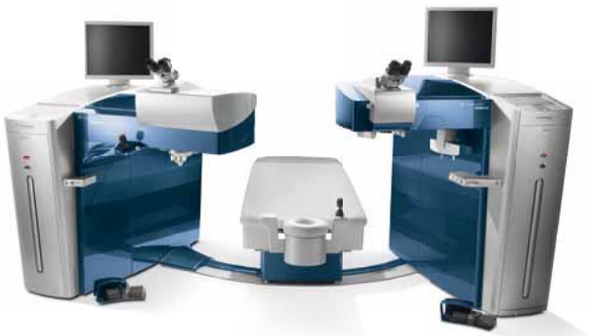

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Health Care Professional Information Sheet-All WaveLight® ALLEGRETTO WAVE® EX500 System Indications

The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System

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

Statements regarding the potential benefits of wavefront-guided and Wavefront Optimized® laser-assisted in-situ keratomileusis (LASIK) are based upon the results of clinical trials. These results are indicative of not only the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System treatment but also the care of the clinical physicians, the control of the surgical environment by those physicians, the clinical trials' treatment parameters and the clinical trials' patient inclusion and exclusion criteria. Although many clinical trial patients after the wavefront-guided and Wavefront Optimized® procedure saw 20/20 or better and/or had or reported having better vision during the day and at night, compared to their vision with glasses or contact lenses before the procedure, individual results may vary. You can find information about the clinical trials below and in the Procudure Manuals for the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System.

As with any surgical procedure, there are risks associated with the wavefront-guided and Wavefront Optimized® treatment. Before treating patients with these procedures, you should carefully review the Procedure Manuals, complete the Physician WaveLight® System Certification Course, provide your patients with the Patient Information Booklet, and discuss the risks associated with this procedure and questions about the procedure with your patients.

INDICATIONS: The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System is indicated to perform LASIK treatments in patients with documented evidence of a stable manifest refraction defined as less than or equal to 0.50 diopters (D) of preoperative spherical equivalent shift over one year prior to surgery, exclusive of changes due to unmasking latent hyperopia in patients 18 years of age or older: for the reduction or elimination of myopic refractive errors up to -12.0 D of sphere with and without astigmatic refractive errors up to

-6.0 D; for the reduction or elimination of hyperopic refractive errors up to +6.0 D of sphere with and without astigmatic refractive errors up to 5.0 D at the spectacle plane, with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D; and in patients 21 years of age or older for the reduction or elimination of naturally occurring mixed astigmatism of up to 6.0 D at the spectacle plane.

LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), and other refractive surgeries. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery including laser system calibration and operation, may use the device as approved. Prospective patients, as soon as they express an interest in an indicated LASIK procedure and prior to undergoing surgery, must be given the WaveLight® System Patient Information Booklet and must be informed of the alternatives for refractive correction including eyeglasses, contact lenses, PRK, and other refractive surgeries.

Clinical Data Myopia: The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System for LASIK treatments of myopic refractive errors up to -12.0 D of sphere with and without astigmatic refractive errors up to -6.0 D at the spectacle plane was studied in clinical trials in the United States with 901 eyes treated, of which 813 of 866 eligible eyes were followed for 12 months. Accountability at 3 months was 93.8%, at 6 months was 91.9%, and at 12 months was 93.9%.

The studies found that of the 844 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 3-month stability time point, 98.0% were corrected to 20/40 or better, and 84.4% were corrected to 20/20 or better without spectacles or contact lenses.

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months post-treatment: visual fluctuations (12.8% at baseline versus 28.6% at 3 months). Long term risks of LASIK for myopia with and without astigmatism beyond 12 months have not been studied.

Clinical Data Hyperopia: The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System for LASIK treatments of hyperopic refractive errors up to +6.0 D of sphere with and without astigmatic refractive errors up to 5.0 D with a maximum MRSE of +6.0 D has been studied in clinical trials in the United States with 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 69.9%.

The studies found that of the 212 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 95.3% were corrected to 20/40 or better, and 67.5% were corrected to 20/20 or better without spectacles or contact lenses.

The study showed that the following subjective patient adverse events were reported as much worse by at least 1% of the subjects (in order of increasing frequency) at 6 months post final treatment: glare from bright lights (3.0%); night driving glare (4.2%); light sensitivity (4.9%); visual fluctuations (6.1%); and halos (6.4%). Long term risks of LASIK for hyperopia with and without astigmatism beyond 12 months have not been studied.

Clinical Data Mixed Astigmatism: The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System for LASIK treatments of naturally occurring mixed astigmatism of up to 6.0 D at the spectacle plane has been studied in clinical trials in the United States with 162 eyes treated, of which 111 were eligible to be followed at 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%.

The studies found that of the 142 eyes eligible for the UCVA analysis of effectiveness at the 3-month stability time point, 95.8% achieved acuity of 20/40 or better, and 67.6% achieved acuity of 20/20 or better without spectacles or contact lenses.

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months post-treatment: sensitivity to light (43.3% at baseline versus 52.9% at 3 months); visual fluctuations (32.1% at baseline versus 43.0% at 3 months); and halos (37.0% at baseline versus 42.3% at 3 months). Long term risks of LASIK for mixed astigmatism beyond 6 months have not been studied.

Clinical Data Wavefront-guided Treatment of Myopia: The WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System used in conjunction with the WaveLight® ALLEGRO Analyzer® device. The device uses a 6.5 mm optical zone, a 9.0 mm ablation/treatment zone, and is indicated for wavefront-guided LASIK: 1) for the reduction or elimination of up to -7.0 D of spherical equivalent myopia or myopia with astigmatism, with up to -7.0 D of spherical component and up to 3.0 D of astigmatic component at the spectacle plane; 2) in patients who are 18 years of age or older; and 3) in patients with documentation of a stable manifest refraction defined as ≤0.50 D of preoperative spherical equivalent shift over one year prior to surgery was studied in a randomized clinical trial in the United States with 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). 178 of the Study Cohort and 180 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.2%.

The studies found that of the 180 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point in the Study Cohort, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better without spectacles or contact lenses. In the Control Cohort, of the 176 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20 or better without spectacles or contact lenses.

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months post-treatment in the Study Cohort: light sensitivity (37.2% at baseline versus 47.8% at 3 months); and visual fluctuations (13.8% at baseline versus 20.0% at 3 months). In the Control Cohort: halos (36.6% at baseline versus 45.4% at 3 months); and visual fluctuations (18.3% at baseline versus 21.9% at 3 months). Long term risks of wavefront-guided LASIK for myopia with and without astigmatism beyond 6 months have not been studied.

CONTRAINDICATIONS: LASIK treatments using the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System are contraindicated if any of the following conditions exist. Potential contraindications are not limited to those included in this list: pregnant or nursing women; patients with a diagnosed collagen vascular, autoimmune or immunodeficiency disease; patients with diagnosed keratoconus or any clinical pictures suggestive of keratoconus; and patients who are taking one or both of the following medications: isotretinoin (Accutane®1), amiodarone hydrochloride (Cordarone®2).

WARNINGS: Any LASIK treatment with the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System is not recommended in patients who have: systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status; a history of Herpes simplex or Herpes zoster keratitis; significant dry eye that is unresponsive to treatment; severe allergies; and unreliable preoperative wavefront examination that precludes wavefront-guided treatment. The wavefront-guided LASIK procedure requires accurate and reliable data from the wavefront examination. Every step of every wavefront measurement that may be used as the basis for a wavefront-guided LASIK procedure must be validated by the user. Inaccurate or unreliable data from the wavefront examination will lead to an inaccurate treatment.

PRECAUTIONS: Safety and effectiveness of the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System have not been established for patients with: progressive myopia, hyperopia, astigmatism and/or mixed astigmatism; ocular disease; previous corneal or intraocular surgery, or trauma in the ablation zone; corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage; residual corneal thickness after ablation of less than 250 microns increasing the risk for corneal ectasia; pupil size below 7.0 mm after mydriatics where applied for wavefront-guided ablation planning; history of glaucoma or ocular hypertension of > 23 mmHg; taking the medication sumatriptan succinate (Imitrex®3); under 18 years (21 years for mixed astigmatism) of age; over the long term (more than 12 months after surgery); corneal, lens and/or vitreous opacities including, but not limited to, cataract; iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eyetracking; taking medications likely to affect wound healing including, but not limited to, antimetabolites; treatments with an optical zone below 6.0 mm or above 6.5 mm in diameter; treatment targets different from emmetropia (plano) in which the wavefront-calculated defocus (spherical term) has been adjusted; myopia greater than – 12.0 D or astigmatism greater than 6 D; hyperopia greater than + 6.0 D or astigmatism greater than 5.0 D; mixed astigmatism greater than + 6.0 D; and in cylinder amounts > 4.0 to < 6.0 D.

Due to the lack of large numbers of patients in the general population, there are few subjects with cylinder amounts in this range to be studied. Not all complications, adverse events, and levels of effectiveness may have been determined.

Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see in such conditions as very dim light, rain, fog, snow and glare from bright lights. This has been shown to occur more frequently in the presence of residual refractive error and perhaps in patients with pupil sizes larger than the optical zone size.

The refraction is determined in the spectacle plane, but treated in the corneal plane. In order to determine the right treatment program to achieve the right correction, assessment of the vertex distance during refraction testing is recommended. Preoperative evaluation for dry eyes should be performed. Patients should be advised of the potential for dry eyes post LASIK and post wavefront-guided LASIK surgery. This treatment can only be provided by a licensed healthcare professional.

Adverse Events and Complications for Myopia: Certain adverse events and complications occurred after the LASIK surgery. Two adverse events occurred during the postoperative period of the clinical study: 0.2% (2/876) had a lost, misplaced, or misaligned flap reported at the 1 month examination.

The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment, corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of >1 mm2; epithelium of >1 mm2 in the interface with loss of 2 lines or more of BSCVA; uncontrolled IOP rise with increase of >5 mmHg or any reading above 25 mmHg; retinal detachment or retinal vascular accident; and decrease in BSCVA of >10 letters not due to irregular astigmatism as shown by hard contact lens refraction.

The following complications occurred 3 months after LASIK during this clinical trial: 0.8% (7/844) of eyes had a corneal epithelial defect; 0.1% (1/844) had any epithelium in the interface; 0.1% (1/844) had foreign body sensation; 0.2% (2/844) had pain; and 0.7% (6/844) had ghosting or double images in the operative eye.

The following complications did NOT occur 3 months following LASIK in this clinical trial: corneal edema and need for lifting and/or reseating the flap/cap.

Adverse Events and Complications for Hyperopia: Certain adverse events and complications occurred after the LASIK surgery. Only one adverse event occurred during the clinical study: one eye (0.4%) had a retinal detachment or retinal vascular accident reported at the 3 month examination.

The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment; lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month; corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of > 1 mm2; epithelium of > 1 mm2 in the interface with loss of 2 lines or more of BSCVA; uncontrolled IOP rise with increase of > 5 mmHg or any reading above 25 mmHg and decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction.

The following complications occurred 6 months after LASIK during this clinical trial: 0.8% (2/262) of eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface.

The following complications did NOT occur 6 months following LASIK in this clinical trial: corneal edema; foreign body sensation; pain, ghosting or double images; and need for lifting and/or reseating of the flap/cap.

Adverse Events and Complications for Mixed Astigmatism: Certain adverse events and complications occurred after the LASIK surgery. No protocol defined adverse events occurred during the clinical study. However, two events occurred which were reported to the FDA as Adverse Events.

The first event involved a patient who postoperatively was subject to blunt trauma to the treatment eye 6 days after surgery. The patient was found to have an intact globe with no rupture, inflammation or any dislodgement of the flap. The second event involved the treatment of an incorrect axis of astigmatism which required retreatment.

The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment; corneal epithelial defect involving the keratectomy at 1 month or later; corneal edema at 1 month or later visible in the slit lamp exam; epithelium of > 1 mm2 in the interface with loss of 2 lines or more of BSCVA; lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month; decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction; any complication leading to intraocular surgery; melting of the flap of > 1 mm2; uncontrolled IOP rise and retinal detachment or retinal vascular accident.

None of the following complications occurred at 3 months after LASIK during this clinical trial: corneal edema; corneal epithelial defect; any epithelium in the interface; foreign body sensation, pain, ghosting or double images; and need for lifting and/or reseating of the flap/cap.

Subjects were asked to complete a patient questionnaire preoperatively and at 3-months, 6-months, and 1-year postoperatively.

Adverse Events and Complications for Wavefront - guided Myopia: Certain adverse events and complications occurred after the wavefront-guided LASIK surgery. No adverse event occurred during wavefront-guided treatments during this clinical study.

The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment; lost, misplaced or misaligned flap or any flap/cap problems requiring surgical intervention beyond 1 month; corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of > 1 mm2; epithelium of > 1 mm^2 in the interface with loss of 2 lines or more of BSCVA; uncontrolled IOP rise with increase of > 5 mmHg or any reading above 25 mmHg; and decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction.

The following complications occurred 3 months after wavefront-guided LASIK during this clinical trial: corneal epithelial defect (0.6%); foreign body sensation (0.6%); and pain (0.6%).

The following complications did NOT occur 3 months following wavefront-guided LASIK in this clinical trial: corneal edema; any epithelium in the interface; ghosting or double images; and need for lifting and/or reseating of the flap/cap.

ATTENTION: The safety and effectiveness of LASIK surgery has ONLY been established with an optical zone of 6.0 – 6.5 mm and an ablation zone of 9.0 mm.

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

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MGD

(Continued from page 28)

Patient Evaluation of Eye Dryness scores at 3 years.[4] Tear break-up times and the Ocular Surface Disease Index were no longer significantly increased at the 3-year time point.

PERSONAL EXPERIENCE

I have performed this thermal pulsation procedure since October 2012 and have found it to be a useful adjunct in the management of dry eye. It is important for patients to understand that the treatment is not a cure and that the amount of symptomatic improvement they will have is dependent on how advanced the disease is prior to treatment.

Patients also must understand that they may continue to require other therapies (topical drops, cyclosporine [Restasis, Allergan], punctum plugs, or doxycycline) after the treatment, depending on the level of disease before treatment.

It took 4 weeks for me to develop an understanding of what kind of result could be expected based on patients' pre-treatment level of disease. Patients with mild to mild/moderate MGD have significant relief of symptoms with the treatment alone. Those with moderate to moderate/severe disease often have relief of symptoms with the treatment plus other therapies, such as punctum plugs, cyclosporine, or doxycycline.

Some patients with severe disease may not have any symptomatic relief at all. The benefit they receive from the treatment is maintaining the small number of glands they have left. This must be explicitly stated to these patients prior to their treatment. I have noted that several patients with severe disease had significant improvement in their symptoms after three treatments in 9 months. This may be a result of the patients having very thick secretions that did not melt after the first treatment.

Severely obstructed meibomian glands can have higher melting points.[5] Multiple treatments over a short period may be of benefit, but the cost is prohibitive and a clinical trial would be necessary to support this observation.

I have also had a patient referred with a persistent epithelial defect (PED) with MGD and aqueous tear deficiency with maximum medical therapy. The PED healed within 1 month status/post-treatment.

Studies have demonstrated the efficacy of the thermal pulsation system. However, if one peruses multiple Internet sites there is considerable patient dissatisfaction. This is likely the result of patients having expectations that are too high for their level of MGD.

It is mandatory that physicians clearly articulate the results that patients are likely to obtain with the treatment. Patients with mild-to-moderate disease have the most relief, in my experience, but may be most reluctant to undergo the treatment because of cost considerations. These are patients who are not likely to require other therapies.

Patients with moderate-to-severe disease will often require other therapies. I currently provide re-treatment to patients with mild-to-moderate disease every 12 months. Patients with moderate-to-severe disease may require treatments more frequently.

The thermal pulsation therapy has proven to be an important addition to my armamentarium in the management of MGD and dry eye. It requires a careful and meticulous pre-treatment evaluation so that the level of disease can be documented and the likely result articulated to patients. ■

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IOL centration: Location is everything

Lens position and capsulotomy size/shape affect centration

By Lynda Charters; *Reviewed by Daniel H. Chang, MD*

TAKE-HOME

- ***IOL centration is affected by both the lens position at the end of surgery and possibly by the effect of the capsulotomy size and shape in the late postoperative period.***

BAKERSFIELD, CA ::
THE FACTORS THAT determine IOL centration are paramount to visual outcomes.

Daniel H. Chang, MD, explained how the effect of the IOL position at the end of surgery and how the capsulotomy size and shape may affect changes in the IOL position in the late postoperative period.

"Good centration is important to maximize the visual quality and minimize the visual side effects of surgery," explained Dr. Chang, who is in private practice in Bakersfield, CA.


Dr. Chang

"For example, with aspheric IOLs, the advantage of the [lens] design is lost when the IOL decentrates by more than 0.8 mm," he said. "The effect of decentration of diffractive multifocal IOLs has not been quantified. Decentration frequently becomes the 'scapegoat' when patients with good Snellen visual acuity are unhappy with the surgical outcome."

DEFINED BY SITUATION

IOL centration has traditionally been defined differently in different situations. In laboratory studies, the optical center or the center of a dilated pupil is considered the center. In clinical settings, monofocal IOLs are considered centered when the edge of the IOL is not observed. For multifocal IOLs, the center of the undilated pupil is considered the center, Dr. Chang explained.

However, none of these definitions takes the visual axis into account. The visual axis (the line that connects the fovea to the nodal point and to the fixation) is related to the pupillary axis (the line from the center of the pupil that runs orthogonal to the cornea) by angle kappa, the angle between the pupillary axis and the visual axis. The corneal vertex, as represented by the coaxially sighted corneal light reflex, is the point where the visual axis intersects the cornea.

Knowing the specific definitions of these axes may help, but "applying this in a clinical setting is the challenge," Dr. Chang said. "There are many ways that IOLs can be aligned, sometimes intentionally and something otherwise."

CENTER ON VISUAL AXIS

Though surgeons have a few different options, Dr. Chang explained that the best place to center the IOL is on the visual axis. This is evidenced by the results of hyperopic LASIK studies and

PMA submitted for inlay

From Staff Reports

IRVINE, CA ::
THE FINAL MODULE of the premarket approval application (PMA) for the Kamra corneal inlay has been submitted to the FDA by AcuFocus, the inlay's manufacturer.

The corneal inlay is designed to treat presbyopia by allowing only focused light to enter the eye.

"Patients, practitioners, and the ophthalmic industry have all been in search of a reliable corneal solution for presbyopia and I believe the Kamra inlay is that solution," said John Vukich, MD, an investigator in the U.S. clinical trials.

The inlay is a novel technology with no similar precedent in the market and has undergone rigorous approval processes in several countries. It is now approved in 47 countries across Europe, Asia-Pacific, Middle East, and the Americas. ■

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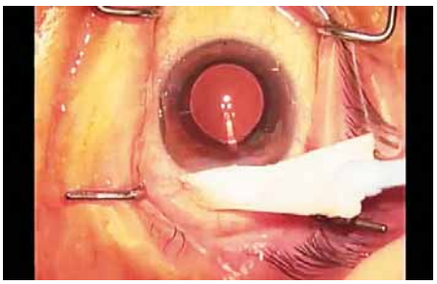

AT THE CENTER OF IT ALL

Good centration is important to maximize the visual quality and minimize the visual side effects of surgery. Go to **http://ow.ly/juU0q** for a video demonstrating how to center a diffractive multifocal IOL. *(Video courtesy of Daniel H. Chang, MD)*

> 'There are many ways that IOLs can be aligned, sometimes intentionally and something otherwise.'
>
> — Daniel H. Chang, MD

eye-model studies. Cosmetically, centering the IOL on the pupillary axis looks better because the pupils can be easily seen both during surgery and postoperative slit lamp evaluations.

"Centration on the visual axis provides the best visual outcomes," Dr. Chang said.

Adjustments in IOL position can be made primarily by moving the lens perpendicular to the primary region of the peripheral bag-haptic contact, which is determined by the design. Dr. Chang provided a simulation of an implanted multifocal, one-piece lens (Tecnis, Abbott Medical Optics), which is a 13-mm hydrophobic, acrylic lens with modified C-loop haptics.

When compressed in an 11-mm bag, the maximum point of contact is about 45° to 60° counterclockwise from the haptic insertions. It is easiest to shift the IOL in a direction corresponding to points about 30° to 45° clockwise from the haptic insertion. Once in the bag, the IOL can be nudged in this direction, and the bag can accommodate this manipulation.

A study performed by Dr. Chang showed that the intraoperative and postoperative day 1 positions of IOLs in 18 eyes were "very consistent." The stability, however, of the centration over time is probably more important.

The capsular edge may become important in the late postoperative period because scarring and fusion of the peripheral capsule occurs, and asymmetric capsular fusion could shift the IOL, he explained. The IOL can shift anteriorly to posteriorly. In cases in which there is asymmetric fusion, asymmetric forces could move the IOL horizontally.

Capsular healing can be dependent on IOL design, Dr. Chang said. He provided an example of an eye with a Tecnis IOL implanted in which the capsular sides were fused nicely. However, in the area central to the location of the haptics, there was no fusion and the capsule was open 4 months postoperatively. Additionally, the capsulorhexis edge remained free of fibrosis and was not touching the IOL.

In another study, Dr. Chang showed that from postoperative day 1 to 12 months, the IOLs did not move significantly (about 0.1 mm) compared relative with the visual axis. There was slightly more movement (about 0.13 mm) of the IOL in relation to the pupil center at month 12.

Factors pertinent to IOL centration are both the IOL position at the end of the surgery and possibly the capsulotomy size and shape. The latter may affect changes in the IOL position in the late postoperative period, but this would depend on the exact shape of the capsulotomy and the design of the IOL, Dr. Chang summarized.

Further study is required to learn how the capsular and IOL position change over time and the effect of the capsulotomy characteristics and IOL design on the changes. Finally, the visual effects of IOL decentration must be determined. ■

DANIEL H. CHANG, MD

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Dr. Chang is a consultant to Abbott Medical Optics. This article is adapted from Dr. Chang's presentation during Refractive Surgery 2012 at the annual meeting of the American Academy of Ophthalmology.

Bringing the 'wow' back to LASIK

How technology, better communication with patients can re-invigorate the market

By Sandy T. Feldman, MD, MS, *Special to* Ophthalmology Times

TAKE-HOME

- ***With a combination of femtosecond laser flap and an ocular lens, more than 50% of patients (versus 17% without the shielding lens) see 20/20 immediately after surgery, relates one ophthalmologist.***

THE DECLINE IN procedure volumes of laser vision correction (LVC) is well documented over the past few years. Economic changes, a sluggish recovery, and what some would describe as LASIK "fatigue" have played a large role.

Refractive surgeons know that LVC outcomes are almost uniformly excellent. However, too often, we fail to share that with patients and other health-care professionals in our communities. The same goes for collective staff

But there is more than just the economy to blame—and it will take more than a resurgent economy to bring LASIK volumes back to pre-recession levels.

Complacency is another major factor in the dip in procedure volumes. With excimer laser systems, custom ablation, and even femtosecond laser flaps being old news, refractive surgery can seem so routine that it feels like there isn't much to talk about. But even without the introduction of paradigm-changing technology, we have seen real advancements in the past few years—advancements that are improving outcomes and giving patients that "wow" factor.

Additionally, the population of candidates for LVC is constantly changing. Every year, millions of patients with ametropia become receptive to the message about what LVC can do for them—either because they have recently become contact lens-intolerant, or because they have just reached an income level that can support elective procedures. If we don't keep talking about it, these candidates will never hear the message.

Most importantly, a 28-year-old patient with myopia today has the same fears that people did in the 1990s: Will it hurt? What if I lose my vision? Can I afford this? Refractive surgery has matured considerably. Those fears are less well founded today than they were a generation ago, but today's patients don't know that.

(FIGURE 1) A new ocular lens, combined with femtosecond laser flaps, improves the patient experience.

'Technology improvements can help resolve patient fears and decrease discomfort in the early postoperative period.'

— Sandy T. Feldman, MD, MS

NEW TECHNOLOGY

For some time now, we have been achieving excellent refractive results. The vast majority of patients see 20/20 or better uncorrected visual acuity after LASIK or PRK, with many seeing better than they did with glasses before surgery.

In my practice, two new technologies have recently made a big difference in how patients subjectively experience the procedure. The first is the femtosecond laser (iFS, Abbott Medical Optics). I originally delayed upgrading from its predecessor (FS60 femtosecond laser), because I was skeptical that results could actually get much better. In fact, I have seen a huge qualitative improvement in day 1 results.

The faster femtosecond laser creates a smoother stromal bed that provides a fine surface for the ablation, and the beveled, reverse-angled flap edge fits precisely back into the bed with almost no gutter.

This makes a difference in how quickly the cornea heals and re-epithelializes. The typical time to create a flap has decreased from about 15 seconds to 10 seconds. While this might not sound like much, when combined with easier docking, it means that the eye is subjected to high pressure for a much shorter period. That reduces the surgeon's stress and limits anxiety and discomfort for patients. From their perspective, the faster you can get through that part of the procedure, the better. That means a better patient experience.

The second technology is a unique ocular lens (Nexis Lens, Nexis Vision). We have begun placing the lens on the eye for 4 hours or overnight after surgery. The lens is similar to a contact lens. However, unlike a typical bandage lens, the lens is thicker and fits more tightly so that it does not move around with blinking (Figure 1).

In lieu of goggles, the lens shields the cornea but also promotes healing by minimizing edema and encouraging dehydration. The lens also provides a scaffold for smoother epithelial regrowth and provides clear optics for faster functional recovery of vision.

Surgeons are accustomed to reporting and focusing on visual results 1 month or 1 year after surgery. But it is important to remember that patients universally fear losing their vision, so excellent vision right away is tremendously reassuring. With this combination of femtosec-

Continues on page 36 : ***'Wow' factor***

IMAGINE THE ABILITY TO UNLOCK NEW TREATMENT POSSIBILITIES

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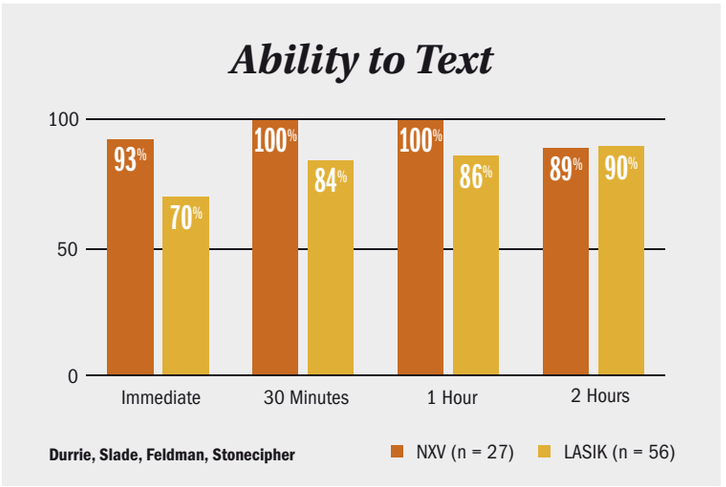
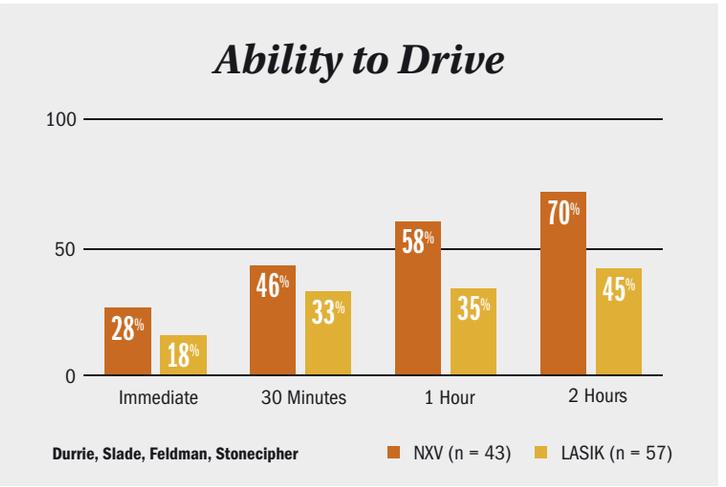


(FIGURE 2) An ocular lens (NXV group), combined with advanced femtosecond laser flaps, improves functional recovery early after surgery, enabling the vast majority of patients to text immediately after the procedure.



(FIGURE 3) By 1 hour after surgery, the majority of patients in the NXV group said they would feel comfortable driving. *(Figures courtesy of Nexis Vision)*

'WOW' FACTOR

(Continued from page 34)

ond laser flap and ocular lens, more than 50% of our patients (versus 17% without the shield) see 20/20 immediately after surgery (Table 1).

Almost 90% of patients see 20/25 or better immediately after surgery. This goes a long way toward quieting the voices in their heads saying, "What if this is as good as it gets?"

These new technologies enhance the patient experience and bring patients better vision and less discomfort in the first few hours after surgery. That is a huge "wow" for the patient, and a win for the practice. It allows us to let patients alert their social media network about the ease of LASIK and how amazing their vision is immediately after surgery (Figure 2).

SPEED OF VISUAL RECOVERY STUDY

In a study with Dan Durrie, MD, Steve Slade, MD, and Karl Stonecipher, MD, we measured visual acuity immediately after surgery, at 30 minutes, and 1, 2, and 4 hours, as detailed in Table 1. We also asked patients whether they would feel comfortable texting or driving. These are common visual activities that serve as good indicators of patients' subjective comfort and clarity of vision after surgery.

The results of this study, which enrolled 100 subjects undergoing wavefront-guided LASIK (43 with the Nexis shield and 57 without it), have been very impressive. The majority in both groups said they were able to text on their smartphones immediately after surgery. The Nexis lens group had an edge over the non-lens group for about 4 hours after surgery. Not surprisingly, patients are less confident about their ability to drive immediately after surgery. About 60% of those with the lens said they were ready to drive as early as 1 hour after surgery, significantly more than those without the lens (Figure 3).

These results raise the question of whether patients could have LASIK and drive themselves home or return to work the same day. While we have not changed our guidance to patients about working and driving, we have stopped advising them they need to go home and take a nap. The purpose of the nap was to get them through the worst of the discomfort and blurry vision—something most patients aren't experiencing any longer.

LASIK is a fantastic procedure already, but technology improvements can help resolve patient fears and decrease discomfort in the early postoperative period. This is a good time to remind refractive surgeons how important it is not to become complacent but to continue to share the joy of LVC with potential candidates and community referral sources.

Anything we can do to bring the "wow" back to LASIK—both in terms of the patient experience and in how we communicate that experience—will help re-build procedure volumes. ■

Percentage with 20/25 or Better UCVA

	With Shield	Without Shield
Immediately after	87%	31%
1 Hour	93%	58%
2 Hours	97%	75%
4 Hours	97%	92%

(TABLE 1) Immediately after surgery and at 1 hour, there are stark differences in visual acuity between the groups with and without the ocular lens. By 2 hours, the non-lens group is beginning to catch up and by 4 hours, there is little difference between the two groups. *(Table courtesy of Nexis Vision; Data of Drs. Durrie and Slade)*

SANDY T. FELDMAN, MD, MS, *is medical director of ClearView Eye and Laser Medical Center, San Diego. Readers may contact her at 858/452-3937 or www.clearvieweyes.com. Dr. Feldman has a financial interest in Abbott Medical Optics and Nexis Vision.*

How to detect artifactual clues in OCT images

Achieve more accurate findings by eliminating the effects of artifacts

By Lynda Charters;

Reviewed by Sanjay G. Asrani, MD

TAKE-HOME

- ***Optical coherence tomography is indispensable for diagnosing glaucoma. However, clinicians should be alert to the effects of various artifacts.***

DURHAM, NC ::

The ability to identify various types of artifacts is crucial when evaluating optical coherence tomography (OCT) images.

OCT has become indispensable for diagnosing glaucoma. However, as with all technologies, there are glitches that can be overcome with proper recognition, explained Sanjay G. Asrani, MD.

Dr. Asrani

"It is critical to recognize artifacts in images, because many ophthalmologists rely on imaging devices to identify glaucoma and detect disease progression," said Dr. Asrani, professor of ophthalmology, and director, Glaucoma OCT Reading Center, Department of Ophthalmology, Duke Eye Center, Duke University, Durham, NC. Among the types of artifacts:

OPERATOR-DEPENDENT ARTIFACTS

Operator-dependent artifacts include acceptance of images with poor signal strength, improper retinal nerve fiber layer (RNFL) circle placement, and truncation of acquired OCT images. Dr. Asrani provided an example of a scan that showed complete absence of the RNFL in one sector, which is highly unusual because of the floor effect of the glial cells.

"This finding indicated the presence of an artifact," he said. "When the scan was repeated, the RNFL appeared to be nearly normal. This happened as the result of truncation because the technician failed to bring the image into the center of the window."

Continues on page 38 : ***Artifacts***

ARTIFACTS

(Continued from page 37)

MISINTERPRETATION ARTIFACTS

Misinterpretation artifacts include localized losses of RNFL or macular thickness classified as normal due to averaging of the thickness values by quadrant or hemisphere and misinterpretation of shadow artifacts.

He provided an example that he referred to as "green disease," in which the green color of the data results provides false assurance that the findings are normal. In this case, the patient had a focal defect that was easily missed by averaging the quadrant data. A second example was that of a shadow artifact caused by a floater that resulted in borderline measurements.

OCULAR PATHOLOGY-RELATED ARTIFACTS

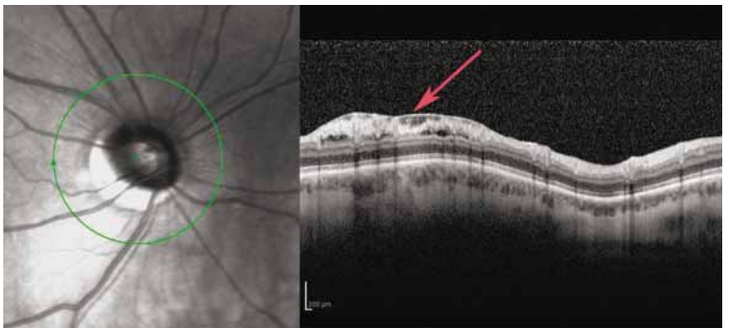
Ocular pathology-related artifacts include the presence of prominent posterior hyaloid and epiretinal membrane (ERM) that create abnormal hyperreflective bands inside the normal retinal boundary. In this situation, the algorithm may identify these pathologies as the retinal boundary, which can result in overestimation of the retinal thickness.

Dr. Asrani showed images depicting a falsely thick RNFL and another of a falsely thick macula, both due to the ERM. In the first example, the clue to the artifact was that the axons appeared to be hanging from the ERM in an area that appeared thickened but was not.

In the second example, scalloped edges around an artificially thick macula were clues to the artifactual effect of the ERM.

In patients with posterior vitreous detachment (PVD), an artifact can result from operator failure to recognize the effect of a partial PVD that causes traction-related thickening of the peripapillary RNFL.

"This is one of the most common artifacts seen," Dr. Asrani emphasized.



(FIGURE 1) **The retinal nerve fiber layer is measured as artificially thick (arrow) due to an epiretinal membrane.** *(Images courtesy of Sanjay G. Asrani, MD)*

A related artifact that is very difficult to detect occurs in cases that seem to have PVD progression and subsequent thinning of the RNFL. However, unless the vitreous interface and the RNFL edges are evaluated, the physician cannot detect whether the vitreous has pulled away from the RNFL, which then relaxes and appears as false progression, he noted.

Myopia, which he referred to as "red disease," presents difficulties. There is a higher percentage of abnormal diagnostic classifications, because the RNFL normative databases usually do not include patients with moderate and high myopia. Myopia is also associated with other artifacts (i.e., difficulty acquiring a good image due to the long axial length or myopic retinal schisis that affects the peripapillary RNFL thickness).

Dr. Asrani described a case in which peripapillary atrophy caused substantial measurement artifacts and another case in which measurements were not obtained because of axial length, posterior staphyloma, and retinal schisis.

SOFTWARE-RELATE ARTIFACTS

Software-related artifacts include absence of eye tracking because of microsaccades, not controlling for head tilt, and the absence of robust segmentation software.

Failure to recognize non-glaucomatous diseases—such as anterior ischemic optic neuropathy, retinal dystrophies, and hemiretinal vein occlusion, among others—is a source of another set of artifacts.

Ocular pathologies, specifically ERM and vitreous traction, caused the most artifacts in macular and RNFL scans, he noted.

"OCT has tremendous potential for glaucoma management, but we need to be aware of artifacts," Dr. Asrani concluded. "Re-acquiring scans or manually correcting segmentation errors, while time-consuming, may be needed for better clinical care. Continued improvements in software and segmentation algorithms may provide increasingly reliable quantitative thickness data." ■

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Dr. Asrani receives lecture fees from Heidelberg Engineering. This article is adapted from Dr. Asrani's presentation during Glaucoma 2012 at the 2012 annual meeting of the American Academy of Ophthalmology.

Dr. Vajaranant tapped for glaucoma award

From Staff Reports

BRIDGEWATER, NJ ::

THE AMERICAN GLAUCOMA Society (AGS) has chosen Thasarat S. Vajaranant, MD, to receive the Thom J. Zimmerman, MD, PhD Memorial Award, supported by Valeant Ophthalmics.

The Zimmerman award will support Dr. Vajaranant's clinical research study, "A Feasibility Study to Assess the Accuracy of Self-reported Glaucoma Outcomes and Participant Interest in Ancillary Glaucoma Studies as Part of the Women's Health Initiative (WHI) Extension." The WHI is a large-scale national study cohort, providing a unique opportunity to build a large multiracial and multiethnic database regarding the genotype-phenotype influence on primary open-angle glaucoma.

Valeant Ophthalmics, a division of Valeant Pharmaceuticals North America LLC, worked with the AGS to establish the award in memory of Dr. Zimmerman, the developer of the glaucoma medication timolol maleate.

Dr. Zimmerman was emeritus professor and chairman of the Department of Ophthalmology and Visual Sciences and emeritus professor of the Department of Pharmacology and Toxicology at the University of Louisville. He was best known for the development of drugs for treatment of glaucoma, including timolol. With his partner, Chris Paterson, he spearheaded the building of the addition to the Kentucky Lions Eye Center and the Rounsavall Eye Clinic, both in Louisville. ■

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Anti-VEGF for ROP may still be in its infancy

Use of laser remains standard primary therapy in most populations

By Lynda Charters; *Reviewed by Michael T. Trese, MD*

TAKE-HOME

- ***Laser remains the standard treatment for infants with retinopathy of prematurity. The safety and efficacy of anti-vascular endothelial growth factor drugs for treating the disease have not been investigated.***

ROYAL OAK, MI ::

Use of anti-vascular endothelial growth factor (VEGF) drugs may not be ready for prime time in the treatment of retinopathy of prematurity (ROP), related one ophthalmologist.

Laser remains the standard treatment for infants with ROP because the safety and efficacy of anti-VEGF drugs for treating the disease have not been investigated, said Michael T. Trese, MD, chief, pediatric and adult vitreoretinal surgery, Beaumont Eye Institute, William Beaumont Hospital, Royal Oak, MI.

Dr. Trese

Dr. Trese discussed the current status of the use of anti-VEGF drugs in this patient population.

BEAT-ROP

Results from the Bevacizumab Eliminates the Angiogenic Threat of Retinopathy of Prematurity (BEAT-ROP) study (*N Engl J Med*. 2011;364:603-615) showed that there was no difference between laser and anti-VEGF drugs for treating zone 2 disease. However, the results showed a significant difference between laser and bevacizumab (Avastin, Genentech) for treating zone 1 ROP, with bevacizumab having greater efficacy.

The difference in efficacy stemmed from the fact that two-thirds of study patients were Hispanic with a more difficult type of ROP to treat. The laser failure rate for zone 1 disease was 42%, as defined by the study. This raised a question about the significance of the results if other treatment failure rates were used, Dr. Trese noted.

The results of three other studies of laser for treating zone 1 ROP, according to Dr. Trese, would not have shown statistical significance between laser and anti-VEGF therapy.

Another question concerns the safety of anti-VEGF drugs for ROP. Seven infants in the BEAT-ROP study died: five in the bevacizumab group and two in the laser group. While the difference between the two did not reach significance, it raises some concern, according to Dr. Trese.

The editorial that accompanied the BEAT-ROP study in the *New England Journal of Medicine* noted that bevacizumab could reasonably be presumed to be safe.

However, there have been other instances in which therapies were adopted based on only short-term results without appropriate studies, Dr. Trese noted. For example, uncontrolled oxygen administration that resulted in the first ROP epidemic; interferon therapy for capillary hemangiomas that resulted in spastic diplegia; and post-natal steroids to wean infants off the ventilator that 10 years later resulted in cerebral palsy.

Intravitreally administered bevacizumab escapes into the systemic circulation. While the vitreous half-life of ranibizumab (Lucentis, Genentech) and bevacizumab are very similar, the peak plasma concentration of bevacizumab is much higher than that of ranibizumab (20 to 687 ng/ml versus 0.79 to 2.9 ng/ml, respectively), and it remains in the circulation for significantly longer (half-life, 20 days versus 0.09 days, respectively).

Another factor is that VEGF is necessary to normal infant development.

"VEGF regulates normal angiogenesis in many organs," Dr. Trese said. "In the central nervous system, it is neurotropic, neuroprotective, and maintains the blood-brain barrier. In the lungs, VEGF has an important role in alveolization, and it has key roles in bone growth and cardiac and kidney development."

Other safety issues include the absence of safety studies to determine the lowest effective dose of anti-VEGF drugs in ROP. Ranibizumab also remains in the general circulation but for a much shorter time than bevacizumab.

"All use of anti-VEGF drugs for ROP or in infants and children is off-label and requires appropriate documentation and consent," he said. "The FDA is currently looking at more rigorous testing of drugs for use in neonates and children."

A problem is that in future studies, assessing the real risk involved in treating premature infants with anti-VEGF drugs may be impossible.

BLOCK-ROP

However, using a low dose of a drug with a shorter half-life may be a better choice. Genentech and the Pan-VEGF Blockade for the Treatment of Retinopathy of Prematurity (BLOCK-ROP) study group are investigating the potential for a cooperative study group to determine the lowest dose and the safest drug to use in these children.

An anti-VEGF drug does have value for treating children with ROP when no laser is available, Dr. Trese noted.

"If a laser is available—and the doctor knows how to perform the appropriate laser treatment, and the population includes fewer children who are Hispanic—I believe that laser is unquestionably safer for the infants," he said.

In addition, Dr. Trese explained, use of anti-VEGF therapy negatively affects ROP by changing it from a disease with a predictable course and a finite follow-up period to one with an indefinite follow-up period that can lead to very late retinal detachment. This makes the physician examination and the parental cooperation difficult when follow-up is need for 6 months or longer.

"Anti-VEGF therapy . . . will most likely have a role in ROP management, but until convincing safety data are available, the right drug and the right dose remain in question," Dr. Trese said. "In my opinion, laser is still the standard primary therapy for ROP in most populations." ■

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Dr. Trese is a consultant for Genentech. This article is adapted from Dr. Trese's presentation during Retina 2012 at the annual meeting of the American Academy of Ophthalmology.

What do you mean, I don't own my website?

How an initial investment of time can reap benefits in site content, design, rankings

By David W. Evans, PhD, MBA; *Special to* Ophthalmology Times

IT STARTED OUT as a routine assessment. An ophthalmologist recently wanted to upgrade his practice's website to improve its appearance, as well as improve its rankings on Google.

During an evaluation of the website, the ophthalmologist was surprised by what he discovered. The content on the procedure pages seemed canned and definitely not individualized, particularly on the LASIK- and cataract surgery-related pages. After additional research, what he discovered was even more startling—the content from the surgeon's site appeared on about 150 other ophthalmology websites.

WHO OWNS THE COPYRIGHT?

The copyright notice at the bottom of the website indicated that both the website company and the surgeon held the copyright. Although this is not a great finding, it might have been tolerable.

Unfortunately, when the surgeon contacted the company to learn more, he found out that he had no rights to any of the content or the design of "his" website. In fact, he did not even own the domain name of the site *("www.drxyzlasik.com")*.

The website company had registered "his" domain name, but retained all the ownership rights. What this registration means is that when this ophthalmologist decides to expand, upgrade, or improve his website, he either has to continue working with the current website company or start over from scratch—new content, new design, and, more critically, a new domain name.

FIVE IMPORTANT QUESTIONS TO ASK

Attaining the maximum benefit from a practice website requires a long-term strategy. The website should be upgraded and enhanced regularly over a number of years. To avoid being held captive by a website development company, here are a few key questions to ask.

TAKE-HOME

- ***Physicians can protect a practice website investment by asking a few questions up front to ensure that they own all aspects of the site and domain name.***

1. WHO OWNS THE DOMAIN NAME OF MY WEBSITE?

The domain name of a website, e.g., *www.johnsmithlasiksurgeonmd.com,* is important for branding the practice. It should appear on all marketing materials and brochures, both physical and electronic.

It also is important to remember that the age of the domain name can influence how well the website ranks on Google—usually, the older the name, the better. The domain name is a practice asset and should be completely owned and controlled by the practice.

When starting out with a new website company, always ask who owns or will own the domain name. If a domain name already exists, check the ownership by visiting *www.whois.sc.*

If the physician is not listed as the registrar of the domain name, then there may be a problem.

2. DO I HAVE DUPLICATE CONTENT ON MY SITE?

Customized, educational website content is essential for creating a unique image for a physician's practice and for

Continues on page 42 : ***Ownership***

OWNERSHIP

(Continued from page 41)

achieving high rankings on Google. Notably, if the content is the same as other websites, then Google is less likely to give the site high rankings.

When developing a new website or upgrading a current website, always ask whether the content will be unique and whether the same content appears in other websites.

An easy way to check if website content is duplicated is to copy a sentence or two of the content from a page on the site. Enclose the content with quotation marks, and then paste this text into the Google search box. Google will show matches for other websites that have exactly the same content.

3. DO I OWN THE DESIGN OF MY SITE?

When contracting with a company to have a new website built, determine who will own the graphic images and design. Even if the physician personally writes the content for the website, he or she still may not own the design. If the physician does not own the design, moving the website to a different company for expansion may require that the site be redesigned and rebuilt—at the physician's expense.

4. WHO PAYS THE LICENSING FEES FOR PHOTOS ON MY SITE?

Many of the photos that appear in ophthalmology websites are derived from online photo catalogs that require a licensing fee. Always find out who will own the photos in the website and whether there are any ongoing licensing fees associated with the site.

Some of the larger suppliers of photos, such as Getty Images, are aggressive about pursuing website owners who use their images without proper licensing fees.

5. WHAT ABOUT FLASH AND VIDEO FILES?

Access to and ownership of the source code for the flash and video files is essential if the physician wants to transfer the website without a hitch. When contracting with a website company for a site that contains flash, video, or both, always find out who owns the rights to the source code. If the physician does not own the source code, then often he or she may have to pay significant amounts to have these files re-created once the decision is made to expand or redesign the site.

Take steps to avoid having to start over each time a decision is made to update or expand a website and improve online visibility. Protect the website investment by asking a few questions up front to ensure ownership for all aspects of the site and domain name.

Read the contract closely and review any terminology that includes "ownership," "copyright," and "cease of contract." This information will give the physician an idea of whether he or she owns—or is just renting—the website. ■

DAVID W. EVANS, PHD, MBA, *is chief executive officer of Ceatus Media Group LLC, San Diego. With a focus on Internet practice marketing, Dr. Evans and his team oversee the search engine optimization and search engine rankings for more than 150 refractive and plastic surgeon websites in five countries. Readers may contact Dr. Evans at 858/454-5505 or dwevans@ceatus.com.*

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Tuttnauer Co. **Tel:** 800/624-5836 **Fax:** 631/737-0720 **Internet:** www.tuttnauerUSA.com	41
Vision Associates **Tel:** 800/346-7486 **Internet**: www.visassoc.com	23

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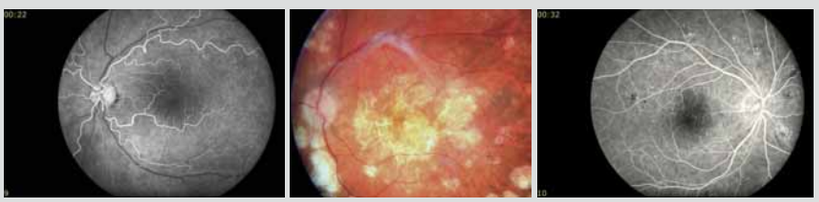

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The Benign Essential Blepharospasm Research Foundation is pleased to offer a research fellowship to support the training of exceptionally qualified physicians or scientists who wish to focus on blepharospasm with and without oromandibular dystonia. Fellowships will be awarded in the amount of up to $75,000 per year for two years.

Physician applicants must be board certified or board eligible in neurology or ophthalmology, have completed a residency, and hold or be able to hold an unrestricted license to practice medicine in the United States. PhDs should have completed their degree.

Deadline to apply for this year's fellowship is June 30, 2013 for a fellowship to begin approximately on July 1, 2014. Fellowship guidelines, application, and instructions may be obtained from bebrf@blepharospasm.org or visit the website, www.blepharospasm.org to download forms.

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Top medical apps in 2013

Mobile technology puts health-care data in palm of hand

From Staff Reports

The use of mobile technology to deliver health-care services and information skyrocketed in 2012.

Some 44 million health apps will have been downloaded by the end of this year (predicted to reach 142 million downloads by 2016),[1] and consumers are now spending $700 million per year on these apps.[2]

There are more than 10,000 health apps in the iTunes app store,[3] the number of American using smartphones for health information grew from 61 million to 75 million in 2012,[2] and 88% of physicians would like patients to monitor their health at home.[3]

Among the medical and health apps that patients are likely to use in 2013:

MEDISAFE PROJECT

MediSafe Project *(http://medisafeproject.com/)* is a cloud-synced pillbox app that not only reminds patients when it's time to take medications, but also sends their family, friends, and caretakers alerts if they miss a dose. Compatible with the FDA's drug database, generic and brand name medications "autocomplete" as users enter them—automatically recording the correct pharmaceutical name, manufacturer, and medication strength. Or, patients can use their smartphone cameras to snap the FDA's universal National Drug Code (NDC) number, found on all original pharmaceutical packaging, to enter a medication.

WEBMD PAIN COACH

WebMD Pain Coach *(http://www.webmd.com/a-to-z-guides/video/pain-coach-long)* helps people with chronic pain conditions make daily health and wellness choices, so they can manage their pain more effectively. From back pain to migraines, the app lets patients record daily pain levels, export their pain history to PDF format, and e-mail it to their physicians. Patients can also select physician-approved goals from five lifestyle categories related to pain condition(s): Food, Rest, Exercise, Mood, and Treatments, view "bite-sized" tips matched with goals and organized into the same five lifestyle categories, and have access to hundreds of articles, videos, slide shows, and quizzes on pain management related to patients' condition(s).

Mobile health-care delivery skyrocketed in 2012

44 MILLION — health apps will have been downloaded by the end of the year (predicted to reach 142 million downloads by 2016)[1]

$700 MILLION — consumers are now spending per year on these apps[2]

10,000 — health apps in the iTunes app store[3]

61 MILLION TO 75 MILLION — growth this year in the number of American using smartphones for health information[2]

88% — of physicians would like patients to monitor their health at home[3]

Sources: iHealthBeat, Healthcare IT News, and MedNEWS Blog

EMOTION SELECT

Part of the 'Spotlight Autism' app series, Emotion Select *(http://www.zbrainy.com/apps/emotionselect/)* helps children with autism spectrum disorder or those suffering other social delays practice learning and identifying emotions. After reviewing illustrations for joy, sadness, anger, surprise, and fear, children are given the chance to anticipate and apply them in "real-life" social situations. Includes statistical analysis for parents, teachers, and therapists to track specific strengths and weaknesses of children's learning progression.

EMERGENCY KIT

Emergency Kit *(http://startlab.us/emergency-kit/)* is an easy way to aggregate patients' most critical information—and could save a life in a medical emergency. Emergency technicians will be able to view vital stats, including blood type, allergies, medications, and emergency contacts, within the app. It can also turn a phone into an SOS light beacon, send out an emergency text message or e-mail with a patient's GPS coordinates, or look up how to treat different injuries. ■

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INDICATION FOR USE. The iStent® Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L) is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. **CONTRAINDICATIONS.** The iStent® is contraindicated in eyes with primary or secondary angle closure glaucoma, including neovascular glaucoma, as well as in patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. **WARNINGS.** Gonioscopy should be performed prior to surgery to exclude PAS, rubeosis, and other angle abnormalities or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. The iStent® is MR-Conditional meaning that the device is safe for use in a specified MR environment under specified conditions, please see label for details. **PRECAUTIONS.** The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the iStent® has not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, chronic inflammation, or an abnormal anterior segment, in pseudophakic patients with glaucoma, in patients with pseudoexfoliative glaucoma, pigmentary, and uveitic glaucoma, in patients with unmedicated IOP less than 22 mmHg or greater than 36 mmHg after "washout" of medications, or in patients with prior glaucoma surgery of any type including argon laser trabeculoplasty, for implantation of more than a single stent, after complications during cataract surgery, and when implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract. **ADVERSE EVENTS.** The most common post-operative adverse events reported in the randomized pivotal trial included early post-operative corneal edema (8%), BCVA loss of ≥ 1 line at or after the 3 month visit (7%), posterior capsular opacification (6%), stent obstruction (4%) early post-operative anterior chamber cells (3%), and early post-operative corneal abrasion (3%). Please refer to Directions for Use for additional adverse event information. **CAUTION:** Federal law restricts this device to sale by, or on the order of, a physician. Please reference the Directions for Use labeling for a complete list of contraindications, warnings, precautions, and adverse events.

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