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SPECIAL REPORT **ASCRS** REFRACTIVE NEWS

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**ASCRS Refractive News** 

#### **PHYSICIANS AS PATIENTS LIKE LASIK OUTCOMES**

By Fred Gebhart

SAN FRANCISCO :: LASIK RESULTS

ARE GOOD. Studies using current LASIK platforms routinely show 20/20 in excess of 80% of eyes and a high degree of satisfaction in 95% of patients. With about 1 million eyes treated annually, LASIK results are so good the U.S. military has accepted the procedure for combat pilots.

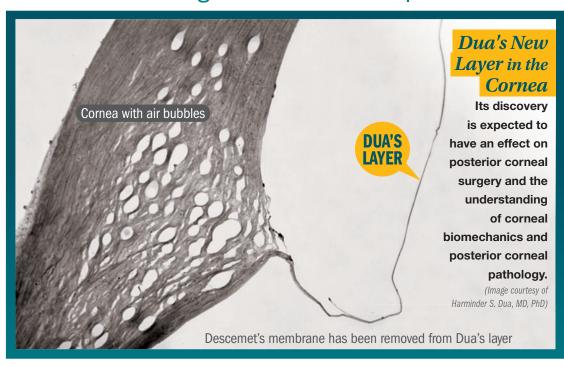
But what about physicians?

"Physicians are skeptical, they are cautious, and they have an extraordi-

( See story on page 17 )

## PEELING BACK THE LAYERS

Discovery of novel pre-Descemet's layer in the cornea has both surgical and clinical implications



By Liz Meszaros

NOTTINGHAM, ENGLAND ::

**SCIENTISTS HAVE DISCOVERED** a

new layer in the cornea. This previously undetected

layer located in the pre-Descemet's cornea is welldefined, acellular, strong enough to withstand up to 1.5 to 2.0 bars of pressure, and has been named Dua's layer, after Harminder S. Dua, MD, PhD, who discovered it.

"Clinical implications of this layer will emerge with time, but the surgical implications are immediately relevant," said Dr. Dua, professor of ophthalmology and visual sciences, University of Nottingham, Queens Medical Centre, Nottingham, England.

"This layer can also be used to support the endothelium in the procedure of endothelial keratoplasty, making handling of the Descemet's membrane transplant safer and technically simpler," Dr. Dua said.

( Continues on page 6 : Dua's layer )



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Indications: TECNIS® Monofocal IOLs are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag. **Warnings:** Physicians considering lens implantation under any of the conditions described in the Directions for Use labeling should weigh the potential risk/benefit ratio prior to implanting a lens. **Precautions:** Do not resterilize or autoclave. Use only sterile irrigating solutions such as balanced salt solution or sterile normal saline. Do not store in direct sunlight or in temperatures over 45°C. **Adverse Events:** The most frequently reported adverse event that occurred during the clinical trial of the 1-Piece lens was macular edema, which occurred at a rate of 3.3%. Other reported reactions, occurring in less than 1% of patients, were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic).

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Caution: Federal law restricts these devices to sale by or on the order of a physician.

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



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#### In Every Issue

## An attention 'grabber'

### Once again, Einstein's theory of relativity gives rise



#### 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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#### ON A RECENT FLIGHT, a famous media expert occupied the seat next to mine.

"I'm in the media business myself," I volunteered. "Chief Medical Editor of Ophthalmology Times. Perhaps you've heard of it."

"No," she replied.

"How do I ensure that all ophthalmologists read my columns?" I asked. "They are extremely busy caring for patients and learning to use electronic medical records, plus [are] bombarded with written materials about new drugs and devices, clinical trials, and practice management."

"You need headlines that are 'grabbers," she advised. She offered the following examples:

- Do you remember when that congressman, whose name rhymes with "cleaner," was caught texting photos of his genitalia to a 21-year-old college student? When first he denied everything and vowed to stay in Congress, the New York Post headline was: "Weiner: I'll Stick it Out."
- **≥** When the Speaker of the House declined to comment on the controversy, CNSNews.com reported: "Boehner Won't Bite on Weiner."
- ▶ When the congressman failed to show up at parades held by constituents, the front page of the New York Post proclaimed: "Hide the Weiner."
- When the congressman stated that he wasn't certain whether the tweeted photos were his. the front page of The Daily showed the man with the headline: "It Could Be My Weiner," The Daily News proclaimed: "Weiner's Pickle," and Jon Stewart led with "The Big Wang Theory."
- When the congressman admitted to ownership of the imaged body parts in question, The Huff-

ington Post led with "Weiner Lets it All Hang Out" and ABC News declared him "The Dork Knight."

- When the president criticized the junior politician ("If it was me, I would resign"), the New York Post's front page proclaimed: "Obama Beats Weiner."
- When he did resign, MetroWeekend New York's front page offered, "He couldn't keep it up." Reporting on the danger of inadvertently distributing personal photos, the Kansas City Star headlined: "The lesson of Weiner's schnitzel: Delete, delete, delete,"
- This year, when rumors began about the disgraced politician "thrusting himself" back into politics and the New York mayoral race, the Drudge Report broke the story with "Will Weiner Rise Again?" and the New York Post's front page offered: "Weiner's Second Coming" and "Erect me Mr. Mayor."
- When the governor of New York commented unfavorably on Weiner's candidacy, saying it would be "shame on us" if he was elected, The Post led with: "Gov takes stiff poke at Weiner" and "Governor Cuomo took a bite out of Anthony Weiner."

"So compare these two possible headlines: 'Congressman Won't Resign' versus 'Weiner: I'll Stick it Out.' Now do you see what I mean by 'grabber'?" she asked.

#### ALL THINGS BEING RELATIVE

"I'm not sure those 'grabbers' will work with ophthalmologists," I responded. "We are a serious lot. Most were at or near the top of their class in high school, college, and medical school. We don't spend our time making jokes, but having intelligent discussions about meaningful use, phototransduction, and bevacizumab."

- "Beva what?" she asked.
- "Never mind," I replied.
- "Well, if what you say is true about them being such intellectuals," she told me, "you'll need a different kind of headline."

In Domell

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Ophthalmology Times is a physician-driven publication that disseminates news and information of00 a clinical, socioeconomic, and political nature in a timely and accurate manner for members of the ophthalmic community.

In partnership with our readers, we will achieve mutual success by:

- Being a forum for ophthalmologists to communicate their clinical knowledge, insights, and discoveries.
- Providing management information that allows ophthalmologists to improve and expand their practices.

Elevating The Quality Of Care In Ophthalmology

Addressing political and socioeconomic issues that may either assist or hinder the ophthalmic community, and reporting those issues and their potential outcomes to our readers.

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# Congressional panel offers plan to eliminate SGR

#### From Staff Reports

WASHINGTON, DC ::

congressional committee wants to reform the Medicare payment system by first repealing the controversial sustainable growth rate (SGR). In recent weeks the House Energy and Commerce Committee released a plan to replace the SGR formula with a system of stable payment updates with a fee-for-service payment option. The committee has reportedly been working on the plan since January 2013.

"The policy would repeal SGR and, in return, replace it with an improved fee-for-service system in which providers—working with the Secretary of Health and Human Services (HHS)—develop quality measures that will lead to better care in a more efficient manner," the committee said in prepared comments.

"Unveiling our committee's draft legislation is an important milestone in our thoughtful, collaborative efforts to repeal SGR. We are working to restore certainty, fiscal sanity, and we will responsibly pay for these reforms," said committee chairman Fred Upton (R-MI).

While the legislation does not specify terms of payments, it does call for HHS to incorporate quality metrics and alternative payment models that reward for quality care.

The draft reflects many of the principles for transitioning to a higher performing Medicare system that the American Medical Association, California Medical Association (CMA), and more than 100 state and specialty medical societies submitted to Congress last fall, officials say.

"While the draft doesn't specify what quality measures would be used, it does say that the measures would be physician developed and Medicare reimbursements would be based on quality scores relative to their peers, improvements in scores from previous years and clinical improvement activities," CMA officials said. "It also states that quality measures would be risk adjusted so that providers are not penalized for treating sicker or more complicated patients."

### **DUA'S LAYER**

( Continued from page 1 )

To define and characterize the novel pre-Descemet's layer in the cornea, Dr. Dua and his colleagues at the University of Nottingham performed a study, currently in press at *Ophthalmology*, in which they included 31 human donor sclerocorneal discs and six controls.

#### BIG BUBBLE TECHNIQUE

Using the big bubble (BB) technique, they injected air into the stroma of donor whole globes (n=4) and sclerocorneal discs (n=21), similar to what is done in the deep anterior lamellar keratoplasty procedure. They then performed the following:

■ Creation of BB, followed by peeling of the Descemet's membrane:

- Peeling off the Descemet's membrane, followed by creation of the bubble; and
- Creation of the BB and continued inflation until the bubble popped to measure popping pressure.

The tissue they obtained from these experiments also underwent histologic examination.
Three types of BB were obtained:

- TYPE 1 a well-circumscribed, central, domeshaped elevation to 8.5-mm diameter (n = 14).
- **TYPE 2** a thin-walled, large BB (maximum: 10.5-mm diameter), which consistently started at the periphery and enlarged centrally (n = 5).
- TYPE 3 a mixed type of bubble (n = 3).

In Type 1 BB, the Descemet's membrane could be peeled off without deflating the BB, indicating the presence of another layer of tissue. In Type 2 BB, this was not possible. Type

( Continues on page 7 : Cornea )

## HEADLINES YOU MIGHT HAVE MISSED

**AS SEEN IN** Ophthalmology Times' weekly eReport. Sign up at http://www.modernmedicine.com/OphthalmologyTimes/enewssignup.

#### EYE DISEASES COST \$139 BILLION A YEAR

VISION-RELATED DISEASES are costing patients, insurance companies, and the U.S. government more than ever. According to a new report commissioned by Prevent Blindness America (PBA) from researchers at the University of Chicago, vision diseases are among the costliest health problems to the U.S. economy. http://bit.ly/11Vy262

## DRY EYE MARKET TO EXPAND GLOBALLY

AS DRY EYE SYNDROME affects more and more patients over the next 10 years, pharmaceutical companies are expecting to expand their clinical products globally to treat the condition, thus tripling the market's global revenue over the next decade.

http://bit.ly/15b0vtX

## PERRIGO ACQUIRES FERA PORTFOLIO

PERRIGO CO. HAS ACQUIRED the ophthalmic portfolio of Fera Pharmaceuticals, a Long Island, NY-based specialty pharmaceutical company, for an upfront payment of \$93 million. Perrigo, a provider of health-care products, purchased the ophthalmic sterile ointment and solution product portfolio from Fera, including nine prescription ANDA products.

http://bit.ly/15b1cn9

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#### **CORNEA**

( Continued from page 6 )

1 BBs could be created even after initial peeling of the Descemet's membrane (n = 5), and this confirmed that the Descemet's membrane was not necessary to create this type of BB.

Popping pressures were 1.45 bar for the Type 1 BB, and 0.6 bar for the Type 2 BB. Histologically confirmed cleavage occurred after the last row of keratocytes. The new layer was found to be acellular, 10.15  $\mu$ m in diameter, and composed of five to eight lamellae of predominantly type-1 collagen bundles arranged in transverse, longitudinal, and oblique directions.

#### FEELING THE IMPACT

According to Dr. Dua, his discovery will immediately have an effect on surgery in the posterior cornea and the gradual understanding of corneal biomechanics and posterior corneal pathologies, including acute hydrops, Descemetocole, and pre-Descemet's dystrophies.

of cleavage in most cases (more than 80% of times), and because it is so tough, it keeps the eye much stronger than it would have been if only Descemet's membrane was left behind or in a PK. Knowledge of this layer will now enable surgeons to understand the operation better and make it safer," he said.

But is he surprised by his discovery?

"I am pleased by my discovery as it explains a few things that were happening during lamellar corneal surgery that we did not previously understand," Dr. Dua said. "It will make the operation safer and may also improve our understanding of some corneal diseases."

#### REACTIONS TO DISCOVERY

Aside from suggesting the need for medical textbooks to be rewritten, the significance of Dr. Dua's discovery of a new corneal layer will take time to become realized.

"It will require, in my opinion, some time to see if others can confirm the existence of this 'new layer' and its potential significance," said Peter J. McDonnell, MD, director of the Wilmer Eye Institute, Johns Hopkins Univer-



### 'I am pleased by my discovery as it explains a few things that were happening during lamellar corneal surgery that we did not previously understand.'

Harminder S. Dua, MD, PhD

Clinically, his discovery will also impact the understanding of several corneal pathologies.

"There are several conditions that affect the back part of the corneal stroma," Dr. Dua said. "The consequences or sequelae of these could relate to this layer and is something that we are currently investigating.

"For example, it is traditionally believed that a sudden water logging of the cornea (acute hydrops) that occurs in keratoconus (dystrophy of the corneal causing progressive ectasia) is due to a break in the Descemet's membrane," he added. "We have hypothesized that this may be due to a break in the Descemet's membrane and the Dua's layer. This not proven, but is something we are investigating."

Surgically, Dr. Dua's discovery may help explain a few inconsistencies as well.

"Thus far, all surgeons thought that they were separating the Descemet's membrane from the stroma in . . . deep anterior lamellar keratoplasty," he said. "We have proved that this is not so, but that this new layer offers the plane

sity School of Medicine, Baltimore, and chief medical editor of *Ophthalmology Times*.

"My view is that this is an interesting and provocative report from a well-respected research group," he said. "My reading of their paper is that this is not a description of a new layer in the sense of how we think of the corneal layers (epithelium, basement membrane, Bowman's layer, etc.), in which the composition is distinct and readily appreciated as such on light and electron microscopy (or even at the slit lamp)."

Rather, this is more the suggestion that a region of the deep stromal layer has a somewhat distinct set of physical and mechanical properties from the rest of the more anterior stroma, he noted.

"So, it will be interesting to see how other means of testing for this confirm or refute the finding and to what degree this might prove to have clinical significance," Dr. McDonnell concluded.

Also weighing in on this new approach is Mark A. Terry, MD, director, Corneal Services,

#### **TAKE-HOME**

▶ The discovery of a new layer in the cornea has many surgical and clinical implications. This layer can support the endothelium in the procedure of endothelial keratoplasty, making the handling of Descemet's membrane transplant safer and technically simpler, according to its discoverer Harminder S. Dua, MD, PhD.

Devers Eye Institute, and professor of clinical ophthalmology, Oregon Health Sciences University, Portland.

"Dr. Dua has taken a new approach to looking at the posterior layers of the cornea and proposes that because the posterior layers of the stroma just anterior to Descemet's membrane react differently to our surgical maneuvers than say, the mid stroma, that this property qualifies this layer as separate anatomical entity," Dr. Terry said.

This concept of a new layer is seen by some as intellectually "splitting hairs" of terminology, whereas others see it as legitimately "splitting cornea," he said.

"Dr. Dua's concept is not without precedent, as Dr. Bowman also recognized the unique qualities of the most anterior layer of the cornea (which bears his name) nearly a century ago," Dr. Terry concluded. "I applaud the fresh approach to corneal anatomy that Dr. Dua has taken, and I look forward to further documentation of the unique benefits of this layer in the treatment of our patients."



Ophthalmologists are tweeting about this discovery. Follow us for updates and other ophthalmic news @OphthTimes

**Isaac Porter, MD** @eyePorter New part of the eye - #Dua's layer discovered in the #cornea! Video info in #AStateofSight - http://youtu.be/BYUsV94IIhw

ISRS, partner of AAO @ISRS\_AAO Human corneal anatomy redefined: A novel pre-Descemet's layer (Dua's layer) http://www.aaojournal.org/article/S0161-6420(13)00020-1/abstract#.Ubo-CsLAM\_I.twitter

**Brandon Lujan, MD** @OCTMD Dua's layer between corneal stroma and Descemet's...new layer, new anatomy! http://huff.to/19q5bzt

#### HARMINDER S. DUA, MD, PHD

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

## Why cultural competency in medical care matters

One glaucoma specialist explains importance of delivering culturally competent care

By Cheryl Guttman Krader; Reviewed by Terri Pickering, MD

ultural competency in medi-

cal care matters because it im-

#### TAKE-HOME

Cultural competency is defined as the application of cultural knowledge and interpersonal and clinical skills to enhance effectiveness in managing patient care. It's also the law.

SAN FRANCISCO ::

proves outcomes, is imperative because of demographic shifts, and is the law.

Terri Pickering, MD, in private practice at the Glaucoma Center of San Francisco, defined cultural competency as the application of cultural knowledge and interpersonal and clinical skills to enhance effectiveness in managing patient care.

"Cultural competency does not mean acquiring complete understanding of each ethnic, religious, or linguistic culture," Dr. Pickering said. "Rather, as it applies to the individual practitioner, the goals of cultural competency are to understand that patients of diverse cultures may have diverse health beliefs and to realize there is more than one way to accomplish health goals."

Statistics on the increasing diversity of the U.S. population and high prevalence of non-English-speaking residents support the need for cultural competency in medical care. Additionally, there is a legal mandate for it based on the Supreme Court's interpretation of Title VI, the Civil Rights Act.

"The Supreme Court determined that discrimination based on language is equivalent to discrimination based on national origin," Dr. Pickering said. "Therefore, any health-care provider who receives federal funding has to make a good faith effort to communicate effectively with all patients or risk losing funding.

"This ruling has implications for licensure, as well as for accreditation for hospitals and

graduate medical programs," she said. "Additionally, certain states have laws requiring physicians to get continuing medical education in language access and cultural competency."

#### BASIC CONSIDERATIONS

There are certain issues and missteps clinicians should be aware of when dealing with ethnic patients in general and some that are specific to certain subgroups. A common mistake made in the situation where a language barrier exists is to underestimate the patient's level of education. Consequences of the incorrect assumption include provision of abbreviated or incomplete patient education that in turn may lead the patient to develop negative perceptions of the health-care system and noncompliance with treatment recommendations.

Other common cultural competency errors are the belief that all people of the same culture are alike, the presumption that cultural differences are superficial, the habit of speaking in a condescending or correcting manner, and the use of children as translators.

Discussing some practices and ideas applicable to specific cultures, Dr. Pickering noted that in some Asian American families, the first born son is often considered the most important family member and may act as the family representative. Another issue to keep in mind that may have relevance to other ethnic groups as well is the importance assigned to herbal medicine.

"Be sure to ask patients whether they are using herbal medicines, and be aware that patients may believe herbal medicines work instantaneously," said Pickering said. "Therefore, they may have the same expectations for Western medicine."

She added that a useful strategy for discussing herbal medicine is to acknowledge respect for it, while noting that it has not been proven to be effective for the patient's disease.

Considerations for interacting with Hispanic American patients include awareness that for

some families, elders are respected, medical decisions are often made as a family unit, and folk medicine ("curanderismo") may play a role. Building trust and friendship is especially important, Dr. Pickering said.

With regard to Muslim Americans, a survey investigating glaucoma medication use during Ramadan showing that only 34% of Muslim American patients would use their glaucoma medications during fasting hours, while 11% stopped treatment completely.

"These findings emphasize the importance of tailoring treatment to patients' expectations and religious beliefs in order to improve compliance," Dr. Pickering said. "Try not to criticize cultural beliefs and instead, work within the patient's belief system to improve compliance with your medical plan."

#### BUILDING COMPETENCY

Dr. Pickering reiterated the importance of developing cultural competency as current conditions represent a perfect storm for promoting health disparities.

"The disease burden is increasing as the population ages and so is the number of patients with low English proficiency," Dr. Pickering said. "Moreover, we are still reeling from the economic recession, and inequalities in income and education are increasing.

"It is important for practitioners to take personal responsibility and be aware of their attitudes and generalizations," she said. "When talking to patients, remember to try to slow down, keeping in mind that 40% to 80% of what we tell patients is forgotten immediately and half of what they do remember is remembered incorrectly."

#### TERRI PICKERING, MD

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Dr. Pickering has no financial interest relevant to the subject matter. This article was adapted from Dr. Pickering's presentation during the 17th annual Glaucoma Symposium presented by the Glaucoma Research and Education Group at Glaucoma 360°, in partnership with the Glaucoma Research Foundation and Ophthalmology Times.



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\*JA. Donnelly, EM. Miglino, Jindra LF. Selective Laser Trabeculoplasty as Primary Therapy in Patients With Glaucoma Ten-Year Experience. Poster presented at: American Society of Cataract and Refractive Surgeons (ASCRS); 2013, Se Francisco.

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## INLAY AN OPTION FOR PRESBYOPIA AT CORNEAL LEVEL

Benefits of small-aperture implant remain stable during follow-up of 5 years

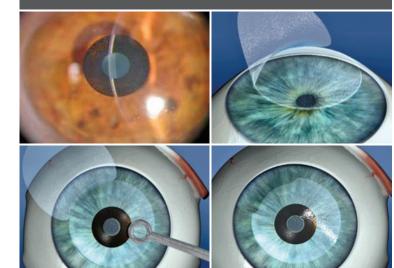
By Cheryl Guttman Krader; Reviewed by Günther Grabner, MD

SAN FRANCISCO ::



utcomes for a cohort of patients with presbyopia with a small-aperture corneal inlay implanted find the device is well tolerated and patient satisfaction is high.

## Surgical Procedure (emmetropes and sim-LASIK)



- ▶ Non-dominant eye only
  - ▶ Topical anesthesia
- ▶ Flap created (170 to 200 µm depth)
- ▶ Inlay insertion and centration → Close flap
- ▶ < 20 minutes start to finish

#### take-home

▶ A small-aperture corneal inlay (Kamra, AcuFocus) has provided safe, effective, and stable improvement of near and intermediate vision in emmetropic presbyopes followed for 5 years.

Implantation of the corneal inlay (Kamra, AcuFocus) improves near and intermediate vision in presbyopic emmetropes, while having minimal effect on distance vision, and its benefits remain stable during follow-up of 5 years.

"The small-aperture corneal inlay is an effective and safe treatment for presbyopia, and patient satisfaction with the inlay is high," said Günther Grabner, MD, at the annual meeting of the American Society of Cataract and Refractive Surgery.

"The inlay is well-tolerated, but can be removed if desired, and I believe it is an excellent option for treating



presbyopia at the corneal level," said Dr. Grabner, professor of ophthalmology and director, Paracelsus Medical University Eye Clinic, Salzburg, Austria.

He presented outcomes for the first cohort of patients with the small-aperture corneal inlay he implanted beginning in September 2006. The inlay available at that time measured 10 µm in thickness

and contained 1,600 microperforations to allow nutrient flow. The current generation of the inlay is only 5- $\mu m$  thick and features 8,400 microperforations.

The series included 32 patients, all of whom had complete follow-up to 4 years, and 17 of whom had reached the 5-year visit. The implantations were done in the nondominant eye under a femtosecond-created flap at an intended

depth of 170  $\mu m$  using topical anesthesia. Mean age of the patients at time of implantation was 51 years.

#### CAREFULLY SELECTED POPULATION

"This was a very carefully selected population for enrollment in the multicenter FDA study, and we screened about 300 patients to identify these 32 individuals who met the strict inclusion criteria," Dr. Grabner said.

Data from follow-up at 4 years for the eye with the inlay showed near uncorrected visual acuity (UCVA) improved from J7/8 at baseline to J2; intermediate UCVA improved from 20/40 preoperatively to 20/25. The patients lost about one line on average for distance UCVA, from 20/16 to 20/20. No eye had distance UCVA worse than 20/32, and binocular distance UCVA stayed unchanged at 20/16. Mean spherical equivalent changed from 0.19 D preoperatively to 0.03 D.

"For the patients seen at 5 years, the results in the inlay eye remain stable, but we can see some age-related loss in near and intermediate UCVA in the fellow eye," Dr. Grabner said.

He added that near vision function was also evaluated using the Salzburg Reading Desk, and the results showed improvements in reading acuity and speed with a decrease in preferred reading distance.

"With this test we have objective evidence of improved near vision function," Dr. Grabner said.

Continues on page 13: Small aperture

## The moment the pulse rate in refractive surgery is defined:

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## Special Report ) ASCRS REFRACTIVE NEWS

## Femtosecond laser procedure for spherical myopia yields solid safety

Accuracy of correction very good, within 'ballpark' of what is achieved with conventional LASIK

By Fred Gebhart; Reviewed by Jon Dishler, MD

SAN FRANCISCO ::

INITIAL FDA CLINICAL trial outcomes of a femtosecond laser system (VisuMax, Carl Zeiss Meditec) to correct spherical myopia showed solid clinical and safety results.

That was the overall assessment by Jon Dishler, MD, Dishler Laser Institute, Denver, and medical monitor and one of five principal investigators for the VisuMax Myopia Study.

#### ADVANCE FOR MYOPIC CORRECTION

"My overall impression is that this could represent a significant advance in the surgical correction of nearsightedness," said Dr. Dishler at the annual meeting of the American Society of Cataract and Refractive Surgery. "It allows for a very precise correction without, to all appearances, any requirement for a nomogram. Visual recoveries have thus far been

very rapid."



Dr. Dishler reported safety outcomes from the initial FDA clinical trial results for the ReLEx smile procedure for spherical myopia correction. The trial was conducted under an investigational device exemption for the femtosecond

laser platform. The system has been used for several years in Europe, Asia, and other regions, Dr. Dishler said, but is still under investigation in the United States.

The procedure involves cutting precisely shaped lenticule from the stroma and removing it through a small incision. Unlike LASIK, no flap is required and tissue is physically removed with no ablation.

The FDA granted permission to study 100 eyes, of which 99 have been operated on. The manufacturer is currently collecting and processing data to support a request to study the remaining 260 eyes and follow the results for at least 1 year.

#### 79 EYES INCLUDED

Dr. Dishler's initial report covered a total of 79 eyes in 79 patients. The approved treatment

sphere range was 1 to 8 D with a cylinder of -0.5 D or less and MRSE of -8.25 D or less. This was a sphere-only study in single eyes with a change in MRSE of 0.5 D or less in the prior year in the eye to be treated. Patients were at least 22 years old and the optical zone was 6 to 6.5 mm.

Most of the patients, 60.8%, were fe-

male and the eyes were roughly balanced, 54.4% right and 45.6% left. The mean age was 35 years, the mean MRSE was -4.33 D, the mean sphere -4.25 D, and the mean cylinder -0.15 D.

"The results seem very promising," he said. "The accuracy of correction is very good and is certainly within the ballpark of what is achieved with conventional LASIK-type procedures."

The mean refraction 1 month postoperatively was MRSE -0.11 D, sphere 0 D, and cylinder -0.22

D. The mean results 3 months postoperatively were similar, MRSE -0.08 D, sphere 0.03 D, and cylinder -0.22 D. Most eyes, 98%, were within 0.5 D of spherical equivalent goal at 3 months and 100% of eyes were 20/40 or better. Most eyes, 98%, 20/25 or better and about 88% were 20/20 or better at 3 months.

#### SAFETY OUTCOMES

Safety results were very good, Dr. Dishler noted. At 3 months postoperatively, no eyes had lost two or more lines of best spectacle-corrected visual acuity (BSCVA), fewer than 5% had lost one line, more than 50% were unchanged, about one-third had gained one line, and a handful of patients had gained two or more lines.

Intraoperative events were few and all resolved, he continued. A difficult lenticule removal resulted in a single radial cap tear. The tear was treated medically and resolved without sequelae. Suction was lost during the cap cut on one eye. The eye was re-docked and the procedure was completed successfully.

There were three cases of diffuse lamel-

lar keratitis, all stage 2 or less. One case was seen 1 week postoperatively and was medically treated without sequelae. The patient had uncorrected visual acuity of 20/16 at 1 month and MRSE was plano.

Two cases were case was seen at 1 day postoperatively. Both were treated medically and both resolved without sequelae. Best uncorrected

> visual acuity at 1 week was 20/25 and BSCVA was 20/12.5 for both.

> A single patient had transient light sensitivity syndrome at 2 months. It was treated medically and resolved without sequelae. Best uncorrected visual acuity at 3 months was 20/25, MRSE was -0.25, and BSCVA was 20/16.

> "There are no ablation issues, such as drying in the cornea or hydration changes," Dr. Dishler said. "This is a very different principle from LASIK. We are cutting and removing a specific shape based

on the Munnerlyn-type formula, so there is no reason it shouldn't be as accurate at higher amounts of nearsightedness as it is at lesser

"Excimer lasers seem to be less accurate in working with larger amounts of correction," he added. "It is a new paradigm for the correction of nearsightedness which may, for certain patients, be preferable because the treatment is not subject to the amount of correction needed and it can be done using a small incision with all the obvious benefits of not requiring a flap." ■



take-home

▶ A femtosecond laser

platform (VisuMax,

**Carl Zeiss Meditec)** 

results for spherical

outcomes 3 months

postoperatively.

showed excellent safety

myopia correction with

promising effectiveness

What are your thoughts regarding the ReLEx smile femtosecond laser technique? Visit Facebook.com/ OphthalmologyTimes to weigh in.

#### JON DISHLER, MD

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Dr. Dishler is a paid consultant for Carl Zeiss Meditec and a primary investigator for the VisuMax Myopia Study.

#### Special Report

## **ASCRS REFRACTIVE NEWS**

## Intraoperative wavefront aberrometry optimizes refractive outcomes

Analysis shows value for improving predictability, especially in long and short eyes

By Cheryl Guttman Krader; Reviewed by Timothy N. Peters, MD

SAN FRANCISCO ::

**USE OF INTRAOPERATIVE** wavefront aberrometry (ORA System, WaveTec Vision) improves refractive outcomes in cataract surgery. Its use is of particular benefit when operating on shorter and longer eyes for which accurate IOL power calculation is more challenging, according to the results of a retrospective study presented by Timothy N. Peters, MD.

"The modern formulas that we use to calculate IOL power perform consistently in providing reasonable outcomes for eyes with 'normal' axial length," said Dr. Peters, private practice, Portsmouth, NH. "However, they have poorer reliability for accurately determining IOL power in eyes at the ends of the axial length spectrum.

"Analyses based on a large population of eyes operated on with intraoperative aberrometry indicate that this technology adds value in all cases and especially for the non-average eye," said Dr. Peters at the annual meeting of the

American Society of Cataract and Refractive Surgery. "The intraoperative aphakic reading generally confirms the lens power I have chosen preoperatively based on standard calculations, but its use has led me to change the plan more than half the time in longer and shorter eyes. Postoperative analyses show that the change was consistently in the right direction."

The effect of intraoperative wavefront aberrometry on refractive outcome predictability was investigated using data from 2,200 eyes in the manufacturer's database. Results were determined for the entire cohort and for subgroups of short (<22.5 mm) and long eyes (>26.5 mm).

For the entire population, the overall mean absolute value prediction error (MAVPE) was 0.33  $\pm$  0.29 D. Spherical equivalent (SE) in about half of the eyes was within 0.25 D of the intended preoperative predicted SE, 79% were  $\pm$  0.50 D,

93% were  $\pm$  0.75 D, and 97% were  $\pm$  1 D. Prediction errors and standard deviations of the means were just slightly higher in both subgroups of eyes with extreme axial lengths. The MAVPE was 0.39  $\pm$  0.35 D for short eyes and 0.36  $\pm$  0.32 D for the long eyes; in both groups ~75% were within 0.50 D of the formula predicted SE.

"Prediction errors should be further reduced by software updates that optimize lens coefficients by axial length group," Dr. Peters said. "In fact, my personal MAVPE for long and short eyes operated on without ORA was 0.6 D, but with a personalization of my ORA outcomes, my MAVPE in these eyes is just 0.3 D."

#### TIMOTHY N. PETERS, MD

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Dr. Peters has no relevant financial interest to disclose.

#### **SMALL APERTURE**

( Continued from page 10 )

Ten patients completed a satisfaction questionnaire at 5 years. When asked if they would have the surgery again, nine responded "yes" and one said "maybe." There were no reports of significant night symptoms. Near vision quality was rated on a scale of 0 (bad) to 7 (very good), and the average score was 5.7.

#### MINIMAL COMPLICATIONS

Complications in this first series of patients included one case of epithelial ingrowth requiring repeated flap lift, but successfully treated. There were two cases of decentered inlays associated with decreased distance UCVA, and one patient developed a hyperopic shift (+2.5 D) associated with inadvertent superficial placement of the inlay.

The decentered inlays were repositioned at 7 months after initial surgery, vision improved within 1 month, and at 30 months, the patients achieved J2 near UCVA and 20/20 distance

UCVA. The superficially placed inlay was removed after 4 years.

"The inlay should be centered over the estimated visual axis and within about 300  $\mu$ m of target to achieve optimum visual acuity," Dr. Grabner said. "Recentration is possible, but it is best done early.

"In the patient with a hyperopic shift, the inlay was placed at 130  $\mu m$  instead of the intended depth of 170  $\mu m$ ," he added. "The eye developed marked topographic changes that we think were the result of epithelial cytokines stimulating the keratocytes and leading to some minimal haze."

## WELL TOLERATED DURING LONG-TERM FOLLOW-UP

The inlay continues to be well tolerated during long-term follow-up. No irritation or inflammatory reactions have been observed, and in testing at 12 months, binocular photopic and mesopic contrast sensitivity were within normal limits.

The inlay does not interfere with examination or treatment of the anterior chamber angle or posterior segment, Dr. Grabner noted.

"I was concerned about being able to see the macula in these older patients who may be developing age-related macular degeneration or diabetic macular edema," he said. "However, optical coherence tomography [imaging] of the retina is not a problem and one can also do a fundus exam without pupil dilation."

In addition to modifications of the inlay itself, there have been changes in the inlay placement procedure and expansion of potential candidates. Currently the inlay can also be placed into a femtosecond laser-created pocket, and using that approach, it can be simultaneously combined with LASIK in patients needing ametropic correction. The inlay can also be placed into a pocket to correct presbyopia in postLASIK or pseudophakic eyes. Dr. Grabner added that some therapeutic applications may emerge in the future with the introduction of a smaller-aperture inlay.

#### GÜNTHER GRABNER, MD

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Dr. Grabner has received travel grants and speakers fees from AcuFocus.

## Special Report ) ASCRS REFRACTIVE NEWS

## Flap creation put to the test of femtosecond laser platform

Observations revealed that flap lifts were uniform; stromal beds were smooth, regular

By Cheryl Guttman Krader; Reviewed by Jeffrey Whitman, MD

SAN FRANCISCO ::

A NEW FEMTOSECOND laser system (Victus, Bausch + Lomb) is a reliable tool for creating high-quality LASIK flaps of intended dimensions.

And, it performs similarly to time-tested



technology, said Dr. Whitman, private practice, Dallas. However, the new femtosecond laser platform is one of only two systems in the United States that can also be used in cataract surgery.

"When new technology becomes available, it is im-

portant to understand how it compares with existing modalities," said Dr. Whitman, at the annual meeting of the American Society of Cataract and Refractive Surgery.

"For LASIK flap creation, we have found that [this] . . . femtosecond laser performs at least as well as the current gold standard, but it brings an added advantage of greater ver-

CREATING THE CORNEAL FLAP

satility," he said. "The ability to use a single platform for corneal and cataract surgery applications is an attractive feature for a practice considering the purchase of femtosecond laser technology."

#### SERIES OF 10 EYES

Dr. Whitman assessed the performance of the new femtosecond laser as a flap-cutting tool in a series of 10 eyes undergoing LASIK for myopic or hyperopic correction. Ease of flap lifting and stromal bed quality was assessed intraoperatively, and the eyes underwent anterior segment optical coherence tomography imaging at 1 month postoperatively for measurements of flap thickness and diameter. Four flap thickness measurements were made in each eye and the data were used to calculate the average flap thickness per eye.

The intraoperative observations revealed that flap lifts were uniform with no central opaque bubble layer issues and stromal beds were smooth and regular.

The flap measurements showed excellent predictability. Targeted flap thickness for the 10 eyes ranged from 110 to 150  $\mu m$ . For the individual eyes, deviation between the intended target and achieved average flap thickness ranged from -0.6 to 2.8 μm with an average of 0.48 µm. Standard deviation for the four flap thickness measurements in each eye was ≤3.6 μm.

Intended flap diameters were 8.7 or 8.8 mm, and the achieved diameter matched the target in 6 eyes and deviated by only 0.1 mm in the other 4 eyes.

#### COMPARING FLAP THICKNESS

Dr. Whitman also compared the flap thickness outcomes using this particular femtosecond laser with those he achieved in a group of 10 eyes undergoing flap creation using a 60-kHz femtosecond laser (IntraLase, Ab-



The flap bed (above) was created by the femtosecond laser platform. The study found that LASIK flaps performed by the laser deviated minimally from targets for thickness and diameter.

(Photo courtesy of Bausch + Lomb)

bott Medical Optics). The comparator group eyes were matched by intended flap thick-

> ness, and across the 10 eyes, the deviation between the intended and achieved average flap thickness ranged from -3.6 to 1.2 μm with an average of -0.88 μm. The standard deviation for the four flap thickness measurements in each eye was ≤5.2 μm.

> Intended diameters for the IntraLase-created flaps ranged from 8.5 mm to 9 mm. The achieved diameter matched the target in 4 eyes and varied by just 0.1 μm in the other 6 eyes.

"Both of these femtosecond lasers provide excellent results in creating flaps with the targeted diameter and thickness," Dr. Whitman said. "The outcomes with the new Victus are as good as if not better than those achieved with the IntraLase." ■

#### take-home

▶ A study assessing the performance of a new femtosecond laser platform (Victus, Bausch + Lomb) showed it created LASIK flaps that deviated minimally from targets for thickness and diameter.

#### see how the femtosecond laser (Victus, Bausch + Lomb) creates LASIK flaps that are uniform with no central opaque bubble layers and smooth stromal beds. (Video courtesy of Bausch + Lomb)

**VIDEO** Go to http://bit.ly/12z9nZl to

f Will femtosecond laser platforms have a place in your practice for creating LASIK flaps? Visit Facebook.com/OphthalmologyTimes and share your thoughts regarding this new technology.

#### JEFFREY WHITMAN, MD

F: docw56@shcglobal.net Dr. Whitman is a consultant to Bausch + Lomb.





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### Special Report ) ASCRS REFRACTIVE NEWS

## **All-femtosecond laser refractive** correction procedure promising

Early data suggest small incision lenticule extraction as effective for myopia as LASIK

**By Fred Gebhart;** Reviewed by John F. Doane, MD

SAN FRANCISCO ::

THE QUEST FOR THE ideal refractive vision correction procedure is likely to include such attributes as accuracy, effectiveness, stability, safety, and the ability to provide quality outcomes.

The ideal procedure would be reversible or adjustable, involve minimal wound healing,



provide immediate and final refractive outcomes, and meet patient expectations. And it must be better than glasses or contact lenses.

"No procedure is perfect on all those counts," said John F. Doane, MD, in private practice at Discover Vision Cen-

ters, Kansas City, MO, and assistant clinical professor, Kansas University Medical Center, Kansas City, KS.

"We are always looking for the next best things," said Dr. Doane at the annual meeting of the American Society of Cataract and Refractive Surgery. "The next best thing in laser vision correction may be all-femtosecond laser procedures."

Dr. Doane presented early results from the first FDA trials of a certain femtosecond laser platform (VisuMax, Carl Zeiss Meditec) to treat uncomplicated myopia. Though the femtosecond laser is in use outside the United States, this trial was conducted under an investigational device exemption. The five study sites included Denver (Jon Dishler, MD); Kansas City (John Doane, MD); Madison, WI (John Vukich, MD); Miami (Wil-

liam Culbertson, MD, Sonia Yoo, MD), and Sioux Falls, IA (Vance Thompson, MD).

#### HOW IT'S DONE

Unlike traditional LASIK correction, which ablates corneal tissue, femtosecond laser refractive vision correction carves a precisely formed lenticule from the stroma. When the lenticule is removed, the corneal radius of curvature flattens to the desired correction. The actual procedure is a femto lamellar keratomileusis, more commonly referred to as SMILE, for small incision lenticule extraction. The surgeon cuts a 90° flap into the corneal surface rather than the familiar 270° LASIK flap to access the stroma. The next step is to process the posterior side of the lenticule, then the anterior side. The lenticule is removed, and the correction is complete.

"Thin sections have been tried in the past, but not with the precision of a femtosecond laser," Dr. Doane said. "This is a kind of backto-the-future keratomileusis technique, such as automated lamellar keratoplasty. We did remove a lenticule of tissue, but we simply didn't have the precision with two passes of a microkeratome that we have with a femtosecond laser."

#### A D VA N TA GES OF PROCEDURE

take-home

**▶** Early FDA data for

a femtosecond laser

platform (VisuMax,

Carl Zeiss Meditec)

show positive results

for corneal refractive

uncomplicated myopia.

surgery to treat

Reliable extraction of a precise lenticule is only one of the advantages of SMILE over LASIK,

> he continued. There is no ablation, no plume, and no hydration concerns. The postoperative cornea is slightly prolate. There is no or minimal induction of higherorder aberrations and the potential for aberration-neutral refractive treatments.

> This initial prospective trial included 64 eyes in 64 patients. The mean preoperative spherical equivalent was -4.46 D. The mean sphere was -4.39 D and the mean cylinder was -0.14 D. Patients were aged 22

to 59 years (the mean age was 35 years) and had no prior ocular surgery or ocular pathologic diagnoses.

"What we really wanted to see was if this procedure is, in fact, as refractively predictable as LASIK, as stable, as safe, and as effective in vision correction," Dr. Doane said. "We hit all of our targets and are very excited about these outcomes."

The mean manifest refraction spherical equivalent 7 days postoperatively was -0.06 D (from -0.38 to +0.25 D) and the same at 3 months. Predictability was excellent, with an R2 at 7 days of 0.9901 and 0.9903 at 3 months. About 95% of eyes were within 0.5 D of the target correction at 7 days and at 3 months.

#### VISUAL ACUITY DETAILS

Best uncorrected visual acuity was 20/40 or better for all eyes from day 1 through 3 months. At 3 months, about 95% of eyes were 20/25 or better and 90% were 20/20 or better. Approximately 55% of eyes had unchanged best-corrected visual acuity at 3 months, nearly 30% had gained one line, 5% had gained two lines, and a few eyes had gained two or more lines. A few eyes lost one line and no eyes lost two or more lines at 3 months.

By 1 month postoperatively, all eyes were 20/25 or better, more than 90% were 20/20 or better, half were 20/16 or better, and nearly 10% were 20/12.5 or better.

Patients were more comfortable following SMILE compared with LASIK, Dr. Doane noted. There were fewer reports of dry eye or other discomfort.

"SMILE provides what current techniques don't-extremely fast visual recovery with preservation of most corneal nerves," he said. "We anticipate more structural and mechanical stability—what we see with a 270° LASIK flap—while maintaining excellent refractive predictability, efficacy, stability, and quality of vision." ■



How do you see femtosecond lasers playing out in refractive surgery? Visit Facebook.com/OphthalmologyTimes and provide your perspective.

#### JOHN F. DOANE, MD

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Dr. Doane reported financial interests in Bausch + Lomb, Calhoun Vision, and Carl Zeiss Meditec.

#### Special Report

## **ASCRS REFRACTIVE NEWS**

## Physicians as patients like LASIK

Surgeon surveys long-term patient satisfaction of laser vision correction among physicians

By Fred Gebhart; Reviewed by Ronald R. Krueger, MD, MSE

SAN FRANCISCO ::

**LASIK RESULTS ARE** good. Studies using current LASIK platforms routinely show 20/20 in excess of 80% of eyes and a high degree of satisfaction in 95% of patients. With about 1 million eyes treated annually, LASIK results are so good the U.S. military has accepted the procedure for combat pilots.

But what about physicians?

"Physicians are skeptical, they are cautious, and they have an extraordinarily high demand for visual function," said Ronald R. Krueger, MD, MSE, medical director, Department of Re-



Dr. Krueger

fractive Surgery, Cole Eye Institute, Cleveland Clinic, and professor of ophthalmology, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland. "So, how well do they do with LASIK? And how satisfied are they with surgery?"

The answer, it turns out, is very well and very highly satisfied.

Dr. Krueger presented the results of longterm patient satisfaction of laser vision correction among physicians at the annual meeting

## take-home

▶ Physicians expressed high rates of satisfaction with laser vision correction up to 10 years following surgery. of the American Society of Cataract and Refractive Surgery. He surveyed all physicians he treated using laser vision correction at The Cleveland Clinic from 2000 to 2011. This was not a study of a particular platform or technique, but a broad sur-

vey that included a variety of platforms, profiles, and keratomes over more than a decade of real-world surgery in a highly demanding population.

Dr. Krueger and his research team were able to identify retrospectively 226 physicians he had treated over that time. He said that while the Cleveland Clinic employs more than 3,000 physicians and the Cole Eye Institute is not the sole venue in which these physicians seek out their treatment, the Cleveland Clinic health plan offers benefits and incentives for employ-

Continues on page 18 : Survey

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## Special Report ) ASCRS REFRACTIVE NEWS

#### **SURVEY**

( Continued from page 17 )

ees using in-house facilities, such as the Cole Eye Institute.

#### PHYSICIANS BECOME PATIENTS

The 226 patients represented 429 eyes. A chart review showed that a majority of the patients, 63%, were male, and the median age was 38 years. There were nine eyes with hyperopia in the group, with a mean refractive error before surgery of +1.25 D. The 420 eyes with myopia had a mean spherical equivalent refractive error of -4.5 D, with a range from 0 to -11.50 D. Most of the eyes, 89%, had LASIK and 11% had PRK. The mean follow-up period was 20 months.

The visual outcomes were good, Dr. Krueger said, with 78% having uncorrected visual acuity of 20/20 or better after surgery and 97% 20/40 or better. Eighty percent of eyes were within 0.5 D of target and 96% were within 1 D of target.

A majority of patients, 86%, had no change in best-corrected visual acuity (BCVA) following surgery. Just 1% of eyes lost two lines of BCVA and 13% lost one line of BCVA.

"[Compiled] over 10 years, these results are not with a single platform or today's latest platform," Dr. Krueger said. "These results include the older lasers we used in 2000 as well as our newer modifications. It is across all platforms, and hence gives a good idea of how well we did with laser vision correction overall."

#### PATIENT SATISFACTION

Beyond these results, he also wanted to assess physician satisfaction over this time. His researchers mailed a physician-specific survey to all 226 physician-patients and received 132 responses, about 58%. Nearly all of the respondents, 97%, completed the full survey. Of the respondents, 28% were surgeons, 43% were non-surgeons who performed procedures, and 29% did not perform either procedures or surgeries. Respondents included cardiac surgeons, neurosurgeons, ophthalmologists, and a variety of other specialties, as well as generalist practitioners.

Physician satisfaction largely mirrored satisfaction in the general population. More than two-thirds of physicians, 70.3%, reported being very satisfied with their surgery and another 25% were satisfied. That agrees with general population satisfaction rates. Nearly all physicians, 96%, said they would repeat the surgery based on their experience and knowledge of their outcomes.

Physicians' assessment of their own visual outcomes was equally positive. Most respondents, 84.3%, said the quality of their corrected vision was better or much better than their BCVA before surgery. None said the postsurgical vision was notably worse, 3.1% said it was slightly worse, and 12.5% said it was about the same after surgery as it was before surgery.

A total of 21% of physicians said they needed spectacle correction after surgery. Of this group, 67.9% said they needed correction for reading and near work, 39.3% while driving at night, and 25% while driving during rain. Smaller percentages reported needing correction doing their job (21.4%), working on a computer (14.3%), watching television or movies (17.9%), and for social life or while driving with glare from oncoming headlights (10.7% each).

Most physicians, 90.6%, said the quality of their vision post surgery has not limited their work as a physician, while 3.9% said only a little bit, 1.6% said a moderate amount, and 3.9% said they didn't know. Overall, 39% said improved vision quality has made performing procedures much easier or better. Another 59.4% reported no difference in performing procedures after surgery.

"Overall, refractive surgery in physicians seems to be successful," Dr. Krueger said. "That is what I thought we would see subjectively. But it is good to know that this demanding physician audience is generally satisfied with their laser vision correction." ■

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Dr. Krueger reported no financial conflicts of interest that could affect this study, except for his employment at the Cleveland Clinic as an ophthalmologist and refractive surgeon.

## Device offers new surface ablation concept

From Staff Reports

SAN FRANCISCO ::

#### WHAT IS THE MOST EFFECTIVE

procedure to remove corneal epithelium? Single metallic blade, hockey-stick knife, or excimer laser? The initial report on the first 25 patients treated with a new, double-blade device was presented by Matsliah Taieb, MD, private practice ophthalmologist in Rishon Le-Zion, Israel.

"This is a new concept in corneal epithelial ablation, epi-Bowman keratectomy (EBK)," said Dr. Taieb, also one of the developers of the device. "The goal is to remove all epithelium and collect it without debris and preserve the integrity of Bowman's layer."

The new device (dubbed Epi Clear) has a single-use, bowl-shaped, double-bladed knife that sweeps away the corneal epithelium and

collects the debris to avoid scratching Bowman's layer or causing other corneal damage. The disposable blade is mounted from a cartridge onto an ergonomic titanium handle that resembles a plastic hockey-stick knife. The surgeon uses a sweeping motion to remove epithelium and the blade design makes it impossible to cut into Bowman's layer.

A prospective trial compared EBK with classic PRK, partial epithelial excimer ablation completed with a hockey-stick knife. Everything except the actual instrument used was the same, Dr. Taieb noted.

Patients were asked to use the anesthetic drops only for extreme pain and to record the number of daily uses. Drops were to be used no more than five times daily. Patients were

followed for 6 months and the procedure was evaluated for duration and efficacy, debris left in the epithelial ablation zone, regularity of the ablation zone border, and the integrity of Bowman's layer and stroma.

"We found we need only a dry cornea to perform a very successful EBK," Dr. Taieb said. "You quickly get a smooth, beautiful lens, in about 10 seconds. With this device, it is impossible to scratch the lens."

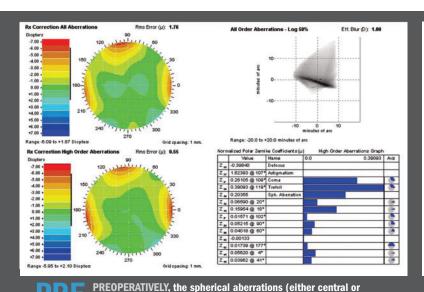
Healing is significant faster with the new device compared with PRK, he continued. The rate of complete closure of the epithelium within 48 hours was more than twice as high in the EBK group compared with the PRK group and both groups had similar uncorrected visual acuity after the epithelium was closed.

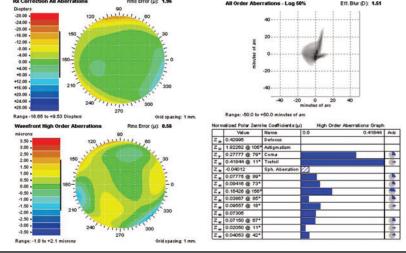
### Special Report ) ASCRS REFRACTIVE NEWS

## **Long-term follow-up outcomes** favorable for bifocal corneal inlay

Results also underscore need for potential candidates to understand minimal monovision

By Cheryl Guttman Krader; Reviewed by Gustavo E. Tamayo, MD





POSTOPERATIVELY, the central spherical aberration Z40 is negative, whereas the peripheral is still positive (Z60). These results are responsible for the increase in the depth of focus and therefore the improvement of presbyopia.

peripheral) are positive. (Figures courtesy of Gustavo E. Tamayo, MD)

SAN FRANCISCO ::

**RESULTS FROM LONG-**term followup support the use of a bifocal corneal inlay (Flexivue Microlens, Presbia) for presbyopia

> correction in emmetropic patients.



Bogota, Colombia.

The outcomes were reported by Gustavo E. Tamayo, MD at the annual meeting of the American Society of Cataract and Refractive Surgery. He is director, Bogota Laser Refractive Institute,

The inlay measures 3.2 mm in diameter and has an edge thickness of only 15 µm. Featur-

ing a peripheral refractive zone and a central neutral zone, the lens is placed in the nondominant eye using a proprietary insertion tool into a femtosecond laser-created pocket at 300 µm stromal depth.

Outcomes for a series of 12 patients followed for a mean of 23 months (range, 18 to 36) were reported. The patients had a mean age of 52 years (range, 47 to 59). Preoperatively, all eyes with the implant had near uncorrected visual acuity (UCVA) 20/400 or worse and

ity (BCVA) of 20/20 or better.

#### UCVA STABILITY

Stability of near UCVA was achieved by 4 months, and at last follow-up, monocular near UCVA was 20/60 or better in all eyes, 20/40 or better in 10 eyes (83%) and 20/30 or better in 9 (75%).

distance UCVA and best-corrected visual acu-

The procedure resulted in loss of distance UCVA in all eyes with the implant, with the mean decreasing to 20/60 initially. However, the eyes with the implant began to recover distance UCVA at 4 months, and at last follow-up, distance UCVA was 20/40 or better in 10 of the eyes with the implant (83%), and unchanged

> binocularly from the preoperative level of 20/20. Consistent with the UCVA outcomes, 10 patients (83%) reported spectacle independence while the other 2 patients indicated they were glasses occasionally.

> "This inlay offers an excellent alternative to correct presbyopia in emmetropic patients and it has benefits of being noninvasive and easily reversible," Dr. Tamayo said.

> "However, as the outcomes in this study show, the procedure induces monovision," Dr. Tamayo

continued. "The monovision is small, wellcontrolled, and easily tolerated. Nevertheless, patient selection is critical for obtaining good results."

Safety data showed patients experienced an initial loss of binocular contrast sensitivity, but it also recovered to baseline and remained stable from 6 months onward. BCVA was unchanged in 10 (93%) eyes with the implant while the other 2 had a 2-line loss.

"No patients suffered incapacitating visual symptoms," Dr. Tamayo said. "Mild haloes were reported by 5 patients, and 2 patients are not driving at night, but the haloes are decreasing with time."

Other results from a satisfaction questionnaire showed 100% of the patients were at least "happy" with the correction, of which twothirds described themselves as "very happy." In addition, all of the patients were willing to have a second procedure as needed.

"Importantly, no patient has wanted the inlay removed, even those who had loss of BCVA," Dr. Tamayo said. ■

#### **GUSTAVO E. TAMAYO, MD**

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Dr. Tamayo is a member of the Presbia medical advisory board.

take-home

▶ Results from 2 years of follow-up demonstrate the efficacy of a bifocal corneal inlay (Flexivue Microlens, Presbia) for correcting presbyopia in emmmetropic patients.

## Special Report ) ASCRS REFRACTIVE NEWS

## Circular, elliptical femtosecond flap comparison takes shape in study

Both femtosecond laser flap configurations provided excellent early results, high satisfaction

By Lynda Charters; Reviewed by Louis E. Probst, MD

SAN FRANCISCO ::

IN A COMPARISON STUDY of elliptical and round femtosecond laser flaps created during myopic LASIK, both flap configurations provided excellent early results and patient satisfaction was very high.

The study identified small increases in higherorder aberrations (HOAs) and spherical aberration, but no increase in patient complaints,



said Louis E. Probst, MD, at the annual meeting of the American Society of Cataract and Refractive Surgery.

In this randomized, prospective trial, all flaps were created with a femtosecond laser (iFS, Abbott Medical Optics). Round flaps were cre-

take-home

**▶** Elliptical and round

femtosecond laser

flaps created during

myopic LASIK provide

excellent early visual

satisfaction.

results and high patient

ated in 52 eyes of 26 patients, and elliptical flaps were created in 50 eyes of 25 patients. Patients were an average of 34 years of age (range, 21 to 60 years).

The eyes of all patients had <6 D of myopia and <2 D of astigmatism preoperatively,

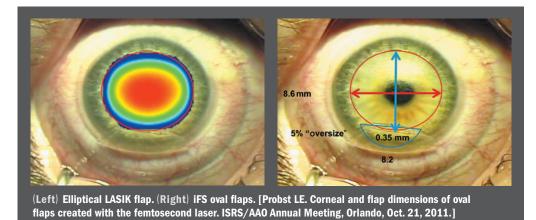
said Dr. Probst, national medical director for TLC Laser Eye Centers, Chicago. Patients in both groups were well matched demographically, with the degree of myopia slightly higher among patients treated with elliptical incisions ( $-2.82 \pm -1.2$ versus  $-3.35 \pm -1.4 \,\mathrm{D}; p = 0.041$ ).

The femtosecond laser parameters in both groups were almost identical (speed, 150 KHz; flap size, circular 8.5 mm and elliptical 8.6  $\times$  8.2 mm; flap thickness, 100 µm;

creation time, 12 seconds; pocket size, 0.35 mm; spot/line separation  $7 \times 7$ ; and side-cut angle, 110°).

#### VISUAL ACUITY COMPARISONS

Preoperative distance best-corrected visual acuity did not differ between the patients treated with circular and elliptical incisions. Uncorrected distance visual acuity (UDVA) 1 day after LASIK was 20/20 in 94.2% of patients with circular incisions and 88% of patients



with elliptical incisions; 57.7% and 65%, respectively, achieved 20/16, and 11.5% and 18% achieved 20/12.5.

(Images courtesy of Louis E. Probst, MD)

One month postoperatively, all patients with circular incisions had 20/20 UDVA as did 94% with elliptical incisions; 80.8% and 78% had 20/16, and; 40.4% and 28% had 20/12.5, and

3.8% and 4% had 20/10.

There were no differences between the groups in sphere, astigmatism, HOAs, or spherical aberration, Dr. Probst said.

Patient satisfaction was high with both incision types. There were no significant differences between the groups in glare and halos under any conditions, such as nighttime and daytime driving or with headlights and computer use.

The postoperative target can no longer be 20/20, Dr. Probst continued. With most patients in this study having 20/20 preoperatively, surgeons must aim higher, because patients expect more.

"We are making vision better, which is exciting," he said.

"Elliptical flaps offer some advantages, because of the precise alignment they allow," Dr. Probst said. "An elliptical flap can only fit into place one way because of its shape. A circular flap can fit in any configuration."

Elliptical flaps are also better suited to the anatomy of myopia. Nearly all patients with myopia, 99%, have a horizontal aspect to their myopia that is better suited to an elliptical flap, he said.

#### ELLIPTICAL FLAP CREATES BETTER HINGE

An elliptical flap also creates a more robust hinge. Dr. Probst advised using superior hinges for a deeper pocket that allows for better gas escape and greater stability.

"Both flap configurations demonstrated excellent early visual results," he said. "There were slight increases in HOAs and spherical aberration. Any subjective visual concerns actually improved from baseline to 3 months postoperatively.

"There were no increases in patient complaints and patient satisfaction with the procedures was extremely high," Dr. Probst concluded.

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Dr. Probst is a consultant for Abbott Medical Optics and TLC Vision.

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## Special Report ) ASCRS REFRACTIVE NEWS

## Femtosecond laser incisions an option for astigmatism after PK

Low-energy incisions are safe, effective, accurate, and reproducible for this patient population

By Lynda Charters; Reviewed by Eric D. Donnenfeld, MD

#### SAN FRANCISCO ::

A FEMTOSECOND LASER platform (IntraLase 150 kHz, Abbott Medical Optics) creates low-energy incisions that are safe, effective, accurate, and reproducible for treating astigmatism associated with penetrating keratoplasty (PK).

Erfan Nadji, MD, and senior author, Henry Perry, MD, along with colleagues, conducted a prospective, interventional case series study to evaluate the efficacy and safety of the femtosecond laser platform for treating this patient population. Dr. Nadji highlighted the outcomes in a presentation during the annual meeting of the American Society of Cataract and Refractive Surgery.

The arcuate astigmatic keratotomies that were created with the femtosecond laser are adjustable, unpaired, proportionally targeted at topographic hemi-meridians, and beveled at a 10° angle. Twenty-four patients with visually relevant corneal astigmatism following PK were included in the study.

#### INCISION DYNAMICS

The investigators created one or two relaxing arcuate incisions on the steep corneal hemi-

take-home

▶ A femtosecond laser

platform (IntraLase

150 kHz, Abbott

**Medical Optics)** 

creates low-energy

effective, accurate

and reproducible for

treating astigmatism

associated with

penetrating

keratoplasty.

incisions that are safe,

meridians guided by a topographic map. According to Dr. Nadji, two 40° incisions were created for astigmatism <4 D (a total of 80°), two 50° incisions for 4 to 6 D (a total of 100°), and two 60° incisions for >6 D (a total of 120°).

For cases in which the hemi-meridians were different magnitudes, the total degrees of the keratotomies were distributed unevenly, said Dr. Nadji, Nassau University Medical Center, East Meadow, NY.

The incisions were made to a depth of 80% of the thinnest corneal thickness, according to tomographic results. The laser settings were as follows: diameter, 6.5 mm;

energy, 1.3 mJ; spot separation, 4 μm; layer separation, 5 μm; and angle of incision, 80°.

## Refractive Comparison Results

	PREOPERATIVE	POSTOPERATIVE	p VALUE
UCVA (logMAR)	1.00 ± 0.35	0.71 ± 0.36	0.049
BCVA (logMAR)	0.57 ± 0.4008	0.18 ± 0.18	0.0045
Mean Cylinder	7.52 ± 2.88	4.58 ± 2.69	0.013
SE	-3.04 ± 3.96	-2.625 ± 3.92	0.79

#### REFRACTIVE COMPARISONS

Patients were examined on the first postoperative day and month 1 postoperatively. Investigators compared the preoperative and postoperative uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), spherical equivalent (SE), and total amounts of topographic and refractive astigmatism.

Dr. Nadji reported using these settings; the arcuate keratotomies remained closed at

> the conclusion of the laser treatment and moderate effort was needed to open the incisions with a blunt instrument.

> The mean preoperative log-MAR BCVA of  $0.57 \pm 0.4008$ decreased significantly to 0.18  $\pm$  0.18 postoperatively (p = 0.0045), and the preoperative UCVA of 1.00  $\pm$  0.35 increased significantly to 0.71  $\pm$  0.36 (p = 0.049). The mean preoperative topographic astigmatism decreased from 7.52  $\pm$  2.88 to 4.58  $\pm$  2.69 (p = 0.013). SE did not change significantly from preoperatively to postoperatively. The average surgically induced

astigmatism was  $4.37 \pm 3.31$ ; the average absolute angle of error was  $14.07 \pm 3.31$ ; and the average index of success was 0.59 ± 0.27, according to Dr. Nadji.

"This was the first prospective study of [this] femtosecond laser system used to treat astigmatism with arcuate keratotomies that are low-energy and thus adjustable, unpaired, proportionally targeted at topographic hemimeridians, and beveled at an angle of 10°," Dr. Nadji concluded.

"The advantages of the incisions created with the femtosecond laser are their accuracy and reproducibility," Dr. Nadji said. "The advantage of low-energy keratotomies is that they can remain closed if a good clinical outcome was achieved." ■



What are your observations of femtosecond laser incisions for astigmatism? Visit Facebook.com/ **OphthalmologyTimes** and present your thoughts.

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Dr. Donnenfeld did not indicate a financial interest in the subject matter.

#### ERFAN NADJI, MD

Dr. Nadji has no financial interest in the subject matter.

### Special Report ) ASCRS REFRACTIVE NEWS

## Phase Illa data outcomes very promising for hydrogel corneal inlay

Initial results show significant gains in monocular UCVA at near and intermediate

By Cheryl Guttman Krader; Reviewed by Stephen G. Slade, MD

SAN FRANCISCO ::

AN ASPHERIC HYDROGEL corneal inlay (Raindrop Near Vision Inlay, ReVision Optics) appears very promising for presbyopia correction in emmetropic patients.

Preliminary results from all patients who have reached 6 months of follow-up in a phase IIIa FDA trial show that implantation of the device in the non-dominant eye is a safe and



effective treatment, said Stephen G. Slade, MD, at the annual meeting of the American Society of Cataract and Refractive Surgery.

The transparent inlay, which measures 2 mm in diameter, is 32 µm thick, and is

take-home

▶ Implantation of

a hydrogel corneal

inlay into the non-

investigated in a

dominant eye is being

phase IIIa FDA trial for

presbyopia correction

in emmetropic patients.

placed onto the

stroma beneath a 150-µm femtosecond laser-created flap, improves near and intermediate vision by steepening the central cornea.

Dr. Slade, private practice, Houston, was an investigator in an earlier study, and he presented data from the first 75 eyes enrolled in the multicenter pivotal study. Eligible patients had MRSE ranging from -0.50 to +1 D, distance uncorrected visual acuity (UCVA) of 20/25 or better bilaterally, and near UCVA

worse than 20/40 in the non-dominant eye.

Mean UCVA values for eyes with the implant

at baseline were ~20/20 at distance (4 m), ~20/45 at intermediate (80 cm), and ~J7 at near (40 cm). At the 6-month visit, mean UCVA improved by 5.4 lines to J1+ at near and by 2.8 lines to 20/25 at intermediate. While there was an average 1-line loss in mean distance UCVA in eyes with the implant to  $\sim$ 20/25, results of a quality of vision survey showed difficulty with tasks involving distance vision was not affected at all.

Visual symptom question-

naire responses showed no reports of severe glare, halos,

blurred vision, double vision, or fluctuation in vision. Moderate glare and moderate halos were reported at rates of 3% and 5%, respectively. There were no cases of interface haze or any other safety issues in the cohort.

"Correction of presbyopia is the biggest unmet need in ophthalmology for the adult population," Dr. Slade said. "Therefore, we are very

excited about these results that so far are meeting FDA benchmarks for approval indicating that the hydrogel corneal inlay is a very promising solution for treating presbyopia."

Contrasting the results with monovision as a standard for presbyopia correction, Dr. Slade noted that whereas there is an equal trade-off in monovision in terms of the magnitude of loss in distance vision versus the gain in near, patients undergoing the inlay procedure benefit with a much greater gain in near vision relative to a minor loss at distance.

"With monovision, there is essentially a 1to-1 exchange between the increase in near vision and the loss at distance," he said. "For the inlay procedure, however, the results from this patient series show the ratio of gain in near vision to loss in distance vision exceeds 5:1."



The transparent inlay, shown above in comparison with a penny, measures 2 mm in diameter and 32 µm in thickness. (Photo courtesy of ReVision Optics)

and removability, he noted.

#### EFFECT SIMILAR TO NATURAL ACCOMMODATION

The inlay has efficacy and safety advan-

tages relative to other treatments for presby-

opia based on considerations of centration ease

While skeptics have questioned how the inlay can improve near vision by inducing a power change over such a small central diameter, results of a study by Adrian Glasser, PhD, show that the optical effect of the inlay is similar to that occurring with natural accommodation (J Vis. 2004;4:299-309). Dr. Glasser and colleagues used a primate model and a Shack-Hartmann wavefront sensor to investigate changes in ocular aberrations occurring over the lens equatorial diameter during accommodation.

The results showed a pronounced and relatively uniform change in optical power centrally, over a 3-mm diameter, with a rapid decrease beyond that area out to the lens periphery, Dr. Slade explained. ■

#### PLACEMENT OF THE INLAY



**▼ VIDEO** Go to http://bit.ly/18tEXMi to see how Jeffrey Whitman, MD, of Dallas, places the near vision inlay in a patient. (Video courtesy of ReVision Optics and Jeffrey Whitman, MD)

#### STEPHEN G. SLADE, MD

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Dr. Slade is a member of the Board of Directors for ReVision Optics.

## How to treat pediatric retinal detachment after initial repair

Careful monitoring of pediatric patients imperative to identifying late re-detachments

By Lynda Charters; Reviewed by Laura A. Vickers, MD

#### **TAKE-HOME**

▶ Recurrent retinal detachments in children can develop months to years after the initial corrective surgery, making careful monitoring of patients imperative to identifying late re-detachments.

DURHAM, NC ::

ecurrent retinal detachments in children can develop months to years after the initial corrective surgery, making careful monitoring of patients imperative to identifying late re-detachments. Laura A. Vickers, MD, representing a research team that includes Joseph Martel, MD, and Prithvi Mruthyunjaya, MD, from Duke Eye Center in Durham, NC, shared the results of a study of pediatric patients with retinal detachments that evaluated the factors involved in retinal re-detachments following successful initial surgical interventions.

## CHALLENGES IN PEDIATRIC CASES

"Compared with adults, pediatric retinal detachments have different etiologies and typically, a later time to presentation," explained Dr. Vickers, ophthalmology resident at Duke Eye Center. "The surgical success rates vary widely, but there are few data on the time to re-detachment, the clinical factors associated with re-detachment, and the benefit of multiple corrective surgeries."

To address these issues, Dr. Vickers and colleagues studied pediatric retinal detachments in patients from 1997 to 2011. Of 314 identified patients, 144 patients (156 eyes) were included; seven surgeons performed all procedures. The investigators sought to determine the sustained re-attachment rate after the initial surgery, the time to re-detachment, and the complication rate after multiple surgeries.

The patient characteristics included median

age at surgery of 11 years and the median bestcorrected visual acuity (BCVA) of counting fingers; 75% were boys, and 49% of patients had undergone a previous intraocular surgery. More than two thirds of the detachments were rhegmatogenous and the remainder was tractional or combined traction rhegmatogenous retinal detachments. Posterior vitreoretinopathy (PVR) was present in 46% of patients at presentation. The initial surgery was combined scleral buckling and pars plana vitrectomy in 63% of eyes, scleral buckling alone in 12%, and vitrectomy alone in 25%.

"After the initial surgery, 53% of eyes had sustained retinal re-attachment with a final median BCVA of 20/200," Dr. Vickers said. "Redetachment occurred during follow-up in 45% of eyes, and in 2% the retina never re-attached, which was associated with a final BCVA of light perception. The median time to retinal re-detachment was 179 days."

This highlights the challenges of retinal detachment repair in a pediatric population, she noted.

#### RE-ATTACHMENT SURGERY RATES

Thirty eyes required two or more surgeries to achieve a final re-attachment rate of 72%. Eyes with the macula re-attached at final follow up had a final mean vision of 20/525, and eyes with complete retinal re-attachment at last follow up had a mean vision of 20/200. The eyes in which the retina re-detached at any point during follow-up had a lower mean vision, and had a higher risk of having no light perception vision, developing phthisis, or needing enucleation, she said.

The investigators found that the factors associated with sustained attachment were macula on status at presentation, a rhegmatogenoustype retinal detachment, and scleral buckling performed during the initial surgery.

The latest re-detachments occurred in eyes with tractional or combined tractional and rhegmatogenous detachments, at more than 2,000 days after the initial surgery. Eyes with

a rhegmatogenous retinal detachment tended to detach at a mean of 116 days after the initial surgery, Dr. Vickers noted.

Eyes in which the retinas re-detached early (less than 40 days after the initial surgery) were more likely to have been rhegmatogenous retinal detachments. Eyes in which the retina re-detached late (40 days to 1 year after the initial surgery) had more retinal breaks, were more likely to have undergone previous pars plana lensectomy, and had more PVR. These eyes were more likely to develop phthisis and no light perception vision, and overall had worse visual outcomes; eyes with very late re-detachment more than 1 year after the initial surgery were more likely to be combined detachments, to have had a previous PPV, and also had worse visual outcomes.

### MORE THAN THREE SURGERIES LESS EFFECTIVE

Eyes that achieved retinal re-attachment through three or fewer surgeries tended to fare better. Eyes that required four to six surgeries for retinal re-attachment trended toward worse visual outcomes and more complications, Dr. Vickers explained.

"Interestingly, in eyes in which the macula was successfully re-attached, if more surgeries were required to achieve this, the trend was toward worse vision," she said.

The investigators also found an increasing rate of complications after four or more surgeries were performed. At the same time, eyes with final macular re-attachment fared better in terms of serious complications than those that remained detached, regardless of how many surgeries were required, suggesting an anatomic benefit.  $\blacksquare$ 

#### LAURA A. VICKERS, MD

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Dr. Vickers has no financial interest in the subject matter. This article was adapted from Dr. Vickers' presentation during the 2012 meeting of the American Academy of Ophthalmology.

## How low is too low?

Identifying the cause of hypotony is key to its prevention and management

By Liz Meszaros; Reviewed by Robert Weinberg, MD

#### TAKE-HOME

▶ Though rare, hypotony after cataract surgery can occur. The ability to recognize common causes of low IOP postoperatively can aid in its prevention and management.

BALTIMORE ::

lem not often seen by ophthalmologists, but when it occurs, elucidating its exact cause and treating it properly is imperative. "Hypotony after cataract surgery is rare, but it can occur," said Dr. Weinberg, chairman of ophthalmology,

Johns Hopkins Bayview Medical Center, Baltimore. "When we're closing cataract wounds, we are obviously concerned about pressures



at the end of the procedures, but we should remember postoperative pressures as well."

ostoperative hypotony is a prob-

Hypotony is defined as low IOP (≤5 mm Hg) that can be acute, transient, chronic, or permanent, and can lead to functional changes (asymptomatic or symptomatic) and

structural changes (reversible or irreversible) over time.

"The question is: 'How low is too low?' Low pressures can sometimes be asymptomatic, and not all chronically low IOPs lead to irreversible vision loss," he said. "But low IOP and poor visual acuity may have obvious correlates."

Hypotony can be defined in terms of time, as acute, transient, finite, prolonged, or persistent.

"It is the persistent hypotony that we want to try to avoid, because there are irreversible structural and functional changes," he said. "We learned about these early in our residencies."

These irreversible structural changes can include corneal astigmatism, anterior chamber shallowing and flare, macular edema, disc edema, and choroidal detachment. Corneal edema is also a possibility, he added.

#### CAUSES OF LOW IOP

Normal IOP depends on adequate aqueous production, an intact corneoscleral wall, attachment of the uvea, integrity of the pars plana and choroidal attachment, and the absence of retinal holes and inflammation.

The most common cause of postoperative hypotony after cataract extraction is a nonhealing or leaking cataract wound. Internal fistulas can occur, connecting the aqueous or the vitreous to the suprachoroidal space and can be caused by a cyclodialysis or a retinal hole. Other causes of hypotony also can include ciliary body insufficiency.

In addition, inflammation can cause decreased aqueous production and low IOPs as well, he added. Non-surgical causes of hypotony include ocular ischemia, dehydration, acidosis, anemia, and myotonic dystrophy.

#### TREATMENT OF HYPOTONY

"How do we treat hypotony? Obviously, the best treatment is prevention," Dr. Weinberg said.

Wound leaks after cataract surgery can be

healed with a pressure dressing or bandage contact lens and time, topical adhesive or placement of additional sutures in the wound. If postoperative hypotony does occur, and there is no obvious wound leak, one should look for a cyclodialysis cleft.

For cyclodialysis clefts, which may be detectable only on gonioscopy and/or anterior segment imaging, treatment consists of diathermy, cryotherapy, laser application to the cleft, or surgical re-attachment.

For significant postoperative inflammation, cycloplegia or corticosteroids should be used.

"In certain patients who have had vitrectomy, cataract detachment, or scleral buckling, I will use a scleral support ring at the time of cataract surgery," Dr. Weinberg said. "I also like to place those support rings in [patients with] high myopia, younger patients, and in patients with scleral thinning."

Surgeons must be aware, however, of the problems that may be associated with scleral support rings, which can include subconjunctival hemorrhage and inadvertent perforation from suture placement—the latter of which can be a cause of postoperative hypotony, he added. ■

#### ROBERT WEINBERG, MD

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Dr. Weinberg has no disclosures. This article was adapted from Dr. Weinberg's presentation at the 25th annual Current Concepts in Ophthalmology meeting, held in association with Wilmer Eye Institute and Ophthalmology Times.

## B + L launches microincision lens in Europe

BAUSCH + LOMB HAS launched its acrylic microincision IOL (Incise) to the European market. This IOL, in combination with the capabilities of the company's Stellaris Vision Enhancement System, allows surgeons to perform microincision cataract surgery less than 2 mm, delivering less invasive surgery for a more rapid visual recovery.

The IOL features aspheric advanced optics designed to enhance visual quality. The combination of an enhanced acrylic, improved Stellaris system capabilities, and a new single-use Incise Viscoject Bioinjector enables 1.8 mm inthe-bag and 1.4 mm wound-assist implantation.

The lens has been designed to minimize posterior capsular opacification with a 360°

barrier edge with a radius of curvature of 5 μm. "The unfolding of the lens was well-controlled, allowing easy placement in the capsular bag," said H. Burkhard Dick, MD, of the University of Bochum, Germany.

The lens has received CE Mark approval in the European Union. However, the lens is not FDA approved in the United States. ■

## practice management

## Three minutes inside the mind of a manager

Be careful of what you ask; it may soon come true, relates columnist

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

#### **TAKE-HOME**

Not all is bluebirds and rainbows in a manager's world. That's why managers are the way we are: Type AAA, hard-driving, tough-sounding, no-nonsense folks you don't want to sit and visit with, relates Dianna Graves.

he other day I was having a "catch-up" visit with one of our physicians. He had stopped in after a whirlwind day in the operating room to see how things were going.

I've known him for more than 20 years—from residency, fellowship, and now partnership. I know that when he stops in to see how things are going, he doesn't really want to know all the gory details regarding the staff. He wants the "bluebirds-and-rainbows" version!

And, I try my best to steer the discussions that way and "sanitize" the staff issues to some degree, lest I am perceived as a downer every time he visits. It sometimes becomes the case of "I want to know—I just didn't want you to *tell* me."

#### ON A NEED-TO-KNOW

I once worked with an administrator who only wanted to know what she needed to know, and then she gave you 3 minutes to put it in a nutshell.

I went into her room one day and said, "I need to tell you this, but you probably don't want to hear it."

She said, "Okay, . . . wait a minute." She shut the door, then sat down, placed her hands over her ears, and said, "Begin."

I condensed the story into the obligatory 3 minutes.

She sat with her hands over her ears, humming for the entire 3 minutes. When I

was done with the story, she took her hands away from her ears and said, "Okay, . . . you told me. Anything else?!"

In a weird way, I felt good because I had semantically told her. So, therefore, I was covered and so was she.

### WELCOME TO MANAGERS' WORLD

That's why managers are the way we are: Type AAA, hard-driving, tough-sounding, no-nonsense folks you don't want to sit and visit with

Even the physicians avoid us because our worlds involve staff Richter-scale dustups, organizational code blues, and mindnumbing cases of listening day after day to personal agenda tsunamis from most of the people who stop in to talk. I'm not looking for someone to hand me the Nobel Peace Prize or the Mother Teresa Kindness Award. I just want someone to have a conversation with me that does not start with: "Why can't . . . ", or "Why won't . . . ", "Why do they . . . ", or "What's wrong with them?!"

It's easy to become cynical and jaded when every conversation can be loaded with true/false statements, or find a word and the hidden message behind "door number 3."

Although I have ruefully stated that there is no manual for managers, there sure are many non-managers out there who believe they could do the job better.

And they are not quiet about their opinions.

And then I have heard the axiom, "Those that can *do*. Those that can't—*teach*."

Continues on page 30: Managers

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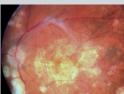
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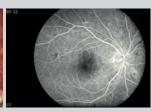


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## ( practice management )

#### **MANAGERS**

( Continued from page 26 )

#### TEACHING BY EXAMPLE

To teach effectively, you need a knowledge base others do not have. I once had one of my college professors lament that the B.S. degree was beginning to take the B.S. too literally.

But "teaching"—whether it is a classroom of students or your staff in clinic—is more than teaching skills and instruments. It's the life lessons: teamwork, cooperation, professionalism, and pride. Those are the skills we teach our staff every day. We do this by how we manage our groups as well as our own individual integrity.

While listening to the visiting doctor reminisce about one of the residents who had drifted through the university program years ago, I began to drift back to when I was graduating from ophthalmic technology school. I had a physician call to tell me that he was going to hire me because I was just what he was looking for to run his fast-paced cornea staff.

When I asked him what he thought I had to offer, he said, "You are the 'she-witch' we need to keep the staff on their game and the practice moving forward!"

I would have been happy simply with the title of manager. She-witch? Not so much.

If I were to take the job he was offering, I envisioned myself being in a cowboy Western. I would be the old gunslinger, and the technicians would be the eager new gunslingers gunning for me. There would al-

ways be someone trying to beat me to the draw. Not a fun way to live your days.

I have to keep reminding others, as well as myself, that being a manager is a position some of us were

groomed for and some of us inherited by default. But, I don't ever forget that from the time I became a COMT, being the manager of a clinic was something I coveted and strove hard for.

I wanted it, and now that I have it sometimes I wonder, now what?

So now, after 20 minutes of light-hearted banter regarding humorous staff tales and past memories of training that I *could* share with the visiting physician, he said he was glad he didn't have my job. He didn't want it!

I told him some days I didn't want it either and maybe I would apply at our local

flower/nursery establishment and apply to be a "Petunia Dead-Petal Picker."

He smiled and said, "I'll go with you."
A little too quickly, and with minimal smile, I said: "No . . . you have to stay here!"

'I have to keep reminding others, as well as myself, that being a manager is a position some of us were groomed for and some of us inherited by default.' — Dianna E. Graves, COMT, BS Ed

He looked shocked for a second, and then smiled and said, "Oh, I get it. You want peace, sunshine, and rainbows. Sure would be quiet."

Then it dawned on me—maybe he was listening after all. ■



DIANNA E. GRAVES, COMT, BS ED, is clinical services manager at St. Paul Eye Clinic PA, Woodbury, MN. Graves is a graduate of the School of Ophthalmic Medical Technology, St. Paul, MN, and has been a member of its teaching faculty since 1983. She can be reached at dgraves@stpauleye.com.

## Patient education materials lacking 'readability'

From Staff Reports

CHICAGO ::

**PATIENT EDUCATION** materials from 16 major medical societies suffer from a lack of readability, making them difficult for patients to comprehend and potentially contributing to poor health literacy, according to a study in *JAMA Internal Medicine*.

The basic problem with some patient education materials from specialty societies is that they are written at too high of a reading level, according to the study, which was authored by researchers from New Jersey Medical School.

The typical U.S. adult reads at a seventhor eighth-grade level, according to researchers. As a result, key health-care groups, such as the American Medical Association and the National Institutes of Health, recommend that patient education materials should be written at a fourth- to sixth-grade reading level. The researchers' analysis, which used 10 different readability scales included in a software package, revealed that all the patient education materials fell short in that respect.

"None of the patient education resources provided by the 16 professional organizations met the recommended sixth-grade maximum readability level or even the seventh- to eighth-grade reading ability of the typical American adult," the researchers reported.

Some of the specialty societies with patient education materials that were analyzed included the American Academy of Ophthalmology, the American Academy of Family Physicians, the American College of Physicians, the American Academy of Dermatology, and American

College of Radiology. Of course, some patient education materials scored higher than others on the various readability scales that the study used.

For example, the New Dale-Chall Readability Formula, which is based on an index of "familiar" words, showed that only family medicine, dermatology, and obstetrics and gynecology were within the boundaries of the average American adult reading level.

The authors concluded that "website revisions may be warranted" to enhance the readability of patient education materials, and noting that pictures and video may be an effective way of increasing patients' comprehension of information that is too complex to explain fully with text.



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