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September 15, 2014 VOL. 39, NO. 17

CLINICAL DIAGNOSIS | SURGERY | DRUG THERAPY

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SURGICAL DECISIONS

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September 15, 2014 VOL. 39, NO. 17
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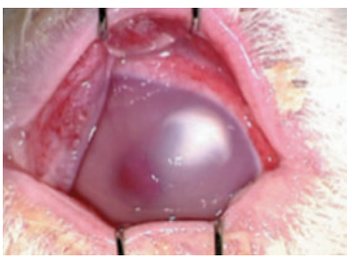
RIBOFLAVIN/UVA HOLDS POTENTIAL FOR KERATITIS



THE COMBINATION of topical riboflavin and ultraviolet A (UVA) light irradiation holds potential as a treatment for infectious keratitis. More research is needed, however, before this novel photochemical therapy might be considered for routine management of corneal infections, said Ashley Behrens, MD.

*(See story on page 10 : **Infectious keratitis**)*

Drug Therapy

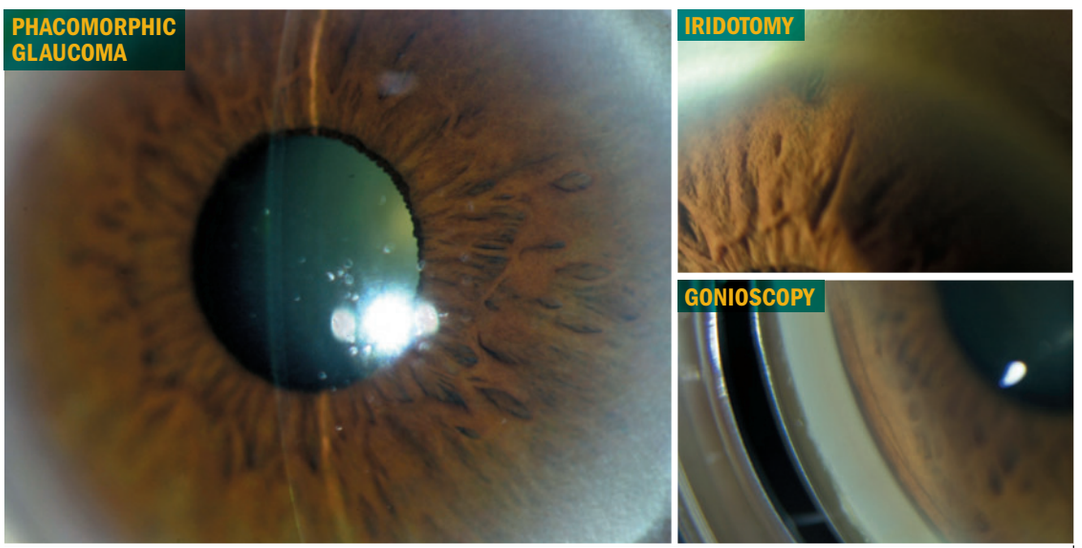
MINING IVAN DATA FOR INSIGHTS ON ANTI-VEGF SAFETY

BELFAST, IRELAND :: **DETERMINATION** of the systemic safety profiles of intravitreal anti-vascular endothelial growth factor (VEGF) therapy is an area of ongoing research. To that end, investigators from the Inhibition of VEGF in Age-related Choroidal Neovascularization (IVAN) trial undertook analyses of data from their study to explore potential associations between serum VEGF and various safety outcomes, said Usha Chakravarthy, MD. The researchers looked at whether change in serum VEGF from baseline to month 12 or average serum VEGF—calculated as the mean of the baseline and month 12 values—predicted the frequency of various events.

*(See story on page 40 : **Safety profiles**)*

Chronic angle closure SURGICAL DECISIONS

Considering LPI or lens extraction in terms of identifying who should be treated and how



ANGLE CLOSURE: A patient treated with phacomorphic glaucoma. His IOPs remained high in spite of a patent iridotomy. Gonioscopy showed extensive appositional angle closure from a large lens. His anterior chamber was very shallow. Cataract surgery opened his angle and he eventually normalized his IOPs without drops.
(Images courtesy of H. George Tanaka, MD)

By Cheryl Guttman Krader;
Reviewed by H. George Tanaka, MD, and Steven D. Vold, MD

LASER PERIPHERAL IRIDOTOMY (LPI) remains the cornerstone of management for patients with chronic angle closure.

However, lens extraction can also open the drainage angle—and depending on individual circumstances—it may be considered as the first-line of surgical intervention whether or not the patient has a significant cataract, according to H. George Tanaka, MD, and Steven D. Vold, MD.

Both glaucoma specialists considered lens extraction a good choice for a patient with an occludable angle who has a visually significant cataract. However, it can also be appropriate for an angle closure patient with minimal to no lens changes who has good visual acuity, but may be a candidate for a presbyopia-correcting IOL in a refractive lens exchange procedure.

"In light of recent advances in cataract surgery, I find myself performing fewer iridotomies for angle closure now than in the past," said Dr. Vold, who is in private practice, Fayetteville, AR. "These patients are often good candidates for multifocal lenses. Removing the lens may help prevent the development of angle-closure glaucoma and simultaneously correct the patient's refractive error and improve quality of vision."

"In a patient who is a presbyopic hyperope with astigmatism and a narrow angle, laser-assisted cataract surgery with corneal arcuate incisions can kill five birds with one stone," said Dr. Tanaka, who is in private practice, California Pacific Medical Center, Oakland and San Francisco. "It will deepen the angle and improve the patient's vision by remov-

*(Continues on page 11 : **Angle closure**)*

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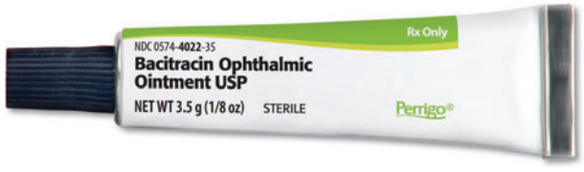

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References: 1. Kempe CH. The use of antibacterial agents: summary of round table discussion. *Pediatrics*. 1955;15(2):221-230. **2.** Kowalski RP. Is antibiotic resistance a problem in the treatment of ophthalmic infections? *Expert Rev Ophthalmol*. 2013;8(2):119-126. **3.** Recchia FM, Busbee BG, Pearlman RB, Carvalho-Recchia CA, Ho AC. Changing trends in the microbiologic aspects of postcataract endophthalmitis. *Arch Ophthalmol*. 2005;123(3):341-346. **4.** Freidlin J, Acharya N, Lietman TM, Cevallos V, Whitcher JP, Margolis TP. Spectrum of eye disease caused by methicillin-resistant *Staphylococcus aureus*. *Am J Ophthalmol*. 2007;144(2):313-315. **5.** Hecht G. Ophthalmic preparations. In: Gennaro AR, ed. *Remington: the Science and Practice of Pharmacy*. 20th ed. Baltimore, MD: Lippincott Williams & Wilkins; 2000. **6.** Bacitracin Ophthalmic Ointment [package insert]. Minneapolis, MN: Perrigo Company; August 2013. **7.** Data on file. Perrigo Company.

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Surgery

8 HYDROGEL CORNEAL INLAY VALUABLE FOR PRESBYOPIA
Device yields low complication rates, very consistent near improvement

Technology

32 YAG LASER VITREOLYSIS TO TREAT FLOATERS
Surgeon's clinical experience shows therapy yields robust safety profile

Clinical Diagnosis

16 TAKING CLOSER LOOK AT GLAUCOMA CARE
Improvements in risk-prevention, risk-modification strategies likely to transform clinical practice

Drug Therapy

36 DARPIN PROMISING IN PHASE II WET AMD STUDY
Research finds functional and anatomic improvements recorded 12 weeks, post-loading dose injections

Special Report

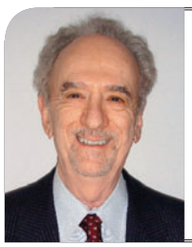
24 MAKING EHR WORK IN THE PRACTICE
Business continuity, remote access among benefits for large, multispecialty eye-care group

InDispensable

41 HOW TO PROMOTE SPECIALTY EYEWEAR
Understanding how to sell wide range of niche optical products to benefit patients, clinic

Life in the Army

Recalling adventures from days as a military physician in France



By Jules Baum, MD

Emeritus professor of ophthalmology, Tufts University School of Medicine, Boston. Readers may contact Dr. Baum at
Phone: 212/222-1024
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WHEN I WAS inducted into the U.S. Army—having to go in under the Berry Plan, as a Captain, after finishing my 9-month basic science course in ophthalmology at New York University (NYU) in 1959—luckily, I was sent to France (1959 to 1961).

Prior to being sent, I had to undergo training at Fort Sam Houston, TX. There were classes in map reading, the use of firearms, and the triaging of wounded Army personnel. I was assigned to a base in Croix Chapeau, a small town outside of La Rochelle, on the Western coast of France and was the only ophthalmologist at a base. This was before my residency at NYU/Bellevue.

> 'In retrospect . . . going to France was a unique opportunity for a young man to gain perspective on the culture of Western Europe.' *– Jules Baum, MD*

If I saw a red eye, I would tell the patient I would be back in a few minutes and go to the library to look up "red eye." If a patient needed more than my inadequate knowledge in medical ophthalmology or required surgery, I would get on an Army plane with the patient and fly to Orleans, where there was an Army ophthalmologist who had just finished his residency.

LEARNING FROM ADVENTURES

Not liking the army, I traveled a lot. "Leave," in the Army, for officers, was based on the Honor Code. My 30-day, allotted leave time grew to 110 days—interesting Honor Code system. I traveled all over France and visited Italy, Switzerland, Germany—including a ravaged East Berlin—Sweden, Denmark, Belgium, Holland, and Luxembourg. I lived in a small room in Army housing (BOQ). We ate on base and at the Officers' Club in La Rochelle. Better food at the Officers' Club. A scotch on the rocks was 50 cents. I heard regular Army officers talking and wishing for war. When I asked why, they said it was the best way to advance in rank.

My friends and I would eat at the French restaurants in town. La Rochelle was a seaside town, and the fish, shrimp, clams, mussels and oysters—all freshly caught—were delicious. The local wine, Muscadet, went well with fish. Other white and red I wines—from all over France—were listed. This was all new to me. The only wine I ever had before this was Manischewitz at Passover Seders.

Being near Bordeaux, I went to the vineyards. In those years, one could visit all the cellars, unannounced, and talk to the chief winemaker (*maître de chais*). He would let us taste the wines in the barrels—Chateaux Lafite, Mouton Rothschild, Cheval Blanc, Haut Brion—Samuel Pepys called it the Irish wine, O'Brian—Latour, Margaux, Petrus, and d'Yquem.

When visiting d'Yquem one time, I saw men wearing brightly colored ribbons with a silver cup (Tastevin) attached around their necks. I was told the group was called La Societe des Chevaliers du Tastevin. Years later, I was inducted into the Society.

On other trips, I meandered around the chateaux of the Loire and Burgundy. In Burgundy, I visited all the famous vineyards. Probably the most exalted of them all is the Domaine de la Romanée-Conti. In the caves, the winemaster let my friend and I taste Echézeaux, Grands Echézeaux, La Tache, Richebourg, and the great Romanée-Conti from 1959, 1960 and 1961. That's 15 wines! When we left in my Peugeot

Continues on page 6 : **Adventures**

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ADVENTURES

(Continued from page 4)

403, I knew I had had too much to drink. The car was weaving across the midline and back.

I went to Clos de Vougeot, the home base of Les Chevaliers du Tastevin. While there at a dinner to which I was graciously invited, we heard a dog bark and someone said: "Throw the dog a Beaune."

I had learned to ski while at Dartmouth, and I skied on the slopes of the Pyrenees and Mont Blanc—all while on leave. I saw the 24-hour race at Le Mans, camping out and sleeping only 2 to 4 hours, adjacent to the track at night. In those days, visitors could walk on the track near the starting point before the race, seeing members of the press photograph the drivers with their beautiful women friends and wives. A Ferrari won.

One trip was to the Dordogne. I saw the original Lascaux cave, before they restricted its visitation due to mold growing on the wall paintings. I also visited Font de Gaume and Les Eyzies. They removed the rocks with the originals and replaced them with duplicates. I went back some years later and the duplicates are seen with brighter colors than the originals.

TREASURED TRAVEL COMPANIONS

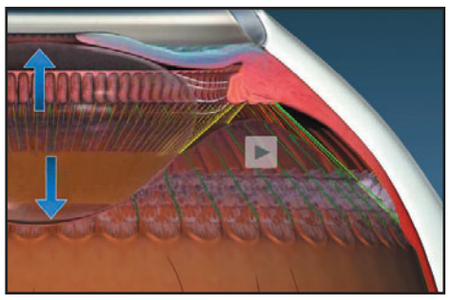
I always traveled with two essential books in my Peugeot: one was the *Michelin Guide* and the other was Alexis Lichine's *Guide to the Wines and Vineyards of France*. Even a restaurant with no stars could be a delightful discovery—everything was homemade. (At present, "homemade" can be deceiving. Many restaurants now claim to have homemade foods, but the chef may open packaged products labeled as fresh or frozen.)

The French government sends inspectors to those restaurants where the chef or owner verifies a homemade meal is prepared from scratch. At such establishments, the inspectors affix a sign in the window that states such. However, the government lacks the manpower to inspect these restaurants.

When eating at a 2- or 3-star Michelin restaurant, everything is fresh and the experience is ethereal. Over a period of 45 years, I have eaten at 23 restaurants with 3-star ratings. The best meal I ever had was at Joel Robechon's first restaurant in Paris. He won his third star award at age 39, the youngest 3-star chef in the history of the *Michelin Guide*. Robechon closed the restaurant 3 years later because he said it was too hard to maintain perfection. He now has other restaurants around the world. Ask me about his mashed potatoes—1 pound of butter for every 2 pounds of potatoes. Memories.

In retrospect—even though Army life was not for me—going to France was a unique opportunity for a young man to gain perspective on the culture of Western Europe. With my 2-year "vacation" at an end, I was ready to focus on my future in ophthalmology. ■

Video



Watch an overview of a computer-animated model of accommodation, as well as the theory of reciprocal zonular action.
Go to **http://bit.ly/1rbHuFd**
(Video courtesy of Daniel B. Goldberg, MD, FACS)

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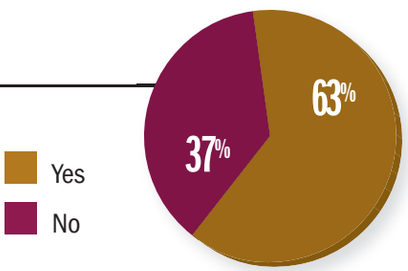
Survey Recap

Do you think corneal collagen crosslinking (CXL) will be approved by the FDA in the United States within the next 12 months?



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Hydrogel corneal inlay studied as 'valuable' tool for presbyopia

Device yields low complication rates, very consistent near improvement, high patient satisfaction

By Cheryl Guttman Krader; *Reviewed by Julian Theng, MD*

SINGAPORE ::

Early outcomes with a transparent, hydrogel corneal inlay (Raindrop, ReVision Optics) support its role as an option for correcting presbyopia, said Julian Theng, MD.


Dr. Theng

"The inlay delivered very consistent near improvement to N5 or better along with improved intermediate visual acuity," said Dr. Theng, chairman and founder, Eagle Eye Centre, Singapore. "There were no significant complications, and patient satisfaction was very high. The surgery involves a learning curve, but the procedure is quick, easy, and reversible.

"Based on this early assessment, I consider the hydrogel corneal inlay a valuable tool in my surgical armamentarium for correcting presbyopia," said Dr. Theng, who reported favorable experience in his first 25 patients who received the device at the center.

The inlay is made of a transparent biocompatible material with properties mimicking a healthy cornea. The device is implanted in the non-dominant eye under a 150-µm corneal flap, creating a smooth focal gradient in the center of the cornea to improve near and intermediate vision.

SERIES FINDINGS

Of the 25 patients in the series, five patients with low hyperopia preoperatively (mean MRSE +0.62 D, range +0.5 to +0.75 D) received the inlay only. The other 20 patients whose preoperative MRSE ranged from –1.25 to +1.75 D (with up to –1 D of cylinder) underwent concurrent LASIK with a target refraction of +0.75 D.

Patients are being followed quarterly. Twenty-one patients were seen at 1 and 3 months, 17 patients were evaluated at 6 months, but only six patients have reached the 1-year visit.

Mean monocular near uncorrected visual acuity (UCVA) in the inlay eye measured at 30, 40, and 50 cm was N10 preoperatively, improved to almost N5 by 1 month for all near distances, and was stable thereafter. For the patients seen at 6 months, near UCVA at 30 cm was N6 or better in 94% of inlay eyes, and among the patients seen at 12 months, 100% saw N5 or better at 30 cm with their inlay eye.

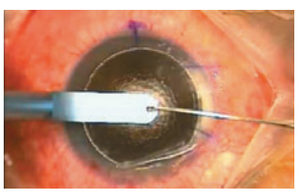
Monocular distance UCVA in the inlay eye was reduced initially, but improved by 1 week and stabilized by 3 months at a level slightly below baseline.

"Most patients are not disturbed by the slight reduction in distance visual acuity, which ranges from 6/6 to 6/12 vision," he said. "What is more striking is that they hardly complain of halos and glares."

Patient satisfaction was very high. Among the 21 patients seen at 1 month, 88% were satisfied and only 6% were dissatisfied. All 6 patients seen at 12 months were satisfied or very satisfied, and all inlays were clear.

"The learning curve for the procedure mostly involves learning to handle the inlay gently to avoid damage and positioning it right over the center of the miotic pupil in order to achieve predictably good results," Dr. Theng said. ■

INLAY SURGERY



VIDEO Watch a procedure using the hydrogel corneal inlay. Go to **http://bit.ly/1nICYas**

(Video courtesy of Julian Theng, MD)

JULIAN THENG, MD

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This article was adapted from Dr. Theng's presentation at the 2014 meeting of the American Society of Cataract and Refractive Surgery. Dr. Theng received a fee and expenses from ReVision Optics. The near vision inlay is an investigational device.

Anterior segment OCT helps define variations in epithelial thickening

Inferior epithelial thinning after LASIK may be related to dry eye associated with condition

By Lynda Charters; *Reviewed by Shaun Robinson, MD*

HOUSTON ::

MYOPIC LASIK and PRK are associated with greater thickening of the paracentral and central epithelium compared with changes in the peripheral epithelium. These central changes may to some extent counteract the myopic effect of the ablation.

Previous studies have reported epithelial thickening after myopic ablations, with the greatest thickening occurring centrally and paracentrally, said Shaun Robinson, MD.

Dr. Robinson

"However, no studies have investigated the regional variations in epithelial thickening after corneal refractive surgery," said Dr. Robinson, who completed his fellowship at Baylor College of Medicine, Houston, and currently is in practice with the Cabarrus Eye Center, Concord, NC.

EPITHELIAL THICKNESS PATTERNS

In light of this, using anterior segment optical coherence tomography (AS OCT) (RTVue-100, Optovue), Dr. Robinson and colleagues from the Cullen Eye Institute, Baylor College of Medicine, conducted a prospective, nonrandomized case series to characterize changes in the corneal epithelial thickness patterns after myopic LASIK and PRK. Eighteen eyes of nine patients who underwent myopic LASIK and 15 eyes of eight patients who underwent myopic PRK were included.

The changes in epithelial thickness were defined as the differences between the epithelial thickness measured preoperatively and postoperatively within each of 17 zones:

- One central 2-mm diameter zone.
- Eight paracentral zones—annulus from 2- to 5-mm diameter.
- Eight peripheral zones—annulus from 5- to 6-mm diameter.

The measurements analyzed at each location were the averages of three scans obtained by AS-OCT centered on the pupil, according to Dr. Robinson.

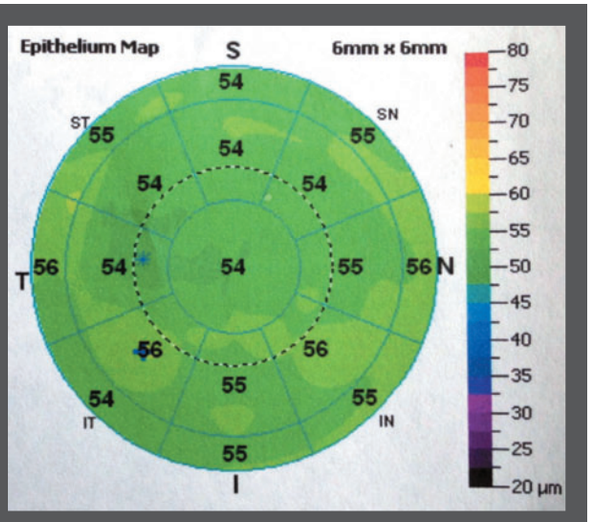
The mean preoperative spherical equivalent refractions in the LASIK and PRK groups decreased from –5.75 ± 2.09 D (range, –0.88 to –8.13 D) and –4.66 ± 2.24 D (range, –1.25 to –8.25 D), respectively, to –0.31 ± 0.41 D (range, –1.25 to +0.12 D) and –0.34 ± 0.66 D (range, –1.50 to +1.00 D) 3 months postoperatively.

The central corneal epithelium increased significantly from 53.52 µm at baseline to 57.43 µm 3 months after myopic LASIK and from 52.47 at baseline to 58.46 µm 3 months after myopic PRK ($p < 0.05$ for both comparisons). The same phenomenon occurred in the paracentral epithelial zones with increases from 53.04 µm at baseline to 57.65 µm and from 53.02 µm at baseline to 57.84 µm, respectively, at the same time point ($p < 0.05$ for both comparisons).

The peripheral corneal zones also increased in thickness from 52.46 µm at baseline to 53.91 µm and from 53.65 µm at baseline to 54.56 µm, respectively ($p < 0.05$ for both comparisons), at the same time point.

However, the increase in the peripheral zone was less than that seen centrally or paracentrally after both LASIK and PRK ($p < 0.05$ for each comparison). Of note, there was no difference between the central and paracentral zones after either LASIK or PRK and there was no difference between LASIK and PRK for any of these three regions ($p > 0.05$).

Interestingly, the epithelium in the inferior peripheral zone became 2 µm thinner after myopic LASIK ($p < 0.05$).



Anterior segment optical coherence tomography (RTVue-100, Optovue) corneal epithelial map of the 17 zones measured in this study. *(Image courtesy of Shaun Robinson, MD)*

"Thickening of the central and paracentral epithelium appears to be a response to thinning of the underlying stroma with myopic ablation, which, in some small measure, counteracts the myopic effect of the ablation," he said.

Investigators concluded that the central and paracentral epithelium had greater thickening compared with the peripheral epithelium after both myopic LASIK and PRK, and this central thickening may resist the myopic effect of the ablation to a small extent. They described the thinning of the peripheral inferior epithelium after LASIK as "surprising and striking."

Dr. Robinson commented that the inferior epithelial thinning after LASIK may be related to LASIK-associated dry eye, but ultimately believes this area needs further study to determine this conclusively. ■

TAKE-HOME

- ***Anterior-segment optical coherence tomography was used to characterize changes in the corneal epithelial thickness patterns after myopic LASIK and PRK.***

SHAUN ROBINSON, MD

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

Riboflavin/UVA for infectious keratitis: Showing potential, work in progress

More research needed before novel therapy may be used routinely for corneal infections

By Cheryl Guttman Krader; *Reviewed by Ashley Behrens, MD*

THE COMBINATION OF topical riboflavin and ultraviolet A (UVA) light irradiation holds exciting potential as a treatment for infectious keratitis.

Further research is needed, however, before this novel photochemical therapy might be considered for routine use in the management of corneal infections, according to Ashley Behrens, MD.

"In vitro studies and some clinical reports show encouraging results using riboflavin/UVA as a treatment for microbial keratitis," said Dr. Behrens, KKESHWEI Professor in International Ophthalmology, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, and executive medical director, The King Khaled Eye Specialist Hospital, Riyadh, Saudi Arabia. "However, some authors report lower success rates, and there is also evidence from patients undergoing corneal crosslinking for ectatic disease developing infectious keratitis after the treatment."

Therefore, riboflavin/UVA for infectious keratitis should be considered a work in progress, Dr. Behrens noted.

"We recommend further research to better characterize its efficacy, and that for now, its off-label use should be undertaken cautiously and only as an adjuvant treatment in select cases," he said.

TAKE-HOME

- ***Encouraging results have been achieved using topical riboflavin and ultraviolet A irradiation to treat infectious keratitis.***

WHAT RESEARCH HAS SHOWN SO FAR

Dr. Behrens has done pioneering research in the use of riboflavin/UVA as a treatment for infectious keratitis. He said that the mechanism of action is likely explained by the generation of free radicals and other cytotoxic riboflavin byproducts (e.g., lumichrome) generated when riboflavin is irradiated by UVA.

Results of a laboratory study conducted by Dr. Behrens and colleagues several years ago (*Invest Ophthalmol Vis Sci*. 2008;49:3402-3408) demonstrated the antimicrobial efficacy of riboflavin/UVA against a number of important ocular pathogens, including drug-resistant species.

In another in vitro investigation, they found that the combination of riboflavin/UVA with propamidine (Brolene) was highly effective in destroying *Acanthamoeba* cysts (unpublished data). Based on that research, riboflavin/UVA was used to treat three patients with medically refractive *Acanthamoeba* keratitis and with a successful outcome (*Ophthalmology*. 2011;118:324-331).

Dr. Behrens observed that there are no controlled studies investigating the efficacy of riboflavin/UVA for the treatment of infectious keratitis, and such research would be very difficult to do.

However, a recent literature search identified 17 papers published between 2009 and 2014 reporting experience in treating 90 patients. The majority of the papers included only 1, 2, or 3 eyes, but with the data pooled, the overall response rate was 94.4%, and all eyes with *Acanthamoeba* keratitis improved, Dr. Behrens said.

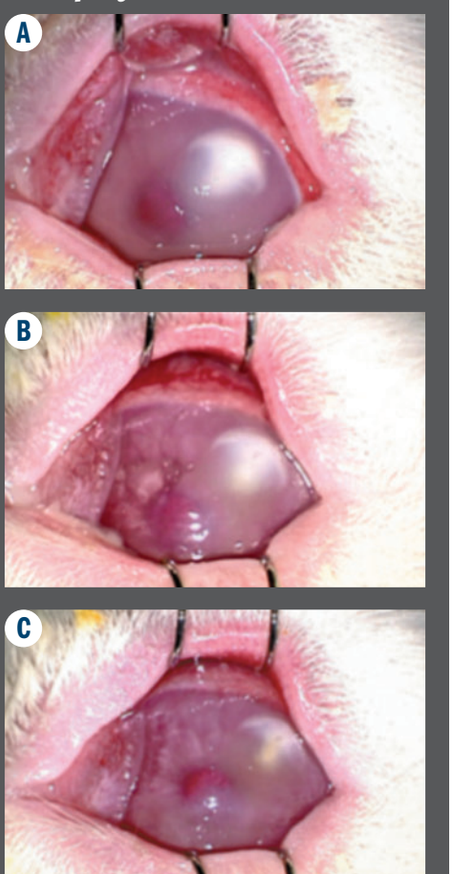
REFINING THE REGIMEN

In addition to its promising efficacy, Dr. Behrens said that riboflavin/UVA holds appeal as a treatment for infectious keratitis because of its convenience compared with current standard antimicrobial regimens. He noted that the application of riboflavin/UVA might need to be repeated a few times until clinical improvement, while the frequency of instillation of topical antibiotic drops might be reduced.

However, there is a need for further research to see if outcomes of riboflavin/UVA treatment might be improved by refining these treatment parameters, Dr. Behrens said.

"Even if we find that the results are optimized by repeating the procedure on several consecutive days, riboflavin/UVA would be a game-changer in terms of treatment for infectious keratitis considering the burden of our current intensive topical regimens," Dr. Behrens said. ■

Staphylococcus aureus



A Application of riboflavin/UVA
B 24 hours **C** 48 hours
Treatment of *S. aureus*-induced keratitis in rabbits. A reduction in the size and clearing of the cornea is observed after 24 hours and 48 hours of a single application of riboflavin/UVA without any additional antibiotic eyedrops.
(Images courtesy of Ashley Behrens, MD)

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This article was adapted from Dr. Behrens' presentation during Cornea Day at the 2014 meeting of the American Society of Cataract and Refractive Surgery. Dr. Behrens holds a patent related to the technology he discussed.

Blepharitis Management: A Clinical Approach

John R. Favetta, MD

Blepharitis refers to a variety of eyelid conditions with multiple, often concomitant, etiologies. Characterized by eyelid inflammation, bacterial overgrowth or infection—or the risk of infection—is also frequently present in blepharitis. As definitions and sub-categories of blepharitis have changed over the years, clear-cut estimates of prevalence have been challenging to obtain; but blepharitis is very frequently seen in ophthalmology practices. Left untreated, the presence of blepharitis may affect the risk of infection following ocular surgery and can limit the success of contact lens wear. A detailed history and careful attention to the lids, lashes, and meibomian glands during the slit lamp examination will aid in blepharitis detection and diagnosis. At a minimum, treatment includes eyelid hygiene; and acute presentations may benefit from combined antiinflammatory/antiinfective therapy. Combination agents can be particularly useful in the treatment of blepharitis.

Blepharitis is a catchall term encompassing the many, often overlapping, inflammatory and infectious conditions of the eyelids. Without a single, etiology-based definition, it has not been possible to gain a good idea of the prevalence of blepharitis. But the conditions that comprise blepharitis are among the most common encountered in a comprehensive ophthalmology practice.[1] Indeed, nearly a third of the patients I see—from young adults to seniors—present with signs and/or symptoms of blepharitis.

It is often useful to distinguish types of blepharitis based on anatomical location. Thus, we have anterior blepharitis, which affects the area around the lashes and follicles, and posterior blepharitis, which affects the meibomian glands and proximate tissues. In either form, multiple causative factors and disease processes may be involved; and anterior and posterior blepharitis often coexist.

Comorbidities, including chalazion and hordeolum, conjunctivitis, keratopathy (from superficial punctate keratitis to peripheral ulceration), and dry eye disease may be present with blepharitis.[2]

Blepharitis affects a broad swath of our patients: we see it in younger patients, who may have associated seborrheic dermatitis or acne rosacea; we see it in contact lens wearers, and in candidates for refractive, cataract, or other ocular surgeries; and we see it in patients who come in simply because they are bothered by its symptoms. I consider it imperative to treat even mild blepharitis, as treatment can reduce the risk of infection and inflammation, and—of particular importance to me as a surgeon—help ensure success for surgical candidates.

PATHOGENESIS

Anterior blepharitis is often associated with excessive bacterial growth on the lid margins. The microbes involved are typically the same species that normally reside there, including *Staphylococcus epidermidis* and *Staphylococcus aureus*.[2] While questions remain about the role(s) of bacteria in blepharitis, it appears that toxic exoenzymes produced by the colonizing species—particularly *S. epidermidis*—irritate the eyelids and ocular surface, causing the release of inflammatory mediators.[1]

In some cases, altered meibomian gland secretions may be an initiating factor, offering a supportive environment for bacterial proliferation.[3] But bacteria can

Please see the full prescribing information for ZYLET® on pages 3 and 4.

also alter ocular surface lipids. For example, lipolytic staphylococcal enzymes break down the wax and sterol esters in the tear film; and the release of irritating breakdown products, including free fatty acids, as well as the resulting tear film instability, contribute to inflammation of the lid margin and conjunctiva.[2]

A number of potential non-microbial factors (eg, age and hormonal changes, medication use) can contribute to the changes in meibum quality and the ductal keratinization that underlies posterior blepharitis.[3] Obstructive meibomian gland dysfunction (MGD) may not be inflammatory in its early stages, but the tear film changes (instability and hyperosmolarity), ocular surface irritation, increased ductal pressure, and bacterial involvement all contribute to inflammation and frank posterior blepharitis.[3]

DIAGNOSIS

In blepharitis diagnosis, history is paramount. Questioning patients about their ocular symptoms throughout the day can be very revealing: when patients describe stickiness and burning upon waking, with improvement through the day and a worsening in the evening, I know to look closely for signs of posterior blepharitis on my examination.

Patients with anterior blepharitis report a gamut of symptoms. Some patients have red and swollen lids; others complain of irritation and burning. Contact lens wearers with anterior or posterior blepharitis may report discomfort and significantly reduced wearing time.

A close look at the lids forms a key part of the examination. Patients with anterior blepharitis often have reddened, swollen lids, telangiectasia, and debris or collarettes along the lashes. In addition, the tear meniscus may be foamy, a result of bacterial lipases causing breakdown of the meibomian lipids. In posterior blepharitis, we often see plugged, pouting meibomian glands that yield turbid, viscous meibum—or no meibum at all. Diagnostic gland expression is helpful in evaluating and grading a patient's underlying MGD.

Again, because either anterior or posterior blepharitis can affect the ocular surface, corneal and conjunctival staining with lissamine green, rose bengal, or fluorescein can help identify tissue changes indicative of blepharoconjunctivitis or blepharokeratoconjunctivitis.

TREATMENT

Eyelid hygiene is a mainstay of my treatment regimen for virtually every stage and subtype of blepharitis. Cleaning the crust, keratinized tissue, and bacteria and bacterial byproducts off the lid margin removes some contributors to the condition. I recommend any of several commercially available lid cleansing pads for my patients, giving a brief demonstration of their use in the office.

For patients with posterior blepharitis, especially, I also add a hot compress and massage step to follow the cleansing scrub; an omega-3 fatty acid dietary supplement may also be part of the regimen.[4,5] Lid hygiene may be performed once or twice a day; in cases where I add a topical pharmaceutical agent, I tell patients to instill their final dose of drug after performing their bedtime lid cleaning and warm compresses.

Because blepharitis is often chronic and recurring, I emphasize to patients that even after we bring their acute condition under control, continued eyelid hygiene and warm compresses will help them maintain a healthy ocular surface.

PHARMACOLOGIC INTERVENTION

Lid hygiene alone is often insufficient to bring the coexisting and mutually-reinforcing inflammatory and infectious aspects of blepharitis under control. Topical corticosteroids, powerful inhibitors of inflammation, can be extremely useful for treating the acutely inflammed lid margin and ocular surface. The risks associated with corticosteroid use—particularly increased intraocular pressure (IOP) and cataractogenesis—are important considerations when selecting an agent and determining the duration of therapy.

In many cases, the presence of bacterial overgrowth and the risk of superficial ocular infection also warrant the use of an antibiotic in treating blepharitis.[6] A combination antibiotic/steroid agent is therefore well suited to address both the inflammatory and the potentially infectious components of this condition.

My agent of choice for treating blepharitis is ZYLET® (loteprednol etabonate and tobramycin ophthalmic suspension 0.5%/0.3%). The steroid component, loteprednol etabonate 0.5%, is one key reason I favor ZYLET® in the treatment of blepharitis.

Loteprednol etabonate combines antiinflammatory potency with an established safety profile.[6,7] The loteprednol etabonate molecule contains an ester group in place of a ketone at the C-20 position. In the eye, the drug undergoes predictable hydrolysis into inactive metabolites, which is thought to contribute to its safety profile.[6,7]

Tobramycin, the antibiotic in ZYLET®, is broadly effective against common ocular pathogens, including the staphylococci often implicated in blepharitis.[6,8]

CASE STUDY: PREOPERATIVE BLEPHARITIS

A 65-year-old male patient presented to our clinic complaining of decreased vision, which upon examination was attributable to cataract. The patient was motivated to undergo surgery, but because the examination also revealed significant lid swelling, telangiectasia, and inspissated meibomian glands, I opted to delay the operation in order to address his blepharitis.

I explained to the patient that treating his inflamed and possibly infected eyelids was important prior to undergoing ocular surgery. I believe that we have the best chance for a good surgical result when the lids and ocular surface are healthy at the outset.

In addition to a routine of eyelid hygiene and warm compresses, I prescribed ZYLET® four times a day for 2 weeks. When the patient returned, his IOP was normal and the redness and edema of his lid margins had greatly decreased. In my opinion, the patient responded to ZYLET® therapy.

At this point, I felt comfortable scheduling the patient for surgery—but I did make clear to him that blepharitis is a chronic condition; and that while his blepharitis was under control at the moment, he would need to continue regular eyelid hygiene and warm compresses, and to return to our office in the event of a significant flare-up.

Please see Important Risk Information on page 1 and the full prescribing information for ZYLET® on pages 3 and 4.

I typically prescribe ZYLET® QID for 10 to 14 days, depending on severity. To this I add eyelid hygiene and, where applicable, warm compresses and omega-3 supplements. I bring patients back within about 10 days to evaluate sign and symptom resolution and to check IOP. When I prescribe ZYLET® for blepharitis, I emphasize to patients that it is intended as short-term therapy only, and that long-term continuation of eyelid hygiene should help reduce the likelihood of recurrence.

CONCLUSION

Paying close attention to the lid margins can be beneficial for patients and practitioners. Neither a pristine surgical outcome nor successful contact lens wear is likely without a healthy ocular surface. Indeed, I have postponed surgeries for patients who present with significant blepharitis. To help get the acute inflammation and bacterial overgrowth of blepharitis under control, treatment with ZYLET® can be important.

John R. Favetta, MD, practices in North Arlington, NJ.

Please see Important Risk Information on page 1 and the full prescribing information for ZYLET® on this page and the next.

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BAUSCH + LOMB

Zylet®

loteprednol etabonate 0.5%
and tobramycin 0.3%
ophthalmic suspension

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ZYLET® (loteprednol etabonate and tobramycin ophthalmic suspension) safely and effectively. See full prescribing information for ZYLET (loteprednol etabonate and tobramycin ophthalmic suspension, 0.5%/0.3%).

Zylet (loteprednol etabonate and tobramycin ophthalmic suspension) 0.5%/0.3%

Initial U.S. Approval: 2004

INDICATIONS AND USAGE

Zylet is a topical anti-infective and steroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. (1)

DOSAGE AND ADMINISTRATION

Apply one or two drops of Zylet into the conjunctival sac of the affected eye every four to six hours. (2.1)

DOSAGE FORMS AND STRENGTHS

Zylet contains 5 mg/mL loteprednol etabonate and 3 mg/mL tobramycin. (3)

CONTRAINDICATIONS

Zylet, as with other steroid anti-infective ophthalmic combination drugs, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. (4.1)

WARNINGS AND PRECAUTIONS

- Intraocular pressure (IOP)- Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored. (5.1)
- Cataracts- Use of corticosteroids may result in posterior subcapsular cataract formation. (5.2)
- Delayed healing–The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of a magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. (5.3)
- Bacterial infections–Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infection. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated. (5.4)
- Viral infections–Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). (5.5)
- Fungal infections–Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. (5.6)

ADVERSE REACTIONS

Most common adverse reactions reported in patients were injection and superficial punctate keratitis, increased intraocular pressure, burning and stinging upon instillation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb at 1-800-323-0000 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

See 17 for PATIENT COUNSELING INFORMATION

Revised: 08/2013

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
2.1 Recommended Dosing
2.2 Prescription Guideline
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
4.1 Nonbacterial Etiology
5 WARNINGS AND PRECAUTIONS
5.1 Intraocular Pressure (IOP) Increase
5.2 Cataracts
5.3 Delayed Healing
5.4 Bacterial Infections
5.5 Viral Infections
5.6 Fungal Infections
5.7 Aminoglycoside Hypersensitivity
6 ADVERSE REACTIONS
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Zylet® is a topical anti-infective and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, and where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

The particular anti-infective drug in this product (tobramycin) is active against the following common bacterial eye pathogens:

Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains.

Streptococci, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae, Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis, Morganella morganii*, most *Proteus vulgaris* strains, *Haemophilus influenzae*, and *H. aegyptius, Moraxella lacunata, Acinetobacter calcoaceticus* and some *Neisseria* species.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

Apply one or two drops of Zylet into the conjunctival sac of the affected eye every four to six hours. During the initial 24 to 48 hours, the dosing may be increased, to every one to two hours. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

2.2 Prescription Guideline

Not more than 20 mL should be prescribed initially and the prescription should not be refilled without further evaluation [*see Warnings and Precautions (5.3)*].

3 DOSAGE FORMS AND STRENGTHS

Zylet (loteprednol etabonate and tobramycin ophthalmic suspension) 0.5%/0.3% contains 5 mg/mL loteprednol etabonate and 3 mg/mL tobramycin.

4 CONTRAINDICATIONS

4.1 Nonbacterial Etiology

Zylet, as with other steroid anti-infective ophthalmic combination drugs, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

5 WARNINGS AND PRECAUTIONS

5.1 Intraocular Pressure (IOP) Increase

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma.

If this product is used for 10 days or longer, intraocular pressure should be monitored.

5.2 Cataracts

Use of corticosteroids may result in posterior subcapsular cataract formation.

5.3 Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as a slit lamp biomicroscopy and, where appropriate, fluorescein staining.

5.4 Bacterial Infections

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

5.5 Viral Infections

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

5.6 Fungal Infections

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

5.7 Aminoglycoside Hypersensitivity

Sensitivity to topically applied aminoglycosides may occur in some patients. If hypersensitivity develops with this product, discontinue use and institute appropriate therapy.

6 ADVERSE REACTIONS

Adverse reactions have occurred with steroid/anti-infective combination drugs which can be attributed to the steroid component, the anti-infective component, or the combination.

Zylet:

In a 42 day safety study comparing Zylet to placebo, ocular adverse reactions included injection (approximately 20%) and superficial punctate keratitis (approximately 15%). Increased intraocular pressure was reported in 10% (Zylet) and 4% (placebo) of subjects. Nine percent (9%) of Zylet subjects reported burning and stinging upon instillation.

Ocular reactions reported with an incidence less than 4% include vision disorders, discharge, itching, lacrimation disorder, photophobia, corneal deposits, ocular discomfort, eyelid disorder, and other unspecified eye disorders.

The incidence of non-ocular reactions reported in approximately 14% of subjects was headache; all other non-ocular reactions had an incidence of less than 5%.

Loteprednol etabonate ophthalmic suspension 0.2% - 0.5%:

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

In a summation of controlled, randomized studies of individuals treated for 28 days or longer with loteprednol etabonate, the incidence of significant elevation of intraocular pressure (≥10 mm Hg) was 2% (15/901) among patients receiving loteprednol etabonate, 7% (11/164) among patients receiving 1% prednisolone acetate and 0.5% (3/583) among patients receiving placebo.

Tobramycin ophthalmic solution 0.3%:

The most frequent adverse reactions to topical tobramycin are hypersensitivity and localized ocular toxicity, including lid itching and swelling and conjunctival erythema. These reactions occur in less than 4% of patients. Similar reactions may occur with the topical use of other aminoglycoside antibiotics.

Secondary Infection:

The development of secondary infection has occurred after use of combinations containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids.

The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used.

Secondary bacterial ocular infection following suppression of host responses also occurs.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic effects: Pregnancy Category C. Loteprednol etabonate has been shown to be embryotoxic (delayed ossification) and teratogenic (increased incidence of meningocele, abnormal left common carotid artery, and limb fixtures) when administered orally to rabbits during organogenesis at a dose of 3 mg/kg/day (35 times the maximum daily clinical dose), a dose which caused no maternal toxicity. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (6 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at ≥5 mg/kg/day doses, and cleft palate and umbilical hernia at ≥50 mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with ≥50 mg/kg/day). Treatment of rats at 0.5 mg/kg/day (6 times the maximum daily clinical dose) during organogenesis did not result in any reproductive toxicity. Loteprednol etabonate was maternally toxic (significantly reduced body weight gain during treatment) when administered to pregnant rats during organogenesis at doses of ≥5 mg/kg/day.

Oral exposure of female rats to 50 mg/kg/day of loteprednol etabonate from the start of the fetal period through the end of lactation, a maternally toxic treatment regimen (significantly decreased body weight gain), gave rise to decreased growth and survival and retarded development in the offspring during lactation; the NOEL for these effects was 5 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to pregnant rats at doses up to 50 mg/kg/day during the fetal period.

Reproductive studies have been performed in rats and rabbits with tobramycin at doses up to 100 mg/kg/day parenterally and have revealed no evidence of impaired fertility or harm to the fetus. There are no adequate and well controlled studies in pregnant women. Zylet should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemic steroids that appear in human milk could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when Zylet is administered to a nursing woman.

8.4 Pediatric Use

Two trials were conducted to evaluate the safety and efficacy of Zylet® (loteprednol etabonate and tobramycin ophthalmic suspension) in pediatric subjects age zero to six years; one was in subjects with lid inflammation and the other was in subjects with blepharoconjunctivitis.

In the lid inflammation trial, Zylet with warm compresses did not demonstrate efficacy compared to vehicle with warm compresses. Patients received warm compress lid treatment plus Zylet or vehicle for 14 days. The majority of patients in both treatment groups showed reduced lid inflammation.

In the blepharoconjunctivitis trial, Zylet did not demonstrate efficacy compared to vehicle, loteprednol etabonate ophthalmic suspension, or tobramycin ophthalmic solution. There was no difference between treatment groups in mean change from baseline blepharoconjunctivitis score at Day 15.

There were no differences in safety assessments between the treatment groups in either trial.

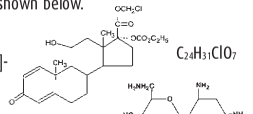
8.5 Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

11 DESCRIPTION

Zylet (loteprednol etabonate and tobramycin ophthalmic suspension) is a sterile, multiple dose topical anti-inflammatory corticosteroid and anti-infective combination for ophthalmic use. Both loteprednol etabonate and tobramycin are white to off-white powders. The chemical structures of loteprednol etabonate and tobramycin are shown below.

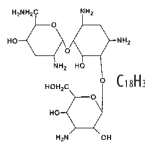
Loteprednol etabonate:



Chemical name: chloromethyl 17α-[(ethoxycarbonyl)oxy]-11β-hydroxy-3-oxoandrosta-1,4-diene-17β-carboxylate

$C_{24}H_{31}ClO_7$ Mol. Wt. 466.96

Tobramycin:



Chemical Name:
O-3-Amino-3-deoxy-α-D-glucopyranosyl-(1→ 4)-O- [2,6-diamino-2,3,6-trideoxy-α-D-ribo-hexopyranosyl- (1→ 6)] -2-deoxystreptamine

$C_{18}H_{37}N_5O_9$ Mol. Wt. 467.52

Each mL contains: Actives: Loteprednol Etabonate 5 mg (0.5%) and Tobramycin 3 mg (0.3%). Inactives: Edetate Disodium, Glycerin, Povidone, Purified Water, Tyloxapol, and Benzalkonium Chloride 0.01% (preservative). Sulfuric Acid and/or Sodium Hydroxide may be added to adjust the pH to 5.7-5.9. The suspension is essentially isotonic with a tonicity of 260 to 320 mOsm/kg.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid.

Arachidonic acid is released from membrane phospholipids by phospholipase A_2. Corticosteroids are capable of producing a rise in intraocular pressure.

Loteprednol etabonate is structurally similar to other corticosteroids. However, the number 20 position ketone group is absent.

The anti-infective component in the combination (tobramycin) is included to provide action against susceptible organisms. *In vitro* studies have demonstrated that tobramycin is active against susceptible strains of the following microorganisms:

Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains.

Streptococci, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some *Streptococcuspneumoniae. Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis, Morganella morganii,* most *Proteus vulgaris* strains, *Haemophilus influenzae* and *H. aegyptius, Moraxella lacunata, Acinetobacter calcoaceticus* and some *Neisseria* species.

12.3 Pharmacokinetics

In a controlled clinical study of ocular penetration, the levels of loteprednol etabonate in the aqueous humor were found to be comparable between Lotemax and Zylet treatment groups.

Results from a bioavailability study in normal volunteers established that plasma levels of loteprednol etabonate and Δ1 cortienic acid etabonate (PJ 91), its primary, inactive metabolite, were below the limit of quantitation (1 ng/mL) at all sampling times.

The results were obtained following the ocular administration of one drop in each eye of 0.5% loteprednol etabonate ophthalmic suspension 8 times daily for 2 days or 4 times daily for 42 days. This study suggests that limited (<1 ng/mL) systemic absorption occurs with 0.5% loteprednol etabonate.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate or tobramycin.

Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma TK assay, a chromosome aberration test in human lymphocytes, or in an *in vivo* mouse micronucleus assay.

Oral treatment of male and female rats at 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (500 and 250 times the maximum clinical dose, respectively) prior to and during mating did not impair fertility in either gender. No impairment of fertility was noted in studies of subcutaneous tobramycin in rats at 100 mg/kg/day (1700 times the maximum daily clinical dose).

16 HOW SUPPLIED/STORAGE AND HANDLING

Zylet (loteprednol etabonate and tobramycin ophthalmic suspension) is supplied in a white low density polyethylene plastic bottle with a white controlled drop tip and a white polypropylene cap in the following sizes:

5 mL (NDC 24208-358-05) in a 7.5 mL bottle

10 mL (NDC 24208-358-10) in a 10 mL bottle

USE ONLY IF IMPRINTED NECKBAND IS INTACT.

Storage: Store upright at 15°-25° C (59°-77° F).

PROTECT FROM FREEZING

17 PATIENT COUNSELING INFORMATION

This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the suspension. If pain develops, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician. As with all ophthalmic preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses when using Zylet.

MANUFACTURER INFORMATION

BAUSCH & LOMB INCORPORATED

TAMPA, FLORIDA 33637 USA

9007705 (FOLDED)
9004405 (FLAT)

Please see Important Risk Information for ZYLET® on page 1.

ANGLE CLOSURE

(Continued from page 1)

ing their cataract and correcting their spherical error, cylinder, and presbyopia."

Dr. Vold said he will also consider lens extraction over LPI in patients with brown or relatively thick irides as those patients are prone to a more robust inflammatory reaction after LPI that will increase the risk for peripheral anterior synechiae (PAS) formation.

Dr. Vold

"To avoid these issues, I might be inclined to perform cataract surgery first in these patients, especially if there is any evidence of cataract," he said.

LPI TECHNIQUE

Dr. Vold said LPI should generally be avoided if the patient has more than 180° of PAS. Due to a reduced incidence of LPI closure postoperatively, Nd:YAG laser is preferred for the procedure over an argon laser. Although the iridotomy is classically placed between 11 and 1 o'clock, Dr. Vold said he commonly places it temporally since use of a superior site can lead to visual symptoms if the lid bisects the iridotomy.

He recommended treating more peripherally at a site beyond the lens equator, and Dr. Vold emphasized the need to make sure the iridotomy is large enough so that it remains patent.

"The traditional LPI size is 150 to 200 µm, but I prefer LPIs of at least 300 µm," he said.

When performing LPI in a patient with suspected angle closure, he recommended checking IOP several weeks after the procedure and obtaining measurements both before and after dilation to make sure that IOP does not increase after dilation. If the IOP rises, iris plateau syndrome should be considered, Dr. Vold said.

TREATMENT DECISIONS

Dr. Tanaka pointed out that there is no good evidence from randomized clinical trials to guide decisions on treatment of patients with angle closure, both in terms of identifying who should be treated and how.

The Effectiveness in Angle Closure Glaucoma of Lens Extraction (EAGLE) study, a prospective, randomized clinical trial now under way in the United Kingdom and Asia, will compare the relative safety and effectiveness of LPI to lens extraction for patients with newly diagnosed primary angle closure glaucoma (PACG).

However, there remains a need for a narrow angle equivalent of the Ocular Hypertension Treatment Study (OHTS) to help inform management decisions on patients who only have narrow angles, Dr. Tanaka said.

Dr. Tanaka

"Prior to OHTS, any patient with elevated IOP would be started on topical treatment," he said. "However, that probably represented overtreatment since only a small minority of patients with ocular hypertension goes on to develop glaucoma. Based on the findings of OHTS and other studies, we can now target patients who should be treated based on individual risk.

"Similarly, we know that not everyone with narrow angles gets into trouble, and there are risks associated with our surgical interventions for angle closure," Dr. Tanaka continued. "On the other hand, we also know that angle closure is a progressive process that becomes irreversible at a certain point."

Therefore, clinicians need some method to identify people at significant risk for progression so that they can be appropriately treated and hopefully prevented from developing glaucoma and even blindness from glaucoma, he said.

Dr. Tanaka encouraged clinicians to use the current staging system for angle-closure disease that divides the condition into primary angle-closure suspect (PACS), primary angle closure (PAC), and primary angle-closure glaucoma (PACG).

PACS is defined by presence of an anatomically narrow angle with a normal IOP and optic disc. With PAC there is evidence of trabecular meshwork compromise. This abnormality can be structural in the form of peripheral anterior synechiae (PAS) and/or functional as manifested by elevated IOP. PACG is diagnosed if patients have developed glaucomatous cupping of the optic nerve.

Dr. Tanaka said he feels comfortable with observing a patient with PACS who has no positive family history of glaucoma blindness. However, he will perform LPI if the patient has any symptoms consistent with intermittent angle closure, has elevated IOP, or has suspicious optic nerve changes.

If the angle remains narrow after LPI, he would not perform lens extraction in a patient with no or minimal cataract unless the patient has evidence of trabecular meshwork dysfunction, a history of symptoms suggestive of intermittent angle closure, a history of systemic medications that can precipitate angle closure, or a need for routine dilated eye examination (e.g., because the patient has diabetes or has existing retinal disease), or does not have reliable access to eye care.

"In those special circumstances, it is reasonable to take out the lens," Dr. Tanaka explained. "However, we will have better answers on the role of lens extraction based on the results of the EAGLE trial." ■

Angle Closure Staging Classification

DISEASE STAGING		≥180° ITC	⇧ IOP and/or PAS	GLAUCOMATOUS OPTIC NEUROPATHY	
PACS	Primary Angle Closure Suspect	+	−	−	Trabecular meshwork at risk
PAC	Primary Angle Closure	+	+	−	Trabecular meshwork dysfunction
PACG	Primary Angle Closure Glaucoma	+	+	+	Optic nerve damage

ITC = Iridotrabecular contact; PAS = Peripheral anterior synechiae (Figure courtesy of H. George Tanaka, MD)

TAKE-HOME

- ***Glaucoma specialists discuss the use of laser peripheral iridotomy and lens extraction as surgical intervention for chronic angle closure.***

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This article was adapted from a presentation by Dr. Tanaka and Dr. Volk during Glaucoma Day at the 2014 meeting of the American Society of Cataract and Refractive Surgery.

Managing small, non-dilating pupils

Mechanical expansion allows benefits of femtosecond laser-assisted cataract surgery

By Cheryl Guttman Krader; *Reviewed by Zoltán Z. Nagy, MD, PhD*

BUDAPEST, HUNGARY ::

PERFORMING femtosecond laser-assisted cataract surgery requires a 6-mm minimum pupil size.

However, with the aid of a device (Malyugin ring, Microsurgical Technology), even patients with a small, non-dilating pupil can derive the benefits of femtosecond laser-assisted cataract surgery, according to Zoltán Z. Nagy, MD, PhD.

Dr. Nagy

"The superiority of the femtosecond laser for performing multiple steps in the cataract surgery procedure is well-established, and while we know that femtosecond laser-assisted cataract surgery can be safely applied in straightforward cases, it can be of particular value in more challenging situations," said Dr. Nagy, professor and chairman, Department of Ophthalmology, Semmelweis University, Budapest, Hungary.

"Small pupils may be a concomitant feature in many such complex cases, but while pupil size and shape are the only known limitations to performing femtosecond laser-assisted cataract surgery, they represent a relative limitation," he said. "With appropriate technique, femtosecond laser-assisted cataract surgery can still be performed safely and effectively in eyes with small, non-dilating pupils."

PREVALENCE OF CASES

Dr. Nagy noted that only a small minority of patients who present for cataract surgery have a small pupil, which may be the result of previous inflammation or trauma, chronic use of miotic medications, or age-related iris atrophy. However, while the prevalence rate of small pupils is only about 2% to 3%, these patients represent a sizeable population considering the number of patients who undergo cataract surgery.

The 6-mm minimum pupil size for using the femtosecond laser assumes creation of a 5-mm capsulorhexis and the need to have a minimum clearance of at least 1 mm between the boundary of the capsule opening and the pupillary margin.

"Hitting the pupil with the laser can cause further constriction, release of inflammatory cytokines from the iris vessels, or bleeding," he explained.

Usually patients respond well to the use of pharmacological dilation with topical drops, and Dr. Nagy also recommended initiating treatment with a topical nonsteroidal anti-inflammatory drug (NSAID) 1 hour prior to the surgery in order to prevent pupil constriction after the femtosecond laser pre-treatment.

"Before we started with this prophylactic NSAID treatment, we encountered pupil constriction in about one-third of our femtosecond laser-assisted cataract surgery cases," he said. "The miosis occurred as a mechanical effect and due to an increased level of prostaglandins in the aqueous. Pre-treatment with the topical NSAID prevents the prostaglandin-induced miosis."

SURGICAL TACTIC

Dr. Nagy said that he prefers to use the Malyugin ring instead of iris hooks to manage small, non-dilating pupils because he considers the Malyugin ring as safer and because its use makes insertion of the femtosecond laser patient interface easier.

When using the Malyugin ring, a corneal incision is created manually, and the pupil expansion device is injected under viscoelastic support. Once the ring is positioned, the viscoelastic is removed, the incision is temporarily sutured using 10/0 nylon, and femtosecond laser-assisted cataract surgery is performed after verifying the pupil is enlarged to 6 mm.

The procedure is performed the same as in a routine femtosecond laser-assisted cataract surgery case, and the Malyugin ring is removed from the eye at the end of the surgery.

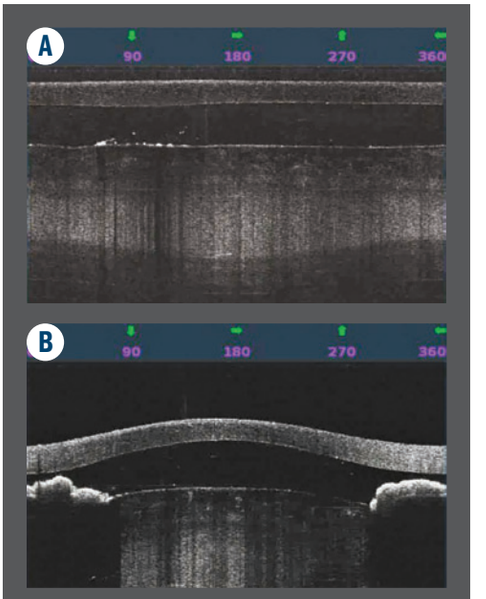
"Femtosecond laser-assisted cataract surgery can be performed in nearly all cases with a small, non-dilating pupil using this technique," he said. "The only limitation might be if there is such abundant iris pigment on the surface of the anterior capsule as to limit absorption of the femtosecond laser energy."

Dr. Nagy and colleagues have published a case describing use of the Malyugin ring during femtosecond laser-assisted cataract surgery in a patient with phacomorphic glaucoma. [Kranitz K, Takacs AI, Gyenes A, et al. *J Refract Surg.* 2013;29:645–648.]

"Whereas average anterior chamber depth is about 3.5 mm, in this patient with phacomorphic glaucoma, the anterior chamber depth was only 1.1 mm," he said. "However, we were able to safely perform the capsulotomy in this very shallow anterior chamber with the aid of the inbuilt optical coherence tomography of the femtosecond laser (LenSx, Alcon Laboratories)." ■

TAKE-HOME

- ***Femtosecond laser-assisted cataract surgery requires a minimum pupil size of 6 mm. If adequate dilation is not achieved pharmacologically, pupil expansion with the Malyugin ring offers a safe and effective solution.***



Optical coherence tomography (analysis, top; real, bottom) of the phacomorph glaucoma patient with very narrow anterior chamber depth. *(Images courtesy of Zoltán Z. Nagy, MD, PhD)*

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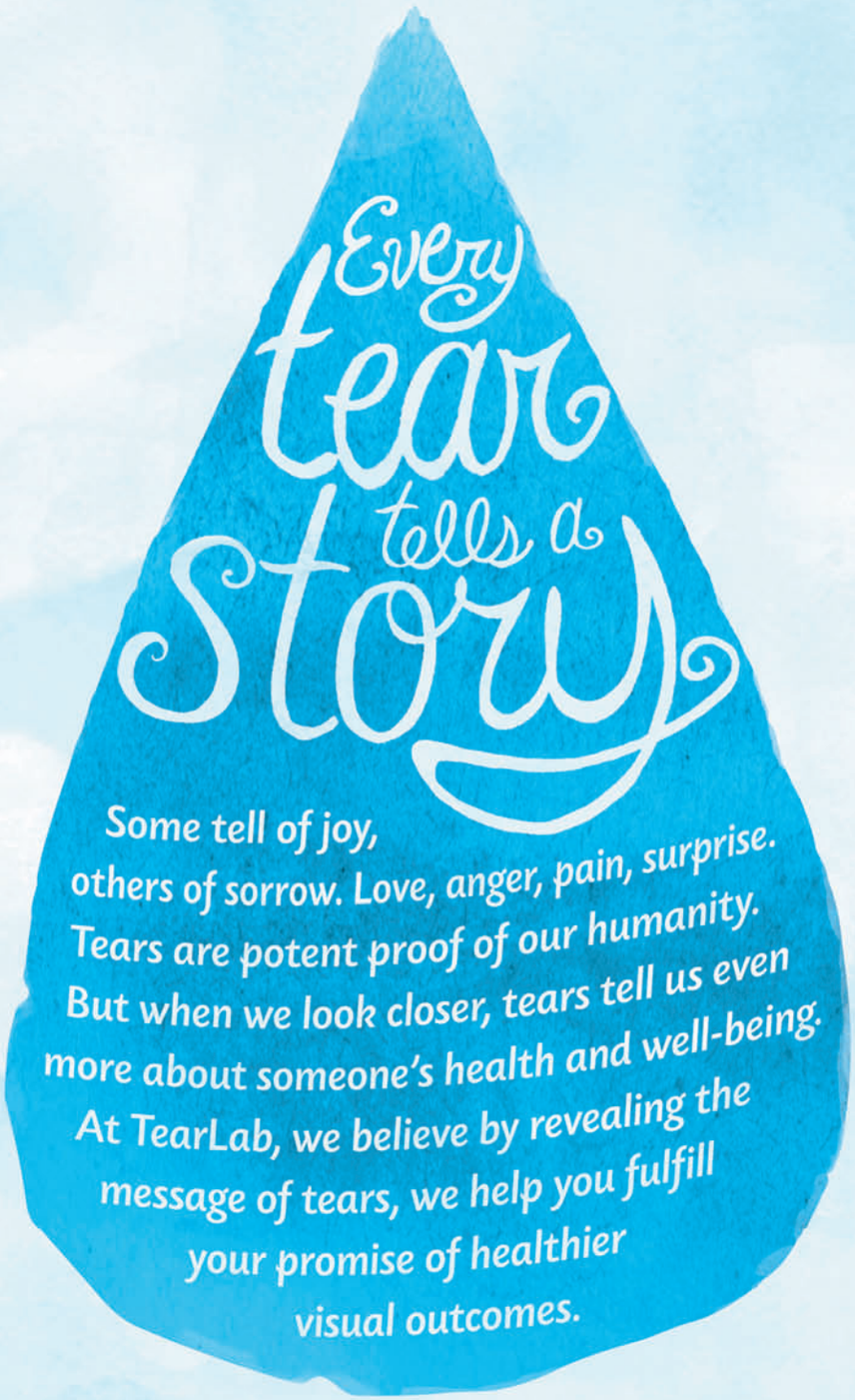
This article was adapted from Dr. Nagy's presentation at Cornea Day during the 2014 meeting of the American Society of Cataract and Refractive Surgery. Dr. Nagy is a consultant to Alcon Laboratories/LenSx.



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Improving LASIK surgery outcomes: Addition of CXL for corneal stability

Theoretical, practical applications explored in wound healing, biomechanical changes

By Lynda Charters; *Reviewed by Ernest W. Kornmehl, MD*

CHICAGO ::

OPHTHALMOLOGISTS ARE faced with wound healing and biomechanical changes after wavefront-guided keratorefractive surgery that include mechanical complications related to flap creation in LASIK and optical complications related to decentration, optical zone size, positive asphericity, and uncorrected higher-order aberrations (HOAs).

Despite advances in laser technology—such as iris registration, multifocal ablations, mixed astigmatism, intraoperative pachymetric monitoring, and the introduction of femtosecond laser technology—the complications related to customized LASIK remain. These include flap complications, custom cornea limitations, and ectasia.

The answer to these problems may be the addition of corneal collagen crosslinking (CXL) performed around the time of LASIK, according to Dimitri T. Azar, MD, MBA, dean, University of Medicine, holder of the B.A. Field Chair in Ophthalmologic Research, and professor of ophthalmology, pharmacology, and bioengineering, University of Illinois at Chicago.

TAKE-HOME

- ***Achieving super-vision after LASIK may rest on the addition of corneal collagen crosslinking around the time of surgery.***

ASPHERICITY-BASED TREATMENTS

Dr. Azar and colleagues have focused their research on improving the spherical aberrations, the 10th-order Zernike polynomials. They started initially by approaching the question of whether simply flattening the central cornea during LASIK in patients with myopia creates problems because of the untreated peripheral cornea.

"Are we creating an oblation cornea with a bigger problem?" he asked.

In a cornea that is perfectly spherical (Q = 0), the rays entering through the corneal periphery are bent more and do not meet the para-axial rays, resulting in poorer image quality, he explained.

Therefore, slightly flattening the peripheral cornea creates negative asphericity, which results in less bending of the rays after they enter the peripheral cornea.

"A prolate cornea provides better image quality," Dr. Azar said.

WAVEFRONT- OR ASPHERICITY-GUIDED TREATMENT

Dr. Azar recounted a study from 2006 in which he and Drs. Sakimoto and Rosenblatt compared the outcomes of custom and non-custom LASIK procedures in published studies. The outcomes that they focused on were the percentages of patients with myopia with 20/20 or better vision, 20/40 or better, within 0.5 or 1 D of the targeted vision, and those who lost two or more lines of Snellen acuity.

When investigators compared the results for patients with 20/40 or better, within 0.5 or 1 D of the targeted vision, and those who lost two or more lines of Snellen acuity, there were no differences between custom and non-custom LASIK.

"When we evaluated the patients with better than 20/20 vision, we found differences of about 10% to 12% in favor of customized LASIK procedures regardless of the degree of myopia," he commented and explained that patients who underwent a customized procedure had a higher probability of achieving 20/20 or better vision.

However, while those results are better in myopic patients compared with non-customized procedure, they still are not achieving super-vision because of limitations in the wavefront analysis.

"Why, despite all of our technologic advances, are we not achieving super-vision?" Dr. Azar posed.

"There are always limitations in customization," he said. "For example, if the same measurement is performed on the same patient multiple times during the day, the results will differ."

In addition, there are limitations in the scanning and tracking laser technology that includes patient factors. More importantly are issues related to postoperative biomechanical changes and wound healing.

"Biomechanics will affect the results especially when procedures go deeper into the cornea," he said. "Wound healing also affects the results. My thesis is that the two go in opposite directions, especially regarding the diameter of the treatment."

Dr. Azar explained that there is a relationship between treatment diameter and depth. For example, with a treatment diameter of 6 mm, the depth is about 12 µm per D; however, if with a treatment diameter of 8.5 mm, the depth doubles to about 24 µm per D.

"Doubling the depth is deleterious for highly myopic patients when performing LASIK," he said.

> 'I imagine the day will come when the technology will become part of LASIK.'
>
> — *Dimitri T. Azar, MD, MBA*

Ectasia is a risk in these patients after LASIK even without pre-existing keratoconus, deep flaps, or high myopia even in patients with normal corneas. The potential for development of ectasia ranges from 0.5% to 5% based on surgeon opinion.

The basic guideline to follow for LASIK, according to Dr. Azar, is that the cornea is more stable with less tissue ablation.

"Reduce the diameter to reduce ectasia," he emphasized.

Regarding the effect of wound healing, the epithelial thickness in the treatment zone differs from that in the untreated zone, which applies more to PRK than LASIK. There are biological phenomena going on that change the epithelial thickness, Dr. Azar noted.

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CUTTING-EDGE ADVANCEMENTS

XFRACTION℠
Optical Path Diagnostix

Exceptional Technology for Excellent Vision

J.C. NOREIKA, M.D., M.B.A. MEDINA, OH

INTRODUCTION:

This article is not about refraction. It is about time, money, productivity and exceptional patient care. It is about the Marco XFRACTION℠ Process. This technologically advanced process gives vision care professionals tools to provide the most precise vision that a patient's anatomy allows. By combining data from wavefront aberrometry and automated refraction, it redefines the professional's understanding of the visual system. It is transformative technology: faster, more accurate, less labor intensive and, ultimately, more cost effective than the standard phoropter refraction. The ensuing clinical vignettes will demonstrate why the Xfraction process sets the refractive and diagnostic standard.

THE REFRACTION:

Refraction is often an afterthought in ophthalmology practices that concentrates on diagnosing and treating pathology. Relegated to the practice's technical staff, it seldom contributes actionable information that aids ophthalmologists in the care of their patients. Xfraction is different; it provides an assortment of customizable diagnostic and therapeutic datasets in flexible, easily interpreted formats. Delivered to the specialist in real time at the point of care, this information renders a comprehensive overview of what, why, and how a patient sees.

WHY XFRACTION℠?:

An ophthalmology practice serves three subsets of patients: those with healthy eyes desiring them to remain so; those affected by vision disorders that can be managed, treated and improved; and, those affected by ocular diseases that current science can only support. Now envision these subsets in a Venn diagram (Figure 2). At its center, the Marco OPD-Scan III assists the ophthalmologist in quickly and accurately consigning a patient to each proper subset. The result enhances delivery of appropriate intervention resulting in efficient, high quality care that exceeds the expectations of even the most challenging patient.

Figure 1: OPD-Scan III as configured on EPIC workstation

Eye specialists take justifiable pride in their clinical acumen and surgical abilities. But, the patient is primarily interested in seeing well. In many general practices, this starts and ends with the refraction. Evaluating key parameters of the visual system, the OPD-Scan III defines the patient's visual capability precisely. "The Xfraction process is highly customizable; systems can be configured to any practice's specifications and **budget** (in an existing office space or in the EPIC workstation)." The flagship Epic workstation is an all-in-one unit that saves time (the physician's most precious commodity), staff labor (a practice's most important cost center), and enhances patient convenience.

The following five common clinical situations are presented to show the functionality and diagnostic capability of this game-changing technology.

CLINICAL VIGNETTE #1: THE MYOPIC ADOLESCENT

The starting point of the Xfraction is the Viewing Software's map. In less than a minute, four separate auto-refractions, a corneal keratometric exam, and a

wave-front analysis of the visual system are performed. This map includes the Root Mean Square (RMS) value. Applying the physics of wave-front aberrometry, this calculation defines the patient's visual potential by evaluating the presence or absence of "aberration" due to tear film, corneal, lenticular and vitreal anomalies. The higher the RMS value, the less likely the patient's eyes will achieve excellent vision, *the refractionist's most diligent and sustained effort notwithstanding.*

Scanning the patient's eyes from tear film to the retina, OPD-Scan III can assess visual potential before the slit-lamp is positioned. If the readings indicate that the wave-front refraction was "sent", the patient's visual system is "very clean", i.e., technically, there are no significant sight-impairing abnormalities involving the aforementioned anatomical structures. "Wave-Front Sent" means there is high correlation between the four auto-refraction measurements and the wave-front analysis. Technically, the software's nomogram has found a low RMS value and differences of less than 0.50 diopters in sphere or cylinder or 10 degrees axis between the 2.6 mm pupil's auto-refractions and the 4 mm wave-front refraction in both eyes.

When the 'wave-front' (WF), refraction is sent, statistical probability indicates that the refraction is accurate; one can confidently predict that little or no additional technical effort is needed to refine it. Alternatively, if the Xfraction process indicates that the 'auto-refraction' (AR), has been chosen and sent, a formal refraction is required to achieve best visual acuity. Utilizing decision-tree methodology, the system guides the refractionist to the most efficient method of correcting the patient's vision.

When a comprehensive refraction is required, the flexibility built into the Epic 5100 and TRS-5100's software enhances speed, ease and accuracy by permitting patients to better judge differences detected by traditional "is one better or two better?" methodology. Because the patient's ability to accurately discern differences is increased, the refractionist's task is simplified. Why is this important? Young, healthy patients often present for services paid through vision care plans. Because reimbursement levels are low and decreasing, a refractionist's speed, accuracy, and efficiency is critical if an economic return is to be realized.

Please note two additional innovations of the Epic-5100 and/or TRS-5100 Xfraction process. Upon completion of the formal software-guided refraction, the patient can immediately compare and contrast her vision through her current glasses' correction and the new Xfraction prescription in rapid succession by a single button push. Viewing this near-simultaneous comparison, the patient can quickly decide if new glasses are warranted. The patient is thus pre-qualified for the optician, an advantage impossible by traditional phoropter refraction.

A second tool involves the visual acuity charts of the OPD-Scan III Viewing Software. In the exam lanes, acuity chart images are presented on LCD screens to demonstrate to patients, significant others or parents how the patient views the world without refraction and with the new Xfraction prescription. For younger or more graphically inclined patients, a beach scene can be chosen to model the differences. This is a powerful teaching tool that engages the patient in the exam process.

CLINICAL VIGNETTE #2: THE ASTIGMATIC PATIENT

The OPD-Scan III Viewing Software's "overview" provides three basic images of each eye: the Axial, Internal OPD, and OPD maps. The OPD map represents the aggregation of the Axial and Internal OPD maps and defines the status of the entire eye. Each provides useful information, the sum of which is more powerful than each individual component.

It is not unusual to interview a new patient who reports they have "a lot of astigmatism"; they will then casually

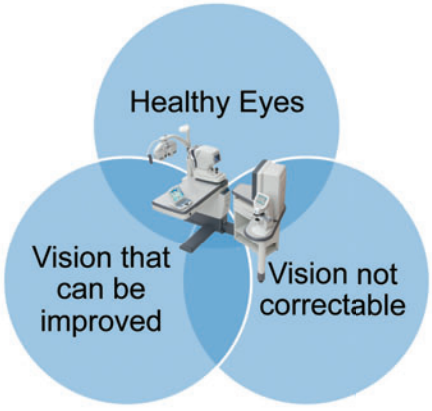

Figure 2: Venn Diagram

ask, "what is astigmatism?" An easy way to get lost in the weeds is to open a discussion on the Conoid of Sturm.

Projecting the Axial map on the exam lane's screen with the Viewing Software, the answer to the patient's query is graphically displayed. The map's colored image illustrates corneal topography and facilitates an explanation in layman's terms. Using the system's Point Spread Function, the actual impact of astigmatism on the patient's vision can be illustrated. The "wow-factor" of this capability should not be underestimated.

The physician can use the three maps to rapidly evaluate the eyes' topography and astigmatic curvatures. The system distinguishes astigmatism at the pinhole automated refraction 2.6 mm, 3 mm and 5 mm zones as well as the mesopic pupil size. Astigmatism that diminishes toward the cornea's periphery has little impact on the quality of the patient's vision. Astigmatism that is seen to increase from the pinhole to 3 mm and 5 mm zones should be addressed; this will be discussed in Clinical Vignette #4.

The OPD-Scan III can identify internal astigmatism, i.e., total astigmatism found behind the anterior corneal surface. This is especially critical when an ophthalmologist advises a prospective cataract surgery patient to consider a premium toric intraocular lens. Unrecognized, internal astigmatism can lead to less than optimal surgical results, patient dissatisfaction and surgeon frustration. It is defined by the Internal OPD

map. An additional tool, the "Subtract Prism" button of the Viewing Software, helps identify the lens as a source of internal astigmatism.

CLINICAL VIGNETTE #3: WHY CAN'T I SEE 20/20?

The science of high order aberrations has shed light on this all-too-common question. OPD – Optical Path Difference – technology can distinguish in seconds if the ophthalmologist is encountering a "clean" eye, i.e., one whose tear film, cornea, lens and vitreous are anatomically normal.

The OPD-Scan III provides several options to elucidate the cause of poorer than expected vision. To evaluate the tear film, increasingly recognized as a necessity for good sight, the system's 33 ring Placido disc is evaluated. Critiquing the quality and symmetry of the rings, a specialist can detect ocular surface abnormalities. More importantly, the images provided by the Viewing Software allow patients to better understand the source of their difficulty. This enhances compliance with proffered therapy.

One of the system's three basic images, the OPD map suggests potential problems at a glance. Color-coded, an OPD image of soft blue, green and yellow tones offers reassurance that the refractive apparatus of the eye is in good condition. "Hot" images showing bright yellows, oranges and reds alert the clinician to look closer to explain the patient's symptoms. The process starts with evaluation of the RMS values at the 3 and 5 mm zones; these data points are found on the OPD and Axial maps and the refraction readout. (Fig. 4 – The OPD Map Graphic)

The RMS values identify those eyes with high order aberrations and transmission defects. Internal high order aberrations cannot be corrected with spherical and cylindric lenses no matter the time and effort expended. If the RMS value is less than 0.4 at the 3 mm zone and less than 0.6 at the 5 mm zone, the patient's best corrected vision will be 20/20 or better (assuming the posterior visual system including the retina, optic nerve, and cortical centers are healthy). RMS values above 0.4 and 0.6 respectively indicate that 20/20 vision is unlikely with spectacle correction. And therein lies the answer to the dreaded question posed above. Identifying high order aberration, the OPD-Scan III allows the specialist to educate the patient why 20/20 vision remains elusive.

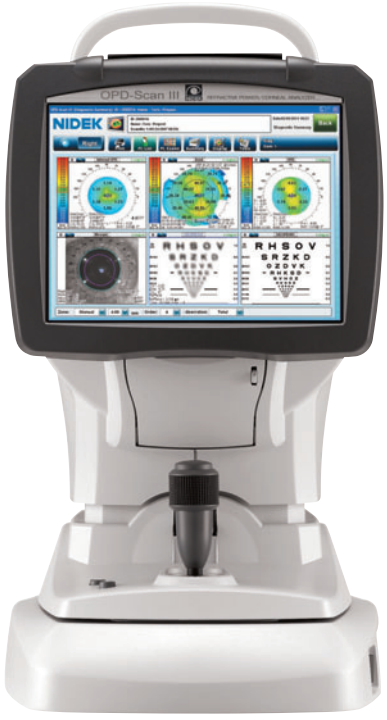

Figure 3: The OPD-Scan III Refraction Viewing Screen

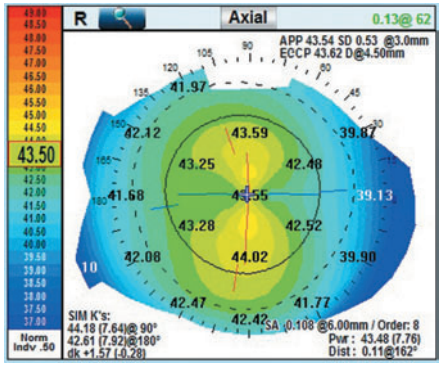

Figure 3a: The Corneal Topographic Map w/ classic bow-tie pattern

Figure 3b: with an image of the point-spread display of an astigmatic patient as it deviates from pin-point

CLINICAL VIGNETTE #4: THE PATIENT WITH A BAGFUL OF GLASSES

You introduce yourself to the patient. You ask what brings him to your office. Without speaking, he points to the pile of glasses on the desk and, with a sigh, states he can't see with any of them. Did I mention it is a late Friday afternoon?

Often, the complaint involves driving at night. Fortunately, the OPD-Scan III excels in this scenario because it provides a most important clue, specifically, does the patient's prescription differ under photopic and scotopic conditions? Looking at the maps, it can be seen that there is a solid-line circle centrally and a dashed-line circle peripherally. These represent the photopic and mesopic pupils. If the astigmatism power bleeds into the periphery, the patient's prescription will change under photopic and scotopic conditions. (As the pupil dilates, more of the peripheral cornea's refractive power comes into play. This fact also applies to patients wearing sunglasses and transition lenses.) By clicking the Day-Night Refraction button, any significant differences are highlighted in red. Best correction may require a second prescription to maximize vision and comfort. The Axial and OPD maps and the Point Spread Function of the Viewing Software graphically depicts this. The OPD-Scan III can formulate the patient's correction to a pupillary diameter of up to 9.5 mm and provide a customized night-driving solution.

But patients are sometimes examined whose anatomy is normal but whose eyes cannot be corrected to 20/20 vision. The RMS value answers the "why" and the Point Spread Function shows the "what". As noted above, the higher the RMS values, the greater the impact of high order aberrations

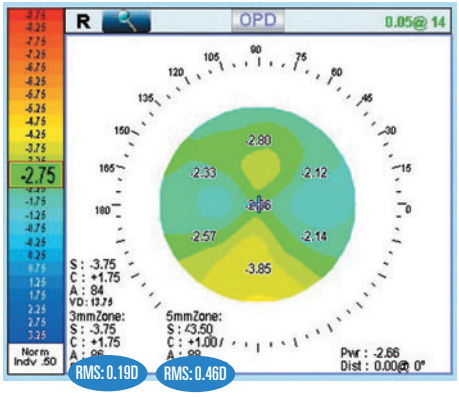

Figure 4 : The OPD Map Graphic

on the quality and quantity of vision. By differentiating corneal surface from internal high order aberrations, the OPD-Scan III can identify those that may be ameliorated by rigid contact lenses. A useful strategy is to identify the problem, determine the refraction providing the best vision and then use Point Spread Function images on the Viewing Software to educate the patient as to what realistically can be achieved. The Point Spread Function compared before and after best correction can reinforce the point. The OPD-Scan III can disassemble the corneal and lenticular components of the Point Spread Function to delineate the effects of nuclear sclerosis, cortical cataracts and tilted or malpositioned intraocular lenses.

The result? Another expensive pair of glasses will not join its bag-encumbered colleagues. Pin-point vision? Not possible. High order aberrations are the reason; the specialist knows this because she has checked the RMS values. The OPD-Scan III Viewing Software helps instruct the patient. And, it is likely that this explanation has never been offered to the patient in the past.

CLINICAL VIGNETTE #5: THE DIAGNOSTIC SURPRISE?

It doesn't happen often. An unsuspecting patient presents for a "routine" eye examination and the ophthalmologist intuits a problem: the patient's symptoms? The level of vision? The many eye doctors consulted in the past? Making or missing the diagnosis can

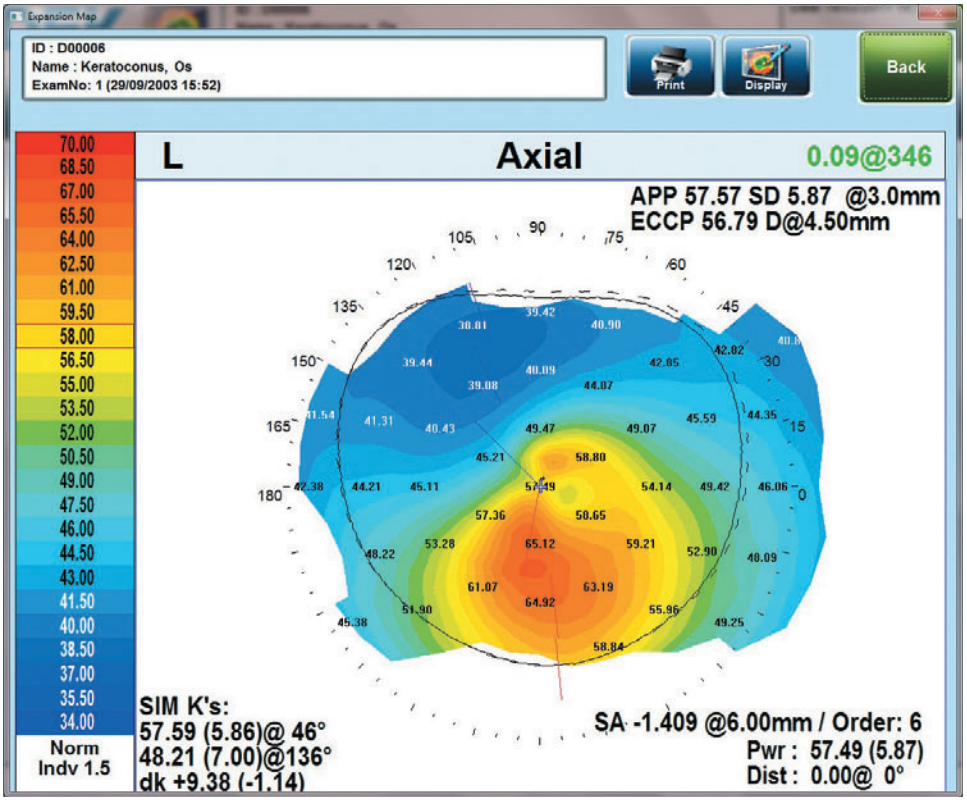

Figure 5: Axial Map with Keratoconus

lie in the doctor's access to information. The OPD-Scan III technology is like the iconic Swiss Army knife; it offers multiple advanced modalities designed into one small, efficient, time-saving footprint of wave-front aberrometry and automated refraction.

Entering the exam lane, a glance at the Viewing Software on the LCD monitor provides the doctor an invaluable first impression. Customization of the Viewing Software permits each physician to choose what appears on the screen. The three basic maps – Axial, Internal, and OPD – are color-coded. Yellow, green, blue? All good. But this patient has an inferior hot spot burning red and orange on the axial map. (Figure 5: Axial Map with Keratoconus) Keratoconus? Forme-fruste? Pellucid degeneration? All this is noted before the doctor sits down. Clicking on the "Subtract Prism" button confirms the problem involves the anterior cornea.

"Cool" colors? Good. But the patient experiences fluctuating vision. Call up the Placido disc. Magnify it on the screen. The mires look warped, irregular. The patient may be relieved to learn that their tear-film instability is not the harbinger of more serious eye disease. The quality of vision and comfort may be enhanced with proper treatment.

SUMMARY:

The XFRACTION℠ Process, with the OPD-Scan III as its crown jewel, is all about diagnostic acumen and clinical outcomes, patient convenience and satisfaction, and practice process efficiency. This technology is impressive, a fact not lost on the patient who has been subjected to traditional phoropter refractions during other encounters.

Yet, as noteworthy as its benefit in the context of the general ophthalmic practice, the OPD-Scan III truly excels in the brave new world of refractive cataract surgery. Beyond the scope of this article, the importance of the OPD-Scan III (in delivering wavefront optimized refractions) to modern premium lens surgery will be addressed in Part II of this series.

Ophthalmology Times
CLINICAL NEWS & ANALYSIS

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He provided the example that with a 5-mm-diameter treatment, 3 µm of tissue hyperplasia will result in loss of the desired treatment effect. Likewise, with an 8-mm-diameter treatment, 22 µm of tissue hyperplasia may result.

"In order regain the ability to achieve customization, the treatment should be wider and wider to preserve the effect of customization," Dr. Azar said. "However, the price of this is weakening of the cornea.

"The effect of the biomechanics and wound healing are pushing surgeons to achieve a certain equilibrium between the two forces," he said.

WHAT IT ALL COMES DOWN TO

The resultant question is: Can aspects of conventional surgery, wavefront-guided surgery, and corneal asphericity be combined to provide custom corneal laser treatments?

"The answer to this lies in crosslinking," Dr. Azar said. "There have been encouraging results of crosslinking in keratoconus. I imagine the day will come when the technology will become part of LASIK."

Crosslinking has also shown encouraging results in postLASIK ectasia.

Incorporating crosslinking into LASIK will result in the ability to use larger diameter treatments during LASIK to maintain the asphericity of the wavefront-based HOA correction and preserve the good outcomes associated with wavefront-guided treatments without risking development of ectasia, Dr. Azar noted. This process is being referred to currently as high-fidelity LASIK.

Recent advances in laser vision correction—including improved technology, patient selection surface ablation, monovision, and asphericity optimized/wavefront-guided custom LASIK—have allowed for better treatments and outcomes, Dr. Azar summarized.

"Despite the improved outcomes, the limitations include the inability to measure and render all HOAs wavelengths, the inability to predict the surgically induced aberrations, and the inability to perfectly position the treatment on the corneal plane," he said. "Other important considerations include biomechanical changes and the wound healing effects that take us in the opposite direction from that desired."

OT A. John Kanellopoulos, MD, of Athens, Greece, in 2007 introduced performing collagen crosslinking (CXL) concurrently with primary LASIK in all patients with hyperopia and myopia considered at risk for ectasia or regression. **Read more about the procedure at http://bit.ly/1Aywil0.**

Important needs requiring improvement in what Dr. Azar believes is a "brilliant" future are the need to prevent ectasia, increase corneal rigidity and stability after LASIK, have large optical zones to preserve the intended HOA correction, and have large optical zones to reduce glare and halos.

"These can be accomplished by collagen crosslinking performed at about the time of LASIK," he said. ■

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This article was adapted from Dr. Azar's presentation of the Barraquer Lecture at the 2013 meeting of the American Academy of Ophthalmology. Dr. Azar is on the board of directors of Novartis and receives research funding from the National Institutes of Health.

New parameter aims to improve visual field sensitivity testing

By Cheryl Guttman Krader

ROTTERDAM, NETHERLANDS ::

POINT-WISE visual field sensitivity analysis can be improved by incorporating an overall visit effect into the data analysis, according to a study by researchers from the Rotterdam Eye Institute.

Designated as the Global Visit Effects (GVE), this new parameter aims to incorporate both measurable factors—such as season, time of day, and reliability indices—and unknown transient factors, such as fatigue, lack of concentration, or delayed reaction time, said Susan R. Bryan, MSc, researcher and PhD candidate, The Rotterdam Ophthalmic Institute, The Netherlands.

"One of the difficulties in modeling visual field data is the large measurement variability, partially due to the subjective nature of the device," Bryan said. "Random measurement errors that are present in the point-wise sensitivity estimates are reduced when calculating summary parameters such as the mean deviation. Other errors, however, are spatially correlated and affect the whole visual field."

The GVE contribution was investigated using data from 50 patients with primary glaucoma who underwent 24-2 full threshold testing.

The analyses included sensitivity estimates in 52 locations in both eyes and used a hierarchical, Bayesian, mixed-effects model with four levels: individual, eye, hemisphere, and location. When comparing the observed data and posterior predicted values for the models, it was determined the GVE significantly improved the model fit, and mean absolute error was 1.94 dB with the GVE and 2.14 dB without it.

Moreover, the magnitude of the GVE effect, 0.82 dB, was much larger than that of any other measurable factor known to affect visual field testing, including season, time of day, percentage of fixation losses, percentage of false positives, and percentage of false negatives, and was 3-fold larger than that of all the measurable factors combined.

"Measurable factors—such as season, time of day and reliability indices—represent one group of such errors and have been evaluated before," Bryan said. "Although these factors are statistically significant, as our study showed, they are rather small, and as such cannot explain the observed global variation in visual fields.

"Our findings confirm our hypothesis that other transient factors modeled as a global visit effects play a more important role, and showed that by incorporating the GVE in our models, better estimates of the real evolution in visual field data over time may be obtained," she continued.

In addition, Bryan said including the GVE changes the estimation of the rate of visual field progression, and also affects the projected future visual field sensitivities, and may therefore have an impact on treatment. For now, clinicians should be aware that even if a new measurement is outside the range of previous measurements, it might just be due to the GVE rather than actual progression, Bryan said. ■

Glaucoma care: Decade ahead to bring momentous advances

Improvements in risk-prediction and risk-modification strategies likely to transform clinical practice

By Cheryl Guttman Krader

SAN DIEGO ::

The next 5 to 10 years will be a period of remarkable research discoveries for glaucoma and their translation into enhanced patient care, said Robert N. Weinreb, MD.

"Glaucoma research has a number of areas that will be transformative and will dramatically change our clinical practice," said Dr. Weinreb, chairman of ophthalmology, director of the Shiley Eye Center and the Hamilton Glaucoma Center, University of California, San Diego.

Dr. Weinreb

Looking forward to what is next in glaucoma, Dr. Weinreb discussed improvements in risk-prediction and risk-modification strategies, increased knowledge of glaucoma pathophysiology, the advent of 24-hour IOP monitoring, and advanced technologies for structural and functional imaging.

A broadened understanding of glaucoma's genetic associations is one of the first events on the horizon, and the information will be valuable in helping clinicians better determine an individual's risk for becoming functionally impaired. To date, there is only limited information about genetic variations associated with glaucoma. However, it is expected that this will change with findings from ongoing studies, including research being funded by the National Eye Institute and others.

"Not all patients progress along the glaucoma continuum to the stage where they become functionally impaired," Dr. Weinreb said. "In the future, we will incorporate findings from genetic analyses in our risk calculators to identify patients at highest risk for progression. Equipped with that information, we can best allocate limited resources for health care."

Increased understanding of the mechanisms of glaucomatous optic nerve damage is also forthcoming, as multiple laboratories elucidate the role of the microcirculation, immune system, and the milieu of inflammatory cytokines associated with glaucoma. More complete articulation of the mechanisms of optic nerve damage will also provide a foundation for developing more effective glaucoma treatment.

24-HOUR IOP MONITORING

The advent of 24-hour, IOP-monitoring systems will transform glaucoma patient care in the near future because it will allow clinicians to better define target IOPs and to treat patients more effectively. One such device, a contact lens-based system (Triggerfish, Sensimed) that detects changes in corneal curvature as a surrogate for IOP, is currently available in Europe. Other implantable devices that measure IOP directly are in development (Implandata and AcuMEMS) and are in clinical trials.

"Today, we make decisions based on a single IOP measurement taken during office hours, but the patient's IOP may be different at other times during the day," Dr. Weinreb said. "With 24-hour, IOP monitoring, we can better understand the impact of IOP, and we will also be able to determine if our treatment target should be based on IOP peak, 24-hour mean, or fluctuation over 24 hours or a longer period."

Dr. Weinreb said that over the next 5 to 10 years, devices will be available that adjust therapy based on continuous monitoring of IOP.

"Such devices might synchronize drug release with peaks of IOP or open conduits to allow aqueous outflow," he added.

DIAGNOSTIC TECHNOLOGIES

According to Dr. Weinreb, use of diagnostic technologies for assessing features of individual retinal ganglion cells (RGCs), as well as the entire visual pathway, may also become part of clinical glaucoma practice within the next decade. Modalities, such as functional magnetic resonance imaging, are already being used in research studies investigating glaucoma-related damage, recognizing that glaucoma is not just an eye disease but a neurodegenerative condition affecting the brain as well.

Neuroprotective strategies are also on the horizon with cell-based strategies likely to be the earliest to become available. Dr. Weinreb noted that studies are underway evaluating the use of neurotrophic growth factor-releasing cells for rescuing damaged RGCs. Eventually, with the use of pluripotent stem cells induced from the patient's own skin fibroblasts, optic nerve regeneration may become a reality.

On the topic of glaucoma risk factors, Dr. Weinreb looked ahead to more information about the role of cerebrospinal fluid pressure (CSF). He cited recent research that identified translamina cribosa pressure difference (IOP minus intracranial pressure) as a powerful predictor for glaucomatous damage in both high pressure and normal tension disease, and noted that the information raises interesting ideas about novel strategies for treating glaucoma based on modulating intracranial pressure.

Finally, Dr. Weinreb said ophthalmologists should expect new information about lifestyle modifications that can be beneficial for glaucoma.

"It is remarkable how few studies have been done on potentially modifiable risk factors like smoking, diet, obesity, and exercise," he noted. "Just like cardiologists do today, I predict that in the future, we will discuss with our patients smoking cessation, altering diet, losing weight, and increasing physical activity." ■

TAKE-HOME

- ***The next decade will be a period of remarkable research discoveries for glaucoma and their translation into enhanced patient care, according to Robert N. Weinreb, MD.***

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This article was adapted from the 2014 New Horizons Forum at Glaucoma 360°, in partnership with the Glaucoma Research Foundation and Ophthalmology Times. Dr. Weinreb did not indicate any financial interest in the subject matter.

Color in a New Light

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Advances in specialty lenses expanding range of options for corneal ectasia

Innovations in designs, materials may accommodate patients with contact lens intolerance

By Lynda Charters; *Reviewed by Deborah S. Jacobs, MD*

BOSTON ::

ADVANCES IN SPECIALTY lenses are enhancing treatment options for corneal ectasia in patients who previously may have been intolerant of contact lenses.

"New designs and materials are more comfortable and physiologic," said Deborah S. Jacobs, MD, medical director, Boston Foundation for Sight, Needham, and assistant clinical professor of ophthalmology, Harvard Medical School, Boston.

Dr. Jacobs

The initial treatments for corneal ectasia—which include keratoconus, pellucid marginal degeneration, keratoglobus, Terrien's marginal degeneration, and post-LASIK ectasia—are correction of the refractive error using spectacles, soft spherical and toric lenses, and conventional rigid gas-permeable (RGP) lenses.

These options are best when myopia predominates over astigmatism and when the dominant eye is less affected. In addition, only RGP corneal lenses can correct irregular astigmatism, Dr. Jacobs noted.

With corneal ectasias it is less likely that the preferred RGP fit—lid attachment—can be achieved, because the corneal RGP lens moves to the steepest part of the cornea, which in the ectasias is typically inferiorily. The result is an intrapalpebral fit, which is inherently less stable. The only choice then is to fit "tight." And therein lies the rub—the patient may end up as being intolerant to the contact lens because of instability with lenses "popping out" or because of scarring or discomfort because of apical bearing and hypoxia.

U.S. ophthalmologists lost interest in contact lenses 25 years ago because of the indisputable superiority of posterior chamber IOLs over contact lenses for cataract patients, and because of the advent of laser refractive surgery. Optometrists, opticians, and contact lens technicians in the United States abandoned RGP lenses in favor of soft contact lenses for correction of refractive error because of greater patient acceptance and ease of fitting.

As a result, Dr. Jacobs explained, "a small minority of contact lens fitters are interested, proficient, and up-to-date regarding innovations in contact lenses."

The new specialty lenses comprise a new field in optometry and an area of growth in the global contact lens industry. She explained that now optometry graduates can do a residency—i.e., an additional year of clinical training after they earn the OD degree—to study cornea and contact lens, ocular diseases.

"Cornea- and contact lens-trained ODs are familiar and facile with the newest contact lens options and often train and work collaboratively with ophthalmologists," she said. "The specialty lens is a growth area in the global contact lens industry."

TAKE-HOME

- ***Specialty lenses are filling the gap for patients with corneal ectasia who previously were considered intolerant of contact lenses.***

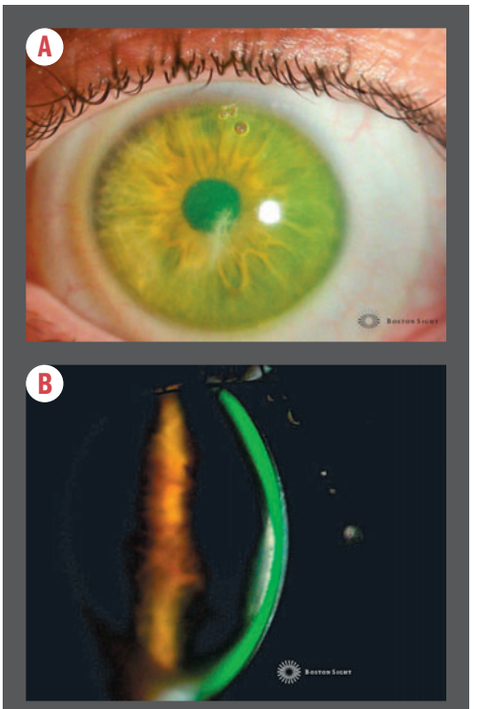
SPECIALTY LENSES

Specialty lens options include RGP corneal lenses (keratoconus designs), piggyback systems, soft lenses (keratoconus designs), hybrid lenses, and mini-scleral and scleral lenses, as well as prosthetic replacement of the ocular surface ecosystem (PROSE) treatment.

RGP CORNEAL LENSES. These lenses provide innovative base curves to accommodate cone and innovative optics to neutralize the characteristic decentration and coma.

PIGGYBACK SYSTEMS. These systems—involving placement of any hard contact lens over any soft contact lens—require creativity, according to Dr. Jacobs. Oxygen transmission decreases with thickness and the central and peripheral thicknesses vary with power.

Newer high-Dk materials—rigid and soft—are helpful. A soft lens with an anterior cutout to serve as a carrier, such as Flexlens (X.Cel) or plus power to stabilize corneal the RGP lens, can be used. These systems may fail with some patients because of acute hypoxia/overwear syndrome, chronic hypoxia/neovascularization, or handling issues.



A Patient with advanced keratoconus and scarring corrected to 20/25 with PROSE treatment.

B Fluorescein highlights the tear-filled reservoir and the lack of corneal touch. *(Images courtesy of Deborah S. Jacobs, MD)*

SOFT LENSES. Innovations in soft lenses—such as the Kerasoft IC (Bausch + Lomb) and NovaKone (Alden)—offer a rigid modulus and large diameter, among other features, that result in mechanical stability and an optical neutralizing tear lens.

HYBRID LENSES. Specialty hybrid lenses for keratoconus were in-

troduced in the 1980s, with SynergEyes lens arriving on the market (Quarter-Lambda Technologies and later SynergEyes) in 2001. The RGP optic has a Dk of 100, but the soft skirt has a Dk of only 9.3. These lenses were prone to failure because of junction fragility with handling. The design is prone to adherence with difficult removal and to chronic overwear syndrome, leading to reduced tolerance and wearing time.

Patients can also develop neovascularization from a combination of the low-Dk skirt, apical hypoxia, and apical bearing. The SynergEyes Duette hyper-Dk design introduced in 2010 has a RGP lens with a Dk of 130 and a silicone hydrogel soft skirt Dk of 83, which may address many of these issues, she noted.

MINI-SCLERAL AND SCLERAL LENSES.

Mini-scleral, semi-scleral, and corneoscleral lenses—e.g., the SoClear Lens (Art Optical) and the Mini-Scleral Design and One Fit Lens (both from Blanchard Contact Lens Inc.)—are evolving with diameters ranging from 13 to 16 mm and high-Dk materials. These contact lenses may come into contact with the cornea at the apex and/or peripherally. The principles of fit are similar to those of RGP corneal lens. Alternatively, fitters seek to achieve a "scleral" fit with no corneal touch. With these lenses, the narrow bearing zone may lead to complications, according to Dr. Jacobs.

Scleral lenses—Jupiter Scleral (Medlens Innovations/Essilor), Tru-Scleral Lens (TruForm Optics), Macrolens (C&H Contact Lens Inc.), and Maxxim (Acculens)—have a minimal diameter of 17.5 mm. "Scleral" fit is also typically understood not to contact the cornea. Historically scleral lenses were molded and were over 20 mm in diameter. These contemporary designs are typically dispensed in diameters of 17.5 to 19 mm, they are now cut on a lathe, and are made of the newer high-Dk materials.

PROSE TREATMENT OF ECTASIA.

The PROSE treatment—developed by the Boston Foundation for Sight—uses FDA-approved, custom prosthetic devices to replace or support the impaired ocular surface functions, Dr. Jacobs explained.

"A PROSE device does not touch the cornea," she said. "The design vaults the cornea and the vault is independent of the base curve."

The design includes a back-surface-bearing haptic that is not specified by superposition of spheres; there may be asymmetrical profiles; and typically, there is no movement on the eye.

In a study of a 2008 cohort of patients with ectasia (89 eyes of 59 patients), all eyes could be fitted with the device. Ninety-three percent of eyes achieved best-corrected visual acuity of 20/40 or better, and there was mean of 27.6-point improvement on the National Eye Institute Visual Function Questionnaire-25 ($p > 0.001$). Documented continued wear at 6 months was reported for 88% eyes.

"Satisfactory fit of a PROSE device was attained in all cases," Dr. Jacobs said. "No cone was too steep. No eyes were excluded because of disease severity." ■

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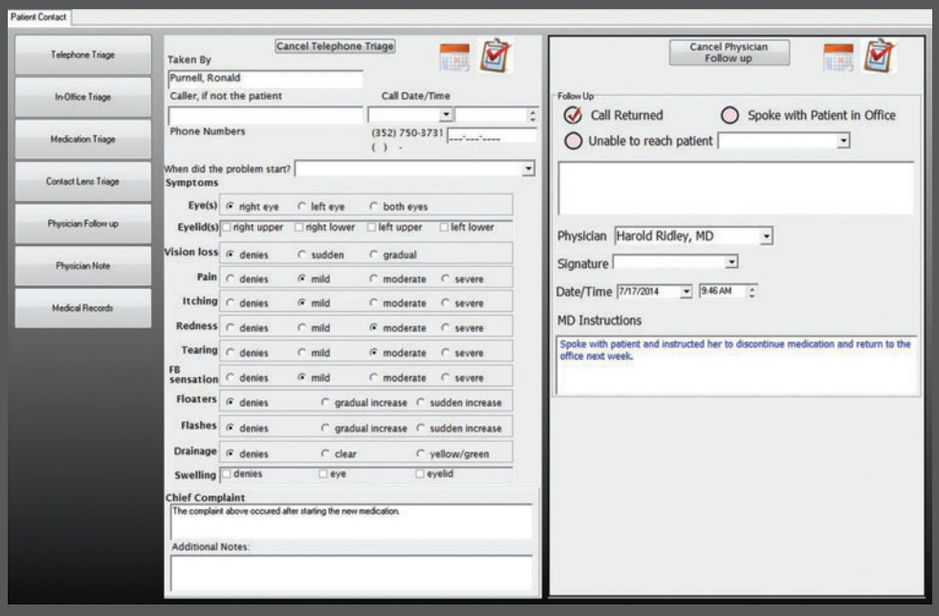
Dr. Jacobs has no proprietary or financial interest in any contact lens or prosthetic device.

LATEST UPDATES REGARDING EHRs

STRATEGIES FOR MAKING A SUCCESSFUL ELECTRONIC HEALTH RECORD IMPLEMENTATION OR UPGRADE

Making EHR workflow user-friendly



(FIGURE 1) An example of a triage sheet with a telephone triage and physician follow-up tab opened. *(Figure courtesy of Ronald J. Purnell, MBA, COE)*

TIPS FOR VETTING AN EHR VENDOR FOR DAILY PRACTICE

Proper planning of time, expense, and resources vital to successful system implementation

By Ronald J. Purnell, MBA, COE

take-home

- **Here are several key steps that every practice should consider for successful implementation of an electronic health record vendor.**

The manner in which a new electronic health record (EHR) vendor is brought onboard depends largely on the practice's culture.

However, here are several key elements that every practice should consider for successful implementation.

ENLIST HELP OF QUALIFIED STAFF

The first step in initiating the EHR system was enlisting the help of tech-savvy, positive, and enthusiastic staff members to help with implementation. For example, one of the staff members came from a primary-care physician's practice where she had been utilizing an EHR system for some time.

She was excited about transitioning to an EHR system, and reassured staff that the process would increase efficiency and would be appreciated in the long run. She was an asset to the core team. Anyone who loves the Internet and is considered to be a computer "geek" should be asked to help.

On the contrary, a staff member who is anxious about computers or who has a negative attitude about EHR in general might be better off being training last, after others have implemented the process.

Staff members were designated from each area of the practice: medical records, billing, front desk, technicians, and physicians.

A solid team allowed the process to run smoothly. Core staff members were responsible for reviewing how information flowed through their area and which paper forms they would need to find an electronic version of, or workaround.

For instance, receptionists have several forms they can create electronically: telephone triage, in-office triage, medication triage, contact lens triage, physician follow-up, physician note, and medical records.

Additionally, though support staff at the vendor (ManagementPlus) was relied on for guidance, most of the customization was performed internally with the help of two computer science college students looking for employment-related experience.

SEEK FEEDBACK FROM PEERS

Extensive communication with administrators across the country was made as well as networking with other eye-care practices that implemented EHR in a short period using stock templates with little or no customization. Although there seems to be no formula for what works and what causes a nightmare, one common thread is a full understanding of what each system is capable of and what limitations each may have.

Choosing an EHR system is like buying a car. For instance, my wife loves her small SUV because it offers good gas mileage, winter drivability, and easy access. Many of our doctors drive full-size, nine-passenger SUVs. My wife's car will never tow four snowmobiles and seven passengers to camp in the winter, but it meets her needs.

There is absolutely no substitute for spending the time and money to visit practices similar in size and make up to see what works

Continues on page 23 : ***Vetting vendor***

Restasis®
(Cyclosporine Ophthalmic Emulsion) 0.05%

For patients with decreased tear production presumed to be due to ocular inflammation associated with Chronic Dry Eye

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Increased tear production was seen at 6 months.[1]

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RESTASIS® (cyclosporine ophthalmic emulsion) 0.05% is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Important Safety Information

Contraindications

RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

Warnings and Precautions

Potential for Eye Injury and Contamination: To avoid the potential for eye injury and contamination, individuals prescribed RESTASIS® should not touch the vial tip to their eye or other surfaces.

Use With Contact Lenses: RESTASIS® should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion.

Adverse Reactions

In clinical trials, the most common adverse reaction following the use of RESTASIS® was ocular burning (upon instillation)—17%. Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Please see Brief Summary of the full Prescribing Information on adjacent page.

Reference: 1. RESTASIS® Prescribing Information.

ALLERGAN

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Selecting an EHR vendor: Taking a proactive approach

Strategies for developing a step-wise fashion to choose system appropriate for practice

By William L. Watson

CHOOSING AN electronic health record (EHR) system is a huge undertaking, no matter the size of the practice. Here is a checklist of key considerations that eye-care professionals should keep in mind before deciding on any EHR system.

1. KNOW THE COMPANY AND SALES TEAM

When shopping for an electronic health record (EHR) vendor, keep in mind that a moving target is being purchased. What is purchased now may transform into a completely different system in a very short time after software updates and changes in government regulations.

Therefore, it is important to consider the sales team and the company, even before the product. Interview the sales representative and ask key questions. How long has the company been in existence? Why and how was the company started? How long has the sales representative been selling the product in the area?

Getting to know the history of a company and its sales team allows you to make a decision based on the integrity of the company, which, in turn, allows you to judge the integrity of the product now and in the future.

2. CHOOSE A SPECIALTY-SPECIFIC EHR

Consider a specialty-specific EHR. Ophthalmic practices operate differently from other medical practices. Ophthalmologists can examine 80 to 100 patients in one day, and their practices require an EHR system that is designed to keep up with that volume.

Also, most ophthalmologists schedule a short period to be with each patient, and that time comes and goes rapidly.

However, the time spent on inputting and updating data for each patient will be longer than the time spent seeing the patient. Specialty-specific EHRs for ophthalmologists and other eye-care specialists are designed with templates to help streamline this process.

3. CONSIDER DATA ENTRY

When taking a demonstration of an EHR system, practice actually entering patients' information. As with any new technology, the initial learning curve will slow down the process, but knowing how the data is entered will provide some insight into whether the system aligns with the practice's workflow.

Also, consider whether it is necessary to transfer data from a patient management system into the new EHR system. Discuss how the old vendor— if there is one—as well as how the new vendor will provide support in this effort as there are no government regulations for transferring an old database into a new system. It can be a painful and costly process that can be made easier with support from the chosen vendor.

OphthalmologyTimes.com
Online Exclusive

REV UP YOUR EHR: HOW TO OPTIMIZE PERFORMANCE

IT'S BEEN SAID that electronic health record (EHR) system adoption is like rebuilding an airplane while it's in flight. So it's not surprising that after the initial period is over and physicians believe they have some idea what they're doing, they may not want to push on any further.

To learn ways to increase revenue and improve practice efficiency and quality, go to http://bit.ly/1nJ0EeX

4. MAKE A VISIT TO PEERS

From experience, one of the most important aspects of choosing an EHR system has been visiting other practices. However, visiting another practice is particularly helpful if the visit is not proctored. If a sales representative is present for the duration of the visit, the practice is not likely to ask the same questions or receive the same answers.

Ask potential vendors if it is possible to visit other practices with a physician and without the presence of a sales representative. One vendor even recommended a visit to a practice using its software without the salesperson present. That spoke volumes and revealed confidence in the product and the support provided. If a vendor is willing to allow that, it is a sign the vendor has nothing to hide.

5. SUPPORT AFTER IMPLEMENTATION

Consider the support that the vendor offers after the EHR system has been implemented. What happens if the system crashes? How does the vendor provide support? Will it be responsive to telephone calls? How is the vendor going to help customize templates? For example, if a physician does not like the way the narrative prints, can someone be called to have it fixed that same day?

6. CONSIDER SCALABILITY

Some aspects of choosing an EHR system are not visible on the surface until cost is discussed. For instance, consider how many licensing fees will be needed. Some EHR vendors charge a license fee for each computer that is in use for the EHR. Consider how many users there are, and whether there are plans to expand users in the future.

For example, my office negotiated unlimited licenses, as we knew we would be expanding. When 3,000 square feet and seven more workstations were added to the office, the practice did not have to pay for each individual new licensing fee. Planning ahead allows a practice to be cost efficient in expansion and in future growth.

take-home

- **Eye-care professionals should have a checklist of key considerations in mind before deciding on an electronic health record system.**

7. VIEW DEMONSTRATIONS

Hold all of the demonstrations in the office so that all staff members can see them, such as in the evening after office hours. After a demonstration, hold a meeting to process what is learned, share thoughts, and take notes. Demonstrations can be spaced out so that there is a 2-week time lapse between each one. This allows staff members to process more fully what has been learned and to ask follow-up questions. ■

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VETTING VENDOR

(Continued from page 20)

for them. Many vendors also have users meetings that are a great way to get a full look at a system and speak with others about their experiences.

DESIGNATE RESOURCES

Many practices that are implementing an EHR system simply do not plan to spend the proper amount of time and money on the process. It takes more effort to lay the groundwork for implementation than it actually does to implement the system.

Practices should consider the time and expense that will be spent on training, customization, and IT support. The team will need dedicated time for testing and training outside of normal clinic operations.

Many practices try various tablets, laptops, personal computers, and touchscreen computers to discern which works best for them.

PHASE IN THE EHR

The decision was made to phase in the EHR system gently. Implementation began in the smallest satellite office, on the slowest day, and with the last new patient of the day. By starting with new patients there are no past records in the system to review and the focus can remain on the current visit.

Additionally, by starting with the last patient, if the process of inputting patient data happens to take an hour then it will not create a ripple effect and cause other patients' visits to be delayed. In the worst-case scenario, the staff just leaves the office slightly later than normal.

Once staff members become comfortable using the system with the last new patient of the day, the process moved to the last established patient and then to the last couple of patients of the day. The number of patients was increased slowly, until EHR was used for all patients. Very quickly, staff members began to build up steam—they understood how the software worked and input data faster than with paper records.

CONCLUSION

Above all, it is imperative for staff members to have realistic expectations for EHR implementation. Mastering an entirely new computer system—similar to studying a new language or learning how to drive a car—it is not something that can be done overnight. Instead, it requires patience and thoughtful planning. ■

RONALD J. PURNELL, MBA, COE, *is the administrator and compliance officer at Eye Care of Maine, Waterville, ME. Purnell has no financial interest in the products or companies mentioned. Readers may contact him at 207/873-2731 or rpurnell@maine2020.com.*

Survive or thrive: Making EHR work in the practice

Business continuity and remote access among benefits realized for large, multispecialty eye-care group

By Nancy Groves; *Reviewed by Tom Burke*

IMPLEMENTING AN electronic health record (EHR) system in a large, multispecialty eye-care group can be challenging, but the benefits outweigh the negatives, said Tom Burke, chief executive officer, Ophthalmic Consultants of Long Island (OCLI).

Burke shared suggestions for making EHR work in an ophthalmic practice, based on OCLI's gradual rolling implementation effort—by location and specialty—that began in July 2012 and will eventually integrate 11 offices. This group has 32 physicians and 400 staff, however, and the equation would not necessarily be the same in a smaller practice.

CHARTING FUNCTIONS

EHR can address many aspects of the medical practice, including essential tasks such as charting, which, when performed manually, has an estimated 15% misfile rate and 7% loss rate.

"We're reclaiming valuable space for clinical uses by using offsite storage and scanning of charts," Burke said.

OCLI has phased out paper charts entirely except for research encounters and one recently purchased location.

"The practice saves time and money by contracting with a company that allows us to manifest our charts via their portal, transports those charts back to their storage facility, and provides scan on demand service directly into our EHR system," he said.

To use the charting function of an EHR system efficiently, Burke suggests performing all chart abstraction for the staff in advance of upcoming visits and having the charts picked up and removed before the appointment, depending on the physician's preference.

"In many cases, doctors preferred to hold onto the physical chart for one or two more appointments, and we accommodated those requests," he said.

He also advises loading as many of the historical images as possible from your diagnostic devices in advance to reduce last-minute requests while seeing the patient.

EHR is also invaluable for documentation, and using this feature helps physicians become more aware of nuances, Burke said. OCLI has a provider approval queue in its EHR system that the doctors review regularly, as well as a quality assurance review.

"By reviewing the chart after it has been created electronically, the provider has a more complete understanding of what the scribes and checkout staff are doing as far as data entry and subsequent claims submission," Burke said. "While reviewing the electronic record in the exam lane or in their queue, they can have more hands-on input for accurate data entry and documented support for their level of coding, the addition of modifiers used, and other tasks."

CLAIMS SUBMISSIONS

The central business office performs daily reviews of diagnostic testing, in-office surgical procedures, and exam claims posting, including modifiers. The claims are scrubbed just prior to submission.

"This error checking in advance of submission leads to a cleaner claim submission, resulting in reduce 'days sales outstanding' and accounts receivable work for other billing department team members. This gets your money into the practice sooner and with lesser cost of correction work after the initial submission," Burke said.

"Efforts to reduce clinical claims adjudication are paying off. The time wasted on pulling records, obtaining a translation of the handwriting of the physician or anyone else who was in the chart is much reduced now with EHR," he added.

The big clinical advantage over time is that each department learns the needs of the other, Burke noted.

"Our staff and the billing department un-

take-home

- **Implementing and maintaining an electronic health record system requires constant auditing and training, but it can also improve efficiency throughout the practice.**

OphthalmologyTimes.com *ONLINE EXCLUSIVE*

SURVEY: PHYSICIAN OUTCRY ON EHR FUNCTIONALITY, COST WILL SHAKE THE HEALTH INFORMATION TECHNOLOGY SECTOR

DESPITE THE government's "bribe" of nearly $27 billion to digitize patient records, nearly 70% of physicians say electronic health record (EHR) systems have not been worth it. It's a sobering statistic backed by newly released data from marketing and research firm MPI Group and *Medical Economics* that suggest nearly two-thirds of physicians would not purchase their current EHR system again because of poor functionality and high costs.

In a surprise finding, nearly 45% of physicians from the national survey report spending more than $100,000 on an EHR. About 77% of the largest practices spent nearly $200,000 on their systems.

While physicians can receive $44,000 through the Medicare EHR Meaningful Use (MU) incentive program, and $63,750 through Medicaid's MU program, some physicians say it's not nearly enough to cover the increasing costs of implementation, training, annual licensing fees, hardware and associated services. But the most dramatic unanticipated costs were associated with the need to increase staff, coupled with a loss in physician productivity.

To read more and view a slideshow of the charts and data tables from *Medical Economics*' exclusive EHR survey, go to http://bit.ly/NsYODH

derstand the records more fully because they can see the entire record and they're learning from it," he said. "We've been able to comply with requests much quicker; we can turn around documentation requests from payers much faster now that we have EHR system."

OFFLINE AND OFFSITE RECORD ACCESS

Describing the impact of the EHR on the practice's business continuity, he noted the offline record reproduction and appointment booking software system the group uses is particularly helpful during situations such as a recent power outage at one site during planned downtime due to the installation of a new generator. Patients could still be seen using paper records produced from PDFs of their prior exams.

Remote access to the electronic records is a popular feature for physicians and staff who are working offsite.

"Records and images can be made available while traveling, for presentations, for studies, for treatment experiences. In case of a snow emergency, we've got records and contact information all ready for everyone. It's much easier than it was in the past," Burke said. "We've got image review and consultation with referral sources, which has been very helpful and is good for networking in your community."

GOING DIGITAL

If your practice is considering an EHR investment, Burke recommends going completely electronic.

"Avoid inefficient paper-electronic hybrid systems," he said. "There are higher costs trying to maintain two, and you also tend to lose or mix records, and that can be very difficult for the practitioner and certainly for the staff members who are trying to provide the records to you in an efficient and timely manner."

He emphasized that implementing EHR entails a transition period that can be difficult for everyone.

"It's a teamwork process," he said. "You have to train, retrain, audit, and retrain again. Your staff and administrators are going through a lot with this, as are the providers. It requires a ton of patience."

While OCLI has invested heavily in EHR and found it advantageous, is it worth it for a small practice today to make the leap?

"We find that not only do we think is it worth it but other practitioners in our community have made that decision. They feel it's worth it as well," Burke said.

Some practitioners have decided against EHR, though, often because they intend to quit practicing medicine in a few years and feel that any penalties they incur before then will be manageable. ■

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This article was adapted from Burke's presentation during a symposium at the 2104 meeting of the American Society of Cataract and Refractive Surgery. Burke did not report any relevant commercial relationships.

Physicians report losing 48 minutes a day to EHR processing

Survey says loss of free time was large and pervasive

By Lisa Smith

ONCE TOUTED AS time-savers, physicians in a recent survey reported losing an average of 48 minutes a day due to electronic health records (EHRs).

A survey by the American College of Physicians (ACP) found that every respondent reported losing some time each day because of EHR use.

The mean loss for attending physicians was 48 minutes, and the mean loss for trainees was 18 minutes.

The ACP queried 845 physicians in December 2012 and received responses from 411 who used EHRs.

Among all respondents, 89.8% reported that at least one data management function was slower after EHR adoption; 63.9% reported that note writing took longer; 33.9% said it took longer to find and review medical data; and 32.2% said it took more time to read electronic notes.

The survey found that the top 20 EHR systems were used by 78.8% of respondents, and that most users had been using EHRs for more than a year.

Survey results were published online September 8 in a letter in the *Journal of the American Medical Association's Internal Medicine*.

The letter stated, "The loss of free time that our respondents reported was large and pervasive and could decrease access or increase costs of care. Policy-makers should consider these cost in future EMR mandates."

The authors note that ambulatory practices may benefit from the use of scribes, standing orders, and talking instead of email to recapture time lost to EHRs.

Regarding the difference between the significantly shorter length of time reportedly lost by trainees versus practicing physicians, the authors speculate that better computing skills and shorter work assignments might be contributing factors. ■

EHR implementation: Examining how training will pay dividends

Understanding system before going live will save money, minimize practice disruption later

By Andrea Downing Peck

TRAINING IS A CRUCIAL PART of successfully implementing an electronic health record (EHR) system. Although you may be tempted to skimp on it to save money, doing so could wind up costing your practice far more in the long run.

"I have not been made aware of any EHR implementation program that failed because of too much training, but I know of a number that have occurred because of too little," says Jason Mitchell, MD, director for the Center for Health Information Technology (IT) at the American Academy of Family Physicians.

"We're talking about significant decreases in productivity for months to years, which could have been avoided if training had been appropriate and expectations about what you will be able to do with the EHR were made clear from the beginning," he adds.

take-home

- **Before starting EHR training, make sure you are clear on your objectives and that the training is tailored to your practice's needs and your staff's comfort level with technology.**
- **Going live with your EHR in stages, rather than all at once, will allow you and your staff to get comfortable with the system and will minimize disruption to the practice's workflow.**

STARTING A TRAINING PROGRAM

Although no prescription guarantees success, experts agree on steps a practice should follow when developing a training regimen aimed at smoothly transitioning from paper to electronic records.

Bruce Kleaveland, president of Kleaveland Consulting Inc. in Seattle, says no "radical new training methodology" is revolutionizing EHR training, but vendors are replacing bootcamp-style training with a more measured approach.

"Most innovation has to do with how you teach a fairly complex application without blowing everybody's mind," he says.

"Training in a more incremental fashion," Kleaveland says. "Dealing with a few components and making sure people master them, and using that as an opportunity to develop a comfort level. Also, physicians need to be cognizant that the way a physician uses an application is different than a front-desk person."

Although training continues to evolve as technology becomes more advanced, Lisa Bradshaw, director of training for NextGen Healthcare's ambulatory division, says that successful EHR training "requires a practice's commitment to and dedication of resources for the project. It is essential [that] there is physician and clinical involvement in configuring software to ensure that expectations, requirements, and standards are met."

Margret Amatayakui, president of Margret/A Consulting LLC says that EHR training should infuse physicians with an understanding of a system's value in clinical decision support rather than simply teach the nuts-and-bolts of screen navigation.

"This is not as simple as taking away the pen and using the keyboard instead," she says. "This is changing how you practice medicine."

Don't underestimate the impact of solid training," adds Michael S. Barr, MD, senior vice president of medical practice for the American College of Physicians, who coauthored the 2011 American EHR Partners' report showing incremental increases in training resulted in measurable increases in clinician satisfaction. "If you think you need 'X' amount of training, you should go 'X' plus."

WHAT WILL IT COST?

Like all other aspects of EHR implementation, the cost of training physicians and staff members to use the system comes with a price tag. The exact amount your practice will pay will vary depending on the type of system you use (SAAS- or server-based), the vendor or consultant providing the training, the extent of the training, and how many people receive training.

An EHR training checklist

- ☑ Reasons for EHR conversion explained to staff
- ☑ Training costs budgeted
- ☑ Physician leadership secured
- ☑ Goals of training program understood
- ☑ Variety of trainer options explored
- ☑ In-house "champion(s)" identified, trained
- ☑ Training program tailored to practice's specific needs
- ☑ Timeline for going live with various elements of EHR established
- ☑ "Dress rehearsal" for going live held

A 2010 study of 26 Texas-based, five-physician primary-care practices found that the teams responsible for implementing the practices' EHR systems required an average of 52.5 hours of training at a cost of $2,777. The system's physician end-users received an average of 23.9 hours of training at a cost of $1,538 per physician.

Results of the study, which was funded by the Agency for Healthcare Research and Quality, were published in the March 2011 issue of the journal *Health Affairs*.

Here are 14 steps to building an effective EHR training program for your practice:

1 GET INPUT FROM STAFF

Staff members who have a role in selecting the EHR have a better perception of the system after implementation. "Becoming an early stakeholder may make you a little more comfortable, because you know what the EHR should do," Barr says.

Special Report) **LATEST UPDATES REGARDING EHRs**

2 LEAD BY EXAMPLE

Physician leadership is crucial when implementing an EHR. "I've been associated with really successful projects and projects that were train wrecks," Kleaveland says. "The big difference is physician leadership, particularly in a small practice. That very much applies to thinking through how you do training and the training process itself."

3 ESTABLISH AN END GOAL

To create a successful training program, Mitchell says, physicians need to know what they want their EHRs to do for their practices. "Have a vision of your practice using an EHR system," he says. "That helps guide the training process. You have to have some idea of where you are trying to get and what the EHR is going to do differently than a paper-based system."

4 UNCOVER TECHNOPHOBES

Staff members who do not have basic computer skills will need extra training to get up to speed before go-live. "If you can't type, that's going to be an issue," Mitchell says. "If using the mouse doesn't make sense to you, if you don't understand key combinations to be able get shortcuts, if using the voice-recognition software takes you 15 minutes, those things are going to destroy you over time."

5 INVESTIGATE TRAINING OPTIONS

Although your EHR vendor is likely to have unmatched knowledge of its product, value-added resellers, consultants, and local regional extension centers (RECs) for health information technology (IT) are worth considering. "Even though vendor representatives should be quite knowledgeable, generally they are the most difficult to schedule and most expensive," Kleaveland says. "If you can find local resources that are knowledgeable, you'd be crazy not to avail yourself of those." (See "Regional Extension Centers" at right)

6 CUSTOMIZE YOUR TRAINING

Because training can cost a small practice nearly as much as the EHR itself, Lou Ann Wiedemann, senior director of health information management practice excellence for the American Health Information Management Association, says that physicians should define in advance their training objectives and ensure training is tailored to their practice.

"There is not a cookie-cutter approach," she says. "Each physician practice is unique in some of the things they are looking for so they need to take that into consideration."

The timing of your training sessions also is key. "You don't want to do training too far in advance or your staff may forget it," Wiedemann says. "You do it too close and you may rush it."

7 HOLD A DRESS REHEARSAL

Before your go-live date, set up EHR test cases using dummy patient charts to simulate common scenarios, such as a follow-up visit for hypertension.

"If physicians are going to be seeing patients with this software in the room, then simulate that so you are not completely freaking out when the patient shows up and you're trying to examine them and document," Kleaveland says. "The patient wonders, 'Are they examining the computer or examining me?' "

8 DON'T TRY TO LEARN EVERYTHING AT ONCE

Heather Haugen, PhD, senior vice president of research, development, and IT at The Breakaway Group in Greenwood Village, CO, says EHR trainers set practices up for failure when they attempt to teach users a vast array of features and functions at once. "If I put you in a classroom for 3 days and I teach you 300 things the EHR does for a physician, you likely won't remember how to log-in when we're done," she says.

Haugen advocates for "scenario-based" learning, which enables users to learn by doing and is modeled after flight simulators in the aviation industry. "Bite-size" training sessions typically are 5 to 7 minutes long and can be done during off hours. This task-based training focuses on physicians and staff first becoming proficient in their primary job tasks.

"Ensuring people can use the application to treat a patient the day of go-live typically means they have to know the key functionality, but they don't know all the bells and whistles and the advanced functionality," Haugen says. "Then overtime they learn that. When the opposite happens, we get in trouble."

9 IMPLEMENT IN STAGES

When Jennifer Brull, MD, a solo family physician in Plainville, Kansas began converting her practice to EHRs, she knew flipping a switch all at once would wreck havoc. Instead, the practice implemented the system in stages over 3 months; first by converting to the new electronic billing system, then transitioning to the EHR's scheduling software, before finally rolling out the clinical portion of the system.

"When we went live with clinical, our front office was comfortable with what they were doing," she explains. "They had a couple of months under their belt doing things the new way so when the back office got really stressed, there wasn't stress in both places."

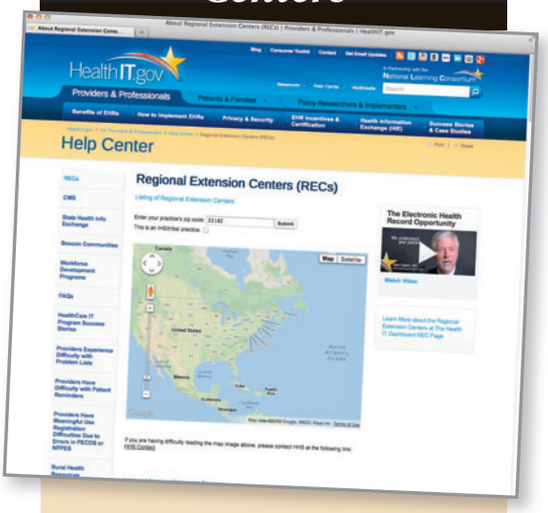
10 UNDERSTAND THE IMPACT ON WORKFLOW

Practice workflows slow by as much as 50% during implementation. Practice management consultant Mary Pat Whaley of Manage My Practice in North Carolina, argues that failing to consider an EHR's impact on workflow can be a major oversight.

"Being trained on the software is totally different from inserting the EHR into the workflow or changing the workflow," she says. "People think, 'We know how to use it. Let's throw it out there and see how it works.' That can be

Continues on page 28 : ***Implement***

Regional Extension Centers



Authorized by the Health Information Technology for Economic and Clinical Health Act, Regional Extension Centers (RECs) have offered physicians EHR education and training services for the past several years.

Although their 4-year federal funding ends this year, some RECs are continuing to sign up providers using remaining grant funds. The availability of training will by location. In Ohio, for example, RECs have provided free EHR education to more than 6,500 providers, and a few of the state's seven RECs have slots remaining.

As of 2014, Communications Director Dottie Howe of the Ohio Health Information Partnership says the organization will begin offering physicians a fee-based package of services for EHR selection and ongoing EHR monitoring through meaningful use stage 2.

Go to **www.healthit.gov/providers-professionals/regional-extension-centers-recs**

IMPLEMENT

(*Continued from page 27*)

devastating to the practice, to morale, and, of course, devastating financially."

11 DEVELOP IN-HOUSE EXPERTS

No matter whether your EHR point-person is called a "champion" or "super user," every practice needs one or more staff members who receive extra training and become resident experts who can help others learn the system, assist at go-live, maintain a relationship with the vendor, and stay abreast of system updates.

"The super user is somebody who is going to be able to troubleshoot after the onsite support and training is no longer available," Barr says. "The more super users you have, the easier it is for somebody to turn and find somebody who can help them."

Brull, however, says she made the mistake of failing to remove some of her champions' regular duties during implementation so they would have time to devote solely to helping others.

"They got through it, but looking back, I would have said 25% of your hours are marked for going around saying, 'Do you need help?' as opposed to letting problems come to them and making them deal with it on top of their regular volume."

12 FOSTER TEAMWORK

Knowing that EHR implementation will cause bumps in the road for staff, the implementation team needs to find ways to boost morale.

When implementation-related issues stressed a member of Brull's staff, the person was likely to find a row of Hershey Kisses lining his or her desk.

"That was a signal to take a deep breath, calm down, and eat some chocolate," she says.

13 THINK LONG TERM

Your practice needs a long-term commitment to EHR training. For 2 years following implementation, Brull made an EHR question-and-answer session a regular item on the agenda during bimonthly staff meetings. Staff could discuss challenges, ask questions, or offer tips to co-workers.

"In the early days we probably took 30 to 60 minutes of our staff meeting just doing things around the EHR implementation," she says. "We never had anybody who had tremendous amounts of frustration build up because they knew every 2 weeks there was that opportunity to ask questions and get feedback from everyone."

14 JOIN USER GROUPS

Online user groups and forums are excellent ways to discover shortcuts, discuss solutions or share concerns about your EHR. Some user groups are associated directly with vendors. Others, such as eCWusers.com are independent groups comprised solely of users of a particular EHR—in this case, eClinicalWorks.

Although Brull stops short of describing her EHR implementation as perfect, she says, "We achieved our objective of moving everyone from a paper world to an electronic world in a way we didn't lose staff and we didn't pull our hair out too much."

Brull established a goal of converting at least one patient's records to the EHR each half day.

At that pace she was able to convert her 2,000 patients to electronic records in about 5 months, compared with another physician with an older patient population for whom the process took 18 months.

She is confident her step-by-step implementation created fewer headaches than if she had tried implementing the system all at once.

Five years after her go-live date, Brull says her patients are benefitting from improved care, with quality metrics rapidly increasing for preventive measures such as colon and breast cancer screenings.

She credits her EHR with enabling her to practice better medicine.

"When you really look at patient population numbers instead of a just the chart of the patient in front of you—which is all you can do in a paper world—it's a real wake up call," Brull says. "That's been really good for us." ■

Finding an EHR vendor Where to begin

THIS BRIEF LISTING of electronic health record (EHR) vendors—though certainly not inclusive of all companies in the ophthalmic space by any means—is a starting point for which to begin the conversion research process.

Compulink
www.compulinkadvantage.com

EyeMD EMR Healthcare Systems Inc.
www.eyemdemr.com

First Insight
www.first-insight.com

ifa united i-tech Inc.
www.ifa4emr.com

ManagementPlus
www.managementplus.com

MedFlow
www.medflow.com

Modernizing Medicine
www.modmed.com

Nextech
www.nextech.com

NextGen
www.nextgen.com

For additional information on these and other EHR systems, go to *http://www.ehrcompare.com/reviews/ophthalmology*

Despite growth in EHR use, data exchange remains low

A STUDY PUBLISHED in *Health Affairs* found that despite gains in electronic health record (EHR) use, rates of information exchange and patient engagement remain low for physician offices.

78%
Percentage of office-based physicians who have adopted some type of EHR.

14%
Percentage of physicians who shared data with providers outside of their office.

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EHR: Analyze cost, usability features carefully when considering switch

Use experience gained during first EHR implementation to make new system work for you

By Derek Kosiorek, CPEHR, CPHIT

ONCE UPON A TIME, a practice management system was the major software purchase for a medical practice. It required significant money, a detailed analysis of work flows, lots of interfaces, extensive training, and a genuine fear of such a system controlling so much information that was vital to the practice. And that was just for the billing system.

Now that we have electronic health record (EHR) systems, the game has changed dramatically. There are very few areas of a medical practice that aren't completely reliant on EHR systems. This makes it vital to have one that works well.

With EHR satisfaction falling at an alarming rate, it is no surprise that practices are beginning to look at replacing their systems. An EHR is nothing more than a tool to manage information. If the tool doesn't do it's job, it's time to get a new one.

Of course, dissatisfaction is only one of many reasons that a practice may need or desire to change its EHR system. Mergers and acquisitions often result in vendors phasing out or reducing support for existing software. A practice's growth can render a system unusable. Organizational relationships with a new group or hospital may make a change more attractive or beneficial to a practice.

Still, the main reason why practices change systems is because the current software is deemed too difficult or impractical to use, and it is hurting productivity or substantially increasing physician time to process patient data.

If you are thinking of changing EHR systems, let's look at some questions you'll need to ask to ensure a successful new EHR implementation.

take-home

- **The best way to compare pricing in an "apples to apples" way is to group the proposals into four areas: software costs, third-party costs, implementation costs, and annual maintenance costs.**
- **Set specific goals for what you want from your new EHR software in the next 12 to 18 months.**

WHERE IS THE DATA?

A current industry buzzword is "cloud computing," which is the practice of keeping your practice's data and information off-site somewhere and accessible via the Internet. But even that term can mean different things depending on various factors. Your system will take on one of three different profiles.

The first is the traditional practice of installing a server or servers in your office and having all computers and locations work with the data on that server. With this method, it is the practice's responsibility to maintain the hardware and all connections to that hardware, including from remote sites and employees working from home. Many practices prefer the inherent security that comes with this setup.

In most cases, however, EHR systems are "cloud hosted," which means the server equipment is located at a facility approved by the vendor. All computers and devices connect to this server remotely, whether they are in your office, at home, or on the road.

Responsibility for maintaining the servers varies depending on the nature of the contract, but most vendors will take on this role. The benefit of this setup is the ability to free up physical space on site and allow the IT staff to focus on other areas of need, or simply reduce the need for IT staff.

A more complicated way to use the cloud is referred to as Software as a Service (SaaS). This is currently the most common way software is built in other industries and for consumer needs. The software is usually run through an Internet web browser, which means access is achieved from any device on the Internet by entering a user name and password. A good example is Internet-based email. Your username/password gets you access, and the user interface is through a web browser.

The best setup depends on your preferences and needs. Most software experts agree that SaaS is where all software is moving, but very few EHR vendors offer this arrangement now.

Ensuring a successful EHR switch

- ☑ ***SET GOALS:*** **Practices switching EHR systems must have clear expectations for what the system will do. Set specific goals for what you want to be happening with your software in the coming 12 to 18 months.**
- ☑ ***LESSON LEARNED:*** **What could be improved from the last install? Did your staff receive enough training? Were the right computers and equipment purchased? Were alerts set properly?**
- ☑ ***NEW TECHNOLOGIES*** **Analyze new ways of doing things when making major changes to your practice. From cloud solutions to mobile devices to remote access, make sure you do the research, and find the most efficient methods to operate your practice.**

WHAT WILL IT COST?

Costs vary greatly and depend on many factors, including the number of staff and office locations and the unique circumstances of your technical infrastructure needs.

I have seen a great many EHR contracts, and I'm convinced that vendors like the fact that pricing structures vary so much. For example, some are based on licenses per physician, some based on licenses per user, and others are based on how many devices or workstations are accessing the product.

The best way to compare pricing in an "apples to apples" way is to group the various proposals you are considering into four areas: software costs, third-party costs, implementation costs, and annual maintenance costs.

Putting all costs and fees into these groups will enable you to make a much more accu-

OUR SCIENCE. YOUR ART. THEIR VISION.

NOW APPROVED FOR DIABETIC MACULAR EDEMA (DME)

As Demonstrated in 2 Pivotal, Phase 3 Trials in Patients With DME Evaluating Mean Change in BCVA* at 52 Weeks vs Baseline[1]

EYLEA® (aflibercept) Injection Offers Extended Dosing in DME—2-mg Every 8 Weeks Following 5 Initial Monthly Doses[1]

Initial Dosing	Follow-Up Dosing
5 Initial 2-mg Injections Monthly (Every 4 Weeks)	2-mg Every 2 Months (Every 8 Weeks)

Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.

*BCVA = best-corrected visual acuity, as measured by Early Treatment Diabetic Retinopathy Study (ETDRS) letters.

IMPORTANT PRESCRIBING INFORMATION FOR EYLEA® (aflibercept) INJECTION

EYLEA® (aflibercept) Injection is indicated for the treatment of patients with

- Neovascular (Wet) Age-related Macular Degeneration (AMD): The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.
- Macular Edema following Central Retinal Vein Occlusion (CRVO): The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly).
- Diabetic Macular Edema (DME): The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 5 injections, followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.

IMPORTANT SAFETY INFORMATION FOR EYLEA® (aflibercept) INJECTION

- EYLEA® (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.
- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs in the VIEW 1 and VIEW 2 wet AMD studies in patients treated with EYLEA was 1.8% during the first year. The incidence of ATEs in the COPERNICUS and GALILEO CRVO studies was 0% in patients treated with EYLEA compared with 1.4% in patients receiving sham control during the first six months. The incidence of ATEs in the VISTA and VIVID DME studies during the first year was 3.3% in the combined group of patients treated with EYLEA compared with 2.8% in the control group.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment.
- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis, retinal detachment, cataract, intraocular pressure increased, and vitreous detachment.

For more information, visit www.EYLEA.com.

Reference: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. July 2014.

Please see brief summary of full Prescribing Information on the following page.

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

TARGETED SCIENCE

REGENERON

07/2014
LEA-0311

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

For complete details, see Full Prescribing Information.

INDICATIONS AND USAGE

EYLEA® (aflibercept) Injection is indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Central Retinal Vein Occlusion (CRVO), and Diabetic Macular Edema (DME).

DOSAGE AND ADMINISTRATION

FOR OPHTHALMIC INTRAVITREAL INJECTION. EYLEA must only be administered by a qualified physician.

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The recommended dose for EYLEA is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months),followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.

Macular Edema Following Central Retinal Vein Occlusion (CRVO). The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection once every 4 weeks (monthly).

Diabetic Macular Edema (DME). The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.

Preparation for Administration

EYLEA should be inspected visually prior to administration. If particulates, cloudiness, or discoloration are visible, the vial must not be used. Using aseptic technique, the intravitreal injection should be performed with a 30-gauge x ½-inch injection needle.

The glass vial is for single use only. Remove the protective plastic cap from the vial. Clean the top of the vial with an alcohol wipe. Remove the 19-gauge x 1½-inch, 5-micron, filter needle from its pouch and remove the 1-mL syringe supplied in the carton from its pouch. Attach the filter needle to the syringe by twisting it onto the Luer lock syringe tip. Push the filter needle into the center of the vial stopper until the needle is completely inserted into the vial and the tip touches the bottom edge of the vial. Using aseptic technique withdraw all of the EYLEA vial contents into the syringe, keeping the vial in an upright position, slightly inclined to ease complete withdrawal. To deter the introduction of air, ensure the bevel of the filter needle is submerged into the liquid. Continue to tilt the vial during withdrawal keeping the bevel of the filter needle submerged in the liquid. Ensure that the plunger rod is drawn sufficiently back when emptying the vial in order to completely empty the filter needle. Remove the filter needle from the syringe and properly dispose of the filter needle. **Note:** Filter needle is **not** to be used for intravitreal injection. Remove the 30-gauge x ½-inch injection needle from the plastic pouch and attach the injection needle to the syringe by firmly twisting the injection needle onto the Luer lock syringe tip.

When ready to administer EYLEA, remove the plastic needle shield from the needle. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top. To eliminate all of the bubbles and to expel excess drug, SLOWLY depress the plunger so that the plunger tip aligns with the line that marks 0.05 mL on the syringe.

Administration

The intravitreal injection procedure should be carried out under controlled aseptic conditions, which include surgical hand disinfection and the use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent). Adequate anesthesia and a topical broad–spectrum microbicide should be given prior to the injection.

Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, a sterile paracentesis needle should be available.

Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment (e.g., eye pain, redness of the eye, photophobia, blurring of vision) without delay (*see Patient Counseling Information*).

Each vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before EYLEA is administered to the other eye.

After injection, any unused product must be discarded.

No special dosage modification is required for any of the populations that have been studied (e.g., gender, elderly).

DOSAGE FORMS AND STRENGTHS

Single-use, glass vial designed to provide 0.05 mL of 40 mg/mL solution for intravitreal injection.

CONTRAINDICATIONS

EYLEA is contraindicated in patients with

- Ocular or periocular infections
- Active intraocular inflammation
- Known hypersensitivity to aflibercept or any of the excipients in EYLEA. Hypersensitivity reactions may manifest as severe intraocular inflammation

WARNINGS AND PRECAUTIONS

Endophthalmitis and Retinal Detachments. Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments (*see Adverse Reactions*). Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately (*see Dosage and Administration and Patient Counseling Information*).

Increase in Intraocular Pressure. Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA (*see Adverse Reactions*). Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately (*see Dosage and Administration*).

Thromboembolic Events. There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence in the VIEW1 and VIEW2 wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA. The incidence in the COPERNICUS and GALILEO CRVO studies during the first 6 months was 0% (0/218) in patients treated with EYLEA 2 mg every 4 weeks compared with 1.4% (2/142) in patients receiving sham treatment. The incidence in the VIVID and VISTA DME studies during the 52 weeks was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in the *Warnings and Precautions* section of the labeling:

- Endophthalmitis and retinal detachments
- Increased intraocular pressure
- Thromboembolic events

The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment.

Injection Procedure. Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis, retinal detachment, cataract, intraocular pressure increased, and vitreous detachment.

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

A total of 2620 patients treated with EYLEA constituted the safety population in six phase 3 studies. Among those, 2019 patients were treated with the recommended dose of 2 mg.

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 1223 patients treated with the 2-mg dose, in 2 double-masked, active-controlled clinical studies (VIEW1 and VIEW2) for 12 months.

Table 1: Most Common Adverse Reactions (≥1%) in Wet AMD Studies

Adverse Reactions	EYLEA (N=1824)	Active Control (ranibizumab) (N=595)
Conjunctival hemorrhage	25%	28%
Eye pain	9%	9%
Cataract	7%	7%
Vitreous detachment	6%	6%
Vitreous floaters	6%	7%
Intraocular pressure increased	5%	7%
Conjunctival hyperemia	4%	8%
Corneal erosion	4%	5%
Detachment of the retinal pigment epithelium	3%	3%
Injection site pain	3%	3%
Foreign body sensation in eyes	3%	4%
Lacrimation increased	3%	1%
Vision blurred	2%	2%
Intraocular inflammation	2%	3%
Retinal pigment epithelium tear	2%	1%
Injection site hemorrhage	1%	2%
Eyelid edema	1%	2%
Corneal edema	1%	1%

Less common serious adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, and endophthalmitis.

Macular Edema Following Central Retinal Vein Occlusion (CRVO). The data described below reflect exposure to EYLEA in 218 patients with macular edema following CRVO treated with 2-mg dose in 2 double-masked, controlled clinical studies (COPERNICUS and GALILEO) for 6 months.

Table 2: Most Common Adverse Reactions (≥1%) in CRVO Studies

Adverse Reactions	EYLEA (N=218)	Control (N=142)
Eye pain	13%	5%
Conjunctival hemorrhage	12%	11%
Intraocular pressure increased	8%	6%
Corneal erosion	5%	4%
Vitreous floaters	5%	1%
Conjunctival hyperemia	5%	3%
Foreign body sensation in eyes	3%	5%
Vitreous detachment	3%	4%
Lacrimation increased	3%	4%
Injection site pain	3%	1%
Vision blurred	1%	<1%
Intraocular inflammation	1%	1%

Less common adverse reactions reported in <1% of the patients treated with EYLEA were cataract, eyelid edema, corneal edema, retinal tear, hypersensitivity, and endophthalmitis.

Diabetic Macular Edema (DME)

The data described below reflect exposure to EYLEA in 578 patients with DME treated with the 2-mg dose in 2 double-masked, controlled clinical studies (VIVID and VISTA) for 52 weeks.

Table 3: Most Common Adverse Reactions (≥1%) in DME Studies

Adverse Reactions	EYLEA (N=578)	Control (N=287)
Conjunctival hemorrhage	28%	17%
Eye pain	9%	6%
Cataract	8%	9%
Vitreous floaters	6%	3%
Corneal erosion	5%	3%
Intraocular pressure increased	5%	3%
Conjunctival hyperemia	5%	6%
Vitreous detachment	3%	3%
Foreign body sensation in eyes	3%	3%
Lacrimation increased	3%	2%
Vision blurred	2%	2%
Intraocular inflammation	2%	<1%
Injection site pain	2%	<1%

Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, eyelid edema, corneal edema, retinal detachment, injection site hemorrhage, and retinal tear.

Immunogenicity. As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading.

In the wet AMD, CRVO, and DME studies, the pre-treatment incidence of immunoreactivity to EYLEA was approximately 1% to 3% across treatment groups. After dosing with EYLEA for 52 weeks (wet AMD), 24 weeks (CRVO), or 52 weeks (DME) antibodies to EYLEA were detected in a similar percentage range of patients. In the wet AMD, CRVO, and DME studies, there were no differences in efficacy or safety between patients with or without immunoreactivity.

USE IN SPECIFIC POPULATIONS

Pregnancy. Pregnancy Category C. Aflibercept produced embryo-fetal toxicity when administered every three days during organogenesis to pregnant rabbits at intravenous doses ≥3 mg per kg, or every six days at subcutaneous doses ≥0.1 mg per kg. Adverse embryo-fetal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastroschisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningocele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternebrae, and ribs; supernumerary vertebral arches and ribs; and incomplete ossification). The maternal No Observed Adverse Effect Level (NOAEL) in these studies was 3 mg per kg. Aflibercept produced fetal malformations at all doses assessed in rabbits and the fetal NOAEL was less than 0.1 mg per kg. Administration of the lowest dose assessed in rabbits (0.1 mg per kg) resulted in systemic exposure (AUC) that was approximately 10 times the systemic exposure observed in humans after an intravitreal dose of 2 mg.

There are no adequate and well-controlled studies in pregnant women. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is unknown whether aflibercept is excreted in human milk. Because many drugs are excreted in human milk, a risk to the breastfed child cannot be excluded. EYLEA is not recommended during breastfeeding. A decision must be made whether to discontinue nursing or to discontinue treatment with EYLEA, taking into account the importance of the drug to the mother.

Pediatric Use. The safety and effectiveness of EYLEA in pediatric patients have not been established.

Geriatric Use. In the clinical studies, approximately 76% (1996/2610) of patients randomized to treatment with EYLEA were ≥65 years of age and approximately 47% (1229/2610) were ≥75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies.

PHARMACOKINETICS

Specific Populations. Patients with Renal Impairment. Pharmacokinetic analysis of a subgroup of patients (n=492) in one wet AMD study, of which 43% had renal impairment (mild n=120, moderate n=74, and severe n=16), revealed no differences with respect to plasma concentrations of free aflibercept after intravitreal administration every 4 or 8 weeks. Similar results were seen in patients in a CRVO study and in patients in a DME study. No dose adjustment based on renal impairment status is needed for either wet AMD, CRVO, or DME patients.

PATIENT COUNSELING INFORMATION

In the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients to seek immediate care from an ophthalmologist (*see Warnings and Precautions*). Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations (*see Adverse Reactions*). Advise patients not to drive or use machinery until visual function has recovered sufficiently.

REGENERON

Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707

U.S. License Number 1760
EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

Issue Date: July 2014
Initial U.S. Approval: 2011

Regeneron U.S. Patents 7,306,799; 7,531,173; 7,608,261; 7,070,959; 7,374,757; 7,374,758, and other pending patents

LEA-0294

rate comparison of what the final costs to your practice will be.

If you are looking at a subscription-based model for one of your vendor candidates, add up the total cost over 5 or 7 years, then compare it with the total cost for the other systems.

HOW DO I AVOID THE SAME PROBLEMS?

Many medical groups go into an EHR implementation without having clear expectations of what the EHR will do.

If you were building a house, you wouldn't start throwing bricks on the ground and hope a functional house is the result. So why do it for software that may cost just as much as the house?

The most important step is to set specific goals for what you want your software to accomplish in the coming 12 to 18 months.

Do you want a system that will help you improve productivity levels? Do you want to reduce patient wait times? Do you want to improve physician satisfaction? How about fewer errors? It may even be that you want employees complaining less.

The point is to set measurable goals so you can revisit them after the implementation so you can decide if the system is meeting your expectations. If you can measure the outcomes, you can determine the level of success after the project is over.

Other questions that should be asked about your last installation include whether your staff received enough training, whether the right computers and equipment were purchased, and whether the alerts were set to trigger at the right times and frequency.

Remember, it is just as important to keep in mind what went right as it is what went wrong. What functionality do you want to preserve in the next generation of your EHR?

BE AWARE OF NEW TECHNOLOGIES

By its nature, technology evolves quickly. When looking at making major changes to your practice, it is important to consider the newer ways of doing things.

The cloud is offering benefits that were not conceived just a few years ago.

Do your physicians or nurses want touchscreen tablets to carry around the office rather than laptops or fixed PCs? It's possible now. What method of remote access will you need to gain access to the system? Do the research and find the most efficient methods.

Whatever system you select, make sure that you plan to open your Internet portal so that patients can access their personal health information.

There are many reasons to do this, because not having a portal will be a detriment to your practice in the coming years.

If you don't yet have a patient portal, you can be sure your competitors will.

Shopping for an EHR system

USE THE FOLLOWING tips as you evaluate systems:

VET THE VENDOR

- Check referrals and references.
- What is the vendor's experience? How many installs and client types? How many providers and sites per business entity?
- Does the vendor have certified products for 2011 and 2014?

VET THE SYSTEM

- Identify the number of installs (business entities) and physicians and nonphysician practitioners that have used the system.
- Break out the numbers by specialty and ownership type (private owned, hospital/IDS owned).
- Is this an integrated EHR with a practice management (PM) component? Or is the PM interfaced with an EHR (were these two separate products that are "married"?)
- If considering just an EHR product, get the details on what PM products interface with the EHR and what is required (cost- and process-wise) to implement and maintain bi-directional integration.
- Find out how long the EHR system has been in in active use

OWNERSHIP HISTORY

- Any mergers?
- Does the company own other products? What are they?
- Is the EHR product the owner's primary source of business?

SEE THE EHR IN ACTION

- Observe in as much detail as possible other practices (at least three practices, if possible) using the system.

Source: Gail Levy, MA, and Kathryn Moghadas, RN, CLRM, CHBC, CHCC, CPC

The true costs of EHR systems

EXPERTS ADVISE PHYSICIANS to analyze all of the costs associated with a new system if they are implementing for the first time or changing vendors.

The analysis should include:

- ***HARDWARE:*** **desktop computers, tablets/laptops, database servers, printers, and scanners.**
- ***EHR SOFTWARE:*** **Potential costs include EHR application, interface modules, and upgrades.**
- ***IT SUPPORT:*** **Implementation assistance costs could include an IT contractor, attorney, electrician, and/or consultant support; chart conversion; hardware/network installation; and workflow redesign support.**
- ***TRAINING*** **in how to use the EHR and associated hardware, and how the EHR will create new work flows.**
- ***ONGOING NETWORK FEES AND MAINTENANCE:*** **Potential ongoing costs include hardware and software license maintenance agreements, contining staff education, telecom fees, and IT support fees. Some practices may need to hire IT operations staff, clinical data analysts, or application analysts. There may also be associated fees to access or transfer your data.**

IT GETS EASIER

Considering the effort you put into implementing your first EHR, you may think that doing it the second time around will be difficult.

Believe it or not, however, it may actually be easier on your practice and your staff members. Your employees are now used to the changes that came from moving from paper to computer, so that hurdle has been overcome.

Having a first go-around with an EHR system means your practice will be more knowledgeable about what it needs in an EHR system, and what questions need answers before committing to a new vendor. ■

DEREK KOSIOREK, CPEHR, CPHIT, *is a principal consultant for MGMA Health Care Consulting Group. He specializes in evaluating and implementing technology solutions for health-care organizations.*

How YAG laser vitreolysis can be used to treat floaters

Surgeon's clinical experience shows therapy yields robust safety profile, quality-of-life benefits

By Inder Paul Singh, MD, *Special to* Ophthalmology Times

Until recently, patients suffering from bothersome floaters had only one of two options: learn to tolerate them, or undergo vitrectomy.

Given that the latter option can be a highly invasive procedure often associated with complications—including infection, macular edema, and retinal detachment—many ophthalmologists, understandably, reserve vitrectomy for only the most severe and distressing cases.[1]

In contrast, vitreolysis—which involves the use of a specially designed YAG laser to vaporize the vitreous strands and opacities—has shown to be highly effective in providing functional improvement with a low complication rate.[2]

A PARADIGM SHIFT

In a study by Cees van der Windt, MD, and colleagues, 100 eyes with posterior vitreous detachment-related floaters persisting for more than 9 months were treated with vitreolysis (n = 65) or pars plana vitrectomy (n = 35). Findings showed that both the YAG and vitrectomy groups reported an improvement in vision at 80% and 90%, respectively.

Additionally, over the 8-year follow-up period, no complications occurred among patients in the vitreolysis treatment arm. Moreover, data from two studies carried out in 1990, demonstrated a near-100% rate of floater removal with vitreolysis. No intra- or postoperative complications occurred in any patient.[3, 4]

Although vitreolysis is a much safer procedure than vitrectomy, medical schools generally do not teach it. Also, because of some problems associated with traditional YAG lasers, some ophthalmologists may be a little reluctant to offer the procedure to their patients. Though initially a little skeptical about vitreolysis myself, after incorporating the multimodality YAG laser technology (Ultra Q Reflex, Ellex) into daily practice, my opinion has changed.

EVOLVING TECHNOLOGY

Traditional YAG lasers typically have larger and less-controlled plasma with more inconsistent power output. Since it can be difficult to focus on small structures—such as vitreous strands—collateral ocular tissue damage may occur.

In contrast, the multimodality YAG laser features an ultra-Gaussian beam mode, teamed with a fast-pulse rise time and a small-spot size meaning with a higher-power density and tightly controlled plasma, fewer shots are required to perform procedures with less cumulative energy delivered to the patient.

Furthermore, the new laser platform incorporates a proprietary slit lamp illumination tower design, which converges the operator's vision, the target illumination, and the treatment beam along the same optical path and onto the same optical plane. The patent-pending illumination mirror—which briefly moves out of the laser pathway during firing—ensures that the laser beam is coaxial for anterior, mid, and posterior vitreous treatment applications and is never obstructed. The illumination tower can be used coaxially to enhance the view of the target opacity and more effectively vaporize it.

In contrast, traditional YAG lasers have illumination delivered from a low, non-coaxial position making it extremely difficult to target the vast array of vitreous opacities in more posterior vitreous locations.

These features are vital when working in the vitreous, as they minimize the potential for focusing errors and reduce the risk of damage to the natural lens or the retina. There is no risk of under- or overdosing the energy due to poor positioning of the illumination tower, while the precision of the two-point aiming system and the wide-offset range ensure accurate positioning of the optical breakdown, thus further protecting surrounding tissue from accidental damage.[5]

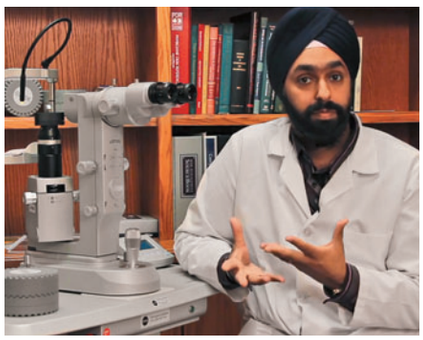
Another important benefit of the laser system is its multimodality. Optimized for both posterior and anterior YAG laser treatment, the platform allows surgeons to perform capsulotomies with new-generation IOLs, peripheral iridotomies for glaucoma, and treat vitreous strands—all with one instrument.

Not as much energy is used when performing iridotomies and simple capsulotomies. This, in turn, reduces the incidence of side effects,

TAKE-HOME

Inder Paul Singh, MD, shares his surgical pearls for how advances in YAG laser vitreolysis can make the procedure a safe and effective option for the treatment of floaters.

MORE ABOUT VITREOLYSIS



VIDEO In this video interview, Inder Paul Singh, MD, shares his pearls for success with vitreolysis. Drawing on his experience with the multimodality YAG laser, Dr. Singh addresses a number of topics ranging from patient selection to treatment protocol, including recommended laser lenses and energy settings.

Learn more at **http://bit.ly/1okehRS**

(Video courtesy of Ellex)

Surgical pearls for adding vitreolysis into daily practice

FOR SURGEONS considering offering vitreolysis, be aware that a learning curve is involved. For example, when I began performing vitreolysis, I hit the lens in two patients; one of these patients required cataract surgery. Consequently, I recommend starting with cases that involve a solitary floater in the middle of the vitreous—i.e., not close to the lens or to the retina—at least until a good degree of comfort with the procedure has been attained.

The floater should also be visible preoperatively when viewed through the slit lamp because it is difficult to start chasing floaters once the patient is positioned at the laser.

Surgeons should also be aware that high-energy levels may be required—e.g., 4.0 to 5.0 mJ—and they should not be afraid of this.

It is also important to understand that a high number of laser shots will likely be required—from a few hundred and potentially up to 900 or even 1,000. If only a low number of shots are used, for example, 200, the procedure may not work. This will depend on the density, size, number, and location of the vitreous opacity.

Some surgeons may be fearful to offer upward of 500 shots in case they cause a retinal detachment or tear, and this is perhaps one of the reasons behind the perception that vitreolysis is not effective. In my experience, it is safe to offer more shots than may be thought to be required.

Additionally, I typically select patients who have had a posterior vitreous detachment. Since the vitreous has detached from the retina, the stimulus for a retinal detachment is decreased.

My final piece of advice would be to build realistic patient expectations. For example, if a patient has a particularly dense floater, he or she may need to be informed that it may take multiple sessions to resolve the issue.

—Inder Paul Singh, MD

such as lens pitting, retinal thickening, increased IOP, or collateral damage to surrounding structures.

QUALITY-OF-LIFE BENEFITS

Having now performed more than 200 vitreolysis procedures with the laser, the effect on patients' quality of life is remarkable—on par with such procedures as cataract surgery and refractive surgery. Some patients tend not to divulge symptoms unless asked, since they have often been told there is nothing that can be done to resolve floaters. However, there are very few procedures that have such great benefits with so few risks.

Findings from a retrospective, observational study undertaken at my practice which included 168 eyes of n = 124 patients (mean age, 66 years [range, 42 to 89 years]) who underwent YAG vitreolysis with the laser (power range 2.0 to 5.5 mJ) demonstrated 92% of patients were satisfied with the procedure. There was one case of IOP spike, and two phakic lenses were damaged, one of which required cataract surgery. No retinal detachment or other retinal complications were seen and there was no anterior chamber or vitreous reaction. ■

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INDER PAUL SINGH, MD, *is in private practice at The Eye Centers of Racine & Kenosha in Wisconsin. Dr. Singh serves on the speakers' bureau with Ellex. Readers may contact Dr. Singh at ipsingh@amazingeye.com.*

Novel IOL achieves continuous vision at all distances in small case series

Device's axiconic-like shape changes ray of light into focal line, provides extended depth of focus

By Cheryl Guttman Krader; *Reviewed by Jérôme Blondel, MD*

ONEX, SWITZERLAND ::

RESULTS OF a prospective clinical trial provide evidence that a novel, microincision, acrylic multifocal IOL (InFo, Swiss Advanced Vision) achieves its goal of providing continuous good vision, said Jérôme Blondel, MD.


Dr. Blondel

"The name of this IOL, InFo, was chosen to reflect that it provides an invariant focus," said Dr. Blondel, lead physician, Clinique de l'Oeil, Onex, Switzerland. "Based on its design and our early clinical outcomes, we believe that it is not just another multifocal IOL, but rather represents an important step forward in the management of presbyopia after cataract surgery.

"However, more data and longer follow-up are needed to understand the efficacy and safety outcomes, including the development of capsular opacification," he said. "A multicenter study is under way."

In contrast with other multifocal IOLs that transform an incoming light ray to two or three focal points by virtue of their bifocal or trifocal design, the new implant has a unique axiconic-like shape that changes a ray of light into a focal line. It thereby provides patients with an extended depth of focus, similar to what is achieved with the natural process of accommodation (~3 D).

The novel optic design also reduces the potential for glare and halos, which are associated with conventional diffractive multifocal optics.

OUTCOMES AFTER IMPLANTATION

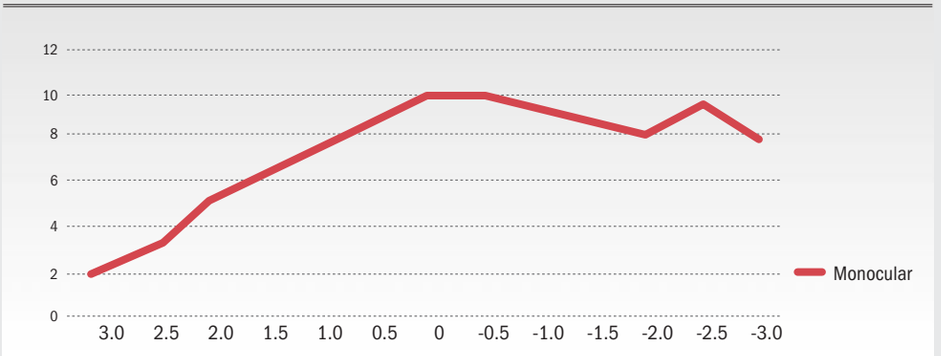
Dr. Blondel presented outcomes after implantation of the axiconic-like multifocal IOL in four patients. Three patients underwent bilateral surgery and the fourth patient, who was amblyopic in one eye, had the IOL implanted only in the fellow eye.

All surgeries were performed through a 2-mm incision. All patients were seen at 1 month, and the first patient with the implant was evaluated at 1 year.

Figure 1: Patient Data

	H.F., female	M.M., male	C. R., male	L.S., female
Age	69 years old	75 years old	76 years old	79 years old
Refraction Preop	1.25 / 1.25	0.75 / amblyopia	1.75 / 1.25	2.5 / 2
Axial Length	23.5 / 23.7 mm	23.6 /	22.6 / 22.5	21.7 / 22
InFo Power	21 / 20.5	19.5 /	21.5 / 22	22 / 21.5
Refraction Postop	0.25 / 0.5	0.25 /	0 / 0.25	0 / 0

Figure 2: Defocalization curve, monocular examination, 1 year after surgery (patient H.F.)



(Figures courtesy of Jérôme Blondel, MD)

Refractive outcomes at 1 month ranged from 0 to 0.5 D, Dr. Blondel said.

Visual acuity testing showed binocular and monocular distance uncorrected visual acuity of 10/10. All patients had 10/10 binocular uncorrected intermediate visual acuity measured at 60 cm, while binocular uncorrected near visual acuity was P2. Only one patient reported using glasses occasionally and only for a specific near task (when knitting for more than 30 minutes). Defocus curve testing performed at 1 year after surgery in the first patient demonstrated excellent results over the distance to near range.

There were no intra- or postoperative complications; no patients complained of glare or halos; and the patients expressed high satisfaction with their outcomes. All four patients said they would recommend the surgery to a friend or family member and that they would undergo the procedure again.

The lens is made of a clear hydrophilic acrylic material (26% water content). It has a square edge, 6-mm optic with an aspheric-front surface. The haptics have a multilink design with four-point attachment and no angulation.

The InFo IOL has the CE Mark but is not approved by the FDA. A toric version is anticipated and new packaging is being developed. ■

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

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DARPin results promising in phase II wet AMD study

Functional and anatomic improvements recorded 12 weeks, post-loading dose injections

By Cheryl Guttman Krader; *Reviewed by Raj K. Maturi, MD*

INDIANAPOLIS ::

A novel anti-vascular endothelial growth factor (VEGF) agent is at least as effective as ranibizumab (Lucentis, Genentech) and shows promise for allowing a longer dosing interval, said Raj K. Maturi, MD.

Such findings are based on results from a phase II study investigating intravitreal abicipar pegol ("abicipar"; Allergan) in patients with treatment-naive exudative age-related macular degeneration (AMD).


Dr. Maturi

"This phase II study was not powered to detect statistically significant differences in efficacy outcomes between treatment groups, but the data are exciting because they suggest that abicipar could offer the benefit of better visual improvement or a prolonged duration of action," said Dr. Maturi, clinical associate professor of ophthalmology, Indiana University School of Medicine, Indianapolis.

"A phase III study is now being planned," he said. "Considering the early results with abicipar and other agents in the pipeline, there is great reason for retina specialists and our patients to be very optimistic about what lies ahead."

WHAT ARE DARPINS?

Abicipar belongs to a new class of small molecule therapeutics know as designed ankyrin repeat proteins (DARPins) that can be engineered to bind one or more target proteins. Abicipar binds soluble isoforms of VEGF-A.

Compared with antibodies or antibody fragments, DARPins have a smaller molecular weight and higher binding affinity.

"The molecular weight of abicipar is 34 kDa compared with 48 kDa for ranibizumab, and 115 kDa for aflibercept (Eylea, Regeneron)," said Dr. Maturi, who is also in private practice, Midwest Eye Institute, Indianapolis.

However, despite its smaller size, abicipar has a longer vitreous half-life than either ranibizumab or aflibercept, 6 days versus 3 and 4.5 days, respectively, in the rabbit vitreous, he noted.

"The early clinical data are encouraging and suggest that abicipar will have a longer duration of therapeutic action than ranibizumab or aflibercept," Dr. Maturi said.

TAKE-HOME

- ***Abicipar pegol is an investigational anti-vascular endothelial growth factor agent belonging to a new therapeutic class known as DARPins. The agent was at least as effective as ranibizumab for the treatment of exudative age-related macular degeneration, and appeared to have a longer duration of action in a recent study.***

ABOUT THE STUDY

The double-masked trial was conducted as the third and final stage of a phase II study program. It randomly assigned 64 patients into three groups to receive abicipar 1mg (n = 25), abicipar 2 mg (n = 23), or ranibizumab 0.5 mg (n = 16). Treatments were administered with 3 loading doses at weeks 0, 4, and 8. Thereafter, ranibizumab was continued on a monthly dosing schedule while further treatment in the abicipar groups was with monthly sham injections.

When patients were evaluated at week 16, 4 weeks after the last ranibizumab injection and 8 weeks after the last abicipar injection, mean improvement from baseline visual acuity was greater in the abicipar 1 and 2 mg groups compared with ranibizumab (6.3 and 8.2 versus 5.3 letters, respectively).

The proportion of patients achieving ≥3-line gain from baseline visual acuity was also greater in the higher dose (2 mg) abicipar group compared with ranibizumab.

At week 20, this change in best-corrected visual acuity was observed in 25% of patients treated with the higher dose of abicipar (2 mg) versus 12% for both ranibizumab and the lower dose abicipar (1 mg).

Analyses of optical coherence tomography images showed macular thickening was quickly reduced following intravitreal injection in all treatment arms.

All treatments were well tolerated, and there were no serious adverse events recorded during the study. Two patients treated with abicipar 2 mg and in 3 patients treated with the 1 mg dose developed ocular inflammation with decreased vision. They were all treated successfully using topical anti-inflammatory medications and recovered vision.

LOOKING FORWARD

"There has been an ongoing effort to modify the manufacturing process to address inflammation, and material from the new manufacturing process will be used in the phase III trials," Dr. Maturi said.

In addition to the potential for having a longer duration of action, the fact that DARPins represent a tunable technology platform that

> 'The potential to provide multimodal treatment using a single agent is very intriguing.'
>
> — Raj K. Maturi, MD

can be modified to bind different target proteins and more than one protein with a single compound is another exciting and attractive feature of this novel therapeutic class, he said.

For example, the early results of Fovista's anti-PDGF drug demonstrate a significant potential benefit of suppressing both VEGF and PDGF. A DARPin effective against both of these cytokines could be manufactured simply by linking an anti-VEGF DARPin with an anti-PDGF DARPin to form a single molecule with both binding properties.

Because the pathogenesis of wet AMD and other diseases being treated with anti-VEGF agents is complex, there is strong believe that combination treatment will likely be more effective than a monotherapy approach.

"Therefore, the potential to provide multimodal treatment using a single agent is very intriguing," Dr. Maturi said. ■

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This article was adapted from Dr. Maturi's presentation at the 2014 meeting of the American Society of Retina Specialists. Dr. Maturi is a consultant to Allergan and has received grant support for clinical studies as well as for investigator initiated trials. Allergan has an exclusive license to abicipar from Molecular Partners.

OT The therapeutic pipeline for neovascular age-related macular degeneration (AMD) contains a host of promising investigational agents. Only time will tell how any one will shape the future of AMD management. For more about what's next in the neovascular AMD pipeline, **go to http://bit.ly/1slKiy3**

Global ophthalmic drug market expected to reach $21.6 billion in 2018

By Colleen McCarthy; *Content Specialist*

NEW YORK ::

THE GLOBAL ophthalmic drugs market—valued at $16 billion in 2012—is expected to reach an estimated value of $21.6 billion in 2018, according to a new market report published by Transparency Market Research.

Globally, the ophthalmic drugs market is witnessing significant growth due to increasing prevalence of eye disorders, such as diabetic retinopathy and age-related macular degeneration. As a result, this market is expected to grow at a compound annual growth rate (CAGR) of about 5.2% during 2013 to 2018.

Some of the key driving factors for the ophthalmic drugs market are rising prevalence of global aging population, increasing government initiatives toward health-care infrastructure in developing countries (such as India and China), technological changes in drug delivery technique, and increasing prevalence of lifestyle associated diseases.

However, the market faces some restraints, such as lack of awareness among people about eye disorders, drying pipeline of ophthalmic drugs, patent expiration of blockbuster ophthalmic drugs, and absence of health insurance in developing countries.

North America has the largest ophthalmic drugs market, whereas Asia is the fastest-growing market. Some of the fastest-growing markets for ophthalmic drugs are China, India, other countries in Southeast Asia, and the Eastern Mediterranean.

According to the World Health Organization, the number of blind people aged 50 years and above will grow in these regions, increasing the demand for ophthalmic drugs.

Conversly, in developed regions, such as North America and Western Europe, rising efforts toward prevention of blindness among the aging population has emerged as a key driver for the market.

Glaucoma has the largest market share in the ophthalmic drug market, and it is expected to grow at a CAGR of about 4.2% during 2013 to 2018. ■

Effects of latanoprostene bunod on IOP explored in crossover study

New compound showing better pressure-lowering efficacy than timolol over 24 hours

By Michelle Dalton, ELS; *Reviewed by John H.K. Liu, PhD*

LA JOLLA, CA ::

ONCE-DAILY latanoprostene bunod lowered IOP more than twice-daily timolol in a crossover study of patients with open-angle glaucoma or ocular hypertension, according to results from the CONSTELLATION study.

Lead author for the study, John H.K. Liu, PhD, of the Hamilton Glaucoma Center and Department of Ophthalmology, University of California–San Diego, La Jolla, CA, said the randomized, single-center, open-label, 2-period, 8-week study included a crossover at 4 weeks between latanoprostene bunod 0.024% once-daily with timolol maleate 0.5% twice-daily.

"A comparison against timolol is an industry standard," said Dr. Liu, adding that it is hoped "this new compound will be compared against other prostaglandin analogues in the future."

THE CONSTELLATION STUDY

The CONSTELLATION study (registered at *clinicaltrials.gov* under NCT01707381) enrolled 20 subjects between 43 and 82 years old who had baseline IOPs of at least 22 mm Hg in one eye and less than 36 mm Hg in both eyes, and a diagnosis of open-angle glaucoma or ocular hypertension.

Both treatment-naïve and pre-treated patients were included (as long as they met the IOP requirements after washout). Among exclusion criteria were patients with irregular daily sleep schedules, as well as patients with previous or active corneal disease, severe dry eye, active optic disc hemorrhage, a history or central or branch retinal vein occlusion, a history of macular edema, or who had very narrow angles. Patients with angle closure, congenital, and secondary glaucoma were also excluded, as were those who underwent ocular laser surgery within 3 months prior to the screening visit.

STUDY DETAILS

Patients were housed in a sleep laboratory for 24 hours and a baseline IOP profile was created. IOP of both eyes was measured with a pneumatonometer every 2 hours in the sitting and supine positions from 8 a.m. to 10 p.m., and in the supine position only from 12 to 6 a.m.

During the first period of the study, subjects were randomly assigned 1:1 to either of two treatment sequences: latanoprostene bunod 0.024% instilled in both eyes at 8 p.m. or timolol maleate 0.5% instilled twice a day at 8 a.m. and 8 p.m.

After 4 weeks of treatment, subjects were housed in the sleep laboratory for a second 24-hour period IOP measurement. At the end of the 24 hours, subjects were crossed over to receive the comparator treatment, which initiated period 2.

"If needed, a washout of glaucoma medication was done before the baseline 24-hour IOP measurement," Dr. Liu said. "After the crossover, the second test agent was treated for 4 weeks. At the same time, the first test agent was in the washout for 4 weeks."

After the period 2 treatment time frame ended, patients returned to the sleep laboratory for a third 24-hour IOP measurement.

HOW THEY DIFFER

Latanoprostene bunod differs from latanoprost in that the former compound is metabolized in situ to latanoprost acid plus butanediol mononitrate. Butanediol mononitrate is a nitric-oxide (NO)-donate moiety, Dr. Liu said.

"Nitric oxide can dilate blood vessels," he said. "Previous animal studies indicated that nitric oxide can also lower IOP."

In this study, latanoprostene bunod lowered IOP for 24 hours (day and night), whereas timolol was able to reduce only daytime IOP. The mean change from baseline in IOP was 3.9 ± 0.28 mm Hg for latanoprostene bunod-treated eyes and 2.4 ± 0.29 mm Hg for timolol-treated eyes during the diurnal/wake period; 2.75 ± 0.45 mm Hg for latanoprostene bunod and 0.2 ± 0.46 mm Hg for timolol during the nocturnal/sleep period; and 3.5 ± 0.24 mm Hg for latanoprostene bunod and 1.7 ± 0.25 mm Hg for timolol during the entire 24-hour period.

Dr. Liu added the sample size was too small to determine if any differences existed by age, gender, or length of time since diagnosis.

Clinically, Dr. Liu said the promising aspect of the study is that latanoprostene bunod "seems to have IOP-lowering efficacy during the daytime and at night."

TAKE-HOME

- ***Findings from the CONSTELLATION study show that once-daily latanoprostene bunod lowered IOP more than twice-daily timolol in patients with open-angle glaucoma or ocular hypertension.***

LATANOPROSTENE BUNOD PROGRAM

Latanoprostene bunod will be co-promoted in the United States by Nicox and Bausch + Lomb. In January 2013, Bausch + Lomb initiated a phase III clinical program for latanoprostene bunod with two pivotal studies, APOLLO and LUNAR. These studies are designed to compare the efficacy and safety of latanoprostene bunod administered once daily with timolol maleate 0.5% administered twice daily in lowering IOP in patients with open-angle glaucoma or ocular hypertension. The primary endpoint of both studies, which will include a combined total of about 800 patients, is the reduction in mean IOP measured at specified time points during 3 months of treatment.

In July 2013, Bausch + Lomb also initiated two studies in Japan. JUPITER is a phase III study enrolling about 130 subjects to demonstrate the clinical safety of latanoprostene bunod 0.024% administrated once daily over a 1-year treatment period. KRONUS is a phase I study to evaluate the effect of latanoprostene bunod 0.024% administered once daily in reducing IOP measured over a 24-hour period in about 24 healthy male Japanese subjects. ■

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This article was adapted from Dr. Liu's presentation at the 2014 meeting of the Association for Research in Vision and Ophthalmology. Dr. Liu has received financial support from Aerie Pharmaceuticals, Alcon Laboratories, Allergan, Bausch + Lomb, NASA, and Sensimed.

Pace picking up for pharmacologic development in glaucoma therapy

Four new drug candidates highlighted in overview of new therapeutics on the horizon for glaucoma

By Fred Gebhart

SAN FRANCISCO ::

"BIG PHARMA" IS ON the hunt for new glaucoma drugs. Evidence to date says the pharmaceutical industry is closing in on new approvals.

"The pace of therapeutic development is picking up in a big way," said Stuart B. Abelson, MBA, president and chief executive officer (CEO) of Ora, an ophthalmic contract research organization based in Andover, MA. "Capital is flowing and programs are moving forward in all phases. Ora's business is growing for a second year in a row at over 100%, adding resources and helping companies move their programs along."

Abelson—along with Joel S. Schuman, MD, FACS, chairman, Department of Ophthalmology, University of Pittsburgh—co-moderated a session at Glaucoma 360° that provided an overview of new glaucoma pharmaceuticals on the horizon. Further updates are always available at *clinicaltrials.gov*.

ABSEE PHARMA

This German company is pursuing what could become the first neuroprotective agent against glaucoma and dry age-related macular degeneration (AMD). The company name, AßSee, is derived from amyloid beta, a peptide thought to play a role in the development of Alzheimer's disease, as well as ocular disease.

An age-related accumulation of Aß in retinal tissues appears to be linked with glaucoma through toxicity to retinal ganglion cells and with AMD through toxicity to retinal epithelial cells, explained Alexander Gebauer, MD, PhD, CEO of AßSee. The company's lead compound, MRZ-99030, impedes formation of these toxic Aß oligomers and promotes the formation of nontoxic forms that are cleared from ocular tissues. The agent is administered as eye drops.

"This is the only topical Aß agent under development," Dr. Gebauer said. "In a rodent model, we saw the death of retinal ganglion cells almost completely stopped by MRZ-99030 eye drops. We saw a 95% protection effect with no increase in IOP. We have phase I results and chronic toxicology with very promising data and excellent safety."

The company plans parallel clinical trials for glaucoma and dry AMD.

"We were encouraged from speaking with the FDA about our regulatory strategy and clinical program," Dr. Gebauer said. "Hopefully, we can bring this compound to market within the next couple of years."

AERIE PHARMACEUTICALS

Aerie is pursuing multiple mechanisms of action to tap the $4.5 billion global glaucoma market. The company is moving forward with two compounds: a dual-action Rho kinase (ROCK) + norepinephrine transport (NET) inhibitor and a triple-action ROCK+NET inhibitor + latanoprost.

"These are both once-a-day topical products, which make them easy for patients to use," said Thomas Mitro, president and chief operating officer. "Both have demonstrated great safety and efficacy in clinical trials. Our products can help meet the unmet medical needs in this huge marketplace."

Lead compound AR-13324 lowers IOP by inhibiting ROCK to enhance outflow through the trabecular meshwork and inhibiting aqueous production by inhibiting NET. Clinical trial data suggest that the compound may also lower episcleral venous pressure to enhance the overall IOP-lowering effect. The agent is effective in lowering IOP regardless of baseline pressure.

The second agent, PG324, is a fixed-combination dose of AR-13324 and latanoprost. The combination of ROCK/NET inhibition plus uveoscleral outflow maximizes the potential for IOP lowering, Mitro said. (See additional articles at *http://bit.ly/1tx2Rxi* and *http://bit.ly/1qihruR*.)

AMAKEM THERAPEUTICS

Belgium-based Amakem Therapeutics is working on its own ROCK inhibitor, AMA0076.

"The elephant in the glaucoma room is hyperemia," said Jack Elands, PhD, Amakem CEO. "Hyperemia is a significant problem with the prostaglandin analogues and is even worse with most of the ROCK inhibitors. Patients don't want hyperemia and if you add a ROCK inhibitor to a prostaglandin analogue, you are adding two hyperemic drugs. That is not good."

Amakem's solution is a ROCK with localized action. Drug that penetrates the cornea moves quickly to the trabecular meshwork, where it increases outflow and reduces IOP. Drug that remains on the cornea is quickly metabolized and eliminated. The localized action all but eliminates hyperemia in animal models and in clinical trials to date, he noted.

"Hyperemia, the lack of hyperemia, is what distinguishes AMA0076 from other ROCK inhibitors," Dr. Elands said. "In our early clinical trials, you have to look closely to see hyperemia. For people in normal conversation in everyday life, you don't see hyperemia at all."

The agent is also effective at lowering IOP. A 28-day trial showed a mean IOP lowering of 20%. IOP measurements taken in the morning showed a clear IOP-lowering effect from eye drops administered the previous evening.

"We have moved from animal models to clinical proof of concept with IOP lowering and no hyperemia," Dr. Elands said. "We are now in phase II dose finding to optimize our formulation."

ONO PHARMA USA

Ono has a long history of work with prostaglandin ligands, a history that is fueling development of a novel FP/EP-3 dual-receptor agonist to treat glaucoma.

Data from a 25-day clinical trial in ocular hypertension and open-angle glaucoma suggest that the company is on track to produce its first glaucoma drug.

Continues on page 40 : ***Pharma pace***

TAKE-HOME

- ***Drug development is picking up as the pharmaceutical industry hunts for new glaucoma therapies. Four new drug candidates are highlighted in an overview of new glaucoma pharmaceuticals on the horizon.***

IVAN data mined for safety insights on intravitreal anti-VEGF therapy

Analyses found a larger fall from baseline serum VEGF was associated with a lower hazard of death

By Cheryl Guttman Krader; *Reviewed by Usha Chakravarthy, MD*

BELFAST, IRELAND ::

DETERMINATION OF the systemic safety profiles of intravitreal anti-vascular endothelial growth factor (VEGF) therapy is ongoing.

To that end, investigators from the Inhibition of VEGF in Age-related Choroidal Neovascularization (IVAN) trial undertook analyses of data from their study to explore potential associations between serum VEGF and various safety outcomes, said Usha Chakravarthy, MD.


Dr. Chakravarthy

They looked at whether change in serum VEGF from baseline to month 12 or average serum VEGF—calculated as the mean of the baseline and month 12 values—predicted the frequency of:

1. arterio-thrombotic events (ATEs) and/or heart failure (events that have been associated with systemically administered anti-VEGF drugs);
2. other serious adverse events (SAEs) not previously associated with VEGF, or
3. gastrointestinal (GI) events.

The analyses found that having a larger fall from baseline serum VEGF was associated with a lower hazard of death. In addition, higher average serum VEGF was associated with a marginally increased risk of ATEs. No other associations were found between decrease in serum VEGF or average serum VEGF and any of the safety endpoints analyzed.

"Our findings offer fascinating insights into the mechanisms that underlie the systemic effects of these local therapies," said Dr. Chakravarthy, lead investigator, IVAN trial, and professor of ophthalmology and vision sciences, The Queen's University of Belfast, Northern Ireland.

"Neutralizing VEGF cannot be good for the vasculature, and hence there is concern that anti-VEGF therapy may induce thrombogenesis," Dr. Chakravarthy said. "However, too much VEGF in cancer patients is a marker for poor prognosis, and our finding associating larger falls in serum VEGF with a lower hazard of death is similar to the observation in cancer trials with bevacizumab where higher serum VEGF was associated with higher mortality."

STUDY ANALYSES

The study included data from 530 IVAN study participants who had serum VEGF measured at baseline and month 12. The laboratory that conducted the serum analyses was masked to all patient clinical information. The analyses of occurrence of SAEs were performed with a mixed effects logistic regression, center-fitted as a random effect. Analyses of time to death were performed with Cox proportional hazards regression center-fitted as a frailty term. Serum VEGF levels and age were analyzed as linear variables, but the validity of the models was tested with fractional polynomials.

There were no significant differences in mean serum VEGF levels at baseline comparing the ranibizumab and bevacizumab arms or the continuous and discontinuous arms, indicating the groups were well-balanced for this parameter. After 1 year, serum VEGF was significantly lower with bevacizumab treatment compared with ranibizumab and with continuous versus discontinuous treatment.

Analyses were also conducted to examine potential relationships between the different safety outcomes and drug (ranibizumab or bevacizumab), treatment regimen (continuous or discontinuous), age (patients categorized into age groups by decade of life), and gender. Their results showed several significant associations with age.

Specifically, for each 10-year increase in age, the hazard of death increased 4-fold , the hazard of an ATE/heart failure increased 2.6-fold, and the hazard of both any other SAE not previously linked to VEGF and of all SAEs combined increased ~40%. The only other significant association found was a 3.5-fold higher hazard of death in the discontinuous versus continuous arm. ■

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This article was adapted from Dr. Chakravarthy's presentation at the 2014 annual meeting of the Association for Vision in Research and Ophthalmology. Dr. Chakravarthy has no relevant financial interests to disclose.

PHARMA PACE

(Continued from page 39)

"Our pre-clinical studies showed significant and profound IOP lowering that was greater than latanoprost alone or in combinations with other agents," said Andrew Wood, PhD, global clinical director. "The phase I safety and tolerability studies that compared four doses [3, 10, 20, and 30 µg/mL] against placebo gave very similar data."

After 14 days of dosing, the 10 µg/mL and 30 µg/mL doses showed a 35% IOP lowering. Latanoprost, based on historical data, provides a 26.8% to 34.4% reduction in IOP over a similar period. IOP lowering was sustained up to 33 hours after the last dose.

"The duration of IOP lowering strongly suggests that this might be a once-a-day dosing drug," Dr. Wood said. "These results suggest the need for additional phase II trials to compare safety and efficacy with other IOP lowering agents, particularly the prostaglandin analogues." ■

Editor's Note: *This article was adapted from the 2014 New Horizons Forum at Glaucoma 360°, in partnership with the Glaucoma Research Foundation and* Ophthalmology Times.

SPECIALTY EYEWEAR PROMOTION CHEAT SHEET

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A collection of eyewear is displayed to catch the eyes of customers and to enhance their experience, making it easier to understand and visualize what style is necessary for their needs. *(Images courtesy of Lisa Frye, ABOC)*

Promoting specialty eyewear within the dispensary

Understanding how to sell wide range of niche optical products to benefit patients, clinic

By Rose Schneider, *Content Specialist,* Ophthalmology Times

BIRMINGHAM, AL ::

No two patients' eyewear needs are the same. While one patient may be highly active and require eyewear sturdy enough for his or her amount of physical activity, another may be a fashionista who enjoys reading and is in need of eyewear with a stylish touch.

Due to individual needs and wants, every practice should know how to promote specialty eyewear properly, according to Lisa Frye, ABOC.

"Many of our patients lead very active lifestyles, and . . . one pair of glasses just will not cover everything," said Frye, a longstanding Fellow of the National Academy of Opticians and who has more than 30 years of experience in optometric management.

Continues on page 42 : ***Specialty***

(In Brief)

Eyewear apprenticeship

SAFILO PRODUCT SCHOOL TEACHES CRAFTSMANSHIP

PADUA, ITALY :: **SAFILO GROUP** announced the launch of the Safilo Product School—offering 3-year apprenticeships to up to 10 young professionals every year, starting in 2015.

The establishment of the product school will provide young apprentices with the opportunity to build foundational mastery across all product functions, and then begin Safilo's career path to form the new generations of eyewear product directors, said the company.

Entry into the program based on selection will be open to talents from technical institutes or universities, and will build on international apprenticeship best practices combining on-the-job learning and job rotation, including a global assignment in Safilo's worldwide operations, coaching by experienced Safilo managers and experts, and regular classroom training.

(Photo courtesy of Safilo)

The focus will be on product creation—from design to product development, from prototyping to manufacturing, materials, quality, pricing, and product concept selling. Additionally, the program also will cover the development of managerial skills and behavioral competencies.

The formal training will be administered in collaboration with national and international partners—universities, technical, and optical product certification institutes, and Safilo's customer and supplier network, supplemented by its own global management team.

"The [school] reflects our commitment to eyewear product craftsmanship and innovation, and our commitment to its future," said Luisa Delgado, chief executive officer of Safilo Group. "With it, we combine our past product tradition with masterful innovation forward that future generations will create when given the opportunity to learn. We aspire to give a sustainable contribution to the youth, our industry and region, reaching beyond our own company." ■

SPECIALTY

(Continued from page 41)

"It is most important that we, as professionals, find solutions for visual needs," she said. "This benefits our patients, allows us to grow our practices financially, and can increase the number of referrals to the office by people who love to tell others about their products."

BREAKING DOWN THE BASICS

The best way to promote specialty eyewear within your practice, Frye said, is to invest in different types of specific solutions and create areas to promote and demonstrate the options your clinic offers.

Frye

Specific areas to focus on, she said, are frames and lenses as the products serve a niche for individual patients.

"(Recently), we were presented products for sunwear that allows a flatter base insert to be mounted into a wrap frame allowing us to use this for creating specialized sunwear for the more myopic patient," Frye explained. " These patients desire to have a wrapped design to block harmful light and ultraviolet, but in the past may have not been afforded a solution."

Asking open-ended questions will help decipher which specialty eyewear is right for your patient, she said.

By asking patients about their specific needs, "we can identify the areas of need and offer solutions to solve them," Frye said. "Even those patients who cannot adapt to progressive multifocal designs have more options than just round segments, blended bifocals, or flattop bifocals these days.

"When a patient can see the demonstration and understand 'what will this do for me' they will respond with 'sign me up,'" she added.

Frye said her clinic has also added specialized equipment to measure for digital technology, which allows further customization eyeglass lenses for specific uses. An added bonus to the equipment is informative videos that explain specific options, such as non-glare, progressive multifocal, office, and computer lenses.

The range of the specialty eyewear is wide, which benefits the patients further, she said.

"Some of the lenses are so great that we have specific lenses for golf, specific lenses for computer use, the ability to place the segment for progressives to accommodate a patient who may have a fused neck and cannot lower their chin to read, or specifically change standard heights for a patient that is suffering from osteoarthritis and cannot straighten up," Frye said. "We (do) not leave out the smaller population segments like children, and those people who shop for cute readers, or fun suns, including readers and suns with attached cords that have magnets made at the bridge for easy on and easy off to hang around a neck."

An assortment of photochromic lens technology is displayed on a shelf to make it easier for patients to focus their attention on specific needs and become more educated about the product.

TAKE-HOME

- ***Offering specialty eyewear—and having knowledge for how to promote these products—will reap benefits not only for patients, but also for the clinic financially.***

FURTHER PROMOTION OPTIONS

Other options to promote the wide range of specialty eyewear is to put displays in the practice's waiting room, allowing patients not only to see them, but also to experiment with them, try them on, and sample which type interests them, Frye said.

"As a patient leaves our waiting room, there is also a safety and sports center display that promotes specialty offerings for active lifestyles, as well as prescription swim goggles, cycling goggles, (and) ski goggles," Frye added.

Practices can also utilize large television monitors to promote and explain information on a loop in exam lanes to help patients identify which products and services the clinic offers are right for them, she said.

Creating specific zones within the practice aimed at promoting the specialty eyewear products, along with brochures explaining the types of offerings and benefits, is a good outlet for patients to begin the process of educating themselves on the products, Frye explained.

As for external promoting, Frye recommended utilizing social media, e-mail and newsletters as forms of getting the word out on your specialty eyewear products.

"If you solve a specific need for a specific group, the word-of-mouth advertisement will continue to grow your practice," Frye said. "Without having to add more exams per day, you can increase your sales and profits by offering a specialty pair of eyeglasses (using e-media) in addition to what you already sell, and do the math, you will increase profits.

"This is definitely a win-win for the practice and the patient," she continued.

Utilizing e-media also creates excitement about the products.

"Remember the days when we set up a trial of clinical studies for new contact lenses? We can apply the same concept to new lenses, new types of sunglass frames, new computer lenses, and great new color options in polarized," Frye said. "The sky is the limit. Educate yourself and your staff about new technology, new product offerings, and find things that will solve a specific need for your patients.

"Be the expert, have fun, and never stop looking for ways to solve a visual need," she added. ■

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Frye has no financial interest in the subject matter.

Ophthalmology Times

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MODERNIZING MEDICINE

The trial close: Right time to ask for the sale from optical customer?

How a shopper's buying signals can be clues that a purchasing decision has been made

Dispensing Solutions **By Arthur De Gennaro**

SELLING IS BOTH an intellectual and psychological enterprise. I find that most opticians are full of product knowledge and can adequately explain the features and advantages of the lenses and frames they recommend to shoppers. In other words, they have the intellectual side of the equation covered.

All the product knowledge in the world, however, will not close most sales. What these opticians miss is the fact that sellers are most effective when they are tuned into the softer side of a sales transaction. This softer side is always emotional and psychologically grounded.

Consequently, as the demonstration progresses, the optician should be paying close attention to the shopper's behavior. What the shopper says or does not say—and how he or she says it—will give the optician powerful clues to what that shopper is thinking and where he or she is in the decision-making process.

TAKE-HOME

- ***The successful optician must have the ability to recognize the signs that a prospective shopper is ready to become a buyer of optical products.***

BUYING SIGNALS

Each shopper has a unique set of needs and wants. During the sales presentation, the shopper is exploring whether he or she can satisfy those needs and wants. As the shopper gets closer and closer to getting his or her needs met, the excitement level will build. This is an indication that desire is building and, as you'll remember, desire is the strongest motive to buy.

There will come a time—presuming the salesperson has thoroughly identified the shopper's needs and wants, presented appropriate products, and explained how those products will benefit the shopper—when the shopper will become convinced of the value of making the purchase. That shopper is close to making a purchase decision and becoming a buyer.

At this time the shopper's behavior will begin to change. He or she may ask: "When can these be ready?" "Can I get this in red?" Or, he or she may ask about warranties and return policies. The shopper may also ask if the eyeglasses can be purchased on a credit or layaway plan.

The shopper's demeanor will also change. He or she will begin to ask fewer questions and stop looking at merchandise or asking questions about it. The tone and tempo of the shopper's voice will likely change. It will not be as excited as before and may not be as forceful.

All of the above are buying signals—nonverbal ways a shopper communicates that he or she is ready to make a purchase. When an optician notices buying signals, it is time to ask the shopper to make the purchase. Since the optician cannot be sure if the shopper will buy, this action is known as the trial close.

If the optician does not pick up on these buying signals, he or she is likely to continue offering the shopper additional products or additional feature/advantage/benefit statements. Continuing to sell when a shopper is ready to buy will cause that shopper to disengage from the transaction. This will result in the shopper becoming mentally distant—and more importantly, emotionally distant.

This distancing of the customer will literally reverse all the hard work the optician has put into the sales transaction. In many cases, it will cause the customer to leave and characterize the optician as insensitive or overly talkative.

LOSING THE SALE

Just as a shopper will display signals that he or she is ready to buy, a shopper may also display signals that he or she is not ready to buy.

Asking questions such as: "Are you here every day?" "Can you write down the names of those frames for me?" or "May I have your business card?" are signals that the shopper is not convinced of the value of the purchase and is not ready to buy. In most cases, the shopper is signaling that he or she wants to continue to shop—only not at your dispensary.

7 Steps of a Retail Sale

1. **OPENING.**
2. **INTERVIEW.**
3. **DEMONSTRATION.**
4. **TRIAL CLOSE.** **The optician asks the customer to make the purchase.**
5. **OVERCOMING OBJECTIONS.**
6. **CLOSING.**
7. **MAINTAINING AN ONGOING RELATIONSHIP.**

CLOSING STATEMENT

An optician attempts to close a sale using what is known as a closing statement. There are quite a few types of closing statements, and these will addressed in another installment of this series.

When the optician uses a closing statement, one of two things will happen. Either the shopper will become a buyer (make a purchase) and the transaction is over, or he or she will raise some objection. How to overcome the shopper's objection is the subject of the next installment in this series. ■

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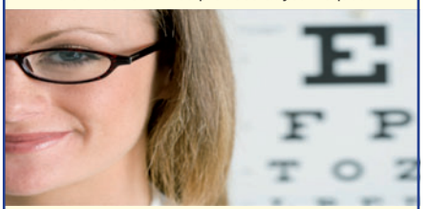

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Lifestyle cooperative poised for needs of aging populace

Tools, services help board-certified ophthalmologists capitalize on opportunities in self-pay market

By Ron Rajecki

NEWPORT BEACH, CA ::

Board-certified ophthalmologists who have grown weary of working harder for less reimbursement now have help in building a new business niche in the self-pay market.

Billing itself as "the first self-pay, lifestyle health-care company," ALPHAEON Corp. offers services and technologies designed to give consumers greater choice, more personalized outcomes, and uncompromised service for their wellness, beauty, and performance needs, according to Robert E. Grant, chief executive officer (CEO).


Grant

It also offers board-certified physicians in three specialties—ophthalmology, dermatology, and plastic surgery—a new path to success in their practices.

The cooperative is a wholly owned subsidiary of growth equity firm Strathspey Crown Holdings LLC, of which Grant is chairman and managing partner. The company's management team includes a number of members with a strong background in ophthalmology:

- Chairman William J. Link, PhD, founded and served as CEO of Chiron Vision and president of American Medical Optics
- Grant served as CEO and president of Bausch + Lomb Surgical and president of Allergan Medical
- Chief Financial Officer (CFO) Mitch Hill is a former CFO of Visiogen
- Chief Technology Officer David Mordaunt, PhD, served in the same role with Bausch + Lomb and also as CEO of OptiMedica and Precision Light.

According to the cooperative, the self-pay, product market is the fastest-growing segment in health care, representing a $20 billion opportunity. Helping board-certified specialists access that market is its aim.

"Our goal is to make health care all about the patient rather than the payers," Grant said. "The only way to do that is by putting doctors in a more prominent role. We want to restore the doctor-patient relationship and place the focus on making the right decisions for the patient, rather than leaving those decisions in the hands of insurance companies. If you can take insurance reimbursement out of the equation, you can rebalance the deck in favor of doctors and their patients."

CONCIERGE SERVICES

The national cooperative lets board-certified specialty physicians provide "concierge" services to self-pay patients. However, Grant stressed the company is not a franchise operation—it wants members to remain independent medical practices that simply take advantage of the benefits offered by being part of the group.

"We never want to own practices," he said. "If fact, our members own us and direct our decisions."

The tools and services the cooperative provides are based on input from members. What the members tell the management team they need to be successful in the self-pay market is what management will seek to find for them. Members are never compelled to buy any of the products that are made available to them.

There will be many technological exclusives, Grant noted. Early examples include exclusive U.S. licenses from Schwind eye-tech-solutions to market the Amaris excimer laser and from Visiometrics to market the HD Analyzer.

GIVING A 'SHOUT' OUT

Perhaps the biggest benefits that members will garner will likely be the interactions they will have with others members, which is included in ShoutMD, one component of the suite of software tools members can access.

ShoutMD is a unique way for specialists to communicate, combining elements of Facebook, LinkedIn, and Twitter, explained Shareef Mahdavi, ALPHAEON's chief marketing officer.

"It offers doctors a network where there's no advertising and no one restricting their freedom of speech," Mahdavi said. "When they post a question, or a 'shout,' they have access to a network of more than 1,000 board–certified specialists who can provide information and advice. And we think it will be 3,000 or more by the end of the year. It's like having partners for advice available 24 hours a day."


Mahdavi

"In addition, ShoutMD is fun," Grant added. "The more relevant shouts the members post, the more likes they get; the more likes they get, the more points they accrue; and the more points they accrue, the better price they get on all of our products."

Deciding when the time is right

WHY IS THE TIME right for a health-care lifestyle cooperative? For some, it's simply a matter of the march of time.

"As we are living longer lives, as consumers and patients, the need for us to have a better quality of life is increasing," said Robert E. Grant, chief executive officer of ALPHAEON. "We don't want to look old forever, and we don't want to feel old forever, so we are willing to invest in life enhancements."

The same patients who would be getting beauty interventions often are the same patients facing challenges, such as presbyopia, dysfunctional lens syndrome, cataracts, and glaucoma, he noted.

"Most of the issues that patients face in ophthalmology tend to be in their aging years, and we see ourselves as a company that is well-positioned to assist those patients in their anti-aging needs," Grant said. ■

A member's experience

VANCE THOMPSON, MD, founder of Vance Thompson Vision in Sioux Falls, SD, said he has long seen the value of focusing on the self-pay lifestyle segment of the market, and he has discovered that it can benefit a practice in unexpected ways.

Dr. Thompson

"I learned many years ago that patients are willing to invest in their health care for things that are not reimbursed by their insurance," Dr. Thompson said. "So, out of a fascination with refractive surgery as well as a deep desire to please my patients, I decided to make that a practice focus. Some things came out of it that I didn't expect."

Not only did it make for a healthy practice financially, it also allowed Dr. Thompson to invest in advanced technology that benefitted both the self-pay side of his practice and the insurance side of his practice.

"Even my Medicare and Medicaid patients could benefit from the technology that I could afford because of the self-pay patients," he said.

So when ALPHAEON was started with a mission to help practitioners with the lifestyle side of the business, Dr. Thompson was quick to get onboard. He points out that the journey to build a successful refractive surgery practice is not easy, in part because there is not much support to teach physicians how to market a practice, educate patients, and create an exceptional patient experience.

"Many companies are good at servicing a practice with quality technology, but how to develop the self-pay side of the practice—which involves a lot of business and marketing acumen—was something that I had to roll up my sleeves and do on my own," he said. "I learned from my peers when I could and my mistakes when I had to."

Today, he cannot imagine why a fellow ophthalmologist would not take advantage of a health-care lifestyle cooperative, such as ALPHAEON, which has made it its mission to help board-certified specialists develop the lifestyle side of their practices without the trial and error he endured.

"Contact a peer who is affiliated with [the cooperative] to learn what it has done for his or her practice," he advised. "Then talk to [the cooperative itself]. If you're looking to add high-end self-pay products and services to your practice, there's no better place to start." ■

Other software tools in the suite include TouchMD, which builds consumer awareness and helps patients' decision making; TrackMD, an inventory management system; EngageMD, which allows for patient relationship management; and FinanceMD, in which ALPHAEON Credit assists patients in moving forward with cash-pay or self-pay procedures. The starting point for board-certified physicians who are interested in becoming part of the cooperative is ShoutMD.

TAKE-HOME

- ***The self-pay, lifestyle health-care market is poised for huge growth as the population of the United States ages. A new cooperative offers a host of tools and services to help board-certified ophthalmologists capitalize on opportunities in the self-pay market.***

EXPANDING MEMBERS

About 400 of the health-care lifestyle cooperative's current 1,000 members are ophthalmologists, and the company is now expanding to cosmetic dentistry and orthopedics. There is no cost to join but physicians must be board-certified.

"We're not exclusionary, but we are an entity with high standards," Grant said. "Self-pay customers have high expectations and the experience must match those expectations. Plus, we believe the best way to protect the long-term viability of any type of elective procedure is through patient satisfaction."

Member companies support each other in the goal of achieving unparalleled patient satisfaction, according to Mahdavi.

"They realize that when they band together through this cooperative, they have a much greater opportunity to grow the market," Mahdavi added.

"Outstanding outcomes and exceptional patient experiences will make for a bigger pie and give physicians the opportunity to be a part of something that's bigger than their own practices," he said. ■

Four ways to protect portfolio, achieve gains

By Robert C. Scroggins, JD, CPA, CHBC

PROTECTING AN investment portfolio sounds like avoiding risk, whereas achieving gains sounds like embracing risk. Are the two objectives in conflict?

Accomplishing both at the same time is not primarily about being good at picking stocks or other investments because statistically, those performing at the top today will likely not be there in a few years. Instead, having success on both fronts at the same time is mostly about the behavior of the investor.

The best decisions regarding development of an investment portfolio can be negated by neglecting behavioral disciplines. Following are some behaviors and related philosophies which, when implemented, do a pretty good job of supporting both objectives.

PRE-DECIDING

You will benefit tremendously by deciding at the start, and for the long term, exactly how much money you will invest in order to achieve your long-term financial goals.

As everyone with a job has experienced, once you start earning money, lots of people are lining up to take it: the mortgage provider, the car dealer, the grocery store, cable company, the timeshare, etc. Investment success starts by adopting the discipline of paying yourself first.

The amount of investments you wish to have in the future will only be achieved over time and through a systematic and regular plan.

Clearly, time is the key element to compounding. It is also the key element to smoothing out investment returns and achieving a good long-term result without taking unreasonable risk. It is difficult to think of a goal in life of any great significance that is accomplished without pre-deciding. Reaching investment objectives is no different.

Deciding the exact amount of money you would like to have at a specific point in the future and the exact amount needed to reach your goal is absolutely necessary to achiev-

Continues on page 50 : ***Portfolio***

PORTFOLIO

(Continued from page 49)

ing it. Of course, the decisions about how to invest are important, too, but not as important as pre-deciding and investing with discipline.

DOLLAR-COST AVERAGING

This is a close cousin to pre-deciding and builds on the idea of smoothing out investment results over a long period.

Dollar-cost averaging is about consistently investing the same amount at regular intervals. For example, if you are investing each month in shares of a particular stock, in the months when the shares are trading at a relatively higher price per share, your money will purchase fewer shares, whereas in months when the shares are trading at a relatively lower price per share, your money will buy more shares. In other words you are "buying low."

This approach is designed to eliminate the gamble that comes with market timing. Conversely, by investing larger amounts less frequently, it is more likely that you will make an investment when the security or market you are investing in is trading at a high point.

USING A CAPABLE FINANCIAL ADVISOR

From the standpoint of behavior, "capability" in a financial advisor—the person or firm you rely on to help you achieve a long-term goal—is not all about his or her own investment acumen.

The current investment world is more complicated than ever, and good investment decisions require specialization across sectors and strategies. Consequently, it is very difficult for one person to know everything. It isn't just about U.S. stocks and bonds anymore. We are functioning in a much different, more globalized economy than a few decades ago.

Technology is driving investment infrastructure as well. Now an individual investor with $100,000 (or less in some cases) can have a separate professionally managed account of individual securities.

Only a few years ago, a capable investment manager wouldn't have even considered separate account management for a client with less than $1 million. Exchange Traded Funds offer a more favorable cost structure and trading flexibility compared with traditional indexed mutual funds. New diversification strategies are coming into vogue all the time.

In addition, each investment manager has his or her own preferred investment strategy: strategic, passive, active, tactical, indexing, alternatives, etc. Very overwhelming, isn't it?

The point here is that in modern times, the capable advisor is not trying to be an expert in everything. He or she is first focused on working with you to create a carefully designed plan that will develop a net worth in line with your objectives for your lifetime and legacy.

Second, instead of watching a stock ticker all day long, an advisor should be researching and vetting investment managers and products. As you evaluate advisors, if a focus on planning is lacking or if he or she alone is the "stock picker," then you may want to keep looking.

STICK WITH THE PLAN

A good investment plan is somewhat analogous to a football playbook. The game is run based on established plays that have been designed for specific situations. New plays generally are not created during the game, and changes to a long-term investment strategy should not be made hastily or in the heat of the moment. Instead, take the time to consider and adjust when necessary, but always work from the plan. ■

ROBERT C. SCROGGINS, JD, CPA, CHBC,
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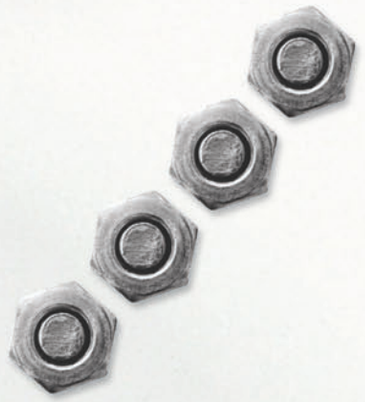

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iTech
BUILDING THE OPHTHALMIC TECH'S COMMUNITY OF PRACTICE

THE TECHNICIAN'S ROLE WITH ANESTHESIA

By Richard J. Ruckman, MD, FACS

The technician is usually the patient's first contact in the clinic. He or she frequently will perform the initial history to include both medical and ocular conditions and may perform the initial stages of the exam, including dilating the patient. As the first contact, the technician has an important role in obtaining a good medical history and a detailed medication and allergy list. In addition, the technician needs to understand the significance of this information in preparing the patient for surgery.

Anesthesia in eye care

Anesthesia is defined as a temporary state involving a lack of pain, loss of memory, muscle relaxation, and/or unconsciousness. In ophthalmology, anesthesia is very broad, ranging from the anesthetic eye drops used in clinic to the sedation and analgesia of cataract surgery and finally to the general anesthesia that may be used for strabismus or retinal surgery. Achieving this wide range of goals may require multiple classes of medications for anxiolytic (anti-anxiety), muscle relaxation, analgesia, and loss of awareness.

Except for a few minor office procedures which may require only eye drops, most patients for cataract, retinal, and many plastic procedures will undergo conscious sedation anesthesia either in the hospital or ambulatory surgery center (ASC) setting. Moderate sedation/analgesia (conscious sedation) is defined as the use of medication which allows patients to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function, protective reflexes, and the ability to respond purposefully to verbal and/or tactile stimulation.[1]

This is usually achieved through a combination of medications, first to relieve anxiety followed by an anesthetic agent which may be topical, locally injected, or systemic. The goal is to provide a safe and controlled environment for the surgeon while at the same time allow the patient to have a relaxed, pain-free experience with rapid return to normal activity.

3 questions techs should be able to answer

1. If the patient has a well-documented procaine (Novocain) allergy, can you instill topical anesthetic to check intraocular pressure?
2. Why is it so important to have a complete medication list not only for the name of the medication but also the dosage?
3. Why is it important to let the doctor know if the patient has been on medications for prostate such as tamsulosin (Flomax)?

For answers, see page 4

Preparing for surgery

In preparation for surgery, all patients undergoing procedures in Medicare-approved facilities are required to have a comprehensive history and physical prior to the surgery. In 2010, CMS provided guidelines to clarify when this needs to be done and what it should include.[2]

The history and physical needs to be:

- Performed by qualified personnel
- Comprehensive
- Placed in the record prior to surgery
- May be combined with the pre-surgical assessment

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- May not be more than 30 days in advance of the procedure

The purpose of the history and physical is to establish the patient's chief complaint, record pertinent findings, and, when appropriate, record laboratory testing. The surgeon ultimately determines the need for the procedure, but much of the initial assessment starts with the technician. It is valuable to the surgeon not only to know the patient's ocular complaint but also the patient's perception of his problem as well as the patient's ability to understand and communicate. Is the patient extremely anxious? Is the patient hard of hearing? What other ongoing medical problems and what medications, both prescribed and over the counter, are present? In addition, baseline vital signs, including height and weight, are essential to calculate dosages for anesthesia.

When the patient is scheduled to undergo a procedure requiring more than local anesthesia, he is usually given a medication first to relieve anxiety, followed by a medication to prevent pain. The medications that are given intravenously must have dosages adjusted for both age and physical condition. This is particularly true for our geriatric patients. Geriatrics is arbitrarily defined as age 65 or older, but aging is associated with a one percent to 1.5 percent decrease in major organ function after age 30.

The anesthesia provider will review the information in the history and physical to make a decision for what medications can be used. Many times with geriatrics, the anesthesia provider may need to reduce the doses by 30 percent to 50 percent and wait longer before being able to fully assess the full pharmacologic effect. This can be particularly true in the patient with multiple medical problems involving the heart, lungs, and kidneys in which the functional age may be much more than the chronological age. These observations of how a patient looks and acts when recorded in clinic will help the anesthesia provider develop a plan for the procedure.[3]

Objective of conscious sedation/analgesia

- **Alternation of mood**
- **Maintenance of intact protective reflexes**
- **Enhanced cooperation**
- **Alternation in perception of pain**
- **Minimal variation of vital signs**
- **Maintenance of consciousness**
- **Some degree of amnesia**
- **Rapid, safe return to activities of daily living**

The success of the patient's clinical and surgical experience depends greatly on the success of the anesthesia. The technician's role as the first contact with the patient is critical in collecting key data to ensure a safe experience for the patient.

Anesthesia and medication

Medication history is important not only for allergies but also the increased risk of bleeding. I've found that over-the-counter medications and herbals such as ginkgo biloba, ginseng, garlic, and ginger as well as high levels of Vitamin E have been associated with increased risk of bleeding. Again, it gets back to that initial assessment, making sure that all medications, including over-the-counter products, are recorded.

In the past, many doctors would have standing orders to discontinue blood thinners prior to surgery. "The issue of the medical-legal aspects is a very critical one… The older literature indicates that anticoagulation should be modified or discontinued prior to embarking on ocular surgery. But a more recent appraisal of the literature shows that certainly cataract surgery can be done safely despite anticoagulation."[4]

The trend now is not to stop most anticoagulants prior to surgery, recognizing that the risk of discontinuing the medication may outweigh the risk associated with the procedure. It is acceptable to continue anticoagulants such as aspirin, clopidogrel (Plavix, Bristol-Myers Squibb), and warfarin (Coumadin, Bristol-Myers Squibb) for both cataract and retinal surgery, although many plastic and strabismus cases will still require some adjustment in blood thinners. If the ophthalmologist feels that blood thinners need to be limited or discontinued prior to the procedure, he may wish to seek evaluation from the patient's internist prior to the procedure. This is especially true if the patient has a drug-eluting heart stent in which there is a risk of occlusion during the first year after placement of the stent.

Richard J. Ruckman, MD, FACS, has been in practice since 1978, specializing in cataract surgery. E-mail him at rruckman@thecenterforsight.com.

Anesthesia, as discussed earlier, uses a wide range of topical, local, and systemic medications. For most cases within the ASC setting, this would involve an IV medication for analgesia or pain relief, amnesia, and relaxation. This is usually followed with a local anesthetic. Local anesthesia is the mainstay for ophthalmology, both in the office and ASC setting. This would include eye drops for topical anesthesia and local injection into the skin or around the globe with retrobulbar or peribulbar block not only to provide pain relief but limit motion of the globe.

There are two general classes of local anesthetics: esters and amides. Esters which include procaine (Novocain, Hospira) are no longer routinely used systemically; but most of our commercially available eye drops such as benoxinate (Fluress, Akorn), proparacaine, and tetracaine are esters. The amides are the injectable class of anesthetics. They include lidocaine, mepivacaine, and bupivacaine and may have additives such as epinephrine to prolong the effect. The ester class of anesthetics has been associated with an increased risk of allergic reaction which may include rash, redness, hives, and asthma; but the amides rarely have been reported to have significant allergic reaction. Because most topical anesthetics such as Fluress are esters, in the presence of a well-documented history of Novocain allergy or in the patient who has a documented reaction to the commercially available anesthetic drops, the use of preservative-free lidocaine can be substituted in the presence of a Novocain allergy.[5]

The amide anesthetics such as lidocaine have traditionally been used for injection into the skin or for peribulbar and retrobulbar anesthesia, both to numb the tissue and limit the movement. In recent years, lidocaine, either as a drop or gel form, has been used commonly in cataract surgery topically on the conjunctiva and in the preservative-free form of lidocaine within the eye. The addition of epinephrine to the intraocular lidocaine may reduce the risk of a tamsulosin-related complication called intraoperative floppy iris syndrome (IFIS).[6]

The success of the patient's clinical and surgical experience depends greatly on the success of the anesthesia. The technician's role as the first contact with the patient is critical in collecting key data to ensure a safe experience for the patient.

Every member of the ophthalmic team has an important role in the ultimate success of the clinical and surgical experience. It starts with the technician's initial contact with the patient. The technician must gain the confidence of the patient, spend the time necessary to identify medications and potential risks, record these findings, and convey key information to the doctor and nurses or ASC staff.

3 answers that techs should know (see questions on cover)

1. If the patient gives a history of a Novocain allergy or reaction to eye drops, then preservative-free lidocaine can usually be substituted.
2. The anesthesia provider needs an accurate detailed history to include the patient's medical problems and precise medication list with accurate vital signs to insure a safe surgical experience.
3. Knowing that the patient has been on an alpha-adrenergic antagonist such as tamsulosin (Flomax) allows the doctor to anticipate the need for extra steps or medications in his cataract procedure. One option is to add epinephrine to the intraocular anesthesia to counter the effect of Flomax.

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Check out this great video resource for cataract surgery anesthesia.

http://www.thedoctorschannel.com/view/topical-or-regional-anesthesia-for-cataract-surgery/

5 things that make a great technician

Some skills can be learned, some just can't be taught

By Dianna E. Graves, COMT

I don't want good technicians working in our clinic. There—now that I have your attention, let me continue.

I don't want good technicians working in our clinic; I want the best technicians working in the clinic. Many people make the assumption that if they pass the JCAHPO, COA, COT, or COMT tests that they are good technicians. That might mean it would also be safe to say that the higher the certification, the better the technician.

I do not believe that your certificate, or lack of certificate, is the true indication of what type of technician you actually are. There are so many intangibles involved in the mix. These skills are very hard to cultivate in a person, and it is very hard to evaluate whether someone might possess them during an interview.

There are five things you must know to be a quality technician:

1. **Histories and vision**
2. **Refractometry**
3. **Pupils**
4. **Anterior chamber depth assessment**
5. **People skills**

1A. HISTORIES

By nature, a history should be a series of specific questions linked together in an orderly sequence that builds on the patient's response. The history is designed to paint a picture of the patient and his eye health.

These are the important parts of the history (in order):

- History of the chief complaint
- Medications and allergies
- Eye history
- General medical history (review of systems)
- Family history

The doctor's exam builds off your history. Your exam and test planning (Does the patient need a brightness acuity test? Does she need a refraction? Does she need a visual field?) build off your history. And billing is also largely based off your history. It is one of the most crucial parts of a technician's job—but most technicians will tell you they hate taking histories and race through this process to get to the more interesting parts of the exam (refractometry and slit lamp).

Why do we dislike it so? Because patient's ramble during their histories. We want them to give us their story in a small, *Reader's Digest*-condensed version; the patient wants to share with us *War and Peace*.

Here are some tips:

- Keeping in mind patients want to tell their story, try to ask yes-or-no questions. If you ask, "So, tell me what happened with your eye,"

> "The doctor's exam builds off your history. Your exam and test planning build off your history.

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"In our office, I look for people who have good clinical skills, and then I look deeper to see where they will fit.

he will begin the story at birth and continue until present day—often with information not pertinent to the problem.

- Put the chief complaint in their words. I have never had patient come in and state, "I am having episodes of metamorphopsia x three days." They say, "I am seeing floating mosquitoes this week."
- When asking about allergies or medications, never carry that information forward in the patient's record. Allergies need to be discussed at every visit. If a patient states he does not have an allergy, write: "Patient denies allergies." The word "denies" implies that you asked the patient, and he said, "no." Do not use the "universal no" symbol (circle with a slash).

1B. VISION TESTING

If you are conducting an exam on a new patient, always check her vision with and without correction. Some techs might think this is a waste of time, especially if the patient is seeing 20/20 with her current correction. Here's a hint: not everyone wears their glasses. It is not uncommon for spouses sharing a pair of glasses. While the patient may see 20/20, it is not really her correction.

If she is a returning patient, always look back at the last correction that was listed, as well as the last refraction the doctor ordered. We often wrongly assume that because the doctor gave her an Rx, she ran right out and got the new glasses. Be triply alert when working with nursing home patients. They might be wearing someone else's glasses.

Some of the most important skills technicians must have to be a great technician are:

- Empathy
- Sympathy
- Listening skills
- Ability to work in a team
- Ability to share and help others in the office grow in their fields
- Wanna

Here are some tips:

- Most of us use projected visual acuity charts. If a patient cannot see the "big E," often a tech will then perform counting fingers (CF) testing at 10 feet or five feet. This is not the best measurement, and in insurance worlds, as well as sometimes the medical-legal world, CF is a lot different than 10/200.
- If you use projectors, get a handheld block E to use if patients can't see the big E.
- If a patient does not see 20/40 or better, always use a pinhole. Pinhole is a great cheat. If the patient's vision improves, it gives you an idea that you might be able to improve her vision with a refraction. If she does not improve, the problem may be an ocular condition (macular degeneration, cataract, etc.).
- When testing children, always note if you, or a parent, is pointing at a letter on the chart. This is called semi blocking. Children will often see up to two lines better when someone is blocking or isolating letters for them to follow. Your doctor will want to know if this is occurring.

2 REFRACTOMETRY

When I was learning refractometry, I was told the number-one sin was over-minusing a patient. Through the years, I have learned that actually the number-one sin is under-plussing a patient, followed closely by over-minusing. In both cases, these two sins occur for this main reason: you are listening too much to what patients want and not giving them what they need.

Common complaints with hyperopes:

- "I used to love to read, but now I am so tired at the end of the day it's no fun."
- "I used to wear glasses when I was younger, but I outgrew it."
- Hyperopic eyes are what I call "martyr" eyes. These patients need glasses, but their brain doesn't want the help. So, the brain works and works to keep things in focus. They get tired, and some people

See **Great technician** on Page 8

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Great technician

Continued from page 6

even complain of headaches or upset stomach.

Be careful of listening too much to what he likes. He may need +3.50 D to correct his hyperopia, but his brain tells him he needs -1.00 D. My personal best example of this: 34-year-old man came to our office five times in a year with the same complaints. He liked being a -3.00 D in the office, but he needed to be a +4.50 D.

Refractometry tips:

- Pay attention to your auto refractor (or retinoscopy). If a patient's auto refractor is -1.50 + 0.75 x 145, why are you giving him -3.50 +1.25 x 145? The answer is usually, "Because he liked it!"
- If it ain't broke, don't fix it. Pay attention to the patient's vision. When the patient comes to clinic and states, "My vision is fine; I just want to get a new pair of glasses. These ones are a little scratched," don't make broad changes. She has no complaints, and her vision is good. All she needs is a quick refinement.
- For every 0.25D you give a patient, he should improve a line (however, this doesn't necessarily work with hyperopes).

3 PUPILS

Pupils should be checked every time on all patients who are being dilated. Technicians will say, "But we just saw the patient three weeks ago, and her pupils were fine." My response is always, "Between the last time you saw her and now, could that patient have had a stroke that no one knows about? Could she have a brain tumor that has suddenly manifested and no one knows about it?" And the answer, of course, is "yes."

Pupil evaluation tips:

- Use a battery-operated transilluminator when you are checking pupils, not a disposable penlight. Penlights are variable, depending on the age of the penlight.
- Have someone in the office show you an afferent pupillary defect (APD) on the next patient who has one. Once you see it, you will never forget it.
- I tell my technicians to always assume that any patient with 20/100 vision or worse has an APD until proven otherwise. It doesn't mean he actually does, but it will make you double-check his pupils because his vision is poor. Regardless of vision, always check those pupils well.

4 ANTERIOR CHAMBER ASSESSMENT

Checking the anterior chamber depth prior to dilation ensures that the anterior chamber is deep enough that you will hopefully avoid an angle closure complication. Once again, technicians will tell me they just saw the patient two weeks ago and the angle was wide open, so they don't need to check it again this week. This goes right along with pupils—a lot can change with a patient in two weeks.

We check every time because the pupil acts like an accordion. When you dilate the patient, her pupil will enlarge to allow more light in. The iris then gets pushed into the anterior chamber. If the anterior chamber depth is narrow to begin with, you may potentially cause a narrow-angle attack. This can also happen when the patient walks into a dark room.

Anterior chamber evaluation tips:

- Do not use a penlight to check the anterior chamber. Have someone show you how to use the slit lamp to check the depth.
- Have someone show you what a narrow angle looks like. Again, once you see it you won't forget it.

5 PEOPLE

Some of the most important skills technicians must have to be a great technician are empathy, sympathy, listening skills, ability to work in a team, ability to share and help others in the office grow in their fields, and finally, "wanna." Wanna is the drive, the fire, the technician's goal to want to be great, not just good. Some might call it passion or drive—I call it "wanna."

These are the people skills that make a good technician great. Unfortunately, those skills can't be taught. You either have them, or you don't. In our office, I look for people who have good clinical skills, and then I look deeper to see where they will fit. Fit is everything to running a healthy clinic. You need the quality technical skills as well as the "fit" in your process of developing a great technician.

I challenge you now to read this article again, and pay attention to what it is saying. Then go look in the mirror and ask yourself the following question: Am I a good technician or a great technician? If you say "good," what will you need to do to become great? You can do this!

> "Pupils should be checked every time on all patients who are being dilated.

The pros & cons of clear lens exchange

Patient selection and realistic expectations are key to success

By Katherine M. Mastrota, MS, OD, FAAO

With evolving cataract surgical techniques and advanced-technology intraocular lenses (IOLs), we now have the facility to offer patients spectacle-independent vision akin to their youth. Under normal circumstances, the discussion of natural lens extraction and replacement comes at the heels of the diagnosis of cataracts. More and more, however, well-informed individuals are requesting lens extraction for refractive purposes even though their natural lenses are clear.

Refractive lens exchange—also referred to as clear lens exchange or, more recently, refractive lensectomy—is now a viable option for patients who are not candidates for other refractive procedures (such as LASIK, PRK, ICL) or who simply wish to avoid the visual consequences of presbyopia with multifocal or accommodating IOLs. There is significant debate among cataract surgeons regarding the ethics of clear lens exchange. The crux of the issue, of course, is the risk, albeit small, of loss of vision (infection, retinal detachment, etc.). The polar opinion is that refractive lensectomy is no different from any other elective refractive procedure.

Another consideration is the potential for a dissatisfied self-pay patient for whom surgical results are underwhelming: the limitations of presbyopia-correcting IOLs are no different for refractive lensectomy patients than they are for cataract patients. Additionally, IOL calculation is less accurate in the patients who would benefit the most from the procedure, that is, those of higher ammetropia, resulting in a post-operative refractive miss.

The importance of patient selection

Derek Cunningham, OD, is director of optometry at Dell Laser Consultants in Austin, TX. Dr. Cunningham is integrally involved in patient selection and IOL planning for clear lens exchange patients that, at Dell Laser Consultants, are 50 percent of its lens surgical volume. Dell Laser estimates that 85 percent of its patients achieve the goal of full-time spectacle independence; the majority of these patients are 40 years of age and older. Half of Dell Laser's refractive lensectomy patients come to the practice referred from patients who are satisfied with their own procedures, or those interested in LASIK, Dr. Cunningham says.

Patient selection and realistic expectations are essential to success with refractive lens exchange, Dr. Cunningham explains. Often IOLs and refractive endpoints are blended to maximize clear vision at all distances.

For example, a diffractive multifocal IOL will be placed in the patient's dominant eye, and a -0.50 D aimed accommodating IOL in the non-dominant eye. The multifocal IOL functions best for distance-near, and the -0.50 D accommodating IOL would give better intermediate vision. The availability of a toric accommodating IOL broadens the scope of patients for whom clear lens exchange can now become an option.

Cost of clear lens exchange

Clear lens exchange is not covered by insurance and the IOL, facility, and surgical fees are not inexpensive. Many practices that offer refractive lens exchange will bundle surface laser touch-up and astigmatic correction in their fees. Remember also that multifocal and accommodating IOL patients require early YAG laser treatment of posterior lens capsule opacities/contraction for optimum performance of the IOL, adding to the cost of the process.

Notwithstanding the aforementioned, clear lens exchange can be the best refractive option for patients with high myopia or hyperopia, the contact lens intolerant, or those who wish to avoid the inconvenience and aesthetic compromise of presbyopia. Be prepared to guide your patients through the non-surgical and surgical options available for their visual concerns.

> "Refractive lens exchange—also called clear lens exchange or refractive lensectomy—is a viable option for patients who are not candidates for other refractive procedures.

Dr. Mastrota is center director of Omni Eye Surgery in New York City.

Guide to maximizing patient satisfaction

How to create a memorable customer service experience for your patients

By Rose Schneider
Content Specialist

Cultivating happy patients before, during, and after a visit to your clinic or practice is key to maintaining a profitable and credible practice.

"The most powerful thing today is what other people say about your practice," said Mark N. King, practice administrator in Cape Coral, FL. "If a patient is really, really happy, she is going to go out and tell one or two people (about her experience). If she is unhappy, she is going to go out and tell eight or 10 people.

Unhappy patients turn potential patients away, which is bad for your practice's perception and bottom line. "As soon as they're out your door, they're going to be on Google or on their cell phones," King said.

To make sure your patients have the best experience possible with your practice, King said there are several essential steps to follow that will ensure memorable customer service:

- Hire the right people
- Train your employees with what you want them to accomplish
- Inspect what you expect
- Reward positive behavior and counsel underperformers
- Give unhappy patients a forum to express their displeasure
- If concerns come up, deal with them head on; do not hide from them

Getting started

In order to get started with a customer service plan, you need to find out what your patients already expect from your practice.

A good question to ask yourself: What are our patients' basic expectations? For example, most patients expect good outcomes from their clinic visits, courtesy from staff members during all stages of their appointments, and timely service.

The key to exceeding those expectations, according to King, is hiring a knowledgeable and friendly staff for your practice. "They're what makes things tick," he said.

An important but overlooked step in the interview process, King explained, is involving the clinic manager because she will be working closely with the new hires and will need to get along. Other suggestions include instituting a multi-step interview process, perform interviews face-to-face, and bring the potential employee to the practice so he can get a real sense of the environment and you can see if he actually fits.

Asking the right questions is also highly important, King said, as well as being prepared and using behavior and competency-based questions.

Train to expectations

Clinic staff can excel with a customer service plan only if they know what you expect. Staff need to be trained with specifics and shown how to interact with patients. If this step is missed, then the practice will not operate to its fullest potential or meet expectations. Both possibilities run the risk of creating a bad customer service atmosphere for patients.

Inspect what you expect

Inspecting how your clinic is run, and most importantly, how you expect it to be run, is key to maintaining good customer service for your patients, King said.

There are various methods—such as utilizing an outside company, various programs, hiring someone to come into your clinic, or inspecting yourself—that all clinics can and should take advantage of to keep tabs on the practice's functionality and how staff members are performing, he said.

"It's amazing what you can find out," said King.

Conducting a survey to find out how long staffers take to answer phones or how long patients are put on hold, for example, is an easy way to generate data on the practice to analyze and find problem areas on which to focus attention.

"You can use these to enhance train-

ing, as well," King said.

Reward and counsel

Using performance reviews to pinpoint the clinic's overachievers, as well as the underperformers, can help the practice's customer service in several key areas, King explained. "Underperformers affect other employees, the practice, and themselves," he said.

Once underperformers have been identified, King said one action any practice should not make—but almost always does—s to load that staff member's duties onto an overachiever because the perception is she can handle it.

"Is it really fair for the high performers to have to do all the work?" King asked.

Doing so, he said, can cause those overachievers to burn out quickly due to an increased workload—as well as low office morale—and eventually leave the practice.

Instead, he suggested, approach the underperformers in a more positive way.

King said three important non-financial motivators may outscore offering monetary inspirations:

- Praise
- Attention from leadership
- Opportunity to lead products or tasks

"These methods engage them and turn their motivation around," he said.

When staff members do excel, King suggested implementing a monthly customer service reward voted on by staff.

"It's easy to look for the bad things, but can you actually document something every day that was positive? That's a little more difficult to do," King said. Such a move is vital to ensuring staff is giving the best customer service they can to patients.

Giving the unhappy a voice

Dealing with unhappy patients is unavoidable, but the most important action the clinic's staff can take is to tackle it head-on.

Said King: "Ask patients about their complaints, not just in a survey, but in person, such as during the check-out process. Ask them details, which helps to get them talking."

Logging the patient's complaints—instead of saying, "Thanks for the comment," and moving on—is an important tool that all staff members should use to show patients their complaints matter to the practice, King said.

Staff should know how to handle these situations due to proper customer service training. Part of addressing a complaint is the ability to apologize to patients for their bad experiences, sympathize with them so the patients know they are being heard, accept responsibility for the negative experiences, and be prepared to help the patient solve the problem.

In most situations, unhappy patients simply want to know the clinic is actually listening to them.

"People just want to know that they've been heard," King said.

While staff will most likely hear the same collection of complaints on a regular basis, and thus can be taught exactly what do say or do during those times, he said it is vital to train the staff to know how to handle the "crazy situations."

"Those are a little tougher, but you've got to be prepared for the unexpected," he said.

Surveys, whether paper or digital, are another way to add a touchpoint in order to find how patients felt their experiences went while visiting your practice.

Paper surveys are helpful tools, King said, because they are easily mailed or given out by the front desk staff members at the end of the patient's appointment.

However, digital surveys tend to have better luck in receiving, more patients' comments, he said. Paper surveys also tend to be more costly.

If choosing paper surveys, King suggested sending the survey to the patient directly after she leaves your clinic because you want her to remember her experience so she can provide the most detailed comments.

"You're most invested in the survey at the time directly after the appointment," he said.

However, while digital may receive more responses than paper surveys due to convenience, King said patients tend to give better, more honest feedback with the paper surveys.

"They're more likely to send the survey back without their name on it and give you their true comments, while with digital they may not because you've got their e-mail addresses," he said.

Keeping an eye on what people are posting online, such as on user review sites such as Yelp or Facebook, is another helpful outlet to understand how patients feel about your practice. Reading these reviews may offer insight on areas that need attention.

"You're looking for trends, so then you can figure out why bad service is happening and then how to fix it," King said.

Overall points

Nevertheless, King said it is ideal to remember that maintaining excellent customer service is not just about maintaining profits and growing the practice.

"It's not all about the money," King said. "Take care of your customers and employees first, and growth and profits will follow."

> "Patient satisfaction is key to maintaining a profitable, credible clinic, and giving great customer service to your patients is the best way to make sure they leave your office happy.

How visual field loss impacts driving

Researchers aim to develop evidence based on visual field location and performance

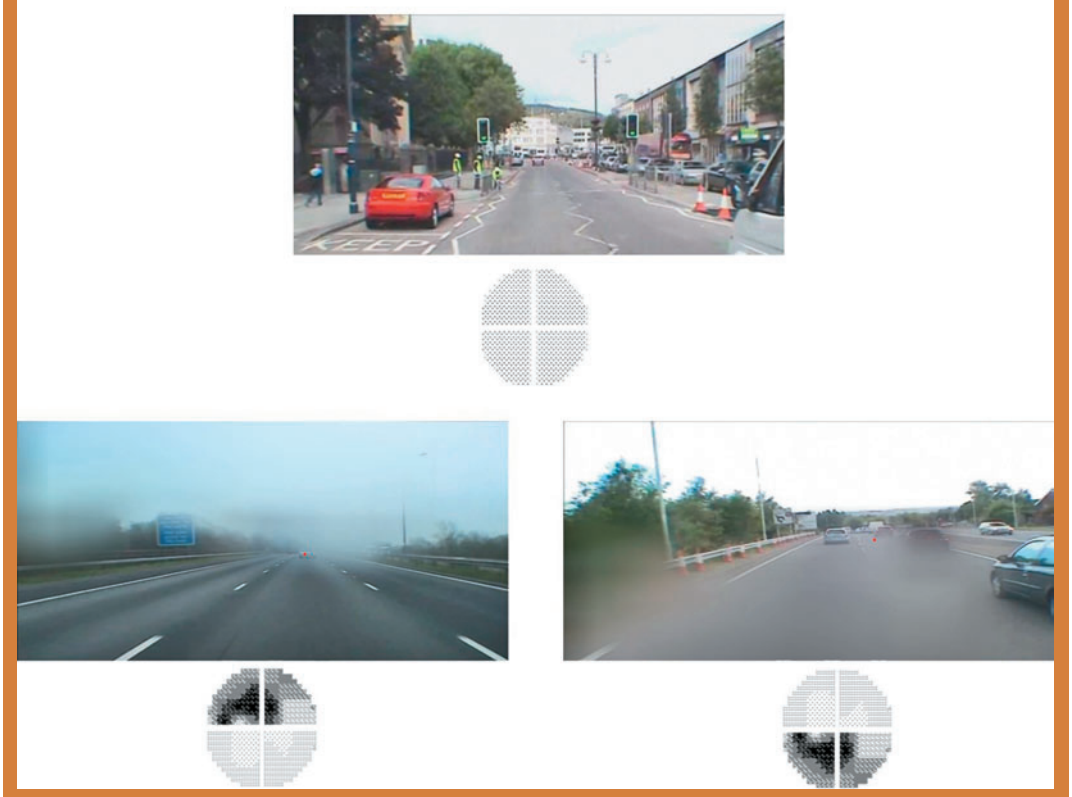
By Cheryl Guttman Krader

Visual field loss can affect driving performance, but the extent of impairment varies depending on the location of the defect, according to the results of a study reported by Fiona C. Glen, PhD and colleagues.

"Binocular visual field loss has been linked to subject-reported driving difficulties and risk of motor vehicle accidents," said Dr. Glen, postdoctoral research assistant, Department of Optometry and Visual Science, School of Health Sciences, City University London. "The results of our study suggest that driving performance and potentially rates of vehicular accidents does not depend simply on the presence of binocular loss, but rather on the location of the defect."

To test their hypothesis, the investigators conducted a trial in which 30 participants with

See **Field loss** on Page 14



Example screenshots taken from the three versions of the Hazard Perception Test. The visual field defects used for each test situation are shown beneath each image. *(Images courtesy of Fiona C. Glen, PhD)*

Cheryl Guttman Krader is a freelance writer based in Deerfield, IL.

Understanding circadian patterns, drug efficacy could improve care

Why eyecare practitioners need to consider factors as guide for management of glaucoma

By Cheryl Guttman Krader

Knowledge about the circadian pattern of IOP and the 24-hour efficacy of glaucoma medications is increasing and is expected to contribute to better medical management of glaucoma in the future, said Sunita Radhakrishnan, MD.

"IOP is not a static parameter and glaucoma is not a 9-to-5 disease," said Dr. Radhakrishnan, private practice, Glaucoma Center of San Francisco. "However, we typically assess IOP in our patients by measuring it only in the daytime and at best during a handful of visits throughout the year.

"This approach seems to be adequate for many patients, since glaucoma progression is typically very slow," Dr. Radhakrishnan explained. "However, more often than not, clinicians are confronted with cases that bring to light how little data we actually have to guide our management decisions. In the future, technology for self-tonometry and 24-hour IOP-monitoring may be used to obtain information on individual IOP circadian patterns and response to intervention in order to guide our decisions on patient care."

Body position as factor

Research conducted at specialized sleep laboratories has provided information demonstrating that IOP varies depending on time of day and body position. The results of these studies show that IOP is higher during the night than during the day and when subjects are in a supine versus upright (lying down versus sitting) position.

Though the change in body position is an important contributor to the nocturnal rise in IOP, it does not explain the entire increase, Dr. Radhakrishnan said.

24-hour efficacy of IOP drugs

Research has also generated information about the 24-hour efficacy of IOP-lowering medications. Results from multiple studies show prostaglandin analogues are effective in reducing IOP during the day and at night, and a study comparing bimatoprost, latanoprost, and travoprost found no statistically significant differences among the three agents in their 24-hour efficacy.

In contrast, studies investigating beta-blockers found they were effective in lowering IOP during the day, but not at night. The finding is consistent with the fact that aqueous humor production, which is inhibited by beta-blockers, is already decreased during the night.

Like the beta-blockers, the alpha-agonist brimonidine was also shown to reduce IOP during the daytime only, whereas the carbonic anhydrase inhibitors dorzolamide and brinzolamide demonstrated efficacy for lowering IOP during the day and at night.

"The beta-blockers, carbonic anhydrase inhibitors, and alpha-agonists have all been shown to be effective for additional IOP lowering when added to a prostaglandin analogue," Dr. Radhakrishnan said. "However, in most of the studies investigating adjunctive therapy, IOP was measured only during the day.

"In one 24-hour IOP study, evaluating the effect of adjunct treatment in patients receiving latanoprost, nocturnal IOP was lower in patients treated with brinzolamide three times a day compared with timolol every morning," Dr. Radhakrishnan said. "In another study, both dorzolamide and brimonidine seemed to perform well when either was used twice daily in addition to a prostaglandin analogue."

Translating to the real world

When trying to apply the findings from these studies to clinical practice, ophthalmologists need to consider that the circadian IOP studies are conducted under rigorous conditions, and so the results may not be applicable to the average patient. Furthermore, in some studies, the carbonic anhydrase inhibitors and brimonidine were administered three times daily rather than on the

See **Glaucoma** on Page 14

Cheryl Guttman Krader is a freelance writer based in Deerfield, IL.

Field loss

Continued from page 12

healthy vision completed the driving Hazard Perception Test (HPT). The computer-based test—a required component of the driving exam for new drivers in the United Kingdom—measures response times for detecting hazards appearing in real-life driving videos.

Participants performed the test three times in random order. One test served as a baseline and was performed without any modifications. In the two other test situations, novel software was used to simulate superior or inferior visual field defects that were linked to the user's real-time gaze.

Study outcomes

The results showed that the participants' mean HPT score exceeded the passing mark in the baseline-testing situation, but not when the testing was performed with either simulated visual field defect.

Compared with the baseline testing without visual field modification, HPT test scores fell 18 percent when the driving exam was done with the simulated superior defect and by 12 percent with the simulated inferior defect. Statistical analysis showed the effect of both visual field defects was statistically significant and also showed the impact of the superior visual field defect was significantly greater than the effect of the inferior visual field defect.

Motive for research

Interest in undertaking this study was motivated by the relative paucity of data on how different types and locations of visual field defect impact driving performance, Dr. Glen said.

"The lack of good scientific evidence in this area was particularly surprising, considering that driver's license eligibility requirements in the United Kingdom include some complicated criteria relating to locations of visual field defects," she said. "However, the existing standards, which are being used to make what is a life-altering decision, have never been documented to impair driving performance."

Furthermore, the use of the binocular visual field test to assess fitness to drive is questionable, since it was never developed for that purpose and has many specifications that are not necessarily relevant to driving, according to Dr. Glen.

The study's finding of significantly worse performance on the HPT when testing was done with the simulated superior visual field defect compared with the inferior visual field defect is not surprising considering the superior field of view is more relevant to the driving scene.

The participants' mean HPT score exceeded the passing mark in the baseline-testing situation, but not when the testing was performed with either simulated field defect.

"However, it is an important finding because the visual field test that is used for determining driving eligibility in the United Kingdom is weighted toward the inferior visual field," she said. "Therefore, our study brings into question the appropriateness of using that test to determine fitness to drive.

"Our research is a first step toward understanding which visual field defect locations are most important for driving and, in turn, devising better tests for assessing fitness to drive in the future," Dr. Glen said.

The research was sponsored by the International Glaucoma Association.

Glaucoma

Continued from page 13

twice-daily schedule that is often prescribed for patients.

However, the most basic issue to consider is the lack of understanding about the clinical relevance of avoiding nocturnal IOP elevations.

"It makes intuitive sense to decrease IOP around the clock," Dr. Radhakrishnan said. "However, it remains to be determined what role nocturnal IOP elevation has on the onset or progression of glaucoma."

In addition, the goal of achieving 24-hour IOP control must be considered in the context of several other factors.

"Although it seems ideal to achieve diurnal and nocturnal IOP lowering for every patient, there is no 'one-size-fits-all' algorithm for managing glaucoma," Dr. Radhakrishnan said. "Treatment decisions need to be individualized taking into account safety, tolerability, efficacy, and cost."

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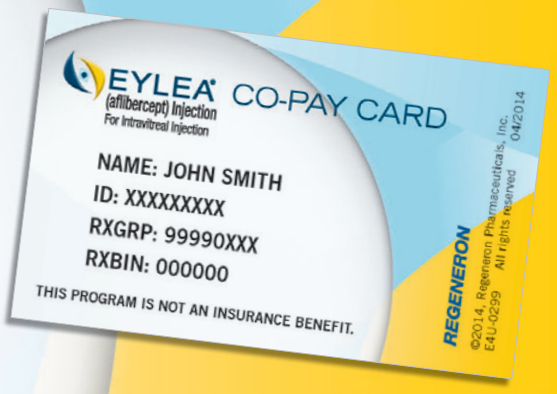

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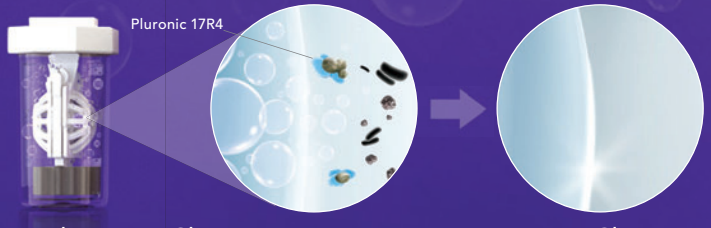

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