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BILLS ACROSS THE COUNTRY

TENNESSEE

Tennessee bill on hold until 2014

ODs must wait until January to learn if they are able to administer injectable anesthetic

By David K. Talley, OD, FAAO
President, Tennessee Association of Optometric Physicians

Optometrists in Tennessee hoped to gain legislative approval to administer injectable anesthetic while performing primary eyecare procedures of the eyelid. Currently, optometrists in Tennessee are able to use topical anesthetics for procedures, such as removing skin tags, papillomas, and chalazia. To that end, two bills (SB 220 and HB 555) proposing such a change were rolled until January 2014: SB 220 was assigned to the general subcommittee of the Senate, and action was deferred on HB 555 in the House health subcommittee.

The legislation remains viable. Hearings took place, but no votes took place in either committee. Rolling bills until the next session is not uncommon with controversial matters. The Tennessee Association of Optometric Physicians (TAOP) will continue to work with Tennessee legislators to prepare for the January 2014 vote.

At the last minute, an intense negotiation with representatives of ophthalmology took place in an attempt to finalize a bill that everyone concerned could support. Ophthalmology's response was not to negotiate in good faith with optometry's representatives but to challenge optometry's accomplishments. Sev-

See **Tennessee** on page 5

SB 220 AND **HB 555** would allow ODs to utilize injectable anesthetic while performing primary eyecare procedures of the eyelid.

FLORIDA

Florida ODs await vote

At stake is the ability to prescribe oral medications

By Gretchyn M. Bailey, NCLC, FAAO
Editor in Chief, Content Channel Director

Tallahassee, FL—At press time, Florida optometrists were awaiting a vote in the Florida Senate appropriations committee on SB 278, a bill which would grant additional prescribing authority to optometrists. Previously, the Florida Senate voted 10-0 to approve SB 278.

"Originally SB 278 was to be voted on by the full Senate as a special calendar item, but it was decided to go the regular, full-three-reading route," says Kimberly Reed, OD, FAAO, associate professor at Nova Southeastern University College of Optometry in Fort Lauderdale. Dr. Reed provided testimony during hearings for SB 278.

The bill would grant optometrists the ability to prescribe oral medication, in the language of SB 278: "requiring a certified optometrist to complete a course and examination on general and ocular pharmaceutical agents before administering or prescribing oral ocular pharmaceutical agents."

A similar bill, HB 239, recently passed the Florida House with a vote of 116-0. "I am very pleased that we seem to have come to an agreement on this bill. It was the direct result of many discussions by interested individuals working on behalf of the patients in the state of Florida," says Dr. Reed.**ODT**

SB 278 would grant ODs the ability to prescribe oral medications

CALIFORNIA

Scope of practice to expand for CA ODs?

By Gretchyn M. Bailey, NCLC, FAAO
Editor in Chief, Content Channel Director

Sacramento, CA—Keep your eye on California. Several bills recently introduced propose to expand the scope of practice for non-physicians in anticipation of a provider shortage after millions of uninsured gain coverage under the Affordable Care Act (ACA). Although details are not final, SB 492, proposed by California Senator Ed Hernandez, OD (D-West Covina), would designate optometrists as primary-care providers to diagnose and treat patients with chronic diseases, such as diabetes. Other bills would allow nurse practitioners to establish independent practices and designate pharmacists as primary-care providers.**ODT**

INSIDE: Special Section
CO-MANAGEMENT
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Optometry Times Mission Statement

Optometry Times is an optometry-driven publication that disseminates news and information of a clinical, socioeconomic, and political nature in a timely and accurate manner for members of the optometric community.

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

- Being a forum for optometrists to communicate their clinical knowledge, insights, and discoveries.
- Providing management information that allows optometrists to enhance and expand their practices.
- Addressing political and socioeconomic issues that may either assist or hinder the optometric community, and reporting those issues and their potential outcomes to our readers.

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Tennessee

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eral undecided legislators saw optometry's effort to compromise with ophthalmology and were angry at ophthalmology's unwillingness to negotiate. This recognition could help optometry in the future.

During negotiations, ophthalmology was concerned only with optometry's current scope of practice. In fact, ophthalmology appeared to be surprised at the extent of our scope of practice. Optometry's lobbyist pointed out the profession's outstanding track record; however, the ophthalmology team replied that it wasn't impressed with optometry's track record, and it is something to sell to the legislature, not to ophthalmology.

The American Academy of Ophthalmology (AAO) stepped in and began using scare tactics. The AAO began ran negative radio ads across Tennessee. AAO representatives also called patients at home to ask if they wanted optometrists performing reconstructive lid surgery.**ODT**

Dr. Talley is part of a group private practice in Memphis, TN.

In Brief

B+L files initial share offering

Rochester, NY—Bausch + Lomb announced that it has filed a registration statement on Form S-1 with the U.S. Securities and Exchange Commission (SEC), through its holding company WP Prism, relating to the proposed initial public offering of its common stock. The number of shares to be offered and the price range for the proposed offering have not yet been determined.

Long-awaited final rule enables healthy vision for America's children

Washington, DC—The U.S. Department of Health and Human Service (HHS) announced final regulations that require the pediatric vision essential health benefit to be a yearly eye exam with materials for millions of children in this country. This final decision will help children access the necessary vision care that will contribute to their healthy development.

Following is an overview of the final rules published by HHS and their potential for optometry:

- Millions of children will gain health insurance coverage through age 18 that includes direct access to their local optometrist for a comprehensive eye exam and treatment, including medical eyecare.
- Pediatric eyecare is confirmed as an "Essential Health Benefit," and must be offered by all new small group and individual health plans as a distinct benefit from well-child care.
- Pediatric eye health care is defined as an annual comprehensive eye exam and treatment, including medical eyecare.
- All new small group and individual health plans—both inside and outside of state exchanges—are required to provide fully integrated coverage for pediatric eye health care and must recognize optometrists as providers of medical eyecare.
- While adult eyecare cannot be an essential benefit, health plans are free to add the benefit if they choose to or if required by a state insurance marketplace or exchange.

SUNY Optometry to develop optometry business management program

New York—SUNY College of Optometry and SUNY Empire State College have signed an agreement to jointly develop and deliver an advanced graduate certificate in optometry business management. The 18-credit, 6-course certificate will be applicable to the MBA program offered through SUNY Empire State College's School for Graduate Studies.

Development of the new joint program is a response to increased interest from optometry students for advanced business education that would complement their clinical training and help them prepare for the demands of managing organizations or working with corporations and government agencies on health care-related concerns.

"The timeliness of such a program is fortuitous, given the acceleration of healthcare reform on the horizon and what that will mean in terms of the practical application of optometry," said Dr. David A. Heath, president of SUNY College of Optometry.

TVC launches resource for low vision patients and caregivers

Alexandria, VA—The Vision Council (TVC) has launched a standalone Web site, www.hatislowvision.org, dedicated to educating consumers about low vision and low vision solutions.

The site was created as a resource for people with vision impairment due to macular degeneration, diabetic retinopathy, glaucoma, and other eye conditions associated with aging. It is fully functional for low vision users. The Web initiative can help answer questions that people with low vision, plus their loved ones and caregivers, may have by addressing its causes and warning signs, as well as vision-enhancing devices and treatments.

Maureen Beddis, vice president of marketing and communications for TVC, said: "During the past year we have been collaborating with key groups in the vision and caregiving communities toward the common goal of raising awareness for low vision and increasing knowledge of low vision solutions for improving quality of life.

UK report calls for standardized collection of quality optical data

London—The College of Optometrists published a new report calling for more efficient collection of quality data about patients' eye health in an effort to improve local eye health services and reduce costs and delays.

David Parkins, vice president of the College of Optometrists and chairman of the data project steering group, said: "Optometrists examine the eyes not only to detect defects in vision, but also to identify signs of injury, ocular diseases or abnormality, and problems with general health, such as diabetes. By taking responsibility for recording all this information and sharing data, optometrists will have the tools necessary to convince commissioners that commissioning from optometrists is good value for money."

The report recommends that standardized electronic and digital systems therefore need to be put in place to bring consistency to data capture and measurement.

"Good quality information is central to providing good quality, patient-centered eyecare. Having more detailed information at your fingertips will help health professionals to better meet the eye health needs of local communities, and ultimately save time and resources," Parkins said. "An improved electronic system for referrals would reduce the cost burden of eye care to the NHS, helping to eliminate unnecessary referral appointments in addition to duplicated tests."

Cataract Co-management—an OD's perspective

By Ernest L. Bowling, OD, MS, FAAO
Chief Optometric Editor

In this month's issue, we focus on cataract surgery co-management. It's a topic especially close to my heart because I ran an optometric co-management center for a few years. It wasn't until I was in that setting that I gave surgical co-management a lot of thought. I mean, I had co-managed more than my share of cataract patients in my two-office practice over the years and felt quite adept at caring for the patient post-surgery. What I learned working with the center's excellent surgeon was that before, I had been doing only part of the job. I also found that I could do more on the front end to make his job—and mine—easier.

For instance, I used to knee-jerk refer the cataract patient to the surgeon without a moment's hesitation, leaving the entire discussion of cataract surgery, risks, benefits, and IOL options to the surgeon and his staff. After all, that's their job, right?

When working at the center, I realized very quickly this approach was incomplete. Many times cataract diagnoses are made by an optometrist. Patients look to us to not only guide them to a surgeon they can trust but to answer their questions about the procedure. And you can bet they are going to have questions about the procedure. While we as ODs may deal with cataract patients on a daily basis and become somewhat impassive to the presentation, you can bet the diagnosis and impending surgery is a major concern to your patient and her family. Besides, we're the ones who took the time to understand the patient's visual needs and built the relationship with the patient over the years. While the patient will have most of the same discussion with the surgeon, pre-operative counseling and establishing realistic expectations by you initially in your office

See **Co-management** on page 11

The whole picture

By Katherine M. Mastrota, MS, OD, FAAO
Associate Optometric Editor

The first Friday of each month, Omni Eye Surgery's referring optometrists meet in the New York office to listen to a lecture over coffee and bagels. With the waiting room set up theatre-style, we all get cozy and enjoy the presentation. Friday, January 25th, at 7:30 a.m. The temperature in NY was in the low teens; we needed to be cozy. The usual crowd, surprisingly, was in attendance. That is a testament to dedication to our profession, our patients, and to education.

The lecture that day was on adult strabismus, delivered by Joseph, Napolitano, MD, Omni's pediatric and adult strabismus surgeon. "Dr. Nap" knows his stuff—strabismus. Our usual lecturer, retina specialist Dr. Burton Wisotsky, lectures on, well, retina. Diabetic retinopathy, retinal macula degeneration, retinal detachments. Peripheral retinal degenerations, hereditary retina degenerations, and retinal lesions. Retina this and retina that. Dr. Douglas Grayson, glaucoma. Open-angle, narrow-angle. Uveitic glaucoma, secondary glaucoma. Fields, OCTs, nerve heads and pachymetry in glaucoma. It's all glaucoma, all the time (with good dose of cataract surgery lessons). And of course, Dr. Maher delivers a top-notch oculoplastic session.

I am delighted to share lecture time with these fine surgeons. This particular Friday I asked our audience what they would be interested in learning more about. The breadth of interests of these doctors was amazing. I received requests that included information on new therapeutics, anterior segment disease, and neuro-optometry. Inquiries for clinical and practice management tips,

See **Picture** on page 11

Are you part of the conversation?

Gretchyn M. Bailey, NCLC, FAAO
Editor in Chief, Content Channel Director

Optometry Times is more than a monthly publication, a weekly e-newsletter, a Web site, a Facebook page, or a Twitter feed. It's a conversation.

This conversation takes place between me, the editor in chief, and you, the reader. It also takes place between one optometrist (the author) and another optometrist (the reader… that's you). Throw in the rest of our staff, our chief and associate optometric editors, our Editorial Advisory Board members, and other readers such as industry representatives, ophthalmologists, technicians, and additional healthcare providers …well, that's a big conversation we have going on.

The most important thing about a conversation is the give-and-take among those participating in the conversation. For example, each month our staff and authors give information in the form of our monthly publication. Plus, every week we send you News Flash, our weekly e-newsletter (are you subscribed yet?). Then a few times a week we share more information via our Facebook page and Twitter feed (following us yet?).

In turn, our readers tell us (and you) what they think. Milton Hom offers his view on contact lens care systems on our Opinion page this month. Ernie Bowling, as he does every month, chimes in about co-managing cataract patients. A New York optician shares a concern in a Letter to the Editor in this issue. And here you are reading my monthly "pearl of wisdom."

Now it's your turn. Will you answer our poll on Facebook? Will you drop us a line telling us you'd really like to see more coverage of <insert topic here>? What about sending a letter to the editor saying you disagree with something we published or you had a similar experience as one of the authors wrote about in last month's issue? Maybe you'll go really crazy and want to write an article!

The cool thing here is that those who contribute are also our readers, and vice versa. It's the giant circle of *Optometry Times* life.

So…how are you going to join the conversation? We're waiting to hear from you!**ODT**

If only you could predict how ocular inflammation will behave.

DUREZOL® Emulsion now has head-to-head data vs prednisolone acetate in patients with endogenous anterior uveitis.[1]

Scan the QR code with your smartphone or log on to **www.inflammationhappens.com** to see the results for yourself.

INDICATIONS AND USAGE: DUREZOL® Emulsion is a topical corticosteroid that is indicated for the treatment of endogenous anterior uveitis.

Dosage and Administration

For the treatment of endogenous anterior uveitis, instill one drop into the conjunctival sac of the affected eye 4 times daily for 14 days followed by tapering as clinically indicated.

IMPORTANT SAFETY INFORMATION

Contraindications: DUREZOL® Emulsion, as with other ophthalmic corticosteroids, is contraindicated in most active 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.

Warnings and Precautions

- 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. If this product is used for 10 days or longer, IOP should be monitored.
- Cataracts – Use of corticosteroids may result in posterior subcapsular cataract formation.
- 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 beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.
- Bacterial infections – Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. 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.
- 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).
- 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.
- Contact lens wear – DUREZOL® Emulsion should not be instilled while wearing contact lenses.

Adverse Reactions

In the endogenous anterior uveitis studies, the most common adverse reactions occurring in 5-10% of subjects included blurred vision, eye irritation, eye pain, headache, increased IOP, iritis, limbal and conjunctival hyperemia, punctate keratitis, and uveitis.

For additional information about DUREZOL® Emulsion please refer to the brief summary of prescribing information on adjacent page.

Reference: 1. DUREZOL® Emulsion Package Insert.

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Peroxide systems revisited

Peroxide is perceived as the gold standard MPS systems are trying to achieve

By Milton M. Hom, OD, FAAO

More than 20 years ago, I anxiously waited for my first peroxide systems to arrive at my office. Back then, we had heat units and then-called chemical systems, forerunners of today's multipurpose solutions (MPS). The heat units would bake on lens protein and require once-a-week enzymatic cleaning. The chemical systems were just that—disinfection chemicals, which sometimes acted too harshly on the ocular surface.

Fast forward to today. The current MPS systems are amazing; much improved over the early days. But peroxide remains pretty much the same with some tweaks on neutralization. When I lecture on contact lenses and care systems, I find that most of us still go to peroxide as our troubleshooter for conditions such as irritation, redness, allergy, discomfort, or other difficulty with MPS (including corneal inflammatory events). Peroxide seems to be perceived as the gold standard MPS systems are still trying to achieve.

> Biocompatibility is the new mantra for the new generation of MPS. No more harsh chemicals.

Despite all of peroxide's benefits, there are still disadvantages to consider. In recent years, the disinfection efficacy against *Acanthamoeba* has come into question. In some systems, the exposure times leave us wanting more. With such short times before neutralization, *Acanthamoeba* cysts can still remain viable.[1-3]

New generation, new mantra

Biocompatibility is the new mantra for the new generation of MPS. No more harsh chemicals. Even peroxide's claim to better end-of-day comfort may have been one-upped by MPS.

Recent work has shown that patients on peroxide systems still experience discomfort, dryness, and have to rely on using rewetting drops. In a study of 150 soft contact lens wearers in the U.S. who wear their lenses 4 days a week or more and use a hydrogen peroxide solution, 43% reported experiencing discomfort and 25% reported experiencing dry eye while wearing their contact lenses. In addition, approximately one third of lens wearers reported use of rewetting drops in addition to their peroxide care systems once per week or more. Ap-

See **Peroxide** on page 11

For the reduction of IOP in patients with POAG or OHTN

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

An alternate route to IOP reduction

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

Indication

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

Important Safety Information

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

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

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

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

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

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

Rescula®
(Unoprostone isopropyl
ophthalmic solution) 0.15%

Brief Summary of Prescribing Information for RESCULA.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

STORAGE AND HANDLING
Store between 2°–25°C (36°–77°F).

For more detailed information please read the Prescribing Information.

Marketed by:

Sucampo Pharma Americas, LLC
Bethesda, MD 20814

Revised 01/2013

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

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Co-management

Continued from page 6

before the referral will help ease the patient's acceptance of the process. That includes letting the patient know what to expect at the initial work-up visit with the surgeon, discussing the procedure, and what will take place post-operatively in your office.

Your pre-op counseling also should include a discussion of IOL options. Baby boomers are a demanding lot and have high expectations. They do not want their vision compromised, and boomers expect high quality, which makes them prime candidate for premium IOLs, including presbyopia-correcting IOLs and toric IOLs.

You can do your patient and the surgeon a huge favor by dealing with any ocular surface problems before the consultation visit. Untreated ocular surface disease can affect IOL calculations and thus post-operative corrections, so any dry eye or meibomian gland dysfunction needs to be addressed sooner rather than later. More on that in a coming editorial. I always leave the patient with a word about posterior capsular opacification. While the results of cataract surgery more often than not exceed the patient's expectations, the patient still needs to know this initial result may not last due to capsular haze but can easily be addressed in the future should the need arise. This discussion lets the patient knows you're going to be with her every step of the way, which is what providing a lifetime of eyecare is all about.**ODT**

Picture

Continued from page 6

pediatric optometry, and how to encourage patient contact lens compliance were filed. My favorite request? "The Future of Optometry."

How fortunate are we optometrists that every day we encounter, recognize, and manage such diverse pathology? As primary-care doctors, we are charged with knowing it all, from childhood disorders to geriatric concerns. Unlike my Omni specialists' narrow areas of expertise, we are abreast of the "whole picture," the "whole person," from refractive error to retinal diagnosis. And, to keep rolling in alliteration, from contacts to cataracts, astigmatism to amblyopia, polycarbonate to polypoidal choroidal vasculopathy.

How cool is that? How cool are we?**ODT**

MY FAVORITE APP

Megaman

At the Low Vision Section's breakfast at the Academy this past year, I learned about the free app Megaman. It features a lux meter to measure light levels—a significant feature because we know light levels make all the difference in the world when it comes to reading, especially small print.

—Milton Hom, OD
Azusa, CA

To the Editor: Quality, safety concerns

I am a licensed optician in the state of New York and a member of the Opticians Alliance of New York. Our membership has a concern regarding the selling of contact lenses over the Internet.

The contact lens patient feels a savings can be made on his part, but at the same time the patient is taking a chance by hoping the contact lens Rx is filled correctly and by a licensed professional.

Has there been an investigation by either the FDA or FTC on this issue?

Anthony Rebaldo
New York

Peroxide

Continued from page 8

proximately 25% of lens wearers reported use of rewetting drops either every day or several times per week.[4]

Looking at the current MPS product set, moisture retention is at the forefront. Previously, MPS were disinfection chemicals disguised in saline. Now, we have multiple conditioning agents that are gentle to the eye and greatly enhance comfort.

We've come a long way, baby.

Take the good with the bad

For those of us in practice, we have to deal with the user-friendliness of peroxide systems. We forget about the long neutralization times (6 hours), leaky cases, and nightmares when traveling. Patients complain the right and left baskets are too difficult to tell apart. Pity the hyperopes and presbyopes. Over the years, I have seen patients drop out of peroxide because it was too much like a chemistry experiment.

The other day I was at a nationwide chain-store pharmacy. I was a little surprised to see a generic peroxide system on the shelf. It looked pretty similar to the real thing. I guess peroxide is no longer immune to the MPS branded vs. private label confusion/drawbacks.

Peroxide still has a place in my practice. But we still need to improve overall lens cleaning, decrease neutralization time, work on comfort, and improve the cases.

Industry, are you listening?**ODT**

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Author Info

Milton M. Hom, OD, FAAO, FACAAI (Sc), Dr. Hom practices in Azusa, CA. He is a scientific fellow of the American College of Asthma, Allergy, and Immunology. Contact Dr. Hom at eyemage@aaahawk.com.

Is it time to say bye-bye to the blade?

Femtosecond lasers bring more to the table that mechanical blades

The majority of anterior segment surgery has historically been performed using metal or diamond blades. Many surgeons predict that soon most, if not all, ocular surgery will be performed with lasers. The new game is the femtosecond (fs) laser.

Application of fs lasers began in 2001 with the approval of the Intralase laser for LASIK flap creation. Table 1 lists some of the many advantages of fs LASIK flaps.[1]

There are fewer flap-related and overall complications with the fs method compared with a mechanical microkeratome.[2,3] Femtosecond flaps result in less loss of BCVA and more gain in BCVA.[4] Thinner, more predictable fs flaps are biomechanically stronger and more stable than blade microkeratome flaps, possibly reducing the risk of post-LASIK ectasia.[5]

Fs flaps are more precise, uniform in thickness (planar), and smoother—resulting in better quality of vision.[6,7] Fs flaps provide LASIK patients with faster visual recovery.[8] Patients who have fs laser flaps also report fewer subjective side effects.[7] While it has taken several years, fs LASIK flap creation has become the standard of care.

Fs laser-enabled keratoplasty (FLEK) shows better long-term outcomes with less residual astigmatism and faster visual recovery compared with mechanical trephine corneal transplants in patients with keratoconus.[9] Fs lasers provide a way to create Intacs intra-stromal corneal tunnels safely and more precisely than previous manual dissection with overall complication rates below 6%.[10]

TABLE 1 Advantages of Femtosecond LASIK Flaps

EFFICACY	SAFETY
1. More precise	Fewer flap complications
2. Uniform planar thickness	Less sight threatening complications
3. Smoother stromal beds	Less night vision disturbances
4. Less induced aberrations	Less dry eye
5. Faster visual recovery	Biomechanically stronger
6. Better visual acuity	Thinner flaps may result in less ectasia
7. Better quality of vision	Less loss of BCVA/ More gain of BCVA

By William Tullo

Dr. Tullo is the vice president of clinical services for TLC Vision and adjunct assistant clinical professor at SUNY College of Optometry.

The first generation of fs cataract surgery began with the approval of Alcon's LenSx in August 2009. At least four fs lasers are currently approved in the U.S. The primary benefit of the fs laser portion of cataract surgery is to improve the safety profile by reducing or eliminating the use of phacoemulsification ultrasound energy often associated with many of the sight-threatening complications in modern cataract surgery.[11] Other benefits may allow better UCVA after cataract surgery due to more precise IOL power selection because of less variable effective IOL position due to more precise anterior capsulotomy and incisional residual astigmatism correction compared with manual procedures.[12] Future fs considerations in ophthalmic surgery include intra-stromal pockets for corneal inlays such as Kamra by Acufocus and intra-stromal presbyopia correction such as Bausch+Lomb's Supracor and Intracor procedures. Improvements in OCT structural imaging and patient interfaces will result in faster and safer procedures.**ODT**

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For allergic conjunctivitis[1]

THE POWER TO CALM THE ITCH

BEPREVE®—FIRST-LINE, YEAR-ROUND, WITH BROAD-SPECTRUM ALLERGEN COVERAGE

INDICATION AND USAGE

BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% is a histamine H_1 receptor antagonist indicated for the treatment of itching associated with signs and symptoms of allergic conjunctivitis.

IMPORTANT RISK INFORMATION

BEPREVE® is contraindicated in patients with a history of hypersensitivity reactions to bepotastine or any of the other ingredients. BEPREVE® is for topical ophthalmic use only. To minimize risk of contamination, do not touch the dropper tip to any surface. Keep the bottle closed when not in use. BEPREVE® should not be used to treat contact lens–related irritation. Remove contact lenses prior to instillation of BEPREVE®.

The most common adverse reaction occurring in approximately 25% of patients was a mild taste following instillation. Other adverse reactions occurring in 2%-5% of patients were eye irritation, headache, and nasopharyngitis.

Made by the trusted eye-care specialists at BAUSCH + LOMB

Please see the accompanying prescribing information for BEPREVE® on the following page.

Reference: 1. BEPREVE [package insert]. Irvine, CA: ISTA Pharmaceuticals, Inc; 2012.

BAUSCH + LOMB

For product-related questions and concerns, call **1-800-323-0000** or visit **www.bepreve.com**.

BEPREVE®
(bepotastine besilate ophthalmic solution) 1.5%

BEPREVE® (bepotastine besilate ophthalmic solution) 1.5%

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% safely and effectively. See full prescribing information for BEPREVE®.

BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% Initial U.S. Approval: 2009

----------INDICATIONS AND USAGE----------
BEPREVE® is a histamine H_1 receptor antagonist indicated for the treatment of itching associated with allergic conjunctivitis. (1)

----------DOSAGE AND ADMINISTRATION----------
Instill one drop into the affected eye(s) twice a day (BID).(2)

--------DOSAGE FORMS AND STRENGTHS---------
Solution containing bepotastine besilate, 1.5%. (3)

----------CONTRAINDICATIONS----------
Hypersensitivity to any component of this product. (4)

----------WARNINGS AND PRECAUTIONS----------
- To minimize the risk of contamination, do not touch dropper tip to any surface. Keep bottle tightly closed when not in use. (5.1)
- BEPREVE® should not be used to treat contact lens-related irritation. (5.2)
- Remove contact lenses prior to instillation of BEPREVE®. (5.2)

----------ADVERSE REACTIONS----------
The most common adverse reaction occurring in approximately 25% of patients was a mild taste following instillation. Other adverse reactions which occurred in 2-5% of subjects were eye irritation, headache, and nasopharyngitis. (6)

To report SUSPECTED ADVERSE REACTIONS, contact ISTA Pharmaceuticals, Inc. at 1-877-788-2020, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION
Revised: 12/2011

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% is a histamine H_1 receptor antagonist indicated for the treatment of itching associated with signs and symptoms of allergic conjunctivitis.

2. DOSAGE AND ADMINISTRATION

Instill one drop of BEPREVE® into the affected eye(s) twice a day (BID).

3. DOSAGE FORMS AND STRENGTHS

Topical ophthalmic solution containing bepotastine besilate 1.5%.

4. CONTRAINDICATIONS

BEPREVE® is contraindicated in patients with a history of hypersensitivity reactions to bepotastine or any of the other ingredients [see Adverse Reactions (6.2)].

5. WARNINGS AND PRECAUTIONS

5.1 Contamination of Tip and Solution

To minimize contaminating the dropper tip and and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

5.2 Contact Lens Use

Patients should be advised not to wear a contact lens if their eye is red. BEPREVE® should not be used to treat contact lens-related irritation. BEPREVE® should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of BEPREVE®. The preservative in BEPREVE®, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of of BEPREVE®.

5.3 Topical Ophthalmic Use Only

BEPREVE® is for topical ophthalmic use only.

6. ADVERSE REACTIONS

6.1 Clinical Trials Experience

The most common reported adverse reaction occurring in approximately 25% of subjects was a mild taste following instillation. Other adverse reactions occurring in 2-5% of subjects were eye irritation, headache, and nasopharyngitis.

6.2 Post Marketing Experience

Hypersensitivity reactions have been reported rarely [two (2) possibly related cases for an incidence of 0.00006%] during the post-marketing use of BEPREVE®. Because this reaction is reported voluntarily from a population of unknown size, the actual incidence cannot be verified. The hypersensitivity reactions include itching, body rash, and swelling of lips, tongue and/or throat.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: Teratogenicity studies have been performed in animals. Bepotastine besilate was not found to be teratogenic in rats during organogenesis and fetal development at oral doses up to 200 mg/kg/day (representing a systemic concentration approximately 3300 times that anticipated for topical ocular use in humans), but did show some potential for causing skeletal abnormalities at 1000 mg/kg/day. There were no teratogenic effects seen in rabbits at oral does up to 500 mg/kg/day given during organogenesis and fetal development (>13,000 times the dose in humans on a mg/kg basis). Evidence of infertility was seen in rats given oral bepotastine besilate 1000 mg/kg/day, however, no evidence of infertility was observed in rats given 200 mg/kg/day (approximately 3300 times the topical ocular use in humans). The concentration of radiolabeled bepotastine besilate was similar in fetal liver and maternal blood plasma following a single 3 mg/kg oral dose. The concentration in other fetal tissues was one-third to one-tenth the concentration in maternal blood plasma.

An increase in stillborns and decreased growth and development were observed in pups born from rats given oral doses of 1000 mg/kg/day during perinatal and lactation periods. There were no observed effects in rats treated with 100 mg/kg/day.

There are no adequate and well-controlled studies of bepotastine besilate in pregnant women. Because animal reproduction studies are not always predictive of human response, BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

Following a single 3 mg/kg oral dose of radio-labeled bepotastine besilate to nursing rats 11 days after delivery, the maximum concentration of radioactivity in milk was 0.40 µg eq/mL 1 hour after administration; at 48 hours after administration the concentration was below detection limits. The milk concentration was higher than the maternal blood plasma concentration at each time of measurement.

It is not known if bepotastine besilate is excreted in human milk. Caution should be exercised when BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% is administered to a nursing woman.

8.4 Pediatric Use

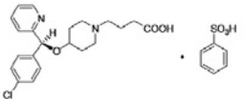
Safety and efficacy of BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% have not been established in pediatric patients under 2 years of age. Efficacy in pediatric patients under 10 years of age was extrapolated from clinical trials conducted in pediatric patients greater than 10 years of age and from adults.

8.5 Geriatric Use

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

11. DESCRIPTION

BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% is a sterile, topically administered drug for ophthalmic use. Each mL of BEPREVE® contains 15 mg of bepotastine besilate. Bepotastine besilate is designated chemically as (+) -4-[[(S)-p-chloro-alpha -2-pyridylbenzyl]oxy]-1-piperidine butyric acid monobenzenesulfonate. The chemical structure for bepotastine besilate is:



Bepotastine besilate is a white or pale yellowish crystalline powder. The molecular weight of bepotastine besilate is 547.06 daltons. BEPREVE® ophthalmic solution is supplied as a sterile, aqueous 1.5% solution, with a pH of 6.8.

The osmolality of BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% is approximately 290 mOsm/kg.

Each mL of BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% contains:
Active: Bepotastine besilate 15 mg (equivalent to 10.7 mg bepotastine)
Preservative: benzalkonium chloride 0.005%
Inactives: monobasic sodium phosphate dihydrate, sodium chloride, sodium hydroxide to adjust pH, and water for injection, USP.

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Bepotastine is a topically active, direct H_1 receptor antagonist and an inhibitor of the release of histamine from mast cells.

12.3 Pharmacokinetics

Absorption: The extent of systemic exposure to bepotastine following topical ophthalmic administration of bepotastine besilate 1% and 1.5% ophthalmic solutions was evaluated in 12 healthy adults. Following one drop of 1% or 1.5% bepotastine besilate ophthalmic solution to both eyes four time daily (QID) for seven days, bepotastine plasma concentrations peaked at approximately one to two hours post-instillation. Maximum plasma concentration for the 1% and 1.5% strengths were 5.1 ± 2.5 ng/mL and 7.3 ± 1.9 ng/mL, respectively. Plasma concentration at 24 hours post-instillation were the below quantifiable limit (2ng/mL) in 11/12 subjects in the two dose groups.

Distribution: The extent of protein binding of bepotastine is approximately 55% and independent of bepotastine concentration.

Metabolism: *In vitro* metabolism studies with human liver microsomes demonstrated that bepotastine is minimally metabolized by CYP450 isozymes.

In vitro studies demonstrated that bepotastine besilate does not inhibit the metabolism of various cytochrome P450 substrate via inhibition of CYP3A4, CYP2C9, and CYP2C19. The effect of bepotastine besilate on the metabolism of substrates of CYP1A2, CYP2C8, CYP2D6 was not studied. Bepotastine besilate has a low potential for drug interaction via inhibition of CYP3A4, CYP2C9, and CYP2C19.

Excretion: The main route of elimination of bepotastine besilate is urinary excretion (with approximately 75-90% excreted unchanged in urine).

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis and Impairment of Fertility

Long term dietary studies in mice and rats were conducted to evaluate the carcinogenic potential of bepotastine besilate. Bepotastine besilate did not significantly induce neoplasms in mice receiving a nominal dose of up to 200 mg/kg/day for 21 months or rats receiving a nominal dose of up to 97 mg/kg/day for 24 months. These dose levels represent systemic exposures approximating 350 and 200 times that achieved with human topical ocular use.

The no observable adverse effect levels for bepotastine besilate based on nominal dose levels in carcinogenicity tests were 18.7 to 19.9 mg/kg/day in mice and 9.6 to 9.8 mg/kg/day in rats (representing exposure margins of approximately 60 and 20 times the systemic exposure anticipated for human topical use).

There was no evidence of genotoxicity in the Ames test, in CHO cells (chromosome aberrations), in mouse hepatocytes (unscheduled DNA synthesis), or in the mouse micronucleus test.

When oral bepotastine was administered to male and female rats at doses up to 1,000 mg/kg/day, there was a slight reduction in fertility index and surviving fetuses. Infertility was not seen in rats given 200 mg/kg/day oral bepotastine besilate (approximately 3300 times the systemic concentration anticipated for topical ocular use in humans).

14. CLINICAL STUDIES

Clinical efficacy was evaluated in 2 conjunctival allergen challenge (CAC) studies (237 patients). BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% was more effective than its vehicle for relieving ocular itching induced by an ocular allergen challenge, both at CAC 15 minutes post-dosing and a CAC 8 hours post dosing of BEPREVE®.

The safety of BEPREVE® was evaluated in a randomized clinical study of 861 subjects over a period of 6 weeks.

16. HOW SUPPLIED/STORAGE AND HANDLING

BEPREVE® (bepotastine besilate ophthalmic solution) 1.5% is supplied in a white low density polyethylene plastic squeeze bottle with a white controlled dropper tip and a white polypropylene cap in the following sizes:

5 mL (NDC 67425-007-50)
10 mL (NDC 67425-007-75)

STORAGE
Store at 15° – 25°C (59° – 77°F).

17. PATIENT COUNSELING INFORMATION

17.1 Topical Ophthalmic Use Only

For topical ophthalmic administration only.

17.2 Sterility of Dropper Tip

Patients should be advised to not touch dropper tip to any surface, as this may contaminate the contents.

17.3 Concomitant Use of Contact Lenses

Patients should be advised not to wear a contact lens if their eye is red. Patients should be advised that BEPREVE® should not be used to treat contact lens-related irritation. Patients should also be advised to remove contact lenses prior to instillation of BEPREVE®. The preservative in BEPREVE®, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of BEPREVE®.

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Irvine, CA 92618

By: Bausch & Lomb Incorporated
Tampa, FL 33637

Under license from:
Senju Pharmaceuticals Co., Ltd.
Osaka, Japan 541-0046

U.S. Patents: 6,307,052; 6,780,877

Adapting to the changing climate

Optometric melanism can enable us to adapt to new paradigm shifts

Adapting to the changing ophthalmic climate is what has enabled our profession to meet the optometric needs of our patients. **Optometry is much like the peppered moth of Great Britain**, which originally had light coloration that effectively camouflaged it against the light-colored lichens attached to the trees—only to witness the Industrial Revolution create widespread pollution and the demise of the lichens.

Optometrists can choose to thrive and not just survive by learning to adapt to new paradigm shifts, much like the peppered moth has done. Co-management of cataract patients is a prime example of addresssing a paradigm shift in the market and the patient base.

The peppered moths rested on blackened soot and, through evolution, the population of dark-colored or melanic peppered moths thrived in place of the aforementioned light moth. This optometric melanism is evidenced in the co-management of our cataract patients, and as witnessed in the evolution of the moth, the strong-minded ODs will flourish.

Optometric melanism is related to the paradigm shift in surgical outcomes. One does not have to look further than cataract surgery to see that a patient is no longer satisfied with the ability to just perceive bright color and shape without spectacle assistance. Patients now expect remarkable uncorrected vision. Refractive surgery has also seen a shift from the satisfied patients being able to function without spectacles, as evidenced by the radial keratometry inconsistencies and seemingly satisfied patients, to the expectation of a 20/20 or better outcome from the first-day visit.

By Marc R. Bloomenstein, OD, FAAO

Dr. Bloomenstein is director of optometric services at Schwartz Laser Eye Center in Scottsdale, AZ. E-mail him at mbloomenstein@gmail.com.

As in the example of the peppered moth, the Industrial Revolution brought amazing change and advanced technology, but the industrial soot left a dark cloud. The cataract surgeries of today must be viewed from "refractive-colored glasses" to help co-manage these lightly colored, like the moth, cataract patients. There are strategies that can be employed in this optometric melanism, which will help you and your patients in the exam lane.

Chief complaint

This may be the biggest melanistic change optometrists have to overcome: the desire to solve all of our patients' complaints. The chief complaint can often be mistaken for a statement of fact. Comments such as: "I have halos at night," "My intermediate vision is not very good," and "Street signs are not that sharp," can and should be regarded as your patient telling you the status of her eye. This is not consistent with having a problem that needs resolving.

Try this the next time you go into a post-operative visit. Do not mention anything about the chief complaint and solely focus on the results of your evaluation. For example, a 1-month post-operative patient with 20/20 UCDVA OU and J2 UCNVA OU has the beginnings of a great result. Focus your attention on how well she is doing visually, what you want her to do with her medications, and when you will see her back. In this scenario, if the patient was truly bothered by the chief complaint, she will stop you and ask for a resolution, or at least a time frame on when the complain will be resolved. As reported by AMO[1] and Alcon[2] in their QOL FDA studies, more than 90% of patients were satisfied, so the likelihood of needing to address the chief complaint is minimal.

Two eyes are better than one

Staying with our evolutionary theme, we have evolved (or intelligently designed, depending on your point of view) with both eyes working in tandem. Therefore, we see better, or at least as good as the best eye, with both eyes open and in the same gaze.

Pre-operatively, you should counsel patients who may have convergence insufficiency, amblyopia, or strabismus about improved quality after the surgery. Always binocularly test your patients post-operatively. Medico-legally, you need to know the individual eye's outcome. However, in practice it is more important to know how the eyes work in the real world. When talking to patients about their outcomes, they look to you as a barometer of their success. Therefore, the true measure of vision is achieved only by both eyes working together. Now, if your patient has one eye that is not doing as well as the other, see the last pearl before you say anything.

Timing is everything

As Einstein pointed out, it is all relative. Timing of the surgery makes a huge ef-

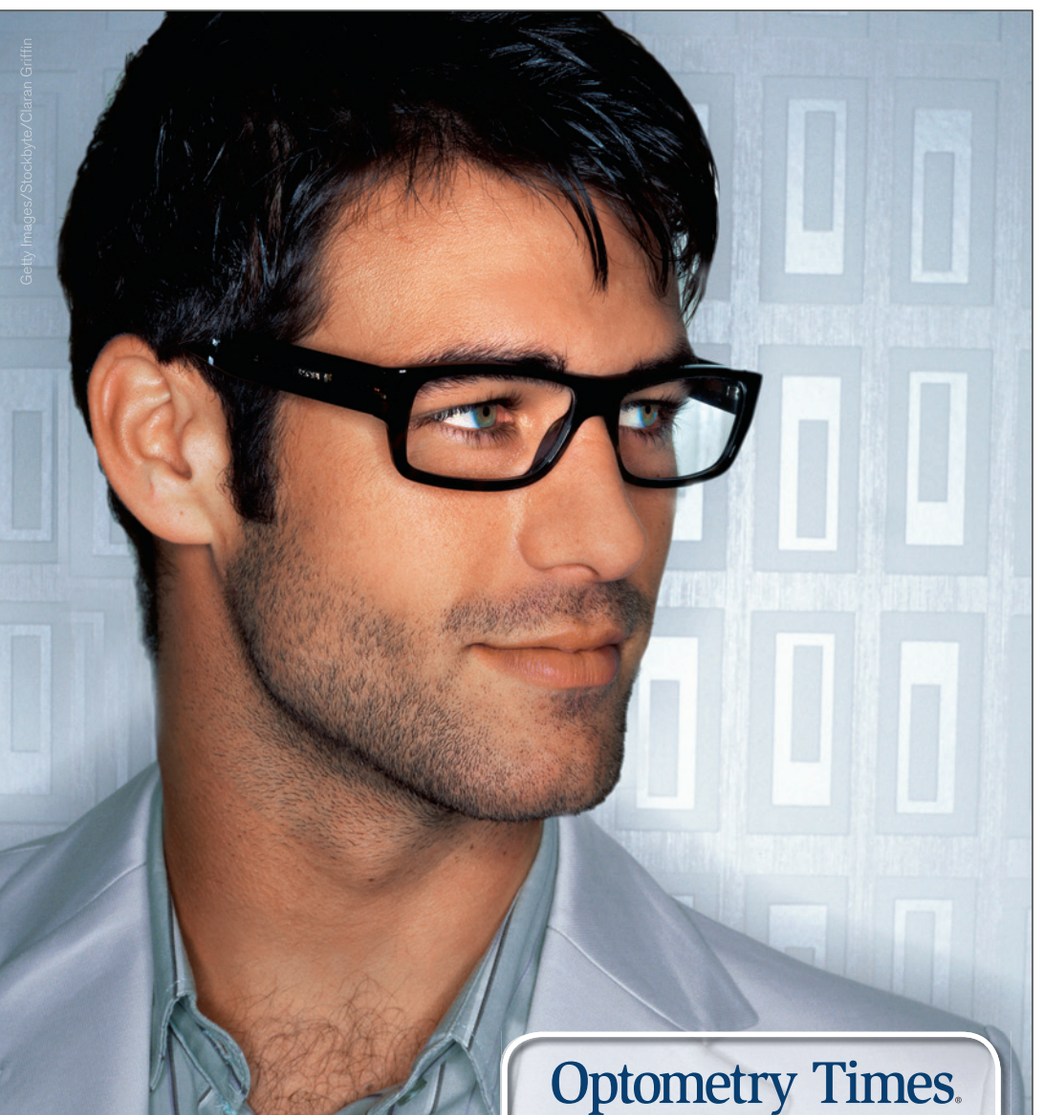
See **Adapting** on page 16

THINKSTOCK/ISTOCKPHOTO

Adapting

Continued from page 15

fect on the results. Modern surgeries are mostly free of micro-cystic edema or striae, although the more recalcitrant cataract may induce some swelling. Yet there still may be some mild corneal edema that will create blur, haze, and often more halos. Moreover, approximately 20% of patients have subclinical cystoid macular edema,[3] which may also contribute to the patient's perception of decreased vision. The post-operative period needs time to remove this inflammation, and setting your expectations around 4-6 weeks is a good practice. Remind patients that the final surgical results can take time, and although they are off to a good start, it may takes weeks for the quality to be there.



More time

The phrase "more time" should become part of your vernacular. Because adaption to slight refractive changes may take weeks to many months, you should not see your patients back on a weekly basis. Much like following a glaucoma patient, the change may be slow, so stretch out your post-operative visits to months rather than the common weekly visits. However, schedule a follow-up visit. A patient who may perceive she is not doing well needs your reassurance and guidance and therefore should be on your recall list. It can often be worse to avoid these patients, even if nothing can be done at the moment, than to see them without resolve.

Scratching the surface

We cannot talk about optometric melanism without mentioning the ocular surface. Picture the windshield of your car after you just had it washed. Now imagine that same windshield after you drive through a mud puddle. Just like your car's windshield, the surface of the eye needs protection. With the eye, clarity is limited by the increased osmolarity and inflammation. Cataract surgery induces inflammation, which in turn creates a greater inflammatory load on your patients. The cognition of this reality and our ability to treat this menacing condition is all the more important with our new-found evolution of refractive cataract patients.

While the peppered moth has adapted to change using industrial melanism, our optometric melanism will enable us to adapt to new paradigm shifts. However, unlike the moth that is camouflaging for survival, we need to display our traits like a male peacock.**ODT**

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Read more about **Co-management** on **page 22**

Compliant* Patients Come In For More Eye Exams.[1]

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Alcon offers the DAILIES® family of daily disposable contact lenses and the AIR OPTIX® family of monthly replacement lenses. Multiple studies have shown that daily disposable and monthly replacement contact lens wearers are more compliant* than those who wear 2-week lenses.[2,3,4] Compliant patients also return for more eye examinations.[1]

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*Compliance with Manufacturer-Recommended Replacement Frequency (MRRF).

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Evaluating evaluations

Learn how to read studies to know if the results are 'good science'

By Jerry M. Stein, PhD, FAAO

Practitioners are slammed with information overload. To help cut through the avalanche, a set of standard questions can be useful for determining if a study is worth investing your time and attention.

Most practitioners are inundated daily with an incredibly large amount of new information describing products or treatment choices. The inflow is familiar to every professional and includes hard-copy journals, e-journals, newsletters, and advertising brochures. Among the possible lines of evidence supporting safety and effectiveness, the presentation of clinical results is always a big plus. However, not every study report should be treated with the same degree of reverence.

Take-Home Message

Practitioners are slammed with information overload. To help cut through the avalanche, a set of questions can be useful for determining whether or not a study is worth investing your time and attention.

After reading about 20 x 10^3 articles during my career as a clinical scientist, I want to share my criteria for assessing studies. These factors will complement the criteria developed by others.[1] The following list of questions may help readers cope with the daily flood of information.

CATEGORY 1: Study Design

Was this a randomized, controlled, double-masked, prospective trial (RCT)?

You can earn 4 credit hours at a prestigious university learning why this is the gold standard among study designs. There are many benefits associated with this approach, but implementation is not universally practical.

The masked RCT design helps reduce the potential for bias that occurs when patients, doctors, and staff learn their assigned treatment conditions prior to or during the evaluation. For example, it lowers the probability that the worst patients were inadvertently assigned to one treatment group. A prospective, controlled design, addressing a well-defined, simple question, reduces the potential that a confounding variable will affect the study results and impact one treatment group and not the other. Overall, this design leads to a stronger cause-and-effect determination.

However, not every study can be conducted as a masked RCT. Studies involving medical devices are particularly challenging. For example, the surgical implantation of an IOL with a unique design creates problems when trying to mask the surgeon. The same is true with unique contact lenses. In the lens care arena, we might want all subjects to use disinfecting solutions dispensed from identical bottles. However, the transfer of the solutions to new bottles can significantly alter the product's chemistry due to interactions with the plastics.

What was the control treatment?

First, I ask whether or not the treatment represents a relevant clinical choice. A head-to-head comparison between two competing treatment approaches can answer key medical and practice management questions. The study might determine that the treatments were basically equivalent or that there were large differences in safety or effectiveness.

However, clever study designers seeking the magic $p < 0.05$ level for statistical significance may choose to aim low, using an older treatment approach as the control in order to ensure that the new treatment wins. While this strategy helps ensure FDA approval and market entry, the old treatment may not represent current standards of practice. In addition, establishing clinical equivalence (i.e., not substantially different) is often much easier than establishing superiority.

Even when a contemporary control treatment is planned, the specific treatment selected can impact study outcomes. If the control (e.g., an established, marketed, effective pharmaceutical) is expected to perform equivalently to the test treatment, expectations of both patients and doctors rise. All measures of effectiveness tend to improve when participants realize that 50% of the patients were assigned a treatment condition recognized as effective. If an ineffective, untested treatment is used as a control (e.g., a placebo) expectations are often driven downward.

Were the right subjects recruited?

Here's the dilemma. The perfect study is populated with patients who show up for all visits and complete all case report form questions with few errors. Perfect subjects have few non-essential pre-existing conditions that impact treatment efficacy and have a low probability for developing unrelated adverse events. Perfect patients are never extremely old, never too young, and never take any OTC or prescription products except those being investigated. Recruiting perfect study subjects allows for analyses to be completed quickly and makes interpretation easy.

Unfortunately, once a drug or device is approved, practitioners cannot control the cases that walk into their waiting rooms. Compared to the study population, real patients often include older and younger subjects, and pregnant women—individuals who represent a much broader cross-section of the population. Enrolling more "Main Street" patients often drives up the number of patients targeted for enrollment and increases study costs. However, there is a strong support for a broader, more realistic inclusion/exclusion criteria that better predicts product performance in the marketplace.

> Anecdotal reports concerning unique cases are extraordinarily valuable for the progression of science and medicine.

Was the number of enrolled patients sufficient?

Numbers matter. Anecdotal reports concerning unique cases are extraordinarily valuable for the progression of science and medicine. This new, initial information is a catalyst for further explorations. However, these seeds should not be mistaken for mature trees. The smaller the study, the smaller the generalization. What is more believable: a 10% advantage in the treatment group in a study involving 10 patients or a 10% advantage in a trial involving 1,000 patients? Common sense and a good statistical analysis lead to the same conclusion.

Was the number of sites sufficient?

Having more study sites matters. Once again, the issue is the generalization of study results. Will the solid results observed among patients in Brooklyn apply to patients in Iowa City? Having a wide geographic diversity has numerous benefits. It helps address confounding variables such as seasonal effects, ethnic variability, humidity, and more. A prominent example is the success of extended-wear lenses worn at sea level (Norfolk, VA) as opposed to higher altitudes (Denver, CO).

Was the study duration sufficient?

Sometimes the answer to an important medical question can be obtained very quickly. For example, was a contact lens comfortable upon application? A quick study can address some simple questions. However, the development of adverse reactions and primary packaging failures are two examples of concerns where time matters. Identifying the weak anti-microbial profile of a lens care product might be observed only after several month of daily usage.

CATEGORY 2: Interpretation

Were inferential statistics performed?

We all hate statistics and suspect that we are being manipulated by the clever geeks. But these calculations can provide useful tools that help guide interpretation. A statistically significant p value ($p<0.05$) means that only 5% of the time there is a Type I error (i.e., the study results found differences comparing the two treatment conditions when, in reality, the treatments should not have shown a difference in the primary endpoint). In other words, the results reported might have been a fluke, but the chances for this are very small. Statistics should not be the only criteria to measure success, but it provides strong support.

Were the results clinically meaningful?

Is the hunt worth the chase? Given enough enrolled patients, even a small difference in the mean values can be shown to be statistically different. For example, in a study comparing two topical anti-infectives, conjunctivitis was resolved after 1.5 days using Treatment 1 compared to 1.7 days with Treatment 2. While these results might be statistically significant, are the differences meaningful? Is it wise to switch your patients to a new product if the clinical benefit is small, and you are able to use a marketed product with an established safety and effectiveness profile?

Were the right questions asked?

You don't know what you don't know. Sometimes study designers and investigators guess wrong. They prepare questionnaires that ask the wrong questions or fail to ask the right ones. Patient interviews and spontaneous comments from investigators frequently provide key information. The casual conversation between a clinical monitor and study coordinator has uncovered many unexpected problems in the consumer products area, requiring re-designs.

Do the results make sense?

My SAT coach always told me to ask whether my mathematically computed answer made sense before I filled in the bubble. The same holds true here. Sometimes the results of a single study are just plain wrong. Resist changing anything in your practice until it makes common sense, especially in cases where safety is at risk.

Can the results be replicated?

Finally, we come to the most important factor: patience. Assessing whether a new treatment or product is a winner may take time. This is especially true regarding safety. We have all experienced situations in which an individual adverse event is initially dismissed as a rare anomaly. A trend might be detectable only after months or years of experience. Tracking results and objectively evaluating your experience over time is very important.

CATEGORY 3: Factors *not* to consider

This guide to interpreting clinical studies would not be complete without commenting on the factors that should not be considered.

Who sponsored the study?

It may be hard to believe, but drug and medical device companies do not have institutional policies that require researchers to lie and cheat. My experience is that companies are populated with honest people who want to develop safe and effective products. Besides, there is too much to lose. Studies destined for FDA review are often designed to the highest standards, and study sites are intensely controlled to avoid fraud. In contrast, self-funded studies at academic sites and NIH-sponsored studies are often only loosely monitored.

Where was the study published?

Getting published in a nationally recognized journal is difficult and very time consuming. The time from initial submission to publication might be measured in years when you add review time, rejections, and re-writes. There is bias by editors and publishers, and this affects acceptance rates. A study published in a contemporary electronic journal or published by a manufacturer should be judged based on the same criteria described above.

What was the study location, school, or institution?

Results of a good study, meeting all design and interpretation criteria, should be considered regardless of the source (author or site). The best ideas and the best studies sometimes come from unknown little places. Studies conducted at nationally recognized institutions should be considered on their merits. **ODT**

10 key questions to ask when evaluating clinical studies

STUDY DESIGN	INTERPRETING THE RESULTS
Was this a masked, randomized, controlled, double-masked, prospective trial (RCT)?	Were inferential statistics performed?
What was the control treatment?	Were the results clinical meaningful?
Were the right subjects recruited?	Were right questions asked?
Was the number of enrolled patients sufficient?	Do the results make sense?
Was the number of sites sufficient?	Can the results be replicated?

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FYI

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Next-generation devices offer new approaches to refractions

Visual optimization can be delivered promptly and efficiently

By Kenneth Daniels, OD, FAAO

Vision is a two-fold experience composed of both acuity and quality. Understandably, acuity remains the primary focus; however, if quality is not optimized, visual complaints may persist even in the presence of 20/20 vision. Eye specialists have developed several approaches to identifying and minimizing the higher-order aberrations that compromise visual quality. But these strategies, which involve the use of wavefront aberrometers and quality-enhancing spectacle lens coatings, still require the initial use of a phoropter to determine acuity. This can produce a drawn-out refraction experience for the patient, aggravated by the lengthy trial-and-error process many patients undergo to determine the best combination of lens coatings required to achieve aberration-free vision.

Quality, acuity in one sitting

In recent years, a group of next-generation devices has entered the eyecare market and offered a new approach to refractions. Such devices include:

- **Profilerplus system (Carl Zeiss Vision)** combined autorefractor, corneal topographer, and wavefront aberrometer
- **Trace (Tracey Technologies Corp.)** ray tracing wavefront aberrometer and corneal topographer
- **Point Spread Function (PSF) Refractor (Vmax Vision Inc.)** is notable among new-generation devices because it improves the accuracy and speed of a typical refraction by allowing visual quality and acuity to be assessed by one machine in a single sitting.

When the PSF device is used in conjunction with the Encepsion lens (Vmax Vision), the precise measurements captured during refraction can be transferred to a spectacle lens that provides a high level of visual quality and clarity.

Much like the traditional phoropter, the PSF Refractor permits subjective determination of refractive error. But, by using the principles of point spread function, this device calculates refractive error with 5 times greater accuracy than a phoropter.[1] This means patients can be refracted down to 0.05 D rather than the standard 0.25 D.

Take-Home Message

A patient can achieve 20/20 vision in a variety of ways, but optimizing visual quality is the only way to ensure complaint-free 20/20 vision. New-generation refractors ensure that visual optimization can be delivered promptly and effectively.

Results from two studies have shown that refractions performed with the PSF Refractor produce more accurate visual outcomes than a phoropter. The first study involved 50 patients who underwent bilateral refraction with the PSF Refractor, followed by phoropter-based refraction. When vision tests, including visual acuity tests (at 100%, 25%, and 12% contrasts) and contrast sensitivity testing (using sine gratings at 6 cycles per degree [CPD], and 12 CPD [charts by Vector Vision]) were performed, with and without spectacle correction, 85% of the group achieved a higher final visual acuity with the PSF Refractor than with the phoropter. These findings were echoed in a similarly executed second substudy, which consisted of 1800 eyes of 900 patients from seven U.S. clinical sites. In this study, the PSF Refractor produced a visual acuity equal to or better than the phoropter in 90% of patients.[1]

The different levels of accuracy achieved with the PSF Refractor relate to each device's choice of refractive target. During phoropter-based refraction, patients are asked to view Snellen chart letters and interpret blur, but this scenario isn't true to everyday life. PSF-based refractions overcome this limitation by asking patients to interact with a real-life target and provide feedback about the true amount of visual distortion seen. This refractive strategy ensures that the resulting refractive prescription given is one that has been optimized to eliminate all visual aberrations and distortions experienced in everyday life.

Subjective vs. objective refraction

I've been using the PSF Refractor for nearly 2 years now. My colleagues and I welcomed the device into our practice because we were already using both wavefront aberrometers and phoropters to assess refraction. Using one technology to measure both quality and acuity was the next logical step. Not only does using one instrument to carry out both parts of the exam save time and increase patient convenience, but study results have also shown that subjective refractions are more accurate than objectively determined refractions, such as those obtained with wavefront aberrometers.[2] This may be because objective measurements account only for the eye's perception of vision but fail to account for the brain's influence on image interpretation. In other words, aberrometers provide a very good estimate, but only a patient can voice exactly what she sees. By using subjective refraction, the PSF Refractor ensures that the patient is the ultimate decider of the best refractive correction.

> Optimizing visual quality is the only way to ensure complaint-free 20/20 vision.

Wavefront aberrometers are a great benefit when used with a phoropter in a refractive practice. However, room for improvement remains, and this is where the new technologies excel. The i.Profilerplus system, which uses the properties of an autorefractor, corneal topographer, and wavefront aberrometer, is reported to refract with an accuracy of 0.01 D and also determines visual quality, much like the PSF Refractor. However, because it uses an objective method of refraction, it remains susceptible to the limitations encountered with objective refraction.[2,3] In my practice, I have used the iTrace system, which offers refractive refining similar to the i.Profilerplus system. I have found that the iTrace system provides refractive outcomes close to that of the PSF Refractor without that device's speed and patient convenience.

Patient perception

If a patient walks into the exam room and can read the 20/20 line on the Snellen chart without hesitation, there isn't a quality concern. However, the patient who comes in and says, "I think it's a T," or "I'm not sure if this is a V or an E," is the one with an obvious quality concern. That patient is most likely appreciating higher-order aberrations, and that's the patient the new generation refractive devices were made for.

Prior to using the PSF Refractor, I used aberrometers as well as phoropters to determine my patients' visual level. Making the change to the PSF Refractor has allowed me to provide an enhanced refractive examination with subjective outcomes that are more consistent with a patient's visual needs. The patient can now react and say, "That's a much better image quality," when he feels that's the case. More direct involvement in the refractive process has increased patient satisfaction. When the 900 patients involved in the aforementioned PSF Refractor study were asked to compare the refractive experience with a phoropter vs. the PSF Refractor, 90% said they preferred the PSF Refractor.[1]

Turning problem identification into real results

Identifying how vision can be improved is useful only when an effective solution exists. Standard spectacles attempt to optimize vision quality and acuity via a variety of methods, such as aspheric lenses and anti-reflective coatings. Standard lens prescriptions offer fairly poor vision quality—patients must rely on specialty lenses and coatings to enhance their quality of vision in a stepwise fashion. The Encepsion lens provides a customized solution that automatically corrects all quality and acuity errors identified during the refraction process. The unique aspect of the Vmax system (PSF Refractor and Encepsion lens) is that a standard lens has distortions to the periphery, which mean that curvature effects increase toward the lens periphery. This, in turn, enhances ghosting, aberrations, and image warping.

With the Vmax system, the refraction achieved is so specific that a prescription of –4.00 spherical, –2.00 cylindrical, can be refined to a level as specific as –4.22 spherical, –1.98 cylindrical. And it is recalculated point by point across the entire lens surface so that the power in every single portion of that lens is corrected right to the edge. In addition, the highest level of anti-reflective coating is used as standard, which ensures that glare from exogenous light in the area is instantly eliminated.

Other lenses currently out on the market aim to optimize quality, such as Physio 360 (Essilor) and HoyaLux TrueForm (Hoya). However, unlike the Encepsion lens, these lenses do not come with a complementary refraction technology. In the absence of a tailor-made technology, it can be difficult to ensure that any refractive measurement captured is specifically matched with the lens prescription produced. Even lenses that come with a refraction technology, such as i.Scription, are based on objectively determined refractions, which can be less accurate than subjectively determined refraction.[4,5]

> Aberrometers provide a very good estimate, but only a patient can voice exactly what he or she sees.

The nighttime vision dilemma

The responses of patients on follow-up visits have been the greatest testament to the difference that PSF-based refraction and Encepsion lenses can make to everyday vision. The best analogy I've heard is that the change is like moving from standard television to high-definition —everything looks crisper and clearer. Patients particularly remark on the manner in which the level of clarity provided by the lens stays the same, even when exogenous lighting is poor. The area in which the PSF Refractor makes the biggest difference to everyday vision is nighttime vision.

One of the most common complaints I receive from refractive patients is that they can't see well at night. This is due to the increase in pupil size and the defocus of light from the peripheral portions of the pupil that occur in low-light situations. A standard phoropter can't assess this nighttime-dependent change, which means that standard prescriptions don't correct for nighttime vision problems. The PSF Refractor has a subjective nighttime vision function, which ensures that a nighttime prescription can be calculated during the refraction process. It does so by allowing the background on which the PSF target is viewed to be darkened to simulate night vision. Once a nighttime prescription has been calculated, the patient can then decide if she wants two pairs of spectacles, one for day and one for night, or if one pair of spectacles with a refractive power balanced between day and nighttime is preferable. Patients have told me that calculating the variance between night and day makes all the difference to their vision. Because the calculation takes only an additional 1-2 minutes, it doesn't affect practice workflow.

End result

A patient can achieve 20/20 vision in a variety of ways, but optimizing visual quality is the only way to ensure complaint-free 20/20 vision. New-generation refractors ensure that this visual optimization can be delivered in a quick and effective manner. Additionally, they provide a solution to perhaps the most frustrating complaint of all—the understanding but inactive doctor. Most patients have experienced the frustration that accompanies telling their doctor about a visual complaint but receiving little action other than a sympathetic nod. These new-generation refractors and spectacle lenses finally offer the solution that patients have been waiting for: a doctor who not only hears a patient's problem but also addresses it.**ODT**

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Prescribing premium IOLs: Working with surgeon, patient for success

The optometrist and the surgeon must team up to best serve the patient's needs

By Kenneth R. Mueller, OD

It is imperative to discuss intraocular lens (IOL) options with our patients requiring cataract surgery. Even if our patient is a poor candidate for a premium IOL, we want the patient to be well informed about what lenses are available. We certainly don't want to upset the patient because we did not tell him about a fancy lens that his golfing buddy just received.

So, who should help the patient decide which IOL option to choose? The optometrist? The surgeon?

A strong case can be made for the primary eyecare professional to be the expert in the area of IOL choice. The primary eye doctor has the opportunity to know and understand the needs and personalities of his own patients and will have the duty of taking care of the ongoing visual needs of those patients for years after the cataract procedure is performed. He must, therefore, have a thorough understanding of the benefits and limitations of each IOL design.

If the cataract surgeon is not the patient's primary care doctor, the optometrist and the surgeon must work as a team to agree on which of the available lens designs to offer and recommend.

We have few approved premium IOLs from which to choose in the U.S. Our colleagues outside of this country, however, are using several designs which may soon find their way to our shores. While the FDA is often criticized for being slow to approve IOL designs, this certainly is a double-edged sword. While we are anxious for new technology and options, we and our patients pay the price when results are less than optimal. Specially trained in optics, optometrists are aware of how a multifocal correction, whether it is in the form of a progressive eyewear lens or in a contact lens, can be completely unsatisfactory to a patient. Obviously, while it is fairly easy to remake a pair of eyewear lenses into a different design or to change from one multifocal contact lens to another, an IOL does not offer the same ease of changeability.

Take-Home Message

Discussing IOL options with cataract patients prior to surgery is of utmost importance. Plus, the optometrist and the cataract surgeon must work as a team to agree on which IOL designs to offer and to recommend.

Making the IOL decision

How should we go about making the IOL decision? For the primary eyecare provider, following are the steps you might take, with the assistance of your technicians and patient education videos, to inform and educate your patient regarding this important decision.

Step One: You and Mrs. Smith decide that her cataracts are at the point that they should be removed.

Step Two: You briefly explain the procedure to Mrs. Smith, including what to expect regarding the procedure, where and by whom the surgery will be performed, and what the post-operative schedule will entail.

Step Three: Mrs. Smith needs to know that she has options regarding her implant. You tell her that not only will she see better without her cataracts, you can now use this opportunity to correct her eyesight so that she is less dependent on glasses or contact lenses. You explain that a single-vision IOL will help her to see well at one distance, usually far away, and that then she would need glasses or contact lenses for near and intermediate work. If she has over about 1.25 D of astigmatism, you might recommend a toric IOL.

You educate Mrs. Smith that she may elect to have an implant to correct both the distance and near vision and that there are multiple options depending upon her needs, some of which offer better near vision, low light vision, distance vision, etc. You also let her know that while a single-vision IOL is generally covered by Medicare or major medical insurance plans, she would pay extra for a premium IOL such as a toric lens or multifocal lens, and you or your technician would be able to discuss that cost in detail, along with any financing options that your practice offers. This is also an excellent time to mention that while these options may free her up from wearing a correction full time, there will probably be times when she will still wear correction, such as when reading small print, working on the computer, or driving at night, and that some options will be better than others for different situations.

If the cataract surgeon is not the patient's primary care doctor, the optometrist and the surgeon must work as a team to agree on which of the available lens designs to offer and recommend.

Step Four: A separate visit may be ideal to decide upon an IOL. It is imperative to discuss wants, needs, expectations, hobbies, vocations, lighting issues, and willingness or unwillingness to spend more for a premium IOL, to ascertain which option would best suit her.

Additional cataract surgery examination protocol should include:

- *Dry eye testing.* As vision with multifocal IOLs in particular can be poor with under-treated dry eyes, you must

not wait to discover ocular surface disease after the procedure. Pretreat with Omega 3s, Restasis (cyclosporine, Allergan), punctal occlusion, artificial tears, etc., until the ocular surface disease is satisfactorily controlled. In poorly responsive cases, patients may be best served with single-vision IOLs.

- *Lid health evaluation.* Clear up any blepharitis pre-surgery.
- *Corneal topography.* Rule out keratoconus and pellucid marginal degeneration, and measure corneal astigmatism. The surgeon will need this information for optimal visual outcome.
- *Biometry (such as with the Zeiss IOLMaster.)* This allows for accurate IOL power prediction.
- *OCT.* Check for signs of maculopathy, such as age-related macular degeneration, because multifocal IOL designs may be a poor option when present.
- *Aberrometry.* Identify patients with extreme aberrations such as coma, spherical, and trefoil, which may make them poor multifocal IOL candidates.

Step 5: When fully satisfied that Mrs. Smith's eyes are ready for their procedures, and you have chosen an IOL design, you are ready to schedule what should be one of the most rewarding events of her life.

IOLs in the U.S.

Four general categories of IOLs are currently available in the U.S.:

- *Single-vision IOLs.* Single-vision IOLs provide excellent vision at one focal point for non-astigmats and can be used for monovision. As with accommodating IOLs, single-vision IOLs provide the most focused light to the retina and may be better the better choice for patients with maculopathy.
- *Toric single-vision IOLs.* Single-vision lenses with astigmatism correction, toric IOLs such as the AcrySof IQ Toric IOL (Alcon) allow patients with larger amounts of astigmatism to be corrected at one focal point without undergoing LASIK, PRK, or lateral relaxing incisions (LRIs).
- *Diffractive multifocals.* Alcon's AcrySof IQ ReSTOR IOL and AMO's Tecnis Multifocal IOL and ReZoom Multifocal IOL are examples. Diffractive designs use concentric rings to split light into multiple focal points. This type often provides excellent near vision but may cause haloing and poor low-light vision.

Steps to making an IOL decision

1. Decide, you and the patient together, that it's time for the patient's cataracts to be removed.
2. Explain the cataract procedure to the patient.
3. Discuss with the patient options available to her, including types of IOLs and differences in correction.
4. Schedule a separate visit to decide upon which IOL.

- *Accommodating/pseudo-accommodating.* The accommodating lens designs that are approved in the U.S. are Bausch + Lomb's Crystalens AO IOL and newer Crystalens HD IOL, which are hinged, single-vision lenses which flex with the muscles of the eye to provide focusing at different distances. The Crystalens AO is thought to offer excellent distant and intermediate vision with variable near efficacy without the addition of low-powered reading glasses. The HD aims to improve near vision.

IOLs outside the U.S.

Outside the US, particularly in Europe, other designs are being used with varying degrees of success, some of which will be available in the U.S. in the future.

- *Diffractive designs.* The weakness of the diffractive platform is that light is split and lost, so lower-light conditions tend to suffer. Newer designs attempt to minimize this. The Carl Zeiss AT Lisa IOL is a diffractive-refractive hybrid lens. PhysIOL's FineVision trifocal diffractive IOL is another of this type, designed to overcome the problem of poor intermediate vision common to many of the bifocal diffractive designs.
- *Toric multifocal IOLs.* Carl Zeiss Meditec AT Lisa Toric and Alcon's AcrySof IQ ReSTOR IOL Toric are diffractive designs which show promise of being approved for the U.S. market.
- *Refractive designs.* A refractive multifocal, such as the Lentis Mplus, uses zones of different powers either in a bifocal design, which creates two simultaneous images, or by using annular zones utilizing pupil size variations to create the appropriate aperture for varying focal points. They use induced higher-order aberrations to create increased depth of focus.
- *Innovative accommodating lens designs.* PowerVision's FluidVision IOL uses silicone fluid stored in the haptics to change the shape of the lens upon accommodation. The Synchrony dual optic accommodating IOL by Visiogen/AMO is already in use in Europe but has not won FDA approval here. It has a moveable anterior optic, which is attached to a posterior optic by spring haptics. Many surgeons are excited by its early efficacy.

Other products on the horizon

LAL, a novel light-adjustable lens design from Calhoun Vision of Pasadena, CA, is made from photosensitive silicone. By shining a particular wavelength of light at the lens, the user can increase or decrease its power, including astigmatism, after which its power is locked in by using another light application. This lens is in clinical trials in the U.S., with hopes of soon gaining FDA approval.

Patients' expectations

As we have found with LASIK and multifocal contact lens patients, patient expectations have a role in choosing candidates for procedures or devices. The patient who is at 20/15 distance and J1 at near may be terribly unhappy because of glare at night, poor intermediate vision, or poor low-light vision, while the patient who is J3 at near may be perfectly happy wearing reading glasses for small print or in dim lighting.

Our premium IOL patients can be the happiest, most grateful people in our practices. It all comes down to proper patient selection, lens choice, and educating our patients about what they can truly expect from a lens. These lenses are very good, not perfect. Even if our patients are much less dependent upon glasses, as opposed to being totally free of glasses, many of our patients will be thrilled with very good… and tell all of their friends.**ODT**

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Five pearls for co-managing the premium IOL patient successfully

The graying baby boom generation offers optometrists a major opportunity for revenue.

By Richard Hyer

Cataract surgery is the most frequently performed surgery in the U.S. and is increasing rapidly: 22 million Americans aged 40 and older have at least one cataract; by 2020, more than 30 million persons will have them.

"Cataracts are now seen every day in clinic. The number of patients being diagnosed with cataracts by optometrists will continue to increase for years to come," said Josh Johnston, OD. "For years you've been hearing about baby boomers, and now they're here. In response to this influx of patients, ophthalmologists' primary focus will shift to providing surgical care. As eyecare evolves, ophthalmology will be busy with the surgical demands from the aging population, so optometry is poised to be the primary eyecare provider."

One baby boomer turns 65 every 8 seconds. In 2011, there were 78 million boomers, of whom a record 2.8 million qualified for Medicare. By 2030 4.2 million a year will cross that threshold,[1] said Dr. Johnston.

These demographics suggest that the baby boom population will put stress on the existing healthcare system and may create significant new opportunity for ODs.

Higher expectations

Optometrists are the gatekeepers to cataract referrals and to intraocular lens (IOL) technology, said Dr. Johnston. Many cataract diagnoses are made by an optometrist, so referring ODs should make a point of discussing all IOL options.

"It's our job to educate patients about cataracts and stay abreast on current treatment options. Patients now have the ability to have laser cataract surgery and choose IOLs that reduce or eliminate the need for glasses after surgery," he said.

The IOL market is forecast to reach $3.1 billion by 2017[2] because of increasing demand for premium products such as multifocal, accommodating, and toric IOLs. Although the adoption level of premium IOLs in the U.S. during 2010 was 13%,[2] the revenue generated by premium IOLs accounted for 39% of the total IOL segment.[2]

"Cataract surgery today has become refractive surgery," said Dr. Johnston.

Patients who choose premium lenses are very demanding, he said. Many had LASIK and automatically assume that cataract surgery will essentially be the same, with the same outcome.

"These patients expect distance, intermediate, and near vision, and spectacle independence," he said.

This underscores the importance of discussing all lens options prior to cataract surgery, so patients know that technology is now available which will allow them to achieve their visual goals.

Optometry is a medical practice, but it's also a business, said Dr. Johnston, so ODs must be mindful of good business practices. As an example, he broke down the typical charges associated with co-managing cataract surgery while also treating ocular surface disease (OSD), which is prevalent in this patient population. This can generate additional revenue of approximately $1,443 per patient. [See box: Financial impact]

22 million Americans
aged 40 and older have
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BY 2020
more than
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Take-Home Message

The aging baby boom generation could create significant new opportunities for optometrists. ODs are the gatekeepers to cataract referrals and to intraocular lens (IOL) technology. Many cataract diagnoses are made by an optometrist, so referring ODs should make a point of discussing all IOL options with patients.

A practice treating just five new cataract patients per month could therefore generate additional revenue of $86,610 per year, and this does not include ancillary revenue sources such as eyeglasses and sunglasses, retail products, optical coherence tomography, endothelial cell counts, and A-scans, said Dr. Johnston.

Five pearls

Dr. Johnston offered five pearls to guide the OD to success when co-managing premium IOL patients: plano outcome; proactive treatment of OSD; pre-operative counseling; proper screening; and picking the right IOL. Dr. Johnston placed particular emphasis on the first two.

PEARL 1 **Plano outcome.** The number-one problem with premium IOLs is residual refractive error (RRE), said Dr. Johnston.

"Not that these lenses cause it, but when people have RRE, that's where the problem is."

Premium IOLs will not perform to their full capacity when residual refractive error is left untreated, he said. Plano outcomes should be the goal.

RRE can cause blurry vision, dysphotopsia, and can even increase symptoms of glare and halos, increasing night vision complaints. Dr. Johnston suggested planning for RRE, including working with a surgeon who adds the cost of enhancement into the initial fee.

"It helps to work with experienced cataract and LASIK surgeons who can bail you

Financial impact of treating OSD and premium IOL co-management

- **92004-$126.50** initial exam; cataract and OSD diagnosed
- **92012-$85.00** follow up treating OS
- **99213-$65.00** additional follow up for OSD
- **92285-(ant. seg. photo) $45.00** performed at baseline exam for OSD
- **68761-E2 & E4 (plugs) $262.00** performed if indicated
- **66984-55 (20% of global) $160.00** shared post op care
- **Co-mgmt. fee $350.00 X 2 = $700.00** for PC-IOL
- **Total (1 patient) $1,443.50 per patient**

** Above based on avg. Medicare reimbursement rates.

** Rates will vary by state and region.

out and treat any RRE."

The OD should be aware that if the problem occurs, it's best to fix the refractive error as soon as possible. "The key here is to take care of it early. I find it best to educate patients early on and let them know things may be blurry and that we can easily fix it. Tell the patient, 'We will need to perform a slight tune-up procedure,'" said Dr. Johnston. Correct the problem as soon as possible after the patient's refraction has stabilized, he said. Validate the patient's complaint and work together to develop a treatment plan.

PEARL 2 **Proactive treatment of OSD.** Next most important is the proactive treatment of OSD. This is important because poor tear film and ocular surface disease change the measured corneal curvature, affecting preoperative biometry. The visual potential can also be limited and can affect the performance of these IOLs.

To evaluate the ocular surface, Dr. Johnston uses diagnostics ranging from fluorescein and lissamine green to a slit lamp exam.

A recent study[3] found that 59% of patients undergoing cataract surgery have blepharitis. Dr. Johnston treats meibomian gland dysfunction (MGD) various ways, including use of Azasite (azithromycin, Merck), Restasis (cyclosporine, Allergan), combination topical drops such as Tobradex ST (tobramycin/dexamethasone, Alcon), oral doxycycline, and gland expression. The LipiFlow Thermal Pulsation System (TearScience), which massages and heats the eyelids, also shows compelling data in early clinical trials and seems to be a promising new treatment option, he said.

"You can't ignore dry eye, meibomian gland dysfunction, and other OSDs. If it's there, you've got to treat it."

The dry eye workup

Dry eye is also uncomfortably prevalent. The PHACO Study[4] found that 62% of patients had a tear break-up time (TBUT) of <5 seconds. The study also found that 76.8% of patients showed positive corneal staining, and 50% showed central corneal staining.

"This study is very significant to optometrists," Dr. Johnston said.

His dry eye treatments range from artificial tears to autologous serum. "I follow the International Task Force guidelines for evaluating and treating dry eye. I recommend using these guidelines to objectively access and treat each patient."

Dr. Johnston finds at least 80% of cataract patients are above severity level I. Restasis is indicated for Stage II and above.

"I use Restasis aggressively in treating dry eye, as it's a chronic inflammatory disease that needs medical treatment."

> It is important to discuss all lens options prior to cataract surgery so patients know that technology is now available which will allow them to achieve their visual goals.

He frequently prescribes OTC palliative artificial tears, but almost always in conjunction with Restasis. "Don't be afraid to prescribe safe efficacious therapeutics available."

Ironically, he said, patients often cannot even recall the trade name of the eye drop they are using every 2 hours. A study by the Gallup organization[5] found that patients use on average six different brands of artificial tears to self-treat dry eye. "The key is for us to make a specific recommendation," said Dr. Johnston. Recommending a specific brand of artificial tears will help patient compliance and hopefully prevent use of non-desired products such as Visine, he said.

"Do we use steroids?" Dr. Johnston asked. "Absolutely." There is evidence for treating dry eye disease with the "soft" steroid loteprednol in conjunction with cyclosporine to reduce signs and symptoms and maximize therapy.

PEARL 3 **Conduct preoperative counseling and setting realistic expectations.** "Always have a discussion prior to surgery so patients will have an understanding of potential side effects and possible visual limitations," he said.

PEARL 4 **Perform a full evaluation.** In Dr. Johnston's words, "from front to back, lids to the retina." His clinic performs topographies, endothelial cell counts, and retinal OCTs on all of these patients to make sure it has the full picture before recommending a premium IOL.

"We even look at the iris to see if there is any evidence of trauma," he said. Patients with floppy iris syndrome, previous trauma, pseudoexfoliation syndrome, or zonular weakness may not be candidates for some IOLs.

PEARL 5 **Pick the right IOL.** Dr. Johnston suggests developing a refractive treatment plan for each patient based on both visual goals and personality types, and then sharing this plan with the surgeon prior to the pre-op consult.

"Optometrists know their patients better than the surgeon in most cases, and it's really helpful to have a clear plan spelled out for the surgeon," he said.

There are many premium IOLs on the market today, Dr. Johnston said, and each has a unique niche. Every premium IOL

See **Pearls** on page 26

Pearls

Continued from page 25

has pros and cons, so he advised selecting one based on the patient's personality and visual demands.

The concern of IOL rotation

Dr. Johnston cited a study which found that 73% of Acrysof Toric (Alcon) lenses rotated less than 5 degrees vs. 37% of Staar Toric (Staar Surgical) lenses.[6]

"Generally, for every 1 degree of IOL rotation, 3.3% of lens cylinder power is lost," Dr. Johnston said. "We have had wonderful results with the Acrysof Toric. It's especially rewarding to use these IOLs in patients after having corneal transplants. We can eliminate large amounts of astigmatism and eliminate the need for glasses at distance."

The Crystalens AO is the only aspheric accommodating IOL on the market in the U.S., said Dr. Johnston. Because it's a monofocal, he said, it is less likely to produce visual side effects such as night vision problems and glare and halos.

"The Crystalens performs well at distance and intermediate; however, patients usually will need a near SRX for close work," he said.

Study compares three lenses

A single-center, open-label study compared AMO's Tecnis Multifocal IOL with Alcon's ReStor +3.00 D and Crystalens IOLs.[7] The study compared corrected and uncorrected visual acuity at distance, intermediate, and near for 207 eyes. Patients also received a questionnaire assessing their level of satisfaction with their vision.

All three groups did well at distance and reported good overall visual satisfaction without correction. Both diffractive multifocal groups reported greater spectacle independence than the accommodating group. The Crystalens group had fewer reports of halos at night than the diffractive multifocal groups. The Tecnis group had the least difficulty reading without spectacles and had a higher percentage of patients report the

Pearls for success

Five pearls for success with premium intraocular lenses

1. Plano outcome
2. Proactive treatment of ocular surface disease
3. Pre-op counseling (and setting realistic expectations)
4. Properly screening candidates
5. Picking the right IOL

Plus three…

+ Picking the right surgeon
+ Posterior capsular opacification
+ Poor IOL centration

See **Pearls** on page 28

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Pearls

Continued from page 26

ability to perform activities at ease without the need of glasses and contact lenses after surgery. The Tecnis IOL also subjectively performed better at night driving, seeing distance, seeing at arms length and reading compared to ReStor.

The Crystalens patients had the highest percentage of patients 20/25 or better at intermediate VA. The Tecnis group had the highest percentage of eyes 20/25 or better at near. Results also showed that Tecnis patients had a superior performance at intermediate and near distances when compared to ReStor, while both had equivalent distance vision outcomes. One hundred percent of patients in the Tecnis IOL group had 20/40 or better distance corrected near visual acuity (DCNVA), with 98% having 20/32 or better DCNVA. In comparison, the ReStor group 90% had 20/40 or better DCNVA, and 77% had 20/32 or better DCNVA. Sixty-four percent of Tecnis patients had 20/40 or better distance corrected intermediate visual acuity compared to 44% of ReStor patients.

Premium IOL technology has improved over the years and optometrists should be comfortable recommending all three of these IOLs to their patients, said Dr. Johnston.

One baby boomer turns 65 every 8 seconds.

IN 2011

there were **78 million boomers**, of whom a record **2.8 million qualified for Medicare**.

BY 2030

4.2 million a year will cross that threshold

And three final pearls…

Three additional pearls are worth considering, said Dr. Johnston.

PEARL 1 **Pick the right surgeon.** It's helpful to work with a cataract and refractive surgeon experienced in LASIK/PRK and skilled in explanting IOLs. "The surgeon should be optometry friendly and willing to participate in co-management," he said.

PEARL 2 **Watch for posterior capsular opacification (PCO).** Even trace to mild PCO can cause problems with diffractive multifocals.

A practice treating just **five new cataract patients per month** could therefore generate **additional revenue of $86,610 per year**, and this does not include ancillary revenue sources such as eyeglasses and sunglasses, retail products, optical coherence tomography, endothelial cell counts, and A-scans. Josh Johnston, OD

PEARL 3 **Don't ignore IOL centration.** "Proper alignment and proper centration with diffractive multifocal and toric IOLs is critical. The lens should be centered on the macula, not the pupil," Dr. Johnston said.

Keep communication open and be mindful of patient expectations to help keep your cataract patients satisfied.**ODT**

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FYI

Josh Johnston, OD

Dr. Johnston disclosed a commercial relationship with Allergan.

Photo finish

Having trouble selling photochromic lenses? These optometric practices have some tips.

By Brian P. Dunleavy

Michael Lange, OD, has a unique take on photochromic eyeglass lenses.

"I believe that, for all patients who wear eyeglasses, their so-called clear or primary pair should have photochromic lenses," said Dr. Lange, owner of a 10-location optometric practice in central Florida.

"When people are out in the sun, their eyes are at least somewhat compromised when it comes to UV rays. They don't have their sunglasses with them all the time. Photochromics don't replace sunglasses, but they at least provide a level of protection from UV light that is better for the eyes than no protection at all. For patients who are going back and forth, indoors and out all day, photochromics are the perfect lens," he said.

With this philosophy, Dr. Lange sells a substantial number of photochromic lenses—in some of his practice locations, as many as 65% of his eyeglass-wearing patients wear them. Of course, not all optometrists are selling photochromic lenses at such a high rate. Industry-wide, photochromics account for roughly 25% of all spectacle lenses sold.

So are optometrists missing an opportunity to sell a premium product to a wider patient base?

Transitions Drivewear sun lenses, equipped with a polarized filter from Younger Optics, darken behind the windshield of a car to block blinding glare—a distinct advantage when driving a car.

Traditional photochromic lenses change from clear indoors to dark outdoors when exposed to UV light.

Display's the thing

Susan Blaine thinks so. Blaine, the optical manager of a six-location eyecare practice in Wisconsin with ophthalmologists and optometrists on staff, is a big advocate for photochromic lenses as well as specialty lenses with photochromic properties.

"As with any other eyeglass lens product, you have to tune into what the patient needs," she said. "You have to ask patients how they spend their time. What do they do during the day? If they're going in and out of stores shopping all day, then maybe a [photochromic] lens will work for them. If they are out on a lake in a boat, probably not."

According to Blaine, the practice she works for has devoted a significant amount of resources on point-of-purchase displays for spectacle lenses in their opticals, installing a putting green in one location, for example. Dr. Lange has installed flat-screen televisions in each of his opticals, which include promotional spots on various lens products, demonstrations of lens technologies, and information on promotional offers available to patients. He' has also developed his own brochures about premium lens products, including photochromics, that explain the technology in ways patients can easily understand. "[Photochromics] are one of the premium products we promote," he noted. "I start talking about them in the exam room, so by the time patients are in the optical, they already have a seed planted."

Rachael Click, OD, who practices in Mount Pleasant, SC, said her practice merely leverages Transitions' position as the "Kleenex" of the eyecare industry. "Because of its consumer advertising, Transitions is to photochromics as Kleenex is to facial tissue," she explained. "But, for our practice, it's more than that. We really believe in the product. We all wear the lenses ourselves, and we can all speak from experience about the benefits for patients. We also really emphasize the importance of UV protection."

To that end, the practice Web site includes the Transitions EyeGlass Guide, a lifestyle questionnaire designed to help patients select the right eyewear for their needs. Because of initiatives such as these, Dr. Click's practice was honored as the 2011 Transitions Eyecare Practice of the Year for its efforts to educate patients on the importance of UV protection for healthy sight.

Transitions Drivewear lenses keep up with constantly change daylight and weather conditions. Behind the windshield, the lenses activate to a copper color that enhances color recognition and depth perception. In bright outdoor light, the lenses activate to a dark red-brown that filters excess light.

'Changing lenses' are changing

It should be noted, though, that Blaine doesn't just sell traditional photochromics that change from clear indoors to dark outdoors when exposed to UV light—to borrow some of the language used by Transitions, the leading manufacturer of plastic photochromic lenses in the U.S. She also is a big proponent of Transitions' relatively new performance sunwear products, lenses that use photochromic technology to go from "dark to darker depending on the sun."

Available Rx-ready styles include:

- Autumn Gold lens from X-Cel Optical, which is designed for hunting and shooting and changes from a yellow to amber shade
- Bell Transitions shield for motorcycle helmets, which changes from clear to gray
- Definity Fairway lens, available from Essilor, which is designed for golfers and changes from amber to dark brown
- Transitions Drivewear, equipped with a polarized filter from Younger Optics, which is designed for driving and changes from green/yellow to copper to dark reddish-brown in response to light
- Neox Transitions, available through the wholesale labs Walman and Soderberg, which is designed for golfers and changes from G22 green to a darker green
- Oakley Transitions adaptive sunlens for runners, cyclists, and golfers, which is available in a variety of colors
- XperioTransitions adaptive polarized sunlens for runners/hikers and water-sports enthusiasts, which is available from Essilor in ash gray/dark gray or caramel/dark brown

New from Transitions is its Vantage lens. Though positioned as an everyday lens—as opposed to a sunlens—the Vantage features variable polarization. Don't forget about Transitions XTRActive lenses, designed for more activation for added protection both outdoors and indoors. XTRActive is Transitions' darkest lens outdoors, even in the hottest temperatures. It also blocks 100% of UVA and UVB rays and, perhaps most significantly, activates behind the windshield of a car.

Dr. Lange said he has used his own version of the Transitions performance lens concept in his practice for years. "For an athlete, we might dip the Transitions lens in a yellow tint so that it is yellow when clear for improved contrast," he said. "Or we might add a gray tint for increased blue light blocking for patients who have had cataract surgery. There are lots of potential uses for these products, if you're creative."

Transitions adaptive lenses can help enhance your patients' vision during outdoor sports or activities. (All photos courtesy of Transitions Optical Inc.)

Is the price right?

Ultimately, Dr. Lange said, the biggest obstacle to fitting more patients in photochromic spectacle lenses is their price tag, given that they can cost as much as $100 more than clear lenses. Dr. Lange acknowledges that photochromics have stereotypically been labeled a lens for "older patients." However, he added, "That's just because patients, at least in our area, can't afford them." In his practice, Dr. Lange has done what he can to keep prices for all premium products at affordable levels by offering promotions and package deals, finding ways to cut his lens supply and processing costs, and passing the savings on to his patients.

"At the same time," he continued, "I try to get patients out of the price mindset. Can you really put a price tag on eye health? I believe [photochromics] are a better lens option for patients' eye health. It's up to me, as the optometrist, to get them to see that. It's not selling, it's prescribing."**ODT**

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In Brief

Zyloware debuts two new spring styles

Sophia Loren M237 is a semi-rimless metal front in a geometric shape. The metal endpiece and temple feature elegant scroll designed cutouts. Handcrafted zyl temple tips and

snap-in nosepads provide additional comfort to the wearer. The SL M237 easily accommodates progressive lenses. Colors: Rose Gold and Brown (shown above).

New to the Randy Jackson Limited Edition collection is model RJ X108. This trendy round frame has a front made of Grilamid, a lightweight, durable polymer. Temples feature a fashionable metal décor near the endpiece. Also, the X108 features snap-in nosepads for perfect fit, and accommodates progressive lenses. Available colors: Black and Red Tortoise (shown above).

For more information, contact Zyloware at 800/765-3700, sales@zyloware.com, or visit *www.zyloware.com*.

Kaleidoscope Collection swings in spring colors

Trendy and colorful, the new Kaleidoscope Collection by Okia is designed to brighten up springtime. Its distinctive

color combination creates an always-changing, mysterious look.

The choice of unexpected colors includes shades of green, red, dark purple, and light blue that enrich the kaleidoscopic textures along the temples. HDA Technology has enabled unlimited design potential, translating kaleidoscope patterns on acetate with a 3-D effect.

For more information, visit Okia Optical Co. at *www.okia.com* or e-mail hd@okia.com.

REM launches V-Lites customizable eyewear

V-Lites are the truly customizable, personalizable brand extension from REM Eyewear's popular Visualites. Consumers can design their own eyewear by choosing from three lens shapes and four colors to create a look that is 100% individualized.

Offering the same lightweight feel as Visualites, the V-Lites eye size possibilities are endless thanks to the classic rimless design that fits any Rx with ease. And V-Lites are

made from ultra-light and flexible TR-90.

Shapes include traditional round, versatile pillow shape and modern rectangle. Colors include a feminine Red/Pink gradient, bold Black/Smoke gradient, and a neutral Tortoise and Crystal.

For more information, go to *www.remeyewear.com* or call REM Eyewear at 800/423-3023.

Switch adds 2 more full-frame sunglasses

Switch Vision has launched two more full-frames sunglasses, bringing the Switch Collection to 21 styles in all. Switch is

becoming known as a performance sunglass collection with its magnetic interchange technology.

See **InDispensable In Brief** on page 34

InDispensable In Brief

Continued from page 33

The Axo and Lynx styles were designed for unisex appeal. Both introduce sporty overmolds and unique color combinations. Axo is available in 3 colors—Crystal Cool Grey, Polar White, and Shiny Black (shown on page 33, bottom, right) and has a large fit size. The Lynx is also available in 3 colors—Crystal Black, Dark Tortoise, and Crystal Cool Grey.

Both styles are available in plano polarized lenses or they can be Rxed, making them ideal for outdoor enthusiasts and athletes who need to maximize optics, comfort, and eye protection, with the ability to change lenses in a matter of seconds.

For more information, go to *www.switchvision.com*.

Catherine Deneuve offers new petite sizes

The Spring 2013 collection from Catherine Deneuve Lunettes was designed with the petite woman in mind, resulting in three ophthalmic and six prescription-ready sunglass styles. The new collection features subtle logo detailing and embellishments that complement muted colors, including burgundy, gold, and pink.

Model CD-317's cat-eye inspired modified oval shaped front in acetate is chic, yet elegant. A stone-enhanced metal trim adorns the handmade acetate temples. Available in jewel-color tones of brown (shown), burgundy, and purple.

All styles include a hard case and a cleaning cloth. Merchandising materials include a one-piece highlighter, four-piece counter display, logo plaques, and counter cards featuring the current campaign image.

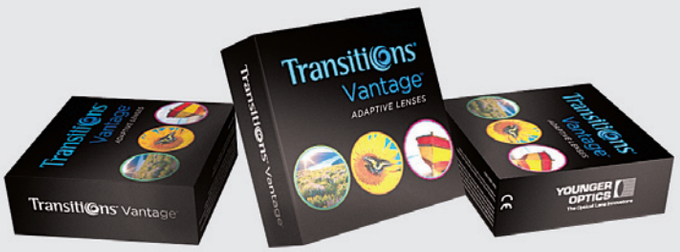
For more information, go to *www.vivagroup.com*.

Younger's PALs now in Transitions Vantage

Younger Optics now offers Transitions Vantage lenses in Image, Younger's progressive lens (PAL) design. Transitions Vantage Image lenses are available in polycarbonate, offering an Rx range of –9.00 D to +7.00 D, cylinder out to –2.00 D. Eyecare professionals can order these lenses from their full-service laboratory.

Transitions Vantage lenses feature variable polarization in bright sunlight, which helps to reduce blinding glare outdoors. According to Younger Optics, Transitions Vantage lenses offer crisper vision in outdoor sunlight compared with other everyday lenses.

Patients who are comfortable with Image progressive lenses may be candidates for Transitions Vantage lenses for their everyday eyewear. ECPs may offer Image NuPolar or Image Drivewear lenses in the same prescription for the patient's sunwear pair.



Younger Optics offers Image PALs in a range of materials and treatments, allowing ECPs greater flexibility when prescribing PALs.

For more information, go to *http://youngeroptics.com*, or call 800/877-5367.

Sun Center display made specifically for sunwear

The new Sol Sun Center by Eye Designs gives eyecare professionals a chic and modern display specifically for sunwear.

The display unit can be made to match any existing Eye Designs furniture collection or it can be incorporated into any optical interior.

The unit includes adjustable shelving in a modern frosted finish for displaying sunwear, cases, and point-of-purchase materials. The three columns of adjustable shelves plus the panel of Wave frame holders can display 92 frames. The Sol Sun Center also features backlit illumination with environmentally friendly LED lighting.

For more information, go to *www.eyedesigns.com* or call Eye Designs at 800/346-8890.

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Croquet

Continued from page 42

originally purchased was designed for children. The mallets were shorter and the balls smaller. But not having played the game since grade school, no one realized it until he and several friends attended a state tournament.

"It was too late to enter, so four of us went to watch the final game," said Dr. Huff, a third-generation family optometrist. "They were using taller mallets, bigger balls, and tighter wickets. The wickets we were using had about one and one-half inch clearance for balls. They were using wickets with clearances of one-sixteenth of an inch, about the thickness of a dime."

Because Dr. Huff and his friends planned on playing tournament croquet, they had to upgrade their equipment. They split the cost of a set of balls at $200, a set of wickets at $300, and mallets, which he compares to golf drivers, at nearly $300 each. While the game can be played on any lawn, a friend spent $3,000 to build a mini croquet court on part of his lawn, which required the yard to be bulldozed and leveled.

Aerial view of Dr. Huff's home croquet court.

"The court was two-thirds the size of a full-size court," he said. "Once we got the better equipment, we realized how hard the game was. So we played out there for 5 years or so and worked on our game."

On the tournament circuit

As Dr. Huff's croquet skills grew, so did his successes playing in national tournaments and the Georgia State Croquet Championship. He explained that there are three tournament levels or divisions: second flight, which is the easiest; first flight, which targets more experienced players, and championship flight, which attracts the game's top competitors. Once a player wins first place in a flight, he can no longer compete in that division. The player must advance to the next level.

In 1999, Dr. Huff won first place in the second flight. Two years later, he competed in croquet Nationals at West Palm Beach, FL.

"I wanted to see how I ranked nationally," he said. "I came in second place in first flight in doubles. The next year I won second place in first flight in singles."

His passion for the game inspired him to build his very own croquet court, which is now on the Georgia state tournament circuit. Dr. Huff said that every other year, croquet players compete in his own backyard—literally. Other times, he hosts pickup tournaments for beginners and unofficial games for former champions, giving him the opportunity to play against the sport's top competitors.

On a national level, Dr. Huff said his best tournament was played on his own lawn. He came in second when competing against seven previous and future national champions.

> 'There's no real prize money playing croquet. It's more for fun and bragging rights.'
>
> James C. Huff, OD

Dr. Huff has no plans to quit playing the game anytime soon. He said most players are retired and fall between the ages of 60 and 80.

"I need to find a way to retire so I can play more and get better," he said. "There's no real prize money playing croquet. It's more for fun and bragging rights."**ODT**

FYI

James C. Huff, OD
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loteprednol etabonate
ophthalmic gel 0.5%

Brief Summary: Based on full prescribing information.

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

INDICATIONS AND USAGE

LOTEMAX is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

DOSAGE AND ADMINISTRATION

Invert closed bottle and shake once to fill tip before instilling drops.

Apply one to two drops of LOTEMAX into the conjunctival sac of the affected eye four times daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.

CONTRAINDICATIONS

LOTEMAX, as with other ophthalmic corticosteroids, 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.

WARNINGS AND PRECAUTIONS

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.

Cataracts

Use of corticosteroids may result in posterior subcapsular cataract formation.

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 slit lamp biomicroscopy and, where appropriate, fluorescein staining.

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.

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).

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.

Contact Lens Wear

Patients should not wear contact lenses during their course of therapy with LOTEMAX.

ADVERSE REACTIONS

Adverse 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.

The most common adverse drug reactions reported were anterior chamber inflammation (5%), eye pain (2%), and foreign body sensation (2%).

USE IN SPECIFIC POPULATIONS

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 flexures) 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 with 0.5 mg/kg/day (6 times the maximum 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.

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

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 appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when LOTEMAX is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment Of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma tk assay, or in a chromosome aberration test in human lymphocytes, or *in vivo* in the single dose mouse micronucleus assay. Treatment of male and female rats with up to 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (600 and 300 times the maximum clinical dose, respectively) prior to and during mating did not impair fertility in either gender.

PATIENT COUNSELING INFORMATION

Administration

Invert closed bottle and shake once to fill tip before instilling drops.

Risk of Contamination

Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the gel.

Contact Lens Wear

Patients should be advised not to wear contact lenses when using LOTEMAX.

Risk of Secondary Infection

If pain develops, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician.

FOR MORE DETAILED INFORMATION, PLEASE READ THE PRESCRIBING INFORMATION.

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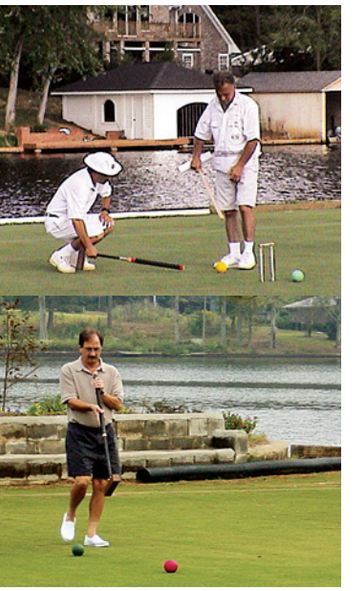

Top: Dr. Huff assists partner David Fell with ball placement. Bottom: Dr. Huff practicing at home. Left: Wide-ange ground view of Dr. Huff's home court.

Eye doctor plays tournament croquet on national level

Optometrist converts backyard into a world-class croquet court

By Carol Patton

James C. Huff, OD, and his wife live in a beautiful home in Carrollton, GA, surrounded by a lake on three sides. That's why Mrs. Huff wasn't exactly thrilled when her husband spent roughly $70,000 to create a championship-sized croquet court in their yard. The project meant cutting down nearly 50 mature trees, some 100-feet tall, to create a perfectly flat 9,000 square-foot area plus a sea wall to avoid erosion of the land.

Some people may call Dr. Huff crazy. He is crazy—crazy in love with croquet and maintaining a world-class lawn. The attraction started rather innocently back in the late 1990s when the Huffs were shopping for a fun game they could play with their friends at an upcoming party. By the time the event ended, Dr. Huff and several guests were hooked.

Since then, he and his friends have played croquet twice a week and compete in state and national tournaments. Dr. Huff has won numerous awards and hosts unofficial tournaments in his yard, enabling him to compete with the game's most skilled players.

Dr. Huff practices at home on his own croquet court.

The right stuff

Dr. Huff said the game is like playing chess, billiards, and golf all at the same time. According to the U.S. rules for domestic croquet (*www.croquetamerica.com*), otherwise known as six-wicket games, the object of the game is to get your team's two balls through all of the hoops—also called wickets—in the proper order and hit the center peg before your opponent.

Unknown to Dr. Huff, the croquet set he

See **Croquet** on page 40

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- LOTEMAX® GEL 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
- 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. If this product is used for 10 days or longer, IOP should be monitored
- Cataracts—Use of corticosteroids may result in posterior subcapsular cataract formation
- Delayed healing—Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation and occurrence of perforations in those with diseases causing corneal and scleral thinning. 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
- 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 infections
- Viral infections—Use of 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 exacerbate the severity of many viral infections of the eye (including herpes simplex)
- 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
- Contact lens wear—Patients should not wear contact lenses when using LOTEMAX® GEL
- The most common ocular adverse drug reactions were anterior chamber inflammation (5%), eye pain (2%) and foreign body sensation (2%)

Please see brief summary of full prescribing information on adjacent page.

*Ophthalmic corticosteroid.

References: 1. LOTEMAX GEL Prescribing Information, September 2012. **2.** Fong R, Leitritz M, Siou-Mermet R, Erb T. Loteprednol etabonate gel 0.5% for postoperative pain and inflammation after cataract surgery: results of a multicenter trial. *Clin Ophthalmol.* 2012;6:1113-1124. **3.** Data on file, Bausch & Lomb Incorporated.

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