August 1, 2013
VOL. 38, NO. 15

Ophthalmology Times®
CLINICAL NEWS & ANALYSIS

SPECIAL REPORT INTRAOCULAR LENSES
TIPS FOR TORIC IOL MARKING // TAPPING INTO TORIC TECHNOLOGY

AMO acquires OptiMedica

WHAT THE $400 MILLION DEAL BRINGS TO LASER CATARACT SURGERY MARKET

By Jennifer A. Webb

ABBOTT PARK, IL ::
Abbott Medical Optics (AMO) will expand into the femtosecond laser-assisted cataract surgery market with the acquisition of Silicon Valley, CA-based OptiMedica Corp. and its Catalys Precision Laser System for up to $400 million.

The deal, announced July 15, allows AMO to jump into an emerging technology that already has won market clearance in 14 countries.

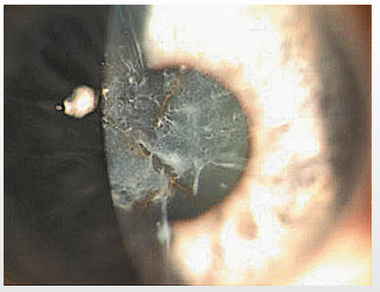
More than 60 units of the laser system, which received FDA approval in 2011, have been used to perform more than 25,000 laser procedures in practices around the world, said Mark J. Forchette, OptiMedica's president and chief executive officer.

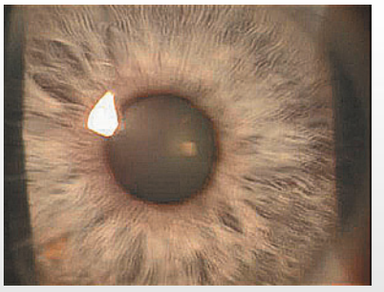
Although most cataract surgeries

(Continues on page 9 : **Acquisition**)

70%
OF HIGH-VOLUME CATARACT CENTERS IN THE U.S. ARE EXPECTED TO PERFORM ***LASER-ASSISTED CATARACT SURGERY*** OVER THE NEXT FEW YEARS

'Gloves Off with Gulani'





In an era of raised expectations, advanced technologies, and dedicated pursuit of"super-vision," *Ophthalmology Times* will introduce a new column in the Sept. 1 issue, "Gloves Off with Gulani," by Arun C. Gulani, MD. This new series will focus on Dr. Gulani's surgical concept that combines all levels of anterior segment surgery to attain the goal of unaided emmetropia or best vision potential. The column will offer cases similar to this patient (above) with scarred central cornea and a history of RK surgery and legal blindness. *See story on page 23*

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Editorial

ARE WE PHYSICIANS WORKING HARD OR HARDLY WORKING?

By Peter J. McDonnell, MD

IN 1930, ECONOMIST JOHN MAYNARD KEYNES AND evolutionary biologist Julian Huxley independently predicted that technologic advancements and increased productivity would result in humans working only 2 days per week.

In 1965, a Senate subcommittee piped in with its analysis that Americans would work 14 hours per week by the year 2000 and take at least 7 weeks of vacation. No less an authority, my father, in a speech in the mid-1960s, asserted that thanks to labor-saving devices like washing machines and dishwashers, Americans would soon

(See story on page 4 : **Editorial**)

Glaucoma

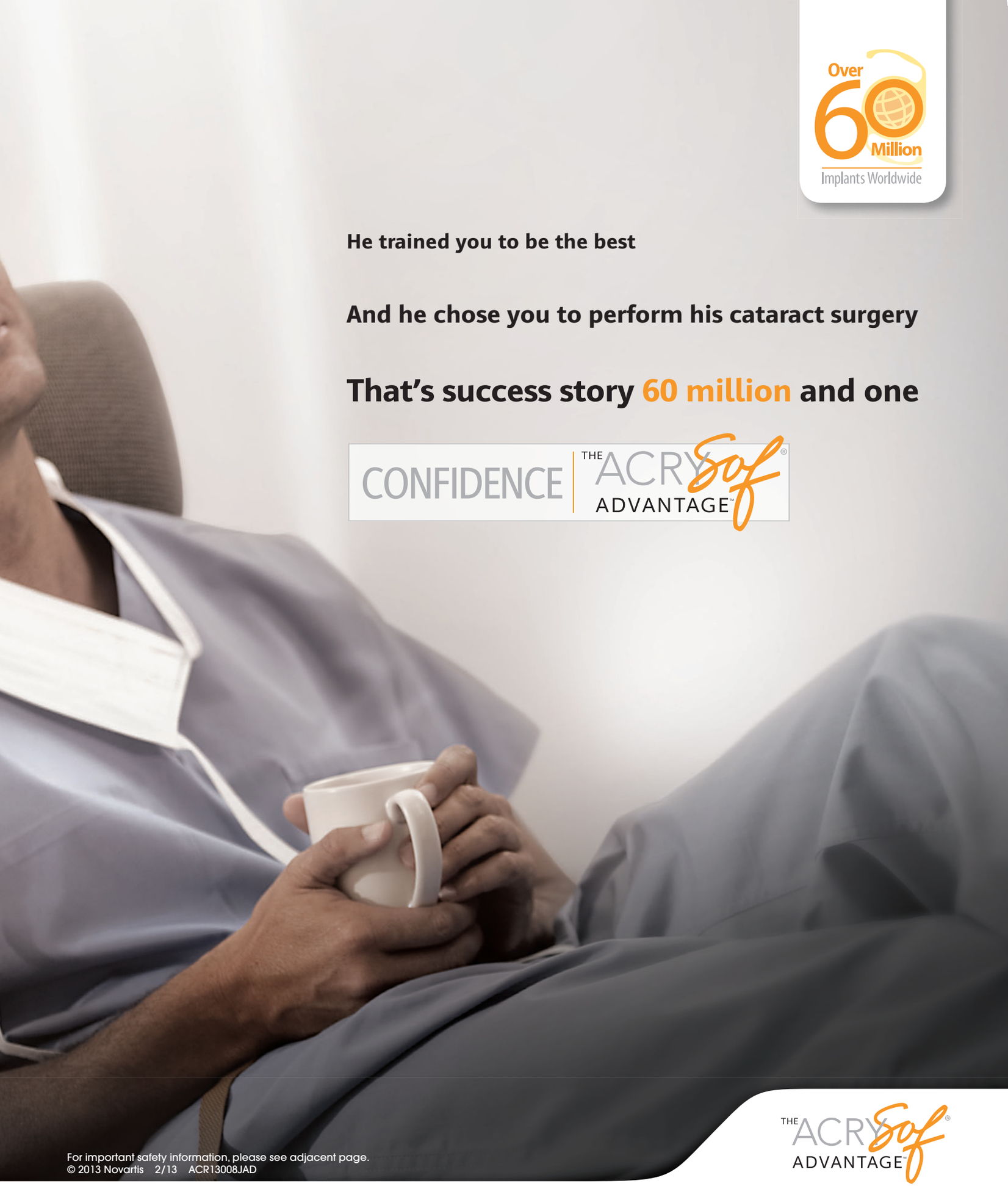
WHY A HEALTHY LIFESTYLE MAY BE BEST PRESCRIPTION

SAN FRANCISCO :: **MARKET DATA AND OTHER** research pointing to the popularity of alternative therapies—combined with evidence that these interventions may not be as benign as consumers believe—underscore the need for ophthalmologists to be prepared to speak about this issue with their patients with glaucoma.

"It's a shame to see a lot of money being spent on ineffective alternative therapies," said John Hetherington Jr., MD, clinical professor of ophthalmology, University of California, San Francisco.

"But the concern extends beyond the

(See story on page 10 : **Lifestyle**)



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Optical theory suggests that high astigmatic patients (i.e. > 2.5 D) may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ Toric Cylinder Power IOLs.
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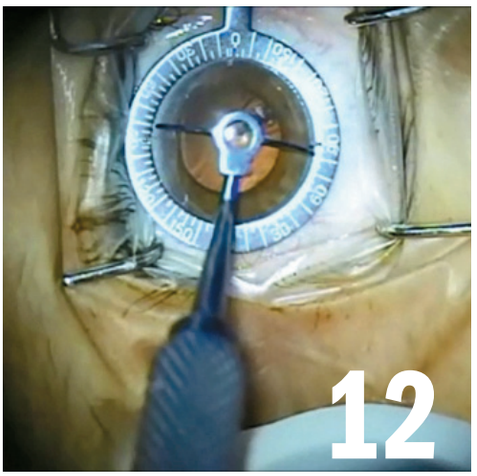
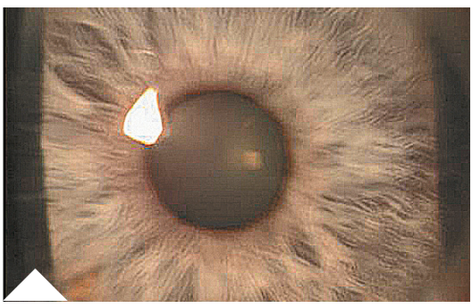


Glaucoma



Refractive

Practice Management

Special Report

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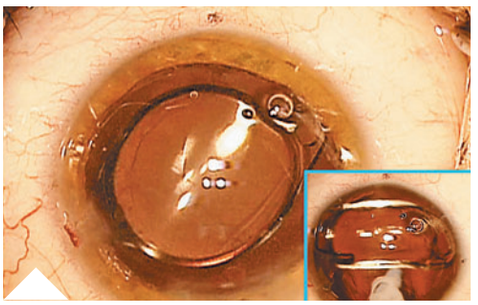

Working hard, hardly working?

Where the experts may have gotten this one wrong

By Peter J. McDonnell, MD

director of the Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, and chief medical editor of *Ophthalmology Times*.

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- **In 30 years, cataract surgery has changed from a 3-day hospitalization to a 3-hour visit to a surgery center.**
- **Vitrectomies that once took 6 hours now take 45 minutes.**
- **Brain tumors affecting vision—their diagnoses once taking many hours of examination, including pneumoencephalography—are now identified promptly by ubiquitous computed tomography and nuclear magnetic resonance imaging devices located in every shopping mall.**

IN 1930, ECONOMIST John Maynard Keynes and evolutionary biologist Julian Huxley independently predicted that technologic advancements and increased productivity would result in humans working only 2 days per week.[1]

In 1965, a Senate subcommittee piped in with its analysis that Americans would work 14 hours per week by the year 2000 and take at least 7 weeks of vacation. No less an authority, my father, in a speech in the mid-1960s, asserted that thanks to labor-saving devices like washing machines and dishwashers, Americans would soon be struggling with the issue of how to use all their free time.

According to Huxley: "The human being can consume so much and no more. When we reach the point when the world produces all the goods that it needs in 2 days, as it inevitably will, we must curtail our production of goods and turn our attention to the great problem of what to do with our new leisure." Pretty self-evident stuff.

HOW'S THAT WORKING FOR YOU?

So how did these experts' predictions work out for you? Bored to tears with all the free time and nothing to do? Are you ophthalmologists currently getting your 14 hours of work per week done in 2 days or 1 long day in the office?

Of course, the experts got this one wrong. Ophthalmologists today work an average of 47 hours per week. That's more hours than dermatologists (45.5) and emergency medicine physicians (46), but less than orthopedic surgeons (58) and urologists (60.5).[2]

So what went wrong to make liars out of geniuses like Keynes and Huxley and even defy a Senate subcommittee (the nerve!)? It is not as though we ophthalmologists have failed to introduce timesaving technology into our profession.

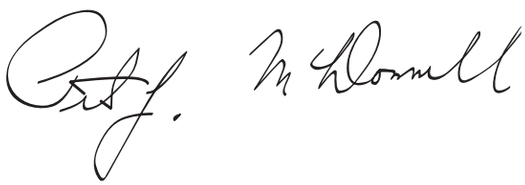
PREDICTION AND REALITY

My explanation for the huge discrepancy between prediction and reality, I am sad to say, is that Huxley's (and my father's) basic premise that humans can only consume "so much and no more" was naïve.

When it comes to food and drink, we are able to consume vastly larger quantities than did our grandparents (hence, the obesity epidemic). Along with our waistlines, our homes have expanded as well, growing from an average of about 800 square feet in the early 20th century to 1,000 square feet in 1950 and 2,200 square feet in the year 2010.[3] I admit to having a much nicer car than I "need," and if my father were alive today he would probably be disappointed in me for the extravagance.

Plus, ever-larger flat-screen TVs and the latest smartphones and tablets have become modern-day necessities, have they not?

Bottom line: Most ophthalmologists are looking at a 5-day workweek for the foreseeable future, and leisure time remains a limited and precious commodity. How best to spend it? By reading *Ophthalmology Times*, of course! ■



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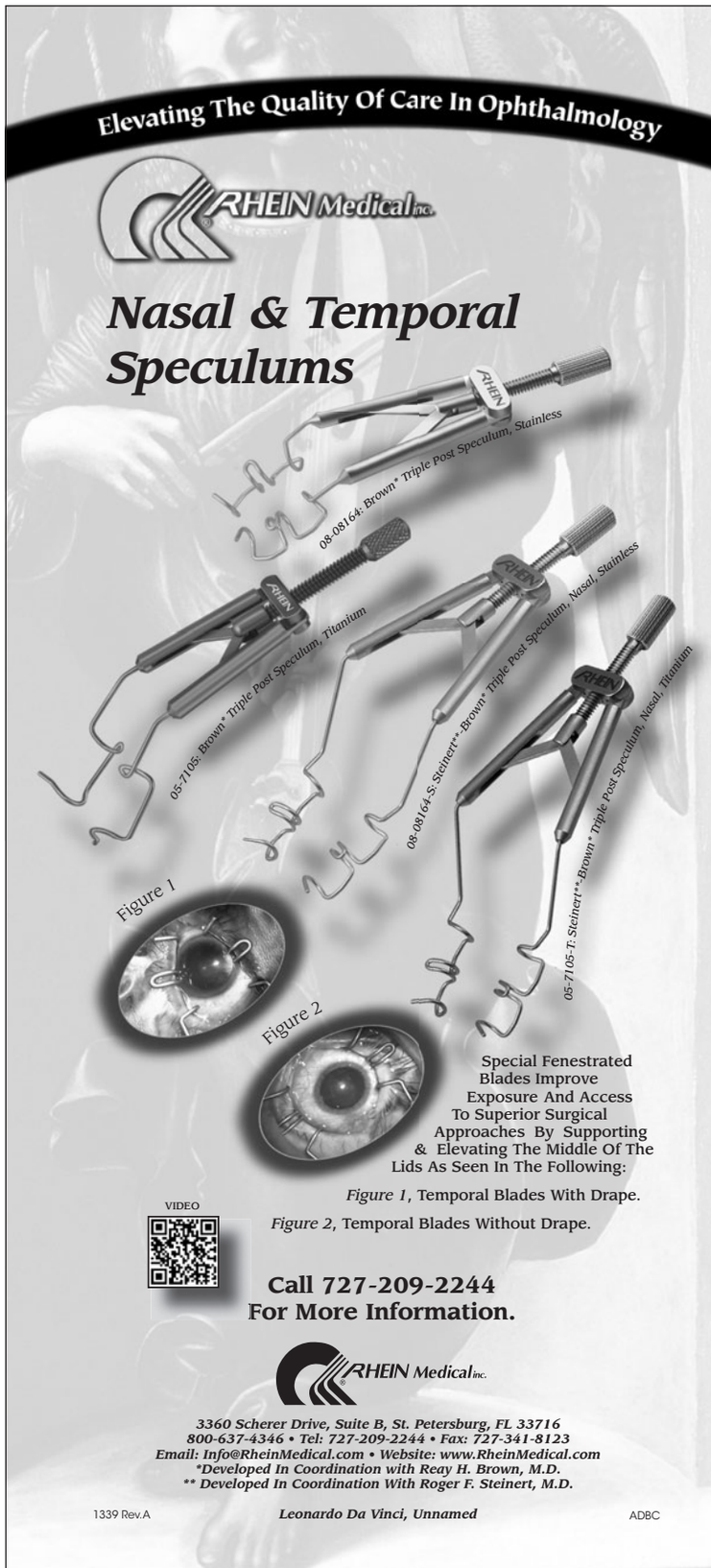
In partnership with our readers, we will achieve mutual success by:

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



Compensation tops physicians' concerns in survey

By Cody Erbacher

More than half of the physicians questioned in the 2013 Physician Practice Preference Survey said compensation is their greatest career concern.

According to the survey conducted by The Medicus Firm, just 32.8% of physicians were satisfied with their 2012 compensation.

The rest of the physician pool reported earnings that did not match the workload, except for the minority (2.6%) that were beyond satisfied with their income.

That's causing nearly one-third (27.8%) of physicians to consider a career change, according to the survey, which accounted for a total of 2,568 physicians representing 19 specialties in 50 states.

The problem isn't just going to disappear, either.

Almost three-fourths of physicians anticipate that their 2013 income will remain about the same, or decrease from their 2012 earnings.

WHAT'S THE MAJOR CAUSE LIMITING INCOME?

Thirty percent of physicians say its reimbursement; while just over 12% say the main factor limiting income is changes stemming from health-care reform.

For these reasons, nearly one-third (30.7%) of in-practice physicians say that financial reward is the biggest single factor in making a change in practice status. While 24.2% say the quality of the practice is a viable option for change.

The practice setting that appeals to physicians the most is single-specialty group/partnership. That option accounts for 28.4% of the in-practice physicians surveyed.

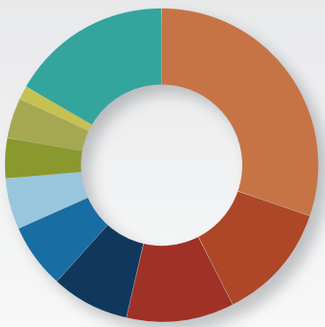
Although in-practice physicians favor the single-specialty group, 28.1% of in-training physicians prefer to be hospital employed.

A hospital practice setting does appeal to the in-practice physician, though.

And the statistics back up that theory. About one in every five physicians say they would prefer a hospital setting, while 24.6% of the physicians surveyed said they closed/left private practice, or plan to in 2013, for employment by hospital or health system.

Other results: 51.6% of physicians will be implementing an electronic health records system, and nearly half (44.6%) will increase working hours. ■

Which of the following do you feel limits your income the most?



30.3%	Reimbursement decreases
12.2%	Changes stemming from health-care reform
11.1%	Personal choice (to work less and earn less)
8.2%	Patient volume/Patient load
6.5%	Payer mix
5.5%	Overhead increases
4.1%	Competition with other physicians
4.1%	Inefficiency
1.5%	Malpractice premium costs
16.4%	Other

(Source: The Medicus Firm's 2013 Physician Practice Preference Survey)

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TRANSITIONS SHIFTS MAJORITY STAKE

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http://bit.ly/13BkfmU

TOPCON LASER GETS 510(K) CLEARANCE

TOPCON MEDICAL LASER SYSTEMS HAS RECEIVED FDA 510(k) clearance for its portable, dual-port, pattern-scanning laser (PASCAL Synthesis). Available in either 532- or 577-nm wavelengths, the device will allow fast and effective treatment of retinal disorders using clinically proven technology, while offering ophthalmologists the option of keeping their current slit lamp set-up, according to the company.
http://bit.ly/17oQCqk

RESEARCH RIGHT AT PHYSICIANS' HANDS

OPHTHALMOLOGISTS AND OTHER PHYSICIANS are finding it more challenging to stay on top of all the clinical research and information that is presented before them. Digital devices may help physicians absorb all this information.
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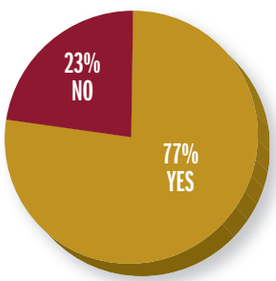
■ Yes, I do.
■ No, I employ an optometrist to do them.

YOU SAID:



NEW

For the treatment of elevated IOP

UNLOCK NEW TREATMENT POSSIBILITIES

SIMBRINZA™ Suspension provided additional 1-3 mm Hg IOP lowering compared to the individual components[1]

- IOP measured at 8 AM, 10 AM, 3 PM, and 5 PM was reduced by **21-35%** at Month 3[2-4]
- Efficacy proven in two pivotal Phase 3 randomized, multicenter, double-masked, parallel-group, 3-month, 3-arm, contribution-of-elements studies[2,3]
- The most frequently reported adverse reactions (3-5%) were blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy[1]
- Only available beta-blocker-free fixed combination[2,3]

INDICATIONS AND USAGE

SIMBRINZA™ (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% is a fixed combination indicated in the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration

The recommended dose is one drop of SIMBRINZA™ Suspension in the affected eye(s) three times daily. Shake well before use. SIMBRINZA™ Suspension may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

IMPORTANT SAFETY INFORMATION

Contraindications

SIMBRINZA™ Suspension is contraindicated in patients who are hypersensitive to any component of this product and neonates and infants under the age of 2 years.

Warnings and Precautions

Sulfonamide Hypersensitivity Reactions—Brinzolamide is a sulfonamide, and although administered topically, is absorbed systemically. Sulfonamide attributable adverse reactions may occur. Fatalities have occurred due to severe reactions to sulfonamides. Sensitization may recur when a sulfonamide is readministered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

Corneal Endothelium—There is an increased potential for developing corneal edema in patients with low endothelial cell counts.

Severe Hepatic or Renal Impairment (CrCl <30 mL/min)—SIMBRINZA™ Suspension has not been specifically studied in these patients and is not recommended.

Adverse Reactions

In two clinical trials of 3 months' duration with SIMBRINZA™ Suspension, the most frequent reactions associated with its use occurring in approximately 3-5% of patients in descending order of incidence included: blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy. Adverse reaction rates with SIMBRINZA™ Suspension were comparable to those of the individual components. Treatment discontinuation, mainly due to adverse reactions, was reported in 11% of SIMBRINZA™ Suspension patients.

Drug Interactions—Consider the following when prescribing SIMBRINZA™ Suspension:

Concomitant administration with oral carbonic anhydrase inhibitors is not recommended due to the potential additive effect. Use with high-dose salicylate may result in acid-base and electrolyte alterations. Use with CNS depressants may result in an additive or potentiating effect. Use with antihypertensives/cardiac glycosides may result in additive or potentiating effect on lowering blood pressure. Use with tricyclic antidepressants may blunt the hypotensive effect of systemic clonidine and it is unknown if use with this class of drugs interferes with IOP lowering. Use with monoamine oxidase inhibitors may result in increased hypotension.

For additional information about SIMBRINZA™ Suspension, please see Brief Summary of full Prescribing Information on adjacent page.

References: 1. SIMBRINZA™ Suspension Package Insert. **2.** Katz G, DuBiner H, Samples J, et al. Three-month randomized trial of fixed-combination brinzolamide, 1%, and brimonidine, 0.2% [published online ahead of print April 11, 2013]. *JAMA Ophthalmol.* doi:10.1001/jamaophthalmol.2013.188. **3.** Nguyen QH, McMenemy MG, Realini T, et al. Phase 3 randomized 3-month trial with an ongoing 3-month safety extension of fixed-combination brinzolamide 1%/brimonidine 0.2%. *J Ocul Pharmacol Ther.* 2013;29(3):290-297. **4.** Data on file, 2013.

NEW

SIMBRINZA™

(brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2%

ONE BOTTLE. NEW POSSIBILITIES.

Alcon®

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BRIEF SUMMARY OF PRESCRIBING INFORMATION
INDICATIONS AND USAGE

SIMBRINZA™ (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% is a fixed combination of a carbonic anhydrase inhibitor and an alpha 2 adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION

The recommended dose is one drop of SIMBRINZA™ Suspension in the affected eye(s) three times daily. Shake well before use. SIMBRINZA™ Suspension may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

DOSAGE FORMS AND STRENGTHS

Suspension containing 10 mg/mL brinzolamide and 2 mg/mL brimonidine tartrate.

CONTRAINDICATIONS

Hypersensitivity - SIMBRINZA™ Suspension is contraindicated in patients who are hypersensitive to any component of this product.

Neonates and Infants (under the age of 2 years) - SIMBRINZA™ Suspension is contraindicated in neonates and infants (under the age of 2 years*) see Use in Specific Populations*

WARNINGS AND PRECAUTIONS

Sulfonamide Hypersensitivity Reactions - SIMBRINZA™ Suspension contains brinzolamide, a sulfonamide, and although administered topically is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration of SIMBRINZA™ Suspension. Fatalities have occurred due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sensitization may recur when a sulfonamide is re-administered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation *[see Patient Counseling Information]*

Corneal Endothelium - Carbonic anhydrase activity has been observed in both the cytoplasm and around the plasma membranes of the corneal endothelium. There is an increased potential for developing corneal edema in patients with low endothelial cell counts. Caution should be used when prescribing SIMBRINZA™ Suspension to this group of patients.

Severe Renal Impairment - SIMBRINZA™ Suspension has not been specifically studied in patients with severe renal impairment (CrCl < 30 mL/min). Since brinzolamide and its metabolite are excreted predominantly by the kidney, SIMBRINZA™ Suspension is not recommended in such patients.

Acute Angle-Closure Glaucoma - The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. SIMBRINZA™ Suspension has not been studied in patients with acute angle-closure glaucoma.

Contact Lens Wear - The preservative in SIMBRINZA™, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA™ Suspension but may be reinserted 15 minutes after instillation *[see Patient Counseling Information]*.

Severe Cardiovascular Disease - Brimonidine tartrate, a component of SIMBRINZA™ Suspension, has a less than 5% mean decrease in blood pressure 2 hours after dosing in clinical studies; caution should be exercised in treating patients with severe cardiovascular disease.

Severe Hepatic Impairment - Because brimonidine tartrate, a component of SIMBRINZA™ Suspension, has not been studied in patients with hepatic impairment, caution should be exercised in such patients.

Potentiation of Vascular Insufficiency - Brimonidine tartrate, a component of SIMBRINZA™ Suspension, may potentiate syndromes associated with vascular insufficiency. SIMBRINZA™ Suspension should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangitis obliterans.

Contamination of Topical Ophthalmic Products After Use - There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers have been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface *[see Patient Counseling Information]*.

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 the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

SIMBRINZA™ Suspension - In two clinical trials of 3 months duration 435 patients were treated with SIMBRINZA™ Suspension, and 915 were treated with the two individual components. The most frequently reported adverse reactions in patients treated with SIMBRINZA™ Suspension occurring in approximately 3 to 5% of patients in descending order of incidence were blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy. Rates of adverse reactions reported with the individual components were comparable. Treatment discontinuation, mainly due to adverse reactions, was reported in 11% of SIMBRINZA™ Suspension patients.

Other adverse reactions that have been reported with the individual components during clinical trials are listed below.

Brinzolamide 1% - In clinical studies of brinzolamide ophthalmic suspension 1%, the most frequently reported adverse reactions reported in 5 to 10% of patients were blurred vision and bitter, sour or unusual taste. Adverse reactions occurring in 1 to 5% of patients were blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperemia, ocular discharge, ocular discomfort, ocular keratitis, ocular pain, ocular pruritus and rhinitis.

The following adverse reactions were reported at an incidence below 1%: allergic reactions, alopecia, chest pain, conjunctivitis, diarrhea, diplopia, dizziness, dry mouth, dyspnea, dyspepsia, eye fatigue, hypertonia, keratoconjunctivitis, keratopathy, kidney pain, lid margin crusting or sticky sensation, nausea, pharyngitis, tearing and urticaria.

Brimonidine Tartrate 0.2% - In clinical studies of brimonidine tartrate 0.2%, adverse reactions occurring in approximately 10 to 30% of the subjects, in descending order of incidence, included oral dryness, ocular hyperemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.

Reactions occurring in approximately 3 to 9% of the subjects, in descending order included corneal staining/erosion, photophobia, eyelid erythema, ocular ache/pain, ocular dryness, tearing, upper respiratory symptoms, eyelid edema, conjunctival edema, dizziness, blepharitis, ocular irritation, gastrointestinal symptoms, asthenia, conjunctival blanching, abnormal vision and muscular pain.

The following adverse reactions were reported in less than 3% of the patients: lid crusting, conjunctival hemorrhage, abnormal taste, insomnia, conjunctival discharge, depression, hypertension, anxiety, palpitations/arrhythmias, nasal dryness and syncope.

Postmarketing Experience - The following reactions have been identified during postmarketing use of brimonidine tartrate ophthalmic solutions in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to brimonidine tartrate ophthalmic solutions, or a combination of these factors, include: bradycardia, hypersensitivity, iritis, keratoconjunctivitis sicca, miosis, nausea, skin reactions (including erythema, eyelid pruritus, rash, and vasodilation), and tachycardia.

Apnea, bradycardia, coma, hypotension, hypothermia, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported in infants receiving brimonidine tartrate ophthalmic solutions *[see Contraindications]*.

DRUG INTERACTIONS

Oral Carbonic Anhydrase Inhibitors - There is a potential for an additive effect on the known systemic effects of carbonic anhydrase inhibition in patients receiving an oral carbonic anhydrase inhibitor and brinzolamide ophthalmic suspension 1%, a component of SIMBRINZA™ Suspension. The concomitant administration of SIMBRINZA™ Suspension and oral carbonic anhydrase inhibitors is not recommended.

High-Dose Salicylate Therapy - Carbonic anhydrase inhibitors may produce acid-base and electrolyte alterations. These alterations were not reported in the clinical trials with brinzolamide ophthalmic suspension 1%. However, in patients treated with oral carbonic anhydrase inhibitors, rare instances of acid-base alterations have occurred with high-dose salicylate therapy. Therefore, the potential for such drug interactions should be considered in patients receiving SIMBRINZA™ Suspension.

CNS Depressants - Although specific drug interaction studies have not been conducted with SIMBRINZA™, the possibility of an additive or potentiating effect with CNS depressants (alcohol, opiates, barbiturates, sedatives, or anesthetics) should be considered.

Antihypertensives/Cardiac Glycosides - Because brimonidine tartrate, a component of SIMBRINZA™ Suspension, may reduce blood pressure, caution in using drugs such as antihypertensives and/or cardiac glycosides with SIMBRINZA™ Suspension is advised.

Tricyclic Antidepressants - Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with SIMBRINZA™ Suspension in humans can lead to resulting interference with the IOP lowering effect. Caution is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines.

Monoamine Oxidase Inhibitors - Monoamine oxidase (MAO) inhibitors may theoretically interfere with the metabolism of brimonidine tartrate and potentially result in an increased systemic side-effect such as hypotension. Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

USE IN SPECIFIC POPULATIONS

Pregnancy - *Pregnancy Category C:* Developmental toxicity studies with brinzolamide in rabbits at oral doses of 1, 3, and 6 mg/kg/day (20, 60, and 120 times the recommended human ophthalmic dose) produced maternal toxicity at 6 mg/kg/day and a significant increase in the number of fetal variations, such as accessory skull bones, which was only slightly higher than the historic value at 1 and 6 mg/kg. In rats, statistically decreased body weights of fetuses from dams receiving oral doses of 18 mg/kg/day (180 times the recommended human ophthalmic dose) during gestation were proportional to the reduced maternal weight gain, with no statistically significant effects on organ or tissue development. Increases in unossified sternebrae, reduced ossification of the skull, and unossified hyoid that occurred at 6 and 18 mg/kg were not statistically significant. No treatment-related malformations were seen. Following oral administration of ^{14}C-brinzolamide to pregnant rats, radioactivity was found to cross the placenta and was present in the fetal tissues and blood.

Developmental toxicity studies performed in rats with oral doses of 0.66 mg brimonidine base/kg revealed no evidence of harm to the fetus. Dosing at this level resulted in a plasma drug concentration approximately 100 times higher than that seen in humans at the recommended human ophthalmic dose. In animal studies, brimonidine crossed the placenta and entered into the fetal circulation to a limited extent.

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

Nursing Mothers - In a study of brinzolamide in lactating rats, decreases in body weight gain in offspring at an oral dose of 15 mg/kg/day (150 times the recommended human ophthalmic dose) were observed during lactation. No other effects were observed. However, following oral administration of ^{14}C-brinzolamide to lactating rats, radioactivity was found in milk at concentrations below those in the blood and plasma. In animal studies, brimonidine was excreted in breast milk.

It is not known whether brinzolamide and brimonidine tartrate are excreted in human milk following topical ocular administration. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from SIMBRINZA™ (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2%, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use - The individual component, brinzolamide, has been studied in pediatric glaucoma patients 4 weeks to 5 years of age. The individual component, brimonidine tartrate, has been studied in pediatric patients 2 to 7 years old. Somnolence (50-83%) and decreased alertness was seen in patients 2 to 6 years old. SIMBRINZA™ Suspension is contraindicated in children under the age of 2 years *[see Contraindications]*.

Geriatric Use - No overall differences in safety or effectiveness have been observed between elderly and adult patients.

OVERDOSAGE

Although no human data are available, electrolyte imbalance, development of an acidotic state, and possible nervous system effects may occur following an oral overdose of brinzolamide. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored.

Very limited information exists on accidental ingestion of brimonidine in adults; the only adverse event reported to date has been hypotension. Symptoms of brimonidine overdose have been reported in neonates, infants, and children receiving brimonidine as part of medical treatment of congenital glaucoma or by accidental oral ingestion. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.

PATIENT COUNSELING INFORMATION

Sulfonamide Reactions - Advise patients that if serious or unusual ocular or systemic reactions or signs of hypersensitivity occur, they should discontinue the use of the product and consult their physician.

Temporary Blurred Vision - Vision may be temporarily blurred following dosing with SIMBRINZA™ Suspension. Care should be exercised in operating machinery or driving a motor vehicle.

Effect on Ability to Drive and Use Machinery - As with other drugs in this class, SIMBRINZA™ Suspension may cause fatigue and/or drowsiness in some patients. Caution patients who engage in hazardous activities of the potential for a decrease in mental alertness.

Avoiding Contamination of the Product - Instruct patients that ocular solutions, if handled improperly or if the tip of the dispensing container contacts the eye or surrounding structures, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions *[see Warnings and Precautions]*. Always replace the cap after using. If solution changes color or becomes cloudy, do not use. Do not use the product after the expiration date marked on the bottle.

Intercurrent Ocular Conditions - Advise patients that if they have ocular surgery or develop an intercurrent ocular condition (e.g., trauma or infection), they should immediately seek their physician's advice concerning the continued use of the present multidose container.

Concomitant Topical Ocular Therapy - If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

Contact Lens Wear - The preservative in SIMBRINZA™, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA™ Suspension, but may be reinserted 15 minutes after instillation.

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6,316,441

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ACQUISITION

(Continued from page 1)

TAKE-HOME

Abbott announced it intends to purchase Silicon Valley, CA-based ophthalmic device company OptiMedica Corp., as well as Brazilian ophthalmic surgical distributor Vistatek. The acquisition of OptiMedica will enable Abbott to expand its vision-care business into the femtosecond laser-assisted cataract surgery market.

are performed manually, about 20% of high-volume cataract centers in the United States perform laser-assisted cataract surgery, said Murthy Simhambhatla, PhD, AMO president. The company expects that percentage to grow to 70% over the next few years.

"I have absolutely no doubt that this will evolve much like phacoemulsification has become a mainstay of cataract surgery, so it's important to evolve it rapidly to meet customers' needs," Dr. Simhambhatla said.

The laser technology is hailed for its ability to produce uniform, noninvasive incisions to replace some of the most technically demanding and variable aspects of cataract surgery.

"It's a great way for surgical centers to differentiate themselves and offer patients the latest and best technology," he said. "There will be growth in this very attractive segment in the near term, then a second wave of growth as medium-volume centers and national health-care systems start to adopt this over time."

While there are several femtosecond laser-assisted systems on the market, Dr. Simhambhatla said the Catalys offers two distinct advantages with its imaging component of the integrated three-dimensional, optical coherence tomography and the smooth, liquid interface with patients.

"We're very excited about the interface that OptiMedica has developed," he said.

AMO will distribute the laser system through its global sales force, which will be able to offer customers a full portfolio of products for cataract surgery, he said.

The transaction is expected to close by the end of the year. Cataract-related sales account for about 60% of Abbott's vision-care segment.

ACQUISITIONS ABOUND

The OptiMedica acquisition was one of two vision-care-related deals Abbott revealed July 15, including the acquisition of ophthalmic surgical distributor Vistatek (see "Abbott purchase expands presence in Brazilian vision-care market"). The company also announced a $310 million deal to acquire IDEV Technologies, a Texas developer of medical devices for interventional radiologists, vascular surgeons, and cardiologists.

"While organic growth remains our top priority, these acquisitions bring Abbott leading technologies to capitalize on growth opportunities," said Miles D. White, chairman and chief executive officer, to analysts in a second-quarter earnings conference call 2 days later. As the market shifts toward premium IOLs, more surgeons will choose to invest in a laser-assisted system for cataract surgery, he added.

Forchette and Dr. Simhambhatla said they expect to build on the laser system with related laser techniques.

"Every step of the way, we've seen great opportunities for products that leverage this technology," Forchette said.

"As soon as we saw we could deliver a capsulotomy with precise size, shape, and position, and that we could consistently fragment and soften the nucleus, it drove us to think about just how far we can take this technology," he said. "It was very natural to think about how this technology interacts with the capsule, lens, and nuclear disassembly technologies—and it becomes a tremendous platform for thought and further innovation."

Integration details—including how many of the OptiMedica staff members are retained by AMO—have yet to be decided, they said.

"We're very excited about the quality of the talent at OptiMedica," Dr. Simhambhatla said. "They have a proven track record of bringing things to market." ■

Abbott purchase expands presence in Brazilian vision-care market

ABBOTT PARK, IL :: **ABBOTT MEDICAL OPTICS ANNOUNCED it has acquired Brazilian surgical distributor Vistatek, expanding the company's vision-care business in Latin America.**

"The acquisition of Vistatek allows Abbott to be closer to the patients we serve and to grow our customer base in the Brazilian market by providing a broad portfolio of vision-care treatment options," said Murthy Simhambhatla, PhD, AMO president. "We welcome the additional knowledge and expertise of Vistatek, which also provides us the infrastructure and foundation to support continued growth in Latin America."

Vistatek is headquartered in São Paulo, Brazil, and has served as a distributor of Abbott's cataract and laser vision correction technologies. Additionally, this transaction coincides with Abbott's 75th anniversary of conducting business in Brazil.

Financial terms were not disclosed.

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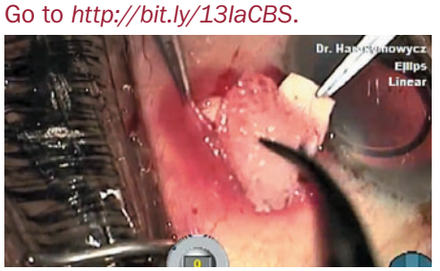

Best prescription for patients: Maintain healthy lifestyle

No solid evidence to demonstrate efficacy of 'alternative therapies' for glaucoma

By Cheryl Guttman Krader; *Reviewed by John Hetherington Jr., MD*

TAKE-HOME

- ***As consumer interest in alternative therapies grows and considering the potential for harm, ophthalmologists need to be prepared to speak about this topic with their patients.***

SAN FRANCISCO ::

Market data and other research pointing to the popularity of alternative therapies—combined with evidence that these interventions may not be as benign as consumers believe—underscore the need for ophthalmologists to be prepared to speak about this issue with their patients with glaucoma.

"It's a shame to see a lot of money being spent on ineffective alternative therapies, but the concern extends beyond the fact that most are useless because there is the potential for them to do harm," said John Hetherington Jr., MD, clinical professor of ophthalmology, University of California, San Francisco.

"Based on my review of the available evidence, my conclusion is that the best thing our patients can do to protect their ocular health and general well-being is to maintain a healthy lifestyle with proper diet, adequate exercise, and enough sleep," he said.

According to one report on alternative therapies, 72 million adult Americans spent an estimated $27 billion annually for these agents. However, that particular study is already a few years old, and the current expenditure level is probably higher, Dr. Hetherington said.

Data on use of alternative medications by patients with glaucoma is available from several studies that suggest it is significant. Wan et al. found that one in nine (11%) patients with glaucoma use these agents, while others reported a range between 7% and 17%.

"However, the real percentage is probably even higher, as many patients probably don't talk about alternative medication use," Dr. Hetherington added.

WHAT TO SAY

Often, when asked by patients about alternative medicines, physicians may say whether it is fine to use them or not. Recently reported results, however, from a large study investigating the potential for niacin to protect against myocardial infarction and stroke raise concern about such passive responses. The study found niacin had no benefit, but in fact may increase the incidence of cardiovascular damage.

"There is often no evidence to demonstrate efficacy of alternative therapies, but these agents have side effects and drug interactions that can make people [feel] worse," Dr. Hetherington said.

ALTERNATIVE THERAPY AND GLAUCOMA

There is little clinical data to support use of any alternative medicines to prevent the onset of glaucoma or its progression. Some evidence shows that the degenerative mechanisms in glaucoma may be similar to those in age-related macular degeneration (AMD) and may provide some justification for the idea that vitamins and mineral supplements—shown to be helpful for preventing AMD progression (i.e., Age-Related Eye Disease Study)—may also be used in managing glaucoma. Additionally, some study data suggest that antioxidants in particular have promise.

However, there is no solid evidence to support recommendations for using these or other nutritional supplements, nor for herbal agents, including gingko biloba, St. John's wart, and marijuana, that are of interest to patients with glaucoma because of purported effects on IOP or antioxidant properties.

There are a number of studies showing that exercise has IOP-lowering effects, and in some studies, the benefit persisted for some time after exercise ended. Citing some of this evidence, Dr. Hetherington mentioned one study reporting that moderate exercise was associated with a 14% decrease in IOP in patients with normal pressures and patients with glaucoma.

Another study found persons engaged in aerobic exercise for 10 minutes had a 1.7 mm Hg decrease in IOP, and two trials reporting that persons who exercised for 3 months had moderate IOP decreases lasting for 3 weeks after the exercise program ended.

However, Dr. Hetherington acknowledged that the question remains whether the effect of exercise is limited to IOP or actually has an impact on glaucoma.

"Although exercise seems to be associated with lowering of IOP, data are needed to show that it has any benefit for preventing visual field loss or affects blood flow in the back of the eye," Dr. Hetherington said. "Perhaps compensatory mechanisms prevent beneficial changes in blood flow and any real benefit from exercise.

"However, we know that exercise has other health benefits, and so it seems to be reasonable to recommend it to patients, especially those with normal-pressure glaucoma for whom we often don't know what else we can do," Dr. Hetherington concluded. ■

Do you agree? Share your comments regarding the benefits of a healthy lifestyle on patients' ocular health. Join the discussion at **Facebook.com/OphthalmologyTimes.**

JOHN HETHERINGTON JR., MD

E: *research@glaucomasf.com*

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

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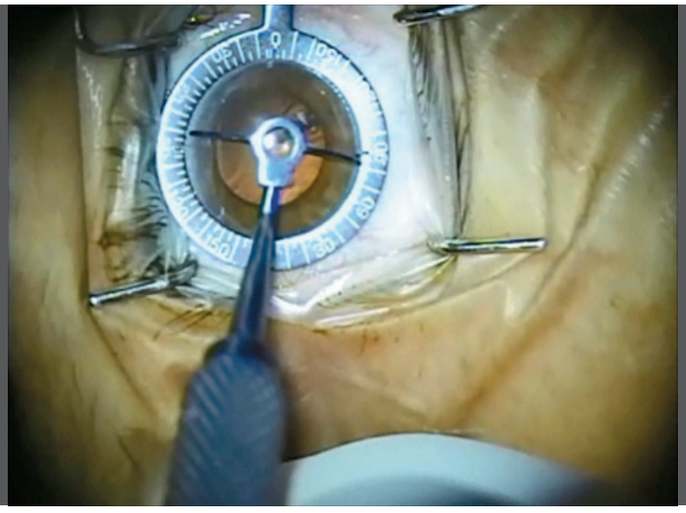
TIPS FOR TORIC IOL MARKING

Why accurate alignment is needed to achieve full benefit of astigmatic reduction

By Cheryl Guttman Krader; *Reviewed by Bonnie An Henderson, MD*



Careful marking of the eye to guide accurate axis alignment of the toric IOL is essential for achieving good outcomes. *(Image courtesy of Bonnie An Henderson, MD)*

take-home

- **Bonnie An Henderson, MD, provides tips for marking the eye to guide toric IOL orientation.**

BOSTON ::

Toric IOL implantation provides a reliably effective method for reducing existing astigmatism in patients undergoing cataract surgery, but careful marking of the eye to guide accurate axis alignment of the IOL is essential for achieving good outcomes, said Bonnie An Henderson, MD.

"Astigmatism correction is becoming a more important component of cataract surgery, as surgeons aim to meet the high expectations of today's patients," said Dr. Henderson, clinical professor of ophthalmology, Tufts University School of Medicine, Boston. "However, carefully marking to identify the steep axis is needed for proper IOL alignment and achieving the desired outcome, because for every 1° that a toric IOL is off-axis, its effect for reducing astigmatism is decreased by 3.3%."

CYCLOROTATION

Providing tips for marking the eye when implanting a toric IOL, Dr. Henderson said the first issue to consider is the possibility of cyclorotation when patients move from an upright position to supine under the surgical microscope. Therefore, placement of the preoperative reference markings that will guide intraoperative marking of the axis should be made with patients in a sitting position.

Dr. Henderson

"Researchers evaluating cyclorotation of the eye in LASIK patients reported an average positional change of 4.1° and rotation of more than 10° in 8% of eyes," Dr. Henderson said. "The resulting misalignment in the latter situation would reduce the astigmatic correction provided by the toric IOL by one-third."

MAKING THE MARK

To make the mark, the surgeon first should instruct the patient to look straight ahead, focusing on a fixed point in the distance past the surgeon's shoulder. While resting one's hand on the patient's cheek to enhance manual control of the marker, marks should ideally be placed on the limbus at the 3, 6, and 9 o'clock meridians of the cornea or at least at 3 and 9 o'clock. For increased precision, the reference marks should be done on a dry eye using a commercially available premarker inked on an ink pad and by first placing the premarker below the eye and then moving it up and straight toward the eye.

"Check that the patient's head is not tilted left or right," Dr. Henderson said. "Make sure the cornea is dry before placing the mark. If the cornea is too wet, use a Weck-cel sponge to dry the area of the eye to be marked.

"Ink the marker in a vertical direction to get more ink, but be careful not to use too much ink," she said. "A large mark from ink that smears or bleeds on the surface will cover a range of degrees and compromise the precision of the IOL alignment."

Intraoperatively, any marking that has faded should be enhanced by hand. Then, using the preoperatively placed reference marks, the steep axis should be marked with an axis marker using a "rock-and-roll" technique rather than by "stamping" the eye.

"I recommend operating on the steep meridian, and marking the steep axis will identify

Continues on page 14 : ***Alignment***

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Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%.

For additional information about PATADAY® Solution, please refer to the brief summary of prescribing information on adjacent page.

References: 1. IMS Health, IMS National Prescription Audit™, August 2010 to December 2012, USC 61500 OPHTH ANTI-ALLERGY. **2**. PATADAY® Solution package insert. **3**. Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, April 2013.

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Carcinogenesis, Mutagenesis, Impairment of Fertility
Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively. Based on a 40 µL drop size and a 50 kg person, these doses were approximately 150,000 and 50,000 times higher than the maximum recommended ocular human dose (MROHD). No mutagenic potential was observed when olopatadine was tested in an *in vivo* bacterial reverse mutation (Ames) test, an *in vivo* mammalian chromosome aberration assay or an *in vivo* mouse micronucleus test. Olopatadine administered to male and female rats at oral doses of approximately 100,000 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of approximately 15,000 times the MROHD level.

Pregnancy
Teratogenic effects: Pregnancy Category C
Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 150,000 times the MROHD and rabbits treated at 400 mg/kg/day, or approximately 100,000 times the MROHD, during organogenesis showed a decrease in live fetuses. In addition, rats treated with 600 mg/kg/day of olopatadine during organogenesis showed a decrease in fetal weight. Further, rats treated with 600 mg/kg/day of olopatadine during late gestation through the lactation period showed a decrease in neonatal survival and body weight.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.

Nursing Mothers
Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when **PATADAY®** (olopatadine hydrochloride ophthalmic solution) 0.2% is administered to a nursing mother.

Pediatric Use
Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

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

ADVERSE REACTIONS
Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%. The following adverse experiences have been reported in 5% or less of patients:
Ocular: blurred vision, burning or stinging, conjunctivitis, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, pain and ocular pruritus.
Non-ocular: asthenia, back pain, flu syndrome, headache, increased cough, infection, nausea, rhinitis, sinusitis and taste perversion.
Some of these events were similar to the underlying disease being studied.

DOSAGE AND ADMINISTRATION
The recommended dose is one drop in each affected eye once a day.

HOW SUPPLIED
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NDC 0065-0272-25

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Special Report) **INTRAOCULAR LENSES**

Harnessing the power of toric technology

How attributes of user-friendly silicone implant may ease cataract surgeons' entry into premium IOL market

By Cheryl Guttman Krader; *Reviewed by Ehsan Sadri, MD*

NEWPORT BEACH, CA ::
OPHTHALMOLOGISTS WHO PERFORM cataract surgery can add value to their practice by offering toric IOLs, suggests one surgeon.

"Toric technology is the fastest-growing segment of the premium IOL market, with the number of units implanted expected to increase from about 286,000 in 2012 to more than 501,000 in 2017," said Ehsan Sadri, MD, private practice, Atlantis Eyecare, Newport Beach, CA.


Dr. Sadri

"There is a large pool of potential candidates for toric IOLs, considering that clinically significant astigmatism of at least 1 D affects as many as half of patients presenting for cataract surgery," Dr. Sadri said. "This population represents 'low-hanging fruit' to convert to a premium IOL procedure, because they understand astigmatism and recognize that it can be visually problematic."

Currently, U.S. surgeons may choose from among three monofocal toric IOLs, said Dr. Sadri, who noted that in his experience a single-piece, silicone toric IOL (AA4203TF/AA4203TL, STAAR Surgical) stands out in several ways.

"[This] toric IOL has the longest track record of all of the available toric IOLs, and its lower price reduces the patient's out-of-pocket expense," Dr. Sadri said. "Not all eyes require aspheric optics, and in fact, a non-aspheric optic is preferred for patients who have had LASIK for hyperopia.

"Compared with acrylic lenses, the silicone material has a lower refractive index that causes fewer optical aberrations and minimizes problems with halos, glare, and glistening," he said.

With its single-piece construction the implant is easy and straightforward to use, and in its current iteration it is well designed to maintain rotational stability. Once implanted, the toric IOL can be rotated clockwise or counterclockwise as needed for final orientation. Whereas off-axis rotation was an issue with the original version of the STAAR toric IOL, this problem has been successfully addressed through design improvements that include an increase in total length along with the introduction of micro-etched haptics and larger fenestrations.

"[This] toric IOL is very user-friendly technology and is very stable," Dr. Sadri said. "Lengthening of its diameter increases rotational stability, especially in larger myopic eyes; the larger fenestrations allow for better encapsula-

ALIGNMENT

(Continued from page 12)

the incisional axis and axis for IOL orientation," Dr. Henderson said.

However, she added that online toric IOL calculators will calculate the correct power and alignment of the toric IOL based on the input for incision location.

So that the markings are made with the eye in its most natural state, the intraoperative marking should be done prior to administering any blocks or making any incisions. However, the accuracy of the marking should be checked a second time prior to implantation of the IOL.

"Measure twice and cut once," Dr. Henderson said. "Then, as a final check, make sure the implanted IOL is on axis prior to removing the drapes." ■

BONNIE AN HENDERSON, MD
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Dr. Henderson is a consultant to Alcon Laboratories and Bausch + Lomb. This article was adapted from Dr. Henderson's presentation at an Alcon-sponsored session during the 2013 meeting of the American Society of Cataract and Refractive Surgery.

tion of the IOL at the capsule equator; and the micro-etching of the haptics has been shown to increase adhesion during the healing process.

"Results from studies evaluating repositioning rates for toric IOLs show essentially similar results among patients with the STAAR platform implanted versus a competing acrylic model," he said.

TORIC TIPS

In order to maximize outcomes when implanting this toric IOL, Dr. Sadri said the capsulorhexis should be no larger than 5.5 or 5.6 mm. It is also helpful to minimize balanced salt solution infusion of the anterior segment, since having the eye relatively but safely soft enables immediate collapse of the capsular bag around the IOL.

Use of a cohesive viscoelastic is preferred as it coats the IOL surface less than a dispersive material. However, surgeons must be meticulous in removing the viscoelastic from behind the IOL at the end of surgery to maximize contact with the posterior capsule.

"Be sure to confirm lens orientation after this step and then again after hydrating the wound," Dr. Sadri said.

GETTING STARTED

The IOL is available in two cylinder powers: –2 D that corrects 1.5 D of corneal astigmatism, and 3.5 D that corrects 2.25 D. Surgeons who are first using the lens might consider taking a conservative approach and focus on implanting the lower power IOL in eyes with up to 2 D of astigmatism. ■

take-home

- **Cataract surgeons wanting to tap into the premium IOL market might consider implanting toric IOLs.**

EHSAN SADRI, MD

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Dr. Sadri is a consultant to Abbott Medical Optics and STAAR Surgical. This article was adapted from Dr. Sadri's presentation at the STAAR Surgical booth during the 2013 meeting of the American Society of Cataract and Refractive Surgery.

Quest for perfect lens calculation progresses

From Staff Reports

HOUSTON ::

THE JOURNEY TO ACHIEVING the perfect lens calculation—one that results in emmetropia without ocular aberrations—began 2,000 years ago, but is now just a few years away from reaching its destination, according to Jack T. Holladay, MD, MSEE.

"What I want [surgeons] to remember most are those individuals who were important in our getting there," said Dr. Holladay, clinical professor of ophthalmology, Baylor College of Medicine, Houston. "I am so appreciative for all of them, and particularly for Dr. [Charles] Kelman."

In his historical overview, Dr. Holladay said the journey to the perfect IOL calculation began with Claudius Ptolemy (born ~90 AD), who was the first to report empirical observations on the refraction of light. It picks up about 1,000 years later when the Ibn Sahl of Sevilla, a Persian mathematician, first discovered the law of refraction, and then fast forwards to 1602 when Thomas Harriott rediscovered principles of light. In 1621, Willebrord Snellius (Snell) derived his formula describing how light acts when it passes through different media, and in 1637, Rene Descartes independently derived laws describing principles of light.

In 1840, Gauss simplified Snell's law and introduced his lens formula that is still taught today.

The first theoretical IOL formula was introduced by Fyodorov in 1967, and multiple subsequent improvements resulted in current, more accurate formulae that use more variables to predict effective lens position (ELP). The development of femto-cataract surgery will further increase the predictability of ELP, Dr. Holladay said.

Technical advances reducing variability in ELP enabled the introduction of aspheric IOLs that provide better-quality vision. Advances in optical biometry and imaging techniques are also playing a role, and intraoperative aberrometry is adding another dimension. ■

Special Report 〉 **INTRAOCULAR LENSES**

Controlled unfolding eases IOL surgery

How lens material, design features add up to excellent performance in surgeon's hands

By Cheryl Guttman Krader; *Reviewed by Uday Devgan, MD*

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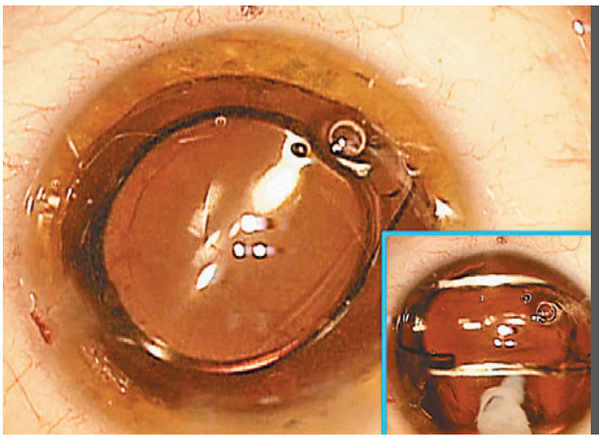

(FIGURE 1) The controlled unfolding of the single-piece hydrophobic acrylic IOL (enVista, Bausch + Lomb) allows time for the surgeon to get behind the IOL optic to remove the viscoelastic completely (inset), before the lens unfolds into its final position (large photo). *(Images courtesy of Uday Devgan, MD)*

LOS ANGELES ::

IN CATARACT SURGERY cases where a monofocal IOL will be implanted after crystalline lens removal, multiple reasons exist where a surgeon might consider a single-piece hydrophobic acrylic IOL (enVista, Bausch + Lomb), notes one surgeon.

For instance, the lens combines the advantages of having an acrylic material with that of single-piece construction, explained Uday Devgan, MD, private practice and chief of ophthalmology, Olive View UCLA Medical Center, Los Angeles.

The IOL became available to U.S. surgeons in June 2012, and Dr. Devgan began using it after the product's launch. Based on his positive experience with the lens over the past year, he said it has become a great option for most patients who are not seeking a toric or presbyopia-correcting IOL.

Dr. Devgan

"Considering both the intraoperative performance of the . . . IOL and the postoperative outcomes I've achieved, it seems that Bausch + Lomb has a winner with its first foray into the hydrophobic acrylic lens market," Dr. Devgan said.

The novel hydrophobic acrylic polymer, which was licensed by Bausch + Lomb from Santen (Japan) and has a 5-year clinical track record, is notable for its robustness and being glistening-free, said Dr. Devgan, in discussing the lens.

"The hydrophobic acrylic material is very resistant to surface damage that can occur during handling, and it is hydrated to an equilibrium water content of 4% that is maintained on the shelf through packaging in saline," Dr. Devgan said. "The hydration intends to prevent the development of glistenings, and appears to be working.

"In my experience, the . . . IOL seems nearly invisible in the eye with no evidence of glistenings or other fine opacities," he added.

take-home

A single-piece hydrophobic acrylic IOL has many features that make it a good choice for a monofocal implant in routine and challenging cataract surgery cases.

CENTRATION AND STABILITY

The hydrophobic acrylic IOL unfolds in a slow and controlled manner that enables complete removal of visco-

Continues on page 17 : ***Unfolding***

‘Locking in’ customized vision

Technology behind light adjustability of IOL addresses residual refractive errors

By Lynda Charters; *Reviewed by Arturo S. Chayet, MD*

TIJUANA, MEXICO ::

DELIVERY OF CUSTOMIZED vision with predictable results may be as close as next-generation technology associated with a light-adjustable IOL (Light Adjustable Lens, Calhoun Vision).

The primary difference between the light-adjustable IOL and other IOLs is the predictable correction of residual refractive error after lens implantation for optimal distance vision. Another difference is the opportunity for customized presbyopia solutions for near and intermediate vision, according to Arturo S. Chayet, MD, medical director, Codet Vision Institute, Tijuana, Mexico.

HOW IT WORKS

The procedure involves a conventional cataract surgery that is followed by adjustment of the light-adjustable IOL 2 weeks later. A light-delivery device is used to irradiate the IOL with a spatially profiled beam. Dr. Chayet explained that over the subsequent 24 hours, the shape of the IOL changes to correct residual spherical and/or astigmatic errors. From between 2 days to 1 week after the irradiation procedure, and with both the surgeon and patient satisfied with the refractive power, the lens power is “locked in.”

The lens, made of silicone, undergoes a photopolymerization process after exposure to the adjustment beam. The subsequent diffusion and power change depend on the profile used, which adds power to the lens. The lock-in procedure ensures that the achieved lens power remains stable.

The results from various studies of correction of refractive errors with the lens have been very good, Dr. Chayet noted. With hyperopia and myopia, about 93% of eyes were within ±0.25 D of the intended correction; for astigmatism, all eyes were within about 0.5 D of the intended adjustment. The postoperative uncorrected visual acuity was 20/20 in 86% of patients 12 months after the lock-in procedure.

TORIC CORRECTION

The light-adjustable IOL also has several benefits for toric correction, according to Dr. Chayet. The same technique is always used for wound placement and IOL placement, the accuracy is within 0.25 D of cylinder and within 1° of the axis, the overall refractive accuracy of sphere and cylinder is very high, up to 2.5 D of cylinder can be corrected, and it can be used along with multifocal corrections, he noted.

A study that compared results for the light-adjustable IOL with those for a toric IOL (AcrySof toric, Alcon Laboratories) showed that 86% of patients with the light-adjustable IOL implanted had 20/20 or better uncorrected visual acuity postoperatively compared with about 30% with the toric IOL.

CLINICAL UPDATES

VIDEO Robert Maloney, MD, director of the Maloney Vision Institute, Los Angeles, discusses the clinical results and current status of the Light Adjustable Lens (Calhoun Vision) in phase II FDA study. Go to **http://www.youtube.com/watch?v=pMTjQbbIOfE.**

PRESBYOPIA CORRECTION

Among the approaches for presbyopia:

▶ ***ADJUSTABLE MONOVISION*** **goes beyond the typical monovision. The dominant eye undergoes implantation and is adjusted for emmetropia, while the non-dominant eye is targeted initially for –1.25 D after the implantation and before the adjustment. During the postoperative evaluation, the adjustment can be locked in or ad-**

Continues on page 20 : ***Adjustability***

UNFOLDING

(Continued from page 16)

elastic from behind the lens. It centers well and maintains good positional stability post-implantation due to its material and haptic design.

“Even in some more challenging cases where there is the potential for increased capsular fibrosis, the . . . IOL tends to keep its form because of its rigid material and [does] not shift around,” Dr. Devgan said.

However, he noted that good visual quality would be maintained if there is some lens decentration because the optic is spherical aberration-neutral.

“Unlike aspheric lenses with negative spherical aberration where visual performance is highly sensitive to decentration, [this] IOL is optically immune to mild decentration because it has zero spherical aberration,” he said. “For that reason, it is a great choice in cases where there are any anatomical issues leading to IOL centration concerns.

“This zero spherical aberration IOL also does not confound any existing aberrations in the eye, which makes it a great choice in eyes with prior keratorefractive surgery, like RK or corneal irregularity,” Dr. Devgan said.

The intraocular stability of the single-piece hydrophobic acrylic IOL also suggests it is a good platform for toric IOL technology, and the presence of two holes where the haptic joins the optic raises the interesting possibility of using those openings to enable suture fixation in challenging cases, said Dr. Devgan, noting that he has not yet tried the latter maneuver. ■

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Dr. Devgan is currently a consultant to Bausch + Lomb and to other companies that market IOLs (Aaren Scientific, Alcon Laboratories, and Hoya). He previously was also a consultant to Abbott Medical Optics and STAAR Surgical.

This activity is supported by an unrestricted educational grant from Allergan, Inc.

Release Date: August 1, 2013
Expiration Date: August 1, 2014

Learning Objectives

- Describe recent guideline protocols for diagnosing dry eye disease (DED), classifying DED severity, and differentiating underlying etiologies of DED
- List the current recommendations for the treatment and follow-up of DED by level of severity and underlying etiologies.

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Meibomian Gland Dysfunction: Prevalence of An Overlooked Cause of Dry Eye

Donna is a 55-year-old attorney who works extensively on her computer each day, frequently reading intricate documents. Several months ago, she began suffering from bilateral contact lens intolerance, ocular discharge, and sensitivity to light. To date, she has visited three different eye care professionals to try to resolve her symptoms. She was diagnosed with chronic bacterial conjunctivitis and prescribed moxifloxacin and artificial tear drops, but she continues to experience symptoms. Donna now reports to your office to seek another opinion.

- What steps would you take to make an accurate diagnosis of Donna?
- Are you versed in the various conditions that fall under the umbrella of dry eye disease, particularly meibomian gland dysfunction?
- And, are you familiar enough with this complicated condition to properly treat Donna?

To learn more about Donna's diagnosis and treatment, go to www.iche.edu/dryeyecase1 and earn even more CE credit!

Dry Eye Disease

Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability, with potential damage to the ocular surface if undiagnosed. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.[1] In the United States, 6% to 10% of women and 4% to 8% of men live with chronic dry eye; the prevalence of the condition increases with age.[2,3]

Dry eye can be classified into various subtypes based on its underlying cause. One of the intrinsic causes of evaporative dry eye is meibomian gland dysfunction (MGD), a chronic, diffuse abnormality of the meibomian glands, commonly characterized by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion. It may result in alteration of the tear film, symptoms of eye irritation, clinically apparent inflammation, and ocular surface disease.[4,5] The actual prevalence of MGD is unknown since it is likely underdiagnosed and therefore underreported, but it does appear to have a higher prevalence in Asian populations.[6]

Diagnosis of MGD-Related Dry Eye

Patients presenting with either ocular surface symptoms (eg, dryness, grittiness, or foreign body sensation) or morphological lid signs of MGD (orifice plugging or lid margin vascularity) should be assessed for evidence of dry eye and ocular surface damage. MGD can exist by itself or as a cause of concomitant evaporative dry eye. The diagnostic goal with these patients is to first identify dry eye of any type and then to distinguish between aqueous-deficient dry eye and MGD-related or other forms of evaporative dry eye.[4,6]

A variety of characteristics are evaluated with tests for MGD, including dry eye symptoms, meibomian function, tear quality, tear volume/secretion, and ocular surface inflammation. Although many of these tests are performed only in specialty clinics, any general eye care clinic can perform a subset of these tests in order to differentiate MGD-related dry eye from other forms of dry eye.

Determining the specific type and cause of dry eye is crucial because this approach permits the clinician to treat the underlying cause of the disease rather than simply reducing or masking the symptoms. In the case of MGD-related dry eye, since MGD is a chronic but treatable condition, symptoms can be dramatically reduced and permanent damage to the meibomian glands can be prevented with proper management.

Treatment of MGD

Treatment of MGD varies widely, likely due to the lack of an accepted staging system or treatment algorithms and the absence of rigorous clinical trials providing level I evidence for specific therapies. However, both a staging system and treatment algorithm have been recently proposed by the International Workshop on Meibomian Gland Dysfunction.[4] The number of therapies recommended increases proportionally with the stage of MGD, and more severe disease supports the addition of supplementary therapies to existing treatments rather than replacing milder therapies with a more aggressive approach (see **Figure 1**).

Patient Education/Behavior Modification

With all forms of MGD (stage 1 to stage 4), patients should be educated on the effect of diet and physical environment on MGD. Behavior modifications, including taking essential fatty acid dietary supplements, particularly omega-3, and modifying the environment to improve ambient humidity, should also be considered as MGD severity increases.[7,8]

Lid Hygiene

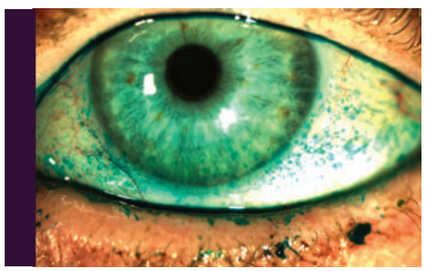
Lid hygiene, which includes both lid warming and mechanical massage of the eyelids, should be considered for stage 1 disease and should be implemented for all other stages. Lid warming is generally achieved by applying warm compresses to the eyes for 5 to 10 minutes once to twice daily, but studies and surveys have demonstrated a wide range of variability in both instructions for lid warming and adherence to this therapy.[7] Mechanical massage of the eyelids serves to express blocked glands. Gland expression has only recently come into clinical focus, and it represents an increased awareness by eye care professionals that eyelid health can impact dry eye symptoms.[9] Eyelid massage should be performed immediately after lid warming because the increased temperature facilitates the flow of meibum via melting of the meibomian lipids.[7,10] As with lid warming, mechanical massage is poorly standardized and has poor compliance.[7]

Lubricants

Non-preserved artificial tears should be considered for patients with stage 2 MGD and implemented for those with more severe disease. Artificial tears are considered a mainstay of treatment,[7] but effective lubricants can take other forms as well, including ointments and lipid-containing liposomal sprays and emollient eye drops. Lubricant ointments have a thicker formulation compared with artificial tears and are used for overnight relief because they may cause unacceptable blurring during the day. Patients with stage 3 or 4 MGD could consider an ointment at bedtime.[7,11] Lipid-containing artificial tears, designed to supplement tear film lipids and stabilize the tear film, are recommended for patients with stage 2 through stage 4 disease.[7,11] Cyclosporine ophthalmic emulsion 0.05% has been shown to improve signs and symptoms of MGD by suppressing inflammation and improving tear film stability directly or through its lipid vehicle.[11,12,13]

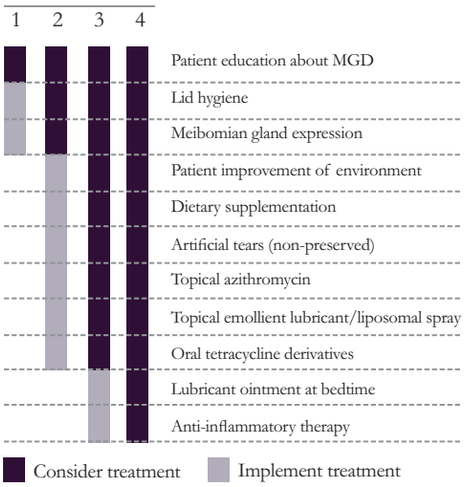
Macrolide Antibiotics

Macrolide antibiotics not only have antimicrobial properties but anti-inflammatory effects as well. Commonly used macrolides include azithromycin, clarithromycin, and roxithromycin, which offer better ocular penetration than older macrolides, such as erythromycin.[7] An open-label study of topical azithromycin added to warm compresses demonstrated that patients receiving both treatments showed significant improvements in meibomian gland plugging, quality of meibomian gland secretions, and eyelid redness compared with compresses alone.[14] A course of topical azithromycin is recommended for patients with stage 3 or 4 MGD [7]; this has been shown to increase comfortable wearing time of contact lenses in an open-label study of patients with contact lens discomfort.[15]



MGD with lissamine green staining of lid margin and inferior cornea and conjunctiva

Severity Stage (Figure 1)



Oral Tetracycline Derivatives

Although tetracycline is a bacteriostatic antibiotic, it is mainly used to treat MGD because of its anti-inflammatory and lipid-regulating properties rather than its antimicrobial properties. Oral tetracyclines studied in clinical trials have demonstrated the ability to improve both the signs and symptoms of MGD,[16] and they are recommended for use in stage 3 or 4 MGD. Treatment options include tetracycline and derivatives, including oxytetracycline, minocycline, and doxycycline.[7] A clinical trial of all 4 antibiotics demonstrated that minocycline and doxycycline are clinically effective at lower doses than the other 2 agents.[17]

Anti-inflammatory Therapy

As mentioned, some therapies, such as topical macrolide antibiotics and oral tetracycline derivatives, have anti-inflammatory properties in addition to other useful biological activities. In some cases, these may be sufficient to control the ocular inflammation associated with MGD. In other cases, additional anti-inflammatory therapy may be needed. Topical corticosteroids, such as loteprednol, fluorometholone, prednisolone, dexamethasone, and difluprednate, are a well-accepted treatment option for ocular inflammation,[18] but they do have potential complications, including elevation of intraocular pressure and cataractogenesis.[19] Thus, this type of therapy is restricted to the short-term treatment of those individuals with the most severe form of MGD (stage 4).

Novel Therapies

A number of novel therapies have recently been developed to improve the management of MGD, including several lid-warming devices. The iHeat Warm Compress® is a waterless eye mask that holds a heated pouch over each eye to provide controlled warmth for 3 to 5 minutes, multiple times per day, to reduce dry eye symptoms.[20] Blephasteam® warms the lids to 42ºC, which is 7ºC above the melting temperature for meibum in MGD patients and safely below the 45ºC safety threshold for corneal temperature.[21] Although currently only available in Europe, Blephasteam has shown a 32% reduction in tear evaporation after a single treatment, as well as significant improvements in visual acuity and non-invasive tear break-up time (TBUT).[22,23] LipiFlow®, the only lid-warming device approved by the U.S. Food and Drug Administration, is a thermodynamic pulsatile treatment that not only warms the lid but simultaneously produces a mechanical massage to express the meibomian glands. In a randomized trial comparing LipiFlow to the iHeat Warm Compress in patients with MGD, a single, 12-minute, in-office treatment with LipiFlow produced significant improvements in both meibomian gland secretion and TBUT for up to 9 months.[24]

A novel way to treat obstructive MGD is through the use of intraductal meibomian gland probing. With this technique, a thin steel probe is inserted through each blocked meibomian glandular orifice and duct after anesthetizing the lids. In a retrospective study, patients with obstructive MGD experienced immediate relief after intraductal probing, as well as symptom relief 4 weeks after treatment.[25] Another novel therapy being studied to treat MGD is topical N-acetylcysteine, which has shown significant improvements in TBUT and Schirmer's scores, although the mechanism of action in MGD remains unclear.[26,27]

Conclusion

MGD is a prevalent condition that can create bothersome symptoms, damage the ocular surface, and permanently destroy meibomian glands. Thus, MGD should be diagnosed in a timely manner using a battery of tests to not only identify this condition but also determine if it is accompanied by evaporative dry eye. Once diagnosed, a multifaceted treatment approach should be planned, based on the severity of the condition. Current therapies, including a chronic management component, can provide significant improvement of the signs and symptoms in most patients. As interest in MGD increases, novel therapies are being developed to further enhance the management of this condition.

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Special Report 〉 **INTRAOCULAR LENSES**

Multifacets of a multifocal IOL

New +2.5 D add version of lens provides visual quality with bilateral or blended approach

By Cheryl Guttman Krader; *Reviewed by Francesco Carones, MD*

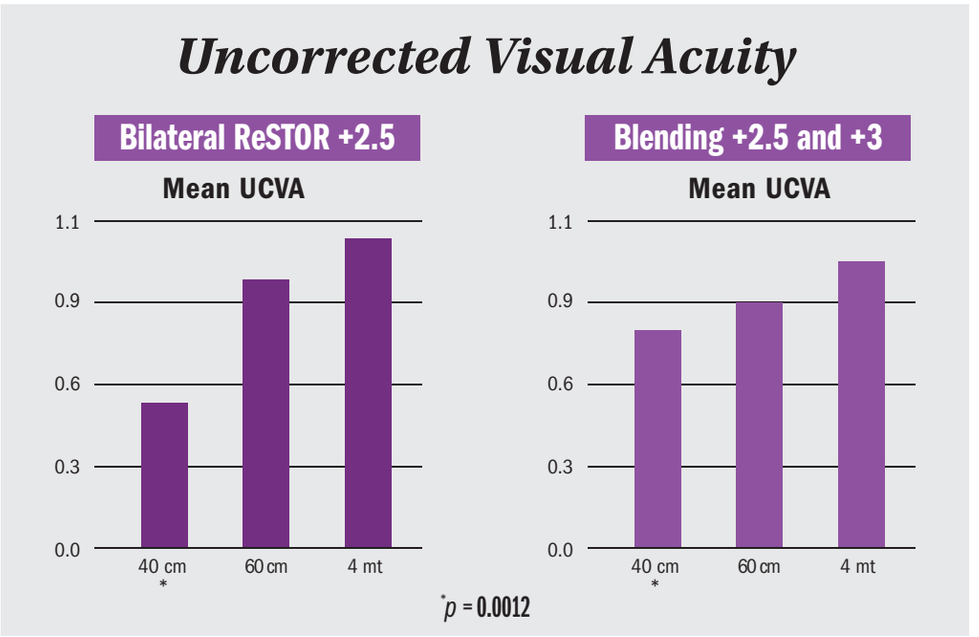
MILAN ::
A NEW +2.5 D ADD version of a multifocal IOL enhances the ability of cataract surgeons to meet the diverse vision needs of their patient population.


Dr. Carones

Francesco Carones, MD, described the design and attributes of the acrylic aspheric apodized diffractive multifocal IOL (AcrySof IQ ReSTOR +2.5, Alcon Laboratories). He also discussed his experience with implanting the lens bilaterally or in a mixed approach, using the +2.5 D add multifocal IOL in the dominant eye and the near distance-optimized +3 D add multifocal IOL in the nondominant eye.

Compared with the +3 D version of the apodized diffractive multifocal IOL, the +2.5 D lens distributes more light energy for distance. It has a larger central zone with a refractive versus diffractive design, noted Dr. Carones, medical director, Carones Ophthalmology Center, Milan.

In addition, the apodized diffractive zone of the +2.5 D IOL features fewer graduated steps over a smaller diameter compared with the +3 D IOL. Whereas the +3 D IOL has 9 steps over a 3.6-mm diameter, the +2.5 D add IOL apodized diffractive zone has 7 steps over a 3.4-mm diameter. The +2.5 D add IOL also has more negative asphericity than the +3 D version, –0.2 versus –0.1 µm.



"The +2.5 D add multifocal IOL provides distance vision quality and contrast sensitivity performance that is comparable to a monofocal IOL, intermediate vision and night vision quality that is better than with the +3 D add multifocal IOL, and good functional near vision exceeding that achieved with a monofocal IOL," Dr. Carones said.

"With these features, the +2.5 D add multifocal IOL is especially well-suited for patients seeking a range of uncorrected vision better than that achieved with a monofocal IOL, who are concerned about quality of vision, but whose primary vision needs are for distance and intermediate tasks," he said.

ADJUSTABILITY

(Continued from page 17)

justed based on patient preference. Patients who chose this option achieved 20/20 near vision (J1).

> ***WITH CUSTOMIZED NEAR VISION,*** the dominant eye can be adjusted to emmetropia; the non-dominant eye can undergo a postoperative adjustment that targets +0.25 D and after the second adjustment, a near add adjustment can be made. Patients with this option also achieved 20/20 near vision (J1). The results from phase II of this approach, in which no adjustment has to be made for photopic vision, showed that 68% of patients achieved 20/20 or better and 73% of patients achieved J2 or better.

> ***WITH CONTROLLED ADDITION OF ASPHERICITY,*** there are two benefits: enhanced distance vision and extended depth of focus for improved intermediate and near vision. The aspheric eye retains most distance vision and the fellow eye has excellent distance vision.

No cases of toxic anterior segment syndrome have developed, indicating that the IOL is highly biocompatible, he said. No macular damage has been seen in any in vitro or in vivo studies. Protective lenses are essential the first month.

"The [light-adjustable IOL] is the next-generation IOL technology for both cataract and refractive lens surgery," Dr. Chayet said. "It is truly a refractive procedure for the phaco surgeon and has been proven effective to correct myopia, hyperopia, astigmatism, and presbyopia.

"In the future, we look forward to wavefront control using this technology," he added. ■

ARTURO S. CHAYET, MD
E: *arturo.chayet@codetvision.com*

Dr. Chayet is a consultant for Calhoun Vision and Nidek. The Light Adjustable Lens is an investigational device and available outside of the United States. This article was adapted from Dr. Chayet's presentation at Refractive Surgery 2012 during the annual meeting of the American Academy of Ophthalmology.

Figure courtesy of Francesco Carones, MD

SURGICAL EXPERIENCES

VIDEO Francesco Carones, MD, of Milan, Italy, shares his personal and real patient experiences, along with insights he has obtained using the AcrySof IQ ReSTOR +2.5 D IOL (Alcon Laboratories). Go to **http://www.youtube.com/watch?v=TpTFAUxEWGE.**

Because the +2.5 D and +3 D versions of the multifocal IOL each have unique benefits, decisions on whether to implant one or the other bilaterally or both in a blended approach depend on the patient's visual needs, Dr. Carones noted. The selection is guided by patient responses to a lifestyle questionnaire that is designed to determine an individual's vision preferences and goals. Other factors considered include the patient's age and height, as generally patients who are younger or taller may do better with bilateral implantation of the +2.5 D IOL.

"However, with proper IOL selection, satisfaction has been high, whether patients [undergo implantation] bilaterally with either lens or . . . a blended approach," Dr. Carones said.

BILATERAL OR BLENDED?

Among 14 patients with the +2.5 D add multifocal IOL implanted bilaterally, all had binocular uncorrected visual acuity (UCVA) that was 20/20 or better at distance, 20/20 or better at intermediate (60 cm), and 20/50 or better at near (40 cm), while 5 (36%) patients achieved 20/20 near UCVA.

Thirty-six patients underwent implantation with a blended approach, receiving the +2.5 D add IOL in the dominant eye and the +3 D add IOL in the nondominant eye. In binocular UCVA testing, all achieved 20/20 or better at distance, whereas 89% saw 20/20 or better at intermediate. Binocular near UCVA was 20/32 or better in all eyes and 20/20 in 75%.

"These results show how the blended approach can increase spectacle independence for patients, but based on patient reports, it does so without significantly decreasing quality of vision or increasing visual symptoms," Dr. Carones said.

The +2.5 D add AcrySof IQ ReSTOR multifocal IOL will be launched later this year in Europe. It has not yet been approved by the FDA. ■

take-home

A new +2.5 D add version of a multifocal IOL features a re-designed optic that enhances visual function at intermediate and distance and delivers excellent visual quality.

FRANCESCO CARONES, MD
E: *fcarones@carones.com*

Dr. Carones is a consultant for Alcon Laboratories. This article was adapted from Dr. Carones' presentation during the 2013 meeting of the American Society of Cataract and Refractive Surgery.

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Special Report 〉 **INTRAOCULAR LENSES**

Toric IOLs versus incisions

What strategies surgeons need to consider in management of astigmatism

By William B. Trattler, MD; *Special to* Ophthalmology Times

THE GOAL OF MODERN cataract surgery is not just to remove the cataractous lens, but also to provide the patient with good uncorrected vision. When evaluating patients for surgery, it is necessary to consider not only the spherical equivalent, but also the expected residual astigmatism.

Even if the spherical equivalent is exactly on target, quality of vision is compromised by residual astigmatism. With approximately 86% of patients with cataracts needing some kind of astigmatism correction,[1] it is not surprising that a number of different treatment options exist.

Here are some of the considerations when deciding how best to address astigmatism in patients with cataracts.

take-home

- **While manual limbal relaxing incisions and femtosecond astigmatic keratotomies can address mild to moderate astigmatism, toric IOLs are quite effective at all ranges of astigmatism, relates one surgeon.**

INCISIONS

About 64% of patients with cataracts are estimated to have corneal astigmatism between 0.25 and 1.24 D,[1] and studies have shown that correction of even low levels of postoperative astigmatism yields better visual acuity and reading performance.[2]

Limbal relaxing incisions (LRI) are perhaps the most common technique to correct small amounts of astigmatism at the time of cataract surgery, and I have been performing them for many years. Providing this treatment is relatively inexpensive, and the procedure is quite reliable for reducing astigmatism of ≤1.25 D, which is sufficient for the majority of patients.

Until the introduction of the toric IOL, the only option for a patient with presbyopia was a presbyopic lens combined with a LRI. This continues to be my preferred method of correction in patients with small amounts of astigmatism.

However, LRIs with a diamond blade do have limitations. Since the incision is made manually, skip lesions can occur and there is always a potential for perforation. In addition, there is more variability in results when attempting to treat higher levels of astigmatism.

With femtosecond lasers becoming more common, femtosecond astigmatic keratotomy is a newly developing surgical procedure that has enormous potential. The ability to program the laser power, length of the incision arc, depth, and even optical zone makes the cuts highly precise and repeatable. There are no skip lesions and a minimized risk of perforation. Centration, angulation, and pairing of incisions can be achieved; and the full potential is yet to be discovered. While more studies need to be conducted and the nomograms refined, initial experience suggests that these non-penetrating arcuate incisions will be very effective at eliminating both small and moderate levels of astigmatism.

TORIC IOLS

I have been using toric IOLs for the correction of astigmatism since they were first approved by the FDA. They have had a great track record, with results very much on target. In a review of 700 toric IOL procedures performed in my practice by six surgeons, only 7 eyes (1%) underwent laser vision enhancement postoperatively due to residual myopia, hyperopia, or astigmatism. Intraoperative aberrometry appears to be a promising technology that can further enhance the success rate for patients receiving toric IOLs.

The recent approval of a one-piece toric IOL (Tecnis Toric 1-piece IOL, Abbott Medical Optics) is expanding our options. The lens was launched in Europe in 2011 and studies thus far show it to have very high rotational stability.[3] In addition, it has –0.27 µm of spherical aberration (SA), fully compensating for the average amount of SA in the cornea.[4] This lens is showing excellent centration and fixation, has very crisp optics, and has not been associated with glistenings.[5]

CAREFUL PREOPERATIVE EVALUATION

Preoperative evaluation is critical for optimizing the success of astigmatism management. Both preoperative topography and keratometry measurement (typically with the IOLMaster [Carl Zeiss Meditec] or Lenstar [Haag-Streit]) are essential. In most cases, topography and keratometry produce relatively close results in both the axis and magnitude of astigmatism.

However, in the presence of significant dry eye or meibomian gland disease, the topography and keratometry will be unreliable. In these cases, the ocular surface condition should be treated, and then the patient can be brought back for repeat testing.

I also consider repeat testing if the topography and keratometry demonstrate significant differences. One important evaluation is to ensure that the astigmatism on topography is regular and not asymmetric. Patients with irregular astigmatism—such as with keratoconus, pellucid, or Salzmann's nodular degeneration, for example—are not the best candidates for a toric IOL.

SUMMARY

Patients undergoing cataract surgery have high expectations, and surgeons can deliver excellent visual results by ensuring that astigmatism present preoperatively is addressed. While manual LRIs and femtosecond astigmatic keratotomies can address mild to moderate astigmatism, toric IOLs are quite effective at all ranges of astigmatism. Careful preoperative evaluation with topography and keratometry can help surgeons identify appropriate candidates for toric implants, and help increase the success rate for all techniques for astigmatism management. ■

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WILLIAM B. TRATTLER, MD, *specializes in refractive, corneal, and cataract eye surgery at the Center for Excellence in Eye Care, Miami. He is a consultant to Abbott Medical Optics. Readers may contact Dr. Trattler at wtrattler@gmail.com.*

Not a candidate for refractive surgery? Not anymore!

Introducing a new series heralding a conceptual change in designing vision

Gloves Off with Gulani ***By Liz Meszaros;*** *Reviewed by Arun C. Gulani, MD*

Editor's Note: Ophthalmology Times *introduces this new series called "Gloves Off with Gulani" that is part of the full-spectrum concept of a "super-specialty," in which Arun C. Gulani, MD, will present prototype case studies and accept input to show how every case—no matter how difficult—deserves a mindset of emmetropia. Look for the first "gloves-off" encounter—"Multifocal IOL nightmare: Reversed to 20/20"—in the Sept. 1 issue of* Ophthalmology Times.

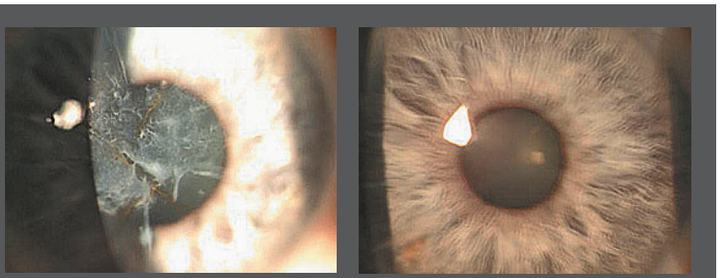
In Arun C. Gulani, MD's contemporary concept of "Corneoplastique" as a super-specialty of LASIK, custom cataract, corneal, and full-spectrum vision refractive surgery, vision becomes the accountable endpoint of all eye surgery through the intelligent manipulation and interplay of the optical components within the eye.

"In this era of raised expectations, advanced technologies, and dedicated pursuit for Super-Vision, I wish to introduce this concept and holistic approach by combining all levels of anterior segment surgery that strives to attain the goal of unaided emmetropia or best vision potential in every eye," said Dr. Gulani, an internationally renowned eye surgeon with a global clientele referred by eye surgeons worldwide, and founder and chief surgeon of the Gulani Vision Institute in Jacksonville, FL.

Dr. Gulani

Envisioning the near future, Dr. Gulani believes there will be no separation or discrimination between corneal, LASIK, or cataract surgeons, because all surgeons will be called upon to use their combined abilities and technologies to manipulate either of these optical components in the eye to address the refractive errors effectively.

According to Dr. Gulani, corneal, LASIK, and cataract surgeons will then all be known as "vision-corrective surgeons," and confidently approach every case planning for unaided emmetropia toward best vision potential.



LEFT The "Gloves Off with Gulani" series will offer case studies similar to the patient here, who presented with scarred central cornea and a history of RK surgery (notice the RK cuts with scar in the preoperative photo, left) and legal blindness. **RIGHT** The patient underwent laser ASA/PRK with "Corneoplastique" concepts and was immediately clear (postoperative photo, right). *(Images courtesy of Arun C. Gulani, MD)*

"This art of blending the full spectrum of ocular surface, corneal, and intraocular surgery in a planned approach either before (to prepare the eye) or after eye surgery (to repair the eye) is the core function of this new super-specialty that keeps focusing on unaided emmetropia in single or staged fashion, especially if you consider that these techniques are all brief/topical/aesthetically pleasing and, therefore, a fond memory for the patient," he noted.

The envisioned goals of Dr. Gulani's super-specialty will be as follows:

- **Raise vision outcomes to beyond 20/20 in virgin eyes.**
- **Reverse practically any refractive complication (including LASIK, radial keratotomy [RK], multifocal implant, etc.) back to 20/20 or best vision potential.**
- **Turn patients who are not candidates because of corneal scars, thin corneas, ectasias, irregular astigmatism, previous refractive surgeries like RK, and so forth, into appropriate candidates.**
- **Apply the full spectrum of anterior corneal refractive and lenticular surgeries including multifocal lens implants along with infinite staged combinations to suit each eye individually.**

'AM I A CANDIDATE?'

"The question *'Am I a candidate*?' then becomes redundant as we can approach practically every eye with a uniquely designed approach (single or staged) for a life free of glasses using individually designed surgeries keeping safety in mind, thus raising the bar on predictability, safety, and reversibility," Dr. Gulani explained.

"This truly then elevates refractive surgery from 'one-size-fits-all' to an art," he added.

In summary, concluded Dr. Gulani, practically any ocular situation—including virgin eyes with basic refractive errors like myopia, hyperopia, and astigmatism of all levels, as well as complex eyes like status postcataract surgery, glaucoma surgery, retinal surgery, LASIK complications, and corneal transplants, as well as traumas—can be addressed to achieve the best unaided visual capacity, provided the patient has visual potential.

Continues on page 24 : ***Gloves Off***

GLOVES OFF

(Continued from page 23)

This, of course, should not be a frivolous advertising gimmick, but instead, a dedicated desire and commitment of every eye surgeon.

"As long as there is no intraocular pathology or disease, such as retinal, neurological pathologies, or uncontrolled glaucoma, there is no reason why we cannot aim toward a perfected visual outcome. This ability to help patients with refractive surgical complications/previous surgeries/etc. toward 20/20 vision is no longer out of reach in aspirations or outcomes, and will raise the level of comfort for surgeons as well as patients. Because when you design surgery for an individual eye, you are planning for success, not just hoping for it," Dr. Gulani said. ■

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What do you think of the "Corneoplastique" concept? Weigh in at **facebook.com/OphthalmologyTimes**.

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Dr. Gulani is director of the Gulani Vision Institute.

How corneal collagen crosslinking indications are expanding

From Staff Reports

NEW YORK :: **INDICATIONS FOR RIBOFLAVIN** ultraviolet crosslinking have been expanding. As such, the technology may be useful for more than just treating keratoconus—by filling a gap in which other surface therapies sometimes cannot be effective.

The indications include stabilizing ectatic corneas, followed by excimer laser ablation or other procedures to improve vision; pretreating eyes at risk for ectasia to increase the number of candidates for refractive corneal surgery, antimicrobial treatment, stabilizing eyes that have undergone radial keratotomy, treating sterile corneal ulceration, and treating corneal edema.

Eric D. Donnenfeld, MD, in discussing new applications, noted that ultraviolet A has a long history of use for sterilizing drinking water and use with riboflavin to sterilize blood products. Dr. Donnenfeld is a founding partner of Ophthalmic Consultants of Long Island and Connecticut; clinical professor ophthalmology, New York University Medical Center, New York; and a trustee of Dartmouth Medical School.

In addition, melting in corneal ulcers can be halted with crosslinking (2.5 mW/cm^2/30 minutes). The crosslinked corneas have increased resistance to enzymatic degradation and melting. Crosslinking may stabilize proteolysis by making collagen less prone to melt by infectious processes and sterilize the infection, he noted.

Possible treatment-related concerns are apoptosis of keratocytes, potential toxicity of the endothelium, limbal cells, and/or goblet cells.

PRK patients may also benefit from UVA crosslinking. Significant improvements in visual acuity have occurred when the technology was combined with topographic PRK after development of post-LASIK ectasia and keratoconus. There is a potential use for UV crosslinking in high-risk PRK (i.e., those with form fruste keratoconus, thin corneas, high myopia, and young patients).

Concerns include the addition of a refractive variable to the procedure due to corneal flattening associated with riboflavin UV crosslinking, Dr. Donnenfeld said.

In addition, patients who have undergone radial keratotomy, have bullous keratopathy, and those with stromal ring implants may benefit from the technology, he noted. In bullous keratopathy, for example, crosslinking improves corneal transparency, corneal thickness, and ocular pain 1 month after treatment, but there is no long-lasting effect in decreasing pain and maintaining corneal transparency in these patients. ■

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No motivation? Try the reverse

Why telling someone that he or she can't do something may produce a different outcome

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

TAKE-HOME

- ***Practicing reverse motivation may be just what the doctor ordered when it comes to helping staff members achieve their goals, relates columnist Dianna Graves.***

My e-mail inbox has been inundated recently with advertisements for web seminars focusing on the topic of staff motivation tips for managers. I signed up for one to be sure I wasn't missing any philosophical pearls that might help my staff be its best.

I have had managers ask me to visit their practices to help with the clinic flow and technician continuing education and to help ensure that the office (technicians/front desk/telephone center) is running at peak efficiency. But when they ask me to help with their staff motivation, I politely tell them that I cannot do this for them. This is something the staff needs to do for itself.

You might think that I have finally gone over the edge. Here is my philosophy on motivation: no manager can motivate his or her staff. Motivation is something that occurs inside each person, and no one can change someone else's motivation level.

I can point out ways that someone can improve as a technician, and maybe even as a person, but these are my opinions to be listened to . . . or not. Similar to the saying, "You can lead a horse to water, but you can't make it drink."

Managers can cheerlead for their employees to strive for personal excellence, to push their standards higher, and to reach for their personal stars, but they cannot make them do any of those things. They either want to or they don't.

And therein lies the rub: Motivation of anyone but yourself is out of your hands.

So, I do not adhere to motivational pearls. I help staff members find their own pearls and then give them the tools to achieve their goals. Sometimes the best way for that to happen is to practice "reverse motivation."

WHAT IS REVERSE MOTIVATION?

Instead of telling someone that he or she can do something, try telling someone that you don't think he or she can do it. The response will tell you where that person is in his or her mind and the potential ability to achieve the goal.

The first time I experienced this was after I had just graduated from college and was doing a job totally out of my field of training. I was working in a traffic safety group outside of Boston. It was a fairly large, prestigious, engineering group. My title was safety technician. But, really, I was a glorified graphics assistant adjusting the fonts on hundreds of pages of landscape and traffic acetates each day for the city of Boston and surrounding areas. No responsibilities—just a pile of acetates to get through every day. I was playing softball at night and living life.

My boss was a hard-driving, taskmaster who did not tolerate fools well. Sadly for all of us, he constantly considered us fools and the ultimate bane of his existence.

After a year and a half, he pulled me aside one day. He told me that he was letting me go, because he had no clue where I was going in this field. He was smarter than me, because I had no idea either. He said he would give me 3 months to find something else.

I was dumbfounded, but it ended up being the best thing that ever happened to me. Shortly after, I was accepted into the

Continues on page 30 : ***Motivation***

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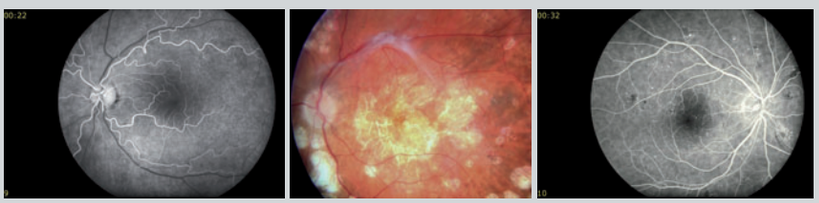

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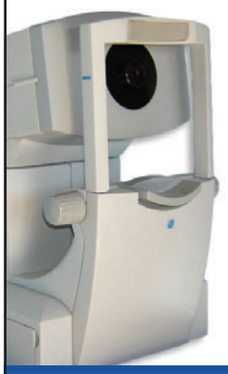

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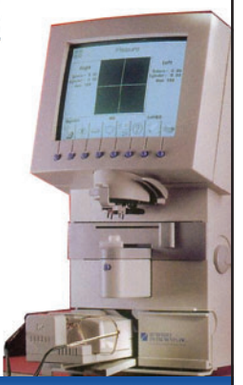

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MOTIVATION

(Continued from page 26)

School of Ophthalmic Medical Technology in St. Paul.

On my last day, he asked me what I was going to do with my life. I told him I was going to the school.

He replied: "A *technology* school? Save your money! You don't have the technical stuff in you . . . . I just don't see it working for you!"

For 2 long years, I did everything I could to succeed at the school. I graduated with a solid "B" average and then passed the COMT test. The whole time I was living for that *one day*, and it came 3 months after graduating.

I was in New England and walked into my former boss' office. He jumped up, smiled, and welcomed me—and when I had a word in edgewise with him—I said: "Leo, I graduated from school and passed my test and am now certified. You were wrong—and I wanted you to know it!"

He replied: "I knew you could do it, but you didn't. So I figured I would give you a parting kick in the pants and see if you took the bait. Good job."

I was totally confused. Until I realized that he was right.

What got me through the school was not really motivation but a skewed definition of motivation to prove him wrong.

TAKING THE BAIT

Years later, I tried this approach with one of my own students at the school. She was a young gal who really didn't seem to want to be in the program, but was there anyway. And soon became the bane of my existence!

Each visual field class, she sat in plain sight and loudly yawned. Her head would bob throughout the lectures. Her classic move was to click her pen over and over until I stared her down.

I pulled her into a room about 4 weeks into the semester and said: "What are you doing here?"

She replied: "You called me into the room!"

"No, what are you doing here in this program, taking the space of someone that really wanted to be here?" I asked. "You're wasting my time and your money because you have to pass my class—and the practical—to graduate, and it isn't going to happen from what I have seen so far."

She glared at me and walked out without looking back. I advised the program director of the discussion and warned that we might be minus a student soon.

And then I sat back and prayed she took the bait. She took it—hook, line, sinker, and boat!

At the end of the semester, she walked through the final with an "A" and then the day of reckoning: the practical. She was controlled and focused and she performed an excellent visual field.

After the practical, I always have a debriefing of students' skills. We sat like wary grizzlies in a very small room. I said: "Thank you for proving me wrong."

> 'Motivation of anyone but yourself is out of your hands.'
>
> — Dianna E. Graves, COMT, BS ED

She countered with: "I worked my tail off this semester to prove you wrong and to hear you say that!"

She is now working in Colorado and, from what I hear, is a darn good technician. And she even smiled and joked with me at the last continuing education meeting.

Of course, I would have been happier with that if it hadn't been during the middle of my lecture. But, everything in time! ■

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

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From Staff Reports

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PHYSICIANS CAN DOWNLOAD A NEW APP to see exactly how the Sunshine Act reporting process will work before results go public next year.

The Centers for Medicare and Medicaid Services (CMS) released two new mobile apps called Open Payments—one for physicians, and one for health-care-industry users—to help healthcare providers to be more aware of transactions being reported for the upcoming Sunshine Act.

The Open Payments app for physicians will allow them to track real-time payments and other value transfers to pharmaceutical and device manufacturers. Physicians will be able to create a profile and keep track of any discrepancies in reporting.

The app for industry users, including hospitals and institutions, will have the same features as the physicians' app, but will also be able to store physician profiles.

The apps are being released in time for implementation of the Physician Payments Sunshine Act, also called the Open Payments program. The provision, a part of the Affordable Care Act, mandates that pharmaceutical and medical device companies report financial relationships with physicians, hospitals and other health-care businesses that amount to more than $100 a year. Companies will begin reporting financial information on Aug. 1, 2013. The list in its entirety will be published annually in September 2014 via an Open Payments website facilitated by CMS. Physicians are not required to report payments, and using the app is not mandated by the Sunshine Act.

Both apps are available for free through the iOS Apple Store for iPhone and iPad users and the Google Play Store for Android devices. ■

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a roundtable discussion held in Seattle, Washington, May 4, 2013.

ACTIVITY DESCRIPTION

During the past 20 years, the therapeutic landscape for intraocular pressure (IOP) reduction in glaucoma management has expanded substantially. A decade ago, it was estimated that there were more than 56,000 possible combinations of available IOP-lowering therapies—and that figure did not include fixed combinations. Since then no new drug classes have been introduced, but the availability of new formulations and novel combinations has increased our options. There are currently 3 modern fixed combinations of commonly used IOP-lowering drugs in the United States and even more are available in international markets. Fixed combinations have numerous benefits and also have several drawbacks. Where do fixed combinations fit into the stepped therapeutic algorithm for glaucoma management? We have always been taught to add medications one at a time in order to avoid overtreating patients. Has this paradigm been altered by the development of fixed-combination formulations? In this educational activity, an expert glaucoma faculty panel will discuss the roles of multiple-therapy IOP control, including that of fixed-combination formulations, in the management of glaucoma.

TARGET AUDIENCE

This educational activity is intended for glaucoma specialists and comprehensive ophthalmologists.

LEARNING OBJECTIVES

Upon completion of this activity, participants will be better able to:

- Discuss the advantages and disadvantages of multicomponent and fixed-combination therapy for IOP management
- Describe the efficacy, safety, and dosing profiles of fixed combinations, and their component medications
- Incorporate fixed combinations as primary therapy for IOP management in appropriate patients
- Incorporate fixed combinations as adjunctive therapy for IOP management in appropriate patients
- Select multi-agent or fixed-combination therapy appropriately for use in regimens to attain optimal adherence and IOP control based on individual patient profiles

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Introduction

We are fortunate to have more options for lowering intraocular pressure (IOP) in 2013 than ever before. In the past few years we have seen the development of new drugs, new formulations of existing drugs, and novel fixed combinations of well-established drugs as well. These myriad therapeutic options allow us to individualize therapeutic regimens as never before, meeting patients' needs for efficacy, safety, tolerability, convenience, and cost. The plethora of choices also comes with clinical challenges, particularly for the many patients with glaucoma or ocular hypertension who require more than 1 agent for adequate IOP control. Despite the nearly 20 years since prostaglandin analogues were introduced and eventually replaced beta-blockers as preferred first-line therapy, we still have incomplete data to guide the optimal selection of adjunctive therapy. Even less clear are best choices for third- or even fourth-line therapy. In this program, we have assembled a panel of glaucoma specialists to discuss the evolving therapeutic treatment algorithm for IOP reduction. We hope it provides some insight into the considerations that should inform the development of a multidrug glaucoma therapy regimen.

—Tony Realini, MD, MPH, and Robert D. Fechtner, MD

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Selecting Adjunctive Therapy

Dr Realini: Consider a 65-year-old woman with early glaucoma who has a target pressure of approximately 16 mm Hg. Her glaucoma has been well controlled using prostaglandin monotherapy for 6 years, but over the last several visits, her IOP has measured consistently in the low 20s, with confirmed visual progression in the form of extension of an inferior nasal step into an inferior arcuate defect. She requires additional therapy to achieve a lower IOP. There are many options for this patient. Dr Flowers, is there any value in switching within the prostaglandin class?

Dr Flowers: I would say no. When bimatoprost, 0.03%, was commercially available, there was some evidence that a subset of patients—maybe 1 out of 5—might benefit by switching from other prostaglandins to bimatoprost, 0.03%,[1,2] perhaps because they were not yet at the top of their dose-response curve, and this formulation had the highest drug concentration in the class. Now that bimatoprost is available only in the 0.01% formulation, I do not think this potential benefit exists anymore. Therefore, at this time there are rare instances in which I see much value switching within classes of prostaglandin analogues.

"There are rare instances in which I see much value switching within classes of prostaglandin analogues."

— Brian E. Flowers, MD

Dr Realini: Does anyone else switch within class?

Dr Buys: Since the availability of generic latanoprost, we are, in fact, switching within the prostaglandin class more often than one might think. There are considerations to generics that we should discuss, and this case raises concerns for me. When I see a person who has had excellent control of IOP for a long time on a stable regimen, and all of a sudden he or she has lost that control, I consider the possibility that the loss of control is related to the switch

to a generic formulation. I have had patients in whom I have switched back to branded product and noted the re-establishment of IOP control.

"When I see a person who has had excellent control of IOP for a long time on a stable regimen, and all of a sudden he or she has lost that control, I consider the possibility that the loss of control is related to the switch to a generic formulation."

—Yvonne M. Buys, FRCSC, MD

Dr Nguyen: I agree that we should always be aware of precisely which formulation our patients are using. I strongly prefer monotherapy whenever possible. I think keeping patients on 1 drop at night is very important, in part because it is a regimen that is easy to adhere to. One important caution in this case—If you switch to a different prostaglandin and see improved IOP, it may not be attributable to better therapeutic response; it may simply be regression to the mean. In a nutshell, this means that if IOP is running higher than usual, it is more likely to be lower at the next visit, no matter what you do—even if you do nothing at all. In this particular case, I do not see any value in switching to a different prostaglandin.

Dr Realini: Dr Nguyen, you mentioned adherence. This case is actually one of my patients. After discussing my concerns about her disease progression with her, she shared that her husband had died recently and she had become depressed and stopped taking all her medications, including her eye drops. This raises a very important issue in clinical practice. How do we address suspected adherence issues with our patients?

"We should always be aware of precisely which formulation our patients are using."

— Quang H. Nguyen, MD

Dr Buys: How we ask about adherence determines what answer we get. We routinely ask patients if they are taking their eye drops, but how we do that is important. I do not ask, "Are you using the same drop as last time?" Inevitably the answer to that question will be yes. Instead, I ask my patients to tell me exactly what drugs they are using and when they are using them. If they can't tell me, they probably aren't adherent. I'm also frequently surprised that patients are taking different drugs from what I intended for them to take. A study performed by our group revealed that 4.2% of patients reported using different drops than those recorded in their charts,[3] and other studies have reported that 40% of patients cannot accurately self-report the glaucoma medications they are using.[4] Once I have established which drug or drugs a patient is on, then I ask, "How many drops do you think you miss each week?" The form of the question gives the patient permission to be honest. Then you can explore the reasons why he or she is missing some doses.

PEARLS ON IMPROVING THERAPEUTIC ADHERENCE

Dr Buys: I have found that sharing test results with patients helps them understand their disease and, I think, encourages them to be more compliant. I find optic nerve imaging very useful for showing patients their own eyes.

Dr Budenz: I am very explicit with patients about when they should be taking their medications, particularly when they are on polytherapy. Too many of our patients get a bottle that is labeled "Use this twice a day," and they will use it at breakfast and lunchtime and not really understand what it means to use a medicine twice a day. Also, I always remind my patients to wait at least 5 minutes between instilling 2 different drops in the same eye. I am surprised at how many patients have not heard that message before.

Dr Flowers: When patients say they forget to take their drops, I think that is a catch-all for several different things. One might be expense. They may not be able to afford the drug and might be too embarrassed to tell us. Or they may be having side effects. If the drug stings or burns, they may not use it, but they do not always admit that is why they are not using it. I cannot overemphasize the importance of finding out why patients are not compliant and then addressing that issue specifically.

Dr Realini: For those patients who truly do forget to take their drops, there are "reminder" apps available. Many of my patients have Smartphones and Tablets (they use them to fill the time while they are waiting for me to come into the examining room). They can download a free or inexpensive app that will serve to remind them when to take a dose of their medications.

"I ask my patients to tell me exactly what drugs they are using and when they are using them. If they can't tell me, they probably aren't adherent."

— Yvonne M. Buys, FRCSC, MD

Dr Flowers: In order to improve adherence, you first have to identify nonadherence. Creating an environment in which the person feels safe to admit nonadherence is very important. I make it clear that no one is perfect, everyone misses some drops. I scale my conversation based on how nonadherent I think the patient really is. For some people, I ask how many drops they miss in a day; for others, I ask in terms of a week. I think people feel more comfortable if they understand that you know they are not taking all their drops.

Dr Realini: Dr Budenz, do you think that adding a second drop affects adherence in a negative fashion? Or in a positive fashion?

Dr Budenz: I think you could argue it both ways. Adding a second drop communicates to the patient a certain seriousness of the disease. People perhaps get more worried if they have to be on 2 medications. But I think, in general, adding a second drop decreases adherence.[5] It is just much more difficult to manage 2 medications in a day. Trying to keep people on monotherapy is definitely beneficial. In this particular case, I do not think that we are going to be able to do that with just a prostaglandin analogue.

Dr Realini: So we are not going to switch within class. We are going to add adjunctive therapy. What are our options for adjunctive medical therapy in this patient, Dr Nguyen, and what are our IOP-lowering expectations of adjunctive therapy?

Dr Nguyen: The options include topical carbonic anhydrase inhibitors (CAIs), alpha-adrenergic agonists, and beta-blockers. In general, I hope for an additional 15% to 20% IOP reduction when adding any of these agents to a prostaglandin.

Dr Buys: We have limited data on the additivity of these drugs to prostaglandins. We have more data on the IOP-lowering efficacy of these drugs as monotherapy. Drugs work consistently less well, however, as adjunctive therapy than as monotherapy. I agree with Dr Nguyen. I would be very happy to get a 15% or more IOP reduction with an adjunctive agent added to a prostaglandin.

Dr Fechtner: Typically, we characterize our expectations in terms of peak efficacy. Drugs have both peak and trough effects, and these effects are likely of different magnitude in primary vs adjunctive use.

Dr Realini: Once we have decided that we need to add something to a prostaglandin, what medication do you add as first adjunct to a prostaglandin, and what do you add next when dual therapy is inadequate?

Dr Flowers: With the caveat that all treatment decisions are individualized based upon several factors, I typically start with a prostaglandin, add a beta-blocker second, and usually offer selective laser trabeculoplasty (SLT) third. This approach is based on a combination of efficacy, convenience, and cost.

Dr Budenz: After a prostaglandin, I add a CAI, and if the patient needs additional IOP reduction, I switch to a fixed combination containing a CAI. Currently that is the dorzolamide/timolol fixed combination. This regimen requires only 2 bottles, which I think patients can handle adequately. After that, I offer SLT.

Dr Buys: My second agent is a beta-blocker, and if the patient still is not at target, then I will transition to a combination agent with either a CAI or an alpha-adrenergic agonist. After that, laser trabeculoplasty.

Dr Nguyen: I do not really have a fixed practice pattern. I like to talk with each patient to get a feel for what he or she might want to do next. I present the options and summarize the data on how well each option is likely to work, discussing the pros and cons of each. Some of the patients in my practice love the idea of laser and being drop-free. Other patients are very conservative and want to try the drops first. I think talking to your patients and getting a feel for their wishes is very important.

Dr Fechtner: I feel very much as Dr Nguyen does. I present the options to the patients, but it seems that most often my thinking evolves into prostaglandin plus fixed combination use, and then we get to laser.

Dr Realini: Do we have good efficacy and safety data for the adjunctive use of second-line drugs with a prostaglandin analogue? Dr Buys, you prefer to add a beta-blocker to a prostaglandin. Are you confident in knowing what to expect when you add a beta-blocker to a prostaglandin?

Dr Buys: In my opinion, the literature in this area is limited. For this very reason, I base most of what I do on what my clinical experience has been.

Dr Budenz: I became disappointed with the adjunctive effect of beta-blockers after results in the trials combining them with prostaglandins were unremarkable, yielding not more than 1 to 2 mm Hg in IOP reduction beyond that attained with the prostaglandin alone.[6-8]

Dr Realini: Dr Budenz, you mentioned that you prefer first a prostaglandin and then a CAI. How comfortable are you that you really have a sense for the expected safety and efficacy profile of that combination?

Dr Budenz: There certainly are not many studies supporting the use of a prostaglandin and a CAI. Because of our experience with adjunctive beta-blocker therapy, I began to try CAIs, and they seemed to work better in my hands. We need more studies in this area.

Dr Flowers: I agree that more studies would be helpful. That said, there are some studies that address the specific question of what to add to a prostaglandin analogue.[9-11] Each study has come to a similar conclusion: the CAI was the most efficacious, followed by the alpha-adrenergic agonist and then the beta-blocker. One might then ask, Why would some choose a beta-blocker as the second agent? There are several reasons: cost, tolerability, once-daily dosing, the fact that the magnitude of the efficacy difference between these agents as adjuncts is small. A generic beta-blocker costs $4, and the studies I spoke of all showed typically less than a 1 mm Hg pressure difference in efficacy between all 3 drugs when added to a prostaglandin. I am willing to give up a fraction of a mm Hg pressure for a $4 once-a-day drop.

Dr Nguyen: The topical beta-blocker literature is confounded by the high prevalence of patients who are taking oral beta-blockers. This may be why we do not see the efficacy we expect from topical beta-blockers—the patients may already be beta-blocked from their oral therapy.

Dr Realini: Now that we have described our preferred order of adjunctive therapy, let us talk about why we do what we do. We have already brought up cost. Other than cost, what drives the choice of adjunctive therapy?

Dr Buys: One of the reasons that I choose beta-blockers is that they can be dosed once a day. The other choices—a CAI or an alpha-adrenergic agonist—require dosing at least twice and sometimes three times daily. To promote adherence, I strive for a regimen that is easiest for the patient.

Dr Nguyen: I choose adjunctive therapy depending on what is known about the drug's pharmacokinetics. Certain kinds of drugs have been shown not to function very well at night. Work from the Hamilton Glaucoma Center sleep laboratory in San Diego, California, has demonstrated nocturnal IOP reduction with CAIs, but not with beta-blockers or alpha-adrenergic agonists.[12,13] That is a big consideration in my view, and why topical CAIs have a big role in my practice.

Dr Fechtner: Regarding dosing regimens for adjunctive CAIs, there is not much in the literature to guide us. As monotherapy, they are labeled for 3-times-daily dosing, although the brinzolamide registry trials compared twice- and three-times-daily dosing and there was not much difference.[14] As adjunctive therapy, brinzolamide dosing is less clear. A retrospective study more than a decade ago demonstrated comparable IOP-lowering effects of twice-daily and three-times-daily CAI dosing as an adjunct to prostaglandins.[9] I will often go off-label and start with twice-daily dosing. If I do this, I try to arrange afternoon visits for those patients, to look at that late afternoon trough and make sure they are not breaking through. There is 1 additional important issue governing drug selection. Much of my choice is taken away from me now by formularies. As a physician, I can recommend what I believe is the best therapy, but the patients, in the end, have tremendous financial pressure from their pharmacy benefit plan.

"As a physician, I can recommend what I believe is the best therapy, but the patients, in the end, have tremendous financial pressure from their pharmacy benefit plan."

— Robert D. Fechtner, MD

Dr Realini: Before we move on, does anyone start 2 adjunctive drugs simultaneously?

Dr Fechtner: In some patients who come in with very high pressures, I will be very aggressive with my next-step medical therapy, particularly with regard to high-pressure advanced glaucoma, knowing that surgery may be imminent. If the patients are markedly responsive, I may back off on the therapy. But for routine patients who do not need urgent IOP reduction, I generally add medications 1 at a time.

Dr Buys: If you start 2 drugs at once, it is sometimes difficult to determine which drop is efficacious. Is one, both, or neither of them? In terms of the side-effect profile, I think that you are exposing the patient to potentially more side effects by starting 2 drugs at once. Unless the pressure is very high, I would usually add 1 at a time.

Dr Budenz: I used to give that exact same answer because you do not know if both drugs are effective, or which drug may be producing side effects. More often, recently, I have been going directly to fixed combinations after a prostaglandin because if a prostaglandin alone is inadequate to control IOP, I want to quickly achieve control. Looking back at the case we started with, this patient has an IOP of approximately 22 mm Hg and her target IOP is in the mid to low teens, given her recent progression. I do not think it is possible to achieve that by adding a single agent. In this particular patient, because she is progressing and we need more dramatic pressure lowering, I would go to a fixed combination to get the pressure into the low teens.

"I have been going directly to fixed combinations after a prostaglandin because if a prostaglandin alone is inadequate to control IOP, I want to quickly achieve control."

— Donald L. Budenz, MD, MPH

Fixed Combinations: General Concepts

Dr Fechtner: Regarding fixed-combination therapy, let us consider a patient who is using 2 IOP-lowering medications and who requires additional IOP reduction. It may be a patient on a prostaglandin and either a beta-blocker, a CAI, or an alpha-adrenergic agonist. What is your third-line drug in such a scenario?

Dr Flowers: My patients typically get beta-blockers second line, and my third-line choice is usually laser. But if I had to choose a third medication, it would be a CAI.

Dr Fechtner: Would you add that as a single agent or as a fixed combination?

Dr Flowers: A fixed combination. Prostaglandin and the dorzolamide/timolol fixed combination.

Dr Fechtner: All right. Dr Budenz, now we have your patient who is on prostaglandin plus topical CAI. What's next?

Dr Budenz: I would switch to fixed-combination beta-blocker/topical CAI.

Dr Flowers: So both of our patients end up on the same 3-drug regimen in 2 bottles.

Dr Budenz: Yes.

Dr Realini: We know more about the additivity of prostaglandins and beta-blockers than about any other combination. This is because of the registry trials for the prostaglandin/beta-blocker fixed combinations.[6-8] Although the 2 drugs in combination are available in other global markets and isolated studies have suggested acceptable

additivity in select populations,[15] they did not work well enough to garner US Food and Drug Administration (FDA) approval. Given this generally poor additivity of beta-blockers to prostaglandins, I do not put my patients on prostaglandin and beta-blocker therapy. However, patients on this regimen do get referred to me. Given what I know about the additivity, I would probably switch from the beta-blocker to a different adjunctive agent rather than add a third agent because I am not convinced that the beta-blocker is working very well. First, I would wash out the beta-blocker and reestablish the prostaglandin monotherapy baseline, and then I would add a CAI and see if that gets the patient's pressure to a target level.

Dr Fechtner: Would anybody add a third bottle to an existing 2-bottle regimen?

Dr Nguyen: I usually do not go to 3 bottles. We have evidence showing that the third bottle doesn't provide much likelihood of long-term IOP reduction.[16]

Dr Buys: I would go to 3-bottle therapy, especially before surgery. That might be a prostaglandin, then a fixed-combination beta-blocker/CAI, and then an alpha-adrenergic agonist.

Dr Fechtner: Dr Buys gets all 4 classes in before going to surgery. Is anybody concerned that the dosing frequency of beta-blockers tends to be once daily when used in unfixed combinations, but increases to twice daily when using fixed combinations?

Dr Nguyen: Yes. I see a lot of referral patients using a prostaglandin with twice-daily beta-blocker scenario. We know that the beta-blocker should be once a day. I am very concerned about the twice-daily dosing.

Dr Realini: Many patients are not controlled on once-a-day beta-blocker in solution. One of the things that Thom Zimmerman taught me was that if you are going to use a beta-blocker once a day, it is incumbent on you to check a 24-hour trough and make sure the drug is lasting that long.

Dr Flowers: That concern was lessened when the gel-forming solution of timolol became available. In comparison to twice-daily beta-blocker in solution, the gel-forming solution dosed once daily provided comparable peak and trough IOP efficacy.[17] There also have been studies comparing once-daily and twice-daily dosing of timolol in solution, and there was no significant difference.[18]

Table 1. Advantages and Disadvantages of Fixed-Combination Agents

ADVANTAGES	DISADVANTAGES
Simpler regimen • Fewer bottles • Fewer drops per day • May improve adherence	Cannot adjust doses separately • Drug concentrations • Dosing intervals
Minimized washout effect	May be more expensive (than 2 generics)
Minimized exposure to inactive ingredients	
May be less expensive (1 co-payment)	

Dr Buys: Beta-blockers are not the only drugs in which we deviate from optimal dosing frequency when used in fixed combination. The CAIs are labeled for 3-times-daily dosing as monotherapy, but the dorzolamide/timolol fixed combination is dosed only twice daily. Not only is this regimen potentially *over*dosing beta-blocker, but it is potentially *under*dosing the CAI. In the registry studies, the fixed combination was slightly less effective than using the 2 drugs in separate bottles.[19] In fact, the label for the fixed combination clearly states that the combination therapy is not as efficacious as the 2 medications given separately.

Dr Fechtner: So the efficacy profile of the fixed combination may differ from the profile of the components dosed in separate bottles. This may also be true regarding safety profiles. When the fixed combination of a beta-blocker and a topical CAI came to market, there were fewer adverse events noted with the fixed combination when compared with its individual components.

Dr Nguyen: Based on observations in international markets, where more fixed combinations are available, it is interesting to note that whenever a beta-blocker is added to a combination, the side-effect profile of the other drug improves. This is true of prostaglandins, CAIs, and alpha-adrenergic agonists. I think there is definitely interaction between the components of a fixed combination, both in terms of efficacy and of safety.

Dr Flowers: That side-effect improvement could be partially attributable to the anesthetic effect of the beta-blocker contributing to less burning. Interestingly, the brimonidine/timolol fixed combination showed significantly less allergy than brimonidine alone in that product's registry data.[20]

Dr Fechtner: So, fixed combinations may perhaps have more favorable safety profiles than unfixed combinations. What are some other advantages of fixed combinations? [See Table 1]

Dr Flowers: Fewer bottles and fewer drops per day. This makes the regimen easier for the patient to follow. It likely improves adherence as well.

Dr Realini: Fixed combinations also minimize the washout effect that happens when patients put their drops in one right after the other. The concern with unfixed combinations is that the first drop gets washed away by the second drop before it gets absorbed.

Dr Flowers: There is also reduced exposure to preservatives with fixed combinations. This is important because preservatives can irritate the ocular surface and many of our patients also have ocular surface disease.

Dr Fechtner: We looked at that situation several years ago and found that nearly half of glaucoma patients have symptoms of ocular surface disease.[21] This number is consistent with other reports.[22] It is surprising how many of our patients have dry eyes.

Dr Flowers: Preservative exposure also may reduce the success of future filtration surgery.[23]

Table 2. Characteristics of Modern Fixed-Combination Glaucoma Products

Brand Name	Active Ingredients	Efficacy vs Components	Common Side Effects (from each product's prescribing information)
Cosopt (also generics)	dorzolamide, 2%/ timolol, 0.5%	Peak –9.0 mm Hg Trough –7.7 mm Hg[a]	Taste perversion (bitter, sour, or unusual taste), ocular burning/stinging, conjunctival hyperemia, blurred vision, superficial punctate keratitis, eye itching
Combigan	brimonidine, 0.2%/ timolol, 0.5%	Peak –7.6 mm Hg Trough –4.9 mm Hg[b]	Allergic conjunctivitis, conjunctival folliculosis, conjunctival hyperemia, eye pruritus, ocular burning, stinging
Simbrinza	brinzolamide, 1%/ brimonidine, 0.2%	Peak –8.9 mm Hg Trough –5.5 mm Hg[c]	Blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, eye allergy

[a]See reference 36.
[b]See reference 20.
[c]See reference 26.

Dr Fechtner: What are the disadvantages of fixed combinations? [See Table 1] We have touched on the potential for slightly less efficacy than with constituent dosing. Are there other disadvantages?

Dr Realini: For one, the inability to independently adjust the doses of the concomitants can be problematic. We cannot adjust dosing frequency and we cannot adjust the concentration of the drugs in the combinations. We talked about once-daily vs twice-daily dosing of beta-blockers. With fixed combinations, there is no choice but twice-daily dosing. With brimonidine, a 0.1% formulation is commonly used, but in the 2 fixed combinations that contain brimonidine, a 0.2% concentration is used, and that may be overkill.

Modern Fixed Combinations

Dr Realini: We currently have fixed combinations of some drugs, but not others. What factors determine which drugs are formulated together in a fixed combination?

Dr Fechtner: Just because you can imagine putting 2 chemicals in the same bottle does not mean you can turn them into a fixed combination. Every single thing that goes in that bottle—from the preservatives to the buffers to the wetting solutions—will affect whether the active ingredients will be stable and bioavailable. There is innovation in each formulation of fixed combinations.

Dr Budenz: Dosing issues also drive the development of fixed combinations. We have these great drugs that are used once a day, others that work only if used twice or three times a day. We have discussed a common practice pattern of adding CAIs to prostaglandins. If we formulate CAIs into fixed combinations, we are forced to either *over*dose the prostaglandin or *under*dose the CAI.

Dr Realini: It occurs to me that the dorzolamide/timolol fixed-combination formulation was feasible mostly by luck. Timolol is formulated at essentially a neutral pH, but dorzolamide requires a pH in the mid-5 range to achieve solubility. Timolol had to be successful in that environment to make that combination agent feasible. We are just lucky that timolol is so versatile in its tolerance of pH adversity.

Dr Fechtner: That pH requirement in part accounts for the stinging and burning seen with products that are formulated with dorzolamide.

Dr Realini: The safety and efficacy profiles of the modern fixed combinations are summarized in Table 2. It is useful to discuss each fixed combination and explore its role in the treatment algorithm. Let us start with dorzolamide/timolol. This combination was first approved by the FDA in 1998. What was its role then, and how has its role evolved over time?

Dr Budenz: Prior to 1996, the beta-blocker was still the preferred first-line therapy. If that did not work, a CAI became a convenient second move. Instead of adding a second bottle, you could just switch from a bottle of beta-blocker to a bottle of the combination. Once the prostaglandins replaced beta-blockers as preferred first-line agents, we used the dorzolamide/timolol fixed combination less and less. It moved from second-line to third-line therapy.

Dr Buys: The dorzolamide/timolol fixed combination is my third-line agent also. Prostaglandin first, beta-blocker second, and then replace the beta-blocker with the fixed combination.

Dr Budenz: I end up at the same place, but I use the prostaglandin first, then a topical CAI, and then switch to the fixed combination as a third agent.

Dr Realini: All of us have described our use of dorzolamide/timolol. Interestingly, we are all using it off-label. It is officially approved for use in patients who are inadequately controlled on a beta-blocker alone. We no longer use it as a next step following timolol monotherapy. Also, it is worth mentioning that there is a new formulation of the dorzolamide/timolol fixed combination, and it is preservative-free.[24] Who might benefit from this product?

Dr Budenz: We all have patients who are either allergic to benzalkonium chloride (BAK) or get toxicity from BAK and other preservatives. It is wonderful that in 2013 we have BAK-free and preservative-free options. As glaucoma subspecialists, we all see referrals from doctors who send patients who are "intolerant to all drops." Some of my most grateful patients are those in whom I can switch to a preservative-free regimen, which now can consist of a preservative-free prostaglandin and a preservative-free fixed combination.

Dr Fechtner: BAK intolerance can be insidious. Most patients seem to tolerate the first eye drop. When they get the second BAK-containing eye drop, or the third, they can become symptomatic. Being aware of the BAK preservative burden, particularly in patients who are symptomatic, is part of our

responsibility. All the modern fixed combinations that have preservatives use BAK. We can reduce the preservative burden when we use fixed combination rather than 2 bottles.

"BAK intolerance can be insidious. Most patients seem to tolerate the first eye drop. When they get the second BAK-containing eye drop, or the third, they can become symptomatic."

— Robert D. Fechtner, MD

Dr Realini: Let us talk about the brimonidine/timolol fixed combination. Dr Fechtner, you published a study regarding this combination as an adjunct to a prostaglandin. Tell us about it.

Dr Fechtner: We presented and subsequently published a study with more than 200 patients on baseline latanoprost therapy with pressures of ≥21 mm Hg in at least 1 eye, then randomized to adjunctive brimonidine/timolol fixed combination or adjunctive timolol.[15] With brimonidine/timolol, we saw an approximately 35% additional pressure lowering at peak. It very much met the target we discussed earlier, a 15% to 20% additional reduction with adjunctive therapy. Timolol also provided additional IOP reduction in this study, but to a lesser extent than brimonidine/timolol.

Dr Realini: We briefly mentioned that the brimonidine/timolol fixed combination had a lower allergy rate associated with it than did brimonidine alone. Why do you think that is?

Dr Fechtner: In the registry studies, where that observation was made, the brimonidine/timolol fixed combination was dosed twice daily, whereas the brimonidine, 0.2%, was dosed 3 times daily.[20] The brimonidine-only arm received 50% more drug, so it is not surprising that those patients had 50% more hyperemia. Also, as Dr Nguyen mentioned, the fixed combinations may have different tolerability profiles than the individual components.

Dr Realini: Where does the brimonidine/timolol fixed combination fit into your treatment algorithm?

Dr Budenz: When I add a CAI to a prostaglandin, some patients have little effect from the CAI. In those people, I'll replace the CAI with timolol, and if we need a third drug, brimonidine/timolol fixed combination is the logical progression.

Dr Nguyen: I see many patients who are on a prostaglandin and brimonidine. When they need something else, I add timolol in the form of brimonidine/timolol fixed combination.

Dr Fechtner: The dorzolamide/timolol fixed combination has recently become available in generic formulations. All of these have an acidic pH to solubilize the dorzolamide component, and they all sting—branded or generic. I believe many of my patients are more comfortable on brimonidine/timolol.

Dr Realini: Most recently, a new fixed combination of brinzolamide and brimonidine has been approved by the FDA. Dr Nguyen, you were the lead author on one of the registry trials. Tell us about this new product.

Dr Nguyen: The 2 phase 3 registry trials compared the brinzolamide/brimonidine fixed combination to each of its components dosed separately.[25-27] All 3 drugs were dosed 3 times daily. Mean IOP reductions from baseline for the fixed combination ranged from 23% to 35%, which was a 1- to 3-mm Hg greater reduction than that achieved with either of the individual components. The side-effect profile was exactly what you would expect based on the known side-effect profiles of the constituent drugs. Adverse events occurring at a rate of 3% to 5% were, in descending order, blurred vision, eye irritation, dysgeusia, dry mouth, and eye allergy. The overall discontinuation rate was approximately 10%, and was similar between the fixed combination and the brimonidine-only groups.

Dr Realini: Where do you think the brinzolamide/brimonidine fixed combination is going to fit in our regimen?

Dr Nguyen: This drug has been indicated for a wide range of uses. You can use it as primary, as adjunctive, or as replacement therapy.

Dr Flowers: The brinzolamide/brimonidine fixed combination will be primarily adjunctive in my hands, likely following a prostaglandin, and probably following laser. The efficacy was a little bit surprising, being comparable to fixed combinations that contain a beta-blocker. It is interesting to see that you can achieve a similar efficacy without having to use beta-blockers.

Dr Budenz: I do not even bother with a fixed combination containing a beta-blocker in patients already on an oral beta-blocker. It is very helpful to have a beta-blocker-free fixed combination. Certainly beta-blockers have overt side effects with which we all are familiar, and they are contraindicated in people with restrictive airway disease and those with slow heart rates. But there also are some covert adverse effects of beta-blockers. Beta-blockers can cause fatigue, impotence, and other issues that we do not often associate with topical eye drop therapy. It is nice to have a fixed combination without the potential overt and covert side effects of a beta-blocker. I am excited about the possibility of finally having a fixed combination that does not involve a beta-blocker.

"I do not even bother with a fixed combination containing a beta-blocker in patients already on an oral beta-blocker. It is very helpful to have a beta-blocker-free fixed combination."

— Donald L. Budenz, MD, MPH

Dr Realini: I think my practice pattern will evolve into prostaglandin first, then CAI, and then the brinzolamide/brimonidine fixed combination. I also think that, with time, I'll start adding this fixed combination as the first adjunct to a prostaglandin. As we have said, no single drug lowers IOP very much when added to a prostaglandin. The "best bang for the buck" may be to treat brinzolamide/brimonidine as a single drug and add it early.

Dr Budenz: The downside to this fixed combination is that it is labeled for 3-times-daily dosing.

Dr Nguyen: That is true. In the United States, it is labeled for 3-times-daily dosing. There are several European studies ongoing that use a twice-daily dosing regimen. We should get that data sometime next year, I believe.

Dr Realini: Are we likely to see data on the additivity of brinzolamide/brimonidine to a prostaglandin?

Dr Nguyen: I think all of us want to see how this new fixed combination will work when used as adjunctive therapy. There are plans under way to conduct a multicenter clinical trial to look at its additivity to a prostaglandin.

Dr Fechtner: When do we use fixed combinations in clinical care? We have talked a lot about adjunctive use when a prostaglandin is our first-line drug. Two of the 3 modern fixed combinations have labeling that include first-line use. Are there situations in which you would initiate therapy using a fixed combination?

Dr Budenz: Occasionally patients present to our office with pressures of 40 to 50 mm Hg. They need rapid and profound IOP reduction. I will use a fixed combination in conjunction with a prostaglandin, maybe even all 4 classes and even an oral CAI initially to get the pressure down. Then maybe I can withdraw some medications once target is reached.

Dr Nguyen: Patients with unilateral glaucoma, such as pseudoexfoliation, may wish to avoid unilateral eyelash changes and hyperemia, so we might not start with a prostaglandin. A fixed combination with an IOP profile similar to that of a prostaglandin would be a good choice here. Likewise, younger patients with pigmentary glaucoma are often active and wish to avoid both red eyes and a beta-blocker. These patients may be good candidates for the brinzolamide/brimonidine fixed combination.

Dr Fechtner: Dr Nguyen makes a good point. The IOP-lowering profiles of the fixed combinations are very comparable to those of the prostaglandins. I participated in 2 multicenter studies comparing dorzolamide/timolol fixed combination to latanoprost, both of which showed similar efficacy when each was used as monotherapy.[28,29] When a patient prefers not to have a prostaglandin as initial therapy or if there is a history of prostaglandin intolerance, I have confidence that I can get the same sort of pressure lowering from the fixed combination that I usually expect from a prostaglandin. I also like using a fixed combination of aqueous suppressing drugs for post-laser IOP spikes.

Dr Realini: Double aqueous suppression is also helpful when dealing with post-trabeculectomy bleb leaks.

Dr Fechtner: How often do we go beyond a prostaglandin and a fixed combination to add that fourth molecule rather than heading to the operating room? What are the considerations?

Dr Buys: I use a fourth drug fairly frequently. I have a great deal of respect for surgery; trabeculectomy is highly effective but also has many risks and complications. I usually go to 4 agents, 2 of them being in combination therapy, before recommending surgery.

Dr Fechtner: Do you find that the use of 4 agents provides a long-term solution, or do these patients usually end up in the operating room despite the use of 4 agents?

Dr Buys: I have had many patients who have found the 4-drug regimen to be a good long-term solution.

Dr Realini: I think a fourth medication invokes the law of diminishing returns. The medicine that you pick as your fourth-line agent is your fourth-line agent for a reason. You either have little faith in its IOP-lowering effect or you have grave concerns about its safety. It is fairly unlikely a patient who is not controlled on 3 preferred drugs can be saved from undergoing surgery by use of that fourth drug. Most of my patients who have surgery are on just 2 bottles, a prostaglandin and a fixed combination. They have had SLT somewhere along the way. I have very few patients on a 4-drug regimen.

"I think a fourth medication invokes the law of diminishing returns. The medicine that you pick as your fourth-line agent is your fourth-line agent for a reason. You either have little faith in its IOP-lowering effect or you have grave concerns about its safety."

— Tony Realini, MD, MPH

Dr Fechtner: We have agreed that there are some patients for whom first-line fixed combination is appropriate, but for most patients we use these drugs as second-line therapy. We have no large head-to-head trials to inform us of the relative safety and efficacy of these fixed combinations when used adjunctively to a prostaglandin. In the absence of these data, what factors do we consider when selecting a fixed combination?

Dr Realini: There are at least 4 prospective randomized head-to-head trials that have compared the fixed combinations, as first-line therapy, though, and not as adjuncts to a prostaglandin.[30-33]

Dr Flowers: Three of those studies showed no differences in efficacy and 1 gave the edge to brimonidine/timolol over dorzolamide/timolol, but that study had only 20 patients. None of the studies included brinzolamide/brimonidine fixed combination.

Dr Fechtner: Are there safety considerations among the fixed combinations that drive our decision making?

Dr Nguyen: There are many patients for whom beta-blockers are contraindicated; I think there is a great deal of undiagnosed restrictive airway disease. Two important epidemiologic studies come to mind. The first was based on data from the National Health and Nutrition Examination Survey and showed that 12% of the adult population in the United States has undiagnosed

obstructive pulmonary disease.[34] The other is a study from 3 US Veterans Affairs Medical Centers that revealed that among patients prescribed a topical beta-blocker, 8% to 10% were also on medications to treat chronic obstructive pulmonary disease.[35] The take-home message is that it may not be safe to prescribe beta-blockers even in the patients for whom we think it is safe. There is a great need for a beta-blocker-free fixed combination. Brinzolamide/brimonidine meets that need.

"There is a great need for a beta-blocker-free fixed combination. Brinzolamide/brimonidine meets that need."

— Quang H. Nguyen, MD

Dr Flowers: One side effect that is underrecognized is somnolence with brimonidine. At one point, I did a study in my practice and had patients fill out an anonymous questionnaire. I was surprised how many people volunteered that they were somnolent on brimonidine.

Dr Fechtner: We have now thoroughly reviewed the considerations involved in constructing and managing multidrug regimens for our glaucoma patients. We have also discussed the roles of fixed-combination products in those regimens. Now let us put what we have discussed into practice by applying our thoughts to 2 clinical cases.

CASE 1

A 65-year-old woman has optic nerve cupping greater in her right eye than in her left, and has a small nasal step visual field defect in the right eye. She has remained stable on a regimen in both eyes of generic latanoprost dosed at night and generic dorzolamide 3 times daily, with IOPs in the 15- to 17-mm Hg range. She was previously on twice-daily dorzolamide but had late afternoon spikes on 2 different diurnal curves that were in the low 20s, so 3-times-daily dosing was deemed necessary. Over the past year, her IOP has crept up from the mid-teens to the 19- to 20-mm Hg range, and she has demonstrated reproducible visual field progression in the form of expansion of her nasal step into an arcuate defect.

Dr Realini: I think we would all agree that this patient needs further IOP reduction. I would like to get her back into the 15- to 17-mm Hg range at which she was previously stable. How might we accomplish that?

Dr Fechtner: Because she needs that afternoon dose of dorzolamide, the dorzolamide/timolol fixed combination may not be ideal for her because it is dosed only twice daily. I might add timolol in the morning rather than put her on a fixed combination.

Dr Flowers: I would also add a beta-blocker as a third bottle. A generic beta-blocker is also the least expensive option. I am not convinced that it will be enough to achieve the low target IOP that this patient needs, but that would be my first step.

Dr Budenz: If she truly needs the CAI 3 times daily, then a fixed combination might not be ideal for her. I think, though, that it is worth trying the dorzolamide/timolol fixed combination twice daily. The added beta-blocker twice a day may help smooth out that afternoon peak and make the mid-day dose of CAI unnecessary.

CASE 2

A 72-year-old man with moderate open-angle glaucoma has early notching of both neuroretinal rims with inferior arcuate defects in both eyes. He has been stable for the past 7 years at a target pressure of 18 mm Hg on travoprost at night and brimonidine in both eyes twice a day. He also has high blood pressure and he takes an oral beta-blocker to control it. He has recently had progression based on both visual field and optic nerve changes.

Dr Realini: What are our options for advancing this patient's therapy?

Dr Fechtner: I want to reiterate something said earlier. When a patient, such as this gentleman, has been stable for a long time and something has changed in his disease, it could be the disease process; but, it could also be an adherence issue. We really have to probe the history and see if there is something else in the patient's life that is affecting the therapy. Has there been a family event or a change in his overall health, or change in systemic medication?

Dr Nguyen: Agreed. And having ruled those issues out, this is a case in which the fixed combination brinzolamide/brimonidine would be useful. A fixed combination containing a beta-blocker might not add much IOP reduction if he is already on an oral beta-blocker.

Dr Realini: Brinzolamide/brimonidine is labeled for 3-times-daily dosing. How often would you dose it in combination with a prostaglandin?

Dr Fechtner: Three times a day until I see data using twice-daily dosing.

Clinical Applications

When selecting adjunctive agents in patients who need more than a prostaglandin, there are several choices and relatively sparse data to form evidence-based guidelines. While individualizing adjunctive therapy, issues to consider in selecting an adjunctive agent include additive efficacy, safety, frequency of dosing, and cost. Numerous fixed combinations of commonly paired glaucoma drugs are available in the United States. At present, none of these contains a prostaglandin, and all but 1 do contain a beta-blocker. The efficacy and safety profiles of these fixed combinations have been reviewed here. The faculty has shared clinical pearls to inform the optimal use of each of these fixed combinations in the multistep glaucoma treatment algorithm. We hope that this educational activity has clarified some of the issues surrounding the development of multidrug regimens for our glaucoma patients who cannot achieve adequate IOP control on monotherapy.

—Tony Realini, MD, MPH, and Robert D. Fechtner, MD

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1. Approximately what percent of patients self-report using glaucoma medications other than those documented in their medical records?
   a. 1
   b. 4
   c. 9
   d. 15

2. When talking to patients about adherence to therapy, clinicians should:
   a. Ask patients if they are taking all their eye drops
   b. Create an environment in which patients feel comfortable revealing nonadherence
   c. Tell patients they may go blind if they miss their eye drops
   d. Tell patients which eye drops they should be using

3. When adding an adjunctive agent to a prostaglandin, it is reasonable to expect an additional IOP reduction of:
   a. 5% to 10%
   b. 15% to 20%
   c. 25% to 30%
   d. 35% to 40%

4. Single-agent options for adjunctive therapy in combination with a prostaglandin include all the following, except:
   a. An alpha-adrenergic agonist
   b. A carbonic anhydrase inhibitor
   c. A second prostaglandin
   d. A beta-blocker

5. Which of the following is false regarding adjunctive therapy to a prostaglandin?
   a. Several studies suggest that carbonic anhydrase inhibitors probably are the most efficacious
   b. The difference in efficacy between beta-blockers, carbonic anhydrase inhibitors, and alpha-adrenergic agonists is fairly small
   c. Issues such as dosing frequency and cost may affect our selection of adjunctive therapy
   d. Most drugs work better as adjunctive therapy than as monotherapy

6. Which of the following is not a reason to consider beta-blockers as adjunctive therapy?
   a. Low cost
   b. Well tolerated topically
   c. Convenient once-daily dosing
   d. Highly additive to prostaglandin agents

7. Drugs that lower IOP effectively at night include:
   a. Beta-blockers
   b. Alpha-adrenergic agonists
   c. Carbonic anhydrase inhibitors
   d. None of the above

8. Which of the following factors govern/s the formulation of fixed combinations?
   a. Solubility
   b. Bioavailability
   c. Compatible dosing schedules
   d. All the above

9. Which of the following is not an advantage of formulating 2 drugs into a fixed combination?
   a. Greater efficacy than when dosed separately
   b. Minimization of the washout effect
   c. Reduction in exposure to preservatives
   d. A simpler medical regimen that may improve adherence

10. All the following are disadvantages of fixed-combination formulations, except:
    a. Inability to adjust drug concentration
    b. More side effects than the 2 constituents dosed separately
    c. Often less efficacy than when constituents are dosed concomitantly
    d. Inability to adjust dosing frequency of individual components

11. The constituents in Combigan are:
    a. Dorzolamide and timolol
    b. Brimonidine and timolol
    c. Latanoprost and brimonidine
    d. Brinzolamide and brimonidine

12. Which of the following fixed combinations contain/s a carbonic anhydrase inhibitor?
    a. Cosopt
    b. Combigan
    c. Simbrinza
    d. Both a and c

13. Which of the following fixed combinations is available in a preservative-free formulation?
    a. Cosopt
    b. Combigan
    c. Simbrinza
    d. None of the above

continued

CME POST TEST QUESTIONS *continued*

14. By what additional amount does brimonidine/timolol lower IOP when added to latanoprost?
    a. 15%
    b. 25%
    c. 35%
    d. 45%

15. Side effects that occur approximately 3% to 5% of the time with brinzolamide/brimonidine include:
    a. Blurred vision, shortness of breath, fatigue
    b. Dry mouth, periocular skin pigmentation, nausea
    c. Blurred vision, bad taste, eye allergy
    d. Dry eye, fatigue, reduced heart rate

16. A topical beta-blocker may have reduced efficacy in patients who:
    a. Have seasonal allergies
    b. Are already using an oral beta-blocker
    c. Are younger than age 50 years
    d. Consume large quantities of caffeine

17. Which of the following is/are an indication for using a fixed combination as first-line therapy?
    a. A patient with a very high IOP who needs rapid IOP reduction
    b. A patient who is intolerant of or nonresponsive to a prostaglandin agent
    c. Prevention of an IOP spike after an anterior segment laser procedure
    d. All the above

18. What 2 factors are the primary considerations when selecting a fixed combination for a patient?
    a. Safety and convenience
    b. Efficacy and convenience
    c. Safety and efficacy
    d. Convenience and cost

19. Useful strategies for improving adherence with therapy include all the following, except:
    a. Adding additional medications
    b. Reviewing test results with patients
    c. Reviewing medications and dosing frequencies with patients
    d. Determining the underlying reason for nonadherence

20. Which of the following is true about the addition of a third or a fourth medication to a multidrug glaucoma regimen?
    a. Adherence probably improves with more complex regimens
    b. Adherence probably declines with more complex regimens
    c. The third or fourth drug usually lowers IOP substantially because the most effective drugs are saved for last
    d. The last drug added usually has the most favorable safety profile

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_____

Circle the number that best reflects your opinion on the degree to which the following learning objectives were met:
5 = Strongly Agree 4 = Agree 3 = Neutral 2 = Disagree 1 = Strongly Disagree

Upon completion of this activity, I am better able to:

- Discuss the advantages and disadvantages of multicomponent and fixed-combination therapy for IOP management 5 4 3 2 1
- Describe the efficacy, safety, and dosing profiles of fixed combinations, and their component medications 5 4 3 2 1
- Incorporate fixed combinations as primary therapy for IOP management in appropriate patients 5 4 3 2 1
- Incorporate fixed combinations as adjunctive therapy for IOP management in appropriate patients 5 4 3 2 1
- Select multi-agent or fixed-combination therapy appropriately for use in regimens to attain optimal adherence and IOP control based on individual patient profiles 5 4 3 2 1

1. Please list one or more things, if any, you learned from participating in this educational activity that you did not already know.

_____

2. As a result of the knowledge gained in this educational activity, how likely are you to implement changes in your practice?
4 = definitely will implement changes 3 = likely will implement changes
2 = likely will not implement any changes 1 = definitely will not make any changes 4 3 2 1

Please describe the change(s) you plan to make: _____

_____

3. Related to what you learned in this activity, what barriers to implementing these changes or achieving better patient outcomes do you face?

_____

_____

4. Please check the Core Competencies (as defined by the Accreditation Council for Graduate Medical Education) that were enhanced for you through participation in this activity.

❑ Patient Care ❑ Practice-Based Learning and Improvement ❑ Professionalism
❑ Medical Knowledge ❑ Interpersonal and Communication Skills ❑ Systems-Based Practice

5. What other topics would you like to see covered in future CME programs?

_____

ADDITIONAL COMMENTS _____

_____

_____

POST TEST ANSWER BOX

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20


A Practical Review of
Multitherapy Control
for IOP
New Insights for
Better Individualization of Therapy
NY Eye & Ear Infirmary
Continuum Health Partners, Inc.
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