Immunomodulators

Consider this treatment option to offer relief for patients with itch.
By Craig S. Steinberg, OD, JD

As happens every January 1, new laws go into effect. One that will impact every contracted Vision Service Plan (VSP) provider—that most don’t even realize affects them—is a change in the California Health and Safety Code.1

This change affects all VSP providers because the VSP contract (called the Network Provider Agreement or NDA) states that California laws apply to the VSP contract.

So, what’s this new law all about and why does it matter?

For many years, when VSP’s special investigations unit (SIU) audited a doctor, SIU investigators examined about 40 records drawn from a three-year period. Investigators then used that sample to extrapolate out how much they believed the doctor had been overpaid and owed back to VSP, based on three years’ worth of patients.

This sampling and extrapolation process

By Gretchyn M. Bailey, NCLC, FAAO

Editor in Chief, Content Channel Director

PHOENIX—Essilor looks to establish a recommended protocol for treating and managing myopia by partnering with 14 ODs on a task force. The company announced its Myopia Initiative in Action (MIA) at its national sales meeting in early January.

“The rate at which the prevalence of myopia is increasing is staggering,” says Milli- cent Knight, OD, FAAO, FAARM, senior vice president of customer development at Essi-
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I have heard doctors of various specialties refer to their Drug Enforcement Agency (DEA) license fees as no more than taxes and prescription drug monitoring programs as government overreach. It is true that when my DEA license is about to expire, I wish the renewal fee was a few hundred dollars less. However, I do realize all that goes into my privilege to judiciously prescribe controlled substances for acute pain to the eye and adnexa.

As for prescription drug monitoring programs, ODs in Georgia with DEA licenses had to register programs, ODs in Georgia with DEA licenses had to register programs, ODs should have vested interest in these programs, which are necessary and even essential to curb drug overdoses in the U.S.

Not surprisingly, fentanyl, a synthetic opioid indicated for severe pain, was at the top of the list by being referenced in the death certificates of 28.8 percent of drug overdose deaths. Heroin and cocaine rounded out the top three, respectively.

ODs should have vested interest in these data, at the very least from the perspective of a concerned citizen. However, as the list of drugs continues, drugs that are commonly prescribed for acute eye pain are listed.

Hydrocodone ranks ninth on the list, referenced in 5 percent of drug overdose deaths in 2016. When a narcotic analgesic is indicated, hydrocodone is a drug of choice for many ODs. It is relatively cheap and readily available in fixed combination with non-narcotic analgesics. It also works quite well at controlling severe pain, say, from a geographic corneal abrasion.

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FEBRUARY 2019 • VOL. 11, NO. 02
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*in solution*
New CA law affects all VSP providers

3 reasons why important
This law is important for three reasons.

First, the new law allows VSP to use sampling and extrapolation, provided its statistical methods are "reliable."

Second, VSP audits can no longer go back three years. The new law limits the company to going back only one year in its audits.

Finally, during the time VSP was pursuing the law, its auditing of contracted providers appeared to nearly stop. However, with the new law in place, optometrists should expect VSP to begin once again auditing its providers.

Conduct a self-audit
There are a number of steps that every VSP contracted doctor can take—some which should be done at least once every year—to help reduce the risk of being audited and increase the possibility that, if they are audited, they will pass.

Identify things in the VSP manual that seem new to you or important for your staff to know

Number one among those things is obvious, yet rarely done: Make sure you and your staff are not and have not been violating VSP’s rules.

With that in mind, here are suggestions for a self-audit:
- Your records must include contact lens fitting information if you billed for contact lens professional services. Don’t bill VSP for a fitting or contact lens service if you didn’t perform a contact lens fitting and simply drop-shipped new contact lenses to the patient. If billing for contact lens-related professional services, your records should reflect that you actually checked the patient’s eyes with the lenses, including over-refraction, visual acuities, and an evaluation of the fit through the slit lamp. You should also document the patient’s lens care and wearing schedule.
- Your records must indicate the dispensing of materials. Though not clearly stated in the VSP manual, VSP expects ODs to record the date materials are dispensed and, for contact lenses, exactly what was dispensed (type and quantity).
- Make sure the fees you charge VSP are the same as the fees you charge cash patients. You cannot have two sets of fees. VSP representatives have called practitioner offices acting as a prospective patient to ask about fees. Then, VSP will compare what the staff quotes with what is billed to VSP as the doctor’s “usual and customary fee.”
- Check that your price list is updated and matches what you charge to VSP. This dovetails with the prior point. VSP may ask for your price list. If what you provide is old with lower fees than what you are billing to VSP, that’s a red flag.
- If you have opted out of using VSP labs in states where this is permitted, make sure your progressive spectacle lens type is billed correctly. If you are using a lab-brand lens, VSP requires it be billed at the lowest reimbursed level, a “K” lens.
- All doctors in the practice who see VSP patients must be VSP credentialed. If a doctor doesn’t appear on the drop-down box when billing VSP, work to get the doctor immediately credentialed with VSP.
- Make sure there is no benefit switching among patients (using one spouse’s benefits for the other spouse’s contact lenses, for example.). In my experience working with ODs audited by VSP, it is not unusual in an unannounced audit to discover a Post-It note stating to use the benefits for a relative.

Make sure you and your staff are not and have not been violating VSP rules

- Make sure that the patient’s record shows that contact lenses were ordered and dispensed if you billed for contact lenses. VSP looks for cases in which contact lenses were billed, but the money was used for glasses or non-prescription sunglasses.
- This is important: If you billed for visually necessary contact lens (VNCL), make sure your fees are based on lens type and complexity and not on the fact that it is VNCL (you generally cannot charge VSP a higher fitting fee for a -10.00 D lens than you do for a -9.50 D lens just because the -10.00 D qualifies as VNCL ).
- If using electronic health records (EHR), make sure the records are properly completed, finalized, and closed. Some EHR systems do not print a complete record until the record is closed.
- Test your EHR system. Print some records to ensure that all exam information prints out. Be sure you and your staff know how to print a complete record of a patient visit.

Know the rules
Spend time printing out and browsing through the most current Provider Reference Manual. This is available on the Eyefinity website under VSPOnline→Manuals→VSP.

VSP updates the manual during the year, so use a yellow highlighter to identify things
Essilor forms task force to combat rise of myopia

Continued from page 1

lor of America.
“True to our mission of improving lives by improving sight,” she says, “we are bringing together some of the industry’s top eyecare professionals with diverse areas of myopia interest and expertise to address this problem together through new research and open collaboration.”

By 2050, almost 50 percent of the world’s population will be myopic without action to prevent it, and almost 10 percent of the world’s population will suffer from high myopia (≤−5.00 D).1

Some 14 ODs are participating in the task force:
- Thomas Aller
- David Anderson
- Craig Brawley
- Mark Bullimore
- Alan Glazier
- John Lahr
- Maria Liu
- Pamela Lowe
- Moshe Mendelson
- Pamela Miller
- Yi Pang
- Earl Smith
- Long Tran
- David Troilo

50% of the world’s population will be myopic without action to prevent it

Myopia is growing at an alarming rate. What made you take bigger interest?

Dr. Miller: Within the last few years, I have noticed an alarming increase in the number of myopic patients, especially young people. There is a fear that children will have increased problems, such as blindness.

Dr. Glazier: I’ve always taken refractive and developmental impact in mind with myopic patients. The most impactful was peer-reviewed research. The most compelling thing for me was data that showed that for every dioptr of myopia, children are at greater risk for health problems.2

It’s not about prescribing, it’s about keeping them healthy for the rest of their lives.

What direction would you like to see profession take?

Dr. Smith: It is critical to promote the incorporation of current strategies to slow the progression of myopia in practice. Research has shown that a number of different strategies are successful in slowing progression of myopia in children. By slowing progression of myopia, it is likely that we can reduce the potential for blinding conditions associated with myopia.3

What are key research takeaways?

Dr. Pang: I was diagnosed with myopia when I was 7 years old. We have strong evidence that shows myopia can be slowed down in children.4 We need more eyecare practitioners actively managing myopia.

So far the most effective methods to slow down about 50 percent.5 I hope researchers can find ways to further slow myopia beyond 50 percent.

What can ODs do to stay up to date?

Dr. Bullimore: We shouldn’t be just correcting the prescription today but thinking about the long-term visual welfare of that child or any patient. We are getting more into preventative care,

VSP providers

in the manual that seem new to you or important for your staff to know. You might even discover that you’re not taking full advantage of all the benefits available.

Most importantly, once an auditor is in your office, it’s too late to protect yourself from a bad audit outcome. Start now.

If an auditor shows up, be polite. Be respectful. Do your best to provide everything the auditor asks for and anything else you think might be helpful to the auditor in showing you are complying with VSP rules. For example, provide material invoices and test results recorded on separate devices like a topographer or optical coherence to-mographer (OCT).

Finally, VSP audits are serious and can have serious consequences. Take them seriously. If you are audited and you don’t receive the outcome you expected, you have rights to appeal the audit. VSP auditors may receive the outcome you expected, you have serious consequences. Take them seriously. If you are audited and you don’t receive the outcome you expected, you have rights to appeal the audit. VSP auditors may
take advantage of VSP’s appeals process because it may result in a better outcome.

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Dr. Steinberg obtained his Doctor of Optometry from the University of Missouri-St. Louis in 1984 and began his law practice in 1996 after completing law school. Shortly thereafter he became involved in reining in illegal sales of contact lenses by out-of-state mail-order contact lens companies. Since then he has become known as an expert in optometric law. Dr. Steinberg has represented ODs in state board discipline, opposing VSP audits, buy-sell agreements and partnerships, and employee litigation. Dr. Steinberg enjoys playing competitive golf in the U.S. and Europe.
and myopia is one important aspect of that. Now we have atropine, spectacle lenses, overnight ortho-k. We have options. As practitioners, it’s our role to tailor those to our individual patients.

I’m an academic and a researcher, but I’m still a closet clinician. It’s important to get therapies into the marketplace but also for doctors to discuss with parents.

The risk of macular disease is substantially reduced with less myopia. If we can lower myopia from 1.00 D, we can lower the risk of macular myopia by 40 percent. This is huge. It’s a lifetime benefit.

Q: How does the rise of myopia affect patients?
Dr. Aller:
Patients are getting more concerned. Some come in knowing what they want, and some know more than some of my colleagues because they have done a lot of research. It’s an opportunity and an obligation to the profession for us to help patients however we can.

Q: How are parents of myopic children affected?
Dr. Tran:
Parents have a feeling of helplessness. It’s important that we provide them with education and treatment options to improve quality of life of young patients.

Q: How do your eyecare colleagues think about treating myopia medically vs. refractively?
Dr. Tran:
The sentiment is that this is a reactive type of treatment due to a prescription change. The mindset isn’t there that we should be treating myopia proactively.

Q: How can industry help?
Dr. Lowe:
The challenge for any industry is to find its why, then how to articulate it. Myopia affects just about every family. Sadly, when you poll patients across America, they don’t know when to seek care.

Myopia is going to be the fluoride to eye care. Patients know to see the dentist twice a year; they don’t know how often to have their eyes checked.

When an informed patient seeks care, I can educate him. It empowers me to use technologies in my office to diagnose or treat. It raises the bar for all industry partners. Industry benefits from that, but mainly our patients benefit from it.

Q: Why now to champion myopia control?
Dr. Tran:
Research shows that activities affect myopia. For example, digital device usage, not as much outdoor time.

Dr. Mendelson:
Look at China. Children are encouraged to study more, and myopia has increased dramatically. I see many parents with a child still in a stroller with a video game or device. We’re losing the ability to use imagination as well as moving more toward blindness.

Q: What is the gold standard for treating myopia?
Dr. Mendelson:
It’s the objective of MIA to determine. Not one method works for everyone.

Dr. Glazier:
Right now there are three methods with research. ECPs will choose based on the child’s age, family income, abilities, or other factors.

Dr. Aller:
Practically every child who is a myope is going to be worse next year unless you do something.

Myopia task force members at Essilor’s national sales meeting in early January.
BACK ROW: Dr. Moshe Mendelson, Dr. Thomas Aller, Dr. Mark Bullimore, Dr. Earl Smith, Dr. Ryan Parker, director of professional education at Essilor.
FRONT ROW: Dr. Millicent Knight, Dr. Alan Glazier, Dr. Pam Lowe, Dr. Yi Pang, Dr. Pam Miller, Dr. Long Tran. Photo courtesy Essilor
Dr. Pang: Illinois College of Optometry has myopia clinic. We have a protocol there to follow to treat the patient individually.

Dr. Knight: We are developing something for a child’s future. Very few parents are going to say no, I don’t want what is best for my child. We need to move away from thinking about how people will afford it and more toward being the doctor.

Closing thoughts

Dr. Tran: We have the opportunity to change the lives of many young patients we see on a daily basis.

Dr. Smith: You spend all your life in a laboratory hoping to have an effect on patients’ lives. This is the first time in my career where I think my work will have a practical significant impact.

Dr. Pang: We need to help our children and myopic patients. Take action now.

Dr. Miller: We have an incredible opportunity ahead of us. It brings us back to the roots of the profession of optometry to help patients. We need to work as a team to educate colleagues and patients.

Dr. Mendelson: Most of my colleagues view myopia as a refractive error, not a disease. If we can educate our colleagues about the consequences of myopia, they will take myopia more seriously.

Dr. Lowe: I’m looking forward to changing patients’ thoughts about myopia.

Dr. Glazer: I want to impact lives not only refractively but also on the health side.

Dr. Bullimore: Take care of your patients in the long term. Be part of a broader healthcare message. Optometrists have such a great opportunity here.

Dr. Aller: Myopia is beginning earlier, progressing more rapidly, and over a longer period of time. It’s a massive opportunity to do something about it now. It’s a professional obligation to do what you can.

REFERENCES


Visibly (formerly Opternative) still the same company

Patients don't understand the dangers of skipping an ocular health exam

By Jeffrey Sonsino, OD, FAAO

Recently, online refraction service Opternative rebranded under its new name Visibly; however, it offers the same online refraction to consumers. The company has raised concerns for optometry since its inception.

Rebranding strategy

The current CEO of Opternative was brought in after one of the cofounders of Opternative, Aaron Dallek, was removed from the company. Although the circumstances of his removal were not made public, Business Insider magazine lists these possible reasons that a founder is removed from his company: He stopped being useful, he got too greedy, he was not the right fit, the board made bad decisions. You get the point. Founders are removed because the company needs to change.

Opternative’s current CEO is Brent Rasmussen, previously affiliated with a staffing company and CareerBuilder. So, a human resources (HR) expert, with no healthcare experience, was brought in to lead a company that claims to provide healthcare services to consumers and is making public statements about healthcare delivery.

Mr. Rasmussen says, “I thought it was important that we rebrand the company with a name that better represents the partnership that we are actually building with individual eyecare professionals and with eyecare professionals who own four or five practices.”

The CEO knows this quote might make its way in front of the public via the media. It would appear that when consumers hear this statement, they may think Visibly must be a legitimate company because it is partnering with doctors. Opternative was in the news in 2018 for “false implication endorsement” by using a doctor locator on its website without the consent of those doctors.

Steven Lee, OD, cofounder and chief technology officer of Visibly, says “the old company name positioned the brand as an existential threat to optometrists and other ECPs.”

Again, I see this statement is an attempt to legitimize Opternative’s status in the market. Past chair of the American Optometric Association Contact Lens and Cornea Section Art Epstein, OD, FAAO, says about this statement, “Regardless of what it’s called, Opternative, now Visibly, does not represent an existential threat. It represents a very real public health threat by diverting patients from effective eye care that for many can be sight- or even lifesaving.”

Health care as business

Venture capitalists and private equity representatives love the idea of entering an established industry, creating an online alternative, and disrupting the business out of existence. Opternative was recently recapitalized with a fresh $9M from Pritzker Group Venture Capital and Trust Ventures. The job of a venture capitalist is only to make money, not to ensure that patients receive proper care and messaging.

Health care is more than simply business. It is people’s well being and their lives. With health care, regulatory requirements protect patients from harm. This is why more than a year ago, the United States Food & Drug Administration (FDA)—not optometry—issued a cease and desist to Opternative, ordering the company to stop marketing its technology to consumers.

The company continues to market its technology to consumers via its website. So, it appears that the existential threat to Opternative is Opternative. If the FDA told me to stop operating, I’d want to change my name to escape that past as well.

ValuJet orchestrated a similar name change to AirTran in the 1990s to escape its past after a plane crashed in the Florida Everglades due to illegally stored hazardous materials. The public didn’t forget the crash, and AirTran was purchased in 2011 by Southwest airlines and ceased flying in 2014.

Mr. Rasmussen says, “Our company believes that every human on earth deserves affordable access to eye care, wherever they are, all of the time.”

In my opinion, he does not understand that his company does not provide eye care. Visibly provides one component of an eye examination, the refraction, that, if separated, would prevent a comprehensive eye exam from being conducted. National standards from both the American Optometric Association and the American Academy of Ophthalmology specify that refraction is only one part of a multitude of measurements conducted during a full eye examination.

Patients who seek care are not aware that blinding eye diseases, like glaucoma, can be detected by testing for other factors alongside a refraction as part of a comprehensive eye examination. Optometrists and ophthalmologists are united in upholding the standard of protecting patients with comprehensive examinations. Companies like Visibly that encourage patients to skip an ocular health examination in favor of only a refraction may put patients at risk in an attempt to boost company bottom lines.

Mr. Rasmussen says that the service Visibly provides is telemedicine. Online technologies are considered telemedicine only if...
THERE’S NO SUBSTITUTE

Xiidra is the only lymphocyte function-associated antigen-1 (LFA-1) antagonist treatment for Dry Eye Disease\(^1,2\)

Xiidra, the first in a class of LFA-1 antagonists for Dry Eye Disease, is a prescription eye drop FDA-approved to treat both signs and symptoms of the disease.\(^1,3\)

There’s no substitute.\(^2,4\)

Check out patient resources, insurance coverage, and more at Xiidra-ECP.com

References:
1. Xiidra [Prescribing Information]. Lexington, MA: Shire US.

Indication
Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

Important Safety Information
Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.
BRIEF SUMMARY:
Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE
Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

DOSEAGE AND ADMINISTRATION
Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single-use container. Discard the single-use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

CONTRAINDICATIONS
Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients in the formulation.

ADVERSE REACTIONS

Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%).

The majority of patients (84%) had ≤3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25 % of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

Postmarketing Experience
The following adverse reactions have been identified during postapproval use of Xiidra. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Rare cases of hypersensitivity, including anaphylactic reaction, bronchospasm, respiratory distress, pharyngeal edema, swollen tongue, and urticaria have been reported. Eye swelling and rash have been reported.

USE IN SPECIFIC POPULATIONS

Pregnancy
There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear.

Animal Data
Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg/kg / day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg/kg /day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg /kg /day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

Lactation
There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from oral administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

Pediatric Use
Safety and efficacy in pediatric patients below the age of 17 years have not been established.

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast.

Mutagenesis: Lifitegrast was not mutagenic in the in vitro Ames assay. Lifitegrast was not clastogenic in the in vivo mouse micronucleus assay. In an in vitro chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation.

Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD] of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.
the standard of care is the same online as it is in person. Venture capitalists are business people, not healthcare providers, and do not understand this concept. The tragedy is that our unsuspecting patients are duped into these schemes and suffer as a result.

The viewpoints expressed here are those of Dr. Sonsino and do not reflect the opinion of the Healthcare Alliance for Patient Safety or the American Optometric Association.

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**IN BRIEF**

Eyenovia shares results for MicroStat MIST-1 Phase III mydriasis study

NEW YORK—Eyenovia, Inc. announced positive results from the MicroStat Phase 3 MIST-1 study. The study examined the safety and efficacy of the company’s first-in-class, MicroStat fixed-combination formulation, with target markets including the estimated 80 million annual pharmacologic mydriasis market in the United States.

The study was a U.S.-based, randomized, double-masked, superiority trial that enrolled 64 subjects, in whom both eyes were treated on separate days with Eyenovia’s proprietary MicroStat fixed combination formulation of phenylephrine 2.5% and tropicamide 1%

MicroStat was compared against each component formulation of tropicamide and phenylephrine, respectively. All treatments were administered using Eyenovia’s OpteJet technology.

For the primary efficacy outcome of mean pupil dilation at 35 minutes post-administration, the MicroStat group demonstrated a statistically and clinically superior mydriatic effect as compared to either component formulation.

Additional outcomes demonstrated 94 percent of eyes achieved 6 mm or greater pupil dilation at 35 minutes post-administration. This compared with 78 percent and 1.6 percent for the tropicamide-only and phenylephrine-only groups, respectively. At 20 minutes, 57 percent of the MicroStat-treated eyes achieved 6 mm dilation or greater versus 38 percent of the tropicamide treated eyes and none in the phenylephrine treated eyes.

“We are excited with the results of the Phase 3 MIST-1 study,” says Sean Ianchulev MD, MPH, Eyenovia’s chief executive officer and chief medical officer.

“The MicroStat fixed-combination administered with the OpteJet delivered strong efficacy and was well tolerated by all subjects. We believe this is the first time in a Phase III FDA registration program that drugs have been delivered to the ocular surface using a smart microdose eyedropper-free delivery system—a meaningful step forward as we try to modernize the legacy eyedropper paradigm. These data from a well-controlled FDA registration study further validate our microdose technology platform and support our extensive clinical development pipeline for other microdosed ophthalmic solutions. We look forward to announcing topline data from our MIST-2 study in short order.”

Says David Wirta, MD, principal investigator of the MIST-1 study: “There are an estimated 80 million in-office exams performed each year in the United States requiring mydriasis, an integral part of comprehensive eye exams. Eyenovia’s MIST-1 study results demonstrate that not only does MicroStat successfully induce significant pupil dilation, but it does so rapidly. We believe that having a fixed combination option to achieve mydriasis has the potential to streamline the in-office examination process, potentially increasing physician efficiency and patient throughput volume.”

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**REFERENCES**


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Dr. Sonsino was faculty at Vanderbilt University Medical Center’s Eye Institute for more than 12 years before entering private practice. He is a Diplomate in the Cornea and Contact Lens Section of the American Academy of Optometry, past chair of the Contact Lens and Cornea Section of the American Optometric Association (AOA), executive board member of the Healthcare Alliance for Patient Safety, and a fellow of the Scleral Lens Education Society. Dr. Sonsino is board certified by the American Board of Optometry, past president of the Middle Tennessee Optometric Association, the 2017 Gas Permeable Lens Institute practitioner of the year, the 2017 AOA’s Advocate of the Year, and the 2016 Optometrist of the Year awarded by the Tennessee Optometric Association.
Intersection of artificial intelligence with epigenetics

Advancements in AI and telemedicine are revolutionizing the optometric field

More efficient and comprehensive telemedicine instrumentation is increasingly combined with even more accurate artificial intelligence (AI). For example, GlobeChek provides consumer access at an airport or mall to multifunctional ophthalmic instruments on a rotating turret.¹

Another example is a collaboration of Silicon Valley’s DeepMind and the new AI system at London’s Moorfields Eye Hospital that can spot 50 eye problems with 94 percent accuracy.²

**Disease testing**

Disease such as Alzheimer’s, age-related macular degeneration (AMD) disrupt the health of the outermost retina.

ODs visualize the pathophysiological effects of these diseases using spectral domain optical coherence tomography (SD-OCT) angiography and swept-source OCT (SS-OCT).

Researchers employ these tools to reveal the impact of aging and environment-related stress on the degeneration of retinal tissue layers composed of neurons, epithelial cells, and blood vessels.³

Some ODs see the power of wide-field and layer-by-layer tomographic retinal/choroidal imaging technology converged with genetic testing.⁴

Those consumer genetic tests indicate the “potential” to develop a disease by providing high-risk allele data on 10 different systemic disease maladies.⁵

**Epigenetics impact**

At the same time, the 20-year-old science of epigenetics is revolutionizing our understanding of the interaction of the environment with individual genetics.

For example, the expression of DNA can be modulated by methylation, histone protein wrapping/unwrapping, and microRNA (miRNA) networks.⁶

The environment, presence of both lifestyle factors, and avoiding negative stressors—not DNA—regulates specific disease outcomes.

ODs can buttress the power of increasing technological observations and data acquisition skills to provide value to each patient using the results of saliva, urine, blood spot, and skin tests.

Eight predictive biomarkers of health describe 92 percent of a patient’s epigenetic risk for multiple diseases (see Table 1).⁶

**Placebo and nocebo effects**

Positive expectations can cause the patient to have a positive effect (placebo effect), while negative expectations can cause a negative outcome (nocebo effect).

We are beginning to understand how consciousness and intent can modulate integral cell membrane proteins and why bedside manner can spell the difference between a good physician and a great physician.⁷

**Reach for health, not disease**

Instead of fighting diseases in 12 physiologic systems, ODs should consider providing the correct environment for repair, maintenance and healing of disease.

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Normal vs. desirable physiologic predictive goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomarker</td>
<td>Typical “normal” ranges</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>4-6</td>
</tr>
<tr>
<td>hsCRP (ng/L)</td>
<td>1-3</td>
</tr>
<tr>
<td>Homocysteine (μmol/L)</td>
<td>4-17</td>
</tr>
<tr>
<td>LRA</td>
<td>N/A</td>
</tr>
<tr>
<td>First AM urine pH</td>
<td>4.6-8.0</td>
</tr>
<tr>
<td>25-OH Vitamin D (ng/ml)</td>
<td>20-40</td>
</tr>
<tr>
<td>Omega 3 index (%)</td>
<td>ND</td>
</tr>
<tr>
<td>8-OHdG (ng/mg creatinine)</td>
<td>4.6-19.2</td>
</tr>
</tbody>
</table>

Source: Russell M. Jaffe, MD, PhD via Health Studies Collegium

**REFERENCES**


Dr. Richer is president of the Ocular Wellness and Nutrition Society. He is associate editor of Journal of the American College of Nutrition and associate professor of family and preventative medicine at Chicago Medical School. Dr. Richer is global scientific director of Zeaxanthin Trade Association, he receives research funding from ZeaVision, and he consults for Bausch + Lamb, Eyecheck, Douglas Labs, and Stereo Optical.
Choose your words carefully with surgery patients

Clear communication and realistic expectations lead to proper understanding

“Oops”—it is a short, one-syllable word that most of us use on occasion—but never by surgeons.

Eye surgery is scary for most patients. Therefore, they hang on every word you say and have responses far different from your contact lens or glaucoma patients.

I first became aware of the importance of words in refractive surgery from John W. Potter, OD. Dr. Potter describes the goal of laser vision correction (LASIK) as “20/happy.”

While it may sound corny at first, it is a phrase I have used for over 20 years with LASIK patients.

Today, with escalating expectations, the phrase “20/happy” may be more valuable than ever.

Patient communication
This phrase can flush out patients with unrealistic expectations. Occasionally, patients say, “No, I want my vision perfect.”

My next move is to ask, “What do you mean by perfect?” If the patient does not have a satisfactory answer, then I would say, “Surgery is never perfect, and maybe this elective procedure is not for you."

Several phrases we use as clinicians warrant a funny look from patients.

Let me start with “comanagement.” Most patients haven’t a clue what that word means. To tell a patient “I comanage with Dr. Gordon,” means nothing. I prefer, “Dr. Gordon is a surgeon I work closely with, and he did my mom’s LASIK.”

I let patients know I provide the care before and after surgery (not pre-op and postop) and answer any of their questions.

Book analogy
Regardless of the tools a surgeon uses, the creation of the LASIK flap is a dissection of the anterior cornea and then the excimer laser vaporizes corneal tissue.

I prefer to use the book analogy when discussing this with patients: I tell them to think of their cornea as a 540-page book. The surgeon opens the book to page 110 and lasers away 60 pages, leaving 370 pages in the book.

The FDA says we need to leave at least 250 pages in the book, so we are safely above that limit.

Cataract surgery
Describing cataract surgery can be just as simple, with only five steps. If I am discussing femto-second cataract surgery, I will say the laser does the first three of the five steps:

First, the surgeon uses the laser to create an incision in the cornea, which allows him to enter the eye with the new lens.

Second, the laser opens the capsule around your lens in a perfect circle. This capsule will hold the new lens in place.

Third, the laser breaks apart your cloudy lens, so the pieces are easy to remove.

The fourth step is to vacuum out the pieces and—finally—in the fifth step the surgeon puts the new lens in place.

Potential outcomes
Prior to LASIK, I discuss with patients the likely outcomes based on their refractive errors. I speak about the potential of a second (enhancement) procedure to get them to “20/happy” and am careful to explain that some patients “over-respond” to the laser while others “under-respond.”

A patient who starts at -4.00 D and ends at -0.50 D is undercorrected, but the treatment was not an under correction. It is not the same as if we put a -3.50 D contact lens on the patient.

The patient’s healing response to the laser applied to their cornea was less than predicted—in this example, approximately 8 µm less. Over- and under-responses are healing concerns, not treatment errors.

Postop care
Describing the postoperative care of LASIK to patients is a delicate balance of its contrasting simplicity and significance.

The worst post-LASIK infection I have seen was a patient who had his surgery outside the U.S., went out drinking that night with his surgeon, and then went surfing the next day.

The extreme pain and “count fingers” vision motivated him to seek treatment from a new doctor. When discussing care after surgery, I am direct in stating the need to take the anti-infection drop and anti-inflammation drop to assure a patient’s eyes heal properly.

I am just as direct in including artificial tears in the patient’s postoperative drop prescription. I tell patients most everyone feels dry and has fluctuating vision at one week, and still half of my patients have some but less of those symptoms at one month. By three months, those symptoms are usually gone.

Realistic expectations
The magic of LASIK is how well patients see the next day—but it does not mean all is done. Patients often ask when their eye will be “healed” at the one-day visit.

I try to keep it simple and say that just bumping the flap can dislodge it during the first week, rubbing can dislodge it during the first month, and beyond a month it takes trauma to dislodge the flap.

Presbyopia
There are 50-year-old -2.00 D myopes who are great candidates for LASIK, and there are those who are horrible candidates. It is not until you discuss vision within arms-length does a patient know where he belongs.

No matter how tedious the conversation, it is exponentially more valuable prior to surgery than after.

Your knowledge of the patient’s visual needs and your ability to communicate is valuable to him achieving “20/happy.”

Patient discussion
The past 20 years have seen dramatic advances in the technology of LASIK. Within this innovation is a patient who desires an understanding of this procedure.

When efficiently explained, the results can be remarkable.

Dr. Owen has served as the president of the Optometric Cornea, Cataract and Refractive Society (OOCRS) and sits on its board of directors. He participates in clinical research and lectures on laser vision correction, cataract surgery, dry eye, and contact lenses. enclitasod@gmail.com

BY JIM OWEN, OD, MBA, FAAO, is director of clinical services for TLC Laser Eye Centers

Focus On

REFRACTIVE SURGERY
A look at the latest and upcoming pharmaceutical patents

Developmental drugs await clinical trial results for public distribution

Recent mergers, acquisitions, and drug patent battles in the pharmaceutical space have led to changes in the ocular pharmaceutical pipeline.

These dynamics have led to a strain on the larger pharmaceutical segment in which new chemical entities have been slower to reach the marketplace. But this does not mean eyecare professionals are not seeing new products.

Innovative chemistry

Start-up pharma companies with and without venture capital backing have given rise to a bumper crop of innovative chemistry. Check the news feed or peruse the stock market quotes to find these organizations. They are everywhere—domestic and international.

I have been trained by my father—an electrical engineer by trade—to always keep my ear to the ground. He instilled this spirit of opportunistic ingenuity that drives my curiosity, especially in the allergy field.

I am sharing updates on drugs in development that are readily available in the public domain, so there are no concerns of trade infringements or secrets.

Start-up pharma companies with and without venture capital backing have given rise to a bumper crop of innovative chemistry

Reproxalap (Aldeyra Therapeutics)

Aldeyra Therapeutics has found a niche in aldehyde chemistry (see “How palyaldehyde levels by creating a trap mechanism to bind to the molecule, which downregulates cytokine release as part of the extended inflammatory cascade."

With this innovative therapeutic approach, human clinical trials were initiated after animal models illustrated reproxalap effective in diminishing ocular redness. An additional caveat showed equivalence to that observed with corticosteroids.

A randomized double-masked, parallel-grouped single-center Phase 2a study enrolled 100 healthy men and women with at least a two-year history of allergic conjunctivitis to grass, tree, or ragweed pollen.

The work demonstrated statistically significant activity (P = 0.009) of the target drug over vehicle in reducing ocular itching and tearing.

Following up on this success, a Phase 2b study was initiated with a randomized, dose-ranging, parallel-group, double-masked, vehicle-controlled, conjunctival clinical trial called “A Multi-Center, Double-Masked, Randomized, Parallel-Group, Vehicle-Controlled, Phase 3 Clinical Trial to Assess the Safety and Efficacy of Reproxalap Ophthalmic Solutions (0.25% and 0.5%) Compared to Vehicle in the Conjunctival Allergen Challenge (Ora-CAC) Model of Acute Allergic Conjunctivitis.”

Known as ALLEVIATE, the trial results are expected to be announced in 2019.

PRO-13 (Realm Therapeutics)

PRO-13 relies on a higher concentration of hypochlorous acid to act as an immunomodulatory agent rather than the antimicrobial component in order to downregulate inflammation.

In preclinical trials there was a significant reduction in cytokines, including IL-4, IL-13, TNFα, IL-1β, IFNγ, IL-6, IL-8, IL-12, and TARC (thymus and activation-regulated chemokine), as well as IL-31 and TSLP (thymic stromal lymphopoietin) in the mediation of itch.

In a multi-center, double-masked, randomized Phase 2 study comparing 0.045% and 0.06% concentrations to vehicle for ocular itch and redness in 90 patients, PRO-13 failed to show efficacy as of March 2018.

Realm has since scrapped further work on this formulation in favor of PRO-22, shifting the company’s focus to atopic dermatitis.

PRT-2761 (Portola Pharmaceuticals)

One of the best examples of collaborative work taking place on a regular basis in the ocular allergy sector is Ora, Inc. For over 40 years, Ora has assisted industry partners of all sizes—from preclinical to pivotal to commercialization of more than 1,600 projects with 46 U.S. Food and Drug Administration (FDA)-approved products.

ORA-CAC (conjunctival allergen challenge), has set the standard with its model for clinical allergy research.

Ora inked a deal with Portola Pharmaceuticals in 2015 to build PRT-2761 (Syk[spleen tyrosine kinase] inhibitor) and focus on the opthalmic segment. The compound has additional value to the parent company in the other key areas
outside of allergy in thrombosis and hematological cancer.14

A growing interest in Syk chemistry, which includes cytosolic non-receptor protein propagates B-cell receptor signaling along with immune and adhesion receptor signal transduction, has encouraged the move.15

This particular compound has the potential to provide a more robust prevention of mast cell activation.

One single-center, randomized, double-masked, vehicle and active-controlled, dose-ranging Phase 2 trial looked at 0.5% and 1% concentrations with active comparators in Patanol (olopatadine, Novartis) and Pred Forte (prednisolone acetate, Allergan).

A 10-Q investor filing illustrated statistical significance in one of two primary endpoints studying ocular itch and conjunctival redness.16,17

Ora is currently exploring the potential to pursue an indication for PRT-2761 in dry eye and other ocular inflammatory diseases in a Phase 3 study.18

What’s next?

Time will tell if these new drugs make it through the rigor of studies and the FDA approval process. However, clearly unmet needs on a global scale still await new solutions.●

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Dr. Ceever is a consultant to Allergan, BioTissue, Johnson & Johnson Vision, Alcon Surgical, Valeant/Bausch + Lomb, TearLab, Epikerates and has received past honoraria from Alcon Vision Care and InVitens Health. ceeverad@gmail.com

IN BRIEF

B+L launches Zen Multifocal scleral lens for presbyopia

BRIDGEWATER, NJ—Bausch + Lomb has launched Zen Multifocal scleral lens for Presbyopia, which will be exclusively available with Zenlens and Zen RC scleral lenses through the company’s Specialty Vision Products unit.

This new scleral lens will allow eye-care professionals to fit presbyopic patients who have irregular and regular corneas as well as those who suffer from ocular surface disease, such as dry eye, with add power ranges from +1.00 D to +3.50 D in 0.25 D steps.

Building upon the Zenlens and Zen RC scleral lens technology, the new Zen multifocal scleral lens incorporates decentered optics, enabling the near position to be positioned over the visual axis.

The multifocal design also offers variable near zones from 1.50 mm to 3.00 mm in 0.50 mm steps.

“The Zen Multifocal scleral lens was developed to address the unique vision needs of presbyopic patients,” says Jason Jedlicka, O.D., FAAO, FLSLS, FCLSA, associate professor and director of the Cornea and Contact Lens Service, Indiana University School of Optometry.

“By aligning the multifocal optics over the visual axis, which in soft multifocal contact lenses provides patients with clear vision over near, intermediate and far distances, the Zen Multifocal design is well-suited for a wide range of customized presbyopic lens wearers,” he says.

With the Zen Multifocal design, eye-care practitioners can continue using the current Zenlens or Zen RC diagnostic sets when fitting patients.

Zenlens and Zen RC are customized scleral contact lenses that were designed to meet the needs of specialty vision patients and eye-care professionals fitting a wide variety of corneal shapes and sizes.

Both Zenlens and Zen RC use Smart-Curve technology, which allows eye-care professionals to simplify fittings by modifying only the parameter they need.●
Innovative mobile technology targets low vision

Blindness is the most feared medical condition in the nation. Second only to the fear of death is the fear of living a life without the benefit of the sense of sight.

Modern concepts of disability
Modern theories teach that disabilities are better understood with the social model of disability instead of the more intuitive and traditional medical model of disability. The social model of disability is based on an individual’s interaction with his environment in contrast with society’s concept of normalcy or the normal body.

We depend on technology and evolving modern conveniences to function in our daily lives. Many of us could not function without electricity, automobiles, trains, subways, smartphones, GPS navigation systems, TurboTax software, or microwave ovens in our current lifestyles.

High myopia was considered a severe disability a century ago. But with more affordable access to spectacles and contact lenses in the 21st century, most cases of myopia no longer represent a disability.

Prevalence of low vision
In the United States alone, both the prevalence and incidence of persons with visual impairment will likely double by the year 2050. It’s important that ODs find ways to take care of the aging population. The most common complaint of low-vision patients is difficulty reading. Thus, most of the technology developed today assists these patients with near tasks, such as reading.

Let’s review clinically relevant, portable low-vision devices and applications. These applications include indications for the future of low vision. Moreover, patients today expect their optometrists to be familiar and fluent with these technologies.

KNFB Reader
KNFB is an app that performs text-to-speech and text-to-Braille. A user must take a photo or import a photo that contains text; the app will analyze the text and read it back to the user. Such text can include mail, price tags, books, and magazines. It can even provide nutritional information on a food label. The app helps users obtain the most accurate photo by utilizing verbal and tactile alignment cues.

KNFB Reader is able to recognize and read in over 10 languages, with more being added as it continues to update. The app is available for iOS and Android devices.

TapTapSee
TapTapSee is a mobile camera app that utilizes Cloud-Sight image recognition API. It uses a device’s camera and voiceover functions to take a picture or video of an object and identifies it out loud.

Double-tapping the right side of the camera screen takes a picture and double-tapping the left side of the screen takes a video. TapTapSee accurately analyzes and identifies objects within a few seconds.

OrCam
OrCam is small camera that attaches to the temple of a patient’s glasses. It makes use of hand gestures and verbal commands to read text, tell the user the date and time, recognizes

See Vision therapy on page 20
COMING 2019

Open your eyes to what’s on the horizon in dry eye.

Sign up for updates at TearCare.com

TearCare is indicated for the application of localized heat when the current medical community recommends the application of a warm compress to the eyelids. Such applications would include Meibomian Gland Dysfunction (MGD), Dry Eye, or Blepharitis.

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Vision therapy
Continued from page 18

faces once taught, and identify products via barcode once taught.

This device is known for its portability and accurate text-to-speech capability. OrCam is able to see a full page of a text and read it back to the user.

IrisVision
Most of the devices already mentioned help patients with the world that is within an arm’s length of reach.1 IrisVision is a wearable virtual reality device that aids with distance viewing.

It wears much like a pair of glasses with a headstrap. But instead of viewing through lenses, the patient views projected images on a Samsung Galaxy S7 smartphone.

It boasts up to a 70-degree field of view with an adjustable “IrisBubble” that allows users to zoom in on a certain aspect of the projected scene.

A unique feature of IrisVision is its ability to change the contrast of the viewed scene to a high-contrast black and white.

Buzz Clip
BuzzClip is a newer device to aid visually impaired persons with mobility.2 It is meant to supplement the common red and white mobility cane.

BuzzClip is a small, wearable device that makes use of soundwave technology to alert users via vibration when an obstacle is in the user’s path. While the standard mobility cane works well to alert users to hazards on the ground, BuzzClip can be placed or held higher up to warn patients of potential hazards that are within their headspace.

The device will vibrate when an object is presented in front of it, allowing users to navigate around objects that may be in their way.

Learning Ally
Learning Ally is a nonprofit edtech organization that serves dyslexic, blind, and visually-impaired students.3

This solution provides struggling readers with equitable access to the books they want to read and the grade-level content they need to read.

Students can become engaged and independent learners through the largest library of human-read audio books and other resources.

Mobile technology
Smartphones, such as the iPhone and Android devices, contain apps for visually impaired patients, such as the big clock and talking calculator.

The big clock increases the size of the phone’s clock display. The talking calculator includes a customizable built-in directory users can record in their own voices. Button names are spoken aloud when a finger is placed over them.

Included in iPhone
- Voiceover
- Screen reader
- Siri
- Speak selection
- Email, text, web page, book reader
- Adjustable voice dialect, speaking rate
- Dictation
- Voice-to-text microphone
- Zoom
- Built-in magnifier (100 to 500 percent)
- Font adjustment
- Color invert or grayscale
- Braille displays
- 40 Bluetooth wireless Braille displays

Apple communities
AppleVis is a community-powered website for blind and low-vision users of Apple products, including the iPhone, iPad, and Apple Watch.4 The website features a comprehensive list of helpful apps.

Conclusion
Advances in low-vision technology allow for visually impaired patients to interact with their environment in ways not possible a few years ago.

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Dr. Wong is a Diplomate of the American Board of Optometry and a member of the AOA Ethics committee and AAO Ethics SIG. He is a past president of the Maryland Optometric Association, and an appointee to the American Medical Association’s Physician’s Consortium for Performance Improvement-FCP’s Technical Advisory Panel for Eye Care Metrics. He lectures on the topics of medical ethics, technology and innovations in eye care, ocular disease, mobile health apps, and contact lenses.

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I enjoy good continuing education. Compelling lectures with high-resolution images keep me engaged, and I enjoy the act of silently quizzing myself to see if I can predict the correct diagnosis of an interesting case presentation.

I usually exit a lecture feeling good about myself, having nodded along with the neat and tidy glaucoma cases consisting of well-defined nasal visual field defects corresponding with temporal OCT defects and the red eyes for which topical steroid therapy saved the day.

I leave thinking, “I got this.” Then, it happens. I get back to work on Monday morning, and the eyes of my first five patients make no sense at all. I’m left wondering where all those tidy cases I just saw in those continuing education lectures went, but such is life in the trenches of primary eye care.

Every now and then, however, I am presented with a complex and multifactorial case filled with lurking variables that I am able to isolate and solve—often with the patient’s help. These are the cases that give me the greatest sense of satisfaction with my practice of optometry.

**Single dilated pupil**

Such a case presented to me a few months ago when a 54-year-old Caucasian female came in complaining of a dilated pupil of one day’s duration. She stated she noted a glare in her right eye the day prior and woke up the next morning with a dilated right pupil and came to my office the same morning.

Her medical history was unremarkable, and she wore glasses mainly for reading. Her affect and mood were appropriate, and she was oriented to time, place, and person. She denied headache, diplopia, malaise, changes in mood, and changes in appetite.

She was quite concerned, and she had performed an Internet search of her condition before coming to see me.

**Clinical details**

Best corrected visual acuity was 20/20 in each eye. Intraocular pressures (IOPs) were 16 mm Hg in the right eye and 18 mm Hg in the left eye.

Her right pupil was fixed, dilated, and did not respond to pupil testing at all. Her left pupil demonstrated brisk responses with no defects.

Extraocular muscle testing was unremarkable for each eye.

Confrontation visual field testing showed her visual field to be intact in all quadrants in each eye, and color vision was normal in each eye.

Besides her fixed dilated right pupil, anterior segment testing was unremarkable.

I took time to accurately test and note that no ptosis was present, either. Optic nerves were distinct and well-perfused in each eye, and blood vessels were of unremarkable course and caliber.

I asked the patient if she had been using any eye drops at all for any reason, hoping that she had perhaps just bought an over-the-counter decongestant and simply used a lot of it in her right eye.

Because the pupil fibers are located on the relatively peripheral aspect of the third cranial nerve, a neurogenic origin of a third cranial nerve defect which spares the levator muscle and extraocular muscles innervated by that nerve would most likely be compressive in origin (for example, an aneurysm or tumor).

The Internet had already informed her of such potential sinister etiologies, and I told her that the lack of headache was at least a good sign.

**Pilocarpine test**

I did have pilocarpine in the office, and I instilled two drops into the patient’s affected eye. During the half hour or so we waited to see if her pupil exhibited sensitivity to the pilocarpine, I went through a laundry list (with the help of my Clinical Ocular Pharmacology textbook and the Internet) of everything I could think of that she may have handled which could have an antimuscarinic effect.

I asked if she had used patches for nausea or seasickness or handled any pills of any kind lately.

All questions led to nowhere.

After a good half hour, the pupil exhibited no sensitivity to the pilocarpine drops,
my pen light, or my binocular indirect ophthalmoscope. A dilated pupil of neurogenic origin would have exhibited sensitivity to the pilocarpine, and I knew, in at least most of my brain, that this had to be a pharmacologically dilated pupil and nothing else. That one little part of my brain, however, was left wondering if I was the one doctor who had that one patient and ends up getting a new disease named after him.

Having rarely, if ever, been confronted with such a scenario, I wasn’t 100 percent set on letting the patient leave with a definitive diagnosis of a pharmacologically dilated pupil but with no clear history of inoculation.

Dog day afternoon
Then, she saved the day by telling me about her dog.
As it turned out, she had been giving her dog drops for an eye condition for several days.
I asked her if she knew the name of the drop, and she could not recall it. I asked her the color of the top, and she said it was red.
I asked her to retrieve the drops and call me with the name. She called and told me it was atropine, the potent dilating and cycloplegic agent often used by veterinarians as well as eye doctors.
I informed the patient that it would take a few days for the atropine to wear off, but that she would get better on her own.
Within a week, she was completely back to normal.
A clear history of inoculation with an agent with antimuscarinic properties makes a diagnosis of pharmacologic dilation vs. neurogenic dilation much more straightforward. Moreover, a careful history and pilocarpine is a lot less expensive than neuroimaging.

REFERENCES

FDA approves eye-tracking test to detect concussion
NEW YORK—Oculogica, Inc. announced that the U.S. Food and Drug Administration (FDA) granted its De Novo request for the commercialization of EyeBOX, the first non-invasive, baseline-free tool to aid in the diagnosis of concussion.
Oculogica will market the device for use in pediatrics ages 5 and older and adults up to 67 years of age.
EyeBOX uses eye-tracking to provide objective information to aid in assessment of patients with suspected concussion via an easy-to-take, 4-minute test, according to the company.
Other diagnostics require a baseline test, typically generated at the beginning of a sport season, pre-injury, and is compared to subsequent test results at the time of a suspected concussion.
Frequently, a baseline assessment is not feasible, especially when evaluating trauma patients in the emergency room.
EyeBOX’s eye-tracking algorithm enables it to be baseline-free, a major advancement for the field.
Results of the Use of Eye Movement Tracking to Detect Ocular-motor Abnormality in Traumatic Brain Injury Patients (DETECT) clinical study of 282 patients who presented in the emergency room and concussion clinic with suspected traumatic brain injury (TBI) formed the basis of the De Novo application.
The DETECT study enrolled 282 patients at six independent clinical sites in the United States and compared EyeBOX results to a clinical reference standard for concussion in patients presenting to emergency departments and sports medicine clinics with suspected head injury.
The study showed that EyeBOX had high sensitivity to the presence of concussion and that a negative EyeBOX result is consistent with a lack of concussion, thus providing objective data for healthcare providers to aid in the evaluation of patients with suspected TBI.
Below the surface
Allergic hypersensitivity reactions affecting the eye are IgE and/or T-cell mediated. IgE-mediated reactions are common and seen in run-of-the-mill allergic conjunctivitis, whereas T-cell-mediated responses are seen in more chronic cases of ocular allergy. T-cell-mediated responses can lead to irreversible changes to the architecture of the ocular surface, causing fibrotic damage and decrease in visual potential.

As environmental allergens encounter IgE-primed mast cells in the conjunctiva, they begin the sensitization phase of a cascade of events that ultimately lead to the classic signs and symptoms of ocular allergy. Namely, the release of histamine, tryptase, IL-4, leukotrienes, prostaglandins, and other mediators from degranulated mast cells cause symptoms of hyperemia, chemosis, tearing, and pruritus and classic conjunctival papillary lesions (see Figure 1). Mast cell-derived mediators can be divided into two groups: those associated with granules (histamine, proteoglycans, tryptase, chymase, etc.), and those synthesized de novo (prostaglandins, leukotrienes, platelet factor, cytokines, etc.).

The de novo products include cytokines (IL-4, IL-5, IL-6, IL-13, TNF-α, and TGF-β) and chemokines (CXCL8, CCL3, CCL5, and eotaxin), which further propagate the allergic inflammatory cascade.

Of the released mediators, histamine and tryptase are the most studied in the tears of patients suffering from ocular allergy. Chronic and often more ominous forms of ocular allergy, including vernal keratoconjunctivitis and atopic keratoconjunctivitis, have been shown to follow an inflammatory cascade that is predominantly mediated by T cells. The activation and subsequent increase of T lymphocytes, namely Th2 cells, in the conjunctiva is thought to have a vital role in a more chronic presentation.

Figure 2. Colored anterior segment photograph of giant papillae found on the superior tarsal conjunctiva in a young male patient with VKC, a Th2 cell-mediated remodeling of the tarsal conjunctiva.

Is TSLP making you itch?
Thymic stromal lymphopoietin (TSLP) is a cytokine and proallergic molecule that is a hidden culprit in the allergic inflammatory response. Though also involved in the propagation of an allergic response, it can cause pruritis.

This happens via TSLP receptors that can be found on sensory neurons and immune cells, specifically dendritic cells, T cells, B cells, natural killer cells, mast cells, basophils, and eosinophils.

Interestingly, downstream production of IL-4, IL-5, and IL-13, the cytokines involved in Th2 mediated allergic response, have been linked to TSLP.

Ocular itch can be a very real and debilitating consequence of allergy and is often not controlled in chronic cases by an antihistamine/mast cell stabilizer combo; potential future pharmacological agents that target TSLP may be a more promising answer.

When to bring in the cavalry
Ocular allergy management can include both allergen avoidance, though easier said than done, and pharmacotherapy.

Common drugs that jump into most clinicians’ minds when presented with a red and itchy eye include vasoconstrictors, antihistamines, mast-cell stabilizers, combo antihistamine/mast-cell stabilizers, nonsteroi-
Allergy

While topical corticosteroids can come in clutch when dealing with severe cases, they are often needed on a chronic course and their prolonged use can prove taxing with serious and unwanted sequelae. Keeping a patient on a chronic topical steroid should not be taken lightly and alternative treatments should be considered if available. Cases in which there is significant remodelling, even fibrosis, of the conjunctiva; corneal involvement; or risk to visual potential should implore a clinician to consider reaching for topical immunomodulators.

Two potential agents to consider are cyclosporine and tacrolimus.

Cyclosporine: Not for weak of heart

Chronic allergy sufferers who are also contact lens users should be refit in a daily modality. Daily replacement allows for mitigation of allergen exposure time on the ocular surface.

Ask your allergic eye disease patients about systemic atopy, including eczema, asthma, and contact dermatitis. It is rare to have ocular manifestations in the absence of systemic disease. In the absence of symptoms or diagnosis of systemic atopy, consider other potentially more ominous differentials.

If patients do not have an established allergist, refer them to one for skin prick testing or specific IgE blood testing. The first management strategy for allergic disease is often allergen avoidance; hence, knowing exactly what a patient is allergic to is important. Furthermore, an allergist may consider systemic management which may help control ocular complications.

Establish that ocular itch is true pruritis and not irritation from dry eye. A simple question to ask: When you rub your eyes, does it relieve the itch or does it make it worse like scratching a mosquito bite? If itch is due to dryness, rubbing produces mechanical stimulation of tears which can temporarily relieve symptoms, whereas true pruritis will worsen with eye rubbing due to further spread of allergen on the ocular surface.

Itchy eyes often lead to eye rubbing. Eye rubbing is a potential risk factor for keratoconus. Keen clinicians not only inquire about eye rubbing but may take it a step further and consider a baseline topography.

Acute allergic conjunctivitis can cause extreme symptoms. Though not often considered, a topical betadine wash may be considered an off-label treatment for severe symptoms to help to provide asepsis of the ocular surface. It should be noted that betadine can cause ocular irritation and should be avoided in non-severe cases.

Most clinicians consider pretreatment of dry eye prior to refractive surgery; however, ocular allergy also warrants consideration. The post-refractive healing process can be complicated with untreated ocular surface disease. Additionally, you don’t want your patients to be enticed to rub post-surgery, especially after LASIK.

Consider increasing cyclosporine to a higher concentration if warranted; 0.09% is now commercially available. If that isn’t up to snuff, higher concentrations can be compounded through compounding pharmacies.

To ensure transparency with your patients, have a frank discussion of off-label use of topical immunomodulators for their refractory allergic condition. Additionally, communication with the patient’s primary-care provider is always best practice.

Keep a pulse on your local area’s pollen count; it is often reported along with the weather and can be helpful to mentally prepare for an uptick in patient’s coming in with symptoms of pruritis (see Figure 3).

10 tips for the itch

1. Chronic allergy sufferers who are also contact lens users should be refit in a daily modality. Daily replacement allows for mitigation of allergen exposure time on the ocular surface.

2. Ask your allergic eye disease patients about systemic atopy, including eczema, asthma, and contact dermatitis. It is rare to have ocular manifestations in the absence of systemic disease. In the absence of symptoms or diagnosis of systemic atopy, consider other potentially more ominous differentials.

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Allergic disease
Continued from page 25

latory which was first developed in the 1970s as a novel drug to inhibit lymphocytes both specifically and reversibly. Its first use was in whole organ, namely kidney and heart transplants, to avoid transplant rejection by modu-lating the host’s immune response.16

Though available in many forms, topical cyclosporine is an established treatment for keratoconjunctivitis sicca. Although the exact concentration of the topical form is up for de-bate, commercially available 0.05% cyclosporine has been shown to be effective in man-aging allergic cases in which management requires a steroid.17

This can prove to be useful in chronic aller-gic disease such as vernal keratoconjunctivitis or atopic keratoconjunctivitis where chronic treatment is required. Clinically, it can be use-ful to pulse a steroid when initially treating with cyclosporine in cases where long-term management is foreshadowed. Prolonged treat-ment with QID dosing of cyclosporine 0.05% has been proven safe and effective in vernal keratoconjunctivitis.18 Restasis (cyclosporine 0.05%, Allergan) is an easy formulation that you may find yourself reaching for off-label.

Recent phase 3 study results have demon-strated Cequa (Sun Pharma), a 0.09% formu-lation of cyclosporine, to be effective in man-agement of keratoconjunctivitis sicca. Though an off-label use, this could be a potential concentration to turn to when 0.05% is not quite potent enough.19

Tacrolimus: Pump up the volume

Like cyclosporine, tacrolimus was first used in organ transplants to prevent transplant re-jection; however, unlike cyclosporine, it is a macrolide that is made via fermentation of Japanese soil containing the bacteria Strepto-myces tsukubaensis.20

It works via inhibiting the production of IL-2, a cytokine key in the proliferation of T cells.21 It is also a calcineurin receptor antago-nist with analogous mechanism of action to cyclosporine but with greater potency.22

Dermatological use is common in ointment form in atopic conditions such as eczema or allergic dermatitis; so, promise has been there for topical use for allergic eye disease. Along with impinging on cellular communi-cation and activation of lymphocytes, tacrolimus reduces the signs and symptoms of ocu-lar allergy by working on the activation and release of mast cells and histamine.23

Research has shown that tacrolimus 0.03% is efficacious, safe, and well tolerated in the treatment of allergic eye disease.24 It has been indicated in reducing recurrences of exasperations of allergic disease.25

There are no current topical formulations ap-proved by the FDA for ophthalmic use; however, Protopic (0.03%, Astellas Toyama Co., Ltd) may be used off-label by applying to the inferior conjunctival fornix.

New research in murine models has shown promising results for a biodegradable, sustained-released, tacrolimus micro-film use in chronic allergic ocular disease. Microfilms loaded with tacrolimus were found to have good biocompatibility, desirable drug delivery, and equivalent efficacy to conventional tacrolimus drops.26

These new delivery systems not only allow for safety in long-term management but provide more convenient regimens for patients which may improve compliance.

Tacrolimus 0.003% is efficacious, safe, and well tolerated in the treatment of allergic eye disease

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Dr. Minhas also serves as the director of on-campus residency programs and primary care/ocular surface disease residency coordinator. She is an enthusiastic reader, enjoys watercolor painting, and is an avid hiker. She recently completed a winter hike in the Grand Canyon. bominhas@salus.edu
Zyloware releases seven new frames for February collection

PORT CHESTER, NY—Zyloware Eyewear has announced the launch of seven new frames this month: Sophia Loren, Stetson, Stetson Off Road, Randy Jackson Limited Edition, Gloria by Gloria Vanderbilt, Leon Max, and Project Runway.

Sophia Loren BR 88 features a full-rim frame, wrapping metal endpiece, and temple with waves of raised detailing accented by crystal décor. This style is offered in two neutral colors—natural and burgundy. The frames include rectangle lens and snap-in nosepads.

Sophia Loren 1562 is offered in a butterfly shape and features a lightweight zyl front with wrapped metal endpieces and temples. This style is available in three colors: natural, mauve, and brown. The natural and mauve colors exhibit a transparent front, while the brown showcases a solid shade of zyl layer over ivory horn. Shiny metal temples incorporate a raised floral design.

Stetson 358 is designed with lightweight construction and includes a full-rim frame with a TR-90 thermoplastic front and rectangle lens. This style is available in two colors: black and grey. The black frames feature a matte front on top of a crystal grey layer, while the grey frames include a solid dark grey front. Both colors feature a stainless-steel temple with a brushed metal finish.

Stetson 360 features a full-rim metal frame in a square shape. This lightweight frame includes wrapping metal endpieces and metal temples with linear stripes running down the exterior. The style is available in gold and gunmetal. Each color features a mix of shiny and matte finishes. This frame includes a wide fit bridge, spring hinges, and snap-in nosepads.

Stetson Off Road 5072 includes a rectangular, full-rim plastic frame. The style is available in black and navy. The black frame features a shiny front and crystal temples, while the navy frame has a matte exterior and shiny tortoise temple.
Randy Jackson LTD X144 includes a rectangular full-rim metal frame with a raised layer on the top half of the front. This style is available in three colors: red, black/gold, and midnight. The red frame features a shiny gold base with recessed detailing in matte red on the front and temple. The black/gold frame features the same shiny gold base but with matte black inlay. The midnight-shaded frame has a shiny brown base and navy inlay. All frames include snap-in nosepads.

Stetson Off Road 5073 is a wide-fitting, full-rim metal frame in rectangular shape. The style is available in black—with a matte finish—and khaki. This frame includes spring hinges and snap-in nosepads.

Gloria by Gloria 4083 includes a semi-rimless frame for women’s style. A geometric silhouette features a sloping metal brow bar that dips at the bridge and raises toward the wrapping metal endpiece. This style is available in black and burgundy. The black frame features a solid, shiny finish throughout with grey pearl temple tips, while the burgundy frame highlights a brushed finish and burgundy pearl temple tips. Both colors feature a square pattern engraved into the metal temple.

Randy Jackson LTD X141 includes a rectangular full-rim metal frame with a raised layer on the top half of the front. This style is available in three colors: red, black/gold, and midnight. The red frame features a shiny gold base with recessed detailing in matte red on the front and temple. The black/gold frame features the same shiny gold base but with matte black inlay. The midnight-shaded frame has a shiny brown base and navy inlay. All frames include snap-in nosepads.

Randy Jackson LTD X143 features a full-rim metal frame in a rounded rectangular silhouette. The style is available in two colors: gunmetal black and black gold. Gunmetal black includes a shiny wire rim and bridge with a silver sheet metal front and shiny black temples. The black gold frame includes a matte black eye wire with a contrasting shiny gold bridge and top bar as well as a matte gold temple.
Leon Max 4069 features a geometric silhouette in two colors. The black frame has a solid black front over ivory with a black and ivory confetti temple. The mauve frame is layered over pale pink on the front with mauve and black pearl marble temples.

Gloria by Gloria 4064 is styled with a cat-eye shaped frame available in blush and denim. The blush frame features a transparent pink tone with burgundy and tan marble temples. The denim frame includes a transparent blue front and an abstract aqua design on the temple. Both colors feature a geometric metal plaque with a shiny gold finish.

Project Runway 136Z shows a full-rim acetate with a modified round shape. The frame features two metal rivets on each side of the front. This style is available in black and tortoise.
Kenzo collaborates with Thélios of LVMH group

Kenzo and LVMH group have collaborated to present the Maison’s first eyewear collaboration for spring/summer 2019. The new release features the varying style of Kenzo with distinctive shapes and vibrant colors.

KZ40004 features a rimless and bejeweled style with a pavé of denim blue or hematite crystal stones.

KZ40005 showcases heart-shaped frames with gold stones on mirror lenses.

KZ40010 is styled with a mask featuring a distinctive and edgy look. The style is available in matte optical white, shiny milky rose, or matte black and blue with rainbow or iridescent lenses.

KZ40002 includes an extra light injection mask with a futuristic metal bar that runs on the eyebrow frame.

KZ40003 has a deep rectangular mask shape, crystal matte or aqua flash lenses, and a frame with a holographic metal bar.

KZ40004 features a rimless and bejeweled style with a pavé of denim blue or hematite crystal stones.

KZ40005 showcases heart-shaped frames with gold stones on mirror lenses.

Continued on page 32
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Continued from page 30

KZ400014 features a modern aviator shape with solid tobacco-toned lenses and metal lines.

KZ40001 is constructed in a cat-like style with different layers of acetate, matte metal, and solid lenses.

KZ400012 is designed in an aviator shape. It is available in peach or Havana-tinted lenses.

KZ400015 features solid smoke or green lenses.

KZ40007 includes a wraparound model in crystal or red.
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Optometry Times
Lyndon Jones, OD, FAAO, FBCLA
Director, Centre for Ocular Research & Education (CORE) at the University of Waterloo, Ontario, Canada

Contact lens research & innovation, playing sport, moving to Canada from the UK

How did you get involved in contact lens research? I chose optometry purely because it had the best intramural rugby team. I knew nothing about optometry, and I found that I absolutely loved it. Optometry in the UK is still a four-year course, but in your fourth year you go into private practice or work at a hospital or teaching institution. I ended up at a teaching institution in London. I happened to be a decent teacher, so the institution offered me a job. We often did clinical trials with contact lens companies, and that’s how I got started.

What do you see coming in the next 10 years of contact lens innovation? In short-term developments, you’ve got photochromic contact lenses and anti-allegy drug-delivering contact lenses. I think we’re going to see other materials where the bulk is delivering oxygen but the surface being modified to enhance wettability and end-of-day comfort. Then we’re looking at bio-sensing lenses that will be able to detect what’s in your tear film. I think that within the next five years we’ll have a product on the market with biomarkers able to detect systemic changes within your body. In the long term, many companies are trying to incorporate electronics into contact lenses. There’s already a commercially available product that can measure intraocular pressure by using a little strain gauge, it’s from a Swiss company. The long-term dream is to have these things look up websites and facial recognition.

How should optometry move forward? There’s increasing pressure on optometry schools to get more disease, diagnosis, and treatment into the curriculum. The problem is that the percentage of patients who actually have disease is a small proportion of what you end up seeing day to day. My concern is that as we move away from the bread and butter of optometry—refraction, pediatrics, contact lenses, binocular vision—someone else will come along and take it. I’m supportive of expanding the scope of optometry; I worry about moving away from the things that many patients need our expertise in.

Do you have any regrets? I regret not being able to play sport at an international level. I would have loved to have been a professional athlete. My son has just signed an NHL contract—he was drafted as a junior player to the Las Vegas Golden Knights. I live vicariously through my son’s hockey. I think having regrets doesn’t help you very much. I mean, you made those decisions; suck it up, princess, and get on with it.

What’s the craziest thing you’ve ever done? The practices that my wife Debbie and I had in the UK were very successful, and we got bored. We wanted a new challenge. I remember saying to my dad, “We’re going to sell out of the practice and go work at university.” The way universities work is that you go there for a period of time on probation. So, he said, “You’re giving it all up to be on probation in a university environment, much less money, in another country. You are out of your mind.” It is the most bizarre decision we ever made, but in hindsight it was the best decision we ever made.

—Vernon Trollinger
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