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TBI, PTSD Strong Indicators of Vision Problems for Veterans

Many veterans of the United States armed forces who have traumatic brain injury or post-traumatic stress disorder also have undiagnosed, chronic vision problems, according to two recent studies.

In a study conducted at the Veterans Affairs Medical Center, in Washington, D.C., researchers found that vision problems in veterans with mild traumatic brain injury are much more common and persistent than previously recognized, with 67 percent of the 31 patients studied reporting chronic vision disorders. Though none of the affected veterans had suffered direct eye wounds, their vision continued to be impaired more than a year after they endured the injuries that caused their TBI.

The vision problems most frequently reported by the veterans in the study were convergence and sensitivity to light. Veterans’ ability to accommodate was also reduced. Other complaints included double vision and floaters. Full recovery of visual function took five years or more in many of the veterans, which is much longer than is typically seen in sports concussions and other non-blast-related TBI.

Blast-related TBI is the most frequent injury of the Iraq and Afghanistans wars. From 2000, the Department of Defense reported 194,561 cases of mild TBI, or about 76 percent of all TBI injuries.

“Physicians who care for veterans with TBI need to know that many of them have vision problems,” said M. Teresa Magone, MD, staff ophthalmologist with the Washington, D.C. Veterans Affairs Medical Center, who led the study. “It is critical that these patients receive vision assessment and when appropriate, be referred to ophthalmologists to make sure they get the eye care they need, for as long as they need it.”

Another study of war veterans, conducted at the Miami Veterans Affairs Medical Center and the Bascom Palmer Eye Institute at the University of Miami, found that veterans who have post-traumatic stress disorder or depression are much more likely to develop dry-eye syndrome than veterans who do not have these psychological diagnoses. In their review of more than two million veterans’ medical records, the research team found that about 20 percent of those diagnosed with PTSD or depression have dry-eye syndrome, a disorder that disrupts the tear glands’ normal ability to keep the eyes moist.

The disorder’s impact on vision can range from mild to severe, causing the sufferer’s eyes to feel scratchy or irritated, to become overly watery, or secrete stringy mucus. Treatment options include simple warm compresses, artificial tears and surgical insertion of plugs to retain tears. In the general U.S. population, the risk of dry-eye syndrome increases with age, affecting about 3.2 million women age 50 and older and 1.68 million men age 50 and older.

“Many vets won’t mention that their eyes always feel gritty or seem to water for no reason, unless they’re asked,” said Anat Galor, MD, an assistant professor of clinical ophthalmology with Bascom Palmer Eye Institute, who led the study. “Since dry eye can escalate and permanently damage vision if untreated, it’s crucial that health professionals who care for veterans with psychiatric diagnoses ask them about specific dry-eye symptoms and refer them to an ophthalmologist if needed.”

Anti-VEGF Works Even in Presence of Macular Traction

Anti-VEGF injections, the primary treatment for wet macular degeneration, a chronic eye condition that causes vision loss, are effective even if patients have macular traction problems, a Mayo Clinic study shows.

It has not been clear whether this treatment would also serve patients experiencing other symptoms, such as vitreomacular interface disease. Mayo

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researchers retrospectively studied 178 patients, of whom 18 percent had VMID over an average of 2.5 years.

Findings showed that while eyes with some kind of macular traction required more injections, they still showed improvement (best-corrected visual acuity) to similar eyes without VMID.

“This finding is significant,” says senior author Sophie J. Bakri, MD, “because it showed that patients with VMID are not necessarily treatment resistant for AMD.” She also says it may help physicians not give up on treating such patients, and understand the need for more doses of medication for those with VMID. Researchers say more study is needed, including a prospective clinical trial.

Kids’ Headaches Not Connected to Need for Glasses

A new study provides the first clear evidence that vision or eye problems are rarely the cause of recurring headaches in children, even if the headaches usually strike while the child is doing schoolwork or other visual tasks. Many parents assume that frequent headaches mean their child needs glasses, so they ask their doctor to refer their child for an eye exam. This study was conducted by pediatric ophthalmologists who wanted to find reliable answers for parents, family doctors and pediatricians facing this common health question.

In this retrospective study, which was conducted at the ophthalmology clinic of Albany Medical Center in New York state, researchers reviewed the medical records of 158 children under age 18 who were seen at the clinic for frequent headaches from 2002 to 2011. All of the children received complete eye exams by the clinic’s ophthalmologists.

No significant correlation was found between their frequent headaches and a need for vision correction. The researchers reached this conclusion by comparing the results of the clinic’s exams of the children with headaches to the records of their previous eye exams and other relevant medical care. Eye health and vision test results remained unchanged from earlier exams for 75 percent of the children. Also, children who already had eyeglasses were not found to need new prescriptions at the time they were seen at the clinic for headaches. Although about 14 percent of the children reported that their headaches occurred while doing visual tasks like homework, and about 9 percent reported visual symptoms associated with their headaches, a need for vision correction did not appear to be the primary cause or a significant factor in any of these cases, according to the study.

The researchers considered it possible that most of the children's headaches resolved over time. Follow-up reports from parents showed that headaches improved in 76.4 percent of all study subjects, including those who did and those who did not receive new vision correction prescriptions. Children who received new prescriptions were not more likely than others to have their headaches improve. Assessing the causes of the headaches and addressing the children’s long-term outcomes were beyond the scope of this study.

“We hope our study will help reassure parents that in most cases their children’s headaches are not related to vision or eye problems, and that most headaches will clear up in time,” said Zachary Roth, MD, who led the research team. “The information should also be useful to family doctors and pediatricians in caring for children and parents who have this common health concern.”

About 30 percent of the children in the study had eye conditions that went beyond the need for vision correction, including strabismus, amblyopia or other rarer, more serious conditions. Seventeen percent had a family history of migraine. Because this was a retrospective study, the researchers were unable to connect these factors with headache causes.

Soothing Sounds Ease Cataract Surgery Anxiety

The use of an audio therapy known as binaural beats can significantly reduce patients' anxiety during cataract surgery, say authors of a recent study in Thailand. The 141-patient study is the first of its kind in cataract surgery.

Binaural beat audio therapy consists of two tones that are each pitched at a specific, slightly different frequency, with each tone delivered to a separate ear via headphones. The technique evokes alpha-frequency brainwaves, a state that is linked to relaxation and reduced perception of fear and pain.

In this study, the researchers combined binaural beats with soothing music and nature soundscapes that included ocean and forest sounds, to provide a pleasant, familiar experience for patients.

The study was conducted using three groups, each consisting of 47 patients, matched for age, gender, cataract type and other health factors. Patients who listened to a binaural beats-music mix before, during and after the procedure had less anxiety and slower heart rate, compared with the control group patients who did not receive the therapy.

Systolic blood pressure was also significantly reduced in both the binaural beats-music mix patient group and a second patient group who listened to music only. Control group patients
heard the usual sounds that occur in a surgical suite. All patients were assessed before and after surgery using the State-Trait Anxiety scale, a standard test used to diagnose anxiety. Their heart rate and blood pressure were also measured before and after surgery.

The research team focused on cataract surgery because it is usually done under local anesthesia, with the patient awake and continuously exposed to unfamiliar, potentially upsetting sounds such as surgical machinery and conversations between the surgeon and staff. Although the procedure is highly effective and safe, patients may be worried about whether their vision and quality of life will be improved or reduced after the surgery. The results were consistent with the finding of previous research on the use of the therapy reducing anxiety in general surgery patients.

“As populations in many parts of the world grow older, it’s increasingly important for ophthalmologists to explore new ways to improve patient care for seniors,” said Pornpattana Vichitvejpaisal, MD, of Chiang Mai University, Thailand, who led the research. “Our study shows significant emotional and physiological benefits from adding binaural beats to music therapy for cataract surgery patients. This provides a simple, inexpensive way to improve patients’ health outcomes and satisfaction with their care.”

Dr. Vichitvejpaisal referenced one of his study participants who reported that during her first cataract surgery, she was afraid from the moment she entered the surgical suite. Though she’d been told it wouldn’t take long, the surgery seemed to drag on endlessly. Receiving sound therapy during her second surgery dramatically changed her experience from start to finish. She said that she felt very little anxiety, and that the surgery was over before she knew it. **Review**
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By Christopher Kent, Senior Editor
Today's high-tech handheld smart devices have remarkable capabilities, and ophthalmologists are learning to take advantage of them.

Feature Article

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By Walter Bethke, Managing Editor
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Careful: There’s An App for That

As we hurdle headlong into the new world of wired health care, it’s clear that there is a lot more going on with the addition of smartphones and tablets than simply a newer, more mobile medium. For better or worse, the new devices are changing the way patients and physicians communicate in ways that older technologies never accomplished.

Freed from the minor nuisance of sitting down at a computer and searching for what might turn out to be questionable medical information, patients with multifunctional mobile devices are downloading medically based apps at an astonishing pace. By 2015, 500 million smartphone users are expected to be using medical apps, according to Research2Guidance, a global mobile research group. There’s little reason to believe that the accuracy of what they’re accessing is different from what’s long been available online.

A letter this month in the journal Patient Education and Counseling highlights the challenge patients face in assessing the reliability of information from medical apps: “Patients ... have a twofold vulnerability, with their lack of formal medical education compounded by a predisposition to anxiety regarding their health, suggested by their use of medical apps in the first instance.” The author cites a recent study of apps in the field of microbiology that reported that “only 34 percent of the commercially available programs examined had obvious supervision of a medical expert in their development.”

It will be no great comfort to know that the task of harnessing the burgeoning medical apps industry falls to the FDA, the same agency regularly blamed by the medical device industry for driving innovation overseas. Kaiser Health News recently reported that the FDA “began regulating a handful of medical apps last year and released a first draft of guidelines requiring mobile apps developers making medical claims to apply for FDA approval. The final regulations have not yet been released, but some developers have complained that the approval process will be too slow.”

Other regulatory efforts are underway, such as the Food and Drug Administration Safety and Innovation Act, which establishes a commission of several government agencies to come up with a proposed strategy for regulating mobile health apps. In predictably glacial fashion, the commission’s report is not due for another 16 months.

In the meantime, caveat app-tor.

An Objective Look at Dry-Eye Syndrome

A new test for the amount of the protein lactoferrin on the ocular surface might hold the potential for diagnosis and treatment.

Walter Bethke, Managing Editor

For decades, clinicians have had to rely on their subjective evaluation of signs and symptoms in order to accurately diagnose and treat dry eye and ocular surface disease. Recent years have witnessed a flurry of developments in the realm of objective dry-eye diagnosis, however, with several devices becoming available around the same time. The newest addition to these objective measurement tools is the Tear Microassay System from Advanced Tear Diagnostics. Here’s a look at how the system works.

Lactoferrin Explained

The Tear Microassay System measures the amount of the protein lactoferrin on a patient’s ocular surface, using it as a marker for dry eye.

“Lactoferrin is a multifunctional protein that’s part of the transferrin family,” explains Terrence O’Brien, MD, professor of ophthalmology at the University of Miami’s Bascom Palmer Eye Institute. Dr. O’Brien has experience working with lactoferrin as a marker for dry eye, and is interested in seeing what this new test may bring to the clinic. “It’s more of a global marker, and it’s present not only in tears but also in saliva, mother’s milk and nasal secretions. It’s also one of the components of the immune response, has demonstrated significant antimicrobial activity and is part of the eye’s natural defenses. This antimicrobial aspect of it is one of the reasons why I’m interested in it. It’s been identified as one of the tear proteins that may be part of the innate defense of the mucosal surface, and it has bactericidal and even fungicidal properties. In addition to binding iron, which bacteria use as an element necessary for their growth, it also binds to the lipopolysaccharide of bacterial cell walls. The oxidized iron that’s part of lactoferrin oxidizes bacteria, forming peroxide. This action affects the membrane permeability and results in the breakdown of the bacteria.

“My interest in this stems from this antimicrobial mechanism being part of the innate immune system, and I think the test may have broader applications,” adds Dr. O’Brien. “For example, it may be that lactoferrin levels can tell us which patients might be at risk for developing an infection from wearing contact lenses.”

The Test

The lactoferrin test consists of introducing a micropipette into the patient’s canthus and harvesting a very small sample of tears, 0.5 µl. The sample is put in a diluent and the mixture is shaken, a step that amplifies the amount of lactoferrin. The mix is then placed in a small well on a strip, and, according to Advanced Tear Diagnostics’ Jeffrey Busby, the diluent chases the tear up the strip and, when the sample is placed in the microassay system, the system determines how much lactoferrin is in the sample. A result of 1.4 is considered normal, and anything below that means the patient has dry eye. According to company studies, the test’s sensitivity is 83 percent, and it’s specificity is 98 percent. There is already a diagnostic code assigned to the test, as well. The system can also process different samples of tears to test for immunoglobulin E, to look for the presence of ocular allergy.

Now that clinicians can use lactoferrin levels to determine if a patient has dry eye, Dr. O’Brien says the next step is to study the results and see how they correlate with signs, symptoms and...
disease severity levels. “We need to figure out the correlation between the quantitative nature of this test result and the severity of the disease,” he says. Some progress has been made along these lines: In a small, non-published study that Dr. O’Brien conducted with Duke University’s Alan Carlson, MD, several years ago, they found lactoferrin levels may be associated with postop LASIK results. In the study, the researchers tested the lactoferrin of 32 patients before their LASIK procedures and then prior to their post-LASIK follow-up exams. Preoperatively, six patients had low lactoferrin, 21 had normal levels, and five had elevated lactoferrin. “We found that those patients who had lower levels of lactoferrin preoperatively were more prone to regression of effect and a lesser outcome of laser vision correction,” says Dr. O’Brien. Elevated lactoferrin suggested an increased risk for postop hyperopia. All of the low-lactoferrin patients had a postop refraction of -0.25 to -1.5 D; only 19 percent of the normal patients were outside the -0.25- to +0.25-D range; and 80 percent of the high-lactoferrin patients had hyperopic refractions of +0.5 D or greater. “It’s possible that an LVC surgeon, or a surgeon planning on implanting an advanced technology IOL, who uses the lactoferrin test to screen patients could uncover individuals who have mild to moderate disease that could impact the outcome,” says Dr. O’Brien. “So, this might be a broad screening tool for OSD as well as a perioperative screening tool that could be used in advance of surgery to uncover patients who may be at risk for a lesser outcome. The surgeon could then treat them preoperatively in an effort to improve the ocular surface.”

As for the steps after a clinician finds that a patient has low lactoferrin, there is some evidence that lactoferrin supplementation can help. In a non-published study outlined in a letter to the editor in Ophthalmology, physicians from Tokyo administered oral lactoferrin to 10 patients with Sjögren’s syndrome and used 14 eyes of seven other Sjögren’s patients as controls. The researchers reported that mean corneal sensitivity, tear breakup time, tear-film lipid layer thickness, vital staining, squamous metaplasia grades, symptoms and goblet cell densities all improved significantly after a month of lactoferrin supplementation. The parameters then worsened a month after supplementation ceased. The control group showed no significant changes. Dr. O’Brien cautions clinicians to evaluate oral supplements carefully, though. “If lactoferrin is low, there are supplements available,” he says. “But these aren’t tightly regulated by the FDA, so evidence is lacking in terms of trials to tell us which form of lactoferrin would be ideal, which dosage is best and if it’s harmful to take too much. We have this problem with other supplements that people may take without knowing their true safety.”

Making Sense of It All

Dr. O’Brien says clinicians now have to determine where lactoferrin testing fits into their dry-eye diagnostic paradigm. “We’re finding out that dry-eye disease involves a complex biological system of multiple molecules, with each playing a different role in terms of normal homeostasis of tear function,” he says. “I think the lactoferrin will be complementary to other tests such as those for tear-film osmolarity and MMP-9 to help us screen for dry eye.”

“Lactoferrin might also have other implications in terms of how the protein really functions in the natural prevention of infection from organisms that blow onto the tear film, in contact lens wearers and in surgery patients,” Dr. O’Brien continues. “However, more work needs to be done to bring a clinical meaning to the quantitative result of the test. To that end, studies are currently being coordinated and are getting under way, and I hope we’ll have some data soon in different clinical settings.”

Dr. O’Brien has no financial interest related to Advanced Tear Diagnostics or its products.

Planning Challenges For Younger Surgeons

Our financial planning series looks at repaying educational debt and what to do with retirement funds when changing positions.

Young surgeons face a host of tough decisions regarding both their present finances and their future financial management. In this column, I’ll discuss two of the more frequent areas for which younger surgeons seek advice.

Graduate Debt Options

Most physicians graduate with an average of $161,290 of medical school debt when entering their training. It can take many people until they retire to pay it all off. For folks in lower-paying specialties or working with employers who have a high supply and low demand for new attending positions, where competitive compensation is not a big factor, these loans present an even bigger burden as they take up a bigger percentage of the monthly budget.

The government has recognized this issue and even its potential as a deterrent to working in underserved areas for some specialists.

For those who are or have done their training and are still working at non-profit, 501(C)(3) or government agencies, there may be some relief available to you after paying your loans for 10 years. This program is called Public Service Loan Forgiveness. Here’s how to qualify:

• You must pay 120 on-time payments under either the IBR (income based repayment), ICR (income contingent repayment) or the standard 10-year repayment program. Whatever is left after these 10 years is said to be forgiven.
• Your loans must be Direct Stafford, Direct Consolidated, or Direct Grad Plus loans. Commercial lenders do not count. You are allowed to reconsolidate your old loan packages into this program to become eligible.

This program started in 2007 and the IBR program came out in 2009. So the first folks who will be eligible to receive some permanent relief will do so in 2017 and more likely in 2019.

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The people who will benefit the most from this are those who pay under the IBR program while in training and then continue the 10-year repayment schedule for the remaining one to seven years as an attending at a qualified agency.

If you think there is a chance that you may be eligible or will qualify for some forgiveness, you should review the Employment Certification Form (studentaid.ed.gov/sites/default/files/public-service-employment-certification-form.pdf). It is recommended that you re-submit this form annually.

A word of caution: The unknown here, as with any government program, is whether it will survive. I would not foresee the government pulling the rug out from those who have documented that they are counting on this program with the Employment Certification Form, but it could at some point stop accepting new applicants down the road.

Handling Retirement Funds

Recognizing that few of us in any field spend our entire career with the same employer, a second area of high interest from young surgeons is moving to a new position. From a financial perspective this usually triggers a whole new set of benefits and decisions to make. One of the biggest decisions that needs to be addressed is what to do with your old retirement account.

You generally have three options:

Jon C. Ylinen, Madison, Wis.
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1) Do nothing and leave it at your old employer’s retirement plan. This choice can limit your investment options. There can also be a challenge in terms of communicating about account changes; updates are usually harder to stay current on. If you make several job changes, it may also become tough to keep track of multiple accounts and asset allocation strategies for each set of investment options. You need to weigh each plan’s investment array, and you should consider costs. One employer plan, for example, may have access to low-cost classes of investment options, but have hidden fees as well.

2) Roll your old account into your new employer retirement plan. Most employer plans allow you to do this. I would recommend using this option for smaller accounts where creating a separate IRA account would become more of a hassle from an ease-of-tracking and fee standpoint. See more on this below.

3) Withdraw your funds. Generally, this option is not desirable for most people, as this action would result in income taxes due on the entire amount withdrawn, and if withdrawn before age 59 1/2, may be subject to a 10-percent penalty.

An IRA rollover can be a beneficial option in other circumstances. An IRA allows you to have the most flexibility in terms of control and asset allocation. I would suggest using an independent platform that allows you to invest your IRA dollars in the widest array of investment options available. One of the biggest constraints that we see in employer-sponsored, qualified retirement plans is that they generally have a limited number of investment options for each asset class, if they even have an option for each asset class. This makes it more difficult to create a well-diversified portfolio. Having the ability to invest in the widest array of choices and not being tied to one set of options is a large advantage. Another nice advantage of an IRA is that you can continue to combine all future retirement accounts into this one IRA account for consolidation and ease of management. You do not have to create a new and separate IRA for each old account. A final benefit that you would have one time in this option is doing an IRA to Roth IRA conversion, if it makes sense in your current tax bracket and overall retirement strategy.

This should not be considered as tax or legal advice. Please consult a tax or legal professional for information regarding your specific situation.

Mr. Ylinen is a financial advisor with North Star Resource Group. He co-authored the book Real Life Financial Planning for Physicians. He maintains a national comprehensive financial planning practice that caters almost exclusively to physicians.

For information on this topic or any other financial matter, direct your inquiries to his website, askjonylinen.com.
The Ins and Outs of Informed Consent

An effective informed consent process helps maintain good communication between the physician and patient.

Q What is informed consent? Does informed consent extend beyond the consent form itself?
A Informed consent is both a discussion and a document. During the discussion of a proposed procedure, an ophthalmologist must disclose the risks, benefits, facts and alternatives to the procedure; verify the capacity of the patient to understand and assent to the procedure; and verify that the patient is there and undergoing the procedure voluntarily. Documentation establishes that this conversation happened, but should not be perceived as the only aspect of the informed consent process.

Q Why should we implement an informed consent process?
A Whenever a medical procedure is proposed, both good professional ethics and the law require that patient and physician discuss inherent risks and benefits. Beyond this, initiating practice guidelines for good informed consent processes can minimize patient surprise over adverse outcomes and help establish and maintain good patient-physician communication. This is particularly important, as a 1992 study has shown that two-thirds of all malpractice cases are associated with patient-physician communication breakdown.1

Q How is informed consent obtained and documented?
A Numerous methods exist to provide and document informed consent. Educational brochures and videos are extremely useful for increasing the patient’s understanding of his condition and the proposed procedure. The patient’s medical record should reflect what materials and videos were provided. Consider asking the patient to sign a document indicating that she received the brochures, as well as having viewed and understood the video information. A signed consent form merely affirms in writing the patient’s understanding of the risks, benefits and alternatives to the proposed procedure.

Note that it is advisable that informed consent forms with multiple pages contain a patient initial on each page and a signature on the last page. This indicates that the patient had the opportunity to review each page and not just the final page of the form.

This article has no commercial sponsorship.
Q **When is informed consent obtained?**

A Timing depends on a variety of factors. Informed consent must include a discussion between the patient and the surgeon. Do not ask patients to sign a consent form until they have had a detailed discussion with the surgeon and their questions answered. After the discussion and educational information is provided, give the patient a copy of the consent form to take home, read and return, if possible. If the patient signs the consent form without the opportunity to take it home and review it, give the patient a signed copy for his records.

The informed consent discussion and the signing of the consent form require that the patient is alert, aware and able to participate in the process. Therefore, informed consent cannot be conducted after anesthesia induction or when the patient’s eyes are dilated to the point that reading ability is compromised.

Q **What information is required to consider the patient “informed”?**

A Legal requirements and case law have spelled out specific informed consent requirements in all 50 states; consult your local medical board for more information about your specific state laws. In general, the discussion should include patient diagnosis, the nature of and proposed treatment(s) or procedure(s), alternatives, risks and benefits of all the proposed and alternative treatment(s), and the risks and benefits of not pursuing any form of treatment. The process should also address any patient concerns, with room at the end of the form to document these concerns and physician response appropriately.

Procedure-specific consent forms are highly recommended, in order to convey only necessary information to the patient. These forms contain detailed information about the specific procedure and give patients substantive information. Patients sign the physician consent form in the physician’s office and it remains a part of the clinic medical record.

Q **Are patients expected to sign separate consent forms at hospitals and ambulatory surgery centers?**

A Yes. In addition to signing consent forms for the surgeon, patients also sign consent forms at the hospital or ASC. Facility consent forms address issues specific to the facility service, such as patient care preferences in the face of catastrophic injury, and are not specific to the risks and benefits of the proposed ophthalmic procedure. These forms are not a substitute for the physician’s consent form.

Q **Are there specific procedures that require informed consent?**

A All services you provide require informed consent. The question is how much and how to document it. Since the discussion between patient and provider is the most important aspect of informed consent, explaining what is being done and why remains a crucial aspect of patient care. Physicians typically have patients sign consent forms for major surgical procedures and tests with associated risks (e.g., fluorescein angiography). Minor procedures might not have a signed consent but, at a minimum, document verbal consent in the medical record.

Q **Where can physicians find prototype consent forms?**

A Some physicians write their own consent forms. Any physician writing his own consent forms should ask his malpractice company to review them for completeness and defensibility. Check with your malpractice carrier for consent forms; the malpractice carrier OMIC provides consent forms on its website at omic.com.

Q **What are some best practices to implement regarding the informed consent process?**

A There are several. You should set aside sufficient time for it and, if extensive, document the amount of time spent. Answer questions honestly and provide information in writing. It is also important to educate staff on the importance of the informed consent process. Finally, be sure that your informed consent forms are written in a language that is easily accessible to your patient population. The Centers for Disease Control and Prevention notes that nearly 90 percent of patients lack the necessary health literacy to fully understand everyday health-care information. For more information on writing in plain language, see nih.gov/clearcommunication.

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The Review Group offers eyecare practitioners quality informational resources dedicated to the growth and education of the profession. The Review Group offers a variety of print and online products to enrich your patient care and practice needs.
To say we live in an era of technological change would be an understatement. According to renowned inventor and futurist Ray Kurzweil, personal computers should have computational ability and capacity equal to that of a human being within eight years. (After that ... look out!) We’re not there yet, but every year new technological devices are appearing with greater information capacity, faster computing speeds and ever-expanding capabilities.

One of the most notable developments in recent years has been the advent of handheld computerized devices such as smartphones and electronic tablets. Not surprisingly, ophthalmologists are among those looking for ways to fit these devices into their daily lives—including their practice of medicine.

Mounir Bashour, MD, CM, PhD, FRCSC, FACS, an ophthalmologist and biomedical engineer in Toronto, Ontario, currently medical director at Lasik MD, the largest refractive surgery group in North America, and a long-time early adopter of new technology, notes that the new handheld electronic devices are turning up everywhere. “The hospitals in our area are talking about abandoning their existing pager systems in favor of switching to a smartphone-based system,” he says. “And I recently ate at a restaurant where they hand you an iPad at the table. The iPad shows the menu with pictures of every item. You pick your food and all of a sudden your food materializes. Very cool.” (He adds that the iPads are inside cases that trigger an alarm if you try to take them out of the restaurant.)

Here, a number of practicing ophthalmologists share ways they’ve found to use these devices to make the practice of medicine easier and more effective.

Using the Technology

Doctors are finding a host of ways to use this technology in practice:

- **Accessing patient information when away from the office.** “I use my iPad for electronic medical records access when I’m offsite at a hospital,” says John S. Jarstad, MD, medical director of Evergreen Eye Centers in Federal Way, Wash., and an adjunct professor at Pacific Northwest University College of Osteopathic Medicine, in Yakima, Wash. “For example, on a cataract surgery day at the hospital I can review chart notes and preoperative data such as IOL-Master results and astigmatism data. In my own operating room we have a regular desktop computer for access—
In the past, I used to have to carry all of the paper charts for the day. And after we switched to electronic medical records, we had to photocopy or print out all of the things we thought we might need during surgery from the patient’s chart—such as the history and physical; the A-scan report; the topography sheets; and the last few eye exams. So the charts got pretty bulky. If you’re carrying 10 or 12 of those to the hospital, you’ve got a pretty heavy briefcase.

“Now, I simply access all of the data using my iPad,” he continues. “I just connect with my server at the hospital. There’s an app you can get for about $89—the Pocket Cloud Remote Desktop from Wyse—that lets you connect via the Internet. We haven’t had any security issues so far, and it’s been really reliable. On the downside, there were one or two times I couldn’t get a signal inside the hospital; then I had to call over to the office and have somebody else log in to my account and give me the information I needed. That’s frustrating, but it’s only happened a couple of times.

“Using my iPad for this purpose was a little awkward at first,” he concludes, “but it’s been a really big help.”

**Patient sign-in.** Dr. Bashour says that when patients come into the clinic they’re handed an iPad with an online form for them to fill in their information. “The information then goes straight into our patient management system,” he says.

**Smartphone photodocumentation.** Many surgeons are now using their smartphones to take external photos of patients’ eyes. “I currently take photos with my iPhone and send them to the patient’s EMR for documentation in cases of external disease, tumors and the like,” says Dr. Jarstad. “This is something I hadn’t really thought of until I had to do it one time out of necessity. Someone borrowed the camera we use for taking external photos and took it to one of our satellite offices. So I thought, ‘What can I use to take a photo?’ I realized my iPhone took pretty good pictures, so I used that, and the quality was quite respectable. I’ve been using it ever since.”

Dr. Jarstad says that among other things he uses his iPhone camera for preop visits with patients who are going to have cosmetic surgery or blepharoplasty. “I submit those to the insurance company for preauthorization, or send them via email to our surgery scheduler or to the patient’s file,” he says. “That’s been really simple and quick. I’ve used it for trauma cases, where we wanted to document something such as a foreign body in the eye. Having that photo also provides documentation if an emergency treatment ever becomes a medical-legal case. It’s really handy because I always have my iPhone with me.

“I think relying on smartphone photos in some circumstances, such as in the emergency room, is becoming quite common,” says Michael J. Hodkin, MD, an anterior segment and corneal surgeon in Muncie, Ind. “It can be very helpful to have a picture for future reference. If one of my colleagues is going to see the patient in the future, we’ll have a record of what the eye looked like originally. Or it can simply serve to jog my own memory.”

“The quality now is good enough to make it feasible for these applications,” adds Dr. Jarstad. “I could see doing operating room videos with it. That’s probably the next step. You can get upgraded apps for taking higher-definition pictures, and the resolution and definition are probably going to get better and better over time. I’m sure there will soon be all kinds of additional options that we can’t even imagine at the moment.”

**Letting patients send pictures to you.** Now that almost everyone seems to have a smartphone with picture-taking capability, some doctors have noted that patients are increasingly using this ability to forward images of their eyes when they have a problem. “Even members of my own family send me pictures of their eye if it’s red or something,” says Dr. Hodkin. “It’s kind of a poor man’s telemedicine. With a smartphone you can take a close-up picture of the eye. It doesn’t always tell the story, but sometimes
you’ll get a clue about what’s going on.”

• **Accessing textbooks.**
  Dr. Jarstad notes that being able to access textbooks on a smartphone or tablet is very advantageous. “You don’t have to carry around large textbooks, and you can access them from remote locations,” he points out. “That could be especially helpful in the Third World, where physicians and residents may have trouble purchasing expensive textbooks and paying for shipping. Everybody there seems to have an iPhone.”

• **Patient education.** “We used to have a video player for showing educational videos, but that was a little cumbersome,” says Dr. Hodkin. “A tablet is much easier to manipulate. The patient can watch the video in her lap. It’s also a teaching tool; you can bring up still pictures and explain things. It’s certainly handier than a flip chart.”

“...there is an extension to the world of the ophthalmologist. It’s going to be difficult for a practicing ophthalmologist to ignore what is going on, because you’re getting a piece of all the world’s digital content of every type, and there is a way to access everything—all the best information is going to be there, all for maybe a few dollars more than a single subscription would cost, it would be extremely convenient for ophthalmologists. It would also be better for the journals, especially the smaller journals, which would be seen by far more doctors. I suspect almost every ophthalmologist would opt for this if it were available. Plus, the journals would know exactly how many eyes are reading every article, which is very valuable information.

“Eventually, I think we will see services that, for maybe $20 a month, give you access to everything—all the world’s digital content of every type, all in one place,” he adds. “It’s going to happen sooner or later, and the people who will be most rewarded are those who make it happen sooner.”

### Enhancing Your Gadgets

In addition to the possibilities inherent in the devices themselves, special attachments and software can add significant capabilities.

• **Smartphone slit-lamp adapter.** One device that Dr. Jarstad has found useful is the Portable Slit Lamp iPhone 4 Imaging Adapter (Keeler Ophthalmic Instruments, $195.00).
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#1004_12/12
This is an attachment for the slit lamp that allows you to use an iPhone to capture slit-lamp photos or videos,” he explains. “I’ve tried it a couple of times, and it works pretty well. Previously, people would try to hold the lens over the ocular in exactly the right position with one hand, then try to focus with the other hand while also keeping the patient’s eye open. Without the device you really need three hands. It’s possible to capture images using your phone without this device, but the attachment makes it much easier to get good, clear photos, in focus. It’s a bit pricey, but it does serve a purpose.”

Pocket A-scan and B-scan devices. Another technology Dr. Jarstad uses when traveling is the PalmScan A2000 A-Scan (from Micro Medical Devices)—a self-contained pocket A-scan on a Palm Pilot platform. (See photo, p. 22.) “It’s like a beefed-up Palm Pilot with an attachment for the A-scan, and it will also do pachymetry,” he notes. “I’ve used that on a couple of mission trips to developing countries including North Korea, Indonesia and the Philippines. It’s nice because it fits in your pocket and doesn’t take up space. It worked superbly and results were very accurate.

“It comes with a little probe that hooks into the top of the device,” he continues. “Then you just take the readings as you would from one of the older A-scans. I think they have an immersion attachment, too. You can run your A-scan calculations and enter your IOL constants and it will give you a printout just as you’d get with a regular A-scan device. It was relatively inexpensive—I think it was a couple thousand dollars. I’m sure something like this will eventually be available for smartphones as well.”

Dr. Jarstad adds that a radiologist he works with has told him about a portable B-scan ultrasound that attaches to the iPhone. “They can use it for obstetrics and other specialties,” he says. “Apparently it works pretty well. It should be a great addition to our medical armamentarium because of its portability.”

Because so many patients today—even senior citizens—rely on smartphones or tablets, one way to help your low-vision patients is to alert them to apps that may improve their quality of life. Here a few worth noting:

- **LookTel Money Reader** ($9.99). Individuals with low vision can have difficulty identifying currency when money is changing hands or needs to be counted. This app allows your smartphone to scan bills and speak the denomination; you simply point the smartphone’s camera at the bill and it immediately identifies it. There’s no need to take a picture of the bill or hold the phone still. The Money Reader can identify bills of several currencies, including the U.S. dollar, euro, British pound, Canadian dollar and Australian dollar. The app can report the denomination in any of 16 languages, including most European and Nordic languages, as well as Russian, Korean, Japanese and Mandarin. The latest version also tells you that the app is working when the screen is tapped, and notifies you if the lighting is inadequate.

- **Digit-Eyes Audio Scanner and Labeler** ($19.99). This app does two very useful things. First, it enables your smartphone to read barcode labels. People with limited vision can scan UPC or EAN (international article number) codes and hear the names of more than 25 million different products. Second, this app allows you to create labels that, when scanned with your device, will announce whatever message you have encoded in your own voice. The user visits the Digit-Eyes website on a device connected to a printer and prints out specially coded QR (Quick Response) barcode labels on inexpensive address label sheets. The user can then attach the barcode labels to anything (files, calendars, CDs, leftover food containers, etc.), scan them once, and record a message. The app will then relay the recorded message any time that barcode is scanned, making it easy to identify an object or its contents, or be reminded of an appointment.

Alternatively, the user can type in a message of up to 100 characters per label, and the program will print out a label that will recite the typed message when scanned. Furthermore, the user can buy pre-printed labels for clothing, designed to withstand washing, bleaching and dry cleaning, that can be sewn in; you can scan them and record any comments about the clothing item (color, fabric care, what it should be worn with). Those comments will be played back any time that label is scanned.

The Digit-Eyes website contains extensive instructional material intended for iPhone and iPad users with limited vision, and the app comes with free online support and tutoring. (For more information, visit Digit-Eyes.com.)

- **Cobra Tag Universal** ($49.99). This physical device, working with a free smartphone app, allows the user to easily find objects that we all occasionally misplace, such as car keys or a purse. The device clamps onto the object; the user opens the app (available for iPhone, iPad, Android or BlackBerry devices), taps the screen, and a loud chirping noise announces the object’s location. The device will also sound an alarm if the connection with your smart device is broken—for example, if you unintentionally leave your smartphone or pad in a restaurant or at someone’s house. The device can also send you a text, e-mail or tweet announcing that your phone or tablet can’t be located, and also show you a map of its own location.

For additional patient-friendly apps, see “Apps for Your Patients (and Their Eyes)” in the September 2012 issue of Review.
he's downloaded DropBox software onto all of his computers. “I just started using this recently,” he explains. “It allows me to place documents or photos into a folder, and because it’s cloud-based, I can view and modify the files from any of my other devices. It automatically updates the files on all of the devices as I work on any copy of the file. For example, sometimes I’ll work on a research project at the office, then on my computer at home, then while on vacation or traveling. The DropBox program updates all of the copies at the same time. Furthermore, it saves the old version, so if I realize I deleted something that I need, the earlier version will still be in there. It’s also a great way to share information with others if I wish. It’s very easy to use; it provides 2 GB of space for free; and it works on both PC and Mac computers. I’ve found it to be very helpful.”

Apps, Perhaps?

As everyone knows, part of what makes smart technology so useful is the availability of a seemingly endless supply of applications that allow the technology to perform specific functions. A number of those apps are designed for use by medical professionals. Some favorites include:

- **Eye Handbook.** Dr. Nicholson finds the Eye Handbook app, developed by ophthalmologists at the University of Missouri Kansas City and Cloud Nine Development, particularly helpful. “It has a wide variety of tools,” he says. “It includes a Snellen-like chart so you can check people’s near visual acuity. It has a pen light if you want to do an exam. It provides information about medications, and you can access the American Academy of Ophthalmology’s Preferred Practice Patterns. It even includes an OKN drum for detecting certain neuro-ophthalmic pathologic conditions. The OKN drum isn’t used as much today as it once was, but it’s one of those tools that every now and then you wish you had.

  “I think Eye Handbook is the app I use the most,” he adds. “And they keep improving it with periodic updates.”

- **Sight Selector.** “The Sight Selector app for the iPad has great pictures and videos you can download onto the iPad for patient education,” says Dr. Nicholson. “It comes with some free basic anatomy photos, but you can purchase specific topics that you might want. My patients like it. I use it on my iPad to show them basic eye information about topics such as astigmatism or the anatomy of the eye. It’s a nice adjunct to the typical globe that we all have in our eye lanes.”

- **E-pocrates.** “This is a free app for looking up drugs,” explains Dr. Hodkin. “It gives you very complete information on the indications and contraindications, the dosage and the cost, in a very user-friendly format.”

- **Podcasts.** “Most smartphones have a podcast app,” notes Dr. Nicholson. “You can subscribe to different topics ranging from ophthalmology to non-medical topics. Some of them are peer-reviewed and some have CMEs available. I have Bluetooth in my car, so if I have a 25-minute commute, I’ll listen to podcasts on the way home.”

- **Glaucoma 5-Year Risk Estimator.** Dr. Nicholson also uses the Glaucoma 5-Year Risk Estimator iPhone app developed with the Washington University School of Medicine in St. Louis. “The ocular hypertension risk calculator is nice for early glaucoma patients with high pressure,” he says. “It lets them know their five-year risk of developing glaucoma.”

- **CataractMobile.** “A fun no-cost app for Apple and Android tablets is cataractMobile,” says Dr. Nicholson. “It’s an animated simulator for performing phaco and making capsulorhexis tears. During the making of the ‘rhexis, you put your finger on the touchscreen and it helps you practice your vectors—in other words, where the torque needs to be placed to tear a nice round ‘rhexis of a certain size. Obviously there’s no tactile feedback, but it does demonstrate the consequences of grabbing the tissue at different locations and pulling in different directions. It can be a very good adjunct to help beginners get used to those forces—and I think that once you get those forces down, making a great ‘rhexis isn’t hard at all.”

- **Coding apps.** “One type of app I use all the time is for ICD-9 coding,” notes Dr. Hodkin. “It’s basically a database for looking up coding, and...
there are many apps out there that can help with this. Of course, our techs handle the coding in most situations, but when there's a question they come to me. These apps help me resolve the tough ones. It's one of my go-to sources when there's a coding challenge."

• The Wills Eye Manual. "It's the same version as the book, but it's on the iPhone or iPad," says Dr. Bashour.

• Lens implant calculators. Dr. Hodkin notes that several of these are available. "An electronic tablet is just as good as a computer for this purpose, but much more portable," he says. "That makes using it much simpler."

A Few Suggestions

Surgeons offer some additional strategies for making the most of today's high-tech handheld technology:

• Use a professional drawing tablet. Smartphones and tablets aren't the only high-tech devices that can be useful to an ophthalmologist. "My practice is retina-only, so images are a huge part of the practice," says Steve Charles, MD, FACS, FIC, founder of the Charles Retina Institute in Memphis, Tenn. "I use a Wacom Cintiq graphics tablet with an LCD display—the one that graphics professionals use. It's my user interface, my connection to our EMR program.

“Some retina specialists make drawings on a piece of paper and then have the drawings scanned in," he continues. "Or they use programs with small pads and create drawings that don't really look like the eye. I decided that it made more sense to draw like an artist. This interface can be used two different ways. It has a selection of symbols and colors, so you can use drag-and-drop and create a color-coded drawing that way. Some of my associates do that. I prefer photorealistic drawings, so I use an electronic pen, create the drawings myself, and then do a lot of hand labeling."

• Have wireless Internet available in your waiting room. "Most of our patients have these devices—even the older folks," says Dr. Hodkin. "They all sit in the waiting room with readers and so forth. It's become part of the culture, and everybody's gotten on the bandwagon. Even our older patients have taken to these devices like ducks to water."

“For that reason, we have wireless Internet in the waiting room, so patients can connect to the Internet with their smartphones or tablets,” he continues. "Having to wait to see the doctor is the most common complaint in most offices. When patients have the opportunity to surf the net on their own device in the waiting room, they have the chance to be productive and/or entertain themselves. They don’t feel like they’re being forced to waste time sitting there, or forced to read our magazines."

• Consider using an in-office BlackBerry-based smartphone system. "We use Outlook and Microsoft Exchange for our in-office communication and e-mail, all connected to an exchange server, making our interoffice e-mail highly secure and HIPAA compliant," says Dr. Charles. "People seem to be obsessed with iPhones, but Blackberrys do several things better. For example, iPhones don’t talk to the Exchange server as well, and there’s no automatic push of your calendar in an Outlook environment. We have a separate BlackBerry Enterprise Server that pushes my calendar and surgery schedule to everyone’s Blackberrys, so all of us see the updated surgery schedule in real-time on our phones. If we need to add a case, everybody can see how full the schedule is."

“I use the same system for my personal calendar, including my travel schedule, but different individuals have different levels of access," he continues. "Both my assistant and I have read and write access; some others can read my schedule but not alter it. Others, who don’t need to know all of the details of my personal schedule and travel plans, cannot access it. Blackberries are actually better than iPhones for this."

"Some surgeons say, ‘Oh, I sync our schedules myself,’ but in my office, the second somebody adds something to my calendar, a flight number, an appointment, the time to make a conference call, it’s automatically on my phone and laptop,” he says. "I think that’s far better."

Concerns and Limitations

Though there’s no end in sight, this technology still raises some concerns, and still has a way to go to fully meet ophthalmologists’ needs. One concern is security—especially important when medical information is involved, and when people are beginning to store information offsite in the cloud.

Dr. Jarstad agrees that this is an issue. “If you store patient information in the cloud, it’s conceivable that someone could hack into the cloud to get digital images of a patient’s eye injury or abuse pictures, something like that,” he says. “But so far the security has been pretty robust. I haven’t seen any issues with that.”

Dr. Charles is skeptical. “Many people seem to be obsessed with the idea of storing information in the cloud,” he notes. “I don’t want to be dependent on communication links and have information stored in far-away places. We don’t use the cloud. We don’t even back up everything at the end of the day. In our office, information is automatically copied onto multiple hard drives in real time.”

Other more basic concerns, such as the possibility of losing a handheld device (or having one stolen) are now being addressed by the devices themselves. “There’s an application from Apple called Find My iPad, or (continued on page 61)
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Retina by the Slice: The Latest in OCTs

Walter Bethke, Managing Editor

Optical coherence tomography has given ophthalmologists a window into the eye that they never had before, and the features of the various OCT devices on the market continue to multiply. With OCTs’ new modules and optional features, physicians can use the devices to evaluate the effects of surgery, diagnose conditions and follow the progression of disease and therapies. Here’s a look at the latest features available on OCT units that can help you better manage patients.

Bioptogen

Bioptigen’s Envisu C-Class spectral domain OCT systems are mobile devices with handheld imaging heads that capture images at 32,000 lines per second down to an axial resolution that the company says depends on the unit purchased. The resolution is 5 to 6 µm (high-res light source unit) or 3 µm (very high-res light source unit, but with slightly less depth of field).

The system provides flexibility, in terms of software function, a higher resolution available through the VHR light source and a very good signal-to-noise ratio so the clinician can get images in real time scanned over a high-density volume,” says Eric Buckland, PhD, chief executive officer of Bioptigen. “Also, you can take the imaging to the patient, rather than having to take the patient to the imaging—that’s a key functionality difference with the system.”

Dr. Buckland notes that, because of its mobility and handheld imaging head, the Envisu C-Class is the only OCT cleared by the Food and Drug Administration for the imaging of children down to the prematurity

Heidelberg says the Spectralis’ new multicolor imaging function can allow clinicians to see certain disease signs better than if they were viewed in simply black and white.
age group and the only one approved for use on anesthetized patients. “It’s cleared for use under anesthesia because it can take images from whatever angle is necessary,” he explains. “It has sufficient ergonomics to allow that sort of imaging without any change to the image quality.”

The Envisu, the standard package of which consists of a lens for retinal imaging and one for imaging the anterior segment, provides images only—no normative data or measurements of normative data. “Our system is really a visualization tool,” says Dr. Buckland. “If one wants to image pathology, understand epithelial and stromal thickness, or determine if a candidate is a good candidate for DSAEK or DALK, our system can show them the detail they need.” For information, visit bioptigen.com.

Carl Zeiss Meditec

Carl Zeiss Meditec recently introduced four new OCT models, and the company says each offers particular features that may appeal to different practices.

• **Cirrus HD-OCT 5000 and 500.** The 5000 model has a feature called FastTrac, which is retina tracking technology that Carl Zeiss Meditec’s U.S. President and CEO Ralf Kuschnerit, PhD, says serves a two-fold purpose: “While the OCT scan is being done, the independent system is tracking the retina,” he says. “And if the patient moves or blinks, this is taken care of, corrected or re-scanned so that there is no motion artifact in the final image. This is especially important for subspecialists who may have patients who find it hard to fixate. The other advantage of the tracking is if you have subsequent scans of different visits, you can position the HD high-resolution raster scan in exactly the same position so that you can better track the progression of the disease.” The tracking can also be turned off for speedier imaging in patients who can sit still, since using the tracking can make an exam longer than not using it. The model 500 doesn’t have FastTrac, but has a much faster OCT scanner than previous models, which the company says makes it easier to align a patient to the system for accurate imaging.

• **Cirrus photo 800 and 600.** These are both combinations of a fundus camera and Cirrus OCT in one unit. The 800 increases the feature count by also offering fluorescein and indocyanine green angiography capability. “If you want to provide advanced care and need versatility but maybe have a space constraint, you might not want to have a separate fundus camera and OCT,” says Dr. Kuschnerit. “By combining Cirrus OCT images with fundus, angiography or autofluorescence images all on one screen, it’s a great way to review the disease state of the patient.”

The new Cirrus models also offer software to analyze such features as the retinal nerve fiber layer, ganglion cell layer and optic nerve head. Available anterior segment imaging allows analysis of the angle and the cornea. For information on CZM’s new OCTs, visit www.meditec.zeiss.com/Cirrus.

Heidelberg Technology

The newest addition to the Heidelberg Spectralis OCT is multicolor scanning laser imaging. Multicolor imaging uses several laser wavelengths (blue, red and green) at the same time to allow the physician to capture and display diagnostic information from different parts of the retina during one OCT exam. “It’s very sharply detailed because the Spectralis is confocal, and blocks light from outside of the focal plane, which allows it to get sharp images,” explains Adam Doherty, Spectralis product manager. “Each laser color goes to a certain depth, giving information from different layers of the retina, with blue being more anterior and red more posterior. The clinician can look at the multicolor image or at each color image separately. The multicolor image is helpful because when you take an image of the fundus and you see blood, cotton wool spots and a vitreous hemorrhage in black and white, sometimes those three things can look very similar. But in multicolor you can see the blood is red and isn’t a cotton wool spot, and the vitreous will be darker and not resemble blood.”

The other feature that’s being manufactured but isn’t released yet is the ultra widefield lens. “The non-contact lens allows the OCT to go out over 100 degrees of the retina,” explains Mr. Doherty. “This makes it easier to get images but also makes getting the images easier on the patient. Normally, a retinal photographer would have to do seven field sweeps, especially for diabetic patients, taking images around the posterior pole with a 30-degree lens, then send the series for studies to get a picture of the whole posterior pole. This lens allows...
The doctor to perform those sweeps, but now out to the far periphery. This may allow physicians to catch disease states in the periphery, such as choroidal ruptures and retinal tears, earlier. Also, if a physician is going to perform a laser treatment in the periphery, he can use one or two of these images to see where he’s going to do the treatment.” Visit heidelbergengineering.com or call 1 (800) 931-2230.

Optopol/Canon

The Optopol Copernicus HR Spectral OCT scans at 52,000 A-scans per second with an axial resolution of 3 µm. The latest feature available to the clinician is the ability to select “choroid” or “vitreous” mode for a particular scan. “For an exam, the clinician can focus the sensitivity of the spectrometer on one end of the spectrum or the other,” explains Arkadiusz Chalecki, the Optopol product manager for OCT. “By focusing, you can get increased sensitivity in the upper part, the vitreous, or the lower part, the choroid. So, for example, in the vitreous mode it can capture floaters, the vitreous or a detachment of the ILM. Though being able to focus on the choroid or vitreous doesn’t matter for most patients, if someone has a specific disease of deformation of the retinal structure, one of these modes can enable us to capture better details. If a patient has photoreceptor or RPE problems, the choroid mode gives better details in that area.”

“Another area where the device’s focusing ability is useful is in the setting of media opacity,” Mr. Chalecki continues. “There are a number of patients with cataract or other media opacities that can block the light from an OCT, making for a diminished signal. This system helps get as much data as possible for the doctor.”

The Copernicus also has a progression module to help the clinician follow a disease. “Since the device always does a very dense 3D raster scan, it is able to recognize blood vessels from one exam to the next,” says Mr. Chalecki. “The system uses the vessels to overlay the exams above each other, so even if a patient doesn’t fixate as well one time or the scan area is shifted from the last session, using the vessels as landmarks we can capture all the scans within the same volume. This allows us to precisely measure the thickness of structures over time and compare the same cross-section slices from different exams.” In the United States, Canon distributes Optopol’s OCT, and can be reached at 1 (800) 970-7227. For information, visit optopol.com.

Optos

Optos says its OCT SLO helps clinicians make better diagnoses by marrying a confocal scanning laser ophthalmoscope with an OCT. “This generates a fundus image as well as an OCT image,” explains Glenn Erickson, director of North American product specialists at Optos. “What makes the OCT SLO different is that it uses a single light source for the beam that’s sent into the eye, rather than two different ones. This gives us pixel-to-pixel registration on the fly between the SLO and the OCT. So, for the user, the two images, the fundus and the OCT, are registered to each other. Anything the user does to one image, he sees on the other. This is in the hardware, and they don’t need to be married up afterwards in the software. This means you always know exactly where you are in the image. For example, with a macular hole, while scanning through it, because you have the SLO in front of you, you can move your scan line into the hole and you see the OCT on the other side of the screen. It allows you to know whether it’s open or closed, because you’re seeing it on the screen. If you didn’t have this, you wouldn’t know if it were open or closed, because you wouldn’t be sure where you were scanning on the retinal surface during an exam.”
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Albert says, “For an accurate glaucoma diagnosis, use hysteresis.”

The New Physics of Glaucoma.
The OCT SLO also has functions for tracking glaucoma progression, though Mr. Erickson says the device does the retinal nerve fiber layer test a little differently. “We use vessel registration and tracking,” he says. “We track back to the same place around the nerve head where the measurement circle was the first time, based on where it was intersecting the blood vessels. This is important because if you’re looking for change you want to go the exact place on the retina—in this case the nerve fiber layer measurement—and look for change over time.” For information, visit optos.com or call 1 (800) 854-3039.

Optovue

The latest additions to the Optovue line of devices are the Total Corneal Power module and the RT-Vue VTRAC Premier real-time, active-tracking OCT.

“Total Corneal Power comes in when the surgeon or staff is doing preop IOL calculations in post-refractive surgery patients,” says Mike Scott, senior product marketing manager for Optovue. “Standard keratometry measures the anterior curvature of the cornea and then makes broad assumptions to extrapolate the cornea power to be used in IOL selection. However, in a post-LASIK patient, for example, the anterior curvature has changed, so if you try to use the same assumptions, the surgery may result in an unexpected postoperative surprise. TCP takes a direct measurement of the front surface and a direct measurement of the back surface of the cornea to calculate the anterior, posterior and net cornea powers. Mr. Scott says the surgeon can then take those corneal powers and enter them into a special OCT-based IOL power calculator for eyes with previous refractive surgery that is available at coollab.net/index.php?id=852.

Though the RTVue system already has vessel registration to allow change and trend analysis, Mr. Scott says that the VTRAC Premier system allows surgeons to get images with even more detail. “It has a scan depth of approximately 3 mm, which gives a larger window into the retina,” he explains. “Combined with its Noise Reduction Technology, the system allows for deep choroidal imaging and measurement, while also providing rich detail in the vitreous. Also, in patients with fixation drift, the real-time, active eye tracking helps capture their images.” The RTVue also has ganglion cell complex analysis, which the company says has been used in more than six years of published studies and clinical use. The GCC and thickness measurements can be compared to a large normative database, as well.

In addition to the RTVue VTRAC Premier, Optovue also offers the iVue, a more compact OCT device. The iVue allows imaging of the anterior segment, posterior pole and optic disc, as well as retinal thickness measurements and optic disk and peripapillary retinal nerve fiber layer assessment. The device’s anterior segment module is offered as standard and provides pachymetric measurements of a 6-mm diameter area of the central cornea, as well as visualization and measurement of the angle. For information visit optovue.com or call 1 (866) 344-8948.

Topcon

The Topcon 3D OCT combines a high-resolution digital fundus camera with the OCT to give the clinician different views of the retina.

The company says the OCT portion of the exam uses its proprietary FastMap software system to allow dynamic viewing of 2D, 3D and fundus imaging. Topcon says FastMap can help when faced with complex pathologies such as vitreous traction, macular edema and retinoschisis. The software also allows the physician or technician to export its images and 3D movies to other devices for presentation purposes. The OCT system can capture images of the fovea and optic nerve in a single scan, and has a choroid reference mode for providing high-resolution views of the choroid. For capturing exam images of high myopes and hyperopes, the system can work with a diopter compensation lens and can provide an extended scanning depth of 2.3 mm.

By employing a non-mydriatic color fundus camera in the OCT system, clinicians may be able to visualize conditions that might not be picked up on an OCT, such as disc hemorrhages, the company says. The camera has a 45-degree field of view and can also provide stereo photos for analysis of optic disk changes. To help orient themselves to areas of pathology that are displayed in the system, clinicians can use the 3D OCT’s PinPoint Registration to link the location of the OCT data points to specific points in the fundus image.

For following patients with glaucoma or retinal pathology, the FastMap software also uses layer detection algorithms to measure such features as total retinal thickness and retinal nerve fiber layer thickness. The physician or technician can manually adjust the imaging grids that are measured in these exams, and can also manually register serial exams or allow the computer to register them automatically for comparison purposes. For information, visit topconmedical.com or call 1 (800) 223-1130.

For many ophthalmologists, OCT technology has become an integral part of their day-to-day practice. The new modules and add-ons available on the various OCT devices should help doctors diagnose and manage disease more quickly, and with even more accuracy.

REVIEW

Feature

OCT Technology
Utilizing the newest technology known to the industry, the HAI CL-1000nc redefines patient comfort and clinical efficiency for specular microscopy. No capture buttons to press, no flash bulb required to take a picture -- simply target the desired area of the cornea for automatic performance at remarkable speed. The HAI CL-1000eva Endothelium Viewing Attachment converts a slit lamp into a specular microscope, saving valuable exam lane space while adding important clinical insight to your practice.

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I decided to purchase the HAI specular microscope and the HAI slit lamp because it adds information to my patients’ needs. I’ll be able to better diagnose conditions in patients with corneal disorders. I’m very impressed with the quality of the images I am getting; I’m very impressed with the company, their dedication and willingness to help.”

— Dr. Edward L. Boshnick, Miami, FL
 Clinically significant diabetic macular edema has long been recognized as a major cause of loss of vision in patients with diabetic retinopathy. As the prevalence of diabetes grows worldwide, the potential loss of vision from DME poses a significant concern with regard to quality of life and socioeconomic considerations.

The treatment for DME with focal/grid laser to microaneurysms or areas of diabetic macular edema has been established since the Early Treatment Diabetic Retinopathy Study. However, when the Diabetic Retinopathy Clinical Research Network (DRCRnet) published a prospective trial comparing standard laser therapy to combination therapy with ranibizumab or steroid, the standard of care became challenged, as the combination therapy group (laser and ranibizumab) demonstrated superior visual outcomes over focal/grid macular laser alone in patients with DME. At one year, no differences were detected between the ranibizumab and ranibizumab/laser arms, and approximately seven injections were necessary in the ranibizumab arms. The two-year safety and efficacy data were presented for the RESTORE Extension Study.

The REVEAL trial had a design similar to that of the RESTORE trial, except that it followed an Asian cohort with DME. At one year, the REVEAL trial also demonstrated the superior outcomes of ranibizumab and ranibizumab with laser (+5.9/+5.7 ETDRS letters gained) versus laser monotherapy (+1.4 ETDRS letter gained). The mean number of injection treatments was 7.8 in the ranibizumab monotherapy vs. 7.4 in the ranibizumab/laser combo therapy. There were no significant safety signals (ocular or systemic) noted in this trial.

Ranibizumab Monotherapy & DME

For many years it has been established that vascular endothelial growth factor plays a role in the creation of retinal ischemia and increased vascular permeability that gives rise to macular edema. The RISE and RIDE trials were identical, but ranibizumab as monotherapy was superior to laser alone. The trial demonstrated that ranibizumab as monotherapy or in combination with focal/grid macular laser provided superior visual acuity outcomes over focal/grid macular laser alone in patients with DME. At one year, no differences were detected between the ranibizumab and ranibizumab/laser arms, and approximately seven injections were necessary in the ranibizumab arms. The two-year safety and efficacy data were presented for the RESTORE Extension Study.

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double-masked, sham-controlled, multicenter Phase III trials evaluating the impact of monthly ranibizumab injections on DME (Ip M, et al. IOVS 2012;53:ARVO E-Abstract 1336). Both trials evaluated sham vs. 0.3-mg vs. 0.5-mg ranibizumab monthly monotherapy in the treatment of DME over a 24-month time frame, with additional treatment and follow-up out through 36 months. After three months of injection therapy in the trial, rescue macular laser could be applied if it were found that central foveal thickness was >250 µm or if there was a 50-µm worsening from the prior month.

For the RISE trial, 377 patients were randomized (127 to sham, 125 to 0.3 mg, 125 to 0.5 mg) with the characteristics similar across the three arms. At 24 months for >15 letter vision gains, 18.1 percent of sham patients versus 44.5 percent of 0.3-mg and 39.2 percent of 0.5-mg ranibizumab patients were noted. In the RIDE study, 382 patients were randomized (130 to sham, 125 to 0.3 mg, 127 to 0.5 mg) with similar baseline characteristics. For the proportion of patients experiencing >15 letter vision gains, 12.3 percent of sham patients versus 33.6 percent of
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0.3-mg versus 45.7 percent of 0.5-mg ranibizumab patients were noted. Pooling the efficacy data, the visual results, both the proportion of eyes gaining three or more lines and mean BCVA, were identical for the two doses. Significant improvements in macular edema were noted on OCT in both ranibizumab arms in both trials; retinopathy was less likely to worsen in ranibizumab-treated patients.

In the RISE study, 11 percent of the sham group eventually required panretinal photocoagulation for eventual progression to proliferative diabetic retinopathy as compared to 0 and 0.8 percent in the 0.3-mg and 0.5-mg ranibizumab arms. In the RIDE study, 12.3 percent of the sham group eventually required panretinal photocoagulation for eventual progression to proliferative diabetic retinopathy as compared to 1.6 percent in both the 0.3-mg and 0.5-mg ranibizumab arms. In both trials, ranibizumab-treated patients underwent significantly fewer macular laser procedures (mean of 1.8 and 1.6 laser procedures over 24 months in the sham groups versus 0.3 to 0.8 in the ranibizumab groups, respectively). Across both trials, endophthalmitis occurred in four ranibizumab patients out of a total of 10,584 injections (0.04 percent), which is reassuringly low. Similar to other large trials with ranibizumab monthly therapy, there were no significant serious systemic cardiovascular adverse effects (deaths from vascular or unknown causes, nonfatal myocardial infarctions, and nonfatal cerebrovascular accidents) detected amongst ranibizumab-treated patients.

Both RISE and RIDE established ranibizumab monthly monotherapy as an efficacious and sustainable treatment for DME, with low rates of ocular and systemic complications for up to 36 months. In August 2012, ranibizumab at the 0.3-mg dose gained Food and Drug Administration approval for the treatment of DME in the United States.

Alternative Treatment Prospects

Besides targeting VEGF with ranibizumab, there are other promising treatment modalities that may offer additional help for the treatment of DME.

Bevacizumab has an established treatment history for macular degeneration and DME. Its use in ophthalmology remains off-label; however, in ophthalmology it is a widely accepted treatment for exudative age-related macular degeneration. Its application to treat DME or proliferative diabetic retinopathy has an extensive clinical history, although long-term, prospective, comparative clinical trial data is limited.

In DME, bevacizumab has been evaluated in a prospective study, the BOLT trial. This study consisted of 80 patients that were randomized to 1.25-mg bevacizumab versus standard macular laser for non-ischemic, center-involving, clinically significant macular edema. At 12 months, bevacizumab led to significant gains in ETDRS letters versus laser monotherapy (median gain of eight ETDRS letters vs. median loss of 0.5 ETDRS letters in the laser group). The application of bevacizumab is a reasonable alternative treatment for DME at the current time.

Similar to bevacizumab, intravitreal triamcinolone for DME also remains an off-label application. In the DRCRnet trial, the triamcinolone with laser therapy arm was found to have visual gains when evaluated in pseudophakic patients. However, the possibility of provoking cataract formation or the potential for steroid-induced ocular hypertension or the possible exacerbation of glaucoma have placed its use secondary to anti-VEGF-based strategies.

Future Therapeutic Prospects

Ozurdex is a sustained-release dexamethasone intravitreal office-based injectable implant that has FDA approval for the treatment of branch and central retinal vein occlusion-associated macular edema and for the treatment of posterior non-infectious uveitis. Its use for DME remains off-label, but promising.

One such study evaluated persistent DME, >90 days to one of two intravitreal dexamethasone implant doses (350 micrograms or 700 µg) versus observation. The study evaluated 171 eyes; at day 180 best-corrected visual acuity improvement of 10 letters or more was seen in 30 percent of eyes in the 700-µg group, 19 percent in the 350-µg group, and 23 percent in the observation group (p ≥ 0.4 for treated vs. observed eyes). There were also significantly greater improvements in central retinal thickness and fluorescein leakage. Another study evaluated the efficacy of Ozurdex in refractory DME in post-vitrectomy eyes and found improved vision and OCT-determined central thickness with the 700-µg implant.

Iluvien is another promising sustained-release steroid, intravitreal, office-based implant that utilizes fluocinolone as opposed to dexamethasone. The advantages of this particular platform include a smaller size (25 ga. as opposed to 22 ga. with Ozurdex) and a longer duration of efficacy (2.5 to three years).

FAME, a prospective, randomized trial, just published its three-year data. The trial evaluated two different doses of steroid implant (0.2 µg / day versus 0.5 µg /day) versus sham control. At three years, the percentage of >15 letters of vision gained was 28.7 percent (0.2 µg /day) and 27.8 percent (0.5 µg /day) in the implant groups compared with 18.9 percent (p=0.018) in the sham group. Virtually all phakic patients developed...
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cataracts, but their visual benefit after cataract removal was similar to that of patients who were pseudophakic at baseline. The incidence of incisional glaucoma surgery was found to be 4.8 percent in the low-dose group and 8.1 percent in the high-dose insert group. Ilivin is approved for treating DME in Europe but not in the United States.

Aflibercept (Eylea) is a commercially available drug that is FDA-approved for the treatment of exudative AMD. Its role in the treatment of DME is promising and currently undergoing Phase III testing for this indication. Aflibercept is a recombinant fusion protein comprising the key VEGF-binding domains of human VEGF receptors 1 and 2 with a higher binding affinity versus ranibizumab and bevacizumab, along with binding capacity for placental growth factor, which has been shown to contribute to excessive vascular permeability and retinal neovascularization.18-19 The Phase II experience of aflibercept for treating DME (DA VINCI trial) was recently published.20 Two hundred twenty-one patients with center-involving DME were randomized to one of five treatment regimens: aflibercept 0.5 mg every four weeks; 2 mg every four weeks; 2 mg every eight weeks after three initial monthly doses; 2 mg dosing as needed after three initial monthly doses; or macular laser photocoagulation. The primary outcomes were BCVA at 24 weeks and at 52 weeks, proportion of eyes obtaining >15 ETDRS letters of improvement compared with binding capacity for placental growth factor, which has been shown to contribute to excessive vascular permeability and retinal neovascularization.18-19 The Phase II experience of aflibercept for treating DME (DA VINCI trial) was recently published.20 Two hundred twenty-one patients with center-involving DME were randomized to one of five treatment regimens: aflibercept 0.5 mg every four weeks; 2 mg every four weeks; 2 mg every eight weeks after three initial monthly doses; 2 mg dosing as needed after three initial monthly doses; or macular laser photocoagulation. The primary outcomes were BCVA at 24 weeks and at 52 weeks, proportion of eyes obtaining >15 ETDRS letters of improvement compared with BCVA at baseline. The incidence of incisional glaucoma surgery was found to be 4.8 percent in the low-dose group and 8.1 percent in the high-dose insert group. Ilivin is approved for treating DME in Europe but not in the United States.

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**Bringing the Focus To the Aqueous**

A look at the composition of our tears and the pros and cons of our current methods of tear measurement.

Mark B. Abelson, MD, CM, FRCSC, FARVO, Nicole Kelley and James McLaughlin, PhD, Andover, Mass.

**Tear dysfunction syndromes**

such as Sjögren’s, evaporative dry eye or aqueous-deficient dry eye represent a spectrum of ocular disorders with a huge impact on vision, ocular health and quality of life. Efforts to develop new therapies to address these conditions face a daunting gauntlet of intrinsic and extrinsic factors that modulate tear production, tear composition and tear function.

While there are a number of tools available for evaluating tears, many seem to fall short in terms of their ability to report reliably and reproducibly on the changing attributes of tear physiology that underlie dry-eye diseases. This month we examine the many ways in which tears are measured, and consider the degrees to which these many metrics measure up.

**Tears 101**

The tear film is an amalgam of ingredients derived from three different sources: goblet cells; meibomian glands; and lacrimal glands.1 The conjunctival goblet cells provide the primary source for the glycoprotein conjugates called mucins that lubricate the ocular surface. Lipids and wax esters from meibomian glands provide a hydrophobic sealant to retard aqueous evaporation. The largest component of the tears comes from the primary and accessory lacrimal glands, which secrete an aqueous mixture of salts, protein and water. The combination of ingredients from these three sources acts as a physical buffer, cleaning fluid and source of nutrients for the underlying cornea and conjunctiva.

Lacrimal secretions are mixtures derived from two cell types found within the acini of the glands. Serous cells form acini that secrete electrolytes and mixtures of many different proteins (estimates suggest 200 to 300 different polypeptides in humans). The release of salts such as Na⁺, K⁺, Cl⁻ and Ca²⁺ provides the osmotic force that pulls water from the gland, forming the bulk of the tear volume.1 Smaller numbers of mucus-secreting acini are also present, secreting soluble mucins such as Muc7. Additional tear components, notably the IgA and IgG antibodies, are secreted by plasma and epithelial cells within the lacrimal gland. The specific protein content of lacrimal secretions varies significantly depending on the nature of the stimulatory input.

Both basal and reflex tearing...
occur in response to autonomic inputs, including stimulation of parasympathetic (via transmitters acetylcholine and VIP) and sympathetic (norepinephrine) nerves. In addition there is evidence that ATP and/or adenosine may act as a positive modulator of lacrimal secretion via P2Y receptors, perhaps via an effect on electrolyte secretion. Higher-order lacrimal secretion control comes from several sources, including central regulation of basal activity and reflexive responses to environmental stimuli via ocular sensory inputs. These are processed by way of the trigeminal nucleus to parasympathetic and sympathetic tracts which feed back to the lacrimal glands, as well as conjunctival sites (including goblet cells) and meibomian glands. Studies in mouse models provide compelling evidence that it is the temperature-sensitive corneal sensory nerves that regulate basal lacrimation, providing a set point of secretory stimulation that is exquisitely sensitive to small changes in corneal surface temperature.

A similar sensory circuit provides input from the upper and lower eyelids, which then feeds back to the orbicularis oculi and levator palpebrae muscles that control blinking. It's worth remembering that a blink exerts several effects on the aqueous tear film: redistribution; drainage; and the pressure that causes meibum gland secretion. A number of studies have established that a primary means of compensation for patients with reduced aqueous tear production is altered blink rate.

Regulating Tear Flow

Layered upon the basal level of tear secretion is a stimulated component that is a response to external and internal factors including diurnal patterns, environmental fluctuations and physiological status. Diurnal changes in tear composition, particularly the variation in the variety and concentration of tear proteins, are well-established. Early studies suggested that the nocturnal tear film lacks a significant reflex tear component, so tear protein levels increase over the course of the time period when the eyes are closed. Additional diurnal changes may underlie daily variation in visual acuity, particularly in those who suffer from dry eye. Most patients with dry-eye disease typically report that their symptoms worsen as the day progresses.

Environmental effects provide the most significant impact on a patient's reflex tearing. Tear flow is stimulated beyond basal levels in response to wind, heat or decreases in relative humidity. The inability to respond appropriately to stimuli such as wind or dryness describes a large segment of the dry-eye population.

Other environmental factors such as light-induced alterations in blink behavior can also have substantial impact on tear turnover and tear-film stability. In addition, there are tear reflex stimuli triggered by either nasal or oral sensory stimuli (one has but to consider the effects of the humble onion). Overall, reflex or stimulated tearing comprises well over half of the total tear volume, and is a key to homeostatic maintenance of tear-film stability and ocular health.

In addition to external factors, systemic physiological factors can also impact the flow of aqueous tears. There is evidence that in older subjects, reduction in whole body hydration can lead to reduced aqueous flow and a concentration of tear fluid components. Interestingly, at least one study suggests that younger individuals have the ability to compensate and produce normal tear volumes, even in cases of dehydration. In addition, there are many over-the-counter and prescription drugs (and perhaps herbal, holistic therapies) that carry with them the baggage of “anti-cholinergic” side effects and the decreases in all types of secretory activity which entails. A classic example is described in a study we did in 2007 that showed some systemic antihistamines can exacerbate the signs and symptoms of dry eye by causing a reduction in aqueous tear production.

Two other key physiological factors that can impact tear flow are the production and secretion of meibum and mucin to complete the triad of components that comprise the tear film. A lack of sufficient meibum, in particular, can alter evaporative properties and result in a reduction of aqueous tears. This highlights the conundrum that while we strive to isolate the specific causes of our patients’ dry eye—aqueous deficiency, evaporative dry eye, Sjögren’s syndrome or MG disease—the interdependence of each facet of the tear film limits our ability to focus treatment on a single underlying defect.

Measuring Aqueous Output

A host of techniques are available for assessing aqueous tear production,
for quantifying tear-film properties and for measuring rates of tear turnover. Each method has advantages and disadvantages but the key hurdle in studies of aqueous tear dysfunction is the disconnect between objective measures and symptomatic disease.

There is a growing realization that while simple tests such as Schirmer’s or the phenol red thread may provide a measure of tear output suitable for a clinical evaluation, they don’t provide a sufficient level of sensitivity or reproducibility to be applied to drug discovery efforts. Evaluation techniques such as the measurement of tear meniscus height or fluorophotometry appear to be better suited for studies in which a specific metric of tear production is needed.

Meniscus measures can be done with a slit lamp, although they are now more often measured using OCT. Both approaches benefit from being relatively non-invasive. This non-invasiveness is key: Because of the sensitivity of feedback inputs, the issue of reflex tearing is a major hurdle to any successful assessment of aqueous output. Meniscus height can be a useful tool to follow changes in an individual, but any population assessment must normalize data to measure relative change. In addition, surface tension issues can significantly change the values obtained by standardized methods and these are subject to fluctuation depending upon the concentration of meibum and mucin, and even on the osmolarity of the tear film.

An evaluation of tear output metrics in the DEWS report states, “For studying the tear film, the greatest opportunity lies in the use of noninvasive techniques involving the sampling of optical radiation reflected from the tear film.” One such non-invasive approach is fluorophotometry (FP), a technique that measures the rate at which tears on the ocular surface are replaced.

Fluorophotometry, which is sometimes referred to as tear turnover, uses a fluorescent tracer in the tears and follows the decline of tracer concentration in tears over time. By measuring the kinetics of this process it’s possible to derive values for tear turnover, total tear volume and tear “flow rate.” While the equipment needed makes the process prohibitively expensive for use in a general practitioner’s office, the reliability and non-invasive nature of the measure suggest that it should be the metric of choice for precise assessment of aqueous production in clinical research.

Homing in on Flow Rates

Like many clinical tools used by the dry-eye diagnostician, FP can be an outstanding evaluation device once the critical parameters are identified and optimized.

In terms of the mechanics of performing FP, a small volume (~1 µl) of tracer fluorophore is applied to the conjunctival fornix. After a brief delay, the ocular surface is scanned for a luminescence signal at regular intervals for 20 to 30 minutes. The decay in the signal represents the continuous dilution of the fluorophore in the tear volume; by measuring the rate of that decay it’s possible to generate a value for the tear turnover rate, typically in the range of two to four minutes (See Figure 1, at left). Extrapolation to a theoretical zero point can also yield a value for the patient’s total tear volume, but the real value in FP may be in its ability to follow changes in turnover rates before and after test compounds.

Studies conducted at our research firm, Ora Inc., have refined the protocols used for FP in order to improve reproducibility while reducing the variability of the method. These improvements include ergonomic optimization during measurements, as well as adjustments to the volume and concentration of fluorophore that’s used for the measurement. With these refinements, FP can be an invaluable tool in clinical studies of dry-eye therapies, either as an inclusion criterion, a clinical endpoint following the clinician’s therapeutic intervention, or both.

A comparison of dry-eye metrics (See Table 1, p. 42) suggests that FP has high sensitivity and specificity, and is superior to the other well-known measures of tear production in terms of its predictive value. Simply stated,
FP displays a superior ability to correlate with other signs and symptoms of dry eye such as corneal fluorescein staining and ocular surface disease index survey data. The biggest challenge to the use of FP as a metric going forward is the need for more studies; it’s possible that FP may be of less predictive value with some forms of dry-eye disease, but considering the complexity of aqueous tear-film regulation this challenge is best met by an empirical approach.

It’s likely that a combination of the current standards of ocular surface staining and ocular surface disease index surveys, in combination with objective metrics such as FP, will provide the jump start needed to gain traction in the search for new dry-eye therapies. **REVIEW**

Dr. Abelson is a clinical professor of ophthalmology at Harvard Medical School and senior clinical scientist at the Schepens Eye Research Institute.


It's an unfortunate reality that topical treatment of glaucoma often leads to—or worsens—ocular surface disease. Studies suggest that anywhere from 40 to 59 percent of glaucoma patients suffer from OSD,1,2 a far greater percentage than is found in the general age-equivalent population. This phenomenon has been studied for decades, so it's well-understood, but it's not something that clinicians tend to focus on when seeing patients in the clinic. Here, I'd like to talk about this concern and suggest some ways we as clinicians can minimize the problem.

Anytime you put a topical therapy on the eye, you'll find changes on the ocular surface that may include tear-film disruption with increased tear breakup time and loss of conjunctival and corneal epithelial cells. To a large extent, this problem can be attributed to the preservative benzalkonium chloride. BAK has detergent properties that disrupt the cellular membranes of bacterial contaminants in multidose containers; but those same properties can trigger apoptosis in epithelial cells of the cornea and conjunctiva, cause chronic inflammation and disrupt the tear film.3,4

Unfortunately, BAK isn’t the only problem. OSD can be a problem even if a medication is preservative-free, because negative changes can also be triggered by active ingredients. Either way, for the patient OSD manifests as foreign body sensation, the feeling of dry eyes and blurriness of vision—symptoms that usually do not escape the patient’s notice.

Don’t Overlook the Signs

To avoid unintentionally adding to the patient’s burden, a couple of key strategies are helpful.

First, don’t fall into the trap of ignoring the problem. When a patient comes into the clinic and we perform a typical glaucoma exam, our tendency is to focus on the disease of presentation: What is the IOP? What does the nerve look like? What’s the condition of the retinal nerve fiber layer? We usually pay less attention to the ocular surface and any related complaints the patient might have, such as blurry vision or foreign body sensation. So the first thing to do is move these issues higher on our priority list.

Second, be sure to check your glaucoma patients for signs and symptoms of dry eye. Left untreated, problems with the tear film can leave the cornea open to epithelial damage from multiple sources, including the environment.

Many clinicians are concerned that checking for dry eye will take up too much time, but it’s possible to do an ocular surface evaluation as part of your normal examination, even in a busy glaucoma clinic. The easiest thing to do is to check the tear-film breakup time using the fluorescein that you instill for the pressure...
percent accuracy. Also, look for high specificity and about 85-
fl uorescein reportedly produces check. (Monitoring TFBUT with
topical medications. trying laser trabeculoplasty instead of
the patient about the possibility of
along with having a discussion with
of steroids to reduce inflammation,
free artifi  cial tears and a short course
consider options such as preservative-
at the outset. For these patients I
I'll get my cornea colleagues involved
and the ocular surface. Sometimes
about trying to restore the tear fi lm
problem with the patient; we talk
of several treatments. You could
have the patient use artifi cial tears—
preserved or preservative-free. If mei-
bomian gland dysfunction is part of the
problem, you could have the patient
start using warm compresses and lid
scrubs. You could also insert punctal
plugs. The downside of the additive
approach is that all of these options
address the OSD from a tear-film
standpoint, but don’t really address
the root cause of the problem—the
impact of the active ingredient and
preservatives (if any) that are in the
medication.

The alternative is to subtract from
the therapy by looking for ways to
decrease the dosing and/or the pre-
servative load the patient is being
exposed to. In terms of switching to
a preservative-free medication, there
are various options on the market
right now, such as timolol maleate,
available preservative-free in Timoptic
in Ocudose; tafluprost, available as
preservative-free Zioptan; and
Cosopt Preservative Free. Or,
you can opt for a medication with
a non-BAK preservative. Some
products have replaced BAK with
alternative preservatives, like
Travatan Z, which is preserved
with Sofzia, or Alphagan P, which
is preserved with Purite. Any of
these lessen the load of BAK on
the patient’s ocular surface.

Given the aforementioned
options, why not just start by
treating with a preservative-free
formulation? The answer may
be partly that we’re all creatures
of habit (both physicians and
patients), but there are other
issues involved. For example,
Zioptan and Cosopt Preservative
Free both come in unit doses, a
format that’s unfamiliar to a lot of
glaucoma specialists from a therapy
standpoint, even though we’ve been
using unit doses of artifi cial tears
and Restasis for many years. Using single
dose packaging is also quite different
from the patient’s perspective; it’s not
yet clear whether patients will favor
this approach over multidose bottles.
And there is the issue of access to
insurance programs, as well as the co-
pay cost when the patient picks up the
medication at the pharmacy.

Another reality is that eliminating
the preservative doesn’t totally get us
off the hook for OSD issues because
the active ingredient may also be
problematic. The entire class of pro-
taglandin analogues is associated with
hyperemia—redness of the eye that
occurs because of vascular dilation
and slight leaking from the vessels in
the conjunctiva. Other medications
like the alpha-agonists, including
Alphagan, are associated with higher
rates of redness and allergic reaction
compared to some of the other
medication classes. Other groups,
such as beta blockers or carbonic
anhydrase inhibitors, may also pro-
duce a hyperemic response, although

Addressing the Problem

Once you’ve identified that a

The small, semicircular corneal abrasions seen above
resulted from a patient contacting her cornea with
the bottle tip as she applied her glaucoma drops. (The
patient’s technique was demonstrated upon request in
the clinic).
probably to a lesser degree. The reality is that these compounds are not naturally meant to be on the eye, so they can all cause some level of ocular surface problems. However, I think it’s safe to say that most of the corneal problems we see, such as epithelial cell loss, are secondary to the preservative. So if a patient has mild OSD, and is pushed to moderate or severe surface disease by a given medication that has a detergent preservative such as BAK, you can probably take the patient back to a mild level of disease by moving him back to a preservative-free medication. You may not get him back to the level where he’d be if nothing were being put on the eye, because he’s still going to have some measure of reaction to the active ingredient. But eliminating the BAK should make a positive difference.

Perhaps the best argument against automatically starting every glaucoma patient on a preservative-free medication is that most patients will do just as well with preserved medications. If a patient diagnosed with glaucoma has a normal ocular surface and no tear-film dysfunction, in my opinion any of the glaucoma medications that are available for use will do very well.

Non-pharmaceutical Options

It’s also true that some patients will be good candidates for the option of switching from topical drops to an alternate treatment such as laser trabeculoplasty; that’s certainly one way to eliminate the ocular surface concerns associated with drops. This should be high on the list of alternatives to consider, especially in patients who are using multiple medications, where reducing the number of drops is not a promising option because of the need for more aggressive therapy.

The typical algorithm for managing a glaucoma patient in the United States and abroad is to start the patient on medical therapy and escalate it, if necessary, from one drop to two or three drops before considering trabeculoplasty. In my practice, I typically start patients on topical therapy, but we usually discuss the option of trabeculoplasty before we initiate any topical medications. Furthermore, I very rarely prescribe more than two topical medications for a given patient before having a more in-depth discussion about trabeculoplasty. My main concern is that adherence is decreased when the patient goes to two medications, and even more so if I consider a third medication. In essence, you’re getting diminishing returns from each medication you add. So when more treatment is required, laser trabeculoplasty has advantages over additional drops.

If we’ve tried trabeculoplasty but the pressure still hasn’t come down sufficiently, the third option is invasive surgery. This is something that, in its current form, I reserve for more advanced disease. That’s primarily because of the risk/benefit ratio created by the efficacy of surgery's

IOP lowering vs. the likelihood of complications from the surgery.

The one exception I currently make is when the glaucoma patient also has a cataract. If a patient is in that category and still needs a lower pressure, I’m likely to suggest just doing the cataract surgery. That alone may produce a 2- or 3-mm decrease in IOP, and it may be possible to get even more pressure lowering by implanting a minimally invasive glaucoma surgery device such as the iStent, recently approved by the Food and Drug Administration. That’s the one situation in which I might opt for glaucoma surgery earlier in the treatment paradigm.

One last thought: If a patient is having issues with topical application causing or worsening OSD, and trabeculectomy has become necessary, I would advise the surgeon to do two things. First, try to lessen the load of medication for two to four weeks before the surgery. Second, place the patient on a mild steroid that will quiet down the conjunctiva and restore the tear film before the surgery. This makes the surgery more likely to be successful because you’re decreasing the inflammatory and scarring response that can occur post-trabeculectomy.

Patient Instillation Problems

Another way the ocular surface can be impacted by the use of topical medications is via patients scraping or pressing the tip of the eye-drop bottle against the cornea. We’ve all seen a patient who has a perfectly circular abrasion on the cornea that matches the bottle opening. (For example, see the photograph on p. 47.) Patients with low vision or elderly patients who have physical limitations have a very difficult time getting their drops
in; sometimes feeling the bottle on the eye reassures them that the drop is actually going onto the eye.

The primary way to avoid this is patient education. In our clinic, when we’re starting topical therapy, we have an artificial tear bottle handy so patients can be instructed in the use of eye drops and be observed when they’re instilling them. I also ask all of my ongoing patients to bring their drops in at every visit so we can review them, and so I can review the patient’s technique if I suspect that a patient is having trouble getting them in.

The point is to actually observe the patient instead of simply assuming there’s no problem. It doesn’t take long to do, and watching the patient instill drops allows me to identify multiple problems with technique, including the potential for injury when the bottle gets too close to the eye. I find this very helpful in terms of preventing damage to the ocular surface and ensuring the effectiveness of the drops, and I think the patients appreciate it as well.

**Going the Extra Mile**

Given that our first priority as physicians is to do no harm, it’s worth making a real effort to prevent ocular surface disease from becoming a problem—or a worse problem—for our patients. If you employ some of the strategies described above, both you and your glaucoma patients should reap the benefits.

Dr. Kahook is a professor of ophthalmology and director of clinical and translational research at the University of Colorado School of Medicine in Denver. He has been a consultant to Alcon Laboratories, Merck, B&L, Glaukos, Ivantis, Clarivista Medical and Allergan, and has received research support from Alcon, Allergan, Merck, Genentech, Regeneron, Clarivista Medical, AMO, Glaukos and the State of Colorado. He has intellectual property interests with AMO, ShapeTech, Dose Medical, Glaukos and Clarivista Medical.

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OPHTHALMOLOGY UPDATE

February 16-17

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• Describe glaucoma microsurgery
• Understand the role of corneal cross-linking in keratoconus and post LASIK ectasia
• Evaluate new technologies in diagnostic imaging
• Summarize the advances of ocular drug delivery systems
• List the risk factors for AMD and explain methods of screening and diagnosis
• Understand emerging issues in glaucoma: risk assessment, generic medications, progression and assessment of the optic nerve
• Review oculoplastics

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Saturday, February 16, 2013
7:30am-4:30pm
Reception to follow

Sunday, February 17, 2013
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LVC Volumes Plunge On ISRS Survey

The increase in volume that appeared on the 2011 survey turned out to be an unfortunate mirage.

Walter Bethke, Managing Editor

In last year’s survey of the U.S. members of the International Society of Refractive Surgery, the volumes of laser vision correction seemed to offer a ray of hope by finally showing an increase after many years of being flat or decreasing. However, survey co-administrator Richard Duffey, MD, of Mobile, Ala., says it looks like those volume numbers were a statistical anomaly, and they’ve since dropped back down on this year’s survey. Here’s a look at the volume numbers from the 2012 survey, as well as other statistics describing your refractive colleagues’ current standard of care. This year, 1,150 surveys were e-mailed to surgeons and 127 physicians (11 percent) responded.

Laser Vision Correction

Volumes are down on this year’s survey, as are preferred flap thicknesses for LASIK.

Dr. Duffey says that, unfortunately, this year’s volume numbers are a reality check compared to last year’s survey. Last year, total LVC volume stood at 570,000 procedures. This year, it’s dropped to 451,000. This even represents a decrease of 8 percentage points from 2010 levels. “I think we had a red herring last year,” he says. “At that time, the survey showed an increase in total LVC volume and we were feeling good that maybe we had reached the bottom of the valley and were starting to climb up the other side. And then the bottom just fell out this year.” Dr. Duffey also conducts a similar survey with ASCRS surgeons, and he says that survey didn’t show a spike last year, but instead showed a steady drop. “We knew that this year’s ISRS survey would determine which survey was right,” he says. “My practice’s volume was up last year, so I tended to take the position that ISRS was correct. Interestingly, my practice is down this year by about 10 percent from two years ago, and about 20 percent from last year.”

For the surgeons who are doing LASIK, the flap thickness that they prefer has steadily gotten thinner over the years. Most surgeons on the survey, 57 percent, prefer 100-µm flaps, which is up from 53 percent last year. Forty percent use flaps between 120 and 130 µm and 3 percent use 150- to 160-µm flaps. Dr. Duffey himself has adopted thin flaps. “Years ago, the argument against thin flaps was they were too flimsy, which would possibly...
give rise to more wrinkles and a higher chance of dislocation,” he recalls. “It turned out that it’s the opposite: They tend to stick better and you get a much better seal along the edge, so I’ve had less epithelial ingrowth. Thin flaps are better, bottom line, and I think people realize that. The desire to avoid ectasia has entered into the decision to use thin flaps, as well.”

Though LVC volumes are down, the large percentage of surgeons who have had it performed on their own eyes and the eyes of their family members speaks to the confidence ophthalmologists have in LVC, says Dr. Duffey. And this confidence may have even helped turn the tide at the FDA LASIK hearings. On the survey, a third of respondents say they’ve had LVC, 29 percent say their spouses have had it, 28 percent say their children have undergone LVC and 59 percent have a sibling who’s had it done. “This actually entered the FDA LASIK hearings to a certain extent,” recounts Dr. Duffey. “The data on family members and surgeons having LVC was enough to turn some heads and make people think, ‘It can’t be all bad if these surgeons and their family members are having it done.’ This was never the case with RK. We hit the sweet spot with LASIK. Years later, some patients wanted to come back and say that we didn’t. It may be a vocal minority of people in whom we didn’t hit the sweet spot, though I’m not sure you could ever hit it with some people, because their personality is such that there is no sweet spot for them. That’s not to say we can’t do better, because we have: For me, enhancement rates have come down from around 20 percent when I first started LVC and was more aggressive with enhancements, to less than 1 percent. The technology has gotten much better, and so have we as surgeons. We also choose patients more realistically now for laser vision correction procedures.”

Other Findings

Dr. Duffey was surprised that 16 percent of the respondents say they’re offering cross-linking, most likely through an investigational device exemption study. “I contemplated getting involved with the IDE after the ASCRS meeting, but the cost of getting into it was substantial, and I didn’t like the fact that the protocol isn’t standardized yet. There’s much discussion about epi-on vs. epi-off, the concentration of the riboflavin and the duration. Because of that variability, I’ve decided to sit back.”

Another interesting aspect of this year’s survey is that a quarter of the respondents say that they would “sometimes” implant phakic intraocular lenses bilaterally during the same surgery, a practice that has historically been taboo because of the bilateral damage that would result if both eyes happened to have the same disastrous complication, such as an infection. “This means the respondents have done it at least once,” says Dr. Duffey. “And 5 percent say they’ve done it at least one time with refractive lens extraction. I do know of people who write about it all the time, saying that if they had someone with some form of dementia who they’re going to have to put to sleep for surgery, it might be better to get both eyes done because it’s hard to select which eye is the better eye to do in a single procedure. I don’t know exactly who these 25 percent are, though, because here we’ve done 3,500 cataracts a year for 23 years and we’ve never once done a bilateral procedure. I sit on the quality assurance committee for an ASC and, believe me, a bilateral case would be brought before everyone even before it ever happened. But, these survey numbers remain consistent from year to year.”
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www.revophth.com/MD_Resources_eRX/
A uncontrolled open trial of 10 healthy volunteers has reported encouraging results on the tolerability and functionality of an ocular telemetric sensor for 24-hour intraocular pressure-fluctuation monitoring. An orbital bandage containing a loop antenna and an 8.7-mm radius prototype ocular telemetry sensor were applied and connected to a portable recorder after full eye examination. Best-corrected visual acuity and position, surface wetting ability and mobility of the sensor were assessed after five and 30 minutes, and four, 12 and 24 hours. Subjective wearing comfort was scored and activities documented in a logbook. After sensor removal, a full eye examination was repeated and the recorded signal analyzed.

The comfort score was high and did not fluctuate significantly over time. The mobility of the sensor was limited across follow-up visits and its surface wetting ability remained good. BCVA was significantly reduced during sensor wear and immediately after its removal (from 1.07 before, to 0.85 after; \(p=0.008\)). Three subjects developed a mild, transient corneal abrasion. In all but one participant, researchers obtained usable data of a telemetric signal recording with sufficient sensitivity to depict ocular pulsation.

J Glaucoma 2012;21:539-544
Smedt S, Mermoud A, Schnyder C.

Meibomian Gland Alterations With Antiglaucoma Eye Drops Researchers from Japan have determined that long-term use of antiglaucoma eye drops is associated with alterations in meibomian gland morphology and function. The subjects were 162 eyes of 162 patients with primary open-angle glaucoma or normal tension glaucoma. Patients were broken into three groups based on the number of antiglaucoma drops administered: 71 eyes of 71 patients (Group 1) received one type of drop, 61 eyes of 61 patients (Group 2) received two types of drops and 30 eyes of 30 patients (Group 3) received three types of drops. There were 75 eyes of 75 healthy volunteers to serve as controls.

Subjective symptoms were evaluated by questionnaire, and lid margin and superficial punctate keratopathy were evaluated by slit-lamp examination. Meibomian glands of upper and lower eyelids were observed and scored using noncontact meibography (meiboscore). Tear-film breakup time was measured and meibum was graded. Results showed that lid margin abnormality, superficial punctate keratopathy, meiboscore and meibum scores were significantly higher in glaucoma patients than in controls (\(p < 0.001\)). Subgroup analysis of the parameters in Group 1 revealed no significant difference between patients receiving prostaglandin and those receiving \(\beta\)-blockers, or among Groups 1, 2 and 3. Multivariate regression analysis demonstrated that meiboscore significantly correlated with lid margin abnormality score (\(p=0.007\)) and TF-BUT (\(p=0.045\)) in Group 1; with TF-BUT (\(p=0.004\)), symptom score (\(p=0.003\)) and age (\(p=0.026\)) in Group 2; and with lid margin abnormality score (\(p=0.001\)) in Group 3.

Cornea 2012;31:1129-1234

High Prevalence of Sleep Disorders in Patients with DME British researchers indicate that while individuals with clinically significant diabetic macular edema have a high prevalence of sleep disordered breathing (SDB), it is unclear what mechanism of SDB contributes to the pathophysiology of CSME.

Eighty patients (40 men) with CSME had a home sleep study to identify SDB. The average patient age was 64.7 years, with a neck circumference of 40.4 cm, body mass index of 30.2 kg/m², glycosylated hemoglobin (HbA1c) of 7.8 percent, and Epworth sleepiness scale of 7.4. Results were compared with relevant control populations, macular thickness was...
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Effect of Laser Fragmentation Grids on Phaco Time

In a prospective, randomized trial, doctors from the Center for Vision Science in Bochum, Germany, compared the effect of different fragmentation softening grids in femtosecond laser-assisted cataract surgery on effective phacoemulsification time (EPT) and found that the use of a 350-µm grid led to a significantly lower EPT than the 500-µm grid.

The study evaluated the feasibility of using a femtosecond laser to perform capsulotomy and lens fragmentation in the treatment of patients with senile cataract. Patients were evaluated preoperatively with the Lens Opacities Classification System III (LOCS III). Eighty patients had laser refractive cataract surgery with 350-µm fragmentation grids; 80 additional patients had laser refractive cataract surgery with 500-µm fragmentation grids. Both groups had phacoemulsification using pulsed ultrasound energy, and the EPT was evaluated.

The mean preoperative LOCS III grade was 3.7 ±0.8 in the 350-µm group and 3.5 ±0.8 in the 500-µm group. The mean laser treatment time was 66.4 ±14.4 seconds in the 350-µm group and 52.8 ±11.9 seconds in the 500-µm grid group. The mean EPT was 0.03 ±0.05 seconds and 0.21 ±0.26 seconds, respectively.

One of the authors reported a financial disclosure as a member of the medical advisory board for Optimedic Corp. No other author of this study has a financial or proprietary interest in any material or method mentioned.

Conrad-Hengerer I, Hengerer F, Schultz T, Dick B.

Limits of Total Wavefront Laser Vision Correction

Researchers from Spain set out to do a prospective, experimental study of the intrasession and intersession precision of higher-order aberrations measured by the Zywave, a commercial Hartmann-Shack wavefront sensor by Bausch + Lomb, in refractive surgery candidates. They concluded that total ocular aberrations, total HOAs and second-order terms can be measured reliably by Zywave aberrometry without anatomic recognition. Third-order terms and Z4 are repeatable, but not as reproducible, between visits. Fourth-order terms, except for Z3 and fifth-order terms are not sufficiently reliable for clinical decision-making or treatment.

To analyze intrasession repeatability, one experienced examiner measured 30 healthy eyes five times successively. Excellent intraclass correlation coefficients (ICCs) were obtained for total ocular aberrations, total HOAs and second order terms (ICC, >0.94). The ICCs for third-order terms were also high (>0.87); however, fourth-order ICCs varied from 0.71 to 0.90 (Z3 =0.90). Fifth-order ICCs were less than 0.85.

To study intersession reproducibility, the same clinician obtained measurements from another 30 eyes at the same time of day one week apart. Only total ocular aberrations, total ocular HOAs, second-order terms, Z3, Z4 and Z5 had ICCs of 0.90 or more. Bland-Altman analysis showed that the limits of agreement were clinically too wide for most higher-order Zernike terms, especially for the third-order terms (>0.21 µm).

Because the variability of Zywave can be a major limitation of a successful wavefront-guided excimer laser procedure, surgeons should consider treating HOA magnitudes that are more than the intrasession repeatability values (2.77 X S_{sw}) as those presented in this study.


Vision Loss During Treatment A Natural Progression of AMD

Vision loss may occur during ranibizumab treatment and is, in most cases, because of the natural course of age-related macular degeneration.

A retrospective analysis of 290 consecutive eyes comprising cohorts from three clinical settings showed that 21 eyes lost ≥15 letters on the Early Treatment Diabetic Retinopathy Study chart one year after the start of ranibizumab treatment. Fundus images of these eyes were analyzed by two independent readers to investigate the causes of visual loss. A second analysis was performed to compare the baseline characteristics of patients who gained (visual acuity gainers) or lost (visual acuity losers) ≥15 letters.

Among the 290 eyes included, the proportions from each center experiencing visual loss were not significantly different (p=0.2631). Mean visual loss of affected eyes was 27 letters. There was no significant difference between these eyes and others as regards age and gender of patients, laterality, type of choroidal neovascularization, number of visits or initial visual acuity. Visual loss was secondary to the progression of atrophy in eight eyes, fibrosis in five eyes, a combination of fibrosis and atrophy in three eyes, and macular edema in three eyes.

(Continued on page 65)
Femtosecond Laser Tools from Accutome

Accutome has introduced three new ophthalmic instruments that aid femtosecond laser-assisted cataract surgery to keep up with advancing procedures.

The instruments are the Eippert Femtosecond Spatula, the Solomon Femtosecond Chopper and the LRI Enhancement Forceps. The new devices help surgeons who use femtosecond cataract lasers to create precise subsurface cuts to the eye.

Each offers specific benefits. The Eippert Spatula helps users accurately open primary and secondary incisions created by the femtosecond laser by offering double-ended sizing for greater versatility and blunt, thin tips to maintain proper wound architecture. The Solomon Femtosecond Chopper’s football-shaped tip is the only instrument designed specifically to chop femtosecond-fragmented nuclei. The LRI Enhancement Forceps, which has a 500-µm gauge to correct the depth of incision, can spread accurate incisions during surgery or after, during a slit lamp examination.

For information, call 1 (800) 979-2020, visit accutome.com or send an e-mail to info@accutome.com.

New Lotemax 0.5% in a Gel Drop Formulation

Bausch + Lomb announced that Lotemax (loteprednol etabonate ophthalmic gel) 0.5%, which received Food and Drug Administration approval in late September 2012 to treat postoperative inflammation and pain following cataract surgery, will be available January 2013 in pharmacies nationwide. The company says Lotemax is a first-in-class gel drop, with a unique formulation technology. Compared to suspensions, the gel drop formulation is more viscous, allowing it to adhere to the ocular surface.

Another important feature of the Lotemax Gel formulation is that it provides dose uniformity, ensuring that a consistent concentration of loteprednol is delivered in every drop, which is not always possible with corticosteroid suspension formulations. The product is also the only ocular steroid formulation containing glycerin and propylene glycol, two known moisturizers, and has a lower concentration of preservative than Lotemax (loteprednol etabonate ophthalmic suspension) 0.5% suspension.

In two four-week clinical safety and efficacy evaluations, Lotemax Gel showed statistically significant resolution of anterior chamber cells and flare vs. vehicle at postoperative day eight. Both clinical trials were Phase III, randomized, multicenter, double-masked, parallel-group, vehicle-controlled studies in patients (n=813) being treated for inflammation and pain following cataract surgery. Ocular adverse drug reactions reported in patients treated with Lotemax Gel were eye pain, anterior chamber inflammation, increased lacrimation, photophobia, eye irritation and eye pruritus. Drug-related blurred vision was rarely reported (0.25 percent; 1/407).

For information, visit bausch.com.

Spectra Iris Indirect Ophthalmoscope from Keeler

Keeler says its new Spectra Iris indirect ophthalmoscope has been specifically designed for portability. Compact and lightweight, the LED indirect has an adjustable aperture for all pupil sizes.

The Spectra Iris’ adjustable aperture slider easily changes the aperture between 20 mm and 60 mm to match pupil size and improve examination.
With variable PD (pupil distance) settings between 48 and 76 mm, there are no restrictions on the user—simply adjust the PD as necessary.

The indirect system is supplied with Keeler’s lightweight wraparound Sport Frames, designed to ensure maximum comfort and balance. It can be worn over glasses and the entire optical unit and light pod can be flipped up to allow direct eye contact when talking to a patient or writing up notes. Spectra Iris can be hung around the user’s neck when not in use, or packed away in its carrying case for storage and transit.

The Spectra Iris can be used continuously for up to four hours on a single battery charge. Its compact lithium ion battery can be clipped onto a belt or stored in its charger when not in use. With a built-in bright, homogeneous LED light source, the need for bulb replacements is eliminated.

Keeler’s Spectra Iris is British-designed and -manufactured. For information, visit Keelerusa.com, e-mail Keeler@Keelerusa.com or call 1 (800) 523-5620.

Mobius Therapeutics Announces J Code for Mitosol Mitomycin Solution

Mobius Therapeutics LLC announced today the Centers for Medicare & Medicaid Services has assigned a product-specific Healthcare Common Procedures Coding System (HCPCS) code for Mitosol (mitomycin for solution) 0.2 mg/vial, Kit for Ophthalmic Use. Mitosol is used as an adjunct to ab externo glaucoma surgery. The new J-code, J7315, becomes effective on January 1, 2013.

“This is an important milestone for Mobius Therapeutics, and we are very pleased that CMS has issued a J-code for Mitosol,” said Ed Timm, CEO and founder of Mobius Therapeutics LLC. “While it may take up to three months for the J-code to be loaded into the entire payer system, the J-code facilitates more rapid reimbursement for providers. Mitosol is manufactured under cGMP controls and provides assured dosing

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None

WARNINGS AND PRECAUTIONS
Pigmentation: Bimatoprost ophthalmic solution has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, perilobular tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as bimatoprost is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of bimatoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the perilobular tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long-term effects of increased pigmentation are not known.

Iris color change may not be noticeable for several months to years. Typically, the upper two-thirds pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither new nor freckles of the iris appear to be affected by treatment. While treatment with LUMIGAN® 0.01% and LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Eyelash Changes: LUMIGAN® 0.01% and 0.03% may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation: LUMIGAN® 0.01% and 0.03% should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular Edema: Macular edema, including cystoid macular edema, has been reported during treatment with bimatoprost ophthalmic solution. LUMIGAN® 0.01% and 0.03% should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Angle-closure, Inflammatory, or Neovascular Glaucoma: LUMIGAN® 0.01% and 0.03% has not been evaluated for the treatment of angle-closure, inflammatory, or neovascular glaucoma.

Bacterial Keratitis: There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the corneal epithelial surface.

Use With Contact Lenses: Contact lenses should be removed prior to instillation of LUMIGAN® 0.01% and 0.03% and may be reinserted 15 minutes following its administration.

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

In clinical studies with bimatoprost ophthalmic solutions (0.01% or 0.03%), the most common adverse event was conjunctival hyperemia (range 25-45%). Approximately 0.5% to 3% of patients discontinued therapy due to conjunctival hyperemia with 0.01% or 0.03% bimatoprost ophthalmic solutions. Other common events (> 10%) included growth of eyelashes and ocular pruritus. Additional ocular adverse events (reported in 1% to 10% of patients) with bimatoprost ophthalmic solutions included ocular dryness, visual disturbance, ocular burning, foreign body sensation, eye pain, pigmentation of the pericorneal skin, blepharitis, catarrh, superficial punctate keratits, eyelid erythema, ocular irritation, eyelash darkening, eye discharge, tearing, photophobia, allergic conjunctivitis, asthenopia, increases in iris pigmentation, conjunctival edema, conjunctival hemorrhage, and abnormal hair growth. Intraocular inflammation reported as iritis, was reported in less than 1% of patients.

Systemic adverse events reported in approximately 10% of patients with bimatoprost ophthalmic solutions were infections (primarily colds and upper respiratory tract infections). Other systemic adverse events (reported in 1% to 5% of patients) included headaches, abnormal liver function tests, and asthenia.

USE IN SPECIFIC POPULATIONS
Pregnancy: Pregnancy Category C.

Tolerogenic effects: in embryo/fetal developmental studies in pregnant mice and rats, abortion was observed at oral doses of bimatoprost that achieved at least 33 or 97 times, respectively, the maximum intended human exposure based on blood AUC levels. At doses at least 41 times the maximum intended human exposure based on blood AUC levels, the gestation length was reduced in the dams, the incidence of dead fetuses, late resorptions, per- and postnatal pup mortality was increased, and pup body weights were reduced.

There are no adequate and well-controlled studies of LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) administration in pregnant women. Because animal reproductive studies are not always predictive of human response, LUMIGAN® should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether LUMIGAN® 0.01% and 0.03% is excreted in human milk, although in animal studies, bimatoprost has been shown to be excreted in breast milk. Because many drugs are excreted in human milk, caution should be exercised when LUMIGAN® is administered to a nursing woman.

Pediatric Use: Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

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

Hepatic Impairment: In patients with a history of liver disease or abnormal ALT, AST, and/or albumin at baseline, bimatoprost 0.03% had no adverse effect on liver function over 48 months.

OVERDOSAGE
No information is available on overdosage in humans. If overdose with LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) occurs, treatment should be symptomatic.

In oral (by gavage) mouse and rat studies, doses up to 100 mg/kg/day did not produce any toxicity. This dose expressed as mg/m² is at least 70 times higher than the accidental dose of one bottle of LUMIGAN® 0.03% for a 10-kg child.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility: Bimatoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses of up to 2 mg/kg/day and 1 mg/kg/day respectively (at least 192 and 291 times the recommended human exposure based on blood AUC levels respectively) for 104 weeks.

Bimatoprost was not mutagenic or clastogenic in the Ames test, in the mouse lymphoma test, or in the in vivo mouse micronucleus tests.

Bimatoprost did not impair fertility in male or female rats up to doses of 6.6 mg/kg/day (at least 103 times the recommended human exposure based on blood AUC levels).

PATIENT COUNSELING INFORMATION
Potential for Pigmentation: Patients should be advised about the potential for increased brown pigmentation of the irises, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuation of LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution).

Potential for Eyelash Changes: Patients should also be informed of the possibility of eyelashes and vellus hair changes in the treated eye during treatment with LUMIGAN® 0.01% and 0.03%. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

Handling the Container: Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to avoid contamination of the solution by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

When to Seek Physician Advice: Patients should also be advised that if they develop an intercurrent ocular condition (e.g., trauma or infection), have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician’s advice concerning the continued use of LUMIGAN® 0.01% and 0.03%.

Use with Contact Lenses: Patients should be advised that LUMIGAN® 0.01% and 0.03% contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to instillation of LUMIGAN® and may be reinserted 15 minutes following its administration.

Use with Other Ophthalmic Drugs: If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.
Digital 3D-Integrated Ophthalmic Microscope

Leica and TrueVision 3D Introduce Digital 3D-Integrated Ophthalmic Microscope

Leica Microsystems and TrueVision 3D announced that key components of the TrueVision 3D intelligent digital visualization and guidance platform have been integrated with select future models of Leica Microsystems’ ophthalmic surgical microscopes and will be marketed under the Leica brand.

By combining world-class Leica Microsystems optics and illumination with state-of-the-art TrueVision digital stereoscopic imaging, the two companies have partnered to debut a new class of surgical stereo microscope. The companies expect the collaboration to establish integrated 3D visualization and guidance as the standard of care in microsurgery.

The 3D digital integrated microscope can also run TrueVision’s Refractive Cataract Toolset application. The toolset generates precise guidance templates in real-time using preoperative data and advanced algorithms. Surgeons view the 3D live image on the microscope’s 3D HD flat panel display with computer generated overlays for dynamic guidance with eye-tracking during the surgery.

The TrueVision digital 3D system is completely integrated with the Leica M844 and M822 ophthalmic surgical microscopes when equipped with the Leica F40 stand. The system features a patented 10-megapixel HD 3D camera in the optics carrier, 64-bit image processing unit contained within the chassis, and dual passive stereo LED-based LCD displays ranging in size from 23 to 32 inches with articulating arms mounted on the microscope base. The 3D-enabled surgical microscopes are capable of displaying the surgical field of view with 3D guidance and digital overlays on secondary 2D or 3D displays in the operating room.

For information, visit leica-microsystems.com or truevisionsys.com.

Review

(continued from page 26)

iPhone,” says Dr. Bashour. “I’ve lost my iPhone four or five times, and every time I’ve been able to locate it by logging onto another computer. It tells me where it is. Furthermore, you can send a message that will appear on the screen for whoever finds it; you can lock it down so it can’t be used; and if necessary you can erase everything that’s on it. You can do all of this remotely.”

In terms of limitations, there are a few things the handheld devices don’t seem up to managing, at least so far. For example, some surgeons are now carrying an electronic tablet during exams, but other doctors believe the technology isn’t up to the task. “That’s the last thing in the world I’d want to do,” says Dr. Charles. “In the office I want to have a fixed, great big screen PC that shows every detail of images; one that’s hardwired to the Ethernet, fast as lightning and secure. You don’t have to worry about battery power or carrying it around or people stealing it. I use an iPad for personal tasks outside the office, and it has great features, but I don’t see it as an EMR tool or email interface. I see it as a specialized tool best used for other purposes.”

Dr. Hodkin agrees that carrying an iPad with you during an exam may be premature. “It doesn’t have enough screen space to do everything we need to do, and the input is more cumbersome because you’re using your fingers instead of a mouse,” he says. “I look at these as niche players for those items that don’t require a lot of input, where portability is the biggest concern. But I think that’s where this is headed.”

The Future of Medicine?

So what does the future hold? “When I first started giving lectures about the wired ophthalmologist back in the 80s, I was considered very far out,” notes Dr. Bashour. “Now, everybody’s connected and using these devices—even ophthalmologists who tend to be late adopters. There’s no question that this kind of technology represents the future of medicine. It’s the future of the world, really.”

Dr. Jarstad does see cost as a factor in how much this type of technology ends up being adopted. “I think if the manufacturers price things correctly, sales will go through the roof,” he says. “Smartphones are becoming so pervasive in the community that anything that’s really useful will probably be bought by ophthalmologists.

“Truly, a digital revolution is occurring right before our eyes,” he adds. “We’re in a fascinating field, and it’s an exciting time.”


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Bilateral branch retinal artery occlusion was suspected secondary to sickle cell disease. The event was likely triggered by dehydration. A fluorescein angiogram demonstrated bilateral macular and peripheral focal non-perfusion (See Figures 4, b & c). Optical coherence tomography showed retinal atrophy and edema in both eyes.

The patient was admitted to the hospital with further treatment coordinated in association with her hematologist. Complete blood count was remarkable for low hemoglobin, and a transfusion of packed red blood cells as well as intravenous fluids was given. A further thrombophilia workup was deemed unnecessary, given the likely known etiology of sickle cell disease.

On follow-up one week later, the patient reported improvement in her vision in both eyes. Visual acuities were 20/25 in the right eye and 20/50 in the left eye. The retinal whitening continued to improve. New salmon-patch hemorrhages were observed superonasally in the right eye, and inferiorly in the left eye (See Figure 5).

Discussion

Sickle-cell disease is an inherited autosomal recessive disease due to mutations in the beta-globin gene on the short arm of chromosome 11. The most common form, designated SS disease, occurs in individuals homozygous for a single point mutation that causes a substitution of valine for glutamic acid at the sixth position in the beta-globin chain. This point mutation results in the production of hemoglobin S. A less common form, SC disease, occurs when an individual has one copy of the allele for hemoglobin S, as well as an allele for hemoglobin C, in which a mutation causes a substitution of lysine for glutamic acid.

Worldwide, around a quarter of a million children are born each year with sickle-cell disease, about 60,000 of which are in the United States. The sickle-cell allele is much more common in African populations, or populations of African descent. Approximately 0.15 percent of all African-American children have SS disease.

Although ocular disease due to sickle cell is more prevalent in SC patients compared to SS patients, the various ocular manifestations of sickle-cell disease occur in both forms. Ocular findings occur in the anterior segment as well as the posterior segment. Comma-shaped capillary segments, most commonly seen on the inferior bulbar conjunctiva, may be present due to transient dilatation of conjunctival blood vessels by abnormally shaped red blood cells. The comma-shaped capillary segments often decrease under the heat of the slit-lamp beam as a result of vasodilation. Sectoral iris atrophy and...
Pupillary irregularities can be seen when iris infarcts occur. At the disc, small dilated capillary vessels appear as small red dots in a linear or Y-shape pattern. These segments consist of pre-capillary arterioles occluded with sickled red blood cells.²

The chorioretinal findings in sickle-cell disease include both nonproliferative and proliferative manifestations. Most vascular occlusions associated with sickle-cell disease occur in the retinal periphery. However, branch retinal artery occlusions, central retinal artery occlusions and choroidal infarction may occur in the posterior pole.¹³ The occlusion usually takes place at the level of the precapillary arterioles. Additional nonproliferative changes include “salmon-patch hemorrhages,” which typically occur in the mid-peripheral retina and represent well-circumscribed preretinal hemorrhages between the sensory retina and the internal limiting membrane, and “black sunbursts,” believed to be a proliferative response by the retinal pigment epithelium to intraretinal hemorrhage that spreads into the subretinal space.³ Angioid streaks occur at an increased rate in sickle-cell disease, and the prevalence increases with age. In one review, 27 percent of patients over the age of 50 with SS and SC disease had angioid streaks.

Proliferative sickle-cell retinopathy is the most vision-threatening complication of sickle-cell disease. It occurs at the junction of perfused and nonperfused retina, most commonly found in the superotemporal followed by the inferotemporal quadrants.⁶ Peak prevalence in SS patients is between 25 and 39 years, with no gender predilection, and in SC patients between 15 and 24 years in men and 20 to 39 years in women. The natural history of proliferative sickle-cell retinopathy begins with peripheral vascular occlusion causing local ischemia and production of vascular growth factors. This causes vascular remodeling and arteriovenous anastomoses, followed by retinal neovascularization, usually in a sea fan shape. The new retinal vessels can cause vitreous hemorrhage and tractional retinal detachments, or they may spontaneously regress. Around 21 to 23 percent of SC patients and 2 to 3 percent of SS patients will have retinal neovascularization with vitreous hemorrhage, and as much as 60 percent of sea fan neovascularization will resolve spontaneously via autoinfarction.⁷

Given the high rates of autoinfarction with spontaneous resolution of proliferative sickle-cell retinopathy, asymptomatic new blood vessels that are not macula-threatening can be observed. Previous treatment modalities have included feeder arteriolar occlusion and cryotherapy, but the current mainstay of treatment is laser photocoagulation. The role of anti-vascular endothelial growth factor agents is not yet clear. Tractional retinal detachments, nonclearing vitreous hemorrhage and macular holes may all be treated with vitrectomy if the vision is affected.

The author would like to thank Mike Dollin, MD, vitreoretinal fellow of the Wills Eye Retina Service, for his time and assistance preparing this case.

REFERENCES


Timolol Effective for Treating Myopic Regression After LASIK

A prospective, randomized, parallel-controlled and double-masked clinical trial from Iran suggests timolol application is effective for treating myopic regression after LASIK, compared with the control group, and that effects last for at least six months after discontinuation.

A total of 102 eyes were evenly and randomly assigned to either Group 1, who received timolol 0.5% eye drops, or Group 2, who received artificial tears. The main outcome measurement of spherical equivalence was limited to patients who attended the final follow-up session six months post-treatment (45 eyes for both groups).

In Group 1, SE improved from -1.48 ±0.99 D before treatment to -0.88 ±0.91 D six months after treatment, and -0.86 ±0.93 D six months after timolol discontinuation. SE was significantly better in Group 1 six months after treatment and six months after timolol discontinuation (p<0.001). In Group 2, it was -1.57 ±0.67 D, -1.83 ±0.76 D and -1.91 ±0.70 D, respectively (p<0.001). SE was significantly better in Group 1 six months after treatment and six months after timolol discontinuation (p<0.001). There was a 0.26-D decrease in the SE improvement every four months after surgery in Group 1 (p<0.001).


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Recent onset of sudden, painless and bilateral decreased vision brings a young woman to seek emergency treatment.

David H. Perlmutter, MD

Presentation

A 21-year-old African-American female presented to the Wills Eye Emergency Room complaining of sudden, painless, bilateral decreased vision, left greater than right. She stated her symptoms began three days prior while on vacation, at which time she reported decreased water intake. She denied any pain with eye movement or other systemic symptoms.

Medical History

Her past medical history was significant for sickle cell SS disease. Her last sickle cell crisis was one year prior. Her sickle cell crises typically involve bone pain, which was absent at the time of her examination.

Examination

Ocular examination revealed visual acuity of 20/25 in the right eye and 20/200 in the left eye. Pupils were equal and reactive, and there was no afferent pupillary defect. Ocular motility in both eyes was full. On confrontation visual fields, there was a small defect in the superior field on the right and the temporal field on the left. Applanation tonometry measured an intraocular pressure of 14 mHg on the right and 12 mmHg on the left. The patient read seven out of eight color plates on the right and eight out of eight color plates on the left, both with some difficulty.

Slit-exam examination revealed unremarkable external and adnexal structures. The scleral and conjunctival exam exhibited a positive comma sign in the inferior fornix of both eyes (See Figures 1a & b). The remainder of the anterior segment exam was otherwise normal.

Posteriorly, the vitreous was clear in both eyes. Segmented disc capillaries were present on both optic nerves (See Figures 2a & b). There was an area of retinal whitening in the posterior pole of each eye (See Figures 3a & b). No thrombus was visualized, and the periphery revealed no salmon patch hemorrhages or neovascularization.

What is your differential diagnosis? What further workup would you pursue? Please turn to p. 64
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**Indication:** LUMIGAN® 0.01% and 0.03% is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

**Important Safety Information**

**Warnings and Precautions:** LUMIGAN® causes changes to pigmented tissues, mostly increased pigmentation of the iris, eyelid, and eyelashes as long as LUMIGAN® is administered. Iris color change may not be noticeable for several months to years. After discontinuation of bimatoprost, iris pigmentation is likely to be permanent, while eyelid and eyelash changes have been reported to be reversible in some patients. Patients should be informed of the possibility of increased pigmentation. The long-term effects of increased pigmentation are not known.

LUMIGAN® should be used with caution in patients with active intraocular inflammation (eg, uveitis) because the inflammation may be exacerbated. Macular edema, including cystoid macular edema, has been reported with LUMIGAN®; LUMIGAN® should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

**Adverse Reactions:** The most common (25%-45%) adverse event with LUMIGAN® was conjunctival hyperemia. Approximately 0.5% to 3% of patients discontinued therapy due to conjunctival hyperemia. Other common events (> 10%) included growth of eyelashes and ocular pruritus.

Please see brief Prescribing Information on adjacent page.

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1. LUMIGAN® 0.01% and 0.03% Prescribing Information,

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