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FDA to Restructure Device Regulations

Changes are in the air to ensure the right policies are in place to encourage safe and effective innovation.

By Bill Kekevian, Senior Editor

The Food and Drug Administration (FDA) has announced it will begin publishing new guidelines on how it regulates health care technologies, such as mobile apps, fitness trackers and clinical decision support software, as part of what it’s calling its “digital health innovation plan.” The guidelines may replace premarket regulation of certain devices, according to the agency.

In a blog post, FDA Commissioner Scott Gottlieb, MD, wrote that the “FDA should […] promote the public health through policies that are clear enough for developers to apply them on their own, without having to seek out, on a case-by-case basis, FDA’s position on every individual technological change or iterative software development.”

“The new guidance will facilitate development of smartphone apps, wearable devices and data-driven diagnosis across health care, including optometry,” says Brian Chou, OD, of San Diego, Calif. “ODs should pay attention to this, since it’ll likely have implications with online refraction and telemedicine.”

According to Dr. Gottlieb’s post, the FDA is considering employing a third-party certification program so that products categorized as “low-risk” can be marketed without FDA premarket review and products designated as “higher-risk” can be marketed with a “streamlined” FDA premarket review.

A representative from the agency confirmed that “the program is currently in development,” but couldn’t share any details about the definition of low- and higher-risk devices. Dr. Gottlieb’s blog post hints that “clinical administrative support software and mobile apps that are intended only for maintaining or encouraging a healthy lifestyle” fall outside the scope of FDA regulation.

(continued on page 6)
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(continued from page 4)

According to an estimate cited on the blog post, 165,000 health-related apps were made available for Apple or Android smartphones in 2016. Added to that, device manufacturers have a wide variety of eye care related medical devices in the works that may soon impact optometric practice. These devices range from retinal implants and drainage stents to smart contact lenses that measure glucose levels or report on a patient’s glaucoma, and online refraction testing software.

“Since the FDA is signaling that it’ll take a hands-off approach toward ‘low risk’ digital health devices, the question is whether the FDA considers refraction and disposable contact lens Rx renewal under that category,” Dr. Chou says. “If so, expect to see even more digital health devices for online refraction and contact lens Rx renewal.”


Substance P: A New Test for Neuropathy

New research suggests low levels of substance P—a nerve cell signaling molecule found in tears—may indicate an increased risk of diabetic corneal neuropathy. After measuring substance P levels in the tears of nine diabetes patients and 17 controls, investigators found the patients with diabetes had lower levels of substance P compared with the controls.

“Substance P plays a role in the maintenance and nutrition of the cornea by promoting migration and proliferation of corneal epithelial cells,” says Maria Markoulli, PhD, MOptom, study author and senior lecturer at the School of Optometry and Vision Science at the University of New South Wales, Sydney, Australia. “The reduction in substance P levels in diabetes may contribute to the poorer wound healing and increased susceptibility to corneal neurotrophic ulcers that is seen in diabetes.”

Challenging Today’s Tools

Confocal microscopy further revealed participants with diabetes had moderately lower corneal nerve fiber density than the controls.

“The association with corneal nerve density and substance P in the tear film led us to hypothesize that substance P could be a marker of corneal neuropathy,” says Dr. Markoulli. “Being able to detect those with corneal neuropathy may help us implement systemic management sooner.”

Although confocal microscopy is the go-to instrument to assess corneal neuropathy, it’s usually only available in the research setting, according to Dr. Markoulli. A more practical tool, such as substance P testing, could be far more applicable in the clinic, she says.

Tomorrow’s Treatment

“Further research of this concept may ultimately result in the development of a topical medication composed of substance P,” says Richard Zimbalist, OD, of Columbia, Mo. “While such a medication may obviously be beneficial for diabetic neurotrophic ulcers, it is feasible to consider the potential implications for corneal surgeries, ulcers and other conditions that rely upon epithelial migration and wound healing.”

While substance P testing could one day be a useful noninvasive test to help assess for peripheral neuropathy in patients with diabetes, the research is still in its nascent stages, says Dr. Markoulli. “We are now running a larger study and exploring other neuropeptides, as well as the link with peripheral neuropathy. At this stage, however, this is all speculation and a lot more work needs to be done to confirm this.”

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early 60% of patients are incorrectly prescribed an antibiotic to treat acute conjunctivitis, according to a new study. After looking at 340,372 patient records with a diagnosis of acute conjunctivitis, researchers found 58% were prescribed antibiotics, approximately 20% of whom received a combination antibiotic-corticosteroid drop. Not only are antibiotics rarely necessary, according to the study authors, antibiotic-corticosteroids are contraindicated for acute conjunctivitis.

The study notes most patients (83%) were diagnosed by a primary care provider (PCP) such as a family physician, pediatrician or urgent care provider, not an ophthalmologist or optometrist. The researchers speculate the challenge of differentiating bacterial conjunctivitis from the viral and allergic forms may be one reason PCPs overprescribe antibiotics. Even mild cases of bacterial conjunctivitis don’t warrant antibiotics, the researchers said, as they usually resolve on their own within two weeks without treatment.

The findings suggest “a pressing need to educate all health care providers better about the fact that most patients with acute conjunctivitis do well with conservative management and do not require immediate antibiotic therapy,” the study says.

In addition to practitioner prescribing habits, the investigators took a closer look at patient prescription filling habits. Sixty-eight percent of patients diagnosed by an urgent care physician filled their prescription, compared with 56% of those diagnosed by a family physician, 44% by an optometrist and only 36% by an ophthalmologist.

While the researchers do not speculate on why such a disparity exists for prescription fulfillment based on the diagnosing practitioner, the study as a whole highlights the need for more education for both practitioners and patients alike on the proper management of acute conjunctivitis.

The authors also note several limitations to the data. For one, the records provide no data on the details that led to the prescription. “No doubt some of the enrollees who had been diagnosed with acute conjunctivitis would have been appropriate candidates for antibiotic therapy,” according to the study. In addition, the results only included patients with commercial health insurance, did not include data on free medication samples frequently dispensed in clinics and excluded inpatient and hospital-acquired cases of acute conjunctivitis.


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OSA Patients at Risk for DR Progression

Obstructive sleep apnea (OSA) patients also diagnosed with Type 2 diabetes are at increased risk for progression to pre-proliferative diabetic retinopathy (DR) and are more likely to progress to sight-threatening DR within four years, according to a new report.\(^1,2\)

In the prospective study, researchers evaluated 230 patients with Type 2 diabetes for retinopathy using retinal imaging, taken during routine care.\(^1,2\) To evaluate OSA, patients were given a home-based, multi-channel cardiorespiratory portable device to use a single time, and the results were scored using American Academy of Sleep Medicine guidelines to discern the presence of the condition.\(^1,2\) The study excluded subjects suffering from any respiratory condition or who had a previous diagnosis of OSA.\(^1,2\)

Results
According to the study, sight-threatening DR was more common in patients with both Type 2 diabetes and OSA compared with those diagnosed with Type 2 diabetes alone.\(^1,2\) They observed DR in 42.9% of patients with both OSA and Type 2 diabetes, compared with only 24.1% of patients in the diabetes-only category.\(^1,2\)

The research also reveals that patients with OSA and Type 2 diabetes, compared with those with diabetes only, are at increased risk of sight-threatening DR over a period of three years and seven months.\(^1,2\) At follow-up, roughly 43 months later, the patients with OSA were 18.4% more likely to develop moderate to severe DR compared with those without OSA at just 6.1%.\(^1\)

Finally, the study shows patients who received continuous positive airway pressure treatment had a lower risk of developing advanced DR compared with patients who did not receive the therapy.\(^1,2\)

Clinical Significance
The study provides crucial observations, says Mohammad Rafieetary, OD, of Charles Retina Institute in Germantown, Tenn. “We already know that OSA is a major risk factor for ischemic optic neuritis, a visually debilitating disease, and that this disease is, along with diabetic retinopathy, another potential complication of diabetes.”

Hypoxia or ischemia is also a major factor for progression and poor prognosis, he explains. “It is sensible to assume any factors that cause oxygen denervation can result in worsening of retinopathy and increased vision loss,” he says. “These also include smoking and increased BMI and obesity.”

Practitioners must pay attention and address all of these potential complicating factors for better patient management, Dr. Rafieetary suggests.

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A Word on DEWS II

Go ahead and call it a watershed, a landmark or a sea change—or even a new paradigm. It deserves it.

When editors see a word or phrase so overused that it has become a cliché, we instinctively reach for the red pen. We prefer language that’s fresh and original, free from the baggage of prior associations. And, ideally, our writing should be as simple as possible. My colleagues on the Review editorial staff know all too well of my distaste for the word *utilize*, which has a whiff of pretension to it. To my mind, *use* is less fussy while saying exactly the same thing.

But some odd ducks find a home within a given community. In medical circles, one of the oddest ducks is *armamentarium*, used to describe the array of treatment options at a doctor’s disposal. Why this vaguely Medieval six-syllable word persists in medical discourse is a mystery. And it grounds all via the same thing.

Another word popular in medical discourse is *paradigm*. To describe the general framework of how experts think or act about something. The related phrase *paradigm shift* marks a point in time when the experts agree that radical change has come to their field—that the profession has suddenly moved forward as one.

While it’s a handy way to convey a complex concept, *paradigm* has been a cliché for decades. Corporate types diluted it through overuse, especially by attaching it to ho-hum projects that didn’t warrant such a potent word, dressing up their language in formal wear when business casual would do. There’s even a Dilbert cartoon from as far back as 1991 parodying this overreach.

So when I say that a paradigm shift has just occurred in dry eye, I don’t do so lightly. But the publication of the Dry Eye Workshop (DEWS) II from the Tear Film and Ocular Surface Society (TFOS) brings so much clarity to the opaque world of ocular surface disease that it’s sure to be seen as just such a turning point for at least the next decade (assuming TFOS has a DEWS III planned for 2027).

DEWS II does away with the artificial distinction between evaporative and aqueous deficient dry eye, stressing that the two appear together far more than previously believed. Similarly, it replaces the familiar three-layer concept of the tear film with a “two-phase” model in which all components, not just the lipids, play a role in evaporation. It updates the definition of dry eye to emphasize the concept of homeostasis, by noting its absence, and establishes its restoration as the goal of therapy. It describes the cyclical, self-perpetuating nature of the pathophysiology and brings to the forefront the role of hyperosmolarity. It provides a systematic approach to diagnosis and proposes a classification scheme driven by the role of symptoms. And it grounds all that in a rigorous scientific method that had been sorely lacking.

This issue of Review of Optometry includes a special report on the TFOS DEWS II paradigm shift. In it, I’m sure you’ll find many new ideas you can utilize to strengthen your armamentarium. Enjoy!
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Lenses for Life

A wellness approach may finally be the answer to contact lens dropout.

**Wellness Three Ways**

One of the best ways we can care for our contact lens patients is by taking a wellness approach. Advanced diagnostic technology, patient education and early disease management are key to preventing contact lens dropout.

**Diagnostics.** Assessing for DED and MGD often involves gland expression, tear film break-up time measurement, meibography and a thorough slit lamp examination with special attention to the lid margins, lashes and assessment for blepharitis. For DED, perhaps the easiest and most accurate diagnostic approach is osmolarity and a validated questionnaire such as the DEQ-5. Specular microscopy may also come in handy for DED suspects.

**Education.** Patients with few, if any, symptoms are less likely to be compliant with treatment or a wellness approach unless we spend time educating them on why it is important. Clinical videos and digital slit lamp images can help patients understand both the disease and the benefits of treatment.

**Management.** The first step for patients showing abnormality in any of the DED tests is switching to daily disposable or higher technology lenses. If MGD is noted, you might prompt a prescription for a tear film replacement. Blepharitis treatment could include mechanical cleaning of the eyelids and daily lid hygiene. Endothelial stress signs would prompt a prescription for a daily disposable or higher technology lens.

DED and MGD patients can still wear contact lenses, but treatment is key to keeping them comfortable and safe.

To ensure patients stay happy and healthy in their contact lenses, we must assess for possible complications at each visit to catch changes early and initiate or modify treatment.

**A Digital Dilemma**

Smartphones, tablets and other digital devices are here to stay, and we can anticipate an upward trend in the development of meibomian gland dysfunction (MGD) and dry eye disease (DED) in our patients.

Studies show that the average patient blinks about 15 to 20 times in normal conversation, but this can decrease by 60% to 75%, or even more, while using a digital device. This lack of proper blinking can result in MGD.

Furthermore, contact lenses are a known contributor to functional changes in the meibomian glands and may also contribute to MGD. So, we must be proactive in screening all patients—and contact lens wearing patients in particular—who spend numerous hours using a digital device.

Catching changes early will help us prevent gland loss, disease formation and contact lens dropout.

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Put on Your Thinking Cap

You’ve gotta write those great ideas down—that’s the only reason I’m not a billionaire.

By Montgomery Vickers, OD

I’ve had some great ideas along the way... haven’t you? I mean, we wake up in the middle of the night, or in my case, I wake up in the middle of an examination somewhere between asking number one or number two, and BOOM! Something brilliant just pops into my little head.

As the patient waits, holding his breath, for me to say “number two,” I realize they already have spiny things to keep grandchildren hypnotized while you watch golf for five hours and, full of disappointment, I say “or number two” to the now cyanotic patient.

But I still say it’s a good idea to have good ideas pop into your head. Most are horse manure, but once in a while someone has an idea that leads to revolutions in optometry.

Just think of all the stuff you wish you had.

Optometry Would-be Greats

Me? I wish I had a pen that would close itself as it approached my once white and now black and blue striped shirt pocket. If it would sign my name every time I laid it on a prescription pad, so much the better.

I want an ophthalmoscope that used a little needle to shoot Botox (onabotulinumtoxinA, Allergan) into the orbicularis so I could see what the heck is going on without having to rassle an eyelid.

I would love a disposable contact lens that didn’t list the power on the blister pack so I would not have to spend at least three hours a week listening to a 55-year-old contact lens wearer tell me they could read the newspaper perfectly when they wore a -2.25 in the right eye in 1984.

Speaking of contact lenses, maybe they can make a multifocal lens that starts beeping when it’s inside out or maybe when it gets close to the hyperopic eye. Better yet, they could make one people can see out of.

I have this idea that once a patient/parent gets to about 86, we could have a convention where we all trade patients/parents.

What about when a Millennial searches for online contact lenses and glasses, all the websites show that spring break picture from freshman year and promise to publish it all over the web for free with every purchase?

What if we teach the concept of astigmatism to 4th graders so the kids, not me, could spend an hour explaining astigmatism to their ignorant parents.

Not-so-optometry Wannabe Greats

How about a small and powerful cell phone that unfolds into a 24-inch computer monitor when you receive a text?

When somebody calls me from a number I don’t recognize, I want to activate an app that has an angry beehive delivered to their doorstep within 24 hours. Shipping is free.

Ideas are good. I once woke up in the middle of the night psyched about an idea that would revolutionize eye care and make me a billionaire. Too bad I didn’t write it down before I peed.

Shouldn’t optometrists elect an absolute, all-powerful ruler who would make amazing changes and have total say over what procedures optometrists can do from now to the end of time? After all is perfect, I can retire and you can elect a new ruler.

You’ve gotta write those great ideas down—that’s the only reason I’m not a billionaire.
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I have a patient with optic nerve drusen who is exhibiting progressive nerve fiber layer loss over time. What can I do?

“In the absence of any substantive medical literature, I don’t treat drusen of the nerve head,” says Bob Vandervort, OD, of Heartland Eye Consultants in Omaha, Neb. In some cases, the literature suggests treating drusen with prophylactic glaucoma medications, but I do not in patients who have no risk factors for glaucoma. Drusen of the optic nerve is a relatively common condition, he says, and, according to the literature, they occur around 1% of the time, though family history increases the incidence. “These incidence reports do not state the amount or grade of drusen. When nerve heads are carefully examined using indirect illumination with a condensing lens at the slit lamp, clinicians sometimes observe isolated or minimal drusen in patients with small optic nerves.”

This purported association, and the concurrent belief that smaller optic nerves may be more susceptible to damage, prompts clinicians to consider some type of prophylactic treatment to slow or halt progressive nerve damage from drusen, according to Dr. Vandervort.

Questions Abound
This vexing question of whether clinicians have justification to treat patients in the absence of evidence. Factors to consider:

A life sentence. Drusen of the optic nerve, no matter how severe, rarely if ever cause any symptomatic vision or visual field loss, says Dr. Vandervort. “Do we recommend a 16-year-old adhere to a lifetime regimen of glaucoma medications in the hope that lowering the IOP will slow or halt their progressive nerve damage? Bear in mind, the nerve loss is likely never to have any meaningful negative impact on the person’s quality of life,” says Dr. Vandervort.

Correlation is not causation. “In patients with symptomatic loss and moderate to severe drusen, is there something else going on?” asks Dr. Vandervort. “Patients are entitled to a diagnosis of more than one disease at a time, and great care needs to be taken to make sure concurrent optic nerve disease such as an active or old optic neuritis did not cause the damage,” he explains.

Evidence is a must. While the literature does not support the notion that lowering IOP will stop progressive nerve damage from optic nerve drusen, “it’s commonplace and accepted” to treat patients with significant ocular hypertension and significant concurrent optic nerve drusen to lower their risk of glaucomatous loss, since the nerve is already compromised from the drusen, says Dr. Vandervort.

Second opinions. Dr. Vandervort surveyed the Keystone Group, a group of highly experienced secondary care optometrists, on how they would manage a patient with progressive loss of nerve fiber and IOPs of 18mm Hg and 19mm Hg. Opinions varied from no treatment and close observation to treatment with glaucoma medications. The consensus was to obtain a second opinion from a neuro-ophthalmologist if at all possible. “And, if the patient suffers any symptomatic vision loss or loss of visual acuity, neuroimaging would be indicated.”

Final Verdict
“I have encountered many patients with moderate to severe drusen of the optic nerve who are 50 years of age or older with significant visual field loss and nerve damage, some with afferent pupillary defects. They’ve been living their lives without visual complaints or disability,” says Dr. Vandervort.

Optometrists should only treat if concurrent glaucoma or risk factors for normal tension glaucoma or primary open-angle glaucoma exist. “It is unfortunate that someone has lost and will probably continue to lose small amounts of nerve tissue, but the loss has no meaningful impact on their lives.”
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Fractures of the bony orbit typically present urgently, as the result of trauma. The threat of a neurological complication can induce a strong sense of anxiety in the patient, but an optometrist’s calm, thorough examination, and the appropriate ancillary testing, will ensure they receive the utmost care and achieve the best possible outcome.

By the Numbers
Epidemiologically, males in the adolescent (81%) and young adult (72%) age groups encounter orbital fractures significantly more often than their female counterparts.1,2 Most often, automobile accidents incite the trauma (45% to 54%),2,3 Falls (17.9% to 20.3%), assault (9.7% to 22.6%) and sports-related injuries (6.3% to 7.8%), round out the other major causes of the fractures.2,3 The bony structures most often succumbing to traumatic insult include those associated with the zygomatic complex: the arch, the maxillary buttress, the inferior orbital rim and the frontal articulation.2 After trauma, these patients will need a prompt and thorough ophthalmic examination.

Pathophysiology
The type and extent of each orbital fracture will determine the ophthalmic and related facial complications that arise from the trauma. Fractures typically affecting the orbit include wall, floor and roof blowouts or trapdoor fractures, Le Fort types II and III fractures and zygomaticomaxillary fractures (formerly known as tripod fractures). The more rare orbital apex fractures have the potential to be visually devastating, due to traumatic optic neuropathies. The orbital floor and medial wall are fractured frequently in blowouts due to the relative delicacy of the thin ethmoidal and maxillary sinus bones.1,5 The most emergent of these fractures are trapdoor blowouts of pediatric orbital floors. In children, orbital bones are more pliable than in adults. Due to this malleability, an inferior blowout creates the trapdoor phenomenon as the inferior orbital contents can become trapped in the rebound of the supple bones.6 These cases are urgent and require surgical repair within 24 hours.6

1,000 Pictures’ Worth
Computed tomography (CT) scans are the standard for assessment of any orbital trauma. Before the advancements in CT scanning, radiologists mostly used standard film radiographs, or x-rays, to evaluate the extent of damage. However, with the greatly enhanced images provided by thin-slice CT scans and the technological ability to perform 3D reconstruction of bone, CT images undoubtedly provide the best assessment of the fractures. They can also be unparalleled in their ability to detect small fractures with a tear-drop sign—a herniation of orbital fat inferiorly through the orbital floor shaped like a tear drop—that may otherwise go unnoticed. With the relatively small spaces between each image and the extensive anatomy being studied, orbital CT scans with 3mm spacing often exceed 1,000 total images. A practitioner can compare the CT scans to clinical signs to establish a diagnosis and initiate comprehensive treatment plans.

Bones-a-Cracklin’
The presenting symptoms with orbital fracture vary from case to case. Depending on the force of the trauma and the resultant injuries, patients could have minimal ocular complaint or may present with significant symptomatology. Commonly, the fracture breaks down the bony barrier between the orbit and one of the facial sinus cavities and the resultant turbulent air flow creates a crackling sound or sensa-
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tion known as crepitus.

While crepitus presents as a symptom, it can also be a sign if the examiner listens observantly. The trauma and sequelae can cause varying pain, diplopia, visual changes and hypesthesia. Intraocular complications can arise in upwards of 59% of cases, highlighting the utmost importance of a thorough exam. Ophthalmic signs and exam findings tend to correlate with the aforementioned symptoms. First, a decrease in visual acuity from various mechanisms—including corneal injury, anterior chamber reaction, visually significant hyphema, vitreous cells or hemorrhage (or both), traumatic optic neuropathy and commotio retinae throughout the macula (Berlin’s edema)—may occur.

Patients will also frequently experience diplopia due to varying etiologies. Possible diplopic causes in orbital fracture include muscle entrapment, cranial nerve paresis, muscular hemorrhage, enophthalmos and orbital hemorrhage. Inferior rim fractures are commonly associated with hypesthesia, as the infraorbital nerve is lesioned, causing a loss of sensation in the corresponding facial structures.

Our examinations may uncover other signs, such as lid/orbital/conjunctival emphysema and ecchymosis, rhinorrhea or lid ptosis. The rhinorrhea must be observed quite carefully, especially in the rare cases of roof fractures, since the leak may be cerebrospinal fluid. Our findings, in combination with the symptomatology, CT scans and etiology of trauma, will determine the next steps.

The Urgency of Observation
Once the appropriate work-up has been conducted and imaging reviewed in a timely manner, we can begin to make our soundest clinical judgments, recommendations and referrals. Our recommendations before surgical consult should focus on prophylaxis such as avoidance of nose-blowing, use of nasal decongestant spray—such as oxymetazoline—

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hydrochloride (Afrin) twice daily as needed for a maximum of three days and the slightly controversial oral antibiotics, usually amoxicillin-clavulanate (Augmentin) 250mg to 500mg TID for 10 days. As we know quite well, orbital cellulitis or abscess is one of the few true ocular emergencies. In the breakdown of the orbital-sinus barrier with these fractures, a direct conduit may be created for sinus microbiota to enter the orbital cavity. Once that cavity is breached, the potential for serious neurologic and systemic consequence increases dramatically.

Although seemingly emergent in our line of primary care work, these cases tend to be managed (or observed) rather conservatively by otolaryngologists. Some concerns that would indicate a need for surgical intervention include diplopia, entrapment of extraocular muscles or any orbital contents), orbital abscess, 2mm or more of enophthalmos, or some combination. In addition, the previously mentioned pediatric trapdoor fractures should be quite urgently referred to surgery, as it is indicated within 24 hours. The surgical intervention may be multidisciplinary based on the structures involved, including otolaryngology and oculoplastics.

The proper primary evaluation and management for fracture patients remains well within the wheelhouse of the primary care optometrist. Through our studies, we have gained an extensive and intimate knowledge of the globe and its encompassing orbital structures. The surgeons will be counting on our thorough examinations, measurements and proper imaging to help guide them in surgical cases or to make initial determinations in regards to the need for surgical intervention. So long as we remain calm and comprehensive in our work-ups, we continue to ensure positive outcomes for our patients.

Dr. Dempsey is a primary care optometry resident at the Salem VAMC in Salem, Massachusetts.

Amblyopia: Ditch the Patch

Research argues in favor of binocular approaches. By Marc B. Taub, OD, MS, and Paul Harris, OD

A 15-year-old teen presented for a routine examination with complaints of decreased vision in the left eye for many years. He received his first pair of glasses at age nine from another clinician. His relevant measurements included: plano OD, +4.50 OS, giving a visual acuity of 20/20 OD and 20/60 OS. He was instructed to use the glasses and return in six weeks to evaluate patching therapy but was not seen back until the current visit—six years later.

He reports receiving average grades in school, ranging from A to C. The patient recorded a 4 on the Quality of Life checklist. This subjective survey consists of 19 items assigned point values ranging from 0 to 4, with 0 indicating the patient never experiences difficulty and 4 indicating the patient always experiences difficulty. A score of 20 is typically indicative of a learning-related vision disorder.

Many times, children who are not engaged in schoolwork and are avoiding visually demanding activities will have a low score. If they were still trying at school work, the score would often be much higher. But, this case offers a different explanation.

Exam

The uncorrected Snellen acuities were 20/15, 20/100, 20/15 at distance and 20/40, 20/200, 20/15 at near. The previous glasses were lost within weeks of the last examination, six years prior. Stereopsis showed 50 seconds of arc on Wirt circles but nothing on global forms. This is a conundrum; however, the best explanation is that the patient used monocular cues to determine and report which circle was popping out and got lucky reporting towards the higher levels of stereopsis.

“Just look retinoscopy” showed a significant difference in the quality of the patient’s reflexes, as the left eye showed a dingier, dirtier reflex.

Retinoscopy at distance was +0.50 OD, +5.00-1.00 X 180 OS. This provided acuities of 20/20 OD and 20/40 OS at distance and near. To use the least amount of lens power to obtain the best visual performance, we determined that plano OD (20/20), +4.00 OS (20/40) was the appropriate starting point.

We considered Worth’s 4-dot testing which, in bright and dim illumination, did not show suppression. This was an improvement. We observed no enhancement in stereopsis; however, this may have been because the patient’s primary strategy was to use monocular cues, which were unchanged. Over time, as the patient learns to use his binocular system in a more balanced way, he should perform much better on stereo testing.

The low score on the symptom-
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survey makes more sense now—suppression is a wonderful patient adaptation to reduce double vision and other binocular-related issues.

Diagnosis
The patient was diagnosed with anisometropic amblyopia in his left eye. The initial treatment included a contact lens fitting to reduce the image size, improve comfort and increase the field of clarity. Spectacles would of course be prescribed as backup, as it is the standard of care. After fitting with a standard two-week disposable in the left eye, the acuity remained at 20/40 at distance and near.

The next step in the treatment sequence in many offices would normally be two hours of patching, five days a week. Due to the growing evidence base (see, “A Fine PEDIGree” at right), we decided to forego patching and take a binocular approach using vision therapy. As amblyopia is more than simply an acuity issue, this approach would improve accommodation, binocularity and eye movements; additionally, it would break suppression. The global view of the treatment was aimed at improving the visual system and how the patient integrated his vision with his other sensory systems, creating a system in which vision is guiding and dominant. We estimated that between 35 to 40 sessions of weekly vision therapy with home-based support was required, in this case, to ensure success.

Follow-Up
After 35 sessions of vision therapy, the patient’s acuities were 20/15, 20/20, 20/15 at distance and 20/20, 20/20, 20/10 at near. Stereopsis was demonstrated at 25 sec of arc on Wirt circles and the patient was able to see the global forms.

A Fine PEDIGree
Treating amblyopia without patches was pioneered and improved by many optometrists more than 50 years ago. Research is critical to refining and understanding the scientific why behind the innovative methods of the past’s refractive experts and innovators.

Over the past 20 years, the Pediatric Eye Disease Investigator Group (PEDIG) has provided this necessary research; ultimately, it has shattered and changed the main premise of the classical amblyopia treatment approach. Due to the multi-centered research, we now know the following:

- Full-time patching is equal to six hours in severe amblyopia.
- Six hours is equal to two hours of patching in moderate amblyopia.
- One drop of atropine once a day is equal to six hours of patching in severe cases of amblyopia.
- Occlusion foil patching is equal to using an opaque patch in moderate amblyopia.

The research showcased too many discoveries to list. It’s thrilling to see researchers addressing the concept of throwing patches and drops out the window in favor of binocular therapy.

In a recent study, the PEDIG group compared a binocular iPad game with patching in patients ages 5 to 13. The study found a 2.5- and 2.8-line improvement in acuity in a group of 5 to 7-year-olds but overall, only 22% in the game group completed greater than 75% of the treatment time (60 minutes per day). In the entire treatment group of 385 children, the acuity improved 1.05 lines in the binocular iPad group vs. 1.35 in the patching group at 16 weeks.

The study determined the lack of participation was, in essence, because the game was too boring. A new study in the works vies for greater compliance with an interactive game called Dig Rush. PEDIG researchers will determine the impact of 60 minutes of game play five day per week while using the prescribed glasses vs. only the prescribed spectacles. Practitioners are looking forward to these results to give further evidence for the binocular approach many practitioners currently employ in their treatment protocols.

In this case, a teen was treated with a mixture of spectacles, contacts and vision therapy to obtain the desired outcome. While the standard of care has shifted over the past 20 years and the standard remains patching on some level, the binocular approach acts to both improve acuity and enhance all other visual skills, including binocularity. It leads to both short and long-term gains and, in our clinical experience, reduces regression (the tendency for those treated with patches only to lose their gains over time).

If your office is not able to tackle amblyopia and, taking it even further, strabismus, using the binocular approach, reach out to the doctors in your area that use the binocular approach every day. Simply use the doctor locator options on the pages for the Optometric Extension Program Foundation (oepf.org/page/map) or the College of Optometrists in Vision Development (locate.covd.org). We promise that your patients will thank you for taking this step to ensure their visual health and long-term success.

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For our practices to thrive we must not only successfully address the visual needs of our patients, but also successfully meet their individual lifestyle needs. These unique needs change over time, with one of the biggest changes being the onset of presbyopia. Many of our patients are not aware of the options to help them address the signs and symptoms of presbyopia and too often make compromises such as wearing readers or discontinuing contact lens wear altogether. With approximately 30% of patients requiring vision correction for presbyopia and only 5% using multifocal contact lenses as their primary vision correction, the presbyopic patient population represents a tremendous opportunity for our practices.1,2

Advances in contact lens material, technology, and design can help us successfully capture this opportunity. Read on to learn more about how our practices are utilizing the Alcon Multifocal Portfolio to satisfy our presbyopic patients’ unique needs and help our practices thrive.

INTRODUCTION

For our practices to thrive we must not only successfully address the visual needs of our patients, but also successfully meet their individual lifestyle needs. These unique needs change over time, with one of the biggest changes being the onset of presbyopia. Many of our patients are not aware of the options to help them address the signs and symptoms of presbyopia and too often make compromises such as wearing readers or discontinuing contact lens wear altogether. With approximately 30% of patients requiring vision correction for presbyopia and only 5% using multifocal contact lenses as their primary vision correction, the presbyopic patient population represents a tremendous opportunity for our practices.1,2

Advances in contact lens material, technology, and design can help us successfully capture this opportunity. Read on to learn more about how our practices are utilizing the Alcon Multifocal Portfolio to satisfy our presbyopic patients’ unique needs and help our practices thrive.

Are we meeting the lifestyle and vision needs of our presbyopic patients if

LESS THAN

50% think their vision is clear at the end of the day with their current contact lenses.

LESS THAN

40% of presbyopes wearing contact lenses feel they are comfortable at the end of the day. Is that good enough?

Presbyopia is a milestone that no one wants to hit, certainly not the 60% of patients in my practice who are emerging or established presbyopes. That is why I find it important when engaging my patients in a conversation about presbyopia that I do so with understanding. I acknowledge the emotions that they are feeling such as frustration, denial and feeling old—and let them know that there are options such as multifocal contact lenses that can help restore their vision and help them maintain their desired appearance and lifestyle.

To determine if I need to have the presbyopia talk with my patients, I have some basic questions that I like to start out with, such as “Are you noticing any changes?” and “Are you wearing your lenses every day and are your lenses comfortable for the whole day?” The important thing is to not lead the patient. Listening is also important because my patients will often drop hints they are experiencing difficulties with their vision, such as stating they have trouble reading in restaurants, can’t work on a computer, or have started borrowing reading glasses from their spouse. When I have the presbyopic discussion, I explain what is happening to their eyes and why this is impacting their vision. I also highlight that this is not a temporary condition.

CONTINUED ON THE NEXT PAGE
DAILIES TOTAL1® Multifocal Contact Lenses

When discussing vision correction options with my presbyopic patients, I find many are not aware that multifocal contact lenses are available, which is why I like to discuss them first. In my practice, I prescribe and dispense a fair amount of bifocal/multifocal glasses, but I know many of my patients want freedom from glasses and the convenience and ability to help maintain their appearance that multifocal contact lenses provide. In every conversation, I highlight that multifocal contact lens technology has come far in the last few years and I have more and better options to meet their needs—such as DAILIES TOTAL1® Multifocal contact lenses. For those patients who have tried multifocal contact lenses in the past, I tell them it is worth giving them another try because the technology is now greatly improved.

I prescribe DAILIES TOTAL1® Multifocal contact lenses for many of my presbyopic patients because the Water Gradient Technology utilized in these lenses makes it incredibly comfortable and patients not only experience all-day comfort but are able to wear these lenses comfortably for longer periods of time than their habitual lenses.5 Comfort is one of the biggest reasons for the decline in contact lens use as patients age.7, 8 If I can put my presbyopic patients in a multifocal contact lens that I know will provide exceptional comfort, even when looking at digital devices, I have a greater chance of my patients having a successful contact lens experience.

Comfort is not the only benefit these lenses offer. DAILIES TOTAL1® Multifocal contact lenses utilize Alcon’s Precision Profile® Design, which provides seamless vision throughout presbyopes’ busy days and various activities, including driving at night.9 The Precision Profile® Design does not only benefit my patients. This design is used across the entire Alcon Multifocal Portfolio and has a simple 2-step process that makes it easy for me to customize the fit for each patient with the right lens for their lifestyle.10

High Rates of Fitting Success with Alcon’s Simple 2-Step Initial Fitting Process

Following Alcon’s fitting guide gives me great success and minimizes valuable chair time. My patients leave my practice with a great pair of multifocal contact lenses, and I can meet their needs quickly and easily. Prescribing DAILIES TOTAL1® Multifocal contact lenses has helped me successfully satisfy my presbyopic patients’ unique vision correction and lifestyle needs and many are so happy with the lenses that they are recommending them and my practice to their friends and family. Sometimes I get patients whose ECPs did not prescribe DAILIES TOTAL1® Multifocal contact lenses and they come to me to get the great lenses their friends are wearing. If you are not fitting your patients with DAILIES TOTAL1® Multifocal contact lenses, there is a good chance they will find an ECP who does. This can have a big impact on your practice outcomes as presbyopes are a very important (and growing) part of all our practices. While we do not yet have the technology to cure patients of their presbyopia so their eyes work like they used to, we can still meet presbyopic patients’ needs of convenience, a more youthful appearance, and good vision. With DAILIES TOTAL1® Multifocal contact lenses, I can also offer my presbyopic patients an exceptionally comfortable contact lens, even for patients who have experienced comfort issues in the past. Having presbyopia does not mean that my patients cannot wear contact lenses, but it does mean that I have to prescribe the right contact lens for them—and for many of my patients, DAILIES TOTAL1® Multifocal is the right lens to meet their unique needs.

*Based on DAILIES TOTAL1® sphere contact lenses.
My practice is made up of approximately 40% to 50% presbyopes, and educating my patients about presbyopia and the available vision correction options is incredibly important to me and my practice. My experience has been that presbyopes are unlikely to bring up their symptoms on their own. Most will try to find a way to cope with their vision changes, thinking that these symptoms are temporary—which is why it is important for me to initiate the presbyopic conversation and make sure my patients are aware of their options. In addition to age, some of the red flags that I look for are complaints from the patient about headaches or needing more light to read. I will also ask how their eyes feel at the end of the day—a question that gives me a good idea if I need to probe further.

The success of my practice at meeting the needs of my presbyopic patients is due in part to the involvement of my staff in the process. My technicians and opticians help to raise awareness of presbyopia, identify patients, and gauge patient interest in multifocal contact lenses, even as part-time use. This “all hands on deck” approach is highly effective at making sure that no patient slips through the cracks and has every opportunity to get the vision correction they want, and also helps my bottom line as many of my patients choose multifocal contact lenses as an add-on to glasses.

When I am discussing the vision correction options with my patients, I go over all the options, pros and cons, because I do not want a patient hearing about another option from a friend and thinking that I am not up to date on what is available. That is why I always discuss multifocal contact lenses and eyeglasses. I can usually judge from the patient’s body language how much interest there is in wearing glasses all the time and if the patient might be a good candidate for multifocal contact lenses. I find that people new to needing vision correction are often times very interested in multifocal contact lenses.

Once the patient has expressed an interest in multifocal contact lenses, my next step is to determine which lens replacement schedule is best. For many of my patients DAILIES TOTAL1® Multifocal is my lens of choice, even for my patients who have had issues with comfort and dryness with other multifocal contact lenses in the past. The unique Water Gradient Technology provides an extremely comfortable wearing experience and the Precision Profile® Design provides seamless vision to help patients see clearly throughout near, intermediate and distance tasks.12 This same optical design is used across the Alcon Multifocal Portfolio, allowing me to accommodate a wide range of presbyopic patients. For patients who are accustomed to a monthly replacement lens, AIR OPTIX® AQUA Multifocal is a great choice. The SmartShield® Technology helps maintain the wettability of the lens and resist deposits for clear and comfortable vision from day 1 to day 30.13-18

For presbyopes who are new to contact lenses, or those that do not need the premium comfort provided by DAILIES TOTAL1® Multifocal, DAILIES AquaComfort Plus® Multifocal is my go-to daily disposable lens. DAILIES AquaComfort Plus® Multifocal contact lenses offer patients the advantage of Blink-Activated Moisture Technology, which releases a moisturizing agent (polyvinyl alcohol [PVA]) across both sides of the contact lens with every blink for all-day comfort.19 This also supports a stable tear film, which is important for comfort and visual acuity.13

Since all the contact lenses in Alcon’s Multifocal Portfolio use the Precision Profile® Design, it is easy for me to customize the multifocal fit to meet my patients’ needs. The center near design of the

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1 In accordance with the Manufacturer’s Recommended Replacement Frequency (MRRF).
DAILIES® Choice

The DAILIES® Choice Program (DAILIESCHOICE.COM) helps new patients with rebate savings of up to $200 on an annual supply of DAILIES TOTAL1® (sphere and multifocal) and DAILIES AquaComfort Plus® (sphere, multifocal, toric) contact lenses.

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CONCLUSIONS

The Alcon Multifocal Portfolio can play a huge part in a successful multifocal contact lens strategy that allows your practice to capture the presbyopic opportunity. Meeting the needs of your presbyopic patients—providing a youthful appearance, convenience and freedom from dependency on glasses, as well as crisp vision—is vital for having satisfied patients who keep returning to your practice. Fortunately, Alcon has three unique multifocal contact lenses that use the same Precision Profile® Design which you can offer your patients, depending on their wearing habits and lifestyle needs, so all your presbyopic patients can see, look and feel their best.

REFERENCES


See product instructions for complete wear, care and safety information.
41st Annual Contact Lens Report

Today’s Contact Lens Materials and Designs

Understanding the makeup of these devices can help ODs select the right option for each patient. By Sruthi Srinivasan, PhD, BSOptom

Even with healthy growth in the number of contact lens (CL) options on the market, one particular burden continues to dog the industry—contact lens discomfort (CLD).1,3

According to the Tear Film and Ocular Surface Society (TFOS) report on CLD, the only CL material-related factor that demonstrates correlation with CLD is coefficient of friction.6 However, until researchers agree upon an industry-standard methodology to measure friction of CL materials, this remains a difficult area to study. Other material-related factors, such as oxygen transmissibility, wettability, modulus and lens dehydration, only display weak links with CLD. Lens replacement frequency, lens design, thickness/bulk and edge configuration also show some relationship to CLD.5

Over the past few years, CL companies have debuted technologies aimed at developing lenses with surface and bulk properties that reduce discomfort. Some Silicone hydrogel (SiHy) materials even hope to address patient-related issues, such as digital eyestrain. This article reviews the latest SiHy materials that manufacturers hope will reduce patient discomfort as well as new CL materials and designs of other lens types.

SiHy Setbacks and Successes

This material now accounts for approximately 55% of all soft lens fits worldwide and 62% in the United States.7 Its increased oxygen transmissibility promised a reduction in the rate of corneal infections, but research shows the risk of microbial keratitis is similar regardless of lens material studied.8-12 In fact, several studies show that SiHy materials doubled the relative risk for infiltrative events.13-16 Studies also suggest that older generation SiHy materials provided only a minimal increase in comfort over conventional hydrogel (CH) materials.5,17 This was due to the incorporation of siloxane groups into SiHy lenses, which made them more hydrophobic and stiffer than
CH materials, but led to issues related to poor lens wettability and mechanical complications. These mechanical complications included mucin balls (Figure 1), corneal erosions (Figure 2), superior epithelial arcuate lesions (Figure 3), epithelial flaps and CL-associated papillary conjunctivitis. The hydrophobic nature of certain SiHy materials tends to deposit high levels of certain lipids and increased denatured protein. Hence, several practitioners still choose to fit CH materials. However, a newer generation of SiHy lenses were designed with these issues in mind. For instance, Air Optix plus with HydraGlyde (Alcon) incorporates two technologies—SmartShield Technology and HydraGlyde Moisture Matrix—which provide a combination of deposit protection and longer-lasting lens surface moisture. According to the manufacturer, lenses with “SmartShield technology” prevent silicone from reaching the surface of the CLs, which helps the lens surface retain moisture and resist deposition with the intention of maintaining comfort throughout the wearing period. “HydraGlyde Moisture Matrix” involves a block copolymer. One side of the HydraGlyde molecule adsorbs onto the contact lens; the other attracts additional moisture, which the manufacturer says results in an envelope of lasting lens surface wettability. In August 2016, CooperVision announced the launch of a new SiHy lens.
Table 2. Daily Disposable Spherical Silicone Hydrogel Contact Lenses

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>USAN</th>
<th>Brand name</th>
<th>Proprietary technology</th>
<th>Wetting agent</th>
<th>Dk/t (&lt;3.000)</th>
<th>Modulus (Mpa)</th>
<th>Water content</th>
<th>BOZR (mm)</th>
<th>Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcon</td>
<td>deleflon A</td>
<td>Dailies Total 1</td>
<td>Water gradient technology</td>
<td>None</td>
<td>156</td>
<td>0.63</td>
<td>33% core t&gt;80% surface</td>
<td>8.5</td>
<td>14.1</td>
</tr>
<tr>
<td>CooperVision</td>
<td>stenflon A</td>
<td>MyDay</td>
<td>Smart Silicone</td>
<td>None</td>
<td>100</td>
<td>0.4</td>
<td>54%</td>
<td>8.4</td>
<td>14.2</td>
</tr>
<tr>
<td></td>
<td>somofilon A</td>
<td>Clariti 1 Day</td>
<td>WetLoc technology</td>
<td>None</td>
<td>86</td>
<td>0.5</td>
<td>56%</td>
<td>8.6</td>
<td>14.1</td>
</tr>
<tr>
<td>Johnson &amp; Johnson Vision</td>
<td>narafilcon A</td>
<td>1 Day Acuvue TruEye</td>
<td>Hydralclear 1</td>
<td>Internal wetting agent: PVP</td>
<td>118</td>
<td>0.66</td>
<td>46%</td>
<td>8.5, 9.0</td>
<td>14.2</td>
</tr>
<tr>
<td></td>
<td>senofilon A</td>
<td>Acuvue Oasys daily contact lens with Hydraluxe</td>
<td>Hydraluxe</td>
<td>Internal wetting agent: PVP</td>
<td>121</td>
<td>0.72</td>
<td>38%</td>
<td>8.5, 9.0</td>
<td>14.3</td>
</tr>
</tbody>
</table>

lens, Avaira Vitality (CooperVision), in sphere and toric options, manufactured from fanfilcon A, which has a high water content (55%) and high oxygen permeability (Dk) and transmissibility level (Dk/t). This material also features a Class 1 ultraviolet (UV) protection rating, and it blocks more than 90% of long-wave and 99% of shortwave UV rays. In July, CooperVision introduced its Biofinity Energys (CooperVision), with digital device users in mind. According to the company, this comfilcon A-based lens has two novel elements: “digital zone optics,” which integrates multiple, front-surface, aspheric curves across the entire optical zone, distributing power evenly and simulating more positive power in the center of the lens; and “aquaform technology,” which has high oxygen transmissibility and low modulus, attracting and binding water.30

In 2016, Johnson & Johnson Vision announced a monthly replacement SiHy lens, Acuvue Vita (senofilcon C). This lens material is designed to incorporate beneficial lipids found in tears within the lens and also helps to maintain lens hydration with reduced evaporation, all in an effort to improve comfort. Johnson & Johnson Vision also launched Acuvue Oasys 1-Day with “Hydraluxe technology,” which uses a tear-infused design that mimics mucins to help support a stable tear film. The material has an enhanced network of tear-like molecules.

This new lens has an increased diameter to ensure full corneal limbus coverage during blinking and includes enlarged optics to help cover larger pupils in low light conditions (Tables 1 and 2).

In February 2016, Bausch + Lomb announced Ultra for Presbyopia, a monthly replacement SiHy lens that incorporates the company’s “MoistureSeal technology” and three-zone progressive design found in Biotrue OneDay for Presbyopia daily disposable CLs. The company says these lenses “maintain 95% of their moisture for up to 16 hours.”31 Bausch + Lomb’s website say the two-phase manufacturing process of these lenses retains moisture and delivers a highly wettable surface. Phase 1 combines long- and short-chain monomers to formulate a unique silicone backbone. In phase 2, the polyvinylpyrrolidone (PVP) grows around and throughout the silicone backbone. The high volume of PVP at the core is meant to provide moisture retention and the tightly compacted PVP at the surface delivers high wettability.

Menicon recently launched Rose K2 Soft CL design for the irregular cornea. Rose K lenses are a frequently prescribed lens design for the correction of keratoconus and irregular cornea conditions and are mostly rigid gas permeable lenses. The newly launched Rose K2 Soft design is a daily wear SiHy soft lens for irregular corneas, available as a three-month replacement lens. The Rose K2 Soft design features an aspheric back optic zone, front surface toricity and front surface aberration control. According to the company, Rose K2 Soft offers edge lift control, prism ballast stabilization and reverse geometry.32 Rose K2 Soft is available now in the United States from ABB Optical, Art Optical Contact Lens and Blanchard Contact Lens.

Scleral Lenses

Over the last decade, CL manufacturers have provided a variety of scleral contact lens (ScCL) designs that have a wide range of applications.33,34 Current ScCLs are manufactured using high Dk materials (e.g., fluorosilicone acrylate). Such materials aid in increasing oxygen supply to the cornea.

Asian patients’ corneas have a smaller horizontal visible iris diameter and are more prolate with a smaller palpebral fissure than Cauca-
sians’ corneas.35 Blanchard designed a lens (Onefit A Scleral lens) to provide optimal limbal clearance and easier handling with a smaller diameter and an altered paracentral geometry.36 Blanchard also launched a new feature called XLC (Extra Limbal Clearance), to its Onefit Scleral Lens Platform to obtain...
Hello Miru.
Bye, bye blister pack.

Introducing Miru 1day, the world’s thinnest package for daily disposable contact lenses.

Miru’s ultra lightweight 1mm thin package is about 1/8th the thickness of a traditional blister pack and was specifically developed to reduce the risk of microbial contamination. When opened, the lens is presented on a special disk, oriented correctly for proper insertion.

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additional limbal clearance, without increasing the lens diameter. In March 2016, Art Optical announced the availability of its new 16.5mm scleral lens, Ampleye. According to the company, this is designed to fully vault the cornea and limbus, without corneal involvement. In addition to a toric haptic, the lenses include a four-zone construction, providing independent zone adjustments for finite control of the lens fit.

The SynergEyes VS (Menicon) scleral lens completely vaults the cornea and limbus, landing entirely on the sclera. Its toric periphery may be precisely controlled in both the flat and steep meridians, aligning with the scleral for ease of landing and stability. This non-rotationally symmetrical lens design incorporates linear landing zones and landing zones with bi-tangential toricity. The linear landing zones are designed to follow the linear (rather than curved) shape of the sclera, accommodating a toric sclera. This should distribute the lens pressure more equally over the sclera due to the adjustable angles of the flat or steep meridians. The company hopes this will improve the scleral lens fit with less risk of air bubble formation or blanching of the conjunctival scleral vessels. The toric landing zones can greatly improve vision in patients with residual astigmatism as they are designed to provide consistent

### Table 3. SiHy and Conventional Toric Hydrogel Contact Lenses

<table>
<thead>
<tr>
<th>Company</th>
<th>USAN</th>
<th>Brand name</th>
<th>Replacement frequency</th>
<th>Water content</th>
<th>Diameter (mm)</th>
<th>BOZR (mm)</th>
<th>Lens type</th>
<th>Design/Stabilization method/markings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcon</td>
<td>lotrafilcon B</td>
<td>Air Optix for Astigmatism</td>
<td>1 month DW or up to 6N EW</td>
<td>33%</td>
<td>14.5</td>
<td>8.7</td>
<td>SiHy</td>
<td>Precision balance 8/4 lens design. Markings at 3, 6 and 9 o'clock</td>
</tr>
<tr>
<td></td>
<td>nelfilcon A</td>
<td>Focus Dailies Toric One-Day</td>
<td>Daily</td>
<td>69%</td>
<td>14.2</td>
<td>8.6</td>
<td>hydrogel</td>
<td>Back surface tri-curve toric design</td>
</tr>
<tr>
<td></td>
<td>nelfilcon A</td>
<td>Dailies Aquacomfort Plus Toric (nelfilcon A) One-Day</td>
<td>Daily</td>
<td>69%</td>
<td>14.4</td>
<td>8.8</td>
<td>hydrogel</td>
<td>Back surface tri-curve toric design</td>
</tr>
<tr>
<td>Bausch + Lomb</td>
<td>balafilcon A</td>
<td>PureVision Toric</td>
<td>1 month DW or up to 30N CW</td>
<td>36%</td>
<td>14</td>
<td>8.7</td>
<td>SiHy</td>
<td>Prism ballast Lo-Torque Design; Marking at 5, 6 and 7 o'clock (30 degrees apart)</td>
</tr>
<tr>
<td></td>
<td>balafilcon A</td>
<td>PureVision2 Toric for Astigmatism</td>
<td>1 month DW or up to 30N CW</td>
<td>36%</td>
<td>14.5</td>
<td>8.9</td>
<td>SiHy</td>
<td>Aspheric optics; Auto Align Design; Marking at 6 o’clock</td>
</tr>
<tr>
<td></td>
<td>alphafilcon A</td>
<td>Softens Toric for Astigmatism</td>
<td>1 month</td>
<td>66%</td>
<td>14.5</td>
<td>8.5</td>
<td>hydrogel</td>
<td>Prism ballast; Aspheric design; Marking at 6 o’clock</td>
</tr>
<tr>
<td></td>
<td>nesofilcon A</td>
<td>Biotrue OneDay for Astigmatism</td>
<td>Daily</td>
<td>78%</td>
<td>14.5</td>
<td>8.4</td>
<td>hydrogel</td>
<td>Peri-ballast (prism free)</td>
</tr>
<tr>
<td></td>
<td>hilafilcon B</td>
<td>SoftLens daily disposables Toric for Astigmatism</td>
<td>Daily</td>
<td>59%</td>
<td>14.2</td>
<td>8.6</td>
<td>hydrogel</td>
<td>Prism ballast; Aspheric design</td>
</tr>
<tr>
<td>CooperVision</td>
<td>comfilcon A</td>
<td>Biofinity Toric</td>
<td>1 month DW or up to 7N CW</td>
<td>48%</td>
<td>14.5</td>
<td>8.7</td>
<td>SiHy</td>
<td>Optimized ballast design Marking at 6 o’clock</td>
</tr>
<tr>
<td></td>
<td>entilcon A</td>
<td>Avaira Toric</td>
<td>Two-week</td>
<td>46%</td>
<td>14.5</td>
<td>8.5</td>
<td>SiHy</td>
<td>Optimized ballast design; Marking at 6 o’clock</td>
</tr>
<tr>
<td></td>
<td>fanfilcon A</td>
<td>Avaira Vitality toric</td>
<td>Two-week</td>
<td>55%</td>
<td>14.5</td>
<td>8.5</td>
<td>SiHy</td>
<td>Optimized Toric Lens Geometry</td>
</tr>
<tr>
<td></td>
<td>omafilcon A</td>
<td>Proclear Toric</td>
<td>1 month</td>
<td>62%</td>
<td>14.4</td>
<td>8.4, 8.8</td>
<td>hydrogel</td>
<td>Prism ballast; Three lines at 6 o’clock (15 degrees apart)</td>
</tr>
<tr>
<td></td>
<td>oculifilcon D</td>
<td>Biomedics Toric</td>
<td>1 month</td>
<td>55%</td>
<td>14.5</td>
<td>8.7</td>
<td>hydrogel</td>
<td>Prism Ballast; Marking at 6 o’clock</td>
</tr>
<tr>
<td></td>
<td>methafilcon A</td>
<td>Frequency 55 Toric/Xcel Toric</td>
<td>1 month</td>
<td>55%</td>
<td>14.4</td>
<td>8.7</td>
<td>hydrogel</td>
<td>Prism ballast</td>
</tr>
<tr>
<td></td>
<td>somofilcon A</td>
<td>clariti 1 day toric</td>
<td>Daily</td>
<td>56%</td>
<td>14.3</td>
<td>8.6</td>
<td>SiHy</td>
<td>Aspheric</td>
</tr>
<tr>
<td>Johnson &amp; Johnson Vision</td>
<td>senofilcon A</td>
<td>Acuvue Oasys for Astigmatism</td>
<td>2 week DW</td>
<td>38%</td>
<td>14.5</td>
<td>8.6</td>
<td>SiHy</td>
<td>Accelerated Stabilization Design</td>
</tr>
<tr>
<td></td>
<td>etafilcon A</td>
<td>1-Day Acuvue Moist for Astigmatism</td>
<td>Daily</td>
<td>58%</td>
<td>14.5</td>
<td>8.5</td>
<td>hydrogel</td>
<td>Accelerated Stabilization Design</td>
</tr>
<tr>
<td></td>
<td>senofilcon A</td>
<td>Acuvue Oasys for Astigmatism with HydraLuxe</td>
<td>Daily</td>
<td>38%</td>
<td>14.3</td>
<td>8.5</td>
<td>SiHy</td>
<td>Accelerated Stabilization Design</td>
</tr>
</tbody>
</table>
Biotrue® uses HA to keep lenses moist for up to 20 hours\textsuperscript{2}

Biotrue\textsuperscript{®} keeps lenses comfortable all day long, with a unique bio-inspired formulation that \textit{works like your patients’ eyes}. The HA in Biotrue\textsuperscript{®} attracts water to the lens surface and envelops the lens in a moisture-rich cushion. No wonder Biotrue\textsuperscript{®} is the multi-purpose solution used by more patients.*

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- Keeps key beneficial tear proteins such as lysozyme active\textsuperscript{1}

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\*Highest household penetration among multi-purpose solutions; IRI Data MULO 52 weeks ending 06/11/17.

REFERENCES: 1. Data on file. Bausch & Lomb Incorporated. Rochester, NY. 2. In vitro studies evaluated the rate of release of sodium hyaluronate (HA), a conditioning agent in the BPZ02 multi-purpose solution, from both conventional and silicone hydrogel contact lenses over a twenty-hour time period. HA was adsorbed on all traditional and silicone hydrogel contact lenses tested upon soaking in the solution overnight. HA is then released from the lenses throughout at least a twenty hour time period when rinsed with Hank’s balanced salt solution at a rate mimicking tear secretions. The in-vitro performance of BPZ02 multipurpose solution suggests that it will provide lens conditioning throughout a twenty hour time period.

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stabilization allowing for a front-surface cylinder.

Myopia Control Lenses
Recent research shows a 32% to 42% reduction in myopia using orthokeratology (OK) lenses.\textsuperscript{39-41} Research also finds partial correction using OK lenses is effective, with high myopes of 6.00D or more partially treated by -4.00D, showing a 76% reduction in myopia progression over one year when compared with spectacle wear.\textsuperscript{42} Children fitted with a dual-focus multifocal OK lens design in one eye and a conventional OK lens in the fellow eye showed short-term changes to the eye in the multifocal OK lens wearing eyes.\textsuperscript{43}

Concentric and aspheric multifocal designs can slow myopia progression.\textsuperscript{44} Concentric bifocal lenses, which have a center distance design surrounded by concentric zones of near and distance powers, reduce myopia progression and axial length in children with esophoric fixation disparities, according to investigators.\textsuperscript{44} Aspheric designs also show reduced myopia progression.\textsuperscript{45} Use of a center-distance aspheric multifocal design can reduce myopic progression by 50% and axial length by 29% when compared with a single vision wearing group.\textsuperscript{46}

Dual-focus designs and peripheral plus powered aspheric designs also show myopia reduction; however, debate about the visual quality reduction caused by the induction of positive spherical aberration when using this approach persists.\textsuperscript{47-50}

Toric Lenses for Astigmatism
A number of new options have recently come to market in this category. In 2017, Bausch + Lomb introduced Biotrue OneDay for Astigmatism daily disposable CLs (nesofilcon A). Initially, these lenses will be available in plano to -4.25D (in 0.25D steps) with cylinder powers of -0.75D and -1.25D and the full range will be available later this year. Johnson & Johnson Vision announced the US launch of Acuvue Oasys 1-Day Brand CLs for Astigmatism. CooperVision announced the limited rollout of Avaira Vitality toric (in the nesofilcon A material). This lens has an optimized ballast toric design and is available in a power range of plano to -6.00D with cylinder options of 0.75D, 1.25D, and 1.75D in axes from 10° to 180° in 10° steps. They have a modulus of 0.6MPa and a Dk/t of 90. Announcements about plus powers, high minus powers and a -2.25 cylinder are expected later in 2017. In June 2016, CooperVision announced the expanded availability of Biofinity XR toric, a monthly SiHy CL. Biofinity XR toric is a cast-molded, made-to-order lens that incorporates the same uniform horizontal thickness and ballast band

![Photo: Jalaiah Varikooty, MSc, BMed](image)

**Fig. 2. This patient displayed epithelial erosion one hour after removing their contact lenses.**

### Table 4. SiHy and Conventional Multifocal Hydrogel Contact Lenses

<table>
<thead>
<tr>
<th>Company</th>
<th>USAN</th>
<th>Brand name</th>
<th>Replacement frequency</th>
<th>Water content (%)</th>
<th>Diameter (mm)</th>
<th>BOZR (mm)</th>
<th>Lens type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcon</td>
<td>lotrafilcon B</td>
<td>Air Optix Aqua Multifocal</td>
<td>monthly</td>
<td>33</td>
<td>14.2</td>
<td>8.6</td>
<td>SiHy</td>
</tr>
<tr>
<td></td>
<td>nefilcon A</td>
<td>Focus Dailies Progressives</td>
<td>daily</td>
<td>69</td>
<td>13.8</td>
<td>8.6</td>
<td>hydrogel</td>
</tr>
<tr>
<td></td>
<td>nefilcon A</td>
<td>Dailies AquaComfort Plus Multifocal</td>
<td>daily</td>
<td>69</td>
<td>14</td>
<td>8.7</td>
<td>hydrogel</td>
</tr>
<tr>
<td></td>
<td>dealfilcon A</td>
<td>Dailies Total1 Multifocal</td>
<td>daily</td>
<td>33</td>
<td>14.1</td>
<td>8.5</td>
<td>SiHy</td>
</tr>
<tr>
<td>Bausch + Lomb</td>
<td>baltifilcon A</td>
<td>PureVision Multi-Focal</td>
<td>monthly</td>
<td>36</td>
<td>14</td>
<td>8.6</td>
<td>SiHy</td>
</tr>
<tr>
<td></td>
<td>baltifilcon A</td>
<td>PureVision2 for Presbyopia</td>
<td>monthly</td>
<td>36</td>
<td>14</td>
<td>8.6</td>
<td>SiHy</td>
</tr>
<tr>
<td></td>
<td>nefilcon A</td>
<td>Bottrue OneDay for Presbyopia</td>
<td>daily</td>
<td>78</td>
<td>14.2</td>
<td>8.6</td>
<td>hydrogel</td>
</tr>
<tr>
<td></td>
<td>samfilcon A</td>
<td>Ultra for Presbyopia</td>
<td>Monthly</td>
<td>46</td>
<td>14.2</td>
<td>8.5</td>
<td>SiHy</td>
</tr>
<tr>
<td></td>
<td>polymacon B</td>
<td>SofLens Multi-Focal</td>
<td>monthly</td>
<td>38</td>
<td>14.5</td>
<td>8.5, 8.8</td>
<td>hydrogel</td>
</tr>
<tr>
<td>CooperVision</td>
<td>somofilcon A</td>
<td>clariti 1 day multifocal</td>
<td>daily</td>
<td>56</td>
<td>14.1</td>
<td>8.6</td>
<td>SiHy</td>
</tr>
<tr>
<td></td>
<td>comofilcon A</td>
<td>Biofinity multifocal</td>
<td>monthly</td>
<td>48</td>
<td>14</td>
<td>8.6</td>
<td>SiHy</td>
</tr>
<tr>
<td></td>
<td>omatifilcon A</td>
<td>Proclear Multifocal</td>
<td>monthly</td>
<td>62</td>
<td>14.4</td>
<td>8.7</td>
<td>hydrogel</td>
</tr>
<tr>
<td></td>
<td>omatifilcon A</td>
<td>Proclear 1 day multifocal</td>
<td>daily</td>
<td>60</td>
<td>14.2</td>
<td>8.7</td>
<td>hydrogel</td>
</tr>
<tr>
<td>Johnson &amp; Johnson Vision</td>
<td>senofilcon A</td>
<td>Acuvue Oasys For Presbyopia</td>
<td>bi-weekly*</td>
<td>38</td>
<td>14.3</td>
<td>8.4</td>
<td>SiHy</td>
</tr>
<tr>
<td></td>
<td>etafilcon A</td>
<td>1-Day Acuvue Moist Multifocal</td>
<td>daily</td>
<td>58</td>
<td>14.3</td>
<td>8.4</td>
<td>hydrogel</td>
</tr>
</tbody>
</table>

*If used in an EW modality, weekly replacement.
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design as Biofinity toric. The commercially available SiHy and CH toric hydrogel CLs, and the stabilization methods and markings used in their lenses, is available for review (Table 3).

Presbyopia Correction
Multifocal lenses have shown improved success in correcting presbyopia when compared with monovision. Commercially available options are shown in (Table 4). Last year, PolyVue launched HD Dailies (hioxifilcon, 59% water content), which incorporate an aspheric curvature for each soft lens power and thickness, and compensate for aberrations caused by lens flexure on the eye. Alcon also introduced Dailies Total1 Multifocal CLs (delefilcon A), which uses the same water-gradent technology as the other lenses in the DT1 product line.

The water gradient technology incorporates what the manufacturer calls core and surface optimization: the core material has 33% water content (low water content helps to deliver high oxygen transmissibility) and the surface employs a hydrophilic gel designed to provide lubricity (>80% water). The outer surface has no silicone and is 100% water.

Cosmetic Lenses
Color CL fits in Asia are quite high when compared with the United States, with about 4% in the United States, and 58% and 41% in Taiwan and Korea. Color CLs are mainly used for cosmetic purposes and they also have prosthetic and special effect applications. There are three types of color soft CL that are used to enhance or alter the eye color: transparent tinted lenses, dot matrix computer-generated lenses, and custom hand-painted soft lenses. Lately, the market has seen a huge increase in the sales of limbal ring CLs. Limbal ring CLs magnify the eye appearance and this is achieved by adding pigments to these lenses. These pigments can be located either on the surface or within the bulk of the limbal CL material. Pigment location on seven different daily disposable limbal ring CL materials was studied and, aside from one lens material, all tested lens materials revealed pigments on the surface. The pigments located on the surface of the CL will either interact with the palpebral conjunctiva or the cornea depending on location of the surface coating (front or back).

Discomfort associated with CL wear continues to be an issue cannot be attributed to any single factor. Further studies are warranted to understand the impact of these new technologies on CL comfort. Novel CL materials and designs have evolved over the past decade. It would be useful for optometrists to stay up to date on novel innovations in CL materials and designs when prescribing, to avoid or solve a number of common patient problems.

Dr. Simrivasan an an optometrist at the Centre for Contact Lens Research (CCLR), School of Optometry and Vision Science, at the University of Waterloo, Ontario, Canada.
Patients diagnosed with corneal ectasia and irregular astigmatism can be a challenge to fit with contact lenses. Options such as soft, conventional corneal gas permeable (GP), hybrid and piggyback contact lenses all come with limitations that stymie success. For example, soft contact lenses may not provide adequate visual acuity, standard GP lenses can decenter or dislodge and the intricacies of piggyback lens systems can be difficult for some patients. In addition, the location or amount of corneal irregularity often makes it impossible to achieve an adequate fit with these contact lenses.

Fortunately, scleral lenses can solve many of these problems. Scleral lenses are large-diameter GP lenses that vault over the cornea and rest on the conjunctiva and sclera. They were the earliest type of contact lenses manufactured and have experienced tremendous growth in recent years. Early scleral lenses—manufactured first from blown glass scleral shells and then PMMA materials—were brilliant, but did not work very well. They caused lens-induced corneal edema due to poor oxygen transmissibility, which led to corneal hypoxia and eventually the discontinuation of lens wear. Additionally, each lens was created by hand and was impossible to replace if lost or broken.

But with today’s improvements and with the right fit, these lenses can help many patients obtain good vision, particularly those with irregular corneas. These fitting tips and tricks will put you on the path to success when fitting scleral lenses for irregular corneas.

Old Favorite, New Twist
Originally, scleral lenses were prescribed as a last resort and were fit to correct irregular astigmatism due to corneal ectasia and to treat ocular surface disease, including patients with compromised corneas. Although glass, PMMA and eventually GP scleral lenses were prevalent throughout the first half of the 20th century, the technology and materials available at that time did not ensure reproducibility or clinical success.

Today, better materials, equipment and design reproducibility have overcome many shortcomings.
Now, scleral lenses are applied with preservative-free fluid in the post-lens-fluid reservoir. This fluid continuously bathes the ocular surface and corrects for corneal irregularities—improving visual acuity by creating a smooth anterior optical surface.

In 2016, almost 60% of practitioners surveyed reported their use of scleral lenses had increased. The role of modern scleral lenses is expanding to include optical correction for both irregular corneas and normal, healthy eyes, as well as for the correction of refractive error and mild to moderate dry eye disease.

**When to Use**

There are many indications for scleral lenses for irregular corneas with ectasias, including for keratoconus, keratoglobus and pellucid marginal degeneration.

Primary corneal ectasias include a group of non-inflammatory conditions of the eye distinguished by thinning of the cornea, which results in a distorted corneal surface. Keratoconus is the most common corneal ectasia and causes bilateral asymmetric thinning of the cornea. Scleral lenses are particularly beneficial in advanced, notably decentered, keratoconus because they provide lens stability and do not dislodge easily. Scleral lenses cover the entire cornea, providing consistent vision along with good comfort, which can be helpful for patients with keratoglobus, a condition characterized by diffuse thinning and a forward protrusion of the cornea. Custom lens designs that correct corneal irregularities also can provide good vision and comfort for patients with pellucid marginal degeneration, a crescent-shaped band of thinning is present in the peripheral, typically inferior, quadrant of the cornea several millimeters from the limbus.

In addition, scleral lenses are indicated for secondary corneal ectasias after corneal refractive surgery such as post-LASIK, post-radial keratotomy (RK) and post-penetrating keratoplasty (PK).

Additional indications for scleral lenses are after corneal transplantation and for corneal scars and degenerations or dystrophies such as Salzmann’s nodular degeneration or Terrien’s marginal degeneration.
Salzmann’s nodular degeneration is a slowly progressive, typically bilateral, condition characterized by gray-white to bluish nodules near the limbus or in the mid-peripheral cornea. Terrien’s marginal degeneration produces slowly progressive peripheral thinning of the cornea.

This HOA map of an eye with keratoconus shows aberrations beyond sphere and cylinder. While all eyes exhibit some level of HOA, eyes with keratoconus quickly exceed normal levels. Here, the level of higher-order root mean square wavefront error (a typical measure of HOA) is 0.54µm, which is well above the level seen in typical eyes for this pupil size.

A New Player: Crosslinking
Practitioners should discuss corneal collagen crosslinking with patients with keratoconus. Ideally, in patients with keratoconus and progressive ectatic disease of the cornea, a corneal crosslinking consultation should be performed prior to initiating a contact lens or scleral lens fitting.

Although there are no definitive criteria for progression, parameters to evaluate progression include: a change in corneal shape, steepening of the cornea, refraction—including irregular astigmatism—and uncorrected and best-corrected visual acuity. After corneal collagen crosslinking, practitioners can fit patients with scleral lenses. Collaborative care with a corneal specialist will help to determine when a fitting is best.

Scleral Lenses

Scleral lenses are particularly helpful for these patients because they correct irregular astigmatism after corneal transplantation, lessen corneal scarring over time, correct corneal irregularities by vaulting over peripheral nodules in Salzmann’s and decrease the amount of corneal neovascularization while continuously bathing the ocular surface during wear.

For corneal scars causing opacity and corneal irregularity along the visual axis, scleral lenses can create a smooth surface and improve vision.

Due to irregular astigmatism in all conditions, patients are unlikely to achieve adequate vision with spectacles, making a good fit with scleral lenses all the more important.

In the Literature
Scleral lenses for corneal ectasia have been at the heart of many investigations, most of which suggest these lenses can improve patient’s visual acuity and quality of life. The research also highlights a few issues that might bar scleral lens success.

In one study focused on visual rehabilitation following PK, 28 of 31 patients were successfully fit with scleral lenses, and visual acuity was significantly improved compared with glasses. However, the researchers reported 12 graft complications, 10 graft rejections and two cases of microbial keratitis. In another study of 34 patients (48 eyes) fit with scleral lenses following corneal transplantation, 40% of eyes achieved 20/20 or better with scleral lenses, and 91.7% of eyes achieved 20/40 or better. Six eyes developed graft rejection, three of which resumed scleral lens wear following resolution of the rejection episode. There were no cases of associated microbial keratitis.

Other researchers evaluated scleral lenses in 45 patients (56 eyes) with unacceptable vision after PK. All eyes achieved an acceptable fit with scleral lenses, although only 19 patients eventually ordered lenses. The investigators speculate that barriers to completing the process included cost, concerns about lens handling and anticipated delays in receiving lenses. There were no reported cases of graft rejection or microbial keratitis in those who completed the fitting process.

One study that compared scleral lens fitting with PK in patients with keratoconus found the scleral lens group demonstrated improved visual acuity more rapidly than surgical intervention. Data shows more scleral lens patients obtained 20/25 visual acuity or better compared with the PK group. In addition, more complications were observed in the PK group than the scleral lens group. Thus, patients with keratoconus who cannot successfully wear other modes of correction can consider scleral lenses before surgical intervention.

Studies also suggest scleral lenses can improve a patient’s quality of life. One study evaluated vision-related quality of life in 30 patients with keratoconus—20 GP lens wearers and 10 non-wearers—and a control group of 30 healthy patients. All subscales of the National Eye Institute Visual Function Questionnaire-25 were lower in the patients who had keratoconus. Improved best-corrected visual acuity was achieved in the contact lens group compared with non-wearers. Patients who had reduced visual acuity in the better eye had worse distance vision, social functioning, mental health and role difficulties. Patients with reduced visual acuity in the worse eye had lower general health scores. In keratoconic
patients, vision-related quality of life was worse compared with the control group. According to this study, a successful contact lens fit that improves visual acuity may improve vision-related quality of life. When other researchers evaluated quality of life before and after scleral lens adaptation in patients with keratoconus or after PK, they found quality of life scores of patients wearing scleral lenses were significantly higher compared with those not wearing scleral lenses.

A Custom Fit
Keratoconus is by far the greatest indication for scleral lens wear in the published literature, as they correct corneal irregularity due to irregular astigmatism and minimize visual distortion. Due to their unique fitting characteristics—individualized central and peripheral corneal sagittal depths, front surface and back surface toricity, multifocal optics and diameters—scleral lenses are ideal to provide optical correction in severe forms of corneal ectasia.

Pre-fit testing. Although scleral lenses are fit on sagittal depth, topography or Scheimpflug tomography of the anterior segment are beneficial prior to scleral lens fitting to determine potential areas of concern such as a protruding graft or areas of corneal elevation. Practitioners must evaluate anterior segment health to rule out preexisting staining, corneal microcystic edema or conjunctival elevations. Obtaining horizontal visible iris diameter and evaluating the patient from the side will help to determine how far the cornea protrudes to aid in initial lens selection. Scleral lenses need to vault over the entire cornea, including the highest point. In patients with keratoconus, the location of corneal ectasia is usually the steepest part of cornea, but not always. In some cases, such as post-PK, practitioners should determine endothelial cell count status prior to commencing a scleral lens fitting.

Fitting tips and tricks. The first step to selecting the best scleral lens for a keratoconic eye is to determine the apex of the cornea. If the corneal apex is within...
the central 4mm of the cornea, a standard geometry lens may achieve a better result. If the corneal apex is outside of the central 4mm, a reverse geometry lens may work better.24,25

In cases of suspected progression, add additional lens clearance (such as 100µm) to avoid corneal touch.24,25

Scleral lenses are known to settle with time. The amount of settling depends on lens characteristics and individual variance and may be up to 200µm.1,4 Wait 20 to 30 minutes at the initial fitting prior to lens evaluation and over-refraction. If needed, incorporate additional sagittal depth for specific lens designs.24,25

Even with ideally fit scleral lenses, at times vision is not as good as expected when fitting patients with keratoconus, and practitioners must consider corneal scarring, lens flexure and correcting higher-order aberrations (HOAs). Although significant central corneal scarring can affect vision, scarring tends to decrease over time with scleral lenses. Practitioners can determine lens flexure with keratometry or topography over the lens and modify the design or add front surface toricity. Also consider reducing lens clearance while avoiding corneal touch or incorporating oblate designs.

Retinoscopy is useful when fitting scleral lenses and especially helpful if HOAs are present. The streak of light with retinoscopy will appear irregular or abnormal, with the possibility of a scissors reflex.24,25

While both corneal and scleral GP lenses can neutralize the irregularity of the front surface of the cornea, irregularity may still exist in the stroma and inferior cornea not managed with standard optical correction. The stability of scleral lenses makes them ideal for the correction of HOAs. For example, one study found HOAs were reduced 63% with corneoscleral lenses in patients with severe irregularity after surgery.26
Adding front surface eccentricity (FSE) to the lens surface may help to improve vision as well.\textsuperscript{27} The higher the eccentricity value, the more rapid the flattening of the lens from the center toward the periphery.\textsuperscript{28} Research suggests FSE may compensate for aberrations from the posterior surface, which may counterbalance the poor alignment of the optical axis between the patient and the lens; the eccentricity also may reestablish a prolate surface, thus improving vision.\textsuperscript{29}

With scleral lens FSE correction, investigators found a greater reduction in spherical aberration (86\%) compared with lenses without eccentricity correction (66\%).\textsuperscript{28} In 11 eyes with advanced keratoconus corrected with a custom scleral lens with wavefront-guided optics, researchers reported effective correction of HOAs.\textsuperscript{29} In seven subjects with moderate to severe keratoconus, one study found an improvement of high contrast visual acuity and a reduction of HOAs.\textsuperscript{30}

**Following Surgery**

Post-PK eyes may have irregular astigmatism and significant graft toricity and decentration, making it difficult to fit corneal lenses. Scleral lenses, by vaulting over the cornea, can be an excellent option for some patients. Still, they come with a few concerns, including graft complications and microbial keratitis.\textsuperscript{18-20}

**Pre-fit testing.** When fitting a patient after PK, the potential for corneal edema is always a concern. Prior to the fitting, practitioners should evaluate the graft with sodium fluorescein for any pre-existing abnormalities such as microcystic edema or corneal staining. Pre-existing corneal edema is a potential contraindication to scleral lens fitting.\textsuperscript{6} Careful documentation or photodocumentation is beneficial, and baseline measurements prior to scleral lens fitting will help to identify cornea edema that may arise with scleral lens wear.

Practitioners should also perform pachymetry, along with corneal topography or Scheimpflug tomography of the anterior segment prior to scleral lens fitting to determine the ideal lens design. Every graft is unique, and different designs such as prolate or oblate may be helpful for different eyes. Pachymetry is particularly helpful to check for pre-existing corneal edema. In these cases, challenge the eye with a scleral lens and remeasure pachymetry to determine if additional edema is present.

Reduced endothelial cell count can lead to corneal edema and preclude a patient from successful scleral lens wear. Thus, if there is any concern of a fragile graft, specular microscopy can help to visualize, analyze and document corneal endothelial cells. Normal
endothelial cell count is 2,500 cells/mm². However, every graft is different. In the adult cornea, the number of endothelial cells decreases with age, stabilizing at around age 50. Research suggests practitioners should avoid fitting scleral lenses with an endothelial cell count less than 800 cells/mm². To determine scleral lens candidacy, investigators suggest challenging a corneal transplant with scleral lenses wear for four to six hours prior to initiating a scleral lens fitting. If corneal edema occurs, scleral lenses are contraindicated.

**Fitting tips and tricks.** It is critical to inform all post-PK patients about the potential for scleral lens wear to exacerbate corneal edema. If a patient experiences hazy vision and sees rainbows around light sources, known as Sattler’s veil, advise the patient to discontinue scleral lens wear immediately, as discontinuing lens wear usually reverses corneal edema. It is important to differentiate Sattler’s veil from post-lens reservoir fogging, which improves with lens removal and reaplication. In addition, front surface scleral lens fogging, unlike Sattler’s veil, improves with cleaning the lens. Current scleral designs have several parameters clinicians can adjust to help patients avoid corneal edema. Consult with your laboratory to request the thinnest lens possible to prevent corneal edema. To increase tear exchange and help deliver more oxygen to the cornea, reduce the post-lens tear reservoir thickness to a minimum while still avoiding corneal touch, add back surface torticity, change the lens diameter and increase the Dk of the lens to at least 124 or higher.

If corneal edema is still present despite these changes, patients may need to reduce their scleral lens wearing time, add hypertonic sodium chloride or topical steroid drops or use a fenestrated lens. When both eyes have undergone PK, the wearing time may differ between the two eyes of the same patient. Removal and same-day reappli- cation may help extend wear time for some. It is essential to carefully monitor for early signs of complications and coordinate care with other eye care providers.

Additionally, peripheral curves that are too steep or tight may cause the lens to seal off, and practitioners will have to flatten the peripheral curves to resolve the issue. Likewise, an inadequate limbal clearance may lead to limbal compression and possibly induce corneal edema. Increasing the limbal clearance or optic zone diameter could improve the scleral lens fit.

Scleral lenses can be a great option for many irregular cornea patients. With the right pre-fit testing and with a firm understanding of the potential fitting challenges, you can successfully fit most irregular cornea patients with scleral lenses. They can go a long way to improve patients’ quality of life, visual acuity and ocular comfort.

**Dr. Barnett is a principal optometrist at the UC Davis Eye Center in Sacramento, Calif. She is a fellow of the American Academy of Ophthalmology, a diplomat of the American Board of Medical Optometry and a fellow of the British Contact Lens Association.**

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These days, soft contact lens wearers have more lens choices than ever before. With the advent of new technologies and expanded parameters in monthly lenses, an uptick in daily disposables and the tried-and-true two-week option still an economical alternative for some, how do you determine which contact lens is best?

When deciding on a replacement schedule with patients, clinicians must initiate a conversation about what the patient values and their ability to remain compliant with the replacement schedule, says Jeffrey Sonsino, OD, of Nashville, Tenn. “The literature is pretty clear about the superior safety profile of daily disposables. For this reason, we tend to prescribe more daily disposables than any other modality,” says Dr. Sonsino.1-3

Yet, not every patient values the convenience and safety profile of single-use lenses, he adds. “Whether it’s cost, perceived environmental effect or any other reason, some patients are more suited to less frequent replacement lenses. At that point, the conversation shifts to their ability to stick to a schedule.”

From cost to convenience to compliance, optometrists with successful contact lens practices weigh in on their prescribing habits, the pros and cons of each option and the key questions they ask when the patient is in the chair.

**Consideration Checklist**

Stephanie Woo, OD, of Lake Havasu City, Ariz., tries to fit all new wearers into daily disposable lenses if their prescription allows.

“Sometimes, patients come to the follow-up visit and want to be refit into a monthly lens, which can be frustrating,” she says. “If someone is happy and comfortable with their lenses, and has good ocular health, I will tend to keep them in their current lenses. I will let them know of new technologies, but I will not push them to try something new if they do not show interest.”

Dr. Woo estimates 60% of her patients are monthly wearers, with 30% in a single-use lens and the remaining 10% in two-week modalities.

For Dr. Sonsino, all new wearers in his practice who are under the age of 16 are automatically placed in daily disposables, unless he is using orthokeratology for myopia prevention and control. Patients who insist on extended wear (EW) lenses are fit with monthly replacement lenses approved for EW, he adds.
“Although there are two-week replacement lenses approved for EW, we prefer the oxygen diffusion coefficient of the monthly lens. Patients with papillary conjunctivitis are refit into daily disposables as their best option to remain in contact lens wear,” Dr. Sonsino adds. He also prescribes hybrid six-month replacement lenses for patients with astigmatism or astigmatism with presbyopia because he feels they offer benefits over soft toric lenses. With greater oxygen permeability afforded by the gas permeable core, they are also a first choice for high myopia or hyperopia, he adds.

Other prescribing considerations on Dr. Sonsino’s checklist are wearing behavior and any new changes in lens technologies.

If a patient has traditionally been a monthly wearer, Dr. Sonsino will not hesitate to recommend the single-use modality. He estimates that 50% of his patients are in daily disposables, 20% in monthlies, 20% in six-month hybrid lenses and 10% in two-week lenses.

When suggesting daily disposables, Dr. Sonsino says his practice is “not afraid to hear the dreaded word ‘no.’ If the patient chooses to stay with their current modality, we will offer the best technology monthly lens for their given history.”

Dr. Sonsino will consider the following when determining the best lens modality:
- Does the patient experience end-of-day dryness?
- Does the patient have deposit build-up?
- Are there signs of corneal neovascularization?
- Does the toric lens show signs of instability during the day?

“It is only by asking probing questions that we can find the best match. And, this keeps our patients returning every year,” he says.

A Lens a Day
The popularity of the daily replacement modality seems to be on the rise. A recent point-of-sales-data report from the market research company GfK Custom Research found that for the first time, in January 2017, sales of single-use contact lenses surpassed monthlies in dollar volume, reaching 38.1% market share worldwide.4 This was up from 31.5% in January 2016.4 In 2012, single-use lenses only represented 17.9% of the market.4

In the United States, the daily disposable lens segment continues to grow at a faster pace than any other modality, increasing 21% in dollar volume year-over-year.4 Additionally, GfK found new products and innovations continue to drive this surge in daily disposable lens sales.4 In 2016, 42% of the growth in the single-use lens category was from product launches in the prior year.4

Kambiz Silani, OD, of Beverly Hills, Calif., fits a majority of his patients in single-use lenses. “This is my lens of choice because patients wear a clean, new lens daily, reducing the chance of dry eye, ocular allergic responses and other contact not replacing soft contact lenses as directed can lead to infiltrative keratitis.
lens-related issues,” Dr. Silani says. His patients often ask for daily disposables because they are convenient, without the need for solutions or cleaning and have a simple replacement schedule, he says.

Dr. Silani estimates 65% to 70% of his patients are in single-use lenses, with the remaining split evenly between monthly and two-week options.

Some optometrists, including David L. Kading, OD, of Seattle, Wash., believe all patients should be in daily disposable lenses. The vast majority of people who wear lenses other than single-use lenses wear them improperly, which may lead to drop outs and discomfort, he says.

A recent study found that replacement noncompliance was only 12% for patients in the United States who wore daily disposables. This noncompliance rate was significantly better than patients wearing either two-week (52% noncompliance rate) or monthly (28% noncompliance rate) disposable lenses.

“We have to look at who the people are who are dropping out of contact lens wear and why they are dropping out,” Dr. Kading says. “We know discomfort and dryness are the two primary reasons.”

In selecting the best modality, solution-induced issues can be eliminated with a single-use lens, Dr. Kading explains. “By going to daily disposables, we get rid of some of the main causes of contact lens issues that result in discomfort and dryness.”

Even patients who are noncompliant with daily disposables still may be better off than those in monthly lenses, Dr. Kading adds. For example, if a patient in a single-use lens wears them for two days instead of one, this scenario is better than a monthly lens option because the patient in the single-use lens is still replacing the lens far more regularly, Dr. Kading says.

“But we certainly want to advocate for daily replacement.”

He estimates 93% of his patients are in daily disposable lenses.

Still, some optometrists do see a few downsides to the daily disposable modality. These include limited parameters for toric and multifocal lenses and patients’ preconceived ideas about cost, Dr. Woo says. Patients may also be concerned about the environmental impact.
with excess plastic and storage space required for a larger number of lenses, Dr. Sonsino adds.

“But, in my opinion, the environmental impact of dumping contact lens solutions down the drain is greater,” he adds.

The Long Game
Dr. Kading sees the demand for two-week lenses shrinking, as these lenses are comprising a smaller and smaller percentage of the market. Additionally, because the majority of manufacturers have recently introduced new monthly lenses, they are taking away some patients in the two-week market, he adds.

While Dr. Silani finds most patients are comfortable with the cost of daily disposable contact lenses and appreciate their benefits, some of his patients like the two-week and monthly replacement lenses as more affordable options.

Two-week lenses, when replaced appropriately, have less cumulative deposit accumulation than monthly replacements, Dr. Sonsino says. Additionally, two-week lenses have a wide range of available powers and some even offer UV-blocking capability. However, their technology has been around for years, and patients tend to abuse the replacement schedule more than with other modalities, Dr. Sonsino says.

Dr. Woo says the majority of her patients are either in a daily or monthly lens, and for those wearing two-week lenses, they are typically noncompliant in the replacement schedule and often will wear the lens for a month at a time.

Monthly lenses have some advantages, according to Dr. Woo, including the availability of a wide variety of material options and parameters such as power, cyl power, axis, base curves and diameters. And in general, patient compliance is good, she says. However, the monthly options are not as healthy for the ocular surface as a single-use lens, and patients tend to be less compliant than those in daily disposable lenses, she adds.

In addition, “if a patient is a part-time wearer, the lenses are stored in solution for several days, which can harbor more bacteria or other microbes compared with a daily lens,” Dr. Woo adds.

Further drawbacks with the two-week and monthly lenses include the fact that patients need to purchase solution, and the lenses must be rinsed and stored overnight, Dr. Silani says. Storage cases introduce an opportunity for organisms to flourish, increasing the risk of contact lens-related adverse events—something single-use lenses avoid. The lenses are more prone to developing deposits, and patients may develop allergies or toxicity to the solution preservatives or the lens deposits. Finally, if the patient doesn’t stick with the replacement schedule, they can increase the risk of contact lens-related issues such as corneal infiltrates or corneal ulcers, Dr. Silani says.

This patient developed a peripheral corneal ulcer due to contact lens over-wear.

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For patients disciplined in other areas of life, this is a wonderful replacement schedule, Dr. Sonsino says. But the literature is clear that the two-week modality is the most widely abused contact lens replacement schedule, he adds.

“For patients who have a more laissez-faire attitude toward structure, the monthly modality is king. Patients may be more likely to stick to a schedule that is the same each month and tie replacing lenses to another monthly activity, like receiving their paycheck. I try not to discuss connecting contact lens replacement to paying bills, as this denotes a negative activity, and we want wearing contact lenses to be a happy experience,” Dr. Sonsino says.

Fitting Extras

After Dr. Woo has determined the prescription and keratometry values, she will ask why a patient wants to wear contact lenses, how long they plan to wear the lenses during the day, if they have allergies and if they will be a full-time wearer.

For new contact lens wearers in Dr. Silani’s practice, he typically presents the three contact lens replacement options, highlights the differences and then helps the patient make the right decision for their health and lifestyle.

“For patients with busy lifestyles or pediatric patients, I commonly advise their best option is a daily, single-use lens,” Dr. Silani says. “For price-conscience patients, I typically recommend we start with a two-week or monthly modality lens knowing that we have the option to switch to daily disposables if complications arise.”

For current contact lens wearers, Dr. Silani asks the patient about their satisfaction level on a scale of one to 10 on comfort, vision and how the lenses feel in the evening. He also asks how long the patient wears the lenses during the day and what time of day the lenses begin to feel uncomfortable.

“If these patients are happy, with no complaints, as well as no signs or symptoms of contacts lens-related issues, then I renew the prescription. On the other hand, if the patient raises concerns to the questions, then I advise we switch to a hydrogen peroxide solution or switch to a daily, single-use contact lens,” adds Dr. Silani.

If there’s an issue related to the anterior segment, such as reduced tear film break-up time, giant papillary conjunctivitis or corneal staining, Dr. Silani will discontinue the contact lens wear, address the health issue, reintroduce the contact lens gradually and consider switching the patient to a single-use contact lens.

Today, optometrists have a plethora of contact lenses from which to choose. And while daily disposable lenses are pushing ahead in the market, some patients may still opt for other replacement modalities.

“While there is a huge push for daily contact lenses, the cost can be prohibitive for many patients,” Dr. Woo says. “Instead of discouraging the patients who might even opt not to wear contacts, being able to give them all their options can help patients try contact lenses if they are interested.”

Corneal topography is exceptionally useful for examining characteristics of the cornea such as shape, curvature, power and thickness. It is also an essential tool for the contact lens specialist.

Over the past 150 years, the use of corneal topography has expanded from mapping of the cornea’s curvature to evaluation of several specific corneal and ocular surface characteristics. Clinicians can use it to assess the ocular surface prior to contact lens fitting, observe how a contact lens alters the shape and quality of the cornea and tear film, and monitor the relationship between the eye and the contact lens during wear.¹

The primary technologies used in modern corneal topography are placido disc, Scheimpflug and scanning-slit topography. Here is a review of the systems and how they can help you better fit, monitor and manage contact lens patients.

Placido Disc Topography
After projecting a concentric annular light source onto the corneal surface, placido disc reflection systems capture the reflected light so their software can measure curvature, irregularities, foreign bodies, tear film nuances and other characteristics of the anterior cornea. These systems are highly dependent on the tear film, which is the part of the ocular surface that is actually reflecting light. This allows for a noninvasive measure of tear film quality, but it can also hinder accuracy when measuring corneal power and shape.

Placido disc systems can be categorized as either small-cone or large-cone systems. Small cones collect more data points and are ultimately more accurate, but large cones are easier to manipulate and data collection can be easier. Some examples of small-cone placido disc systems include the E300 (Medmont), Keratron (Optikon), Keratron Scout (Optikon) and Keratron Piccolo (Optikon), while large-cone system examples include the Keratograph (Oculus), Atlas (Zeiss) and ReSeeVit (Veatch Ophthalmic Instruments).

Scheimpflug and Scanning-Slit Topography
The primary difference in output data from a placido disc system when compared with a Scheimpflug or scanning-slit topography system is that the latter two provide information about the posterior cornea. Rotating Scheimpflug cameras, such as the Pentacam (Oculus), use off-axis light to capture precise measurements of the anterior and posterior surfaces of the cornea, allowing the system to calculate global pachymetry and allow characteristics such as corneal swelling...
to be monitored during contact lens wear.\(^2\) Scanning-slit topographers, such as the Orbscan (Bausch + Lomb), project two vertical scans through 40 optical slits at fixed angles to analyze the curvatures at the anterior and posterior corneal surface, also allowing the system to gather posterior data, including thickness.

**Contact Lens Management**

Corneal topographers collect tens of thousands of data points from the corneal surface. From these data points, power, shape and other characteristics of the cornea can be calculated. Display options for this information depend on what information is needed, which makes a thorough understanding of the different corneal topography map types important. While there are dozens of different display options in the various topography instruments, the following are the most applicable to contact lens care.

**Axial Display Map**

The most traditional way to view a topography image is with the axial display map (Figure 1). One positive of this map is that it is the best way to get a quick overview of the corneal power. It can be also misleading, however, because it averages the data to create a “smooth” map, making it less accurate than other power maps (i.e., tangential). Central data is more accurate than peripheral data on the axial map because the average of the central curvature is portrayed. For specific information about the corneal shape and power, other displays will be more helpful.

**Tangential Display Map**

The most sensitive of the power maps are tangential display maps, and as such, they measure power and curvature at individual points on the cornea the most accurately. Often, a lens fitter must be aware of the precise changes to the corneal curvature when making clinical decisions. Some indications of corneal topography will benefit from use of the tangential map display more than others. For example, tangential maps may be beneficial in orthokeratology (ortho-k), especially when evaluating the shape of the peripheral cornea, as this display provides the most accurate peripheral data.\(^3\)

Additionally, evaluating a contact lens power while it is on the eye can be done using the tangential display map, especially when a patient is wearing a multifocal lens and the positioning of the optics is important (Figure 2). The display will show the power of the contact lens over the cornea, so that an examiner can accurately observe the positioning of the lens optics or to get a better clinical picture of what optics are on the surface of the eye when the patient is wearing a contact lens. The tangential display is also the most sensitive to changes in corneal curvature caused by distortion or warpage of the cornea from contact lens wear.

**Elevation Display Map**

The go-to option for conveying the true shape of the cornea is the elevation display map. It is important to note that placido disc systems use complicated algorithms to calculate the corneal elevation, while Scheimpflug systems measure the elevation directly, so the latter system may give the most accurate data.\(^4\) Regardless, both systems output elevation in reference to a “best-fit sphere,” which is calculated and extrapolated through the cornea. The systems then calculate areas of relative elevation or depression based on the deviation from the best-fit sphere, and the deviation values are displayed in microns (Figure 3).

**Fig. 2.** These axial and tangential power maps show an eye wearing a +2.50 center distance soft multifocal lens design.

**Fig. 3.** Here is an example of an elevation map from the Pentacam.
3). In placido disc systems, only the anterior surface is measured, while Scheimpflug systems measure both the anterior and posterior elevations. Clinically, both technologies are adequate for contact-lens-related use.

This elevation display map is important when first determining the best lens design to fit on an irregular cornea, specifically when deciding between a corneal or scleral gas permeable (GP) lens. Corneal GP lenses rest on the corneal surface, so the anterior shape of the cornea is important in predicting their success. The elevation display map shows the shape of the anterior surface, which is important because as the irregularities of the cornea become greater, the surface is less likely to be symmetrical, making it difficult to fit a mostly symmetrical lens on top of the surface.

Based upon clinical experience, a difference in corneal elevation greater than approximately 325µm (between the highest peak and lowest point of elevation) will lead to limited success with corneal GP fit stability. GP lenses fit onto a cornea with these levels of elevation difference will rock on the eye, fall out of place intermittently and often cause discomfort and visual instability in wearers.

Individuals with this amount of elevation variation will likely need a scleral lens, which is less sensitive to corneal elevation differences because they vault the cornea.

The elevation display map is also useful in ortho-k management. Evaluating this map at baseline will allow practitioners to determine if the corneal shape is regular enough to support an ortho-k lens. More specifically, it will help them decide whether to use a dual-axis or single-axis lens. A patient with astigmatism will have differences in elevation between the two major meridians. If this difference in elevation is greater than about 15µm between the meridians, a dual-axis option will be needed to ensure the same depth remains evenly distanced from the cornea throughout the entire return zone. In ortho-k, this is essential to ensure even distribution of the displaced cells.

**Corneal Thickness Display Map**

Pachymetric capabilities are only available in Scheimpflug cameras and scanning-slit topographers, since these instruments measure posterior as well as anterior surface characteristics. This display can be used to stage diseases (i.e., keratoconus), but in active contact lens wear, the primary use of this display is to monitor corneal thickness changes due to contact lens-related hypoxia.

Evaluating corneal thickness changes during contact lens wear is important for scleral lens wearers, as they may be more prone to hypoxic complications. The corneal thickness display map is helpful for these patients (Figure 4).3-8

The corneal thickness display map can also be beneficial in ortho-k management, allowing practitioners to monitor corneal thickness changes as tissue is displaced from central to peripheral. This is a great supplement to the tangential and elevation displays and can be valuable when making determinations about lens fitting. When ortho-k lenses for myopia are worn, tissue is moved from the central cornea to the periphery. As a result, the central cornea will become thinner and the peripheral cornea thicker. The sensitive global pachymetry measurements can show if there is asymmetry in the movement of tissue centrally to peripherally.

**Tear Break-up Display**

Among the most novel options on modern topography instruments for contact lens management are tear break-up displays (Figure 5).

Noninvasive tear break-up scores can be measured prior to initiating contact lens wear to gauge the quality of the natural tear film and see how it is affected by contact lens wear.4 A measurement is taken prior to lens wear and then compared to the subsequent measures to see how tear film quality is objectively affected in lens wearers with and without the lens in place.

Tear break-up displays can also be used when taking topography over the top of a contact lens. The surface wettability of the lens can be indirectly evaluated using this display, and a quantitative score will allow monitoring over wear time.

In addition, some instruments allow for video recording broken down by frames per second. This allows practitioners to dynamically evaluate changes in the tear film quality as patients blink.

**Additional Features**

Beyond the various displays that can be applied to contact lens management, many modern topography systems have additional features that
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are applicable to contact lens care.

Contact lens fitting software allows practitioners to simulate a contact lens on the ocular surface and empirically order lenses that incorporate the entire shape of the cornea, including peripheral eccentricities, to provide a more customized contact lens fit. These programs have been shown to be effective at predicting the fit of a corneal keratoconus lens.10

Design-specific software, in which practitioners can upload topography images to simulate lens fits prior to ordering, is also available through lens manufacturers. These programs are most useful with corneal GP fitting, as the base curves of irregular corneas are not as predictive of scleral fitting.11

The OxiMap feature of the Keratograph calculates the Dk profile of specific contact lenses, and since the Dk is usually reported for powers of -3.00D only, this is useful information when practitioners want to know the specific Dk in all areas of the lens. This feature also aids practitioners in understanding the Dk profile of high-power lenses, or when fitting patients who are prone to hypoxic complications.

Many topography systems feature photography. These instruments are capable of snapping photographs of the iris and pupil behind the cornea in addition to the cornea. Practitioners can use these photographs to measure pupil size and centration. When fitting bifocal lenses for presbyopia and myopia control, this feature allows practitioners to match pupils to the optics of the lens, maximizing the understanding of optic placement for each individual. From this, practitioners can also calculate horizontal visible iris diameter and glean information about eyelid placement in relation to the cornea and pupil.

Meibography can be done using some topography systems to show changes in meibomian gland (MG) quality throughout contact lens wear. There is some evidence that the amount of MG atrophy may be greater in chronic contact lens wearers, and patients with MG atrophy may experience reduced comfort, so a system to monitor MG quality could help practitioners confirm a correlation.12-15

Meibography images also allow for subjective MG evaluation, and enhancements of the resulting images can reveal the location of tortuosity and atrophy.

Aberrometry can also be used on many topography systems to troubleshoot visual dissatisfaction with contact lenses. If a patient has nonspecific visual complaints, taking these measurements with and without contact lenses in place can help determine which modality is most appropriate. If an excess amount of aberration exists prior to contact lens wear, the patient will be best suited for a rigid modality. Aberrometry taken over a contact lens will show how well a lens is able to correct higher-order aberrations.

Corneal topography is an established and important technology for measuring the shape and power of the cornea. It allows practitioners not only to fit contact lenses to match the power and shape of the cornea, but it also helps them to evaluate intricacies of the contact lens relationship with the ocular surface. As these systems continue to develop modules to better evaluate corneal surfaces and tear film, practitioners can provide more specific and advanced management to their contact lens patients.
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Practitioners can confirm a case of suspected Horner’s syndrome through in-office pharmacological testing in a straightforward manner, but differentiating benign from life-threatening causes can pose a significant challenge. Symptoms and signs, along with a thorough patient history and review of systems, can help the clinician localize a potential causative lesion and, in turn, help direct neuroimaging studies and subsequent referral to an appropriate specialist.

Beyond the Cookbook
All optometrists can recite the classic triad of -osis findings associated with Horner’s syndrome: ptosis, pupillary miosis, facial anhidrosis. Some cases can also include heterochromia of the irides if the syndrome developed prior to two years of age. Often, patients will display a dilation lag in dim illumination; that is, the affected pupil will slowly dilate and the anisocoria will diminish after several minutes in a dark room.

However, not every case of Horner’s syndrome will manifest classically; a “cookbook” approach to diagnosis is insufficient. It is incumbent on the clinician to use every clue in the presentation to suspect Horner’s syndrome may be present. In such cases, the dilation lag may be quite helpful in prompting pharmacologic testing.

Knowledge of the relevant anatomy is critical to localize the cause of confirmed Horner’s syndrome. A three-neuron arc provides sympathetic innervation to the eye. Horner’s syndrome is an interruption along this oculosympathetic pathway, between its origin in the hypothalamus and the ipsilateral dilator muscle of the eye. The first-order neuron originates in the hypothalamus, where it descends through the brain stem to the ciliospinal center of Budge, between C8 and T4 of the spinal cord. At this level, it synapses with the second-order neuron whose preganglionic cell bodies give rise to fibers that exit the spinal cord through the ventral spinal root; from here, they pass over the apex of the lung and enter the sympathetic chain in the neck, where they synapse in the superior cervical ganglion.

There, in the superior cervical ganglion, cell bodies of third-order neurons give rise to postganglionic fibers that travel with the internal carotid artery through the cavernous sinus towards the eye. These postganglionic fibers form the long posterior ciliary nerves,
which course with the branches of the fifth cranial nerve to inner- 
vate the iris dilator muscle, Müller’s muscle and lacrimal gland.\textsuperscript{1,9}  
Additionally, post-ganglionic sympathetic fibers, responsible for 
facial sweating, follow the external carotid artery to the sweat 
glands of the face.\textsuperscript{1-8}

**Pharmacological Testing**  
Historically, topical liquid 10\% cocaine was used to identify the 
presence of Horner’s syndrome, and topical hydroxyamphetamine 
was used to aid in localizing a postganglionic lesion.\textsuperscript{4,8,10} Today, 
these agents are not practically available; instead, the diagnosis of 
a suspected Horner’s syndrome can be confirmed by pharmacological 
testing with apraclonidine 0.5\% or 1\%.\textsuperscript{4,8,10}  
In Horner’s syndrome, the 
affected pupil and levator undergo 
denervation hypersensitivity.\textsuperscript{10-15} Apraclonidine is an alpha-2 adrenergic agonist that also acts as a very 
weak alpha 1-adrenergic agonist; when topically applied in Horner’s 
syndrome, it causes dilation of the affected pupil and possibly lid 
elevation, without change to the normal pupil.\textsuperscript{10-15} These changes 
are so dramatic that a ‘reversal’ occurs; the normal pupil and lid 
now appear ptotic and miotic in comparison with the apraclonidine-
positive eye.  
Although sensitivity of apraclonidine testing is very good, false 
negative testing with apraclonidine may occur in acute Horner’s syn-
drome as the test relies on denerva-
tion hypersensitivity, which may 
not have had time to occur.\textsuperscript{12,13} However, there are reports of posi-
tive apraclonidine tests within a few hours of the onset of symptoms 
related to Horner’s syndrome.\textsuperscript{14,15} Again, if the findings are equivocal 
but suspicion still high, one must go with clinical intuition and inves-
tigate further.

**Finding the Cause**  
A careful physical exam and patient history can help guide 
imaging studies to aid in determining the location of the lesion.\textsuperscript{19}  
Once Horner’s syndrome is diagnosed 
(such as with a positive apraclonidine test), 
a directed evaluation is always preferable 
to non-specified testing. This is where 
knowledge of anatomy, symptoms and associ-
ated finding becomes crucial. For example, if 
there is a positive history of neck or facial 
pain, headache, recent 
neck trauma, ipsilateral 
vision loss or transient numbness or weakness on the opposite side 
of the body, an astute clinician should suspect acute carotid artery 
dissection and order emergent neuroimaging.\textsuperscript{18-22}  
In cases caused by internal carotid artery dissection, significant 
risk exists for major stroke within the first two weeks of onset.\textsuperscript{18-20} 
Computed tomography (CTA) or magnetic resonance angiography 
(MRA) of the neck and cervical spine, which must include Circle of 
Willis and the orbits down to the level of the aortic arch (T4-T5), 
which includes the carotid arteries 
and intracranial vessels as well as lung apices, is recommended.\textsuperscript{16,22}  
For cervical arterial dissections, 
CTA is the preferred imaging 
modality as, though MRI shows 
resolution with high contrast, it has 
lower temporal and spatial resolu-
tion.\textsuperscript{23}  
In cases involving acute pain 
with onset of Horner’s syndrome, 
the patient requires emergency 
referral with imaging performed
After Apraclonidine: The Next Steps

Once the apraclonidine test is positive for Horner’s syndrome, here are the next four steps in your clinical workup:

**Step 1: Probe the patient’s history to see if the lesion can be localized.** Any head, neck or eye pain can be suspicious for internal carotid artery dissection. Facial weakness or numbness generally localize to abnormalities within the middle cranial fossa. Tobacco history can cause concern for cancer at the lung apex. Other lung pathology may indicate sarcoidosis or tuberculosis. Dermatologic vesicles and neuralgia can identify zoster as a cause. Cluster migraines also can cause Horner’s syndrome. Thus, a physical examination and history, often done in concert with an internist, help dictate management.

**Step 2: Look for other neurologic signs.** Cranial nerve VI palsy in association with Horner’s syndrome identifies cavernous sinus as an area of interest, but does not rule out a brain stem lesion. Current or past history of optic neuritis can indicate MS.

**Step 3: Look at the age of the patient.** Young people can suffer from MS and older people can suffer from stroke. Always assess GCA risk in patients older than 60.

**Step 4: Obtain the appropriate imaging.** It’s best to image the area of suspicion as identified above. If that is unrevealing, the patient must be imaged from chest to head including MRA or CTA of neck for carotid dissection, MRI of brain with and without contrast with attention to middle cranial fossa and cavernous sinus, and chest/neck MRI or CT to include the brachial plexus and cervical spine. Non-targeted evaluations are often non-productive, but still recommended to rule out treatable pathology. Unless the patient has an emergency situation regarding carotid dissection, consider referring to a primary care physician or neurologist for an overall health evaluation with consideration for these conditions.

**Carotid artery dissection, which affects the third-order neuron, can result from relatively minor trauma, or can occur spontaneously in patients with histories of connective tissue disease such as Ehlers-Danlos syndrome, Marfan’s syndrome or those with long-standing hypertension.**

In patients with histories of tobacco use, ipsilateral shoulder or arm pain or muscle weakness of the hand and arm, localization could lead to a lesion at the apex of the lung. As the oculosympathetic plexus courses over the apex of the lung via the second-order neuron, multiple pulmonary pathologies can cause Horner’s syndrome. For instance, Pancoast syndrome is a malignancy of the superior pulmonary sulcus most often caused by non-small cell lung carcinoma. Pancoast tumor has a rapid and high mortality rate.

Neuroradiological evaluation, typically including MRI of the chest and neck with and without contrast, and physical examination, often performed in concert with an internist, may lead to other chest and lung pathologies, including sarcoidosis or tuberculosis. Suspicion of cancer warrants a referral to primary care.

**Other Neurological Signs**

In patients presenting with abducens (cranial nerve VI) palsy in addition to Horner’s syndrome,
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clinicians should pay attention to the cavernous sinus.1,12 The oculосomatosympathetic plexus travels with the abducens nerve within the cavernous sinus.1,12 MRI of the brain with and without contrast, with attention to the middle cranial fossa and cavernous sinus, is warranted.

However, lesions of the first-order neuron including brain stem lesions in Horner’s syndrome may also cause abducens nerve palsy, so additional clinical signs and symptoms can aid in localization. Patients with first-order neuron Horner’s syndrome typically present with widespread neurological symptoms including contralateral hemiparesis, contralateral hypesthesiap and hypohidrosis of one side of the body.1,13 Pontine lesions such as stroke may additionally result in dizziness, nausea and difficulty swallowing.17 In cases of nystagmus, vertigo and vomiting—in addition to Horner’s syndrome, lateral medullary infarction or Wallenberg syndrome—may be present.15 Horner’s syndrome with trochlear (nerve IV) palsy suggests the dorsal mesencephalon is an area of interest for clinicians to investigate.19

In cases of Horner’s syndrome, consider the age of the patient. In younger patients, demyelinating disease, including MS, can be a potential cause of Horner’s syndrome. In older patients, stroke, zoster and GCA are etiologies that practitioners should consider.1,12

When no diagnostic clues are identified following a complete clinical examination, a non-targeted evaluation, including imaging of the upper chest, neck and brain, must be performed.15-17 MRI of the neck and chest including the lung apex, MRA or CTA of the neck and cervical spine, and MRI of the brain, with attention to the middle cranial fossa, is recommended. Imaging centers may have a protocol for dealing with Horner’s syndrome to ensure that proper studies are done. In many cases, even with extensive imaging, an underlying cause may not be determined.9-15

With any radiology referral, it is important to provide the neuroradiologist with all available localizing information available—including the anatomical location of Horner’s syndrome—to allow for clinical-radiologic correlation.11 Remember, a neuroradiologist cannot help you if you do not:

1. order a scan,
2. order the correct scan, and
3. specify what you are looking for.

Once Horner’s syndrome has been identified with a positive apraclonidine test, the real work begins. Optometrists must use their knowledge of anatomy and rely on the history and clinical exam to determine potential causes, send to an emergency room when appropriate, order necessary diagnostic testing and communicate with other medical specialists when necessary.

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TIME TO UPDATE YOUR 
PLAQUENIL SCREENING PROTOCOL

The sooner you diagnose hydroxychloroquine-induced macular toxicity, the better. New guidelines can help. By Beth Norris, OD, and Sara Henney, OD, with Sara Weidmayer, OD

Plaquenil (hydroxychloroquine, Sanofi-Aventis) has been used as anti-rheumatic drug therapy for conditions such as systemic lupus erythematosus (SLE) and rheumatoid arthritis for years, despite its risk of irreversible macular toxicity. Historically, patients have been monitored using subjective measures such as visual field testing and objective findings during fundus examination, often leading to diagnosis of late-stage toxicity. However, it is crucial that clinicians identify the earliest signs of toxicity, as the risk of progressive vision loss extends even after discontinuation of Plaquenil. This is where new guidelines and advanced technology can help.

This article discusses the risks associated with Plaquenil therapy and the updated American Academy of Ophthalmology (AAO) guidelines designed to help clinicians better detect and monitor macular toxicity associated with long-term Plaquenil use. Several diagnostic tools are key to detecting macular toxicity as early as possible. Because fundus photography does not identify early findings, it is no longer a recommended screening tool.

Because fundus photography does not identify early findings, it is no longer a recommended screening tool.
early as possible to ensure discontinuation of the drug before adverse sequelae threaten patients’ vision.

New Guidelines
In 2016, the AAO published updated ocular examination guidelines for screening patients on Plaquenil therapy (Table 1). Recommended testing still includes a comprehensive eye exam with dilated funduscopy, as well as 10-2 sita standard (ss) visual field (VF) testing using a white stimulus within the first year of use. A white stimulus is recommended over a red stimulus as it provides a pattern deviation plot and can distinguish regional loss from background sensitivity. The baseline examination should also include one objective test such as spectral-domain optical coherence tomography (SD-OCT), multifocal electroretinogram (mfERG), fundus autofluorescence (FAF) photos or a combination of the three. The guidelines no longer recommend supplemental screening tools such as fundus photography, Amsler grid, color vision, time-domain OCT, full field electroretinogram and electro-oculogram.1

The new guidelines recommend a maximum daily Plaquenil use of less than or equal to 5.0mg/kg/day of real weight, as opposed to ideal weight, as it correlates better with risk of toxicity. Researchers now know the drug is retained in adipose tissue, and short-statured or thin patients may be significantly overdosed if based on ideal weight. Risk is most accurately assessed on the basis of duration of use relative to daily dose by weight. However, wider test patterns (24-2 or 30-2) are needed for Asian patients in whom toxicity often manifests beyond the macula.2 Since these guidelines suggest additional testing, clinicians should educate patients of Asian descent on the need for more follow ups to perform the additional field testing.

The Risk
Although Plaquenil has a relatively safe systemic profile overall and Plaquenil macular toxicity is rare, clinicians must be cognizant of its potential for visual devastation. The 2016 AAO guidelines state the overall prevalence of toxicity in a five-year study population to be 7.5%—updated from the 2011 prevalence of 1% after five years of Plaquenil treatment.1,2

Each patient’s risk depends on daily dose and duration of use. At recommended doses (<≤ 5.0mg/kg/day of real body weight), the risk of toxicity is less than 1% up to five years and less than 2% up to 10 years.3,4 However, this rises dramatically to almost 20% after 20 years of treatment.1,3 If the patient is taking the standard 400mg dosing per day, the calculated cumulative dose at seven years would be 1,022g.4

Thus, patients who are taking higher dosages for longer durations are at an increased risk for developing both structural and functional changes.

In addition, many patients taking Plaquenil may concurrently be on methotrexate for the management of their autoimmune condition. Research shows these patients are at risk for optic neuropathy as well as Plaquenil toxicity.4 Thus, all Plaquenil screening protocols should be followed as well as periodic SD-OCT RNFL to monitor for optic neuropathy. These patients also should take folic acid to help mitigate this risk.

Screening
The AAO guidelines recommend patients receive a baseline examination within the first year of Plaquenil use and an annual screening after five years of use, or earlier in higher risk patients (Table 2).1 Those at higher risk include patients taking a daily dose greater than 5.0mg/kg of real weight, more than five years of use, renal disease, concomitant tamoxifen use or macular disease.1 In a recent demographic study, researchers determined that age and risk of toxicity have no significant association, as elderly patients do not have less resistance to the toxic effects of Plaquenil.1 While the liver participates in the clearance of Plaquenil, no clear connection between liver disease and toxicity has been demonstrated.

The 2011 AAO guidelines recommended that concomitant macular disease be an exclusion criteria for Plaquenil use, as it masks the early signs of toxicity and renders screening less effective or impossible.5 Patients with underlying macular disease that interferes with the interpretation of screening tests should avoid taking Plaquenil.

As the risk increases two-fold

Table 1. AAO 2016 Revised Screening Guidelines for Plaquenil Toxicity1

<table>
<thead>
<tr>
<th>Baseline exam—perform within one year of initiating treatment</th>
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<tbody>
<tr>
<td>Perform:</td>
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<tr>
<td>Visual acuity</td>
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<tr>
<td>Dilated fundus exam</td>
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<tr>
<td>10-2ss visual field (white stimulus)</td>
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<tr>
<td>24-2ss or 30-2ss visual field (white stimulus) for Asian patients</td>
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<tr>
<td>One objective test:</td>
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<tr>
<td>SD-OCT</td>
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<td>mfERG</td>
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<td>FA</td>
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*Annual screening for toxicity will follow these same guidelines, and should begin five years after initiating Plaquenil therapy.
Case 1

A 44-year-old Hispanic female presented to the clinic for a yearly comprehensive eye examination without visual complaints or ocular discomfort. Her ocular history was remarkable for Plaquenil macular toxicity in the left eye.

Her medical history was significant for SLE, which was diagnosed 15 years earlier. For the last 14 years, she took 200mg Plaquenil BID. Her estimated cumulative dose was 1,080g. At her last visit one year ago, she was advised to discuss with her rheumatologist discontinuation of Plaquenil treatment secondary to findings of early toxicity. She is now taking methotrexate 250mg per week to replace Plaquenil.

On examination, her best-corrected visual acuity measured 20/20 OU. Her pupils were equally round and reactive to light with no afferent defect. Confrontation visual fields were full to finger counting OU, and ocular motility testing was normal.

The anterior segment examination was remarkable for a reduced tear film and trace papillae OU. Her intraocular pressure (IOP) measured 15mm Hg OU.

On dilated fundus examination, her optic nerves appeared healthy with average-sized cups with shallow slopes and good rim tissue and perfusion OU. The vessels were of normal caliber, and her peripheral retina was remarkable for a congenital hypertrophy of the retinal pigment epithelium (RPE) in the left eye. We noted changes in the RPE nasal paracentral to the macula in the left eye on the FAF photos (Figure 1). We also performed an SD-OCT of the macula (Figure 2).

The patient has been followed with 10-2ss VF testing since the initial 2014 field, which showed a few scattered paracentral defects. The patient discontinued Plaquenil one week after the 2014 VF due to the signs of early toxicity. When the 10-2ss testing was repeated a year and a half later in 2016, it showed diffuse central/paracentral defects that had progressed since the patient had discontinued the medication (Figure 3).

The patient returned to the clinic three months after the 2016 VF testing, for an mfERG to better monitor the changes since discontinuing Plaquenil for more than a year (Figure 4). The mfERG showed evidence of macular depression in the left eye worse than in the right. No further treatment was recommended, considering long-term discontinuation of Plaquenil was already recommended one year prior.

We determined the patient had Plaquenil macular toxicity in the left eye, and the mfERG confirmed subclinical macular involvement in the right eye but did not have any signs of optic neuropathy in either eye. She is being followed closely every six months and is taking folic acid to mitigate this risk.
from five to 10 years of use, high-risk patients, once they reach a cumulative dose of 1,000g, should be monitored more frequently for retinal toxicity.1,2

Because of the decreased clearance of medication, patients with renal disease have an increased risk of circulating levels of Plaquenil. Clinicians must remain cautious with these patients, as they have unpredictably high blood-drug concentration levels and need close monitoring with more frequent follow-up visits.

Although the mechanism of action is unclear, patients undergoing concurrent tamoxifen treatment have a five-fold increased risk of toxicity.1 Concomitant use should be avoided, but if it is unavoidable or advised by the patient’s rheumatologist, these patients require more frequent follow-up visits for retinal toxicity.1

**The Particulars of Dosing**

Calculating a patient’s dosing is first determined by commencement date of medication and daily dosing, based on their current body weight (in kilograms). According to the 2016 AAO guidelines, 5.0mg of Plaquenil per kg (of real weight) per day should be therapeutically effective for most patients (Table 3).1

**What to Look For**

The most common subjective patient symptoms in early stages of toxicity include difficulty reading, photophobia, metamorphopsia and reduced color vision.5,6 In later stages peripheral visual field loss and photopsia have been reported.5,6

The mechanism of action of Plaquenil is not well established, although research suggests Plaquenil alters the RPE lysosome PH, resulting in higher levels of lipofuscin, which has been associated with photoreceptor degeneration.6 In addition, Plaquenil binds to melanin of the RPE, which may serve to concentrate the agents and contribute to, or prolong, their toxic effects. Clinical findings in the anterior segment may reveal vortex keratopathy, which typically does not impact vision and is reversible after cessation of Plaquenil within six to eight weeks.5 The earliest clinical signs associated with Plaquenil toxicity are subtle changes at the macula that may be visualized as fine pigmentary mottling. In its late presentation, Plaquenil toxicity progresses to a symptomatic para-central, and eventually central, scotoma with a characteristic bull’s eye maculopathy.6

Once there is evidence of toxicity, Plaquenil should be permanently discontinued, since its toxic effect is related to cumulative dose and could cause a permanent central scotoma, blindness or both. Because functional damage can occur prior to structural damage, early detection is key to reducing the patient’s risk of going blind.

**Diagnostic Tools**

When patients are taking Plaquenil long-term, clinicians can use SD-OCT and FAF to objectively monitor for possible retinal changes. However, evidence suggests electrophysiological changes occur prior to the structural changes identified on SD-OCT and FAF—indicating a need for earlier testing for high-risk patients.7 Both the 2011 and 2016 AAO guidelines suggest mfERG testing is an effective adjunct test.1,2 These specialized ancillary tests often make it easier to diagnose Plaquenil toxicity.

Automated threshold visual fields. The 10-2ss VF test is quite sensitive in reliable patients, but some tests are more reliable than others. The new guidelines recommend performing 10-2ss VF testing on non-Asian patients, and a wider test pattern (i.e., 24-2 or 30-2) in addition to 10-2 for Asian patients secondary to the risk of toxicity beginning beyond the central macula.

Proper field interpretation is key, as loss can be both parafoveal and extrafoveal. Also, any abnormality on the VF should be taken seriously. Uncertain VF changes should warrant retesting for both reliability and repeatability. If VF testing is inconclusive, the practitioner should

**Table 2. Factors Increasing the Risk of Plaquenil Retinopathy**

| Daily dosage | > 5.0mg/kg real weight |
| Duration of use | > 5 years, assuming no other risk factors |
| Renal disease | Subnormal glomerular filtration rate |
| Concomitant drugs | Tamoxifen use |
| Macular disease | May affect screening and susceptibility to Plaquenil |
consider evaluating with other objective tests, such as SD-OCT, FAF or mfERG.

SD-OCT. As early damage from Plaquenil occurs, SD-OCT shows localized thinning of the photoreceptor layers in the parafoveal region in non-Asians and near the arcades in many Asian eyes. An abnormality at the inner-outer segment junction on SD-OCT indicates structural change, which may appear before, concurrently or after functional change on VF testing. Researchers describe SD-OCT parafoveal defects associated with Plaquenil toxicity as a “flying saucer sign,” which is a late manifestation. SD-OCT may not be as sensitive as VF testing or mfERG, but when all ancillary testing is taken into consideration, this should allow for earlier detection of Plaquenil toxicity.

SD-OCT is readily available in most offices, making it one of the most common testing modalities; however, one study suggested OCTs remained normal while VF 10-2 indicated parafoveal ring scotomas in 10% of toxic cases. At the same time, the researchers found no cases in which the opposite was true, when RNFL loss in the central five to 10 degrees was evident with OCT but showed no corresponding vision loss on the VF testing.

FAF. With Plaquenil toxicity, research shows FAF has an increased signal with increased accumulation of lipofuscin and a decreased signal, indicative of RPE loss. Early Plaquenil toxicity can start as a fine pericentral ring of hyperautofluorescence, which can progress to pigment mottling and, subsequently, generalized hypoautofluorescence due to loss of pigmented epithelium. These changes can be more subtle than those found on SD-OCT.

In one study, investigators looked at the ability of trained clinical observers to correctly indicate toxicity based on FAF or SD-OCT and found a 73.7% correlation of FAF abnormalities with toxicity and an 84% correlation of loss or disruption seen on the OCT with correlating toxicity.

mfERG. This imaging technique can help to detect local variations in retinal function in multiple areas, by detecting the combined responses of photoreceptors, bipolar cells and

Case 2

By Sara Weidmayer, OD

A 67-year-old Caucasian male with seropositive rheumatoid arthritis was evaluated to rule out macular toxicity given chronic Plaquenil use. He had taken 400mg/day from 2002 to 2010, at which time he was decreased to 200mg/day until 2015 when the dose was again increased by his rheumatologist to 400mg/day. He weighed 128.9 pounds at that time, so 400mg/day was equivalent to 6.83mg/kg actual weight/day, and his cumulative dose was approximately 1,546g; both his current and cumulative dosages put him at higher risk of developing toxicity.

He had no ocular or visual complaints. He had been monitored annually in our clinic for many years given his Plaquenil use, and there had been no evidence of Plaquenil-induced ocular toxicity to date. His baseline visual fields with white stimulus were normal.

On dilated fundus exam, findings in the right eye were normal, but the left eye’s macula was noted to have a subtle granular appearance to the superior parafovea. His macular OCT was normal with a full ellipsoid zone in both eyes. However, VF testing indicated decreased paracentral sensitivities in both eyes (Figure 1). Due to the concerning VF results, the patient was instructed to return as soon as possible for repeat, confirmatory testing including macular OCT, VF and photographs with autofluorescence. An mfERG at this point would have been ideal, but was not readily available.

On follow up, his exam findings were stable and he had repeatable (though somewhat varied) VF defects. Photographs and autofluorescence imaging were unremarkable parafoveally. We contacted the patient’s rheumatologist with the recommendation to permanently stop Plaquenil use due to clear evidence of macular toxicity. Because visual loss from Plaquenil toxicity can continue to progress, even after the cessation of the medication, the patient has been followed at six-month intervals for monitoring. This case demonstrates why both structural and functional testing is important when evaluating for Plaquenil toxicity.

Dr. Weidmayer practices at the VA Ann Arbor Healthcare System in Ann Arbor, Mich., and is a clinical instructor for the University of Michigan Department of Ophthalmology and Visual Sciences.

Fig. 1. A 10-2 VF with white stimulus OD and OS shows reduced sensitivities paracentrally.
Müller cells. It extracts hundreds of focal ERGs from a single electrical signal, creating a topographic map of retinal activity that allows clinicians to accurately assess a small area of the central retina.

Research suggests mfERGs can be sensitive enough to detect these variations in early Plaquenil toxicity. The retinal function is measured monocularly in response densities or amplitude per unit retinal area. These amplitudes are measured from the first negative wave to the first positive wave, in concentric rings from the center of the retina to the periphery. This format can detect central and pericentral depression, even when visual acuity and fundus findings are normal.2,10

Plaquenil toxicity shows a paracentral depression, or a decrease in amplitudes with prolonged implicit times associated with ring two (which correlates to the intersubfield of the OCT or the central five to 10 degrees).2,10

In one study, researchers used mfERG to confidently reassure patients of normal functioning retinas when a VF was abnormal; they also demonstrated that early Plaquenil electrophysiological changes may be reversible when the drug was discontinued early.11

Other researchers suggest that a paracentral decrease in amplitudes and increase in latency on mfERG may be more specific to Plaquenil toxicity than VF testing and SD-OCT, allowing for the differentiation of maculopathy vs. vision loss from an optic nerve pathology. They conclude that mfERG testing may be a reliable objective test with good specificity for detecting and tracking Plaquenil toxicity.5

Yet another study found that the high false-positive rates of some studies suggest that cases detected by mfERG may be subclinical examples of retinopathy at risk of progressing to disease detected on other, morphology-based tests. Furthermore, the study suggests detectable electrophysiological changes precede morphological changes evident on other structural testing modalities such as the SD-OCT or FAF.7

One study suggested mfERG as the new standard testing modality for Plaquenil toxicity.5 mfERG diagnostic testing is both an objective measure and an evaluation of the retinal performance, possibly indicating its usefulness as a solitary screening tool.

### Repeat Testing

Researchers have noted progressive damage after cessation of Plaquenil treatment up to three years after discontinuation.12 This suggests the need for repeating 10-2 VF testing after cessation of the medication. Early detection of Plaquenil toxicity is known to prevent visual acuity loss and serious progression after the therapy is stopped.13

The inconsistency of abnormalities seen on FAF, OCT and 10-2 VF testing and interpretation indicates the need for a better screening method. The untrained eye may not see changes in an atypical, high-risk patient, or may associate early changes to poor reliability during automated perimetry testing.

Many clinicians may even dismiss early changes as inconsequential. But when these tests are taken in conjunction with one another, the specificity is quite high for detecting Plaquenil toxicity.

Regardless of the guidelines, clinicians should tailor the testing based on the individual patient. The bottom line for Plaquenil toxicity

### Sidelined Screening Tools

Prior to the 2011 AAO guideline, other ancillary testing was considered as part of the screening protocol. The following tests are no longer recommended:

- **Fundus photography.** The clinician may choose to take fundus photos to establish a baseline and monitor for other maculopathies, but the AAO guidelines indicate photos are not sensitive enough to detect early Plaquenil changes.2,6

- **Amsler grid.** Amsler grid monitoring is no longer recommended because most patients lack the understanding of how to perform the test accurately. In addition, patients are often unable to reliably discern the subtle changes associated with Plaquenil toxicity, unlike with wet AMD.2,6

- **Color vision.** Clinicians may perform color vision testing, although it is recommended only at the initial baseline to rule out congenital color defects. The AAO guidelines also stress that color vision defects can be associated with many maculopathies and neuropathies, making it non-specific to Plaquenil toxicity.2,6

---

**Table 3. Calculating Daily and Cumulative Dosage of Plaquenil**

<table>
<thead>
<tr>
<th>Daily dosage</th>
<th>Cumulative dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>= ((\text{mg/day}))</td>
<td>= Number of years (\times 0.400\text{g/d} \times 365\text{d/yr})</td>
</tr>
<tr>
<td>([\text{weight (pounds)}/2.2 \text{pounds/kg}])</td>
<td></td>
</tr>
</tbody>
</table>

**Example:**

\[
400\text{mg/day} \times \left(\frac{220 \text{ lbs}}{2.2 \text{ pounds/kg}}\right) = 400\text{mg/kg/day}
\]

**Example:**

\[
10\text{yrs} \times 0.400\text{g/d} \times 365\text{d/yr} = 1460\text{g}
\]
screening is simple; clinicians must recommend discontinuation of the medication at the earliest signs of toxicity, as this can result in permanent and progressive vision loss.

Drs. Norris and Henney are staff optometrists at the VA Health Care System in Orlando.

The authors would like to thank Saad Shabbik, MD, MBA, for his help collecting and interpreting the multifocal ERG testing.

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According to the 2016 AAO guidelines, Asian patients on Plaquenil should do yearly 30-2 visual field testing due to damage beginning:

- Extramacularly
- Centrally
- Peripherally
- a and c.

Which of the following tests is no longer required, according to the 2016 AAO guidelines?

- SD-OCT.
- mfERG.
- 10-2s VF.
- Color vision.

The 2016 AAO guidelines state the overall prevalence of Plaquenil toxicity in a five-year study population was:

- 7.5%.
- 1%.
- 5%.
- 15%.

On SD-OCT, the clinician should be looking for interruption in the:

- Inner-outer segment junction.
- Photoreceptor layer.
- Inner plexiform layer.
- d. a and b.

Which of the following tests is still recommended as a screening tool for Plaquenil toxicity?

- Amsler grid.
- Color vision.
- Fundus photography.
- d. 10-2s VF white stimulus.

The most common subjective patient symptoms in early stages of Plaquenil toxicity include all of the following except:

- Difficulty reading.
- Photophobia.
- Metamorphopsia.
- Scotoma.

Because the risk increases two-fold from five to 10 years, high-risk patients should be monitored more frequently when they reach a cumulative dose of:

- 800g.
- 1,000g.
- 1,500g.
- 2,000g.

What ring segment on the mfERG is affected in Plaquenil toxicity?

- Ring A.
- Ring two.
- Ring three.
- d. All rings.

What does the mfERG demonstrate in a patient with Plaquenil toxicity?

- Scotoma.
- Amsler grid.
- Color vision.
15. All of the following is true about Plaquenil toxicity at recommended doses except:
   a. The risk of toxicity up to five years is less than 1%.
   b. The risk of toxicity up to 10 years is less than 2%.
   c. The risk of toxicity rises dramatically to almost 20% after 20 years of treatment.
   d. The risk of toxicity rises dramatically to almost 25% after 20 years of treatment.

16. The 2016 AAO guidelines recommend patients get a baseline examination within ____ of Plaquenil use and an annual screening after ____ of use, or earlier in higher risk patients.
   a. One year, two years.
   b. Five years, one year.
   c. One year, five years.
   d. Two years, two years.

17. Those at higher risk for Plaquenil toxicity include:
   a. Daily dose >5.0mg/kg of real weight.
   b. More than five years of use.
   c. Patients with renal disease.
   d. All of the above.

18. Clinical findings of Plaquenil toxicity in the anterior segment may include:
   a. Band keratopathy.
   b. Narrow angles.
   c. Vortex keratopathy.
   d. None of the above.

19. The area that is affected in the macula on the SD-OCT corresponds to the:
   a. Central five degrees of the retina.
   b. Central five to 10 degrees of the macula.
   c. The fovea.
   d. None of the above.

20. Which is a subjective test recommended for Plaquenil screening?
   a. FAF.
   b. SD-OCT.
   c. 10-2ss.
   d. mfERG.

Answers to CE exam:

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Rate how well the activity supported your achievement of these learning objectives: 1=Poor, 2=Fair, 3=Neutral, 4=Good, 5=Excellent</td>
</tr>
<tr>
<td>2.</td>
<td>21. Improve my clinical ability to screen for and diagnose hydroxychloroquine toxicity.</td>
</tr>
<tr>
<td>3.</td>
<td>22. Become familiar with the new AAO guidelines for screening patients on hydroxychloroquine therapy.</td>
</tr>
<tr>
<td>4.</td>
<td>23. Increase my understanding of the risks associated with hydroxychloroquine toxicity.</td>
</tr>
<tr>
<td>5.</td>
<td>24. Better understand the new diagnostic tools that can help detect hydroxychloroquine toxicity.</td>
</tr>
<tr>
<td>6.</td>
<td>25. Increase my knowledge of the dosing particulars of hydroxychloroquine therapy.</td>
</tr>
<tr>
<td>7.</td>
<td>26. Improve my ability to communicate with patients about the risks and the need for periodic screening.</td>
</tr>
<tr>
<td>8.</td>
<td>Rate the quality of the material provided: 1=Poor, 2=Fair, 3=Neutral, 4=Good, 5=Excellent</td>
</tr>
<tr>
<td>9.</td>
<td>27. The content was evidence-based.</td>
</tr>
<tr>
<td>10.</td>
<td>28. The content was balanced and free of bias.</td>
</tr>
<tr>
<td>11.</td>
<td>29. The presentation was clear and effective.</td>
</tr>
<tr>
<td>12.</td>
<td>30. Additional comments on this course:</td>
</tr>
</tbody>
</table>

Post-activity evaluation questions:

21. Improve my clinical ability to screen for and diagnose hydroxychloroquine toxicity.
22. Become familiar with the new AAO guidelines for screening patients on hydroxychloroquine therapy.
23. Increase my understanding of the risks associated with hydroxychloroquine toxicity.
24. Better understand the new diagnostic tools that can help detect hydroxychloroquine toxicity.
25. Increase my knowledge of the dosing particulars of hydroxychloroquine therapy.
26. Improve my ability to communicate with patients about the risks and the need for periodic screening.
27. The content was evidence-based.
28. The content was balanced and free of bias.
29. The presentation was clear and effective.
30. Additional comments on this course:

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By submitting this answer sheet, I certify that I have read the lesson in its entirety and completed the self-assessment exam personally based on the material presented. I have not obtained the answers to this exam by any fraudulent or improper means.

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Coding Long-term Medications

Understanding the fundamentals is key to a long and happy life of reimbursement.

By John Rumpakis, OD, MBA, Clinical Coding Editor

Patients taking Plaquenil (hydroxychloroquine, Sanofi-Aventis) on a long-term basis may leave you scratching your head when it comes to coding the patient encounters. Although coding for long-term medications is not a difficult process, it often involves communicating with other physicians or specialists to obtain accurate information. While this clinical example focuses on Plaquenil, the concept works for any long-term medication.

ICD-10 Classifications

The ICD-10 section that covers long-term drug therapy is Z79, with many subsections and specific diagnosis codes.

Because Plaquenil does not have its own specific category, clinicians should use Z79.899—Other Long Term (Current) Drug Therapy. But getting the right code is just one step in the process of correctly documenting the encounter.

Code the Condition

When coding for these individuals, it is important to understand the mechanism in place. The patient is taking a long-term medication for a specific systemic condition, such as rheumatoid arthritis (RA), so the first step is coding for that. This is where communication with other physicians is paramount. You and the patient's other providers need to remain consistent with the ICD-10 code used to describe the condition for which the patient is being treated. Once you know the primary systemic condition, you can code the medication use and any adverse effects that require further attention.

Example: Plaquenil

Here's the coding for a patient taking Plaquenil for RA:

1. Report M06.08 for RA, other, or M06.9 for RA, unspecified (always report the systemic disease state first).
2. Report Z79.899 for Plaquenil use for RA.
3. Always report both. Link to both, and if the carrier does not pay on the Z code, link to the M code first (or only link to the M code).
4. If maculopathy is present, report the adverse effect of the hydroxychloroquine as well:
   - T37.2x5A: Adverse effect of anti-malarials and drugs acting on other blood protozoa, initial encounter.
   - T37.2x5D: Adverse effect of anti-malarials and drugs acting on other blood protozoa, subsequent encounter.
   - T37.2x5S: Adverse effect of anti-malarials and drugs acting on other blood protozoa, sequela.

Understanding what you are clinically evaluating in a patient taking long-term medications and following the basic ICD-10 rules will help you be quite successful in caring for these patients and adding a valuable care component to your practice.

Send questions and comments to rcodingconnection@gmail.com.
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I’ve recently seen some compelling data regarding the use of multifocal lenses for myopia control. What are the particular parameters that make this an effective treatment option and is there an ideal age at which I should consider using such a design?

“Custom soft multifocal lenses are an essential part of my own protocol,” says Kevin Chan, OD, center director for Treehouse Eyes, the first United States healthcare provider exclusively dedicated to myopia control. “Of course, like any contact lens fit to any patient, clinical outcomes may vary from patient to patient, so there is no single best answer to the question that applies to every patient.”

For David Kading, OD, owner of Specialty Eyecare Group in Seattle, “our normal, and first-line, treatment is usually orthokeratology.” However, “gaining in popularity are soft lens multifocals,” he adds.

Data from a prospective three-year study (funded by CooperVision) of 144 kids ages eight to 12 presented at the British Contact Lens Association meeting in June found that a dual-focus soft lens was able to slow myopia progression 59% by cycloplegic spherical equivalent refraction and 52% by mean axial elongation. Dr. Chan says that, generally, “the younger the better. We’ve treated kids as young as six years old.” Dr. Kading concurs: “Like any option for myopia control, we really want to start the treatment as soon as we can. In our clinic we like to initiate treatment as soon as we start seeing the patient progressing.”

For best keep tabs on myopia progression, Dr. Kading begins by looking closely at the progression rates, family prescriptions and activities the kids are involved in starting around five years old. “However, we have fit kids as young as four into myopia treatment,” he adds.

As long as patients and parents are “motivated and eager to slow down the myopia,” effective treatment is certainly attainable in these cases, Dr. Chan says. “With patience, and enough time, the technical aspects of lens insertion and removal are certainly trainable and should not be a barrier to treating these kids.”

A nine-year-old female presented to the clinic for evaluation of poor vision in both eyes. Her grandmother said the girl’s vision had always been poor. At a visit four years earlier, her acuity was measured at 20/70.

The grandmother felt it was now significantly worse and revealed that the patient was born at 37 weeks, weighed 6.8 pounds and had a normal birth and development. However, when speaking directly to the girl, she demonstrated poor mentation and was unable to recall simple things (i.e., the date of her birthday).

**Diagnostic Data**

Entrance testing revealed a visual acuity of light perception (LP) in both eyes. Her pupils were equally round and reactive to light. There was no afferent pupillary defect in either eye. Confrontation visual fields were unobtainable.

Extraocular movements were full, but there was nystagmus in both eyes. Intraocular pressures (IOP) were within normal limits, measuring 15mm Hg OD and 16mm Hg OS.

Anterior segment was within normal limits and unremarkable in both eyes. Dilated fundus examination revealed a normal vitreous OU. Other changes can be seen in the fundus photos (Figure 1). Fundus autofluorescence (FAF) and optical coherence tomography (OCT) were also obtained (Figure 2).

**Take the Quiz**

1. What is the likely diagnosis?
   a. Leber’s congenital amaurosis.
   b. Retinitis pigmentosa.
   c. Stargardt’s macular dystrophy.
   d. Batten disease.

2. Which condition below is associated with an accumulation of lipofuscin in neuronal tissue, including the brain, retina and peripheral nerves?
   a. Neuronal ceroid lipofuscinosis.
   b. Retinitis pigmentosa.
   c. Multiple sclerosis.
   d. Age-related macular degeneration.

3. In regards to FAF imaging, hyperautofluorescence is considered indicative of______.
   a. Cystoid changes.
   b. Loss of lipofuscin.
   c. Increased lipofuscin or storage material such as lipoproteins and hydrophobic peptides.
   d. None of the above.

4. What is the likely prognosis for this condition?
   a. Continued profound vision loss to no light perception.
   b. Slow improvement of visual acuity.
   c. Geographic atrophy of the retina and retinal pigment epithelium.
   d. Stabilization of acuity to 20/400.

*For answers, see page 98*

**Discussion**

Based on the profound vision loss and retinal changes, coupled with evident developmental problems, our patient likely has the neurodegenerative condition Batten disease. Specifically, the condition is classified as a neuronal ceroid lipofuscinosis (NCL) and represents a group of...
disorders that have a characteristic accumulation of lipofuscin in the neuronal tissues including the brain, retina and peripheral nerves.2 The clinical ocular features of Batten disease include optic nerve pallor, central macular mottling, attenuated arterioles and peripheral retinal granularity.3 All these retinal changes were noted on clinical examination of our patient.

The literature describes the following four forms, often collectively referred to as Batten disease:1

- **Halitza-Santavouri disease** has an infantile onset.
- **Jansky-Bielschowsky disease** has an infantile onset.
- **Batten-Mayou Syndrome** has a juvenile onset.
- **Kufs disease** has an adult onset.

These children suffer from severe psychomotor deterioration that leads to vegetative states, seizures, profound visual loss secondary to retinal degeneration and, ultimately, premature death.1 NCL disorders are inherited in an autosomal recessive manner.2 The rate of progressive vision loss that occurs in NCL disorders is extremely rapid, with profound vision loss occurring in a matter of months.1

**Identification**

The differential diagnosis for this patient includes retinitis pigmentosa (RP) and Stargardt’s disease (SD). RP represents a group of retinal degenerative diseases that begin by affecting the rod photoreceptors and eventually lead to degeneration of the cone photoreceptors.5 SD is the result of a mutation in the ABCA4 gene that leads to accumulation of byproducts within the retinal pigment epithelium (RPE) that cause dysfunction and death of the photoreceptors.5

Appropriate ancillary testing for any patient with a suspected hereditary retinal disease includes full-field electroretinography (ERG), electrooculography (EOG), dark adaptation, perimetry testing, OCT, FAF and genetic testing. ERG studies of Batten disease patients are often abnormal early on and eventually becomes flat or undetectable. FAF shows an accumulation of storage material that hyperautofluoresces. This storage material appears similar to ceroid and lipofuscin, but is actually a mixture of lipoproteins and hydrophobic peptides.1,2 Hypoautofluorescence on autofluorescence imaging is indicative of atrophy.6 Lastly, OCT imaging will show small hyper-reflective bodies at the RPE level.1,2

In the past, biopsies from the brain and full-thickness rectal biopsy were the standard protocol for diagnosing NCLs. These biopsies looked for inclusion bodies in the cells of these tissues. Currently brain biopsies are no longer justifiable for the diagnosis of NCL. Rather muscle biopsy may represent the best approach to ultrastructural diagnosis of the disease; however, muscle biopsies are not ideal for differentiating between the four forms of NCLs as the fibers only show curvilinear inclusions.1

As patients with Batten disease may be nonresponsive and have potentially poor prognosis, genetic testing is necessary to confirm the diagnosis. Our patient was referred to a genetics specialist the same day. The genetics specialist counseled the patient and family on the possible results. It was also recommended that siblings of the patient be genetically tested as well.

Until recently, there has not been a treatment for Batten disease; however, on April 27, 2017, the FDA approved the drug Brineura (cerliponase alfa, BioMarin) as a treatment option for the specific form of Batten disease known as Jansky-Bielschowsky disease. It is the first FDA-approved treatment shown to retard ambulatory loss in pediatric patients ages three and older suffering from the late infantile NCL type 2. Brineura is an enzyme replacement therapy. Its main component, cerliponase alfa, is the recombinant form of human TPP1, the specific enzyme that is deficient in those suffering from this form of Batten disease.7

**Fig. 2. Autofluorescence of the right (at left) and left maculae.**

Dr. Diego is a resident at Bascom Palmer in Miami.

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In June 2017, a patient made his way back to our office after several years of absence, during which he had moved and sought care from another provider. When he presented back to me, I reviewed the old records and found that there were some early cataracts seen at the last visit, as well as a notation about him being a glaucoma suspect, based on disc asymmetry. His current medications included atorvastatin, doxazosin, finasteride and lisinopril. He reported no known allergies to medications.

Examination
At the most recent visit, entering visual acuities were 20/50- OD and 20/40- OS uncorrected. Best-corrected vision was 20/25+ OD, OS and OU through hyperopic astigmatic correction. Pupils were equal, round, responsive to light and accommodation and showed no afferent pupillary defect.

A slit lamp examination of his anterior segments was unremarkable except for corneal arcus OU. Applanation tensions at 9:10am were 12mm Hg OD and 12mm Hg OS. IOP readings were similar to previous visits, with an overall average IOP of 14mm Hg OD and OS, with max IOP readings of 18mm Hg and low readings of 10mm Hg. Van Herick angle estimations demonstrated open angles. Pachymetry readings were 557µm OD and 565µm OS.

Through dilated pupils, his crystalline lenses were characterized by mild nuclear and both anterior and posterior cortical cataracts, slightly worse in the left eye than in the right, but consistent with his best-corrected visual acuities. He had bilateral PVDs that had been noted years earlier. His cup-to-disc ratios at this visit were estimated at 0.45 x 0.45 OD and 0.3 x 0.3 OS. Previously, they were 0.3 x 0.3 OD and 0.25 x 0.25 OS. Was there inherent change over time, or is this an example of intraobserver variance? It was hard to tell at first, so we ordered imaging of the optic nerves to compare with the patient’s previous images.

Imaging
Both maculae were characterized by fine drusen centrally, in the right eye slightly more than in the left, with an epiretinal membrane (ERM) noted temporally in the left eye. The retinal vasculature was characterized by moderate arteriosclerotic retinopathy symmetric bilaterally. Posterior vitreous separations were present in both eyes. His peripheral retinal evaluations were entirely normal in both eyes.

Heidelberg retinal tomography (HRT 3), optic nerve optical coherence tomography (OCT) and

This multi-modal image highlighting the retinal ganglion cells shows a wedge defect extending from the optic nerve between the four and five o’clock positions.

Analysis of the BMO profile of the left eye demonstrated a robust ganglion cell thickness throughout the entire left optic nerve similar in appearance to these HRT 3 scans of the same eye.
multicolor disc images were obtained from both eyes. The HRT 3 imaging demonstrated no substantive change in the neuroretinal rims in either eye as compared with the baseline images from 2010. Given that, I made the assumption that the apparent change in the cup-to-disc ratio was attributed to intraobserver variance.

Multimodal optic disc and macular imaging demonstrated findings consistent with the fundus views; namely, fine drusen in both eyes and an ERM in the left. Interestingly, we noticed a nerve fiber layer wedge defect in the left eye extending from the optic nerve between four and five o’clock to the temporal macular area.

OCT images of both optic nerves, using software highlighting Bruch’s membrane opening (BMO), were obtained, as well as macular scans. Analysis of the BMO profile of the left eye demonstrated a robust ganglion cell thickness throughout the entire left optic nerve similar in appearance to the HRT 3 scans of the same eye.

In regards to his macular scans and, in particular, looking for comparative thinning in the macular region that corresponds to the wedge defect seen on the multimodal images, we need to keep in mind the ERM in the left eye. While glaucomatous disease can be seen in macular scans, confounding macular diseases such as age-related macular degeneration and ERMs can complicate the interpretation of such scans. As such, while ERMs can result in increased focal retinal thickness and, subsequently, hide retinal thinning, due to glaucomatous disease, examination of the ganglion cell layer thickness alone will not be affected.
by an ERM. Thus, ODs must look at the macular scans specifically from the perspective of the ganglion cell layer maps.

**Discussion**

When the patient was initially seen in 2010, imaging technologies at that time concentrated on the neuroretinal rim and the perioptic retinal nerve fiber layer. While macular OCT technology existed then, its use was primarily for macular disease. Given that approximately 50% of the ganglion cells in an optic nerve originate in the macula, it makes intuitive sense to look at macular ganglion cell scans to see if the findings match up anatomically with what you are seeing clinically.

Since the original scans of this particular patient did not include macular scans, we had no reference point upon which to base any comparison of the current macular scan. As you can see in the macular ganglion cell layer thickness scan on page 88, there is thinning in the area of the RNFL wedge defect seen in the multicolor image extending to the horizontal raphe. Anatomically, that matches with a glaucomatous defect. But, in reality, this defect may very well have been present in 2010; it just wasn’t imaged.

So how is a doctor to sift through this data? While there is correlation between the ganglion cell maps and the RNFL wedge defect, we don’t know if this is a new finding or not. Put another way, we don’t know if this has changed over time. And therein lies the caveat: if this is glaucoma, there will be change over time. All other indices were stable (HRT 3 imaging, stereo nerve photography and visual fields), though we now do see a wedge defect and corresponding thinning in the same ganglion cell region.

The patient is 82 and he still has a robust neuroretinal rim. I felt it prudent to take a wait-and-see approach. There was no immediate need to begin therapy to lower IOP at this time. However, that may change as time passes and more test results are obtained. Will that wedge defect worsen? Will that ganglion cell sectoral thickness decrease? Only time will tell. Would I be surprised if we do see change over time? Not really. But if I do, and it is consistent, then I will begin medical therapy. But for the time being, slow and steady—and monitoring for change over time—is the course.
Laser refractive laser surgery has been making patients happy since the early 1990s, with the advent of photorefractive keratectomy (PRK), followed by laser-assisted in situ keratomileusis (LASIK). In 2016 another innovation further improved the refractive surgery experience for patients with the FDA approval of the VisuMax femtosecond laser (Zeiss) for small-incision lenticule extraction (SMILE) procedure.

How it Works
SMILE is a femtosecond laser procedure designed to correct nearsightedness. The laser first creates a disc (lenticule) of tissue within the cornea without lifting a flap or removing the epithelium. A 2.5mm to 3mm incision is made, through which the surgeon removes the lenticule. The result is the same as myopic LASIK because the amount of tissue removed is the same.1

Patient Selection
As with other refractive procedures, the ocular surface needs to be healthy, and dry eye should be treated prior to the procedure. Ideal patients should have no signs of ocular disease in the anterior or posterior segment. Corneal topography should be normal with no evidence of irregular astigmatism or keratoconus. Currently, SMILE is approved to correct myopia of -1.00D to -8.00D with -0.50D or less of cylinder in patients 22 years or older with stable nearsightedness that has changed by no more than 0.50D in the year. SMILE can treat astigmatism in Europe now, and hopefully in the United States in the future.

Some advantages of SMILE over LASIK include fewer symptoms of dry eye, less compromised corneal sensation and, possibly, greater biomechanical stability.2-4 Unfortunately, patients who need an enhancement must have a secondary PRK to ensure it does not interfere with the original SMILE procedure. In addition, SMILE is only FDA approved to treat spherical myopia, limiting the patient population indicated for the procedure.

Postoperative Care
Similar to LASIK, follow-up care usually consists of one day, one week, one month, three month, six month and one year visits. A typical postoperative drop regimen consists of a broad-spectrum antibiotic QID for one week then BID for one week.

With SMILE, patients often enjoy fewer dry eye symptoms and a faster visual recovery more comparable with LASIK than PRK.2-4 SMILE is still a tissue subtraction surgery and comes with a few concerns. Clinicians must monitor corneal topographies and warn patients against post-op eye rubbing because it can lead to corneal ectasia. As with LASIK, diffuse lamellar keratitis is possible during the post-op period. This can be managed with a short course of steroid drops, and patients rarely need a referral back to the surgeon to rinse the interface. Conditions such as dry eye and epithelial ingrowth can occur after SMILE and are treated the same as in LASIK patients.

Because SMILE comanagement is similar to that of LASIK and PRK—which we have been doing since the 1990s—we can be just as confident when caring for SMILE patients.

Drs. Rasmussen and Schweitzer practice at Vance Thompson Vision in Sioux Falls, SD, and are adjunct professors at the Illinois College of Optometry.

Optometrists have yet to reach a consensus on the meaning of optic disc hemorrhage (ODH) and management of patients when it develops. We don’t know what causes ODH. Some even consider the development of an ODH to be progression of disease.

During training, we were taught that if any patient who is being treated for glaucoma develops an ODH, whatever treatment they were receiving was not good enough. We’ve come a long way from then, but much of the mystery remains unsolved.

Is It ODH at All?
Before embarking on a glaucoma diagnostic evaluation or amplification of therapy in an already-diagnosed patient, ensure that what you are looking at is truly a glaucoma-related disc hemorrhage and not something else. Features of a true ODH include small size, contiguous with the neuroretinal rim, residing within the retinal nerve fiber layer (RNFL) and typically occurring at the superior, superior-temporal, inferior or inferior-temporal margin of the disc. Numerous other conditions, such as posterior vitreous detachment, optic neuropathy, diabetes, anemia, hypertension and retinal vascular disease, can cause optic disc hemorrhaging and parapapillary retina. This may lead to a glaucoma mimicking and misdiagnosis, but these other conditions typically don’t have the same features of a true glaucomatous ODH.

What Causes ODH?
Researchers suspect one of two likely drivers of this condition—mechanical vascular disruption and ischemic vascular dysregulation. The mechanical theory posits that shifting of tissue causes rupture of small blood vessels around the level of the lamina cribrosa or margin of the optic disc, ultimately resulting in ODH. Research using enhanced-depth imaging optical coherence tomography shows associations between laminar defects and ODH, supporting this theory. Additionally, this helps explain recurrent ODH developing in essentially the same disc location. The ischemic vascular theory suggests that systemic vascular diseases, platelet dysfunction, primary vascular dysregulation, vasospasm and faulty autoregulation of the blood flow to the anterior optic nerve result in ODH. Patients with normal tension glaucoma experiencing exaggerated dips in blood pressure at night are at increased risk of ODH, lending credence to an ischemic etiology. Certainly, there is merit to this theory, but it does fail to explain the stereotypical location of most ODH, in addition to recurrent ODH in the same location as previous hemorrhages, and existence of strictly unilateral hemorrhages.

What Comes First?
It remains unclear if ODH is a precursor to glaucomatous damage or merely an epiphenomenon of the disease process. Some evidence suggests that glaucomatous structural and functional abnormalities exist prior to ODH. Conversely, other research shows that ODH precedes RNFL thinning seen on OCT. Numerous reports identify ODH as an independent risk factor for glaucoma progression. However, major glaucoma studies do not consider the development of ODH itself to be the marker of progression. A 2001 study identified ODH as a risk factor for normal tension glaucoma progression. Curiously, the authors also found that in eyes with baseline ODH, lowering intraocular pressure (IOP) did not positively affect the visual outcome of the disease. Researchers in the Early Manifest Glaucoma Trial found that ODH was a risk factor for worsening disease.

The study also found that not every patient with glaucoma will develop ODH and that lowering IOP did not prevent ODH from
Case in Point

A 61-year-old male being treated for POAG for five years presented for his regularly scheduled progress evaluation. His entering, untreated peak IOPs were 30mm Hg OD and 20mm Hg OS. His central corneal thickness was average at 536µm OD and 531µm OS. He showed no evidence of angle closure or secondary glaucoma, but he had moderately damaged optic discs and RNFL in each eye. He was initially started on a prostaglandin analog and, through subsequent follow-up care, medications were added to further lower IOP. Currently, he uses latanoprost and dorzolamide/timolol FC in each eye with a consistent IOP of 10mm Hg to 12mm Hg OU. His most recent dilated exam and disc photography showed a developing ODH inferior-temporal in the left eye. Our review of older photographs found he had two previous ODHs in the same location in the last five years.

On every visit, we look at the optic discs (dilated or undilated) on every glaucoma patient, mostly to screen for ODH. Typically, when we see an ODH develop in a treated glaucoma patient and IOP could be easily reduced further without invasive options (such as adding an additional medication to a treated IOP of 19mm Hg), we consider doing so. However, if further IOP reduction cannot be easily and safely done (such as a patient on maximal medical therapy or with a very low IOP already where surgery would be the next option), we typically monitor closely and intervene further only when we see definitive disc, RNFL or visual field deterioration.

For this patient, since his treated IOP was in the 10mm Hg to 12mm Hg range, and further reduction could not be easily achieved medically, we elected to monitor him. To date, five years after beginning therapy and having three ODHs over time in his left eye, we saw no change to his visual field, optic disc or RNFL.

ODH cannot be prevented from recurring simply by lowering IOP, nor should that be the goal. Recognize that ODH is a strong risk factor for glaucoma progression, and that lowering IOP is for the overall visual health of the patient. We cannot stop ODH from occurring by lowering IOP, nor are we doing poorly in our treatment plan should one develop in a patient. ■

What’s a Doc to Do?

ODH is, like glaucoma itself, a complicated phenomenon that cannot be easily explained by IOP, mechanical or vascular factors alone.1 Glaucoma patients experiencing ODH clearly have an increased risk of progression. It has been suggested that glaucoma treatment intensification may have a beneficial effect in reducing the rate of thinning of the RNFL.5-14 Most definitely, glaucoma patients manifesting ODH should be observed more closely with frequent disc photographs, OCT and visual fields. Then, practitioners must decide if the current level of IOP is adequate or if therapy should be amplified.

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- Embracing and enhancing the didactic philosophies in the O.D. program;
- Maintaining and expanding the high quality clinical practice environment for optometry students on rotation;
- Precepting students on clinical rotation at the Midwestern University Eye Institute;

b) Service
- Helping to maintain and grow the state of the art optometry program with a strong interdisciplinary focus that meets the needs of patients in the surrounding community; is efficient, patient friendly, and cost-effective;
- Working closely together with all optometry and ophthalmology faculty to provide a complete range of eye and vision care services;
- Participating in leadership roles in state, regional, and national optometry organizations;

c) Scholarly activity
- Engaging in research and scholarly activity, including presentations at scientific meetings, research, and publication in peer reviewed journals sufficient to qualify for academic advancement in a non-tenure track position.

QUALIFICATIONS: Candidates must possess a Doctor of Optometry degree from an ACOE-accredited institution, must have completed an ACOE-accredited residency, and must be eligible for an optometric state license in the state in which the college is located. Primary eye care clinical expertise is also required.

CONTACT INFORMATION: Interested applicants should apply online at www.midwestern.edu and include curriculum vitae and letter of interest specifying the position and college that he/she wishes to be considered for. Inquiries may be directed to Dr. Joshua Baker, Dean, or Dr. Mary Lee, Vice President & Chief Academic Officer, Pharmacy and Optometry Education; Midwestern University; jbaker@midwestern.edu or mleexx@midwestern.edu.

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Diagnostic Quiz

That’s Gonna Leave a Mark

By Andrew S. Gurwood, OD

History
A 27-year-old black female was referred to the office by another local practitioner in the hopes that we would investigate an unusual, brown corneal ulcer in her right eye, with specific instructions to rule out fungal infection.

Her history uncovered that she had felt something in that eye since last week after working in the garden. She explained that her eye had been red and painful for the last four days, but that her vision was intact. She went to her own eye doctor the day before.

Her systemic history was non-contributory.

Diagnostic Data
Her best corrected entering visual acuities were 20/20 OD and 20/20 OS at distance and near. Her external examination was normal with no evidence of afferent pupil defect. The biomicroscopic examination of the anterior segment shows the lesion (Figure).

Goldmann applanation tonometry measured 15mm Hg OU.

Dilated examination uncovered normal posterior poles with no peripheral pathologies OU.

Your Diagnosis
Does the case presented require any additional tests, history or information? What steps would you take to manage this patient? Based on the information provided, what would be your diagnosis? What do you believe is the patient’s most likely prognosis? To find out, please visit us at www.reviewofoptometry.com.

Retina Quiz Answers (from page 84): 1) d; 2) a; 3) c; 4) a.
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References:

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