QUARTER 1 2012 | Volume 7 Number 1

eyeCare Africa

YOUR CONNECTION TO THE WORLD OF VISION

Helps prevent eyes from ageing.

A blurry field of vision develops as one result of ageing, but it is in our power to influence health in old age to the good. AMD is a widespread eye disease and the most frequent cause of blindness.

The risk factors of AMD:

Age
At 50 the risk of getting AMD is estimated at 2%. It rises to 30% by age 75.

Heredity
Those with direct family members diagnosed with AMD are at a greater risk.

Macular pigment level
Thinner pigment cannot protect the macula effectively.

Gender
Women may be at greater risk of getting AMD than men.

Smoking
Smoking increases the risk of getting AMD.

Nutrition
Malnutrition weaken the protection against free radicals.

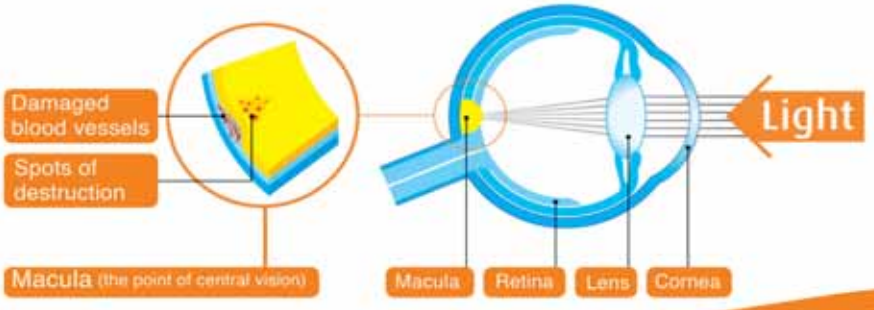
Sun
Significant cumulative light exposure increases the risk of getting AMD.

What is AMD?

Age-related macular degeneration is a breakdown of the macula. AMD is the leading cause of irreversible vision loss.

In Europe every second person over 65 years of age already has degenerative signs in their eyes!* Every year *new* patients come for treatment. This number is increasing annually as this disease becomes increasingly widespread.

* Euroeye study



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Editorials

PROF ALAN RUBIN

Kollbaum, in this first issue of *EyeCare Africa* for the year 2012, refers to a study by Holden *et al* (2008) that estimates that although about 1 in 7 people in the world are presbyopes, less than 1 in 10 of these people use contact lenses as their primary method of refractive compensation. Even where presbyopes with multifocal or other contact lenses achieve reasonably good distance and near visual acuity with such contact lenses often they are not entirely happy with their overall quality of vision (due to factors such as ghosting of images). This is thus an area where investigators will need to make significant improvements before these contact lenses (for presbyopia) can achieve broader use. Kollbaum briefly discusses interesting work being done towards improving custom-designed presbyopic contact lenses through manipulating aberrations such as defocus and spherical aberration to reduce ghosting through manipulation of levels of contrast. Kollbaum also mentions researchers who are having promising success with other types of contact lenses such as photochromatic contact lenses or with drug delivery contact lenses that dramatically improve medicinal treatment of the eye and simplify drug treatment of conditions such as glaucoma. See also the article by Eiden and Denaeyer that discusses modern advances in specialized soft contact lens for mainly keratoconic eyes.

Two papers in this issue consider firstly very exciting research into the use of alternative sensory stimulation to replace vision and secondly nanotechnology to improve medical treatment of retinal disease. The paper by Arnoldussen and Fletcher briefly discusses a small digital device with multiple electrodes that provides, to the wearer's tongue, mild and variable electrical stimulation relating to video information collected via a camera attached to a spectacle frame. The video images contain pixels that represent different levels of luminance; for example, black or dark pixels and white or bright pixels and by changing the level of electrical stimulation to the tongue the user can differentiate between the types of pixels and make some sense of the image. (One might imagine a similar device that could stimulate the skin rather than the tongue and similarly allow the blind or visually impaired individual to see through the skin.) The pattern of electrical stimulation of the tongue enables the wearer to become aware of the vision input, recognize symbols and even move around their environment. Nanoparticles can transport and transfer viruses, genes and other molecules such as cholesterol. Nanoparticles may be more effective than alternative treatments, for example, with intravitreal injections of nanoparticles in the case of retinal disease.

Another thought-provoking article by Kershner briefly considers more complicated intraocular lenses (such as multifocal or diffractive IOLs) and their potential impact in relation to the plasticity or adaptive ability of the human brain. There is some suggestion that one might more clearly select out those patients that could more easily adapt neurologically to vision with these more complicated IOL types and thus avoid using such intraocular lenses with others that may not adapt so readily. Also, it may even be possible to train or medicate patients prior to cataract surgery to permit them to better adapt to their changed visual world and thereby enhance the surgical outcome and level of satisfaction that these patients later experience with their IOLs.

Compliance to proper care with contact lenses or with taking medication for disease can often be an issue with some patients and Hickson-Curran points out that studies indicate that sometimes up to 40% of patients even with serious disease may fail to properly comply with their medical care and drug treatments. Patients wearing contact lenses may similarly be negligent as two recent online surveys by Hickson-Curran *et al* suggest. For example, only about half of the patients in these surveys apparently cleaned their hands prior to handling their lenses in the mornings after waking. (The possibility also exists that some of these patients did not answer honestly and so, in reality, this finding could even be far worse.) Many patients do not rinse their contact lens cases or replace them regularly and patients often misunderstand that rinsing their cases does not mean rinsing with ordinary tap water. As we already know with ordinary contact lens care, patients often misinterpret instructions, either obtained directly from their clinicians or via the information on contact lens containers or pamphlets. In the paper by Szczotka-Flynn and Chalmers one of the consequences, namely corneal infiltrates, of poor patient compliance with soft contact lenses is described with an emphasis on relevant risk factors. (Of course, such infiltrates are occasionally an issue in non-contact lens wearers also.)

Papers by Murphy, and also by Michalewska and Nawrocki, consider the important role of modern technology such as used with measurement of macular pigment density or assessment of retinal regeneration. Some of these instruments are changing our understanding of modern ophthalmology and optometry and also providing important areas for future growth in eye and vision care. In a similar fashion, Caffery emphasizes the role of optometry in correctly identifying patients with various types of autoimmune disease, and thereafter in co-managing these challenging clinical patients together with medical specialists such as rheumatologists and ophthalmologists. Ashrafzadeh focuses on modern innovations in LASIK and cataract surgery and the potential impacts on ophthalmic surgeons and also their patients having undergone such surgeries.

Enjoy reading your new issue of *EyeCare Africa!*

Professor Alan Rubin, DPhil(RAU)
Optometric Science Research Group / Department of Optometry / University of Johannesburg

DIRK BOOYSEN

This issue covers topics relevant to the management of anterior segment problems including bespoke contact lens fitting. Caffery's article deals with dry eye and specifically with Sjörgen's syndrome and the optometrist's role in the diagnosis of autoimmune rheumatic disease. Soft contact lens options for keratoconus are discussed in the article by Eiden and Denayer. Although most of the lenses are not available in South Africa, the Kerasoft IC and Soflex lenses are frequently used by local practitioners. The article elaborates on the design, fitting, and optics of these lenses and concludes with a number of case studies. An interesting article by Kollbaum deals with new opportunities to grow the contact lens market. The issues of myopia progression control, presbyopia correction, drug delivery, photochromic contact lenses, as well as diagnostic contact lenses are discussed. Other articles in this issue deal with compliance in contact lens wear, cataract surgery after LASIK, premier IOLs, SD OCT, and visual perception devices for the blind.

Finally, it is with great sadness that we say farewell to "oom" Flippie Bruwer who died during March this year. Although a controversial figure in some aspects, he had the interest of our profession at heart and will be missed. I can only thank him for his dedication and contribution to the profession of optometry in South Africa. The *EyeCare Africa* team extends its heartfelt condolences to the Bruwer family.

Dirk J. Booysen, Dip. Optom FOA(SA), MCOptom(UK),TMOD(USA),CAS(USA)

Publisher's Note

Dear Reader,

As the publisher of *EYECARE Africa* I am delighted to inform you that we have signed a new agreement with Springer Science & Business Media UK Limited (www.springer.com) for a period of two years starting with the current issue.

We hope that this is, and will continue to be, a valuable part of your continued professional reading. Having access to these international journals, encompassed in our agreement, *(Contact Lens Spectrum, Eyecare Business, Ophthalmology Management, Optometric Management, Retinal Physician)* gives our editors Prof. Alan Rubin and Dirk Booysen a plethora of articles to choose from when selecting articles for each issue. Our editors endeavour to select articles that are relevant to our local market as well as being the most current international information thereby keeping you up to date with the latest trends and developments.

Please feel free to send me any suggestions or ideas that you feel we may use to improve the publication going forward.

Enjoy this issue!

Reni Rouncivell
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Survey results shed new light on the top noncompliance behaviors, and practitioners offer tips on how to improve adherence to lens wear and care regimens.

BY SHEILA B. HICKSON-CURRAN, BSC (HONS), MCOPTOM, FAAO

Compliance Before, During and After Contact Lens Wear

Patients who do not adhere to their prescribed regimens exist in all areas of health care. Studies have shown that about 35 percent of patients with glaucoma do not use their IOP-lowering drops as directed (Dietlein *et al*, 2005), 38 percent of patients with Type II diabetes fail to adhere to their insulin regimens (Cramer, 2004), and more than 40 percent of patients do not take their osteoporosis medicine (Boccuzzi *et al*, 2005). Failing to take medication for these diseases can have a significant impact on morbidity and mortality.

As we know, contact lens wearers often do not fully adhere to their practitioners' instructions on how to safely wear and care for their lenses. Fortunately, serious negative consequences such as microbial keratitis are unusual, but the rarity of serious complications may actually reinforce poor lens wear and care habits.

"Generally, I think patients want to do what is best. The intent to comply is there, if not always the execution," says Susan Kovacich, OD, clinical associate professor at the Indiana University School of Optometry. "But when they begin to extend their wearing schedules or skip care steps without any negative consequences, patients become even more relaxed about proper lens care."

Key Areas for Compliance

In a recently published paper, two colleagues and I summarized the evidence in the literature on a wide range of contact lens compliance steps and categorized them according to the degree of clinical importance associated with skipping or irregularly performing each step (Hickson-Curran *et al*, 2011). In the same paper, we reported the results of two online surveys to assess how well U.S. wearers of frequent replacement (not daily disposable) contact lenses adhere to common guidelines for healthy lens wear. To avoid biasing respondents to report better compliance than they actually practiced, the surveys were completed at home or other locations, and they were not in any way associated with eye care visits or eyecare practitioners' offices.

The first 645 contact lens wearers (ages 12 to 39), who were members of a consumer panel, were asked about lens replacement frequency. They may have also been asked about other products (e.g., cell phones, laundry detergent), so they were not aware the survey was sponsored by a contact lens company. A separate panel of 787 contact lens wearers (ages 18 to 39) was asked, again in an online survey, about a wide range of contact lens-related behaviors, including hygiene, cleaning practices and case replacement.

The results of both surveys, especially in the context of the literature on each topic, provide ample evidence that patients need to be educated continually.

Before: Hand Washing and Lens Replacement

Prior to contact lens wear, we want patients to wash and dry their hands, rinse the lenses correctly with solution (depending on modality and care regimen) and adhere to their replacement schedules.

Of these steps, poor hand washing is the most closely associated with an increased risk of infection (Radford *et al*, 2009). According to our survey, just a little more than half the respondents (56 percent) washed their hands with soap before handling lenses in the morning.

"This might seem like a basic hygiene step that we wouldn't need to mention, but we do," says Arti Shah, OD, FAAO, a private practitioner in Santa Monica, Calif. "I emphasize washing with soap that is not cream-based and drying hands completely before handling lenses."

Patients' compliance with lens replacement schedules has been a major topic of discussion among practitioners and contact lens manufacturers. Several studies suggest a relationship between modality and compliance (Dumbleton *et al*, 2010; Yeung *et al*, 2010), with most researchers agreeing that patients who wear daily disposable lenses exhibit the most compliant behaviors (Dumbleton *et al*, 2009). The simplicity of the daily disposable modality makes it easy to explain and remember.

Dumbleton and colleagues (2010) reported that compliance with a replacement schedule, regardless of modality, is associated with better comfort and vision at the end of the day and at the end of the wear cycle. Other research also suggests that comfort declines and unscheduled visits for clinical complaints, such as dryness, increase with longer periods of wear, even within the recommended replacement cycle (Hickson-Curran *et al*, 2010.

We do not have much data about the safety implications, if any, of various frequent-replacement modalities or of overwearing lenses beyond the recommended replacement schedule. Some recent studies that have attempted to make such connections have inherent weaknesses. If patients are not prospectively randomized to modality, the more frequent replacement groups are likely to contain a greater proportion of patients who were prescribed a shorter replacement cycle by their doctors specifically because those patients are compliance-challenged, prone to allergy or have already experienced an adverse event, hence biasing the sample.

The results of our lens replacement survey indicate generally low compliance with practitioners' recommendations on replacement frequency. I do not believe that modality "causes" noncompliance. Rather, compliance is a function of three factors: 1) how

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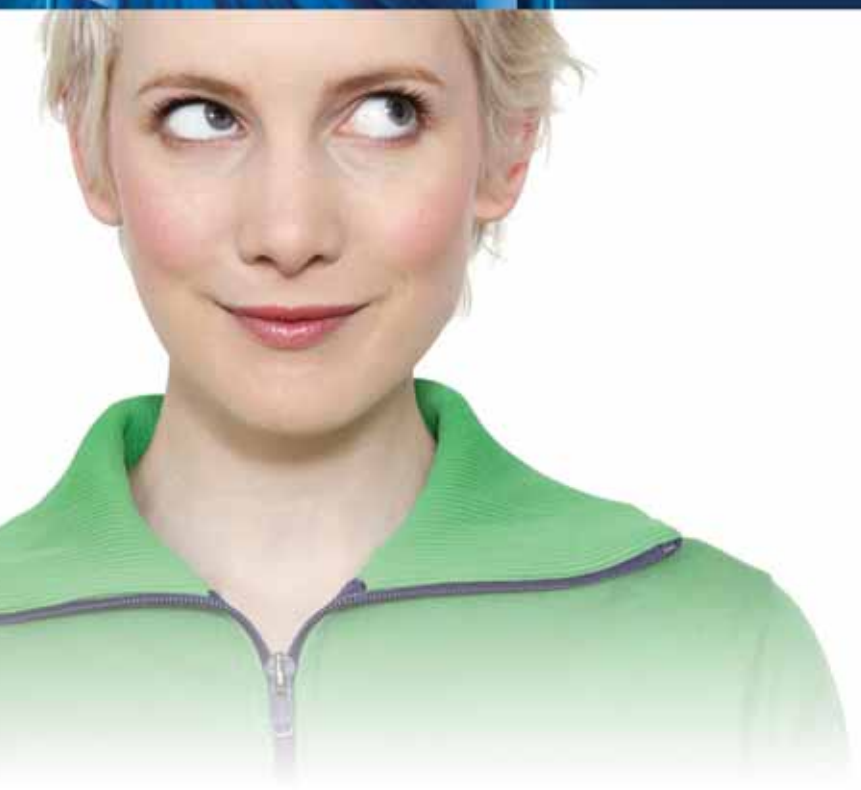

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Compliance Goes High Tech

According to the Global Mobile Health Market report, 1.4 billion people will own smart phones by 2015—and about 500 million of them will be using health-related applications for their mobile devices.

With all these computer-literate, smart phone-toting patients, practitioners should stay on top of the latest high-tech approaches to reminding them about contact lens replacement and office visits. Here are some options to consider:

- Popular calendars, including Microsoft Outlook Calendar, Google Calendar and Apple's iCal, all allow users to establish recurring calendar appointments or tasks with reminders that pop up on the screen and sync to smart phones, too.
- iTunes offers four contact lens reminder "apps" for the iPhone. BlackBerry and Droid each have a few, as well. Together, the app stores already boast a total of 17,000 mobile health applications.
- Acuminder (www.acuminder.com) lets patients sign up for free text messages or e-mail reminders when it is time to change their lenses or schedule an appointment, regardless of the brand of lenses they wear.
- LensAlert cases keep the reminder right where patients keep their lenses.
- A video on YouTube highlights why patients need to clean their lenses and stay on their replacement schedule. To view, go to http://www.youtube.com/acuvue#p/c/5D2215A5200FDECF/0/0rEcXTNF1To.

well patients understand the wear schedule; 2) their desire to comply; and 3) if they remember to make time in their busy lives to change their lenses on schedule.

Another factor, of course, is what instructions patients are given by their practitioners, and this isn't always well controlled. In one recent study, for example, 49 percent of the prescribing optometrists recommended a replacement schedule other than 2 weeks for patients wearing lenses the manufacturer recommended for 2-week wear (Dumbleton *et al*, 2010). This makes the question of compliance murkier, because a patient may be following his practitioner's instructions, but the practitioner has recommended a replacement frequency that differs from the lens manufacturer's recommendation.

"Trying to make patients happy by giving them a longer wear schedule than what the manufacturer recommends is not the answer," says Dr. Kovacich. "All the clinical trials are performed with specific wear intervals based on the individual lens materials and wetting agents. It behooves us to recommend those same intervals, both for performance and consistency." She finds that patients are much more likely to adhere to their lens replacement schedule when they have fresh lenses on hand. "That's why we strongly encourage every patient to purchase an annual supply of lenses," she says. "When you break down the price for them, including rebates and insurance, most patients will agree that an annual supply is worthwhile financially, too."

Smartphone-based applications and electronic reminder services are a great way to help tech-savvy patients remember when to replace their lenses, Dr. Shah says (see "Compliance Goes High Tech," below), but for those who just can't seem to stay on track, she is quick to suggest daily disposable contact lenses.

During: Overnight Wear and Water Exposure

The most important risk factor for microbial keratitis is overnight contact lens wear (prescribed or not). Epidemiological studies have shown the rate of microbial keratitis with overnight wear of soft contact lenses has remained steady at 4 to 10 times the rate of microbial keratitis with daily wear (Schein *et al*, 2005; Stapleton *et al*, 2009; Schein *et al*, 1989). Overnight wear is also associated with higher rates of corneal infiltrates (Stapleton *et al*, 2007; Szczotka-Flynn and Diaz, 2007).

When warning her patients about sleeping in their lenses, Dr. Shah focuses on the eye's need for oxygen. "That gives me an opportunity to talk about the benefits of silicone hydrogel materials, as well as the importance of having spectacles in addition to contact lenses," she says. "Not having functional eyeglasses can be a major contributor to noncompliance. When patients can't read without their lenses, they are most likely going to fall asleep in them."

Contact with water is another major concern during contact lens wear. In one study, 96 percent of lenses worn for 30 minutes of swimming were contaminated with pathogens, compared to only 19 percent of those not worn during swimming (Choo *et al*, 2005). Wearing goggles appears to reduce but not eliminate the bacteria adhering to lenses (Wu *et al*, 2011).

Although clinicians instruct patients how to apply, remove and clean their contact lenses, Dr. Shah says the missing piece is what not to do while wearing their lenses.

"When I tell patients that I don't want them to swim in lakes or pools, engage in water sports, use a hot tub or shower while wearing their lenses, they are very surprised, because they have never heard that before," Dr. Shah says. "I tell them it's just not worth the risk of getting an infection that might keep them out of contact lenses and will certainly cost a lot of time and money to take care of."

After: Cases and Cleaning

Considering current patterns of contact lens case cleaning, exposure to tap water is highly likely. More than half our survey respondents (53 percent) reported that they rinse their cases with warm or hot tap water, and 19 percent said they rinse with cold water (Table 1).

"Patients really don't perceive their tap water as 'dirty,'" Dr. Kovacich says. "After all, they drink it and bathe in it. When we say, 'rinse your case,' they assume we mean with water. We need to be very clear and specific about the fact that tap water should never come into contact with soft contact lenses."

TABLE 1 - Lens Exposure to Tap Water

LENS CASE CLEANING METHOD INVOLVING CERTAIN OR POSSIBLE EXPOSURE TO TAP WATER (N=787)	
Rinse lens case with warm or hot tap water	53%
Wash lens case with soap	20%
Rinse lens case with cold tap water	19%

Of even greater concern than how patients clean their cases is the finding that many rarely if ever clean them. Only 26 percent of respondents to our survey reported cleaning the case daily. The median was 2 to 3 times per week, which may not be unreasonable, but one in three respondents clean the case monthly or even less often (Figure 1).

The ideal interval for case replacement is unknown. The FDA recommends replacement every 3 to 6 months, and some practitioners advise replacement every 1 to 3 months. About 40 percent of the people we surveyed said they use a lens case for a full year or longer.

"Topping off" or failing to completely empty and replace the contact lens disinfecting solution in the case is a common practice that was linked to the Fusarium keratitis outbreak a few years ago (Chang *et al*, 2006; Levy, 2007). Less than half the respondents in our survey (46 percent) said they fill the lens case with solution every evening, meaning that the other half performs this necessary step irregularly.

Rubbing lenses is another aspect of the cleaning regimen that is often ignored. Although the literature is quite clear that rubbing helps to remove the microbial load on the lenses (Kilvington and Lonnen, 2009; Buck *et al*, 2000) and may play an important role in preventing microbial keratitis (Ahearn *et al*, 2008; Butcko *et al*, 2007), the "no rub" language on many multipurpose solution labels has left many patients understandably confused. The majority of our survey respondents (75 percent to 77 percent) omit this step.

Dr. Kovacich finds it important to share with her patients new data on the benefits of rubbing contact lenses while cleaning them. "I always try to give them some facts to support what I'm recommending. It makes the instructions more memorable, and it helps to counteract that natural human tendency to skip steps."

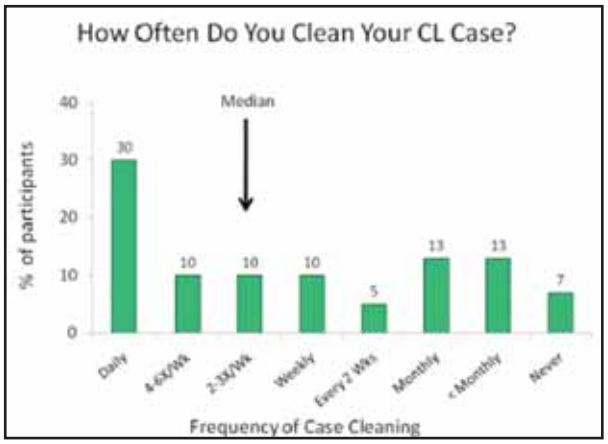

Figure 1. Survey results of how often patients clean lens cases.

Making a Difference

Solving the compliance puzzle requires that we first understand the reasons for poor compliance, which can be grouped into three general categories: 1) Patients who do not understand instructions; 2) Patients who ignore instructions, believing "nothing bad will happen"; and 3) Patients who forget or procrastinate. Each of these reasons requires a different approach.

When patients don't understand the clinician's instructions (or the reason for them), more education is needed. Dr. Shah says the data suggest she needs to redouble her efforts with established contact lens wearers who may have accumulated bad advice and developed bad habits over the years. "The toughest cases are the patients who feel comfortable and see fine, even though they don't adhere to my instructions," she says. "Sometimes the best approach is to just start over with a new lens, a shorter wearing schedule, a new solution, new eye drops and new instructions for care."

What should you do when a patient ignores your instructions because he believes nothing bad will happen? One of Dr. Shah's patients, a 45-year-old man who had been sleeping in conventional hydrogel lenses for 2 to 3 weeks at a time, was skeptical about needing to change. "What turned it around was when I told him he had some corneal edema, and a change in his prescription after 1 week of daily wear proved me right," she says. "That seemed to validate the message for this patient."

It may be that certain types of patients are simply more likely to be noncompliant. My co-author in the recent study on compliance, Robin Chalmers, OD, FAAO, an Atlanta-based clinical trial consultant, has been investigating safety and compliance patterns by age as co-chair of the Contact Lens Assessment in Youth (CLAY) team.

"We are finding that the youngest contact lens wearers (ages 8 to 15 years) are likely very compliant," Dr. Chalmers says. "They are under their parents' guidance, have access to care, and they seem to be wearing lenses appropriately." In the 16- to 25-year olds, however, she has seen a higher rate of corneal infiltrates and other events that interrupt contact lens wear. She suggests that practitioners might want to rethink how they prescribe for this age group. "Rather than looking for the cheapest option for that freshman in college, they might want to consider daily disposable lenses for this compliance-challenged and higher-risk group."

Finally, busy lives, procrastination and forgetfulness are all major factors in contact lens noncompliance. Just as we don't all floss our teeth or exercise as often as we should, patients lose track of dates and forget to carry out key steps in the care regimen. If practitioners focus on changing the behaviors with the greatest clinical impact and providing convenient reminder tools, they can help bring patients closer to full compliance.

Dr. Kovacich is a consultant for Ciba Vision. Dr. Shah is a professional affairs consultant for Vistakon and Clinical Research Optometrist for AcuFocus. Dr. Chalmers is a clinical trial consultant with consulting relationships with Alcon Research Ltd., Bausch + Lomb, Ciba, Johnson & Johnson Vision Care and Inspire Pharmaceuticals.

Sheila Hickson-Curran is director of Medical Affairs for Vistakon, Division of Johnson & Johnson Vision Care Inc.

Researchers are exploring novel applications - both vision-related and non vision-related - for contact lenses. Here's a peek at the future.

BY PETE S. KOLLBAUM, OD, PHD, FAAO

These Aren't Your Father's Contact Lenses

Seven billion people now inhabit the world in which we live. Approximately 3.5 billion of these people require vision correction; however, only about 120 million people wear contact lenses. Doing some simple math, we can easily see that tremendous growth opportunities exist in the contact lens market.

Some 3 billion people who need vision correction choose not to wear contact lenses for some reason. Can we, as contact lens practitioners and contact lens manufacturers, remove some of the obstacles that are preventing these people from wearing them? And suppose we could expand the functionality of contact lenses to make them useful even for people who do not require vision correction? Perhaps an additional 3 billion people would have the opportunity to use contact lenses.

This article briefly describes some of the ongoing research efforts aimed at expanding the use of contact lenses in people who require vision correction, as well as those who do not, opening up the potential growth in contact lens use by 98 percent.

VISION-RELATED GROWTH OPPORTUNITIES

Control of Myopia Progression

According to best estimates, by the year 2020, there will be between 1.6 billion and 2.5 billion people with myopia in the world (Holden *et al*, 2008). Some regions in Asia, such as Hong Kong, China, Singapore and Taiwan, are experiencing an "epidemic" of myopia (Rose *et al*, 2008), and it is clear that, regardless of the reason for this spike in myopia, a well-researched and validated prevention or treatment option for myopia progression must be found.

Although researchers have found that alignment-fitted GP lenses do not successfully control the progression of myopia in children (Walline *et al*, 2004), numerous pilot studies comparing children of similar age and baseline refractions in the United States (Rah *et al*, 2002; Walline *et al*, 2009) and Hong Kong (Cho *et al*, 2005) have shown orthokeratology GP lenses can reduce axial growth rate and spherical equivalent refraction.

Recent research suggests the peripheral retina may be important in controlling eye growth (Smith *et al*, 2007) and that peripheral retinal blur is a major factor leading to uncontrolled axial length growth (Mutti *et al*, 2000). Some potential for retardation of myopia has been shown with the use of currently available center-distance multizone lenses, initially designed to correct presbyopia (Aller and Wildsoet, 2008; Walline, 2011).

Additionally, a "dual-focus" lens designed with the specific aim of controlling myopia is currently available in Hong Kong. This lens, MiSight (CooperVision), has a center zone and several peripheral annular zones to correct distance vision, while alternate concentric rings induce myopic defocus. A study by the inventors of the MiSight lens design found that the lens significantly reduced the rate of axial length growth and refractive error change over a one-month period (Anstice, 2011). Longer-term studies are in progress.

A review of the patent literature suggests other companies are working on lens designs with myopia control capabilities (e.g., Holden and de la Jara, 2007).

One potential concern is that, like the decreased quality of vision sometimes noted with multizone lenses to correct presbyopia (e.g., Richdale *et al*, 2006), similar visual degradation may be experienced by children wearing multizone lenses to control myopia, which may hinder their daily performance or may make them not want to wear the lenses. A recent study of 24 young subjects (Meyer *et al*, 2010) has shown, however, that wearers of the newly developed dual-focus lenses specifically designed to control myopia progression have good measured visual acuity and good patient-reported vision quality that did not differ significantly from typical presbyopic multifocal corrections; however, low contrast acuity was slightly worse than optimal spectacle correction. Figure 1 shows the mean and 95 percent confidence intervals for the measured logMAR acuity and patient-reported vision for a group of subjects while wearing a traditional presbyopic design, the new dual-focus design and optimally corrected with spectacle lenses. Although promising, these results indicate multizone lenses, like multifocal lenses, may not be for everyone, but rather are most beneficial for patients most concerned about myopia progression, where any potential slight decrease in image quality is worth the gain achieved in controlling myopia progression.

Correction of Presbyopia

It is estimated that more than 1 billion people in the world have presbyopia (Holden *et al*, 2008), but fewer than 7 percent of these people wear contact lenses to correct their presbyopia. Despite the availability of alternative lens designs and potentially improved vision with GP lenses, most lenses being prescribed today are hydrogel or silicone hydrogel (Morgan *et al*, 2011). If we assume this preference trend will continue, this suggests that although new soft designs are released by contact lens manufacturers each year, there may be a barrier to the success of these designs. Typically, measured visual acuity with these lenses is quite good; however, patient-reported quality is sometimes decreased (Richdale *et al*, 2006). What this means is that, although a patient may be able to read 20/20 on the acuity chart, he may not be satisfied with the quality of his vision.

This altered letter quality may be a direct result of the lens design. For example, multifocal lenses or lenses with a gradient power change from the lens center to the periphery typically contain higher levels of spherical aberration. This results in multiple focused/defocused images being formed on the retina simultaneously. Figure 2a depicts an eye wearing a multifocal lens with positive spherical aberration, where the peripheral rays of light focus on the retina (dashed line) in front of the central rays of light. Similarly, in bifocal lenses or lenses with discrete power zones, there will always be focused light and light defocused by the amount of the lens add power. Figure 2b shows a two-zone bifocal lens, in which the center of the lens contains the near power. In

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this example, light passing through the central, near-powered section of the lens is focused on the retina (dashed line); however, the distant light passing through the peripheral, distance-powered annulus creates a blurred image on the retina. In both of these cases, the combinations of focused and defocused light create multiple images, which wearers of these lenses may report as ghosting or shadowing.

Several different methods have been proposed to reduce ghosting with presbyopic designs yet avoid the dissimilar image quality between the two eyes common to monovision. For example, clinicians have long employed forms of modified monovision. Recently, adaptive optics systems have been used to induce specific combinations of optics or modified monovision in the two eyes. Specifically, researchers have found that a small amount of defocus or add power (e.g., +1.50D) combined with a small amount of spherical aberration (Zheleznyak *et al*, 2011) yields intermediate acuity that is superior to typical monovision.

At Indiana University, we have employed computational modeling, physical modeling and psychophysical testing to evaluate an alternative way to combine spherical aberration and defocus (Kollbaum *et al*, 2011). Our hypothesis is that if spherical aberration were always combined with defocus of the same sign, the contrast of the overall image would be decreased and, therefore, the noticeability of the ghosting would be decreased. Figure 3 depicts a sample distance-corrected patient viewing at distance while wearing a +2.00D center-distance bifocal contact lens. The image on the left represents what the patient would see if his eye had negative spherical aberration. Although the focused portion of the letters remain legible, the defocused or ghosted images immediately surrounding the letters are also quite visible. The image on the right represents what the patient would see if his eye had positive spherical aberration. Although the overall contrast of the image is slightly decreased, the visibility of the ghosted image is dramatically decreased. This work, combined with our other work, suggests that a strategy of adding negative spherical aberration to the distance zone of a lens and positive spherical aberration to the near zone of the lens may assure that defocus for both distance and near targets is always accompanied by the same sign of spherical aberration, reducing the visibility of the ghosted image.

NON-VISION-RELATED GROWTH OPPORTUNITIES

Drug delivery contact lenses

Ocular drug delivery has always been problematic, and current ophthalmic drug delivery depends greatly upon topical drops. Although eye drops account for 90 percent of all ophthalmic solutions used, we know that only 5 percent of the drug actually penetrates the cornea and reaches the ocular tissue (Gulsen and Chauhan, 2004). This poor penetration rate leads to the necessity for increased drug volume and the potential for systemic problems or side effects (Ciolino *et al*, 2009; Gulsen and Chauhan, 2004).

Although drug uptake and delivery associated with conventional soft contact lenses has proven inconsistent in many cases (Karlgard *et al*, 2003a; Karlgard *et al*, 2003b), recent advances in nano and polymer technology have opened the possibility of more consistent release of a drug from a soft contact lens. Some of the common uses for a vehicle of this nature include the administration of glaucoma, dry eye and topical antibiotic treatments.

In one technique, called microemulsion, the drug molecules can be encased within a protective hydrocarbon micelle, which is engineered to penetrate the corneal cells. These emulsified drug particles can then be loaded into a hydrogel soft contact lens and once the lens rests on the eye, the particles diffuse. The microemulsion technique increases membrane permeability, thus increasing the bioavailability of the drug and ultimately providing a sustained release of the drug into the deeper corneal layers. Because the rate of the drug release can be controlled, a uniform low-level dose of the drug is provided (Sahoo *et al*, 2008). Furthermore, recent research has shown that the additional infusion of fat-soluble vitamin E along with a drug into a soft contact lens can increase the diffusion time of the drug (Peng and Chauhan, 2011).

Although researchers have demonstrated preliminary success (Gulsen and Chauhan, 2004), commercial development of these lenses will require additional work. If these technologies come to fruition, however, they may replace traditional ophthalmic drops as a means of treatment for many ocular conditions in patients of all ages. Instead of prescribing a 6-month supply of glaucoma drops, for example, imagine prescribing a 6-month supply of contact lenses that will release a controlled dose of the medication all day, every day.

Photochromic Contact Lenses

Another example of a revolutionary advancement in polymer technology is the development of photochromic contact lenses. Using a microemulsion technique similar to what is used for ophthalmic lenses, researchers at the Institute of Bio-engineering and Nanotechnology (IBN) in Singapore claim to have developed the world's first photochromic soft contact lens.

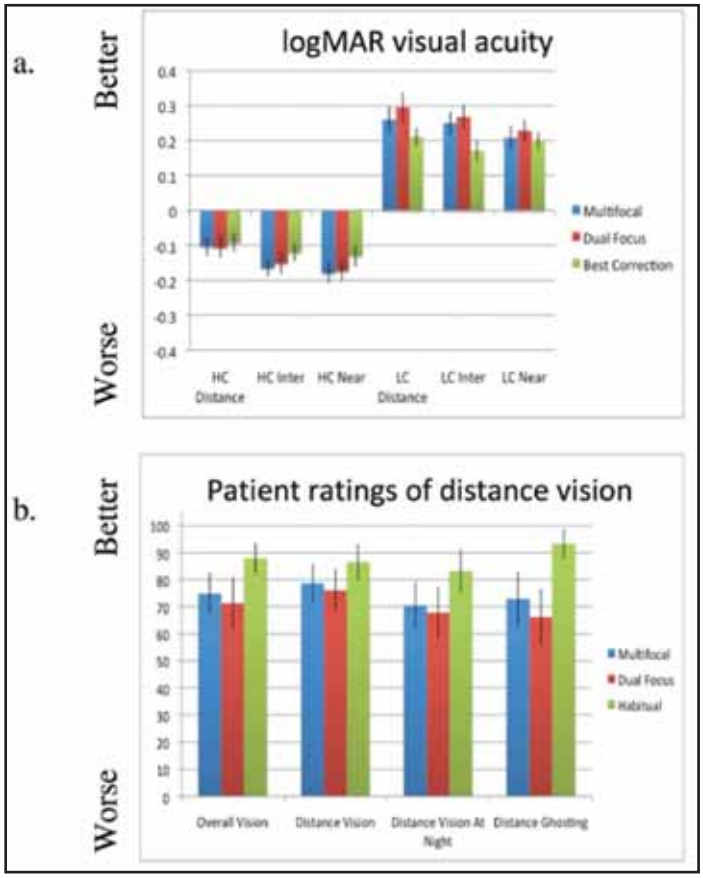

Figure 1. (a) Mean binocular logMAR distance letter acuity and (b) patient-reported vision for typical multifocal, dual-focus and habitual lens correction.

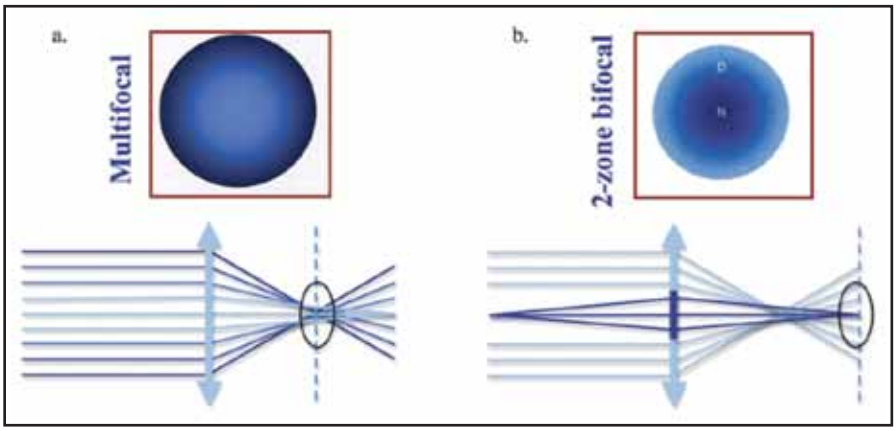

Figure 2. Ray diagrams of an eye wearing (a) a multifocal lens with positive spherical aberration and (b) a 2-zone bifocal lens.

Figure 3. Simulated retinal images of a distance-corrected eye wearing a +2.00D add center-distance bifocal lens. The eye on the left has negative spherical aberration; the eye on the right has positive spherical aberration.

The lens shown at the top of Figure 4 is a prototype lens (www.technologyreview.es /biomedicine/23922). IBN researchers are still pursuing commercialization of this technology, but if they are successful, these types of contact lenses would benefit patients who want improved sun protection but are not able to wear traditional sunglasses.

Contact Lenses for Diagnosis

Another area of untapped potential for contact lenses is their use as diagnostic devices, such as for use in glaucoma. Although glaucoma is a common cause of blindness, a definitive treatment for this disease has proven elusive. Traditionally, glaucoma therapy involves managing intraocular pressure (IOP) with medications administered topically, sometimes several times a day. Treatment is often hindered, however, when patients do not adhere to their therapy. The drug delivery contact lenses described above may help overcome this challenge.

Likewise, successful treatment hinges on the clinician's ability to accurately diagnose glaucoma and monitor the efficacy of therapy. For example, a patient's IOP may be within normal limits at the time of his office visit, leading the clinician to conclude the current treatment is successful (or that no treatment is necessary). At other times during the day, however, the patient's IOP may be much higher. Sensimed, a Swiss biotech company, has developed the Triggerfish lens, a single-use SiHy contact lens aimed at providing continuous IOP measurements (Figure 4 center and bottom). The lens is embedded with a microprocessor and a strain gauge that encircles its outer edge. When fluid accumulates in the eye, the diameter of the cornea changes, and that change is detected by the strain gauge. This information is then sent wirelessly to a receiver. The company has received safety approval for this lens in Europe, and approval is expected from the U.S. Food and Drug Administration by the end of this year.

Contact Lenses for All

We live in a rapidly changing world. As times change, we change how we view things, and new opportunities arise. I have briefly discussed a few newly available and developmental technologies that may lead to new commercial products, giving us opportunities as contact lens practitioners to expand our roles. These technologies include some that aim to improve vision and

Figure 4. (Top) Prototype photochromic contact lens; (center and bottom) Triggerfish lens for continuous IOP measurement.

others that aim to capitalize on other uses for contact lenses. Finances aside, in theory, these new technologies have the potential to make virtually everyone a contact lens wearer and to make contact lenses drastically different from what they were just a few decades ago when our fathers (in the figurative sense for all and the literal sense for some) were fitting these lenses.

Dr. Kollbaum is an assistant professor at the Indiana University School of Optometry, where he teaches and performs translational research in the areas of contact lenses and clinical optics. He has received research funding from Ciba, CooperVision and Vistakon. He has filed a patent application regarding a technology discussed.

BY LORETTA B. SZCZOTKA-FLYNN, OD, PHD, FAAO, AND ROBIN CHALMERS, OD, FAAO

Corneal Infiltrates: Managing Risks With Soft Lens Wear

Corneal infiltrates can occur in contact lens wearers and nonwearers alike and are a result of a stimulus that directs infiltration of leukocytes into the cornea (Josephson,1979). Recently, clinical reports have purported an increased incidence of corneal infiltrates with silicone hydrogel lenses and multipurpose care solutions (Hine, 2008; Kislan, 2011;Sacco, 2011). This review summarizes the incidence of and risk factors for corneal infiltrates across various soft lens types and summarizes what is known about risks for corneal infiltrates with silicone hydrogel lenses and multipurpose care solutions in the peer-reviewed literature.

Symptomatic Infiltrate Rates

The rate of corneal infiltrates documented in any given study is significantly affected by definition and frequency of examination. The most clinically relevant rates probably come from clinical studies that report symptomatic corneal infiltrates, since those encompass patients who present for care related to corneal infiltrates. During 30-night extended wear with silicone hydrogels, the incidence of symptomatic corneal infiltrates (or >= Grade 2) has been documented at 2.5 to ~6 percent per year (Chalmers, 2007; FDA Summary of Safety and Effectiveness Data [balafilcon A], 2001; FDA Summary of Safety and Effectiveness Data [lotrafilcon A], 2001). A meta-analysis of 23 extended-wear studies from the 1990s until 2006 reported the annual rate of symptomatic and asymptomatic corneal infiltrate events to be 14.4 percent for silicone hydrogels and 7.7 percent for hydrogel materials (Szczotka-Flynn, 2007).

Risk factors for corneal infiltrates with daily wear of silicone hydrogels have been established, but the incidence is not known. A university-based study team assessed corneal infiltrates in a series of 3-month, nonrandomized, prospective clinical trials with 558 individuals wearing a variety of silicone hydrogel lenses for daily wear and using modern lens care products (Carnt *et al*, 2009). In these trials, the rate of symptomatic corneal infiltrates was ~20 percent when annualized to 1 year but varied widely by care solution brand and lens material. Subjects in university studies are sometimes examined frequently, which may increase the observed incidence of corneal filtrates (Chalmers, 2007). In two large, multicenter, retrospective chart reviews, the incidence of corneal infiltrates across multiple lens types for patients presenting for eye care in optometry school clinics was just over 3 percent per year in studies that reviewed records from 6,117 patient-years of contact lens wear (Chalmers *et al*, 2011; Chalmers *et al*, 2011). These rates may more closely align with what practitioners see in practice.

Risk Factors

Risk factors are estimates of how much a certain factor increases or decreases a person's chance of developing a specific disease. In health research, the best approach is to consider the multivariate risk factors, because they account for the influence of many factors that each person may carry that may influence (or confound) one another. For example, corneal infiltrate risk may be higher for patients wearing silicone hydrogel contact lenses because they are more likely to sleep in these lenses,even if they have been prescribed for daily wear. A multivariate analysis will control for overnight wear and material separately and measure the influence of each factor. We present multivariate factors here.

Studies of risk factors for corneal infiltrates have been consistent, and they include factors brought by the patient, the lens wear modality, the lens material and the care products. Significant factors related to patients include male gender (du Toit, 2002), smoking (Szczotka-Flynn *et al*, 2010; McNally *et al*, 2003), absolute refractive error ≥5.00D (Chalmers *et al*, 2007), history of previous complications (McNally *et al*, 2003) and young age (Chalmers *et al*, 2007; Chalmers *et al*, 2011; Chalmers *et al*, 2011; McNally *et al*, 2003; Chalmers *et al*, 2010).

Substantial lens bacterial bioburden increases the risk for corneal infiltrates during silicone hydrogel lens extended wear more than eight-fold (Szczotka-Flynn *et al*, 2010), and similar results have been found with low-Dk HEMA-based materials (Wilcox *et al*, 2011). Bioburden is responsible for more than 70 percent of the total risk of corneal infiltrates in silicone hydrogel extended wear (Szczotka-Flynn *et al*, 2010).

Extended wear increases the risk for corneal infiltrates 2.5-fold to eight-fold across various soft lens types (Chalmers, *et al* 2011; Efron *et al*, 2005; Radford *et al*, 2009). Although corneal staining is common during extended wear with silicone hydrogel lenses, it is not associated with the development of a corneal infiltrate (Szczotka-Flynn *et al*, 2010). One study claimed daily disposables did not lower corneal infiltrate risk (Radford *et al*, 2009), but more recent studies find either no difference (Chalmers *et al*, 2010) or up to a 12.5-fold lower risk of corneal infiltrates for daily disposables compared with reusable lenses (Chalmers *et al*, 2011).

Products associated with increased risk include multipurpose disinfection systems (about a three-fold increased risk compared to peroxide systems) (Chalmers *et al*, 2011) and silicone hydrogel lenses. In at least four studies, silicone hydrogel materials have been associated with about a two-fold greater risk for corneal infiltrates compared with hydrogel materials, regardless of overnight wear (Szczotka-Flynn, 2007; Chalmers *et al*, 2011; Chalmers *et al*, 2011; Radford *et al*, 2009). This increased rate of corneal infiltrates in silicone hydrogel wearers is perplexing, as we effectively prescribe these lenses to avoid the hypoxic complications we have observed in the past.

The previously mentioned case series and repeated lens-solution trials reported on patients with corneal infiltrates that were believed to be associated with an interaction between Opti-Free Replenish (Alcon Laboratories Inc.) and silicone hydrogel lenses. That finding did not hold up in a recent retrospective, multicenter, case-control study that had the capability (power) to detect whether specific products or combinations of lenses and lens care products had at least a 1.8-fold increased risk for corneal infiltrates (Chalmers *et al*, 2011). A case-control study compares product use among patients who develop disease and patients from the same practice and time period who remained disease free and, thus, accounts for the market share of a product that can confound the findings seen in a case series. This study found that more than 45 lens-solution combinations were used by 166 patients who presented with corneal infiltrates related to contact lens wear and that the risk was not limited to a very few products. No significant increase in risk was seen with any one lens care product when other factors were taken into account (multivariate analysis). There are perhaps some regional effects driving the corneal infiltrate cases in the private practice case series.

Implications of the Evidence

Although the increased rate of corneal infiltrates with silicone hydrogels is apparent in the literature, the benefits of these lenses may outweigh this risk, at least for many patients. The higher incidence of corneal infiltrates found in prospective studies frequently includes asymptomatic events, while the benefits include reduced hypoxic complications and longer wearing times for the same level of microbial keratitis risk (Schein *et al*, 2005). Regarding care solution interaction as a risk factor, it is important to evaluate study design when interpreting results.

The most recent literature suggests that no single lens brand or lens care product is associated with a significant increase in risk that even begins to approach the risk associated with extended wear (2.5-fold to eight-fold), use of reusable lenses compared to daily disposable (12.5 times higher), smoking (four-fold) or having a contaminated lens during extended wear (greater than eightfold). Clinicians should use such evidence-based research to customize a treatment plan and guide patients into the best lens for that person.

Dr. Szczotka-Flynn is a professor at the Case Western Reserve University Department of Ophthalmology & Visual Sciences and director of the Contact Lens Service at University Hospitals Case Medical Center. She has received research funding from Alcon, CooperVision and Vistakon. Dr. Chalmers is an independent clinical trial consultant and an adjunct professor at Indiana University School of Optometry. She is a consultant or advisor to Alcon and Vistakon and an advisor to Bausch + Lomb.

In many cases, soft contact lenses provide optimal comfort and vision for patients with keratoconus.

BY S. BARRY EIDEN, OD, FAAO, & GREGORY W. DENAEYER, OD, FAAO

Keratoconus Fitting With Specialty Soft Lenses

Fitting keratoconic eyes with contact lenses is synonymous with fitting GP contact lens designs. The firm nature of GP lenses allows them to mask corneal irregularity by creating a post-lens tear layer.

Although standard soft contact lens designs can correct ametropia and regular astigmatism in a keratoconic eye, they do not perform as well for correcting irregular astigmatism because their thinness and inherent flexibility cause them to conform to front-surface cornea irregularity (de Brabander *et al*, 2003; Holden and Zantos, 1981). In addition, standard soft contact lenses typically are not available in parameters that will fit the steeper corneas of many keratoconic eyes. There are, however, specialty soft contact lens designs that not only successfully fit keratoconic eyes but also provide improved visual acuity by correcting for mild to moderate amounts of irregular astigmatism.

Need for Soft Lenses

According to the baseline findings in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) study, 65 percent of patients with keratoconus were wearing GP lenses and 73 percent reported comfortable lens wear (Zadnik *et al*, 1998). Unfortunately, some keratoconus patients cannot wear GP lenses because of discomfort, and their only option is a corneal transplant.

Improved hybrid and scleral lenses now provide alternative options for patients who previously could not wear corneal GP designs. That said, however, in our experience some patients would prefer a soft contact lens design if available. But can a soft lens deliver acceptable vision to these patients?

Yamazaki *et al* (2006) reported on 66 patients (80 eyes) who were fitted with a specialty soft lens for keratoconus after experiencing reduced tolerance or poor fitting with other designs. The eyes were grouped according to severity of keratoconus, as follows: 15 percent incipient, 53.7 percent moderate, 26.3 percent advanced and 5 percent severe. The results showed that 91 percent of the eyes achieved visual acuity better than 20/40 with a specialty soft lens design for keratoconus. The base curve most frequently used was 7.6mm in 61 percent of the eyes.

Specialty Soft Lens Characteristics

Specialty soft contact lenses for keratoconus (Table 1) are lathe-cut to allow for customization. These lenses are available with relatively steep base curves (4.1mm to 9.3mm, depending on the design) to accommodate the increased sagittal height of a keratoconic eye.

Soft contact lenses designed for keratoconus are generally thicker centrally than standard soft lenses, ranging from 0.3mm to 0.6mm. This increased center thickness helps prevent the lens from conforming to the irregular shape of the cornea. In other words, the soft lens starts to behave like a GP, which allows it to mask some mild to moderate irregular astigmatism. Increasing lens thickness, however, decreases the lens's oxygen permeability, thus raising a concern that the eye will develop hypoxiarelated complications.

As lathe-cut silicone hydrogel lenses become available in keratoconic designs, they will be preferable for many patients. A few of these lens designs have adjustable midperipheral curves that allow the practitioner to adjust the movement and fit of the lens independent of the base curve. A lenticular midperiphery and periphery thins the lens design outside the optical zone, thus improving overall oxygen permeability and comfort (Figure 1). These lenses are available in the high spherical and toric powers commonly required for keratoconus. Some soft contact lens designs for keratoconus are available in reversegeometry configurations and, as such, can be applicable to post-keratoplasty cases that have residual anterior surface irregularity.

TABLE 1 - Soft Contact Lenses for Keratoconus

MANUFACTURER	LENS
Accu Lens	Soft K
Advanced Vision Technologies	Soft K
Alden Optical	NovaKone
Art Optical (distributed by B+L)	KeraSoft IC
Continental Soft Lens	Continental Cone
Gelflex USA	Keratoconus Lens
Marietta Vision	Soflex Soft
Ocu-Ease/Optech	Ocu-Flex 38 Keratoconus
Strategic Lens Innovations Corporation	Soft K
United Contact Lens	UCL-55
X-Cel Contacts	Tricurve Keratoconus
Visionary Optics	HydroKone
UltraVision CLPL	KeraSoft IC
World Vision	Perfect Keratoconus

Figure 1. Profile of a soft contact lens fitted for keratoconus.

Fitting Specialty Lenses

Fitting specialty soft lenses for keratoconus typically requires a diagnostic fitting set because empirical prediction of lens performance in terms of required sphere, cylinder, axis and center thickness is highly unreliable in these cases. If you do not have a fitting set, you can order a lens based on the manufacturer's fitting guidelines to function as your initial diagnostic lens.

The lens should align with the cornea centrally to provide the best vision possible. Use high-molecular weight fluorescein with a cobalt light and Wratten filter to check for bearing or excessive vault. Edge fluting or lens movement of greater than 1mm indicates the lens is fitting excessively flat. Perform a sphere-cylinder over-refraction to determine power. If the patient is not achieving his best potential vision with over-refraction, consider performing topography over the lens to measure the amount of residual irregularity. Increasing the center thickness by 0.1mm to 0.3mm may be necessary to improve vision if significant irregularity remains. Discuss specific adjustments for a particular lens design with the manufacturer's consultants to fine-tune the final parameters.

Wavefront-guided Soft Lenses

Although specialty soft lenses for keratoconus can mask mild irregular astigmatism, we believe that wavefront-guided soft lenses for keratoconus will eliminate more significant amounts of higher-order aberrations and maximize visual acuity. The difficulty of successfully correcting for asymmetric higher-order aberrations is that soft lenses translate and rotate on the eye. De Brabander *et al* (2003) reported on simulated optical performance of custom wavefront soft contact lenses for keratoconus and found that translation errors negatively affected performance and should not exceed more than 0.5mm. It has been suggested that partial correction of higher-order aberrations may be beneficial when a lens exhibits significant translation and rotation (Guirao, 2002).

Marsack *et al* (2007) reported on a patient with moderate keratoconus whose habitual lenses were soft torics and who was refitted with custom wavefront-guided soft lenses. The patient had a 1.5-line improvement of visual acuity and a 50 percent reduction in higher-order aberrations. It may also be possible to customize the back surface of a soft contact lens to improve the fit on a keratoconic cornea. Customized back-surface soft contact lenses, as compared to conventional soft contact lenses, improved lens stability by a factor of 2 for translations and a factor of 5 in rotational orientation in a study by Chen *et al* (2007).

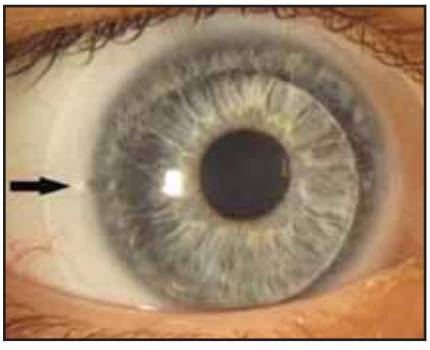

Figure 2. This soft toric lens for keratoconus is well-centered on the patient's eye. The arrow points to the temporal toric marking.

Case Examples

Case #1 A 14-year-old boy reported for evaluation of keratoconus. His manifest refraction was OD +0.25 –3.25 x 015 20/40 and OS +0.50 –1.50 x 165 20/20. Topography showed moderate nipple keratoconus of both eyes. His corneas were without striae or scarring. He was interested in contact lenses for improved vision for lacrosse. After discussing contact lens options, the patient wanted to try a soft keratoconus lens design. He was diagnostically fit using HydroKone (Visionary Optics) soft lenses (hioxifilcon 59%) with a base curve of 8.5mm, secondary curve of 8.6mm, overall diameter of 14.8mm and center thickness of 0.4mm. The lenses had adequate centration and coverage with 0.5mm movement. An over-refraction was performed over the diagnostic lenses to determine power.

After several follow-up visits and one power adjustment of the right eye, the final lens powers were OD plano –1.12 x 085 20/40 (Figure 2) and OS plano sphere 20/20 (final center thickness 0.49mm OU). The power of both lenses compared to the manifest refraction illustrates how effectively the increased center thickness of the lens can mask astigmatism. The patient is scheduled for future corneal crosslinking.

Case #2 A 32-year-old patient who was previously unsuccessful with soft toric and GP lenses was interested in other options. His spectacle prescription was OD –1.50 –3.25 x 093 20/30 and OS –0.50 –3.00 x 079 20/30. Topography showed moderate oval cones on both eyes. Slit lamp examination showed the patient's corneas were clear without scarring. The patient was fitted with HydroKone (Visionary Optics) soft contact lenses (hioxifilcon 59%) with a base curve of 8.5mm, secondary curve of 8.6mm, diameter of 14.8mm and center thickness of 0.4mm. This diagnostic lens showed significant inferior decentration in the right eye, which was fitted first. A second HydroKone diagnostic lens with a base curve of 8.1mm and secondary curve of 8.6mm centered well and had 1mm of movement on both eyes; it was custom ordered after over-refraction. The final lens powers were OD –3.00 –3.00 x 070 20/25 and OS –3.25 –2.25 x 86 20/20 (final center thickness 0.49mm OU, Figure 3).

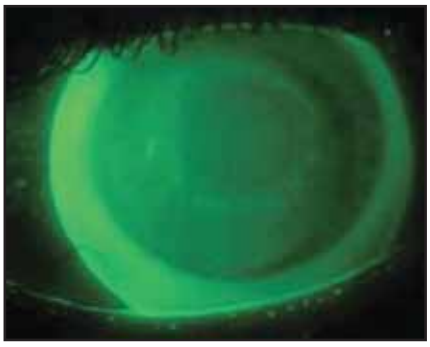

Figure 3. Fluorescein highlights the fit of this soft toric lens for keratoconus on the patient's right eye.

Case #3 A 22-year-old man was evaluated for symptoms of unilateral blurred vision with his eyeglasses, which was worsening over the past 2 years. Frequent prescription changes for the left eye failed to provide clear vision with eyeglasses. Interestingly, both of the patient's parents were keratoconus patients (with the father having advanced disease requiring penetrating keratoplasty). Manifest refraction was OD +0.75 –1.00 x 95 20/20–, OS –5.25 –1.25 x 65 20/50. Biomicroscopy failed to show any abnormalities in the right eye; however, the left eye had +2 Vogt's striae and a notable partial inferior Fleischer's ring. Pentacam corneal analysis revealed bilateral corneal ectasia that was significantly more advanced in the left eye compared with the right eye (Figure 4).

The patient was fitted with a NovaKone (Alden Laboratories) lens (hioxifilcon 54%). This design is available in a series of "IT" values (0 to 4) corresponding to variable center thicknesses that are used to mask corneal irregularities.

The left eye was evaluated with a diagnostic lens with a base curve 1mm flatter than the mean keratometric findings. The first diagnostic lens demonstrated peripheral edge fluting and decentration. A second lens with a base curve 0.4mm steeper resulted in appropriate movement and centration without peripheral edge fluting. The over-refraction resulted in visual acuity of 20/30. The center thickness of the diagnostic lens was IT 2. The final lens for the left eye had a 6.6mm base curve, 8.2mm peripheral curve, 15mm overall diameter, IT 3 center thickness (with peripheral lenticularization) and power of –7.00 –1.00 x 90. Visual acuity with the final lens was 20/20–. The right eye was successfully fit with a conventional soft toric lens from SpecialEyes Laboratories (hioxifilcon 54%) in the following parameters: base curve 8.1mm, overall diameter 14.5mm and power +0.75 –1.00 x 100. The resultant visual acuity was 20/20 OD.

Case #4 A 27-year-old man with a 5-year history of keratoconus had been wearing conventional disposable soft lenses on both eyes with poor vision, after trying unsuc-

cessfully to wear GP lenses. Vision with his habitual lenses was OD 20/20 and OS 20/50. Manifest refraction was OD –2.25 –1.00 x 65 20/20, OS –2.00 –5.00 x 70 20/40+. Biomicroscopy revealed a partial Fleischer's ring inferiorly and +2 Vogt's striae in the left eye. Pentacam corneal analysis revealed bilateral keratoconus, significantly more advanced in the left eye compared with the right eye. Both eyes had inferiorly displaced cones, but the one on the left was larger and much steeper in comparison to the right. Corneal thickness at the apex of each cone was OD 523 and OS 437 microns.

The patient was diagnostically fit with a KeraSoft IC silicone hydrogel lens (distributed by Bausch + Lomb [B+L] and manufactured by Art Optical as part of our participation in a premarket clinical trial). Based on the position and size of the cone, as well as the peripheral corneal curvature, a diagnostic lens with a base curve of 8.2mm and standard periphery was evaluated. The lens edge demonstrated mild fluting, and movement was somewhat greater than desired. A diagnostic lens with steep periphery was selected and demonstrated excellent centration and movement. Over-refraction resulted in 20/20– acuity. We ordered a lens with these fitting parameters and a power of –1.75 –4.00 x 80 (based on lens over-refraction). At dispensing and at the 2-week follow-up visit, vision with the lens was 20/25+, fit was excellent, comfort was described by the patient as "wonderful" and physiological response was excellent.

The KeraSoft IC contact lens is being manufactured initially by Art Optical from the Contamac silicone hydrogel lens material efrofilcon A (74% water, Dk 60). It is an anterior aspheric design lens with a consistent center thickness of 0.4mm, available in a variety of base curve and peripheral curve options. It also can be produced in a reverse-geometry configuration. Unique to soft contact lens designs for keratoconus, the KeraSoft IC contact lens can also be produced with what the manufacturer terms "sector management control," whereby any two quadrants of the lens periphery can be fabricated steeper or flatter. This is occasionally needed in cases where the inferior corneal periphery is very steep compared with the rest of the cornea.

Expanding Options

Contact lens management of keratoconus—and all contact lens cases, for that matter—requires that three criteria are met: adequate vision correction, acceptable comfort and appropriate ocular health response. Contemporary management of keratoconus with contact lenses encompasses numerous design categories, including GP corneal lenses, GP scleral contact lenses, hybrid contact lenses, piggyback lens systems and soft contact lenses. Depending on the degree of corneal distortion and the associated best-corrected visual acuity with spectacles, patients with keratoconus may be able to successfully wear either standard soft lenses or custom specialty soft lenses designed for keratoconus.

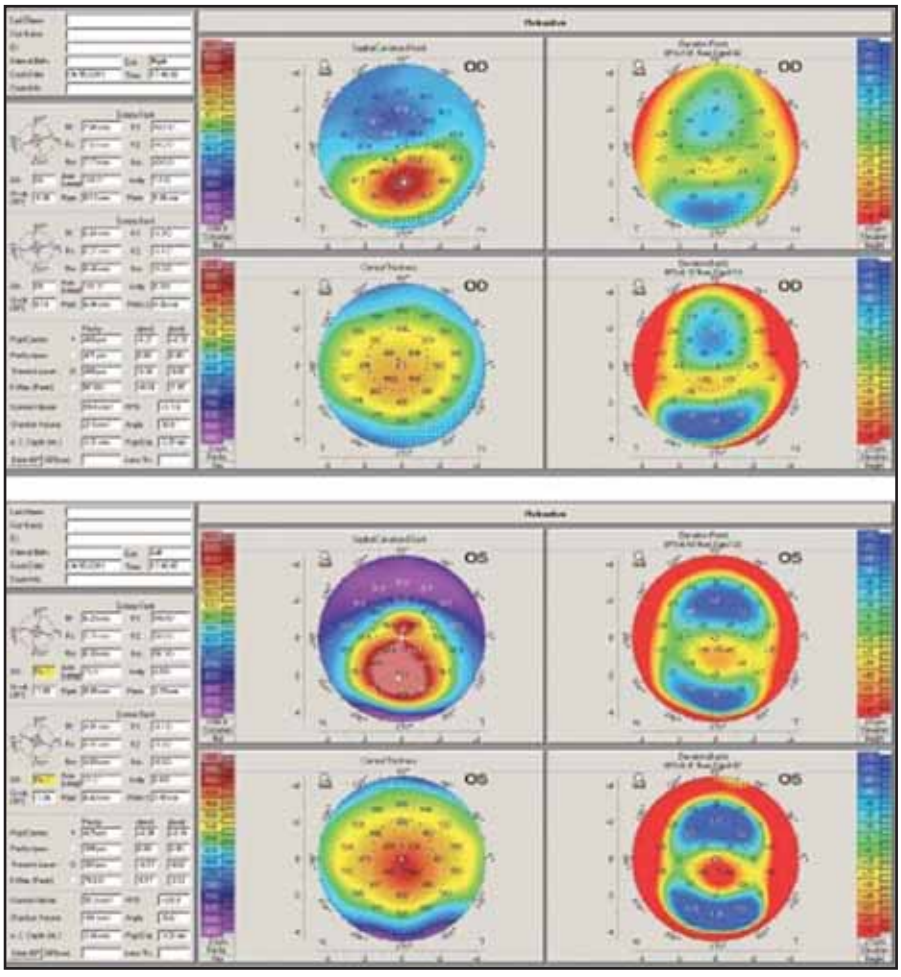

Figure 4a (top). Case 3: Pentacam corneal analysis OD. Figure 4b (bottom). Case 3: Pentacam corneal analysis OS.

Standard soft contact lenses are typically limited to mild cases of keratoconus that can achieve normal visual acuities with spectacle correction (typically better than or equal to 20/25). Although both lathecut and molded disposable contact lenses can be used in these cases, the final power parameters that produce best-corrected visual acuity may or may not be consistent with the manifest refraction. Often, because of unpredictable lens draping over the keratoconic cornea, the spherical, cylindrical and axis parameters of the successful contact lens may be quite different from what was predicted from the manifest refraction.

For cases of more advanced corneal irregularity and reduced best-corrected spectacle acuity in keratoconus, specialty custom lathe-cut soft contact lens designs are required. Centrally thickened designs will mask corneal irregularity and provide acceptable visual acuity in many cases. The primary advantages of these contact lenses include improved comfort and the ability to center well while still correcting vision adequately. The most significant physiological concern with these contact lenses is hypoxia, owing to the significantly greater lens thicknesses used in these designs. The utilization of peripheral lenticularization, greater-than-average contact lens movement and higher oxygen transmission materials addresses this concern.

The fitting of keratoconus patients with contact lenses is not synonymous with fitting GP lenses. In many cases, soft contact lenses can provide optimal comfort, vision and physiological response for patients with keratoconus.

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By being judicious about identifying secondary Sjögren's Syndrome, you can grow your practice.

BARBARA CAFFERY, O.D., PH.D., TORONTO, CAN.

Practice Rheumoptometry

Optometry could and should be Rheumatology's best friend. After all, we have the ability to be the first to identify autoimmune rheumatic diseases, such as Sjögren's syndrome, in our eye exam, enabling us to refer these patients to rheumatologists for further diagnostic testing and systemic management of their condition. Once this co-management of patients begins, rheumatologists will reciprocate by referring their patients to us for both primary and secondary Sjögren's syndrome (SS) management. Also, once the rheumatologist sees you can treat SS, he'll be more likely to refer to you for other ocular problems.

Considering an estimated 1.5 million U.S. adults have rheumatoid arthritis (RA), and a recent CDC survey suggests that SS is as common as RA and much more common than systemic lupus erythematosus (SLE), scleroderma and ankylosing spondylitis, it's definitely worth forging such a relationship.[1]

While I have no doubt some O.D.s and rheumatologists have and continue to work together, I also know that other O.D.s are losing out on this practice-building opportunity because many secondary SS patients remain un-diagnosed for several years. The reasons: SS symptoms may mimic those of menopause, drug side effects, allergies or the aforementioned medical conditions themselves along with fibromyalgia, chronic fatigue syndrome and multiple sclerosis.[2] Also, autoimmune diseases have exacerbations and remissions so that all symptoms of the condition are not always present at the same time. In addition, SS can involve many body systems (e.g. the brain, lungs, skin, stomach, liver and extremities) leading doctors to sometimes treat each symptom individually rather than recognize they comprise SS. Finally, diagnosing SS is challenging because those who have it often try to cope with its symptoms on their own. As an example, someone who has dry mouth, may simply drink more water to conquer the problem.[3] With the recent media attention surrounding Venus Williams' diagnosis of SS, however, it is hoped that those who have been trying to cope on their own will now seek their optometrist or primary care physician to determine whether they too, have SS.

Here, I provide an overview of SS, how to arrive at a definitive diagnosis and how to treat it, so you can take advantage of the benefits of seeing these patients.

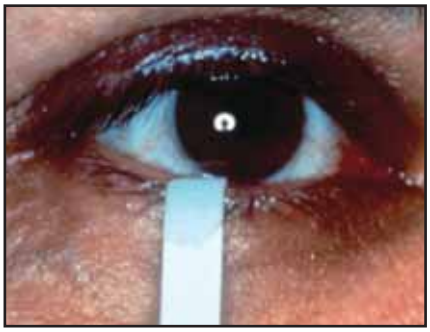
SS overview

SS is a chronic systemic rheumatologic autoimmune disorder characterized by lymphocytic infiltration and malfunction of the exocrine glands. It can effect the brain (concentration/memoryloss); the nose (nasal dryness, recurrent sinusitis, nose bleeds); the mouth (dry mouth, dental decay, chewing, speech and taste); the digestive tract (difficulty swallowing, heart burn, reflux esophagitis); the lungs (recurrent bronchitis, pneumonia, interstitial lung disease); the liver (abnormal liver function tests, chronic active autoimmune hepatitis, primary biliary cirrhosis); the stomach (gastroparesis, autoimmune pancreatitis); and cause peripheral neuropathy (numbness and tingling in the extremities.)[4] It is named for Henrik Sjögren, a Swedish ophthal mologist who first described the condition. (Dr. Sjögren died in 1986 at age 87.)

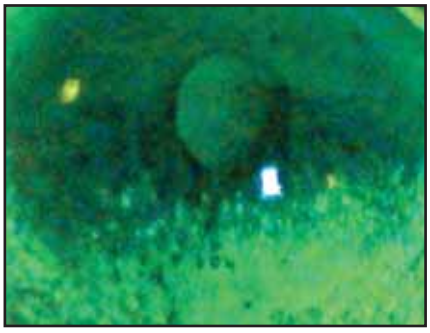
Nine out of ten SS patients are women, although the condition can occur in both men and in children.[2] There is some controversy as to the age of SS onset, as the disease can exist for a long time in subclinical form, making the disease duration of most patients uncertain.[5,6] Some report two age peaks in the diagnosis of this disease: 20 to 30 years after menopause and the mid 50 years.[7] Others state the age of onset as approximately 45 years.[8-10]

The symptoms of SS vary but may include: a dry, gritty or burning sensation in the eyes; dry mouth; difficulty talking, chewing or swallowing; a sore or cracked tongue; a dry or burning throat; dry or peeling lips; a change in taste or smell; increased dental decay; joint pain; vaginal and skin dryness; digestive problems; dry nose and fatigue.[4] In addition, these patients are also 16 times more likely to develop lymphoma, and they are at high risk for fatigue and depression.[11-16] (These whole-body disease characteristics alone emphasize the need for early diagnosis and management. Remember: A grateful patient is your best marketing vehicle.)

The syndrome can present as secondary SS, which by definition is associated with rheumatoid arthritis, SLE or scleroderma, or as primary SS, which presents absent of an underlying rheumatological disease.



The criterion for objective dry eye in Sjögren's syndrome is Schirmer 1 scores ≤5mm in at least one eye or staining scores of ≥4/9 in at least one eye.



Adding fluorescein and grading the amount of corneal staining from 0 to 3 will help you diagnose Sjögren's syndrome.

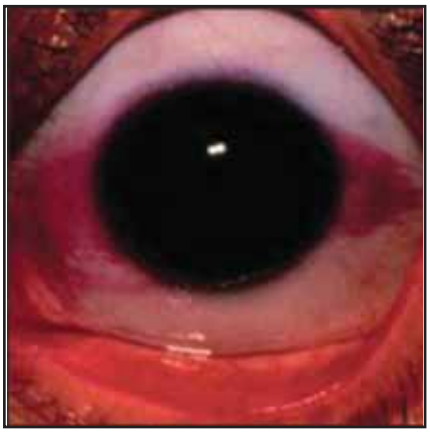
The Toronto Sjögren's Syndrome Clinic is now investigating the prevalence of secondary SS in other autoimmune diseases, such as CREST (calcinosis, Raynaud's phenomenon, esophageal dys-function, sclerodactyly and telangiectasia) syndrome.

I suspect that in the future, more autoimmune diseases will appear on the list of those associated with SS as well. It is my suspicion that the involvement of dry eye in these other autoimmune diseases has been ignored in the past, as dry eye is considered a very minor aspect of systemic autoimmune disease. Patients with dry eye will be quick to tell you otherwise.

Making the diagnosis

To determine whether the patient has SS:

► ***Inquire about the presence of systemic disease.*** On the patient's history form, include check boxes next to rheumatoid arthritis, systemic lupus erythematosus and scleroderma for the aforementioned reasons.



Be aware that the presence of lissamine green staining of the temporal bulbar conjunctiva is the most important variable (of more than 90 variables measured at our Sjögren's syndrome clinic) in suspicious Sjögren's syndrome and in differentiating it from other forms of aqueous deficient dry eye.

► ***Inquire about dry eye symptoms.*** On the patient's history form, ask whether he/she is experiencing ocular dryness. This question is crucial because as mentioned above, many SS patients are stoic individuals. In fact, a recent survey of SS patients revealed a lack of patient-physician dialogue about symptoms, such as dry mouth, contributed to a delayed diagnosis.[3]

► ***Ask about dry mouth.*** Include this question on your patient history form: "Can you eat five soda crackers without drinking water?" If the patient writes "no," you have a SS suspect.

If the patient has a diagnosis of RA, SLE or scleroderma or if either dry mouth or dry eye symptoms are reported, move on to the following tests:

► ***Measure the ocular dryness level.*** Use Schirmer 1 testing. The criterion for objective dry eye in SS is: Schirmer 1 scores ≤5mm in at least one eye or staining scores of ≥4/9 in at least one eye.

► ***Grade corneal staining.*** Add fluorescein, and grade the amount of corneal staining from 0 to 3.

► ***Grade the temporal and nasal sections of the bulbar conjunctiva.*** Employ lissamine green stain, and grade from 0 to 3. Please be aware that the presence of lissamine green staining of the temporal bulbar conjunctiva is the most important variable (of more than 90 variables measured at our SS clinic) in suspicious SS and in differentiating it from other forms of aqueous deficient dry eye.[17]

Now, total your scores out of nine.

If there is no underlying systemic diagnosis but symptoms of dry eye and dry mouth are present, as are the objective signs of dry eye, you are well on your way toward a diagnosis of Primary SS (PSS). Although the complete diagnosis is not in your hands, you are often the first healthcare provider to entertain the possibility. (In this case, you can garner reciprocal referrals from primary care physicians.) In PSS, testing is required by several disciplines to determine each of the following six criteria:

1. Symptoms of dry eye for at least three months.
2. Symptoms of dry mouth for at least three months.
3. Signs of dry eye: Schirmer 1 scores of ≤ 5mm in five minutes and/or Rose Bengal or fluorescein staining scores of ≥ 4/9 in at least one eye. This scoring is a sum of the cornea, nasal and temporal conjunctiva graded 0 to 3.
4. Signs of dry mouth: salivary flow by unstimulated spitting in a cup of ≤ 1.5ml in 15 minutes.
5. Positive blood serum findings of autoantibodies to Ro and/or La.
6. Positive salivary gland biopsy score: ≥ 1 focus score in 4mm of tissue.

A minimum of four of these six criteria must be met, including one of serum-positive or biopsy-positive results to garner a PSS diagnosis, according to the gold standard American European-Consensus Criterion (AECC) for SS.

A referral letter to a family practice with specific instructions to test the serum for ANA, RA, anti-ro and anti-la moves the PSS diagnosis forward. If anti-ro or anti-la is present, the diagnosis is confirmed. If not, a minor salivary gland biopsy is required.

The current standard diagnostic criterion for secondary SS is also a part of the AECC.18 In the presence of an associated autoimmune disease (RA, SLE, etc.), the presence of ocular symptoms or oral symptoms combined with any two of the objective signs of dry eye, objective signs of dry mouth and histopathology define secondary SS. Thus, the diagnosis of secondary SS is completely in your hands.

Treatment

Currently, SS has no cure. That said, you can offer your patients symptomatic relief in the form of lubrication, lid scrubs and hot soaks, punctal occlusion, anti-inflammatory topical therapy, such as cyclosporine ophthalmic emulsion 0.05% (Restasis, Allergan), and/or pulsed steroids and scleral contact lenses (the fluid reservoir acts as a liquid bandage and provides dryness relief). Always reassure these patients that their dry eye is manageable but not curable and that they will not lose their vision. The latter is an important bit of information for those who are really frightened because of their chronic symptoms.

The rewards

Don't underestimate the personal and practice-building rewards of diagnosing and managing SS. You'll build a network of referring rheumatologists and primary care physicians, who will likely also refer their patients to you for other ocular issues, and you'll foster patient loyalty and referrals, as you've given a name to their symptoms, reassurance they're not "going crazy" and therapeutic interventions that can provide relief.

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The following technology facilitates retinal disease diagnosis, enhancing patient care and your practice's reputation.

ROBERT J. MURPHY, CONTRIBUTING EDITOR

The Latest Retinal Disease Diagnostic Devices

Recent advances in retinal disease diagnostic devices are enabling eyecare practitioners to identify subtle changes in pathology that not that long ago eluded detection. As a result, patients at risk for retinal disease-associated vision loss are being discovered earlier, allowing for the preservation of vision.

Here, retina experts discuss these recent advances.

Digital fundus cameras

Digital fundus cameras and their associated software have paved the way for enhanced resolution and magnification and a wide field of capture. Also, most of these devices allow you to create a montage of images that display multiple views of the retina, so you can monitor change in pathology through time. The most recent additions to this technology are multiple spectral images and autofluorescence imaging, says Jerome Sherman, O.D., a distinguished teaching professor at the State University of New York College of Optometry in New York, NY.

Multiple spectral image systems employ light-emitting diodes (LEDs) each with their own spectral color to penetrate different depths of the retina all the way to the choroid, he says. For example, deep red and infrared LEDs penetrate well into the choroid, unmasking disorders, such as an early choroidal melanoma, often invisible to ophthalmoscopy, explains Dr. Sherman.

Autofluorescence is an indicator of the aging pigment lipofuscin found within the retinal pigment epithelium (RPE). RPE abnormalities adversely affect the overlying photoreceptors. Specifically, the absence of a normal glow may signal an overall retinal degeneration, such as retinitis pigmentosa, says Dr. Sherman. For example, autofluorescence imaging may help you detect early evidence of age-related macular degeneration (AMD), and, thus, discuss with the patient the importance of lifestyle changes and the benefits of the age-related eye disease study formulation, should the patient make a good candidate for it. (See "Supplements for AMD," article.) Panoramic autofluorescent imaging devices are also now available, allowing the clinician to image 200° of the fundus in a single image, Dr. Sherman says.

Excessive autofluorescence, or hyperautofluorescence, is likewise a danger sign, says Dr. Sherman. "Hyperfluorescence means that the retinal pigment cells are sick and stressed. And typically, cells that are sick and stressed will eventually die," he explains.

As a result, the technology is also ideal for detecting evidence of geographic atrophy (GA) of the RPE, an advance form of non-exudative or "dry" AMD, Dr. Sherman says. He adds that zones representing GA appear black with this technology.

Spectral-domain ocular coherence tomography

As with standard OCTs, spectral-domain, or SD-OCTs, provide cross-sectional images and retinal thickness measurements (with normative databases) useful for diagnosing optic nerve diseases, such as glaucoma — they reveal the retinal nerve fiber layer and ganglion cell complex — and those diseases affecting the macula and elsewhere in the retina. Specifically, they penetrate to all retina layers, which is useful for diagnosing retinal degenerations involving the RPE and its associated photoreceptors in conditions, such as retinitis pigmentosa, cone dystrophies, vascular occlusive disease, achromatopsia and acute zonal occult outer retinopathy, explains Dr. Sherman. Also, these devices can help you identify the particularly important photoreceptor integrity line (PIL) layer overlying the RPE Virtually all patients who have a photoreceptor degeneration have an abnormal PIL, Dr. Sherman says.

In addition, SD-OCTs "perform 1,000 A-scans in .04 seconds, they acquire images in large blocks of the retina, allowing for 3D imaging, and they allow you to segment out [isolate specific layers of the retina]," explains Mark T. Dunbar, O.D., director of optometric services and optometry residency supervisor at the Bascom Palmer Eye Institute, which has multiple locations in Florida. "For example, if you wanted to look specifically at the RPE or the ganglion cell layer, you could isolate that particular layer of the retina, which may be helpful in the diagnosis of various retinal diseases and glaucoma." He adds that SD technology also provides three-to-five microns of resolution, giving you enhanced detail.

Further, SD-OCTs can be invaluable in monitoring for retinal and RPE changes secondary to hydroxychloroquine sulfate, USP (Plaquenil, Sanofi-Aventis), a drug commonly prescribed to treat autoimmune diseases, such as lupus and rheumatoid arthritis, Dr. Dunbar says. Whereas previously clinicians would monitor these patients annually with visual fields, color vision and Amsler grid testing, clinicians now monitor potential Plaquenilinduced retinal toxicity using SDOCT, fundus autofluorescence or multifocal electroretinography, research shows.[1,2,3]

Macular pigment optical density meters

Recent research has shown that the macular pigment, which consists of the carotenoids lutein, zeaxanthin and meso-zeaxanthin, serves as a filter over the photoreceptors protecting them from harmful UV radiation, a risk factor for AMD. Further, this research shows that one's macular pigment optical density (MPOD) measurement can indicate the patient's risk for AMD.[4,5] Due to these findings, MPOD measuring devices have become available.

"These tests enable you to pick up precursor signs of impending macular degeneration, so you can then give patients a head start on taking the necessary steps, such as changes in diet, changes in lifestyle, or nutritional supplementation, to forestall its development," says Jeffrey D. Gerson, O.D., a private practitioner in Shawnee, Kan.

The currently available MPOD measurement devices have all been shown to reveal diminished macular pigment long before the appearance of drusen or other evidence of AMD via heterochromatic flicker photometry (HFP). HFP is a subjective psychophysical technique that employs flickering blue-green LEDs and an array of target sizes, to produce a density (e.g. MPOD unit) between 0 to 1.6. A low MPOD measurement is indicative of AMD risk.

Something else to consider: Because research has shown that macular light flash vision recovery measurements can indicate early macular conditions, technology is now available that uses photo-stress testing to aid in retinal disease detection.

Preferential hyperacuity perimetry (PHP) systems

PHP systems detect the conversion from non-exudative ("dry") AMD to the neovascular ("wet") form of the disease via visual hyperacuity, or Vernier acuity, instead of visual acuity, to determine visual object misalignment. Visual hyperacuity has been shown at least 10 times more sensitive than visual acuity.[6]

"The idea behind PHP is that instead of identifying a choroidal neovascular membrane when the patient's vision is 20/400 and he can't read anymore, you pick up changes before a person ever notices it," explains Dr. Gerson.

PHP devices measure the central 14° of visual field, detect visual object misalignments in the magnitude of three-to-six seconds of arc and provide 82% accuracy for detecting choroidal neovacularization. Finally, PHP has been found to maintain a low false-positive rate (8.1%).7 To use a PHP device, the patient points to flashing dots on a touch screen that have a deviating signal on distinct areas of the macula.

One PHP system designed for home use provides a daily means for patients to check for signs of conversion. The patient hooks the device into a phone line or cellular modem, and the data from each daily test is automatically sent to a live, ongoing data-monitoring center, which then posts the data on a secure website, where the patient's eyecare practitioner can review it. When the data-monitoring center notes a statistically significant change in test scores, the patient and doctor are notified immediately via phone.

Ultrasound

These devices can help the eyecare practitioner to differentiate a choroidal nevus from a potential melanoma, detect a retinal detachment or other anomaly through opaque media, such as a dense cataract — protecting one from malpractice lawsuits — and they're ideal for the retinal evaluation of pregnant women, who shouldn't be dilated, say those interviewed. The most recent advancement to this technology: Some are portable and handheld, facilitating their use and allowing for the examination of patients who have physical disabilities.

"The latest devices are comprised of portable probes that attach to any computer via a USB port, and the USB ports also allow you to store images, share them with patients and e-mail them to colleagues," explains Dr. Sherman. He adds that he encounters indications for ultrasound use a few times a week.

Out with the old?

With these latest devices, one can't help but wonder whether the traditional retinal disease diagnostic devices, such as the slit lamp biomicroscope and associated condensing lenses, are now obsolete. Not so fast, say those interviewed.

"I think it's important that the clinical exam start with ophthalmoscopy because the findings of the ophthalmoscopy guide you to the other retinal disease diagnostic devices you may want to take advantage of," says Dr. Gerson.

Diana Shechtman, O.D., an associate professor at Nova Southeastern University College of Optometry, in Fort Lauderdale, Fla. adds, "We never want to lose our clinical skills. After all, they are the reason we were able to diagnose and monitor retinal disease before all this technology became available, and they are the reason we're able to use this technology to make management decisions."

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BY ROBERT M. KERSHNER, MD, MS, FACS

Neuroadaptation & Premium IOLs: What Does the Brain Think?

The evolutionary history of the primates that predate us can be traced back more than 65 million years. That is a significant period of time in which to evolve sensory systems that have assured our survival. So how could such a complex structure as the eye have evolved by chance? Even Darwin acknowledged that the eye did not fit well into his theory. Fortunately, the development of the eye itself corresponds to every stage of development that we have uncovered in every existing living species.

The first animal with a primitive eye lived more than 550 million years ago. According to scientific calculations, that would mean only 364,000 years was necessary for our camera-like eye to first appear. If primate vision required a "perfect" optical apparatus in order to survive, then today we would all be emmetropic. Yet we are not. Our vision evolved in an unusual way using neural adaptation to compensate for and enhance the visual process.

So how does the brain react when something artificial, like a premium IOL, is implanted into the eye? This article will explain the adaptation mechanism and how new technological developments make the process more successful.

The Changing Brain

The adult nervous system is remarkably plastic and its ability to modify input is quite rapid. Through this process of neuroadaptation, the brain modifies its sensory input to gain a survival advantage. It is a fundamental component of sensory information processing. Neuroadaptation can take as little as a tenth of a millisecond or a few minutes to occur, and is experienced with regularity within the visual system. An illustration of this remarkable plasticity is Adam Kohn's demonstration of a perceptual reduction in contrast when viewing a high-contrast pattern of vertical bars (by rapidly moving your eyes across the pattern to prevent retinal afterimage) and then quickly looking at a similar pattern in a subsequently viewed stimulus and seeing a reduced low-contrast image (Figure 1). This aftereffect does not reduce sensitivity to the original contrast pattern, suggesting that the appearance of the bars is orientation and spatial-frequency specific.

Where is Neural Integration And Adaptation Occurring?

Neural adaptive roles in the consolidation of memory, emotion, addictive behaviors, navigation and spatial orientation are all linked to the hippocampal region of the brain. There is no question that this region plays a crucial role in neuroadaptation. However, virtually every area of the cerebrum, including the visual cortex, plays a part.

Normally, a visual stimulus will traverse from the ipsilateral geniculate nucleus to the primary visual cortex (V1) of each occipital hemisphere by splitting into two primary pathways — the so-called dorsal stream and the ventral stream. The dorsal stream travels first into V2, then onto the dorsomedial area and V5 before it ends up in the posterior parietal cortex.

For example, stimuli traveling in the dorsal stream will require adaptation of neurons in cortical area MT (V5), an extrastriate visual area containing a high proportion of neurons that are selective for the direction of motion and an object's location. This information is used to control hand-to-eye coordination.

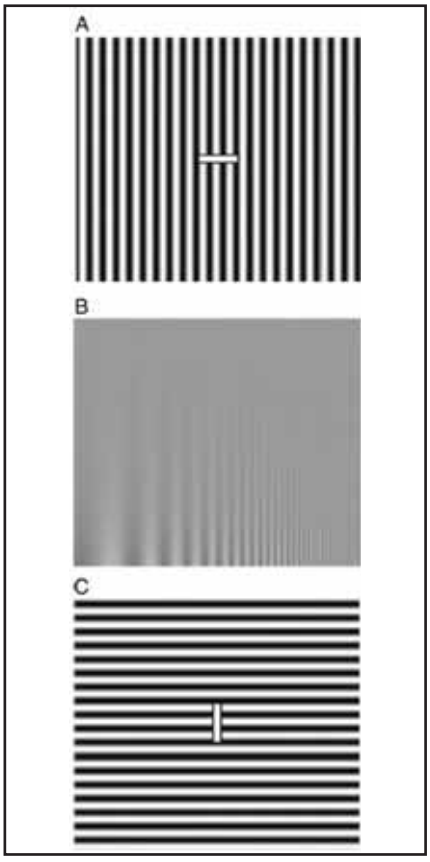
Contrast Adaptation

Neuroadaptation is a cortical neuron response's ability to be altered by a recent stimulus. Unlike light adaptation, which occurs entirely in the retina, contrast adaptation begins at the earliest stages of the visual system — the retinal ganglion cells — and then evolves to include wide areas of the cerebral cortex.

You probably learned as a child that prolonged viewing of a moving stimulus while looking at a static image makes the nonmoving image appear to move in the opposite direction (the well-known motion aftereffect, MAE). Models of visual motion processing suggest that some form of opponent processing is occurring where the response to stimuli moving in one direction is subtracted from those moving in the opposite. Contrast sensitivity and its relationship to motion occur within the same brain areas and are critical to important daily tasks such as driving an automobile.

Diffractive and Refractive Technology

Most multifocal IOLs in use today are either diffractive, refractive or a combination of both principles. Diffractive multifocal IOLs are pupilindependent and sacrifice intermediate vision by focusing incoming light rays at two points either near or far. Refractive multifocal IOLs are pupildependent, incorporating different refractive zones to create focal points at varying distances. Many patients with refractive IOLs find vision at intermediate distances better, but have difficulty with near. Lens manufacturers have used both optical principles, such as in the combined apodized, diffractive-refractive IOL, and others are developing newer multi-



REPRINTED WITH PERMISSION FROM KOHN, AJ. NEUROPHYSIOL 2007;97:3155-3164.
Figure 1. Perceptual reduction in apparent contrast. Slowly move your eyes back and forth (to prevent retinal afterimages) along the white bar at the center of A for 30 seconds, then transfer your gaze to the test image in B. A low-contrast portion of the image (top) should briefly appear invisible. Adaptation with the pattern in C does not reduce sensitivity to the test pattern, demonstrating the orientation specificity of the effect. Note that the aftereffect is also spatial frequency specific: lower (left) and higher (right) spatial frequencies in the test image are not affected by adaptation with A.

zonal and progressive lens designs in an effort to address these limitations.

What role does neuroadaptation play when a patient is faced with alterations to the visual system induced by the new premium IOLs? These lenses do not replicate the natural state. Just as patients have trouble adjusting to their first pair of progressive add eyeglasses, premium IOL patients will be challenged by their perceptive change. How quickly and how well a given patient adapts to this change will determine if they are satisfied with the surgical result or not. It is incumbent upon the surgeon to take the time to thoroughly discuss the implications of this change with respect to the patient's day to day needs before the patient undergoes surgery. Inquiring as to which visual tasks a patient is looking to improve can go a long way to improve satisfaction.

Particular attention needs to be placed on patient education of the process of neuroadaptation and possible training techniques to increase awareness. Patients have high expectations when it comes to time and demand immediate results. If they are told ahead of time to expect a gradual adaptation period following their surgery, they will most likely accept this prospect. If the patient is impatient, it might be better to forego the premium IOL altogether and go with one that provides goof-proof results. Patients are always more likely to be accepting if their surgeons explain in terms they can understand before surgery day, address specific surgical needs of the patient during the procedure and forewarn of what the patient can expect visually after the surgery.

I have previously investigated and published the role of IOL optics in image contrast sensitivity. Our findings compared the effects on retinal imaging and functional visual performance of an aspheric intraocular lens (Tecnis Z-9000) with those of conventional spherical optics — silicone (AA4207VF) and acrylic (AcrySof SA60AT). With functional acuity contrast testing, we found that use of an aspheric IOL creates a measurable 38-47% increase in photopic and a 43-100% increase in mesopic visual performance.

We know that improvement in visual perception is due in large part to the improved optics of the aspheric IOL, which corrects for the cornea's positive spherical aberration. Analyzing digital fundus images taken through these lenses corroborated this further. What we did not know then, but know now, is that at least some of the improved visual quality can be attributed to the neuroadaptation process — something much more difficult to analyze objectively.

Visual Disturbances

Neuroadaptation can occur within the visual system in response to either a monocular or binocular visual disturbance. Visual adaptation depends to a great extent on visual awareness. In the case of a monocular visual disturbance, the brain learns to compensate by altering its perception. It has been shown that even in cases where a clear image is focused onto the retina, neuroadaptation may have to kick in if there are inherent optical aberrations within the visual system that the brain cannot accept.

Given time, the mind applies its negating effect to the undesirable pattern. If age and time work in the patient's favor, then the final image ultimately becomes acceptable. However, sometimes surgeons intentionally disrupt the "one-eye, one-image" perception that is required for successful merging of the images from two eyes, such as when implanting an IOL style for one eye that is different from the other. In this case, the brain is presented with a perceptive paradox that it is not wired to undo.

The study of neuroadaptation is based primarily in psychophysics. Two extensively studied phenomena are known as binocular rivalry and visual crowding. These visual phenomena are capable of erasing visual stimuli from conscious awareness. Unlike factors that lead to visual processing early in the system, processing of these phenomena occur within the primary visual cortex (V1) and the middle-temporal visual areas. Brain imaging and EEG studies have demonstrated that suppression of unwanted images during retinal rivalry reduce the visual stimuli perceived in the monocular regions of V1 and keep them from conscious awareness. Research in this area suggests that suppression of vision rivalry and crowding involves a reduction of neural activity, not an increase or elimination.

How the brain recruits the neurons to make this happen is just beginning to be understood. Every processing point along the visual pathway contributes to the final clearly perceived optical image, and an interruption in the smooth flow of information anywhere in the visual stream can become problematic. Until the image signal hits the sixthorder neurons, both images are monocular. It is here where ocular dominance and retinal rivalry exist. From the lateral geniculate bodies, the images begin to fuse. Flood these centers with retinal signals from multiple images and the deep centers of the brain that need to make sense of the chaos begin to fail. Like contrast, neural adaptation associated with both retinal rivalry and image crowding occur at the earliest stages of visual processing.

When reading, our eyes move in spurts across the page. To meld the saccadic movement of our eyes into a smooth perception of letters and words requires higher cortical processing. The brain adapts to the information from these images and combines them across glances. If, during the course of our lives, we lose the ability to modulate visual in formation, such as what occurs following a stroke, retraining the brain to perceive visual stimuli differently is necessary.

Conclusion

How do we integrate what we have learned from neurophysiological study into an understanding of the neuroadaptative processes in our patients as we modify a lifetime of visual perception with one quick stroke of a diamond blade? Perhaps we can garner some information from the work done with the visual rehabilitation of stroke victims. In these cases, patients have normally functioning retinas, ganglion cells and optic nerves, yet pieces of the image cannot reach the optical centers of the brain that are needed to process them due to ischemic neuronal damage. Patients with chronic visual field defects can be rehabilitated with a computer-based program over a three-month period. Objective studies show that the visual-evoked response and positron emission tomography imaging (PET scan) improve both functionally and clinically following rehabilitation.

Can we truly screen our patients for those most likely to benefit from premium IOLs and avoid those who will not? There is reason to believe that patient-profiling data based upon personality, risk-taking behavior and visual demands may help. The pleasure-seeking areas of the brain (limbic system, amygdala, thalamic nuclei) are in close proximity to the neuroadaptative centers of the brain (hippocampus). Most surgeons would probably avoid operating on gamblers, drug addicts and bungee jumpers. However, one hypothetical approach worth investigation might be to start our patients on dopamine prior to surgery.

We surgeons should ask ourselves some questions before we cut. If we can retrain a brain whose optics have changed, how best should it be done? Should we delve into the cortical abilities of our patients? Can manufacturers purposefully design optics to enhance an individual's interpretation of visual input? The answers to these questions are not simple. Solutions to the problems we face will not be easy. What is certain is that an assessment of our patients' behavioral, social and psychological needs are at least as important as the measurement of their acuity and A-scan.

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BIBLIOGRAPHY AVAILABLE ON REQUEST

BY AMIN ASHRAFZADEH, MD

Former LASIK Patients' Challenge to the Cataract Surgeon

Cataract surgery has undergone a major evolution over the past decade with the addition of new technologies such as the accommodating, pseudo-accommodating and astigmatically correcting intraocular lenses. Likewise, LASIK surgery has also enjoyed enormous popularity and evolution over the last 15 years. The transection of these two surgeries in the same population presents new challenges and opportunities. Accuracy of results, quality of results, customer service and management of expectations are all areas that will require our attention more and more each day. Here's a look at what we surgeons can expect, and the problems we will have to solve for our patients.

The New Cataract Patient

Barbara Millicent Roberts of Willows, Wisc. is 52 years old. She has had multiple careers — airline attendant, pilot, astronaut, NASCAR driver and also a doctor. She looks amazingly well and young and seems to have perfect vision. Just in case this little biography isn't ringing any bells, "Barbara Millicent Roberts" is the official name of the "Barbie" doll from Mattel Corporation. Many of our patients are living in not so dissimilar fashion. Many have had LASIK surgery and are now at the age where they have become presbyopic and are also developing cataracts. Can you imagine Barbie with reading glasses? Neither can many of those who grew up playing with Barbie and Ken.

So how many such folks are we talking about? The excimer laser has been FDA-approved for refractive surgery since 1995. That makes 16 years of history, with many of those years reporting more one million procedures per annum. Even in the economically challenging time that we are currently experiencing, in the year 2010 approximately 800,000 procedures were performed. That makes about 20 million laser refractive procedures in the United States alone. For years, the average age for a LASIK patient was late 30s; basically, people who could afford the procedure. These patients are the people with the means and demands — and now they are older. They hate the readers and are not used to hearing "no." Furthermore, this recession is an absolute enigma to them, as is the notion of reining in their spending habits.

LASIK has been a great success and many of these patients have touted its results. Now that they are developing presbyopia and possibly cataracts too, they are looking toward the second miracle. Can we as ophthalmologists meet that high demand of perfect precision?

Can We Deliver?

Not so fast, partner! The accuracy of reaching within 0.5 diopters of the intended target for wavefront-guided IntraLase LASIK was 87%, and it was 98% for reaching within 1.0 diopters, in the Stanford LASIK eye surgery study.1 The accuracy of reaching within 0.5 diopters of the intended target for cataract surgery is about 55% and it is 85% for reaching within 1.0 diopter (See Table 1). Why such a big difference?

In cataract surgery, many major variables play into an accurate calculation. The keratometry, axial length measurement, surgically induced astigmatism, surgical technique capsulorhexis), manufacturing lens tolerance of the IOL and many others lead to major variability. A more standard uniform wound incision and capsulorhexis, using the femtosecond laser, has led to a much more predictable and accurate effective lens position for the IOL and consequently the reach within 0.5 diopter of the intended target has risen from the 50-60% to 70-75% as reported by Robert Cionni at the 2011 AAO Annual Meeting in Orlando.[2]

That is great! And while I am grateful for increased accuracy, the truth is, that still leaves room for improvement. Ken Hoffer, MD, using the Orange intraoperative wavefront aberrometer from WaveTec Vision, was able to push his 56% within 0.5 diopter of intended target to 81%, according to data he presented in September at the 2011 ESCRS meeting.3 However, in eyes that are post-LASIK, his results even when using the Orange remained in the 50% range. Where do we go from these numbers? Enhancements!

Enhancements Come to Cataract Surgery

Enhancements are a standard element of discussion with refractive surgery. So why is it that although refractive laser procedure results are far more accurate than cataract surgery, enhancements are not a standard part of discussion for cataract surgeons? It is simply a matter of habit. Cataract surgeons have never had to really be accountable for their refractive results. Astigmatism and needs for presbyopic correction always gave the cataract surgeons the option of "get new glasses and all will be perfect." Now that cataract surgeons are entering the realm of refractive surgery, glasses are no longer the only option, nor the preferred one. To avoid disappointment on the part of the patient and negative postoperative feedback, cataract surgeons need to get in the habit of discussing enhancements. With the ease of online review sites, social media and word of mouth, it is essential to avoid the negative feedback towards the technology and/or the surgeon.

Figure 1. When performing the clear corneal incision, take care not to intersect the LASIK flap.

Table 1. Great Expectations, Imperfect Results

	Wavefront Optimized IntraLase LASIK	Wavefront Customized IntraLase LASIK	Standard Cataract Surgery	Cataract Surgery with Femtosecond Laser	Cataract Surgery with orange
Within 0.5 D	78%	87%	55%	70-75%	81%
Within 1.0 D	98%	98%	85%		
Source	Ref. 1	Ref. 1		Ref. 2	Ref. 3

Table 2. IOL Guidelines

Type of Lens	Hx of Myopi LASIK	Hx of Hyperopia LASIK
Toric	OK	OK
Accommodating	OK	OK
Multifocal	OK	Not the best choice

My personal rate of enhancements for iLASIK (CustomVue, IntraLase LASIK) procedures is less than 5%. My personal rate of excimer laser use after premium IOLs, intended or unintended, is less than 15%. Without some reasonable numbers to discuss with the patients, it is hard to give them a sense of what they should expect. So far, I have had very understanding patients on both the iLASIK and the cataract surgery enhancement sides. I attribute that to my frank discussion preoperatively with my patients outlining the expectations along with the potential for enhancements when the case warrants.

When patients have previously had LASIK surgery, now all bets are off! I discuss with them the greater difficulty in properly calculating their IOL power and how they may need an enhancement. I inform them that there are currently more than 16 different formulas for estimating post-refractive IOL power, and the steps taken in calculating their IOL power, including the use of Haigis-L formula on the IOLMaster and the ASCRS.org post-refractive IOL calculator. I generally quote them a 25% chance for needing an enhancement.

All premium IOL patients need to be treated as LASIK and cataract work-up patients. Preoperative testing should include corneal topography, pachymetry, posterior corneal surface mapping, specular microscopy, macular OCT and ganglion cell layer analysis. If the patient is not a good LASIK candidate, he should not have a premium IOL, except possibly a toric IOL without enhancement.

So who does the enhancement? Either the primary surgeon, or a designee. Leaving the patient stranded is not only poor form, but also will kill the goose that lays the golden eggs. If you currently do not do LASIK or PRK, consider learning PRK. In many cases, though, it might be easier to simply pass these patients along to your local refractive colleague. If you have not supported that colleague over the years, it is easy to do so now with the corneal and refractive consults. Explain that, in exchange for your support, you expect equal support in caring for enhancements. Discuss hand-off of patients to the surgeon and back, cost and support structure. Is your refractive colleague willing to review your upcoming premium IOL case with you and lend you a review? It is amazing how a little friendly collegial support will spark something so beautiful. If you haven't given it a try, please do and surprise yourself!

The Post-LASIK Scenario

In case of post-LASIK eyes, several factors become paramount. A patient who has had a hyperopic LASIK treatment is probably not going to do well with current market multifocal IOLs due to the higher-order aberration profiles of the cornea and the implants. However, myopic LASIK treatments are fine with the current multifocal IOLs (Table 2). The main concern remains: Can the cornea withst and another enhancement and yet maintain stability? Patients with history of low refractive error correction will have a narrower range of results and may need small enhancements.

On the other hand, patients with previous high refractive treatment have a wider range of results and may need greater enhancement — yet they are the ones with the least corneal tissue available for enhancement. For every one diopter of refractive error, one may need up to 15 microns of stromal tissue for enhancement. Therefore a 3D refractive surprise could need 45 microns of stromal tissue for ablation. A patient who was previously a −8.0D myope and now has a corneal pachymetry of 400 microns, only has 350 microns of stromal tissue (less 50 microns for epithelium). This patient barely has any leftover tissue for an enhancement to be done safely. Tread cautiously.

A Rewarding — And Demanding — Demographic

With the baby boomers (born 1946–1964), now reaching presbyopia and cataract age, we are going to be facing a large population that want what they want and have the money to pay for it. They demand service and expect delivery. Among these patients, some might be preselected for premium IOLs — especially ones who have had LASIK. Although they pose a challenge, many have hated their glasses all their lives and now that they no longer have that perfect post-LASIK vision, they are most grateful to regain their visual freedom. They tend to be among some of the happiest group of patients. You will find that meeting their vision demands is well worthwhile.

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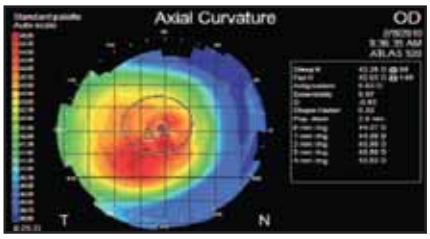
Real-World Challenges

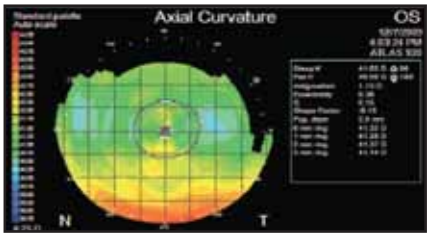
Case #1



In 2006, a 59-year-old female had LASIK surgery performed by me. At the time, we determined that monovision LASIK would best fit her lifestyle. Her refraction was +1.50 −0.75 x 055 OD → 20/15 and +1.13 −0.75 x 080 → 20/15. Her pachymetry was 545 µm OD and 532 µm OS. We aimed for a −1.50 sphere residual refractive error in the right eye. Her results six months postop were right on target with 20/50, J1+ OD and 20/15 OS uncorrected.

However, she began to have significant myopic shift over the course of the next two years in her right eye. Two and a half years later, we did a cataract surgery for her right eye aiming for a −1.50 to −1.75 diopters post-operative refraction. I used the Atlas corneal topographer and the IOL Master (both Carl Zeiss Meditec) data to use in the ASCRS.org's calculator. The suggested results of the Masket and Haigis-L formula were used and resulted in a perfect −1.75 postoperative result. We chose a monofocal implant for her because of the sum of higher-order aberrations of the hyperopic treatment and the fact that multifocal implants may lead to poor visual quality.

Case #2



Also in 2006, we performed LASIK on a 51-year-old female with a desired outcome of monovision. Her pre-LASIK refractions were −5.00 +0.75 x 090 OD → 20/15 and −5.00 +1.25 x 180 → 20/15 with pachymetry of 539 µm OD and 546 µm OS. The intended residual myopia for her left eye was −1.50 diopters. She had an excellent outcome; however, over the course of the next four years she presented progressive myopia with increasing nuclear sclerotic cataract OU. The Visante omni (Carl Zeiss Meditec) examination revealed a completely normal posterior corneal elevation. I used the Atlas and the IOL Master data to input into to the ASCRS.org's calculator. Given that she had a myopic ablation, her higher-order aberrations were compatible with multifocal IOLs. We chose a Tecnis Multifocal IOL for her and she had an outcome of 20/15 OU, J1+ uncorrected. She strongly prefers the multifocal implants over her previous monovision.

BY ERINN MORGAN

12 for 2012: Top Trends for the new year

Ever wish you had that mythical crystal ball to peer into to see where your business will be going in the future?

Our Top Trends list serves up the next best thing, with a dozen points of insider information on focused directions and targeted trends culled from the Eyecare Business Market Trends 2011 Report.

Should you worry more about the economy or rest easy?

What will be the key categories for growth in the dispensary?

Should your business be selling products online?

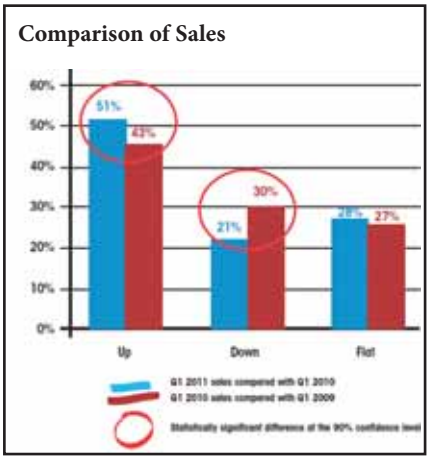
Are you green enough?

The answers to these burning questions and more are revealed in our trends list below. Read on for a good glimpse into the future of optical.

#1: IT'S TIME TO THINK POSITIVE

Tired of all the drama over the economy today? The results of the Eyecare Business Market Trends 2011 Report reveal that ECPs may be able to rest a bit easier in 2012. In fact, eyecare professionals reported that the recent economic downturn only had a moderate (46 percent) to slight (33 percent) impact on their business.

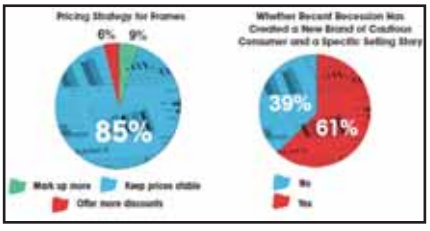
A smaller number (only 15 percent) say that it has had a major impact. Even better news is that most (51 percent) reported that first quarter sales were up for 2011. In 2010, only 43 percent said that first quarter sales for the year were up. While ECPs continue to list the turbulent economy as their leading business challenge, it was ranked as such by a smaller number in 2011 (46 percent) than in 2009 (58 percent).



#2: A NEW CUSTOMER

The new economy has borne a new consumer who is both wary and educated. In fact, six in 10 ECPs say they believe that the economic slump has created a new brand of cautious consumer that requires a new selling story, according to the Eyecare Business Market Trends 2011 Report. As such, a full 39 percent of ECPs say that they are reassessing their inventory mix to reflect their changing customer base.

Most (85 percent) also say they are keeping prices stable in the dispensary—a cautious, wait-and-see strategy. At the same time, 28 percent say they are choosing quality over quantity, opting to move to a smaller but higher-end selection of product.

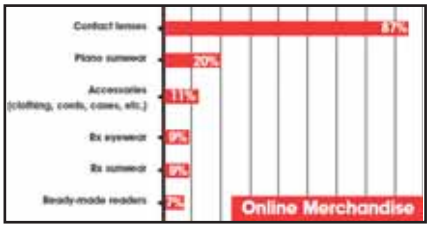


#3: GETTING ONLINE

While chain stores and behemoth e-retailers are jumping into the game of selling eyewear online, this does not yet seem to be a growth area for most ECPs. Only 18 percent of eyecare professionals say they have an e-commerce website.

Additionally, the majority of eyecare professionals who are not currently selling online say they do not plan to do so in the next two years. A full 66 percent say they do not plan to begin selling online, while 34 percent say that they do have plans in the works for an online product offering.

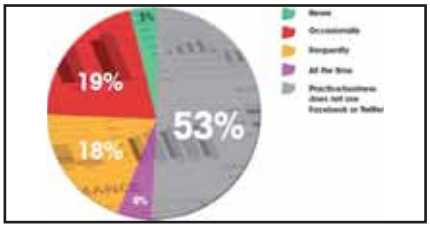
Still, 18 percent say their websites offer information and e-commerce. Of those selling online, the majority offer contact lenses (87 percent), plano sunwear (20 percent), accessories like clothing, cords, and cases (11 percent), Rx eyewear (nine percent), and Rx sunwear (nine percent).



#4: GOING SOCIAL

Are ECPs into social networking? Overall, it's not a huge priority; but it does seem to be a growing trend in the eyewear industry. Six percent of eyecare businesses say they use Facebook, Twitter, or both "all the time," while 18 percent say they use it "frequently." Reaching out into cyberspace, most ECPs say they do have a web presence (75 percent), but the majority (57 percent) say they use it only to provide information to existing and prospective patients.

Use of Facebook and Twitter



#5: RETURNS: FINDING A NEW WAY

Tougher returns policies for frames and equipment are changing the ways in which ECPs are managing unsold inventory, especially on the frame front. While 70 percent say they return their unsold products to vendors, this is a notable decrease from 2009, when 76 percent of ECPs said the same.

Today, 53 percent say they deal with unsold inventory by running sales and promotions, while 21 percent say they use aggressive board positioning. There was a marked jump in those ECPs (19 percent) who say they deal with unsold products by donating them to charity, an 11 percent increase from 2008.

MANAGING UNUSED INVENTORY

Tactic	2008	2009	2011
Return to vendor	74%	76%	70%
Sales/promotions	44%	53%	53%
Aggressive board position	19%	30%	21%
Donate	8%	13%	19%
Web sales	1%	0%	1%
Other	5%	3%	2%

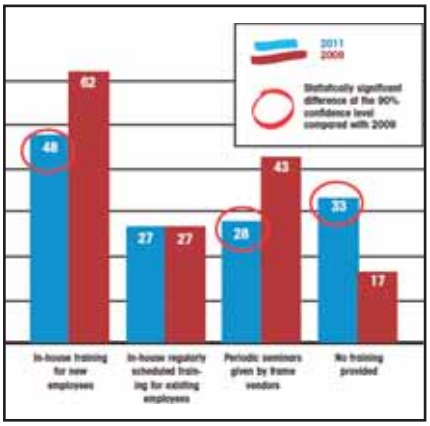
#6: TRAINING SLOWDOWN

While a large number of reps and vendors offer in-office training options for ECPs and their staff, the Eyecare Business Market Trends 2011 Report found a significant downslide in the share of ECPs who provide training for their employees.

A whopping 33 percent say they provide no training for employees whatsoever, a number that was up significantly from 17 percent in 2009. Just 48 percent say they provide in-house training for new employees, an amount that was down from 62 percent in 2009.

Additionally, the number of those who provide periodic seminars given by frame vendors was down to 28 percent in 2011 from 43 percent in 2009. At the same time, a full 68 percent of ECPs noted that the No. 1 way they keep up with the constantly evolving lens market was information from manufacturer reps.

Staff Training (% of ECPs)



#7: RISING ABOVE

How are eyecare professionals moving above and beyond the woes of an unpredictable economy?

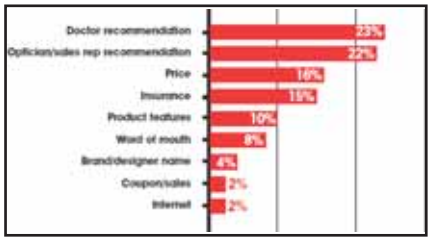
When asked how they are overcoming today's business challenges, the majority (68 percent) say they are boning up on customer service. The runner-up strategy (with 39 percent) was "re-assessing inventory mix to reflect a changing customer base." This was followed by proactive marketing maneuvers, with 28 percent saying they'd be offering more promotions and another 28 percent saying they would increase their advertising efforts.

#8: DOCTOR'S INFLUENCE

What most influences the customer's eyewear purchase? While the doctor's recommendation is still king with 23 percent of ECPs noting this as the one factor that most influences purchases, doctors have lost a few percentage points from 2009 to price, which was reported by 16 percent as the most important factor.

In second place with 22 percent noting it as the most important factor was the optician's or salesperson's recommendation. On the lower end of the scale were brand/designer names with four percent and product features with 10 percent.

Perceived Influences on Consumer Purchasing



#9: GOLDEN OPPORTUNITIES

Where will the future growth come from? When asked for the three areas expected to grow the most over the next three years, the largest percentage of ECPs (46 percent overall/61 percent ODs) listed primary care opportunities such as glaucoma/allergy management.

Next on the list was regular eye exams, which was reported as an opportunity by 45 percent of ECPs. While eyeglasses came in third place with 43 percent of ECPs noting it as an area of growth, the number was down from 58 percent in 2009.

Fifth on the list was sunwear, which jumped up significantly in importance, with 31 percent of ECPs reporting it as a growth area. In 2009, only 18 percent of ECPs felt the same.

#10: SQUEEZED BY COSTS

While things are looking up for ECPs in 2012, there are still some business challenges that must be faced. The increasing cost of optical goods is a top concern for ECPs (26 percent, an increase over previous years' survey results).

Most ECPs say they have dealt with cost objections primarily by moving to lower-cost options (42 percent, up from 36 percent in 2009). Discounting merchandise is 33 percent of respondents' primary method to overcome cost objections.

#11: REP RELATIONSHIPS

For better or worse, richer or poorer, ECPs' relationships with their representatives and vendors are marriages that attempt to stand the test of time (and the economy).

When rating the importance of certain representative qualities, ECPs say that the most crucial were "being customer-oriented," "having the willingness to be accountable for their products' performance and reliability," and having a personal "knowledge of my business."

Asked what would cause them to reject working with a specific vendor, 43 percent of the eyecare practitioner respondents say "poor customer service" would be the be all and end all. Other top-rated factors were "return policy," "price," and "vendor reputation."

#12: GOING GREEN

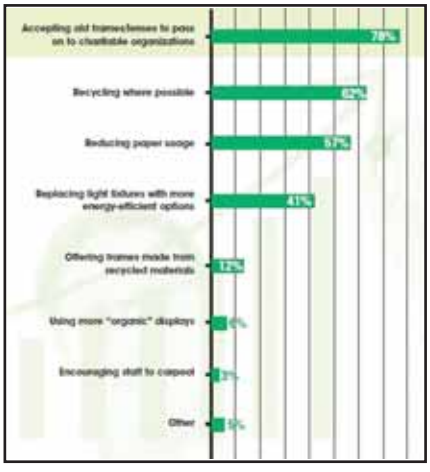
On an eco-conscious note, the majority of eyecare professionals are contributing to the "green" effort in a variety of ways. A large number (78 percent) are accepting old frames and lenses in their office to pass on to charitable organizations.

A full 62 percent say they are recycling where possible, and 57 percent are reducing paper usage. An impressive 41 percent are replacing light fixtures with more energy-efficient options.

On the product front, 12 percent say they are offering in the dispensary eco-friendly frames made from recycled materials.

Interestingly, 22 percent of ECPs say they consider environmentally conscious equipment to be "very important," while 57 percent say it is "somewhat important."

The "Green" Effect



Imaging offers clues to the possibility of regeneration in humans.

ZOFIA MICHALEWSKA, MD, PHD • JERZY NAWROCKI, MD, PHD

Retinal Regeneration as Illustrated by SD-OCT

The first remarks on retinal regeneration date back to the 17th century, when Charles Bonnet discovered that newts could regenerate their eyes after surgical removal of small parts.[1] Early in the 20th century, regeneration of the lens and retina was the main experimental model for regeneration research.[2] As in most mammals, loss of neurons in the human retina does not naturally lead to their replacement. However, several strategies have been described that lead to repair.

Optical coherence tomography has become an important tool in the last decade, as it enabled, for the first time, the visualization of fine retinal structures with details that could be only compared to histological studies. Developments in this technology have lead to increased imaging speed and resolution and brought spectral-domain optical coherence tomography to everyday ophthalmic practice. The possibilities of in vivo visualization of the human eye are awesome.

RETINAL REGENERATION IN ANIMALS

While there are great possibilities for regeneration of the eye in nonvertebrates, the more complicated the ocular tissue the more complicated the regeneration process. Different fish species, for example, have the ability to generate new retinal neurons in adult life and thus to replace damaged retinal cells. In the first days after retina damage, new ganglion cells are produced in fish from pluripotent stem cells, most probably Müller cells. The next step is axon growth, which reconnects retinal tissue to the optic nerve head.[3]

For many centuries, urodeles have been known for their capability for regeneration of the retina and lens. Despite intense studies, no specific retinal progenitor cell has been found in these animals. Again, Müller cells dedifferentiate and initiate the reparation process.[4]

In the avian retina, Müller cells may serve as retinal progenitor cells in the first postnatal week, whereas later in life, only peripheral Müller cells have this capability in chicks.[5] The avian retina becomes mitotically active two days after chemical destruction of bipolar and amacrine cells. The mitotically active cells have a marker of Müller cells. It has been suggested that Müller cells in chicks may serve as progenitor cells for all retinal neurons.

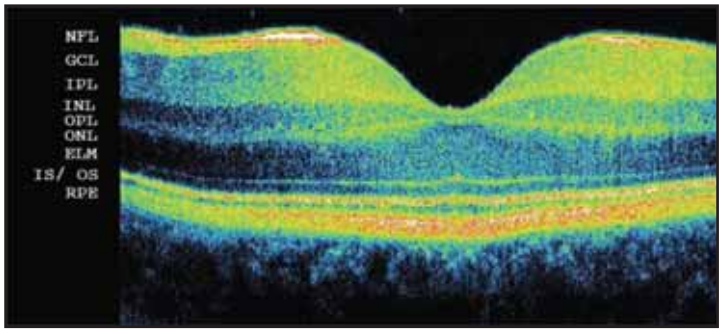


Figure 1. Spectral-domain optical coherence tomography of a healthy fovea: NFL: nerve fiber layer; GCL: ganglion cell layer; IPL: inner plexiform layer; INL: inner nuclear layer; OPL: outer plexiform layer; ONL: outer nuclear layer; ELM: external limiting membrane; IS/OS: junction between inner and outer segments of photoreceptors; RPE: retinal pigment epithelium.

It has long been believed that the adult mammalian retina is incapable of regeneration. More recently, it was proved that, after injury, Müller glial cells proliferated to produce rod photoreceptors and bipolar cells in the adult rat retina.[6] Also, stem cells capable of generating new neurons[6,7] are present in the nonpigmented ciliary margin in rodents.[8]

There are several explanations for retina regeneration in animals. A small zone of mitotically active cells in the adult retina, called the ciliary marginal zone (CMZ), was the first explanation to be offered. This zone consists of cells that resemble retinal progenitor cells. Unlike the CMZ of fish and amphibians, the cells at the margin of the chick retina only generate bipolar and amacrine cells in the undamaged retina, suggesting that the progenitors in the CMZ may be restricted to producing particular neuronal cell types.[5] In primates there is lack of evidence of a persistent CMZ after birth.

The second explanation proposed was that an intrinsic progenitor cell, recently identified as Müller glia, which normally produces only rod photoreceptors during the growth of the fish eye, is responsible for regeneration.[9,10] Müller glial cells are able to dedifferentiate, and they have the potential to become retinal progenitors.[11] They act as intrinsic retinal stem cells that normally have a very long cell cycle and are activated after injury.[12,13]

Numerous genes are expressed by retinal progenitor cells. *Ascl1a* was described to be responsible for dedifferentiation of Müller cells into multipotent progenitors.[14]

HUMAN RETINAL ANATOMY AND PRENATAL DEVELOPMENT

The retina in vertebrates develops from paired optic vesicles, being anterior parts of the neural tube. As soon as optic vesicles form optic cups, retinal progenitor cells are present. They enable differentiation of all types of retinal neurons and Müller glia cells. It has been known since the mid-19th century that retinal neurons differentiate in a specific order from retinal progenitor cells.

Ganglion cells, cone photoreceptors, horizontal cells and most amacrine cells are generated during early stages of development, and rod photoreceptors, bipolar cells and Müller glia are generated in the latter half of the period of retinogenesis.[15] Apicolaterally, Müller cells are connected to their neighboring Müller and photoreceptor cells by specialized junctions to form the outer limiting membrane.

SD-OCT demonstrates high-resolution images of the retina (Figure 1), which may resemble histological dissection. Several layers, such as the nerve fiber layer, the junction between the inner and outer segments of photoreceptors, and the retinal pigment epithelium, have a high degree of backscattering, which produces highly reflective bands on SD-OCT images. The inner and outer plexiform layers have slightly more backscattering than the ganglion cell layer and inner and outer nuclear layers; thus, those structures may be differentiated.

Reflections on OCT from the IS/OS are thought to arise from the abrupt change in the optical index of refraction at the boundary between the inner segments and the highly organized structure of the outer segments. To visualize particular retinal layers with SD-OCT, the layer has to be perpendicular to the incoming OCT beam. Thus, the IS/OS is visible in the healthy retina and may be missed in detached tissue (Figure 2a). If, on the other hand, the SD-OCT device is turned a little bit to the side, it is possible to detect the Henle's fiber layer.[16] The Henle's fiber layer is also visible if neurosensory retina is detached, as in central serous chorioretinopathy. The Henle's fiber layer forms the outer two-thirds of the outer plexiform layer. Henle's fibers are axonal extensions of photoreceptors, enveloped in lucent outer cytoplasm of the Müller cells, and they run obliquely from the center out to their pedicles (Figure 2b).

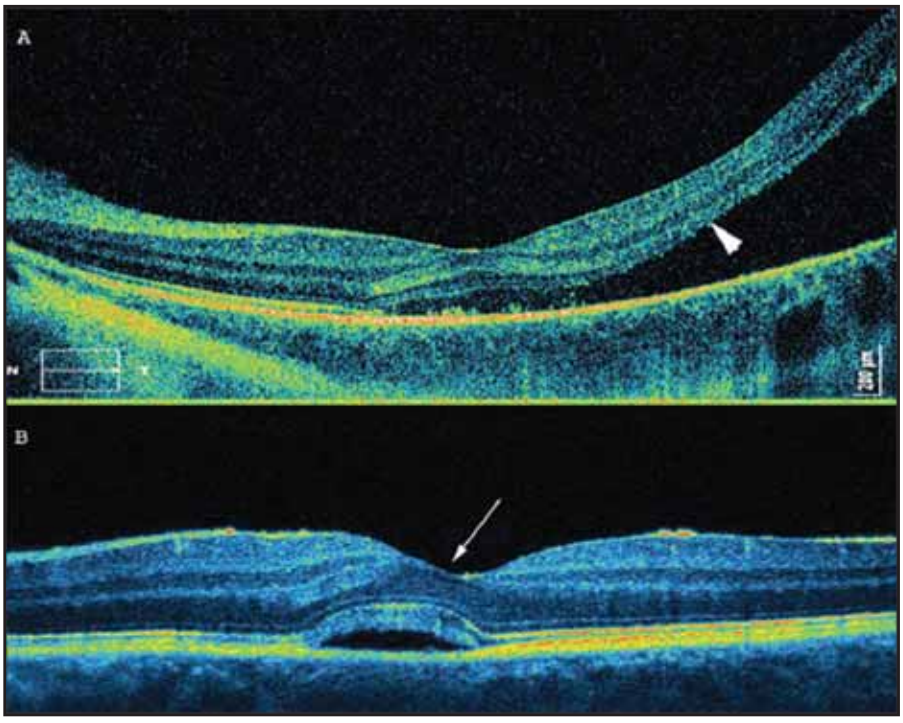


Figure 2. Retinal detachment near the fovea. (A, top) The arrow shows the presumed IS/OS line, which is not visible central serous chorioretinopathy. (B, bottom) The arrow shows Henle's fibers.

SD-OCT STUDIES ON RETINAL REGENERATION

Restoration of retinal structure, either spontaneously or following surgical or medical intervention, has been described in many clinical entities. Causes and underlying processes may differ and are presented here.

Macular Hole

Since the introduction of pars plana vitrectomy as the method of choice in full-thickness macular hole treatment, the success rate has reached almost 100%.[17-24] However, in some patients, especially with large, long-standing macular holes, incomplete improvement of visual acuity is observed immediately after surgery. This outcome is due to different defects of the particular retinal layers, which can be observed on SD-OCT (Figure 3). IS/OS defects have been reported to have the strongest influence on visual acuity.

Recently, several authors have analyzed postoperative changes in retinal morphology after macular hole surgery, and it was proved that visual acuity may improve for at least 12 months after surgery.[23]

Improvement of visual acuity corresponds with improvement of morphology in the outer retinal layers and with restoration of the IS/OS line. Michalewska *et al*. reported on 71 eyes, among which 93% had photoreceptor defects one week after surgery, and 29.5% had defects 12 months after surgery. The linear photoreceptor defect continuously decreased in size with time (from a mean of 882 µm one week after surgery to 60 µm 12 months after surgery).

Injury has been described as a signal for activation of Müller cells. It is likely that peeling of the internal limiting membrane, which is not a pathological tissue but part of the retinal structure, simulates injury, provoking gliosis.[25]

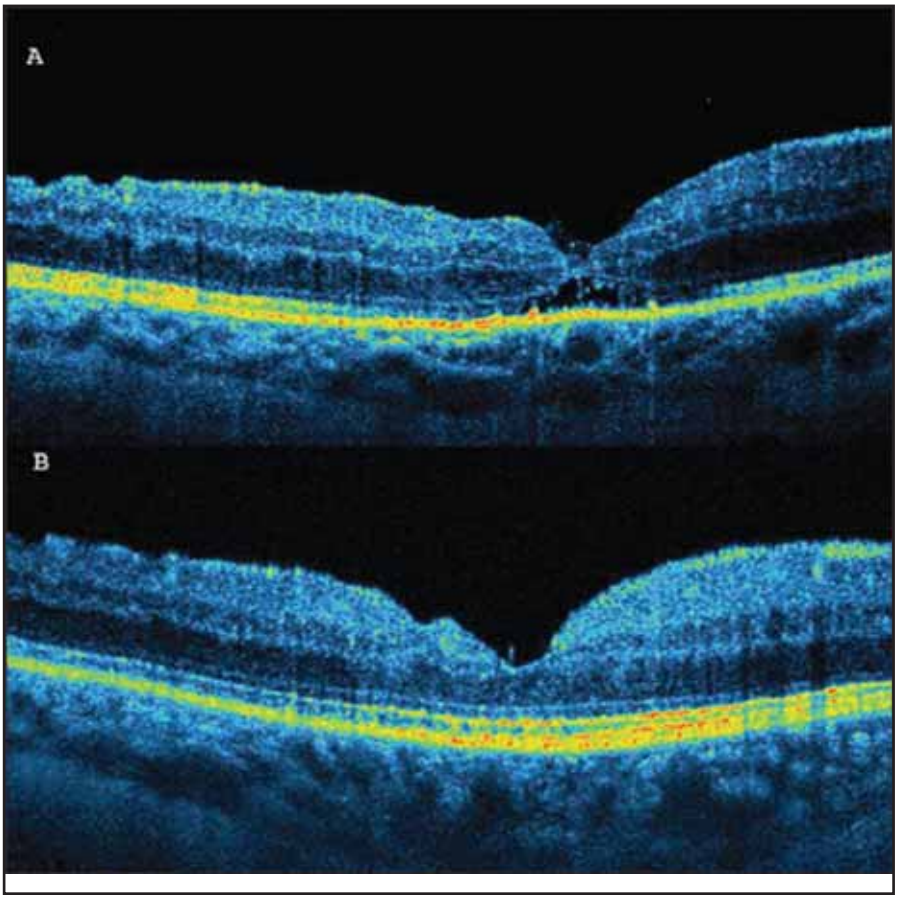


Figure 3A (top). SD-OCT one month after macular hole surgery. A hyporeflective area beneath the outer nuclear layers is visible. The junction between the inner and outer segments of photoreceptors (IS/OS) is incomplete. (B, bottom) SD-OCT 12 months after macular hole surgery. Complete restoration of the IS/OS line is observed.

It must be remembered that what we see with SD-OCT is not really the photoreceptor layer but the junction between inner and outer segments. If outer segments are dam-

aged, then the line may be defective. Thus, injury may provoke phagocytosis of the damaged cells and production of new outer segments. This process may cause the IS/OS line to reappear.

Another theory is that injury may provoke edema of Müller cells and enlarge the distances between particular photoreceptors. This result would move each photoreceptor slightly to a new position. Such pushing of photoreceptors may also improve the IS/OS line visible on SD-OCT.

Lamellar Macular Hole

Lamellar macular holes appear on SD-OCT examination as non–full-thickness macular holes, coexisting with epiretinal membranes in most cases (Figure 4). Recent SD-OCT studies have proved that IS/OS defects may be present in lamellar macular holes.[26,27] Michalewska *et al*. presented a disruption of the line representing the junction of the inner and outer segments of photoreceptors in 10 of 26 patients qualified for surgery. The mean linear diameter of the defect was 848 µm before surgery. Pars plana vitrectomy with ILM peeling and no tamponade was performed.

Interestingly, 12 months after surgery, photoreceptor defects diminished in six eyes, which correlated with improvement of visual acuity. As ILM peeling was performed in all cases in our study, it might have been a signal for retina restoration.

Central Serous Chorioretinopathy

Central serous chorioretinopathy (CSC) usually occurs in young men. The typical SD-OCT appearance is focal serous retinal detachment in the macular area. Most cases of serous choroidal retinopathy resolve spontaneously. However, in some long-lasting cases, laser treatment or PDT with low-dose verteporfin is advised. Decreased visual acuity, besides normalization of the fovea contour in OCT, may be noted, both after spontaneous resolution and after treatment. This result has been reported to be due to persisting defects of the junction between the inner and outer segments of the photoreceptors, as visualized with SD-OCT.[28]

Ojima *et al*. examined 74 eyes with resolved CSC using SD-OCT. In 71.6% of cases, the IS/OS line had no defects immediately after resolution of the focal detachment, which corresponded to good visual acuity. Fifteen eyes with defects of the IS/OS were followed up for about 11 months. It was, however, reported that in nine of 15 eyes after resolved CSC, which initially showed disruptions of the IS/OS line, a recovery of this line presented with time.[29] In those eyes, visual acuity had a continuous tendency to improve. In the other six of 15 eyes, the defects remained unchanged.

AZOOR Complex

Acute zonal occult outer retinopathy, first described by Gass, is nowadays defined as a group of diseases (AZOOR complex30) with different etiologies but similar clinical appearances, among those: multiple evanescent white dot syndrome, multifocal choroiditis and panuveitis, and acute macular neuroretinopathy. These diseases mostly affect young women and present with visual field loss and photopsias. SD-OCT shows loss of the IS/OS boundary and noticeable focal outer nuclear layer thinning during acute phases of the diseases.

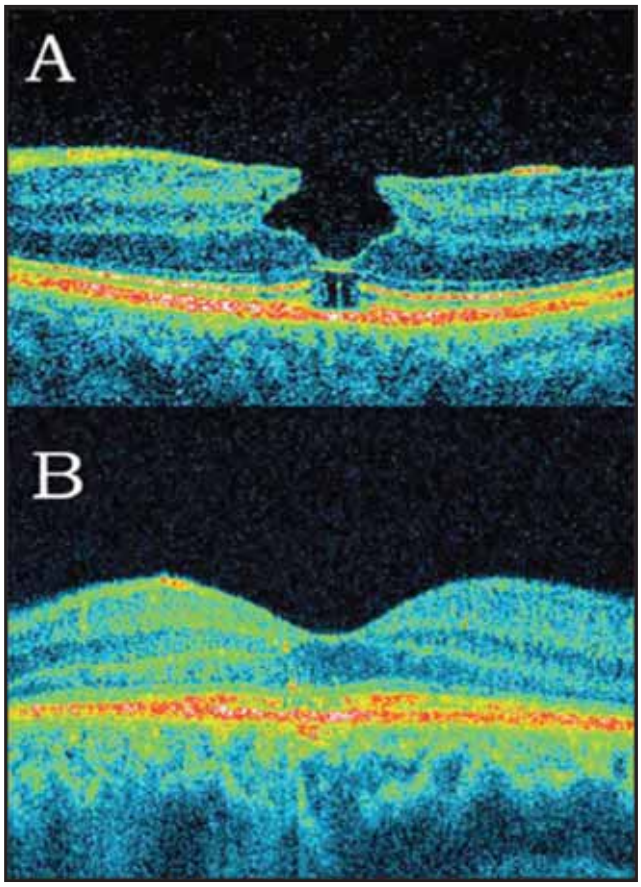


Figure 4A. Lamellar macular hole with epiretinal membrane and defect of the junction between inner and outer segments of photoreceptors in the same eye surgery. (B) Restoration of the IS/OS line may be observed.

Multiple evanescent white dot syndrome (MEWDS) is a disease of unknown origin, affecting mostly young women. Multiple white spots visible on the fundus, decreased visual acuity, and spontaneous resolution after one or two months are typical. Indocyanine green and fluorescein angiography suggest that the changes are located in the outer retina and RPE. Improvement in visual acuity may correlate with restoration of the IS/OS junction.[31,32] It must be noted that, in MEWDS, even if the IS/OS line is defective, the external limiting membrane is present with no defects in all cases. It has been reported that defects in the IS/OS line completely disappear with time.

Sikorski *et al*. hypothesized that the IS/OS line may be invisible on SD-OCT because photoreceptors are swollen.[33] They do not regenerate but become visible when the process is over. Hangai *et al*. demonstrated that the areas of IS/OS defects correlate with moderate reflective focal lesions and with hypofluorescent lesions on indocyanine green angiography.[34]

Vogt-Kobayashi-Harada Syndrome

Vogt-Kobayashi-Harada syndrome is a systemic inflammatory disorder in which the autoimmune system is reactive against melanocytes. Spaide *et al*. reported, however, on regeneration of outer retina viewed with foveal cone densitometry, focal macular electroretinogram, and time-domain OCT.[35]

Healing of Photocoagulation Lesions

Panfundus photocoagulation is the treatment of choice for proliferative diabetic retinopathy. During photocoagulation, a number of photoreceptors are destroyed; thus, oxygenation of the rest of the retina improves. Side effects include, among others, retinal scarring, which induces scotomas and which may increase with time. Animal studies have been performed to understand the process better.[36-38]

In rodents, lesion size was found to decrease over time due to migration of photoreceptors from the untreated surrounding areas filling in the damaged outer retina. Lesions of 200 µm showed resolution of damage in the photoreceptor layer, whereas 800 µm lesions did not. This observation suggests that photoreceptor migration/restoration may have a finite limit.[39]

The process of the repopulation of regions of photoreceptor damage by healthy photoreceptors was described to be associated with actin.[40] These results are interesting, but it must be taken into consideration that no retinal scarring is observed in rodents. Histological studies on rabbits seem to be a model more similar to the human eye.

A study using a semiautomated retinal photocoagulation system (Pascal, Topcon

Medical) was performed. This system enables the surgeon to control precisely the lesion size and the amount of energy used. One hour after laser was performed, damage was seen in all retinal layers and in the RPE and partially in the choroid, with coexisting tissue edema in moderate and intense lesions. In barely visible lesions, only the outer retina was affected.

One day after treatment, the edema had almost resolved. No matter how intense the laser was, the photoreceptors remained damaged, and pyknotic nuclei were present in the outer nuclear layer. In intense and moderate lesions, pyknotic nuclei were also observed in the inner nuclear layer. The lesion size contracted continuously for about two months and then stayed unchanged for up to half a year after laser. An interesting aspect is that, in intense and moderate lesions, the lesion size contracted to about 40%, but barely visible spots almost completely disappeared. The authors observed that pigmented cells invaded all retinal layers with coexisting gliosis.[36] Lateral photoreceptor migration was observed up to four months after laser.

Kriechbaum *et al*. presented for the first time the in vivo appearance of photocoagulation lesions in SD-OCT in diabetic patients. The laser burns were visualized with SD-OCT after one day, and tissue damage could be observed in the outer retinal layers, beginning with outer plexiform layer. They reported that, one week after photocoagulation, the size of the lesion contracted in comparison to its transversal and longitudinal diameter. The line representing the junction between the inner and outer segments of photoreceptors and another hyper-reflective line representing the RPE unified, forming one hyper-reflective structure.

In the first three weeks following laser injury, the defect of the IS/OS line enlarged slightly. However, it was noted that outer nuclear layer partially recovered. It must be noted, though, that the ONL remained thinned a little bit three to six months after laser burns were performed, and the photoreceptor layer defect was not observed to have changed.[41]

The same group analyzed SD-OCT after grid laser photocoagulation in diabetic macular edema. One day after the laser burns were performed, there was damage to the photoreceptor layer, RPE and, to some extent, to the outer nuclear layer. It seems interesting but further studies of how the lesions would change with time are required.[42]

To conclude, after laser application, some extent of photoreceptor migration and recovery of the destructed photoreceptor layer were observed in rodents and rabbits,

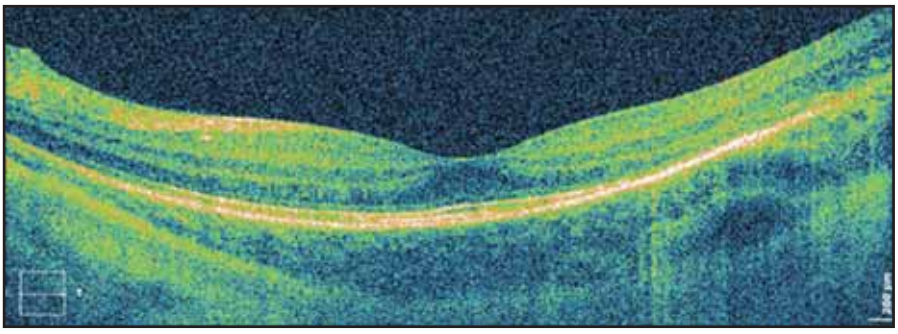


Figure 5. The same eye as shown in Figure 2A after scleral buckling surgery. A res toration of the line representing the junction of inner and outer segments of photoreceptors is visible.

but in vivo SD-OCT studies did not confirm that result for humans. Taking into consideration that the primary endpoint of photocoagulation is the destruction of photoreceptors to increase retinal oxygenation, no restoration of photoreceptors following laser-induced injury can explain why this technique is so successful for most patients.

Solar Retinopathy

Solar retinopathy occurs due to looking straight into the sun, sometimes accidentally, but most frequently during a solar eclipse or with "sun gazers," who look directly into the sun because of religious reasons. The retinal image of the sun in zenith is about 160 mm, which is about 20% of the total macular area. If the pupil is in miosis at about 3 mm, sun watching elevates retinal temperature about 40°C, whereas to photocoagulate retinal tissue 100-200°C is needed. Thus, short-term sun-watching causes a chemical response and not the burning of tissue.[43]

If the pupil is dilated, exposure is prolonged; if enlarging glasses are used, photocoagulation is possible. Bechman *et al*. were the first to report hyporeflective areas on TD-OCT in the region of the IS/OS and RPE observed 48 hours after exposure, which disappeared nine days later.[44]

Defects can be seen on SD-OCT in the photoreceptor layer in solar retinopathy that correspond to microperimetric changes. It was reported that those changes may partly or completely disappear at least six months after exposure.[45]

CONCLUSIONS

Partial or complete restoration (Figure 5) of defects in the line representing the junction of the inner and outer segments of photoreceptors has been described in a wide range of diseases. Various explanations may be appropriate for these findings.

Some hypotheses suggest that the observed phenomenon is only a masquerade of regeneration. It had already been suggested that the hyper-reflective IS/OS line appears due to back-reflection of the perpendicular photoreceptor stack. If the photoreceptors are not perpendicular to the reflectance beam, they may not be clearly visible. It may also be true that if photoreceptors are detached or are not ideally regular, then the light is not ideally back-scattered, and the IS/OS line may not be seen on SD-OCT.

Another hypothesis is that swollen photoreceptors may not be visible with SD-OCT. If the swelling abates, the photoreceptors become visible again. A further hypotheses is based on the idea of partial regeneration.

It must be remembered that the hyper-reflective line described as the photoreceptor layer is, in reality, the junction between the inner and outer segments of photoreceptors. The outer segments are continuously phagocytized and produced throughout life. If damage affects only the outer segments of photoreceptors, without destruction of the photoreceptor body, then the line probably becomes invisible. After restoration of the outer segments of photoreceptors, the line probably becomes visible again.

After surgical removal of the ILM, Müller cells begin to swell. That swelling may then move photoreceptors to new places. Pulling those particular photoreceptors a little bit apart might look like restoration of the IS/OS line.

However, retinal regeneration was proved to be possible in mammals in experimental studies. SD-OCT images presenting restoration of the IS/OS line often correlate with visual recovery, thus some extent of retinal regeneration should also be considered. Future studies may explain the phenomenon.

It must be considered that, in eyes without RPE damage, restoration of the IS/OS line may be possible, and improvement of visual acuity may continue over many months.

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REFERENCES AVAILABLE ON REQUEST

By using their tongues, sightless people may be able to "see" again.

AIMEE ARNOLDUSSEN, PHD • DONALD C. FLETCHER, MD

Visual Perception for the Blind: The BrainPort Vision Device

Individuals with LP or NLP vision are among the most challenging, and heartbreaking, patients we encounter. Our ability to improve their circumstances is woefully limited. Any efforts that can provide them with some gain in sensory input will improve their independence, and with it, their quality of life.

The BrainPort vision device is an investigational, non-surgical visual prosthetic that translates information from a digit al video camera to the user's tongue, using gentle electrical stimulation. With training, totally blind users learn to interpret the images on their tongue as information about the scene in front of them (Figure 1). The benefits include increased independence, improved safety, mobility, object recognition and the ability to apply the technology toward specific hobbies and recreational situations. Past users have used the device to read words, play games such as tic-tac-toe, build a snowman and recognize the holds while rock climbing.

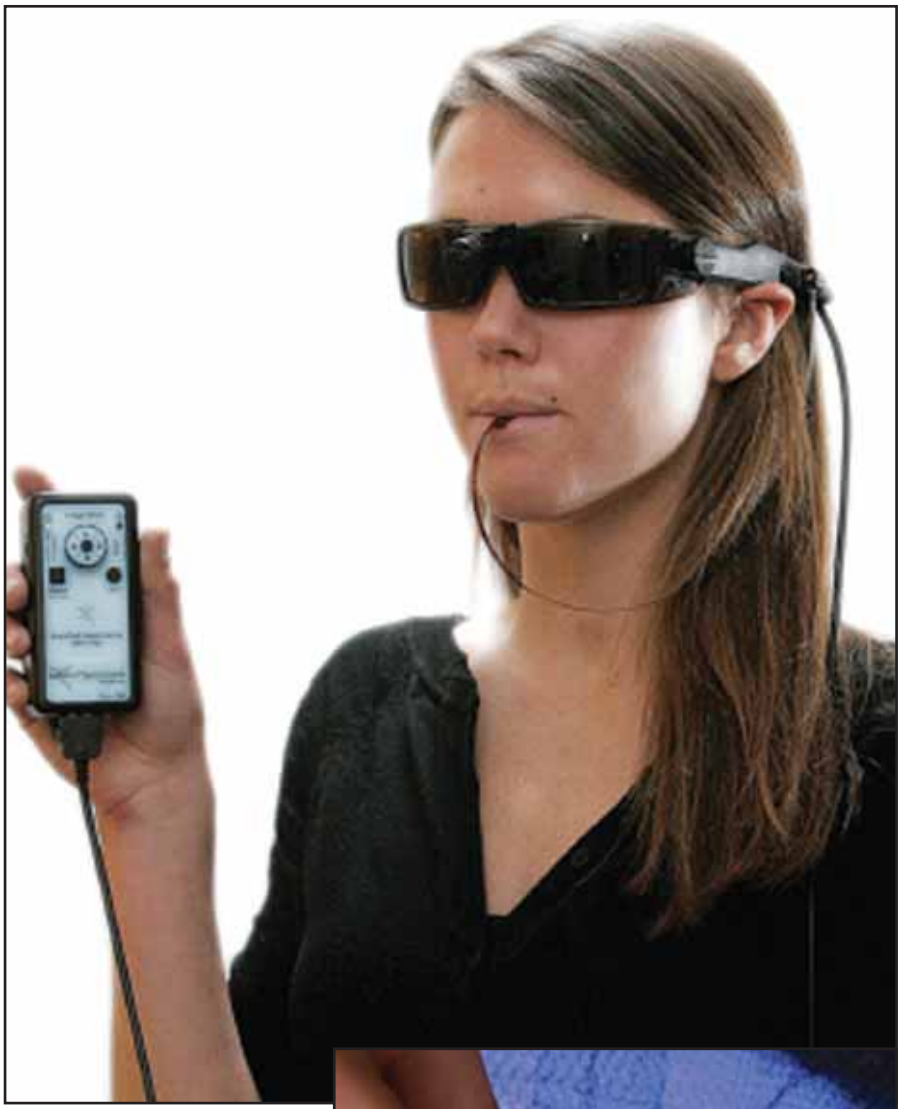

Figure 1. With training, totally blind users learn to interpret the images on their tongue as information about the scene in front of them.

The BrainPort vision system consists of a postage-stamp–sized array of 400 electrodes placed on the top surface of the tongue (Figure 2), a digital video camera affixed to a pair of sunglasses and a hand-held controller for settings, such as zoom and

Figure 2. The BrainPort vision system consists of a postage-stamp–sized array of 400 electrodes placed on the top surface of the tongue.

Figure 3. Training performance is monitored using an accessory that displays video from the user mounted camera (top) and provides a visual depiction of the stimulation pattern on the tongue (bottom).

control of the stimulation level. Visual information is collected from the user-adjustable head-mounted camera (field of view 3° to 73°) and is sent to the BrainPort handheld controller.

The controller translates the visual information into a stimulation pattern that is displayed on the tongue. The tactile image is created by presenting white pixels from the camera as strong stimulation, black pixels as no stimulation and gray pixels as medium levels of stimulation, with the ability to invert contrast when appropriate. Users describe the perception as moving pictures drawn on their tongue with effervescing bubbles.

PATIENT SELECTION CRITERIA

The BrainPort vision device is initially being studied with individuals having no useful vision (light perception or worse), as preliminary clinical studies have confirmed successful use by these individuals. Because the BrainPort vision device requires a training period, initial users are more likely to be younger, technologically savvy and independently mobile users. Unlike other visual prosthetic technologies (retinal and cortical implants), the BrainPort provides benefits for a wide range of blindness etiologies (including both congenitally and acquired) and does not require any surgery.

TRAINING

Training is provided by an orientation and mobility instructor, a low vision professional, or those with similar backgrounds in blindness rehabilitation. Training performance is monitored using an accessory that displays video from the user-mounted camera and provides a visual depiction of the stimulation pattern on the tongue (Figure 3).

Training occurs across a variety of tasks to encourage generalized learning. New users receive at least 10 hours of training prior to independent use. Skills are expected to continue to develop beyond the initial training period.

CURRENT RESEARCH

Wicab Inc., the developer of the technology, has launched a one-year FDA clinical study (October 2011) to evaluate the safety and efficacy of the BrainPort vision device in subjects who are profoundly blind, with only light perception or worse. Participants meeting the study criteria will be given training and access to a BrainPort vision device to use at home. Participants will make quarterly clinic visits to monitor safety and efficacy, which will be evaluated by an object-recognition task, a word-identification task and a mobility task.

Seven sites across the United States and Canada (New York, Pittsburgh, Chicago, Wichita, Pensacola, New Orleans and Toronto) will be enrolling 75 participants. For this and other current or future stud ies, doctors can refer patients to Wicab best via e-mail (vision@wicab.com) or by contacting one of the seven the FDA sites directly. Each FDA site is recruiting local subjects within a two-hour driving radius of the site.

Wicab hopes to have FDA approval and have the BrainPort ready for sale in the United States within two years. They are working on overseas approval also, which would allow sales in the EU in approximately March 2012 and in Canada in mid-2012.

In addition to this FDA study, Wicab has received three years of funding via the Defense Medical Research and Development Program of the Department of Defense in conjunction with University of Pittsburgh Medical Center and Carnegie Mellon University. The enrolled subjects, including veterans blinded in recent conflicts, are steering future device development by participating in clinical assessments and providing feedback following their use of the device both at home and in the clinic. Through iterative feedback from subjects, the development team will implement and test hardware and software device enhancements.

CONCLUSION

The BrainPort vision device allows users to directly and independently perceive the environment in a novel way. The information enables an empowering sensory experience with which users are able to direct their attention at will and interpret the information themselves. Primary benefits include improved safety, mobility and object recognition. Secondary benefits include applying the technology toward specific hobbies and recreational situations. These benefits may enable greater independence at home and school and in business, greatly improving quality of life. Sparing the patient from a need for surgical implantation, as is common in other visual prosthetics, greatly increases the number of potential patients that can benefit from the device.

Aimee Arnoldussen, PhD, is a neuroscientist at Wicab Inc. Donald C. Fletcher, MD, is director of the Frank Stein and Paul S. May Center for Low Vision Rehabilitation at the California Pacific Medical Center in San Francisco, senior scientist at the Smith-Kettlewell Eye Research Institute in San Francisco, and medical director of the Envision Low Vision Rehabilitation Center in Wichita, KS. Dr. Arnoldussen reports significant financial interest in Wicab as an employee. Dr. Fletcher reports minimal financial interest in Wicab. He can be reached via e-mail at floridafletch @msn.com.

Esmé Prins-van den Berg, Healthcare Navigator

THE ETHICAL RULES OF THE HEALTH PROFESSIONS COUNCIL OF SA: ARE THEY ANTI-COMPETITIVE?

Statutory organisations such as the Health Professions Council of SA (HPCSA) that had rules, which contained restrictions and which restrictions had the effect of substantially preventing or lessening competition in a market, could apply to the Competition Commission for exemption of those Rules from the Competition Act 89 of 1998. The Commission could exempt all or part of the Rules for a specified period if the restrictions were reasonably required to maintain professional standards or the ordinary functioning of the professions.

This meant that if a body like the HPCSA had Ethical Rules that were or might be transgressing the Competition Act, it could apply for exemption in respect of those Rules from the Competition Commission. The Commission could grant exemption if the restrictions contained in the Rules were for example required to maintain professional standards. If exemption was granted, the Rules would then not be regarded as transgressing the Competition Act, although they might be restrictive. If exemption was not granted it could mean that the Rules were not transgressing the Act or that the Rules should not be maintained by the relevant body as they in fact constituted or resulted in anti-competitive conduct, which was unlawful.

ETHICAL RULES

The HPCSA applied for exemption from the Competition Act in respect of the following Ethical Rules that applied to optometrists:

1. RULE 3(2): CANVASSING AND TOUTING

This Rule prohibited practitioners from canvassing or touting for patients either personally or by a third party on their behalf.

"Canvassing" referred to conduct (verbally or through the printed or electronic media) that drew attention to one's personal qualities, superior knowledge, quality of service, professional guarantees or best practice. "Touting" referred to conduct (verbally or through the printed or electronic media) that drew attention to one's offers, guarantees or material benefits that did not fall in the categories of professional services or items, but were linked to the rendering of a professional service or designed to entice the public to the professional practice.

2. RULE 4: INFORMATION ON PROFESSIONAL STATIONERY

Rule 4 restricted practitioners to the printing of only certain specified information such as their names, professions, addresses and telephone numbers on their stationery, which included letterheads, account forms and electronic stationery.

3. RULE 5: NAMING OF A PRACTICE

This Rule prohibited practitioners from using names other than the name(s) of a registered practitioner(s) who practised or used to practise in that particular practice. Trade names and terms such as "hospital", "clinic" or "institute" could not be used in the name of a practice.

Optometrists could, however, use a name for which they had obtained prior approval from the Professional Board for Optometry and Dispensing Opticians provided that such a name was not indecent, misleading or deceptive, was in keeping with the professional image or dignity of the profession, did not claim prominence for a registered optometrist and the names of the responsible practitioners were displayed together with or alongside the practice name.

4. RULE 7: FEES AND COMMISSION

The Rule relating to fees and commissions prohibited amongst others practitioners from accepting commission or material consideration from any other practitioner or person in return for the purchase, sale or supply of goods used by them in the conduct of their professional practice. Other prohibited conduct included:

- The payment of commission to persons for recommending patients;
- Perverse incentives, i.e. any payment, benefit or material consideration that was intended to persuade a practitioner to act in a way that was not scientifically, professionally or medically indicated or to under-service, over-service or over-charge patients; and
- The sharing of fees with a person or practitioner who has not taken a commensurate part in the services for which the fees were charged or the charging of fees for services not personally rendered (excluding those rendered by an employee, partner, shareholder or locum).

5. RULE 8(4): PARTNERSHIP AND JURISTIC PERSONS

This Rule prohibited a practitioner from practising in any other form of practice than those prescribed (i.e. partnerships, associations and incorporated companies) that had inherent requirements or conditions that would violate any of the Ethical Rules.

6. RULE 8A: SHARING OF ROOMS

Rule 8A prohibited practitioners from sharing rooms with person or entities not registered in terms of the Health Professions Act.

7. RULE 10: SUPERSESSION

The Rule related to supersession required a practitioner who took over a patient from another practitioner to inform the firstmentioned practitioner of such take over before proceeding with treatment.

Optometrists were allowed to conduct mobile practices in areas where optometric services were not readily available subject to the provisions of the rule on supersession. Certain conditions were, however, prescribed for this purpose, namely

- The practice could only operate in a defined area;
- The equipment to be used for comprehensive visual examinations had to be in accordance with the guidelines issued by the Professional Board;
- Optical appliance dispensing was conducted by the practitioner at the site visited;
- The practitioner who operated the mobile practice also had an established practice from which the mobile practice was operated;
- Patients were informed of the contact details of the established practice and of

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the nearest health facility with which the practitioner had made arrangements for emergency ocular health care; and

- Prior written approval to conduct such mobile practice was obtained from the Professional Board.

8. RULE 18: PROFESSIONAL APPOINTMENTS

The Rule related to professional appointments required employers to be approved by the HPCSA before they could employ practitioners. Employers approved by the HPCSA were the public service, universities, training institutions (limited for purposes of training and research) as well as all registered persons within the HPCSA who might employ fellow registered practitioners. Other potential employers needed to apply to the HPCSA for approval. Criteria such as the motive/goals, whether services were delivered on a not-for-profit basis, training of students, clinical independence of practitioners and the method of remuneration were considered in such applications.

9. RULE 23: MEDICINE AND MEDICAL DEVICES

This Rule prohibited practitioners amongst others from participating in any activity that would amount to trading in medicine. Furthermore, practitioners might not advocate the use of any medication if they would derive any consideration for such medicine.

10. RULE 23A: FINANCIAL INTERESTS IN HOSPITALS

Rule 23A imposed requirements on practitioners who had shares or financial interests in hospitals or health care institutions and referred patients to such hospitals or institutions for admission or treatment. The restrictions imposed related to the purchasing of such interests, returns on investment, review systems, advertising and promotion, preferential use and approval by the HPCSA.

COMPETITION COMMISSION DECISION

The Competition Commission had rejected the HPCSA's application for exemption and did not find that any of the Rules transgressed the Competition Act as such. It considered the following factors in its deliberations:

- Nature of the restraint on competition contained in the Rules;
- Effects of the Rules on competition;
- Rationale given by the applicant for any restraint;
- Views of interested parties; and
- International norms.

The Commission nevertheless expressed the view that the application of the Rules could have a negative effect on competition in the health professions. In its view there were less restrictive means of achieving the HPCSA's objectives with the Ethical Rules, namely to maintain professional standards and the ordinary functioning of the health professions. The Commission indicated that this would be further discussed with the HPCSA.

The Competition Commission also stated that international norms indicated that there was a need to have less restrictive Ethical Rules to protect competition such as introducing mechanisms that would curtail commercial, over-servicing and perverse incentives on the part of registered practitioners and enforcement of personal liability for practitioners employed by corporates.

The Commission gave the following specific reasons for its decision to reject the HPCSA's application:

- There was no evidence that the following Rules would lead to a substantial prevention or lessening of competition in the market:
- Naming of a practice (Rule 5);
- Fees and commission (Rule 7);
- Sharing of rooms (Rule 8A); and
- Supersession (Rule 10).
- The broad manner in which the following Rules were worded did not constitute a contravention of the Competition Act as such:
- Partnership and juristic persons (Rule 8(4));
- Professional appointments (Rule 18);
- Medicine and medical devices (Rule 23); and
- Financial interests in hospitals (Rule 23A).

The Commission was, however, of the opinion that depending on how these rules were applied, it could result in anti-competitive conduct in contravention of the Act. If the application of a Rule resulted in anti-competitive effects, it would be assessed and addressed on a case-by-case basis.

- The restrictions contained in the following Rules were not reasonably required to maintain professional standards or the ordinary functioning of the health professions:
- Canvassing or touting (Rule 3(2)); and
- Information on professional stationery (Rule 4).

CONCLUSION

The effect of the decision of the Competition Commission was that all the Ethical Rules of the HPCSA remained valid and enforceable. It did, however, imply that practitioners who wished to engage in conduct, which was prohibited by the Ethical Rules (e.g. to practise in a different practice model from those approved by the HPCSA or to include other information than that prescribed on professional stationery), could potentially use the mechanisms in the Competition Act to obtain approval for their conduct if the prohibition imposed by the HPCSA had anti-competitive effects.

It was also possible that the HPCSA might revise its Ethical Rules with time in terms of its further engagement with the Competition Commission in this regard.

References:

1. Ethical Rules of Conduct for Practitioners under the Health Professions Act, 1974. GNR 717 of 4 August 2006.
2. Notice 817 of 2011: Notice in terms of Item 4(c) of Part 1 of Schedule 1 of the Competition Act 89 of 1998 (Amended): Application for Exemption by the Health Professions Council of SA in terms of Part A of Schedule 1 of the Competition Act Case Number: (2008Jan3456). Rejection of Exemption Application. Government Gazette 34767 of 25 November 2012.
3. Undesirable Business Practice Policy of the HPCSA. 2005.

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1. Go to www.medspec.co.za 2. Click on the *EyeCare Africa* Ethics CPD programme button. 3. Complete the registration form and click the submit button. 4. You will be directed to your landing page, where the questionnaires will be displayed. 5. Click on the questionnaire which you would like to complete, once completed click submit.

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Vibrant & on-trend Oakley collection unveiled at Luxottica Media day

The media day was held at Maremoto, a boutique hotel and restaurant on 230 long street Cape Town. It was well supported by media from all sectors who were very impressed with the Oakley styles for summer 2011. Oakley ambassadors such as Roxy Louw, Vanessa Haywood, Ryan Sandes and Enzo Kunn just to name but a few were also in attendance.

Oakley Lifestyle

Style never stops evolving, and neither does Oakley. The clearest evidence of their perpetual forward motion resides in their women's New Releases sunglasses- a collection of women sunglasses in shapes and styles that deliver the freshest new looks to complement your lifestyle. The Oakley range has grown from strength to strength and has the support of many including model and surfer Roxy Louw, the face of Oakley this summer. The men's collection is an expression of Oakley Lifestyle. Inspired by their athletes, the cultures they live in and their approach to life, this collection is rendered with clean and uncomplicated style. It balances a pure and authentic look with innovation and craftsmanship the world has come to trust from Oakley.

"In sunglasses, as in life, it's not enough just to stand out. You've got to back up the flash with substance. That's why superior athletes and popular people rock Oakley men's sunglasses . Some shades protect your eyes. Others protect your image." The Oakley sunglasses in the Lifestyle collection do both. The Oakley attitude abides.. limited edition Frogskins that illuminate in UV light, attracted a lot of attention, lookout for these and other styles around town!

About Oakley

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References: 1. Kaercher T, Buchholz P, Kimmich F. Treatment of patients with KCS with OPTIVE™: results of a multicenter, open-label observational study in Germany. *Clin Ophthalmol* 2009;**3**:33-39. 2. OPTIVE™ Efficacy Measures, Data on file, Allergan. 3. OPTIVE™ Technical Document. 4. Simmons PA *et al.* Effect of Compatible Solutes on Transepithelial Electrical Resistance and Uptake in Primary Rabbit Corneal Epithelial Cell Layers Model. *Invest Ophthalmol Vis Sci* 2007; **48**: E-Abstract 428. OPTIVE™ Lubricant Eye Drops. Contains carboxymethylcellulose sodium 5 mg/ml and glycerine 9 mg/ml. Complementary medicine reference number: 420519. For full prescribing information refer to the package insert. Applicant: Allergan Pharmaceuticals (Pty) Ltd, PO Box 6024, Halfway House, 1685, South Africa (Co. Reg. no. 1964/005576/07) Telephone: + 27 (0) 11 545 6600, Facsimile: + 27 (0) 11 315 6008, ZA/0020/2011.

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