Outdated FDA protocols don’t account for real-world usage, newer lens materials and virulent organisms. Proposed updates could bring big changes.

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Putting it On the Map: Fitting Rigid Lenses Using Corneal Topography
Familiarizing yourself with corneal mapping can lead to more success with your contact lens patients.
By Vivian Phan Shibayama, OD

Forward Thinking: Where Can New Lenses Lead Your Practice?
From sclerals to daily disposables and tinted lenses, new designs can add to your practice if you’re willing to change your mindset.
By Jane Cole, Contributing Editor

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By Mike Christensen, OD, PhD, and Tressa Larson, OD

CE — Reality Check: How FDA Testing Falls Short
Outdated FDA protocols don’t account for real-world usage, newer lens materials and virulent organisms. Proposed updates could bring big changes.
By Yvonne Tzu-Ying Wu, PhD, MPH, An Truong, B.Optom, and Fiona Stapleton, PhD
Lipid-binding Differences Noted

D eposition of cholesterol on contact lenses varies significantly between lens materials, reports a study in the January 2016 *Optometry and Vision Science*.1 Though silicone hydrogel (SH) materials are known to increase oxygen transport to the ocular surface, certain chemical components within these materials may also negatively impact wettability (and potentially patient comfort) if exposed to very high levels of lipids.2-4 To date, however, no study has investigated the degree to which daily disposable lenses uptake lipids—in particular, cholesterol.

Researchers at the University of Waterloo in Canada incubated three SH materials and four conventional hydrogel (CH) materials in an artificial tear solution containing radioactive C-labeled cholesterol. Each was submerged for two, six, 12 and 16 hours to simulate typical daily disposable lens wear times.

Results indicated both contact lens type and length of incubation were factors in the amount of cholesterol deposition. No significant difference in the amount deposited on the SH materials was observed; a difference did exist among the CH materials. Overall, however, SH materials deposited more cholesterol than CH materials.

These results suggest a number of things, the authors say. First, daily disposable patients who exhibit relatively heavy levels of lipids in their tears due to factors such as meibomian gland dysfunction may benefit from certain CH lens types, such as nelfilcon A and etafilcon A materials. Additionally, wearers who require higher oxygen transport but exhibit oily tears should be aware of potential wetting issues when wearing SH daily disposable lenses.

Other caveats: this study only considered one lipid type, cholesterol (many others are found in the tear fluid); the deposition of certain lipids could be beneficial to lens wear (as previously reported by the same group); and the amount of lipid deposited may not be as important as whether the lipids under investigation are oxidized or remain in their natural state.1


SPEED Questionnaire Vetted

The Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire is comparable to the Ocular Surface Disease Index (OSDI) questionnaire for separating asymptomatic and symptomatic dry eye patients, reports a study published in the February 2016 issue of *Cornea*.1 Investigators compared the answers of 657 undergraduate students at the University of Cape Coast in Ghana, determining the internal consistencies of the OSDI and SPEED questionnaires to be approximately the same (i.e., 0.897 and 0.895, respectively). However, the SPEED questionnaire was relatively better in terms of internal consistency compared with the OSDI questionnaire, indicating it is a valid measure for dry eye and could be used in epidemiological studies and clinical practice, the researchers say.


IN BRIEF

Researchers from the University of Missouri School of Medicine have identified a link between administration of the varicella zoster virus vaccine for chickenpox and shingles and presentation of keratitis. Though the potential for corneal inflammation as a side effect of the vaccine is low, primary care physicians should inform all patients prior to administration, the researchers say.


Consider reinforcing orthokeratology education, particularly for male patients, reports a study in the January 2016 issue of *Eye & Contact Lens*. Researchers in southern Taiwan identified a total of 86 microbial strains from 38 tissue-positive specimens taken from orthokeratology lens case fluids of 41 pediatric wearers. Interestingly, frequently reported pathogens (i.e., Serratia marcescens, Pseudomonas aeruginosa and Staphylococcus aureus) in contact-lens related microbial keratitis were identified less commonly in this study; additionally, the lens cases of male subjects exhibited a higher microbial bioburden than those of female subjects.


A comparison of femtosecond laser-assisted LASIK and small-incision lenticule extraction (SMILE), published in the February 2016 issue of *Cornea*, suggests both procedures achieve similar good visual outcomes in the correction of myopia and myopic astigmatism; however, patients who underwent SMILE exhibited a lower induction rate of spherical aberration six months postoperatively, suggesting long-term outcomes of the procedure may ultimately be more beneficial.1 However, further research is needed based on a larger sample size to confirm this.

Corneal Diameter Affects Postoperative Astigmatism

Corneal diameter should be determined prior to cataract surgery, as it can lead to varying degrees of corneal astigmatism depending on the type of incision used, reports a study in the January 2016 issue of Cornea.1 Other factors already known to impact postoperative astigmatism include incision size, configuration and location relative to the limbus, as well as the axis on which the main incision is performed.

Researchers observed cataract procedures performed on 330 eyes at the General Hospital of Piraeus “Tzaneio” Attiki in Greece from February 2011 to October 2013. Patients were divided into four groups according to corneal horizontal diameter, i.e., white-to-white (WTW) distance: group A ≤ 11.6mm; group B 11.7mm to 11.9mm; group C 12.0mm to 12.2mm; and group D ≥ 12.3mm.

At the first postoperative month, surgically-induced astigmatism (SIA) was 0.98D ± 0.65D in group A, 0.79D ± 0.43D in group B, 0.68D ± 0.45D in group C and 0.53D ± 0.32D in group D, while at six months postoperatively, SIA was 0.77D ± 0.43SD in group A, 0.69D ± 0.34SD in group B, 0.62D ± 0.36SD in group C and 0.49D ± 0.27SD in group D.

These data indicate that a change greater than 0.5D in corneal astigmatic power at the first and sixth months postoperatively was significantly lower in eyes with WTW distance 12.0mm to 12.2mm and ≥ 12.3mm, compared with eyes with WTW distance ≤ 11.6mm and 11.7mm to 11.9mm. In effect, the researchers note, the smaller the cornea, the larger the effect on the power of postoperative astigmatism.

“...these findings are important because it identifies an additional perioperative variable that is helpful in improving astigmatic results following cataract surgery,” Eric Donnenfeld, MD, a surgeon on Long Island, says.

Researchers also classified the participating eyes into groups of either right or left to evaluate if superior and superomedial incisions in the left eyes lead to greater SIA due to the primary incision being situated closer to the optical center of the cornea and the placement of the phaco probe against the nose and brow. They also examined whether superior and superolateral incisions produce more postoperative astigmatism in against-the-rule astigmatic eyes than in with-the-rule eyes.

Ultimately, however, results indicated no differences in SIA between right and left eyes, and the type of astigmatism could not be accounted for, due to the unvaried patient base. The results are further limited by the evaluation of anterior surface topography, the researchers note. Research that includes posterior corneal effects is needed to more fully evaluate astigmatism-induced results.

This Year, Strive to Avoid Stress

If you are like most of us, decreasing tension in 2016 is a laudable New Year’s resolution.

Many of us in practice—especially for 10 years or more—know all too well how stress can lead to some amount of professional “burnout.” It has a pervasive effect on nearly every action we perform daily, from the degree of care we provide our patients to our relationships with friends, family and coworkers. Symptoms of burnout include mental and physical exhaustion, stress, depersonalization (i.e., cynicism and sarcasm) and a reduced sense of accomplishment.1,6 While burnout is common in most industries, it’s on the rise among health care professionals in particular.2

A recent Mayo Clinic study assessing the incidence of burnout symptoms, such as work/life imbalance, depression and suicidal ideation among physicians found that 54.4% of those surveyed reported one or more symptoms of burnout in 2014, compared with 45.5% in 2011 (p=0.001).4 With respect to individual symptoms, the rate of physicians with a healthy work/life balance decreased in the three-year span measured, with only 40.9% of practitioners reporting they had sufficient time for personal and family life in 2014.5,3 Long-term consequences linked to burnout included: (1) lower patient satisfaction and quality of care; (2) higher medical error rates and risk for malpractice; (3) higher physician and staff turnover; (4) physician alcohol and drug abuse; and (5) physician suicide.4,5

LOW BATTERY

What is causing this epidemic? Mark Linzer, MD, offers a list of specific drivers below: 1 Stress. Research has demonstrated you’re 15 times more likely to burn out if you operate under constant stress. Ongoing concern for medical errors and potential malpractice cases also raises stress levels; additionally, payers may obstruct tests that you deem necessary, limiting your ability to provide the best patient care possible.

2 Chaos. Caring for patients is what keeps most doctors motivated, but caring for too many of them under a stressful environment is generally what burns them out. Recent changes imposed by government entities and payers have further heightened the demand.

3 Discord. Motivation wanes quickly if your practice ideals and values don’t match, or if a healthy camaraderie does not exist between members of your practice.

4 Depersonalization. We often serve as the emotional buffer between the patient and our own environment, sometimes limiting our ability to connect with them. And, after years of practice, things can begin to seem mundane or depersonalized.

5 Interference. Leaving insufficient room for personal schedule changes and needs in daily life can lead to negative spillover into work life, and vice-versa.

6 Neglect. Self-care is critical—when you neglect yourself, you neglect your patients. Taking time to relax to ensure you can focus when needed and provide the best care possible.

PHYSICIAN, HEAL THYSELF

Let’s face it—work is stressful. Indeed, that’s why they call it work. But the difference between manageable levels of stress and complete professional burnout is the ability to recover when not working.6 Personal downtime is key, and we all need an activity that brings us joy. It is vital that we carve out some time from our workweek to do the things we love.

Research has shown prevention and treatment measures for burnout should be approached both on the personal and organizational level.6 Personal burnout prevention measures involve maintaining self-awareness, appreciative inquiry, narrative medicine and maintaining a healthy work/life balance.5,6 Measures that can be taken at the organizational level include the creation of specific programs to support health care providers and the allowance for flexible work hours.

Remember, we have a lot to bring to the battle against burnout: intelligence, good incomes, support from family and friends and life outside of health care and an overall investment in education and self-growth.6 None of us are immune to burnout—make avoiding it your resolution for 2016.6

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Solution Savers

Lens care can make or break the contact lens experience for patients. Here’s how to tip the odds in favor of success.

Even as we recognize that the newest contact lens development efforts give us viable options for everyone, including our most difficult patients, it is important to remember most lenses prescribed today in North America continue to be two-week and monthly disposables, despite the influx of daily replacement options. How, as eye care practitioners, can we help patients choose the right solution, and how does this help our goal of practice building? Reminding patients—both old and new—of proper contact lens care and solution use is key to maintaining a healthy patient population and even drawing in new ones.

A tremendous amount of research documents widespread lack of contact lens compliance, which can significantly affect the patient’s wearing experience.1,2 Although poor hygiene during lens care and handling typically dominates discussions of noncompliance, inattention to lens/solution compatibility when purchasing care products is also a concern among practitioners.

Patients face the challenge of selecting the right solution for their lenses following the initial fitting appointment, especially as many multipurpose solutions created decades ago remain packaged similarly to even the most recently engineered products. Intentional mimicry in product design by generic or store-brand products can mislead patients into making poor choices at the drugstore.

KNOW YOUR SOLUTIONS

Biotrue (Bausch + Lomb), OptiFree PureMoist (Alcon) and Revitalens OcuTec (Abbot Medical Optics) are three of the latest additions to the multipurpose solution options. Biotrue contains hyaluronic acid, a glycosaminoglycan that temporarily binds to the surface of the lens to increase daily comfort.3 OptiFree PureMoist contains the copolymer polyoxyethylene-polyoxybutylene under the trade name HydraGlyde, which is said to improve lens surface wettability and end-of-day comfort.4 Revitalens OcuTec contains the wetting agent Tetronic 904 in attempts to optimize surface moisture.5

Other disinfection options come in the form of hydrogen peroxide systems—most notably ClearCare (Alcon), the newer ClearCare Plus (Alcon) and PeroxiClear (Bausch + Lomb). Overall, peroxide systems have remained the mainstay for individuals with multipurpose solution sensitivities due to the lack of chemical preservatives in the peroxide. For those individuals prone to developing giant papillary conjunctivitis (GPC) who may not be good candidates for daily disposable contact lenses, hydrogen peroxide disinfection works remarkably well as a solution option after the patient’s GPC has been appropriately managed (Figure 1).

And in fact, peroxide systems are having a bit of a renaissance lately, as practitioners see them as a possible bulwark against noncompliance. Patients can’t “top off” their solution if using peroxide, for instance.

ClearCare is a one-step peroxide system that combines disinfection and storage capabilities into a single entity. Patients can either rub and rinse the lenses with this solution and then place them in the lens case cage prior to submerging them in the solution, or place the lenses in the cage, rinse them for five seconds and then submerge the entire entity. An overnight soak in ClearCare requires six hours of neutralization prior to lens wear. Alcon recently added HydraGlyde to its ClearCare formulation under the name ClearCare Plus.

PeroxiClear, another one-step peroxide disinfection solution, has a four-hour soak requirement for neutralization. This time frame may be better suited for contact lens wearers with less consistent schedules who may require a faster cleaning method. Disinfection occurs via a platinum-modulating compound known as carbamide: when the platinum disc is submerged in peroxide, the carbamide binds to the platinum to inhibit the neutralization rate. This keeps the peroxide at a higher concentration than normal (i.e., when not in the presence of carbamide), and increases the total exposure of the lenses to the peroxide.6,7 During the first 60 minutes of soaking, the carbamide loses its affinity for the platinum disc, causing the platinum disc to rapidly neutralize the peroxide in the system. This rapid neutralization is what allows wearers to remove the lens from the peroxide solution after only a four-hour soak and comfortably place it on the eye.
UNDERSTAND THEIR DIFFERENCES

New technologies can help create better wearing experiences for the patient—which is why practitioners must remain cognizant of the number of store-brand peroxide systems that are also available. While similar at first to some of the branded systems, they, in fact, have significant differences that can irrevocably alter a patient’s wearing experience.

A number of structural differences exist between branded peroxide basket-and-disc systems and generic formulations. In non-branded peroxide solutions, the platinum disc is typically located at the bottom of the vial that holds the peroxide rather than attached to the basket that contains the lenses. While a seemingly trivial detail, this difference can affect the neutralization profile of the peroxide: because the platinum disc is attached to the basket containing the lenses, the lenses and platinum disc are submerged into the peroxide simultaneously to provide maximum exposure of the lenses to the peroxide. In contrast, the placement of the platinum disc at the bottom of the vial in store-brand products means that the neutralization process begins as soon as the peroxide is placed in the vial containing the platinum disc.

Giving a little extra attention to contact lens care guidance means healthier, and thus happier, patients—and happier patients means more referrals.

The Case of the Finicky Fungus

Treating with antibacterial drugs can be tempting when presented with acute infection, but first make sure the agent matches the organism.

A 68-year-old Caucasian female contact lens wearer presented for an emergency evaluation on a Sunday evening with a complaint of severe pain in one eye. Her history was significant for an eight-day treatment of that eye with topical Vigamox (moxifloxacin, Alcon) QID and an unspecified steroid drop BID. According to the patient, she initially responded well to the aforementioned treatment, but had since developed a case of intense ocular pain and mild vision loss over the past 24 to 48 hours.

A physical examination revealed the right eye to have normal visual acuity at 20/20- with correction. The left eye with correction was 20/50, pinholing to 20/25-. An external exam revealed a notable area of conjunctival inflammation and hyperemia located in the inferior nasal sector. The remainder of the conjunctiva was relatively clear.

An anterior chamber reaction was present, but less than 1+, and the globe demonstrated a remarkable hyperemia located in the inferior nasal sector. The margin of the lesion appeared well-defined, and the tissue was not soft or pliable as before; however, the anterior chamber appeared slightly softer than previously noted. A trace infiltrate was also apparent below the epithelial defect with no thinning observed. Additionally, the anterior chamber showed trace cell. In light of the relative status quo of the presentation, I elected to continue the recently instituted therapeutic course, but watch the patient carefully. The patient was scheduled for another follow-up exam two days hence, but contacted the office late the following day to advise that the eye had become markedly worse in the last 12 hours, with an increase in redness and discomfort, and a decrease in vision clarity.

Clinical assessment that evening revealed a lesion with minimal increase in the stromal infiltration in the anterior stromal bed immediately below the lesion. The margin of the lesion appeared improved and well-circumscribed, and the tissue was not soft or pliable as before; however, the anterior chamber showed an increase to 1-2+ reaction, with no hypopyon. No significant stromal haze was present outside the area of defect. The globe itself was 3-4+ hyperemic, with an intense zone of ciliary flush.

At that point, I advised the patient that because of the duration of treatment without visible success, I

The patient was advised of possible etiologies and alternate treatment options, as the lesion had shown no improvement after a week of therapy. Scrapings from the patient were cultured on chocolate, blood, thioglycolate and Sabouraud’s media and plated on slides. These were delivered to the laboratory for assessment of cellular constitution, as well as resistance and sensitivity. Because of the eight days of prior treatment, expectations for growth were relatively limited; however, I asked that the plates be kept by the laboratory for further evaluation of atypical organisms—specifically, Nocardia, atypical Mycobacterium and other fungi that require an extended growth opportunity to demonstrate their presence.

With regards to the current presentation, potential factors of note included an insufficient dosing regimen, given that current therapy was being administered QID with no significant effect. The possibility that the organism was resistant to Vigamox was also considered; thus, the question was whether to maintain the current agent, add an additional therapeutic item and change the dosage, or switch to a more aggressive therapeutic regimen. Given the late hour of the day and the limited pharmacy options available at that time, I elected to increase the Vigamox to Q2h and add Neosporin ointment TID to the affected eye to increase gram-positive bacterial coverage until fortified agents became available if needed. I also elected to discontinue the steroid that was being administered BID, given the lack of positive response, and add homatropine 5% TID in light of its effect on pain.

THE TWIST

Two days after the aforementioned change in therapy, no notable improvement in the course or symptoms was observed, though the margins of the lesion appeared slightly softer than previously noted. A trace infiltrate was also apparent below the epithelial defect with no thinning observed. Additionally, the anterior chamber showed trace cell. In light of the relative status quo of the presentation, I elected to continue the recently instituted therapeutic course, but watch the patient carefully. The patient was scheduled for another follow-up exam two days hence, but contacted the office late the following day to advise that the eye had become markedly worse in the last 12 hours, with an increase in redness and discomfort, and a decrease in vision clarity.

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At that point, I advised the patient that because of the duration of treatment without visible success, I
was becoming concerned that this was not a typical bacterial infection, and that the lack of resolution warranted a change in therapeutic intention. I placed the patient on vancomycin Q1hr alternating with Vigamox Q1hr, and discontinued the Neosporin. The patient was atropinized in the office, and then subsequently scripted for atropine on a once-daily basis, given the significant decrease in her discomfort level as a result of the relaxation of the ciliary spasm.

The laboratory was contacted that evening for culture evaluation; no growth was reported. The patient was seen 36 hours after initiation of the additional vancomycin therapy and reported that the eye felt mildly improved. Clinical assessment showed no change in the lesion, although there was a notable decrease in the inflammatory response of the anterior chamber secondary to the use of the atropine.

In the case of lesions of this duration without notable response, the possibility of a viral or other non-bacterial etiology must be considered, though given the appearance of this lesion and the lack of relative neurotrophia on examination, this was unlikely. That being said, the patient was placed on 500mg valacyclovir TID PO and asked to return in two days. At subsequent visits over the following week, the patient showed no notable change. The vancomycin and Vigamox were reduced to QID as a result of the lack of response, and the patient was maintained on oral antiviral therapy. The atropine was decreased to once every other day.

A NEW HOPE
At this point, discussions with respect to the lack of efficacy of any of the interventions, as well as the lack of progression of the lesion and the absence of a positive laboratory outcome from the cultures, led to the decision for a second opinion.

Due to the lack of response to a traditional therapeutic regimen, even though the lesion was without satellite involvement and minimal to any infiltrative change or necrosis, the next step was to institute a topical antifungal agent.

The patient was placed on Q2h natamycin therapy with maintenance of topical Vigamox QID and the oral antiviral, and discontinuation of the vancomycin. The laboratory again reported no growth; ironically, however, the patient showed improvement in the first 24 hours on the natamycin. By the third day, the lesion had improved dramatically. It was at this time that laboratory results indicated a Fusarium infection.

The natamycin was maintained with an antibiotic to provide prophylaxis against infection from an opportunistic agent while the eye was compromised by the fungus. The patient’s acuity ultimately returned to almost 20/20 without correction. The anterior chamber was quiet at the last visit, and the lesion was completely resolved.

One interesting aspect of this case: this patient was an avid gardener and, despite the late phase of the season in the north, fungus is not typical; however, the decision to discontinue the steroid and obtain a true picture of the disease state was the key point. In this case, the net change in status was mild, unlike other fungal cases I have managed where discontinuation resulted in rapid progression of the disease state. Having treated one of the first patients in the United States during the Fusarium outbreak several years ago, I requested that the patient bring her contact lenses, lens case and solution to the office to forward to the laboratory for assessment. As of four weeks later, no growth had been identified.
Familiarizing yourself with corneal mapping can lead to more success with your GP contact lens patients.

By Vivian Phan Shibayama, OD

Although the manual keratometer has served eye doctors well for over 150 years, the advent of corneal topography has revolutionized our ability to discern corneal shape characteristics, as topographers have largely replaced the keratometer as the essential component in the contact lens fitting process. Allowing practitioners to see beyond the 3mm limit of the keratometer, a corneal topographer also gives us the ability to analyze the cornea in three dimensions when assessing shape characteristics.

Especially now that the technology is equipped to provide more information about the cornea than just the central curvature readings, we must consider how best to use these maps to benefit our contact lens practice. For example, proper analysis of the map can help us select a more accurate initial lens, determine lens type and assist in making the proper adjustments to the lens fit.

This article will cover the different types of corneal topography maps and how to use this information to fit corneal rigid gas permeable (GP) and scleral lenses.

**TYPES OF TOPOGRAPHY**

There are two methods of recording corneal topography: reflection-based and projection-based. Reflection-based topography—the most widely used—is further divided into raster photogrammetry and placido-based topography. Raster photogrammetry reads curvature by taking multiple triangulated measurements using a projector and two cameras. Currently, this relatively new technology is being used to measure scleral curvature for scleral lens fitting. Placido-based topographers, in contrast, use multiple concentric rings reflected off the corneal surface to analyze corneal curvature using slope; the height of the cornea is extrapolated from these measurements. This method is dependent on the quality of the reflection, so images are sometimes

**ABOUT THE AUTHOR**

Dr. Shibayama recently completed a one-year specialty contact lens fellowship at the Jules Stein Eye Institute following graduation from the Pennsylvania College of Optometry, before taking over the specialty lens practice from her mentor, Barry Weissman, OD. Her practice consists of 80% specialty fits, including keratoconus, post-corneal transplants, scars, dry eyes, post-refractive ectasia and infantile aphakia.
difficult to capture if the cornea is badly distorted, as in the case of advanced ocular surface disease (Figure 1).1

Projection- or elevation-based topography measures the anterior and posterior corneal surface by both reflection and light projection through the cornea. The Orbscan (Technolas) uses optical slit-scan imaging and the Pentacam (Oculus) uses rotating Scheimpflug imaging to acquire data (Figure 2). Projection-based topography measures height and specific points on the cornea. From height, the slope and radius of curvature are measured, making these measurements more precise than reflection-based topography. In addition, projection-based topography does not rely on the quality of the reflection from the cornea and can read badly distorted corneal surfaces.1

Types of Topography Maps

- Axial Map. This displays the rate of local curvature change of the anterior surface, based on the placido image. Curvature measurements are made between the placido rings. Light is assumed to be refracted from the corneal surface, using the optical center as the reference points; as such, the map is more sensitive to changes in central curvature versus in the periphery.2 Axial maps are particularly useful for determining the meridian, regularity and amount of astigmatism.

- Elevation Map. The most valuable map for corneal GP fitting, the elevation map appears most similar to the contact lens fluorescein pattern. In this display, different elevations on the cornea are measured from an average reference point. Areas higher than the reference will appear red and yellow, while the lower areas will appear green or blue. It is important to combine data from both the axial map and elevation map while fitting contact lenses.

While the axial map will demonstrate the curvature of the eye, the elevation map will provide more detailed information with regards to the unique shape of the cornea—the steepest point of the cornea is not necessarily the most elevated.

- Tangential or Instantaneous Map. This is the most sensitive map for determining changes in curvature in the peripheral region of the cornea. These maps include peripheral curvature in the calculations for scaled curvature and don’t use a central reference point.2 It is particularly useful when fitting corneas that have curvature changes in the periphery, as in post-refractive surgery patients (Figure 3).2 Tangential maps can also help determine the exact shape and size of the cone in keratoconus.3

Fig. 1. Poor image capture from a patient with ocular surface disease.

Fig. 2. Scheimpflug image from Pentacam.

Fig. 3. Comparison of axial and tangential maps on a post-refractive patient. Readings of center curvature are the same, but vary greatly in the periphery.
Fitting Rigid Lenses Using Corneal Topography

**Projection-Based Maps**

- **Anterior Float.** After calculating a best-fit sphere for the anterior corneal surface, the anterior float demonstrates elevation above and below this hypothetical plane, with warm colors present above the sphere and cool colors present below it. This map is useful in assessing the regularity of astigmatism and areas of asymmetry, and is similar to the axial map.

- **Posterior Float.** A display of the elevation above and below a best-fit sphere for the posterior cornea surface is used here similarly as in the anterior float. Acquiring a map of the posterior surface has become the gold standard in ruling out the presence of forme fruste keratoconus in patients during LASIK consultations. Changes in the patient’s epithelial basement membrane and Bowman’s layer are the first histological changes in keratoconus.

Traditionally, only the anterior surface of the cornea is evaluated when fitting a contact lens; as such, any irregularity of the posterior cornea is assumed to remain uncorrected by placement of a contact lens on the anterior surface, thus affecting the patient’s final visual acuity (Figure 4). Posterior elevation topographic maps may be able to provide practitioners with better target visual acuity for contact lens fitting. Within the visual axis, for patients with a posterior elevation between 70µm and 100µm, a practitioner should expect no better than 20/30 acuity; between 130µm and 140µm, no better than 20/40 acuity; and greater than >200µm, no better than 20/70 acuity.

**GP Fitting**

The primary goal of GP fitting is to respect the shape of the cornea as much as possible without inflicting damage or changes on the ocular surface. In the case of a normal cornea, it is not always necessary to use corneal topography to design lenses; however, peripheral corneal data can be valuable in determining what type of lens to choose for your patients. This data is especially important if the practitioner decides to fit a larger diameter.

Corneas with a higher rate of flattening may benefit from aspheric designs. The term **eccentricity value** (E value) describes the rate of flattening in the cornea (Figure 5). Normal corneas exhibit an E value of approximately 0.55. Higher than average E values indicate a prolate cornea that flattens at a more rapid rate, such as in keratoconus.

Corneal alignment of the GP lens in the midperiphery can be managed by increasing or decreasing the E value of the GP according to the E value on the topography. In normal corneas, contact lenses with normal eccentricity values can decenter on patients with higher than average E values. In an irregular cornea, such as in a keratoconus patient, the midperiphery is usually significantly flatter than the apex. Increasing the E value in both cases will assist in the alignment of the lens without sacrificing the alignment of the central fit.

When fitting a toric cornea, an axial topography map can be used to visualize the nature of the astigmatism (i.e., how regular or irregular it is and how far it extends throughout the cornea). This information can help the practitioner make decisions about diameter and the peripheral fit of the lens.
In multifocal lens fitting, new theories in multifocal design have emphasized the importance of the centration of multifocal optics in order for the fit to be successful. The topographer can be used to obtain an objective measurement of pupillary size to assist in optic zone design (Figure 5). Topography can also be used to check multifocal optics alignment through the patient’s line of sight while the patient is wearing the lens (Figure 6).7

Some topographers come equipped with software programs that can assist virtually with contact lens fitting. Brand name lenses as well as generic lens parameters are preloaded into these programs for the practitioner to choose from. These programs allow the practitioner to select a lens and will simulate the fluorescein pattern of the lens using the patient’s corneal map. The practitioner can then adjust the lens parameters and see the changes in the fluorescein pattern.8

KERATOCONUS
In keratoconus, the key to lens selection is to determine the size, shape and location of the cone. To do this, again, compare the axial, tangential and elevation maps. The axial map will show the overall shape and curvature of the eye, while the elevation map will show the shape of the cone. Tangential maps can help the practitioner measure the size and shape of the cone, which can be helpful in determining overall diameter as well as optic zone size (Figure 4). Tangential maps may also provide more accurate curvature information about the periphery of the cornea to aid the practitioner in designing peripheral curves for the patient.

Small diameter lenses are best for the nipple form of keratoconus—in which the cone is located centrally, steeply curved and typically less than 5mm in diameter—while large diameter lenses are preferable for decentered cones, which are displaced from the apical center into the inferior quadrant. Large diameter lenses are also best for oval cones, which typically measure more than 5mm in diameter and are characterized by a broad area of elevation in the inferior cornea, as they provide forced centration over the pupil. Reverse geometry lenses can also be helpful for centration with a secondary curve steeper than the central base curve to accommodate the decentered cone without excessive central vault.

Pellucid marginal degeneration (PMD) is typically characterized by the presence of a “kissing doves” pattern on the axial map (Figure 7), which represents the thinning that occurs 1mm to 2mm away from the limbus. Once a diagnosis of PMD is confirmed, the elevation map should be referenced to find the location and elevation of the cone.

Traditional keratoconic lenses do not fit patients with PMD; instead, these patients should be fit with large diameter reverse geometry lenses or scleral lenses to accommodate the steepness in the mid periphery.1 Once the diameter and lens design is determined, the next step is to select the base curve. There are many opinions on the best way to choose the initial lens for your patient, from selecting the

Fig. 6. Topography over multifocal GP showing line of sight centered on the right (fit on K) and decentered up on the left (fit flat).

Fig. 7. A patient with PMD. The tangential map shows steepening inferior to what is displayed in the axial map.

Fig. 8. Comparison of theoretical Medmont software fluorescein pattern compared to real diagnostic lens.
lens based on the yellow curvature on the axial map to fitting
0.2 flatter to average K reading and selecting the reference sphere
from the elevation map. The best suggestion is to follow the method
of the fitting guide of the lens that is being used.1

POST-GRAFT FITTING
There are many factors to consider when choosing the right type of
lens for a patient who has undergone corneal grafting. The physi-
ologic needs of the donor cornea must be respected, reducing me-
chanical and hypoxic stress to the cornea and the risk of neovascu-
larization and rejection. Generally, contact lenses don’t cause graft
rejection; however complications from contact lens wear can.10,11
Gas permeable lenses in general offer the best visual correction, and
corneal GPs specifically have the best oxygen transmission. Corneal
GPs should be considered first with fitting post graft patients.10
Approximately 20% of patients who undergo PKP still have irreg-
ular astigmatism and benefit from GP correction.12
When selecting an initial diagnostic lens, compare the axial and
elevation maps to determine the shape of the graft. Larger diameter
GP lenses (i.e., 10.5mm to 12mm) are best suited to cover the graft/host
junction of most grafts, while keratoconic designs fit optimally
over prolate grafts (31% of grafts), which are steeper in the center and
flatter in the periphery. Oblate or plateau-shaped corneas (31% of
grafts) typically benefit best in a reverse geometry design that is
flatter in the center with a steeper secondary curve (Figure 9). In the
case of a mixed prolate/oblate cornea with symmetrical astigmatism
(18% of grafts), use the axial map to determine how regular the astig-
matism is and how far it extends throughout the graft.

Bitoric or back surface toric designs are best suited for corneas
with symmetrical astigmatism, as they distribute the weight of the
lens as evenly as possible (Figure 10). This lens can be fit much like
a traditional bitoric, using the axial map curvature readings to
align the flat base curve to the flat meridian. Add only two-thirds
of the total toricity to the steep meridian—it is safer to add less
toricity than is believed necessary to encourage lens rock and tear
exchange.13 A bitoric lens that is too tight can result in mechanical
trauma to the graft.

Grafts with asymmetrical astigmatism account for 9% of grafts.
These corneas are most successful in large diameter spherical lenses,
which mask the irregular astigmatism. Thirteen percent of grafts are
tilted (i.e., transitioning from steep to flat). Tilted grafts are consid-
ered by many practitioners to be the most difficult to fit, and often
require a large diameter GP lens or scleral lens.12

SCLERAL LENSES
Similar to keratoconic lens designs, each scleral lens fitting set
will recommend its own method of choosing an initial diagnostic
lens. Practitioners may be directed either to begin by selecting the middle lens in the set or using the patient’s sagittal height, horizontal visible iris diameter or a trial-and-error method to find the right lens. Since these lenses are fit predominantly based on sagittal height, keratometric readings don’t typically provide enough information to tell us which lens would fit the patient best; instead, these readings give information on the pathology and general shape of the cornea to help us determine if we need to fit the lens flat (for post-refractive cornea) or steep (for keratoconus). However, topography systems do offer more information about other aspects of the corneal surface that can help practitioners make a decision. This includes:

- **Elevation Map.** This indicates the most elevated area of the cornea, which is crucial to know when selecting a lens to fit. If the elevation is decentered, a reverse geometry scleral lens allows for vault in the midperiphery without too much central clearance.

- **HVID.** Horizontal visible iris diameter is an important measurement because it is necessary for the scleral lens to clear the limbus and land outside the corneal/scleral junction. Knowing the HVID measurement of the patient’s eye will help you select the right diameter for your patient.

- **Sagittal Height.** The most accurate method of selecting an initial scleral lens, sagittal height is the measurement from the center of the cornea to the intersection of a specific chord length. Most topographers give the sagittal depth of the patient’s cornea to a chord length of 10mm. If fitting a 15mm lens, 2,000µm—the average sagittal height for most eye types from a chord length of 10mm to 15mm—will need to be added. Another 350µm should also be included to account for necessary corneal clearance. Sagittal height will also need to increase when increasing the lens diameter; roughly 300µm per millimeter of lens diameter change is considered ideal.

- **Fitting the Periphery.** New technology from a few different companies has given us the ability to map the scleral contour, making it easier to fit patients with toric scleras. Visionary Optics has a unique design that maps scleral curvature to better align the peripheral fit of its Europa lenses. The sMap3D system (Precision Ocular Metrology) incorporates raster photogrammetry, which takes multiple, triangulated measurements using a projector and two cameras to determine corneal and scleral measurements. Fluorescence is used to image the bulbar conjunctiva. Images are taken while the patient is looking straight ahead, up and down; these three images are then pieced together to create a three-dimensional model of the eye, sent to the laboratory and used to assist in the manufacturing of the lens.

In conclusion, a proper assessment and comparison of the various topographical maps will enable practitioners to streamline contact lens fitting. Some say contact lens fitting is more of an art form than a science. With that said, I don’t believe technology will ever fully replace the judgment of a skilled practitioner; however, if used properly, topographers can assist in reducing chair time, increasing patient success and keeping costs down.

Talk to any contact lens practitioner about the patient habits that bother them most and “failure to replace lenses on time” will always be near the top of the list. Patients have been known to come in wearing lenses that are months or even years past their expected replacement date. Despite all the education about health benefits and greater comfort from frequent or daily replacement, a fair amount of patients just don’t feel compelled to change something they perceive to be working just fine.

Are practitioners sometimes guilty of the same inertia? Many rely on a few go-to modalities—tried and true lenses they have turned to for years because they believe in the idea, “If it’s not broke, don’t fix it?” If patients wearing older lenses remain truly happy and healthy, odds are they can continue without incident. But if such habits keep practitioners from exploring newer designs that might lead to more success with existing or new lens wearers, experts say it’s time to break from this routine; it could be holding the practice back.

“We often don’t even realize the habits we develop in clinical practice,” says Mile Brujic, OD, of Premier Vision Group in Ohio. “Certain procedures and protocols become so routine that we don’t even think about them. This is most often true in our contact lens practices.”

Many of today’s new lens designs provide patients with more comfort and clarity, and fewer limitations, than ever before. But doctors who feel their current product mix is good enough will miss out.

Practice management consultant Gary Gerber, OD, of New Jersey adds that incorporating new lens options demonstrates a message of progress. “Just like many patients are wired and plugged in [with the latest technology] to some extent, they also expect their consumer and health care experiences to be as up to date,” he says. “If you do not offer new products, or at least mention or broadcast that you do—even if they may not be clinically appropriate for every patient—you’re sending a message that not only are you out of date, but out of touch.”

LENSES AS PRACTICE BUILDERS

“Recent advancements make it possible to fit almost anyone in contact lenses, if they so choose,” says optometrist Gina Wesley of Complete Eye Care Medina in Minnesota. “Between the expansion of the daily disposable parameters in torics and multifocals, colored lenses, new monthly options and the wide range of prescriptive sclerals, advancements in this arena have never looked better.”

These options offer practitioners the ability to fit a patient quicker and more effectively, which increases the value of the service offered, she adds. “Your patient appreciates the advancements and less chair time is necessary, which is better for the practice. New designs open the door to multiple contact lens prescriptions, just like we prescribe multiple spectacle prescriptions.”

Newer lens designs also offer distinct financial benefits to the practice, in addition to their major health benefits to patients, says David Kading, OD, of Specialty Eyecare Group in Seattle. Though some of the newer options have higher price tags, Dr. Kading believes optometrists should still market these lenses to patients because of their positive effect on patient well-being.

“As optometrists, we often don’t think our patients are willing to update beyond the old technology because it’s going to cost more money or because the patient may think that what they have is fine or good enough,” he says. “Our job is not to save our patients money or keep them in
Where Can New Lenses Lead Your Practice?

From sclerals to daily disposables and tinted lenses, new designs can add to your practice if you’re willing to change your mindset.

‘good enough’ lenses, but to give them the healthiest and most appropriate option for their unique needs. With that mindset, we need to educate patients on the new designs and technologies that will ultimately serve their long-term better health.”

Maintaining the belief in the individual as one’s best source of marketing for contact lens fittings pays off, Dr. Wesley points out. “You know exactly what this patient would benefit from, or is eligible to wear, and you can tailor your message to give that patient options. This, in turn, leads to word-of-mouth and referrals.” Initially, she discloses, in 2012 only 8% of her contact lens patient base wore a daily disposable lens; that number is up to 75% today.

For Justin Bazan, OD, of Park Slope Eye in New York, more contact lens design options mean an achievement of better performance in both the industry and private practice. “We have seen advances in contact lens materials develop to the point where end-of-day comfort issues are minimal—if not non-existent—for many patients,” he says. And newer designs benefit wearers “because they provide the patient with the performance they demand and need,” he says. “They help benefit the practice by generating strong word of mouth and help build the practice’s positive reputation in the community.”

SPECIAL DELIVERY

When Stephanie Woo, OD, joined her practice in Arizona, this board member of the Scleral Lens Education Society knew she faced a major challenge. The 25-year-old practice focused on primary care and ocular disease management, not on specialty lenses as she had hoped. However, Dr. Woo wasn’t deterred.

“I knew there had to be plenty of potential specialty contact lens patients out there that just didn’t know what options they had,” she says. “I was committed to recommending specialty contact lenses to any patient who was a good candidate.” Most of her current specialty lens wearers began as ‘regular’ patients sitting in her chair for their annual eye or contact lens exam. Today, Dr. Woo estimates she sees three to four returning specialty lens patients on a daily basis and performs three to five new fits per week. These include gas permeable (GP), bitoric, GP multifocals, scleral lenses for regular and irregular corneas, scleral multifocals, soft custom lenses, prosthetic soft lenses,

Dr. Woo prepares to take a mold of a patient’s sclera with the EyePrintPro scleral lens design system.
orthokeratology, myopia control, hybrid lenses, hybrid multifocals and EyePrint ocular prosthetic lenses.

By offering specialty lenses, Dr. Woo gives options to patients who thought they would never see that clearly again. This is both truly rewarding in the personal sense and also a benefit to her practice, she says.

“Specialty contact lens patients are extremely loyal to the practice, and offering this unique service helps our business grow,” Dr. Woo explains. “Specialty lens patients are some of the happiest patients, and they are quick to refer all of their friends and family to the clinic. It gives us the opportunity to help many people.”

For other optometrists looking to add specialty lenses to their practices, her marketing advice is simple: explain to the patient during the exam why they would be a good candidate. Dr. Woo also suggests directing the patient to try a new contact lens, letting them know it may improve their vision and also reassuring them that if the lens doesn’t improve vision or if the fit is uncomfortable, they can always return to wearing their old contacts or glasses.

“This statement puts patients at ease, knowing they are not inadvertently committing to these lenses if things don’t work out. Most of my patients are willing to at least try a specialty lens if they understand why they need it.”

Dr. Kading points out that sclerals are one of the hottest areas of growth in the contact lens industry. “I think custom lenses are one of the biggest innovations in the past few years, and they are also providing a dramatic impact on patients’ lives,” he explains. While it’s true that scleral lenses can generate substantial revenue for the practice, he says, “more importantly, the patients who need them are often on disability, unable to work, can’t see well or comfortably go about their day. And, we’re able to quickly improve their life. What could be better than that?”

**DAY-TO-DAY BENEFITS**

Daily disposable contact lens options are another distinct piece of the market, one that has benefited from materials advances in recent years that improve comfort without compromising quality. One of the best ways to introduce the possibility of daily disposable contact lenses to patients is to simply ask how comfortable they are in their current lenses. When doing so, avoid simple yes/no questions. You want to engage the patient in conversation.

“A number of patients who come into our contact lens practices are less comfortable in their lenses than we think they are,” explains Dr. Brujic. He adds that while a patient may say they are happy and comfortable in their current lens, they may actually be very close to petering out of contact lens wear. As a method of dropout detection, Dr. Brujic routinely asks his patients to rate their comfort level 10 minutes after they place lenses on their eyes in the morning on a scale of one to 10. Then, he asks his patients to grade their comfort five to 10 minutes prior to removing the lenses in the evening.

“We have found, in these seemingly happy contact lens wearers, that there is a precipitous drop.” He’ll then investigate closely at the slit lamp for clinical factors affecting the ocular surface. “But, it also gives me a great opportunity to talk about new technologies,” he says.

Photo: Jason Miller, OD

Encouraging contact lens patients to share their experience on social media is another way to market your practice. It builds word of mouth about what makes your care unique.

Dr. Kading estimates the newer generation of daily disposables represents 93% of his contact lens wearer population. In addition to greater comfort, Dr. Kading believes dailies are the healthiest and most innovative of the soft lens options for his patients. Patients who are recommended dailies tend to purchase their lenses at regular intervals. “Being compliant is obviously better for the patient’s health,” he says. Typically, a sale of daily disposable lenses pays the practice double what a monthly disposable lens would pay. To offset the higher cost of the lenses for the patient, he typically informs them they will save between $200 and $400 annually by not having to purchase contact lens solution.

“That profitability is obviously much appreciated,” Dr. Kading acknowledges, “but again, first and foremost, we want to do
what is in the best interest of the patient.”

**TARGETING PRESBYOPES**

Many of today’s presbyopes want to lose their glasses—and new multifocal contact lens designs provide attractive options for patients as well as another avenue to expand a practice. This is an often-cited area of practice where old habits and misperceptions do a disservice to patients and practices alike. Multifocal lenses, while still requiring patient adaptation and realistic expectations, have evolved rapidly in recent years.

Dr. Kading believes that the use of practice management software can help identify patients that are suited for newer presbyopia lens designs, giving practitioners the opportunity to target them through direct mail, social media and e-mail. He says that from a marketing standpoint, it’s best to specifically target the appropriate patient base for multifocal lenses, so practitioners can avoid coming across in an inappropriate manner to those who are not good candidates. Additionally, it saves time. “It’s like sending out a Lipitor commercial to the mass public,” he explains. “It’s definitely going to benefit some people, but for others, it’s going to be a waste of time and money. We want to make sure our marketing is very pointed.”

For those who’ve previously worn or at least tried multifocals, eliciting the source of their dissatisfaction can help you tailor the new message. What one patient struggled with—e.g., reduced comfort, poor intermediate vision, astigmatism—another might not even notice. This is a good opportunity to explain that today’s options are likely better than when they first tried and failed.

The opportunity to expand your contact lens practice and increase your bottom line has never been greater. For those still clinging on to their usual contact lens staples, your colleagues suggest it’s high time for a change.

“My challenge for you is to think about why you are selecting the lenses that you are and remember that there is a large armamentarium of lenses to select from that may better benefit your patient,” Dr. Brujic says. “Do this and you will reinvigorate your contact lens practice, not only in enhancing your perspective on lens selection but also by providing your patients the best lens possible.”

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Managing patients with dry eye symptoms remains a well-known challenge despite the wide array of topical, mechanical and oral therapies available today. To put it another way, there would be no need for palliative artificial tears if we could truly conquer the underlying processes that lead to dry eye symptoms. Although treatment options abound, they are fraught with compromises and shortcomings.

Technological advances like LipiFlow (TearScience), BlephEx (Scope Ophthalmics) and intense pulsed light (IPL) devices have been used to treat meibomian gland dysfunction (MGD)—the most common form of dry eye—and Demodex; however, equipment costs and space requirements often limit widespread use in practice.1 Practitioners can also prescribe less expensive options like hot compresses and lid soaks to loosen debris and instigate meibum flow, but some critics say heat from these treatments does not penetrate deep.
enough or last long enough to have a positive effect on MGD.

Other therapies like lid disinfec-
tants (e.g., Cliradex and Avenova) or lid scrubs (e.g., Ocusoft, TheraTears and Systane) have also been used to treat blepharitis; these have shown a clinical benefit when used regularly. Long-term effects with respect to more chronic cases remain unknown, however. Other research has suggested omega-3 and omega-6 fatty acids taken orally may have a positive but limited effect on meibomian gland inflammation and oil quality. Autologous serum and amniotic membranes (e.g., Prokera, AmbioDisc and BioDOptix) may be used to en-
hance epithelial repair, but remain expensive and hard to procure.

In light of these controversial options, many practitioners would agree the first-line treatment for dry eye remains over-the-counter (OTC) artificial tears. OTC tears are simple enough to use, with a variety of well-known indications, including dryness, irritation and discomfort relief. However, despite their simple indications, these drops are complex formulations with a host of active and inactive ingredi-
ents that can be difficult to evaluate. Why is this?

<table>
<thead>
<tr>
<th>Table 2. Approved Active Emollients</th>
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</thead>
<tbody>
<tr>
<td><strong>Emollients</strong></td>
</tr>
<tr>
<td>• Anhydrous lanolin</td>
</tr>
<tr>
<td>• Lanolin</td>
</tr>
<tr>
<td>• Light mineral oil</td>
</tr>
<tr>
<td>• Mineral oil</td>
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<tr>
<td>• Paraffin</td>
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<tr>
<td>• White ointment</td>
</tr>
<tr>
<td>• White petrolatum</td>
</tr>
<tr>
<td>• White wax</td>
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<tr>
<td>• Yellow wax</td>
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</table>

**FDA FOLLIES**

Last year, Dr. Christensen received a call from a friend looking for information on studies used for approval of OTC tears, as he had been having difficulty locating any. What he didn’t realize was that none currently exist. Though numerous well-controlled industry-sponsored, randomized clinical studies that support product package claims are available, no FDA trials for drop efficacy have been instituted.

Why are some ingredients labeled as active and others inactive, and why do the companies seemingly only expound on what is special about the inactive ingredients? What differentiates one company’s product from that of a competitor with the same active ingredients?

In 1988, the FDA finalized a monograph to help expedite artificial tears, coded “lubricant eye drops,” to the market. Its primary purpose was to reduce the costs and barriers associated with new product development, thus easing manufacturing and marketing efforts. Under the new document,
ARTIFICIAL TEARS: LOOKING BENEATH THE SURFACE

The company must notify the FDA of its intention to release an artificial tear to the public. To approve the drop, the agency evaluates its safety via toxicology testing and checks to ensure good manufacturing procedures. The monograph contains specific details on the indications for use; namely, one of the following:

- Temporary relief of burning and irritation due to dryness of the eye.
- Temporary relief of discomfort due to minor irritation of the eye or to exposure to wind or sun.
- As a protectant against further irritation or to relieve ocular dryness.
- As a lubricant to prevent further irritation or to relieve ocular dryness.

Table 3. Approved Inactive Ingredients

<table>
<thead>
<tr>
<th>Inactive Ingredients</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Sorbitol</td>
<td>Lowers the viscosity of gelling agents.</td>
</tr>
<tr>
<td></td>
<td>Dissipates quickly, optimizing viscosity.</td>
</tr>
<tr>
<td>*Hyaluronic acid</td>
<td>Binds multiples of its weight in water.</td>
</tr>
<tr>
<td></td>
<td>Lowers tear osmolarity.</td>
</tr>
<tr>
<td></td>
<td>Adheres to ocular surface.</td>
</tr>
<tr>
<td></td>
<td>Stabilizes and evens out the tear film.</td>
</tr>
<tr>
<td></td>
<td>Highly viscous until blinking thins it out.</td>
</tr>
<tr>
<td></td>
<td>Improves cell-cell adhesion.</td>
</tr>
<tr>
<td>*Sodium hyaluronate</td>
<td>Protects and promotes healing of corneal epithelium.</td>
</tr>
<tr>
<td></td>
<td>Changes viscosity upon blinking (i.e., more viscous while the eye is open).</td>
</tr>
<tr>
<td></td>
<td>Improves tear break-up time and helps spreading.</td>
</tr>
<tr>
<td></td>
<td>Helps control localized inflammation.</td>
</tr>
<tr>
<td></td>
<td>Reduces mucous strands.</td>
</tr>
<tr>
<td></td>
<td>Lowers tear osmolarity.</td>
</tr>
<tr>
<td></td>
<td>Retains water, increasing surface wettability.</td>
</tr>
<tr>
<td>*Levocarnitine</td>
<td>Blunts the damaging effects of high osmolarity by preventing stress activation.</td>
</tr>
<tr>
<td>*Erythritol</td>
<td>Absorbed by dehydrated cells to promote hydration.</td>
</tr>
<tr>
<td></td>
<td>Prevents cell shrinkage and inflammation.</td>
</tr>
<tr>
<td>*Hydroxypropyl guar</td>
<td>Increases viscosity.</td>
</tr>
<tr>
<td></td>
<td>Mimics the mucin layer of the eye.</td>
</tr>
<tr>
<td></td>
<td>Binds to cornea and aqueous layer.</td>
</tr>
<tr>
<td></td>
<td>Prolongs the efficacy of active ingredients.</td>
</tr>
<tr>
<td></td>
<td>Actively crosslinks/gels at pH above pH 7.</td>
</tr>
<tr>
<td>*Polyacrylic acid</td>
<td>Increases viscosity/retention time of tears.</td>
</tr>
<tr>
<td>*Tyloxapol</td>
<td>Surfactant and mucolytic agent.</td>
</tr>
<tr>
<td>*Tromethamine</td>
<td>Organic amine proton acceptor.</td>
</tr>
<tr>
<td></td>
<td>Emulsifying agent that thins waxy agents.</td>
</tr>
<tr>
<td>*Boric acid</td>
<td>Buffer systems used to obtain a pH for the artificial tear that is healthy and comfortable for the eye.</td>
</tr>
<tr>
<td>*Borate buffer</td>
<td>A pH of 8.5 is most comfortable for dry eye patients (normal tear pH is about 7.5).</td>
</tr>
<tr>
<td>*Sodium-citrate</td>
<td>Buffer systems used to obtain a pH for the artificial tear that is healthy and comfortable for the eye.</td>
</tr>
<tr>
<td>*Phosphate</td>
<td>A pH of 8.5 is most comfortable for dry eye patients (normal tear pH is about 7.5).</td>
</tr>
<tr>
<td>*Phosphate-acetate</td>
<td>Buffer systems used to obtain a pH for the artificial tear that is healthy and comfortable for the eye.</td>
</tr>
<tr>
<td>*Phosphate-citrate</td>
<td>Buffer systems used to obtain a pH for the artificial tear that is healthy and comfortable for the eye.</td>
</tr>
<tr>
<td>*Phosphate-citrate-bicarbonate</td>
<td>Buffer systems used to obtain a pH for the artificial tear that is healthy and comfortable for the eye.</td>
</tr>
<tr>
<td>*Sodium hydrosolde</td>
<td>Buffer systems used to obtain a pH for the artificial tear that is healthy and comfortable for the eye.</td>
</tr>
<tr>
<td>*Calcium chloride</td>
<td>Electrolytes are added to maintain or lower tear osmolarity, as high osmolarity products pull water from epithelial cells, interfering with metabolism.</td>
</tr>
<tr>
<td>*Magnesium chloride</td>
<td>Some of the added electrolytes are also important for corneal epithelial metabolism.</td>
</tr>
<tr>
<td>*Potassium chloride</td>
<td>Some electrolytes are part of buffer systems.</td>
</tr>
<tr>
<td>*Zinc chloride</td>
<td></td>
</tr>
<tr>
<td>*Sodium chloride</td>
<td></td>
</tr>
<tr>
<td>*Sodium citrate</td>
<td></td>
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<tr>
<td>*Sodium lactate</td>
<td></td>
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<tr>
<td>*Sodium bicarbonate</td>
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</table>

The FDA also requires manufacturers to include the following box statement on the box: “Stop use and ask your doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the aforementioned condition worsens or persists for more than 72 hours.”

The active ingredients in the monograph comprise a list of demulcents or emollients (Tables 1 and 2). A demulcent is a high molecular weight polymer substance that relieves irritation of the mucous membranes by forming a protective mucous-mimicking film that acts to lubricate, protect and increase the viscosity of the eye drop. Emollients, in contrast, are oleaginous substances that include fats and oils, which work to reduce evaporation. As part of the monograph’s development, the FDA deemed a specific range of concentrations as safe and effective for these drugs; it was also decided that extra or repetitive testing was unnecessary for future products.

In this sense, the ingredients listed in the monograph are “safe,” and overuse constitutes minimal risk to the patient. Only these ingredients can be considered for the fast track of FDA approval. Therefore, the result of the simplified monograph ruling had an unforeseen consequence: it has resulted in a plethora of products on the shelf but no new active ingredients in nearly 30 years. A new polymer requires a new drug application process to show that it is a pharmacologically active drug. Significant improvement in a sign and symptom must be shown; additionally, results using the new formula must be demonstrated. This is an exceedingly difficult task and sometimes not worth the investment of time and funding, since it can be added as a non-pharmacologically active polymer under the non-active ingredients.
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DIFERENCE MAKERS
Other than the typical ingredients in artificial tears like boric acid, calcium chloride, magnesium chloride, potassium chloride, purified water and preservatives, inactives like hyaluronic acid along with hydroxypropyl guar, erythritol/levocarnitine and sodium provide the distinguishing factors that give each artificial tear its unique characteristics, improving their efficacy (Tables 3 and 4). For example, BlinkTears (AMO) contains polyethylene glycol 400 0.25% as an active ingredient and sodium hyaluronate as an inactive ingredient. Sodium hyaluronate is a humectant that binds many times its weight in water, reduces mucous strands and is better at lowering tear osmolarity than glycerin.

Refresh Optive Advanced (Allergan) incorporates carboxymethylcellulose sodium 0.5%, glycerin 1% and polysorbate 80 0.5% as actives with castor oil, erythritol, levocarnitine and carbomer copolymer type A as inactives. Systane Ultra (Alcon) uses polyethylene glycol 400 0.4% and propylene glycol 0.3% in conjunction with HP-guar as an inactive. Retaine MGD (Ocusoft) contains light mineral oil 0.5% and mineral oil 0.5% as actives and a number of inactives (e.g., cetalkonium chloride, glycerol, poloxamer 188).

There can also be differences in pH and osmolarity, depending on the characteristics the company wants to exhibit. Systane Gel Drops (Alcon) fall at pH 7.0, while Systane Ultra (Alcon) falls at 7.8. A pH that more closely matches that of the patient’s tears will result in less stinging on instillation and better overall comfort. Some tears are significantly hypoosmotic to the tear film, which is around 305 mOsmols (for example, TheraTears is at 181 mOsmols), while others are isosmotic or just slightly hypoosmotic. In general, a tear that is relatively hypoosmotic to the tears of the patient will blunt the damaging effects of high osmolarity.

In addition to OTC eye drops, a number of companies have been diligently working on the development of new prescription drugs for dry eye, but none have thus far met the criteria for approval. Dry eye treatment trials include subjective accounts of patient comfort, and the FDA is typically wary of using subjective data as a factor in its ap-

<table>
<thead>
<tr>
<th>Preservative</th>
<th>Concentration Range</th>
<th>Additional Effects (+/-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium chloride (BAK)</td>
<td>0.004% to 0.02%</td>
<td>- Increases drug penetration.</td>
</tr>
<tr>
<td>Polyquaternium-1</td>
<td>0.001%</td>
<td>- Causes superficial epithelial damage. Reduces the density of conjunctival goblet cells, which decreases aqueous tear film production.</td>
</tr>
<tr>
<td>Sodium perborate</td>
<td></td>
<td>- Vanishing preservative: Upon exposure to an aqueous environment, it is catalyzed into hydrogen peroxide, water and oxygen.</td>
</tr>
<tr>
<td>Stabilized oxychloro complex</td>
<td>0.005%</td>
<td>- Degrades to water, oxygen, sodium and chlorine free radicals when exposed to light.</td>
</tr>
<tr>
<td>Sodium chlorite</td>
<td>0.005%</td>
<td>- Mixture of 80% chlorine, 11% sodium chloride, water and trace electrolytes that breaks down into sodium and chloride ions, oxygen and water when exposed to light.</td>
</tr>
<tr>
<td>Polyhexamethylene biguanide (PHMB)</td>
<td>0.02%</td>
<td>- Beneficial against bacteria and Acanthamoeba, however, its antifungal activity is limited. Lethally alters the transcription of bacterial DNA.</td>
</tr>
<tr>
<td>Chlorobutanol</td>
<td></td>
<td>- Alcohol that increases lipid solubility and is able to cross the bacterial lipid layer. Has extensive anti-bacterial action, causing cell lysis by disruption of microbial cell membrane lipid configuration.</td>
</tr>
<tr>
<td>EDTA (edetate disodium or ethylene diamine tetraacetic acid)</td>
<td>1%</td>
<td>- Chelating agent that binds metals, which inactivates them.</td>
</tr>
<tr>
<td>Ethanol</td>
<td></td>
<td>- Enhances the activity of quaternary ammonium bases and sorbate.</td>
</tr>
</tbody>
</table>
approval process. For these and other reasons, Restasis (cyclosporine, Allergan) has remained the only prescriptive dry eye drug for over a decade. While others will eventually follow, until that time, it is important to understand the difference in the inactive ingredients contained in OTC eye drops and make specific recommendations to your patients. Even a savvy ingredient-reading patient may not be able to make sound choices in eyedrop use simply by reading the packaging labeling, so offer informational packets in-office, and discuss all potential complications with other medications the patient may be taking.

6. Freeman PD, Kahook MY. Preservatives in topical ophthalmic medications: historical and clinical per-
8. Zheng LL, Myung D, Yu CQ, Ta CN. Comparative in-vitro cytotoxicity of artificial tears. JSM Ophthal-
REALITY CHECK: Outdated FDA protocols don’t account for real-world usage, newer lens materials and virulent organisms. Proposed updates could bring big changes.

By Yvonne Tzu-Ying Wu, PhD, MPH, An Truong, B.Optom, and Fiona Stapleton, PhD

There has been a dramatic shift in contact lens disinfection solutions in the last decade, with multipurpose solutions (MPS) largely replacing more traditional multiple-step systems consisting of separate cleaning and disinfecting liquids, or unpreserved saline in conjunction with chlorine-releasing tablets. Currently, over 90% of patients report use of an MPS for lens disinfection; hydrogen peroxide, polyhexamethylene biguanide (PHMB)-based and polyquaternium-1 (Polyquad)/myristamidopropyl dimethylamine (Aldox)-based systems are considered the most commonly used.1,2

While use patterns have evolved, regulatory policy has lagged behind. Manufacturers must comply with FDA guidelines to obtain clearance for the sale of contact lenses and lens care products in the United States. The guide documents in question—Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses and Guidance for Industry: Premarket Notification 510(k) Guidance Document for Contact Lens Care Products—were published in 1994 and 1997, respectively. Due to subsequent updates in contact lens technology and reports of adverse health incidents, including widespread *Acanthamoeba* keratitis, these documents have been deemed by many to be out of date.3-5

The Division of Ophthalmic and Ear, Nose and Throat Devices (DOED) has since suggested a number of changes to these documents—namely, the addition of a test protocol to evaluate MPS efficacy against *Acanthamoeba* keratitis. Other suggestions include the prevention of environmental contamination, particularly as a result of water contact, and the impact of contact composition on MPS efficacy.2 For example, ionic charge, lens material porosity and relative hydrophobicity are markedly altered between traditional hydrogel lenses and newer silicone hydrogel lenses; these properties are known to impact microbial adhesion and the uptake and release of MPS preservatives, which may compromise disinfection efficacy.6-9

This article provides an overview of specific issues identified with current MPS guidelines and standards applicable to MPS products sold in the United States. Proposed modifications raised by various expert bodies in an attempt to address these issues will also be discussed.

CONTACT LENS-RELATED *ACANTHAMOEBA*

These microorganisms exist commonly in freshwater and soil environments as either an active trophozoite or dormant cyst form, the latter of which is encased in a double-layer cellulose wall that enables it to withstand harsh environmental conditions, including exposure to extreme temperature, pH and dryness.4,14 As a result, they exhibit resilience to many forms of disinfection.3-5 Pathogenic organisms known as endosymbionts, which include *Pseudomonas* and *mycobacterium*, may also grow and replicate within the cytoplasm of *Acanthamoeba*, further enhancing its virulence.6,12

*Acanthamoeba* keratitis (AK) is a rare but serious corneal infection that is often sight-threatening despite medical interventions. Beginning in June 2003, investigators identified increased outbreaks of the disease in the Chicago-Gary-Kenosha metropolitan area; consequentially, Complete Moisture Plus (AMO) was recalled in 2007 after a national inquiry found it resulted in an increased...
risk of *Acanthamoeba* keratitis. An elevated level of the disease continued to persist following the recall, however, suggesting the recalled MPS may not have been the sole culprit.

Several subsequent studies have endeavored to elucidate the persistence of the *Acanthamoeba* infections post-recall. Additionally, a microbiology workshop involving the FDA, eye care professionals, microbiologists and members of industry convened in 2009 to discuss testing protocols for *Acanthamoeba* disinfection efficacy. Below is a general overview of the testing parameters proposed at this meeting:

- What should be the challenge size for testing MPS in the absence of a contact lens?
- Which *Acanthamoeba* strains should be tested?
- How should the cells be grown in order to obtain cells in the trophozoite stage of growth?
- How should cells in the cyst stage be produced?
- How should the number of survivors of trophozoites or cysts be measured?
- What should be the protocol to use when testing for MPS efficacy in the presence of a contact lens?
- What should the overall performance criteria be for the different possible test scenarios?
- Should the MPS’s ability to cause the *Acanthamoeba* cells to encyst be measured?

Other microbiological test method workshops (one in May 2014; the latest in November 2014) have been held by the FDA following the 2009 meeting to accommodate further discussion of test parameters—namely, what strain of organism to cover, life cycle (both trophozoite and cyst stage), growth method and how to encyst *Acanthamoeba*. No consensus has been reached thus far regarding an appropriate microbiological test method for *Acanthamoeba*; however, suggestions of critical test parameters include the use of at least two different *Acanthamoeba* strains in cyst form and use of an inoculum size no greater than 1,000 to 10,000 cysts or trophozoites.

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Disclosure Statement: Drs. Wu, Truong and Stapleton have no financial interest in any products mentioned in this article.
REALITY CHECK: HOW FDA TESTING FALLS SHORT

Research also indicated *Acanthamoeba* grown in the presence of bacteria demonstrate less variability in their susceptibility to the MPS tested, as opposed to when grown axenically (i.e., in the absence of other microorganisms). Acanthamoeba cysts produced from growth on non-nutrient agar (known as the starvation method) are significantly more resistant to disinfection by PHMB-based MPS compared with cysts induced by Neff’s encystment medium. Therefore, the microbiological and nutritional environment are both significant factors in modifying cyst resistance, and the susceptibility of Acanthamoeba to biocides may vary depending on the experimental conditions.

As manufacturers continue to evaluate MPS efficacy against the test organisms, precise standardized experimental protocols and conditions still need to be defined in order to obtain valid results from multiple sites. Further research is also still warranted to finalize a testing guideline for solution efficacy against the forms of Acanthamoeba likely to be encountered in real world conditions.

**LENSESOLUTION INCOMPATIBILITY**

Preservative uptake—the absorption of preservative from the solution within the lens case into the lens matrix—is evaluated based on the amount of preservative absorbed from the solution in question at different points in time until a concentration plateau is obtained. Release describes the sequestration of preservative from the lens into an aqueous solution, such as the tear film. Distinct factors that affect uptake and release include water content, charge, relative hydrophobicity, surface treatment and porosity of lens material, in conjunction with the concentration, charge, ionicity in the product matrix, molecular weight and hydrophobicity of the care component. Variations in the adsorption of the solution components by lenses can lead to differences in the amount and rate of release onto the ocular surface; both can compromise disinfection efficacy of the solution (see, “Silicone Takes Over,” page 33).

Preservative uptake and release are assessed for new solutions according to ISO11986, “Ophthalmic Optics—Contact Lenses and Contact Care Products—Determination of Preservative Uptake and Release,” which guides testing to determine if ocular irritation is likely to occur from preservative uptake and subsequent release.

At this time, preservative uptake is assessed by the International Standards Organization and is not currently required for FDA premarket testing of contact lenses and lens care products (see, “Going Global,” page 34). However, the FDA has proposed updates to its guidelines advising that manufacturers demonstrate that representative lenses do not decrease the concentration of preservative below the specified concentration range when incubated in a care product solution. The proposed acceptance criterion is that preservative concentration in the lens case should remain within the manufacturer specifications after the recommended soak time. Lenses that do not pass should be labeled as such on the product and packaging or subjected to additional disinfection efficacy testing prior to approval for the US market. This is the first time an acceptance criterion for preservative uptake will be introduced into the guidance.

In addition to concerns regarding compromised disinfection efficacy, preservative uptake and release are critical determinants for solution-induced corneal toxicity. Despite being asymptomatic, a significant proportion of contact lens wearers (i.e., 37% of subjects) that used a PHMB-based system displayed a level of staining consistent with the classic solution-based toxicity reaction. Studies have also reported an increased rate of corneal staining associated with several care systems in combination with silicone hydrogel materials.

Several MPS systems were reformulated in an attempt to improve their compatibility with the newest lens materials in order to minimize staining potential. A clinical test matrix for silicone hydrogel lenses was also proposed by the FDA to address clinical performance.

However, some researchers have questioned whether staining has significant clinical relevance, casting doubt on whether the FDA’s clinical test matrix is appropriately set up with adequate consideration of these clinical parameters.

**LENSE WEAR PATTERNS**

Research groups continue to investigate if lens wear noncompliance may have contributed to a *Fusarium* outbreak in the United States and Singapore. The major noncompliant behaviors identified thus far are: reuse of solutions, especially after lens storage; lack of a manual-rub cleaning step; overnight use of daily wear contact lenses; and the use of lenses past their recommended replacement date. Other research indicates poor hand washing and lack of understanding regarding proper use of lens care products are other significant noncompliance behaviors, among others.
It has been suggested that solution testing should take into account such behaviors; however, many researchers agree testing for such an array of noncompliant behaviors and situations is nearly-impossible.

Artificial tear use may also have an impact on disinfection efficacy. Certain artificial tear components may be used by infective microbes as a source of energy or to enhance the growth of biofilm on the contact lens surface. Handling a contact lens may also contaminate its surface with organic material, which can neutralize certain disinfectants. ISO14729 does not require organic soil to be used when evaluating MPS disinfection; however, the September 2014 microbiology workshop yielded the suggestions of adding an organic soil test (i.e., 1x107 to 1x108 CFU/mL heat-killed Saccharomyces cerevisiae yeast cells in heat-inactivated bovine serum) and an artificial tear component test (0.5% hen egg lysozyme, 0.1% porcine stomach mucin, human serum, 0.2% bovine serum albumin, 1% albumin, 0.1% mucin and 0.2% mucin) to the standard testing protocol.

Additionally, recent research has found that conditioning bacteria to human tear fluid or corneal epithelial cells may upregulate virulence gene expression in bacteria, including those genes resistant to killing. Therefore, the antimicrobial efficacy of MPS against host-conditioned microbes may be reduced when compared with non-conditioned laboratory standard strains. Use of conditioned bacteria for ISO testing may better reflect the actual MPS biocidal activity against bacteria likely to be encountered in situ.

While the inclusion of these parameters is expected to simulate a more realistic portrayal of daily lens wear and the factors that might complicate it, the obstacle of how to standardize such parameters, including how to ensure uniformity of human tear conditioning fluid or appropriate incubation times for artificial tear interference testing. Thus, establishing standard testing parameters and setting passing criteria requires further evaluation to adequately replicate real life conditions.

**Inside the Bottle**

Traditional multipurpose disinfection solutions consist of different components that combine to achieve various tasks required for contact lens care. Most MPS products are marketed as single solutions for cleaning, disinfection and storage purposes; each has a specific formulation, though the primary components typically remain the same. These include:

- **Preservatives.** These substances are responsible for killing microbes residing in and on the contact lenses and also inhibiting contamination of the MPS solution itself for prolonged use after opening. Preservative uptake and release profiles vary depending on the kind used in the MPS formulation, which can lead to differing disinfection efficacies. Too much of a preservative released from the lens into the tear film can also result in corneal toxicity.

- **Surfactants.** These are amphiphilic chemicals similar in nature to a detergent that aid in removal of loosely bound protein deposits of an inorganic or lipid nature. Due to the amphiphilic nature of surfactants, they may potentially act as lubricants by reducing surface tension. This increased wettability buffers interacting ocular tissues from hydrophobic areas on the surface of the contact lens. Typical MPS surfactants include isopropl alcohol, sodium citrate, sodium phosphate, polyvinyl alcohol and sodium borate.

- **Chelating Agents.** These substances bind proteins and metals like calcium to prevent deposition on the contact lens surface. Ethylenediaminetetraacetic acid (EDTA) is the most common MPS chelating agent. EDTA has been shown to be an adjuvant that can enhance biocidal activity.

- **Bufffers.** Buffers help maintain the pH of the MPS to ensure biocompatibility a enhance comfort and reliability of the component agents. Common MPS buffers include borate, phosphate, bicarbonate, citrate and nitrate.

- **Wetting Agents and Lubricants.** These decrease surface tension to increase the wetting angle of the contact lens surface, which leads to improved comfort of the contact lens via reduced friction between the contact lens and ocular surface and eyelids. Common wetting agents and lubricants include Tetronic 304, poly(oxyethylene)-poly(oxybutylene), hydroxypropyl methylcellulose, hyaluronic acid, carboxymethylcellulose and propylene glycol.
REALITY CHECK: HOW FDA TESTING FALLS SHORT

Given the controversies, recommendations encourage manufacturers to make evaluating MPS in the presence of contact lenses a standard, at least with respect to biocompatibility. Additionally, lens/solution incompatibilities should be labeled on the product and packaging to help contact lens wearers make an informed decision about their choice of lens care product. The FDA has also proposed incorporating other specific parameters, including the addition of two new strains of Pseudomonas to the test panel and use of organic soil to reflect real-life scenarios.

GP LENS CLEANING

In some cases, contact lenses and lens cases act as vectors for microbes derived from the environment, delivering these microorganisms to the ocular surface where complications may arise. Studies have identified exposure of contact lenses to sources of water, including tap water, as risk factors for Acanthamoeba keratitis.47-53 However, while rinsing with tap water has long been advised against as part of the soft lens care regimen, many GP lens care regimens continue to include use tap water for rinsing as part of their care process.15

The Centers for Disease Control (CDC) revised its Consumer Updates website in 2010 to convey the elimination of water for GP lens care, and the FDA published an addendum to the 510(K) contact lens care labeling guidance; however, some GP lens solutions continue to recommend its use, and many consumers remain unaware of the change.54,55 Potential alternatives to tap water with GP lenses do exist—for example, sterile saline rinses—but the uptake of such options seems to be low.

The group also discussed a related issue regarding scleral contact lenses, which are typically inserted with a fluid reservoir. Often, unpreserved saline is used, but tap water may also be used in some cases. While this may present several problems, it is not clear how common this practice is.

BIOFILM FORMATION

Microbial phenotype and gene expression can also affect a microbe’s susceptibility to disinfectants and thus the efficacy of a solution. As mentioned previously, the physical form(s) of the organism have differing biocide resistances. Bacteria conditioned with human tear fluid or with epithelial cells may secrete factors that hinder biocidal activity. The low metabolism of bacteria residing in biofilms may also increase their resistance to antibiotics and disinfectants.13,56,57

Many studies have reported that while some disinfecting solutions perform better than others in reducing planktonic bioburden, most were not effective in reducing biofilm.17,58-61 One study shows that while planktonic organisms may be susceptible to PHMB- and Polyquad-based disinfecting solutions, the susceptibility of these same strains of bacteria contained in a biofilm is considerably reduced.62

Additionally, microbial adhesion and biofilm formation is enhanced in silicone hydrogel lenses compared with conventional hydrogel lenses.14 Researchers hypothesize this observation is due to the increased hydrophobic phases, increased protein/lipid deposits on silicone hydrogel lens and higher oxygen transmissibility/availability.53,56,62 Even though these observations are mostly in vitro, further study regarding MPS efficacy against biofilm should be considered to warrant safe lens wear.

COMFORT AND CONVENIENCE

Several MPS systems have been reformulated to improve their compatibility with silicone hydrogel lens materials in an attempt to decrease corneal staining potential. In addition, manufacturers have tried to improve comfort for lens wearers by adding wetting agents. However, while wettability is related to improved lens wear comfort, the recalls of two MPS systems (Complete Moisture Plus and Renu with MoistureLoc) has been hypothesized to be the result of a combination of effects, including the addition of moisturizing agents for comfort.15,21 No isolated MPS component appears to be singularly responsible for enhanced rates of Acanthamoeba encystment and thus increased resistance to biocidal activity.67,68 The interaction of components within a formulation—biocide, buffer and moisturizing agent—appear to interplay, in a so-far unpredictable manner, to affect the eventual biocidal activity.67,68

It is difficult to find the critical balance between improved wettability and solution disinfection efficacy without compromising either. Further research is needed to carefully evaluate the balance between these factors for successful lens wear.

Members of the DOED plan to revise the 1994 guidance document for daily wear contact lenses and the 1997 guidance document for lens care products to reflect advancements in contact lens materials, microbial outbreak incidents and increased understanding of the pathogenesis of certain microbes such as Acanthamoeba.
Silicone hydrogel lenses (the first generation: balafilcon A and lotrafilcon A) were first introduced to the market in the late 1990s, when manufacturers began to inject silicone polymers into the original hydrogel monomers to improve material performance (i.e., oxygen permeability, ion transport, deposit resistance and mechanical properties). However, while silicone polymers allow high oxygen transmission, they are hydrophobic and thus require the hydrogel polymer water phase to allow transport of gases like oxygen and carbon dioxide, ions and tear film components across the lens.

Additionally, the contrasting properties of the constituent materials of a silicone hydrogel lens result in significantly different lens surface characteristics compared to conventional hydrogel materials, including wettability, deposition of proteins and lipids and lens/solution interactions (e.g., uptake and release of preservative by the lens or biocide sequestration).

A decades-old grouping system developed over 20 years ago, based on contact lens water content and charge, has proved effective for predicting potential solution incompatibilities with the varied range of poly(HEMA) lenses available on the market; however, similar incompatibilities could not be predicted when silicone hydrogel lenses were added to this conventional grouping system (Table 1). For example, the multi-purpose solution preservative Aldox, which features a positive charge and hydrophobic tail, demonstrates strong interactions with silicone hydrogel materials—that is, all silicone hydrogel lenses, regardless of ionic charge and/or water content, uptake a greater amount of Aldox compared to poly(HEMA) contact lenses. A silicone hydrogel material group was added to the classification upon identification of this issue and subdivided into five subgroups to account for differences in poly(HEMA) content (Table 2).

### Table 1. Conventional Hydrophilic Material Groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Low Water Content (&lt;50%), Nonionic*</td>
</tr>
<tr>
<td>II</td>
<td>High Water Content (&gt;50%), Nonionic*</td>
</tr>
<tr>
<td>III</td>
<td>Low Water Content (&lt;50%), Ionic*</td>
</tr>
<tr>
<td>IV</td>
<td>High Water Content (&gt;50%), Ionic*</td>
</tr>
</tbody>
</table>

*Being ionic in pH = 6.0 – 8.0.

### Table 2. Silicone Hydrophilic Material Groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V-A</td>
<td>No Water Specification, Ionic*</td>
</tr>
<tr>
<td>V-B</td>
<td>High Water Content (&gt;50%), Nonionic*</td>
</tr>
<tr>
<td>V-C</td>
<td>Low Water Content (&lt;50%), Nonionic*, Hydrophilic-monomer Only</td>
</tr>
<tr>
<td>V-Cm</td>
<td>Low Water Content (&lt;50%), Nonionic*, Surface Treated (ST)</td>
</tr>
<tr>
<td>V-Cr</td>
<td>Low Water Content (&lt;50%), Nonionic*, Non-ST, Semi-interpenetrating Network</td>
</tr>
</tbody>
</table>

*Being ionic in pH = 6.0 – 8.0.
REALITY CHECK: HOW FDA TESTING FALLS SHORT

In most countries, an MPS must meet the International Organization for Standardization (ISO) disinfection criteria before it can obtain licensing, prior to any specific country requirements. There are two pathways to obtain ISO classification, specified by ISO 18259 (Figure 1).26 The first is for a solution to satisfy the primary criteria of a stand-alone test; that is, the solution must have a greater than or equal to 3-log reduction (i.e., 1,000 times smaller than the original amount) in each of the three test bacteria and a greater than or equal to 1-log kill (i.e., 10 times smaller than the original amount) in each of the test fungi. The secondary criteria for the stand-alone test is that the solution must demonstrate the concentration of each of the three bacterial species is reduced by 1 log unit at minimum, and that the sum of the log reductions of the three bacteria exceeds 5 log units.

Supplementing the less stringent secondary criteria of the stand-alone test is the regimen test, which requires the solution reduce microbe numbers to a certain level after a lens rubbing and rinsing process. The specific standards for antimicrobial activity and test microbes specified by ISO18259 are detailed in Table 3.27

Table 3. Criteria for the Stand-alone and Regimen Tests for Contact Lens Disinfecting Solutions

<table>
<thead>
<tr>
<th>Microbe Type</th>
<th>Test</th>
<th>Fusarium solani (ATCC 36301)</th>
<th>Candida albicans (ATCC 10231)</th>
<th>Pseudomonas aeruginosa (ATCC 9027)</th>
<th>Serratia marcescens (ATCC 13880)</th>
<th>Staphylococcus aureus (ATCC 6538)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stand-alone Test (Primary Criteria)</td>
<td>1.0 log unit</td>
<td>1.0 log unit</td>
<td>3.0 log unit</td>
<td>3.0 log unit</td>
<td>3.0 log unit</td>
<td>3.0 log unit</td>
</tr>
<tr>
<td>Stand-alone Test (Secondary Criteria)</td>
<td>Stasis at the soaking time</td>
<td>Stasis at the soaking time</td>
<td>Minimum 1.0 log unit</td>
<td>Minimum 1.0 log unit</td>
<td>Minimum 1.0 log unit</td>
<td></td>
</tr>
<tr>
<td>Regimen Test (Includes all mgf recommended procedures, including rub/rinse)</td>
<td>&lt;10CFU on lens</td>
<td>&lt;10CFU on lens</td>
<td>&lt;10CFU on lens</td>
<td>&lt;10CFU on lens</td>
<td>&lt;10CFU on lens</td>
<td></td>
</tr>
</tbody>
</table>

ATCC: American Type Culture Collection; CFU: colony forming units
* Based on average reduction at manufacturer’s recommended disinfection time.

REALITY CHECK: HOW FDA TESTING FALLS SHORT

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1. Under FDA criteria, for contact lenses to be designated as being ionic, the pH must fall between:
   a. 6.0 and 9.0.
   b. 5.0 and 7.0.
   c. Anything lower than tear film pH.
   d. There is no pH requirement for “ionic” designation at FDA.

2. Preservative uptake and release by contact lenses is influenced by all of the following except:
   a. The type of preservative in the MPS used to disinfect lenses.
   b. The pore size and water content of the lens material worn.
   c. The contact lens case used for storage.
   d. All of the above influence preservative uptake and release.

3. Which of the following is a contact lens solution-related compliance concern?
   a. Wearing lenses beyond the recommended wearing time.
   b. Washing hands before handling lenses.
   c. Topping-off or re-using MPS.
   d. B and C are correct.

4. The FDA will most likely do the following in the next guidance document revision:
   a. Add “real world” testing measures such as organic soil.
   b. Add the number of days a lens can be worn for extended or continuous wear.
   c. Add Acanthamoeba and possibly other organisms to the test panel.
   d. A and C are correct.

5. Biofilms allow various organisms to communicate with one another. The main concern regarding biofilms is that they:
   a. Hinder disinfection solution efficacy.
   b. Promote human corneal epithelial apoptosis.
   c. Decrease tear film pH, thereby decreasing all-day lens comfort.
   d. Increase the metabolism of resident bacteria, making the strain more resistant to treatment.

6. In the FDA guidelines for Stand-alone Testing, the log reduction requirement for Acanthamoeba is:
   a. 3 log reduction.
   b. 1 log reduction.
   c. 4 log reduction.
   d. There is no requirement for Acanthamoeba in the Stand-alone Test series.

7. Which of the following is not a documented risk factor for Acanthamoeba keratitis?
   a. Topping off or re-using solutions.
   b. Swimming or showering in contact lenses.
   c. Being an adapted/veteran lens wearer.
   d. Forgetting to rub lenses after removal.

8. Buffers in contact lens solutions are used for which of the following?
   a. Maintaining the desired pH of the solution.
   b. Removing deposits and bacterial load.
   c. Binding proteins.
   d. All of the above are correct.

9. Which of the following best describes the rate of Acanthamoeba keratitis incidence following the 2007 MPS solution recall?
   a. The rate steadily decreased after 2009 as a result of the recall.
   b. The rate initially decreased after the recall to the recalled solution pre-launch level, but has increased beyond that point since 2009.
   c. No outbreak was noted prior to 2007, so this question is not appropriate.
   d. The rate remained the same until today as it was in 2007.

10. Silicone hydrogels differ from conventional hydrogel lenses by which of the following characteristics?
    a. Ionic charge.
    b. Hydrophobicity.
    c. Material pore size.
    d. All of the above are correct.

11. The FDA panel of organisms in Stand-alone Testing (Primary Criteria) includes all of the following, except:
    a. Pseudomonas aeruginosa.
    b. Serratia marcescens.
    c. Acanthamoeba castellani.
    d. Fusarium solani.

12. The role of the preservative in contact lens solutions is which of the following?
    a. Disinfecting a lens.
    b. Inhibiting contamination of the MPS solution when used for prolonged periods of time.
    c. Serving as a natural buffer for the tear film.
    d. A and B are correct.

13. Microbial susceptibility to various disinfectants is influenced by which of the following?
    a. Microbial strain.
    b. Level of bioburden.
    c. Microbial phenotype.
    d. All of the above are correct.

14. Acanthamoeba has a significant ability to survive when challenged by disinfection. Which of the following are accurate statements relating to Acanthamoeba and solution disinfection?
    a. Acanthamoeba has an innate ability to regulate its pH by osmotic means to survive when exposed to MPS.
    b. Acanthamoeba can encyst when challenged by cell crowding, reduced pH and sometimes even MPS exposure.
    c. Only Acanthamoeba cysts infect corneal tissue, so it doesn’t matter that they can survive when exposed to MPS.
    d. Pre-cystic Acanthamoebae are much easier to kill than trophozoites with MPS.

15. Alternatives to using water with GP lenses include all of the following, except:
    a. Only fit patients with scleral lenses, obviating the need to use tap water when inserting GP lenses.
    b. Use sterile hospital or inhalation saline (0.9%) as a rinse.
    c. Rinse the cleaner off with MPS and insert directly from an approved conditioning solution.
    d. A and B are correct.

16. The Fusarium keratitis outbreak of 2005 resulted in a voluntary solution recall. Which of the following related statements are accurate?
    a. The strain of Fusarium responsible for the outbreak was from Group IV and did not relate to any water vector.
    b. Use of this solution reduced the recalled MPS’s biocidal efficacy and was discontinued over time, posing increased risk to the patient.
    c. The isolates evaluated were clonal, and related infections were probably due to contamination that occurred at the manufacturing plant.
    d. The rate of infection was extremely high compared with the 2007 Acanthamoeba outbreak.

17. In addition to organic soil, which factor may ultimately contribute to infection and reduced MPS efficacy?
    a. Wearing of lenses overnight while taking aspirin.
    b. Use of certain brands of artificial tears while wearing contact lenses.
    c. Running of a marathon while wearing lenses.
    d. Use of certain brands of facial moisturizers.

18. Which of the following material properties is not important in classification of silicone hydrogels?
    a. Water content.
    b. Ionicity.
    c. Surface treatment (i.e., wettability, deposition characteristics).
    d. All are important factors to consider when classifying these lenses, since they are uniquely different than conventional hydrogel lenses.

19. Which of the following statements on testing MPS efficacy against protozoa are true?
    a. Infection rates are so low that it’s impossible to determine the species responsible for most infections.
    b. It’s uncertain as to what inoculum size is ideal for testing, since we don’t have data that translates easily to infection potential.
    c. Axenic growth of Acanthamoeba and solution disinfection?
    d. B and C are true.

20. Which of the following is true regarding the Regimen Test (ISO8259)?
    a. It’s generally considered a more stringent test than the secondary criteria of the Stand-alone Test.
    b. It does not require using a rub and rinse phase.
    c. It uses a designated log cut-off.
    d. It includes Acanthamoeba in its panel of organisms tested.
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Good Chemistry

Are you up to date on pairing GP lenses and solutions? Here’s a look at what makes a perfect match.

Good Chemistry

Good as permeable (GP) contact lens performance is highly dependent on the quality of the lens surface. A clean, wettable lens allows for both a higher degree of vision clarity and better patient comfort. Accordingly, proper care of GP lenses is instrumental in ensuring successful wear.

With the variety of cleaning products available, however, it’s no wonder many patients become confused regarding which solutions to use. To help differentiate, let’s take a moment to review the fundamental components of successful GP lens care: surface cleaning and disinfection.

SURFACE CLEANING

Early GP lenses were manufactured with silicone/acrylate copolymers to increase oxygen permeability, resulting in negatively charged hydrophobic lens surfaces that attract positively charged proteins and lipids. Modern GP lenses added fluorine (fluorosilicone/acrylate) to the mix, resulting in a lower surface tension that reduces deposit adherence and increases surface wettability for greater ease of lens cleaning.

GP cleaners that contain abrasive surfactants like the Original Formula Boston Cleaner (Bausch + Lomb) and the now-discontinued Opti-Clean II (Alcon) are traditionally more effective when used with lower-Dk, early-generation GP lenses that bind more protein. Newer cleaners including Boston Advance Cleaner (Bausch + Lomb) and Opti-Free Daily Cleaner (Alcon) use smaller-diameter abrasive particles; however, these are still classified as mildly abrasive and should be used with caution on higher Dk GP lenses, as they can scratch the surface and reduce center thickness. Abrasive cleaners are also contraindicated for use with any GP lens that is plasma treated. If a non-abrasive daily cleaner is required, Optimum Extra Strength Cleaner (Lobob Laboratories), a preservative-free formula, can be used.

Other daily cleaners include the isopropyl alcohol-based Sereine Extra Strength Cleaner (Optikem International) and Walgreens Extra Strength Daily Cleaner. Both contain the same ingredients as the MiraFlow (Alcon) daily cleaner that was discontinued in 2010. Note, the original MiraFlow formulation was recently purchased by an independent practitioner and is distributed online only through a direct-to-consumer website.

Patients who are heavy protein depositors may benefit from an additional enzymatic or solvent cleaner that can be used periodically. Current enzymatic cleaners come in liquid form, allowing them to be added directly to a storage solution. Boston One-Step Enzymatic Cleaner (Bausch + Lomb) is recommended for weekly use, while SupraClens Daily Cleaner (Alcon) is recommended for every day use.

Formerly an in-office cleaner only, Progent (Menicon) incorporates a mixture of sodium hypochlorite and potassium bromide to remove proteins and is recommended for use on a biweekly basis. Because this formulation

What is Plasma Treating?

Plasma is a gas that is ionized into a mixture of highly reactive negatively charged particles. During treatment, GP lenses are placed in a vacuum chamber, where oxygen plasma breaks up and removes surface contaminants including grease, lipids and other residues. This process improves the lens’ initial wettability and comfort by reducing the wetting angle.

Plasma treating should be thought of as a “deep clean” process rather than a coating treatment. Lenses with a plasma treatment are shipped hydrated, so excessive handling should be avoided prior to dispensing. Although the plasma treatment will wear off over time, abrasive cleaners are not recommended for use to avoid accelerating the breakdown. Most laboratories recommend cleaning the lens with Boston Simplus (Bausch + Lomb), Unique pH (Menicon) or a hydrogen peroxide-based solution.
is essentially bleach, it is recommended only for patients who fully understand how to use it properly.

In general, lenses should not soak in any of these liquids for more than 30 minutes, to avoid discoloration. Less frequent use of an enzymatic cleaner or Progent may be sufficient for lenses containing fluorosilicone/acrylate materials.

Following use of daily cleaners, GP lenses should be rinsed thoroughly prior to lens insertion. While many GP wearers rinse with tap water, this is controversial. To reduce the risk of microbial exposure, rinsing with a sterile saline or multipurpose solution is typically recommended.

**DISINFECTION AND STORAGE**

Once the lens surface has been cleaned, a GP lens should be soaked overnight. Depending on the storage method, the lens is disinfected using either preservatives or hydrogen peroxide. There are several preservatives used in GP solutions that are either bactericidal or bacteriostatic in nature. These typically have larger molecular weights, limiting their ability to bind to a GP lens. Common preservatives include chlorhexidine gluconate, benzyl alcohol, polyquaternium-1 (polyquad) and biguanides.

The Boston Conditioning Solution and Boston Advance Formula Conditioning Solution (Bausch + Lomb) are both packaged independently, but are part of a two-bottle system with their daily-cleaning counterparts. Both solutions use chlorhexidine gluconate 0.003% as a preservative, and contain polyvinyl alcohol (PVA) and a cellulose viscosifier to coat the lens surface, providing both moisture and a cushioning effect for added comfort. The Advance Formula Solution has an added preservative, polyaminopropyl biguanide 0.0005% (PAPB), and derivatized polyethylene glycol as an additional wetting agent.

Other solution options for cleaning, disinfecting and storage (CDS) include Optimum CDS (Lobob) and MeniCare CDS (Menicon). Both solutions use the same formulation with lauryl sulfate salt of imidazoline and octylphenoxypolyethoxyethanol to clean the lens, and are preserved with benzyl alcohol 0.3% and edetate disodium 0.5%. Both CDS solutions recommend a rub and rinse prior to overnight soak, and should be thoroughly rinsed prior to lens insertion. Optimum CDS can be purchased independently or as part of a combined care system kit with the Optimum ESC and Optimum wetting/rewetting drops.

If a patient develops a preservative sensitivity, hydrogen peroxide-based solutions can be used as an alternative. Solutions containing a 3% hydrogen peroxide concentration are particularly effective against multiple pathogens, including bacteria, viruses, fungi and protozoa, as peroxide produces free radicals that can penetrate a microbe’s cell membrane and destroy its DNA. However, the solution’s pH of 4.0 means that a neutralization step is also required prior to lens placement on the ocular surface. Additionally, because hydrogen peroxide cannot penetrate the matrix of GP lens, as it can a soft hydrogel, GP lenses still require a

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Dextenza on Deck

Could the latest approach to steroid therapy conquer noncompliance once and for all?

Topical medication compliance is an ongoing struggle for many optometric practices today. Patients report issues with frequency of administration, cost of medication and associated side effects of instillation (e.g., stinging, hyperemia), while practitioners struggle with lack of patient adherence. Since the process of ensuring medications are adequately taken can be frustrating for all those involved, researchers continue to search for newer and better ways to deliver therapeutic doses of medicine via simpler methods.

Dextenza (sustained-release dexamethasone 0.4mg, Ocular Therapeutix) aims to provide a new way to deliver steroid therapy. Rather than administering a drop or injection, an intracanalicular depot is inserted into the puncta to provide a one-month tapered release of preservative-free medication to the ocular surface. At the end of 30 days, the biodegradable hydrogel depot is absorbed by the body, eliminating the need for removal. Ocular Therapeutix is evaluating the use of Dextenza in various conditions, including allergic conjunctivitis, postoperative pain and inflammation, and inflammatory-related dry eye. Below, let’s examine these conditions individually.

**ALLERGIC CONJUNCTIVITIS**
The initial Phase III clinical trial for Dextenza in the fall of 2015 yielded mixed results. While it did meet the primary endpoint of relieving conjunctival redness. Still, the drug was qualified as safe and well-tolerated. Researchers have since revised the protocol for a second, Phase III multicenter, 1:1 randomized, double-masked, vehicle-controlled trial, where the sole primary endpoint will be a reduction in ocular itching by day seven following insertion.

"AN INTRACANALICULAR DEPOT IS INSERTED INTO THE PUNCTA TO PROVIDE ONE-MONTH TAPERED RELEASE OF MEDICATION."

**POST-OP OCULAR PAIN**
Ocular Therapeutix received acceptance for a New Drug Application (NDA) from the FDA for the treatment of ocular pain following ophthalmic surgery, based on data from a single Phase II and two Phase III clinical trials—the latter of which achieved the primary endpoint of reduction of ocular pain but not the second primary endpoint of absence of cells in the anterior chamber.

In the Phase II trial of 247 patients, researchers found statistically significant differences between the Dextenza-treated group and placebo for both pain and absence of cells in the anterior chamber (p<0.005). All patients retained the device through day 14, and 97% of patients retained it through day 30. No long-term intraocular pressure spikes were observed. Rescue medications were required by a smaller number of Dextenza subjects (20.7% vs. 72.4%) compared with the number of placebo subjects at days 14 and 30; the Dextenza subjects also exhibited fewer adverse events (13.8% vs. 43.8%).

Unfortunately, the 240-patient Phase III trial failed to meet the primary endpoint for reduction of ocular inflammation (Dextenza 39.4% vs. placebo 31.3%). A third Phase III trial aimed at achieving the same primary endpoint recently began enrolling patients, and it is the company’s intention to file a supplement to the NDA if the study is successful.

The two prospective, multicenter, randomized parallel-arm, double-masked, vehicle-controlled Phase III trials were completed with a total of 487 patients undergoing unilateral clear corneal cataract surgery. Patients were randomized 2:1 to receive either Dextenza or a placebo vehicle punctal plug. As stated, the two primary efficacy endpoints were absence of cells in the anterior chamber at day 14 and the absence of pain, subjectively reported on a scale of 0 to 10, at day eight. Secondary efficacy endpoints were absence of flare in the anterior
chamber at each visit and absence of cells and absence of pain at each visit, other than the day used for the primary efficacy measure.

The new Phase III trial expected to constitute the supplement to the NDA allows for modifications of the original protocol, including a 1:1 (rather than 2:1) randomization of patients; the exclusion of patients undergoing treatment with high doses of oral NSAIDs; and improved training and guidance for on-site clinical investigators regarding adherence to study protocols, including the appropriate use of rescue medications.

INFLAMMATORY DRY EYE
At the end of 2015, results from a Phase II exploratory clinical trial for the treatment of signs and symptoms of moderate to severe dry eye disease were released. The prospective, randomized, parallel-arm, double masked, vehicle-controlled study included 43 patients (86 eyes) at two sites in the United States. Patients were initially treated with a placebo punctal plug for 45 days; those patients who benefited were excluded from the subsequent treatment phase. Treated patients were randomized 1:1 to receive either Dextenza or a placebo vehicle for 30 days.

Total corneal staining at day 30 showed the Dextenza group had statistically significant improvement at day 30 as compared to placebo (p=0.018). Subjectively, there was improvement as measured by the standard patient evaluation of eye dryness (SPEED) questionnaire for dryness, itchiness and scratchiness. There were no intraocular spikes noted, and there was a 96% retention rate of the drug depots throughout the 30-day trial.

While the results from these trials are mixed, it remains clear that an alternative method of drug delivery can be effective for certain ocular conditions and symptoms. Hopefully, this is the gateway to further research that will enable us to offer our patients a cost-effective, safe and easy method to overcome some common ocular issues that are undermined not by pharmaceutical shortcomings but, rather, human ones.

THE GP EXPERTS: GOOD CHEMISTRY
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rubbing step for proper cleaning. Current peroxide-based solutions on the market include ClearCare Plus (Alcon), PeroxiClear (Bausch + Lomb), and OxySept UltraCare Formula (AMO).

MULTIPURPOSE SOLUTIONS
For some patients, cleaning and disinfecting a GP lens with two separate solutions can be burdensome or confusing. A multipurpose solution (MPS) may be a more convenient and appropriate choice for these patients. Boston Simplus (Bausch + Lomb) contains the surfactant poloxamine 1107 and hydroxyalkylphosphonate to remove protein deposits, chlorhexidine gluconate and PAPB preservatives to disinfect the lens, and glucam-20 and hydroxypropylmethylcellulose (HPMC) for cushioning and wetting. Product guidelines recommend that lenses be removed every night and directly in solution; in the morning, the lens should be rubbed gently on either side for 20 to 30 seconds and rinsed prior to lens insertion.

Unique pH multipurpose solution (Menicon) is the same formulation as the former Opti-Free GP (Alcon). Preserved with polyquad and EDTA, Unique pH also contains hydroxypropyl guar, polyethylene glycol, tetronic 1304, boric acid and propylene glycol to aid in cushioning and wettability. The formula also allows the solution to adjust viscosity based on the pH of the ocular surface. While no rinsing is typically required, if the SupraClens (Alcon) enzyme is added to the solution, the lens should be rinsed thoroughly prior to insertion.

With any lens/solution combination, practitioners should inform patients regarding proper use and potential problems to watch for. Always be sure to remain up to date on the latest research to ensure your recommendations are the best option for your patients.

What’s in a Name?

Even the smallest changes in how your staff members present themselves to patients can have the biggest impact.

Recently, an intense discussion among our clients occurred about a seemingly benign subject—staff uniforms. Specifically, name tags: where can they be bought, and should the practice logo be printed on them?

As I often do when things become nitty-gritty, I took a step back to examine the big picture of this particular practice-building topic. Why would a practitioner mandate (or not) that staff wear uniforms and if they do, why a particular type, style or color? What about the pros and cons of using name tags vs. writing the staff member’s name in embroidery? Why display any name at all? And what about complementary items like laboratory coats and/or ties?

There is, of course, no universal answer for these questions—it depends upon the practice’s model, mission statement, values, culture and long-term goals. It is more than likely, however, that every practice has one communal thread tying them all together: they are all attempting to connect and relate to patients, which benefits both the clinical care aspect and the business as a whole.

So, with respect to the staff dress code? After a recent visit to a Westin Hotel, I believe the answer to this question is, in fact, yes.

**NICE TO MEET YOU**

Her name tag read: *My name is Shannon. My passion is cooking.* Though I’m not a foodie and I only have a limited interest in cooking, this simple line caught my attention. In effect, it brought to the forefront the woman’s individuality and gave me the feeling that if I had a problem during my stay, I could rely on her to help me resolve it more so than someone else. And if I didn’t have a problem, I would still have an “insider” at this particular hotel the next time I came.

During my short stay, I learned about other employees at the hotel with passions that varied from sports and travel to film. I developed an underlying feeling that during staff meetings, the presentation likely began with the maintenance engineer taking about his weekend gardening project, rather than the upcoming elevator closure schedule, and I also thought that during a particular grinding and challenging work day, an employee touching base with a returning guest who recognized them and remembered the employee’s daughter’s soccer team, helped that employee get through the day a little easier.

See what that simple name tag change led to a better connection between an employee and a guest, a better sense of teamwork among employees and a better overall mood in the work environment. These are the real reasons for the Westin’s name tag technique—reasons that can easily be applied in the context of an optometry practice.

So, the next time you have to make a business decision, no matter how seemingly small—what is smaller than a name tag, anyway?—make it in the context of looking at the bigger picture. Ask yourself, “Why am I doing this, what are its long-term benefits and how is it going to support my practice mission and values?” As is often the case, and as you saw with the name tags, these decisions are rarely obvious and take some creativity. If you’re a self-employed decision-maker reading this, don’t worry about the immediate repercussions. Adding a name tag is a simple and inexpensive change. Just go with it and see what happens.

And the next time you see me, my tag will say, “My name is Gary Gerber. My passion is helping optometrists succeed.”
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