Breaking the Cycle of Discomfort

Advanced contact lens materials and manufacturing process deliver exceptional comfort*

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- Preventing Dehydration Blur
- Growing a Practice With a Novel Contact Lens Technology

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<table>
<thead>
<tr>
<th>Dk/t</th>
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<th>ASPHERIC OPTICS</th>
<th>THIN EDGE DESIGN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bausch + Lomb ULTRA® contact lenses</td>
<td>163</td>
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<tr>
<td>ACUVUE OASYS</td>
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<td>AIR OPTIX AQUA</td>
<td>138</td>
<td>102</td>
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<tr>
<td>Biofinity</td>
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**REFERENCES:** 1. Data on file. Bausch & Lomb Incorporated. Rochester NY; 2013. 2. Results from a 22-investigator, multi-site study of Bausch + Lomb Ultra contact lenses with MoistureSeal technology, on 327 current silicone hydrogel lens wearers. After 7 days of wear, subjects completed an online survey. Subjects rated performance across a range of attributes. Preference comparisons represent only those subjects expressing a preference. Ratio is based on the average across the silicone hydrogel lenses represented in the study.

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Contact Lens Discomfort Defined
By Katherine M. Bickle, OD, MS & Kelly K. Nichols, OD, MPH, PhD
Each year, patients in our practices are struggling with lens wear, and in some cases, dropping silently out of lens wear. How do we get to the bottom of this problem?

Breaking the Cycle of Discomfort
By Katarzyna Wygladacz, MS, PhD; Daniel Hook, BS, MS, PhD; Robert Steffen, OD, MS & William Reindel, OD, MS
Advanced contact lens materials and manufacturing process deliver exceptional comfort.*

Clinical Performance of Samfilcon A Silicone Hydrogel Contact Lenses
By Robert Steffen, OD, MS; Mohinder M. Merchea, OD, PhD, MBA; Marjorie J. Rah, OD, PhD & William Reindel, OD, MS
New technology aims to make lens wear more comfortable despite increased digital viewing.

Preventing Dehydration Blur
By Kristen R. Hovinga, MS; Paul D. Ludington, MS, Mohinder Merchea, OD, PhD, MBA, & Robert Steffen, OD, MS
The increased use of digital devices in today’s society has made it more important than ever to address lens dehydration.

A One-Step Hydrogen Peroxide-based Contact Lens Solution
By Kimberly A. Millard, MS; Daniel Hook, PhD; Andrew Hoteling, PhD & Katarzyna Wygladacz, PhD
Development of a cleaning and disinfecting solution with a platinum-modulating compound.

Growing My Practice With a Novel Contact Lens Technology
By Matthew Ward, OD
Even when patients say, “I’m happy with the lens I have.”

*MoistureSeal technology, as part of the Bausch + Lomb Ultra contact lens material (samfilcon A), represents a significant achievement in integrating novel material chemistry and a two-phase manufacturing process to produce a unique silicone hydrogel lens designed to address the cycle of discomfort many wearers encounter each day and enhance the overall lens wearing experience particularly at the end of the day.
Prescribing for Presbyopia  
By Thomas G. Quinn, OD, MS, FAAO  
Patient Characteristics Affect Multifocal Lens Performance

GP Insights  
By Edward S. Bennett, OD, MSEd, FAAO  
Using Peroxide With GP Lenses

Contact Lens Design & Materials  
By Neil Pence, OD, FAAO  
Characteristics of a New Silicone Hydrogel Contact Lens

Dry Eye Dx and Tx  
By Katherine M. Mastrota, MS, OD, FAAO  
Ocular Surface and Tear Film in Contact Lens Discomfort

Contact Lens Care & Compliance  
By Michael A. Ward, MMSc, FAAO  
New Option for Peroxide Disinfection

Contact Lens Practice Pearls  
By Jason R. Miller, OD, MBA, FAAO  
The Contact Lens Conversation

The Business of Contact Lenses  
By Gary Gerber, OD  
Assessing the Value of Adding New Technology

Pediatric & Teen CL Care  
By Jeffrey J. Walline, OD, PhD, FAAO  
Myopia Control Consent Form

Treatment Plan  
By William L. Miller, OD, MS, PhD, FAAO  
Learnings from the Contact Lens Discomfort Workshop
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In its time
Thickness of material

In its prime
Anterior aspheric optics

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When treating irregular corneas with a soft lens, there was a time when “thickness of material” was thought to be the best approach. Today, there is KeraSoft® IC. Its patented design “drapes” over the cornea to correct the vision rather than simply “mask” the irregularity. This enables KeraSoft® IC to have a thinner optical center than in traditional designs, while still providing excellent visual acuity – a significant factor to consider when choosing a lens that meets your patient’s needs. And for comfort, KeraSoft® IC is made of a quarterly replacement silicone hydrogel*.

* Definitive Material.

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New Concepts
Aimed at Improving Vision and Comfort

Technology is continually expanding and moving boundaries for us in all aspects of our lives. It is truly amazing and exciting to see the conveniences that new technologies afford us each day. On the other hand, technology creates occasional headaches — literally and figuratively in the medical sense.

Computers and other digital devices and their use, particularly over long periods of time, are clinically associated with a variety of ophthalmic-related conditions including headaches, eyestrain and fatigue, discomfort and dry eye. It is thought by some that these problems are further exacerbated by the use of contact lenses, but this is not entirely clear. There is no doubt that the optical quality and vision-related performance of a contact lens depends on a stable pre-lens tear film.

This special edition of Contact Lens Spectrum explores some of the challenges we face when patients come to us with complaints of fatigue, discomfort and the like.

Often, these problems are a challenge to manage given that employment or social needs mandate our patients’ use of technology. We as eye care practitioners need contact lens materials and designs that will help us overcome these challenges, allowing our patients to wear contact lenses in a variety of environments. In this special edition, you can learn more about one such technology, aimed at improving the wearing experience of our patients who use digital devices. I applaud manufacturers who are working to improve contact lens materials and designs that will allow for more satisfied patients and greater success in contact lens practice.
Research About the Ocular Surface and Contact Lens Wear

Our understanding of the critical importance of a healthy ocular surface for successful contact lens wear is becoming more apparent as research continues to tell us of the intimate relationship between the two. Over the past few years, landmark efforts have been made to clarify our understanding of this relationship as expressed by three international workshops held by the Tear Film and Ocular Surface Society (TFOS):

1. The International Dry Eye Workshop (DEWS) 2007 (DEWS Report, 2007)
3. The International Workshop on Contact Lens Discomfort 2013 (Nichols et al, 2013)

These workshops each brought together the leading experts in their fields to organize current knowledge and encapsulate current approaches to diagnosis and management of these clinically challenging entities. As stated by the authors, “The International workshops provide a consensus overview of the field as a snapshot in time.” The documents published are based on extensive international literature reviews of current research. They give us a heretofore unavailable evidence-based foundation from which ongoing research will allow us to continue to better understand how to manage patients with ocular surface disease (with or without contact lens wear). Let’s look at some of the most current research in this area and see how it furthers our understanding.

General Perspectives of Dry Eye and Ocular Surface Disease

A recent publication authored by many of the original DEWS participants evaluated where we are in the understanding of dry eye disease (DED) since the original DEWS report was published in 2007 (Bron et al). They once again reviewed some of the most impactful research in this area and see how it furthers our understanding.

Conclusion was that although most patients present with symptoms, a significant number of patients with objective evidence of disease are asymptomatic. Diagnosis by symptoms alone is insufficient. Additionally, all objective tests for DED are variable in patients with DED. This variability isn’t seen in healthy individuals. As an example, with effective treatment, tear osmolarity has been reported to return to normal, and the variability found prior to treatment is reduced. Finally, the authors stated that many new therapeutic approaches are under development, including anti-inflammatory agents, secretory stimulants, tear film stabilizers, and others. With incorporation of improved endpoints for clinical trials, it’s likely that a variety of therapeutic agents will emerge in the foreseeable future.

Taking a simpler approach, a group of European dry eye experts (ODISSEY European Consensus Group) met to come up with a consensus approach to the diagnosis and severity grading of dry eye disease (Baudouin et al, 2014). The authors stated that due to its multifactorial nature, clinical and biological signs of DED can be inconsistent and sometimes discordant with symptomatology. Using a consensus-based approach, the group assessed 14 commonly used DED severity criteria. The panel agreed that following confirmed DED diagnosis, just two crite-
Evolving Technologies in the Diagnosis of Dry Eye Disease

A review of currently available and emerging technologies utilized in the diagnosis and evaluation of dry eye disease was recently published. In addition to a group of commonly performed diagnostic tests and procedures, the authors reviewed a number of new technologies in development (Zeev et al, 2014). Optical coherence tomography (OCT) of the anterior segment is able to measure the inferior tear meniscus height with the advantage of being objective, reproducible and non-invasive. A developing system for tear meniscus height measures utilizes reflective meniscometry. Measured with a slit lamp-mounted instrument, this technology seems to be as reliable as OCT—but much less expensive. Tear film stability can be measured using modified videokeratography systems. The software analyzes dynamic changes in tear film stability over a 10 second time period and quantifies the results with measures of surface regularity and surface asymmetry. Similarly, aberrometry is being used to evaluate dry eye influences on higher order aberrations (HOAs), both in terms of overall degrees of HOAs as well as dynamic changes in HOAs over specific time periods. Tear film interferometry measures the lipid layer thickness, which is reduced in cases of MGD and EDE. Some instruments such as LipiView (Tear Science) can quantify lipid layer thickness while other less expensive systems such as the Keratograph 5M (Oculus) can record video images of the lipid layer, and via subjective observation of the birefringence color pattern, lipid layer thickness can be estimated. Meibomography allows the clinician to view the meibomian glands (MGs). A number of systems (such as the Keratograph 5M) have been developed and grading scales determining the degree of MG loss (atrophy) have been proposed. Biomarkers in the tear film can be measured clinically to provide diagnostic information regarding ocular surface disease. For example, the recently introduced InflammaDry test (Rapid Pathogen Screening) detects elevated levels of matrix metalloproteinase-9 in the tear film, which is an inflammatory biomarker common to dry eye. Measurements of lactoferrin and IGE in the tear film as measured by the TearScan Microassay System (Advanced Tear Diagnostics) can help the clinician differentiate allergic eye findings from dry eye or determine that both are present. Ocular surface and tear film temperature diurnal variations have been shown to be greater in dry eye disease as compared to normal eyes. Ocular surface thermography systems have been introduced that may have diagnostic value in DED.

MGD, Dry Eye and Contact Lens Wear

The relationship between MGD and dry eye has been conclusively shown to be strong. In fact, the authors of the International Workshop on Meibomian Gland Dysfunction state that MGD is now considered the leading cause of dry eye (Nichols et al, 2011). Ongoing research into MGD is allowing us to better diagnose and treat this condition.

Recently, researchers in China again confirmed the relationship between MGD and dry eye (Feng et al, 2014). 264 randomly selected patients (528 eyes) suffering from dry eye disease were enrolled in the study. Tear-film break-up time (TBUT) was measured and tear-film production was evaluated by the Schirmer test I (SIT). Subjective symptoms were also scored. Meibomian glands were observed using a non-contact meibography system. Meibomian dropout was scored for each eyelid. SIT and TBUT were significantly negatively correlated with the meibomian gland photographic score, whereas corneal fluorescein staining was positively correlated. The authors concluded that a large proportion of meibomian dropout cases were found among patients with DED, indicating that treatment targeted at the meibomian gland will continue to be an important direction for treating DED. They felt that meibography is recommended as a routine test for dry eye disease.

A Japanese study evaluated the relationship between contact lens wear and meibomian gland dropout (Arita et al, 2009). A group of contact lens wearers and an age matched group of non-contact lens wearers wearing healthy controls were evaluated with the following tests: slit-lamp examinations of the eyelids, corneal and conjunctival staining using fluorescein, measurement of tear film TBUT, noncontact meibography, and
measurement of tear production using the Schirmer I test. Results showed the meiboscore, which measures meibomian gland dropout, was significantly higher (P<0.0001) in CL wearers than in the control group. The average meiboscore of CL wearers was similar to that of a 60- to 69-year-old age group from the normal population. A significant positive correlation was observed between the duration of CL wear and the meiboscore. Contact lens wear was associated with a decrease in the number of functional meibomian glands and this decrease was proportional to the duration of CL wear.

**Contact Lenses and Dry Eye**

Dry eye symptoms are one of the most common complaints from contact lens wearers and have been reported to be a major reason for discontinuation and dropout from contact lens wear. A multicenter prospective study was conducted that evaluated a group of soft contact lens (SCL) wearers who reported significant SCL-related dryness symptoms (Young et al, 2012). The group was comprised of both patients with definitive ocular signs of dryness and patients with no observable signs of dryness. The symptomatic SCL wearers reported significant SCL-related dryness symptoms via a self-administered questionnaire of frequency and intensity of dryness following a dry eye (DE) physical eye examination. DE etiology was assigned post hoc by an expert panel, and those with and without significant DE-related signs were analyzed by univariate logistic regression. Possible DE etiologies were aqueous tear deficiency, SCL-induced tear instability, meibomian gland dysfunction, or “other.” Wearers without signs that qualified for any DE etiology were designated as No DE Signs (NDES). Results indicated that of the 226 SCL symptomatic wearers examined, 23% were without signs, 30% had evidence of aqueous tear deficiency, 25% had evidence of SCL-induced tear instability, 14% had meibomian gland dysfunction, and 8% had “other” diagnoses. The NDES wearers were significantly more likely to be male (36% vs. 19%, p = 0.013), were less likely to have deteriorating comfort during the day (81% vs. 97%, p = 0.001) and reported longer average hours of comfortable wear (11 ± 3 vs. 9 ± 4 h, p = 0.014). The researchers concluded that symptoms of dryness in SCL wearers stem from a variety of underlying causes. However, nearly one-quarter of these symptomatic SCL wearers appear to be free of clinical signs of dryness. They stated that the effective management of CL-related dryness requires a comprehensive range of clinical assessments and the use of a diverse range of management strategies.

Over the past number of years, there has been a great resurgence in the fitting of scleral gas permeable contact lenses. One of the key proposed indications for scleral lens fitting is for the management of ocular surface diseases. A retrospective study was conducted at a tertiary referral center in order to describe the management of ocular surface disease with commercially available scleral lenses (Schornack et al, 2014). Researchers reviewed the medical records and analyzed a survey mailed to all patients who completed the scleral lens fitting process to evaluate the long-term success of scleral lens therapy in the management of ocular surface disease. Of the 212 subjects, 115 (188 eyes) successfully completed the scleral lens fitting process, and therapeutic goals (improved comfort, ocular surface protection, or resolution of keratopathy) were achieved in all but 2 of these subjects. Visual acuity improved with scleral lens wear when compared to habitual correction. The most common indications for scleral lens therapy were undifferentiated ocular surface disease, exposure keratopathy, and neurotrophic keratopathy. Subjects had attempted an average of 3.2 (range, 0-8) other forms of intervention before scleral lens wear. Scleral lens fitting was completed in an average of 3 visits (range, 2-6), with an average of 1.4 lenses/eye (range, 1-4). Three patients experienced complications during scleral lens wear that resolved without loss of visual acuity, enabling resumption of scleral lens wear. The conclusions of this study are that commercial-
The Impact of Dry Eye on Visual Performance

A significant number of patients experience dry eye disease (DED) and seek relief of their dry eye symptoms. Beyond the subjective symptoms of DED, what do we know about the effect of DED-related visual disturbances on our patients’ daily activities?

Between 5-30% of individuals are estimated to have DED (McCarty et al, 1998; Lin et al, 2003). DED can be challenging for not only the patient but for the eye care professional diagnosing and implementing treatment due to the lack of correlation between signs and symptoms (Nichols et al, 2004). There is not one specific test that definitively confirms a DED diagnosis. Tear film instability (Tutt et al, 2000; Montes-Mico et al, 2004; Begley et al, 2006) and a decreased tear break-up time can cause transient visual disturbances, while centrally located superficial punctate keratitis can result in constant symptoms that include decreased visual acuity (Huang et al, 2002) and decreased reading speed (Ridder 3rd et al, 2013).

Eye care providers strive to find an appropriate balance when factoring in patient signs and symptoms to properly diagnose and treat their patients. Visual symptoms for dry eye patients can vary dramatically in frequency and severity. The differences in visual demands, which are unique to each patient, make it difficult to test patients under their specific conditions in an exam room setting. However, this should not discourage you from obtaining a thorough history to determine the conditions in which your patients are most bothered by visual disturbances and their impact on the patient’s daily life. A patient may report blurred vision, yet is able to read 20/20. How might this influence their work performance?

The Economic Burden

A recent study conducted in Japan evaluated work productivity and performance in those without DED, probable DED, and definite DED (Uchino et al, 2014). Total workplace productivity loss was slightly greater in those with definite DED (4.82%) compared to those without DED (3.56%). Factoring in the average annual salary of the employees affected by DED, they estimated wage losses of $1,178 with overall company production losses averaging $6,160. Reductions in time management and both mental and interpersonal function were also found to be related to DED, demonstrating that the impact of patients’ symptoms on everyday life can be dramatic. By understanding and treating your patient’s symptoms, we are not only making them more comfortable but also potentially reducing workplace productivity loss. What about the influence of DED on non-work activities?

Dry Eye Disease and Daily Life

Driving response times are slower in patients with DED than those without DED (Deschamps et al, 2013). Response times have been shown to be correlated with corneal higher-order aberrations, indicating that disruptions in the tear film may play a factor in driv-
The effect of DED on visual function is more likely to be observed when functional factors such as reading speed are evaluated.

Tions in visual acuity during your examination? While DED can disrupt the tear film, patients are able to blink and re-establish the tear film momentarily during these tasks so that you do not detect a reduction in visual acuity (Ridder 3rd et al, 2013). However, the effect of DED on visual function is more likely to be observed when functional factors such as reading speed are evaluated. Average reading speed for DED patients (134.9 words per minute) have been shown to be slower than for normal patients (158.3 words per minute), demonstrating the functional effect of DED on daily visual tasks. How can you be most effective and efficient at understanding the symptoms of this type of patient?

Application in the Clinical Setting
Understanding specific situations in which patients have been shown to experience visual disturbances due to DED allows you to ask targeted questions (e.g., questions related to reading, driving, use of electronic devices, etc.). This can help you better understand the patient who reports sometimes vague issues regarding visual performance but has 20/20 Snellen acuity. Questionnaires can also be administered by your staff to quickly address specific DED-related questions. Being able to review the patient’s responses prior to your examination allows for a more efficient and targeted patient history. DED patients are more likely to report difficulties with reading (odds ratio [OR] = 3.64), watching television (OR = 2.84), completing professional work (OR = 3.49), and driving during the day (OR = 2.80) and night (OR = 2.20) on surveys (Miljanovic et al, 2007). At follow-up visits, patients can complete the same questionnaires to assess for improvements in these areas after treatment.

In summary, studies demonstrating a relationship between symptoms and daily tasks can aid in asking targeted questions about difficulties that your dry eye patients may experience but do not know how to report during an eye examination. Understanding these relationships can allow you to more effectively identify DED-related issues so that you can quickly diagnose and treat these patients. CLS

For references, please visit www.clspectrum.com/references.asp and click on document #SE2014.
Patient Characteristics Affect Multifocal Lens Performance

It’s common to consider lens design features when choosing a multifocal contact lens, but individual patient characteristics should be considered as well. Most contact lens fitters understand the importance of pupil size and how it impacts the information received by the visual system through a simultaneous vision multifocal contact lens. Pupil size is one of the primary reasons it’s best to over-refract a simultaneous vision multifocal lens using loose lenses. Over-refracting behind a phoropter likely will lead to relative pupil dilation compared to what would be present in a more natural environment.

Although pupil size decreases with age, the change in size with illumination follows a similar slope for all age groups (Plainis et al, Oct. 2013). It is therefore important to consider light level when assessing multifocal contact lens performance on presbyopes of all ages.

Advancing age offers some benefits in that at least one study found subjects with small pupils to have better near vision than their counterparts when wearing a center near soft multifocal lens design (Plainis et al, Jan. 2013).

Spherical Aberration
The good news for the more advanced presbyope with regard to pupil size is tempered, at least somewhat, by changes in ocular spherical aberration over time. The same study that evaluated the impact of pupil size on visual performance of a center near soft multifocal lens also found a decrease in near acuity with higher levels of ocular spherical aberration, which, unfortunately, increases with age.

Degree of Presbyopia
Of course, where the patient is along the presbyopic spectrum has a huge impact on the performance of simultaneous vision design multifocal contact lenses. One study evaluated the performance of three different soft multifocal designs (Acuvue Oasys for Presbyopia, Air Optix Aqua Multifocal, Biofinity Multifocal) on a group of low add (ages 40 to 45 years) patients (Vasudevan, 2013). No statistically significant differences in accommodative response, measured optical aberrations, or in visual performance were found between the lenses.

However, with advancing presbyopia, there is greater likelihood that distance and near correction will interfere with each other. This commonly requires biasing one eye for distance and the other for near to meet most of the patients’ visual needs with a multifocal contact lens. Ocular dominance can play a role in determining which eye is biased for distance and which for near.

Ocular Dominance
Many contact lens providers assess ocular dominance by asking patients to line up an object while looking through outstretched hands, a tube, a camera, or some other similar device. This form of testing determines sighting dominance, which is a measure of how the body is wired, similar to identifying the dominant hand (right or left). Schor and colleagues (1987) found ocular dominance determined via this method has little correlation with monovision or multifocal lens success.

However, evidence supports an approach that assesses dominance by introducing plus in front of each eye separately, under binocular conditions, then determining which disturbs distance vision more significantly (Robboy et al,1990; Collins and Goode,1994; Handa et al, 2005). The dominant eye is the one more bothered by the plus in front of it. Place the near biased multifocal contact lens on the other, more “tolerant,” non-dominant eye.

Adaptability
We all recognize that some patients are more visually sensitive than others. Those with a more adaptable visual system tend to...
Using Peroxide With GP Lenses

Hydrogen peroxide disinfection offers benefits over other care systems. It consists of a 3% hydrogen peroxide solution, typically accompanied by a neutralizing tablet or disc. It has been found to be safe, effective and preservative-free (Henry and Do, 2014). It produces a free radical superoxide that is toxic to microbes (Ward, 2013). And, whereas other systems often demonstrate incomplete effectiveness against Acanthamoeba, hydrogen peroxide has been shown to be effective against both the trophozoite (Hughes & Kilvington, 2001) and cyst (Mowrey-McKee & George, 2007) forms of Acanthamoeba. It is also an effective cleaner due to its low ionic composition and hypotonic nature. It has the ability to lyse proteins and lipids from the lens surface while also penetrating microbial biofilms (Gromacki, 2012).

Because the active disinfectant ingredient is hydrogen peroxide and not a preservative, it is a good system for both dry eye patients and those who are hypersensitive. All of these attributes also would be beneficial for individuals who aren’t particularly compliant with lens care.

Hydrogen Peroxide and GPs?

However, do these benefits make hydrogen peroxide systems effective for rigid gas permeable (GP) lenses? The answer is yes. Peroxide’s ability to act as a disinfectant and remove protein buildup on GP lenses is advantageous (Gromacki and Ward, 2013). Because GP lenses don’t absorb a significant amount of the storage solution, patients can safely rinse this solution from the surface with a morning saline rinse prior to insertion.

Hydrogen peroxide is one of the preferred modalities in 48% of respondents to a scleral lens survey by Eef van der Worp for his I-Site newsletter (2010) and was the preferred modality in 23% of respondents in a CL Today Quick Poll on scleral lens care (Nichols and Gromacki, 2013).

Peroxide Systems Available

Presently there are two hydrogen peroxide systems cleared by the FDA for use with GP lenses: PeroxiClear from Bausch + Lomb and Clear Care Cleaning & Disinfecting Solution from Alcon. Both are one-step systems.

In March 2014, Bausch + Lomb introduced the PeroxiClear hydrogen peroxide system indicated for use with all lenses, including GP lenses. This solution is a unique formula that contains Triple-Moist Technology, which claims to provide up to 20 hours of moisture according to Bausch + Lomb. PeroxiClear has a shorter neutralization cycle (4 hours) than Clear Care. The Clear Care peroxide system requires a 6-hour soak. It contains Pluronic 17R4 as a cleaning agent.

Both systems contain a platinum disc attached to the lens case that will initiate the neutralization of hydrogen peroxide process immediately after insertion of the lens into the case, but the neutralization occurs at different rates for each solution.

B+L recommends that users discard the bottle and lens case 90 days after opening or after 35 uses, whichever comes first. Clear Care packaging recommends users dispose of the old case with each new purchase of Clear Care.

Regardless of the system used, a digital cleaning step is recommended by both manufacturers prior to disinfection.

Peroxide Works With GP Lenses

The traditional use of hydrogen peroxide disinfection for GP wearers who have dry eye or preservative sensitivity is likely to increase as a result of both a new system indicated for GP lenses as well as the increasing popularity of scleral lens designs. With the benefits of effective lens disinfection and cleanliness, hydrogen peroxide should be considered a viable — if not preferred — lens care option for your new and existing GP wearers.
Characteristics of a New Silicone Hydrogel Contact Lens

In the past few years, new silicone hydrogel contact lens introductions have been limited to the daily disposable category. In fact, it has been several years since a new monthly or semi-monthly silicone hydrogel product had appeared, until the spring 2014 launch of the new Bausch + Lomb Ultra contact lens with MoistureSeal technology.

Bausch + Lomb Ultra contact lenses have several unique material innovations. Compared to hydrogel lenses, silicone hydrogel contact lenses are significant because of the oxygen permeable characteristics of silicone. To achieve the goal of increased oxygen transmission and the related health benefits for the cornea that silicone allows, other less desirable characteristics of silicone must be accounted for. Silicone is a stiffer, higher modulus material with very poor wetting characteristics. The lens design team is challenged to overcome these negative attributes in an attempt to achieve an ultimate balance of health, wettability, comfort, vision, and handling.

One of the unique aspects of the Bausch + Lomb Ultra (sam-ficon A) material involves the make-up of the silicone component. Rather than having a single silicone material incorporated into the silicone hydrogel product, Bausch + Lomb Ultra utilizes a combination of three distinct types of silicone. The lens takes advantage of slightly different attributes of the three silicone materials. By finding the optimal mix of three different silicones, the material is able to provide a balance of high oxygen transmissibility and low modulus.

The second significant innovation related to Bausch + Lomb Ultra contact lenses involves the polymerization process. In a unique two-phase curing process, the silicone components polymerize first in the mold when subjected to specific radiant energy. This forms a basic structure or framework for the eventual silicone hydrogel contact lens.

In a time-delayed second phase, polyvinylpyrrolidone (PVP) is then polymerized through and around this silicone lattice-like framework. The lens designers tell us that this allowed significantly more PVP to be incorporated into the silicone hydrogel, which should result in enhanced moisture retention characteristics for the material.

The final result of the material and manufacturing science efforts is a 46% water content silicone hydrogel lens with one of the lowest modulus values in the monthly silicone hydrogel category. The Dk/t is 163 at the center of a -3.00 diopter lens, which has a center thickness of 0.07 mm. The lens is produced with a 14.2 mm diameter, and has an 8.5 mm base curve. The edge design shows a tapered, relatively thin profile.

The Bausch + Lomb Ultra contact lens employs aspheric optics designed to correct the average spherical aberration of the eye, similar to other lenses made by the company.

Bausch + Lomb has introduced the lens as a monthly replacement contact lens. Currently, the FDA has granted clearance to Bausch + Lomb Ultra for daily wear. Power availability will be from +6.00 to –12.00 D, in 0.25D steps for most of that range, but 0.50D steps above –6.00D.

The result of polymer chemistry, manufacturing and lens design innovations, the Bausch + Lomb Ultra silicone hydrogel monthly replacement contact lens should be a welcome addition to the contact lens market. Achieving the desired balance of health, vision, comfort and handling attributes is not only the goal of contact lens manufactures, but of the practicing contact lens fitter as well. CLS

Dr. Pence serves as associate dean, Clinical and Patient Services, Indiana University School of Optometry in Bloomington, Ind. He is a consultant or advisor to B+L, Alcon, and Vistakon and has received research funding from AMO. You can reach him at pence@indiana.edu.
Ocular Surface and Tear Film in Contact Lens Discomfort

In the fall of 2013, the Tear Film and Ocular Surface (TFOS) Society published The TFOS International Workshop on Contact Lens Discomfort (CLD) report (Nichols et al, 2013). This international consensus follows two prior workshops, the Dry Eye Workshop (DEWS) and the Meibomian Gland Dysfunction (MGD) Workshop.

These workshops constructed an evidence-based approach for evaluating their target subjects. And, equally important, they proposed direction for continued information and data gathering in areas showing promise for identifying the elusive mechanisms core to clinical dysfunctions.

Questions Answered
The CLD Workshop was charged with addressing the following concerns: Why do contact lens wearers develop discomfort? How is CLD defined? How can we classify it? Who gets CLD? How does CLD happen? How do we manage CLD? How do contact lens materials, designs, and care impact CLD? How do we design clinical trials to answer these questions?

Subcommittees of the CLD Workshop investigated how, or if, contact lens interactions with the ocular surface and tear film contributed to lens-wearing discomfort, or rather “adverse ocular sensation”—that is, dryness, irritation, discomfort, fatigue, and so on — during lens wear.

Findings
Interestingly, in an evidence-based review, there was no significant association with morphologic changes in the corneal epithelium (barrier function, staining) or corneal hypoxia with CLD. Of note, the conjunctiva, both bulbar and marginal (the leading edge of the palpebral conjunctiva as it moves across the contact lens surface, or “lid-wiper”) proved to be a tissue more closely linked to the development of CLD.

Additionally, contact lens wear does appear to affect the morphology and function of the meibomian glands. Furthermore, the frequency of meibomian loss is higher in contact lens wearers compared with non-lens wearers. Thus, contact lens wear may result in MGD.

Tear film changes occur with the introduction of a contact lens to the ocular surface. Consider that the presence of a contact lens on the eye divides the tear film into a pre- and postlens tear film, creating new ocular interfaces within the ocular environment. The direct biophysical impact of the resultant decreased tear film stability, increased tear evaporation rate, reduced tear film turnover and tear ferning are associated with CLD. (Tear ferning is the branching crystallization pattern of tear fluid once collected and dropped on a microscopy slide and allowed to dry; ferning is an indication of tear functionality).

Does contact lens wear cause dry eye or does dry eye cause contact lens discomfort? There is much to discover about the dynamic interplay of the ocular surface and a contact lens. The CLD Workshop report is a compendium of what we know and a guide to follow as we search for more answers in CLD and ocular surface disease. CLS

For references, please visit www.clspectrum.com/references.asp and click on document #SE2014.

Dr. Mastrota is secretary of the Ocular Surface Society of Optometry and center director at the New York office of Omni Eye Services. She is a stock shareholder of TearLab Corporation and a consultant or advisor to Alcon, Allergan, B+L, Nicox, OcuSoft and Sarcode Bioscience. Contact her at katherinemastrota@msn.com.
New Option for Peroxide Disinfection

Peroxiclear is a new entrant to our peroxide-based contact lens disinfectant armamentarium. It’s a one-step 3% hydrogen peroxide ($\text{H}_2\text{O}_2$)-based cleaning and disinfecting system, which claims to keep lenses cleaner and moister for longer periods with complete disinfection and neutralization in a 4-hour time frame.

Chemistry

Peroxiclear contains Bausch & Lomb’s Triple-Moist technology, which employs three moisturizing ingredients: poloxamer 181, propylene glycol and carbamide. Poloxamer 181 is unique to this product. It’s a surfactant that persists on lens surfaces and helps to attract and spread moisture over the surface of the contact lens.

Propylene glycol (PG) is a surfactant, wetting agent and dispersant and is a common component in artificial tears. PG mixes completely with water and can hold approximately 2.8 times its weight in water (Bausch & Lomb, Patent EP0969812A1, 2000).

Carbamide functions as both a moisturizing agent and a platinum-modulating agent (PMC) (Millard et al, 2014). As a PMC, it reversibly binds to the platinum on the neutralizing disc, slowing the initial rate of neutralization of hydrogen peroxide.

This process allows a higher concentration of peroxide over a longer time frame, which effectively strengthens the antimicrobial activity of the system.

The platinum disc catalyzes the breakdown of $\text{H}_2\text{O}_2$ into oxygen and water. As this reaction proceeds, the platinum disc neutralizing site reverts to solution and lens surface, increasing availability of peroxide molecules to interact with platinum disc neutralizing sites.

Peroxiclear has a disinfection and neutralization time of 4 hours. This 3% $\text{H}_2\text{O}_2$/platinum disc neutralization system claims 99.9% disinfection efficacy, which is consistent with other one-step peroxide-based systems. Peroxiclear is preservative free.

Peroxide Disinfectants

Hydrogen peroxide disinfecting systems offer antimicrobial efficacy without the use of preservatives. Microfiltered, stabilized and buffered 3% hydrogen peroxide is the disinfectant in peroxide-based systems, which are effective against a wide variety of organisms, such as bacteria, fungi (including spores and yeasts), viruses and some protozoa.

Hydrogen peroxide destroys pathogens by oxidation, creating the free radical superoxide, which is toxic to DNA. Peroxides denature proteins, thus damaging necessary microbial cell structures (Ward, 2006).

The hydrogen peroxide in these systems must be neutralized prior to lens wear because unneutralized peroxide is toxic. A concern with any hydrogen peroxide disinfection product is the potential for contamination of lenses stored in previously neutralized peroxide solution. Although hydrogen peroxide systems have high antimicrobial efficacies at full strength, once neutralized, they become unpreserved aqueous bathing solutions, capable of supporting microbial growth.

That said, peroxide systems work fine if used on a daily basis. They are approved for 7 days of storage, but patients should pay attention to the inside of the lens case cap as little or no disinfection occurs on this surface. Patients can disinfect the cap by rinsing it with fresh peroxide.

Remember to instruct patients to always follow the instructions of each individual care system.

CLS

For references, please visit www.clspectrum.com/references and click on document #SE2014.
1. A total of 300 eye care practitioners asked patients to use Biotrue. 811 self-identified OPTI-FREE RepleniSH users used Biotrue for at least 3 days and responded to an online survey.

2. Results of a U.S. in vitro study performed to evaluate the rate of release of wetting agents from various silicone hydrogel lens materials over a period of 20 hours.

3. Results of an in vitro study following FDA/ISO stand-alone procedure for disinfecting products modified with organic soil added to create a more rigorous test condition. Primary criteria for effective disinfection are defined as a reduction in the number of microorganisms by a minimum of 3 logs (99.9%) and a reduction of mold and yeast by a minimum of 1 log (90%) within the recommended disinfection time.

4. Results from a 22-investigator, multi-site study of PeroxiClear™, with a total of 440 eligible subjects. Subjects were asked to use either PeroxiClear™ or Clear Care for 3 months. Subjects completed performance surveys at 2-week, 1-month, 2-month, and 3-month visits.

5. Results from a 21-investigator, multi-site study of PeroxiClear™, with a total of 297 eligible subjects who were habitual Clear Care users. After 7 days of use, subjects completed an online survey. Consumers rated the performance of PeroxiClear™ across a range of attributes and compared the performance to their habitual Clear Care solution.

6. High-resolution/accurate-mass (HR/AM) mass spectrometry was used to detect and quantitate the relative amounts of surfactant retained on lenses from PeroxiClear™ and Clear Care solutions after 20 hours of wear. PureVision ® 2, ACUVUE OASYS, and AIR OPTIX AQUA lenses were soaked in solutions for 12 hours prior to patients wearing lenses for 20 hours.

7. Results of an ex vivo study measuring deposits on worn contact lenses to compare the clinical performance of PeroxiClear™ and Clear Care solutions. Lenses were worn daily for 1 month (silicone hydrogel and Group IV hydrogel lenses) or 3 months (gas permeable lenses). A total of 374 lenses were randomly selected for image analysis. Lenses were scored for mean density of deposits and percent coverage of deposits.

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**Exceptional Lens Care Solutions from Bausch + Lomb**

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- pH balanced to match healthy tears
- Kills 99.9% of germs

**Peroxide**

PeroxiClear™
- 3% Hydrogen Peroxide Cleaning & Disinfecting Solution
- Excellent All Day Comfort
- Moisturizes Lenses All Day
- Maximum Cleaning Power
- Disinfects in Only 4 Hours
- Preservative Free

**Rigid gas permeable**

Boston ADVANCE® Conditioning Solution
- For Rigid Gas Permeable Contact Lenses
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9 OUT OF 10 Prefer Biotrue® over the leading multi-purpose solution*

The most advanced* peroxide
* Compared to Clear Care

#1 doctor recommended RGP brand*
* Symphony Health Solutions, data on file.
REFERENCES:

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Contact Lens Discomfort Defined

Each year, patients in our practices are struggling with lens wear, and in some cases, dropping silently out of lens wear. How do we get to the bottom of this problem?

Contact lens discomfort (CLD) is a frequently reported symptom of patients wearing contact lenses and a primary reason for contact lens “drop out” (Dumbleton et al, 2013; Richdale et al 2007; Young et al 2002). Reported rates of contact lens “drop out” range between 23-34% (Dumbleton et al, 2013; Richdale et al, 2007; Pritchard et al, 1999). To summarize, half of your contact lens patients experience frequent discomfort, and on average, one of every four drop out of lens wear entirely, which can significantly impact your practice bottom line. We practitioners who fit contact lenses may consider changing the patient’s lens material, replacement schedule, wearing time, lens care solution, adding additional therapy, or a combination of the above as possible treatment options to appropriately address the patient’s needs. However, there is a lack of literature detailing the classification, definition, and etiology, which are needed for the appropriate treatment and management of CLD. Thus, the Tear Film and Ocular Surface Society (TFOS) conducted an International Workshop on Contact Lens Discomfort to address topics related to CLD and provide an appropriate foundation for further research, diagnosis, treatment, and management of CLD with an ultimate goal of keeping patients successful contact lens wearers. The Executive Summary along with the entire report can be found in the October 2013 issue of Investigative Ophthalmology & Visual Science (IOVS) (Nichols et al, 2013).

Defining Contact Lens Discomfort

To provide a detailed description of the condition that can also be utilized for future work, the TFOS Workshop developed the following definition for CLD:

“Contact lens discomfort is a condition characterized by episodic or persistent adverse ocular sensations related to lens wear, either with or without visual disturbance, resulting from reduced compatibility between the contact lens and the ocular environment, which can lead to decreased wearing time and discontinuation of contact lens wear” (Nichols et al, 2013).
The Defintion and Classification Report classified CLD into two main categories, discomfort related to the “contact lens” and/or the “environment” (Nichols et al, 2013). The contact lens category is further separated into 4 subgroups, “contact lens material, contact lens design, contact lens fit and wear, and lens care,” while the four subgroups of environment are “inherent patient factors, modifiable patient factors, ocular environment, and external environment.” While some of these factors have been more thoroughly investigated or validated than others, it is necessary to develop an understanding of the role each of these factors has on CLD with future studies. Previous studies evaluating contact lenses that differ by only one factor, such as water content, have been lacking in the literature, in part due to the difficulty in separating material factors. Patient factors and environmental factors have been studied to some degree, although not in a systematic way. There is much work to be done.

By definition, CLD symptoms diminish or cease after contact lens removal. Thus, this workshop summary was not focused on underlying dry eye in contact lens wearers. Reported symptoms from patients with contact lens dry eye may be similar to CLD, but these symptoms are present with and without contact lens wear, thus the terminology should not be used interchangeably.

A patient’s progression with CLD is also outlined within the report. First, an initial awareness of symptoms and difficulty with lens wear (“strugglers”) can progress to reduced comfortable and total wear time, which can ultimately result in discontinuing contact lens wear permanently. Consider where your contact lens patients fall on this scale and how you can utilize your clinical expertise and the evidence-based approach of the CLD workshop to prevent them from dropping out of contact lens wear through early identification and appropriate management. The goal of successful contact lens wear should be paramount in today’s clinical practice.

**Identifying Patients With Contact Lens Discomfort**

While CLD symptoms can vary, patients will typically report some type of dryness, irritation, fluctuation in vision, discomfort, or foreign body sensation after contact lens insertion, and these symptoms may increase in frequency and severity throughout the wear time. This cycle typically continues every day. Obtaining a thorough history from the patient is crucial with appropriate questions or factors to consider including the patient’s age, gender, medical history, and medications, onset and frequency of symptoms, previous and current lens material and care system(s). Important questions to determine where a patient is in the progression toward discomfort include total wearing time and comfortable wearing time. Are both of these enough for the patient? If a patient has tried every care system and many different lenses, he is at much higher risk of discontinuing contact lens wear. Lens replacement schedule, usage of topical eye drops or other therapies, compliance, and environmental concerns also can provide direction in crafting an appropriate management plan.

Even if a patient is symptomatic, there may be a lack of signs to correlate with these symptoms. Therefore, when treating and managing these patients, relying on the patient’s symptoms is important as this can be the driving force for the patient ultimately choosing to continue with contact lens wear. Questionnaires such as the Contact Lens Dry Eye Questionnaire (Nichols et al, 2002), the Ocular Surface Disease Index (Schiffman et al, 2000), or the Standard Patient Evaluation of Eye Dryness survey (Ngo et al, 2013) may be useful tools to incorporate into your practice. Staff members can administer and grade these questionnaires to assist you in identifying or monitoring patients who may be at risk for CLD.

**Contact Lens Materials, Design and Care**

There are many factors that we as practitioners consider when choosing an appropriate lens material, assessing the lens fit, and choosing a suitable lens care solution for our patients. Based upon current knowledge and studies reported in the literature, it is dif-
CONTACT LENS DISCOMFORT

Difficult to determine the true role that contact lens materials and design (lubricity, surface treatments, water content, modulus, Dk/t, and so on) and lens care have on contact lens discomfort. However, the lens edge design can impact a patient’s level of comfort and result in clinical signs. Further discussion on this later.

Although there is no true agreement on the optimal composition of a lens care solution in terms of improving comfort, patient education remains crucial. Patients must be instructed not only how to most effectively use their solution but also proper contact lens wearing and replacement schedules. Revisiting this issue with staff who routinely train patients can promote compliance.

Impact on the Ocular Surface and Adnexa
While some corneal (hypoxia, stromal infiltrates, neovascularization, endothelial changes), conjunctival (bulbar hyperemia), or limbal changes may lead to changes in your treatment and management of the patient, there have been no direct associations between these factors and contact lens discomfort. However, there appears to be a stronger link with the bulbar conjunctival staining and “lid wiper” changes assessed with lissamine green. Sodium fluorescein instillation may be more commonly used in clinical practice to assess corneal staining, tear break up time, etc., the use of lissamine green can provide valuable information related to the severity and pattern of conjunctival staining. Additionally, as reported in the literature, changes to the “lid wiper” area have also been related to CLD. Although sodium fluorescein instillation may be more commonly used in clinical practice to assess corneal staining, tear break up time, etc., the use of lissamine green can provide valuable information related to the severity and pattern of conjunctival staining. Additionally, as reported in the literature, changes to the “lid wiper” area have also been related to CLD.

The true role of lens deposition and its impact on contact lens discomfort remain unknown, but this should not discourage practitioners from changing lenses, care solutions, or other therapies if lens deposition is resulting in other issues for the patient.
tion of the meibomian glands. Arita and coworkers have used infrared meibography to associate gland loss with years of lens wear (Arita et al., 2009). These studies will be useful in determining which comes first in this chicken-and-egg argument.

In summary, the meibomian glands and LWE have been shown in the literature to have a stronger connection to CLD than other areas of the ocular surface and adnexa (Henriquez and Korb, 1981; Korb et al., 2002). Lissamine green testing is quick and provides little to no discomfort to the patient while potentially providing valuable information as you’re managing a patient with contact lens discomfort. Further research investigating the association between CLD and the meibomian glands or LWE to better understand their role in CLD is worthwhile and needed.

Contact Lens Wear and the Tear Film
A pre-and post-lens tear film is created after the application of a contact lens. This disruption of the tear film has been shown to negatively impact the evaporation rate and stability of the tear film, and these factors have been associated with CLD (Fonn et al., 1999; Glasson et al. 1999; Kojima et al., 2011). Despite these changes to the tear film that occur with contact lens insertion, there are successful contact lenses wearers, and thus, it is important to consider that there are multiple factors on the ocular surface that contribute to these changes and the patient’s symptoms, as well as factors that determine success (Craig et al., 2013). In the future, we believe we will continue to see lens materials and care systems designed to have minimal impact on the normal tear film and even help prevent lens material dehydration. This may result in better stability of the tear film with lens wear, which will provide practitioners with additional options to reduce CLD symptoms in patients while also providing better and more stable vision.

Treating and Managing Your Patients with CLD
Although a contact lens patient may report symptoms of discomfort, we must also consider that there are other potential non-contact lens-related factors or etiologies of this discomfort. It is important to appropriately treat and manage these factors, which can help you determine whether the discomfort is truly contact lens-related (Papas et al., 2013).

The CLD report reviewed the existing literature surrounding management of discomfort with contact lens wear. While the terminology used in defining subjects for the multitude of studies varied, some common themes emerged (Papas et al., 2013). After treating any other underlying conditions, switching the contact lens material may be chosen as a treatment option. In a rigid lens patient, consider changing to a lens with a steeper base curve in a soft lens patient and using a larger diameter lens as this may provide some relief of symptoms. Additionally, switching to a daily disposable contact lens may provide some improvement in CLD. (Solomon et al., 1996; Cho and Boost, 2013).

While there are some therapies that have been utilized in treatment of dry eye such as artificial tears, fish oil, topical medications, such as cyclosporine A (Kim et al., 2009; Rao, 2010), topical azithromycin (Opitz DL and Tyler KF, 2011; Luchs 2008), and steroids (Pflugfelder et al., 2004), punctal plugs (Ervin et al., 2010), and avoiding certain environments, such as low humidity, and so on (Gonzalez-Garcia MJ, 2007), further research is needed to determine the benefits of these treatments with CLD.

Conclusion
While we still have much to learn about CLD, we now have a definition and classification scheme that provides a foundation on which future research can be focused to help us better understand this condition through the CLD reports (Nichols et al., 2013). Practitioners, researchers, and companies are constantly striving to develop and provide new contact lens materials, lens care solutions, and other treatment options for our patients to reduce or even better prevent symptoms associated with contact lens discomfort. These efforts will ultimately result in more of our patients being successful contact lens wearers.

The meibomian glands and lid wiper epitheliopathy have been shown in the literature to have a stronger connection to CLD than other areas of the ocular surface and adnexa.
References


During thousands of blinks each day, a contact lens wearer’s eyelid slides across the surface of the contact lens. Spreading and maintaining the tear film across the surface of the lens between each blink is important in providing a smooth, slippery surface for reducing friction, sustaining the integrity of epithelial cells, and maintaining quality optics. Alterations in the tear film lead to eye complaints and can have a variety of causes including environmental factors such as low relative humidity or high room temperature, demanding task content such as high demand tasks that reduce blinking and increases exposed surface area, and individual factors such as blinking anomalies and contact lens use (Wolkoff et al, 2005).

The wearing of the contact lens on the surface of the eye alters the integrity of the tear film and changes the evaporation rate (Tomlinson et al, 1982; Korb, 1994; Guillon et al, 2008). Between blinks, the rapid evaporation results in tear film break-up that leads to increases in the local osmolality of the tear film (King-Smith et al, 2008). Increased tear film osmolality that results from tear film thinning (evaporation or dewetting) is believed to be the cause of contact lens–related dry eye (Nichols, 2006). Today, contact lens wearers spend greater amounts of time using digital devices. To fill the void in the market for a contact lens that can meet the changing demands of patients in an increasingly screen-centric world, new approaches to material development are required.

Hydrogel contact lenses have polymer networks with varying water-binding characteristics. An effective barrier that retards the evaporation of the tear film is important for a slow tear film thinning rate. A long standing challenge of silicone hydrogel materials has been associated with the hydrophobic nature of silicone. The inclusion of silicone into contact lens materials improves the oxygen permeability of the material; however, increased levels of silicone result in increased hydrophobic properties of the bulk and surface chemistry for the lens material. As contact lens material science advanced, methods to make...
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silicone hydrogels more wettable progressed from modification of the surface with plasma treatments to adjusting the bulk chemistry of the material by adding wetting agents. In parallel, advancements in manufacturing capability were needed to compliment new materials to help ensure the lens is biocompatible and stable over a designated period of lens wear and lens care.

Unique Chemistry & Polymerization Process
To dramatically improve the effects of material and surface interaction, more complex strategies must be applied. This includes development of materials that withstand a range of user conditions and refinement of designs and geometries that minimize the impact of friction and wear. MoistureSeal technology, as part of the Bausch + Lomb Ultra contact lens material (samfilcon A), represents a significant achievement in integrating novel material chemistry and a two-phase manufacturing process to produce a unique silicone hydrogel lens designed to address the cycle of discomfort many wearers encounter each day and enhance the overall lens wearing experience particularly at the end of the day.

MoistureSeal technology uses a unique reaction sequence that starts with the formation of a silicone matrix (with high Dk/t and low bulk modulus) followed by the time-delayed addition of internal, permanent wetting agents to drive water content and surface wettability. In Phase 1 of the polymerization process, a unique combination of long and short chain silicone polymers creates a flexible silicone matrix with channels for oxygen transmission. The long chain silicone provides low modulus while the short chain silicones provide the majority of oxygen transport capability and structural integrity (for great handling characteristics).

In Phase 2 of MoistureSeal technology, polyvinylpyrrolidone (PVP), a humectant that is highly soluble in water, physiologically compatible, non-toxic, essentially chemically inert, temperature-resistant, pH-stable, non-ionic, and colorless is permanently entangled throughout the silicone matrix. PVP is a very hydrophilic compound that is frequently used in medicine, pharmaceutical technology, and cosmetics. (Foltzmann et al, 2008). In fact, PVP has been used in another silicone hydrogel contact lens (senofilcon A) successfully.

While other lens manufacturers start with fully formed, large PVP molecules and then add silicone (Figure 1 A), MoistureSeal technology starts with the silicone backbone and polymerizes PVP in-situ around and throughout the silicone matrix (Figure 1 B). This process of “growing” the PVP from its molecular building blocks maximizes the utilization of PVP and results in significantly more PVP (4x as much of the wetting agent) than the silicone hydrogel lens material, senofilcon A. Importantly, the manufacturing method that starts with fully formed PVP molecules cannot achieve the same concentration of PVP capable through MoistureSeal technology without sacrificing optical clarity of a lens due to phase separation of the PVP and silicone components. Only MoistureSeal technology allows for 4x more PVP in Bausch + Lomb Ultra contact lenses while maintaining optical clarity (Hoteling et al, 2014).

The water-loving polymer PVP is grown permanently around the silicone matrix in order to “hide” the hydrophobic silicone and to hold water throughout the bulk and at the surface of the lens. The PVP

Figure 1. Different approaches for PVP entanglement: (A) Fully formed PVP integration with silicone (B) PVP grown around a silicone backbone via MoistureSeal Technology resulting in 4x more PVP.
in Bausch + Lomb Ultra contact lenses brings high water and wettability everywhere on the lens and not just at its surface. MoistureSeal technology also helps Bausch + Lomb Ultra contact lenses retain this high level of water throughout the day.

**Surface Wetting and Friction**

A wettable contact lens surface is essential to reduce friction and surface deposition and to improve optical quality and comfort. Two common assessments used to evaluate contact lenses at the surface involve measuring wetting angles and coefficients of friction. These assessments provide insights regarding the interactions between the lens, the tears, and the eyelid when the lenses are worn. When silicone’s hydrophobic structure is more prominent at the surface of the lens, the contact angle and coefficients of friction values are higher (Read et al, 2011; Jacob, 2013). Polymer chemistry and manufacturing processes, such as MoistureSeal technology play an important role in masking the silicone structure for improved wetting.

Captive bubble contact angles were collected for the Bausch + Lomb Ultra, Air Optix Aqua (Alcon), Oasys (Vistakon), Biofinity (CooperVision) and Dailies Total1 (Alcon) silicone hydrogel lenses in order to assess and compare wettability. To remove components of the packaging solution from the samples, lenses were rinsed in HPLC grade water prior to testing. Lenses were placed onto a curved sample holder and submerged into a quartz cell filled with HPLC grade water. Advancing and receding captive bubble contact angles were collected for each silicone hydrogel lens type.

The advancing angle is believed to represent the ability of the tear film to fill in dry patches resulting from the breakup of tears, while the receding angle provides insight on the integrity of the interaction between the surface and the tear (Cheng et al, 2004). A contact angle of 0° indicates complete wetting, values between 0° and 90° indicate the surface is wettable to varying degrees, and values above 90° indicate the surface is not wettable. Advancing and receding contact angle measures indicated surface wetting was similar between Bausch + Lomb Ultra, Air Optix Aqua, Oasys, Biofinity and Dailies Total1 lenses (Figure 2 A).

Blinking is essential for maintaining a healthy ocular surface and clarity of vision. The blink cycle includes a fast phase during closure and a slow phase as the eye reopens (Kwon et al, 2013). As the eye-lid moves across an opposing surface, it encounters resistance. Friction forces of Bausch + Lomb Ultra, Air Optix Aqua, Oasys, Biofinity and Dailies Total1 contact lens materials were investigated using a novel measurement technique that mimics the applied pressure, sliding speeds encountered by a contact lens on the human eye, and controls for variables such as temperature and the surface area of lens and interface interaction.

Coefficient of friction measurements were performed using a rheometer outfitted with specially designed tooling to hold and rub a contact lens immersed in borate buffered saline at 25°C. Static friction was taken as a measure of friction at the start of the blink phase. Fast and slow kinetic friction was taken as measurements during a constant rotation speed test to model friction encountered during lid closure and opening, respectively. Measurements were made using samples of each contact lens either directly out of the package or after being worn on-eye for 4 hours. Forces applied to the lenses in this study mimicked eyelid pressure to be more representative of an in-vivo environment compared to previous studies. The method is highly reproducible and controlled. Methods such as glass ramp techniques that lack standardization when comparing different lens materials, specifically the glass ramp method does not control the speed of the lens across the control surface, nor does it quantify the distance that a lens needs to move down the ramp to achieve constant speed. Constant speed is a critical variable used to accurately measure friction between two surfaces. Additionally, the glass ramp test does not control for the force (or load) applied to the lens since the surface area of lens material exposed to the glass may vary from lens to lens. Furthermore, this method cannot discern between low versus high-speed kinetic friction, which may be important with respect to the blink phase. All of these factors may lead to potentially biased outcomes when comparing different contact lenses when measuring coefficient of friction using a glass ramp test.

**During contact lens wear, friction and wearing down of the surface are undesirable characteristics that can impact the patient experience.**
Mean static and kinetic friction results measured on a rheometer are presented for unworn (out of pack) and worn lenses (Figure 2 B-D). Friction at the initiation of movement was similar for all materials out of the package, except Dailies Total1, which was significantly higher than the other lenses (Figure 2B). After wear, the static friction measure indicated the Air Optix lens and Dailies Total1 had greater resistance. For fast kinetic measures of friction (Figure 2C), the Air Optix lens also demonstrated greater resistance out of package and after wear, while the Bausch + Lomb Ultra, Oasys, Biofinity, and Dailies Total1 lenses showed low friction. The slow kinetic friction measurements demonstrated that all materials have low friction during this phase of the blink cycle (Figure 2D).

Bausch + Lomb Ultra lenses demonstrated low coefficient of friction regardless of the simulated blink speed and performed very consistently even after 4 hours of wear. The high level of wettability and low friction that MoistureSeal technology provides may improve the overall wearing experience of patients.

**Surface Smoothness & Integrity**

During contact lens wear, friction and wearing down of the surface are undesirable characteristics that can impact the patient experience. A smooth, durable surface is essential for spreading the tear film, reducing friction, and providing precision optics. MoistureSeal technology delivers a lens that withstands the rigors of a planned replacement lens wear schedule. To demonstrate the smoothness and durability of the Bausch + Lomb Ultra lens surface, Atomic Force Microscopy (AFM) and X-ray Photoelectron Spectroscopy (XPS) were used to evaluate the morphology, roughness, and elemental composition of new (unworn) Bausch + Lomb Ultra, Oasys, Biofinity, and Air Optix Aqua contact lenses (Wygladacz et al, 2014). The impact of a lens care regimen on surface characteristics was simulated by performing rub/rinse cycles using renu fresh multi-purpose solution (30 cycles for Bausch + Lomb Ultra, Biofinity, and Air Optix Aqua; 15 cycles for Oasys). The AFM assessment provided morphology and surface roughness information and the XPS evaluations provided insights regarding elemental changes at the surface. Mean surface roughness was compared using a t-test between new lenses directly out of the blister to lenses of the same brand/type after simulated wear cycling (p-value <0.05 was considered significant).

Figures 3 A and B illustrate the surface smoothness of an unworn Bausch + Lomb Ultra lens,
Figure 3. AFM surface topography images (40 x 40 μm) of new (A) and cycled (B) Bausch + Lomb Ultra lens surfaces, new (C) and cycled (D) Oasys lens surfaces, new (E) and cycled (F) Biofinity surfaces, and new (G) and cycled (H) Air Optix Aqua lens surfaces.
and the durability of the Bausch + Lomb Ultra lens surface that was unaffected by 30 rub/rinse cycles with an MPS (p=0.145). In addition, the AFM results confirmed the deposition resistance properties of the samfilcon A material as there were no atomic element differences between new and cycled surfaces of the lens.

With each blink, it is essential that the tear film is distributed and maintained across the surface of the lens.

Bausch + Lomb Ultra contact lenses. The Oasys lenses demonstrated a visible change in roughness (Figure 3 C and D) with completion of 15 rub/rinse cycles (p<0.005). The AFM topography images for new and cycled Biofinity contact lenses showed a significant change in surface roughness (p<0.005). New Biofinity lenses had randomly distributed rough and tall domains that were removed and left “pockets” in the surface with rub/rinse cycling (Figures 3 E and F). The AFM topography images of new and cycled Air Optix Aqua lenses demonstrated that the plasma-coated surface was also altered by the 30 rub/rinse cycles (Figure 3 G and H) (p<0.005). The numerous cracks on the surface of cycled Air Optix Aqua lenses resulted in significantly higher concentrations of silicone being detected with the XPS elemental analysis.

The surface analyses demonstrated that even a gentle lens care system can have an impact on the surface morphology and exposure of atomic elements associated with non-wetting chemistry. Oasys, Air Optix Aqua and Biofinity lenses demonstrated statistically significant changes in surface roughness with 15 (Oasys) or 30 (Air Optix Aqua and Biofinity) rub/rinse cycles. The Bausch + Lomb Ultra lenses demonstrated no statistically significant changes in surface morphology, roughness, or elemental composition after simulating 1 month of wear.

Summary

Today, new knowledge gained from advances in materials chemistry and manufacturing processes enables designers to achieve significant improvements in contact lens characteristics. With each blink, it is essential that the tear film is distributed and maintained across the surface of the lens. To enhance the lens wearing experience, a lens must provide a smooth, slippery surface for reducing friction, sustaining the integrity of epithelial cells, and maintaining quality optics. The lens performance must be sustained through varied environmental conditions, during diverse tasks performed by the contact lens user and over the planned replacement period. The combined wetting, friction, durability, dehydration and vision quality testing confirm that the Bausch + Lomb Ultra contact lenses with MoistureSeal technology can provide an improved wearing experience for the contact lens wearer.

References


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Break the Cycle of Discomfort
for unsurpassed comfort & vision all day¹

See what happens when eye care professionals wear them for the first time at www.BLUltra.com

"It's like wearing nothing." — Dr. Greg Usdan, Memphis, TN

REFERENCE: 1. Results from a 22-investigator, multisite study of Bausch + Lomb ULTRA® contact lenses with MoistureSeal® technology, on 327 current silicone hydrogel lens wearers. After 7 days of wear, subjects completed an online survey. Subjects rated performance across a range of attributes. Preference comparisons represent only those subjects expressing a preference. Ratio is based on the average across the silicone hydrogel lenses represented in the study.

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See better. Live better.
For over a decade, there have been dramatic changes in materials and design of soft contact lenses. Clinical performance advancements were typically led by advancements in polymer and surface chemistry and lens design characteristics. Examples include the integration of silicone into hydrogel materials to increase oxygen transmissibility, enhanced surface treatments with plasma or internal wetting agents to improve comfort, and lens design advances to improve vision.

Over this same period, there have been dramatic changes in the way we use our eyes with digital display devices. The types and use of devices with smaller screen sizes have increased, where 55% of American adults report having a smartphone, 42% own a tablet computer, and 32% own an e-reader, Figure 1 (Pew Research, 2014). These devices are designed for reading and use at close range that result in the eyes constantly refocusing and repositioning to process content. With increased concentration associated with visual tasks on digital devices,

New technology aims to make lens wear more comfortable despite increased digital viewing.

By Robert Steffen, OD, MS; Mohinder M. Merchea, OD, PhD, MBA; Marjorie J. Rah, OD, PhD, & William Reindel, OD, MS

Figure 1. Changes in digital display device ownership.
control these variables independently as they can alter polymer formulations and lens designs and then evaluate the clinical impact of each variable. Not surprisingly, an extensive review of the literature revealed that there are few proven links between contact lens discomfort and factors related to current contact lens material, the lens design, or the care system (Jones et al, 2013). Similarly, a thorough review of the research associated with the tear film indicated that no single biophysical component could be singled out as responsible for discomfort (Craig et al, 2013). However, in considering other biophysical interactions, meibomian gland dysfunction and lid wiper epitheliopathy demonstrated the strongest link to contact lens discomfort (Efron et al, 2013).

In a survey of over 800 contact lens wearers, 72% indicated they would be very or quite disappointed if they could no longer wear their contact lens (Gallup, 2013). Therefore, to maintain patient satisfaction with the care provided, it is important for eye care practitioners to help patients continue with their favored vision correction. While a comprehensive assessment and intervention commonly occurs when a patient expresses dissatisfaction, the introduction of new technology offers practitioners the opportunity to address common complaints or provide patients with a more successful experience.

Before adopting new technology eye care practitioners will typically ask about its effectiveness in the real world. By allowing wide patient selection criteria, data collected in a “real world” evaluation captures clinically important information relevant to a particular population or treatment. Real world clinical evaluations can broaden knowledge of patient outcomes and can capture valuable, real-time patient data that is not present in controlled clinical trials. The purpose of this study was to evaluate the performance of the Bausch + Lomb Ultra contact lenses with MoistureSeal technology and advanced aspheric optics when worn by experienced silicone hydrogel contact lens wearers.

**Study Design**
This was a prospective, single arm, open-label clinical study. Independent eye-care practitioners from 22 investigational sites enrolled patients. Institutional review board approval was obtained for the study, and patients signed an informed consent form. To be
NEW PRODUCT

included in the study, patients needed to:
- Spend at least 3 hours each workday using a computer or electronic device (i.e., smartphones, tablets, eReaders)
- Subjects were myopic and required lens correction from -0.25 D to -6.00 D in each eye
- Have worn their current lens brand for a minimum of one year
- Wear their current lenses for a minimum of 12 hours per day at least four days per week
- Be between the ages of 18 and 35 years
- Have <= Grade 1 for corneal and conjunctival assessments (see below)
- Be absent of any corneal infiltrates

At the initial visit, patients rated symptoms associated with their habitual brand of lenses using a 0-100 scale, with 0 denoting the least favorable rating and 100 denoting the most favorable score. To add context, descriptors were added to the rating scale for each category. As an example, the “end-of-day comfort” category designated 100 as “excellent; cannot be felt,” 80 as “very comfortable; just felt occasionally,” 60 as “comfortable; noticeable but not irritating,” 40 as “uncomfortable; irritating or annoying,” 20 as “very uncomfortable; very irritating or annoying,” and 0 as “painful; difficult to wear lenses.”

Practitioners completed a slit lamp evaluation using a five-point scale. Slit lamp signs of epithelial edema, epithelial microcysts, corneal staining, limbal injection, bulbar injection, tarsal conjunctival abnormalities, corneal neovascularization, and corneal infiltrates were graded using an ordinal, text-based scale from which numeric grades in integer steps were assigned, 0 (no finding), 1 (trace), 2 (mild), 3 (moderate) and 4 (severe). Patients with any graded infiltrate were not eligible for participation. For the remainder of graded signs, patients with findings greater than grade 1 were not eligible to participate. Practitioners also collected sphero-cylindrical refraction, slit lamp evaluation, lens centration and movement, and visual acuity (VA).

Patients were re-fitted to Bausch + Lomb Ultra contact lenses with MoistureSeal technology and Biotrue multi-purpose solution for 2 weeks. After the first seven days of product use, subjects responded to a Web-based subjective assessment evaluating comfort, wettability, lens cleanliness, and other compo-

### TABLE 1

| Subject demographics and baseline eye characteristics.a |
|-----------------|-----------------|-----------------|-----------------|
|                 | TOTAL N = 341   | ACUVUE OASYS N = 130 | AIR OPTIX AQUA N = 132 | BIOFINITY N = 79 |
| **Age**         |                 |                 |                 |                 |
| Mean            | 26.8            | 27.4            | 26.5            | 26.2            |
| Min, max        | 18, 35          | 18, 35          | 18, 35          | 19, 35          |
| **Gender (%)b** |                 |                 |                 |                 |
| Female          | 69.5            | 66.2            | 69.7            | 74.7            |
| Male            | 30.5            | 33.8            | 30.3            | 25.3            |
| **Diagnostic refraction sphere,D** |                 |                 |                 |                 |
| Mean/Median     | -3.36/-3.25     | -3.37/-3.00     | -3.23/-3.125    | -3.54/-3.50     |
| Min, max        | -6.75, -0.25    | -6.50, -0.25    | -6.75, -0.75    | -6.50, -1.00    |
| **Diagnostic refraction cylinder,D** |                 |                 |                 |                 |
| Mean/Median     | -0.21/0.00      | -0.21/0.00      | -0.20/0.00      | -0.23/0.25      |
| Min, max        | -0.75, 0.00     | -0.75, 0.00     | -0.75, 0.00     | -0.75, 0.00     |

a Demographics and baseline eye characteristics are reported for eligible, dispensed subjects/eyes.
b Percentages are based on the number of subjects with responses.
c Diagnostic refraction sphere and cylinder are summarized at the eye level, while all other parameters are summarized at the subject level.
ments of satisfaction with daily contact lens wear. Patient questionnaires were completed outside of the practitioner’s office to help ensure a higher level of objectivity.

After 14 days of wear, the patients rated symptoms associated with the Bausch + Lomb Ultra contact lenses. Practitioners once again collected spherocylindrical refraction, slit lamp evaluation, lens centration and movement, and visual acuity (VA: made using logMAR acuity charts). In addition, practitioners provided their perspective on satisfaction overall and ease of fit through an on-line survey.

Statistical Methods
Continuous data was summarized using descriptive statistics: n, mean, standard deviation, minimum, and maximum. The differences in continuous endpoints between study visits were assessed using paired t-tests. The differences in dichotomous categorical endpoints between study visits were assessed using McNemar’s tests. The p-values presented were two-sided, and evaluated using a 0.05 alpha level for each comparison. There were no interim analyses.

RESULTS
Study Subjects
Three hundred forty one silicone hydrogel patients were enrolled: 132 Acuvue Oasys (Vistakon) patients, 130 Air Optix Aqua (Alcon) wearers, and 79 Biofinity (CooperVision) wearers. Table 1 lists study subject demographics and baseline eye characteristics for the total population of dispensed patients and the three habitual lens cohorts. Average age for the study population was 26.8 years with 69.5% being female and 30.5% male. The median refractive sphere and cylinder power was -3.25 D and 0.00 D, respectively. A comparison of habitual contact lens powers to study lens powers indicated that 92.7% of lenses were within +/- 0.25D. The most common branded contact lens care products used prior to entering the evaluation were Biotrue Multi-Purpose (22.6%) and Opti-Free PureMoist by Alcon (16.4%), Table 2.

The average daily wear time with habitual lenses was 13.9 hours. During a typical day, the study population spent an average of 4.8 hours using a computer/laptop at the office and an average of 1.9 hours at home, Table 3. In addition, other digital devices (smartphone/tablet/e-Book) were used an average of 3.1 hours. Playing electronic games was reported to have the least amount of activity of those surveyed.

Table 4 presents the Snellen-equivalent, contact lens VA measures for the habitual lenses and dispensed Bausch + Lomb Ultra lens at the dispensing visit and for the Bausch + Lomb Ultra lens at the 2-week follow-up visit. For these acuity measures completed in-office, the proportion of eyes with VA better than or equal to 20/20 were similar: 92.2% for the habitual
lenses, 95.6% for the Bausch + Lomb Ultra lens at dispensing visit, and 93.3% for Bausch + Lomb Ultra lens at the 2-week visit.

**Fit Characteristics**

Bausch + Lomb Ultra contact lenses were fully centered for 92.7% of eyes at the dispensing visit and for 95.1% of eyes at the follow-up visit, Table 5. There were no reports of corneal exposure at either visit. Adequate lens movement was reported for 95.7% of eyes at the dispensing visit and 96.6% of eyes at the follow-up visit. There were no reports of lens adherence at either visit.

**Slit Lamp Findings**

Slit lamp findings for each eye were graded for severity on a scale of 0 (no finding) to 4 (severe finding). Subjects were not enrolled into the study if habitual lens slit lamp findings of grade 2 or higher were present. Results from the dispensing visit (habitual lens) and the follow-up visit (after wearing Bausch + Lomb Ultra) are summarized in Table 5 for the dispensed eyes. At the 2-week follow-up visit, only 2 eyes (0.3%) had findings greater than grade 2.

**Symptoms**

The in-office mean ratings of symptoms associated with the subject’s habitual lenses and symptoms associated with the Bausch + Lomb Ultra contact lenses are summarized in Table 6. The difference between the habitual baseline and Bausch + Lomb Ultra ratings at the 2-week visit was evaluated for statistical differences. All categories evaluated had ratings statistically more favorable for

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**Table 4. Snellen equivalent Visual Acuity for Habitual lens and Bausch + Lomb Ultra lens**

<table>
<thead>
<tr>
<th>Snellen Equivalent</th>
<th>Habitual @ Dispensing Visit</th>
<th>Bausch + Lomb Ultra @ Dispensing Visit</th>
<th>Bausch + Lomb Ultra @ 2-week Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/9.5</td>
<td>0.3%</td>
<td>0.6%</td>
<td>0.9%</td>
</tr>
<tr>
<td>20/12.5</td>
<td>6.2%</td>
<td>10.0%</td>
<td>10.2%</td>
</tr>
<tr>
<td>20/16</td>
<td>41.1%</td>
<td>46.3%</td>
<td>46.8%</td>
</tr>
<tr>
<td>20/20</td>
<td>44.6%</td>
<td>38.7%</td>
<td>35.4%</td>
</tr>
<tr>
<td>20/25</td>
<td>6.7%</td>
<td>3.7%</td>
<td>5.8%</td>
</tr>
<tr>
<td>20/32</td>
<td>1.0%</td>
<td>0.7%</td>
<td>0.5%</td>
</tr>
<tr>
<td>20/40</td>
<td>0.1%</td>
<td>0.0%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Worse than 20/40</td>
<td>0%</td>
<td>0%</td>
<td>0.1%*</td>
</tr>
</tbody>
</table>

* No reduction in best spectacle corrected visual acuity was observed for this subject’s eye as Snellen acuity was 20/20 at both baseline and exit.

**Table 5. Graded slit lamp findings for dispensed eyes**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Dispensing Visit</th>
<th>Follow-up Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
<td>Trace</td>
</tr>
<tr>
<td>Epithelial Edema</td>
<td>100</td>
<td>0.0</td>
</tr>
<tr>
<td>Epithelial Microcysts</td>
<td>99.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Corneal Staining</td>
<td>78.5</td>
<td>21.5</td>
</tr>
<tr>
<td>Limbal Injection</td>
<td>91.7</td>
<td>8.3</td>
</tr>
<tr>
<td>Bulbar Injection</td>
<td>87.2</td>
<td>12.8</td>
</tr>
<tr>
<td>Tarsal Conjunctival Abnormalities</td>
<td>75.6</td>
<td>24.4</td>
</tr>
<tr>
<td>Corneal Neovascularization</td>
<td>98.0</td>
<td>2.0</td>
</tr>
</tbody>
</table>
the Bausch + Lomb Ultra contact lenses with the exception of Ease of Handling at Insertion which was not statistically significantly different. The largest differences favoring the Bausch + Lomb Ultra contact lenses were associated with comfort at end of day, (less) dryness, lens cleanliness upon removal, and vision in low light (p<0.05).

**Patient Experiences**
Through the on-line survey, subjects rated performance attributes in various real-world situations. Overall, 87.4% rated the Bausch + Lomb Ultra contact lenses as either “excellent,” “very good,” or “good.” Acceptance ratings for vision and comfort experiences associated with Bausch + Lomb Ultra were very high, Table 7. The proportions of subjects in agreement with the different performance statements associated with vision and comfort experiences were statistically significantly greater than 50%. Clear vision throughout the day (88.7%), when driving at night (88.0%), and when focusing for a long time at digital devices (87.4%) offered the highest agreement ratings. For comfort, the highest agreement ratings were for when driving at night (88.3%) and when focusing for a long time at digital devices (85.3%).

Preference results associated with comfort and vision are presented in Figure 3 and 4, respectively. In comparing Bausch + Lomb Ultra contact lens vision and comfort performance to the subject’s habitual lens, preference differences were statistically significant for the total cohort and for each of the individual silicone hydrogel lens brands (p<0.05). For all subjects with a preference, the Bausch + Lomb Ultra lens experience was preferred for prevention of tired/fatigued eyes when focusing for a long time at digital devices (3.0:1).

**Investigator Perspectives**
Following the completion of each subject, the cumulative investigator satisfaction ratings demonstrated overall satisfaction with the outcomes for 98.2% of patients. Based on the performance and fit characteristics, investigators indicated that the Bausch + Lomb Ultra contact lens was easy to fit for 98.9% of the patients evaluated (Figure 5).

**Discussion**

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**TABLE 6**

Mean rating for each symptom category using a scale of 0–100 (100 represents the most favorable rating) at baseline (Habitual) and after 2 weeks of wear.

<table>
<thead>
<tr>
<th>Symptom Category</th>
<th>Habitual</th>
<th>Bausch + Ultra</th>
<th>Difference†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort Upon Insertion</td>
<td>81.4</td>
<td>86.5</td>
<td>+ 5.5*</td>
</tr>
<tr>
<td>Comfort at End of Day</td>
<td>62.8</td>
<td>75.4</td>
<td>+12.9*</td>
</tr>
<tr>
<td>Dryness</td>
<td>68.5</td>
<td>80.9</td>
<td>+12.8*</td>
</tr>
<tr>
<td>Redness</td>
<td>84.8</td>
<td>89.0</td>
<td>+4.5*</td>
</tr>
<tr>
<td>Vision</td>
<td>88.5</td>
<td>89.7</td>
<td>+1.5*</td>
</tr>
<tr>
<td>Vision in Low Light</td>
<td>80.5</td>
<td>87.4</td>
<td>+7.2*</td>
</tr>
<tr>
<td>Lens Cleanliness Upon Insertion</td>
<td>87.3</td>
<td>90.6</td>
<td>+3.4*</td>
</tr>
<tr>
<td>Lens Cleanliness Upon Removal</td>
<td>76.7</td>
<td>85.4</td>
<td>+8.8*</td>
</tr>
<tr>
<td>Ease of Handling/Insertion</td>
<td>87.0</td>
<td>86.8</td>
<td>-0.2</td>
</tr>
<tr>
<td>Ease of Handling/Removal</td>
<td>85.2</td>
<td>89.5</td>
<td>+4.3*</td>
</tr>
</tbody>
</table>

† Positive values indicate Bausch + Lomb Ultra lens rating is more favorable than Habitual lens rating
*Statistically significant p<0.05
The patients enrolled in this prospective, nonrandomized, open-label multi-center trial used various digital devices throughout their day that accumulated to over 9 hours (average).

The Bausch + Lomb Ultra contact lens with MoistureSeal technology is designed to meet the demands of today's contact lens users. Long hours using digital display devices with infrequent and incomplete blinks can create wearing comfort and vision challenges that previous generations of silicone hydrogel lenses may not have been designed to address. In this study sample of current silicone hydrogel wearing patients, the Bausch + Lomb Ultra contact lens improved the wearing experience associated with comfort and vision. The in-office assessment of comfort symptoms indicated that the Bausch + Lomb Ultra contact lens provided significant improvements in end-of-day comfort and a reduction in dryness.

### Table 7

<table>
<thead>
<tr>
<th></th>
<th>% Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provide clear vision</strong></td>
<td></td>
</tr>
<tr>
<td>Throughout the day</td>
<td>88.7%</td>
</tr>
<tr>
<td>In dry environments</td>
<td>80.4%</td>
</tr>
<tr>
<td>When working for long hours at a computer</td>
<td>83.7%</td>
</tr>
<tr>
<td>When driving at night</td>
<td>88.0%</td>
</tr>
<tr>
<td>When focusing for a long time at digital devices</td>
<td>87.4%</td>
</tr>
<tr>
<td><strong>Comfortable</strong></td>
<td></td>
</tr>
<tr>
<td>Throughout the day</td>
<td>82.2%</td>
</tr>
<tr>
<td>In dry environments</td>
<td>79.1%</td>
</tr>
<tr>
<td>When working for long hours at a computer</td>
<td>82.2%</td>
</tr>
<tr>
<td>When driving at night</td>
<td>88.3%</td>
</tr>
<tr>
<td>When focusing for a long time at digital devices</td>
<td>85.3%</td>
</tr>
</tbody>
</table>

Prevent eyes from feeling tired or fatigued even when you focus for a long time at digital devices.

Figure 3. Percent of subject preference for comfort attributes
NEW PRODUCT

that the Bausch + Lomb Ultra lens advancements will provide an improved lens wearing experience.

Throughout the evaluation, there were no device related adverse events reported. Slit lamp findings revealed that 99.7% of eyes had minimal findings (no findings or trace or mild findings). Only two eyes associated with two patients had slit lamp findings greater than grade 2. With all subjects using Biotrue multi-purpose solution, these low level of findings highlight the biocompatibility of both the Bausch + Lomb Ultra contact lens and Biotrue multi-purpose solution.

Investigators assessed centration and movement fitting characteristics at dispensing and after two weeks of wear. There were no reports of corneal exposure or lens adherence at either visit. Together with the fit, vision, and symptoms reports collected at all visits, practitioners expressed high levels of satisfaction overall (93.2%) and satisfaction with the ease of fit (98.9%).

Visual tasks connected with digital displays have been associated with changes in rate of blinks, the extent of blinks and the integrity of the tear film (Cardona et al, 2011; Chu et al, 2014; Himbaugh et al, 2009; Jansen et al, 2010; Patel et al, 1991; Portello et al, 2013). These alterations in blink patterns are also related to symptoms of dryness, discomfort,

When asked to assess lens comfort in various real world situations, the on-line survey substantiated the acceptability of the Bausch + Lomb Ultra contact lenses when worn in dry environments, when focusing for a long time at digital devices and when using a computer for a long time. The improvements in comfort were noted in patients re-fitted from Acuvue Oasys, Air Optix Aqua, and Biofinity contact lenses.

With MoistureSeal technology, the Bausch + Lomb Ultra contact lens is designed to retain moisture and provide a smooth optical surface to help prevent dehydration blur. The advanced aspheric optics design can also help reduce blurred vision, halos and glare in low light conditions. Although the “in-the-chair” Snellen visual acuity measurements were similar between the habitual and Bausch + Lomb Ultra lenses, the Bausch + Lomb Ultra contact lens performance results highlighted improvements in the wearing experience associated with vision in real world situations that cannot be simulated in a practice environment. Both the in-office assessment of vision symptoms and the on-line survey substantiated improvements when wearing the Bausch + Lomb Ultra contact lenses compared to the habitual silicone hydrogel lenses. The preference associated with clear vision when working long hours on a computer and while driving at night indicate

Figure 4. Percent of subject preference for providing clear vision in real world conditions

<table>
<thead>
<tr>
<th>Situation</th>
<th>Bausch + Lomb Ultra Preferred (%</th>
<th>Habitual Preferred (%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Throughout the day</td>
<td>52.5</td>
<td>14.4</td>
</tr>
<tr>
<td>In dry environments</td>
<td>52.1</td>
<td>19.6</td>
</tr>
<tr>
<td>When working for long hours at a computer</td>
<td>59.2</td>
<td>12.9</td>
</tr>
<tr>
<td>When driving at night</td>
<td>53.7</td>
<td>10.1</td>
</tr>
<tr>
<td>When focusing for a long time at digital devices</td>
<td>51.8</td>
<td>13.8</td>
</tr>
</tbody>
</table>
blurred vision and visual fatigue. The extensive use of visual display activities by the patients in this study likely contributed to their reported symptoms of dryness, tired eyes, eye strain, blurriness or fluctuating vision when they entered the evaluation. While previous silicone hydrogel contact lenses have made advancements in material chemistry and design, discomfort, blurry vision and cessation of lens wear continue to challenge contact lens wearers and eye care practitioners. With the MoistureSeal technology and aspheric optics, the Bausch + Lomb Ultra contact lenses deliver improved comfort and vision wearing experience for patients. As vision demands associated with digital display devices increase, the Bausch + Lomb Ultra contact lens with MoistureSeal technology offers eye care practitioners a valuable tool for meeting patient’s needs. CLS

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1. Devi, Ownership Over Time, Pew Research Center’s Internet & American Life Project. 2/15/2014. Available at: pewinternet.org/data-trend/mobile/device-ownership/


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We live in a screen-centric world where consumers spend more than 10 hours a day using technology or electronic devices (Ipsos, 2012) and contact lens wearers are still looking for a lens that consistently provides comfort and clear vision throughout the day. With previous generations of contact lenses, patients have reported lower satisfaction and increased risk of dropping out of contact lens wear with increased hours of use of digital devices (Kadence, 2013).

One challenge associated with sustained visual tasks such as focusing on digital device screens is preventing lens dehydration and maintaining the pre-lens tear film (PLTF) between successive blinks. Sustained visual tasks are also known to reduce blink rates (Bentivoglio et al, 1997; Cardona et al, 2011; Himebaugh et al, 2009; Portello et al, 2013). In general, the literature suggests that the resting average blink rate of 15 times per minute may be reduced to an average of 5 times per minute (Bentivoglio et al, 1997; Cardona et al, 2011; Himebaugh et al, 2009; Portello et al, 2013).

The quality and stability of the PLTF affects both the comfort and visual experience of the contact lens wearer. In one study, sixty percent of contact lens wearers who experienced symptoms of blurry or fluctuating vision felt that these symptoms had a negative impact on contact lens comfort (Donnelly 2013). Ideally the PLTF would remain stable for the same period of time as the pre-corneal tear film of the non-lens wearer. In reality however, the lens alters the normal structure and evaporation of the tear film and these factors have been associated with contact lens discomfort and can reduce visual quality (Guillon et al, 2008; Korb, 1994).

PLTF stability is affected by both the magnitude and rate of water loss across the anterior surface of the lens (Nichols et al, 2006). Different contact lens materials behave differently in their ability to resist dehydration and maintain a consistent optical surface for great vision. Minimizing water loss across the surface of a lens may help to maintain a stable tear film, giving...
LENS DEHYDRATION

from polymethylmethacrylate (PMMA) and mimics the optics and physical dimensions of an average human eye with a 7.8mm radius and +0.18mm of spherical aberration over a 6mm pupil. The USAF target (Figure 2) contains a series of horizontal and vertical 3-bar patches that represent specific spatial frequencies expressed as line pairs per millimeter. These spatial frequencies can be used to determine the contrast (the white letters against the black background) and resolution (the clearness or sharpness of the vertical and horizontal lines) thresholds for a contact lens when conformed to a model cornea. An image quality metric which incorporates a cross-correlation algorithm for determining resolution and contrast was used on each of the USAF target images to generate a predicted logMAR visual acuity score for each lens. This easily understood metric provides a value which can be used to quantitatively assess changes in image quality for each lens over time.

Each lens was initially blotted to remove excess packaging solution from the lens surface and was conformed to the PMMA model cornea. Two drops of rewetting solution were used to simulate a fresh tear film after a blink. Multiple images of the USAF target were captured through each lens under ambient room conditions (70ºF and 50% RH). Images were acquired every second for a total of 30 seconds and the predicted logMAR score for each lens at each time point were averaged for the 30 lenses measured for each brand. A Two Way – Repeated Measures ANOVA was conducted on the individual predicted logMAR scores using time and lens type as the main effects. Post-hoc analysis was performed using Tukey’s HSD test.

Results

Figure 3 shows USAF target images representing the average logMAR score for each lens type captured at every ten-second time point. These images represent...
The Bausch + Lomb Ultra lens demonstrated better predicted logMAR scores at time-zero and at each additional time (10s, 20s, and 30s) compared to the three commercial lens products (p < 0.01 in all cases). At time-zero, the Bausch + Lomb Ultra lens had at least a one-line improvement in predicted logMAR acuity compared to the other three silicone hydrogel lenses. Additionally, after 30s, the Bausch + Lomb Ultra lens had a 1.7 line average improvement over the lenses.

Discussion
With the increased use of digital devices over the last several years, patients have reported lower satisfaction and increased risk of dropping out of contact lens wear as they spend more time using digital devices (Kadence 2013). Recommending a contact lens that improves patient experiences in these visual environments may improve patient satisfaction and retention in contact lens wear.

The ability of a contact lens material to resist dehydration and maintain a consistent optical surface may help to provide a more consistent optical surface. Dehydration blur has been shown to be variable across different contact lens materials, and this may have a significant impact on visual quality and overall comfort that a patient experiences in contact lens wear in a variety of visual environments.

Figure 4 shows the mean predicted logMAR as a function of time for each lens, along with the ± one standard deviation for the sample of (30) lenses for each lens type. From this graph, it is evident that the Bausch + Lomb Ultra lens provides better image clarity and stability over time compared to the other products tested.

Different contact lens materials behave differently in their ability to resist dehydration and maintain a consistent optical surface.
The better visual quality and predicted logMAR scores with Bausch + Lomb Ultra compared to the other leading silicone hydrogel lenses in the market is supported by aspheric optics and unique lens material properties that allow the lens material to help resist dehydration. Bausch + Lomb Ultra lenses start off clearer and remain clearer over the full 30 second test period in this in-vitro model designed to demonstrate the inherent ability of the lens material to resist dehydration. The 30-second time period is longer than the average inter-blink period that the vast majority of patients would experience, even under reduced blink rate situations such as with the use of digital devices.

References
Don’t just meet the needs of your patients—exceed them.

New Bausch + Lomb PeroxiClear™—the most advanced* peroxide solution.

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<th>Feature</th>
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Switch your patients to the most advanced* peroxide solution. Request your care kits today at Bausch.com/Peroxiclear.

*Compared to Clear Care

REFERENCES:
1. Results from a 22-investigator, multi-site study of PeroxiClear™, with a total of 440 eligible subjects. Subjects were randomized to use either PeroxiClear™ or Clear Care for 3 months. Subjects completed performance surveys at 2-week, 1-month, 2-month, and 3-month visits.
2. Results from a 21-investigator, multi-site study of PeroxiClear™, with a total of 297 eligible subjects who were habitual Clear Care users. After 7 days of use, subjects completed an online survey. Consumers rated the performance of PeroxiClear™ across a range of attributes and compared the performance to their habitual Clear Care solution.
3. High-resolution/accurate-mass (HR/AM) mass spectrometry was used to detect and quantify the relative amounts of surfactant retained on lenses from PeroxiClear™ and Clear Care solutions after 20 hours of wear. PureVision2, ACUVUE OASYS, and AIR OPTIX AQUA lenses were soaked in solutions for 12 hours prior to patients wearing lenses for 20 hours.
4. Results of an in vitro study measuring deposits on ACUVUE OASYS lenses. Lenses were subjected to 14 cycles of deposition with a lipid and protein solution mimicking the human tear film followed by a cleaning regimen with either PeroxiClear™ or Clear Care 3% hydrogen peroxide systems. Each deposition/cleaning cycle was representative of one day of patient use. Cycled lenses (n=3) were analyzed for deposits using image analysis. After 14 cycles, lenses cleaned with PeroxiClear™ had only 8.0% surface coverage compared to 33.0% for lenses cleaned with Clear Care.
5. Results of an ex vivo study measuring deposits on worn contact lenses to compare the clinical performance of PeroxiClear™ and Clear Care solutions. Lenses were worn daily for 1 month (silicone hydrogel and Group IV hydrogel lenses) or 3 months (gas permeable lenses). A total of 374 lenses were randomly selected for image analysis. Lenses were scored for mean density of deposits and percent coverage of deposits.

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The concept of using hydrogen peroxide to disinfect contact lenses was originally introduced in the early 1970s (Aquavella, 1971). Subsequently, a family of 3% hydrogen peroxide-based lens care solution products were developed and commercialized. Currently, peroxide solutions remain a significant part of the US soft contact lens care solutions market and are used by approximately 20% of contact lens wearers (Nichols, 2014).

Hydrogen peroxide-based lens cleaning and disinfecting systems need to achieve adequate disinfection and also reduce the 3% hydrogen peroxide to residual levels that are safe for the human corneal surface. For any 3% hydrogen peroxide system, the residual hydrogen peroxide concentration following neutralization must result in minimal to no change in the cellular structure or integrity of the corneal epithelium and also must not elicit a physiological response that may lead to patient discomfort. Although the safety threshold levels reported in the literature remain controversial, these values typically range from 100 – 250 ppm (Chalmers and McNally 1988, Paugh, Brennan et al. 1988, Konynenbelt, Mlnarik et al. 2011).

Two different types of peroxide lens care systems have been introduced to clean and disinfect soft contact lenses and reduce the 3% hydrogen peroxide to a safe residual level. They are classified as either one-step or two-step contact lens disinfecting systems based on the method used to neutralize the hydrogen peroxide.

Two-step systems require a separate neutralizing agent, typically a tablet, which is added during the disinfection step and releases an enzyme such as catalase. Hydrogen peroxide levels remain at 3% until the catalase is released from the coated tablet and then rapidly decrease to safe residual levels. Two-step hydrogen peroxide systems are generally considered very effective at disinfection based on the initial high peroxide concentration. However, it has been shown that the catalase tab-
Platinum Modulating Compounds

Platinum modulating compounds (PMCs) are organic molecules that typically consist of nitrogen, carbon, and oxygen. Two examples are carbamide and thiourea (Figure 1), which when added to a 3% hydrogen peroxide solution may effectively control the neutralization process (Millard et al, 2013). Depending on the compound properties, this interaction may be reversible or irreversible (Millard et al, 2013). PMCs have the ability to slow peroxide neutralization during the initial disinfection time (i.e., the first 30-60 minutes) leaving a solution virtually free of viable organisms while at the same time rendering residual peroxide concentration levels that are non-irritating to ocular tissues in only four hours (Millard et al, 2013).

Mechanism of Action

To further understand the mechanism of action of PMCs and how they could be applied to develop a next generation hydrogen-peroxide system, the interaction between peroxide neutralizing discs and PMCs has been evaluated (Millard et al, ARVO, 2014). Although many PMCs were screened (Millard et al, GSLS, 2014), carbamide and thiourea were selected for further study. These compounds are structural analogues that differ only by one atom and yet their neutralization profiles are distinctly different. Equimolar amounts of carbamide and thiourea were added to 3% hydrogen peroxide solution and the neutralization profiles were measured. In addition, a solution of 3% hydrogen peroxide without the addition of a PMC was used as a control. Figure 2 shows that the addition of a PMC to the peroxide disinfecting solution modifies the neutralization profile of hydrogen peroxide, effectively increasing the amount of total peroxide exposure available to kill microorganisms. The goal of incorporating a PMC is to increase the total peroxide exposure while reducing the actual time of disinfection, and thus allow for safe levels of residual peroxide to be achieved in a shorter overall regimen.
To better understand the mechanism of action, the interaction of carbamide and thiourea test solutions with platinum discs was studied using two complementary surface sensitive analytical techniques; time of flight secondary ion mass spectroscopy (ToF-SIMS) and X-ray photoelectron spectroscopy (XPS). While ToF-SIMS analysis provides qualitative information and determines the structural constituents of a molecule, XPS was used to identify the elements present on the surface and quantitate them.

Platinum discs were incubated overnight with 10 mL of 2% carbamide or thiourea in 20 mM phosphate buffer saline (PBS) solutions. The discs were rinsed with purified water then carefully cut and mounted for ToF-SIMS and XPS characterization.

The ToF-SIMS results definitively showed that both carbamide and thiourea were present on the platinum disc surface. The images in Figure 3 show the relatively uniform distributions of carbamide or thiourea observed on the platinum surface.

XPS analysis was used to quantitate the concentration of the detected elements distributed over the surface of the platinum discs. Concentration of nitrogen, the element common for both PMCs, was used to compare affinity of carbamide and thiourea to platinum substrates. The data is shown in Table 2. The calculated atomic concentration of nitrogen for the discs exposed to thiourea buffered solution (N1s = 11.6 ± 2.1) was two times higher than the value calculated for the discs soaked in carbamide buffered solution (N1s = 5.8 ± 1.8). These results indicated stronger attraction of thiourea to the platinum discs and correlated well with the differences in neutralization profiles displayed in Figure 2.

Additionally, the XPS results demonstrated a decrease in platinum concentration (Pt4f7) for the discs incubated in any PMC solution (Pt4f7 = 19.6 ± 4.7 (carbamide), Pt4f7 = 14.2 ± 1.8 (thiourea), respectively) compared to the fresh platinum substrates (Pt4f7 = 25.3 ± 8.0). This indicates that the discs soaked either with carbamide or thiourea were covered with PMC compounds and therefore lower platinum concentrations were detected by XPS.

Coverage of the platinum discs with PMC components was of interest in these studies. Spatial distribution of the elements such as nitrogen and sulfur over the platinum cut discs was examined by XPS mapping (Figure 4). Concentration of the element of interest was displayed using a color-coded intensity scale. While black indicated no particular element was detected, the areas of intensity that appeared yellow-to-white corresponded to its highest concentration.

![Figure 2. Neutralization profiles of 3% hydrogen peroxide solution with addition of equimolar concentrations of platinum modulating compounds (PMCs) and a neutralization profile recorded for a 3% peroxide control solution.](image_url)
PEROXIDE SOLUTIONS

Figure 3. ToF-SIMS results for carbamide and thiourea

on the surface. XPS mapping performed for the discs incubated in carbamide and thiourea showed uniform distribution of PMCs over the platinum disc surfaces and no evidence of PMC component aggregation was detected.

Leveraging PMCs in Novel Lens Care Solution Development

The PMC interaction with the platinum sites on the neutralizing disc is new technology that allows for the controlled neutralization of a 3% peroxide solution. PMCs help one-step peroxide systems mimic the slow initial neutralization of a two-step peroxide system without the inconvenience of a second step. This PMC technology was incorporated into the development of a one-step peroxide system — PeroxiClear cleaning and disinfection solution — which utilizes a combination of three different moisturizing agents to attract, spread and retain moisture on the surface of the lens. Carbamide, one of these three ingredients, serves a dual purpose as both a natural moisturizing factor to help prevent dehydration, and as a platinum modulating compound.

The addition of a PMC in PeroxiClear solution alters the typical peroxide neutralization profile compared to other peroxide contact lens cleaning and disinfecting solutions. For example, in a comparison of total peroxide exposure for PeroxiClear and Clear Care (Alcon), the mean total AUC measurements were calculated at 4 hours for PeroxiClear and 6 hours for Clear Care. Both product systems were tested four times and peroxide concentrations were plotted to generate neutralization curves. As a result of the slower initial neutralization produced by the PMC, PeroxiClear had a statistically significantly higher total peroxide exposure in 4 hours compared to Clear Care after 6 hours (based on manufacturer recommended disinfection times) (p<0.0001) (Figure 5).

In addition to total peroxide exposure, the mean residual hydrogen peroxide concentration for PeroxiClear 3% hydrogen peroxide system was also tested. Ten lens cases were cycled one time with 10 mL aliquots of the solution and soaked for the recommended regimen time of 4 hours. Residual peroxide

Figure 4. Spatial distribution of nitrogen (N1s) and sulfur (S2p) over exemplary platinum (Pt4f7) cut discs exposed to carbamide and thiourea buffered solutions.
Concentrations were measured using redox titration with a Mettler Toledo T50 Auto-Titrator. The mean residual peroxide level for PeroxiClear solution after 4 hours was 64.8 ± 12.3 ppm, well below thresholds for ocular detection or cellular changes (Chalmers et al, 1988; Paugh et al, 1988; Konynenbelt et al, 2011).

**Physico-Chemical Changes**

When XPS elemental composition data was used to quantitate the relative amounts of carbamide adsorbed to the platinum sites during the neutralization process for PeroxiClear at 0, 5, 15, 30 and 60 minutes, an increase in the carbamide detected on the platinum sites on the coated disc surface was evident from 0-30 minutes. At 60 minutes, the atomic coverage (%) decreased.

The loss in affinity of carbamide for the platinum surface after 60 minutes may be attributed to the simultaneous physico-chemical changes in temperature, pH and osmolality within the case during the first 60 minutes of neutralization. This is evidenced by the results of timed evaluations of temperature, pH and osmolality during the neutralization process. Within the first 0-60 minutes of neutralization, the temperature of the carbamide test solution increases, the pH increases and the osmolality decreases rapidly.

**Conclusion**

Combination of a suitable PMC such as carbamide with 3% hydrogen peroxide was shown to be a breakthrough approach that may improve the performance of peroxide-based lens care solutions. Application of this technology in PeroxiClear cleaning and disinfecting solution allowed for a higher total hydrogen peroxide exposure, in only 4 hours, and residual peroxide levels that are non-irritating to ocular tissues.

**References**


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US/OCD/14/0054
Silicone hydrogels were first introduced in the late 1990s. The goal was a healthier contact lens when compared to the low Dk hydrogel materials available at the time to improve oxygen transmission to the eye. While we’ve seen a decrease in conditions such as corneal edema, microcysts and neovascularization, and a reduction in limbal redness (Fonn et al, 2006), the most common complaint I hear from patients is about contact lens-associated dryness. This isn’t news to any of us. With research indicating current contact lens dropout of 10 to 20% annually (Rumpakis, 2010), we have yet to address the issue of dryness. The digital age of constant computer and smart phone use doesn’t help the matter. With a 65% decrease in blink rate with sustained visual tasks (Patel et al, 1991), contact lens patients may experience daily grittiness and irritation to a greater extent than we are possibly aware.

In my practice, I like to offer my patients a healthy contact lens with exceptional comfort and optics in one package. Over the past few years, we’ve been fortunate to have new materials introduced for daily disposable use, monthly use, and even new cosmetic lenses. How do my staff and I engage in a discussion about new contact lens technology in a presumed-satisfied contact lens wearer who walks in after 18 months for a prescription renewal?

**Asking the Right Questions**

Does this sound familiar? You enter the room to see your next contact lens patient. You drop into the chair, smile at the patient, and welcome him to your office. You thank him for choosing to come to you for his eye care. One of the first questions you ask is “So how are your contact lenses?” The patient reports they are “fine.” That may seem sufficient at first thought. If patients truly had problems, they would tell us, right? Studies indicate that as many as 2 out of 3 patients don’t discuss contact lens issues they may be having with their eye care practitioner (Kadence survey, 2012). Why is this? Are they afraid we’ll tell them they can no longer wear contact lenses if they say they experience contact lens discomfort, or their eyes feel dry or they struggle...
with their vision through the day? And what impact does this unrecognized or hidden dissatisfaction have on the risk for contact lens dropout?

**Taking the time to ask open-ended questions may lead to a more successful contact lens patient, which in turn could increase the patient’s loyalty to you and your practice.**

For example, asking a patient about their end-of-day comfort can frequently result in a patient response of “they’re fine.” We could leave it at that and let muscle memory take over. We could reach for the same box of lenses the patient has been wearing and send him off with a prescription or usually something less than an annual contact lens supply, with the hope that he’ll return for an eye exam in 12 to 18 months. But is this patient truly happy and satisfied with contact lens wear? Have we done our due diligence in assessing patient satisfaction?

Fitting contact lenses is a routine/repetitive part of practice for most of us, a routine that we don’t even think about most of the time. It’s become a habit, and habits (good or bad) are very hard to change. In fact, fitting contact lenses is such a strong habit that many of us can do it without even ‘actively’ thinking about it (like when you end up in your drive way and can’t quite remember all the things that you encounter on the way home). Once habits are established, they actually involve less thinking or engagement on our part.

All of us have habits, including many good ones. The key is to recognize a habit loop and what the cues are which trigger them (Duhigg, 2014) in order to understand how we can change them for the betterment of our patient’s contact lens-wearing experience and our practice profitability. One of the simplest habit changes we’ve employed where I practice is to ask more detailed questions about each patient’s contact lens experience. For example, “Do your lenses feel just as good in the evening as they do in the morning? Do you find your vision fluctuating throughout the day? Do you find yourself blinking or rubbing at your eyes to try to clear up your vision?” Taking an extra 30 seconds to ask these questions (or have your staff ask during a patient work-up) can better elicit any issues the patient may be having, that our routine questions may not be able to uncover. This gives us an incredible opportunity to introduce new technology and improve patient satisfaction. The patient will appreciate our practice more and also be more likely to remain in contact lens wear. Taking the time to ask open-ended questions may lead to a more successful contact lens patient, which in turn could increase the patient’s loyalty to you and your practice.

Another habit I’ve tried to change in my practice is related to asking patients how many boxes of contact lenses they would like to purchase at the end of a visit. This habit is the reason why so many of our patients typically used to order only one or two boxes. We know this leads to the risk of non-compliance (using the contact lenses longer than recommended) or ordering contact lenses online or from another provider. In my practice, I prefer to recommend monthly replacement lenses and my newly established habit is to assume that a patient wants an annual supply of lenses from our office. We no longer ask patients “How many?” Instead we say, “The doctor has approved an annual supply.” This, in addition to competitive pricing and rebate programs, helps to keep patient contact lens purchases in our practice.

In my practice, I’ve implemented a change in many of the habits we’ve developed in how my staff and I interact with contact lens patients and I can see the return on the investment in a better relationship with my patient and more patients choosing to get their annual supply of contact lenses from my office versus shopping around.

**The Next Best Thing**

I pride myself on offering the newest and greatest in contact lens technology, particularly for patients who may be experiencing dissatisfaction associated with dryness symptoms or discomfort with their current contact lenses. But it’s up to us, the eye care professionals, to uncover the underlying dissatisfaction before it leads to a patient discontinuing contact lens wear.

As I become more familiar with a new lens technology, I typically start to recommend this new technology to all patients, even those who don’t have outright complaints of discomfort. Imagine that. Taking a patient with zero complaints, 20/20 vision and a white healthy eye, and offering him something new. Waste of time? No way. Although a patient may not have an overt complaint, he may not recognize that there could be a higher benchmark for comfort or vision. I’ll ask my patient, “Would you like to have more
Although a patient may not have an overt complaint, he may not recognize that there could be a higher benchmark for comfort or vision.

comfortable, consistent vision throughout the day? Would you like a contact lens that dehydrates more slowly, such as when you work on the computer?

Summary

Novel contact lens technology now provides patients with an exceptionally healthy contact lens, providing comfortable and great vision throughout a full day of wear. More and more patients are returning to my office stating that while they thought their old lenses were “comfortable,” this new lens brings “comfort” to a whole new level. Where some of my patients may have come to think that contact lens wear was not going to be a long-term option for them because of ongoing discomfort or vision issues, we’re finding great success in fitting new contact lens options coming on the market. CLS

References


4. Exploring Comfort and Vision Survey - Kadence International, 2012. Phase 1: A total of 568 contact lens wearers (136 daily disposable, 432 planned replacement) completed an online survey regarding comfort and vision symptoms associated with contact lens wear. Phase 2: A random subset of 287 contact lens wearers (78 daily disposable, 209 planned replacement) were then asked to track vision and comfort symptoms and complete a second online survey.


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The Contact Lens Conversation

In the changing face of health care, contact lenses are vitally important to most eyecare practices. Advanced contact lens materials, designs and solution systems have improved our ability to provide a comfortable contact lens-wearing experience, but we need to better utilize new technology and work to understand our patients’ concerns and comfort issues so we can keep them comfortable in their lenses. All of this starts with asking the right questions.

How do you talk to your patients about the comfort of their contact lenses?
• Is it a quick, “how are you doing with your contact lenses? Good? Then I’ll renew the contact lens Rx with the same lenses.”
• A little more involved, “Do your lenses feel comfortable?”
• Or is it a full press, “Do your contact lenses feel as comfortable at the end of the day as at the beginning? Are they equally comfortable at the beginning of the wear cycle compared to the end of the wear cycle? When using a computer, do you experience any intermittent blur? Do you work outdoors and if so, do you use eye drops during the day to help with comfort?”

In addition, how are comfort questions asked?
• Via a paper questionnaire?
• By staff during the history?
• Or do you ask patients?

Address the Issue
Contact lens comfort needs to be at the forefront, because the statistics are staggering — a single dropout could cost $275 in lost annual revenue, and this doesn’t include the future value of treating the patient and potential referrals (Rumpakis 2010). As a vast majority of contact lens dropouts are due to discomfort (Nichols et al, 2005; Guillon and Maissa, 2005), exploring ways to improve comfort must be at the heart of your efforts.

Look for It
A careful corneal evaluation can identify potential complications along with specific treatment regimens for contact lens candidates. A detailed corneal assessment before, during and after the initiation of contact lens wear — is essential to preventing contact lens dropouts.

This is a great time to ask about comfort. Ask when you’re behind the slit lamp and you may be surprised what you hear.

Silent Dropouts
Don’t assume your patients are wearing their contact lenses comfortably; they may have silently dropped out of contact lens wear without your knowledge.

To prevent or identify these silent dropouts, consider asking or having your staff ask these core questions.
• Rate your comfort from 1 to 10 upon contact lens insertion
• Rate your comfort from 1 to 10 at the end of the day
• How many hours do you wear your lenses per day and would you like to be able to wear them longer?
• Rate your vision while at the computer

Then, you follow-up with more probing questions from behind the slit lamp.
For example, you could say “Comfort is a priority in my office. Is there anything you would like to see improved with your current lenses or the wearing schedule?”

If there are concerns, address them and offer alternatives. If comfort truly is a focus within your contact lens practice, a protocol for these questions should be developed and used at every encounter. We all want our patients to feel as comfortable as possible in their contact lenses.

When we continue to offer the newest innovations in contact lens materials, modalities and care products, we can be confident we’re giving our patients their highest chance for success.

CLS

For references, please visit www.clspectrum.com/references.asp and click on document #SE2014.

Dr. Miller is in a partnership private practice in Powell, Ohio, and is an adjunct faculty member for The Ohio State University College of Optometry. He has received honoraria for writing, speaking, acting in an advisory capacity, or research from Alcon, Allergan, CooperVision, and Visioneering Technologies. You can reach him at drmiller@eyecarepowell.com.
Assessing the Value of Adding New Technology

Making a decision about whether to bring a new product or technology into your practice isn’t always as straightforward as it may seem. On the clinical side, the decision is relatively easy, especially for new products. For example, if a new contact lens is clinically superior, and you’re committed to providing the best care to your patients, the decision is already made. This assumes you have a practice mission that includes this sentiment about patient care. This goes to the difference between simply saying you’ll do something vs. actually doing it. In this case, if your practice is about providing the best — provide it.

Of course, “new” doesn’t always equal “best.” But since it often does, it behooves you to at least try new products so you can decide for yourself. Waiting until others have tried something new isn’t necessarily bad, but there can be significant marketing benefits to being a “first mover.”

Because of the cost, it’s often more challenging to introduce new technology (versus products) into your practice. Fitting a new contact lens may involve little or no investment, but that’s often not the case with technology.

Usage and ROI
The biggest wildcard for most practices is anticipated usage. If you lease something, it’s easy to calculate how many times per month you’ll need to use the device to cover the cost of the lease. Of course, using new technology to break even is a poor business strategy so it’s better to build in the desired amount of profit you’d like each month and use that to evaluate ROI and guide your decision. Some of the profit may come directly from the device and some of it may come indirectly from it. For example, if it’s used to help diagnose dry eye, you may find added revenue in the extra office visits and products you sell for dry eye.

Volume
Anticipated volume predictions are easy. Just make a list of how many times in a month you would have used the new technology, if you had it. Then, you can determine if the new equipment is a fiscally sound purchase. Remember to consider any incremental profit you’d make from additional visits or sales of products.

So for example, if the widget payment is $1,000 per month and you plan on charging (and collecting) $50 from each test you run and selling $50 worth of related products, and you want to make $1,000 a month profit, you’ll need to use the widget 20 times per month and sell products to all 20 patients.

Gauging Patient Interest
To use this model, you have to know what you’ll charge and have a good sense of your patients’ willingness to move forward with recommended tests or treatments. That part is as easy as asking, “Mrs. Dry Eye, we’re considering adding some new technology to the office. It helps to better diagnose your dry eyes and it works by . . . The charge for the test is $XX and it is (or isn’t) covered by your insurance. If we were to bring it into the office, how likely would you be to have the test done?”

Patients who express an interest should be kept on a list and notified as soon as you’re trained on the new equipment. Depending what you buy, what it costs and your patients’ interest, you might consider paying cash versus financing if enough patients are on your list.

Assess Before You Invest
If you assess anticipated usage and ROI, along with volume and patient interest, you should have a pretty good idea if it makes sense to move forward with a particular piece of new technology.
A burgeoning area of contact lens innovation is myopia control. While there are several brands believed to slow myopic growth of the eye, none are approved by the FDA for the purpose of myopia control. Although contact lenses currently used off label for myopia control are approved for wear without age restriction, the FDA is requiring data on safety as well as efficacy for pediatric contact lens wear with a myopia control indication. Because cases of microbial keratitis or corneal infiltrative events are rare, examining the safety of contact lens wear in children requires an exceedingly large, long-term study. Therefore, FDA approval for myopia control is not expected any time soon and lenses used as such are done so in an off-label manner.

In light of that fact, practitioners should not advertise myopia control with a particular brand or even modality of contact lens. Furthermore, parents must be made aware that the contact lenses are not approved by the FDA for myopia control. It can be stated that they are approved for wear by children, but not to slow the progression of nearsightedness in children. Acknowledgment by the parent that the contact lenses are not FDA approved for use is important, so an informed consent document is important. The document should clearly state that the lenses are not FDA approved for myopia control, provide a general statement of risk regarding contact lens wear, and indicate the evidence for myopia control. Figure 1 shows information from the informed consent document used at the Kids Contact Lens Clinic at The Ohio State University College of Optometry.

Dr. Walline is an associate professor at The Ohio State University College of Optometry. His research interests primarily involve pediatric contact lenses and myopia control. He has received research funding from Johnson & Johnson Vision Care. You can reach him at walline.1@osu.edu.

### TABLE 1

**Sample Consent Form Information**

We insist that parents of patients opting for any of these off-label treatments must sign a form to indicate consent before we will start treatment. Here is some of the information we would include on that form.

**Corneal Reshaping**—Corneal reshaping contact lenses are worn during sleep and removed in the morning. They temporarily change the shape of the cornea (the clear window on the front of the eye), so that the child can see clearly all day long without glasses or contact lenses. During the first two weeks of wear, your child will experience changing vision. When the vision gets worse, he may put on glasses to provide clear vision. Although the chance of an eye infection is still very low (about one case per 500 years of wear), it is greater for corneal reshaping contact lenses than usual daytime contact lens wear because the contact lens is worn overnight.

**Soft Bifocal**—Soft bifocal contact lenses are routinely worn to help people over 40 years of age read clearly as well as see far away. Children may not see quite as clearly with these contact lenses as other types of contact lenses, but there are no additional risks compared to regular daily contact lens wear.

**Atropine**—Atropine is an eye drop that typically makes light seem bright because it makes the pupil (black hole in the middle of the eye) bigger, and it blurs near vision because it reduces the ability to focus the eyes while looking at near. Low concentration (0.01%) atropine has been shown to slow the progression of nearsightedness by 61% without increasing pupil size or decreasing near vision dramatically. Only 8% of children complained of problems with low concentration atropine, and glasses can reduce symptoms if your child notices poor reading vision or lights seem too bright.
Learnings from the Contact Lens Discomfort Workshop

As with the Dry Eye WorkShop (DEWS) report and the International Workshop on Meibomian Gland Dysfunction (MGD) before it, the Contact Lens Discomfort Workshop has established a foundation of what is known and unknown in an important dilemma interfering with successful contact lens wear in our patients. The recently published report exhaustively covers all aspects related to contact lens-related discomfort (TFOS 2013).

One report within the comprehensive workshop covers the treatment and management of the condition and discusses what evidence-based medicine exists for particular therapies. Level I evidence would be that which is conducted using carefully controlled randomized clinical trials. Level II evidence could come from well-designed non-randomized trials. While the lowest form of evidence would be related to case reports, descriptive reports, expert opinions and the like. Anecdotal or personal preference modes of treatment, although important, would not be considered to rise to the level of scientific rigor often considered.

Table 1 illustrates areas often chosen by eyecare practitioners to address when trying to solve contact lens discomfort (CLD) in their patients. This column will succinctly address the evidence to date regarding each category.

### Initial Considerations: Replacement Schedule, Materials and Parameters

Replacement frequency, material and parameter changes are often among the first areas addressed when treating contact lens discomfort. The evidence to date (Level II), suggests that daily disposable contact lenses could be one way to address the discomfort problem. This may be related to the elimination of a contact lens care system. Practitioners also have distinct opinions regarding material choices to address CLD. On the surface, it appears as though switching to a silicone hydrogel lens may be mildly helpful in improving comfort. However, studies for both hydrogel and silicone hydrogel exist that demonstrate the effectiveness of each. The issue is related to methodologies employed by each that tend to decrease the level of evidence for individual outcomes. Parameter changes more favorable to promoting comfort include contact lens edges with a knife profile, steeper base curves and larger overall diameter lenses. The practical problem with each of these parameter changes is that typically, unless custom-made lenses are ordered, a practitioner is unable to change any of these parameters in isolation.

### Wetting Agents

Contact lenses with intrinsic (material laden) or extrinsic (blister pack) wetting agents are another factor used to solve CLD. No evidence exists for the use of intrinsic wetting agents in enhancing comfort. However, Level II and III evidence exists showing that extrinsic wetting agents do increase comfortable wear, albeit short-lived in many cases.

### Care Systems

Level II evidence suggests that contact lens care system choices favor matching them with individual contact lenses types, even if the manufacturers of each are disparate. Level I evidence is conflicted with regards to particu-
Treatment Plan

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Once contact lenses and care systems are addressed by the ECP, the next most commonly performed intervention to address CLD involves topically applied tear supplements to the contact lens and ocular surface. Most consider this the mainstay of therapy for mild to moderate degrees of CLD. Most evidence, Level II and III, concludes that this therapy is beneficial to improving CLD. Earlier studies indicate that even 0.9% saline could be helpful. More recent studies favor complex tear supplements that may include polyvinyl alcohol (PVA), carboxymethylcellulose (CMC) and Povidone. There is also evidence (Level II) that hydroxyl propyl cellulose (Lacrisert) inserts are helpful in improving comfort with contact lenses at least to 1 month.

Environmental Considerations

Environmental interventions, though intuitive, have little basis in published literature. Some level III studies indicate that smoke, pollen, dust and low humidity should be avoided to improve comfort. Blinking behavior modification to improve comfort has not been proven in the literature.

Nutritional Supplements

Nutritional interventions, although part of clearly proven non-contact lens dry eye therapy, finds little evidence for combating CLD. One Level I study showed that the use of Omega-6 improved comfort in contact lens wearers, however the study was only conducted on a cohort of female subjects. Evidential support of improving hydration levels to treat CLD is currently not supported by the literature.

Punctal Occlusion

The evidence supports the use of punctal occlusion to improve comfort. The occlusion should be performed with silicone plugs and both the inferior and superior puncta should be occluded.

Steroids and NSAIDs

No studies exist for demonstrating the use of steroids and non-steroidal anti-inflammatories for use with soft contact lens discomfort. Although Level II evidence shows that dicyofenac improves comfort in RGP contact lens wearers in the early adaptation period. One Level I study, albeit open label, demonstrated the effectiveness of azithromycin (bid) for 1 month in improving comfort in contact lens wearers. Future research involves medications that focus on neuromodulators such as resiniferotoxin, which target nociceptive neurons and modulate the pain response.

For references, please visit www.clspectrum.com/references.asp and click on document #SE2014.

Check out the Report

In conclusion, I encourage you to consult the full report to garner specific details, study references and results for each category. CLS

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Dr. Quinn is an advisor to the GP Lens Institute and an area manager for Vision Source. He is an advisor or consultant to Alcon and B+L, has received research funding from Alcon, AMO, Allergan, and B+L, and has received lecture or authorship honoraria from Alcon, B+L, CooperVision, GPLI, SynergEyes, and STAPLE program. You can reach him at tguinn3@gmail.com.
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REFERENCES:
3. Twenty-two subjects participated in a randomized, double-masked, contralateral eye study to evaluate water loss of Biotrue® ONE day, 1-Day ACUVUE MOIST, and 1-Day ACUVUE TruEye. After 4, 8, 12, and 16 hours of wear, lenses were removed and immediately weighed (wet weight). The lenses were then completely dried and reweighed (dry weight). The percent water loss was then calculated for each lens from the wet and dry weights.