

PSS NEWS

An On-Line Publication for COPE Continuing Education in Optometry

Contact Lens Update

2.0 Hours - COPE 71272-CL

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Learning Objectives:

1. Understand the different types of contact lenses.
2. Understand the latest advances in these lenses that have become available to the practitioner.
3. Gain an understanding of the technologies of the future.

With the year 2020 in the rear-view mirror, we look forward to a better 2021. Along with so many other things, one of the sequelae of the COVID-19 pandemic was optometry's loss of in-person education, whether through national meetings, regional meetings, or simply meeting with our industry sales representatives. As a result, we may not have received a comprehensive summary of the myriad technical advances in contact lenses that have occurred during the past several months—or experienced their positive impact on our practices. Here's a primer on what we may have missed.

Soft Contact Lenses

Daily Disposables

Research has shown that daily disposable contact lenses provide our patients a healthy, comfortable, lens-wearing experience. This begins with their superior safety profile as compared with reusable lenses. Several studies have looked at adverse events with soft contact lenses and have found that they are

least prevalent with the daily disposable modality.¹ One paper measured corneal infiltrative events (CIEs) in particular. The authors discovered that the CIE rate for daily disposable lenses was significantly lower compared to those for reusable contact lenses (0.2% per year versus 3.3-7.2% for other the other replacement schedules).² Other researchers studied microbial keratitis and found that its risk is lowest with soft contact lens-related is lowest for daily disposables as compared with other replacement modalities.³

When lenses are worn for longer replacement periods, noncompliance with their proper care plays a larger role. It can result in deposition on the lenses. These deposits make the lenses less comfortable, leading to irritation, and/or discontinuation of contact lens wear.⁴

What's more, dirty contact lens cases serve as vectors for biofilms and microbial replication.⁵ Noncompliance rates with contact lens and case care range from 28-87%.^{6,7} This in turn can lead to infection.

Many studies have found that the compliance with replacement is best with daily disposables (88%, as compared with 72% for monthly and 48% for two-week lenses.)⁸

Lastly, daily disposables are convenient. They simply need to be disposed at the end of the day, rather than cleaned, eliminating the need for disinfection solutions.

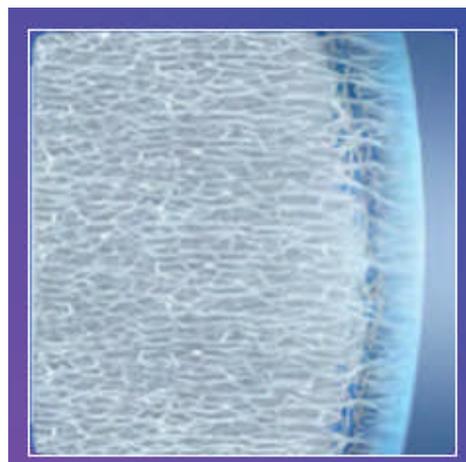
Silicone hydrogel (SiHy) materials represent one of the most important innovations in the history of soft contact lenses. They impart unprecedented oxygen permeability to soft disposable lenses. Because so many contact lens-related complications result from hypoxia, this has proven to be an advantage over HEMA-based hydrogels.

Silicone had long been utilized in rigid gas permeable and silicone elastomer lenses. Now we are harnessing the capability of linking it to a hydrogel component. Additional advantages of these materials over traditional hydrogels include better durability, less protein deposition, and increased end-of-day comfort. The latter can extend wearing time for dry eye patients. It is important to keep in mind that these materials are truly different than HEMA-based soft polymers. They are innately hydrophobic; a surface-treatment, internal wetting agent, or innovative lens matrix must be present to provide the wettability necessary for successful wear. Since silicone is more permeable to oxygen than water (the opposite is true for traditional plastics), in general, the lower the water content, the higher the permeability. The potential drawbacks for some patients include increased lipid deposition and stiffness of the material, reflected by higher modulus of elasticity values. Rarely, this increases the potential for mechanical irritation to the eye.

As a result, it is no surprise that industry is constantly innovating to produce the healthiest, most comfortable silicone hydrogel

daily disposable lens, and there were two notable lenses recently launched.

Precision1 (Alcon) features SmartSurface Technology, which creates a microthin (~2 to 4 microns) layer of moisture on the lens surface. The core of the lens has a 51% water content, which increases to 80% at the outer surface (Figure 1).



Alcon says that this permanent layer provides longer-lasting surface moisture, supports a stable tear film for precise vision, and provides dependable comfort. The lens also provides ease of handling, according to the company. Precision1 lenses are manufactured in verofilcon A silicone hydrogel material and feature a class 1 ultraviolet blocker, Dk/t of 100 at -3.00D, and a core modulus of 0.6 MPa.⁹ In January, 2021, Alcon launched Precision1 for Astigmatism, its first toric daily disposable SiHy lens.

Infuse (Bausch + Lomb) is comprised of kalifilcon A, with a water content of 55%; modulus of 0.5 MPa; a reported Dk/t of 134 @ -3.00D and a class II UV blocker. The “ProBalance Technology” formula includes the osmoprotectants erythritol and glycerin and the electrolyte potassium; and two moisturizers, Poloxamine 1107 and Poloxamer 181. This increases ocular surface homeostasis, according to B+L. B+L says that ProBalance Technology is infused into the lens material during the manufacturing

process, and these ingredients are released during lens wear.¹⁰

Custom Parameter Soft Contact Lenses

Although the vast majority of our patients can be successfully fitted in disposable soft contact lenses with parameters from our fitting sets, there are always patients who require custom soft lenses. These include patients who require a/an:

1. Larger lens diameter
2. Higher lens powers (sphere or cylinder)
3. Additional prism ballasting
4. Axis in 1 degree increments

After a very successful run, Hydrasoft (CooperVision) Lenses have been discontinued. Many patients, particularly those with high astigmatism and/or custom parameters, are looking for another option. Fortunately, we have the following made-to-order lenses for our regular cornea patients that are available +/-30.00 D; 10 D of cylinder; and axes around the clock.

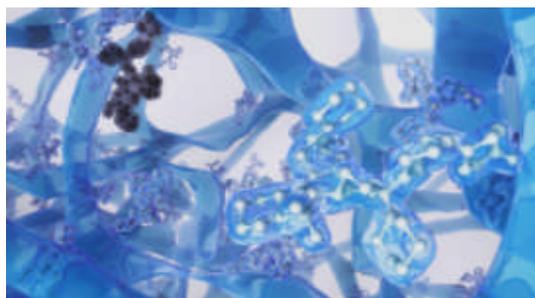
- Alden HP Toric (Bausch+Lomb SVP)
- Alden Classic Toric (Bausch+Lomb SVP)
- Flexlens Toric (X-Cel Specialty Contacts)
- Horizon Toric (X-Cel Specialty Contacts)
- Naturasoft Toric (Advanced Vision Technologies)
- XPToric (Visionary Optics)¹¹

Photochromic Soft Contact Lens

Acuvue Oasys with Transitions (Johnson & Johnson Vision Care) is the first-ever contact lens that contains a photochromic additive copolymerized homogeneously throughout the lens matrix. As a result, the lens responds to light, blocking out both blue light and UV rays. It blocks up to 15% of light indoors and up to 70% of visible light at full activation outdoors. It begins to darken as soon as it is exposed to sunlight,

is dark in 45 seconds, and fades from dark back to clear within 90 seconds.¹²

The lens is composed of senofilcon A with a two-week replacement schedule. Doctors have observed the lens to improve squinting; color contrast; glare from computers; light sensitivity outdoors and indoors; symptoms from migranes; and night driving.¹³ (Figure 2)



Soft Toric Multifocals

Contact lens options for the presbyope include reading glasses over distance contact lenses, distance glasses over near contact lenses, monovision, soft multifocal contact lenses, and gas permeable (GP) multifocal contact lenses. Monovision was historically the first option for many practitioners. It involves fitting one eye for distance and one eye for near. Reported success rates vary but the best candidates for soft lens monovision correction are patients with low addition powers and minimal astigmatism. The modality does, however, have its limitations. It can affect binocularity, which may reduce fine stereopsis and cause intermittent blur (due to an inability to suppress the out-of-focus eye.) Driving a car, especially at night, may be difficult. In addition, as presbyopia advances, monovision may no longer provide optimal correction for an intermediate working distance.¹⁴

There are currently 24 soft toric multifocal lenses available today.¹⁵ They include aspheric center distance (most minus power centrally), aspheric center near (most plus power centrally), concentric center distance,

and concentric center near designs.

In the past 18 months, we have seen the launch of soft toric multifocals in two very successful monthly replacement lenses. First came the Bausch + Lomb Ultra Multifocal for Astigmatism contact lenses. The silicone hydrogel lens (samfilcon A) combines the company's 3-Zone Progressive multifocal design with its OpticAlign toric design. There are two addition and three cylinder options.¹⁶

In the spring of 2020, CooperVision released its Biofinity Toric Multifocal. It contains the company's Optimized Toric Lens Geometry, including uniform horizontal iso-thickness, a ballast band design, a large toric optical zone, and a smooth continuous surface. Its Balanced Progressive Technology offers "multiple zones of vision" with the choice of center Distance or center Near optics. The lenses are available in cylinder powers from -0.75 to -5.75 (0.50 steps), an axis of 5 degrees to 180 degrees in 5-degree steps, and add powers of +1.00, +1.50, +2.00, and +2.50.¹⁷

Myopia Control

Age is the most accurate indicator of myopic progression, with younger onset associated with faster progression. These patients will then show higher levels of myopia.^{18,19}

There is evidence to demonstrate that center distance soft multifocal contact lenses, gas permeable orthokeratology (OK) lenses, and .01-.05% atropine can slow myopia progression.^{20,21} Atropine's mechanism for slowing eye growth is currently unknown. OK and soft multifocals are both thought to reduce a patient's amount of peripheral hyperopic defocus and provide a peripheral myopic blur to the retina.^{22,23} Research estimates that overnight OK can reduce axial elongation by approximately 45-50%.^{24,25}

At the moment, OK lenses are only United States Food and Drug Administration (FDA)-approved for myopia correction, not the

slowing of myopia progression. As a result, fitting them for myopia control purposes is still considered off-label.

This time last year, CooperVision launched the MiSight contact lens, the only treatment currently FDA-approved to slow the progression of nearsightedness.^{23,26} Over a period of three years, MiSight was shown to reduce myopia progression by 59% as compared with a single vision one day lens.²³ It is a hydrogel (omafilcon A) daily disposable lens with a four-ring structure containing two correction zones, two treatment zones, and center-distance optics. It contains a +2.00 add and is approved for children between 8 and 12 years of age with prescriptions between -0.75 and -4.00.

Clinical research is exploring using pharmaceutical and contact lens methods together but no conclusions have been made regarding which combinations work best. In addition, there is no current paradigm that indicates which treatment/combination of treatments is optimal for a given child.²⁷

Gas Permeable Contact Lenses

There have also been advances in gas permeable materials and lenses in the past several months. Research has shown that many scleral lenses, even in high-Dk materials, do not provide sufficient oxygen to the cornea, based on Holden and Mertz's criteria.²⁸ Given the popularity of these lenses and our patients' reliance on them for adequate vision, the market was in need for materials with higher oxygen permeability.

Acuity Polymers received 510(k) clearance from the U.S. FDA for the Acuity 200 GP contact lens material in a variety of designs and indications for daily wear. Acuity 200 (fluoroxfocon A) has the highest gas permeability (200 Dk) of any GP material on the market to date, according to the company. Acuity Polymers says that Acuity 200 offers exceptional permeability and wettability for

healthy lens wear while providing excellent all-day comfort, whether in a scleral or corneal lens design.²⁹

Contamac introduced its own version of tasilfocon A, naming it Optimum Infinite. With its method of measurement, the material registered a Dk of 180. It has a specific gravity of 1.2 and a high flexural modulus of 1341MPa, which according to the company defies the high-Dk-low-flexural modulus convention.³⁰ Both this and fluoroxofocon A contact UV blockers and can be coated with Tangible Hydra-PEG (Tangible Science).

Scleral lenses convey many benefits as compared with their corneal counterparts, including improved comfort, centration, corneal protection, and a larger optic zone diameter. There have been several advances in scleral multifocal lenses as well. Candidates for scleral multifocals include patients with irregular corneas, against the rule corneal cylinder, and/or dry eye; current scleral wearers, and those who require immediate comfort. The issue with sclerals, however, is that they do not always center perfectly; the tendency is for the lens to ride inferiorly and temporally. This is a problem for multifocal lenses that do not move or translate, as the multifocal optics need to line up with the visual axis for optimal correction at all distances. In addition, the visual axis tends to be located slightly superior-nasal to the cornea's optical center.³¹ These issues compound and could result in less-than-optimal visual results with a scleral MF lens. To address both of these issues, some laboratories have incorporated offset optics in their MF lenses to ensure that the patient is looking through the center of the lens' optics.

AccuLens developed OnPoint, a diagnostic tool that precisely places the multifocal optics over the pupil. Trial lenses stabilized with double slab-off prism contain laser alignment grid marks that enable the doctor to measure the angle and offset of the optics. The

technology is available for either the Maxim or Easy Fit scleral lenses, in their center near "periscopic" design. (Figure 4)



The Zenlens and Zen RC Multifocals (Bausch + Lomb Specialty Vision Products) are other lens designs that recently incorporated offset optics within their scleral multifocals.

Contact Lens Care

Tangible Hydra-PEG is a coating applied to a GP contact lens to render it more wetttable and resistant to deposits. Polyethylene Glycol (PEG) can be permanently bonded to the lens to encapsulate the entire lens. The coating, which according to the company makes lenses more comfortable, can wear off. Enter Tangible Boost (Tangible Science), which just launched in January of this year. It is an at-home treatment patients can use to restore a thicker and denser coating to an already-coated lens. It requires a 30 minute treatment once per month and is available by prescription only.³²

Because scleral lenses completely vault the cornea, they must be filled with solution prior to application. This solution must be nonpreserved, to minimize reactions with the tear film and epithelial layer. For several years, there were no FDA-approved solutions for this purpose. 0.9% sodium chloride (NaCl) inhalation solution was the first choice for many practitioners,³³ as it was widely available, inexpensive, and generally healthy. A few years later, two nonpreserved NaCl

solutions (LacriPure, Menicon; and ScleralFil, Bausch + Lomb) were approved by the FDA. One more (VibrantVue Scleral Saline, ABB Optical/Visionary Optics) was approved in August, 2020. Last year, a formulation containing several nutrients— Calcium, magnesium, potassium, phosphate, and sodium- was introduced. Nutrifill (Contamac) was specifically formulated to use with scleral GP contact lenses. It is preservative-free, with a pH (7.4) and osmolarity (300) to mimic human tears.³⁴ (Figure 5)



Johnson & Johnson Vision Care purchased AMO from Abbott (now AbbVie) in 2016. About a year ago, they renamed Blink RevitaLens Multipurpose Disinfecting Solution (formerly RevitaLens OcuTec) to Acuvue RevitaLens MPDS. It contains alexidine and polyquaternium as preservatives/disinfectants, boric acid, sodium borate, Tetronic 904, edetate disodium, sodium chloride, and purified water.³⁵

The Contact Lens Rule³⁶

In place since August of 2004, the United States Federal Trade Commission's (FTC) Contact Lens Rule imposes obligations on both eyecare prescribers and contact lens sellers. The prescriber must provide the patient a copy of the contact lens prescription after the completion of a contact lens fitting, and also must verify or provide the prescription to authorized third parties. The Rule also requires that contact lens vendors sell contact lenses only via a valid prescription that the seller received from either the patient or prescriber, or has verified via direct communication with the prescriber.

On October 16, 2020, the FTC released its amendments to the Contact Lens Rule. Congress later instructed the FTC to delay the implementation and enforcement until March 31, 2021. After a contact lens fitting, prescribers will be required to do one of the following to confirm that a patient received their prescription:

- request that the patient acknowledge receipt of the contact lens prescription by signing a separate confirmation statement;
- request that the patient sign a prescriber-retained copy of the prescription that contains a statement confirming the patient has received it;
- request that the patient sign a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming the patient received the prescription; or

provide the patient with a digital copy of the prescription, and retain evidence that it was sent, received, or made accessible, downloadable, and printable.

If the patient refuses to sign a confirmation statement or other receipt, the prescriber must note this in the patient's medical record. The prescriber must also keep a record of the CL prescription confirmation in the patient's medical record file for at least three years.

The Final Rule attempts to address concerns about sellers verifying prescriptions by leaving incomplete or incomprehensible automated telephone messages with prescribers. Sellers who use automated telephone messages for verification must:

- record the entire call and preserve the complete recording;
- start the call by identifying it as a prescription verification request made in accordance with the Contact Lens Rule;
- deliver the verification message in a slow and deliberate manner and at a volume that the prescriber can understand; and

- make the message repeatable at the prescriber's option.

The Contact Lens Rule already prohibits prescription alteration, but the Final Rule defines “alteration” to include sellers providing, as part of a verification request, a brand or manufacturer other than that prescribed to the consumer. The Final Rule also clarifies that the only permissible substitution involves private label lenses; private label and brand name lenses can be substituted for each other when they are identical lenses made by the same manufacturer.

Reference Guides

It is difficult keeping up with all of the new lenses and expanded lens parameters, so there are several reference guides available to keep it all straight. They include:

- *Tyler's Quarterly**#
- *Contact Lens Compendium* (Centre for Ocular Research and Education)#
- *Contact Lenses & Solutions Summary* (*Contact Lens Spectrum*)#@
- www.eyedock.com*+
- *Annual Contact Lenses and Lens Care Guide* (*Review of Cornea & Contact Lenses*)#

*subscription required (discontinued 3/2021)

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On the Horizon

Various companies are developing new soft and GP lenses for myopia control. At least two of the GPs currently approved for overnight OK but also used for myopia control may also receive FDA-approval for the latter in the next 12 months.²⁹ Industry is also developing new solutions more similar to the

tears for filling scleral lenses prior to application. Regarding scleral lenses, the use of scleral profilometry will improve fitting, reduce the number of exchanges, and perhaps even allow them to be fitted empirically.³⁷

Lentechs has developed Apioc, a soft multifocal lens approved by the FDA with a novel method of correction. It is designed to float above the cornea on the tear film and to be suspended from the inside of the upper lid. Rather than the lens moving with the eye, the eye moves down behind the lens to access the prescriptions for distance, intermediate, and near. It is likely to be launched in the 3rd quarter of 2021.

Other companies will launch enhancements to their current offerings; for example, the Acuvue Oasys Multifocal (Johnson & Johnson Vision Care) will be made available in the spring of 2021. This new lens, manufactured in the two week Oasys' senofilcon A material, will utilize the optical design and hybrid back curve of the 1 Day AV Moist Multifocal.

Dozens of companies are developing “smart” contact lenses.³⁸ One goal will be to provide medical treatment (e.g. release antihistamine, glaucoma medications, anti-inflammatories, or antibiotics). Other lenses will serve as health trackers, measuring glucose or intraocular pressure levels. In addition, industry is developing contact lenses that can aid in low vision by zooming in and out, or magnifying vision with aid of a tiny telescope within the lens. Lastly, the Mojo Lens (Mojo Vision) recently was voted the “best new gadget” in the Last Gadget Standing competition at the 2021 Consumer Electronics Show (CES). It is an “augmented reality” scleral lens that can provide real-time contrast and lighting enhancements as well as zooming capability. It also can provide heads-up display information such as the weather or lead one to where his car is parked. Clinical tests are likely years away, and optometrists will play a vital role as they will need to ensure the healthy fitting of the scleral lens platform.³⁹

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Please note that all 50 states have different rules and regulations concerning the acceptance of correspondence/internet continuing education. Please verify with your state board of optometry as to the amount of allowable hours and acceptable categories/topics in your particular state.

Questions:

1. All of the following are acceptable ways of treating presbyopia with contact lenses except:
 - a. distance contact lenses with spectacles over the top for near
 - b. monovision
 - c. orthokeratology
 - d. GP multifocal contact lenses
2. Which United States Agency is responsible for the Contact Lens Rule?
 - a. Food and Drug Administration (FDA)
 - b. Homeland Security Agency (HSA)
 - c. Federal Trade Commission (FTC)
 - d. Transportation Security Administration (TSA)
3. Which of the following is a product currently approved by the FDA to slow myopia progression:
 - a. Center near soft multifocal
 - b. Atropine
 - c. GP ortho-K lens
 - d. None of the above
4. The limitations of correcting presbyopia with monovision include:
 - a. the inability to correct vision with toric contact lenses
 - b. difficult to fit
 - c. for advanced presbyopes, may not correct for the intermediate viewing distance
 - d. poor prognosis with GP contact lenses
5. Which of the following is NOT a benefit of scleral contact lenses, as compared with corneal GP lenses?
 - a. Comfort
 - b. Easier removal
 - c. Larger optic zone
 - d. Corneal protection
6. Concentric center near bifocal contact lenses have:
 - a. enhanced near acuity in dim environments
 - b. maximum minus power centrally

- c. larger diameters
- d. maximum plus power centrally

7. Which of the following is TRUE concerning soft toric multifocals?
- a. They haven't been invented yet
 - b. They are available only in center near optics
 - c. There are currently 24 different lenses on the market
 - d. There are very limited add powers
8. According to the Final Contact Lens Rule:
- a. Private label and brand name lenses can be substituted for each other when they are identical lenses made by the same manufacturer.
 - b. Sellers may no longer contact prescribers via automated telephone messages.
 - c. Sellers must charge the same amount as prescribers.
 - d. Prescribers must keep a record of the CL prescription confirmation in the patient's medical record file for at least seven years.
9. Studies indicate that the highest rates of noncompliance with recommended replacement is with which contact lens category?
- a. Daily
 - b. Biweekly
 - c. Monthly
 - d. None of the above
10. The only photochromic contact lens available on the market blocks out ____% of visible light outdoors?
- a. 15%
 - b. 35%
 - c. 70%
 - d. 90%
11. The Add power of the only soft contact lens FDA-approved for myopia control is:
- a. +1.00
 - b. +1.50
 - c. +2.00
 - d. +2.50
12. Per the FDA, the only soft contact lens currently approved for myopia control may only be used in patients aged:
- a. 6 to 10
 - b. 8 to 12
 - c. 10 to 14
 - d. 12 to 16
13. Reference guides for contact lenses include all of the following EXCEPT:
- a. *Tyler's Quarterly*
 - b. *Contact Lens Compendium* (Centre for Ocular Research and Education)
 - c. *Annual Contact Lenses and Lens Care Guide (Review of Cornea & Contact Lenses)*
 - d. *AAO Cornea, Contact Lenses and Refractive Technologies Lens Guide*

14. Which of the following is NOT an appropriate solution with which to fill a scleral lens prior to application?
- GP multipurpose solution
 - Nonpreserved sodium chloride inhalation solution
 - Nonpreserved 0.9% saline
 - Nonpreserved nutrient-filled physiologic solution
15. Which of the following is a characteristic of daily disposable contact lenses?
- Fewest corneal infiltrative events
 - Lowest risk of microbial keratitis
 - Best compliance with replacement
 - All of the above
16. Which of the following is a characteristic of silicone hydrogel materials?
- High protein deposition
 - Innately hydrophobic
 - Low oxygen permeability
 - Little to no lipid deposition
17. Which of the following is a reason for fitting a custom parameter soft contact lens?
- Daily disposability
 - Silicone hydrogel material
 - Additional prism ballasting
 - Axes in 10 degree increments
18. Scleral GP lenses tend to decenter:
- down and out
 - up and in
 - down and in
 - up and out
19. A newly FDA-approved GP material has the highest Dk to date, which is:
- 400
 - 200
 - 100
 - 50
20. Which of the following is NOT a contact lens technology currently under development?
- Medication-releasing contact lens
 - Eyelid-suspended soft multifocal
 - Augmented reality scleral lens
 - Lens containing human epithelial cells