MARCH/APRIL 2021

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REVIEW OF CORNEA & CONTACT LENSES

THE SOFT LENS

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THE SOFT LENS, 50 YEARS ON

From its tentative beginnings in 1971 to the juggernaut of today, we look backward—and forward—at the category's wide scope of success.

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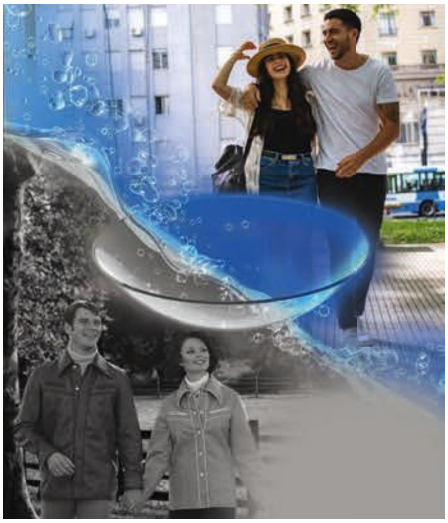
Review of Cornea & Contact Lenses | March/April 2021



features

We wish to express our gratitude to the Optometric Historical Society and its journal, *Hindsight: Journal of Optometry History*, for assistance in researching the topics covered in this month's feature articles. The Society is supported by Optometry Cares—The AOA Foundation. For more information, visit www.aoafoundation.org.

departments

IN BRIEF

■ A new study found that **patient compliance was lower than expected among patients with corneal diseases, even for severe cases such as corneal graft recipients. The older participants in the study were more diligent than the younger ones.** Investigating eye drop adherence patterns in 199 adults with corneal diseases, researchers found that 72% of patients were considered nonadherent by the Adherence to Refills and Medications Scale and 33% by the Voils' Medication Adherence Scale.

Asfuroğlu A, Kan O, Asfuroğlu M, et al. Association between dry eye and polycystic ovary syndrome: subclinical inflammation may be part of the process. Eye Contact Lens. 2021;47(1):27-31.

■ Researchers suggest that **contact lenses infused with gold nanoparticles may offer certain colorblind patients a safer and more effective way to decipher red and green**. The gold lenses were more selective in blocking wavelengths than two commercially available pairs of tinted glasses. Additionally, **the gold contact lenses matched the wavelength range of the previously investigated pink-tinted lenses, minus the problematic leaching dye and subsequent safety concerns**. The investigators plan to conduct clinical trials with the gold-infused lenses on human patients to evaluate comfort.

Salih AE, Elsherif M, Alam F, et al. Gold nanocomposite contact lenses for color blindness management. ACS Nano. February 11, 2021. [Epub ahead of print].

■ **Evaluate patients for fungal or *Acanthamoeba* keratitis before deciding on the use of topical corticosteroids for the treatment**. In a study of 14 eyes, researchers found steroid use did not affect the visual prognoses in the eyes with bacterial keratitis; however, vision was lost in two eyes with fungal keratitis. Two of the six *Acanthamoeba* keratitis eyes also lost vision. The study concluded that **microbiological evidence, as well as a differential diagnosis of herpetic stromal keratitis, is needed when prescribing a topical steroid for suspected infectious keratitis**.

Hirano K, Tanaka H, Kato K, Araki-Saasaki K. Topical corticosteroids for infectious keratitis before culture-proven diagnosis. Clin Ophthalmol. February 16, 2021. [Epub ahead of print].

Overminus Lenses May Encourage Myopic Shift

In the first large-scale randomized clinical trial to evaluate the effectiveness and safety of overminus spectacle therapy for intermittent exotropia, researchers found that children three to 10 years old exhibited improved distance exotropia control after 12 months of overminus spectacle wear. However, this treatment was associated with an increased myopic shift, and its effect on distance exotropia control was not maintained after tapering off treatment for three months and examining the children three months later.

The study enrolled 386 children age three to 10 with intermittent exotropia, a mean distance control score of two or worse and a refractive error between 1.00D and -6.00D. Participants were randomly assigned to overminus spectacle therapy (n=196) or to non-overminus spectacle use (n=190) The overminused subjects wore -2.50D correction for 12 months, then -1.25D for three months, followed by non-overminus spectacles for three months.

The team reported an improved mean distance control at 12 months in participants treated with overminus spectacles compared with non-overminus spectacles (1.8 vs. 2.8 points). However, there was little or no difference in mean distance control between the groups at 18 months (2.4 vs. 2.7 points).

The myopic shift from baseline to 12 months was greater in the overminus group than the non-overminus group (-0.42D vs. -0.04D), with 33 of 189 children (17%) in the overminus group vs. two of 169 (1%) in the non-overminus group displaying a shift greater than 1.00D.

"This randomized controlled trial is the first study to provide robust evidence that overminus lens treatment is associated with a greater myopic shift, particularly in children who are already myopic before initiating treatment," wrote researcher Angela Chen, OD, in a *Practice Update* commentary. "This finding is of great importance for clinicians who routinely recommend overminus lenses to treat exotropia, even as a temporary treatment before considering surgery or orthoptics.

Chen AM, Erzurum SA, Chandler DL, et al. Overminus lens therapy for children three to 10 years of age with intermittent exotropia: a randomized clinical trial. JAMA Ophthalmol. March 4, 2021. [Epub ahead of print].

Photo: Jasleen Jhaji, OD

Children three to 10 years old exhibited improved distance exotropia control after 12 months of overminus spectacle wear.

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Crosslinking May Also Help Halt Myopia Progression

Corneal collagen crosslinking (CXL) with riboflavin and UVA has been successful in preventing keratoconus progression and corneal warpage, and new research suggests this technique also shows promise in myopia. Through animal studies, an investigative team from China found that the modified CXL procedure may potentially help control the pathologic process of myopia, even though further investigation into its safety is necessary.[1]

CXL with riboflavin-UVA is a minimally invasive procedure without allograft material implantation, which makes it possible to reduce complications such as infection and rejection, the researchers explained. "Its effectiveness, stability and safety make it hopeful to arrest progressive myopia or to inhibit the over-expansion of the sclera," they wrote in their paper.[1]

One study in the review used white rabbits as a model. The right eyes underwent CXL using riboflavin and UVA radiation, and every quadrant had either two or six scleral irradiation zones. The eyelids of the right eyes were sutured after therapy to establish myopia. Outcomes showed that CXL with riboflavin and UVA effectively prevented occlusion-induced axial elongation and that the size of the treatment area was effective.[2]

Another investigation established a lens-induced myopia model in guinea pigs to develop methods of CXL for the treatment of progressive myopia. The results indicated that CXL using riboflavin and UVA irradiation effectively prevented the progression of myopia by increasing scleral biomechanical strength. Additionally, scleral collagen fiber arrangements of the crosslinked eyes were denser and more regularly distributed than the myopic eyes.[3]

More recent studies have investigated the effect of oral administration of riboflavin combined with whole-body UVA irradiation on the biochemical and biomechanical properties of the sclera in a lens-induced myopic guinea pig model. This technique appeared to increase the strength and stiffness of the sclera by altering the biochemical and biomechanical properties and resulted in greater decreases in axial elongation and myopic diopter in the treatment group.[4]

As for the technique being used to prevent myopia, the appropriate timeline for interventional treatment should be further investigated, the investigators said. Scleral CXL has not yet been done on human eyes *in vivo*, so potential problems should be investigated further, including long-term safety and stability of CXL, proper parameters such as exact position and suitable area of the eye to be treated, amount of energy needed and exposure time, they concluded.[1] RCCL

1. Zhang F, Lai L. Advanced research in scleral cross-linking to prevent from progressive myopia. Asia Pac J Ophthalmol. January 25, 2021. [Epub ahead of print].
2. Dotan A, Kremer I, Livnat T, et al. Scleral cross-linking using riboflavin and ultraviolet-a radiation for prevention of progressive myopia in a rabbit model. Exp Eye Res. 2014;127:190-5.
3. Zeugolis D, Liu S, Li S, et al. Scleral cross-linking using riboflavin UVA irradiation for the prevention of myopia progression in a guinea pig model: blocked axial extension and altered scleral microstructure. Plos One. 2016;11.
4. Li X, Wu M, Zhang L, et al. Riboflavin and ultraviolet A irradiation for 51. the prevention of progressive myopia in a guinea pig model. Exp Eye Res. 2017;165:1-6.

mp | My Perspective ▸

By Joseph P. Shovlin, OD

The Bio-Data Rat Race

Despite some worries, the future looks bright regarding genetic testing.

This month I want to take a look at the incredible field of genetic testing. Two recent advances for the cornea will soon impact the way we practice in a very positive way, namely early detection. In particular, the first test will help us make a timely diagnosis for keratoconus and other corneal diseases; the second will help us identify corneal pathogens, especially when standard cultures and PCR testing fails to identify the causative organism(s).

GENETIC DETECTIVES

AvaGen (Avellino) will be the first commercially available test of its kind (Q2 2021) to help identify patients that have risk of developing keratoconus and certain other corneal dystrophies. It will be helpful to provide timely alerts to those predisposed to keratoconus. If detected, preventative strategies such as warning not to rub one's eyes, sleeping on their back and perhaps getting collagen crosslinking early are all important to minimize morbidity. AvaGen looks at over 1,000 variants across 75 different genes for keratoconus and over 70 TGFBI mutations for corneal dystrophies.[1]

Metagenomic deep sequencing (MDS) is genetic testing that simultaneously and independently detects nucleic acid fragments of any pathogen that might be present and allows ongoing pathogen discovery. MDS is currently not FDA approved and not yet in the mainstream. It's primarily used when there is obvious infection but no known cause after standard testing. Investigators at UCSF are doing incredible work with this technology trying to streamline workflow issues, detection limits and interpretation difficulties to eventually make this routine. It's a promising test with some challenges including cost, differentiating pathogenic organisms causing infection from commensals and the ethical question of generating genetic data (disease causing genetic mutations).

We're familiar with the limitations and errors with standard cultures and the profiling required ahead of time for PCR testing. Corneal cultures—our gold standard—have a sensitivity of only about 60%. Unlike PCR testing, a targeted test where you need to ask for specific pathogen identification probes, MDS is an unbiased method for detecting pathogen(s) responsible for any corneal infection overcoming the need to separate the genomes or culturing the microbes.[2,3] In other words, you don't have to ask ahead of time to probe for any specific pathogen. Similar to any diagnostic assay, clinical diagnostic correlation and assessment of treatment response remain important.[2]

DATA VULNERABILITIES

I must digress a bit and share some potential problems of such technology when not used properly or as intended. A recent *60 Minutes* presentation interviewed local Scranton star, William Evanina, director of the National Counterintelligence and Security Center.

Throughout the interview, Bill stressed the national security risks of foreign adversaries having access to our biologic and healthcare data. Our government is primarily concerned with their ability to generate genomic data and the potential to control the United States's healthcare and pharmacy companies. Bill suggests that those quick to offer their services for COVID testing across the United States likely showed significant interest because, apparently, our DNA is so valuable. Might they one day circumvent and do an "end-around" on our healthcare system and target citizens directly? On one hand, all of this might be good for future treatment and cures, but what else exists that might be unfavorable to our healthcare system? It's an interesting interview to check out.

I see the field of genetic testing and nucleic acid analysis as an exciting frontier with many rewards, and at the same time with a few risks. As long as we use the data as its intended—namely to treat and eventually cure the population at risk—science advances. And if we not do not abide by that goal, the consequences are serious. Let's hope Bill Evanina is looking at a worst-case scenario and being overly cautious in his assessment of how this data is being used and targeted for future use.

On a more positive note, the advances mentioned above will soon help us better serve our patients from the front to the back of the eye. through genomic testing. I can't wait to use them. RCCL

1. Genetic Testing Registry. AvaGen test for keratoconus risk factors adnd corneal dystrophies. www.ncbi.nlm.nih.gov/gtr/tests/569033/. Last updated September 16, 2020. Accessed March 15, 2021.

2. Gallon P, Parekh M, Ferrari S et al. Metagenomics in ophthalmology: hypothesis or real prospective? Biotechnol Rep. 2019;23(9):e00355.

3. Seitzman GD, Hinterwirth A, Zhing L et al.: Metagenomic deep sequencing for the diagnosis of corneal and external disease infections. Ophthamology. 2019;126(12):1724-6.

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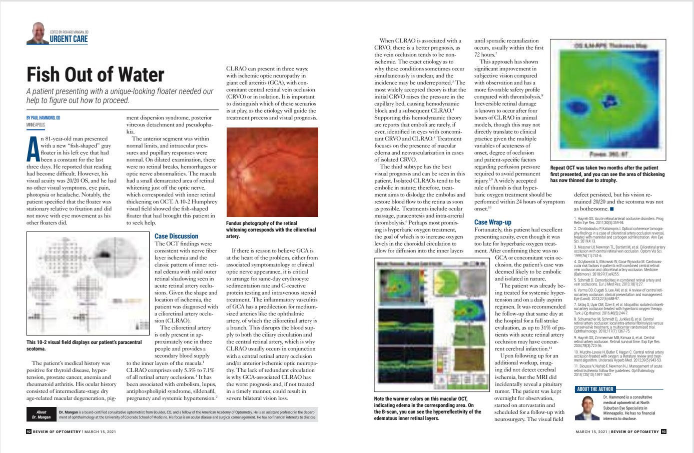

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By Lindsay Sicks, OD

Confronting Compliance

Having patients demonstrate they understand can help this challenging and complex process.

When discussing solutions with patients, how do you ensure proper compliance with your recommendations? We always strive to provide thorough education at the initial visit. We may recommend purchase of specific items and through specific channels (*e.g.*, online, in-office purchase). Regardless of how carefully worded our instructions, or how thoughtful our recommendations, patients can still be led astray by incorrect recall or faulty logic.

EARLY TROUBLES

Recently, I had the privilege of fitting a family friend with keratoconus in scleral lenses for the first time. After failing in corneal lenses seven years ago, this 34-year-old was hesitant. I reassured him that we would work together to achieve success, and I felt his odds would be improved with scleral lenses.

His spectacle refraction was -4.25 -1.00 x 080 OD with a VA of 20/70 and -2.50 -1.75 x 150 OS with a VA of 20/30. Minimum pachymetry values were 430µm OD and OS 472µm OS. We fit Valley Contax Custom Stable Elite 15.8mm scleral lenses, designed using profilometry scans from the Eaglet Eye Surface Profiler (*Figure 1*). His deep-set eyes made obtaining sufficient maps in the vertical meridian more challenging, but we were able to obtain an adequate fit after exchange.

His newfound distance vision with scleral lenses was 20/20 OD and 20/25 OS. When he took the lenses home, I let him know he could text me at any time with questions. I was amazed at what he asked when given all-hours access. This patient contacted me to confirm which eye drops were appropriate for use and when to discard preservative-free saline. He was also not correctly rinsing his lenses with hydrogen peroxide solution before soaking, nor was he using that solution daily. His lenses were coated in a commercially available surface coating specially designed to improve lubricity, and his leaving them dry in the case every other night was problematic. Lack of adherence to appropriate procedures resulted in post-lens tear reservoir debris and front surface non-wetting (*Figure 2*).

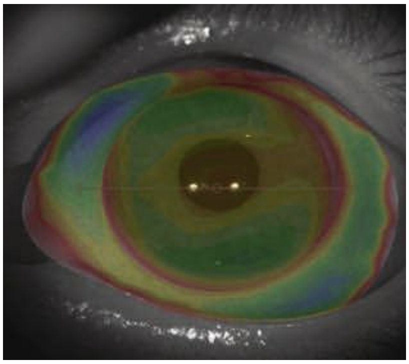


Fig 1. This profilometry image helped design our patient's scleral lens.

THOROUGH EDUCATION

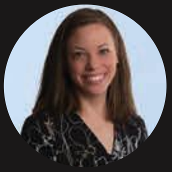
This scenario left me feeling a bit embarrassed at how I had failed to properly emphasize critical lens care items. With patients like this in mind, here are some strategies to overcome common pitfalls when confronting patient compliance with contact lens solutions.

Ensure your technicians and staff are highly trained. Consider training all staff to instruct patients in the same way you would. This means ensuring staff is familiar with the proper protocols for each solution you prescribe. "Is there a rinse step? How long is the rubbing step? What should the patient do if they drop a lens in the sink or on the floor? When should solutions be discarded? What if the tip of the bottle is contaminated? How do I clean my case? Can I use water to rinse my lenses?" These are critical questions staff should anticipate and prepare for, whether they pertain to GP, soft or other specialty lenses.

Place emphasis on the intricacies of each particular solution during training. Solutions carry varied recommendations for the required rub and rinse steps. Specifics for each brand can be found on the package insert. For new wearers, this information is critical to enforce proper protocols. For previous wearers, this information can dispel old myths or correct bad habits. For all wearers, these steps reduce the bacterial bioburden on the lens and reduce the incidence of complications.

Sometimes the latest research has recommendations that differ from the package insert. For example, some solution package inserts still contain the now ill-advised recommendation to rinse GP lenses with tap water. Another one is a recent study that suggests rubbing is essential to remove stubborn oily deposits from orthokeratology lenses even if using a hydrogen peroxide system.[1]

Incorporate video education. Using videos to deliver key points in the contact lens care regimen can help ensure consistency and



incorporate visuals with your message. You can use videos that are readily available, such as those from solution manufacturers, contact lens manufacturers or educational societies. For a low-cost custom option, create your own videos and have your staff members star in them. Outline scripts where you include the key points you wish to address. Don't forget to reinforce the importance of thorough handwashing before and after lens handling.

Give written instructions. Whether provided by a manufacturer or drafted specifically for your practice, handouts supply patients with a tangible reminder of the knowledge they've gained during training. These instructions, when vetted by the practitioner, are much better for patient education than anything your patient may find online. You probably don't want patients navigating random YouTube videos or online forums in a panic! Ensure the signs and symptoms of potential infection are highlighted on any handouts and include your office emergency contact for any questions that may arise.

Prescribe solutions to patients. Consider your patient's lenses and make a single recommendation for which solution you believe will work best. Whether it's a two-bottle (cleaner/conditioner), a multipurpose or a hydrogen peroxide based system, avoid giving multiple options. The last thing you want to do is give your patient "choice overload." You are the expert in what solutions work best with which lens materials and patient

Fig. 2. This front surface non-wetting of the scleral lens was caused by lack of adherence to solutions regimen.

scenarios. While you may not have a prescription pad handy in the era of electronic health records, you can still prescribe a solution that will best meet the patient's needs. Follow-up on these recommendations at each aftercare visit so you can troubleshoot issues that arise, such as preservative sensitivity or improper procedures.

Review proper procedures at each aftercare visit. If you are not personally doing the case history at each contact lens aftercare visit, get in the habit of asking patients which lens solutions are being used. Confirming these items, even mid-exam, can reveal crucial discrepancies.

I sometimes find the same solution listed in the chart for the last several visits, but, suddenly, the patient changes their routine. "I got this other type of saline because I thought it was the same." "I borrowed this new kind of solution from my sister." "This brand was on sale last week, so I bought a twin-pack." "I found an old, travel-sized bottle of lens solution under my sink." You name it, we've heard it—so we still need to take the time to ask.

Have the patient show and tell. One additional strategy to ensure proper compliance is to have patients show you what they are doing. Patients may hesitate (because it feels like a test) but encourage them to keep going. If your patient is shy, at least have them talk you through the steps they take in their care regimen. Gently point out any places they could improve and correct the procedures where indicated.

Ask if there are any questions. After patient education is complete and the patient is ready to leap out of your chair, stop and ask if there are any remaining questions. The strategy here is to use the phrase, "What questions do you have for me?" rather than, "Do you have any questions?" It's a classic positive psychology tactic. You are giving the patient permission to ask questions. When you say, "Do you have any questions?" the tendency is to say "Nope!" and end the conversation. Avoid that abrupt ending and welcome the patient's inquiries by extending them permission to continue.

Solutions compliance will continue to be a challenge in our practices for all types of patients, new and established. Incorporating strategies to improve compliance now can help drive comfortable lens wear for your patients for years to come. RCCL

1. Cho P, Poon HY, Chen CC, Yuon LT. To rub or not to rub?–effec gid contact lens cleaning. Ophthalmic Physiol Opt. 2020;40(1):17-23.

MATERIAL GAINS: 50 YEARS OF THE SOFT CONTACT LENS

A closer look at the evolution of lens materials and what comes next.

By Catlin Nalley, Contributing Writer

Today, soft contact lenses represent a massive industry that provides a host of innovative options to meet the needs of millions that are comfortable while also providing excellent visual acuity. The range of corrections available has expanded significantly since the birth of the soft contact lens, and discoveries continue to enhance the available offerings. With both daily disposables and longer-wear options, individuals have the opportunity to select a lens that works best for not only their vision but also their lifestyle.

Since the first soft contact lens was approved by the Food and Drug Administration 50 years ago, the market has grown exponentially, and significant technological advancements have occurred to get us to where we are now. The journey to FDA approval began in the late 1950s/early 1960s with Otto Wichterle, a chemist based in Prague, Czechoslovakia. Professor Wichterle, with his assistant Drahoslav Lim, developed hydroxyethylmethacrylate (HEMA) and recognized this new polymer's potential as a contact lens material.[1]

Photo: Mile Brujic, OD

Corneal infiltrate from sleeping overnight in a HEMA material contact lens. Progress in materials science has helped reduce incidence of lens-related complications such as these.

The US government decided in 1968 that soft hydrogel lenses should be classified as a drug and, therefore, would require FDA approval.[2] In late 1971, Bausch + Lomb received marketing approval for the Soflens (polymacon). Within one year, three soft lens materials were available in the United States. There were 35 by 1994, and in 2010 the number of soft contact lens materials had reached 90.[3]

Today we have over 160 different soft contact lens brands in different modalities available in spherical, toric, multifocal and specialty designs. The current lenses meet the many needs of consumers while pushing the boundaries of innovation.

FROM THEN TO NOW

The first hydrogel lenses represented a sea change in the contact lens market, offering consumers a level of comfort that had never been available before, compared with their corneal PMMA lenses. This new material revolutionized the field and opened the door to future developments.

"A driving force behind the soft lens was comfort and wearing time," notes Dwight Akerman, OD, former vice president and global head of professional affairs and business development for Alcon. "Consumers and doctors were amazed at how comfortable soft contact lenses were compared with rigid lenses."

Initially, it was marketed as a yearly replacement lens, Dr. Akerman recalls. And so, wearers had to go through aggressive cleaning regimens to ensure disinfection and to maintain comfort. Patients had to use a contact lens cleaner, then rinse it off with saline before placing it into a heating unit to disinfect the lens. Then, once a week, they would clean the lenses with enzyme tablets to remove protein deposits, according to Karen Yeung, OD, senior optometrist at UCLA's Arthur Ashe Student Health and Wellness Center. Dr. Yeung notes that homemade saline with salt tablets and distilled water resulted in a high incidence of corneal infections.

"This was the dominant modality for many years; however, it soon became obvious that there were deficiencies with both the material and frequency of replacement," Dr. Akerman says. "Specifically, there were issues with buildup, especially tear protein on the surface of the contact lens, which can cause irritation and inflammation on the eye."

The complications associated with hydrogel lens materials, especially protein deposits, could result in a short wearing life. Research found that proteins could begin early. For high-producing patients, deposits could be detected after one minute of wear and within 30 minutes the lenses could begin to spoil. Patients who wore these lenses also experienced neovascularization and papillary conjunctivitis due to inflammation.[2]

It was the inventor of the soft contact lens himself, Dr. Wichterle, who would first propose the idea of disposable contact lenses. During a 1980 meeting of the International Society for Contact Lens Research, he said, "Once deposits occur, we could reject the lens and take a new one! I believe we are now very close to the development of technology which will cause a dramatic drop in the selling price of lenses. Once you are able to buy a lens for one dollar or less, lens spoilage won't play a role. If a lens is spoiled, it will be cheaper to buy a new lens than to buy expensive solutions and waste time with cleaning."[2]

Technology for developing lenses was improving, but it would be many years before his vision became a reality. Soft contact lens manufacturing was still a very manual process in which workers would have to handle every contact lens. In 1987 Vistakon (now Johnson & Johnson Vision Care) was able to mass produce contact lenses more efficiently. Acuvue lenses were first developed as one-week extended wear contact lenses. There was the belief that handling the contact lenses increased the risk of infections, so it would be better to minimize handling by sleeping in the contact lenses and removing the contact lenses in a week. Unfortunately, the rate of infection and complications is much higher with extended wear lenses.

"While some of the HEMA lenses were approved for extended wear, lack of oxygen transmissibility led to irritated eyes and, in some cases, infections," Dr. Akerman says. "Eyecare professionals actively discouraged patients from wearing these lenses despite FDA approval."

Extended wear waned in popularity in 1989 when concerns regarding the risk of complications arose. Research showed that the incidence of ulcerative keratitis increased for individuals who wore soft contact lenses for an extended period.[4] As a result, manufacturers reduced extended wear from 30 to seven days and included information on risks in their product labeling.[3]

In 1995, the whole industry changed when Johnson & Johnson introduced the 1-Day Acuvue (etafilcon A) lens, the first daily disposable, notes Lyndon Jones, PhD, FCOptom, director of the Centre for Ocular Research & Education (CORE) at the University of Waterloo.

Research has shown that the prevalence of complications was significantly lower among individuals who wore daily disposable lenses than those who used less disposable and conventional soft daily lenses.[5,6] Additionally, researchers have found that patients with disposable daily wear lenses reported symptoms less frequently at routine visits and were less likely to unscheduled visits for complications and symptoms.[5]

The low oxygen transmissibility of the current soft contact lenses also

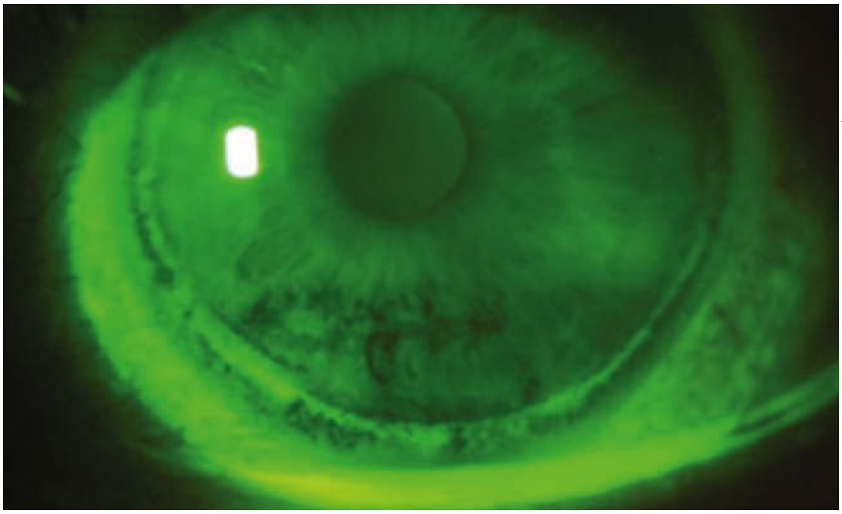
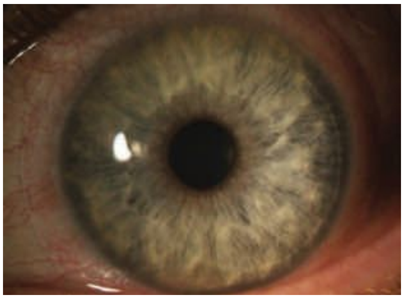


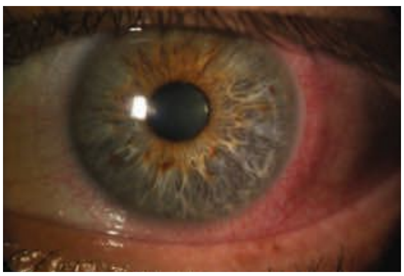
Photo: Ken Daniels, OD

Even though the introduction of silicone hydrogel lenses achieved notable benefits for eye health, the material is still susceptible to complications, especially when worn beyond the recommended wear schedule, and in this case of circumlimbal epithelial splitting from extended wear.

Photos: Ken Daniels, OD



Contact lens–induced acute red eye response (CLARE) from extended wear SiHy lenses.



CLARE presenting with extreme conjunctival injection in the absence of corneal infiltrates.

presented a challenge. Innovations in materials were needed to address this. "While hydrogel lenses offered a new level of comfort, the material suffers from low oxygen transmissibility and deposit buildup, especially tear protein buildup on the surface of the lens," explains Dr. Akerman. "Therefore, polymer chemists at the various contact lens companies continued to explore ways to address these issues, but it would be quite some time before we saw another major breakthrough in materials."

The next significant milestone in soft contact lens materials occurred in the late 1990s with the advent of silicone hydrogels. This material sought to bring together the benefits of highly oxygen permeable silicone monomers with the wettability and comfort of hydrogels.

"Silicone hydrogels were an exciting development for eyecare professionals as well as consumers," Dr. Akerman recalls. "These lenses allowed plenty of oxygen to reach the cornea resulting in white, healthy-looking eyes. This was especially valuable to patients who wore their lenses all day, every day."

Silicone hydrogels renewed interest in extended wear and, in 2001, the FDA approved the Ciba Vision Night & Day contact lens for up to 30 nights of continuous wear. Approval followed soon after for Bausch + Lomb's PureVision lens.[7] These first-generation silicone contact lenses had a highly rigid modulus due to the high silicone content and low water content, notes Dr. Yeung. "Later generations of silicone contact lenses were more comfortable as the modulus was decreased by lowering the silicone while increasing water content without compromising too much on oxygen transmissibility."

The first daily disposable silicone hydrogel lens was introduced in 2008.[8] The convergence of these two paths of innovation—daily disposable replacement and new silicone hydrogel materials—was a turning point for the industry, notes Karen Walsh, MCOptom, a clinical scientist at CORE. With fewer complications compared with reusable lenses, evidence supports the use of daily disposables for many patients. The addition of silicone hydrogel materials offers long-term advantages for a patient's health.[8]

"Daily disposable silicone hydrogels were something practitioners had been wanting for years because we could see the advantages they would bring," Dr. Walsh says. "Since they were introduced, we have witnessed a significant increase over time of available materials and lens designs in this category that can meet the needs of a wide range of patients."

Today, daily disposable silicone hydrogel lenses are the fastest-growing category in contact lenses worldwide, according to Dr. Akerman, who notes that while an important addition to the market there is still a place for older materials. "They're still very appropriate for many patients, especially in the daily disposable category. Part-time wearers can benefit from these lenses, which also come at a lower cost."

OPPORTUNITIES FOR GROWTH

While great strides have been made in the last 50 years, there are still opportunities for growth and improvement in the soft contact lens.

Multifocal and toric soft contact lenses have seen advancements since they were introduced decades ago. In 2002, the first daily disposable astigmatism lens design (Focus Dailies, Ciba Vision) was introduced in 2002. The Focus Dailies

Selected Highlights in Soft Contact Lens Development

1971: FDA approves first soft contact lens (soflens, Bausch + Lomb)

1983: First soft color contact lenses

1987: First disposable soft contact lenses launched

1996: First daily soft disposable contacts were released

1997: First monthly silicone hydrogel contact lenses (Night & Day, Ciba Vision)

2004: Second-generation silicone hydrogel contact lenses (Acuvue Oasys, Johnson & Johnson)

2005: Third-generation silicone hydrogel contact lenses (Biofinity, CooperVision)

2008: Silicone hydrogel daily disposable contact lenses enter the market

2013: First water-gradient soft contact lens material (Dailies Total1, Alcon)

2019: First soft lens approved to slow the progression of myopia in children (MiSight, CooperVision)

Progressives (Ciba Vision) was the first daily multifocal lens. The first disposable presbyopic lens (Acuvue Bifocal, Johnson & Johnson)—a one-week extended wear lens—entered the market in 1998. Focus by Ciba Vision was launched in 1999—the first disposable toric lens with monthly replacement.[2]

The market continues to expand for these more specialized lenses; however, gaps remain. “Right now, we are only able to correct certain higher order aberrations,” notes Joseph Shovlin, OD, of Scranton, PA, past president of the American Academy of Optometry. “And I think that’s the next frontier: to be able to correct greater aberrations effectively for better acuity—super acuity, if you will.”

There is room to improve the optics of these lenses, Dr. Shovlin suggests, noting that while significant progress has been made correcting astigmatism and there are good options available today, advances are still needed in presbyopic designs. “I believe that is the desire for the future: to find the lens that works for every presbyopic patient,” he says.

This is a challenging endeavor, Dr. Shovlin acknowledges. “The problem with soft lenses is figuring out how to impose the optics to simultaneously correct distance and near vision,” he explains, while also urging practitioners to remember all of the progress that has been made.

“Early on we didn’t even think about correcting astigmatism,” Dr. Shovlin emphasizes. “We didn’t even think about correcting presbyopia. We were just hoping to correct low to moderate amounts of myopia and now we can correct virtually any amount of myopia.”

With today’s lens options, “we can correct high amounts of astigmatism at an around-the-clock axis, and we can find a successful option for patients who are presbyopic, probably about 70% of the time,” he continues. “We’ve got a long way to go, but we’ve come a long way, and I think it’s important to recognize the significant advances that gotten us to where we are today.”

Table. Pros & Cons of Soft Lens Materials[14]

	Pros	Cons
Hydrogels	• Comfort and durability • Price • Copolymer possibilities	• Low oxygen permeability • Higher rate of complications in extended wear • Protein deposits
Silicone Hydrogels	• Comfort and durability • High oxygen permeability • Reduces the risk of eye hypoxia • Good option for extended wear • White, healthy looking eyes	• Price (although there are some more affordable options available today) • Need for hydrophilic comonomer • Lipid deposits

Myopia control with soft contact lenses is another hot topic, notes Dr. Yeung. “Currently the only FDA-approved myopia control contact lens, MiSight by CooperVision, is a one-day HEMA hydrogel contact lens,” she says. “Because the pediatric patients will be wearing contact lenses for many decades, inevitably a one-day disposable silicone myopia control contact lens will emerge in the market.”

ONGOING INNOVATION

Materials scientists continue to look for new ways to both enhance and revolutionize soft contact lenses. There are a number of avenues being explored; some are showing promise now while others may take longer to become a reality.

While silicone hydrogel materials, both in daily disposable and other replacement modalities, have addressed the oxygen transmissibility issues of the early lenses, one area of ongoing focus is comfort.

“Now, the innovations we see from major manufacturers are focused on initial and end-of-day comfort,” notes Dr. Akerman. “Many consumers—especially those who spend most of their time in front of a digital device —still have dryness and discomfort issues, particularly after hours of wear.”

The goal of manufacturers is to make lenses as comfortable at the end of the day as they are when a consumer first puts them in their eye, explains Dr. Akerman, noting a number of recent innovations.

For example, Bausch + Lomb recently introduced the Infuse daily disposable lens, which is designed to address end-of-day discomfort.[9] The Precision1 (Alcon) daily disposable lenses were released in the last year. This lens uses a permanent, micro-thin layer of moisture at the lens surface to support a stable tear film.[10] Dailies Total1 has a water gradient to improve ocular dryness. Other products designed to improve comfort include the MyDay (CooperVision) and Acuvue Oasys 1-Day (Johnson & Johnson).

“Comfort is king,” emphasizes Dr. Akerman. “And if a patient can’t wear the lenses comfortably all day, they tend to be dissatisfied and frequently will dropout. These innovations also offer improvements to visual acuity, but the number one innovation addresses dryness and comfort.”

Other areas of exploration center on contact lenses as drug delivery systems. Unlike administering agents with eye drops, a drug-loaded contact lens could provide higher drug

Contact Lenses and the Ocular Surface

While innovations continue to improve the optics and comfort of soft contact lenses, it is important not to forget about the ocular surface. Just as there have been advancements in contact lens materials, significant work has been devoted to helping practitioners improve the ocular surface and tear film.

"Despite significant improvements, we still have some comfort issues for patients, especially towards the end of the day," says Dr. Walsh, who notes that when a patient complains of discomfort, clinicians will often change the lens type and may add a lubricating drop.

"We can now be more scientific and much like we would with a dry eye problem, we can address ocular surface-related issues to improve contact lens comfort," she continues. "As a profession, we are getting better at looking at the whole system when it comes to our patients."

Dr. Jones agreed, while highlighting that dropout rates remain higher than practitioners would like. "We're still seeing about 20% of patients dropping out and some of that is related to handling issues; however, many are a result of vision and comfort challenges.

"You can take the best lens and solution in the world and if you put it into an eye that simply doesn't have a good ocular surface or a good tear film, it's probably not going to be successful," he emphasizes. "This is where optometrists play a key role in helping patients have optimal outcomes."

bioavailability.[11] A number of different systems have been explored. For example, a new device has been developed using vitamin E nano-barriers to extend drug release.[12]

"We are in an exciting era of new technology," notes Dr. Yeung. "Johnson & Johnson is soon to launch their latest contact lenses pre-loaded with ketotifen, an antihistamine to help contact lens wearers with their ocular allergies. Researchers in the University of Manchester are creating contact lenses to treat corneal melting.

"A new company called Mojo Vision is coming out with smart contact lenses that have a pinpoint computer screen embedded into the contact lenses," she continues. "The contact lens could have a speech app that allows you to see your pre-written script as you recite it in front of your audience. The Apioc (Lentechs) lens is now undergoing clinical trials for a novel approach to correct for presbyopia with translating soft contact lenses. The list goes on."

What could the long-term future of soft contact lenses look like? There are a number of possibilities, according to Dr. Yeung. "I can imagine a world where contact lenses just self-disintegrate in the eyes towards the end of the day so that we would never have to deal with patient noncompliance or with plastic waste," she muses. "Or just a pair of contact lenses that you never have to remove and adapts to our changing prescriptions.

"We, of course, have lots of room for more improvement for the current contact lenses, but we have come a long way and I am looking forward to where things will be in the future."

PROACTIVE APPROACH

As advancements continue, the growth of contact lens market depends not only on innovation and new developments but also on the optometrist. The tremendous advances that have occurred since the soft contact lens was first introduced only make a difference if practitioners fit patients, notes Dr. Jones, who encourages ODs to adopt a proactive approach as opposed to waiting for patients to ask for lenses, which will help enhance their practice.

Optometrists have the chance to help patients become dual wearers. Dr. Jones believes that every spectacle wearer should be given the opportunity to wear contact lenses, and every contact lens wearer needs backup spectacles.

"Contact lens companies have given us great products, but practitioners need to embrace them and use them on their patients if we're going to see a growth in the contact lens market," he concludes. RCCL

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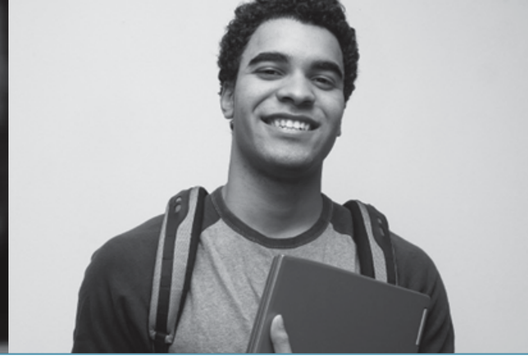


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MANUFACTURING A BRAND-NEW INDUSTRY

From humble origins, soft contact lens production ramped up as continual innovations paved the way for a half-century of progress.

By Catlin Nalley, Contributing Writer

In the 50 years since the soft contact lens first arrived on the market, remarkable progress has been made. What began with a child's building kit and a phonograph motor is now a multi-billion-dollar industry.[1,2]

"Since the soft contact lens was first introduced in 1971, the industry has seen significant growth and advancements," notes Joseph Shovlin, OD, of Scranton, PA. "As innovations in materials grew, so did efforts to enhance manufacturing processes. Different manufacturers developed an assortment of technologies to allow for today's high production rates of quality lenses."

Today, an estimated 45 million individuals wear contact lenses, 90% of whom use soft lenses.[3] To meet the needs of this market, there was a concerted effort to develop not only revolutionary materials, but also manufacturing processes that could keep up with innovation and allow for the mass production.

"The contact lens industry has seen massive improvements, even in the span of my career," emphasizes Nashville contact lens specialist Jeffrey Sonsino, OD. "The incremental improvements in manufacturing each year have culminated in the ability of manufacturers to cost effectively produce daily disposables, which are the crown jewels of the contact lens industry."

He goes on, "When Don Korb created the CSI lens, it was arguably the greatest material ever made to that date. Its downfall was protein and lipid deposition after a month's worth of wear. Manufacturing techniques and yield rates at the time did not allow the lens to be produced in a daily disposable. But now, we can develop similar materials that are highly cost-effective, reproducible and safe for wear."

THE GROWTH OF AN INDUSTRY

Otto Wichterle, a chemist from Czechoslovakia, produced the first four hydrogel contact lenses using the spin casting process he pioneered.[4] He created the device with a children's building kit, a bicycle dynamo belonging to one of his sons and a bell transformer.[5] HEMA, the polymer created by Wichterle, was heated with a hot plate and added to the mold through a tube while it was spinning.[6]

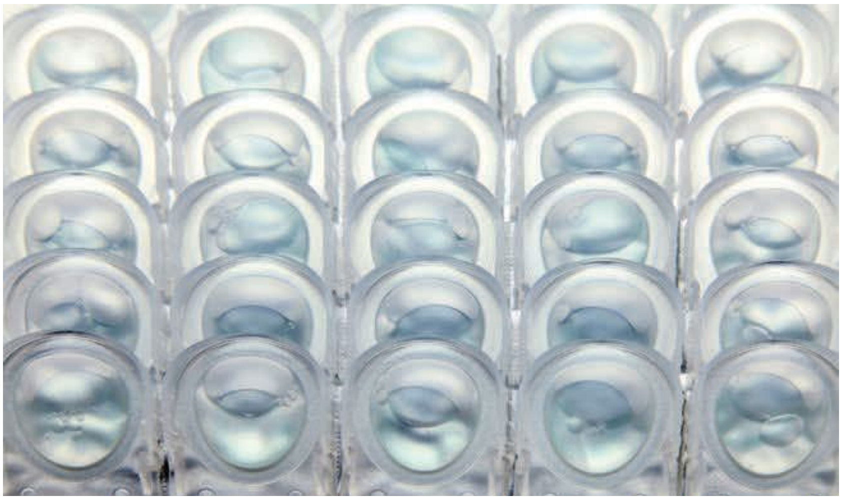
And this is how Wichterle invented spin casting—a new way of manufacturing lenses that would play a central role in the growth of this industry. He went on to develop another way to produce soft contact lenses in 1963 using lathing machines.[4] In 1966, sublicensing of Wichterle's patent was granted to Bausch + Lomb, who received exclusive rights for the spin casting process and non-exclusive rights to hydrogel lens distribution.[6]

In the early days of contact lenses, high manufacturing costs were largely contributed to labor. Trained technicians magnified and inspected early lenses more than 10 times to look for any flaws. Advancing production techniques eventually made this rigorous inspection unnecessary.[6]

Lathe cutting was used to produce PMMA and early hydrogel lenses. This technique has its limitations, including a higher expense since it requires a lathe to cut each lens out of dry material followed by hydration of the final product. This process, which has poor reproducibility, required an evaluation of every lens before it was sent to the consumer. Conversely, spin casting allows for higher production. Additionally, the lens optics can be varied by changing the speed of rotation as well as the mold shape. In 1980, manufacturers started using cast molding for contact lens production. This shift sought to produce low water content polymacon lenses while increasing production capacity without additional labor.[6]

With the introduction of disposable lenses, manufacturing companies had to ramp up production without sacrificing quality. Stabilized soft molding, which is a cast molding process acquired from a Danish engineer, allowed for volume production and led to the United States launch of Acuvue (Johnson & Johnson Vision Care) in 1987.[7]

Another significant innovation was Johnson & Johnson's move away from injection vials to the blister pack that we see today, according to Ross Grant, an optometrist and business consultant to the contact lens industry. They reduced costs by producing molds and packaging into blister packs on the production line. The per-lens cost was lowered with the reduction of labor and an increase in automation.[6]



The now-ubiquitous blister pack was revolutionary upon its introduction. As a means of packaging and distributing lenses at high volume, the cost per lens was reduced from that of glass vial production lines and more elements of the manufacturing process could be automated—bringing additional cost savings as well as shortening production time.

In all of these manufacturing processes, polymerization of monomers using UV light or heat was required, explains Dr. Grant. This resulted in residuals inside the lens, which were toxic. Before sterilizing and packaging the lenses, a lengthy extraction process was required.

In the mid-'90s, Ciba Vision launched a project that aimed to further streamline the manufacturing process, Dr. Grant says. "Through these efforts, they did away with the extraction process," he recalls. "Instead of starting with monomers and polymerizing them, they polymerized until you had a fairly viscous liquid." The result was a relatively small molecule that was still polymerized and didn't have any toxic residue present, which was then put in the mold.

"It was then exposed to UV light and crosslinked. These small molecules joined together, and you ended up with the gel, which was the contact lens," Dr. Grant continues. "This process was much faster than previous methods. Ciba Vision then automated the system, allowing for the production of mass quantities of lenses."

The first daily disposable lens launched in 1995 (1-Day Acuvue, J&J). To make daily lenses a cost-effective product, J&J created a second-generation manufacturing process called 'Maximize.' This process, which integrated stabilized soft molding manufacturing, optimized polymerization, and included

Lens Manufacturing Lingo

Spin Casting: Monomer liquid is injected into a spinning mold. Heat or UV light is used to initiate polymerization. This method uses centrifugal force to form the shape of the base curve while the shape of the front curve is created by the mold.

Lathe Cutting: The anhydrous polymer is first cut to small buttons and the surface of the lens is cut by lathe tool to the required curvature. Both sides are then polished to remove any roughness before the lens is soaked in a saline solution to hydrate. Lastly, the lens undergoes a sterilization process.

Molding: This method is used to manufacture some brands of soft contact lenses. Opposing molds are used to cause the materials to become the necessary shape inside the mold. Injection molding and, most recently, computer control, are also used.

Stabilized Soft Molding: Developed for high volume production, this method mixes an inert water substitute with lens monomers prior to polymerization; water replaces the substitute at hydration.

the use of conveyors, robotics and a computerized high-resolution inspection of lenses among other improvements.[6]

"Daily disposable lenses transformed the industry," says Dr. Grant. "You're producing 730 lenses for one person compared to 104 for weekly disposable lenses.

"That is a massive increase in volume and normally you trade off some quality for quantity," he explains, who notes that this was not the case for daily disposable lenses. "These lenses were extraordinary in the quality that they delivered."

This was achieved through automation and cast molding, according to Dr. Grant. Up until this point, spin casting and lathing were predominantly the two technologies used to manufacture soft contact lenses. "Even with automation, lathing is quite inefficient," he notes. "You cut away more than you leave behind."

Ongoing efforts dedicated to the advancement of manufacturing techniques—both with small changes and significant innovations—have led the industry to where it is today, allowing for the production of soft lenses on a scale that could hardly be imagined 50 years ago.

"Over the course of decades, the machines used to produce contact lenses have become much more automated and precise," notes Tony Hough, MBA, BA, a longtime industry consultant. "Around the '70s/'80s, almost all lens cutting was done with manual equipment, eventually moving to semi-automatic and later on, highly automatic. At the same time, underlying technology, such as air bearing spindles, allowed for an improvement in the quality of lenses produced. Together, we have the ability to mass produce high-quality lenses to meet the growing demands of the market."

ENTERING THE MARKET

In an industry dominated by major players, gaining a foothold can prove challenging for a new manufacturer. Are the barriers to entry too high? It may be difficult, but not impossible if the company can fill a gap in the market.

One example of this is Eyeris, a new contact lens company that puts the doctor/patient relationship at the forefront of their mission. Dr. Sonsino, co-founder of the company, attributes Eyeris's success to its unique business model and growing concerns around industry practices that are removing ODs from the equation.

"It all comes back to patients and doctors," notes Dr. Sonsino. "Certain direct-to-consumer companies are seemingly operating outside of prescription requirements and the law. As practitioners, we're seeing the direct results of this bad behavior with patient complications." Dr. Sonsino recalled a patient who purchased lenses from an online retailer for three years without that company requiring a valid prescription. This patient ultimately needed a corneal transplant.

At Eyeris, the doctor is in control of the process from start to finish. "Patients can purchase online directly from Eyeris, but doctors know that patients are receiving only the type of lens and quantity that they prescribe, all while realizing the margin on those sales," Dr. Sonsino explains. "This is a better model not only for doctors, but also patients. We give consumers the cost convenience and comfort they desire, while requiring regular visits to their optometrists."

As a growing start-up, how does Eyeris offer affordable options while contending with the costs of manufacturing and distribution? "One of the ways that we were able to produce lenses at a much lower cost than the big four was to work around them," says Dr. Sonsino. "We produce Eyeris lenses with our own manufacturing lines in Asia."

The quality control is held to the same standards as American manufacturers and the company uses the same techniques, he explains. For example, Eyeris uses UV crosslinking of monomers instead of heat as many Asian manufacturers do. Additionally, the company does not invest in a national sales force or rebates, according to Dr. Sonsino, who notes that these practices significantly raise the cost of a lens.

WHAT COMES NEXT?

As advancements continue, how will manufacturing processes continue to evolve? According to Mr. Hough, there will be a focus on refining current technologies and an ongoing shift toward further automation.

"If you look forward 20 years from now, I believe the majority of lenses will be made using exactly the same methods we employ today," he notes. "We may run a bit quicker and jump a bit higher, but you'll see the same core technologies."

But processes will certainly keep evolving. "We continue to see improvements and more manufacturers making lenses for more complex prescriptions," Mr. Hough continues. "The large companies now have very sophisticated, specialized manufacturing units that are filling in the ends of ranges. That's the type of investment that I think we will see more of, as well as further emphasis on automation and some robotics."

Improvements in manufacturing processes will allow companies to address those patients with specialty needs, emphasizes Dr. Grant. "While high-volume molding processes can produce very large quantities of lenses, it

Shifting the Industry Mindset

While ongoing advancements are crucial, so is a shift in mindset and industry practices, according to Dr. Sonsino.

"Manufacturing techniques are not going to fix the current problems in the industry; what we need is a change in manufacturer behavior," he elaborates, noting that for the most part, the contact lens manufacturing industry has forgotten the importance of speaking to consumers.

As a result, direct-to-consumer companies have filled this void and are trying to work around the doctor, Dr. Sonsino notes. "If nothing is done to counter this irresponsible messaging, there will be a tipping point where consumers no longer understand the need for legitimate eye care."

The demand for soft contact lenses will continue. What could change, according to Dr. Sonsino, is how lenses are delivered to patients. Will it be doctors or online middlemen who act as the voice to the patient?

He emphasizes the importance of treating contact lenses as a medical device, not a widget. "Without intervention, large, direct-to-consumer companies will continue to lobby for the deregulation of prescription requirements," Dr. Sonsino says. "As doctors, we know this will result in more ocular complications, but the question is, can we properly educate regulators?"

is not flexible," he explains. "For instance, in the case of toric lenses, where you have a sphere power, cylinder and an axis, the number of stock-keeping units goes up exponentially."

"Developing manufacture processes that can better cope with this is important," he continues. "A few things have been done, such as semi-molding—a combination of precision molding and lathe cutting."

Another avenue that has possibilities for the future is 3D printing. This technology could potentially allow for more customizable lenses without the need for post-processing, such as grinding or polishing.[8] However, this approach remains largely unexplored and will likely not be a viable innovation in the immediate future.

"3D printing is something I don't think we have fully explored in the way that we could," notes Dr. Grant. "Theoretically, you could have someone sit in front of a machine that connects to a 3D printer and creates a lens. While I believe we are several years from this becoming a reality, this approach does have possibilities for patients with specialty needs."

In an industry committed to innovation, ongoing refinement of current technologies as well as new developments will allow consumers to access cutting-edge products, no matter how unique an individual's needs. RCCL

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ADVANCES IN OPTICS DRIVE SOFT LENS SUCCESS

Achieving crisp vision for all refractive errors in a hydrogel material was no easy task. Let's look at the stumbling blocks and successes that brought today's lenses to life.

By Ian Cox, PhD, Pete Kollbaum, OD, PhD, and Eric Papas, PhD

By the 1960s, corneal lenses made using PMMA could be manufactured to correct myopia, hyperopia, astigmatism and even novel bifocal designs for presbyopia correction, but wearing times were often limited by the loss of vision caused by light scatter in the corneal epithelium, reported as "Sattler's veil." Ironically, the good optics of these lenses were compromised by the poor physiological response of the cornea to typical periods of wear.

It was the physiological response of the cornea to contact lens wear that became the primary focus of contact lens research during this time.

In 1960, Wichterle and Lim, two Czechoslovakian chemists, researched hydrogels and began to formulate the world's first "soft" contact lenses from their newly invented HEMA hydrogel material.[1,2] This 38% water content material was highly flexible, more oxygen permeable and significantly more comfortable than the rigid PMMA corneal contact lenses that were available. Wichterle's new hydrogel materials and a novel molding process called "spin casting" were ultimately licensed to Bausch + Lomb, and in 1971 the company obtained approval from the Food and Drug Administration to sell hydrogel lenses in the United States.[3]

EXCLUSIVE EXCERPT

This article is excerpted from "How Contact Lenses Have Influenced Research Developments in Optics and Vision Science" by the same authors, to be published in *Hindsight: Journal of Optometry History* later this year. Readers interested in obtaining copies of *Hindsight* should contact David Goss, OD, at dgoss@indiana.edu.

The first lens made commercially available was the Bausch + Lomb C-series contact lens. This fit the eye with considerable decentration and movement due to its 12.5mm diameter modeled from the traditional hard lens fitting philosophy. Although the optics were compromised by the wildly aspheric posterior lens surface produced by the spin-casting manufacturing process, the lens was extremely comfortable compared with the PMMA corneal lenses it competed against in the marketplace.[4]

The rapid commercial acceptance of soft contact lenses quickly led to development of additional designs by Bausch + Lomb and others. It was over this time that soft lenses become manufactured with larger diameters and greater sagittal depths to provide a more centered, less mobile lens fitting. In addition, spherical optical surfaces were now generated to minimize unwanted optical aberrations of

ABOUT THE AUTHORS

Dr. Cox, a researcher with over 30 years' experience in ophthalmic medical devices, is an adjunct professor at the Center for Visual Science, University of Rochester, NY.

Dr. Kollbaum is associate dean for research, director of the Borish Center for Ophthalmic Research and an associate professor at the Indiana University School of Optometry.

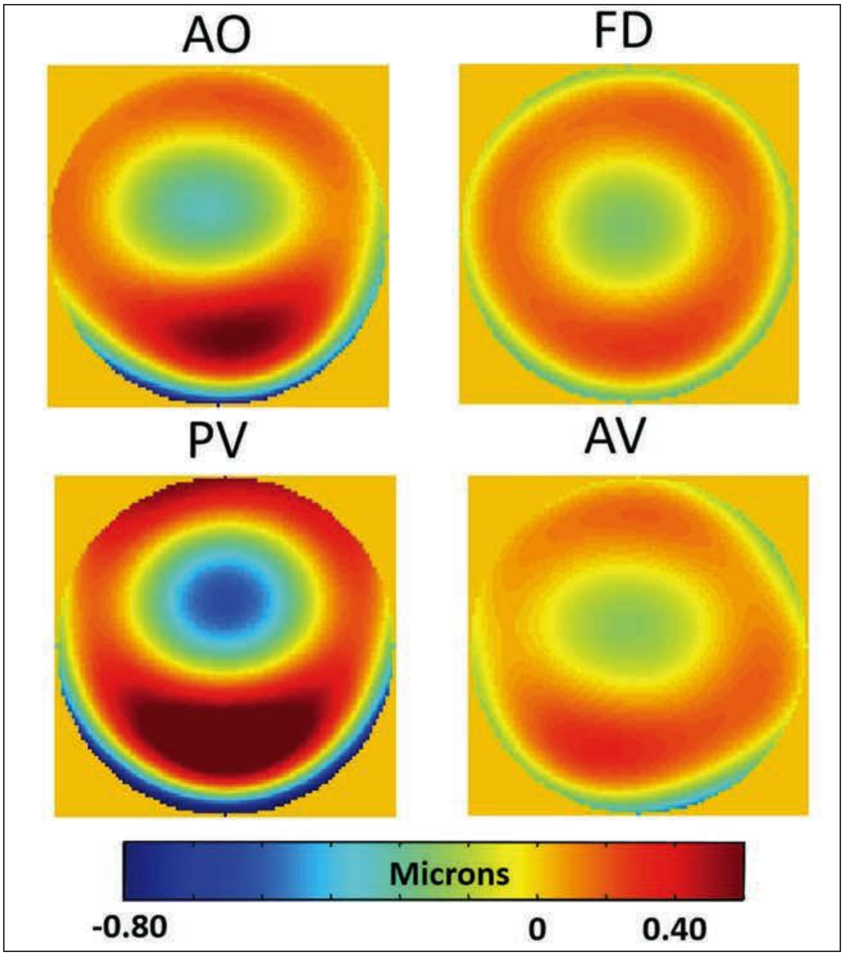
Dr. Papas is a professor in the School of Optometry and Vision Science at the University of New South Wales in Sydney, Australia.

those first, uncontrolled, aspheric designs. Comfort was no longer an issue for all waking hours of wear, and compared with PMMA lenses, the physiological response of the cornea was greatly improved.

Soft lenses were initially only available in spherical powers to correct myopia and later hyperopia, but by the mid to late 1970s soft lenses to correct astigmatism became available.[5] Unlike rigid lenses that mask the astigmatic component of the cornea, soft lenses largely conform to the underlying corneal shape, and so the toric shape of the cornea is transferred to the front surface of the soft lens. The addition of an astigmatic correction to the soft lens required a method of stabilization and orientation to be built into the physical shape of the lens.

The most successful designs used an increasing thickness profile in the vertical meridian of the lens, allowing the squeeze force of the upper eyelid to stabilize the lens on the eye between blinks. While successful, lenses manufactured for this approach were difficult to make repeatedly, and so toric soft lenses were not widely accepted until the mid 1980s. At this time, Bausch + Lomb developed a lathe that could generate a toric surface without distorting the button, eliminating the inherent stress that plagued the optical quality of earlier designs and contributed to the consistency that clinicians expect with modern toric lenses.

The toric-generating lathes were the forerunners of today's computer numeric control (CNC) lathing technology that is the backbone of the contact lens industry. Ultimately, many soft lenses were cast molded between two rigid plastic mold surfaces in the 1980s. This process was also adopted for toric soft lenses within



Higher-order wavefront error maps (6mm pupil) of four different soft toric contact lenses (all -3.00D nominally labeled power) as measured with an aberometer off of the eye in a saline-filled wet cell. Lower-order aberrations, including sphere and astigmatism, have been zeroed to show only the higher-order aberrations.

AO: AirOptix for Astigmatism (Alcon); FD: Focus Dailies Toric, now discontinued (Alcon); PV: PureVision for astigmatism (Bausch + Lomb); AV: Acuvue Oasys for Astigmatism (Johnson & Johnson Vision Care).

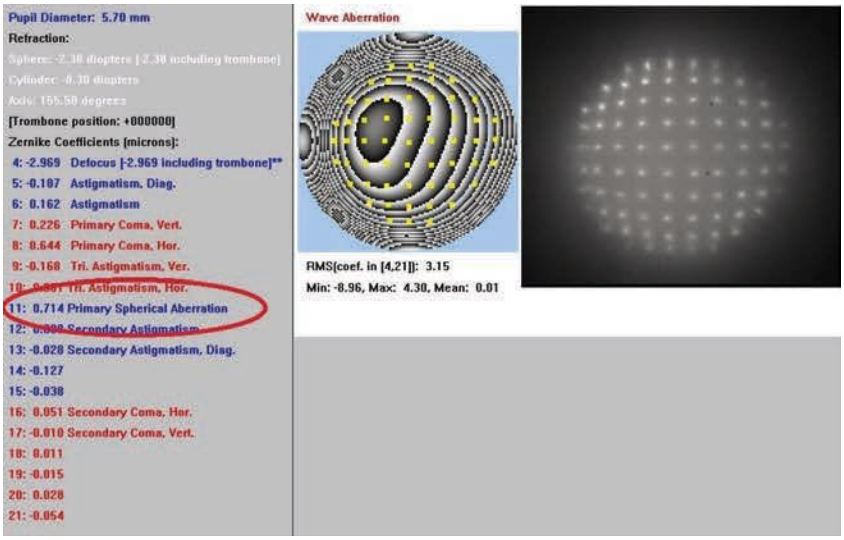
a decade, to provide lenses with little lens to lens variance and high optical quality surfaces. However, the tooling creating the molds for these lenses is still generated using the same CNC lathes often used for directly lathing precise, and sometimes quite complex, lens surfaces.

MULTIFOCAL LENSES FOR PRESBYOPIA

Correction of presbyopia was a new optical frontier for soft contact lenses during the 1980s and '90s.

Such products were introduced by Bausch + Lomb and Ciba Vision in 1982.[6] In B+L's case, experience with significant spherical aberration in their first lenses for myopia helped them manufacture a lens with spherical aberration aimed to expand the depth of field of the wearer.

Ironically, after spending years trying to eliminate spherical aberration inherent in their spin-cast



Early prototype Shack-Hartmann wavefront image and Zernike output for a positive spherical aberration multifocal aspheric soft contact lens on eye. Note that the different spot size spacing indicates leads to the high Zernike spherical aberration value.

lens products, they purposely reintroduced positive spherical aberration into the design of their PA1 single (center distance) add bifocal to extend the depth of focus of the wearer. The Ciba "BiSoft" bifocal lens was a center-distance annular bifocal design with multiple add powers available. Both lenses were designed to provide improved distance and near vision for presbyopic patients using a "simultaneous imaging" concept.

In this approach, light from both distant and near objects passes through the pupil simultaneously. Those light rays most conjugate to the retina and the field object will provide the most in-focus image on the retina, while those that are out of focus for that object-plane will reduce the contrast, and potentially even the resolution of the retinal image. In these simultaneous image lenses, theoretically no movement or decentration of the lens is required to provide the visual transition from distance to near focus. Patients demonstrated acceptable distance and near visual acuity in the exam room, but reports of glare, haloes and poor vision in dim light, particularly while driving, led to low levels of acceptance with these and later multifocal contact lenses of the era.

An alternative form of correction for presbyopes—monovision, where single vision lenses are used to correct one eye for distance and the other for near—was rarely prescribed amid concerns from practitioners that the compromise in binocularity was too severe and that the patients were effectively monocular at both distance and near focus.

In the late 1980s and early 1990s, the introduction of an alternative simultaneous image design, the diffractive lens, reignited interest in bifocal contact lenses. Specifically, the unique diffractive designs of the rigid Pilkington Diffrax and soft Hydron Echelon lenses, respectively, eliminated the impact of pupil size on the proportion of light dedicated to the distance and near retinal images that plagued more traditional refractive optics solutions.[7,8] While clinical use demonstrated that the performance of the lenses was not pupil dependent, diffractive optics suffered from other problems. Most significant, and perhaps the main reason that they were not more successful, is that an inherent limitation of diffractive optics occurs when light is divided between the distance and near foci.

At this point, a significant proportion of light (up to 20%) is lost to other, higher orders of diffraction.[9] From a practical standpoint, this light might be considered "scattered" across the retinal image, causing a reduction in contrast.[10] Wearers perceived this scattering as a "graying" or a "washing out" of the visual scene and sometimes complained of reduced vision in conditions of low illumination or contrast. When combined with their relatively expensive cost at the time, these difficulties limited uptake of the concept in the marketplace. Interestingly, diffractive intraocular lenses are now quite common despite the design's lack of success within contact lenses.

HOAs & THE PROMISE OF BETTER VISION

The development of clinically applicable Hartmann-Schack wavefront sensors in the late 1990s provided the breakthrough needed to understand the link between the theoretical design and visual performance of single vision and multifocal soft contact lenses and the clinical reality of the retinal image quality that these lenses were providing.

Early population measurements of the wavefront error of the eye of large contact lens wearing age populations, identified the presence of significant levels of higher order wavefront aberrations over and above the defocus and astigmatism that traditional refraction methods had identified.[11] For many patients who exhibited large amounts of these higher-order aberrations (HOAs), retinal image quality was significantly compromised even with a best sphero-cylindrical correction in place, and especially under low illumination, large pupil conditions.

This aberrometry technique was quickly adopted to measure the true optical performance of rigid and soft, single vision and multifocal contact lenses *in vivo*, but also proved to be an ideal method to evaluate the optical performance of contact lenses off the eye.[12-15] Wavefront sensor technology combined with the next generation CNC lathing technology allowed the potential for new and varied optical designs for contact lenses to be imagined and developed.

Clinical and laboratory wavefront sensors became available commercially in the early 2000s and ignited significant research interest in the potential of altering the optics of contact lenses to improve vision in patients. This work has largely focused on either obtaining some improvement for the average eye within the population or more significant improvement in individual eyes with more significant higher order aberrations (*e.g.*, older eyes and those with corneal shape-related pathologies such as keratoconus).

Of course, the combination of the eye plus contact lens optics are what provide the resulting vision for the wearer. Clinically, this result is typically verified by an in-office contact lens over-refraction, but there are several variables that may complicate this seemingly simple combination. As is well known, the eye contains inherent lower-order (*e.g.*, sphere and astigmatism) as well as HOA.

Several population studies have determined that many eyes have varying amounts of positive or negative higher-order aberration. However, due to some eyes having positive and other eyes negative amounts of these aberrations, when averaged across the population the resultant magnitude is largely zero.[16] This is not true for spherical aberration, however, where the average ocular spherical aberration for the typical young adult population is positive and approximately 0.18µm in magnitude (over a 6mm pupil).[17]

Additionally, the lens itself could be made with aberration by chance or by design. Specifically, spherical contact lenses, by design, contain spherical aberration due to their highly curved anterior and posterior surfaces; minus lenses containing negative spherical aberration and plus lenses positive spherical aberration.[18-20]

In theory, either the spherical aberration of the lens, the eye or both could be corrected by creating a precise, radially symmetric asphericity in the contact lens. Interestingly, because of its inherent spherical aberration, a spherically surfaced soft contact lens of around -7.00D has a magnitude of spherical aberration sufficient to counteract the average spherical aberration of the population.

Since substantial amounts of negative spherical aberration occur for powers as low as –4.00D, many myopic contact lens-wearing patients may have some spherical aberration corrected even by a typical single vision soft contact lenses.[21] Those outside this range may experience little change, or a worsening, of their eye plus lens aberration.

For instance, patients with positive defocus corrections (*i.e.*, hyperopes) will experience even greater levels of positive spherical aberration, due to the combined effect of their inherent, ocular, spherical aberration and that induced by their spherical contact lens. Alternatively, it is possible to minimize the visual effects of spherical aberration by providing an appropriate, aspheric correcting surface on the contact lens, tailored for all defocus corrections. Indeed, several manufacturers (Bausch + Lomb, CooperVision) did just this, starting in the late 2000s, by commercializing products, both spherical and toric, that used aspheric surfaces to minimize total eye plus lens spherical aberration for the average eye. The intention was to improve the quality of vision under low illumination conditions.

However, if this correcting lens (or any lens) is not centered on the eye, other visually degrading aberrations are introduced. Specifically, in the case of a lens with spherical aberration, coma is introduced in amounts directly proportional to the magnitude of the decentration.[22] As decentrations can be as much as 1mm horizontally and vertically in some lenses, this could have a substantial negative visual impact.[23,24] Also, it is well-known that rigid lenses (*e.g.*, corneal GP) do not conform to the cornea, so introduce a tear film with optical power and aberration. However, although assumed to conform completely to the cornea, it has been shown that soft lenses do not always do so, but rather exhibit some partial flexure. This flexure, therefore, induces aberration when on the eye.

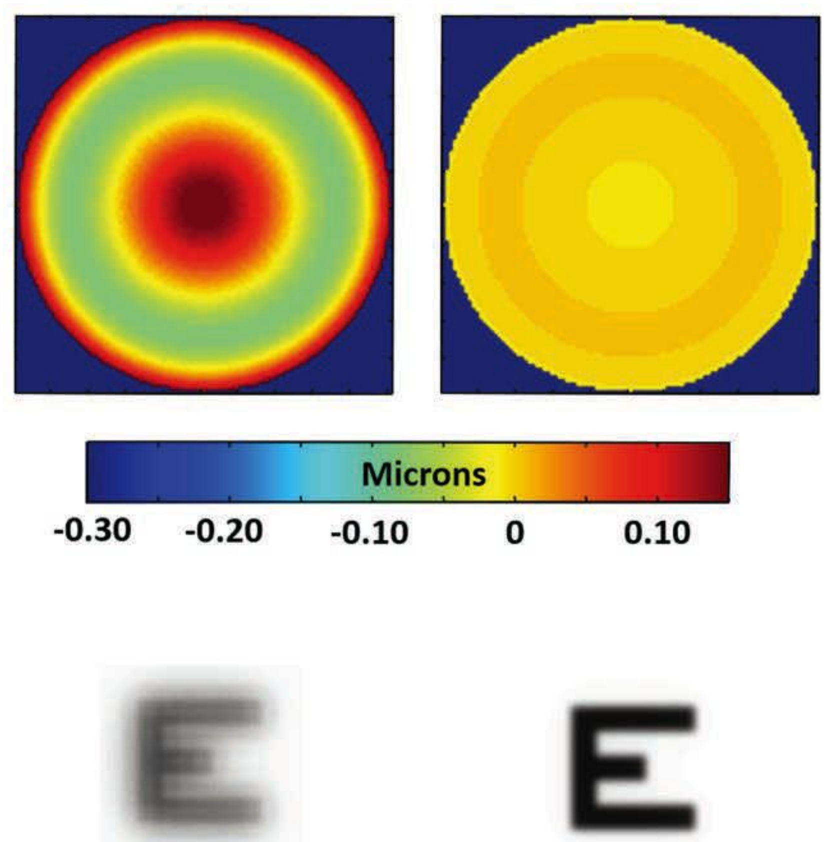
For example, high power lenses may not induce the desired levels of sphere correction, and also induce unintended levels of spherical aberration.[25-27] Specifically, they may introduce spherical power errors as high as 0.50D to 1.00D, and spherical aberration errors up to around 0.20µm (for a 6mm pupil). These levels of error are more than sufficient to degrade vision. Also, importantly, these levels of aberration are dependent on the lens power, thickness and material/modulus.[22]

All the issues described above need to be addressed if the optical performance of the contact lens-wearing eye is to reach its maximum potential. Some manufacturers have attempted to minimize these issues. For example, aspheric lenses that have no spherical aberration as a function of lens power have been created to make them resistant to on-eye positioning errors and not introduce further aberration.

Another approach combines the issue just described to create a lens that also accounts for on-eye flexure changes.[28] Additionally, as mentioned above, while spherical aberration is clearly the largest higher-order ocular aberration in the general population, it is quite often not the dominant aberration in individual eyes. Third-order Zernike aberrations, such as coma and trefoil, are frequently problematic, even though their population average is close to zero.

Unlike the approaches described above, these aberrations must be corrected by a rotationally stable contact lens, manufactured using a process capable of creating non-rotationally symmetrical surfaces. Clearly then, a contact lens must be designed to correct both symmetrical and non-rotationally symmetrical HOAs of the eye plus contact lens system, if visual benefit is to be maximized across a substantial proportion of the population.

Several research groups have attempted making customized



Higher-order wavefront error (top row) and the resulting image simulations (bottom row) of the sum of the contact lens spherical aberration and that of the average eye while wearing a spherical lens that is of -1.00D (left) and and -7.00D power (right) with a 6mm pupil.

higher-order wavefront aberration correcting soft contact lenses to minimize the effects of some of the problems described above.[29,30] Due to the amounts of on-eye movement, even in soft contact lenses, limiting some of the achieved benefit, other groups continue working on similar concepts for scleral lenses with smaller on-eye movements.[31,32] Results have been promising to date, with significant reductions in eye plus lens HOAs from these custom aberration-correcting contact lenses. Interestingly, however, the improvement in visual performance recorded by subjects wearing these lenses, while measurable, does not correlate well to the magnitude of HOA reduction observed.[31] It has been demonstrated that some patients with chronic HOAs, caused by corneal pathology, may adapt to their reduced retinal image quality and therefore, will require a period to "re-adapt" to the improvement provided by a custom correction.[33]

Clinical and laboratory wavefront sensors have also improved the design and manufacturing quality of multifocal contact lenses during the 2010s with most current designs incorporating multiple zones of continuous curvature to provide an increased depth of focus, from distance through intermediate and near.

These improved multifocal designs aim to better meet the visual needs of the current era in which computers and hand-held electronic devices dominate the work environment, while simultaneously reducing the impact of glare and halos caused by sharp optical junctions between the power zones of previous lenses. In addition, many earlier presbyopic contact lenses were designed by adding the multifocal optical component to the single spherical surface of a single vision lens, without taking into consideration the inherent spherical aberration of the base lens design. This led to lenses having different optical power profiles depending upon their back-vertex power.[31]

Current generation multifocal lenses can be designed and tested with wavefront sensing metrology to ensure that all back-vertex powers have the same multifocal power profile across the optical zone. The resulting hope is that this leads to a consistent fitting experience for contact lens practitioners as they work with patients across a wide range of refractive corrections. Clinically, multifocal lenses now have an increased acceptance over monovision for presbyopic patients seeking a contact lens correction. This confirms the improved optical performance of these lenses that enhanced metrology and manufacturing has made possible.

CONCLUSION

Industry and clinicians alike have made great strides in understanding the optical challenges of a soft material over the past 50 years.

Today's lenses address nearly all refractive challenges with at least some success, and often complete avoidance of the need for spectacle lens wear. The work continues apace and future generations of lenses will no doubt exceed today's standards. RCCL

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REPLACEABLE LENSES, IRREPLACEABLE PROGRESS

Contact lens wear schedules overcame early growing pains, leading to today's healthier, multi-wearing schedule options.

By Jane Cole, Contributing Editor

Optometrist Christine Sindt recalls the first set of soft contact lenses (CLs) she wore in the mid-1980s. These yearly-replaced lenses came in vials that doctors had to often carefully dig out with a special, sharp tool, sometimes cutting themselves in the process. And patients, like Dr. Sindt, tried to get as much wear out of their costly contacts as possible.

"I remember seeing visible deposits on the lenses, and I tried to pick them off with my fingernails. We didn't think as much about lens solutions back then, since they were mainly used to keep the lenses wet and from dehydrating."

Additionally, these early soft CLs sometimes turned different colors if wearers took certain medications or used eye drops, Dr. Sindt says.

"People wanted to keep the lenses as long as they could, because contacts were so expensive back then," she explains.

Today, the soft contact lens has undergone a dramatic evolution from its inception to now offering weekly, biweekly, monthly and daily disposable lens replacement options, including healthier schedules, more advanced materials and customized optics for specialty lens patients.

As the first soft contact lens to enter the US market celebrates its 50th anniversary, contact lens experts share some milestones, lessons learned, and their thoughts on the robust current market.

SOFT LENSES MAKE THEIR BIG DEBUT

Soft lenses became commercially available in London in 1970 through Global Vision (de Carle & Galley) and Contact Lens Manufacturing (Clulow & Cordrey), and their entry into the market was quickly followed by larger scale manufacturing and global supply from Bausch + Lomb with the Soflens in 1971. This was followed by launches from Hydron Lenses and Titmus Eurocon a year later, says optometrist Jill Woods, head of clinical research in optometry and vision science at the University of Waterloo's Centre for Ocular Research and Education.

Within just a few years, multiple soft lens products entered the market, and some were spun-cast and others lathed, she explains.

"The introduction of soft lenses led to a rapid growth in CL use worldwide," Dr. Woods says. "Soft lenses were adopted very quickly because of the vastly improved comfort they offered compared to the rigid lenses of that time, which were made of PMMA."

From a design and material perspective, the early lenses were quite crude by today's standards, but nevertheless, a gigantic revolutionary breakthrough considering the limitations with lens technology that existed back then, says Joseph Shovlin, OD, of Scranton, PA, past president of the American Academy of Optometry.

Due to the high costs of soft contact lenses in the early days, it was unusual for people to have a spare pair, Dr. Woods says. Patients kept their single set of lenses for a year or longer, and very high-volume CL practices carried only a small inventory of their most popular brands in a handful of powers to offset the one or more weeks it took to receive a new order, she says.

DISPOSABLES ALTER THE MARKETPLACE

The 1970s and '80s were decades of significant improvement in overall comfort and physiologic response, Dr. Shovlin says.

In 1984, Johnson & Johnson Vision Care (then called Vistakon) initially purchased technology from the Danish-based Synoptic group for the Danalens, a high-water extended wear lens, which the company paired with etafilcon A, a material it had acquired a few years earlier.[1]

After three years of development, Vistakon launched the seminal Acuvue lens in 1987. The Acuvue disposable was initially introduced as a two-week extended-wear lens to be worn and then thrown away.[2]

Once it was proven that disposability could work, other manufacturers rapidly launched their own frequent replacement lenses in the now-familiar blister packs.[1]

Following Vistakon, Bausch + Lomb added the Sequence in 1988, while Ciba launched the Newvues disposable lenses.[3] In 1990, Ciba introduced Focus monthly lenses and Bausch + Lomb launched Medalist four-packs for quarterly replacement.[3]

The 1980s and '90s were also a time of great strides in innovation, and many drivers were behind the uptick in soft lens use, Dr. Shovlin says.

"It was the quest pushed to provide better products looking to improve upon what was already deemed to be revolutionary. Things evolved based primarily on the excitement and enthusiastic response from both patients and practitioner acceptance for this new modality," he explains.

Still, challenges arose with the new disposable options, including poor lens centration, deposit-related disease such as giant papillary conjunctivitis and physiologic findings with lens-induced edema, according to Dr. Shovlin. Manufacturers responded with new materials and designs, frequent lens replacement options and more effective solutions that caused less toxicity, he adds.

Despite the lenses growing in popularity, not everyone was on board initially.

"Some doctors still had that value driven thought process to keep the lenses as long as possible, and they believed, if patients cleaned the lenses really well, they didn't need to replace them that frequently, Dr. Sindt says. "But there were a lot of health problems that ensued."

The rise of disposable lenses also changed the way ODs practiced.

The most revolutionary aspect of disposable lenses was that suddenly, it was practical for the practitioner to stock an inventory on site. Instant access not only improved customer service to existing wearers, but it also made CLs more accessible and facilitated impromptu lens trials," Dr. Woods explains.

EW LENSES SURGE —UNTIL INFECTIONS SPIKE

Extended wear (EW) lenses hit the market in 1981, and the first ones were for aphakic patients after cataract surgery, since IOLs had not yet hit the mainstream, says optometrist Michael Ward, director of contact lens services at Emory University.

"If you had a mono aphakia patient with too much distortion, it was wonderful when extended wear first came out, but then we started to see the complications with the lens," Dr. Ward says.

Once a popular choice, extended wear lost favor in the late 1980s, when researchers found a much higher incidence of ulcerative keratitis with this modality compared with daily wear.[4] As such, manufacturers at the time voluntarily reduced allowable wearing times from 30 to seven days.[5]

Despite its waning popularity, extended wear saw an uptick in the early 2000s when manufacturers turned to silicone hydrogel material, which overcame earlier EW problems, including hypoxia (read more about SiHy lenses ahead).[5]

Today's modern designs have followed suit and adapted with a focus on safety and the need for oxygen to the cornea and a high Dk/t of 125 x 10-9.[6]

EMBRACING THE DISPOSABLE CONCEPT

In 1996, Bausch + Lomb was faced with a class action lawsuit that alleged the company's SeeQuence2 lens under different brand names, including Medalist, Optima FW and Criterion Ultra FW, were essentially the same, yet being sold at different prices.

"They had a quarterly replacement vs. a monthly replacement, vs. a two-week replacement, and they were all the same lens," Dr. Sindt explains. "That became a shocking idea to the industry. That was really the turning point for people to start thinking lenses could be made less expensively at the same quality, and maybe we should be replacing these lenses more frequently."

DAILY DISPOSABLES DISRUPT THE MARKET

Vistakon launched the first daily disposable hydrogel lenses in 1994, which eliminated solution issues and also reduced the risk of complications, infections and deposits.

Despite some initial hesitancy by doctors to recommend this "pricey" replacement option, Dr. Sindt says dailies quickly caught on.

"I think our whole society transitioned to disposable," Dr. Sindt says. "People don't want to reuse

Lens Care Updates Keep Pace with Soft CL Innovations

As soft contact lenses have morphed for the better over the past five decades, their care and cleaning systems had to also change to keep up with the new materials and wearing regimens.

"It's been a very interesting evolution that we've gone through," says Dr. Ward.

Like the earliest soft CLs, the first care systems were rudimentary. Additionally, little was known about the potential for soft lenses to cause infection, Dr. Woods adds.

Unlike PMMA lenses, it was understood that the first generation of soft CLs needed to be stored wet, and initially, saline was thought to be sufficient, Dr. Woods explains.

"Very early disinfection involved boiling the lenses in saline. It was quickly recognized that a better disinfection was required. To achieve better cleaning and disinfection, when soft lenses were dispensed, they were accompanied by an arsenal of lens care items that resembled a chemistry set," Dr. Woods says.

Heat Disinfection

The first soft lens care disinfection systems were multi-stepped and heat-based, says Dr. Ward. Early soft lens wearers had to use a daily cleaner, rinse the lens with homemade saline and then put the lens and saline into a heating unit that was plugged into an electrical outlet for disinfection.

While the heat system was effective for the most part, it was eventually taken off the market due to the homemade saline, which led to a rash of *Acanthamoeba* keratitis cases that became so unbearable to the afflicted, a number of people had their eyes enucleated, Dr. Ward explains.

Early lens disinfection also consisted of enzyme tablet cleaning. This step helped remove enzymes that bonded with amino acids that attached to the lens. The buildup of protein over time became an irritant source that caused inflammatory conditions such as giant papillary conjunctivitis, Dr. Ward says.

Chemical Cleaning

Heat disinfection was quite effective but had its share of issues, Dr. Shovlin says. "Not all lenses that were being developed could be heated, deposits accumulated readily and the heating process was somewhat labor intensive. For these reasons, chemical disinfection was deemed essential," he says.

Heat lost favor with clinicians in the early 1980s with the introduction of hydrogen peroxide/oxidative disinfection and new preservatives being used for disinfection, Dr. Shovlin adds.

These new chemical cleaning products may have seemed like an initial breakthrough from the previous heating method, but they still caused problems in some patients. The chemicals could be harsh, and lenses required a saline rinse before being stored overnight in the disinfecting solution, followed by another saline rinse in the morning before lens application, Dr. Woods says.

Additionally, wearers still had to do an enzymatic treatment once a week to get rid of proteins so the lenses would last longer.

Optometrist Jason Miller recalls getting his first pair of contacts in the mid-80s and the myriad cleaning steps that went into taking care of them, including the weekly enzyme step. Despite following the protocol, trouble still arose when he had an adverse reaction to a lens cleaning solution that contained thimerosal and his eyes turned red.

In addition to thimerosal, the early chemical products were preserved with chlorhexidine and benzalkonium chloride. Despite the saline rinsing, a high number of allergic reactions occurred, which caused red eyes, corneal staining and infiltrates, tarsal changes and discomfort, Dr. Woods says.

Peroxide Systems

In response, the industry in the early 1980s developed 3% peroxide overnight disinfection systems, with the peroxide neutralized in the morning by diluting or adding a catalyst. These two-step peroxide systems were effective disinfectants and less toxic to the eye; however, the surfactant cleaner was still necessary to clean the lens prior to overnight disinfection.

With these systems, the lens was first cleaned by rubbing with a surfactant cleaner, the cleaner was then rinsed off with a saline solution and the lens was placed in peroxide in a special upright, basket-style case and left for eight hours, typically overnight. In the morning, the peroxide solution was discarded and a neutralizing solution was poured into the case. This solution neutralized the peroxide over a specified period of time, often as short as 10 minutes, which rendered the lens safe and comfortable to apply, Dr. Woods says.

However, there was an inherent risk with these two-step systems—the potential for patients to forget the neutralizing step and insert the lenses in their eyes directly from the peroxide—which could cause a stinging response or even corneal fluorescein staining, lid swelling or ocular redness.

Additional peroxide systems were developed using other neutralizing systems, such as dilution, thiosulfate and catalase.

"Hydrogen peroxide remains an excellent lens care product, and when used appropriately, it both cleans and disinfects. It may be the best option for reusable soft and rigid specialty lenses," Dr. Shovlin says.

MPS Makes a Splash But Encounters Early Trouble

Toxicities and allergic reactions commonly noted in chemical solutions were the driving force and need behind the development of new forms of chemical disinfection and multipurpose solutions (MPS) with today's more friendly preservatives, Dr. Shovlin says.

"Multipurpose solutions were very revolutionary at the time," Dr. Miller adds. "Patients could cut back on steps to clean their lenses, and the solutions were effective. Multipurpose solutions were easier to use, and patients were more compliant."

Although the rise of MPS solutions put the disinfectant and cleaner all in one bottle, the early ones went through a series of gyrations, according to Dr. Ward.

By the mid-2000s, a number of MPS solutions had to be reformulated due to a rash of infections, including Complete Moisture Plus MPS (Abbott Medical Optics, now J&J), after the CDC discovered some wearers contracted *Acanthamoeba* keratitis. Bausch + Lomb also recalled and soon thereafter discontinued its Renu with MoistureLoc after an outbreak of *Fusarium* keratitis.

"Industry has done a very good job of correcting the problems they had in the past," Dr. Ward says.

"No Rub" Hype

When many MPS products first launched, it was thought rubbing the two-week or one-month replacement lenses for few seconds after removal and prior to soaking could be dropped, Dr. Woods says. This "no-rub" brought strong marketing campaigns, touting how easy the products were to use.

"Unfortunately, it quickly transpired that the physical act of rubbing the lens was a significant step in reducing bacterial load on the lens to a level that the care product could manage. In many instances without rubbing, the lens was being re-worn with higher than ideal contamination," Dr. Woods says. "This understanding, coupled with rising case reports of serious corneal infections, led to a swift return to practitioners recommending the rubbing step."

New Materials Spur MPS Changes

The evolution of the MPS included changes to chemical compositions aimed at reducing the ocular response while maintaining cleaning and disinfection efficacy. The main improvements included new preservatives that were larger than the low molecular weight chlorhexidine and thimerosol used in the previous disinfection products, Dr. Woods says.

Other important updates: Bausch + Lomb pioneered the use of PHMB (Dymed) in its Renu products, soon followed by Alcon incorporating polyquaternium-1 (Polyquad) in its Opti-Free range. Other recent MPS additions include Aldox, alexidine and povidone-iodine, Dr. Woods says.

"The multipurpose solutions we have today are really good," adds Dr. Ward. "The current generation of products is safe, non-toxic, and really refined."

Another driver behind the updates in MPS solutions included the ushering in of new materials. Traditional soft hydrogel CLs made from HEMA polymers took a backseat when silicone hydrogels were introduced, and MPS solutions had to adjust as SiHys absorb more oils since they are lipophilic and are harder to keep clean, Dr. Ward adds.

Lens Care Freedom with Dailies

One of the most significant milestones in soft CLs has been the growth of single-use, daily disposable soft lenses, which eliminates the need for lens care solutions.

"We don't have the toxicities we used to see. And now with daily disposables, there's no need to use solutions," Dr. Ward says. "We used to say the solution is more likely to cause the complication than the lens choice."

things. They want everything new all the time, and the concept of healthcare became very important. We don't reuse bandages or medical equipment, so why reuse a CL?"

As more patients and doctors become experienced with daily disposables, their popularity will continue to increase, predicts Justin Bazan, OD, of Brooklyn, NY. "It becomes apparent that, in nearly all comparisons, they are superior to a planned replacement contact lens."

Still, current challenges include the expansion of parameters for certain wearers, including those wanting torics or multifocals. "We are at a point now where the vast majority of our patients have the option of wearing a daily disposable, but there is still a small subset that doesn't have the option. Financial, manufacturing and logistical considerations come into play as to how soon we will have a daily disposable option for that last group of patients," Dr. Bazan suggests.

SIHY LENSES CHANGE THE MATERIAL LANDSCAPE

Considering CL material, the evolution of SiHy lenses was enormous, Dr. Sindt says. "That was probably the biggest revolution we've had in contact lenses, maybe ever."

In 1999, Ciba Vision launched Focus Night & Day (lotrafilcon A) with 175 Dk/t, and Bausch + Lomb came out with PureVision (balafilcon A), with 110 Dk/t, which both exceed the oxygen transmissibility requirements needed to avoid overnight corneal swelling.[5]

Silicone hydrogels represented a revolution in contact lens materials because they could transmit higher levels of oxygen through the lens, and this transmission no longer relied on the water content of the material as in the previous generation of hydrogel lenses, explains Dr. Woods.

Prior to SiHy lenses, frequent replacement soft hydrogel lenses were available, but hypoxia-related complications existed with full-time daily and extended wear.

"There have been definite health benefits attributed to the higher delivery of oxygen to the cornea. While serious corneal infections and inflammation have not been eradicated, their severity has been reduced and recovery rate improved," Dr. Woods says.

SOFT CLS' FUTURE LOOKS BRIGHT

Today's soft contact lens replacement cycles have expanded dramatically to include myopia control, torics, multifocals and specialty lenses.

"What I'm really excited about is the idea of correcting higher order abberations and making the lens customizable for the patient, whether it's the material or the coating on the lens," Dr. Sindt says. "We're starting to see things like Hydra-PEG on soft lenses, and customized optics. I think all of this is going to lead to better health, a better wearing experience, and it's going to tie the patient more closely to the doctor since the patient will see the value of the product the doctor is prescribing. That's what really excites me about the future of where we're going." RCCL

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By Cory Collier, OD

When Toric is Not Enough

The more experience you have with unique lens designs, the more comfortable you'll feel trusting your clinical intuition in situations like these.

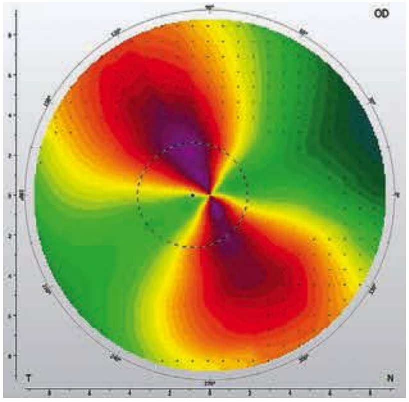
With the increased availability of quadrant-specific scleral lenses, our ability to fit highly asymmetric eyes continues to improve. The following case highlights a patient with profound corneal astigmatism that extended into his scleral anatomy who found success with a quadrant-specific scleral lens.

THE CASE

A 47-year-old male presented for a contact lens fitting. He had been wearing glasses since he was a young child; however, he had no history of contact lens wear. He was interested in a contact lens option to wear primarily during exercise. Up until this point, he typically went uncorrected during recreational activities.

Manifest refraction was +1.00 -7.00x037 OD and +0.50 -7.25x157 OS with 20/25 vision OU. Slit lamp exam was not suggestive of ectasia. This was confirmed by topography, which displayed a high degree of oblique but regular astigmatism. The astigmatism was noted as limbus-to-limbus, a generally accepted misnomer that implies the astigmatism extends across the breadth of the cornea based on the pattern extending across the entirety of the topographic image. This contrasts with central corneal astigmatism, in which the astigmatic pattern is confined to the center. It is particularly noteworthy for patients with a high degree of regular astigmatism, as it has been shown that the orientation of the flat corneal and scleral meridians is typically similar in these individuals.[1]

Based on the patient's plan to wear contact lenses while exercising, I eliminated corneal GPs from consideration. We ultimately decided on sclerals as an option that would allow for part-time wear, perform well in the intended environment and provide stable vision correction less prone to unacceptable rotation.



Limbus-to-limbus corneal astigmatism.

DIAGNOSTIC FITTING

I used a diagnostic fitting set with a standard 210µm of scleral toricity (Custom Stable Elite lenses by Valley Contax). This is indicated by steps of 30µm with a flat meridian standard of +3 (90µm) and a steep meridian standard of -4 (-120µm).

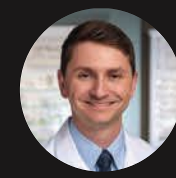
After 25 minutes of settling, the central clearances in the right and left eyes were 175µm and 150µm, respectively. Limbal clearance was full and appropriate at roughly 25µm. The right lens was rotated 30° to the right, and the left lens was rotated 25° to the left. I judged this rotation by documenting the location of the flat meridian markings (+3) relative to the horizontal meridian.

In assessing the fit of the scleral landing zones, the flat meridians of each eye displayed symmetrical mild edge lift. The superior steep quadrant was aligned, while the inferior steep quadrant displayed excessive edge lift with rapid fluorescein exchange. Even minor manipulation of the eyelid and/or lens allowed air bubbles to rapidly enter the central reservoir of the lens from the inferior quadrant. After a brief evaluation, central bubble formation necessitated the removal and reinsertion of the lenses for further evaluation.

After another period of settling, over-refraction resulted in +2.75 -2.25x035 OD and +2.75 -1.50x145 OS with 20/20 acuity OU. Keratometry over the settled lens yielded a spherical result, confirming no lens flexure was present. As a result, residual cylinder would need to be incorporated as a front toric.

Since the superior and inferior quadrants displayed different fit patterns, a quadrant-specific, rather than a toric, lens design was required. The flat meridian (roughly nasal and temporal in this case) was steepened two steps from +3 to +1. As the superior quadrant was already aligned, it was ordered as standard. The inferior quadrant was steepened by 420µm (-14 steps) to address the inferior edge lift. This was an educated approximation, as the magnitude of edge lift was extreme, limiting precision.

The parameters ordered for quadrants one through four in both eyes were +1, -4, +1 and -18, respectively. To compensate for the rotation present, 30° was subtracted from the over-refraction axis OD and 25° was added OS. The over-refraction, trial lens power (+2.00 OD, +2.00 OS) and trial lens rotation (30° right OD, 25° left OS) resulted in a final



power of +4.75-2.25x005 OD and +4.75-1.50x170 OS. When making significant changes in the scleral landing zone, it is possible the ordered lens will not rotate in the same orientation as the diagnostic lens. This may impact the physical and refractive outcomes of the lens. Despite this possibility, a spherocylindrical over-refraction was used to determine the final lens power for this patient.

DISPENSING

After insertion, the lenses were left to settle for 20 minutes. The patient exhibited excellent visual acuity at 20/20 OD and OS, subjective vision improvement, ideal central clearance of 150µm and appropriate limbal clearance. Despite an improved fitting relationship along all meridians, significant edge lift remained in the inferior quadrant of both eyes. An additional 300µm (10 steps) of inferior steepening was incorporated, resulting in -28 steps in quadrant four.

The new lenses were aligned in all quadrants. The patient continued to have excellent vision and noted the lenses as extremely comfortable. The patient enjoyed continual success through the two-year follow-up.

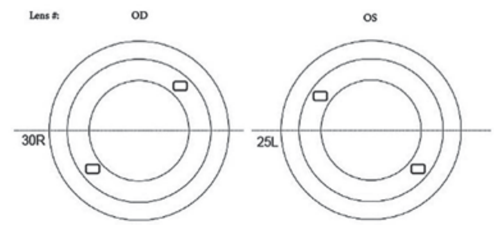
DISCUSSION

Having a comprehensive understanding of scleral shape plays an integral role in a successful scleral lens fitting. Numerous technologies have helped increase our knowledge, including Scheimpflug imaging and AS-OCT. As these imaging techniques become more readily available, we can take advantage of the data we gain from them, even if we do not directly use them in the clinic.

A recent study demonstrated several key findings related to OCT and scleral lens fitting.[2] First, corneoscleral and scleral angles of tangency vary circumferentially around the limbus.[2] Second, the sclera's rotational asymmetry generally increases as distance from the limbus increases.[2] Clinically, we can generalize that while the sclera is not truly symmetrical even at the corneolimbal transition, its variance is relatively low. Generally, this allows symmetric lens designs to find success when fitting small diameters (≤15mm). At larger diameters, the scleral asymmetry increases to a clinically significant range, indicating the need for asymmetric designs.

The Scleral Shape Study Group extended our understanding of scleral profiles further.[3] Reviewing the circumferential elevation profile at 16mm, scleral shape can be grouped into spherical, regular toric, asymmetric single elevation or depression and irregular toric.[3] Although these groups do not directly represent specific scleral lens designs, it can be inferred that near this diameter, symmetrical lens designs offer the least utility with toric or even quadrant-specific designs indicated for optimal success in a large proportion of patients. With this information, we can recognize fitting patterns during the fitting process, allowing for more strategic lens designs.

A final point of interest is that scleral shape varies between those with normal corneas and those with corneal ectasia. Those with ectasia are more likely to fall into the latter two, more irregular scleral-shaped groups, suggesting quadrant-specific or freeform lenses (ones aided in design by scleral shape imaging) may be more necessary in this population.[4]



Lens rotation noted during diagnostic fitting.

The patient in this case had one large depression consistent with the asymmetric single elevation or depression group. This necessitated a quadrant-specific design with a final sagittal depth of 870µm from the peak of the flat meridian (+30µm or +1 step) to the trough of the inferior quadrant (-840µm or -28 steps).

This patient's quadrant-specific lens design was extreme, and I struggled to wrap my mind around his significant inferior scleral depression. I ordered lenses based on what I observed and, after one remake, landed on a pair the patient has been successfully wearing for several years.

I've since encountered more cases like this and gained confidence in quadrant-specific designs. Empowered by an understanding of scleral shape patterns, fitters can trust what they see and employ these unique technologies to improve patient outcomes. RCCL

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By Aaron Bronner, OD, and Alison Bozung, OD

This or That

Apical corneal ring infiltrates are commonly associated with *Acanthamoeba* keratitis, but that doesn't mean this is always the correct diagnosis.

A 74-year-old man was sent in for an emergency evaluation of a corneal disorder. He was not experiencing any acute distress or pain; however, he stated that he had been dealing with poor, blurry vision in his left eye for the previous three weeks. As he had been traveling over that timeframe, a non-local facility provided most of his care. He estimated he had been seen four times by an optometrist who had placed him on various combinations of antibiotics and steroids to no avail. He only recently returned home, where his primary optometrist saw him twice and ultimately referred him to us.

EXAMINATION

At the time of the patient's initial exam at our facility, he was on moxifloxacin QID and prednisolone acetate Q2H OS. Habitual glasses correction yielded 20/25 vision OD and 20/400 OS. His pupils were normal and reactive without an afferent pupillary defect. Slit lamp exam was unremarkable OD. His left eye showed 2+ to 3+ injection, with the greatest area of involvement around the limbal region. The cornea showed a large apical ring infiltrate that was dense and well-defined. The central corneal had 2+ central edema within the margins of the ring. Fluorescein staining showed partial epithelial breakdown over the ring. Centrally, the epithelium was intact. The anterior chamber showed modest flare, with no cell or hypopyon in sight. The iris had a small stromal hemorrhage at five o'clock.

We tested the patient's corneal sensation with dental floss. He had slight sensitivity to touch in all quadrants OS compared with his fellow eye, which exhibited a hypersensitive response. This illustrates the importance of testing both eyes when establishing neurotrophy.

After examining the patient, we questioned him more closely. He denied contact lens use, had not experienced any trauma to the eye, didn't splash tap water in his eyes and had not used a swimming pool or hot tub recently. He had no previous history of eye problems aside from glasses and had never had an episode like this before. His history was negative for any known autoimmune disorders, such as rheumatoid arthritis and polyangiitis with granulomatosis. He further denied any history of cold sores or previous issues with his eye that might suggest herpes simplex. He did, however, have a positive response to questioning about shingles. He described an episode two months earlier where he developed a small, crusted lesion on the left side of his forehead. He thought it was a spider bite and went to Urgent Care, where the staff suspected a mild shingles flareup. He took a course of valacyclovir and oral antibiotics, and the lesion resolved.

DISCUSSION

Apical corneal ring infiltrates are an interesting phenomenon in ocular disease. These entities are most frequently seen in late-stage *Acanthamoeba* keratitis (AK) and are associated with a poorer medical prognosis. Patients usually require a transplant to clear the resultant scars. Despite this association, diagnosing all apical rings as AK is a poor strategy, as they may also be caused by bacteria,

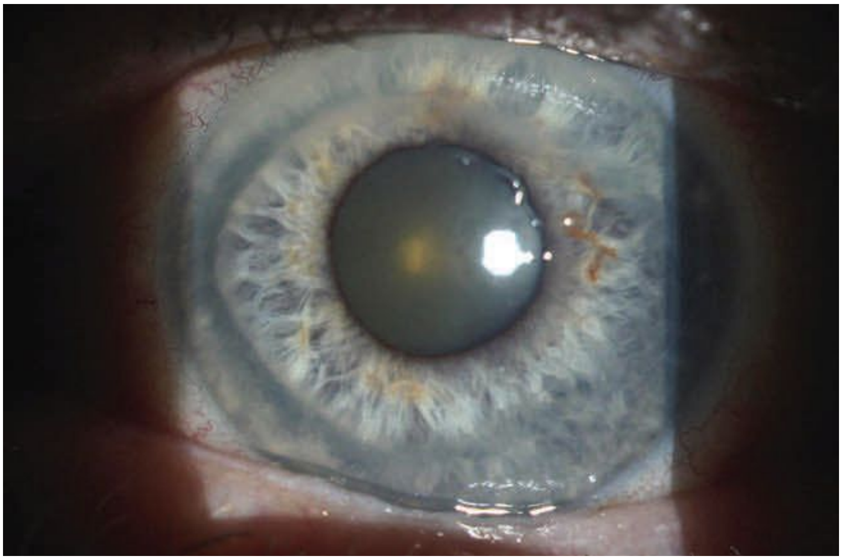
The patient's eye at presentation shows 2+ to 3+ injection, a dense apical ring and central stromal edema.

fungi, viruses, protozoa, autoimmune disease or corneal foreign bodies, all of which have their own distinct treatments and prognoses. Apical rings may even be confused with corneal neurotrophic ulcers. Therefore, it is important to understand how these different etiologies of rings vary from one source to the next and proceed accordingly with the clinical exam and specific history. This enables the clinician to navigate this differential of multiple severe pathologies with more confidence.

While the clinical appearance of this pathology was most in line with AK, the underlying diagnosis required us to look at the clinical picture in combination with the history. And in this particular case, there were no supportive historic elements that pointed toward AK. The patient was not a contact lens wearer, had no history of ocular trauma and denied even remote use of a hot tub or swimming pool. He lacked all identifiable historic risk factors for AK, making this diagnosis less of a possibility but not completely ruling it out. Similarly, the patient lacked all risk factors for other forms of microbial keratitis.

The patient's symptoms also suggested an alternate cause. Again, his sole concern was his reduced vision, and he had no discomfort. While minimal and even total lack of pain has been reported in AK cases, it's the exception, not the rule, in a condition where marked pain is the norm.

Given the patient's full clinical picture, his reduced corneal sensation—which while more suggestive of herpes can also be present in



Upon resolving, the inactive ring also thinned.

AK—the lack of identifiable risk factors for AK or other forms of microbial keratitis and the history of a possible recent bout of shingles involving the left side of the face, we decided we were most likely dealing with an atypical case of herpes zoster ophthalmicus serpiginous keratitis.

We educated the patient on the severity of the pathology and potential for ongoing vision loss. For treatment, we reduced his steroid dosage to QD, not wanting to fully discontinue therapy immediately for fear of creating a massive rebound inflammation. We also placed him on both Zirgan (ganciclovir ophthalmic gel, Bausch + Lomb), which has theoretic efficacy against the varicella zoster virus, five times daily and valacyclovir 1000mg TID.

Given the abnormal features of this disease presentation, we had the patient undergo blood work to test for ANCA, Rf, HSV and VZV antibodies. He was only positive for VZV antibodies.

If the patient had failed to respond to our therapy promptly, we would have sent him for confocal microscopy imaging. Fortunately, he responded positively to treatment, and within a week's time, the ring was re-epithelialized and inactive. Unfortunately, the ring thinned as it resolved, despite the addition of doxycycline to our regimen, resulting in an irregular and steep central cornea. Though the patient undoubtedly improved since presentation, his best spectacle-corrected acuity remained reduced at 20/50.

This case illustrates the importance of ensuring the clinical picture and case history all fit together prior to rushing to a diagnosis based purely on a suggestive, but non-pathognomonic, finding. RCCL

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