Contact Lenses in Canada

Contact Lenses for Irregular Corneal Astigmatism
Corneal Gas Permeable Lens Update
The Latest in Hybrid Lenses
Scleral Lenses: Where are We Headed?
The Missing Piece of the Puzzle
As primary care practitioners, it can be difficult to decide which aspects of your practice to invest in. The days of “generalized” Optometry practice are nearing an end as residency training becomes more commonplace for Optometrists. With high rates of competition in urban settings, Canadian Optometrists are looking to differentiate themselves. It is smart business practice to fine-tune your clinic to offer the most up-to-date services such as diagnostic imaging, vision therapy, low vision, or specialty contact lenses, to name a few.

This supplement serves to introduce this exciting, rapidly evolving time for the specialty contact lens industry. Researchers across the world are investigating new coatings for contact lenses, solutions that lubricate the lens and provide nutrients for the cornea, contact lenses that measure intraocular pressure (e.g. Sensimed’s recently FDA-approved Triggerfish lens) or glucose levels, or provide Google-Glass-esque technology on a contact lens platform. The fastest growing aspect of specialty contact lenses over the last ten years is undoubtedly scleral contact lenses. As our ability to understand and assess scleral topography expands, scleral lenses have shown their benefits not only for irregular astigmatism, but also to manage ocular disease such as dry eye, recurrent corneal erosions, neurotrophic keratitis, among others. This increased knowledge translates into a lasting impact on the lives of our patients.

Canadian practitioners often struggle to obtain access to all lens designs and solutions due to our small market size. We are very grateful for the generous support of this supplement by X-Cel Specialty Contacts and we welcome X-Cel Specialty Contacts’ efforts to emerge as the leader in the Canadian market.

This supplement was enriched by many authors who are leaders in this field, not only in Canada, but internationally. I am extremely honoured to have practitioners from coast to coast, in a variety of clinical settings, volunteer their advice and clinical pearls to guide Canadian Optometrists in their day-to-day contact lens practice.

Finally, I would like to thank Dr. Ralph Chou and the Canadian Journal of Optometry for inviting me as a guest editor for the supplement. I am very grateful to spread my enthusiasm for specialty contact lenses, and to continue to advocate for the unserved patient demographic who benefits from this technology.

Hopefully, this supplement will encourage you to add specialty contact lenses as the missing piece to your practice.

Andrea Lasby, OD, FAAO
Supplement Editor
## CONTENTS

### RESEARCH

<table>
<thead>
<tr>
<th>Page</th>
<th>Title</th>
<th>Author(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Visual Rehabilitation with Contact Lenses for Irregular Corneal Astigmatism</td>
<td>Buddy Russell, COMT, FCLSA, FSLS, LDO</td>
</tr>
<tr>
<td>18</td>
<td>Corneal Gas Permeable Lens Update</td>
<td>L. Sorbara, OD, MSc, FAAO, FBCLA</td>
</tr>
<tr>
<td>22</td>
<td>The New Generation of Hybrid Lenses</td>
<td>Vishakra Thakrar, OD, FAAO, FSLS</td>
</tr>
<tr>
<td>24</td>
<td>Case Report:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ultrahealth Lens Excellent Option for Corneal Thinning Disease</td>
<td>Vishakra Thakrar, OD, FAAO, FSLS</td>
</tr>
<tr>
<td>25</td>
<td>Scleral Lens Troubleshooting Q&amp;A</td>
<td>Langis Michaud OD MSC FAAO (Dipl) FSLS FBCLA; Jennifer Liao, OD</td>
</tr>
<tr>
<td>32</td>
<td>The Scleral Lens Industry:Where are we Headed?</td>
<td>Andrea Lasby, OD FAAO</td>
</tr>
<tr>
<td>36</td>
<td>Scleral Lens: Case Study One</td>
<td>Andrea Lasby, OD FAAO</td>
</tr>
<tr>
<td>38</td>
<td>Scleral Lens: Case Study Two</td>
<td>Andrea Lasby, OD FAAO</td>
</tr>
</tbody>
</table>

### On the Cover:

**X-Cel Specialty Contacts**

recessed cut-out piggy-back silicone hydrogel lens

*Image courtesy of Buddy Russell*
Visual Rehabilitation with Contact Lenses for Irregular Corneal Astigmatism

Buddy Russell, COMT, FCLSA, FSLS, LDO

Empowering the patient
We have all experienced praise, thanksgiving and other tokens of appreciation from patients for our services. When these events occur, it reminds us that we can and do make a difference in the lives of our patients. I will never forget a gentleman a number of years ago who commented that I had “empowered” him. To empower someone means to increase the spiritual, political, social and economic strength of the individual. Those who are empowered develop confidence in their own abilities. Optometrists, specifically contact lens professionals (ECP), are in a position to deliver goods and services to patients who need us to empower them. The patients who will be discussed in this article are often incapacitated without contact lenses to provide them with visual correction that conventional spectacles cannot correct. These are often the patients that we, as contact lens professionals, develop a relationship with through the years as we continue to help empower them with our services. It is the responsibility of the Optometrist to stay up to date with the various tools in the toolbox that may be required to meet the needs of this patient population, those who have irregular corneal astigmatism.

Corneal Astigmatism
Irregular corneal astigmatism occurs when the two principal meridians of light are not 90 degrees apart. In addition, the refractive error will vary through a single meridian. The amount of irregular corneal astigmatism is not readily measured by a keratometer since the principle meridians are not perpendicular to each other. However, the manual keratometer does provide an objective reflection of the anterior corneal surface to evaluate the quality of the mire reflection. The use of corneal topography is considered the gold standard to diagnose corneal irregularities that often limit a patient’s best spectacle correction. Patients who are diagnosed with corneal irregularities will often be fitted with a contact lens that in most cases provide a new, smoother and more regular refractive surface that improves visual acuity.

Conditions that may result in irregular corneal astigmatism
- Corneal ectasias
  - Keratoconus
  - Pellucid marginal degeneration
  - Terriens
- Surgically induced corneal irregularities
  - Incisional: RK / AK / Hex K
  - Ablative: Lasik / Lasek / PRK
- Penetrating keratoplasty
- Implants
  - Intra-corneal ring segments (ICRS)
  - Keratoprosthesis
- Corneal scars
  - Trauma
  - Salzmann’s
- Eyelid lesions
  - Tumors
  - Hordeolum / chalazion

Contact Lens Options
The contact lens industry has a number of options for the ECP to manage irregular corneal astigmatism. Each lens type will be discussed:
- Conventional Soft lens
- Custom soft
- Corneal GP
- Tandem
- Hybrid
- Corneal scleral
- Scleral
Conventional Soft Lens

In some cases, the “draping” effect of a conventional soft lens may provide a smoother refracting surface and improve visual acuity. In the example below, the use of a single use soft lens was applied and rendered an improvement in the best spectacle correction and managed the patient’s anisometropia. While a soft lens of minimal thickness will not neutralize the total amount of corneal irregularities over the visual axis, they may decrease the surface irregularities enough to manage the patient’s visual complaints.

Case in point, Figure 1, is the topography of a 62-year-old female who had become increasingly intolerant to contact lens wear despite multiple attempts at refitting with options including GP, tandem, custom soft, hybrid and scleral. Her visual acuity was “acceptable” in her left eye with spectacles. However, her best spectacle vision with the right eye was a blurry 20/150. The application of a -3.00 D single use soft lens decreased the central corneal irregularities enough to improve her vision with a spectacle over correction to 20/40. (Figure 2)

Custom Soft Lens

The single most important parameter by which we enhance visual acuity with most custom soft lens designs for an irregular corneal surface is lens thickness. By increasing the central thickness to 0.30mm to 0.50mm throughout the optics portion of the soft lens, the refraction over the lens often yields an improvement in vision. The new refracting surface is best visualized by evaluating the mire reflection with a manual keratometer over the contact lens compared to the mire reflection of the corneal surface without the lens (Figures 3-4). The more regular the mire reflection, the better the vision. In addition, evaluation of the mire reflection before, during and after the blink may aid the ECP as to how the lens is aligned over the visual axis. For instance, if the mire reflection is relatively clear and regular pre-blink then blurs during the blink and becomes clearer again post-blink, the curvature of the lens may be slightly flat over the visual axis. Conversely, if the mires are slightly blurred pre-blink, then becomes clearer with the blink and then blurs again, the fitting relationship may be slightly steep. When the thicker lens is aligned properly, the improvement in mire quality should be the same pre, post and during a blink. In addition to...
Corneal GP

Despite rumors of the death of corneal GP designs, in most specialty contact lens practices, they remain alive and well. A well-fitted GP corneal lens can often be tolerated by the large majority of patients while they provide good vision and safe long term wear. Whether the ECP chooses to use a proprietary GP design or specify all the parameters to be fabricated, the goal is to as equally as possible distribute the mass of the lens on the corneal surface while maintaining stability. Many specialty fitters have evolved into using larger lens diameters to accomplish this goal. Larger diameter GP designs may be better tolerated than smaller diameters due to a decrease in corneal nerve innervation in the peripheral cornea.

GP Case Histories

Subjective

This case will discuss a 58-year-old gentleman who was referred to the Emory Contact Lens Service for contact lens fitting. He complained of poor and fluctuating vision that he managed by rotating three pair of spectacles all with different prescriptions; and the patient stated that he is not comfortable driving after dark due to his vision. He recently attempted to wear contact lenses fitted at another ophthalmologic practice, yet he told us that these contacts did not improve his vision and were difficult to tolerate.

The man underwent refractive keratotomy in both eyes approximately 14 years ago. In addition, the patient had Type II diabetes mellitus controlled with diet, exercise and medications. At the time of treatment, he was using no eye medications and had no known drug allergies.

Objective

Vision with “best” spectacles
- OD 20/40 PH 20/25
- OS 20/70 PH 20/30

MR
- OD +1.75 +0.75 x 125 = 20/40
- OS +1.75 +1.25 x 075 = 20/60 +2.00D add OU

MK
- OD ~33 / ~38 @ 150 3+ mire irregularity
- OS ~36 / ~37 @ 055 3+ mire irregularity

(Slitramp Figure 5)

Slit lamp evaluation revealed radial and transverse incisions in both corneas (Figure 6). One of the transverse incisions in the right cornea had a buried suture. A few of the incisions tended to gape with only a thin epithelial plug covering the wound that allowed fluorescein to pool. Both eyes had mild cataractous changes, with the left eye being more affected than
the right. In addition, a thick tear film and moderate posterior blepharitis was present.

**Assessment**
- Irregular corneal astigmatism s/p RK / AK OU
- NS (nuclear sclerosis) OS > OD
- Flat pigmented choroidal lesion OD (stable per MD notes)
- No diabetic retinopathy noted (per MD notes)

**Plan**
The patient was fitted with GP contact lenses with the following parameters:

- OD 38.00D Plano 12.3 mm Titan design OU Figure 9
- OS 37.50D +0.50D 12.3mm Boston® XO material by Polymer Technology
  - Proprietary optic zone and curve system (X-Cel Specialty Contacts)

With the contact lenses in place, the patient’s vision was OD 20/20 and OS 20/30. The patient tolerated the lenses approximately 14 hours per day, and was pleased with the improvement in the quantity and quality of the vision. He was compliant with lid hygiene and the use of preservative-free, artificial tears to manage the blepharitis.

**History of Refractive Keratotomy**
Until a few years ago, if someone were to have asked me, “Where and when did RK begin?” I would have said, “In Russia by a guy named Fyodorov after he observed a near-sighted child’s unaided vision improving following an accident on a playground.” I would have been wrong. The development of refractive keratotomy should be credited to a brilliant and astute Japanese clinician named Tsutomu Sato. And, his life’s story is quite interesting.

Sato was the third son of the surgeon who founded and owned the Juntendo University Hospital in Tokyo. Sato’s two older brothers were both professors of internal medicine at the university. Sato himself graduated from Tohoku University and joined the ophthalmologic staff of Tokyo University in 1932. Under the direction of his academic advisor and mentor, Professor S. Ishihara, Sato became interested in the study of ocular refractions. Sato was not only extremely smart and driven, he also knew how to make the right moves to help advance his career; he married his famous mentor’s daughter and rose to full professor at the university in a short period of time.

The years between 1933 to 1936 proved to be the turning point in Sato’s life. This is when he got the idea of making incisions on the posterior surface of the cornea for the treatment of keratoconus. This procedure was implemented as a result of his observation of corneal flattening following spontaneous
breaks in Descemet’s membrane known as hydrops. He became aware that there was a greater flattening effect with these breaks than that induced by injury to Bowman’s layer. Sato is quoted as having said, “The discovery and development of new techniques begin with the close observation of the patient’s illness.”

During these years of World War II, Professor Sato sought to cure myopia to help his nation’s efforts in strengthening the military. He felt the urgent need to eradicate myopia so that Japan’s military power would be strengthened. Sato emphasized that Japanese soldiers who had myopia could not become fighter pilots and good marksmen. In other words, the greater the number of soldiers with myopia, the weaker the military power of the nation. Until his death in 1960, Sato continued to study the effects of the strategic placement of incisions on both the posterior and anterior cornea, publish his results, and be a mentor to many in his field.

There are some amazing stories about Sato recorded by his friend and colleague Koichiro Akiyama, MD. One story recounts how Sato literally slept with the encyclopedia. Before he went to bed each night, he would take a volume from a huge set of encyclopedias and fall asleep reading the contents. It is said that he knew everything in these books from A to Z because he had memorized them. Another interesting aspect about Sato is how he won the love and admiration of his disciples and students. He instructed and directed his staff like a father; but was also a man of immediate action and expected his instructions to be carried out right away. A split second delay would ensure a loud, barking reprimand for the guilty party. Yet, when it came to tutoring, he was a gentle and patient teacher. He taught his disciples the meaning of dedication and showed them what medical research should really be. The staff at the university called him “our daddy.”

Keratoconus Case
The majority of conditions encountered in a contact lens practice are diagnosed and managed based on the traditional presentation of the condition. But, when you are faced with an atypical representative of the condition, you are forced to think outside the box. The following two cases that were referred to the Emory Contact Lens Service by different outside ophthalmologists are certainly examples of this. Both of these patients were diagnosed with keratoconus and referred for contact lens management. Each of these cases will demonstrate that keratoconus can present in more than the classic form.
**Subjective**
The first case is a 53-year-old male with a long-standing history of poor vision in both eyes. He described monocular diplopia in each eye that had worsened over the past two years. The patient stated that he has worn glasses since he was a teenager and has never attempted contact lens wear. He further stated that he has never been advised of a cornea problem contributing to his poor vision. The Ophthalmologists at the Veterans’ Hospital have followed him for retinal changes over the past five years. This is following an HIV positive diagnosis.

**Objective**
VA OD 20 / 60+1 PH 20/30
OS 20 / 60-1 PH 20/30

MR OD -8.50 +9.25 x 010
OS -8.50 +9.75 x 180
(current spectacle Rx)

K’s OD 54.50 / 59.25 x 05 3+ mire irregularity
OS 52.00 / > 62.00 x 180 3+ mire irregularity

AT* OD 10
OS 10
*Applanation tonometry

Slit lamp evaluation revealed marked corneal thinning in the superior quadrant in both eyes. In addition, subepithelial scarring was noted in both eyes (Figure 8)

The patient was fitted with gas permeable lenses with the following parameters:

- OD 48.50D -3.75D 10.0mm med edge lift
- OS 49.00D -4.00D 10.0mm med edge lift

Apex Design by X-Cel Specialty Contacts OU

The contact lenses improved the patient’s vision to 20/25 OU. The lenses do exhibit interaction at the corneal apex in both eyes. However, no epithelial breakdown has occurred with lens wear.

**Case 2**
**Subjective**
This case describes a 60-year-old male who complained of poor vision in his left eye. Two years ago, he was told he had a cataract and an irregular cornea in the left eye. At that time, he felt that his vision was adequate to meet his needs and did not pursue treatment. Since that time, his vision has become more problematic. The referring ophthalmologist did confirm nuclear sclerosis and keratoconus and suggested that a contact lens might improve his vision. He has never attempted contact lens wear.

**Objective**
VA OD 20 / 50 PH 20/40
OS 20 / 400 PH 20/50

Current Rx
OD -1.75 +1.00 x15
OS -6.50 +2.00 x85 (slab off OS)

MR No improvement
*positive scissor reflex OS>OD

K’s OD 42.25 / 43.75 x 27 trace irregular
OS 47.00 / 49.87 x 112 3+ irregular

*Note: Could not obtain corneal mapping due to extremely deep set eyes

Slit lamp evaluation revealed apical thinning and scarring at the apex of the left cornea (Figure 9) In addition, moderate corneal guttata is present in both corneas.

The patient’s left eye was fitted with a gas permeable lens with the following parameters:

- OD 48.00D -6.25D 8.8mm med edge lift
- OS 49.00D -6.25D 8.8mm med edge lift

Apex Design by X-Cel Specialty Contacts

The contact lens improved the vision to 20/50. The contact lens was fitted relatively steep as to minimize lens dislocation due to the deep set eye position.

**Discussion**
The classic description of keratoconus (KC) is a non-inflammatory corneal ectatic disorder that is typically bilateral with an incidence of approximately 1 per 2000 in the general population. Typical clinical signs of corneal irregularities including inferior steepening, scissoring reflex, stress lines (Vogt’s striae), stromal thinning, iron rings (Fleischer’s ring) and scarring (epithelial and subepithelial) help aid in the diagnosis. The advent of computer-assisted videokeratoscopes has enhanced the practitioner’s ability to document even the earliest and most subtle corneal changes. This ability is especially important to screen those patients that are being evaluated for potential refractive surgery. The classic description of the topographies most often seen in KC includes compression of the corneoscope rings, a localized area of increased surface power and an inferior-superior power asymmetry.
Keratoconus has been reported in association with many non-ocular systemic disorders including atopy, Down syndrome, Ehlers-Danlos syndrome and mitral valve prolapse. In addition, KC has also been reported to occur associated with a number of ocular conditions including aniridia, blue sclera, floppy eyelid syndrome, congenital cataracts, vernal conjunctivitis and atopic keratoconjunctivitis to name just a few.

The cases outlined in this article demonstrate two atypical manifestations of keratoconus. The first case can be referred to as superior KC (Figure 8). This superior location has been reported and treated with a blepharoptosis procedure (Kim T., Khosla-Gupta B., Debacker C., “Blepharoptosis-induced Superior Keratoconus.” Am J Ophthalmol., 2000 Aug;130(2):232-4). The second case demonstrates that KC can be seen concurrent with other corneal disorders such as Fuch’s endothelial dystrophy (Figure 9). Several authors have reported the association of keratoconus and Fuch’s. Both cases also demonstrate that scarring of the keratoconic cornea can occur in the absence of a contact lens.

When fitting the keratoconic cornea with a rigid contact lens, two basic philosophies are apical touch and apical vaulting. The fitter must determine which philosophy will provide the best outcome based on other factors. The factors to be considered might include lid position (upper and lower), topography, location of the apex in relation to the pupil, and eye position within the socket. The two different cases being discussed in this report demonstrate flexibility in fitting philosophy. Due to the location of the steeper area of the cornea in case one, a large flatter fitting lens was necessary to maintain centration of the optical zone over the pupil. Diagnostic lenses utilized during the fitting process revealed that the steeper the base curve, the more superior the lens positioned. In contrast, the patient described in case two required a steep lens to cornea relationship to stabilize the lens on the cornea and avoid lens dislocation. The deep set eye position is often problematic in obtaining corneal topography as well as maintaining the lens on the cornea.

**Remember these objectives when fitting keratoconic corneas**
- Maximize vision and minimize flare by designing a lens that maintains centration of the optical zone over the pupil.
- Minimize the interaction of the corneal apex and the posterior surface of the lens. Pay careful attention to the dark area (corneal apex) during the blink. Determine if an exchange of tears during the blink results in a lightening of the dark area. This exchange of tears is necessary to avoid epithelial breakdown.
- Be flexible in your philosophy based on other factors that can be seen with the disorder.

**Tandem / Piggy-back Contact lens fitting**

First described by Westerhout in 1973, utilizing a soft lens under a rigid corneal lens to improve comfort it is still utilized to manage patients with irregular corneal astigmatism. The major difference at present is the soft material and GP material used are both more oxygen permeable. This increased use of oxygen flux materials helps avoid the corneal edema associated with lens wear.

There are two basic fitting techniques to consider:
- Fit a soft lens, preferably silicone hydrogel, then fit a GP over the adjusted topography
- Fit a GP, then apply a low power silicon hydrogel soft lens under the GP

I prefer the second option as I consider the soft lens as “training wheels”. Some patients will use the soft lens during early adaption and then discontinue the soft lens. Other patients may only use the soft lens when environmental factors dictate, such as spring pollen. This suggested technique offers additional advantages. The characteristics of the GP fitting can be further adjusted by altering the soft lens power. For instance, increasing the soft lens minus power will “tighten” the edge of the GP while increasing the plus power of the soft lens will “loosen” the GP edge lift. The effective power of the soft lens typically yields approximately 20% to the tandem system of correction. For example, a +5.00 soft lens under a GP will impact the total power of the system by approximately one diopter. One of the most important factors to consider is the modulus of the soft lens. The higher the modulus, the stiffer the soft lens. Some of the higher modulus soft lens materials will not drape the irregular surface. (Figures 10-11)

The use of fluorescein is used to evaluate the corneal lens relationship with the piggy-back system in place. Care system considerations include using a GP cleaner for the GP lens, storage for both the GP and the soft lens in a multipurpose soft lens or hydrogen peroxide product and the application of the GP to the soft lens with a soft lens product. The application of the GP lens over the soft lens when conditioned with a GP solution will cause toxicity.

Another piggy-back option that may be utilized is a design that incorporates a “cut-out” on the anterior surface of the soft lens. (Figure 12) The diameter of the GP lens fitted is typically 1mm smaller than the cut-out of the soft lens. (Figure 13) The recessed portion of the soft lens helps maintain the optics over the visual axis. These tandem design soft lens may be fabricated in HEMA or a latheable silicone hydrogel material.
Piggyback Case History

**Subjective**
JB is a 45-year-old engineer who was originally referred to the cornea service in April 1997 for a penetrating keratoplasty following radial keratotomy (RK). Following the Cornea service examination, JB was referred to the Emory Contact Lens Service for evaluation and possible fitting. His right eye only was fitted at that time with a gas permeable lens that he wore with reasonable success for about two years. An uneventful penetrating keratoplasty procedure was ultimately performed on the right eye with an outstanding outcome. Approximately one year later, while assembling a gas grill, JB suffered a ruptured globe of the right eye that resulted in wound dehiscence and lens expulsion. The patient is being followed by the Cornea service, the Glaucoma service for traumatic glaucoma, and the Retina service for lattice. Lattice is a peripheral retinal degeneration that is seen most often in myopic patients. Patients having been diagnosed with lattice are followed in the Retina service as they are more predisposed to retinal detachments or holes due to thinning. He presented at this point to the Contact Lens service for contact lens fitting in both eyes.

**Objective**

<table>
<thead>
<tr>
<th>Unaided vision</th>
<th>OD HM*</th>
<th>PH** 20/400</th>
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<td></td>
<td>OS 20/400</td>
<td>PH 20/30</td>
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*Hand motion
**Pinhole

Figure 10. Higher modular soft lenses will not often drape the corneal surface.

Figure 11. Thinner modulus silicone hydrogel on the same eye as Figure 10.

Figure 12. X-Cel Flexlens piggy-back cut out lens.

Figure 13. Clinical slide of X-Cel Specialty Contacts recessed cut-out piggy-back lens.
Current Spectacle Rx
OD Balance
OS -3.00 + 5.00 x 37 = 20/50

Manifest Refraction
OD +6.00 +6.00 x 55 = 20/80 VD 12mm
OS -3.50 +5.50 x 40 = 20/40

Manual Keratometry
OD 41.00 / 46.50 @ 60  2+ mire irregularity
OS  33.00 / 41.00 @ 45  3+ mire irregularity
(Figure 14 reveals an area of inferior ectasia in the left eye)

Slit lamp evaluation revealed a centrally clear graft OD with a single running suture and several interrupted sutures in the five o’clock position of the donor/host interface. There was a slight anterior chamber reaction with pupil dilation and a mild follicular response. The left eye revealed RK and AK scars along with an ectactic area infratemporally with an iron pigment deposition line.

Assessment
• Aphakia OD
• Irregular astigmatism OU (status: post PK OD and post RK OS)
• Anisometropia
• Follicular conjunctivitis OD (not uncommon with some glaucoma medications)
• Iris sphincter muscle dysfunction following trauma OD
• Glaucoma OD
• Lattice OU

Plan
JB was fitted with GP lenses with the following parameters:
OD  9.00 mm +16.00 D  11.0 mm
   9.6 mm oz, 0.4 mm / 10.50 mm secondary curve,
   0.3 mm / 13.25 mm peripheral curve, 9.5 mm lenticular bowl
OS 8.90 mm  -1.00 D  11.5 mm  Pinnacle™
   Design by X-Cel Specialty Contacts
   170 AEL (axial edge lift)

In addition, an Air Optix® Night & Day™ 8.6 mm -0.50 D 13.8 mm under the left GP provides the “buffer” to eliminate the mechanical trauma to the ectatic area of the left cornea. This fit was further complicated by having to fit the lens large and flat enough to stay attached to the upper lid. Currently, JB is able to see 20/25+ with each eye individually. He wears the lenses approximately 12 hours a day without difficulty.

Discussion
Silicone Hydrogel Lenses
The addition of the silicone hydrogel lens option is one of the most exciting tools the contact lens practitioner has added to his/her toolbox in a long time. Silicone hydrogel lenses may be the most studied lens technology to date. Thousands of “eye years” of clinical trials have already been documented. Whether you choose to be conservative or aggressive in how you present continuous wear to your patients, the literature indicates the problem of oxygen transmissibility has been overcome with Air Optix® Night & Day™ lenses.
Oxygen Transmission

In 1980, Mertz determined that when the eye is closed overnight during sleep, the cornea swells 4%. Four years later, Holden and Mertz established that a minimum of 87 Dk/t was required of a contact lens material to limit the corneal swelling to the 4% level with overnight wear. At that time, a soft lens material did not exist that could meet this criteria. As a result, patients who chose to sleep in a contact lens overnight were predisposed to the consequences of corneal edema. The most concerning of these complications was, and still is, microbial keratitis. Work by La Hood, et al, in 1988 and later confirmed by Harvitt and Bananno in 1999, increased the magic number to 125 Dk/t.4

What makes this new lens material so much more permeable to oxygen? In a word: silicone. Silicone is far more soluble to oxygen than water in traditional hydrophilic lenses. Manufacturers of hydrophilic lens materials are limited in the amount of water that can be added to a monomer. The higher the water content, the more fragile the lens. To counter this effect, manufacturers tend to increase thickness as the water content increases often neutralizing the overall increase in oxygen transmissibility. To put the difference in silicone and water transmissibility in perspective consider this; 100% water has a Dk/t of only 80.

Another Consideration

Piggyback lens systems are usually attempted when all else has failed. When a patient requires the optics that only a GP lens can provide, yet struggles to tolerate the lens the number of hours needed, consider the “buffer.” However, only consider using this technique if the lens to cornea relationship is good. Do not use it as a crutch to compensate for a less than appropriate fit. The “buffer” can sometimes be used on a short-term basis until the patient fully adapts to rigid lens wear.

Plan

Due to his multiple ocular problems, JB will be followed by eye care practitioners the rest of his life. Prior to piggybacking the left eye, JB developed chronic surface keratopathy over the thin elevated area. Because he has radial keratotomy scars to the limbus, piggybacking could lead to developing vessels within the incisions.

Piggy-back Case History

Subjective

This case will discuss a 33-year-old female who was originally referred to the Emory Contact Lens Service in 1998 for contact lens management. At that time, she had become “contact lens intolerant.” With the diagnosis of keratoconus (KC), it was critical for her to be able to wear her gas permeable lenses to maximize her visual acuity. She tolerated her new fitting with good vision in both eyes until late 2005 when she underwent a penetrating keratoplasty procedure in the right eye. She presented for visual rehabilitation in the operated eye. She was a healthy, young woman who was using no systemic medications and had no known drug allergies. Her ophthalmic drops included Systane® PF OD and Pred Forte OD.

Objective

Vision

OD 20/40 (spectacles -150 +1.00 x 180)
OS 20/25 (piggyback contact lens system)
MR OD -2.00 +1.50 x 10 = 20/30
OS -14.00 +3.00 x 58 = 20/100
MK OD 44.12 / 46.25 @ 15 1+ mire irregularity

Slit lamp evaluation of the right eye revealed a clear graft centrally with interrupted sutures that was buried. The surface was absent of keratopathy, the wound had good apposition and the anterior chamber was deep and quiet. The left eye revealed a well-fitting GP lens over a silicone hydrogel soft lens. The left cornea had some central scarring but no edema, keratopathy or vascularization.

Assessment

• Keratoconus s/p penetrating keratoplasty OD
• Irregular corneal astigmatism OS>OD
• Anisometropia with poor BCV (best corrected vision) OS

Plan

The patient was fitted with a piggyback system over the corneal transplant with the following parameters:
OD (gas permeable lens) base curve 7.10mm, power -4.50D, diameter 9.8mm, optic zone 8.4mm, peripheral curves 0.5mm/8.20mm, 0.2mm/11.00mm, Boston® XO

OD (soft lens) base curve 8.3mm, power -1.25D, ACUVUE® ADVANCE™

Her habitual care system is the Boston® Original Cleaner for gas permeable cleaning only, along with Clear Care (Alcon) for both the soft and the gas permeable lenses for disinfection.
With the soft lens in place, the GP lenses are applied with AMO’s blink™ Contacts eye drops.

**Discussion**

**Corneal Transplants**

The World Health Organization reports that corneal blindness affects more than 10 million people worldwide, however only 100,000 people receive corneal transplants each year. That equates to only 1% of those individuals needing a corneal transplant actually receiving one. This shortfall is due to a combination of the unsuitability of some patients to receive a corneal graft and the inadequate supply of donor corneas. Those of us who live in the U.S. have access to a good supply of corneal banking tissue compared to third world countries. The results of a paper published last year concluded a total of 80% of the world’s blind live in developing countries.

Retinal diseases are the most significant causes of blindness (40 to 54%) in established economy nations, while cataracts (44 to 60%) and corneal diseases (8 to 25%) are the most common causes of blindness in countries with less developed economies (“The Value of Corneal Transplantation in Reducing Blindness.”) A large percentage of individuals receiving a corneal transplant in the U.S. are older. Many of these patients require a contact lens to achieve their best corrected vision following surgery. Often the challenges of fitting the eye are easier than “fitting the patient” in this age population. They often have no contact lens history, don’t want to wear a contact lens, they face application and removal challenges due to dexterity and fear, not to mention many of these patients live alone and can’t see out of the other eye. However, as a contact lens practitioner, we have the opportunity to receive instant gratification when we assist corneal surgeons in delivering the ultimate vision that only a contact lens can provide for these patients.

**Contact Lenses after Penetrating Keratoplasty**

The outcomes of penetrating keratoplasty (PK) procedures are viewed differently by the surgeon and the patient. The surgeon makes his or her best attempt to maintain clarity as the graft heals. Vision early on may not be very good so valiant efforts of adjusting sutures before the tissue scars are often made to “round the eye out” to improve vision. After several months if the graft is clear the surgery was a success, right? To the surgeon, absolutely! Success to the patient? Maybe. The final vision is often the gauge used to determine the level of success from the patient’s perspective.

The factors that affect the shape of the corneal surface include suturing technique, intraocular pressure, graft sizing and healing variances. The vision following surgery is dependent on the axial length, anterior corneal shape, posterior corneal shape, focusing power, media opacities, retinal function and any other pathologic findings. It is not uncommon, nor a surprise, when patients need a contact lens following corneal transplantation.

The type of contact lens required after corneal transplants is determined by corneal shape, refractive error, patient needs and expectations. The most common reason for a contact lens after PK is irregular corneal astigmatism. This being the case, GP lens materials and designs are the standard of care in order to provide full visual rehabilitation.

**Piggyback Lens Considerations**

The vast improvements in soft lens materials over the past few years have given a rebirth to piggyback lens fitting. The previous concerns specifically related to oxygen transmissibility are all but forgotten with the advent of silicone hydrogel materials. There are at least five reasons to utilize piggyback lenses after corneal transplants:

• Provide a smooth, wettable protective surface with which the GP lenses will interact
• Minimize foreign body sensation
• Minimize foreign bodies being pumped under the GP lens by the tear film
• Alter the shape of the anterior corneal curvature by using the power in the base soft lens
• Improve vision without the GP lens

**Hybrid lens designs**

The original hybrid design was initially developed by Erickson and Neogi and acquired by Precision-Cosmet in 1977. During the past 40 years, this concept has been modified to incorporate improved materials and design options. At present, Synergeyes is the only maker of hybrid designs approved for use by the FDA in the states. Hybrid lens designs in general are often criticized for their shortcomings. These shortcomings are often associated with long term hypoxia especially noted with earlier designs. The implementation of a silicone hydrogel skirt along with an increase in the DK of the GP portion has decreased some of the concerns associated with hybrid designs. In addition, changes in the design of the landing area of the GP and soft lens interface have decreased mechanical compression clinically seen with hybrid designs. Latest generation hybrid designs such as UltraHealth, ClearKone and Duette may be considered for patients in the presence of corneal irregularities.
Scleral Lens

Scleral lens usage has arguably changed specialty contact lens practices more in the past five years than any other lens modality. Essentially, any and all refractive errors and ocular surface disorders can be successfully managed with well-fitted scleral contact lenses. In addition to the improved vision in cases of irregular corneal astigmatism, the improvement in quality of life for many of these patients treated with scleral lenses projects the contact lens professional as a hero.

Contact lens manufactures using computer driven multi-axis lathes produce fitting kits that allow the ECP to determine the final lens parameters. These diagnostic lenses allow the fitter to measure the clearance over the corneal surface, interpret the alignment of the haptic and determine the appropriate power. Scleral lenses are manufactured in high oxygen flux materials to supply the oxygen needs of the cornea through diffusion, as scleral lenses do not usually move during the blink. Lenses that rest on the cornea, limbus and scleral are referred to as corneal scleral. Lenses that rest solely on the scleral are referred to as scleral lenses. The proper reference can be further distinguished as mini-scleral or full scleral depending on the overall diameter of the lens and whether that diameter is 6mm greater or smaller than the corneal diameter.

When fitting a scleral lens, the lens is applied to the surface of the eye with fluorescein and unpreserved saline. After the lens has settled into the soft mucous membrane of the bulbar conjunctiva, the ECP determines corneal and limbal clearance. This clearance can be estimated with an optic section (Figure 15) and a biomicroscope and / or determined with an anterior segment OCT. The appropriate corneal clearance will vary dependent to the various corneal elevations found in individual corneas. The appropriate amount of clearance over an irregular surface is debated. Most scleral fitters prefer a minimum of 200 microns of corneal clearance on average after the lens has settled into position. Most lens settling occurs over 4-8 hours, so it is recommended to see patients after 6-8 hours of wear to determine the end of day corneal clearance of the lens. This final resting position may take approximately a month of consistent wear to stabilize. There are factors that are yet to be completely understood in regards to scleral lens fitting. The primary goal is to have appropriate clearance of the cornea and limbus and align the haptic without causing blanching (Figure 16), compression or edge impingement. Proper alignment of the haptic may be the most difficult parameter to determine. Toric and asymmetrical haptic designs may be necessary to maximize patient comfort and provide a device for safe long-term wear.

Corneal topographers can be used to determine corneal diameter, location of the corneal apex and the sagittal height of the corneal surface at approximately a 10mm chord. Using the topographers’ elevation algorithms may help the fitter appreciate the high and low areas of the cornea. Anterior segment depth measurements obtained using optical coherence tomography (OCT) or Scheimpflug imaging is another way to evaluate and potentially improve the fit of a scleral lens (Figure 17). These instruments, unlike topographers obtain objective measurements of the corneal and sclera out to approximately 15mm. The use of an anterior segment OCT can be used to determine accurate measurements of clearance at follow-up visits. Most ECP’s will need to depend on their clinical skills with the slit lamp to determine the clearance with optic section illumination. New instrument developments such as the sMap3D topographer (Precision Ocular Metrology) uses a structured light approach for three-dimensional mapping.
to obtain measurements of the cornea and scleral with a 22mm maximum field of view. The sMap3D takes multiple triangulated measurements using a single DLP projector and two cameras positioned laterally on each side. Fluorescein is added to the eye prior to capturing multiple images and the software “stitches” the images together. This software can then provide a “virtual” fit screen allowing the ECP to simulate various lens parameters. This virtual fit screen is then sent directly to the manufacturer for analysis and fabrication.

Possibly the most difficult part of scleral lens fitting is haptic design determination. The variations in scleral shape, conjunctival chalasis (Figure 18), previous glaucoma surgery (Figure 19) and otherwise benign conjunctival changes such as pterygiums and pingueculas (Figures 20-21) can cause fitting difficulties. These conjunctival challenges may require toric, asymmetrical or notching of the haptic to provide an optimum ally fitted scleral lens.

**Practical Scleral Lens Considerations**

1. “My vision gets cloudy”
   First, determine why the vision becomes cloudy. Rule out central corneal edema then determine if the anterior surface is cloudy or the chamber is clouded by tear film debris. (Figure 22) Patients may be able to help you if you ask them to moisten a q-tip or the edge of an application tool and wipe the front surface of the lens to determine if the cloudiness decreases or resolves. If the cloudiness does not change, remove and refill the lens to determine if the chamber is accumulating debris. If chamber debris is causing the cloudiness, consider the following:
• re-evaluate corneal clearance—if possible, decrease the vault to decrease the volume of debris that is present
• re-evaluate haptic alignment—there may be an area with excessive clearance allowing debris to be pumped into the chamber. Considering a toric haptic may improve this fitting relationship
• determine if limbal clearance is appropriate—consider decreasing
• address any tear film issues such as MGD and initiate proper treatment if indicated

2. “My lens feels ok but my eye gets red when I remove it.”
In most cases, the patient is describing rebound hyperemia caused by a tightly-fitted haptic. Scleral lens patients are often comfortable with a lens that does not move on the eye. However, a scleral lens that is too tight needs to be addressed. This is often seen with follow-up visits scheduled later in the day. We routinely “spin” the lens while doing a slit-lamp evaluation gauging the amount of resistance and dragging of the underlying tissue. The lens should spin relatively easy and if toric, return to the path of least resistance location in a few blinks. The lens should always be removed at these visits to evaluate the cornea and ocular surface. Good baseline documentation is essential to follow any findings to determine if the condition is better, worse or unchanged. I routinely take baseline slit-lamp photographs to aid in these assessments.

3. “I feel the lens.”
Lynette Johns, OD shared a pearl with me many years ago. She suggested that patients squeeze their eye tightly and they will often point to a specific area. This area is usually where the haptic is not aligned properly. This misalignment could be causing sensation on the bulbar conjunctiva or the lid requiring a change in design. If the lids are help held wide open, there should be no awareness of the lens. Asymmetrical and toric haptic designs are probably underutilized in many practices that fit sclera lenses.

4. “Which care system is best?”
Our practice tends to prefer hydrogen peroxide care systems. The diameter and depth of the lens may not allow these care systems to be used as the cases are not always large enough or deep enough to avoid potential damage. In addition, daily digital cleaning upon removal is essential. We also recommend inhalation saline for application.

Conclusions
As you can see, there are a number of ways that ECP’s can restore good vision in patients who have irregular corneal astigmatism. Each ECP will tend to develop his or her own opinions as to which contact lens modality is best for each individual patient. Ongoing learning and clinical experience with each lens type will help us help our patients.

References
Who can benefit from GP lenses?
Topographic information helps us decide whether GP lenses are appropriate for some patients. With the exception of patients suffering from dry eye, improved and more stable vision and high oxygen transmission to the ocular surface due to tear exchange and high lens Dk, GP lenses are optically excellent for cases of both regular and irregular corneal astigmatism and corneas with high and low eccentricities that are either prolate or oblate in shape.1

Topographers help with fitting GP contact lenses because they have their own built-infitting nomograms. Unfortunately the simulated fluorescein patterns given by topographers may not simulate accurately the on-eye pattern but may still be useful in showing change.

Topography/Tomography leads us to GP design selection:
Regular astigmatism (<2.25D) and prolate shape
When regular astigmatism is detected by the corneal topographer, and is less than 2.25 D, a spherical GP lens may be appropriate to fit regardless if the astigmatism is central or from limbus to limbus. The lens diameter is based on the given HVID, or white to white. The back optic zone radius (BOZR) of the lens can be calculated based on the amount of corneal astigmatism that the simulated K’s from the topographer has given the fitter. The usual fitting nomogram is based on fitting the lens steeper than Flat K, the more corneal astigmatism is present.2 The topographer gives us an e-value and so the appropriate AEL of the lens can be calculated or adjusted based on the sodium fluorescein (NaFl) pattern seen with the trial lens on the eye. Most standard trial lens sets are based on a constant AEL of approximately 0.12mm which is appropriate for a cornea with a rate of flattening (e-value) of 0.55. If the cornea has a high e-value i.e. rate of flattening, then a regular GP lens with an AEL of 0.12mm will be too tight in the periphery as detected with NaFl. So we need to vary the AEL of the GP lens based on the e-value that we have and increase it when the e-value is high or reduce it when the e-value is low to achieve the appropriate amount of axial edge clearance (AEC) on eye.

A front surface toric lens may be fitted on the same eye as just described, but where there is residual astigmatism due usually lenticular astigmatism present when the GP lens in on the eye. residual astigmatism is placed on the front surface of the GP lens along with 1 to 1.5Δ of prism ballasting to maintain the lens and the astigmatism at the correct axis after each blink.

PEARL: Due to the curvature of the eyelids and their interaction with the lens, a prism ballasted lens will usually rotate nasally by roughly 15°. To compensate for this rotation, you can apply “LARS” (left add, right subtract). For a right lens, subtract 15° from the axis. For a left lens, add 15° to the axis. This will ensure vision is clear upon delivery of a prism ballasted design.3

Regular astigmatism (>2.25D) and prolate shape
When the topographer now indicates astigmatism that is greater than 2.25D then consideration of whether the astigmatism is central or limbus to limbus is required. The most appropriate fitting of the GP lens would be if the back surface were made toric, so that the lens is stable on the cornea and aligns with each meridian allowing for smooth movement with the blink.

When the back surface of the lens is toric then the corneal astigmatism has been over-corrected by one third of the total corneal cylinder amount, due to the difference in refractive index between the lens and the tear film in each meridian. For example, if the cornea has 3.25D X 180 of corneal astigmatism and the lens is fitted having a difference in each meridian of 3.00D, then when the lens is on the eye, there is 1/3 X 3.00D of cylinder induced, that is +1.00D X 180 of...
induced astigmatism. If there is lenticular astigmatism that can neutralize this induced amount of astigmatism, or reduce the amount to less than 0.75D, then the lens will be solely a back toric lens. If there is lenticular astigmatism but it is not equal and opposite in direction and in fact adds to the induced astigmatism then the lens will be a cylindrical effect bitoric lens and the total amount of cylinder is on the front surface of the lens. If there is zero lenticular astigmatism, then the full amount of the induced astigmatism will be on the front surface of the lens creating a spherical power effect lens. No prism ballasting is required with back surface toric lenses.4

Now considering the peripheral system of these back or bitoric lenses, it is important whether the cornea has central or limbus to limbus astigmatism as dictated by the corneal topographer. The AEC will not be even in each meridian if the peripheral system of the lens does not mimic the periphery of the cornea when fitting back or bitoric lenses. If the back or bitoric lens is placed on a cornea with central astigmatism, the peripheral system should be spherical, as the cornea is in shape. This will ensure that the lens has an unequal AEL in each meridian, as the cornea has unequal e-values in each of the principal meridians. Having the lens design mimic the corneal shape will result in a more even NaFl pattern not only centrally but in the periphery also. On the other hand, if the cornea has limbus to limbus astigmatism, then the e-value in each meridian is more likely to be equal and so the back or bitoric lens should have equal AEL’s in each meridian also. This can be achieved by making the lens periphery toric which will result in a more even AEC in each meridian.

**Irregular astigmatism and prolate shape**

Irregular or non-orthogonal astigmatism is present in cases of Keratoconus and other irregular corneal surfaces without any surgical intervention. In cases of KC or PMD, the corneal shape identified by the corneal topographer is still a highly prolate ellipse or may even be hyperbolic due to great difference between the very steep apex on the cone relative to the flat and usually unaffected corneal periphery. KC can be viewed as having one of three shapes: the cone can be within the central 2mm of the cornea and is called a centred or nipple cone; the cone can be displaced inferior and temporal outside of the central 2mm zone and is called an oval cone; and finally two-thirds of the cornea can be affected by the thinned cone and is called a globus cone. These variations all result in the presence of irregular WTR or oblique astigmatism. PMD, on the other hand, has a characteristic pattern of a “kissing dove” or butterfly where the thinnest zone is inferiorly located and results in high amounts of irregular ATR astigmatism.5
The size and location of these variations in corneal ectatic disorders identified with the corneal topographer aid in the selection of our specialized lens design. The size and location of the cones also vary as the condition progresses (steepening with decreasing thickness) and therefore changes in lens designs must be considered. For the centred cone, the size of the cone appears to decrease in diameter as it steepens with time. The contact lens design must also have a design that simulates the change in corneal shape; such lenses are those with floating back optic zone diameters (BOZD). These lenses (for example, Rose K) have progressively smaller BOZDs with steeper BOZR and therefore are ideal for the centred or near centred cone. On the other hand, for the oval cone, the size of the cone increases in diameter as the cone steepens over time (steepening with decreasing thickness) and therefore a choice of a lens design that has progressively larger BOZDs with increasing lens diameters and having fixed BOZDs would be more appropriate in order to achieve a centred and more comfortable lens. For example moving from a CentraCone lens (9.6/6.25mm, Blanchard, Sherbrooke, Quebec) for the early stage oval cone to a CentraGraph (10.1/7.0mm, Blanchard, Sherbrooke, Quebec) for the later and more advanced stage of the enlarging oval cone. For cases of PMD the cone is quite large and varies in size somewhat, but a larger diameter lens with a large BOZD would be appropriate at any stage (e.g. any 11.2mm lens with BOZDs ranging from 8.0 to 9.4mm). Improvement in visual acuity over spectacles can be achieved when fitting these lenses with a gentle three point touch NaFl pattern. In a study by Jupiter et al they found that 33% of a keratoconic population have 6/6 or better acuity and 85% with 6/12 acuity or better with GP lenses compared to 13% and 56% respectively, with the same vision wearing spectacles.

Other uses for spherical GP lenses are for irregular astigmatism induced by corneal scars, corneal distortion due to log term use of poor fitting lenses and ocular surface disease. All of these can induce corneal distortion that appears as irregular astigmatism. For these corneae, large diameter GP lenses can provide the optics and rehabilitation to the corneal surface that is needs due to the material (non-water) and high Dk of GP lenses.

Regular or irregular astigmatism and oblate shape

In cases where PKP or other refractive surgery has resulted in regular or irregular astigmatism and with an amount of <3.00D of astigmatism, a spherical GP lens can be fitted. It would be prudent to use a lens design that follows the contour of the corneal shape to achieve lens centration and stability. Reverse geometry design lenses, where the secondary curve is steeper by 2.00 to 6.00D than the spherical BOZR of the lens have been used in these cases. The corneal topographer describes the oblate shape and gives you a radius at the steepened zone that can be used to decide how much steeper the mid-periphery of the lens should be compared to the BOZR.

In cases where there is >3.00D of regular astigmatism and an oblate shape, then a back or bitoric design may be more appropriate, but a reverse geometry secondary curve may not be available yet. Newer lathes may in the future provide toric optic zones with reverse curves in the mid-periphery.

Problem Solving and Other Issues:

When prescribing GP contact lenses regardless of the lens design it would be prudent to ensure that the highest DK material is used to reduce bacterial adhesion to the lens surface. Lenses should be lenticulated in order to reduce the mid-peripheral thickness since oxygen transmission is based on the overall thickness of the contact lens. These newer higher oxygen lenses have plasma surface treatment to give the lens a very wettable surface. Although the plasma surface treatment may deplete with time, the initial comfort that it adds for the neophyte lens wearer will allow for lens adaptation.

The maintenance of a clean and disinfected lens surface of GP lenses can be achieved with either two bottle or one bottle care systems. Two bottle systems include Boston Advance Cleaning, Disinfection and Storage solution from Lobob and Unique pH from Menicon. There are concentrated cleaners that help to reduce any denaturation of protein on the lens surface, which is usually the culprit for discomfort and palpebral conjunctival effects. These can include: Boston One Step Liquid Enzymatic Cleaner (B+L), Optimum Extra Strength Cleaner (non-abrasive, Lobob)(can be purchased online) and Progent biweekly cleaning system (mix Progent A and B with rinsing solution, Menicon). In addition, there are re-wetting drops specific for GP lenses, though many ocular lubricating drops can be used with GP lenses. These include; Boston Rewetting drops and Optimum Wetting and Rewetting drops (can be purchased online). It is important to remember that exposure to tap water should be avoided at all times to reduce the risk of serious corneal infections. Discomfort should not be an issue to the initiated GP lens wearer. Larger diameter lenses with highly polished and minimal thickness bevelled edges that slip slightly under the upper eyelid allowing for a smooth transition of the upper lid along with a wettable surface due to the use of concentrated...
cleaners and plasma surface treatment all contribute to improving and maintaining lens comfort. One can minimize corneal staining by avoiding harsh apical bearing with lenses that are too flat. Monitoring corneal topography on a six monthly basis will determine if any progression of the cone is occurring. When fitting corneal GP lenses, if we keep the optic zone of the lenses as large as or slightly larger than the diameter of the cone, there will be a better match in the sagittal depth of the lens with the sagittal height of the cornea. This will result in a thin tear film over the apex of the cone, minimal lens movement and will minimize corneal scarring.

For the still intolerant patient, we can consider the use of piggybacking lenses, meaning having a well fitted GP lens lie over the top of a soft lens to improve comfort by reducing lens movement and cushioning the lens edge with the soft lens. To improve the amount of oxygen passing through this lens system, it would be advisable to use silicone hydrogel materials for piggybacking as clearly the amount of oxygen transmitted would be reduced with a two lens system. Other advantages of the piggyback system with silicone hydrogels in addition to improve comfort are: reshaping the corneal contour slightly and corneal protection when chronic abrasions are present and improved over hydrogels. Centration can only be offered by having plus power in the soft lens, when there is no counter-sink. The plus (+0.50D) power aids in lens centration by tightening the central fit of the GP lens over it, bringing the lens to the centre of the soft lens.

Recently there has been a trend towards moving to mini or semi-scleral contact lenses for patients whose comfort cannot be improved. One must consider the expense of these lenses, difficulties in insertion and removal and lower oxygen transmission not only centrally but at the limbus before moving toward this option. Proper training with this modality may be needed in order to minimize complications and provide comparable vision.

**Conclusion**

GP lenses still have a place in the fitting of high numbers of regular, and any number of irregular corneal astigmatism using the simpler fitting approaches provided. In conclusion, the use of imaging techniques should aid in contact lens design and not just be used for the early diagnosis of corneal conditions.

**References:**

Hybrid contact lenses have become an important part of specialty contact lens practices today. Hybrid technology was created in the 1980s with the novel idea of binding soft and gas permeable (GP) lens materials together to make a GP centre with a surrounding soft skirt. Unfortunately, the decreased oxygen permeability of the HEMA material and poor fitting characteristics of the lens caused many complications and deterred widespread use of the lens.

In 2005, a new generation of hybrid lenses were launched. These lenses included Synergeyes A, PS, KC and Multifocal (MF), followed by ClearKone in 2009 (Synergeyes Inc., Carlsbad, CA). These designs were created to fit normal, oblate and prolate corneas, however fitting challenges existed. These challenges led to the release of a second generation of Synergeyes hybrid lenses including: Duette for normal corneas, and Ultrahealth for irregular corneas. These lenses incorporate a GP centre to provide sharp vision, and a silicone hydrogel skirt to improve comfort, stability and centration over traditional GP lenses. The soft and GP materials are held together with strong covalent bonds called a HyperBond junction.

Synergeyes is the only company currently manufacturing hybrid lenses. The fitting philosophy is not only different from the previous generations of hybrid lenses, but also different from any other specialty contact lens on the market including GP, soft or scleral lenses.

Fitting Regular Corneas
The Duette (Synergeyes Inc.) family of lenses includes Duette, Duette Progressive, and Duette Multifocal. These lenses are empirically fit, so no fitting sets are necessary and chair time can be minimized. Indications for Duette include myopia, hyperopia, and regular corneal astigmatism up to 6.0 D. They may also be used for mild corneal irregular astigmatism, but this is considered an off-label use. Limitations include patients with lenticular cylinder.

Duette Progressive and Duette Multifocal are indicated for presbyopes, especially astigmatic presbyopes. The soft skirt allows better centration to maximize the optics of the GP portion. The Duette Progressive is a dual aspheric lens with a centre near design and 3 add powers. The Duette Multifocal has 2 different centre near progressive zone sizes: small and large.

All Duette lenses are empirically fit approximately 0.5 D steeper than Flat K. Before insertion, 1-2 drops of saline or artificial tears should be added to the lens. The lens is placed onto the eye with a DMV suction cup. The lens should settle for 5-10 minutes before assessing the fit. Fit assessment is similar to that of a soft lens; there should 0.5 to 1 mm of movement and good centration. If the patient finds the lens uncomfortable or if there is difficulty removing the lens, the skirt may need to be flattened. On the other hand, if the lens decenters, the skirt may need to be steepened. No fluorescein is necessary to determine the fitting characteristics of this lens.

Fitting Irregular Corneas
Ultrahealth is designed for irregular corneas including keratoconus and post-surgical corneas. Figure 1 demonstrates a well-fit Ultrahealth lens. Its reverse geometry design allows the lens to vault over central cornea. There are 2 zones where the lens lands on the cornea: Inner Landing Zone (ILZ) and Outer Landing Zone (OLZ). The ILZ is wide area where the GP portion makes gentle contact with the cornea, and the OLZ is where the soft skirt first sits on the cornea. The lenses range from vaults (VLT) of 50 to 550 µm. The amount of vault is altered by changing the base curve of the lenses VLT 50 to 250µm and by changing the reverse or lift curve of the lenses VLT 300 to 550µm.

To fit the Ultrahealth lens, the fitting guide should be followed closely. The first lens inserted should always have a VLT of 250µm with an 8.4 flat skirt. To properly assess the fit, a generous amount sodium fluorescein is added into the bowl of the lens prior to insertion. Once the lens settles for 5-10 minutes, the fluorescein pattern is assessed with a
Wratten filter. The over-refraction can be conducted during the settling period, as long as the lens is not bearing on the cornea. After settling, 100 to 150µm of clearance should ideally be present between the lens and the cornea.1 This can be analyzed with an optic section or with an anterior segment OCT (Figure 2). If the lens is bearing on the cornea, the vault should be increased by 100 to 150µm. If there is pooling, the vault should be decreased by 100µm to prevent seal off.1 This process should be continued until the ideal vault over the cornea is achieved. In addition, the lens with the highest vault that demonstrates apical bearing should be noted. The lens will settle an additional 30-60µm over the course of wear.

Next, the peripheral skirt is adjusted. The skirt should be steepened in cases of edge fluting, when bubbles are flushing in on the blink or when there is heavy bearing at the ILZ.1 The skirt should be flattened when there is clearance under the ILZ after settling or if there is a noticeable impression ring present after lens removal.1 The vast majority of Ultrahealth lenses utilize a flat skirt.2

Ultrahealth FC Oblate Design
The Ultrahealth FC is designed for oblate corneas such as postsurgical corneas and midperipheral steepening conditions like pellucid marginal degeneration.1 It incorporates a variable reverse curve to accommodate the various oblate corneas.1

The main difference in fit assessment between the Ultrahealth and Ultrahealth FC is that on initial fitting 50µm of clearance is necessary between the lens and the cornea.

Patient education
After dispensing the both Duette and Ultrahealth lenses, practitioners need to properly educate their patients about the care involved. Firstly, when the lens is inserted, it should not be pushed on forcefully. This may cause a suction effect and block tear exchange causing poor vision and comfort. Lenses should be gently placed on the eyes. If bubbles are present on insertion, the lens needs to be reinset. Recommended cleaners include hydrogen peroxide or multipurpose solutions approved for silicone hydrogel lenses.

Conclusion
The newest generation of hybrid lenses have an important place in contact lens practice for both normal and irregular corneas. With proper training, it is likely that the adoption of these lenses will continue to grow in both mainstream and specialty contact lens practices worldwide.

References

Figure 1. Ideal fit of an Ultrahealth lens. The fluorescein pattern demonstrates clearance over the central cornea. The Inner landing zone (ILZ) shows light feather touch where the GP material contacts the cornea. The Outer landing zone (OLZ) is a wider area of touch where the soft skirt sits on the cornea. (photo courtesy of Synergeyes Inc.)

Figure 2. Anterior segment OCT of an Ultrahealth lens. The lens vaults well over the central cornea and makes contact at the ILZ and OLZ. This is a very accurate method of measuring lens clearance. (photo courtesy of Synergeyes Inc.)
Ultrahealth Lens Excellent Option for Corneal Thinning Disease

Vishakra Thakrar, OD, FAAO, FSLS

A 65-year old Caucasian male presents for contact lens fitting of the left eye due to keratoconus. He has pellucid marginal degeneration OD and keratoconus OS, strabismic amblyopia OD, and primary open angle glaucoma OU. He had been wearing a Softperm contact lens in the left eye for 13 years and his lens on presentation was 4 years old. Glaucoma medications included Cosopt bid OU, Alphagan tid OU, and Xalatan hs OS. He also had a history of strabismus surgery OD for exotropia and dry eye OU. His medical history was unremarkable.

On examination, entrance visual acuities were OD 20/400 with no correction and OS with the Softperm lens was 20/30. Pinhole acuities showed no improvement OD or OS. He had a 40 pd right constant exotropia. Slit lamp exam showed inferior corneal thinning in the right eye and grade 2 meibomian gland dysfunction. In the left eye, there was grade 2+ inferior corneal neovascularisation, grade 2+ central haze, and peripheral corneal scarring 360 degrees due to the poor oxygen permeability of this lens. Intraocular pressures with Goldmann tonometry were 11 mm Hg OU. With respect to contact lens fitting, he had previously tried soft and gas permeable lenses unsuccessfully.

An 18.2 scleral lens was fit on this patient. This lens gave him 20/30 vision in his left eye and his comfort was excellent. However, several months after fitting, the patient had a trabeculectomy OS. When the patient starting wearing the scleral lens again, the haptic portion of the lens put pressure on the filtration bleb resulting in an increase of pressure from 11 mmHg to 19 mmHg within 30 minutes of wear. The design of this lens could not be modified to accommodate the bleb, so the scleral lens was immediately discontinued.

The patient was then fit into the Synergeyes Ultrahealth lens OS. The soft skirt was able to adequately drape the bleb without affecting the intraocular pressure and fit the cornea adequately. This lens gave 20/30- vision with no residual astigmatism. The parameters of his lens was OS VLT 290/-15.00/7.95/ 14.5. After 1 month of wear, the lens fit well and showed about 50 u of central clearance, with good movement. To control the dry eye and to decrease the toxic effect of his glaucoma medications, he was put on Hylo (Candorvision) drops prn OU, Restasis (0.05% Cyclosporine ophthalmic emulsion, Allergan, Inc.) OU, and Ocunox ointment (Candorvision) hs.

This case demonstrates that the Ultrahealth lens is an excellent option for patients with corneal thinning diseases who also have conjunctival or scleral irregularities.

Figure 1. Axial power corneal topography of patient’s right eye. The topography is consistent with mild pellucid marginal degeneration.

Figure 2. Axial power corneal topography of patient’s left eye. The topography is consistent with keratoconus.
Scleral Lens Troubleshooting Q&A

Langis Michaud, OD, MSC, FAAO, (Dipl) FSLS, FBCLA and Jennifer Liao, OD

About the Authors
Langis Michaud is a full professor and practices at Université de Montréal since 2001, as the chief of the contact lens department. He also treats anterior segment diseases. He had been involved in numerous clinical studies for pharmaceutical and contact lens companies. Jennifer Liao is the Director of Contact Lens Services at the Vision Institute of Canada, and is a contact lens specialist at the Therapeutic Contact Lens Clinic at the Kensington Eye Institute in Toronto, Ontario.

1) What are your tips for avoiding fogging under the lens?

Michaud: Debris in the reservoir is mainly lipidic and mucoid in nature. It stems from friction of the lens on the goblet cells and the conjunctival surface. Its limited movement upon blinking leads to transmembranial mucin disruption and shredding of epithelial cells. Through the effect of diffusion and suction (not to be confused with negative pressure), this debris is attracted to the fluid reservoir under the scleral lens, where it remains trapped. One way to reduce pollution in the reservoir is to limit the clearance over the limbus. It is also possible to adapt the fit by lowering the mechanical impact of the lens on the conjunctiva. This can be achieved by designing a back-toric surface or to ask for toric haptics.

The mini-scleral lens (< 15 mm) can be adapted with limited central clearance, which also translates into a reduced clearance over the limbus. Because of this lower central clearance, these lenses can land more nicely on the conjunctiva and, due to their smaller diameter, rub less on the conjunctiva. It is just like an airplane landing at the airport. Scleral lenses (like a 747), which are bigger, start their descent from 20,000 feet and have to land with an increased angle (nose dive), which impacts considerably on the fragile conjunctival epithelium. Because of their size, they need more plastic to be supported, increasing the mechanical impact on the conjunctiva. The mechanical impact is variable from quadrant to quadrant because of the rotationally non-symmetrical toric profile of the conjunctival tissue. Mini-sclerals (Cesna planes) start their descent from 10,000 feet instead. They do not need that much plastic on the conjunctiva to support them. Consequently, their angle to approach the tarmac is reduced, and they can land nicely on the conjunctiva, minimizing their mechanical impact.

Asking a keratoconus patient to remove his or her scleral lenses once or twice a day to replenish the fluid reservoir can be conceivable if this patient has no other option to restore his or her vision with comfort. Although not convenient, it could be acceptable. It is a different story for current refractive error wearer. This person will most probably never agree to remove and reinset the bigger scleral lenses during work hours. Instead it is preferable to fit her with mini-sclerals, keeping the full benefit of this modality without the burden of having to deal with the debris accumulating in the reservoir.

Liao: Fogging under the lens is often related to uneven scleral haptics on the conjunctiva. My first approach to avoid fogging is to evaluate for uneven scleral landing zones, by slit lamp assessment and with a sodium fluorescein tear exchange test to assess uneven flow patterns under the lens. Toric peripheral curve modifications on scleral lens designs have often helped under-lens fogging issues.

Another common approach I take is changing the filling solution. Before Unisol was discontinued, I commonly had patients change their filling saline to the Addipack 0.9% non-buffered NaCl saline. A simple change to a non-buffered saline often made a significant difference. If fogging continues with the 0.9% NaCl, I encourage the use of a higher viscosity, preservative-free artificial tear in addition to the non-buffered saline - such as Systane Ultra or Refresh Optive.

Finally, I evaluate for the ability to decrease vault of the lens. Several contact lens experts have found correlations between increased vault and mid-day fogging, and have suggested to avoid central lens vaulting greater than 400 microns, if possible.
**Scleral Lens Troubleshooting Q&A**

**CLINICAL PEARL:** Limiting the clearance over the limbus and lowering the mechanical impact on the conjunctiva are key issues to alleviate accumulation of debris in the reservoir. Going smaller (<15mm of lens diameter), changing to toric haptics, and decreasing central clearance are efficient ways to achieve both of these objectives.

**2) How do you combat anterior surface wetting issues?**

**Michaud:** Patients reporting high level of deposits on the lens should be assessed to identify ocular surface disorders (moderate to severe eye dryness, with mucoid deposits) or lid margin diseases (blepharitis). This explains 90% of the deposits. Consequently, to reduce the level of deposition, you have to treat the ocular surface/lid disease first. Maintenance therapy with regular lid hygiene is a must.

As a second step, I look at lipid sources: hand cream, perfumed soaps, mascara, etc. I try to eliminate most of these contaminants. With the same rationale, I question any topical product the patient may use: artificial tears, over-the-counter products, topical medication, etc. Obviously lipid-based products and gels should be banned or applied before or after lens wear. Any contact with the lenses should be avoided.

Once done, the selection of the material is crucial. It has to feature a reduced wetting angle. In that regard Tyro 97 (Menicon) or Optimum materials (Contamac) offers angles lower than 10 degrees and should be preferred. In comparison, Boston material features wetting angles of 30 degrees or more. Deposits occur at a faster rate on such material.

Fourth, care regimen can help to reduce the level of deposits. An alcohol-based cleaner can help (available through internet), or switching patient to hydrogen peroxide may be useful. In-office cleaning with Boston professional cleaner or Progent (Menicon) allows to deeply clean the lenses periodically.

Finally, frequent application of non-preserved and non-lipid based artificial tears help to dilute deposits.

Education is also another piece of that puzzle. In very severe eye dryness, patients already develop a lot of mucus threads without contact lenses. When we consider fitting them in sclerals, it is quite obvious that these filaments will adhere to the lens surface. It takes 2-3 months to regulate the ocular surface and to reduce significantly the mucus production. Patience is the key word here. In very rare cases, I ask the patient to wet a Q-tips and to use it as a “squeegee” to clean the surface of the lens. I try to avoid removing the lenses during the day because it increases surface irritation and generates more mucus secretion.

**CLINICAL PEARL:** In presence of debris, it is important to assess and to treat aggressively ocular surface and/or lid disorders as a first step, before modifying the material, the lens design or the care regimen.

**Liao:** Anterior surface wetting is closely related to a patient’s ocular surface health, so maintaining ocular surface health while wearing scleral lenses is important to avoid wetting issues. I stress for patients with ocular surface disease and severe meibomian gland dysfunction to continue with their dry eye regiments - continue with non-preserved artificial tears, hot compresses, and taking omega-3 supplements if able.

To help create a smooth lens surface before wear, I have my patients rub their lenses with Boston Conditioning solution prior to insertion. If the anterior surface continues to have wetting issues throughout the day, rubbing the front surface with a Q-Tip soaked with Opti-Free Pure Moist I find “washes” the surface and re-coats the lens with a sustained smooth surface.

**3) What is the minimum corneal endothelial cell count you are comfortable fitting a scleral lens on to avoid corneal decompensation? How often do you measure this?**

**Michaud:** Natural endothelial cell loss is estimated at a rate of 0.5% per year. Grafted patients lose 50% of their endothelial cells in the 3 years following surgery. The cells that remain are fragile and can be considered survivors.

It is important to state that it is now a proven fact that scleral lenses, even manufactured with the highest DK, are triggering central corneal edema, to the level of 2 to 4%, of fitted with clearance over 200µm and if they are more than 250µm thick. This is the case of the majority of larger scleral lenses.

Based on that potential oxygen deprivation, there is a general agreement that under 800 to 1000 cells/mm² it becomes difficult to maintain graft/corneal transparency. Moreover, loss of endothelial cells combined with deprived oxygen delivery may increase the chances of developing neovascularization and may potentially lead to graft rejection.

To keep myself on the safe side, I use a 1500 cells/mm² as my limit to consider scleral lenses. I evaluate it by specular microscopy once a year at least on at risk patients. I do not do a cell count on regular patient at baseline. Over 1500 cells/mm² I feel comfortable to fit sclerals but, even at this level, I try to rely on thinner lenses and to fit them with limited clearance (<200 um after stabilization) to optimize oxygen delivery.
Michaud and Liao

Liao: I evaluate endothelial integrity by slit lamp evaluation and take into account history of surgery - graft, cataract, refractive surgery - prior to and throughout all scleral lens fittings. Unfortunately, due to my lack of ease accessing a specular microscopy, I currently do not routinely measure endothelial cell count. However, literature and expert lecturers have suggested that endothelial cell counts under 800 cells/mm² commonly lead to corneal edema with scleral lens wear, therefore all post-transplant and trauma cases should be followed carefully to monitor for corneal decompensation.¹⁰

CLINICAL PEARL: Scleral lenses should not be considered as the best option to be selected for patients where endothelial cells count is less than 1000 cells/mm².²

4) Unfortunately, Canada does not have access to many of the GP Solutions our neighbours to the South do. What is your favorite solution recommendation for your scleral lens patients?

Michaud: For the majority of my patient I recommend the latest hydrogen peroxide solution, Peroxiclear. Its basket is larger compared to the older generation of products. In addition, this solution contains moisturizers which help to condition the lenses during overnight soaking. It is non-preserved, which is also a benefit.¹¹

If peroxide is not considered a safe or a practical alternative for a given patient, then I recommend 2-steps Boston Advance cleaning system. I try to avoid all-in-one gas permeable cleaning solution because it is not as powerful as a dedicated cleaner.

Liao: I recommend Clear Care to my patients most for daily cleaning. To improve wettability of lens, I often suggest rubbing with Boston Conditioning solution or OptiFree PureMoist prior to insertion. It is great that Progent is now available for more intense cleaning of highly deposited lenses when needed.

CLINICAL PEARL: Hydrogen peroxide represents a safe alternative to clean and store scleral lenses. Non-preserved, it helps to minimize toxic or allergic reactions especially in sensitive patients.

5) What is the ideal scleral lens vault you shoot for?

Michaud: This depends on the type and the size of the lenses fitted on an eye. Smaller lenses (15 mm or less) need less fluid layer to support them while larger lenses necessitate to be fitted with higher clearance.

For 15mm or less, I look for 225-250 µm at insertion, and to get 200 µm after stabilization (30 minutes). Smaller lenses are losing 100 µm in average during the day, so I keep 100 µm as the minimal level of clearance expected after a full day of wear. For larger lenses (16 mm and over), starting point is 325-350 µm. The clearance will drop by 75-80 µm during the day. So I end up with 250-275 µm after a full day of wear.

At this level, it is very possible to trigger corneal hypoxia with unknown long term consequences.

Corneal hypoxia

Scleral lenses and the fluid layer under their surface act as a reservoir. Theoretically, the ideal combination of lens and fluid layer thicknesses have been demonstrated to be 250 µm and 200 µm respectively, in compliance with the Harvitt-Bonnano criteria for alleviating corneal hypoxia.⁸ This model was challenged because clinically, practitioners did not see obvious signs that chronic corneal hypoxia had occurred. There were almost no reports of corneal hazing or the presence of microcysts or neovascularization. It was also argued that scleral lenses had been successfully used for many years to treat ocular surface disease, which would not be possible if hypoxia was involved.

However, clinical studies have since been published confirming that scleral lens wear is associated with induced corneal swelling varying from 2 to 4% in normal corneas,¹²,¹³,¹⁴ in keratoconus,¹⁵ and especially in cases where the endothelial cell layer is compromised.¹⁶,¹⁷ An interesting in vivo study also confirmed a reduction in oxygen diffusion to the cornea if the tear fluid layer thickness increased.¹⁸ In fact, in that study, large scleral lenses fitted with a 400 µm fluid layer thickness delivered 30% less oxygen to the cornea than a similar lens fitted with a 200 µm fluid layer thickness.

Other studies have increased knowledge about scleral lens behavior. We know that tear exchange is limited once the lens is settled, at 0.2% per minute.¹⁹ This means that it would take more than 8 hours to replenish the entire bowl under a scleral lens. Tear mixing is another factor that must be taken into account, as preliminary data from a study conducted in Berkeley, California, proved that tear mixing is limited in lenses.
fitted with less or more than optimal clearance (established at 200 µm under the lens). Tear exchange is also delayed when clearance is excessive. Consequently, fresh tears and tear mixing may only marginally to the required oxygen supply to the cornea once scleral lenses are settled.

**Clinical implications**

As stated, however, many clinical studies based on pachymetry have proven that hypoxia occurs. More convincingly, equivalent oxygen percentage (EOP) is highly reduced when clearance under scleral lenses is higher. Some authors consider 3% edema as not clinically significant, comparable to physiological edema seen upon awakening. They also consider this level to be similar to those encountered in the 1980s when patients were fitted with low oxygen-permeable (low-Dk) hydrogel contact lenses.

These comparisons are misleading. In fact, physiological edema never lasts for more than an hour; the cornea is therefore never exposed to chronic hypoxic stress during the waking hours. As for the hydrogel lenses, at that time, no other soft lens option was available. Consequently, the industry was pushed to develop higher Dk material, which became reality when silicon-hydrogel lenses were introduced in the 1990s.

**CLINICAL PEARL:** Since the long-term clinical impact of chronic hypoxic stress is unknown and because options exist for fitting scleral lenses without inducing hypoxia, practitioners should favor smaller, thinner scleral lenses with reduced clearance.

**Liao:** Depending on the type of scleral lens and corneal condition, I usually aim for a vault between 150-300µm. In some severe ectasias or corneal irregularities, it is difficult to clear the most elevated portion of the cornea without causing higher-than-desired clearance in other areas.

Practitioners and lens manufacturers recommend different amounts of scleral vault, however, I attempt to keep vaults lower if possible. A lower lens vault often provides better lens centration, decreases chances of mid-day fogging, and is thought to maximize oxygen to the cornea. As Dr. Michaud mentioned, decreased oxygen permeability with greater scleral lens tear reservoirs increases the risk of corneal hypoxia. Although there is little evidence that clinically significant corneal edema is provoked with modern high Dk materials of scleral lenses, I attempt to maximize Dk by ordering 100+ Dk materials and fitting with lower vaults when possible.

**Michaud:** I am now 90% sclerals and 10% small gas permeable lenses to fit on irregular corneas. Sclerals are my go-to-lenses for a vast majority of my patients. Simply stated, small regular gas permeable lenses hurt. Ask any patient wearing GP lenses, with no complaints, to switch over scleral lenses, and you will see the difference. Imagine for a new wearer!

However, I save smaller lenses for cases when sclerals cannot be considered: compromised endothelial cell counts, presence of blebs, pinguicula or pterygion that make scleral lenses fits challenging. Very steep, advanced keratoconus can also be better served with a piggy back system compared to a scleral not vaulting enough over this elevated apex.

**CLINICAL PEARL:** Scleral contact lenses can now be considered as the standard of care for fitting patients with irregular corneas.

**Liao:** Switching from a corneal to scleral GP design is a decision I make after evaluating topographies and the existing corneal GP (cGP) lens on the eye. Corneal topographies provide information about the corneal condition and allows for monitoring of corneal changes over time, however, knowing whether cGP lenses are still successful in treating the condition requires, in my opinion, evaluation of the existing cGP lens. Based on topographies, some common factors that make me consider switching from corneal to scleral designs include:

1. **Topographical shape** – is the irregularity central or peripheral, and how extensive is it? Corneal GPs tend to be less stable and fit poorer on corneas with non-central irregularities.

2. **Magnitude of irregularity and keratometry values** – Keratometry values > 52.00D with high disparity between superior and inferior cornea require much steeper corneal GP designs. This leads to decreased optical zone sizes in the lens, therefore impacting visual potential, and often more customization of peripheral curves is needed. I find scleral lenses become more successful in cases of highly irregular and ectatic corneas.

3. **Amount of Astigmatism, internal versus corneal** – Corneal astigmatism greater than 2.50D often requires a back surface toric or bitoric design with corneal GP lens. With high
corneal astigmatism, I tend to start with a scleral design – I find a thicker lacrimal lens and increased lens thickness to control for flexure allows for more success in negating corneal astigmatism.

Other common reasons for why I switch from corneal to scleral GP designs for patients are: poor comfort, poor lens stability, compromise of corneal integrity, dry eye symptoms, and inability to achieve acceptable fit or vision with a corneal GP design.

Although scleral lenses can improve the factors listed previously, I often consider some negative aspects to making this change in lens design. First, scleral designs cost more than corneal GP designs. Secondly, scleral lenses are more cumbersome to insert and remove, require more solution (filling saline) and require learning of new insertion and removal techniques for existing lens wearers. Third, switching to scleral lenses requires a new fitting, which requires time, more visits to the office, and often, extra fitting fees for the patient.

7) What is your typical follow-up schedule for completed scleral lens fits?

Michaud: I like to see the patient as soon as 1 week after delivery of the lenses because I really want to evaluate the compliance and possible issues with handling, presence of insertion bubbles, etc. We know that patients cannot absorb all of the information we provide them at delivery so I just want to make sure they are on the right track for a successful wear. Then after, I see them at 3 months and every 6 months.

When using sclerals as part of ocular surface disorder treatment, follow-ups schedule can be tighter based on the medication and other elements in play.

Liao: I usually follow patients 1 to 3 weeks after dispensing, depending on the fit and condition. Once I am satisfied with the fit for longer term wear, I will follow in 3 months and then 6 months.

CLINICAL PEARL: Scleral lenses should be followed-up as for any other lens types, except if they are used in conjunction with medication or to manage an ocular surface disorder when closer monitoring is needed.

8) Conjunctival Prolapse has been shown to be a common, temporary finding, that is relieved after lens is removed. What are your tricks for avoiding conjunctival prolapse? What causes this phenomenon?

Michaud: Prolapse is a conjunctival fold draping over the cornea. It happens on patient with loose conjunctival tissue, and most likely when inferior quadrant conjunctival elevation is lower than the cornea.21 We also have to remember that once settled, there is no tear exchange. Instead, the fluid dynamics creates a suction force toward the fluid reservoir. Debris accumulates in the reservoir as a consequence of this fluid dynamics. Conjunctival tissue follows IF there is enough clearance over the limbus to allow it.

Conjunctival prolapse is considered benign but no one really knows what the long-term effect of such clinical occurrence is. Nobody evaluated the clinical effect of covering the limbal area, where the stem cells are located, with conjunctival tissue, on a chronic basis.

As is for hypoxia, I try to alleviate conjunctival prolapse whenever possible. This begins by tracking the potential candidates by conducting conjunctival or ocular surface topography. Second, this occurrence is met when you have a larger scleral lens, rubbing heavily on the conjunctiva. Prolapse NEVER occurs when fitting lenses 15 mm or less in diameter because their limbal clearance is lower.

If I have to rely on a larger diameter scleral lens, my only option would be to design quadrant specific peripheral curves in order to try matching the conjunctival profile and to keep the limbal clearance as minimal.

Liao: A literature review by Walker et al.4 describes the phenomenon of conjunctival prolapse occurring due to the negative pressure forces beneath a lens, causing the loose perilimbal conjunctival tissue to be pulled under the scleral lens.

Decreasing lens diameter to minimize contact with the area of conjunctival chalasis has been my first approach to minimizing conjunctival prolapsed (hooding). I also try decreasing limbal clearance or clearance adjacent to the lens periphery, usually by adjusting the mid-peripheral or 4th scleral curve, to allow for a more uniform landing zone on the conjunctiva.

Walker et al, suggests, “decreasing clearance, specifically in the limbal zone, to create a more uniform shaped tear film reservoir.”
CLINICAL PEARL: Options exist to alleviate conjunctival prolapse. This is another good reason to keep the diameter of sclerals at 15 mm or less.

9) How do you utilize anterior segment OCT to assist in your scleral lens designs?

Michaud: Anterior segment OCT is a “nice-to-have” equipment to assist us in the fitting of scleral lenses. In fact, a good slit-lamp evaluation can lead to the same positive outcome for the patient. OCT only confirms what you saw under the microscope.

However, where OCT is most valuable at follow-up. At that moment, the clearance under the lens may be difficult to evaluate and OCT is of a great help to assess the lens position and how deep it sank in the conjunctiva. Troubleshooting becomes easy when you can rely on such precise information.

There are numerous and essential data we can get from OCT assessment after 6-8 hours of scleral lens wear. It is hard to duplicate what OCT brings at follow-up.

Instilling fluorescein over the lens is not always helpful, tear exchange being limited in most cases. It would take a lot of time to wait for complete fluorescein mixing in the reservoir.

Newest imagery systems help us to map the ocular surface up to 21 mm of diameter. There are 2 eye profilers in the market, one able to generate a 3D mapping of the cornea, the conjunctiva and most importantly, of the junction between them. When considering fitting scleral lenses over 15 mm diameter, we know that we will deal with conjunctival toricity, which varies from quadrant to quadrant and from patient to patient. Conjunctival mapping eases the fitting process and reduces significantly the chair time involved.

Liao: I find anterior segment OCT very helpful for scleral lens treatments for a few reasons:

First, it allows for a precise and quantitative measure of lens clearance in all areas of the cornea. It allows assessment of clearance where visualization by slit-lamp would be difficult. Especially in cases of ectasia, grafts, or scarring where irregular corneal shapes can have sharp elevations, an OCT can help determine how much and which curve of the scleral lens needs to be adjusted.

Secondly, like other photographic devices, it allows for monitoring of lens fit over time. Taking anterior segment OCT images at follow-ups allows for evaluation lens or ocular changes with time.

CLINICAL PEARL: Fitting and following up scleral lens wear without OCT and topography is equivalent to assess and manage a glaucoma patient with a direct ophthalmoscope only. It is feasible, but technology provides valuable data that eases the fitting and troubleshooting processes.

10) What techniques do you employ to help you deal with pingueculae, pterygium, or other scleral irregularities during a scleral lens fit?

Michaud: This all depends on the size, location and features of these elements. As for the pingueculae, you have the option of limiting the scleral lens diameter to do not interfere with it, or to increase the diameter to try to vault over it. The latter can be more difficult to achieve as it could be difficult to go small enough to clear the pinguecula. If a pinguecula is clinically significant, and raised over the conjunctiva, I habitually prefer to consider a hybrid lens instead of a scleral.

This is even more true for the pterygium. If scleral lenses are necessary, there are a few options available. Alden optical offers the option of micro-vaulting the ocular surface, and EyePrint Pro is manufacturing a lens based on the mold of the eye. Both can manage the presence of significant pterygium. Otherwise, this is one of the rare cases where I consider fitting a small gas permeable lens as my first option.

As the scleral is highly irregular in nature beyond 15 mm diameter, it has become a standard of practice to prescribe toric haptics or to design a back-toric lens periphery to try matching the conjunctival profile. To rely on spherical haptics leads to misalignment in at least one quadrant. Larger lenses tend to decenter, generating reduced visual acuity, increased high order aberrations, etc. and they can be uncomfortable. Scleral lenses with limited diameter (<15 mm) are not associated with decentration and do not need to be designed with toric peripheries. They are associated with less issues to troubleshoot.

Liao: I often attempt to have the scleral lens land inside or outside of the pinguecula or pterygium, by adjusting lens diameter. When this is not possible, I utilize toric peripheries to avoid compression or rebound injection of these areas of the conjunctiva. Specifically with pingueculae, I have found success with my recent experience using the Zenlens (by Alden Optical) microvault. Taken from Alden’s Zenlens brochure, “The MicroVault” creates a precisely designed flute or ripple in the edge of the Zenlens to vault it up and over the peripheral obstruction.”
Michaud and Liao

CLINICAL PEARL: Options exist in scleral lenses to manage conjunctival irregularity. However, pinguecula and pterygium can justify the fitting of hybrid or regular small gas permeable lenses as lenses of choice.

References

Figure 1a. Conjunctival prolapse due to excessive limbal clearance under a scleral lens.

Figure 1b. Sodium fluorescein staining of conjunctival prolapse immediately after scleral lens removal.

Both photos courtesy of Maria Walker O.D., University of Houston College of Optometry
The scleral lens industry has come a long way since the first glass scleral contact lenses were developed in the late 1800’s. In fact, there has been an explosion of research and development in this area over the last 10 years as practitioners have found scleral lenses provide superior centration, stability, and comfort compared to smaller lens designs.

**Current Scleral Lens Prescribing Patterns**

Scleral lens use for both pathological and normal corneas has exploded over the last five years. In 2015, 20% of all gas permeable (GP) contact lens prescriptions are now attributable to scleral lenses.¹ A total of 37% of practitioners who responded to the recent international contact lens prescribing survey believe that sclerals have the greatest potential for growth out of all of the specialty lens designs in the next 12 months.¹ With more options available for normal corneas, irregular astigmatism, and ocular surface disease, scleral lens use is bound to increase to prevent GP lens dropout due to comfort issues seen with corneal GP designs.

Results of the Scleral Lenses in Current Ophthalmic Practice Evaluation (SCOPE)²³ survey were recently released. The authors sought to determine the current practice patterns of practitioners who fit and customize scleral lenses. From January to March 2015, 989 respondents were surveyed (723 with more than five scleral lens fits were considered established scleral lens fitters in this survey) from over 40 countries, totalling approximately 84,000 scleral lens fits. The study answered the following questions:

**What are the indications for a scleral lens? (Figure1)**

In the SCOPE survey, 74% of new fits were due to irregular astigmatism. 16% were indicated for ocular surface disease, and 10% for refractive error (normal corneas).

**What size of scleral lenses are most common?**

The majority (65%) of scleral lenses prescribed range from 15-17mm in diameter. Only 16.8% of lenses prescribed were larger than 17mm, and 17.9% of lenses prescribed were smaller than 15mm.

**Are Scleral Lenses Safe? (Figure 2)**

Of over 84,000 scleral lens fits, only 70 cases of microbial keratitis were reported in the study. The most common complication was handling errors, followed by corneal edema and neovascularization. Additional complications reported were conjunctival changes, limbal stem cell deficiency, corneal epithelial irregularities without frank defects, fluid reservoir debris, and lens surface deposits.

**Which insertion solution should be recommended?**

The SCOPE study revealed that practitioners are most often prescribing single use vials for insertion solution. Unisol (Alcon) was a close second, though it has recently been discontinued, so more practitioners may be switching to single use vials. About one-third of practitioners also recommend preservative free artificial tears. It was disappointing to see that a small amount of practitioners still recommend Sensitive Eye Saline (Bausch and Lomb) or other multipurpose solutions, which may lead to toxic keratopathy due to the preservatives in the solution.

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**About the Author**

Andrea Lasby practices at Mission Eye Care in Calgary and focuses on specialty contact lens fits and ocular surface disease management. She volunteers for numerous committees on the Alberta Association of Optometrists and Canadian Association of Optometrists while continuing her duties as current President of the Calgary Society of Optometrists.
Which Cleaning/Disinfecting/Storage Solution should be recommended?
In regards to solutions used for cleaning and disinfection, almost all practitioners recommended hydrogen peroxide, daily cleaner or GP conditioning solution. Just over one-third of practitioners recommend Progent (Menicon). Still, almost 30% of practitioners said they recommend tap water some, most, or all of the time. Given the risk of pseudomonal infection from water exposure, more education is required to inform all practitioners and patients to avoid tap water for all contact lenses.

How long are patients wearing their lenses?
The SCOPE study also investigated how long patients are wearing their lenses for each day. The average daily wear reported was 11.8 hours, with a minimum of 2 and maximum of 19 hours. Almost a quarter of practitioners recommended periodic removal of their scleral lenses during the day most or all of the time.

Advances in Imaging
Optical Coherence Tomography (OCT) was first proposed for fitting scleral lenses in 2008. Since then, anterior segment OCT has transformed the way the practitioner can evaluate scleral lenses. Not only can OCT determine central clearance, but also limbal clearance and scleral alignment of the landing zone. For extreme corneal irregularities like tilted grafts or Salzmann’s nodules, this technology is extremely valuable to ensure there is no lens touch after a full day of wear and settling. Only 48% of practitioners are using anterior segment OCT to help aid in the fitting process, so this is an instrument that can certainly give value to practitioners aiming to grow their specialty lens practice.

Advances in anterior segment OCT imaging also allows for monitoring of pachymetric indices, allowing the practitioner to monitor progression of keratoconus over time. Fourier-domain OCT is useful for corneal epithelial imaging, measuring the thickness from the corneal surface to Bowman’s membrane. Epithelial thickness has been shown to become abnormal without overall corneal thickness becoming abnormal and the epithelial pattern standard deviation (PSD) has excellent diagnostic accuracy for sub-clinical forme-fruste keratoconus. These key features will allow for earlier detection of keratoconus.

CLINICAL PEARL: Not only will anterior segment OCT help to more accurately fit scleral contact lenses, but new advances will help to diagnose and monitor progression of keratoconus.

Advances in Preventing Anterior Surface Non-Wetting
One of the most common complications with scleral lens wear is anterior surface non-wetting. Besides recommending warm compresses and omega-3s, there are also two lens characteristics to consider. Plasma treatment has helped to treat all GP polymers to remove any remaining residues (i.e. oils, solvents, waxes) from the manufacturing process. Treating the GP lenses with plasma utilizes electrical energy to change the electrical structure of the lens surface which significantly reduces the wetting angle and enhances initial surface wettability.

However, the newest innovation currently under development to address anterior surface non-wetting is Contamac’s Hydra-PEG (polyethylene glycol) coating (Figure 3). By maintaining a fluid film on the anterior surface of the lens, Hydra-PEG reduces the coefficient of friction between the eyelid and the surface of the lens. Hydra-PEG is on schedule

Figure 1. The most common indications for scleral lens wear.

Figure 2. The most common complications with scleral lens wear.
Figure 3. An illustration of Hydra-PEG’s polymer coating attracting water to the surface of the contact lens.

Figure 4. Initial data from Contamac’s research on the increase in comfort of an optimum extra lens with Hydra-PEG coating.
to be FDA approved in the third quarter of 2016, and has been shown to improve wettability, lubricity, scleral fogging, surface water retention, and lengthen anterior lens tear breakup time. It is also resistant to protein and lipid deposition (Figure 4). Hydra-PEG coating will be available not only for sclerals, but also hybrids, corneal GP and soft contact lenses.

The Holy Grail of Scleral Lens Design
The possibility of empirically fitting a scleral lens has been a dream of many practitioners for years. Recent developments in scleral profilometry are providing new insight to help expand our knowledge regarding the average shape of the sclera. Beyond a 15mm chord, the average sclera of normal eye has a high degree of asymmetry, which means that lenses larger than 14.5mm in diameter often benefit from toric peripheral curves. This asymmetry has been shown to be independent of the amount or axis of corneal toricity. There are currently two scleral topographers on the market which measure sagittal height of the sclera, rather than curvature. The Eye Surface Profiler (Eaglet Eye) measures up to a 20.0mm chord, and the sMap3D (Precision Ocular Metrology) measures up to a 22.0mm chord. These topographers allow the practitioner to customize the vault of the lens and the shape of the periphery of the prior to ordering. However, a diagnostic lens is still required for confirming the power of the lens.

New Lens Design Advances
No two scleras are exactly the same, which is why recent advances in scleral lens design now allow practitioners to fit lenses on patients for whom fittings have been unsuccessful in the past. Sectorial lens modifications such as notching or microvaulting allow for release of lens weight over irregular scleral elevations such as pinguecula, pteryiga, symblepharons, blebs, and more. For extreme cases of scleral lens irregularity, ocular moulding (Eye Print Pro) allows for an impression to be taken of the eye, and then a computer-aided laser design of the impression creates a lens with an exact fit of the eye to be produced.

Where do we go from here?
Even with all of the upcoming advances in the scleral lens industry, practitioners still need to keep a toolbox of lens designs on hand to meet the individual challenges for every unique patient. There will always be a need for corneal GP, piggyback, intralimbal, hybrid and specialty soft contact lenses. Nevertheless, the scleral lens market will continue to flourish as options for increased lens stability, comfort, visual acuity and therapeutic treatments are available.

References:
Case Report

Scleral Lens: Case Study One
Andrea Lasby, OD, FAAO

This case utilizes a microvault edge design (Alden Optical) to demonstrate one way of avoiding impingement on a conjunctival pinguecula. Adjusting diameter, toric peripheries, and notching the lens are other options to ensure a healthy scleral lens fit over conjunctival irregularities.

A 42-year-old male presented for a contact lens fitting of the left eye due to higher order aberrations caused by a corneal ulcer 6 months prior. He also had a history of radial keratotomy (RK) in 1996 in both eyes. He was fit originally into a SynergEyes Ultrahealth Flat Curve lens, but was not satisfied with the best corrected visual acuity of 6/7.5+1 in the lens.

Best corrected visual acuity in spectacles was 6/6 OD and 6/9 OS. Automated keratometry provided K values of 38.25@134/39.25 OD and 39.00@095/39.75 OS. Upon slit lamp examination there were 8 linear RK scars OD and OS. The corneas were otherwise clear. There was also a small pinguecula on the bulbar conjunctiva OS approximately 2mm nasal from the limbus.

Due to the presence of the nasal pinguecula, the patient was fit into Alden’s Zen oblate scleral lens, as it has the capability of microvaulting over any irregular, raised area on the sclera. The final diagnostic lens chosen was a 16.0mm diameter lens with a base curve of 10.00 and 4.100 sag. With an over-refraction of +6.00DS, the patient was able to see 6/6-1 The lens fit with 180µm of vault after thirty minutes of settling, and there was nasal and temporal impingement at the edges of the lens (Figure 1). Limbal clearance was acceptable at 75µm.

The first lens ordered based on the fit of the diagnostic lens was:
Zen Oblate
BC 10.00 Diameter 16.0 +4.50DS 4.200sag
Standard Limbal Clearance Zone
Advanced peripheral edge system (APS):
flat 4 horizontal/standard vertical
Microvault parameters: location:
180 degrees, 1mm size, 200µm depth

Upon delivery and follow-up, there was 162µm of vault after 6 hours of wear. Over-refraction was +0.50-0.75x150 with five degrees of counter-clockwise rotation from the horizontal meridian. Although the toric periphery system relieved the majority of the temporal impingement, there was still nasal impingement over the pinguecula, causing redness at the end.

Figure 1. Optovue anterior segment OCT of edge impingement on the nasal pinguecula using the final diagnostic Zen lens choice with a standard advanced peripheral system (APS) edge design.
of the day (Figure 2). Not only was the depth of the microvault inadequate, but the width of the microvault did not cover the majority of the pinguecula. The advantage of the microvault is the lens was completely stable, so a front toric design could be utilized in the next lens to provide even better visual acuity. The second lens ordered was:

**Zen Oblate**
BC 10.00 Diameter 16.0 +5.00-0.75x150 4.200sag
Standard Limbal Clearance Zone
Advanced peripheral edge system (APS): flat 5 horizontal/
standard vertical
Microvault parameters: location: 180 degrees, 2mm size,
500µm depth

The new lens provided best corrected visual acuity of 6/6 OS, with 0.00DS spherocylindrical over-refraction. Central clearance was 171µm after seven hours of wear. There was no edge impingement or redness at the end of the day (Figure 3). The patient was instructed to use Boston Advanced for disinfecting and storing the lens, and to fill the lens with addipak 0.9% sodium chloride inhalation solution. At the 6 month follow-up, he was still able to wear the lens for 12 hours per day with no complications.
This case utilizes a toric periphery edge design with changes to overall lens diameter to avoid conjunctival vessel blanching and impingement. As with this case, the majority of scleras have been found to have with-the-rule toricity.

A 68-year-old male presented for a contact lens fitting of the right eye due to keratoconus. Originally from Europe, he had previous experience with 20.0mm diameter sclerals in the past, but was currently wearing a 15.8 mm MSD (Blanchard) on the right eye, and was satisfied with the comfort and vision of a corneal gas permeable lens on the left eye. He was referred by a local Ophthalmologist who was deferring a full-thickness corneal transplant OD until his cataract progressed to the point where he could do both procedures at the same time.

Best corrected visual acuity in his current lenses was 6/15 OD and 6/6 OS. Topographies showed severe corneal steepening OD (Figure 1). Upon slit lamp examination, there was marked inferior corneal steepening OD>OS, with corneal scarring and Vogt’s striae present over the apex of the cone OD.

Current fit of the MSD showed approximately 300µm central clearance, 75µm of limbal clearance and impingement and congestion of the nasal conjunctival vessels, causing staining after sodium fluorescein instillation (Figure 2). The current lens was already a flat 2 in the periphery, and unfortunately, the lens could not be made flatter in this design.

The patient was refit into a Custom Stable Elite Toric Scleral Lens (Valley Contax). The advantages of this set is that the lenses already come with toric peripheries, so the practitioner can more accurately make changes to the edge design as necessary. The final diagnostic lens was a 15.8mm diameter lens with a BC of 7.85mm and a sag of 4.570. With an over-refraction of -3.75DS over the initial -2.00DS power, the patient was able to see 6/15+2. Limbal clearance was 50µm, the scleral landing zone of flat 5 horizontal by steep 2 vertical showed slight impingement 360 degrees. The lens was rotated 25 degrees clockwise of the horizontal meridian, and was stable in that position.

The first lens ordered based on the fit of the diagnostic lens was:
Custom Stable Elite Toric
BC 7.85mm Diameter 15.8 -5.75DS 4.570sag
Standard Limbal Clearance Zone (LCZ)
Flat 7 horizontal/Standard Vertical Scleral Landing Zone (SLZ)
(Figure 3)

With age, the conjunctiva becomes looser and conjunctival chalasis becomes more common. As the lens settled on the

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Figure 1. Medmont topographies of the a) right and b) left eye. Central scarring over the apex of the cone causes irregularity of the topography of the right eye.

Figure 2. a) Nasal impingement caused by a steep lens edge of the original MSD lens. b) Sodium fluorescein staining left behind on the nasal conjunctiva after removal of the MSD.
eye over 6 hours, redundant conjunctiva was seen anterior to the lens edge, causing redness and dryness even though no blanching of the vessels was noted. The lens settled to only 76µm of central clearance after eight hours of wear. However, vision improved to 6/12 with zero over-refraction. To avoid further complications due to lens settling causing conjunctival chalasis, a smaller lens was ordered. Parameters were adjusted to increase the central clearance, but keep the power the same relative to the current lens. The landing zone was made spherical as the sclera typically becomes more symmetric closer to the limbus. The second lens parameters ordered were:

Custom Stable  
BC 7.03mm Diameter 14.8 -10.75DS 4.290sag  
Standard LCZ, Flat 4 SLZ

After delivery and six hours of wear, there was 214µm of vault. Best corrected visual acuity was 6/12 with zero over-refraction. There was no longer any end of day redness with lens wear, and the patient was comfortable wearing the lens for up to thirteen hours per day. At the 6 month follow-up, all findings were stable, and there was no impingement or blanching of the nasal conjunctival vessels (Figure 4).

This case demonstrates that use of toric peripheries helps to relieve conjunctival vessel impingement. However, in more elderly patients with looser, redundant conjunctiva, decreasing the diameter of the lens will limit edge interactions with the conjunctiva over a more spherical landing area closer to the limbus. Figure 5 shows the marked difference between the original 15.8mm spherical edge and the finalized 14.8mm spherical edge as it lands on the patient’s nasal conjunctiva.

Figure 3. Optovue anterior segment OCT of the temporal edge of the 15.8mm Custom Stable Elite Toric lens causing conjunctival chalasis over the anterior surface of the lens in primary gaze OD. When looking to the patient’s left, there was no conjunctival chalasis noted as the redundant conjunctiva was stretched.

Figure 4. Finalized fit of the Custom Stable Elite Toric 14.8mm diameter scleral lens. The patient was able to wear the lens up to 13 hours per day with no redness or irritation.

Figure 5. Optovue anterior segment OCT images comparing the scleral lens edge landing over the nasal conjunctiva of the a) original MSD edge causing impingement, and b) the finalized Custom Stable Elite Toric lens with a toric scleral landing zone with no impingement or blanching.
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