CONTINUING EDUCATION

SPECIALTY SCLERAL LENS DESIGNS AND APPLICATIONS

DANIEL G. FULLER, OD

First in a series of four scleral CE activities for 2022

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CONTENT SOURCE

This continuing education (CE) activity captures key statistics and insights from contributing faculty.

ACTIVITY DESCRIPTION

The goal of this article is to expand clinicians' understanding and knowledge of basic scleral lens fitting considerations, including applications and patient selection. Practitioners will learn about new technologies on the horizon, what constitutes an ideal scleral lens fitting relationship, and proper scleral lens care and handling.

TARGET AUDIENCE

This educational activity is intended for optometrists, contact lens specialists, and other eyecare professionals.

ACCREDITATION DESIGNATION STATEMENT

This course is COPE approved for 2 hours of CE credit.
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DISCLOSURES

Daniel G. Fuller, OD, reports no conflicts of interest.

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RELEASE DATE: FEBRUARY 1, 2022
EXPIRATION DATE: DECEMBER 1, 2024

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Practitioners who regularly read this and other contact lens-related journals are likely aware of the growing interest in scleral contact lenses over the last decade. This resurgence in scleral lenses has been driven by improvements in material oxygen permeability and in manufacturing equipment. Scleral lens fits were estimated to be second only to corneal GP fits as part of the total number of contact lens fits/refits in GP designs in 2020 (Nichols and Fisher, 2021). The growth in market share of scleral lenses reflects practitioner acceptance of the role of these lenses in clinical practice and the enhanced training in scleral lenses that interns receive from academic programs.

The number of publications related to scleral contact lenses has exploded (Figure 1) as the science, clinical evidence, and practitioner feedback drive product innovation. Practitioners may find it challenging to keep pace with this volume of new information. This article summarizes some basic fitting considerations and important design innovations, and it discusses some emerging technologies related to scleral lenses.

BASIC FITTING CONSIDERATIONS

Scleral lens designs are indicated for both irregular and regular corneas, either with or without underlying corneal or ocular surface pathologies. The safety and efficacy of scleral lenses are well established. The majority of complications associated with scleral contact lens wear are lens-related issues such as spoilage and those resulting from handling (Fuller and Wang, 2020). Physiology complications are uncommon, tend to be self-limiting, are manageable, or reflect a progression of an underlying condition; these include hydrops, inflammatory events, abrasions, neovascularization, and even microbial keratitis (Fuller and Wang, 2020; Tan et al, 1995a; Tan et al, 1995b; Walker et al, 2016). Their use along with corneal cross-linking is responsible for reducing the demand for keratoplasties among keratoconus patients (Coppen et al, 2018) and for the restoration of quality of life among our patients (Kreps et al, 2021).

The Scleral Lenses in Current Ophthalmic Practice Evaluation (SCOPE) study, which surveyed both new and experienced fitters, reported that scleral lenses are overwhelmingly indicated for irregular corneas (74.2%) compared to regular corneas (25.8%), with keratoconus, pellucid marginal degeneration, and post-surgical fits leading the way (Nau et al, 2018). Specific indications include ectasias, refractive errors of all types, limbal stem cell deficiencies, Stevens-Johnson syndrome and toxic epidermal necrolysis, graft-versus-host disease, Sjögren's, keratoconjunctivitis sicca, exposure, neurotrophic keratitis, and trauma (Nau et al, 2018).

The learning curve can be steep for neophyte scleral lens fitters. In a study of a single practitioner, success improved significantly after fitting between 61 and 80 eyes, with a commensurate reduction in the number of trial lenses required from 2.4 to 1.5 (Macedo-de-Araújo et al, 2019). The authors note that success may be different for other practitioners using different trial sets or technologies to assist the fitting process and that it is influenced by the complexity of the underlying fitting conditions (Macedo-de-Araújo et al, 2019). That said, the number of lenses reportedly needed to obtain a successful fit is in line with the work of others (Gemoules, 2008; Schornack and Patel, 2010). Success may improve with a better understanding of what an optimal fit looks like and how to select parameters.

When getting started with fitting scleral lenses, practitioners often ask what the ideal fitting relationship is between the lens and ocular surface. The short answer is the one that improves vision the most, impacts ocular physiology the least, and best fits the patients' lifestyle. The health needs of an individual eye vary from patient to patient. There is a range of evidence-based guidelines grounded in clinical experience that can inform practitioner choices.

Scleral Lens Diameter Overall lens diameter selec-

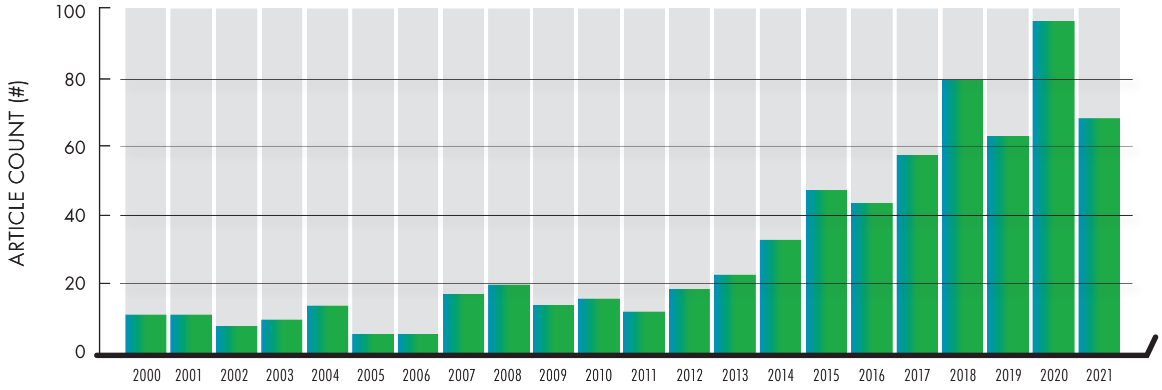

Figure 1. Number of articles in PubMed returned by year on the query of "scleral contact lenses" 1/1/2000 to 9/22/2021.

tion (larger for ocular surface disease, smaller for ectasias) requires consideration of corneal diameter, shape, curvature, and apical location on the cornea. One suggested approach is to select a diameter based on horizontal visible iris diameter (HVID), limbal zone width (1.5mm), landing zone width, and peripheral curve widths (Fadel, 2017; Fadel, 2018). The SCOPE study reported that the diameters that most practitioners fit are normally distributed with a mean of 16.0mm ± 1.0mm (Harthan et al, 2018).

Clearance and Settling Optical zone parameters based on theoretical calculations suggest that to meet the oxygen demands of the cornea in an open-eye state, the lens center thickness should be < 250µm, with a Dk > 125 and tear reservoir thickness in the 100µm-to-300µm range after settling (Barnett et al, 2021; Michaud et al, 2012; Jaynes et al, 2015; Dhallu et al, 2020; Compañ et al, 2014; Compañ et al, 2016). Increasing the central clearance from 200µm to 400µm decreases the oxygen available to the cornea by 30% (Giasson et al, 2017). Endothelial bleb response to hypoxia occurs within the first 15 minutes of wear, and corneal edema appears to be largely stromal in nature (Vincent et al, 2019). The significance of chronic corneal edema of < 2% while wearing scleral lenses is not known but is well documented (Vincent et al, 2019). The lack of agreement between the theoretical models and clinically observed hypoxia reflects limitations in theoretical model assumptions (Bergmanson et al, 2015).

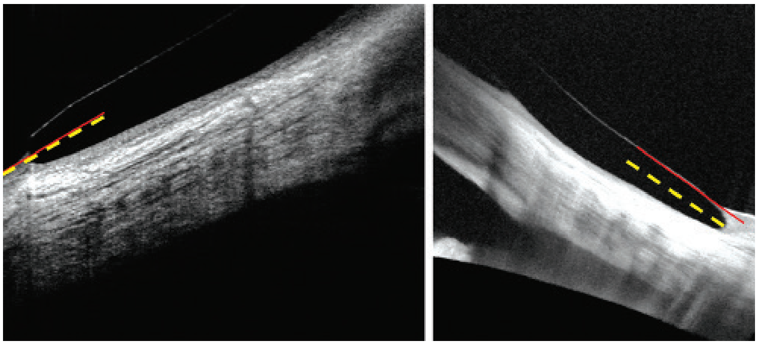

Figure 2. (Left) Appropriate edge alignment between landing zone and bulbar conjunctiva. (Right) Bearing of landing zone and edge.

Multiple studies report varying amounts of settling in the 100µm-to-200µm range over an eight-hour period, with additional settling of 20µm due to compression of the supporting tissues that continues to change over at least two months (Barnett et al, 2021; Otchere et al, 2014; Alonso-Caneiro et al, 2016; Kauffman et al, 2014; Esen and Toker, 2017; Otchere et al, 2017). Fifty percent of the settling likely occurs within the first hour (Barnett et al, 2021), and 80% occurs by two-to-four hours (Barnett et al, 2021; Esen and Toker, 2017). The tear reservoir must be thicker at initial lens application to account for lens settling, and practitioners should wait 20-to-30 minutes before assessing final clearances. Applying these guidelines to apical clearance may result in excessive clearances at the base of the apex or in other areas, requiring you to adjust accordingly.

Limbal clearance in the transition zone is also important. A suggested maximum value for limbal clearance is 60µm, and a wide range of settling values from 50µm to 100µm has been reported (Vincent et al, 2019). Adjusting limbal clearance often requires changes in base curve radius, diameter, and/or changes to the width of the transition zones.

The landing zone and lens edge should transition softly to the ocular surface, aligning with the bulbar conjunctiva and neither lifting off from the surface or bearing with impingement (Figure 2). Excessive edge lift can result in discomfort, while insufficient lift may cause hyperemia and other unknown long-term consequences

(Jedlicka, 2015). It is known that landing zones induce compression of the limbal and conjunctival-episcleral tissues of 12% and 30%, respectively, after three hours of wear; these values do not return to baseline completely within three hours after lens removal (Alonso-Caneiro et al, 2016). The potential consequences of long-term tissue compression require further study.

Intraocular Pressure There are controversies regarding the potential impact of scleral lens wear on intraocular pressure (IOP) caused by possible reductions in aqueous outflow. The evidence is conflicting due to differing techniques used to obtain IOP measurements, and surrogate endpoints such as changes in optic nerve morphology have been observed in some studies (Barnett et al, 2021). This serves as a reminder to closely monitor scleral lens wearers who have compromised optic nerves, as a significant number of these patients have comorbidities.

OPTICAL ZONE INNOVATIONS

Discussing the optical advantages of scleral contact lenses requires us to expand our thinking about refractive considerations. Lower-order aberrations (or defocus) constitute 90% of total aberrations in a normal eye, while higher-order aberrations (HOAs) comprise the remaining 10% (Lawless and Hodge, 2005). HOAs degrade the quality of vision, particularly for patients who have irregular corneas (Lawless and Hodge, 2005). Spherical aberration, coma, and trefoil are among the most relevant (Marsack et al, 2013). Factors influencing the amount of HOAs experienced by a patient include pupil size, accommodation, decentration of the optics, and tear film stability. In a normal eye, the positive spherical aberration of the cornea is neutralized by the negative spherical aberration of the crystalline lens (Lombardo and Lombardo, 2010).

Aligning the optical correction of a scleral contact lens with the optics of the eye contributes to improved vision for patients who have irregular corneas. There are inherent difficulties with a “one-size-fits-all” approach to the central optic zone design. The HOAs of importance are unique to each patient whether they have normal corneas or those with keratoconus, grafts, or other diseases. Modifications to the front-surface optics by manufacturers include the addition of asphericities of varying degrees; this improves vision for some but not for others (Vincent and Fadel, 2019). Initial experimentation with customized front-surface, wavefront-guided optics has led to commercially available designs. Although significant visual improvements are possible by reducing HOAs, improvement of root mean square (RMS) values and of contrast sensitivity appear to be limited by long-term neural adaptations (Sabesan et al, 2013; Sabesan and Yoon, 2009; Hastings et al, 2019; Marsack et al, 2014). These studies further reinforce the importance of lens centration and optical alignment in overcoming HOAs.

Multifocal toric soft contact lens options are increasingly available with rapid delivery of stock as well as made-to-order (MTO) designs. Some MTO options offer decentered optics that provide success where other designs fail. This point is not lost on an increasing number of scleral contact lens manufacturers, many of whom offer the option to decenter multifocal optics in their designs. Multifocal optics in scleral lenses are always in a simultaneous vision design and may be applied to the front or to the back optic zone surface (Figure 3). As you might imagine, these work best on normal corneas that have regular astigmatism and fewer HOAs.

Some manufacturers offer elliptical optical, transition, and landing zone options to improve lens stability and the tear reservoir profile by accommodating the elliptical nature of the corneal dimensions. This becomes increasingly important when the difference between dimensions is > 0.5mm (Barnett et al, 2021).

Finally, it is worth noting that manufacturers can add varying amounts of prism—both vertical and lateral—to the optic zone. Vertical prism is more readily available (Vincent and Fadel, 2019). Success with lateral prism has been reported by clinicians and by manufacturers of customized designs created from impression molding of the eye (Frogozo, 2016; Bragg and Sindt, 2015; Parker, 2015; Lee et al, 2021). Being able to maintain centration and rotational stability are advantages over soft or other GP designs that offer prism.

TRANSITION ZONE INNOVATIONS

The transition zone connects the optical zone and the landing zone. Manufacturers offer bitangential curve or multicurve scleral lens designs. Multicurve transition zones ease the transition to the landing zone. These transition zone curves vary in geometry from concave and convex to straight or tangential (van der Worp, 2015). The normal anatomy of the corneoscleral limbal junction angle varies across the same and opposing meridians, being flatter nasally and steeper temporally (Walker et al, 2020). The angle connecting the anterior corneal curvatures to the limbal region is within 3° of being a linear tangent in 80% of cases (Hall et al, 2013).

An insufficient amount of clearance can cause mechanical damage to the epithelium, abrasions, and can even induce limbal stem cell deficiency; excessive clearances may allow conjunctival prolapse or may create a hypoxic environment resulting in edema, cysts, bullae, neovascularization, and even scarring (Walker et al, 2020; Isozaki and Chiu, 2018; Yeung et al, 2020; Walker et al, 2016; Fadel, 2019). Insufficient transition zone clearance results in physiological compromise. Excessive clearances loosen the fit and encourage inferior

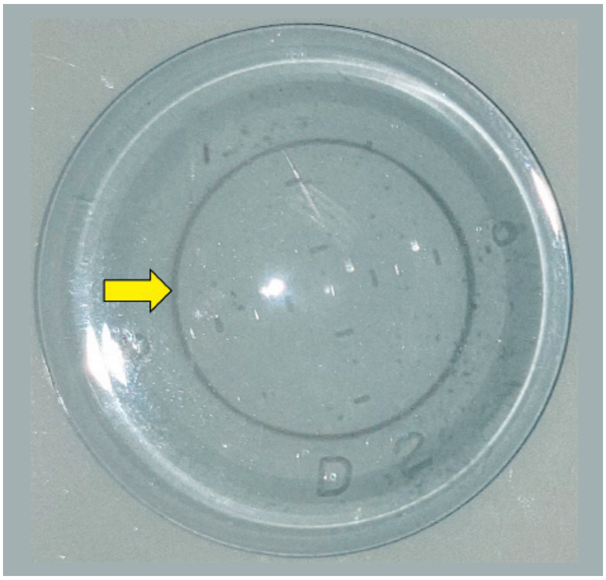

Figure 3. Multifocal scleral lens distance-center (yellow arrow) with various zones identified in a reticule form.

decentration, degrading visual performance as well as risking physiological compromise.

Manipulation of the overall lens diameter may resolve some issues related to limbal clearance. Increasing the diameter effectively pulls the transition zone away from the limbal region; increasing clearances while decreasing the overall diameter brings the transition zone into closer approximation with the limbal region. However, the corneal shape is a horizontal ellipse, with a typical difference between major meridians of 0.2mm to 0.4mm (Barnett et al, 2021). This may result in discrepancies between the horizontal and vertical limbal clearances, requiring an oval lens design (Fadel, 2019).

Not all irregular corneas are prolate in shape with a symmetrical contour, e.g., central keratoconus. Some prolate corneas are highly asymmetric, e.g., oval keratoconus, pellucid marginal degeneration, or decentered grafts. Oblate shapes are common after refractive surgery, e.g., laser-assisted in situ keratomileusis (LASIK), photorefractive keratectomy (PRK), and radial keratotomy (RK). For these eyes, a reverse curve in the limbal zone may be essential. For all of these reasons, adjustments to the transition curve(s) are more common than diameter adjustments are when troubleshooting a fit.

Several manufacturers label trial lenses as either prolate or oblate for practitioner convenience. All manufacturers can produce lenses with either shape. Some manufacturers allow practitioners to adjust transition curves while keeping the sagittal depth constant; others require a compensation in sagittal depth, as the transition zone either raises or lowers the central sag. Some offer quadrant-specific, zonal, or sectored adjustments, creating a semi-customized approach to improve optical performance and to reduce problems such as "midday fogging" (Erdinest et al, 2021; Barnett et al, 2020). However, there does not appear to be a significant relationship between midday fogging and tear exchange (Skidmore et al, 2019). Patients wearing impression-based designs still experience midday fogging, which implicates other contributory associations including increased leukocytes as well as lipids and tear debris (Barnett et al, 2021). Use of scleral profilometry, topographic mapping, and impression molding offer increasingly customized designs that create a uniform tear reservoir thickness across the entire ocular surface (Figure 4).

Fenestration(s) in the transition zone (Figure 5) may improve tear exchange, oxygen availability, and flushing of tear reservoir debris (Skidmore et al, 2019; Rosenthal et al, 2005; Fadel and Ezekiel, 2020; Ko et al, 1970). Fenestrations equalize the sub-atmospheric pressure in the tear reservoir with the ambient atmospheric pressure, and they result in additional settling (Ritzmann et al, 2018). Fenestrations are not commonly used.

LANDING ZONE INNOVATIONS

The landing zone should evenly support the mass of a scleral contact lens while providing centration in a stable manner without adversely impacting physiology. One of the challenges in satisfying these goals arises from the effects of a rotationally asymmetric scleral topography. The Scleral Shape Study Group published findings suggesting that only 5.7% of scleral shapes are spherical, while 28.6% are regular toric, 40.7% are asymmetric with high and low points, and 26% have a periodicity different than 180º (DeNaeyer et al, 2017). The authors concluded that two-thirds showed an irregular pattern, and the remainder could be fit with spherical or toric landing zones. Additionally, the nasal contours are higher and flatter compared to the steeper and lower temporal dimensions (Fadel, 2018). This information helps us understand why we may see sectoral or localized blanching or impingement when a symmetrical landing zone is used in a stock lens design. We may improve the alignment in such cases by using a toric or quadrant-specific landing zone (Fadel, 2019; Barnett et al, 2020), semi-custom, and impression-based designs.

Landing zone curvatures, landing zone width, total lens diameter, and edge profiles may all be modified to help alleviate bearing or impingement. These parameters must often be modified in concert with each other to avoid a hinge effect, resulting in either a tight or a loose fit (Fadel, 2018). Obstacles on the ocular surface (e.g., pingueculas, filtering blebs, tubes, and shunts) require further modifications such as notching, microvault, truncation, and fluid channels to improve tear exchange (Figure 6) (Walker et al, 2020).

CUSTOM DESIGN TECHNOLOGY

This review of specialty scleral lens designs and applications follows the evolution of technologies away from purely stock designs toward increasingly customized ones. Study data clearly suggests that patients experience better optics, comfort, and physiology when a lens follows the contours of the ocular surface while aligning with the scleral profile (Vincent and Fadel, 2019; Walker et al, 2020; Fadel, 2019).

Innovations that have facilitated this evolution include hardware and software from topographers, scanning slit tomographers, and scleral profilometers that link directly to manufacturers. Impression-molding options also interface with scanning devices (Barnett et al, 2021). These devices allow practitioners to evaluate the scleral profile out to 20mm or more, which far exceeds the 10mm-to-15mm view provided by a typical topographer (Bataille and Piñero, 2020). This reduces the need to extrapolate 10mm data out to 15mm or more when selecting diagnostic lenses. It also provides opportunities to measure the heights of obstacles, e.g., pingueculas, blebs, and shunts. These innovations also permit empirical ordering and consultation on even the most complex designs (Barnett et al, 2021).

Some of these devices obtain images in primary gaze, while others stitch together images from multiple gazes. Proprietary software packages, which either reside in the diagnostic instrumentation or interface with a device so that data may be imported, give skilled practitioners direct control over the design process. Empirical design work eliminates the need for multiple diagnostic lenses, the risk of cross-contamination, and potential damage to the compromised ocular surface tissues (Barnett et al, 2021). There is a lack of study data directly comparing diagnostic trial fitting against empirical fitting. Intriguing questions remain regarding first-order success rates, particularly as they relate to practitioner learning curves and to practitioner skill level.

SURFACE TREATMENTS

There is ongoing interest in reducing contact lens dropout rates by improving both initial and long-term comfort. A polyethylene glycol (PEG) surface treatment is available for use on soft, GP, and hybrid lens materials. Published results suggest that there may be little initial benefit to coating corneal GP designs (Debarun and Wolffsohn, 2021).

Subjects who had discomfort and symptoms of dry eye with their habitual scleral lenses experienced significant improvement in comfort and physiological findings over a 30-day period after their lenses were treated with the PEG-based agent (Mickles et al, 2021). However, routine application of this surface treatment has not been evaluated in a large-scale prospective study among asymptomatic subjects who do not have physiological signs of ocular surface disease or of other disease states.

BULK PROPERTIES

Experts have raised theoretical concerns over the potential for corneal hypoxia resulting from decreased oxygen transmissibility (Dk/t) with increased tear reservoir thickness in scleral lens wear (Michaud et al, 2012; Jaynes et al, 2015). While this does not appear to be supported in clinical practice (Bergmanson et al, 2015), it led to calls for higher-oxygen-permeable materials in the 125Dk to 150Dk range (Dhallu et al, 2020; Bergmanson et al, 2015).

The tisilfocon A material (Dk 163 to 189) exclusively dominated the category of GP materials that have a Dk of > 150 for nearly two decades in the United States. A second U.S. Food and Drug Administration (FDA)-approved material, fluoroxyfocon A (200 Dk), recently entered this class, further expanding the frontiers of hyper-Dk materials (Benjamin, 1993; Young and Benjamin, 2003). Much work is needed to aid our understanding of the roles of limbal metabolism, tear mixing, and tear exchange at various boundaries before the models align more closely with our clinical observations. However, it appears that the low levels (in the 2% range) of chronic corneal edema and the endothelial changes observed (Giasson et al, 2019) are not broadly impacting safety with scleral lens wear. Individual circumstances must always be considered for our patients (Walker et al, 2016; Vincent et al, 2019). The deeper the sagittal depth, the more hyperopic the prescription, and the more compromised the endothelium, the more that the highest-Dk materials are needed.

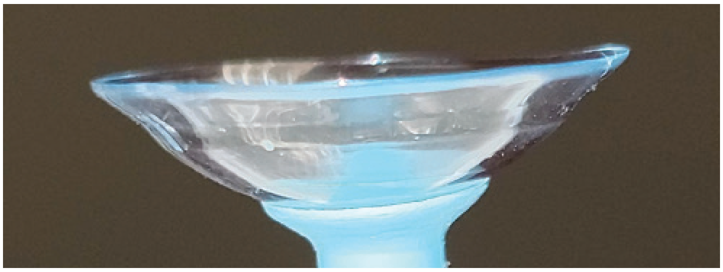

Figure 4. Semi-customized design with transition and landing zones that follow the contours of the scleral profile while creating a consistent tear reservoir thickness.

HANDLING AND CARE

Scleral lens handling is a challenge for most wearers even while experiencing improved vision and quality of life (Shorter et al, 2020; Macedo-de-Araújo et al, 2020). It

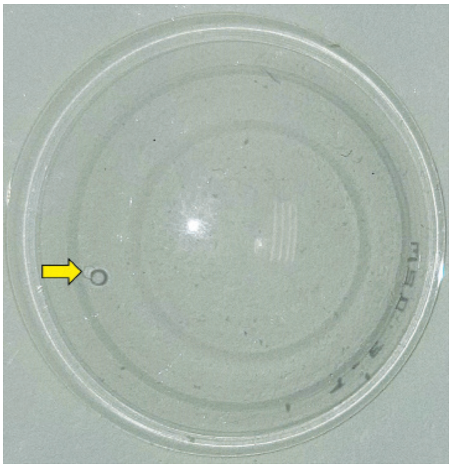

Figure 5. Fenestration (yellow arrow) and shadow behind. You can also see the shadows of the various curves of this four-zone design.

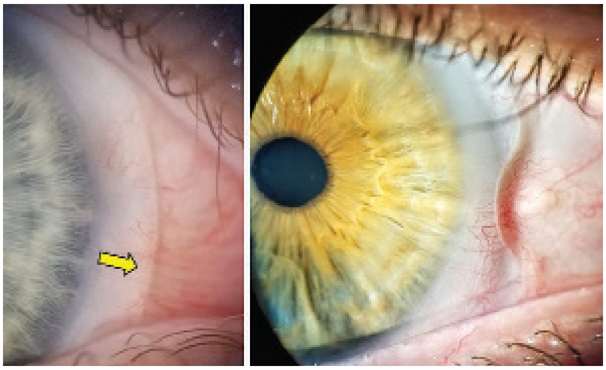

Figure 6. (Left) Microvault over area of a previously excised pinguecula and (right) a notch around a pinguecula.

is worth remembering that some patients may have mild-to-profound vision loss even with scleral designs. Dexterity issues can compound subnormal and low-vision concerns to further complicate application and lens care.

The Scleral Lens Education Society (SLS) offers patient education and support materials at scierallens.org. The GP Lens Institute (GPLI) at gpli.info and the Association of Contact Lens Educators at AOCLE.org offer additional support materials as well. There are also a number of archived webinars on the SLS and GPLI sites to further expand your knowledge.

Expert patients may be able to apply and remove their lenses using just their fingers. However, a variety of devices are available to assist with the application and removal of scleral lenses. These include plungers, devices that hold the lens and free both of the patients' hands to retract their lids, lighted devices to aid fixation, and a variety of self-made devices to stabilize the lens while freeing patients' hands.

Deep-well cases for both multipurpose and peroxide-based systems are available for storage to reduce the risk of lens breakage. Care systems consist of cleaning, disinfection, conditioning, and application solutions. Cleaning, disinfection, and conditioning care kits for GP and soft lens care systems work well. These are available as either single-step or multi-step care systems. For lenses coated with the PEG-based treatment, the manufacturer notes that only certain care systems are compatible with and will not damage the coating. Never use tap water when caring for any contact lens or devices.

Consider patient lifestyle and underlying pathologies when selecting a care system. Patients who have ocular surface disease (aqueous-deficient dry eye, evaporative dry eye, or mixed mechanism) may require the addition of enzymatic or chlorine-based protein removers.

Application solutions are available as buffered or non-buffered saline. One application solution contains electrolytes, which more closely mimic the natural human tears (Fogt et al, 2020). All work well. FDA-approved solutions are available from multiple manufacturers online and in retail stores. They are supplied in unit-dose vials and in larger bottles that should be discarded two weeks after opening, as they are preservative-free.

Off-label solutions include preservative-free artificial tears in lieu of non-preserved saline for application, autologous serum for patients who have persistent epithelial defects and neurotrophic lesions, and cocktails of the above with saline. Large-scale, prospective studies to evaluate their safety and efficacy are lacking. Preserved agents should never be used due to their potential to damage the cornea.

Extended wear of scleral lenses is not indicated, but there is evidence regarding the efficacy of this for recalcitrant persistent epithelial detachments. In such cases, the scleral lens is worn for 24 hours, with brief removal to clean and refill the bowl with non-preserved fluoroquinolone (Rosenthal and Crouteau, 2005; Jacobs et al, 2021; Ciralsky et al, 2015).

SUMMARY

It is possible to take a deeper dive into any of these topics, and many controversies still exist. This article cites a number of review studies that summarize the work of many great minds. The progression of technology is amazing, and it enhances our ability to service the needs of normal and pathological states. This is truly an example of evidenced-based medicine leading to evidence-based practice. **CLS**

For references, please visit www.clspectrum.com/references and click on document #315.

Dr. Fuller is chief of the Cornea Contact Lens Service at The Eye Center, Southern College of Optometry and is a Diplomate in the Cornea, Contact Lenses and Refractive Technologies Section of the American Academy of Optometry. He is an advisory board member of the Gas Permeable Lens Institute.