

SCLERAL LENS TROUBLESHOOTING FAQs

DESCRIPTION

This module was developed as a collaborative effort between the GP Lens Institute and the Scleral Lens Education Society. The goal of the module is to answer commonly asked questions pertaining to scleral lens applications, fitting, problem-solving, and lens care.

The contributors are Advisory Board members of the GP Lens Institute and leaders in the Scleral Lens Education Society and include the following individuals: Tom Arnold OD; Bruce Baldwin OD; Melissa Barnett OD; Ed Bennett OD, MSED; Karen Carrasquillo OD, PhD; Greg DeNaeyer OD; Daddi Fadel DOPTOM; Melanie Frogozo OD; Matt Kauffman OD; Langis Michaud OD, MSc; Pam Satjawatcharaphong OD; Muriel Schornack OD; Jeff Sonsino OD; Mindy Toabe OD; Maria Walker OD; Stephanie Woo OD.

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I. DEFINITION, INDICATIONS AND LENS SELECTION

1. How is a scleral lens defined? (Bruce Baldwin, OD)

Internationally accepted standards define a scleral lens as a rigid gas permeable lens that is large enough to make contact only with the sclera, completely vaulting over the cornea. A scleral lens can be further subdivided into mini-scleral and full-scleral.

Scleral lenses should not be confused with large diameter, custom tinted, soft “sclera” lenses, often bought illegally off the Internet.

The Scleral Lens Education Society (www.sclerallens.org) defines scleral lenses via their overall diameter as listed below:

NAME	DIAMETER	FITTING RELATIONSHIP
Corneo-Sclera	12.9 – 13.5mm	Corneal bearing and scleral touch
Semi-Scleral	13.6 – 14.9mm	Corneal and scleral bearing
Mini-Scleral	15.0 – 18.0mm	Scleral bearing and minimal corneal clearance
Full Scleral	18.1 – 24+mm	Scleral bearing and maximum corneal clearance

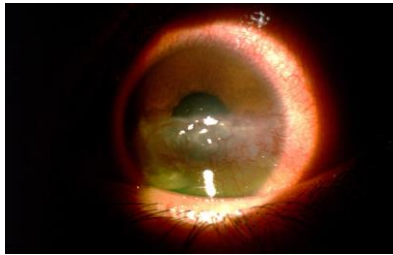
How are scleral lenses prescribed? Scleral lenses are prescribed by a provider licensed in a state or country to write a legal prescription for an ocular device such as a contact lens. Scleral lenses cannot be legally purchased off the Internet without a prescription. A scleral lens prescription results from a comprehensive examination and lens fitting. Lenses are fit using a set of diagnostic lenses placed on the eye to obtain an accurate fit. Scleral lenses may also be designed with special measuring instruments, such as scleral topographs or a custom impression mold of the eye.

2. Who are the patients that benefit from scleral lenses? (Bruce Baldwin, OD and Melissa Barnett, OD)

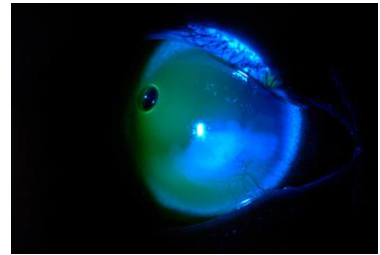
Anyone who wants to wear contact lenses and has been unsuccessful with any other type of lens wear may be successful with scleral lenses. In particular, patients with a history of eye disease or infection (Figures 1 – 4), trauma, surgery (Figures 5-10), or dry eyes are good candidates for scleral lens wear. Some scleral lens laboratories manufacture bifocal (or multifocal) scleral lenses that may have advantages over other types of multifocal lenses.



1. A patient with Grave's Disease (contributed by Dr. Pam Satjawatcharaphong)



2. A corneal scar from constant lagophthalmos protected and rehabilitated with a scleral lens (contributed by Dr. Melanie Frogozo)



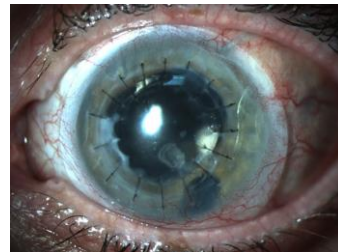
3. Another patient with a corneal scar from constant lagophthalmos protected and rehabilitated with a scleral lens (contributed by Dr. Melanie Frogozo)



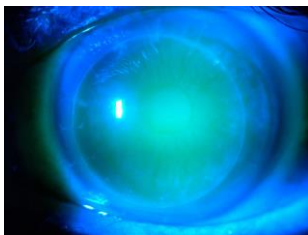
4. Persistent epithelial defect protected by a scleral lens (contributed by Dr. Melissa Barnett)



5. Pediatric bilateral aphakic patient wearing scleral lenses (contributed by Dr. Melanie Frogozo)



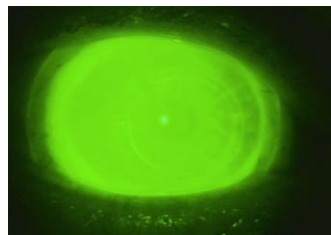
6. Post penetrating keratoplasty patient (with shunt) in scleral lens wear (contributed by Dr. Pam Satjawatcharaphong)



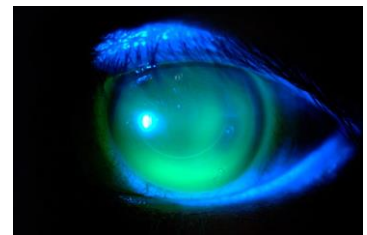
7. Post penetrating keratoplasty patient with scleral lens wear (contributed by Dr. Melanie Frogozo)



8. Post-Intacs patient wearing scleral lenses (contributed by Dr. Tom Arnold)



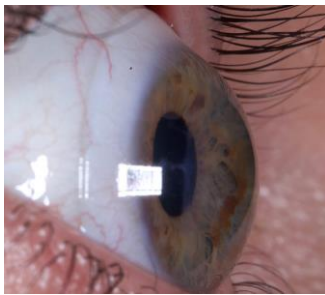
9. Post-Intacs patient wearing scleral lenses (contributed by Dr. Maria Walker)



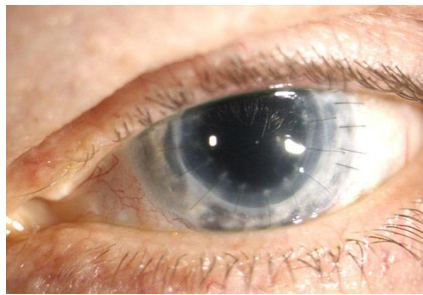
10. Post-Intacs patient wearing scleral lenses (contributed by Dr. Melanie Frogozo)

Scleral lenses are a fantastic option for the management of corneal irregularities on the front surface of the eye or dry eyes. A large diameter lens can vault irregular surfaces such as keratoconus (Figure 11), pellucid marginal degeneration, or ocular trauma (Figure 12) and is also useful in diseases that affect the ocular ecosystem, such as severe dry eye due to Sjögren's disease, Graft-versus-host-disease (GVHD), Stevens Johnson Syndrome (SJS) (Figure 13), chemical burns, neurotrophic keratopathy and post-refractive surgery complications.

Large diameter scleral lens designs are handled and cared for differently than corneal gas permeable (GP) lenses or soft contact lenses.



11. A profile view of a keratoconus patient wearing a scleral lens (contributed by Dr. Tom Arnold)



12. A molded scleral lens on a post golf ball rupture (contributed by Dr. Tom Arnold)



13. Scleral lenses on a patient with Stevens-Johnson syndrome (contributed by Dr. Jeff Sonsino)

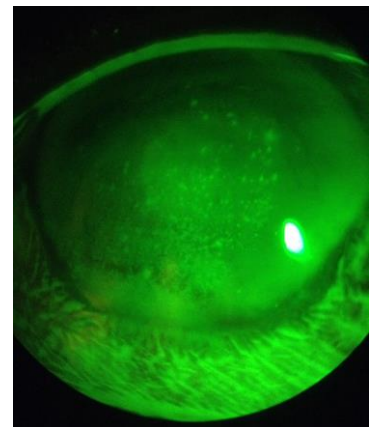
3. How can scleral lenses help dry eye patients? (Bruce Baldwin, OD)

a. How dry eye patients can benefit from scleral lenses and why.

Scleral lenses, when properly fit, vault over the cornea and maintain a fluid chamber between the lens and the eye. This fluid chamber, sometimes called a liquid corneal bandage, can provide a moist, comfortable environment for dry eye patients. (Figure 14) The scleral lens prevents contact between the eyelid and the surface of the eye, and protects the cornea from the outside environment.

b. How fitting a dry eye patient differs from an irregular cornea patient.

Scleral lenses prescribed for management of dry eye may be somewhat larger than those prescribed to manage other ocular conditions, but the fitting process and goals are similar regardless of indication for lens wear. However, patients with dry eye disease may have lower tear production or a higher concentration of inflammatory mediators in their tear film. These factors may lead to a higher risk of either lens surface deposits or post-lens fluid reservoir debris.



14. An ocular surface disease patient who could benefit from scleral lenses (contributed by Dr. Tom Arnold)

4. Do scleral lenses reduce the need for corneal transplants? (Bruce Baldwin, OD and Ed Bennett, OD, MSED)

The most common eye disease resulting in a full thickness corneal transplant in 2014, for both the United States and internationally was keratoconus. <http://restoresight.org/wp-content/uploads/2015/03/2014-Statistical-Report-FINAL.pdf>

Keratoconus can cause severe vision loss. If there is no significant scarring of the cornea, contact lenses – including scleral lenses – can restore sight to functional levels, delaying or avoiding the need for corneal transplantation. Other conditions that cause severe vision loss can only be adequately corrected with scleral lenses or surgery. Those patients also have the option to delay surgery.

Whether scleral lenses have delayed or prevented corneal surgery has yet to be established. However, as discomfort is the leading cause of contact lens dropout (Begley, Caffery & Nichols, et al, 2000; Hewett, 1984) and as corneal GP lenses on an irregular cornea tend to result in a less than optimum fitting relationship, it is certainly possible that the emergence of scleral lenses has presented practitioners with an option that would all but eliminate corneal surgery for patients experiencing lens-induced discomfort. In fact, two recent studies have supported this. Koppen et al (2018) found that 40 of 51 eyes with severe keratoconus that would have otherwise necessitated a corneal transplant were successfully treated with long-term scleral lens wear. Ling et al (2020), evaluating 2806 eyes with a diagnosis of keratoconus or corneal ectasia found that only 3.2% of eyes necessitated any form of keratoplasty and concluded that patients who wear contact lenses successfully – of which sclerals were one of the primary modalities – have almost one-fifth the risk of undergoing keratoplasty.

5. When to select a scleral lens versus other options (i.e., corneal GP, hybrid, custom soft) in keratoconus? (Bruce Baldwin, OD and Stephanie Woo, OD)

As of 2016, there are 19 scleral lens manufacturers in North America, and numerous other companies in Europe, India, Australia, and other countries (Tylers Quarterly, <http://tylersq.com>). The SCOPE study, conducted in 2015, found that, while corneal GP's were most commonly reported as the first lens option considered for patients with keratoconus, scleral lenses were only slightly less likely to be considered first-line treatment. (Shorter E, et al, 2018) With the availability of many lens designs, scleral lenses have become a first option for many practitioners. Other lens types are indicated for fit, comfort or cost reasons. With severe keratoconus, the optic zone of a corneal GP lens may be smaller, which can reduce vision at night. Scleral lenses have larger optic zones, which may help keratoconus patients achieve better vision. If a keratoconus patient complains of lens dislodgement, this could also be reason to try a scleral lens.

When performing contact lens fitting for a patient with keratoconus, it is important to balance vision, cost, comfort, and burden of care. Discussion with each individual patient about their specific needs and priorities can help to determine which options are most likely to best meet the patient's needs.

6. Scleral lenses as a viable option for healthy eyes? (Bruce Baldwin, OD and Stephanie Woo, OD)

a. Are scleral lenses a viable option for healthy eyes, and if so, who are the best candidates?

Many practitioners are using scleral lenses for “normal” eyes. Reasons for choosing a scleral lens over a traditional lens type include: dry eyes, high refractive error – including myopia, hyperopia, and astigmatism (Figure 15) – durability, and stability for athletics or work environments. Other candidates include aphakia, anisometropia, and presbyopia. Scleral lenses are also a great option for patients wearing soft toric lenses who complain of fluctuating vision or poor comfort and have been found to be comparable in comfort and preferable in visual acuity when compared to soft toric lenses. (Michaud L, et al, 2018; Harthan J, et al, 2018)



15. A teenage patient with high hyperopia and astigmatism fit into scleral lenses (contributed by Dr. Melanie Frogozo)

The 2015 SCOPE study estimated that approximately 8% of scleral lenses prescribed were for patients with uncomplicated refractive error. A follow-up study by the SCOPE study group which evaluated patient outcomes of scleral lens wear found that only 4% of patients wore lenses for correction of uncomplicated refractive error. (Nau C, et al, 2018)

b. Who are good candidates for multifocal scleral lenses?

When traditional soft or rigid multifocal lenses have not given adequate vision or comfort, scleral lenses in multifocal designs can provide good and comfortable distance and near vision. The high quality optics of a GP lens yields impressive near and distance vision with scleral lenses. They are a great option for patients desiring excellent all-around vision with good comfort.

Patients with presbyopia and astigmatism should consider a scleral multifocal lens as well. Frequent replacement of soft multifocal lenses can be quite expensive. Although a pair of multifocal scleral lenses can also be expensive, the long-term cost can be competitive due to the durability of a scleral lens.

II. LENS DESIGN AND FITTING

1. Lens Selection (Stephanie Woo, OD)

a. When to select a smaller scleral versus a larger scleral lens design?

Smaller diameter lenses work well for patients with smaller horizontal visible iris diameter (HVID) and relatively normal cornea shapes.

Larger diameter scleral lenses are often used for highly irregular corneas or patients with a large HVID. The diameter selection varies by practitioner.

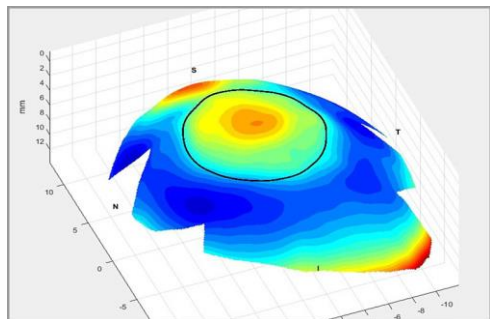
b. Which patients are good candidates for an impression or image-based scleral lens design?

Any patient who is a candidate for a regular scleral lens is also a candidate for a custom scleral lens. Impression-based lenses are perhaps most appropriate for individuals with highly irregular scleral surfaces. These lenses are designed and created by obtaining an impression of the entire ocular surface (including the cornea, limbus, conjunctiva, and sclera), sending the impression mold to a laboratory, where a 3-D scanner is used to create an extremely precise custom device. (Figures 16 and 17) Image-based lenses are created from a scan of the ocular surface (obtained by using an ocular surface profilometer). Scans are sent to the laboratory, and custom lenses are created from these images. Both techniques provide a great option for patients with conjunctival anomalies, those needing prism in any direction, and extremely difficult fits.

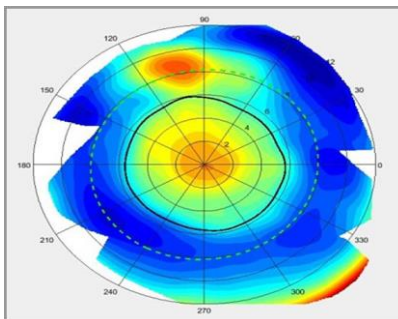
2. Can scleral lenses be fit empirically or is a diagnostic fitting set required? (Stephanie Woo, OD)

There are a few available instruments that are able to map the corneal, limbal, and scleral shape. Using this technology can improve the success rate when fitting scleral lenses. (Figures 18-20) Even when using imaging technology, however, placement of a diagnostic lens (either corneal GP or scleral lens) on the eye is frequently necessary to determine the appropriate lens power. If you do not have access to this technology, a diagnostic fitting set is recommended. Anterior ocular contour, corneal eccentricity, conjunctival thickness and elasticity, lid tension, tear film and sagittal height all influence the fitting relationship of the scleral lens. Evaluating a scleral lens on the eye after settling 20-30 minutes results in more accurate assessment of the scleral lens fit.

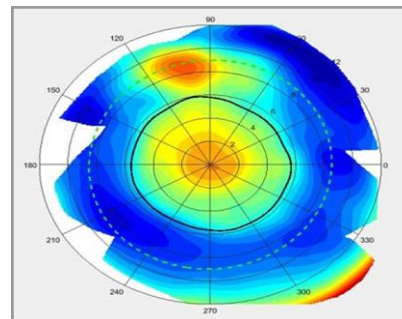
18.-20. The benefits of a corneal-scleral topographer showing the sMap3D images of a patient with a history of corneal transplant and glaucoma (contributed by Dr. Matt Kauffman)



18. Shows the topography; note that the bleb was superior



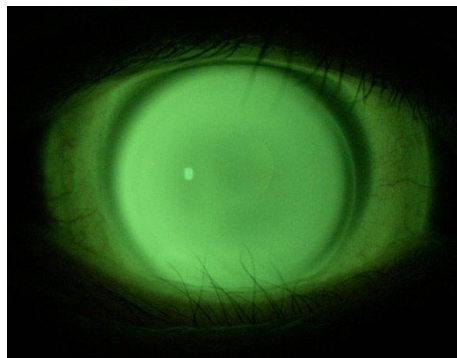
19. The green dotted line outlines a 16mm scleral diameter lens



20. The green dotted line outlines an 18mm scleral diameter lens



16. A good mold for an EyePrint scleral lens (AVT) (contributed by Dr. Tom Arnold)

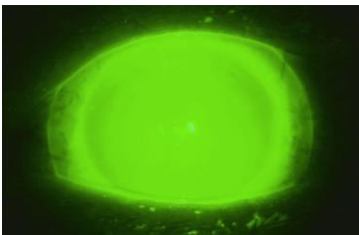


17. A good molded scleral lens fit (contributed by Dr. Tom Arnold)

3. What is the appropriate amount of clearance? (Greg DeNaeyer, OD and Melissa Barnett, OD):

a. What would represent an optimum central clearance (before and after settling)?

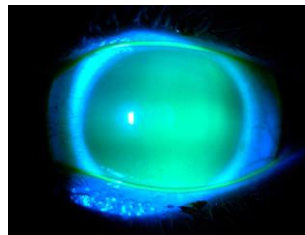
The optimum central clearance may be influenced by scleral lens design, diameter, and ocular condition. However, this would amount to 200-300 microns pre-settling and 50-200 microns post-settling. (Figures 21-24) There is theoretical and experimental evidence suggesting that oxygen transmissibility is improved with relatively less central corneal clearance. (Michaud, 2012) In general, less central clearance is needed for scleral lenses designed for normal corneas compared to those designed for eyes with ocular pathology or irregular astigmatism. (Kim YH, et al, 2018; Kim YH, et al, 2017; Tan B, et al, 2019) However, more recently published evidence suggests that the amount of central corneal clearance may not be directly associated with corneal hypoxia. As of yet, only one study has reported central clearance values for established, successful scleral lens wearers; Sonsino et al (2013) reported successful scleral lens wear with 100-600 microns of clearance. Clearly, additional study is needed to assess the impact of corneal clearance on long-term scleral lens outcomes. At present, prescribers would be advised to make sure that complete clearance is obtained (and maintained over time), and to monitor the cornea closely for any signs of hypoxic or mechanical stress regardless of the amount of clearance observed.



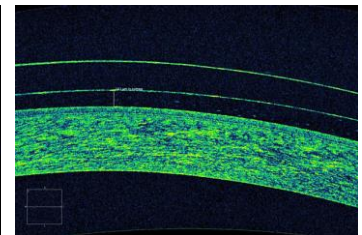
21. An optimum overall fluorescein pattern of a scleral lens (contributed by Dr. Maria Walker)



22. An optimum overall fluorescein pattern of a scleral lens (contributed by Dr. Melissa Barnett)



23. An optimum overall fluorescein pattern of a scleral lens (contributed by Dr. Melanie Frogozo)



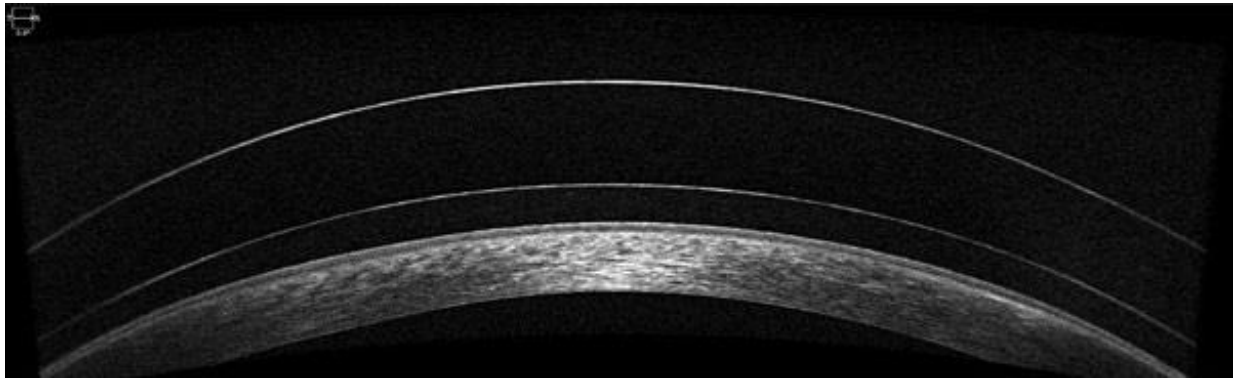
24. An OCT image of optimum central clearance of a scleral lens (contributed by Dr. Tom Arnold)

b. How much does a lens settle and how long does it take?

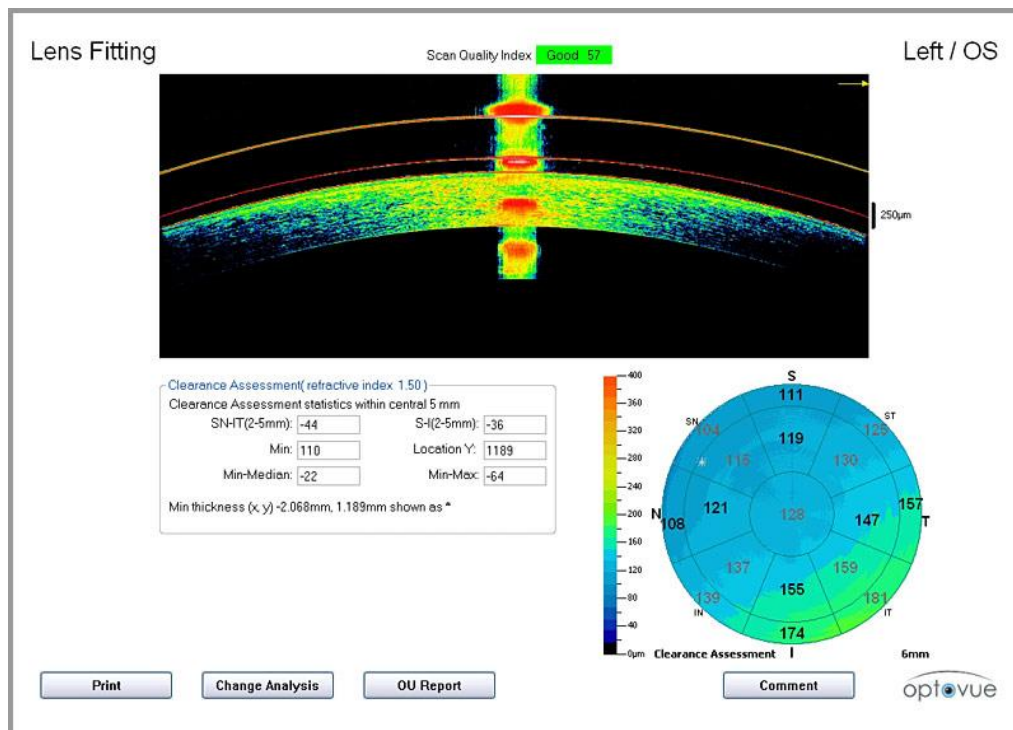
A lens can settle up to 200 microns. (Kauffman et al, 2014; Caroline and Andre, 2013; Mountford, 2012) There is both short term settling (during the course of a day – most diurnal settling occurs within the first few hours of wear) and long term settling (over months of wear with the initial lens). One study was able to demonstrate that 50% of scleral lens settling occurs 30 minutes after initial lens application (Courey C, Michaud L, 2017).

c. How should the amount of central clearance be determined?

The most accurate way to measure central corneal clearance is with anterior segment optical coherence tomography (OCT). (Figures 25, 26)



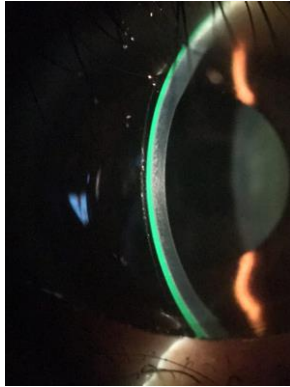
25. An OCT image illustrating good central clearance with a scleral lens (contributed by Dr. Tom Arnold)



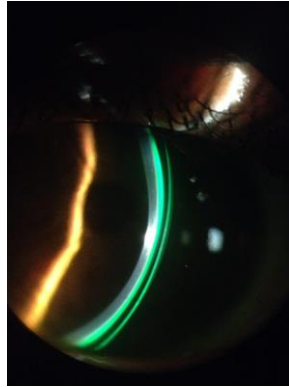
26. An OCT image illustrating good central clearance with a scleral lens (contributed by Dr. Maria Walker)

Additionally, the central clearance of a scleral lens can be estimated by comparing the post lens fluid reservoir using slit lamp biomicroscopy (slit beam turned approximately 45 degrees) with the known thickness of the applied scleral lens. (Figures 27-29)

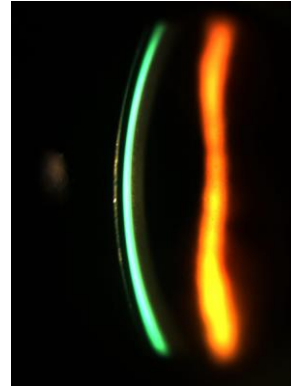
For example, if the lens thickness is 300 microns (the dark section of the optic section) and the fluorescein-stained tear film is approximately one half of that thickness, the thickness of the tear film is approximately 150 microns.



27. Viewing the optic section of a scleral lens exhibiting good central clearance (contributed by Dr. Tom Arnold)

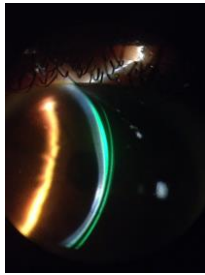


28. Viewing the optic section of a scleral lens exhibiting good central clearance (contributed by Dr. Tom Arnold)

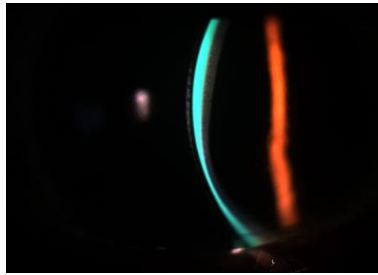


29. Viewing the optic section of a scleral lens exhibiting good central clearance (contributed by Dr. Pam Satjawatcharaphong)

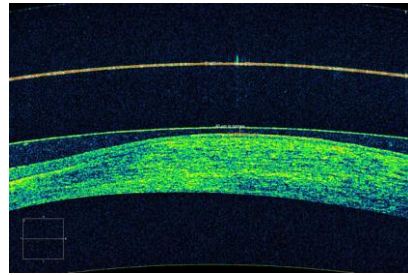
Insufficient clearance is shown in Figures 30-32; excessive clearance is shown in Figures 33-35; and a comparison is given in Figure 36.



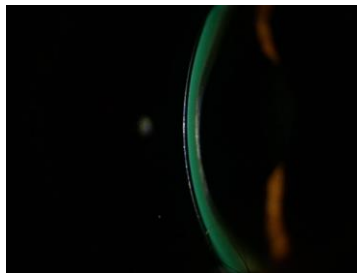
30. A lens with insufficient central clearance via optic section (contributed by Dr. Tom Arnold)



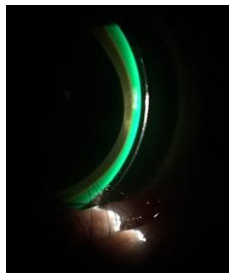
31. A lens with insufficient central clearance via optic section over the apex of the cone of a keratoconic patient (contributed by Dr. Pam Satjawatcharaphong)



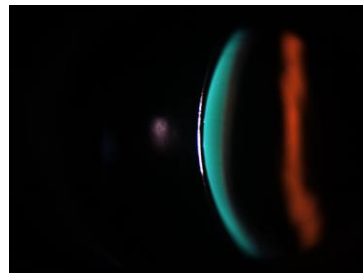
32. A lens with insufficient central clearance via OCT (contributed by Dr. Tom Arnold)



33. An optic section showing excessive central clearance or vault (contributed by Dr. Tom Arnold)



34. An optic section showing excessive central clearance or vault (contributed by Dr. Tom Arnold)



35. An optic section showing excessive central clearance or vault (contributed by Dr. Pam Satjawatcharaphong)



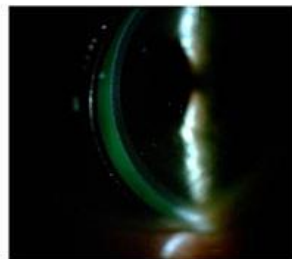
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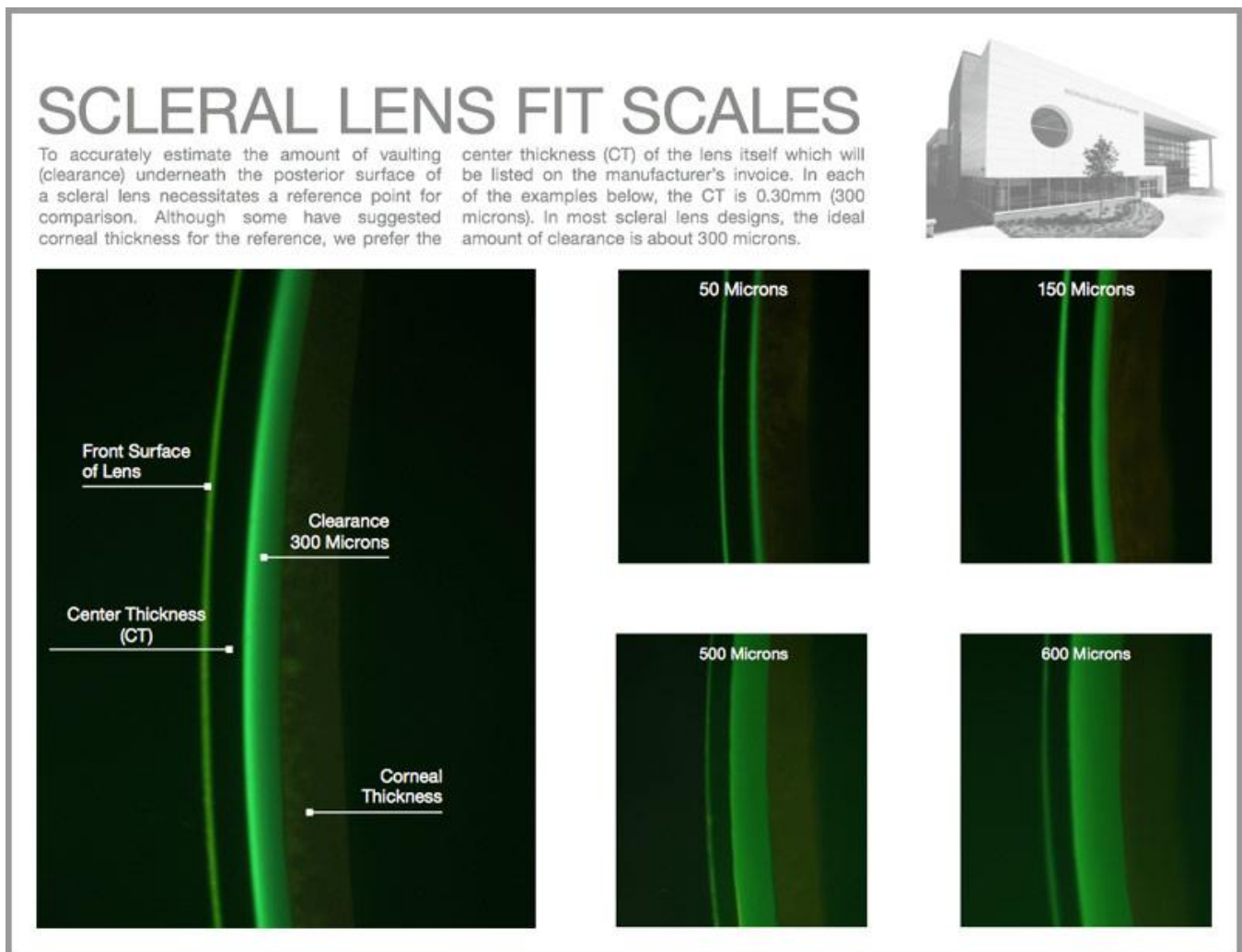


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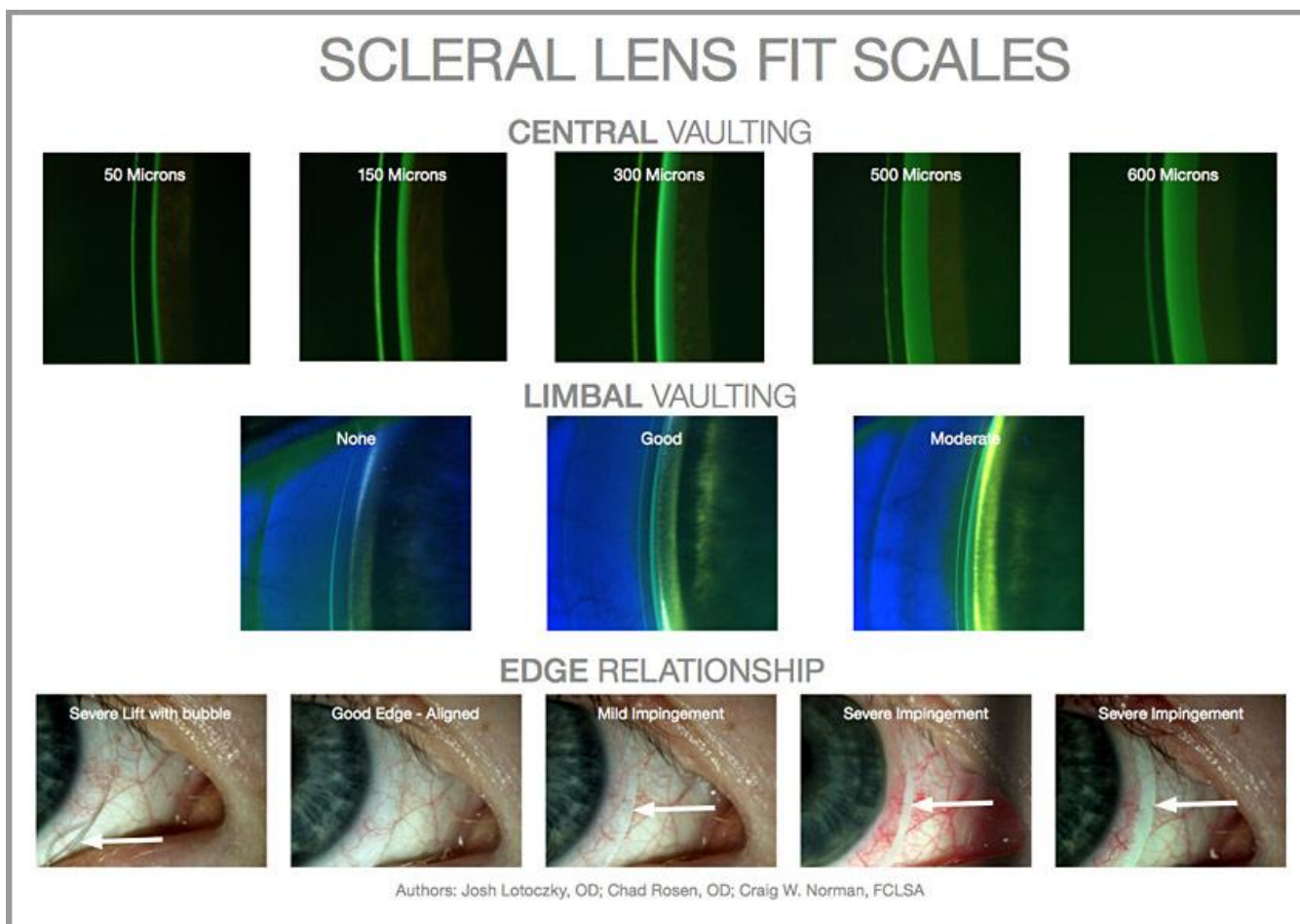


36. A comparison of insufficient, optimum, and excessive central clearance (contributed by Dr. Matt Kauffman)

A very useful tool is the Michigan College of Optometry Scleral Lens Fit Scales (Figures 37, 38): <http://www.ferris.edu/ScleralLensFitScales>



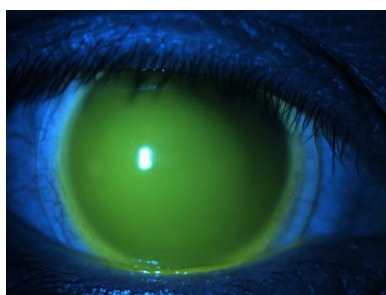
37. The MCO Scleral Lens Fit Scales showing determination of central clearance



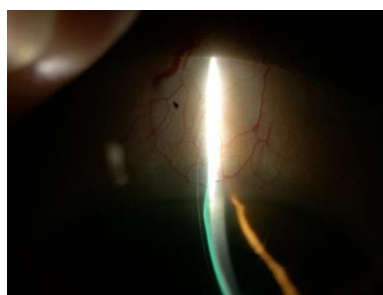
38. The MCO Scleral Lens Fit Scales showing central, limbal, and edge assessment

d. What would constitute optimum limbal clearance and how should it be evaluated?

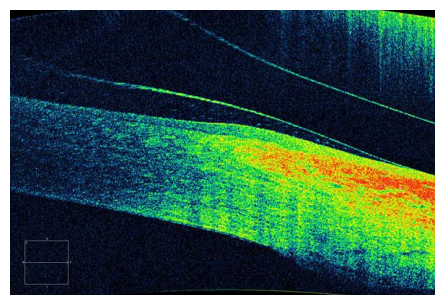
The scleral lens should clear the limbus by at least 50 microns. (Figures 39-41) Avoid circumferential limbal bearing of the lens, which could lead to discomfort, keratitis, formation of corneal epithelial bullae, and neovascularization. (Nixon AD, et al, 2017)



39. A frontal view of a scleral lens exhibiting both good central and limbal clearance (contributed by Dr. Pam Satjawatcharaphong)



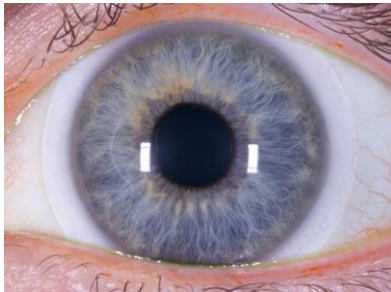
40. Good limbal clearance superiorly with a scleral lens (contributed by Dr. Tom Arnold)



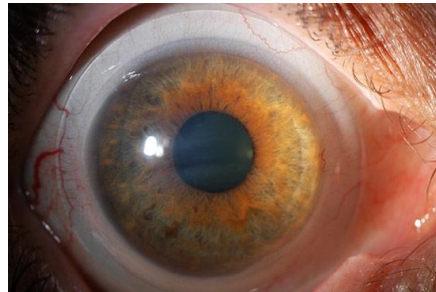
41. Good limbal clearance as shown with an OCT (contributed by Dr. Tom Arnold)

4. What would constitute an optimal landing zone and how should it be evaluated? (Greg DeNaeyer, OD)

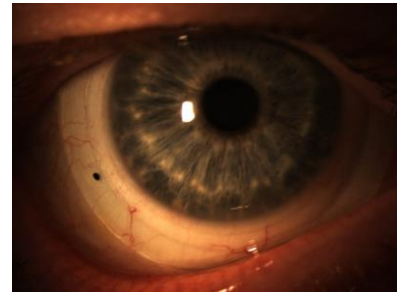
The landing zone of the scleral lens should rest evenly on the bulbar conjunctival/scleral surface without compression, impingement, or edge lift. (Figures 42-48). Compression or impingement will result in blanching of the blood vessels with slit lamp examination. Additionally, this scenario can cause the lens to be difficult to remove. Edge lift, resulting from a mismatch between the landing zone design and scleral shape, can create either a shadow at the lens edge or result in a visible bubble that can be observed with slit lamp examination. Additionally, edge lift will cause fluorescein to uptake under the lifted edge. Optical coherence tomography (OCT) can also be used to further evaluate for compression, impingement, or edge lift of the landing zone.



42. Good overall scleral fit with optimum scleral landing (contributed by Dr. Tom Arnold)



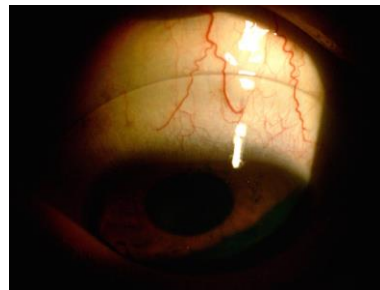
43. Good overall scleral fit with optimum scleral landing (contributed by Dr. Melissa Barnett)



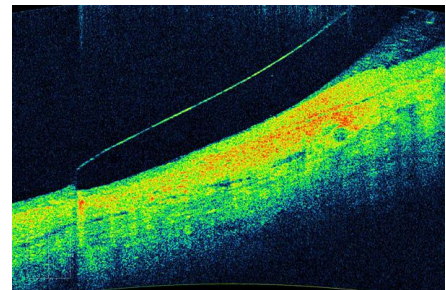
44. More magnified view of a good overall scleral fit with optimum scleral landing (contributed by Dr. Pam Satjawatcharaphong)



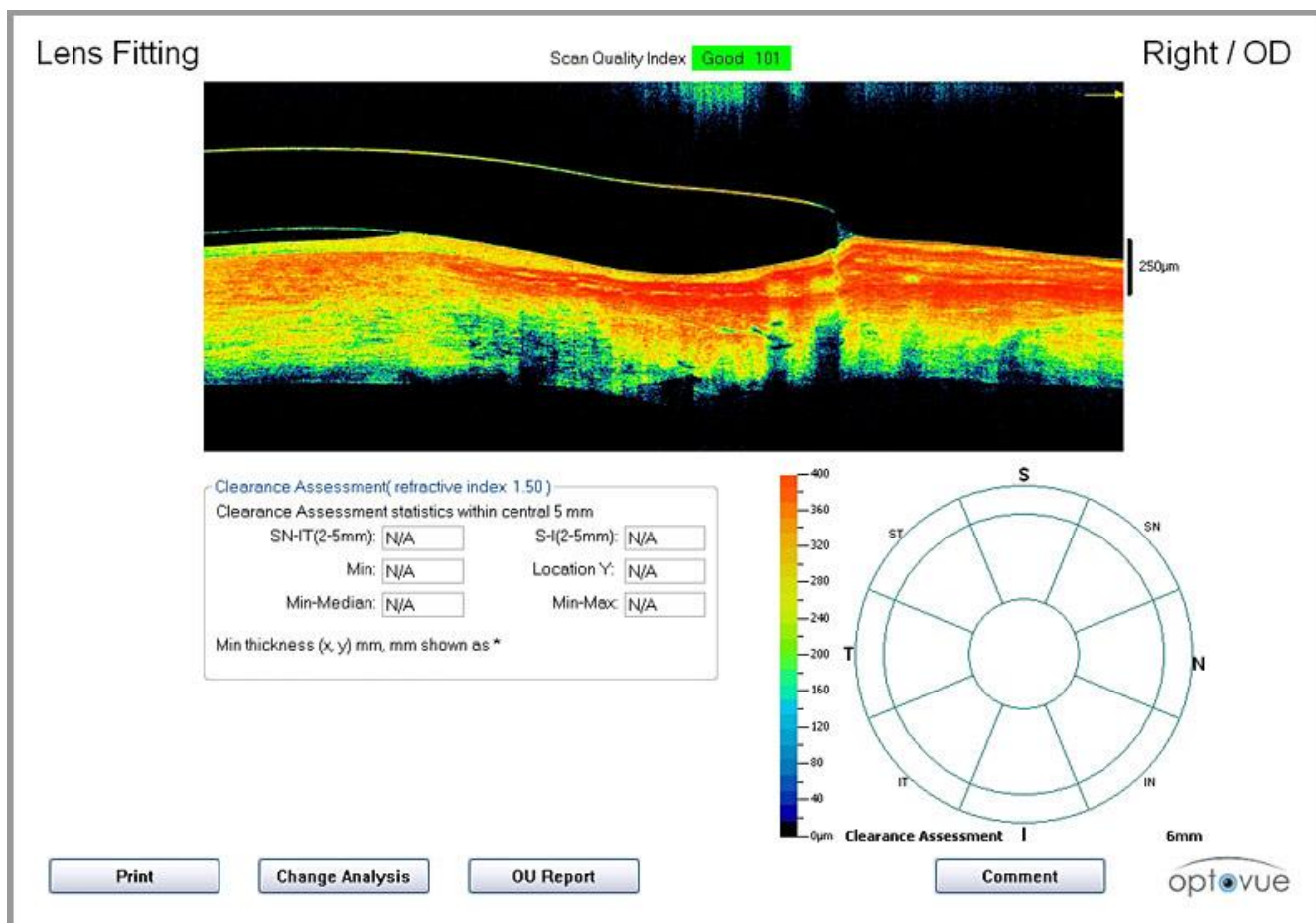
45. A view of the inferior sclera of a lens that is exhibiting good landing on the sclera (contributed by Dr. Pam Satjawatcharaphong)



46. A view of good scleral landing superiorly (contributed by Dr. Melanie Frogozo)



47. An OCT image of optimum edge landing on the sclera (contributed by Dr. Tom Arnold)



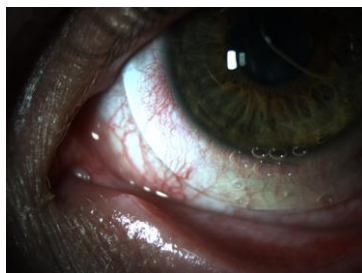
48. An OCT image of optimum edge landing on the sclera (contributed by Dr. Maria Walker)

5. When would a back surface toric haptic be recommended? (Greg DeNaeyer, OD)

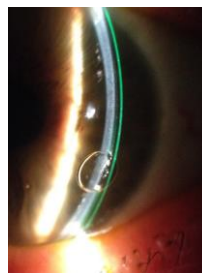
Regular toricity of the bulbar conjunctival/scleral surface occurs in 28.6% of patients presenting for scleral lens fitting. (DeNaeyer G, et al, 2017)(Figures 49-51) In these cases using a back toric landing zone will result in landing zone alignment, which will improve patient comfort and decrease reservoir debris.(Figure 52)



49. Peripheral bubbles observed due to lack of lens alignment with the sclera (contributed by Dr. Pam Satjawatcharaphong)



50. Peripheral bubbles observed due to lack of lens alignment with the sclera (contributed by Dr. Pam Satjawatcharaphong)

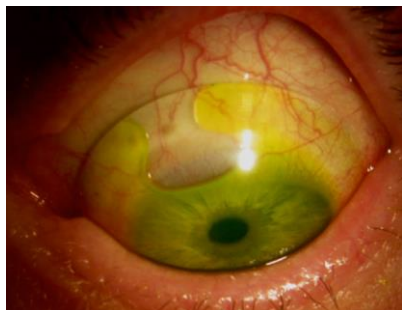


51. Peripheral bubbles observed due to lack of lens alignment with the sclera (contributed by Dr. Tom Arnold)

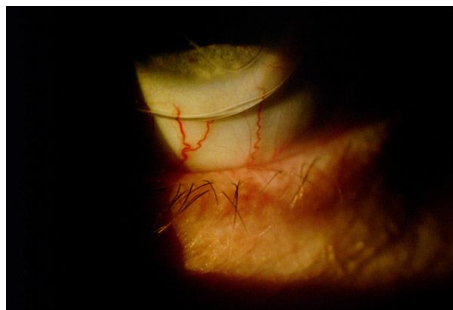


52. A toric scleral lens aligning well with cornea and sclera (contributed by Dr. Greg DeNaeyer)

Use a back surface toric if edge lift is observed in opposing quadrants. (Figures 53-55)



53. Poor superior alignment and edge lift of a scleral lens with spherical peripheral optics (contributed by Dr. Greg DeNaeyer)

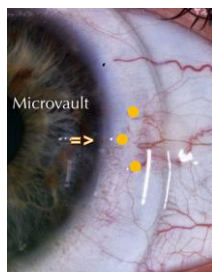


54. Inferior edge lift with a scleral lens with spherical peripheral optics (contributed by Dr. Melanie Frogozo)



55. Inferior edge lift with a scleral lens with spherical peripheral optics (contributed by Dr. Melanie Frogozo)

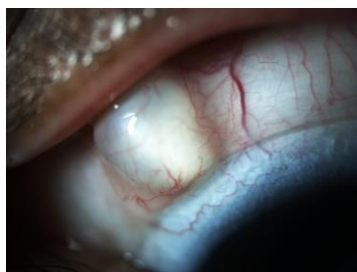
Toric diagnostic lenses or corneo-scleral topography can be used to determine the amount and location of toricity in the landing zone to achieve alignment. If using diagnostic lenses, start with 200 microns and increase this amount as necessary. If scleral toricity is asymmetric, then a quadrant-specific landing zone will be necessary to achieve alignment. Focal areas of landing zone adjustment – including a localized vault or a notch - can be necessary in eyes with significant scleral obstacles, such as pingueculae or conjunctival blebs. (Figures 56-63)



56. A microvault with a 17mm diameter lens (contributed by Dr. Tom Arnold)



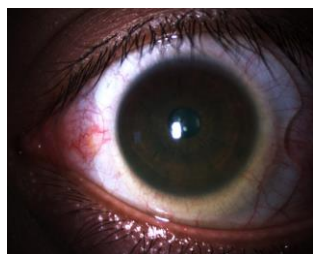
57. Demonstration of a scleral lens with a notch (contributed by Dr. Matt Kauffman)



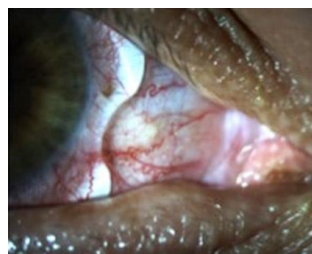
58. and 59. Elevated conjunctiva with spherical lens (58) and with a notch (59) (contributed by Dr. Pam Satjawatcharaphong)



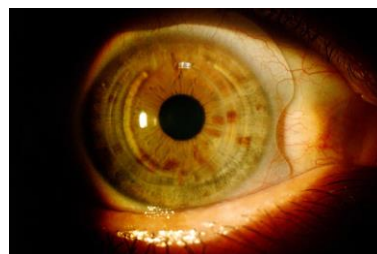
60. Notch application in a patient with a history of glaucoma and a corneal transplant (contributed by Dr. Matt Kauffman)



61. Notch application for a patient with a pinguecula (contributed by Dr. Pam Satjawatcharaphong)



62. Use of a notch with patient with elevated conjunctiva (contributed by Dr. Melissa Barnett)



63. Notch application for a keratoconic/Intacs patient with a pinguecula (contributed by Dr. Melanie Frogozo)

6. When would a front toric lens be indicated? (Greg DeNaeyer, OD)

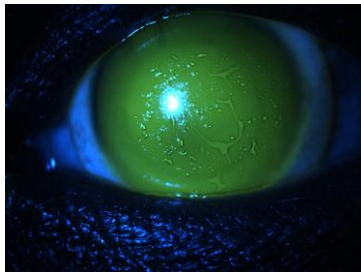
Front surface toricity should be prescribed for residual astigmatism. The lens will be ballasted by either double slab-off prism or back surface toricity so that it maintains rotational stability. For cases where a patient will be wearing glasses in conjunction with a scleral lens, then you could add the residual astigmatic correction to the glasses prescription rather than the scleral lens. Some keratoconus patients fit with a scleral lens will subjectively manifest residual astigmatism with over-refraction that is helping mask residual coma rather than astigmatism. In this case, adding the front surface toricity is rarely helpful. Lens flexure can induce residual astigmatism. This can be observed by taking a topography over a fit scleral lens. Alignment of the haptic zone to the scleral surface will eliminate this issue.

III. PROBLEM-SOLVING

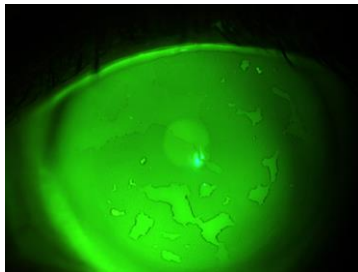
1. What are common causes of reduced vision with scleral lenses? (Muriel Schornack, OD)

a. Front surface deposits

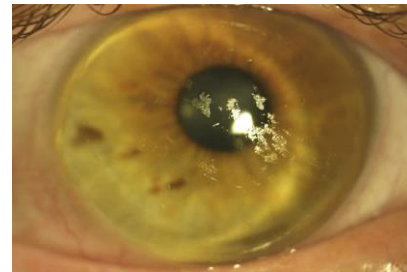
Causes. There are many conditions that may cause poor anterior surface wettability. (Figures 64-69) These include poor tear chemistry, especially in patients with severe dry eyes from conditions such as GVHD, SJS, severe Meibomian Gland Dysfunction (MGD), blepharitis, rosacea and atopic conditions. In addition, oily substances may enter the tear film, or solutions that are not compatible with the lens material may contribute to poor surface wettability.



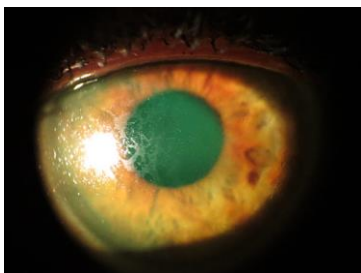
64. Lens surface nonwetting
(contributed by Dr. Pam Satjawatcharaphong)



65. Poor surface wettability
(contributed by Dr. Stephanie Woo)



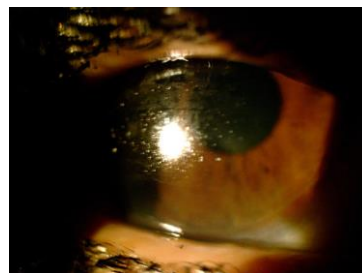
66. Localized areas of poor surface wettability
(contributed by Dr. Maria Walker)



67. Lens surface deposits
(contributed by Dr. Stephanie Woo)



68. Lens surface filming
(contributed by Dr. Maria Walker)



69. Lens surface film
(contributed by Dr. Melanie Frogozo)

Treatment. Managing patient expectations: if a patient is wearing a scleral lens to protect the cornea because they have poor-quality tear film, we're basically trading one dry surface for another. These patients may need to remove the lens several times daily for cleaning and

conditioning. We also need to recognize that we need to use materials with very high oxygen permeability (Dk) values for scleral lenses. These materials tend to be more hydrophobic (and lipophilic): not a great combination for these patients. Aggressive treatment of ocular surface disease is imperative. There are a variety of options to manage front surface debris depending on the cause. Fogging may be due to oil-based lotions, makeup, and soaps. Ask patients about hand soap and change soap to contact lens hand soap or acne treatment hand soap. Recommendations include the following.

- i. Remove the lens and clean with an extra-strength cleaner.
- ii. Consider plasma treatment or retreatment of lens.
- iii. Treat ocular surface disease aggressively.
- iv. Apply makeup, facial moisturizers, etc. after lenses are inserted.
- v. Manually polish the surface with an approved gas permeable polishing solution.
- vi. Moisten a cotton swab or removal plunger with solution and clean the surface on-eye.

b. Flexure

How is lens flexure diagnosed and managed? Sphero-cylindrical over-refraction is step one. If unexpected cylinder is found, measure keratometry or topography over the lens. If either show cylinder that matches over-refractive cylinder with a spherical scleral lens, it is likely that the lens is flexing. Incorporating toricity in the lens flange or increasing flange thickness may reduce flexure.

2. What are the causes and management of tear reservoir debris? (Muriel Schornack, OD and Melissa Barnett, OD)

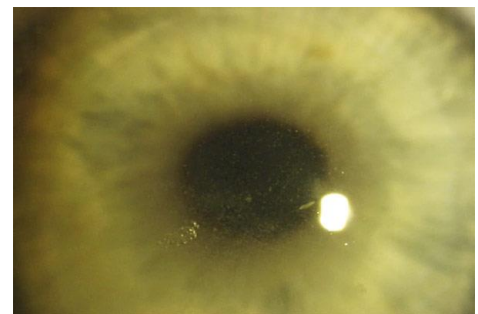
a. Tear reservoir debris is a relatively common problem, often resulting in patient symptoms of midday fogging of vision.

(Schornack MM, et al, 2020; Pucker AD, 2019; Skidmore KD, 2019) (Figures 70, 71)

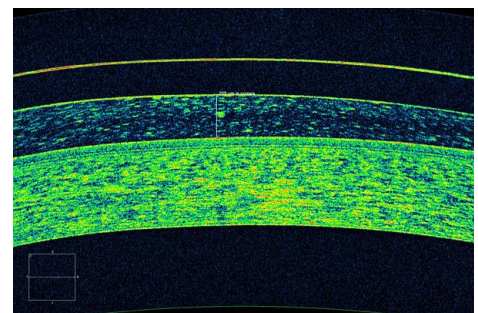
Several theories have been proposed, none have been definitively proven as of yet, although there was a study that analyzed lipid composition of post-lens fluid in high-debris compared to low-debris patients. (Walker, 2014) The high-debris patients had **higher lipid concentrations**. These include the following:

Theory #1: Poor edge design or inadequate landing zone / lens edge alignment allows for uptake of debris from the tear film into the post-lens fluid reservoir. Debris gets in, but cannot get out, thus collecting over time.

Theory #2: Corneal epithelial cells turn over relatively rapidly. When a scleral lens is in place, those cells are released from the ocular surface, but become entrapped behind the lens. This may be more pronounced if the patient is using a solution that is incompatible with their ocular surface to fill the bowl of the lens prior to application.



70. Mid-day fogging resulting from tear reservoir debris (contributed by Dr. Maria Walker)



71. OCT image of debris in the tear film (contributed by Dr. Tom Arnold)

A recent study by Schornack et al (2020) found no association between mid-day fogging and lens diameter, haptic design, or care products. However, the study did report that patients who reported redness before, during, or after scleral lens wear were also more likely to report mid-day fogging. Walker (2020) has reported increased concentrations of MMP-9 and MMP-10 in the fluid reservoir following several hours of scleral lens wear. Findings from these two studies suggest that inflammation may play a role in the development of mid-day fogging.

It is likely that the origins of this phenomenon are multifactorial and may be specific to individual patients. Additional research in this area will hopefully illuminate not only the cause of this phenomenon but will also identify strategies which may mitigate patient symptoms due to mid-day fogging.

b. Bubbles in the tear reservoir.

Scleral lens discomfort may be a result of **bubbles trapped in the lens fluid reservoir**. There are a variety of sources that cause bubbles to occur. Bubbles may be caused by incorrect application techniques or if an aerated solution is used to fill the bowl of the scleral lens.

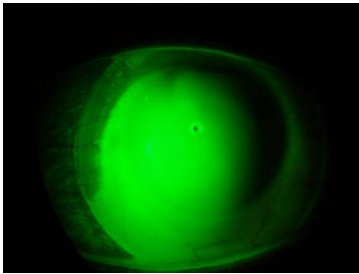
The training and re-training of scleral lens application is critical. If an insertion bubble occurs, it is important to remove and reinsert the lens. If the lens is not removed, corneal desiccation can occur. If the scleral lens landing zone has misalignment, bubbles may result. Edge lift in one or more quadrants or a lens with excessive movement may allow bubbles to enter. In these scenarios, revision of the fit is required.

Other management methods:

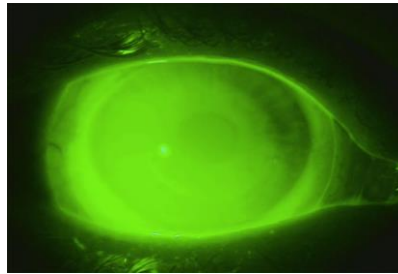
1. Sometimes patients need to remove and refresh the lens in order to eliminate debris in the reservoir. Additionally, patients may use a more viscous solution in the bowl of the lens with lens application.
2. Modifying the scleral lens fit may be needed to reduce symptoms of mid-day fogging. Altering haptic design or changing sagittal depth or lens diameter may all be options to manage reservoir debris.
- 3) Aggressively managing pre-existent ocular surface disease may also reduce the likelihood of mid-day fogging.
- 4) Modifying the patient's care regimen (cleaning, disinfection and filling solutions) could also be considered.

3. How important is scleral lens decentration? (Ed Bennett, OD)

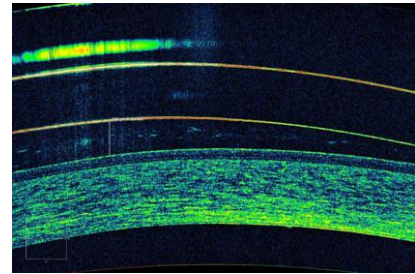
As the nasal sclera is typically more elevated than the temporal sclera it often results in some temporal decentration of the lens. (Caroline, 2013) (Figures 72-74)



72. Inferior-temporal decentration of a scleral lens (contributed by Dr. Pam Satjawatcharaphong)



73. Inferior-temporal decentration of a scleral lens (contributed by Dr. Maria Walker)



74. An OCT image of temporal decentration of a scleral lens (contributed by Dr. Tom Arnold)

In addition, the mass of a scleral lens can also result in some inferior decentration as well. In fact, it has been quantified to be, of average, .62mm temporally and .91mm inferiorly. (Vincent SJ, Collins MJ, 2019) Often this is not a significant problem but can, in some cases, result in a change in the lens-to-cornea fitting relations with a resultant localized area of corneal bearing. Decreasing lens mass and either decreasing lens diameter (which also decreases mass) or adding toric haptics if a larger diameter ($\geq 16\text{mm}$) scleral lens may help provide better centration.

Decentration can result in increased high order aberrations. (DeNaeyer, 2014) Retroillumination photography to identify the center of the scleral lens optics, pupillometry to identify the center of the pupil, and wavefront aberrometry to quantify high order aberrations can assist in the design of a lens with a decentered optical zone.

4. Poor Patient Compliance (Melissa Barnett, OD)

Poor patient compliance may also lead to complications such as extended wear and/or over-wear. In some rare cases, extended wear of scleral lenses is medically necessary; this requires close monitoring and follow-up.

Patient education is key to insure proper compliance. Questions at each visit include average wearing time of scleral lenses, wearing time at the time of the visit, all solutions used, and any additional products.

5. Scleral Lenses and Hypoxia (Langis Michaud, OD)

a. How is scleral lens-induced hypoxia diagnosed?

There are three type of studies published that investigated the occurrence of corneal hypoxia induced by scleral lens wear.

Two articles (Michaud, 2012; Jaynes 2015) were based on a theoretical model, and both confirm that scleral lens wear may induced corneal edema if the lens thickness exceeds 250 μm and if the clearance under its surface is higher than 200 μm . Obviously, because the tear fluid layer is wedge-shaped, this affects the central cornea only.

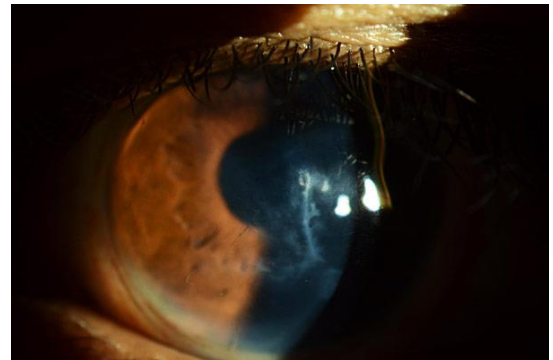
Clinical studies have since been published confirming that scleral lens wear can be associated with an induced corneal swelling varying from 1 to 4% in normal corneas (Compañ 2014, Ng 2015, Miller 2015), in keratoconus (Soeters 2015) and especially in cases where the endothelial cell layer is compromised (Lau 2015, Riff 2015). These studies are based on pachymetry. However, it is not still clear if hypoxia is the only factor involved in corneal swelling during scleral lens wear.

More interestingly, an in vivo study also confirmed a reduction in the oxygen diffusion to the cornea if tear fluid layer thickness increases (Giasson 2015). In this study, authors used the EOP approach and evaluated, directly on the cornea with probes, the oxygen consumption after exposure to several gases (reference curve) and then after wear of scleral lenses fitted with 200 and 400 microns of clearance. Their results are highly significant in that increased clearance reduces oxygen diffusion to the cornea by 30%.

In fact, considering an optimal Equivalent Oxygen Percentage (EOP) level of 9.9% to avoid corneal hypoxia (Benjamin 1988), scleral lenses (18.0 mm in diameter, with an average lens thickness of 310 microns) fitted with 200 μm of clearance lead to an EOP value of 9.0%, while the same lens with 400 microns decreased EOP to 6.2%.

Considering these results, it is now a proven fact that scleral lenses are inducing chronic corneal edema when the lens thickness is higher than 250 μm and when clearance exceeds 200 μm . (Figure 75)

Vincent (2016) suggested that this level of hypoxia may be considered benign, comparable to physiological edema seen after sleeping. If the value is the same (2-4%), this type of comparison cannot be made because physiological edema does not last for more than 1h00 while induced edema remains present for all wearing hours and more, the time for restoration to occur when cornea is exposed to air.



75. Hypoxia induced by a scleral lens
(contributed by Dr. Jeff Sonsino)

At this point, nobody knows what will be the impact of such a chronic corneal edema, especially on compromised tissues. More research is needed to analyse the long-term outcome, but in the meantime, it is recommended to fit scleral lenses with the lowest clearance possible and to manufacture scleral lenses as thin as possible.

It should be noted that hypoxia is not clinically visible before reaching 8-10% level, which is not the case here. Also, edema does not affect the limbal area, clearance over the limbus being limited under 100 μm . Consequently, neovascularization is not triggered. Notwithstanding this absence of visible clinical signs, studies showed that edema occurs with unknown long-term impacts.

There are ways to alleviate this hypoxic stress, especially by designing thinner lenses fitted with less clearance. This could be more easily achieved when using scleral lenses of smaller diameter (<16 mm). Larger lenses (>16 mm) have to be fitted with higher clearance, to be well supported, and made thicker, in part to keep their geometrical stability. They are mainly used to treat ocular surface diseases, where the risk/benefits are positive in light of hypoxic stress.

b. What oxygen transmission (Dk/t) is necessary in a scleral lens to minimize corneal edema?

Referring to Harvitt-Bonnano (1999) criteria, it is 33 for daily wear and 125 for extended-wear. Scleral lenses DK should be evaluated in conjunction with the tear fluid layer, both acting as resistors in series. Sclerals are made of high DK material varying from 100 to 150 Fatt units, and the tear layer is characterized by a DK of 80 Fatt Units. These values are influenced by the thickness of the lens and the thickness of the tear fluid layer (clearance) which reduces the oxygen permeability. To respect Harvitt-Bonnano criteria, scleral lenses should be 250 thick and fitted with 200 μm clearance maximum, if using a DK material of 150 Fatt units.

Oxygen can come from other sources, such as tear exchange and tear mixing. However, it is known that tear exchange is very limited once scleral lenses are settled on the conjunctival surface. Vance (2015) evaluated the rate of exchange at 0.2%/minute. As for tear mixing, it was also proven that it is not contributing significantly to replenish oxygen under the scleral lenses.

6. What causes bulbar conjunctival redness and how should it be managed? (Langis Michaud, OD)

Bulbar conjunctival redness may come from different sources (Figure 76):

- Infection
- Mechanical trauma /irritation /Blood vessels compression
- Inflammation

Infection. The first article published in a peer-reviewed journal about scleral lenses dates back to 1946 (Carlson, 1946). Since then, 219 other contributions have been published, increasing knowledge about scleral lens wear (Pud Med Search¹).



76. Localized conjunctival vessel congestion with scleral lens wear (contributed by Dr. Tom Arnold)

Among these, only ten relate to adverse events such as acute red eye, microbial keratitis, and complications after post-surgery fittings. Specifically, microbial keratitis was related to extended wear, non-compliance, or an eye with severe ocular surface disease (Zimmerman, 2014; Fernandes, 2013, Walker, 2015). Patients that are immunosuppressed can also be more at risk than others.

The overall safety of the devices was also assessed in eight review papers, which reported no significant negative impacts from scleral lens usage. Of these published articles, 133 described the successful use of scleral lenses fitted on irregular corneas to improve ocular surface, including 14 retrospective studies.

Mechanical trauma/Irritation/Compression. It is now known that the sclera is a non-symmetrical rotational toric surface. At 15 mm, sclera displays, in average around 1.5 D of toricity, which increases up to 5D at 18 mm of chord length. (Van der Worp, 2010).

¹ Pub Med Search with the keywords scleral, scleral contact lenses, fluid-ventilated contact lenses, and PROSE between Jan 20 and Jan 24, 2016.

Scleral lenses designed with spherical haptics will display meridional lens misalignment, leading to impingement in some quadrants. This triggers a compression of the conjunctival tissue and its vasculature when lenses are steeper than the scleral profile. Clinically, this is visible as a blanching of the conjunctiva where the pressure is present.

As a consequence, blood flow is impinged, causing engorgement before and after this area. (Figures 77-83) This becomes visible as redness outside the lens edge and at the margin of the area where the pressure is exercised.

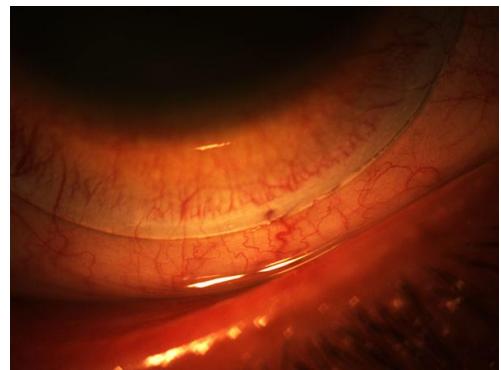
Visser et al (2006) found an increase in wearing time and comfort when designing scleral lenses with toric haptics, offering a better overall alignment with the conjunctiva in every quadrant. Currently, it is highly recommended to design lenses with back-toric peripheral curves for any scleral lens prescribed with a diameter of 16 mm or larger.



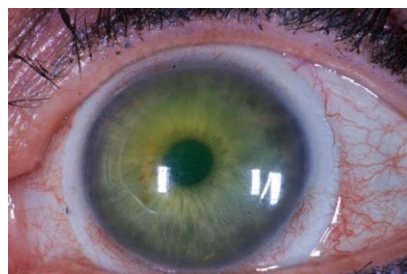
77. Localized impingement of the conjunctival vasculature (contributed by Dr. Tom Arnold)



78. Localized impingement of the conjunctival vasculature (contributed by Dr. Pam Satjawatcharaphong)



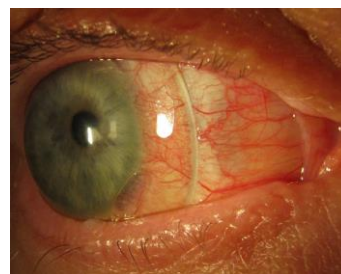
79. Impingement of the conjunctival vasculature (contributed by Dr. Pam Satjawatcharaphong)



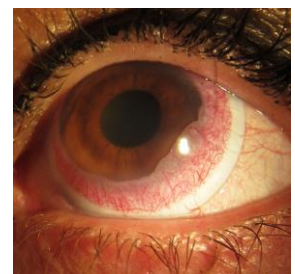
80. Impingement of the conjunctival vasculature (contributed by Dr. Tom Arnold)



81. Impingement of the conjunctival vasculature (contributed by Dr. Stephanie Woo)



82. Moderate impingement of the conjunctival vasculature (contributed by Dr. Greg DeNaeyer)



83. Severe impingement of the conjunctival vasculature (contributed by Dr. Greg DeNaeyer)

Inflammation. Inflammation is not widely cited as a source of adverse events related to scleral lens wear. However, Walker (2015) suggests that it is underestimated and can lead to discontinuation of scleral lens wear. With an increased usage of scleral lenses, inflammation – not related to an infectious event – will probably become more clinically visible.

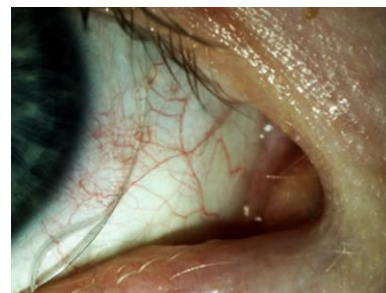
Inflammatory mediators, released from the ocular surface can remain trapped under the scleral lens, which may contribute to raise the inflammatory response. In addition, cellular debris and toxins released from the normal corneal metabolism are also kept trapped under the scleral

lenses, knowing that tear exchange is practically absent once the lens is settled. This could be another triggering factor to initiate inflammatory reaction such as overall redness and sterile corneal infiltrates.

7. If the lens results in persistent awareness/discomfort, what are possible causes and management options? (Langis Michaud, OD)

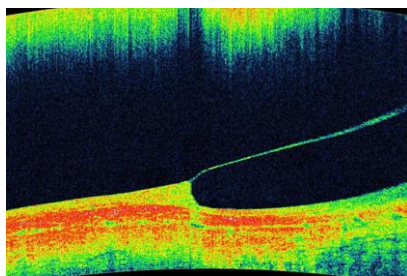
The great majority of the time, lens awareness and discomfort are caused by lens-to-lid interactions, mostly when the lenses are fitted too flat on the conjunctival tissue. At this time, edge stand-off occurs, which raises the level of lens awareness and discomfort. (Figure 84) Every lens being different, practitioner should consult the fitting guide to resolve this issue: by modifying the peripheral curves only, or by altering the overall lens fitting.

One other cause may be the presence of an air bubble trapped under the lens. Due to the tear stagnation under scleral lenses, bubbles are not moving. The cornea under the bubble dries and the patient feels burning and discomfort sensations. Most of the time, these bubbles are due to mishandling, at insertion. Revisiting handling procedures, using more viscous solution to instill in the bowl and/or designing a smaller diameter scleral lens can help.

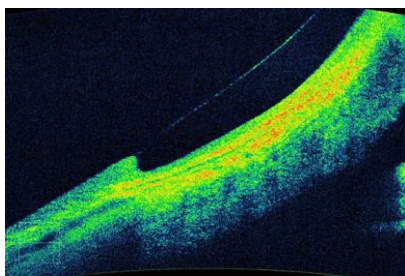


84. Edge standoff with a scleral lens (contributed by Dr. Melissa Barnett)

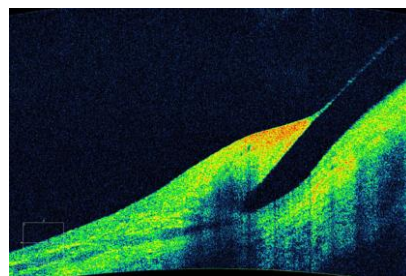
Discomfort can also occur after 4-5 hours of wear. This is called the tight lens syndrome and is triggered by a lens becoming too steep, sealing off the ocular surface after a few hours of wear. (Figures 85, 86) Some conjunctival tissues are smoother and scleral lenses sink in them more. This can contribute to develop a tight lens syndrome. (Figure 87)



85. An OCT image of edge "toeing" or embedded into conjunctiva (contributed by Dr. Tom Arnold)



86. An OCT image of edge "toeing" or embedded into conjunctiva (contributed by Dr. Tom Arnold)



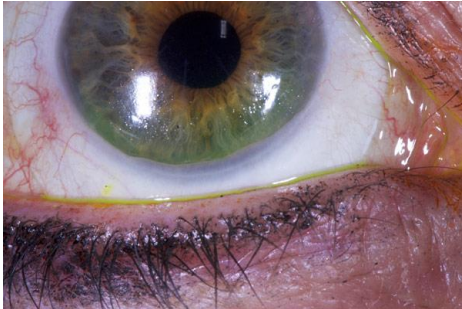
87. Extreme toeing of a scleral lens edge into a boggy conjunctiva (contributed by Dr. Tom Arnold)

To manage this issue, revisiting the fitting is essential: reducing the lens vault and the clearance over the cornea is a first step to do, then flattening the peripheral curves may also help. Going smaller will also help to meet both requirements.

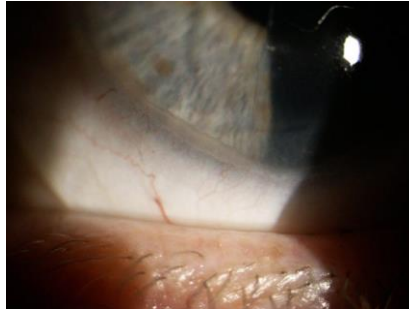
8. What is conjunctival prolapse and how should it be managed in a scleral lens wearer? (Langis Michaud, OD)

Conjunctival prolapse represents an entrapment of the conjunctiva, draping over the cornea, near the limbal region, under a scleral contact lens. (Figures 88-96) It occurs in the inferior quadrant on patients with loose conjunctival tissue (conjunctivochalasis), more so in elderly patients.

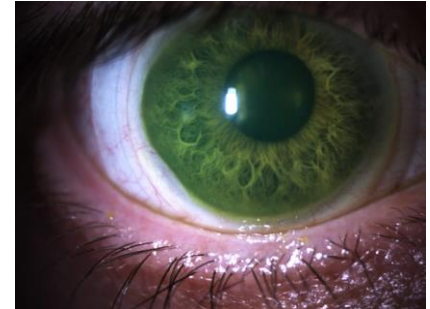
Several conditions should be present to lead to chalasis: large scleral lens, decentered, and fitted with higher clearance over the limbus, and on a patient where the conjunctival tissue is lower than the cornea. This was also associated with pellucid-marginal degeneration due to inferior corneal typical profile. Finally, it was reported that handling the lens, with too much pressure, can increase the risk of inducing prolapse. (Miller, 2015).



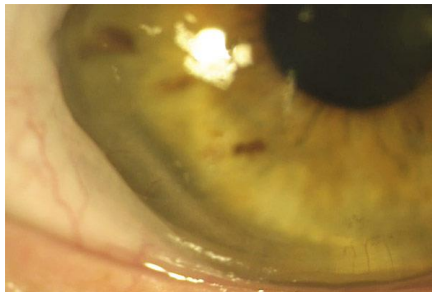
88. Mild inferior conjunctival prolapse (contributed by Dr. Tom Arnold)



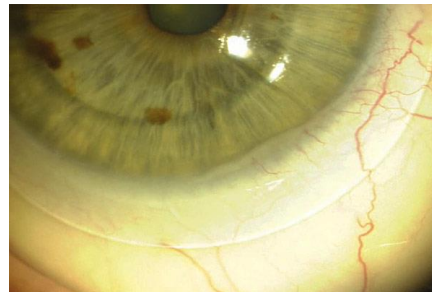
89. Mild conjunctival prolapse (contributed by Dr. Tom Arnold)



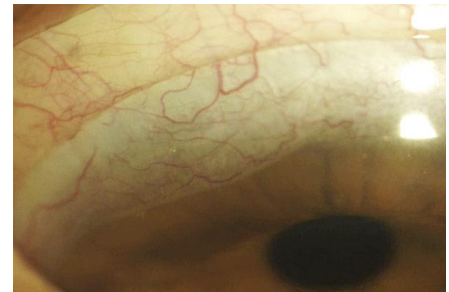
90. Mild conjunctival prolapse (contributed by Dr. Pam Satjawatcharaphong)



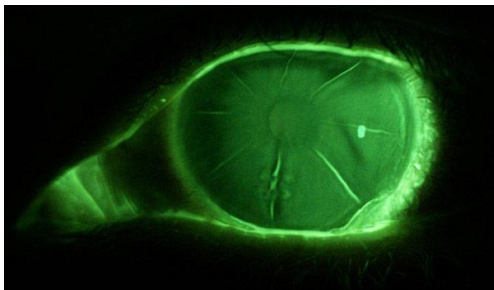
91. Mild conjunctival prolapse (contributed by Dr. Maria Walker)



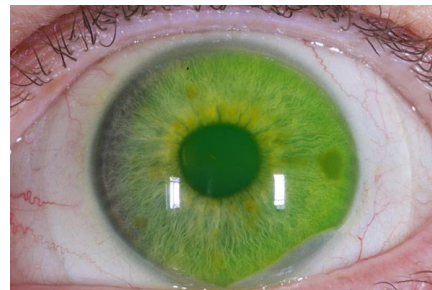
92. Mild conjunctival prolapse (contributed by Dr. Maria Walker)



93. Superior conjunctival prolapse (contributed by Dr. Maria Walker)



94. Mild conjunctival prolapse in a post radial keratotomy patient (contributed by Dr. Tom Arnold)



95. Moderate conjunctival prolapse (contributed by Dr. Tom Arnold)



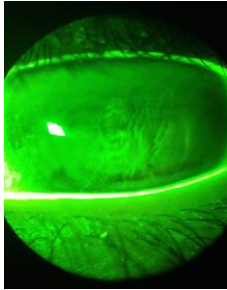
96. Moderate conjunctival prolapse (contributed by Dr. Pam Satjawatcharaphong)

This phenomenon is considered benign, but the real potential for negative outcome in the long term is not known. Considering that the conjunctiva remains draped over the stem cells for many hours, it is probably wiser to alleviate prolapse occurrence. One way to accomplish this is to limit the clearance over the limbus by modifying the peripheral curves or selecting a smaller diameter scleral lens. Handling should be revisited as well.

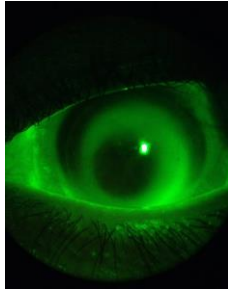
9. What causes corneal staining in a scleral lens wearer? How should it be managed? (Langis Michaud, OD)

As it is the case for other types of contact lenses, staining associated with scleral lens wear can originate from different sources: mechanical, hypoxic, and chemically induced.

Mechanical. Especially for scleral lens beginners, handling lenses could be an issue. Especially with larger lenses, which are more difficult to handle resulting in a corneal erosion, which is visible as a mechanical staining. (Figure 97) Proper lens insertion and removal education should be provided. Compliance to the proper procedures should be reassessed during follow-up visits.



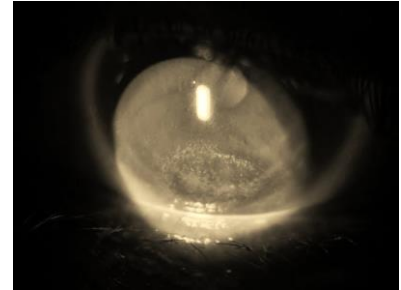
97. Post contact lens wear corneal staining (contributed by Dr. Tom Arnold)



98. Corneal bearing with a scleral lens (contributed by Dr. Tom Arnold)



99. Inferior corneal bearing with a scleral lens (contributed by Dr. Pam Satjawatcharaphong)

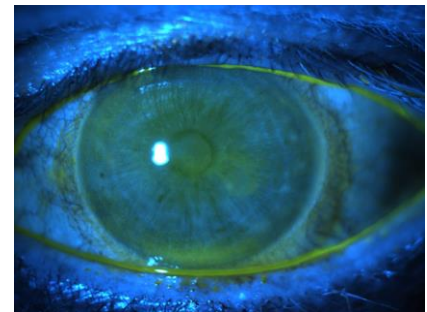


100. Corneal staining resulting from corneal bearing with a scleral lens (contributed by Dr. Pam Satjawatcharaphong)

Mechanical staining can also occur from a lens that results in central/paracentral bearing. (Figures 98-100)

Hypoxic. Microcystic edema can occur if the clearance over the limbus is too high and if there is a fluid layer stasis. This is especially true for patients fitted with high convex scleral lenses.

Chemically induced. This is the primary cause of corneal staining related to scleral lens wear. The use of preserved products to fill the contact lens, before insertion, allows preservative agent to remain in contact with the cornea during all wearing hours. This may initiate a toxic reaction visible as a diffused punctate keratitis. (Figure 101)

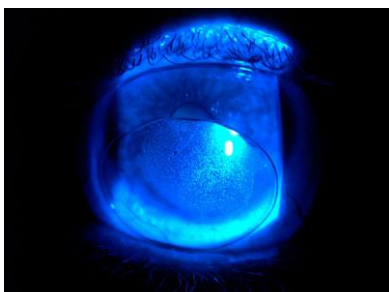


101. Solution toxicity staining with a scleral lens wearer (contributed by Dr. Pam Satjawatcharaphong)

This is a very similar reaction to the one described as SICS in soft lenses (Luensmann, 2012). This can be overturned with the use of non-preserved saline or non-preserved artificial tear solutions.

10. What should be done if you observe air bubbles when evaluating a scleral lens on the eye? (Langis Michaud, OD)

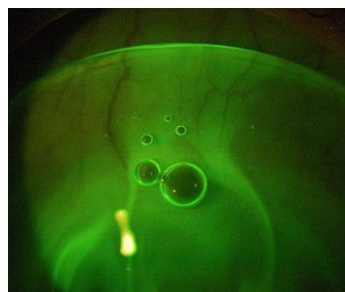
Bubbles come first due to mishandling during insertion. (Figures 102, 103) Some fluid is lost, and then an air bubble comes into play. It can also occur from a misalignment of the lens in one quadrant. (Figure 104)



102. Large bubble resulting from scleral lens insertion (contributed by Dr. Matt Kauffman)



103. Large bubble resulting from scleral lens insertion (contributed by Dr. Matt Kauffman)



104. Peripheral bubble resulting from poor peripheral lens alignment (contributed by Dr. Karen Carrasquillo)

If there is a significant edge stand-off, then a tiny air bubble can be formed under the surface of the lens at every blink. Then the small bubbles gather together and are generating a bigger one.

A spherical lens on a highly toric cornea or scleral can result in peripheral bubbles. Toric haptics can often be beneficial in these cases.

Bubbles can alter visual acuity if they are located centrally. They can also initiate discomfort because the cornea will dry under their surface. This is why bubbles are not tolerable, even if they are small, if they don't move.

Depending on the cause, central bubbles can be eliminated by revisiting handling instructions or by using more viscous solution in the bowl (less likely to spill over during insertion). For those generated by a misalignment, prescribing back-toric haptics can fix the issue.

11. What does a compression ring indicate when a scleral lens is removed? (Langis Michaud, OD)

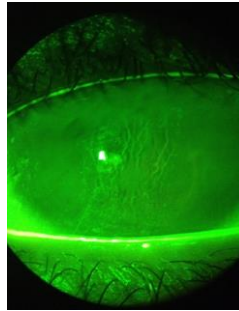
This is a sign of a very tight lens. This can come from a lens vaulting too much over the ocular surface, or a lens with peripheral curves not well aligned with the conjunctival profile.

Ideal clearance over the cornea is 200 um once the lens is stabilized. Then managing the scleral lens fit to achieve this objective can help to alleviate compression. If this is not enough, modifying peripheral curves, by flattening the outer ones, will fix the issue. Flattening the curves without reducing the overall clearance is not recommended, because it will transfer the pressure nearest to the limbus.

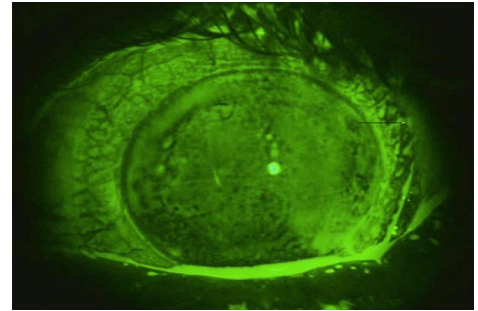
12. What is epithelial bogging and is it significant? (Ed Bennett OD)

According to Caroline and Andre (2015) upon lens removal the ocular surface looks “water-logged” and irregular. (Figures 105, 106)

It could result from constant contact between the corneal epithelium and a sodium chloride inhalation solution that contains no nutrients or electrolytes to benefit the cornea. It is often transient, lasting the first 4 – 6 weeks of lens wear.



105. Epithelial bogging (contributed by Dr. Tom Arnold)



106. Epithelial bogging (contributed by Dr. Maria Walker)

The patient is typically asymptomatic, and epithelial bogging may represent a relatively benign condition, although an argument for the use of a solution with nutrients for the epithelium or the use of a “cocktail approach” in which a non-preserved artificial tear is used in combination with a sodium chloride solution can be made.

IV. CARE AND PATIENT EDUCATION (Daddi Fadel DOPTOM, Mindy Toabe, OD)

1. What solution should I use to fill the bowl of the scleral lens?

A sterile, single dose, non-preservative saline solution is recommended to fill scleral lenses. There are numerous sterile preservative-free saline solutions available with a range in pH and come as either buffered or non-buffered formulations. These solutions are approved by the United States Food and Drug Administration (FDA) for application with scleral lenses.

They can be used to rinse lenses prior to application, remove debris and bacteria after the disinfection process and to rinse lens cases or lenses as needed during the day.

LacriPure (Menicon)- 98 day supply as single use 5 mL ampules

ScleralFil™ (Bausch + Lomb)- 30 day supply as single use in 10mL ampules

Nutrifil (Contamac)- 35 day supply as single use in 10mL ampules

Purilens (The Lifestyle company) is a solution that contains buffers. It is not unit-dose and is available in a 4ml bottle which needs to be replaced every 15 days.

2. What care systems for disinfection and storage can be used with scleral lenses?

Hydrogen peroxide solutions with a concentration of 3% (30,000 ppm) are the first choice for use with scleral lenses. (Harthan J, Nau C, Barr J, et al, 2018; Harthan J, et al, 2019) Hydrogen peroxide care systems need to be neutralized with a platinum catalytic disc to breakdown the hydrogen peroxide into water and oxygen prior to inserting scleral lenses. The platinum disc becomes less effective over time and should be replaced about every 90 days (100 cycles). Hydrogen peroxide solutions neutralize into saline within 4 to 6 hours and do not provide constant disinfection throughout the storage period. (Bergenske, 1994)

Use this disinfection process on a daily basis as case contamination is increased in part-time wear where the solution is not replaced on a regular basis. Scleral lenses should not be stored in

hydrogen peroxide solution for more than one night since the disinfection process is not continuous. This care system works especially well for those patients who are sensitive to chemicals and preservatives in multipurpose solutions.

The level of compliance with hydrogen peroxide is high since it is straightforward. Also, “topping off” hydrogen peroxide solution is not practical. (Dumbleton et al., 2007)

Examples of hydrogen peroxide care systems include: Clear Care® Cleaning and Disinfection Solution (Alcon®), Refine One-Step™ (Coopervision®), Oxysept® Ultracare® Formula (Abbott Medical Optics), and Clear Care® Plus Cleaning and Disinfection Solution (Alcon®).

Multipurpose solutions for rigid gas permeable lenses can also be prescribed for use with scleral lenses. This solution option is convenient and can be used for both cleaning and disinfecting the scleral lens if there is a concern about using a multi-step regimen. Multipurpose solutions should be stored at room temperature and replaced every 28 days after the bottle is opened. (Barnett M, 2020) This care system solution should not be reused in the case and should be changed daily. Scleral lenses should not be stored in saline solution or tap water since these options do not provide disinfection against microorganisms. (Zimmerman A, Marks A, 2014)

3. How do you clean scleral lenses?

Scleral lenses should be cleaned daily by rubbing the lens for a minimum of 15 seconds (Sticca et al., 2017) with a surfactant combined with isopropyl alcohol or an approved MPS solution if Hydra-PEG coating is present. Cleaning a scleral lens in the palm of the hand with a lens cleaner prepares the lens surface for disinfection, kills microorganisms, and helps to remove debris that gets trapped under the lens. Discard cleaning solution bottles every 28 days due to risk of microbial contamination. (Barnett M, 2020)

4 How do you rinse scleral lenses?

Rinse scleral lenses with saline solution, not tap water. It is important not to use tap water to rinse scleral lenses or their storage cases due to the association of acanthamoeba keratitis with tap water use. (Seal DV, et al, 1999) Rinsing the scleral lenses with saline solution to remove the cleaning agent will enhance disinfection and avoid risk of chemical toxicity of the cornea.

5. What type of case can be used to store scleral lenses overnight?

A hydrogen peroxide solution needs either a large disinfection case or two smaller cases (one for each lens). A basket case increases the risk of chipping or breaking a scleral lens when inserting or removing the lens. The baskets should remain closed while inserting the lens into the case for the disinfection process.

A large basket case, the PROSE Disinfection Case, is available from dryeyezone.com. This case does not have a neutralizing disc attached to the bottom of the basket. Thus, a neutralizing disc needs to be taken off of a hydrogen peroxide basket case and placed in the bottom of the PROSE Disinfection Case.

A multipurpose disinfection system maintains disinfection over time and requires a case large enough for the solution to cover the lens completely. (Seal DV, et al, 1999) An option may be the Boston Scleral Lens Case designed to hold lenses up to 23.50 mm in diameter and up to 10.00 mm in sagittal depth.

6. How should a scleral lens case be cleaned and stored during the day?

The most effective way to clean a storage case and remove biofilm is to rub the case, rinse the case using a multipurpose solution or saline solution, wipe the case with a tissue and then air-dry the case face down (multipurpose solution case) or on its side (hydrogen peroxide basket case). (Tilia D, et al, 2014; Vijay A, et al, 2014) This process removes excess moisture and decreases the risk of microbial keratitis and airborne contamination. (Hall BJ, Jones L, 2010; Wu Y, et al, 2015)

Tissue wiping after rinsing the case is crucial. Air drying the cases without tissue wiping will lead to the evaporation of the liquid part of the multipurpose solution while the salt will remain in the case.

Adding additional multipurpose solution in the evening will create a mixture of the salt that remains in the case with the multipurpose solution potentially altering the osmolarity of the multipurpose solution, from isotonic to hypertonic. (Fadel & Toabe, 2018; Fadel & Toabe, 2020) A hypertonic solution may increase survival of *Staphylococcus aureus*. (Cho & Boost, 2009)

Placing a case on a clean tissue prevents the case from coming into contact with a contaminated surface. Lens cases should not be stored in the bathroom or near the toilet to reduce contamination.

7. What is the importance of washing hands prior to lens care?

Washing hands with soap and water rather than just water or not at all decreases the risk of contamination while using a dirty towel will increase the chances of infection. Hands should be dried completely using a clean towel to avoid spreading contamination to the scleral lens.

Mechanical friction of the hands or in the storage case does remove contaminants; however rubbing the case without washing hands with soap and water causes increased contamination compared to not rubbing lens cases because dirty fingers can transfer contaminants. (Wu Y, et al, 2015)

8. How often should a scleral lens case be replaced?

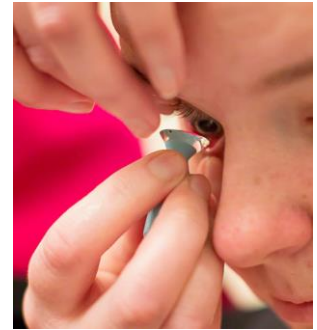
To decrease microbial contamination and biofilm formation, eliminate tap water use and discard cases on a monthly basis. The FDA recommends replacing cases and solutions every 90 days. (www.fda.gov) A report showed that case replacement every two weeks significantly reduces the incidence of microbial contamination. (Szczotka-Flynn et al., 2009) Therefore, it is suggested to replace the lens case often or every time a new bottle is used. (Fadel & Toabe 2018).

9. What devices are available to apply a scleral lens?

Insertion devices used with scleral lens include large plungers. The DMV scleral cup is a large plunger with a hole in the center to limit suction to the lens. (Figure 107) A DMV vented scleral cup, with a hole on the top and bottom of the plunger, is also available, and is used to limit suction completely.

Both plunger designs can be used with a scleral lens for insertion although the DMV vented scleral design may be easier for insertion since it alleviates suction allowing for a smoother insertion process. Pinching the plunger at the junction between the cup and the handle will remove the plunger from the scleral lens in the event of the plunger remaining on the scleral lens upon insertion.

A small plunger can be used for insertion but does require balancing the lens on the small plunger as well as pinching the plunger from the scleral lens upon completion of insertion.



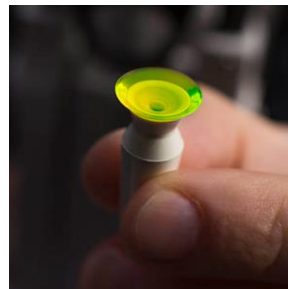
107. Large plunger used for inserting a scleral lens (contributed by Dr. Karen Carrasquillo)

10. What techniques are available for applying a scleral lens?

There are two methods for scleral lens insertion: the manual approach and the application method using an application accessory.

The manual techniques consist of using two or three fingers. With the two-finger approach, the lens is placed on the index and middle of the dominant hand, which serves as a support. With the three-finger approach, the thumb, index, and middle fingers of the dominant hand are used to create a stand for scleral lens application.

With the accessory method, an application accessory, or DMV, Scleral Cup is prepared by wetting the DMV Scleral Cup's surface with one to two drops of sterile non-preserved saline solution. Hold the outside edge of the lens and place it on the application accessory.



108. A plunger filled to the top with saline and fluorescein dye (contributed by Dr. Jeff Sonsino)



109. A plunger slightly overflowed with saline with fluorescein dye (contributed by Dr. Stephanie Woo)

The lens is then overfilled with sterile non-preserved saline solution appearing convex above the lens. If this is being performed in-office, a fluorescein strip should be dipped into the saline such that the fluorescein pattern can then be observed. (Figures 108, 109)

The eyelids are held open with the non-dominant hand. As the solution touches the eye, the lens is applied gently. The eyelids are released once the lens is on the eye.

11. Should inspection of the lens be performed after lens application?

Look in the mirror after applying the scleral lens and inspect the eye for air bubbles that could cause discomfort and decrease vision. The use of the phone torch or a LED light, combined with a magnified lens, may be helpful to check for air bubbles. An air bubble creates a dry area underneath the lens and can cause corneal desiccation over time.

Air bubbles may appear upon application if the head pulls back and is not parallel to the ground causing the lens to tilt upon application and allowing air between the solution and the eyeball. If an air bubble is present, the lens should be removed and reapplied.

12. What are some clinical pearls to ensure patient success when applying a scleral lens?

It is advised to sit in a chair, lean forward with the chin towards the chest and the head parallel to the ground. The eyes should face a mirror on the table covered with a clean towel. The eyelids are held wide open with the pointer finger on the upper eyelid and middle finger or thumb on the lower eyelid using the non-dominant hand. While holding the eye open, the lens is applied straight up onto the eye.

Overfill the bowl of the lens with sterile non-preserved saline so that the saline appears as a convex or round surface above the lens. Look straight down toward the mirror on the table or look at the plunger or the black hole of the plunger while applying the lens. If needed, the other eye is closed. If using a large plunger without a hole, the plunger is gently squeezed in order to release suction.

It is necessary to feel the liquid, push a little more, than close the eye around the DMV Scleral Cup before pulling it away from the eyelids. Keep looking down and allow the lens to settle before looking around.

13. What is recommended when a patient experiences difficulty with scleral lens application?

During application, the lens may touch the lid and decenter on the plunger or the fingers requiring the patient to reposition the lens. If a lens is not centered on the plunger initially, air bubbles may enter under the lens.

Lid control is key to successful lens application. Hold the lids open with one hand and don't let go of the lids until the DMV plunger has been removed from the scleral lens. Keep your face parallel to the floor as the lens is applied to the eye. This position will help to maintain the fluid in the bowl of the lens so that air does not get underneath the then during application.

There are other non-approved, non-preserved single use options available to fill scleral lenses. A more viscous artificial tear such as carmellose sodium (Preservative Free Refresh® Celluvisc® Lubricant Eye Gel by Allergan) or carboxymethylcellulose sodium (Refresh Optive Preservative-Free Lubricant Eye Drops from Allergan) may be used in combination (50/50) with non-preserved 0.9% sodium chloride inhalation solution or may be used alone. The increased thickness of the combination solution prevents debris from migrating underneath the lens. The combination solutions also help increase comfort, prevent loss of fluid with scleral lens application and avoid air bubbles.

14. What accessories are available to remove a scleral lens?

The most efficient tool for the removal of scleral lenses is a removal device, the DMV Ultra Contact Lens Remover. This is a small plunger with suction capabilities to hold on to the large lens during the removal process. The DMV Classic can also be used for removal. The DMV 45 angled lens remover is angled at 45 degrees to eliminate the hand from interfering with vision during scleral lens removal with a mirror. The Royal Removal (Amcon The Eye Care Supply Center®) is a rubber-free plunger which may be helpful for patients who have latex sensitivity. (Figure 110) The Magic Touch (Amcon The Eye Care Supply Center®) Vented Inserter/Remover is angled at 20 degrees with a hollow shaft. Suction may be controlled by squeezing the handle. (Figure 111)



110./111. Top: Amcon Royal Removal. Bottom: Amcon Magic Touch Vented inserter/remover.

15. What techniques are available for removing a scleral lens?

Removal of a scleral lens can be performed with the manual two finger method or with a removal accessory such as the DMV Ultra Contact Lens Remover, a small plunger.

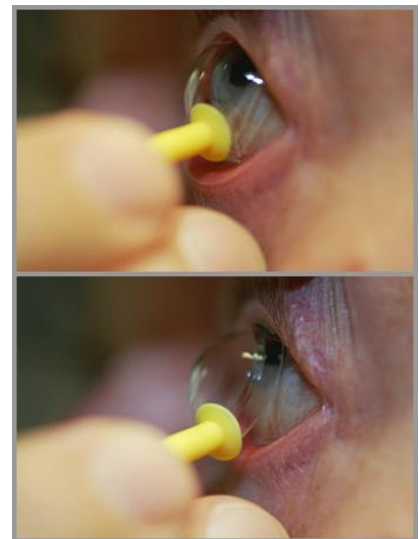
With the manual two-finger method, look down, then move the lower eyelid outward while applying mild pressure to eyeball. Next, the lower eyelid is gently pushed with the index finger underneath the lower edge of the lens and the lens is removed.

With the DMV Ultra Contact Lens Remover, hold the eye open and apply the small plunger to the lens in the peripheral inferior or superior quadrant, not in the center of the lens. The lens is removed by releasing suction of the lens on the eye with the removal accessory. (Figures 112, 113)

16. What are some clinical pearls to ensure patient success in removing a scleral lens?

Sit in a chair and place a clean towel on a flat table prior to scleral lens removal. Place a make-up mirror on the table and look into the mirror while removing the lens. Wet the surface of the plunger with one to two drops of sterile non-preserved saline solution. Prepare the eye with preservative-free saline or artificial tears to wet the eye and loosen the lens prior to scleral lens removal.

Pressing just below the lens at the edge of the lens with the DMV Ultra Contact Lens Remover may be helpful in breaking the seal of the lens allowing for a bubble to form under the lens to loosen the lens prior to removal. A further tip for an easier lens removal, is to identify an area where the lens is slightly lifted off of the conjunctiva and place the removal accessory in that area.



112./113. Lens removal with a suction cup (contributed by Dr. Melissa Barnett) Top: Proper placement of suction cup on the inferior region of the lens. Bottom: Lift down and out to remove lens.

17. How are application and removal devices for scleral lenses disinfected?

Application and removal accessories, also known as plungers, should be disinfected with alcohol after each use and then allowed to air dry. Cleaning is critical as an old device can become cracked, leave residue on the lens surface, and not provide good suction on the scleral lens. The Boston Foundation for Sight recommends that application and removal accessories should be replaced every 6-12 months, or sooner if the edges become rough, uneven, or if suction is not sufficient. Application and removal accessories may not be readily obtainable at the local pharmacy. An on-line resource for the accessories is the dryeyeshop.com.

18. Where can I find useful tools for scleral lens handling?

a. See Green Lens Inserter

The See Green Lens Inserter by Dalsey Adaptives (<http://dalseyadaptives.net/store/>), is available both with and without The See-Green[®]™ System Light & Stand. (Figure 114) The lighted plunger helps center the device for application. The stand holds the plunger and lens in place prior to application. This is helpful for patients who have unsteady hands or for those who need both hands to hold their eyelids open.



114. Lens insertion with the use of the Green Lens Inserter from Dalsey Adaptives (contributed by Dr. Karen Carrasquillo)



115. Lens insertion with the EZi Scleral Lens Applicator by Q-Case, Inc. (contributed by Dr. Jeff Sonsino)

b. EZi Scleral Lens Applicator

Another tool is the EZi Scleral Lens Applicator by Q-Case Inc. (<http://ezibyqcase.com/>). (Figure 115) This accessory is placed on the finger like a ring and has a base for scleral lens application. This design provides stability and allows patients to apply scleral lenses with one finger.

c. Chio Contact Lens Remover Tool

This device has a detachable plunger that can be placed in the application or removal position as needed. Holding the device with the dominant hand, place the end of the device on the tip of the index finger. After lens removal, press the quick release button to free the lens from the plunger. (www.cliaraeye.com) (Figure 116)



116. Chio Smart Contact Lens Inserter and Remover from Cliara Eyes



117. Patient using an "O" Ring device (contributed by Dr. Daddi Fadel)

d. Number 8 "O" Ring

A third option is a #8 O ring that is available at any hardware store. O ring dimensions are $\frac{3}{8}$ " x $\frac{9}{16}$ " x $\frac{3}{32}$ ". The scleral lens rests on the O ring on a patient's finger, which can allow for stable application.

d. Orthodontic Ring

An additional option for scleral lens application is a sterile orthodontic ring placed on a patient's hand. These come in packages of 100 and may be used for single use application of scleral lenses.



118. Upside down coffee cup used as a plunger stand (contributed by Dr. Daddi Fadel)



119. Cups used as stands (contributed by Dr. Daddi Fadel)



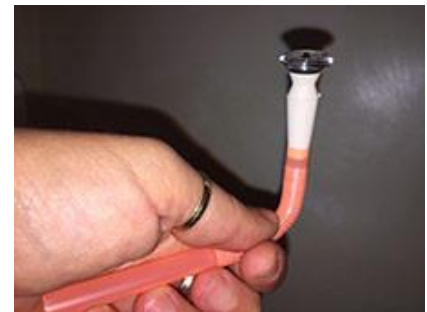
120. A color pen used as stand (contributed by Dr. Daddi Fadel)



121. Large bend plastic drinking straw to stabilize and extend plunger (contributed by Dr. Daddi Fadel)



122. Thin bend plastic drinking straw to stabilize and extend plunger (contributed by Dr. Daddi Fadel)



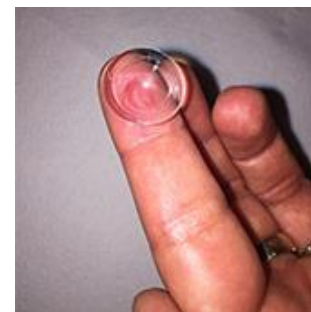
123. Vented plunger on the bent plastic drinking straw (contributed by Dr. Daddi Fadel)



124. Bottle used to create an indentation on the finger (contributed by Dr. Daddi Fadel)



125. Indentation on the finger (contributed by Dr. Daddi Fadel)



126. Indentation to stabilize the lens on the finger (contributed by Dr. Daddi Fadel)

In-Office Disinfection of Multi-Patient Use Diagnostic Contact Lenses

Gas permeable

- 1 Place 3% hydrogen peroxide with GP lens in a non-neutralizing case.
- 2 Disinfect lens for 3+ hours.
- 3 Rinse GP lens with Multipurpose Solution (MPS). Pat dry, store dry.

- Multipurpose solutions are acceptable for rinsing.
- ISO recommends this process every 28 days for soft or hybrid diagnostic lenses if they have been opened and not re-used and subsequently re-disinfected in that time period.

These methods have been approved by the American Academy of Optometry Section on Cornea, Contact Lenses and Refractive Technologies and The American Optometric Association, Contact Lens & Cornea Section adapted from the Standard of the International Organization for Standardization (ISO); ISO 19979:2018(E).

Created by Angelica Polizzi, 2020 OD candidate.

Hybrid and Soft

- 1 Place 3% hydrogen peroxide with soft or hybrid lens in non-neutralizing case for 3+ hours.
- 2 Transfer soft or hybrid lens to a neutralizing case. Fill with fresh 3% hydrogen peroxide. Add neutralizing disc or tablet as recommended by manufacturer.
- 3 Neutralize lens for 6+ hours, or as directed by manufacturer.
- 4 Rinse soft or hybrid lens with MPS. Store in a disinfected case with MPS.

V. RESOURCES (Pam Satjawatcharaphong, OD)

1. Where can I go for resources to help with scleral lens education?

There are many resources – notably available from the GP Lens Institute and the Scleral Lens Education Society - that provide general scleral lens education in the form of case reports, webinars, publications, lectures, and workshops. Numerous resources can be found online from the sites listed below:

- Scleral Lens Education Society (SLS): <http://www.sclerallens.org>
- Gas Permeable Lens Institute (GPLI): <http://www.gpli.info/scleral-lenses>
- Contact Lens Manufacturers Association (CLMA): <http://www.clma.net>
- A Guide to Scleral Lens Fitting, 2nd edition, by Eef van der Worp: <http://commons.pacificu.edu/mono/10>
- Clinical Guide for Scleral Lens Success by Melissa Barnett and Daddi Fadel: <https://www.scleralsuccess.com/>
- Michigan College of Optometry Scleral Lens Fit Scales: <http://www.ferris.edu/ScleralLensFitScales>
- The Summit of Specialty Contact Lenses Scleral Lens Webinar Series (www.thesummit-ssc.com)

2. How can the laboratory consultant help with scleral lenses?

- a. Benefits of a consultant. The consultants from each laboratory understand scleral lens fitting concepts well and are particularly well-versed in their own designs. They can be very helpful resources when it comes to selecting the appropriate initial diagnostic lens based on individual patient needs, as well as troubleshooting difficult fits. Consultants may also have recommendations for appropriate lens materials and solutions to optimize patient comfort and vision with scleral lenses.

What information should I provide to the laboratory consultant to optimize success with scleral lenses? Scleral lenses can be successfully fit in office using a diagnostic lens set and slit lamp examination, and verbal descriptions of the fit are often sufficient for laboratory consultants to help with decisions regarding parameter changes. However, if your office has a corneal topographer, anterior segment OCT, or slit lamp camera (including adaptors for smart phones), this additional information may also be helpful to provide to a consultant.

- b. Options for scleral imaging/molding techniques that may allow for more successful empirical lens ordering in the future.
- Visionary Optics sMap 3D: <http://www.visionary-optics.com/products/smap3d>
 - Eaglet-Eye Eye Surface Profiler: <http://eaglet-eye.com/eye-surface-profiler-now-on-sale>
 - EyePrintPro: www.eyeprintpro.com

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