CHAPTER 15

SCLERAL LENSES

Early "scleral shells" ranged from 19 to 21 mm in diameter and were made of blown or ground glass. These devices did not achieve widespread acceptance, due to severe the corneal hypoxia they induced, as well as the challenges of lens manufacturing [294, 295]. The development of impression moulding techniques and materials in the 1930s led to an increase in interest in scleral contact lenses, both for management of ocular disease, and for correction of refractive error [296]. However, interest waned in the mid-1900s, mainly because other contact lens designs became more widely available in polymethylmethacrylate (PMMA), gas permeable and hydrogel materials. Although scleral lenses were largely supplanted by these newer corneal contact lenses as well as hydrogel lenses throughout the 1970' and 1980's, they continued to be prescribed as therapeutic devices [297, 298]. One reason RGP scleral lenses did not gain widespread use by clinicians was due to the lack of the commercial availability of large diameter lens buttons of RGP materials. Technological limitations, in corneal imaging systems and contact lens lathes available at the time, also challenged early scleral lens design and development [297]. Availability of RGP scleral lenses has now expanded dramatically. A few RGP materials, including Boston XO, XO^2 and Equalens II (Bausch and Lomb, Rochester, NY), Optimum Extra (Contamac, Grand Junction, CO), Tyro-97 (Lagado Corporation, Engelwood, CO) and Paragon HDS (Paragon Vision Sciences, Mesa, AZ) are now available in large-diameter buttons. Improvements in our ability to assess the contour of the entire corneal and scleral surface facilitate the design of large-diameter lenses. Computer-driven lathes can now accurately produce large-diameter lenses to precise specifications [297].

TERMINOLOGY

The Scleral Lens Education Society (SLS), recently recommended internationally recognised nomenclature for describing scleral lenses according to size and fit characteristics. The recommendations of the SLS are based on the lens' resting point on the ocular surface, not on lens diameter. Simply put, if a rigid gas permeable (RGP) lens rests completely on the cornea, it is called a corneal lens. A lens that partly rests on the cornea, centrally or peripherally, and partly on the sclera is called a corneo-scleral lens. A lens that rests entirely on the sclera, is a scleral lens, no matter how large that lens is [299].

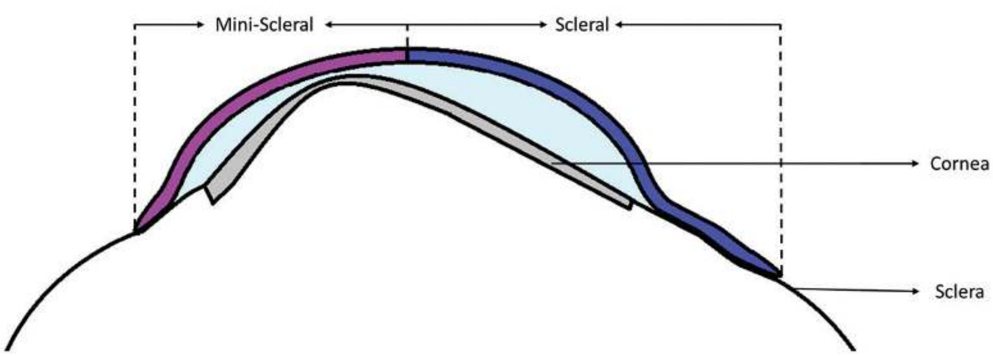
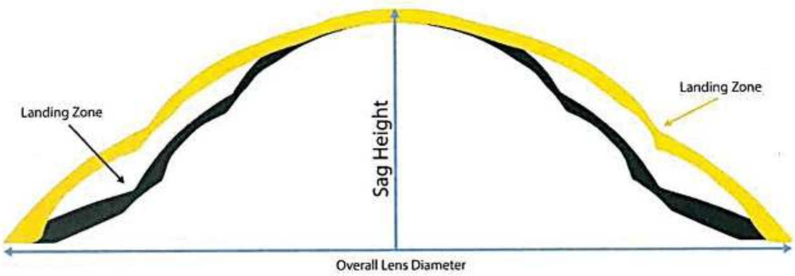


Figure 64: Diagram illustrating the difference between a mini-scleral and scleral lens

ANATOMY OF A SCLERAL CONTACT LENS



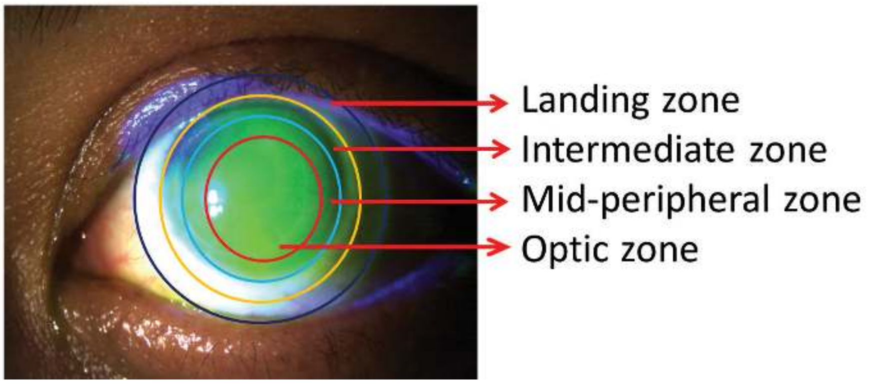


Table 38: Scleral Lens Society Terminology, describing the different lens types [299]

Terminology	Alternative names	Diameter	Bearing	Tear reservoir
Corneal		8.0–12.0 mm	All lens bearing is on the cornea	No tear reservoir
Corneo-scleral	Corneal-limbal Semi-scleral Limbal	12.5–15.0 mm	Lenses share bearing on the cornea and the sclera	Limited tear reservoir capacity
Scleral	Haptic	15.0–25.0 mm Mini-scleral 15.0–18.0 mm Large-scleral 18.0–25.0 mm	All bearing is on the sclera	Mini-scleral, somewhat limited tear reservoir capacity Large-scleral, almost unlimited tear reservoir capacity

INDICATIONS FOR SCLERAL LENSES

Scleral lenses can be used to improve vision, to protect the cornea in ocular surface disease, where the tear reservoir between the lens and the eye is beneficial, for corneal ectasia whether iatrogenic or from corneal disease, and for cosmetic purposes [15]. The following list gives some indications [297]:

- Ocular surface disease
- Stevens–Johnson syndrome
- Chronic graft vs. host disease
- Exposure keratopathy
- Neurotrophic keratopathy
- Cicatrising conjunctivitis
- Persistent epithelial defects
- Sjögren syndrome

- Corneal dystrophy/ degeneration
- Congenital corneal hypoanaesthesia
- Visual rehabilitation/corneal irregularity
- Primary corneal ectasia, keratoconus and pellucid marginal degeneration
- Status post (S/P) penetrating keratoplasty
- S/P refractive surgery
- Corneal scarring
- Correction of refractive error
- Aphakia
- High ametropia (nonaphakic)
- Cosmesis and in several sports including free diving
- RGP intolerance
- Sustained drug delivery to the cornea
- Incomplete lid closure, ectropion, entropion, symblepharon and trichiasis
- Iatrogenic corneal ectasias – LASIK, PRK, LASEK, RK
- RGP intolerance

FITTING PROCESS

Several studies have reported the number of lenses and visits needed to complete the fitting process. This serves as an indication of the complexity of scleral lens fitting. Schornack, 2015 found that fitting could be completed in an average of approximately three visits, and that the process usually requires no more than two lenses per eye [297]. In contrast, Pecego et al., 2012 reported that the fitting process required an average of 6 visits and 3 lenses per eye [300]. Paul Rose and Jennifer Choo, 2013 taught 17 individuals with experience fitting corneal RGP's a 5-step system for fitting corneo-scleral lenses. These practitioners then attempted to fit 120 eyes with scleral lenses. Their success rate was over 75% [301].

Scleral lenses are primarily fitted based on sagittal depth and therefore keratometric readings are of relatively limited use. Two eyes with the same keratometric values can have totally different sagittal heights [15]. Sagittal height is dependent on a number of variables; including lens diameter, radius of curvature, asphericity of the cornea and the shape of the anterior sclera [297, 299, 302, 303]. The inability to measure the anterior sclera up to now made calculation of the sagittal height virtually impossible in clinical practice. However, with advanced topographical technology such as the AS-OCT, Pentacam, and more recently, profilometry [98], the total sagittal height of the anterior eye can be measured and potentially matched by scleral lenses of the same sagittal height [14, 303]. Most clinicians use fitting sets, in which the anterior surface topography can be diagnostically met in a clinically proven, successful way.

5 STEP FITTING SYSTEM [15]

Step 1: Choosing the Overall Lens and Optic Zone Diameter

Total Diameter

The total lens diameter is the first and most basic consideration for eye in the scleral lens fitting process. Larger diameter lenses create larger tear fluid reservoirs. Typically, the more clearance required, the larger the lens diameter should be. This means that for a fragile corneal epithelium, a larger lens may be required to completely clear the cornea. Larger diameter lenses are also typically suggested for large sagittal height differences on the cornea, such as found in corneal ectasia. With bigger lenses, a much larger area of bearing is created in the landing zone, which prevents local areas of excessive pressure and may improve comfort of wear. Mini-scleral lenses may potentially “sink” more into the conjunctiva.

Smaller diameter scleral lenses, such as corneo- or semi-scleral RGP’s, may be easier to handle and hey may not need to be filled with fluid upon lens placement. Fewer air bubbles form under these lenses and they also move more on the eye. Smaller diameter lenses are useful when fitting the “more normally shaped” corneas and for non-compromised eyes. Because, the clearance is smaller than with larger diameter scleral lenses, visual acuity is typically good with these lenses. Another advantage seems to be that smaller diameter lenses tend to avoid problems resulting from the scleral toricity, which increases towards the extra ocular muscle insertions. Large lens diameters may tend to decentre more, typically toward the inferior temporal direction due to the flatter superior nasal shape of the eye.

Optic Zone Diameter

The optical zone is important for the optical outcome. Therefore, it should not interfere with the pupil diameter. When determining optical zone diameter size, decentration of the scleral lens should be taken into account. The size of the optical zone diameter itself depends on the lens design used. It should cover the pupil zone fully to prevent any optical disturbances.

Step 2: Corneal and Limbal Clearance

Corneal Clearance

Corneal clearance is probably the single most important advantage that scleral lenses have over corneal lenses. Up to 600 microns of corneal clearance can be achieved if desired, although this is considered excessive. The preferred terminology in evaluating clearance is an “increase or decrease” in sagittal height – hence, using microns as the main metric. The terms “flat” and “steep” are best avoided when referring to the increase or decrease in clearance. Although, confusingly perhaps – steepening a lens base curve increases the sagittal depth, and flattening a base curve decreases the sagittal depth of a lens.

Sagittal Depth

Theoretical can be mathematically determined using the following formula:

$$S = r - \sqrt{(r^2 - p(d/2)^2)}/p$$

r = corneal or scleral curvature
p = cornea or sclera shape factor ($p = 1 - e^2$)
d = cornea or scleral diameter
e = corneal eccentricity

Using this formula, a typical eye with a HVID of 11.9 mm, radius of curvature of 7.85 mm, an eccentricity of 0.55 and a scleral radius of curvature at a cord of 15.00 mm would have a theoretical ocular sagittal height of 3150 microns. Sagittal height is affected by the following ocular parameters, listed in order of importance) [303]:

- Corneal diameter
- Corneal eccentricity
- Corneal curvature
- Scleral radius
- Scleral eccentricity

Scleral lens sagittal depth is dictated by both corneal and scleral components of the eye as well as the desired amount of apical or corneal clearance.

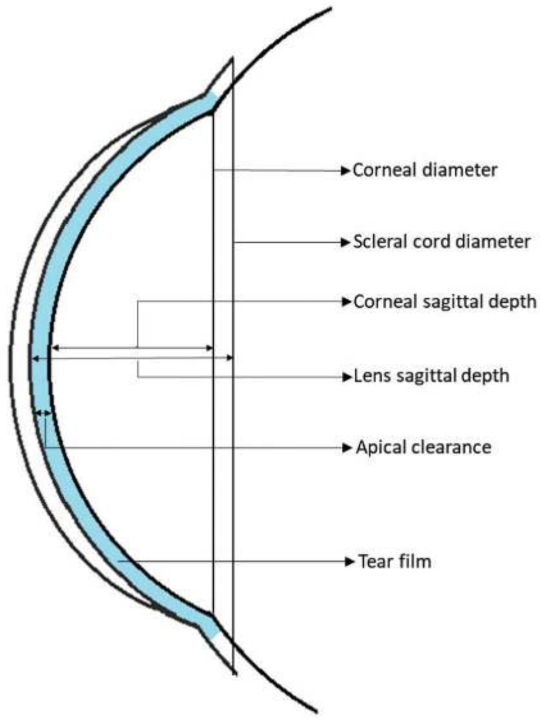


Figure 65: Sagittal depth explained

What is the Ocular Sagittal Depth in Normal and Irregular Eyes?

In a study of 204 normal eyes, Hall et al., 2013 found the mean corneal sag at 3170 ± 200 µm, and the ocular sag at 15 mm 3700 ± 170 µm [304]. Sobara et al., 2010 calculated the ocular sag at 15 mm to be 3740 µm [305]. In a later study, Sobara et al., 2013 looked at keratoconus and "normal" patients and calculated the corneal sag at 3410 compared to 2420 µm in the normal group. They also found that the variation in sag was greater in the keratoconic group than in the normal group (880 vs 90 µm). The study also looked at the ocular sag at 15 mm and found that in the keratoconic it was 3930 compared to 3700 µm in the normal group. Finally, the variation in sag was also greater in the keratoconic compared to the "normal" group (250 vs 160 µm) [306].

The studies by Hall and Sorbara used AS-OCT to measure the corneal sagittal depth at a cord of 15 mm. This technology is expensive and not common in general optometric practice. However, corneal topography systems are commonly used in contact lens practice and these instruments can provide sagittal data. In a study by Wayne Gillan, 2016 the Oculus Keratograph was used to determine corneal sag at a 10 mm cord in keratoconic and normal corneas. He found that the sagittal data compared favourably with those found by other researchers [307]. Several publications suggest that the sag difference between a 15 mm chord and a 10 mm chord is approximately 2000 µm, for both normal and keratoconic corneas [14, 15, 303, 304]. It is therefore, possible to extrapolate the sagittal depth at a 10 mm cord to a cord of 15 mm by adding 2000 µm to get an indication of the ocular sag that can be used to select a trial scleral lens [307].

Trial/diagnostic lens sag = sag at measured cord (normally 10 mm) + adjustment for lens size (normally 2000 µm for 15 mm lens) + desired apical clearance (normally 200–300 µm).

Finally, as a rule of thumb, if the lens is larger than 15 mm the sag can be further increased by 300 µm per mm of lens diameter (30 µm per 0.10 mm).

What is the Correct Amount of Apical or Corneal Clearance?

There are no "rules" for the exact amount of central corneal clearance, but typically a minimum of 100 microns seems desired, although in corneo-scleral lenses there may be much smaller clearances. With full scleral lenses, a clearance of 200–300 microns is usually considered sufficient, but this can go up to 500 microns if desired in exceptional cases with the larger diameter lenses [15, 303, 308]. Mini-scleral lenses are positioned in between corneo-scleral and large-scleral lenses with regard to the level of clearance. For comparison, and as a reference when evaluating the clearance on-eye, the average corneal thickness of a normal eye is in the 530 micron range centrally, with values up to the 650 micron range in the periphery near the limbus [309]. A comparison of the tear lens, lens thickness and corneal thickness is can be used to estimate apical clearance when either the corneal thickness or lens thickness is known (Figure 71). AS-OCT will give exact values in microns of the apical clearance, but these instruments are expensive and may not be available. Manufacturers will usually provide the centre thickness information of their diagnostic lenses, which could serve as a benchmark in evaluating corneal clearance.

The desired sagittal depth differs with the condition – e.g., a keratoconus patient typically needs a larger total sagittal lens height than a normal shaped eye. Adding another 100 microns of clearance or so may prove to be useful in kerataconus eyes, to account for potential progression of the ectasia in the future [303]. In managing ocular surface disease, scleral lens specialists sometimes indicate that larger sagittal heights are preferred to create a full, thick, tear layer between the lens and the cornea. On the other hand, to prevent debris build up and potential fogging, lowering the clearance may be desirable [298].

Oxygen delivery to the cornea is impacted by the scleral lens and the tear lens thickness. The Dk of the tear layer is considered to be around 80 x 10–9 (cmmlO$_2$)/(mlsecmmHg). Michaud et al., 2012 predicted the transmissibility (in Fatt units) of a lens with materials of different Dk values and different apical clearance values [308]. Using their model it is evident that a lens that has a Dk of 100 with an apical clearance of 400 µm and 350 µm thickness is predicted to have a transmissibility of 11.7 Fatt units [308]. Corneal swelling can be predicted for systems with such low transmissibility by using data from a study conducted by Holden and Mertz, 1984. In this specific case, the corneal will likely swell in the region of 11% which is much higher than overnight selling of 4% without lenses [29].

Table 39: The effect of apical clearance and lens DK on oxygen transmissibility [308]

Lens Dk = 100	Clearance in Microns	100	150	200	250	300	350	400
Lens thickness in microns								
250		26.7	22.8	20.0	17.8	16.0	14.5	13.3
300		23.5	20.5	18.2	16.3	14.8	13.5	12.5
350		21.1	18.6	16.7	15.1	13.8	12.7	11.7
400		19.1	17.1	15.4	14.1	12.9	11.9	11.1
450		17.4	15.7	14.3	13.1	12.1	11.3	10.6
500		16.0	15.5	13.3	12.3	11.4	10.6	10.0

Clinical studies, using pachymetry, confirm that scleral lens wear can be associated with an induced corneal swelling varying from 1 to 4% in normal corneas and keratoconic corneas [310, 311]. Swelling is especially prevalent in cases where the endothelial cell layer is compromised [312, 313]. 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 [314]. In this study, Giasson et al., 2017 used the EOP (equivalent oxygen percentage) approach, and evaluated directly on the cornea with probes, the oxygen consumption after exposure to several gases 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 EOP level of 9.9% to avoid corneal hypoxia [33], scleral lenses, 18.0 mm in diameter, with an average lens thickness of 310 microns, fitted with 200 um 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 oedema when the lens thickness is higher than 250 um and when clearance exceeds 200 um [314].

Vincent et al., 2016 conducted a study to examine the change in corneal thickness and posterior curvature after 8 hours of mini-scleral lens wear. The authors concluded that although a small amount of corneal swelling was induced following 8 hours of mini-scleral lens wear (on average <2%), modern high Dk mini-scleral contact lenses that vault the cornea do not induce clinically significant corneal oedema or hypoxic-related posterior corneal curvature changes during short-term wear. They suggested that this level of hypoxia (2 to 4%) may be considered benign and comparable to physiological oedema seen after sleeping [315]. However, this type of comparison cannot be made, because physiological oedema does not last for more than an hour while scleral lens induced oedema remains present for all wearing hours, as well as the time for recovery when cornea is exposed to air. The impact of such chronic corneal oedema, especially on compromised tissues, is not clear and needs further investigation. It is therefore recommended to fit scleral lenses with the lowest clearance possible and to manufacture scleral lenses as thin as possible [316]. It should be noted that hypoxia is not clinically visible before reaching 8–10% level, and that the oedema does not affect the limbal area, clearance over the limbus being limited to <100 um. Consequently, neovascularisation is not triggered. Notwithstanding this absence of visible clinical signs, studies showed that oedema still occurs with unknown long-term impact on the health of the cornea [316].

Hypoxic stress can be minimised by fitting thinner, smaller diameter (<16 mm) lenses to minimise apical clearance. Larger lenses (>16 mm) have higher apical clearance and are thicker to keep their stability. These larger lenses are mainly used to treat ocular surface disease, where the risk/benefits are positive in light of hypoxic stress [316].

What Oxygen Transmission (Dk/T) is Necessary in a Scleral Lens to Minimise Corneal Oedema?

The Harvitt-Bonnano, 1999 criteria, recommends a lens Dk/t of 33 for daily wear and 125 for extended-wear [37]. Scleral lens Dk/t should be evaluated in conjunction with the tear fluid layer, both acting as resistors in series. Scleral lenses are made of high Dk materials varying from 100 to 150 Fatt units and as stated previously, the tear layer is characterised by a Dk of 80 Fatt Units. Therefore, oxygen transmissibility is influenced by the thickness of the lens and the thickness of the tear fluid layer or apical clearance [308, 314]. According to Compan et al., 2014 scleral lenses should be 250 μm thick and fitted with a maximum of 200 μm clearance to respect the Harvitt-Bonnano criteria, when using a Dk material of 125–150 Fatt units [310]. Oxygen can come from other sources, such as tear exchange and tear mixing. However, it is known that the tear exchange is very limited once scleral lenses have settled on the conjunctival surface. Vance et al., 2015 found the rate of tear exchange in scleral lens wearers was 0.2%/minute [317]. This means that it would take around 8 hours for the PoLTF to exchange. Therefore, tear exchange is unlikely to contribute to oxygen replenishment under scleral lenses. To avoid significant hypoxia it is recommended to use:

- Lenses with high Dk values >150
- Maximal centre thickness of <250 microns or less,
- and final tear lens thickness not exceeding 200 microns

Evaluation of Central Corneal Clearance

It is advised to start with a lower sagittal height lens for a particular cornea, and then gradually try diagnostic lenses with more sagittal height until the lens no longer shows apical touch on the cornea, or it shows a "feather touch" as with corneo-scleral lenses. One can also start with an increased sagittal height and gradually go lower. It is advisable to fill mini-scleral lenses with non-preserved saline upon lens placement to avoid air bubbles. Tear film exchange is limited once the lens is placed on the eye. A green, even fluorescein pattern should be visible in front view, preferably without bearing zones. As previously stated, the human eye is capable of observing 20 microns or more of fluorescein layer thickness. Anything less will appear black, but this doesn't necessarily mean there is actually "touch" [88]. If corneal bearing is visible in mini-scleral lenses, the sagittal height of the lens is too low and need to be increased. Air bubbles beneath the lens, if not caused by incorrect lens placement, can be a sign of excessive corneal clearance with a small landing zone. Excessive clearance, 500 microns or more, even if no bubbles are formed, can sometimes reduce visual acuity and cause visual disturbances and "fogging". The goal with mini-scleral lenses is to find the minimum sagittal height that vaults the cornea with little to no apical bearing [308, 316]. Although, central clearance is desired at all times, it should be noted that central bearing with scleral lenses is typically well tolerated when compared to corneal RGP lenses. This is presumably because scleral lenses usually do not move enough to irritate the apex of the cone. Caution must be taken to ensure there is no corneal staining after removal of these lenses.

To further evaluate corneal clearance, an optical section with the slit lamp can be used to observe the post-lens tear film thickness, with and without fluorescein (Figure 71). AS-OCT can also be used to accurately measure the apical clearance with scleral lenses *in situ*.

Scleral lenses need time to settle as they can "sink" into the conjunctiva to some degree, but this is subject to high individual variance. It is recommended to wait about 20–30 minutes before evaluating the lens on the eye. Most of the sinking seems to take place in the first two hours of lens wear. But the best time to evaluate the overall sinking would be at the end of the day, after at least eight hours or more of lens wear [318]. Hence, when fitting scleral lenses, an extra margin in terms of clearance should be considered. Starting off with a slightly excessive clearance may not be a bad idea, this will allow plenty of space for the lens to "settle".

More About Lens Settling

Archimedes' principle applies to scleral lenses, when placed in water the scleral lens will sink due to negative buoyancy and the specific gravity of the lens material. In a similar fashion, the lens will sink to the surface of the eye. Suction is created due to the loss of fluid between the lens and the eye, which is not replaced by the natural tear film, as tear film exchange is minimal with scleral lenses. This suction holds the lens on the eye and leads to delayed settling, as the cornea moves closer to the lens. Suction force is greater for larger diameter lenses - ±18% increase when diameter is increased from 14.6 mm to 16.00 mm. The conjunctival tissue is viscoelastic, this can result in the lens sinking into the tissue, with the amount of sinking depending on the landing zone width of the lens [319].

How Much Does Scleral Lenses Settle or Sink?

According to Caroline and Andre, 2012 scleral lenses sink by 70–180 microns [320] and Mountford, 2012 suggests 146–186 microns [321]. Buaer and Lotoczky, 2013 measured settling of 100–150 microns over an 8 hour period [322]. Bray et al., 2017 published an average sink rate of 86 microns after 6–8 hours [323]. According to Esen and Toker, 2017 the average amount of settling was 62.8 microns after 8 hours, 80% of which occurred during the first 4 hours of wear [324]. It is generally accepted that scleral lenses settle after insertion, with maximum setting occurring after ±8 hours of continuous wear. Percentage of setting over time is as follows [322]:

- 20 minutes ± 25%
- 60 minutes ± 59%
- 2 hours ± 71%
- 4 hours ± 87%
- 8 hours ± 98%

Settling can also be predicted by the following formula:
Final Settling = 4 (initial clearance – clearance after 20 minutes wear)

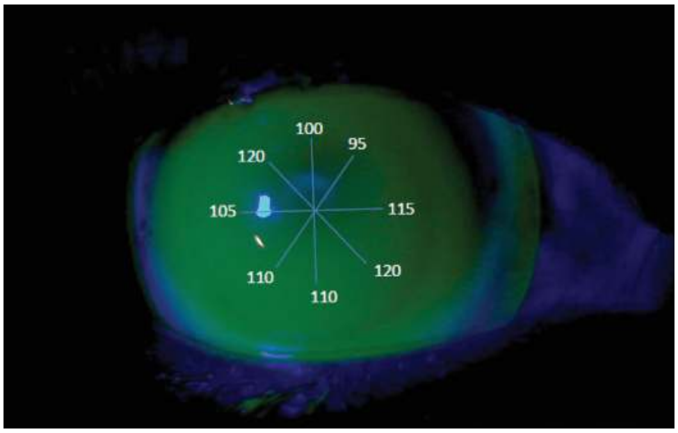


Figure 66: NAFL pattern with a mini-scleral lens indicating apical clearance values

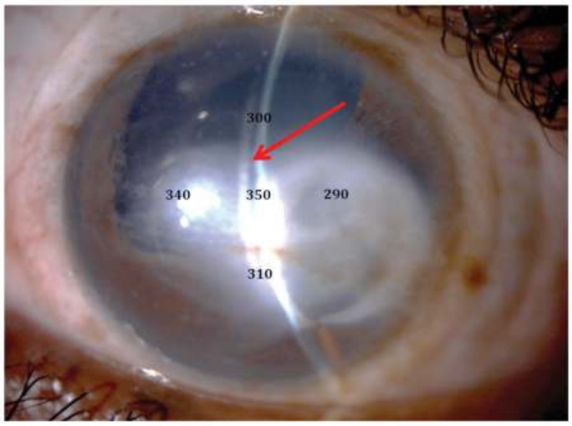


Figure 67: Optic section showing apical clearance compared to lens thickness

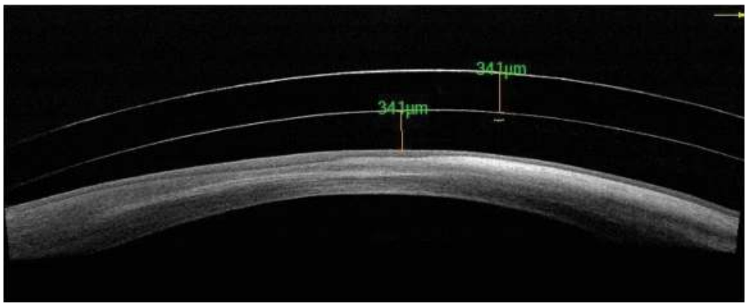


Figure 68: OCT measurement of lens thickness and apical clearance

Figure 69: A minic-scleral lens fitted on a severely scarred cornea

Peripheral Corneal Clearance

Once corneal clearance has been established over the centre of the cornea, the clearance over the rest of the cornea may need to be adjusted. At this point, the base curve radius (BC) of the lens may come into play. Choosing the BC of the lens slightly flatter than the flattest keratometry values usually helps alleviate pressure in the peripheral optical zone and limbal area. A flatter BC can be used to create limbal clearance. However, changing the BC of the lens means that the sagittal height of the lens may also be altered. Flattening the BC will reduce the sagittal height of the lens. This means that the sagittal height may need to be adjusted to compensate for the radius changes. However, many manufacturers already compensate for this automatically; a change in radius results by default in an alteration in sagittal height.

Sagittal height is also dependent on lens diameter. If the lens diameter is increased while the BC is kept stable, the total sagittal height goes up, which can be quite dramatic in terms of an increase in volume. Conversely, a smaller lens decreases the sagittal height if the BC stays the same, unless the manufacturer compensates for this automatically. Therefore, in principle, one parameter cannot be changed without taking others into account.

Limbal Clearance

The limbal area is important and should also be taken into consideration. This is where the stem cells are located, which are crucial for corneal health, in particular for producing new epithelial cells, which are then distributed over the entire cornea. Limbal pooling may be important to bathe the fragile limbal stem cells. Less clearance in this area, may lead to corneal touch upon lens movement. A limbal clearance of 100 microns is often striven for, but this depends on lens size. Any type of mechanical pressure and especially limbal staining is unacceptable in all types of scleral lens wear.

Limbal clearance can be achieved in different ways but choosing a BC slightly flatter than the flattest keratometric values helps alleviate pressure in the limbal area. With corneo-scleral lenses, it is hard to avoid the limbal zone, since by definition, this is where part of the lens' landing zone is positioned. The aim is to avoid excessive pressure in the limbal zone. Fluorescein evaluation should reveal minimum bearing in the limbal area, which should be checked regularly for staining. AS-OCT imaging can precisely determine the amount of clearance from centre to limbus in microns. Therefore, it is a useful tool in lens fit assessment.

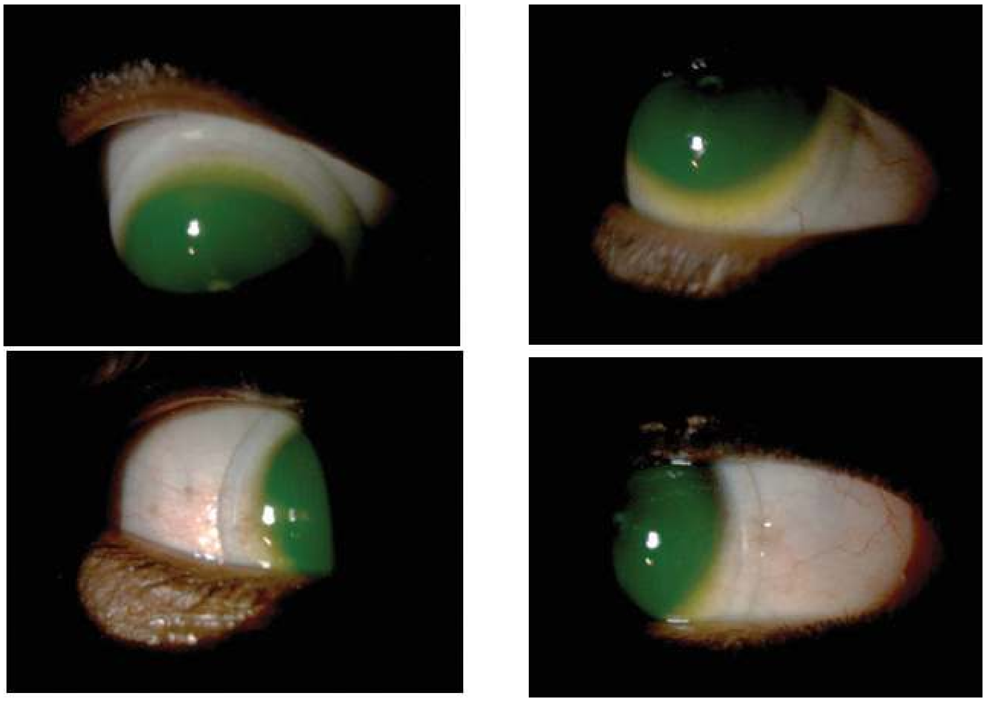


Figure 70: Limbal clearance in a mini-scleral lens

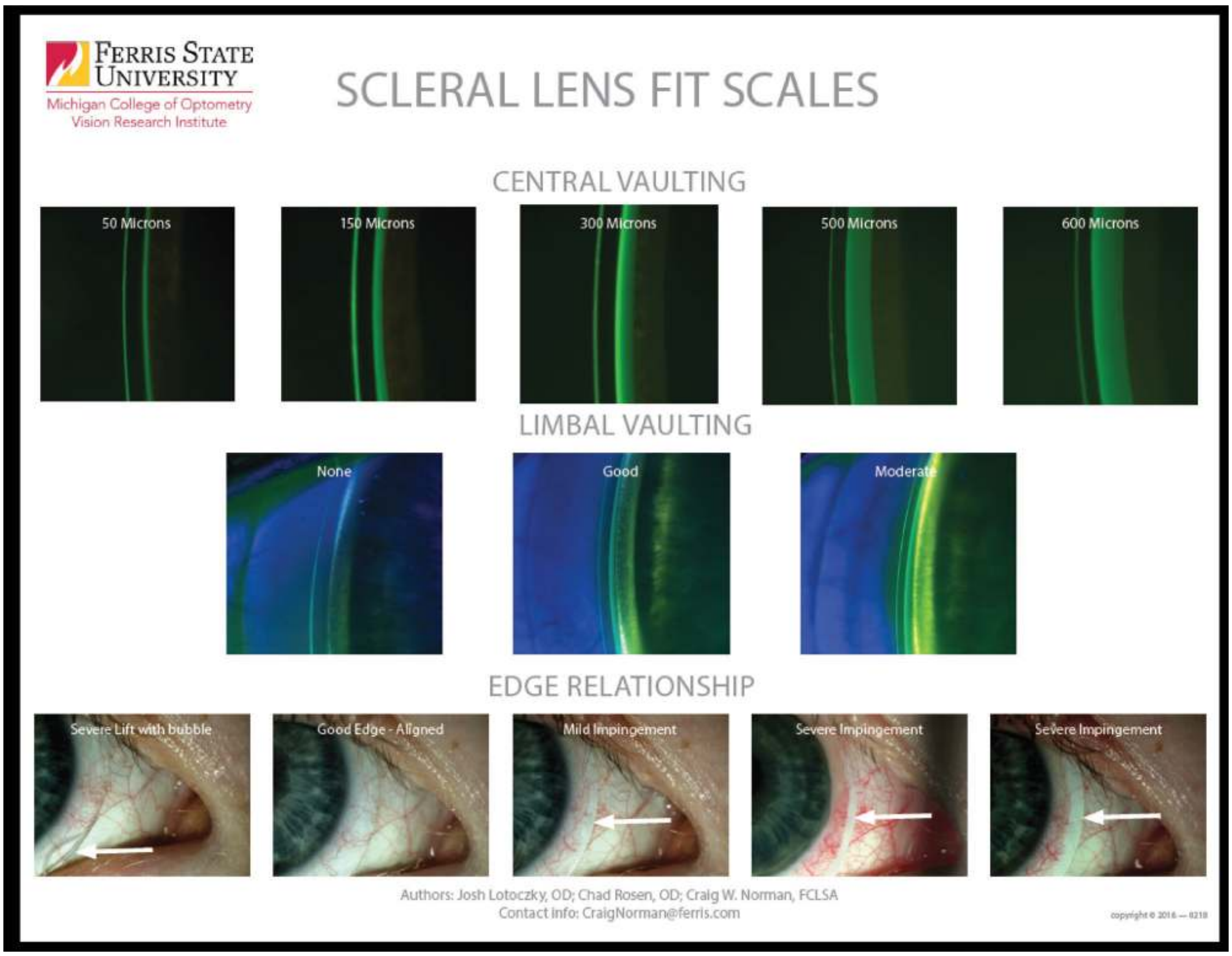


Figure 71: Scleral lens fitting scales courtesy of Ferris State University, Michigan College of Optometry, Vision Research Institute

Step 3: Landing Zone Fit

The goal with the zone is to create an alignment with the sclera or corneo-scleral transition. The corneo-scleral profile can be evaluated using the slit lamp with a cross-sectional view of the anterior ocular surface, or by simply observing the anterior ocular shape without magnification, by having the patient look downward to get a first impression of the anterior ocular surface shape using the Meier grading scale as described previously [13]. Trial lenses can also be used to observe and potentially adjust the alignment of the landing zone with the anterior ocular shape. Ideally, instruments such as the Eye Surface Profiler should be routinely used to measure the anterior ocular surface shape to choose the first trial lens to match that [16]. A scleral lens has its main weight bearing literally on the landing zone. The larger the scleral lens, the more lens weight is distributed over a larger area of the sclera.

Once the trial lens is placed on the eye, the fit is assessed based on how the landing zone bears on the ocular surface. A ring of bearing on the inner part of the landing zone indicates that the landing zone is too flat. Air bubbles in the periphery of the lens also indicate flat landing zones. Frothing may be present at or under the peripheral lift, indicating the same effect. Additionally, fluorescein evaluation can be helpful in evaluating the landing zone. Keep in mind that fluorescein is absorbed by the by the conjunctiva, making fluorescein evaluation more difficult. It is very helpful to look at pressure of the lens periphery on the bulbar conjunctiva (Figure 71). Localised areas of the conjunctiva surrounding the limbus can be "whitened" because compression of the lens on the conjunctiva restricts blood flow, this is referred to as conjunctival blanching. Circum-corneal blanching or blanching in more than one direction, seems more problematic than a single area of blanching, which may be acceptable at times. Blanching must be assessed in different gaze positions. Compression or blanching typically will not result in conjunctival staining following lens removal but rebound hyperaemia at the location of the compression may be seen.

Step 4: Lens Edge

As with RGP corneal lenses, a scleral lens needs some edge lift. However, this should not be excessive, or it may affect comfort. Although scleral lenses do not move much and is movement is not usually achieved, good edge lift may promote healthy lens wear. With the push-up test it is preferred if the lens showed some mobility. Mini-scleral lenses may sink more into the tissue, because they have a smaller landing zones, exhibiting less movement. Since the weight of the corneo-scleral lens is balanced on the cornea and sclera, they move more with the blink. Often, full scleral lenses show more movement than mini-scleral lenses, because the asymmetry of the peripheral scleral shape may cause the lens to rock. The landing zone is an important variable concerning lens mobility, blanching in this area should be avoided. Changing the lens edge does not necessarily have an influence on lens mobility, especially if blanching is present.

The edge lift can be changed by changing the landing zone angle or by choosing a steeper landing zone radius of curvature. The edge lift can be assessed in several ways. One is to simply observe the edge lift with white light and assess how much it "sinks" into the conjunctiva and/or whether there is a lift-off, in which case a dark band or shadow will be visible under the lens edge. Using fluorescein can also be helpful. Some practitioners observe the volume of the tear meniscus that is present around the lens edge to evaluate this parameter. AS-OCT imaging may be helpful as well, but care should be taken, because an artefact occurs at the edge of the lens due to a difference in index of refraction between the cornea and the contact lens that causes a displacement. The instrument can only account for a single index, so when a lens of a different index is imaged, this artefact results in an overestimation of the AS-OCT image regarding the amount of "sinking" of the lens into the conjunctiva.

The scleral lens fit can be very different 360 degrees circum-corneally. This is due to the asymmetrical nature of the anterior ocular/scleral surface. If one or more areas are considerable outliers, either by lift (causing air bubbles) or by impingement/blanching, an asymmetrical lens design may be required. Applying toric and/or quadrant specific back surfaces to lenses may be one of the more challenging aspects of scleral lens fitting, but at the same time it also is one of the most promising. Asymmetrical back surface design scleral lenses can significantly improve scleral lens fit and comfort of wear. Visser et al.,2006 reported that toric scleral lenses allow for a more equal distribution of pressure over the sclera, which promotes anterior ocular surface health and improves comfort of lens wear. It also creates a stable lens on the eye. The lens finds its own resting position, just like a back toric corneal RGP lens would.

Typically, toric scleral lenses have fixed differences in sagittal height between the two principal meridians. The exact difference in microns between the two meridians depends on the lens manufacturer and is often confidential. The range can be up to, or more than, 1000 microns, but based on theoretical considerations of anterior ocular surface shape, the difference between segments can be around 500 microns within the average eye over a 20 mm chord and much less for a 15 mm chord. At a cord of 15 mm, scleral toricity averages 1.50D and at 20 mm this increases to 3.0D. The temporal sclera is significantly flatter than the nasal sclera. Therefore, it makes sense to fit toric mini-scleral lenses with a minimum of 0.30 mm difference in their peripheral curves at a cord of 16.00 mm [16]. The flat and steep meridians need to be assessed independently of one another in the same fashion one would assess a standard scleral lens. If the fit is unacceptable in one meridian, this meridian should be flattened or steepened accordingly, and the same process should be repeated in the opposite meridian. This opens-up the ability to add front surface optical applications such as a cylinder, which are often required for residual astigmatism.

What About Tear Exchange?

As mentioned previously the amount of tear exchange under a scleral lens is minimal and limited to a rate of 0.2% per minute once the lens settles on the eye. Based on this rate, it would take >8 hours to replenish the fluid under a scleral lens [317]. Paugh et al., 2018 found that tear elimination rates for the scleral RGP CL wearers averaged 0.57 (±0.6) %/min for the 0–30-min and 0.42 (±0.5) %/min for the 30–60-min period [325]. Tear exchange is considered important in contact lens wear to reduce post-lens debris. This compromised post-lens tear reservoir has been called a “toxic swamp” or a “contact lens-induced cesspool”. Muntz et al., 2015 suggested that the accumulation of metabolic by products and debris in the post-lens tear film contribute to the onset of adverse events such as epithelial bogging, primarily by altering the epithelial barrier function [79]. The incidence of microbial keratitis (MK), contact lens acute red eye (CLARE) and contact lens-induced corneal oedema increases when there is inadequate tear exchange.

Step 5: Over-Refraction

Creating the optimal lens fit is the first and most important objective, refractive power is the last consideration. The over-refraction should be converted for vertex distance if it exceeds 4.0D spherical equivalent. For over-refraction, trial lenses and frames rather than a phoroptor are recommended. Be careful to not over minus especially in higher prescription, binocular refraction using a +3.00D lens in-front of the eye not being examined usually helps prevent this.

COMPLICATIONS

Despite the fact that much of the literature reviewed described the therapeutic use of scleral lenses in the management of significant ocular disease, a limited number of complications have been reported. Individual case reports described microbial keratitis, *Acanthamoeba* keratitis and non-ulcerative keratitis associated with scleral lens wear. The incidence of microbial keratitis associated with scleral lens wear has not been definitively determined, but two studies have reported incidence rates of 0.5% and 1.6% [298, 326]. Given the severity of ocular surface disease described in these studies, it is difficult to determine whether the complication was truly a result of scleral lens wear or simply a manifestation of the underlying disease. Other complications include conjunctival prolapse, conjunctival compression, surface soiling most likely, due to the landing zone of the scleral lens interfering with the conjunctival beaker cells, tear film fogging, epithelial bogging and post-lens debris, which consists mainly of lipid and mucous. Conjunctival prolapse is common in patients with conjunctivochalasis (loose conjunctiva), and although most authors regard this as not serious and effort should be made to change the fit of the lens to reduce the prolapse. Corneal oedema and staining also occurs and all the other complications expected with RGP lenses can occur.

Front Surface Deposits

There are many conditions that may cause poor anterior surface wettability. These include poor tear chemistry, especially in patients with severe dry eyes from conditions such as Sjörgens syndrome, 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.

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. Scleral lens materials have very high oxygen permeability (Dk/t) values. These materials tend to be more hydrophobic and lipophilic, leading to surface deposits. 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 their hand soap and change the soap to contact lens compatible hand soap or acne treatment hand soap. Further recommendations include the following [327]:

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

Flexure

If unexpected residual astigmatism (RA) is found, measure keratometry or topography over the lens. If this shows cylinder that matches over-refractive RA 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.

Tear Reservoir Debris and Midday Fogging

This is a relatively common problem, often resulting in patient symptoms of midday fogging of vision [327]. Several theories have been proposed, none have been definitively proven yet, although there was a study that analysed lipid composition of post-lens fluid in high-debris compared to low-debris patients. This study showed that the high-debris patients had higher lipid concentrations in the post lens tear film [328].

Proposed theories:

- 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 [329]
- Corneal epithelial cells turn over relatively rapidly. When a scleral lens is in place, those cells are released from the ocular surface, becoming 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. It is likely that it is both of these factors (and probably several others) contribute to this phenomenon [79]

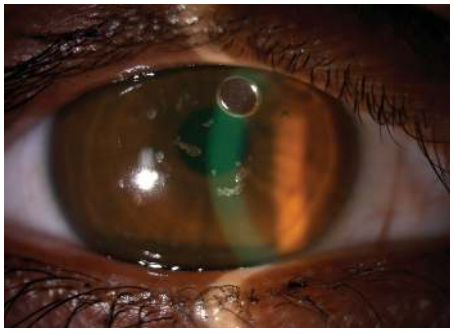


Figure 72: Debris and bubbles in the tear reservoir

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 [15, 327, 329].

Bulbar Conjunctival Redness

The most likely causes of bulbar redness include; infection, mechanical trauma, irritation, blood vessel compression and inflammation

- ***Infection.*** There is not much literature relating to adverse effects with scleral lenses. Only a few articles 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 [328, 330, 331]. Patients that are immunosuppressed can also be more at risk than others. Recent review papers reported no significant negative impacts from scleral lens usage [297, 302, 328, 332]
- ***Mechanical trauma/Irritation/Compression***. It is now known that the sclera is a non-symmetrical rotational toric surface. At 15 mm, the sclera displays around 1.5D of toricity, which increases up to 3D at 18–20 mm of chord length [14–16]. Scleral lenses designed with spherical haptics will have 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 [316]. Clinically, this is visible as a blanching of the conjunctiva, where the pressure is present. Consequently, blood flow is impinged, causing engorgement before and after this area. 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 [329, 333]
- ***Inflammation.*** Inflammation is not widely cited as a source of adverse events related to scleral lens wear. However, Walker, 2016 suggests that it is underestimated and can lead to discontinuation of scleral lens

wear [328]. 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 [79]. In addition, cellular debris and toxins released from the normal corneal metabolism are also kept trapped under the scleral lenses as, 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 [79]

Conjunctival prolapse

Conjunctival prolapse represents an entrapment of the conjunctiva, draping over the cornea, near the limbal region under a scleral contact lens. It occurs in the inferior quadrant on patients with loose conjunctival tissue (conjunctivochalasis), more so in elderly patients [316, 329]. The suggested pathogenesis is related to induced pressure forces that can pull the conjunctiva under the lens. These forces are greater with greater vault over the limbal area and may be related to the inferior scleral lens positioning in most patients. Minimising the vault over the limbal region without creating an area of touch appears to be the best treatment and prevention strategy in susceptible patients. This can be achieved using non-rotationally symmetrical designs, especially in lenses that are larger than 15.0 mm [329, 334]. Prolapse is also associated with pellucid-marginal degeneration, due to the typical thin elevated inferior corneal profile [316]. Finally, it was reported that handling the lens with too much pressure can increase the risk of inducing prolapse [334]. Conjunctival prolapse 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. 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 [316, 334].

What is the Difference Between Conjunctival Prolapse and Conjunctivochalasis?

Conjunctivochalasis occurs more frequently as patients age and in female patients [335]. It often occurs inferiorly and is related to dry eye disease. It is thought to interfere with the lower tear meniscus, delaying tear clearance from the eye. Additionally, it is more problematic in downgaze and when digital pressure is applied. The latter may represent a similar mechanism for conjunctival prolapse. Conjunctivochalasis is also frequently seen in contact lens patients, especially RGP lens wearers: again, the mechanisms (inflammation produced by mechanical stress that leads to friction and/or dryness) may be similar to that of conjunctival prolapse [335].

Compression Rings

A compression ring 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 100–200 µm, once the lens is stabilised. 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 closer to the limbus.

Epithelial Bogging

According to Caroline and Andre, 2015 upon lens removal, the ocular surface looks "water-logged" and irregular. This could result from constant contact between the corneal epithelium and the saline used in the tear reservoir. Saline solution contains no nutrients or electrolytes to benefit the cornea. Epithelial bogging is often transient, lasting the first 4–6 weeks of lens wear. The patient is typically asymptomatic, and epithelial bogging may represent a relatively benign condition. However, an argument can be made for the use of a solution which includes 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, to fill the lens bowl prior to insertion. [336].

Staining

As it is the case for other types of contact lenses, staining associated with scleral lens wear can be induced by different sources including; mechanical, hypoxic and chemical trauma. Chapter 16 will look at the causes in more detail.

- ***Mechanical:*** For scleral lens beginners handling lenses could be an issue. Larger lenses are more difficult to handle resulting in corneal erosions visible as corneal staining. Proper lens insertion and removal education should be provided and compliance to the proper procedures should be reassessed during follow-up visits
- ***Hypoxic:*** Microcystic oedema 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 the 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 and is a very similar reaction to that described as SICS in soft lenses [337]. The use of non-preserved saline or non-preserved artificial tear solutions can alleviate this problem

What is the Effect of Scleral Lenses on IOP?

Nau et al., 2014 postulated that compression of the episcleral veins and the tissue deformation of Schlemm’s canal, which lies beneath the landing zone of the scleral lens, may elevate intraocular pressure. They found that wearing a 15 mm scleral lens for two hours does not raise IOP in normal subjects [338]. Vincent et al., 2017 postulated that scleral lenses elevate IOP as a result of post-lens fluid forces exacerbated by eyelid tension or ocular versions [339]. These forces alter the lens fit and result in corneal bearing or increased conjunctival and scleral tissue compression. Several studies have investigated the influence of short-term scleral lens wear on IOP. On average these studies, in young healthy adults wearing various types of scleral lenses for short periods (30 minutes to 8 hours), show a modest change in IOP of less than 1.5 mmHg. This minimal (non-statistically significant) increase in IOP during scleral lens wear suggest that on average scleral lenses do not substantially elevate IOP in the short-term, despite primarily superficial tissue compression near the scleral spur [339].

In contrast to the studies described by Vincent et al., 2017, McMonnies, 2016 suggest that a tight scleral lens fit might increase IOP [340]. The tightness of a scleral lens fit increases with an increase in tear surface tension and the development of a suction pressure. Tight digital forces can elevate the IOP to approximately double the normal IOP levels, but IOP rapidly returned to normal after the digital pressure was removed. McMonnies, 2016 also states that measuring IOP after removal of the scleral lens cannot capture IOP during lens wear, because post-wear readings can only be indirectly relevant to lens *in situ* IOP. The lowered IOP after lens removal may be an indication of elevated IOP and accelerated aqueous drainage during lens wear. It may also be due to a response of the eye after manipulation of the globe during the removal process, especially if the lens is fitted tight and there is difficulty breaking the ‘suction’ force between the lens and the sclera [340].

Considering the above information, scleral lens fitting in patients with ocular hypertension and glaucoma is not encouraged. Further well-designed studies are required to accurately measure IOP changes following long term lens wear and in eyes with corneal abnormalities. New techniques to measure IOP during scleral lens wear should also be considered.

FITTING PEARLS [15]

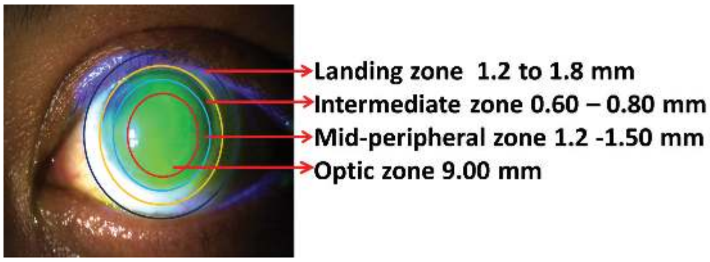
Overall, the fit of a scleral lens can be divided into two parts; the central fit (over the cornea called the "corneal chamber") and the peripheral fit (over the conjunctiva).

- Examine the entire corneal chamber under diffuse cobalt blue and high illumination. Note any areas of bearing just as with a corneal RGP contact lens (Figure 71). When fitting an irregular cornea, it is common to observe touch or bearing in the mid-peripheral or peripheral cornea once acceptable central clearance has been obtained. In these cases, additional clearance must be created in the problem area without grossly increasing the central clearance. A reverse geometry design can be employed to vault over the areas of touch/bearing, but compensatory flattening of the base curve must be done to avoid excessive central clearance
- Apical clearance should be kept to a minimum to maintain corneal physiology
- Limbal clearance is important and should be maintained to ensure the health of the stem cells, ensure at least 50–100 microns of limbal clearance in all quadrants (Figure 71)
- The BC of the scleral lens can be used to adjust the peripheral fit and limbal clearance. The BC is usually selected close to or slightly flatter than the flattest-K. The peripheral portion of the lens should align with the bulbar conjunctiva. Impingement occurs when there is compression or focal blanching of blood vessels, which can occur anywhere on the scleral haptic, not just the edge. Compression or general indentation of the conjunctiva, whether at the edge or mid-periphery of the lens, may result in seal off, suction and indentation. When blanching occurs, flatten the peripheral curve associated with the area of blanching. It is important to ensure that the landing zone and peripheral curve of the scleral lens does not cause conjunctival blanching. This should be evaluated circumferentially and a toric curve should be used if necessary to improve the fit
- Excessive movement and/or bubble formation after lens insertion may indicate the peripheral curve(s) are too loose. Therefore, tighten the peripheral curve(s)
- It is beneficial to perform computerised topography over the contact lens in situ after it has settled for a few minutes. This can reveal any lens flexure. More than about 0.50D of toricity can be significant and should be addressed by increasing the centre thickness if it interferes with vision
- Check for Tear Exchange. Before a scleral lens is dispensed, proper tear exchange must be demonstrated. Apply the lens without fluorescein in the filling media. After the lens has been properly applied, instil a generous amount of fluorescein dye over the top of the lens (superior sclera) with a dye strip. Periodically examine the tear lens and check for dye that has made its way behind the lens into the tear chamber. After several minutes, there should be at least a small amount of dye in the tear lens. Tear exchange does not need to be rapid, but it is critical for a proper fit. If in the test for tear exchange, there is no fluorescein seen in the corneal chamber after waiting for several minutes, flatten the peripheral fit or increase the overall diameter
- Use the highest Dk/t material available and the minimum centre thickness possible to prevent corneal hypoxia

IDEAL MINI-SCLERAL LENS

- Diameter 15.6–16.20 mm
- 9.00 OZD
- Limbal zone/intermediate zone width 0.60–0.80 mm
- Mid-peripheral zone with 1.2–1.5 mm

- Scleral landing zone width 1.2–1.80 mm
- Minimum peripheral curve radius 14.60 mm
- Toric peripheral curve ≥0.3 mm (depending on total diameter) difference between flat and steeper curve
- I never fit mini-scleral lenses with apical clearances of more than 200 microns
- Maximum transmissibility material available.



ROSE K2 XL SEMI-SCLERAL LENS

The Rose K2 XL lens is a semi-scleral proprietary design, which bears on the cornea as well as the sclera. This specific design differs from a mini-scleral lens mainly due to tear exchange taking place and it is fitted more like a conventional corneal RGP than a scleral lens. The lens is fitted with minimal corneal bearing (feather touch) and the edge design can be altered (flatter or steeper) to improve the fit. The lens is also available in toric back surfaces, with prism ballast, front surface toric designs and quadrant specific designs. Fitting nomograms can be downloaded from the manufactures web site or obtained from *The Contact Lens Laboratory of SA (www.contactlenssa.co.za).*

What Adjustments Can Be Made to South African Manufactured Mini-Scleral Lenses?

Base curves and sagittal depths of mini-scleral lenses are not adjustable after the lens has been made. However, the following adjustments are possible to mini-scleral lenses.

Power Changes

Power changes depend on lens thickness. Usually up to +1.50 and -2.50D spherical power and up to -2.50D cylindrical power can usually be easily added to mini-scleral lenses, due to their thickness.

Edge Lifts

Edge lift changes depend on radial edge thickness. Thinner edges may produce smaller diameters with narrower landing zones and sharper edges.

Normally up to +3.0 increased to relieve toe fits.

Normally up to -3.0 decreased to relieve heel fits.

Adding a Toric Periphery.

Toric curves are added to the back peripheral surface to reduce lens flexing, it can also mask low amounts of residual astigmatism and act as a 'stabiliser' to lock the scleral lens into place and stop rotation. This then allows the addition of cylindrical power at any given axis on the front surface of the lens.

Diameters

Although it is generally recommended to keep the mini-scleral lens landing zones as wide as possible, overall lens diameter can be decreased simply by rolling the edges until the desired diameter is reached.

Fenestrations

These vary in position depending on fitting regime. Some practitioners fit using a fenestrated fitting set, where the lens is fenestrated over the limbal area to "try" to relieve pressure at the limbus. Peripheral fenestrations in the landing zone can be added to regular sclerals to assist in removal of tight lenses. I do not use any fenestrations when fitting scleral lenses and find that many of the fitting problems can be alleviated by using toric lenses.

Limbal Blending

This is an effective adjustment, which may improve clearance over the limbus.

Pterygium Notch

A small notch or cut out in the lens edge of a rotation stable mini-scleral lens can be used to avoid contact with a pterygium or pinguecula.

Chip Removal

Rolling the edge or slight truncations can be performed to remove or smooth out small edge chips.

Engraving

The lab can engrave numbers, letters and symbols on scleral lenses. This is performed on the front surface of the lens and does not interfere with vision or comfort.

Hollow-Out

Although uncommon, hollow-outs can be performed on rotationally stable mini-scleral designs to assist in clearing elevated areas on the cornea, such as fibroplastic nodules or scars.

When fitting irregular corneas, I continue to promote, first and foremost, the fitting of corneal RGP contact lenses. I remain an advocate of scleral lenses but reserve them for patients who have ocular surface disease or when the cornea exhibits asymmetric height differences, usually more than 350 μm, that prohibit successful fitting with a corneal lens design.