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Clinical Indications for Advanced Scleral Lenses

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Introduction

The origins of scleral lenses date back to the early 20th century when ground glass was used to manufacture scleral shells to improve vision, and to protect and support the ocular surface.¹ More than 120 years later, current scleral lenses are used for the same general purposes of sight restoration and ocular surface rehabilitation. Today's scleral lenses are made of highly breathable polymers allowing them to be worn successfully for multiple hours in a day.² Furthermore, our access to sophisticated technology allows for the production of highly customized and reproducible lenses (**Figure 1**).

Today's Scleral Lens Wearer

One of the primary indications for a scleral lens fit is to improve visual quantity and quality in patients with the potential for acuity gains.³⁻⁶ For patients diagnosed with corneal ectasias such as keratoconus;



Figure 1. A custom scleral lens designed with channels and fenestrations to optimize lens wear for a post-penetrating keratoplasty patient with 20-year-old graft tissue; courtesy of Dr. Stephanie Ramdass.

Lens Use	Improve Visual Function	Relieve Ocular Discomfort	Rehabilitate Ocular Surface
Clinical Indications	• Keratoconus • PMD • TMD • Post-LASIK ectasia • Post-RK ectasia • Post-PK • Post-traumatic scar • Aphakia • High refractive error (including oblique astigmatism)	• Stevens-Johnson syndrome • Ocular cicatricial pemphigoid • Keratoconjunctivitis sicca • Sjögren's syndrome • Exposure keratopathy	• Limbal Stem Cell Deficiency • Neurotrophic keratitis • Chemical burns • Graft-versus-host disease

Table 1. Indications for fitting a custom scleral lens; courtesy of Dr. Stephanie Ramdass.

pellucid marginal degeneration; Terrien's marginal degeneration; post-refractive surgery ectasia; and post-keratoplasty astigmatism, spectacle lenses offer minimal improvement in visual function. A true scleral lens is fit large enough to completely vault the corneal surface so that the underlying tear reservoir can neutralize the uneven refracting surface. The anterior surface of the scleral lens then becomes the new smooth refracting surface. Patients with ectasia report drastic improvements in quality of life (QOL) due to significant increases in visual acuity and contrast sensitivity.^{7,8} Many patients can finally seek meaningful employment, return to work, and successfully pass driving tests.⁹

The most rewarding patients to fit with scleral lenses are those seeking relief from ocular discomfort. Patients with a history of Stevens-Johnson syndrome and ocular cicatricial pemphigoid have constant pain due to mechanical dysfunction with each blink from keratinized lid margins. Trichiasis and chronically inflamed deficient conjunctival tissue result in desiccation of the corneal epithelium and a loss of corneal tear film homeostasis. These patients habitually live in the dark and spend most of their days with their eyes closed. They often enter the examination room wearing darkly tinted sunglasses. Often immediately after trial scleral lenses are inserted, the patient can raise their head to meet the clinician's eyes as the lens protects the delicate ocular surface from continuous microtrauma.^{10,11}

In patients with conditions involving aberrant corneal wound healing such as limbal stem cell deficiency, graft-vs-host disease or neurotrophic keratitis, larger diameter scleral lenses (i.e., > 18 mm) known as prosthetic replacement of the ocular surface ecosystem (PROSE) help to support the

ocular surface and stabilize or reverse the negative sequelae associated with these conditions.^{12,13} When appropriately fit and worn as directed, scleral lenses have not been reported to lead to regression of corneal neovascularization and corneal opacification over time.¹⁴ **Table 1** summarizes the most common clinical indications for fitting a scleral lens based on the category of lens use.

Optimizing the Scleral Fit

There are several methods to fit a scleral lens; however, the key step is to understand the ocular surface involved. A thorough case history, including charting current and previous ocular medications, is important to achieving fitting success. In the case of a diagnostic scleral lens fitting, topography and tomography scans are needed for all patients with irregular ocular surfaces in order to understand the distribution of the corneal astigmatism and to determine corneal elevation differences. These two factors assist in selecting the correct sagittal depth of the first trial lens (**Figure 2**).^{15,16} A measurement of the horizontal white-to-white or visible iris diameter will help to select the correct scleral lens diameter of the initial trial lens. Alternatively, a scleral lens can be ordered empirically via impression-based technology whereby a mold using ocular non-toxic material is taken of the eye; a manufacturing lab then employs instrumentation that takes a 3D scan of the mold to create a highly customized first scleral lens.¹⁷ Ocular surface profilometry is another tool that can greatly reduce chair time by accurately mapping out the lumps and bumps of the ocular surface via sophisticated software algorithms. This technology also results in the ability to empirically order a scleral lens.

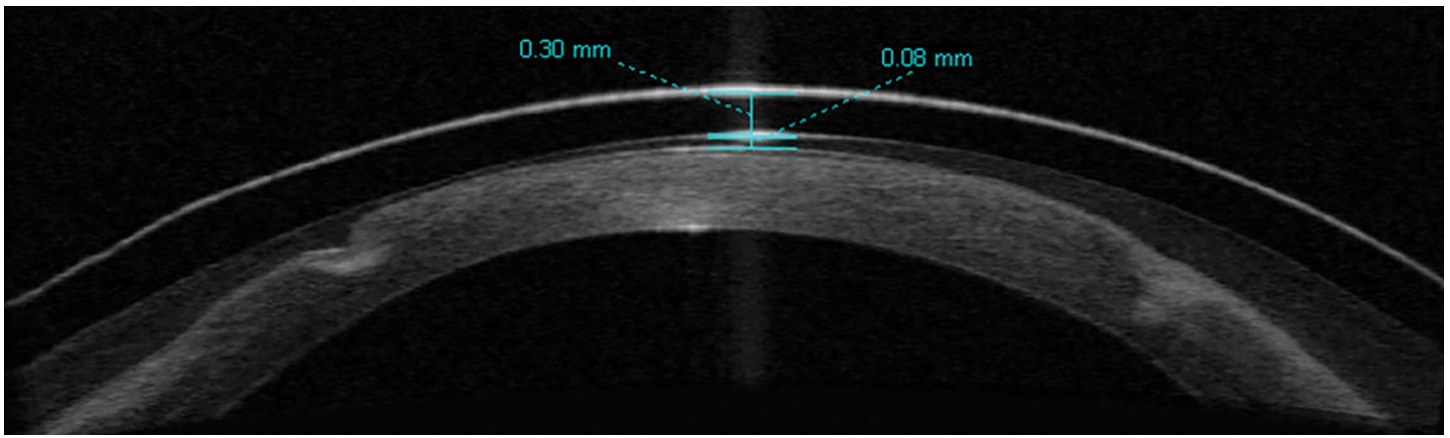


Figure 2. An anterior segment OCT cross-section that highlights a lens thickness of 300 microns and an insufficient amount of clearance of the lens over the irregular corneal surface; courtesy of Dr. Stephanie Ramdass.

In addition, it is important to photo-document the patient's scleral lens journey. Before applying a scleral lens on a patient's eye, baseline ocular staining with fluorescein or lissamine green with anterior segment photography are helpful not only to educate patients on their condition but also to monitor the impact of the therapeutic lens fitting over time.

Scleral Lens Wearer Triumphs and Challenges

As impactful as scleral lenses are when initially dispensed to patients, there are some situations in which the initial excitement wears off. In patients with ectatic disease, correcting irregular astigmatism and higher order aberrations can present a trade-off. Despite efforts to maximize visual acuity with spherical and spherocylindrical over-refraction, during follow-up visits patients may complain of ghosting or shadows around images they see.^{18,19} An aberrometry measurement overtop the scleral lens when worn can aid in the understanding of any residual high-order aberrations (HOAs).²⁰ At the forefront of scleral lens research is custom HOA correction to advance visual acuity from good to great. While this technology is costly due to the high level of customization in these types of scleral lenses, some patients are seeking this cutting edge technology.

In patients with ocular surface disease, the fluid filled chamber that vaults over the entire corneal surface provides a soothing bath of moisture to alleviate chronic corneal pain symptoms. However, a scleral lens is still a large piece of plastic that the lids must blink over in order to maintain visual function. The most difficult scleral lens fit is in patients with tear-deficient conditions who are able to see 20/20

during their baseline scleral lens consultation visit or who require a high level of visual acuity throughout the day. A scleral lens can initially be life-changing for these types of patients; however, they are often plagued by poor wettability of the scleral lens surface, protein deposits that are not cleared from the front of the lens with each blink, and fogging of the tear chamber.²¹ This can lead to a visual decline and, in some patients, results in discontinuation of lens wear.

There are several clinical contraindications to scleral lens wear. In patients with corneal graft tissue that has low endothelial function (less than 1,000 cell/mm²), wearing a scleral lens can result in corneal edema and ultimately graft rejection.²² Localized epithelial bullae can be observed while a scleral lens is worn. These findings can be seen as a negative staining pattern when fluorescein is applied to the ocular surface after lens removal.²³ Despite using highly permeable scleral lens materials to optimize health of the corneal surface, decreasing the volume of the tear chamber laying beneath the scleral lens surface, and modifying the scleral lens fit to include customizations such as channels or fenestrations, some of these patients will only be able to wear their scleral lens for a limited period during the day or not at all.²⁴ These types of eyes should undergo a wear-time challenge during their initial scleral lens dispense, where the patient is observed at T=1, 2 and 4 hours post-scleral lens insertion. This provides a clinician with insights into the compatibility of the compromised ocular surface with an overlying scleral lens. Should this fail and the corneal edema persists, the patient should be referred to a cornea specialist for consideration of an endothelial keratoplasty.

Co-Management Considerations

Some patients undergo partial or complete tarsorrhaphy in an attempt to save the ocular surface and preserve sight. Scleral lenses are an excellent alternative to protect the cornea and conjunctival tissues while restoring cosmesis for patients. During the scleral consultation visit, if it is determined that a patient can benefit from a scleral lens fit, a report to the referring surgeon or oculo-plastics specialist can include a request to open up the lids and increase the aperture opening. This provides the patient with a chance to achieve success with scleral lens insertion and removal.

Another anatomical limitation is the presence of symblepharon that limits successful scleral lens wear.²⁵ While a scleral lens can be notched to accommodate for this obstacle, symblepharon release with a mucus membrane graft can allow a patient to better insert their scleral lens and increase their lens wear time during the day (**Figure 3**).

Lastly, as a scleral lens rests with a footprint on the conjunctival surface, the presence of conjunctivochalasis can result in discomfort with lens wear over time. This loose tissue can get sucked toward the limbal border, contributing to a phenomenon called conjunctival prolapse, or can bunch up along the edge of the scleral lens.²⁶ If the scleral lens cannot be modified to accommodate for this redundant conjunctiva, the excess tissue can be cauterized. Scleral lens wear can resume once the surgeon has determined that the treated area is sufficiently healed.

Conclusion

Scleral lens fitting is rewarding for clinicians and even more so for patients who are thankful for a renewed sense of self-confidence and a drastic improvement in their quality of life. There are several clinical indications where a scleral lens can be used, as discussed above; however an astute fitter will understand when simply vaulting over the ocular surface is not in the best interest of the patient, and advanced customizations are warranted. The science of scleral contact lenses is continually evolving and utilizing advanced skills and technology are important to identify the correct modifications needed to optimize a scleral lens fit. As developments occur, situations that result in scleral lens failure can be minimized.



Figure 3. The presence of a symblepharon can limit the successful insertion and comfortable wear time of a scleral lens. Customizations, such as decreasing the diameter or notching the lens, can prevent direct contact with the conjunctival scar tissue; courtesy of Dr. Stephanie Ramdass.

Financial Disclosures

Honoraria/Speaker's Fees: Bausch + Lomb, SVP, SynergEyes, and Pentavision LLC.

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