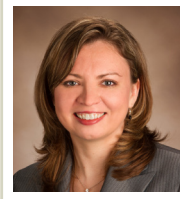


Contact Lens Update

CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

Perspectives on scleral Lenses: past, present and future

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Melissa Barnett is an optometrist at the UC Davis Eye Center in Sacramento and is the Immediate Past President of The Scleral Lens Education Society.

Lynette K. Johns is an adjunct assistant professor and clinical attending in specialty contact lenses at the New England College of Optometry.

The concept of a contact lens designed to completely vault the entire corneal surface and rest on the conjunctival and scleral tissue has been around since the 16th century.¹ This family of contact lenses is known as scleral lenses, and their use in practice has experienced tremendous growth in recent years.

The earliest type of contact lenses manufactured

Conceptualized by Leonardo DaVinci in the early 16th century,¹ scleral lenses went on to be the earliest type of contact lenses manufactured.² The first scleral lenses, designed in 1887 by Fredrich A. Müller and Albert C. Müller, were used to manage ocular surface disease.^{3,4} They were thin, lightweight blown glass shells with clear corneal regions, white scleral portions and no refractive power. Adolf Eugen Gaston Fick, a German ophthalmologist, described the use of scleral lenses with optics added to correct vision in 1888.⁵ Using these lenses, which were impermeable to oxygen, Fick also observed clouding of the corneal epithelium (corneal edema), later known as Fick's phenomenon or Sattler's veil.

The original glass scleral lenses evolved to lenses made from impermeable polymethyl methacrylate (PMMA) or Perspex. The early literature from this era of scleral lens technology reports on scleral lens design, manufacturing techniques and indications for their use.⁶ In 1983, Don Ezekiel provided the first reports of the use of gas permeable (GP) materials to make scleral lenses.⁷ The introduction of GP scleral lenses was a turning point in scleral lens history and marked the beginning of the resurgence of this contact lens modality. Publications after 1983 describe major indications for use, along with the visual and functional effects of scleral lens wear.⁶ During their early years, scleral lenses were most often used as a last resort when other options had failed. Scleral lenses were fit with incredible success to correct irregular astigmatism due to corneal ectasia and to treat ocular surface disease, including those with compromised corneas.

Scleral lens indications are expanding to be used for normal, healthy eyes

Recently, indications for scleral lenses have expanded to include their use with normal, healthy eyes.⁸ Scleral lenses are now being recommended for corneas with a regular, normal, prolate shape without disease, ectasia or irregularities.

Several studies have evaluated patient quality of life with scleral lenses. A retrospective study evaluated the quality of life of patients with keratoconus or for the treatment of astigmatism after penetrating keratoplasty who failed to adapt to rigid gas permeable lenses.⁹ In this study, scleral lenses showed significant improvement in the quality of life for patients who were unsuccessful or intolerant to conventional rigid gas permeable contact lenses.⁹ The authors concluded that scleral lenses were a viable option prior to surgery.

Scleral lenses are used in PROSE (prosthetic replacement of the ocular surface ecosystem) treatment.

The Boston Foundation for Sight, now known as BostonSight of Needham, MA gained FDA approval for the Boston Scleral Lens and lenses now used in prosthetic replacement of the ocular surface ecosystem (PROSE) treatment. These scleral lenses help with many conditions, including irregular and distorted corneas, ocular surface disease and post-surgical indications.¹⁰⁻¹⁵ A study evaluated use of scleral lenses in PROSE treatment and found improvement in the Visual Function Questionnaire scores (NEI VFQ-25), the Ocular Surface Disease Index (OSDI) and significant improvement in vision-related quality of life.¹⁵ Additionally, only minimal handling related difficulties were reported.

Scleral lenses can present unique challenges

While there are many published benefits of scleral lenses, they also can invoke specific changes to ocular physiology that are unique to their use, such as epithelial “bogging” (squishy, soft, water logged epithelium), epithelial bullae,¹⁶ conjunctival prolapse and limbal bearing.¹⁷ Scleral lenses allow only minimal tear exchange¹⁸ and there is a potential for fogging in the post-lens fluid reservoir.^{19, 20} Exogenous tear debris aspirates into the post lens tear reservoir. This fogging occurs with varying frequency and depends on landing zone fitting characteristics in combination with the patient’s tear film.

The literature has demonstrated that post-lens tear debris consists of a high concentration of lipids; and complications related to tear reservoir clouding are especially common in those with ocular surface disease.²¹ Non-wetting or poor wetting is relatively common during scleral lens wear, and this can result in suboptimal or “cloudy” vision.²⁰ Several studies have reported difficulty with scleral lens handling as the primary reason for dropout.^{22, 23} Scleral lens dropout rates vary in the literature, ranging from 25% to 49%.^{22, 23} Thus, assessing the scleral lens fit, vision and care and handling is critical to success.

Currently, there are many questions about the effect of the combination of the permeability of the material used (Dk), lens thickness, and post-lens fluid layer thickness on corneal physiology, hypoxia and edema. Theoretical modeling studies of oxygen transmissibility and tension agree that scleral lenses should be manufactured with high Dk materials (>125-150+), low center thickness (200-250 microns) and low corneal clearances (less than 150-200 microns).²⁴⁻²⁷ One study demonstrated a 30% reduction in oxygen tension with an increase of 200 additional microns of clearance.²⁸ Another study reported 1.7% corneal edema after eight hours of scleral lens wear.²⁹ Clinically, this low level of edema does not result in any visible signs of hypoxia such as microcysts or striae, and it falls below the typical 4% physiological overnight edema that occurs without contact lens wear.³⁰ Interestingly, clinicians observe ghosting of neovascularization in patients with diseased corneas who wear scleral lenses, which may suggest that hypoxia is not a significant factor or that compensatory mechanisms are involved.³¹

Scleral shape

It has been established that scleral shape is not rotationally symmetric or spherical, but rather asymmetric.³² Although corneal and scleral toricity are not associated,³³ the sclera, similar to the cornea, may have steep and flat meridians.³⁴ The flattest curvature is typically observed nasally and the steepest curvature temporally.³² An optimal alignment of the scleral lens in all meridians on the scleral is essential. Scleral lenses, especially larger diameter lenses, should align to both principal meridians. Toric or quadrant-specific landing zones can help to achieve ideal scleral alignment and have numerous advantages. Incorporating back surface toricity can help reduce lens decentration, lens distortion,³² excessive debris,³² the formation of air bubbles, conjunctival prolapse, localized conjunctival vessel blanching^{35, 36} and lens impingement.^{13, 37} In turn, patients experience improved comfort, increased wearing time, overall satisfaction, better visual quality and enhanced optical correction.³⁸⁻⁴⁰ Not all scleral lenses need toric or quadrant-specific landing zones and their need is based on the shape of the

individual sclera.

Fitting scleral lenses

With the resurgence of scleral lenses, there is renewed interest in the topography of the anterior corneo-scleral junction. It is of interest that OCT measurements show the shape of the transition area between the cornea and sclera appears to be straight in many cases.^{8, 33} In a study of 96 eyes of 48 normal subjects, shape was evaluated in eight different meridians on the anterior ocular surface; the majority of the corneo-scleral junctions exhibited tangential shapes.^{8, 33} As a result of this research, newer scleral lenses incorporate tangential landing zones to improve overall alignment with the ocular surface.

Research of the anterior ocular surface and scleral lenses continue. In a research setting, multiple types of instrumentation are used to examine features of scleral lenses. For a practitioner in clinical practice, a slit lamp is essential. Placido-based or Scheimpflug topography and optical coherence tomography are helpful. Continued research may guide the practitioner to determine the ideal scleral lens for each instance.

Prescribing and management trends

The Scleral Lenses in Current Ophthalmic Practice: an Evaluation (SCOPE) study used a survey to evaluate the prescribing and management of scleral lenses by 700 international practitioners.⁴¹ Investigators found that the majority of practitioners fit 15-17 mm diameter scleral lenses (65%). Most practitioners recommended preservative-free saline in single use vials (60%) or bottled products (57%) in the bowl of the lens for scleral lens application.⁴¹ The most common disinfection system (61%) recommended by practitioners was a hydrogen peroxide-based system.⁴¹ More data from this extensive international survey is anticipated to be published.

Educational resources

There are several useful resources available for scleral lens education. 'A Guide to Scleral Lens Fitting Version 2.0' updated in 2015 by Eef van der Worp can be downloaded from the Pacific University website.²⁶ 'Scleral Lens Fit Scales' is a guide to estimating central clearance; this guide is available in English and Spanish and can be downloaded from the Ferris State University website (http://www.ferris.edu/HTMLS/colleges/michopt/vision-research-institute/pdfs-docs/Scleral-lens-fit-scales_v2.pdf). A book dedicated to scleral lenses titled 'Contemporary Scleral Lenses: Theory and Application' by Melissa Barnett and Lynette Johns (Bentham Science Publishers) will be released later in 2017.

A multitude of resources regarding scleral lenses can be found on the Scleral Lens Education Society (SLS) (<https://www.sclerallens.org>), Gas Permeable Lens Institute (GPLI) (www.gpli.info) and Accademia Italiana Lenti Sclerali (AILeS) (www.ailens.it) websites. Topics include scleral lens indications, lens selection, scleral lenses-induced complications and lens care. Meetings such as the Global Specialty Lens Symposium (GSLS), The British Contact Lens Association (BCLA), The Netherlands Contactlens Congress (NCC) and the Cornea & Contact Lens Society of Australia (CCLSA) are meetings that regularly provide education for practitioners wishing to learn more about scleral lenses.

Further exploration

In the first meeting of the International Forum for Scleral Lens Research (IFSLR), numerous research questions arose. As with all new technologies, there remain many questions regarding scleral lenses that require exploration. Some of these include developing a better understanding of ocular shape, scleral lens design, their physiological response when worn and questions around disinfection solutions, in addition to development of standardized scleral lens terminology.

Despite the numerous unknowns about scleral lenses, their life-changing effects are indisputable. Scleral lenses are a contact lens modality that offer many benefits. Research will hopefully catch up to answer these questions and ensure their continued safety and effectiveness.

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