Contact Lens Update
CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

Scleral Lens Update: Current and Future Applications

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Scleral lenses were first conceptualized by Leonardo DaVinci in the early 16th century,[1] and were the earliest type of contact lenses manufactured.[2] Scleral lenses have evolved from glass and PMMA to gas permeable (GP) materials, [3-6] reducing the adverse physiological effects induced by the original scleral lens materials. The shortcomings of early designs included very poor oxygen transmissibility, which led to lens-induced corneal edema, later known as Fick's phenomenon or Sattler's veil, corneal hypoxia, and ultimately discontinuation of lens wear. Also, each lens was handcrafted and impossible to replicate if broken or lost. In recent years, improvements in manufacturing techniques and ocular imaging have led to a resurgence in scleral lens prescribing.[7,8] There are numerous optical and therapeutic indications that may result in a patient being prescribed scleral lenses,[9,10] the major ones being visual rehabilitation in irregular corneas, therapeutic treatment of ocular surface disease and correction of refractive error in normal or healthy eyes. Currently, 10% of all contact lenses fit globally are comprised of GP materials.[11,12] The majority of these are corneal lenses (75%), followed by scleral (13%), orthokeratology (8%), and hybrid lenses (5%).[11,12] The expanding scleral lens modality has been variously termed "the rigid lens renaissance: a surge in sclerals",[13] "scleral lenses are blooming"[14] and "scleral GP lenses have come of age".[15] Additionally, the number of publications in the peer reviewed literature on this topic is rapidly increasing.[16]

Scleral lens practitioners carefully and systematically successfully manage patients who have challenging eyes, partially or completely restoring their vision, and often their functionality.[16] Scleral lenses not only manage a condition, the technology treats the entire person, and even entire families.[16]

Fifteen years ago, only a handful of specialized practitioners were successfully fitting scleral lenses, and only a few laboratories were producing them.[17] Today, multiple manufacturers are developing new and innovative scleral lens designs, solutions, and technologies. Thus, scleral lenses are becoming far more "mainstream" in contact lens practice.[17] Studies have assessed the practitioner learning curve when fitting scleral lenses. With practitioner experience, both the number of trial lenses required to achieve the best fit and the number of reorders with time was reduced.[18,19]

Scleral Lenses Reduce the Need for Corneal Transplantation

Keratoconus is the most prevalent primary corneal ectasia, which commonly causes bilateral asymmetric thinning of the paracentral cornea.[26] Due to its progressive nature, early diagnosis and management is critical. Corneal collagen cross-linking with prompt intervention can halt the progression of keratoconus. Scleral lenses should be considered for all patients with advanced corneal ectasia for visual rehabilitation and to neutralize irregularities of the corneal surface.[27] Scleral lenses may reduce or delay the need for corneal transplantation, with the indication for keratoplasty being cited as one-fifth in a keratoconus population.[28] Scleral lens fitting outcomes were compared to keratoplasty in a keratoconus population.[27] In the scleral lens group, vision improved more rapidly,

mean visual acuity was better after one year, and fewer complications were experienced compared to those who underwent keratoplasty. Ling et al. evaluated the influence of scleral lenses on the rate of corneal transplantation for keratoconus.[28] In this study, a total of only 3.2% of eyes underwent keratoplasty. [28] In a study by Koppen et al, the need for keratoplasty was reduced by more than half in a severe keratoconus population.[29] Scleral lenses were used to successfully treat 40 of 51 eyes with severe keratoconus. In their practice population, the indication for corneal transplantation was 1.65%.[29] Scleral lenses should be considered for patients with keratoconus prior to surgical intervention for those who cannot successfully wear other modes of correction.

Scleral Lenses as Ocular Drug Delivery Systems

The utilization of scleral lenses as drug delivery devices has been demonstrated.[30] Scleral lenses have been reported as drug delivery systems to deliver antibiotics,[31,32] anti-vascular endothelial growth factor (anti-VEGF) agents,[33-35] and stem cells with compounded products.[36] The large fluid reservoir provides a protected environment in which the corneal surface is continuously bathed in preservative-free fluid. These lenses are inherently stable to provide continuous ocular penetration of a drug. Scleral lenses exhibit minimal tear exchange after lens settling; tear exchange has been reported at 0.2% per minute of wear.[37] If a topical drug is applied over a scleral lens, there is minimal accumulation in the post-lens fluid reservoir. Alternatively, drugs applied in the reservoir prior to lens application should remain for the majority of the scleral lens wearing time. The replenishment of fluid under a scleral lens requires more than 8 hours of lens wear. A study evaluated post-lens tear dynamics at two different time points, during and after scleral lens wear with post-lens tear fluorescence.[38] Approximately one-third of the subjects had no tear flow into the post-lens fluid reservoir after 5 hours of lens wear.[38] Scleral lenses may function as an ideal drug delivery system to provide a therapeutic level of drug at the desired target tissue, with minimal variability and have a duration appropriate for the therapeutic indication.[30]

Midday fogging

Post-lens tear reservoir debris (midday fogging) occurs when debris accumulates between the scleral lens and cornea, and may occur after minutes to hours of lens wear.[39,40] Midday fogging requires frequent lens removal and reapplication, which is clearly an inconvenience for scleral lens wearers. The literature has demonstrated that post-lens tear debris consists of a high concentration of leukocytes,[41] lipids,[42] and external tear film debris.[43] Complications related to tear reservoir clouding are especially common in those with ocular surface disease.[44] There are numerous proposed causes of scleral lens fogging, including increased tear exchange and accumulation of tear debris in the lens reservoir, increased mucin production from rubbing of the conjunctival tissue, accumulation of protein and lipid deposits on the front surface of the lens (Figure 1) and corneal edema (Figure 2).[45]

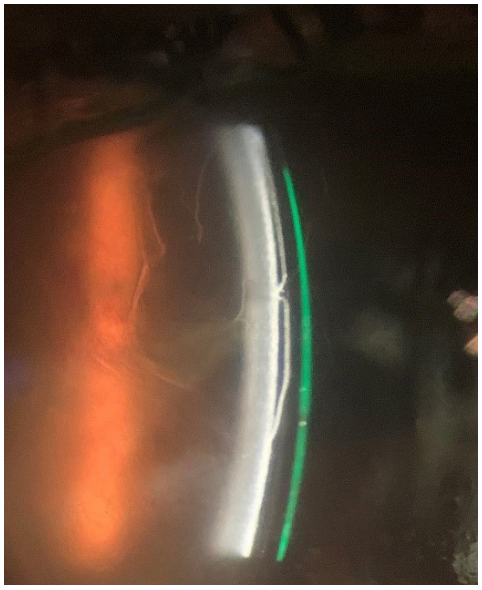

Figure 1: Corneal edema in a patient with severe dry eye and neurotrophic keratitis.

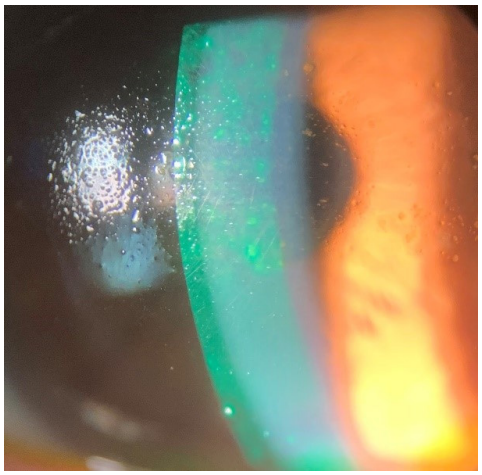

Figure 2: Surface debris on a scleral lens

Fogging is typically associated with debris, either on the front surface of the lens or in the post-lens fluid reservoir. Symptoms of fogging are similar, despite the cause. Corneal edema should be ruled out immediately by removing, cleaning and reapplying the scleral lens. If a patient experiences rainbows around lights (Sattler's veil) or vision continues to be blurred, evaluate the cornea for corneal edema. Midday fogging is diagnosed through biomicroscopy, OCT, or Scheimpflug imaging, rather than symptoms alone, since corneal edema or a non-wetting anterior lens surface can also cause visual symptoms during lens wear.

Factors associated with patient-reported midday fogging in established scleral lens wearers were evaluated.[46] Midday fogging was self-reported in 64 patients of 248 survey respondents (25.8%). Midday fogging was not correlated with demographic characteristics (age, sex, race/ethnicity), scleral lens indications, mean lens diameter (P = .30), haptic design (P = .29), use of a daily cleaner (P = .12), disinfection/storage solution used (P = .71), or filling solution (P = .65). Associated redness or irritation were more frequently reported in patients who described

midday fogging compared with those who did not experience the condition (P = .03). Elevated inflammatory mediators in the post-lens fluid reservoir of patients with midday fogging, or ocular redness or irritation associated with scleral lens wear suggests that ocular surface inflammation may be contributory.

A recent study investigated if midday fogging could be mitigated by a novel scleral lens filling solution, which closely approximates the ionic concentration and pH of human tears.[47] This study is reviewed in the 'Feature article' section of this issue.

In Office Disinfection

In a scleral lens practice, both empirical fitting and diagnostic lens fitting with trial lenses can be effective. Historically, the use of diagnostic, or trial, contact lenses is customary. Practitioners commonly apply one or more lenses during a diagnostic fitting, which must be disinfected prior to storage and use on another patient to prevent transfer of potential pathogens. These pathogens may be introduced into the system from one patient to another or may be transferred by the practitioner or staff during handling and storage, or both. According to the new Guidelines for Handling of Multipatient Contact Lenses in the Clinical Setting, contact lenses are divided into three categories for disinfection purposes:[48] Soft contact lenses (hydrogel and silicone hydrogels); GP lenses (corneal and scleral lenses); hybrid lenses (composite; composed of a GP center with a hydrogel periphery).

All contact lenses should be initially rubbed with a daily surfactant cleaner, which is used to remove particulate matter, deposits, and debris from contact lenses to ensure more effective disinfection. Next, diagnostic lenses are soaked in non-neutralized ophthalmic grade 3% hydrogen peroxide solution for a minimum of three hours.[48] Finally, the lenses are neutralized by rinsing with sterile saline or multipurpose solution and then stored dry in a disinfected case. These steps are summarized in a downloadable reference factsheet found in the 'Clinical insight' section of this issue. In addition, the 2018 ISO Standards suggest documenting each contact lens disinfection and maintaining a record for each diagnostic fitting set. The record should include the reference number for each lens, the patient reference for each lens, date(s) of use, date(s) of disinfection, method of disinfection, and the person performing disinfection. This record could prove helpful in tracing any infection arising from use of that diagnostic lens.

The Future of Scleral Lenses

Since scleral lenses are rotationally stable with minimal movement with the blink, they are now being used as a stable platform for a range of optical applications. A reflecting telescopic system embedded within a scleral lens has been developed [49-51] that can alternate between unmagnified and 3x magnification in response to a controlled blink. This system has potential applications for the military (rapid hands free distance magnification) and low vision rehabilitation (Figure 3).

Figure 3. Scleral lens-based telescope.
Image courtesy of Glenn Schuster.

A smart device is an electronic device that connects to other devices to support everyday human activities and connect, share, and interact with their users. Mojo Vision unveiled their smart scleral lens in January 2020. It incorporates a 480µm display, roughly the size of a grain of sand, comprising of 70,000 pixels supported by several micro-components, including a microprocessor and an image sensor[52] (Figure 4). The display delivers a world-record pixel pitch of over 14,100ppi and a pixel density of over 200Mppi^2, making it the smallest, densest display ever designed for dynamic, or moving content. The lens draws its power from a tiny-solid state battery, which can be recharged in the lens case at the end of the day and will be paired with another device to send and receive data. This invisible computing device has many potential applications, including low vision rehabilitation and visual augmentation.[53]

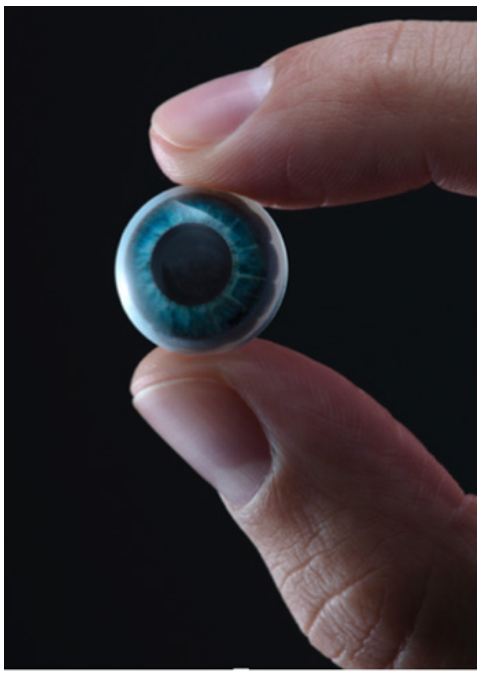

Figure 4. Image of a smart scleral lens. Image courtesy of Mojo Vision.

The past decade of modern scleral lenses has demonstrated the amazing benefits of this technology. In parallel with the increase in utilization, scleral lens publications continue to increase each year. However, there are still numerous research questions to be answered. These include whether there is a potential increase in intraocular pressure with scleral lens wear, their physiological response when worn, questions around lens materials, application and disinfection solutions and a better understanding of ocular shape. Scleral lenses are a modality that offer numerous advantages and changes lives for the better and the future of scleral lenses is bright.

Educational resources

There are many useful resources available for scleral lens education. A book solely dedicated to scleral lenses titled '*Contemporary Scleral Lenses: Theory and Application*' by Melissa Barnett and Lynette Johns (Bentham Science Publishers) is available in hardback, paperback and pdf versions.[20,21]

Scleral Lens Issues and Complications: Their Recognition, Etiology and Management by Daddi Fadel is available in print and e-book versions.[22] '*A Clinical Guide to Scleral Lens Success*' by Melissa Barnett and Daddi Fadel is a practical guide to scleral lens fitting, is available in English, Italian, Spanish, Russian and Portuguese and can be downloaded from the Scleral Success website.[23] '*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.[24] '*Scleral Lens Fit Scales*' is a guide to estimating central and limbal clearance and the edge relationship.[25] This guide is available in English and Spanish and can be downloaded from the Ferris State University website.[25]

A multitude of resources regarding scleral lenses can be found on the Scleral Lens Education Society (SLS) (sclerallens.org) and Gas Permeable Lens Institute (GPLI) (gpli.info) websites. A dedicated Facebook group 'Scleral Lens Practitioners' welcomes everyone with an interest in scleral lenses. Meetings such as the Global Specialty Lens Symposium (GSLS), The British Contact Lens Association (BCLA), The International Congress of Scleral Contacts (ICSC), The Nederlands Contactlens Congress (NCC) and the Cornea & Contact Lens Society of Australia (CCLSA) are events that regularly provide education for practitioners wishing to learn more about scleral lenses.

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