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ADVERSE EVENTS ASSOCIATED WITH SCLERAL LENS WEAR

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Although the original description of scleral lenses fabricated from rigid gas permeable materials was published in 1983,¹ the benefits of scleral lenses used to treat corneal irregularity and severe ocular surface disease were not immediately recognized by the eye care community at large. However, the past decade has witnessed an explosion of interest in scleral lenses. The Scleral Lens Education Society, an organization dedicated to teaching contact lens practitioners the art and science of prescribing scleral lenses, was founded in 2009, and now has nearly 3,000 members along with over 100 Fellows who have demonstrated competence in scleral lens fitting. The SCOPE (Scleral Lenses in Current Ophthalmic Practice Evaluation) study team conducted a worldwide survey of scleral lens providers in 2015 and identified 723 providers who had fit 5 or more lenses. An estimated 84,375 patients were reported to have been fit with scleral lenses by these providers. Respondents to the survey represented all practice modalities and represented 47 countries from around the globe. The study also confirmed that interest in scleral lenses is relatively recent; 80% of respondents began fitting lenses in 2007 or later, and 54% fit their first lens in 2009 or later.²

When scleral lenses were being prescribed by a limited number of providers primarily for management of severe eye disease, a thorough understanding of the risks associated with scleral lens wear was not critically important. In patients who would otherwise

be at risk of severe vision loss, the benefits of scleral lens wear were believed to easily outweigh any risk that might have accompanied their use. However, as more providers have begun to fit scleral lenses, indications have expanded beyond the use of scleral lenses only as an option of last resort. The SCOPE study also reported that scleral lenses are used almost as often as corneal RGPs for management of corneal irregularity.³ Scleral lenses are also being marketed for correction of uncomplicated refractive error.⁴ As indications expand to include eyes that are not at imminent risk of severe compromise without scleral lens therapy, and as a larger population begins to wear these lenses, the balance between risks and benefits must be considered.

Scleral lenses are fabricated from many of the same materials as corneal rigid gas permeable lenses, but differences in characteristics of lens design and fit make it impossible to assume that complications of scleral lens wear will be identical to those that have been reported with corneal lens wear. The interaction between a scleral lens and conjunctival tissue differs markedly from other types of contact lenses; corneal rigid gas permeable lenses do not extend onto the conjunctiva, and hydrogel lenses largely drape over the tissue. Alteration of conjunctival tissue has been reported (mainly as a change in goblet cell density) with other lenses designs,⁵ so it would be reasonable to suspect that scleral lens wear could potentially

alter conjunctival structures. However, a preliminary study comparing baseline impression cytology to repeat testing following 12 months of scleral lens wear showed no significant alteration in overall conjunctival structure in patients with dry eye disease⁶; this finding certainly deserves additional investigation. Lens thickness, combined with the thickness of the post-lens fluid reservoir, changes lid position; the lid must now pass over the surface of the lens, which may be 0.5 mm or more from the ocular surface. Scleral lenses may also introduce additional metabolic challenges to the cornea. Calculation of the oxygen permeability of the lens/fluid reservoir complex has suggested that scleral lenses may induce corneal hypoxia.^{7,8} In an effort to reduce the amount of particulate matter that can accumulate in the post-lens fluid reservoir over time, it has been suggested that scleral lenses be fit with little or no tear exchange. This could lead to tear stagnation and an accumulation of toxic metabolic waste products in the reservoir. Even if fitting characteristics are not considered, disruption of normal tear composition is likely to occur when the bowl of the lens is filled with saline prior to application. A recent study of scleral lens wearing subjects has shown an increase in MMP-9 levels after scleral lens use,⁹ and the study of impression cytology did find an increase in the number of eyes expressing the HLA-DR antigen (an inflammatory mediator) in patients with Sjogren's syndrome following 12 months of scleral lens wear.⁶ Whether this occurs as a result of tear film disruption, changes in metabolism or mechanical insult has yet to be determined.

With all of these potential problems, along with the fact that scleral lenses are still prescribed primarily for eyes with some form of ocular disease, one might expect that a review of published scleral lens-related literature would reveal numerous complications of scleral lens wear. In fact, the number of complications reported is relatively small. Microbial keratitis is generally considered the most serious complication of contact lens wear, because it may result in permanent vision loss due to corneal scarring. As of yet, just three case reports describe scleral lens-related keratitis, and one of these cases was most likely non-infectious in origin.¹⁰⁻¹² Several additional retrospective case series report isolated cases of microbial keratitis. In a

review of outcomes of scleral lens treatment for ocular surface disease, Schornack et al mentioned a case of coagulase-negative *Staph aureus* in the context of severe immunocompromize due to treatment for systemic graft versus host disease.¹³ Severinsky reviewed outcomes of scleral lens wear in 31 patients (36 eyes) who had undergone keratoplasty, and reported two cases of microbial keratitis, which he attributed to patient non-compliance.¹⁴ A detailed report of the use of scleral lenses in the management of thermal facial burns in 10 patients described two cases of microbial keratitis; multi-drug-resistant *Acinetobacter* and *Pseudomonas* infiltrates were reported in one case, and multi-drug-resistant *Pseudomonas* and methicillin-resistant *Staphylococcus aureus* were identified as causative organisms in the other case.¹⁵ In 2000, Rosenthal et al reported 4 cases of microbial keratitis in the context of extended wear of scleral lenses for management of persistent corneal epithelial defects.¹⁶ A follow-up study, published in 2013, suggested a protocol which may minimize the risk of infection for patients who require extended scleral lens wear for management of such conditions.¹⁷

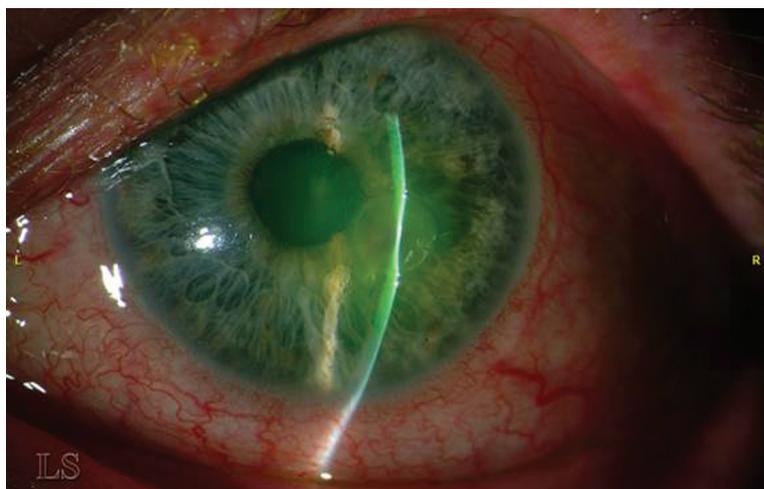
Microbial keratitis is not the only corneal complication of scleral lens wear, however. A 2017 study by Nixon et al reported peripheral corneal epithelial bullae following six hours of wear of mini-scleral lenses. The authors postulate that this finding, which appears to be unique to scleral lens wearers, may be due to weakening of the tight junctions present between epithelial cells due to mechanical force exerted by the scleral lens. Areas of peripheral corneal touch, documented with anterior segment OCT, corresponded to the location of this finding.¹⁸ Corneal epithelial bogging, another phenomenon unique to scleral lens wear in which the cornea appears somewhat corrugated without frank epithelial defects immediately following removal of a scleral lens, has been reported, but has not been formally investigated.¹⁹ Corneal graft rejection was reported in approximately 1/3 of patients described in Severinsky's 2014 study.¹⁴

Respondents to the SCOPE survey² were asked to estimate the number of scleral lens patients who had experienced complications due to scleral lens wear. Specific complications listed included those that have been reported with use of other contact lens

FIG. 1 Conjunctival hypertrophy secondary to sectoral haptic impingement.



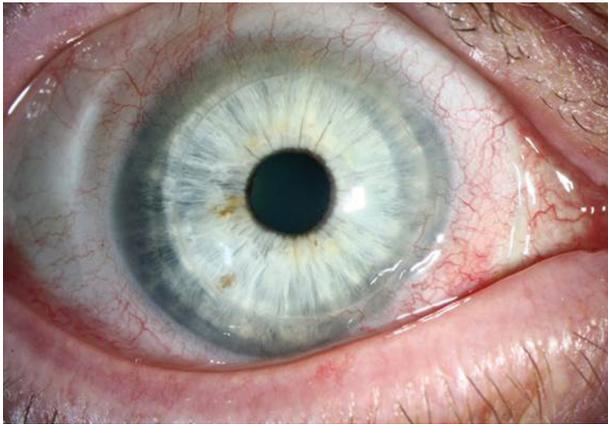
FIG. 2 Microbial keratitis in an immunocompromized patient.



modalities: corneal bullae, edema, infiltrates, hemorrhage, or neovascularization; microbial keratitis; and giant papillary conjunctivitis. Up to three additional free-text responses were permitted to allow respondents to report complications not specifically listed. Corneal edema was the most commonly reported complication (n=385), followed by neovascularization (n=238), infiltrates (n=147), bullae (n=86), microbial

keratitis (n=70), and intracorneal hemorrhage (n=49). The only keyed conjunctival complication listed was giant papillary conjunctivitis, which was reported in 138 patients. However, a number of free-text responses described other conjunctival complications, including hyperemia, blanching, hypertrophy, and chalasis. As an instrument to quantify complications of scleral lens wear, the SCOPE study had several limitations.

FIG. 3 Persistent compression of conjunctival tissue present 6 weeks after discontinuation of scleral lens wear.



No comprehensive chart review was required, so there may have been significant under-reporting of complications due to recall bias. Conjunctival complications may occur more frequently than the survey results suggest because no conjunctival complications other than giant papillary conjunctivitis was included as a keyed response; reporting conjunctival complications required additional input. Incidence rates of various complications cannot be calculated, because the study did not attempt to ascertain the number of years of scleral lens wear represented by patients of survey respondents. However, the study did estimate the total number of patients who had been fit with scleral lenses by eye care providers who participated in the survey at over 80,000. Even if one assumes that the rate of complications is much higher than reported, it appears that the risk of sight-threatening complications is relatively low, especially given the fact that most of the patients fit with scleral lenses had some type of ocular pathology prior to initiation of lens wear.

As indications for scleral lens wear continue to expand, research dedicated to quantifying and qualifying adverse ocular events or sequelae associated with their use will be of paramount importance. At this time, single case reports of complications observed in clinic would provide researchers with some direction for more formal study. Reports of scleral lens outcomes should include lens failures

and complications noted during the course of care. Given that most single practices do not have enough patients to do meaningful epidemiological research, multi-centre studies will be essential to determine the incidence of scleral lens-induced ocular pathology. Comparisons between complication rates/risk factors with scleral lenses and other lens modalities would give clinicians and patients the information needed to make informed decisions as to the most appropriate contact lens modality for a particular clinical presentation. While it may be most appropriate to concentrate initially on complications that could potentially be sight-threatening, we must be mindful of the fact that scleral lenses may be associated with anterior segment tissue changes that are not observed with other contact lenses.

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