Scleral contact lenses are large diameter, rigid gas permeable (GP) contact lenses that are designed to vault over the cornea and extend onto the sclera. The complete clearance of the cornea creates a fluid reservoir between the lens and the cornea that acts to optically neutralize corneal irregularities and hydrate the ocular surface. Since there is complete clearance of the cornea, the fitting process for scleral lenses is fundamentally different from traditional corneal GP lenses. In the latter, the appropriate base curve and alignment of a lens with the central cornea is more important. For scleral lens fitting, having a lens with a slightly greater sagittal depth than the anterior segment of the eye and an alignment of the lens periphery with the sclera are more important. With modern advancements in oxygen permeable materials and manufacturing techniques, scleral lenses are gaining popularity for a variety of clinical indications, which include vision improvement and corneal protection. Since the early 2000s, scleral lens use globally has steadily increased and now comprises almost 1% of all lens fits.

Dry Eye Syndrome (DES) or Dry Eye Disease (DED) is also commonly known by the term “keratoconjunctivitis sicca” and is an intense area of focus for eye care clinicians and researchers. The new Tear Film & Ocular Surface Society (TFOS) Dry Eye Workshop II (DEWS II) defines dry eye as “a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms in which tear film instability and hyperosmolarity, ocular surface inflammation, and damage and neurosensory abnormalities play etiological roles.” The complexity of this disease is often reflected in the range of assessment methods used to diagnose, characterise and grade the severity of the condition, as well as the ever expanding range of treatment strategies.

Scleral contact lenses are traditionally a tool employed by specialty contact lens fitters, though it is increasingly being found in the toolbox of dry eye specialists. In fact, the U.S. Food and Drug Administration (FDA) recently included DES for the first time in the approval of a scleral lens for the management of ocular surface disease. This new standard will allow the use of scleral lenses for dry eye to move away from an “off-label use” in these situations, additionally permitting insurance reimbursements, and will likely be followed by other lens designs receiving similar clearance. It is clear the momentum of scleral lens use does not show signs of slowing down anytime soon.

A recent review summarizes the evidence surrounding the use of scleral lenses for the treatment of dry eyes. The fitting of scleral lenses and outcome measures are discussed, with a consideration for lens care and handling, as well as a brief look at complications.
Scleral lens use in dry eye syndrome

In the hierarchy of treatment options for DES, scleral lenses are reserved for more advanced cases of the condition. The original TFOS DEWS Report recommended implementing scleral lenses if other conservative treatment options such as artificial tears, lid therapy, topical pharmaceuticals, or punctal plugs were inadequate, and before systemic anti-inflammatory agents or surgery were attempted. Preliminary presentations of the DEWS II Report appear to make similar recommendations regarding DES treatments with scleral lenses.

The review acknowledges that the principal role of scleral lenses has been for the management of corneal ectasias, and the expanding scope of this treatment to include ocular surface disease can be attributed to advancing technology and manufacturing capabilities. It reports 18 different manufacturers in the U.S. that offer 41 different lens types. In terms of scleral lens nomenclature, the recommendations of the Scleral Lens Education Society are described. This naming system emphasizes the fitting relationship with the eye and whether the lens rests on the cornea and/or sclera, instead of classifications based on linear dimensions.

The preliminary examination of a patient, including ocular and medical history and auxiliary testing, is important for determining a patient’s candidacy for scleral lenses and for guiding the fitting process. The iterative procedure of trialing pre-formed lenses during a diagnostic fitting exam is essential for achieving appropriate corneal vault, limbal clearance and peripheral landing zone alignment. The authors note that advancements in imaging technology such as optical coherence tomography (OCT) will facilitate the fitting process, but it is not yet ready to replace the use of trial lenses. Indeed, more recent papers involving Scheimpflug imaging and Fourier based profilometry have shown promising results in this area.

When the outcome measures of patient comfort and vision were examined, scleral lenses performed consistently well. Across almost all reports that were studied, scleral lens wearers showed improved scores on Ocular Surface Disease Index (OSDI) and Visual Function Questionnaire (VFQ) assessment tools, as well increased visual function. This was a reliable finding despite the wide range of conditions included in the study samples, such as exposure keratopathy, graft-versus-host disease, Graves’ ophthalmopathy and Salzmann’s nodular degeneration, and there was no relationship between these outcome measures and the cause of dry eye syndrome.

Fitting factors that correlated with good outcomes of success included a corneal vault of 0.2-0.3mm and a limbal clearance of 0.1mm. While these exact clearance amounts appear to be debated among scleral lens fitters, most agree that these large diameter lenses should be fit with minimal lens and post-lens tear layer thicknesses and with high Dk materials.

Scleral lens care and handling were also examined and the importance of using a non-preserved saline solution for filling the bowl of the lens prior to insertion was noted. Since Unisol-4 (Alcon) has been discontinued, 0.9% NaCl sterile inhalation vials are a frequent recommendation. A patient can perform insertion and removal using their fingers or a plunger. Proper training on these techniques is valuable for scleral lens wearers because difficulty with lens handling is a common finding in scleral lens studies and likely impacts discontinuation of scleral lens wear.

Complications from scleral lens wear were reported to be both minor and infrequent. Reduced visual acuity after short periods of lens wear was listed as one example and this was attributed to the accumulation of debris in the tear layer between the lens and cornea. Lens removal, rinsing and re-insertion were recommended to remedy this problem. Conjunctival prolapse, where loose conjunctival tissue folds over the cornea due to negative pressure underneath the lens, is a complication that requires more studies to understand its incidence and consequences. Other complications such as corneal neovascularization, corneal edema, corneal abrasion and giant papillary conjunctivitis were listed, but cited from a study that is over 20 years old, indicating the need for research in this area using modern lens designs and materials. However, a couple of examples of recent case reports of infectious complications related to scleral lens wear were provided.
Conclusion

This review concludes that scleral lenses are a successful treatment option for DES that is well tolerated by patients, especially in cases where conventional remedies have been inadequate. There are currently a wide variety of lens designs to choose from made by a number of different manufacturers. The studies that were examined indicated that scleral lenses consistently help to improve comfort and visual function in those suffering from DES, but also that more research is required to better describe optimal fitting characteristics and complications.

REFERENCES