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Optical considerations for scleral contact lenses: A review

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ABSTRACT

Scleral contact lenses have a range of therapeutic and optical applications. In recent years, scleral lens prescribing has increased due to significant advances in ocular imaging technology, lens manufacturing processes, and the widespread availability of scleral lenses globally. While the optical principles of scleral lenses are identical to those of corneal rigid lenses (i.e. the post-lens tear layer neutralises the majority of anterior corneal astigmatism and higher order aberrations), the nature of scleral lenses and their typical fitting characteristics means that many of the assumptions of 'thin lens' paraxial optics traditionally used for corneal rigid lens calculations may be inappropriate in certain clinical scenarios. This review provides a comprehensive overview of a variety of lens and fitting characteristics that are unique to scleral lenses, or not typically encountered with corneal rigid lenses, and how these factors may potentially influence optical performance based on theoretical modelling, in particular; scleral lens parameters, the post-lens tear layer, and dynamic changes during lens wear. Current front and back surface lens designs and future scleral lens applications are also discussed, along with lens modifications to improve visual outcomes and transient changes in corneal optics induced by appropriately fitted modern scleral lenses.

1. Historical optical challenges

1.1. Corneal oedema

Since the introduction of haptic contact lenses in the late nineteenth century, corneal oedema during lens wear still remains a potential optical challenge for both patient and practitioner. Müller [1] eloquently described his visual experience after inserting glass scleral lenses with a back optic zone radius (BOZR) steeper than 7.5 mm; "*A strange phenomenon occurred… a very gradual increase in veiling of the visual field appeared which seemed to surround objects in mist… this veiling became so strong in the end that the visual acuity decreased to a large extent. As soon as the mist reached a certain intensity, a rainbow appeared around lights…*". Müller's mist and Fick's phenomenon [2], later known as Sattler's veil [3], all referred to the rapid onset of corneal oedema following a short period of scleral lens wear which manifested as hazy blurred vision and rainbow like rings that are typically also observed in an acute angle closure glaucoma attack. Initially, patients could only endure short periods of wear separated by breaks to allow visual recovery. Apart from lens removal, a range of treatments were attempted to minimise or delay the onset of visual symptoms such as altering the pH, osmotic concentration, or temperature of the solution used to fill the scleral bowl [4–7], fitting a flatter haptic to allow some tear exchange at the expense of comfort [8], and slowly increasing wearing time [9]. Over time, fenestrations became the optimum solution to extend lens wearing time without compromising vision [10–12] and eventually scleral lenses were manufactured in gas permeable materials, although were often still fenestrated [13–15]. Currently, modern sealed scleral lenses made from highly oxygen permeable materials induce ~2% corneal oedema in young healthy eyes [16–20]. However, in compromised or older corneae with reduced endothelial cell counts [21,22], scleral lens wear can induce epithelial and stromal corneal oedema which can significantly affect vision.

In a series of seminal experiments, Smelser [5] observed that the angular size of the halos produced during scleral lens wear were the same as those generated in an oxygen depleted atmosphere (using goggles to expose the cornea to various gas mixtures). He further observed that Sattler's veil did not develop if a large mobile air bubble was trapped within the post-lens tear layer, or if the lens had multiple fenestrations, and attributed the alterations in corneal optics during scleral lens wear to the disruption in the normal water removal process from the cornea. Following further work using a rabbit model [23], Smelser determined that scleral lens induced oedema was due to stromal fluid retention and suggested that the disruption of stromal

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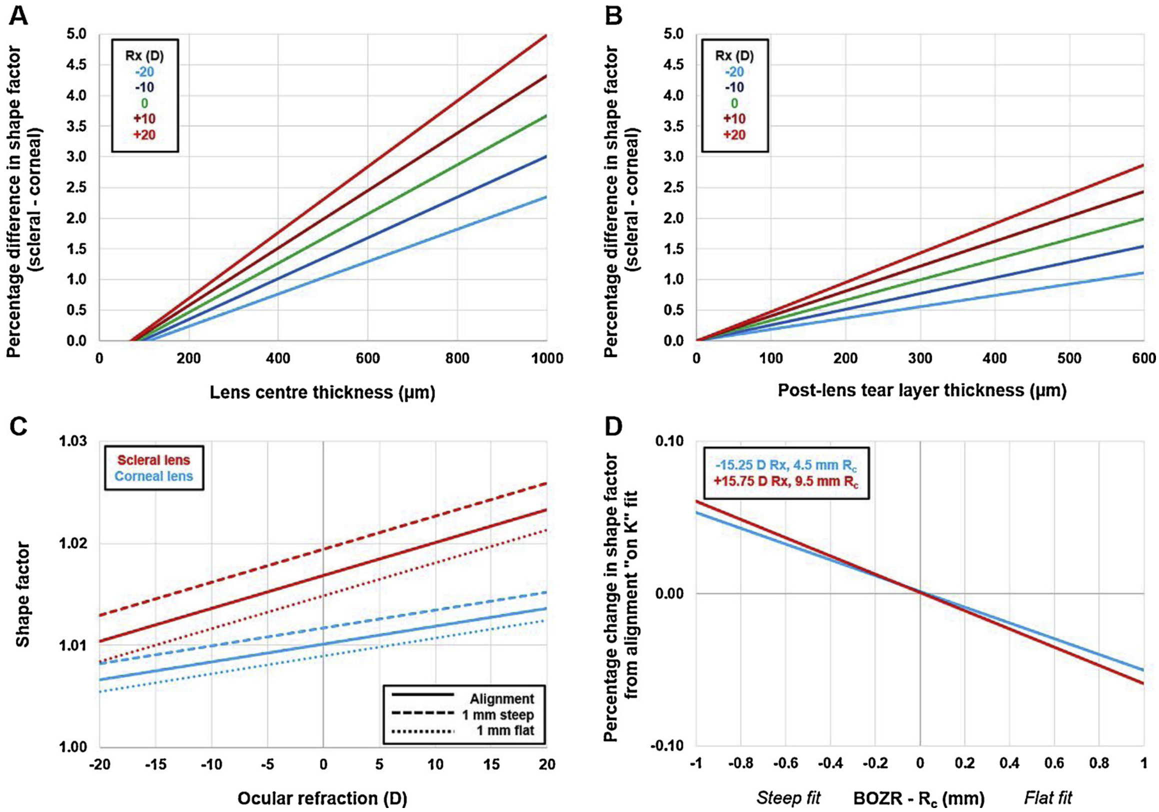

Fig. 1. The influence of scleral lens centre thickness (A), the post-lens tear layer thickness (B), and lens fit (optic zone alignment with the central cornea) on shape factor (image magnification) for a contact lens and liquid lens system (C and D). In all modelling a refractive index of 1.336 has been used for the post-lens tear layer and 1.437 for the rigid lens material. (A) The percentage difference in shape factor (image magnification) between a scleral and corneal rigid lens as a function of lens centre thickness over a range of ocular refractions assuming; a central corneal curvature of 7.5 mm, alignment fits with a BOZR of 7.5 mm, negligible post-lens tear layer thickness for the corneal lens and a fixed post-lens tear layer thickness of 200 μm for the scleral lens, and a fixed corneal lens centre thickness of 250 μm. (B) The percentage difference in shape factor (image magnification) between a scleral and corneal rigid lens as a function of post-lens tear layer thickness for the scleral lens fit over a range of ocular refractions assuming; a central corneal curvature of 7.5 mm, alignment fits with a BOZR of 7.5 mm, scleral and corneal centre lens thickness of 250 μm, and negligible post-lens tear layer thickness for the corneal lens. (C) The shape factor (image magnification) for alignment, 1 mm steep, and 1 mm flat scleral and corneal rigid lens fits over a range of ocular refractions assuming; a central corneal curvature of 7.5 mm, scleral and corneal centre lens thickness of 250 μm, a negligible post-lens tear layer thickness for the corneal lens, and fixed post-lens tear layer thickness of 200 μm for the scleral lens. (D) The percentage change in shape factor (image magnification) for two specific scleral lens examples (a steep cornea fitted with a high minus lens, 4.5 mm/-15.25 D, and a flat cornea fitted with a high plus lens, 9.5 mm/ + 15.75 D) as a function of lens fit (optic zone alignment with the central cornea) assuming a fixed post-lens tear layer thickness of 200 μm and a lens centre thickness of 150 μm for the minus lens and 800 μm for the plus lens.

collagen fibres produced significant changes in corneal clarity. Kanai and Kaufman [24] also observed unequally spaced collagen fibres within swollen stromal tissue, supporting Smelser's proposal for corneal haze due to keratocyte and collagen fibre separation.

Conversely, Miller et al. [25] attributed glare sensitivity experienced during contact lens wear to epithelial oedema based on careful clinical observation with slit lamp biomicroscopy. Lambert and Kylce [26] also concluded that the diffuse halo observed around a point source of light and the glare experienced during early scleral lens wear was due to changes occurring between corneal epithelial cells in response to hypoxia. Using an in-vitro rabbit model, corneal epithelial cell separation appeared to generate potential light scattering sites, presumably due to a differential in the refractive index between the intra and extracellular space. A small increase in light scattering due to stromal oedema was also observed (when oedema reached 10%), but the visual manifestations of Sattler's veil were attributed primarily to epithelial cell changes. During modern scleral lens wear, changes in the optics of the cornea causing visual symptoms may be a result of epithelial cell changes (due to hypoxic stress [21], mechanical trauma [27], or forces generated during lens wear [18,28–31]). Significant stromal oedema may also affect vision, however, it is minimal in eyes with robust endothelial function fitted with highly permeable sealed lenses (< 2% on average) [19].

1.2. Lens manufacture and assessment

The manufacture of glass scleral lenses for optical correction was extremely challenging. Glass blown scleral lenses could not be made accurately to a specified power and often displayed significant front surface toricity [32]. In 1931, Rugg-Gunn [33] stated; "*We must admit the blown glass to be a triumph of human skill… The molten glass is endowed with the necessary form and curvature by blowing alone and undergoes no further manipulation to give it optical effectivity. The act of successful blowing entails an exquisite co-ordination of hands, lips and eye - a combination of qualities essential to success…Few craftsmen even of the highest grade possess the necessary qualities ofco-ordination, patience and skill.*"

In contrast, the first ground glass preformed scleral lens produced by Himmler for Müller in 1889 corrected -14 D of myopia within half a dioptre [34]. Concerning early ground glass scleral lenses Rugg-Guun [33] reflected; "*The equipment of the optical manufacturer was manifestly unequal to the task… The technique of grinding out of a single piece of glass a small, fragile bowl, complicated in form, mathematically exact in curvature, and polished so finely as to be tolerated by the eye, is obviously one of great precision and delicacy… The curvatures of both surfaces must be optically exact and the thickness of the optical area uniform and accurate. The material, moreover, is very thin and very hard, qualities which add to the difficulty of working. The manner in which these difficult problems were*

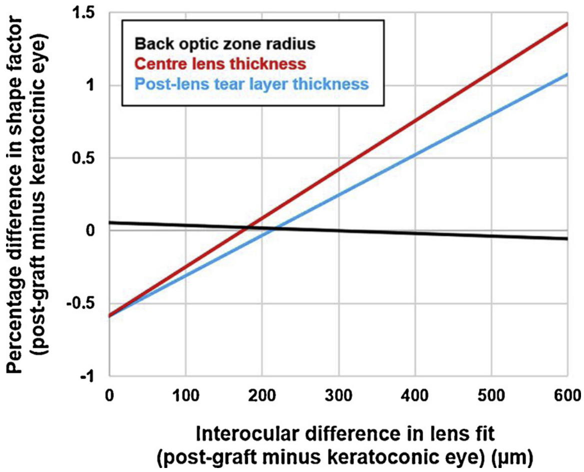

Fig. 2. Theoretical modelling of the effect of varying the interocular difference back optic zone radius, lens centre thickness, and the post-lens tear layer thickness upon the interocular difference in shape factor (image magnification). This particular example considers a steep keratoconic cornea (mean central corneal curvature of 5.4 mm and spherical equivalent ocular refraction of -10 D) and a flat post-graft cornea in the fellow eye (spherical equivalent ocular refraction of 0 D), both fitted with scleral lenses with the BOZR equal to the mean central corneal curvature. The parameters for the keratoconic fit remain fixed (BOZR 5.4 mm, post-lens tear layer thickness 200 µm, lens centre thickness 250 µm) and the post-graft cornea lens parameters are varied; for BOZR modelling the post-lens tear layer thickness is 200 µm and the lens centre thickness is 250 µm, for lens centre thickness modelling the post-lens tear layer thickness is 200 µm and the BOZR is 8.9 mm, and for post-lens tear layer thickness modelling the lens centre thickness is 250 µm and the BOZR is 8.9 mm.

finally solved by the firm of Zeiss should prove, when fully known, to be one of the romances of optical history."

While these technical manufacturing challenges have been virtually eliminated for the modern practitioner due to technological advances in lens materials and highly accurate computer aided lathes, a number of other optical challenges described in the initial era of lens fitting relating to the post-lens tear layer still persist, such as the introduction of unwanted or excessively large and immobile air bubbles due to improper lens insertion [9,35], inappropriate haptic alignment, or a fenestration. The somewhat unpredictable nature of scleral lens settling [36], which often necessitated the need for lens modifications to achieve an appropriate physiological and refractive outcome (e.g. altering or grinding out the back optic zone), has also been minimised since the use of a cobalt blue filter was described to enhance the assessment of sodium fluorescein during contact lens fitting in 1938 [37] along with the introduction of much the lighter polymethyl methacrylate (PMMA) lens material, the introduction of slit-lamp biomicroscopy in contact lens practice [4], and most recently the advent of anterior segment optical coherence tomography (OCT) imaging which allows the reliable quantification of corneal clearance and settling dynamics [38].

2. Comparisons between corneal and scleral rigid contact lenses

2.1. Retinal image size

In 1968, Stone [39] compared the optical benefits of scleral and corneal rigid lenses for the correction of aphakia. At the time, haptic lenses were the preferred correction in order to minimise mechanical insult to the scarred limbal region, and their stability was favoured over corneal rigid lenses which would induce a vertical prismatic imbalance associated with lens movement or decentration in unilateral aphakia. However, a scleral lens increases the retinal image size compared to an equivalent corneal rigid lens (primarily due to the substantially thicker lens and post-lens tear layer), which may prevent fusion in monocular lens wearers. Fig. 1 displays the theoretical relationship between shape factor (image magnification) and lens centre thickness, the post-lens tear layer thickness, and the fit of the lens (the BOZR relative to the central corneal curvature) for a range of ocular refractions using Bennett's simplified approximation for shape factor of a rigid lens and post-lens tear layer in combination [40]:

$$Shape\ factor = 1 + t(K + C) - (\frac{t_1}{n_1})F_2$$

where t is the reduced thickness of the contact lens and post-lens tear layer (m), K is the ocular refraction (D), C is the central corneal curvature keratometry value (D, assuming a refractive index of calibration of 1.336), t_1 is the contact lens centre thickness (m), n_1 is the refractive index of the contact lens material, and F_2 is the power of the back surface of the contact lens/anterior surface of the post-lens tear layer interface (D).

This modelling highlights the relative difference in shape factor for scleral and corneal rigid lens corrections and indicates that lens thickness and apical clearance, rather than the fitting relationship, have the greatest impact upon the shape factor and therefore the overall magnification of the optical system. Therefore to minimise potential interocular differences in retinal image size between the fellow eyes in unilateral scleral lens wearers, the centre lens thickness and apical clearance should be as low as possible (with the optimal values dependent upon the refractive error of the fellow eye and how corrected).

Similarly, for bilateral scleral lens wearers, the interocular difference in centre lens thickness and apical clearance influence magnification to a much greater extent than the interocular difference in the BOZR. Consider an extreme example of interocular differences, in which one cornea of a patient is steep (e.g. keratoconus with a mean central corneal curvature of 5.4 mm and spherical equivalent ocular refraction of -10 D), and the fellow cornea is relatively flat (e.g. post-penetrating keratoplasty with a spherical equivalent ocular refraction of 0 D), and both eyes are fitted with scleral lenses with BOZR equal to the mean central corneal curvature. If both eyes are fitted with lenses of identical centre thickness (250 µm) and post-lens tear layer thickness (200 µm), but the mean corneal curvature of the post-graft eye is varied, and therefore the BOZR required for an alignment fit is also varied, the interocular difference in magnification varies by ~0.02% per 0.1 mm (per 100 µm) difference in BOZR between the two eyes. If the mean central corneal curvature and BOZR are fixed (5.4 mm for the keratoconic eye and 8.9 mm for the post-graft eye) and the lens centre thickness is held constant (250 µm), but the post-lens tear layer thickness is varied for the post-graft eye, the interocular difference in image size varies by ~0.28% per 100 µm difference in apical clearance. Similarly, if the BOZR and post-lens tear layer thickness are fixed in both eyes (200 µm) and the lens centre thickness is varied for the post-graft eye, the interocular difference in image size varies by ~0.33% per 100 µm difference in lens centre thickness. This modelling is displayed in Fig. 2 and highlights that between eye differences in the post-lens tear layer thickness and lens centre thickness have a substantially greater influence upon the interocular difference in image magnification than between eye differences in the BOZR (by a factor of ~15x in this example).

For simplicity, this example ignores meridional differences in corneal curvature and ocular refraction which are common in keratoconus and post-penetrating keratoplasty, and assumes for the sake of modelling that lenses of significantly different BOZR have the same centre thickness. It should be noted that an identical fit between the fellow eyes (equal post-lens tear layer thickness or lens centre thickness) may not result in equal image magnification, as the magnitude of anisometropia also influences the interocular difference in shape factor. In Fig. 2, interocular differences of up to 300 µm in apical clearance and lens centre thickness result in < ± 0.50% difference in shape factor, with equal magnification observed for between eye differences of 177 and 209 μm in the lens centre thickness and post-lens tear layer thickness examples respectively.

2.2. Visual acuity

In a large case series of over 500 patients, primarily with corneal ectasia or post-penetrating keratoplasty, Pullum and Buckley [41] commented that in some patients who were critical observers, vision was inferior when refitted into a scleral lens compared to their previous habitual corneal rigid lens. The authors attributed this to the closer alignment (and possibly apical touch) of corneal lenses with the anterior corneal surface, than with sclerals. However, differences in visual outcomes between the two lens types in these particular patients (or for what percentage of patients this occurred) were not presented. In a smaller retrospective analysis, Salam et al. [42] directly compared visual outcomes in 18 eyes of 15 patients (predominantly keratoconus and corneal graft cases) who originally wore corneal rigid lenses but ceased lens wear for a variety of reasons including discomfort, lens intolerance, or an inappropriate or unstable fit, and were refitted with scleral lenses. The mean astigmatism was 9.7 D (range 3.5–18 D) and on average, visual acuity improved from 6/18 with corneal lenses to 6/9 with scleral lenses. The authors advocated that the superior visual outcomes with scleral lenses in these particularly abnormally shaped corneae were due to the ability to vault the cornea without the need for close alignment. Increased lens stability, despite the need for relatively thick lenses, may have also improved lens centration and the elimination of any induced prismatic effects associated with excessive corneal rigid lens decentration. This small case series highlights some fitting benefits of scleral lenses that may translate to improved optical outcomes in complex corneal shapes.

2.3. Accommodation

Recently, Yildiz et al. [43] compared the total ocular higher order aberrations (HOA's) between two cohorts of keratoconic patients fitted with either a scleral or a corneal rigid lens. No significant differences were observed between the two groups over a range of accommodation demands. However, since the two lens designs were fitted to two different patient cohorts, it is not possible to draw reliable conclusions regarding the differences in visual or optical outcomes between corneal and scleral lenses in the correction of keratoconus during active or relaxed accommodation. Anecdotally, Shmidtke [44] noted a spasm of accommodation in new scleral lens wearers, particularly hyperopes, which diminished following adaptation to lens wear, and attributed this to a mechanical foreign body sensation, even with optimally fitted lenses, stimulating excessive accommodation. Bier [45] also observed that more plus power was often required following a few weeks of wear and attributed this to temporary ciliary spasm in scleral lens neophytes during the initial fitting, which relaxed after a period of lens wear. In a recent retrospective analysis of ~400 scleral lens fittings, ~15% of lens remakes were required for changes in lens power only, typically after one month of lens wear, potentially due to under correction during the initial fitting process [46].

3. Lens optics or modifications

3.1. Toric front surface

As for corneal rigid lenses, the fluid reservoir behind a scleral lens neutralises ~90% of anterior corneal astigmatism [47], but in some particular instances residual astigmatism is encountered during scleral lens wear. Residual astigmatism may arise due to the natural internal optics of the eye (e.g. significant posterior corneal astigmatism in keratoconus, lenticular astigmatism, or crystalline lens dislocation), or a result of scleral lens decentration [48,49], flexure [50], or warpage (see Sections 4.3 and 5.1).

Another clinical scenario which results in residual astigmatism arises when a toric intraocular lens (IOL) has been implanted to minimise the amount of post-operative astigmatism in keratoconus or post-penetrating keratoplasty, but a rigid contact lens is still required following surgery to optimise vision due to the irregular corneal shape. In such cases, a rigid lens will neutralise the anterior corneal optics, however, significant residual astigmatism then manifests due to the toric IOL which requires a front surface toric rigid correction or a rigid-soft toric piggyback correction [51]. While toric IOL's are relatively stable over time, significantly reduce spherical and astigmatic refractive error, and decrease spectacle dependence [52,53], this surgical intervention cannot correct irregular corneal astigmatism. In addition, the reliable quantification of the magnitude and orientation of total ocular astigmatism in the presence of irregular corneal astigmatism is difficult. Numerous authors [54–56] advocate that toric IOL's should only be considered in mild-moderate cases of stable keratoconus with low levels of irregular corneal astigmatism, when the patient has satisfactory visual acuity with spectacles (i.e. patients who are highly unlikely to require rigid corneal or scleral contact lens correction following cataract surgery to improve vision).

Aside from confirmed cases of significant internal astigmatism, in 1957 Bier [45] proposed that front surface toric corrections should only be considered if the residual astigmatic error that arises during the scleral lens fitting process is consistent in both magnitude and orientation on at least two separate occasions, and further recommended ignoring residual cylindrical over corrections of ≤ 0.50 DC, and approaching up to 1.00 DC over-refractions with caution. Applying any front surface optical correction to a scleral lens requires excellent rotational stability to ensure the correct lens orientation. This may be achieved using a range of more recent manufacturing techniques including dual thin zones, prism-ballast, or double slab-off designs, or incorporating a customised back surface haptic landing zone (toric, quadrant specific, or impression based).

3.2. Aspheric front surface

All contact lenses have inherent optical aberrations that influence the quality of vision during lens wear, dependent upon the interaction with the unique HOA profile of the individual eye. Conventional spherical rigid lenses significantly alter the magnitude of spherical aberration within the combined optical system of the eye and contact lens due to their steep surface curvatures, dependent upon various corneal and contact lens parameters (e.g. the radius of curvature, asphericity, refractive indices, lens centration, back vertex power [BVP]) and the pupil size (greater increases in positive spherical aberration for more positive BVP's and larger pupil diameters) [57–59]. The asphericity (eccentricity) of the front or back surface of a rigid contact lens can be altered to modify the sign and magnitude of spherical aberration introduced during lens wear (or as a presbyopic correction).

Kerns [60] investigated the visual outcomes in patients with residual astigmatism during conventional spherical corneal rigid lens wear when refitted with an aspheric front surface correction (rather than a front surface toric) and observed a significant improvement in visual acuity from ~6/6 to ~6/3.8 in young healthy eyes. Since the magnitude of residual astigmatism was unchanged with an aspheric front surface correction, the improvement in visual acuity was attributed to a reduction in spherical aberration. Similarly, a number of studies have investigated the objective and subjective visual benefits of altering the front surface eccentricity of scleral lenses.

Gumus et al. [61] trialed the PROSE (prosthetic replacement of the ocular surface ecosystem) lens, with front surface eccentricities (e^2) of 0.0, 0.3, 0.6, and 0.8, in patients with a range of corneal pathologies who were unsatisfied with their level of vision in conventional soft or corneal rigid lenses. In 27% of eyes, an aspheric front surface provided improved visual acuity, or was subjectively preferred, over the spherical front surface lens. Overall, the PROSE lens significantly reduced the total ocular HOA's by ~69-77%. Eyes fitted with the aspheric front surface lenses displayed ~3x greater natural levels of total root mean square error (RMS) spherical aberration (i.e. habitual spherical aberration without contact lens correction) compared to eyes which showed no visual benefit from an aspheric front surface correction, indicating that modifying the front surface eccentricity of a scleral lens may only be beneficial in some patients, and is most likely dependent upon the habitual total ocular HOA profile. Importantly, the interaction between lower and HOA's may also play a role in optimising visual acuity and minimising optical phenomenon such as shadowing and monocular polyopia [62].

In a follow-up study, Hussion et al. [63] also examined the effect of front surface eccentricity of the PROSE lens in five keratoconics. The outcome measures of visual acuity and HOA metrics varied considerably between subjects and with each lens design (i.e. a reduction in HOA metrics was not consistently observed with increasing eccentricity). The front surface eccentricity that provided the best visual performance did not always display the lowest level of total ocular RMS, spherical or comatic aberrations (possibly because visual acuity was not measured over the same fixed 4 mm pupil diameter used to analyse the HOA metrics of the lens corrected eye). This study also highlights that improving visual outcomes through modifications to the front surface asphericity of scleral lenses is most likely dependent upon the unique HOA profile of each individual eye, and that the optimal front surface correction may vary between patients and potentially between the fellow eyes of the same individual.

3.3. Wavefront guided front surface

Alterations in corneal shape and regularity due to ectasia, keratoplasty, or refractive surgery can result in substantial increases in anterior and posterior corneal aberrations (by a factor of up to 2-6x) [64–66]. Despite optimal sphero-cylindrical correction and the neutralization of the majority of anterior corneal surface abnormalities with a scleral lens, patients with significant residual internal HOA's may still report bothersome visual disturbances such as glare, haloes, shadowing, or monocular polyopia during rigid lens wear. In an attempt to improve the visual outcomes in such patients with significant internal HOA's, scleral lenses with customised wavefront guided front surface designs have been developed. Customised wavefront guided optical designs have been utilised previously in soft lenses for keratoconus, however, lens decentration and movement upon blinking resulted in only modest improvements in visual acuity [67,68], or significant residual internal HOA's still impaired vision [69–71].

Sabesan et al. [72] developed a front surface wavefront guided scleral lens using a quadrant specific back surface haptic design to minimise movement. Internal HOA's (the contribution of both the posterior cornea and crystalline lens) were measured using a Hartman-Shack aberrometer during cycloplegia, with a quadrant specific back surface scleral lens on eye with conventional spherical front surface optics. This aberrometry data was used to generate the customised front surface HOA correction after accounting for lens decentration and movement. In a small sample of eyes with severe keratoconus, correction with the customised front surface design resulted in a threefold reduction in the total HOA RMS value compared to the standard spherical optical correction (from 1.17 ± 0.57 μm to 0.37 ± 0.19 μm over a 6 mm pupil). A mean ~2 line improvement in visual acuity was also observed and a 1.5–2.5x increase in contrast sensitivity over a range of spatial frequencies, with all subjects reporting a marked improvement in image quality compared to the conventional scleral lens. However, the average visual acuity with the customised scleral correction (~0.2 logMAR) was worse than anticipated based on population HOA and visual acuity data from normal eyes (~ -0.10 logMAR). The authors attributed this to a potential neural adaptation, analogous to meridional amblyopia, following long-term exposure to significantly altered retinal image quality in keratoconus, which is supported by similar findings when correcting lower and HOA's in keratoconic eyes using adaptive optics [73].

Marsack et al. [74] also examined the change in HOA's and visual acuity in a small sample of eyes with moderate to severe keratoconus using a customised HOA front surface correction for residual internal aberrations. A back surface toric landing zone was used for stabilization and residual aberrations were measured using a Hartman-Shack aberrometer with an aspheric scleral lens on eye during cycloplegia. Total HOA's were significantly reduced with the customised scleral lens (~0.30 μm) compared to the standard aspheric scleral (~0.53 μm), and were comparable to age-matched population HOA data (~0.32 μm). However, the mean habitual visual acuity only improved from 0.14 logMAR (found with conventional soft and rigid corrections) to -0.01 logMAR with the customised scleral lens compared to an age-matched anticipated visual acuity of -0.14 logMAR. This data further supports earlier findings [72,73] that despite a significant reduction of residual aberrations in keratoconus, neural adaptation to long-term altered image quality may limit the visual potential with customised HOA scleral devices in the short-term and a period of visual adaptation with the new customised correction may be required before a significant improvement in vision to expected age-matched values is observed [74].

Front surface wavefront guided scleral lenses are commercially available through some manufacturers. A front surface aberration profile can be generated based on the measurement of all residual internal aberrations [72,75], or the posterior corneal aberration data derived from the posterior corneal elevation (aligned to the visual axis) [76], taking in to consideration the refractive indices of the cornea and scleral lens. However, no data has been published concerning the optical or visual outcomes with these commercially available devices.

While decentration and rotation of the optic zone relative to the pupil or line of sight will adversely affect optical and visual outcomes of a customised HOA front surface scleral lens design, a range of other factors during lens wear may also affect lower and HOA's (e.g. lens flexure and wettability, discussed in Sections 4.2 and 4.3). Regarding lens rotation, Ticak et al. [77] demonstrated the advantage of a toric haptic to improve stability during scleral lens wear. Averaged over an hour of wear, a rotationally symmetric spherical back surface design demonstrated ~11 ± 11° of rotation compared to three different back surface toric designs of varying complexity, all of which yielded rotation values of ~1 ± 1°. The authors calculated that this reduction in lens rotation would potentially improve visual acuity by ~1 line in keratoconic eyes. Sabesan et al. [72] also examined the rotational stability of two scleral lens designs with a different front surface optical correction, both manufactured with a quadrant specific back surface toric landing zone. Averaged across both lenses (fitted to 20 keratoconic eyes), the mean absolute lens rotation was 20 ± 17°, and the variation in lens rotation between the two lens designs was minimal (2 ± 10°). Lens rotation between the fellow eyes of an individual was similar and typically displayed mirror symmetry (mean absolute difference in lens rotation was 9 ± 10°). An analysis of the temporal dynamics for a single lens fit suggested good stability for this lens design, with the lens rotating between 0-2° over a twenty second period including blinking.

3.4. Multifocals

Current prescribing data in the United States (a survey of ~100 practitioners) indicates that multifocal scleral lenses account for ~2% of all contact lenses prescribed and ~10% of all multifocal designs prescribed [78]. The use of multifocal scleral lenses may increase in the coming years as more practitioners take advantage of this lens modality for presbyopic patients with regular astigmatism or ocular surface disease, as a potential myopia control intervention, or a stable lens platform for researchers to trial different multifocal designs for other applications such as orthokeratology [79].

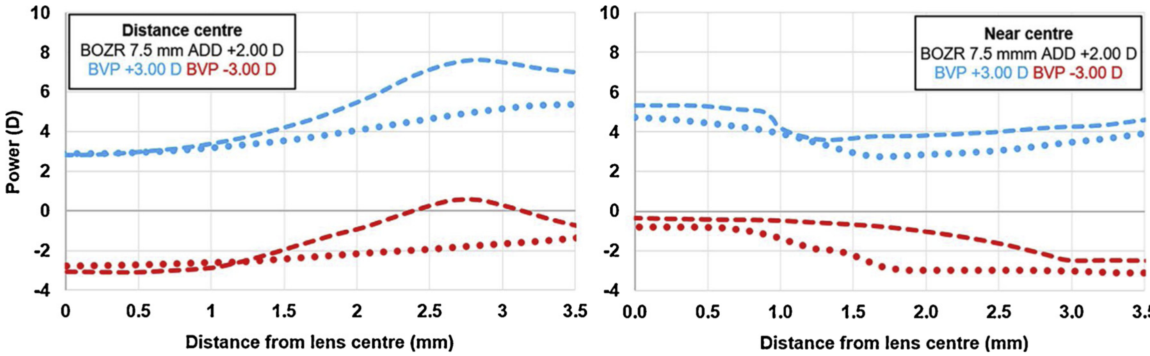

Fig. 3. Anterior surface refractive power profiles of various multifocal scleral contact lenses derived from the NIMO TR1504 contact lens power mapper, demonstrating variations between different designs across the optic zone for both distance and near centre lens lenses (± 3.00 D back vertex power and +2.00 D near addition) while controlling for back optic zone radius (data extracted from Kargenian et al [80]). Dotted and dashed lines of the same colour represent different scleral lens designs with the same nominal back optic zone radius (BOZR), back vertex power (BVP), and near addition (ADD).

Since scleral lenses do not move substantially with blinking or downward gaze, translating bifocal lens designs are not a feasible multifocal correction and either concentric or aspheric simultaneous vision designs (centre distance or near) are applied to the front or back surface of the lens. The parameters available vary considerably between laboratories and lens design (e.g. central optic zone diameters ranging from 0.5–7 mm and near addition powers from +0.50 to +5.00 D), with some designs allowing complete customization (including offset of the optic zone). The power profile of different multifocal lenses across the optic zone can vary substantially between products, even with an identical BOZR, BVP and centre distance/near design [80] (Fig. 3), which highlights the importance of working closely with the manufacturer to understand each lens design in order to optimise patient outcomes. As for all multifocal contact lens fittings, fitting scleral multifocal lenses requires consideration of the visual demands over a range of working distances, binocularity requirements, the pupil size over a range of lighting conditions, and patient expectations.

3.5. Prism and binocularity

Concerning prism and scleral lenses, Rugg-Gunn [33] stated "*… there is no theoretical reason why a contact glass should not be made with a prism worked on its outer surface to neutralize convergence…. Practically, however, it would not be possible to keep the prism in its correct position.*" Almost a century later, it is possible to incorporate a limited amount of prism into some scleral lens designs (up to ~5 Δ) by altering the anterior lens surface profile (thickness) within the optic zone, however, excellent stability with respect to lens movement and rotation is required. A limited number of case reports have described the use of prism within a scleral lens to correct binocular vision anomalies. Bragg and Sindt incorporated 3.5 Δ base-up within a customised scleral lens (EyePrintPRO) to eliminate vertical binocular diplopia in a 48 year old with longstanding keratoconus, high myopia, and a 4 Δ right hypertropia [81]. This correction resulted in 1–2 Δ of right hyperphoria in primary gaze, and single binocular vision. Parker [82] also described the use of a scleral lens to correct high myopia and presbyopia and eliminate intermittent vertical diplopia in a 55 year old male with a customised EyePrintPRO multifocal design incorporating 3.75 Δ split between the eyes. Similarly, Frogozo [83] incorporated a prismatic correction within the EyePrintPRO (6 Δ base out split between the eyes) to eliminate constant horizontal diplopia due to head trauma in a 73 year old male, while also correcting irregular anterior corneal astigmatism due to bilateral radial keratotomy.

Interestingly, Sherafat et al. [84] described the benefits of scleral contact lenses, without prism, in a small case series of patients with asymmetric keratoconus and impaired binocularity (exotropia with either suppression or diplopia), presumably due to long-standing impaired vision in the eye with more advanced corneal disease. With a scleral lens correcting the eye with substantially worse vision, and despite the persistent reduced visual acuity following scleral lens correction relative to the corneal rigid lens corrected fellow eye, 90% of all patients demonstrated a significant improvement in binocular function with 60% displaying a phoria, 30% a microexotropia with either single binocular vision (80%) or persistent central suppression (20%). The reminaing 10% of patients had a persistent exotropia with suppression. These data suggest that in some particular cases, scleral contact lenses without a prismatic correction may restore binocularity and enhance ocular alignment due to an improvement in visual acuity in patients with long-standing asymmetric corneal disease who may have developed sensory exotropia and subsequent suppression.

Prismatic correction can be incorporated within scleral lenses for patients with both regular and irregular corneae to eliminate binocular diplopia. However, the magnitude of prism that can be prescribed is currently limited to ~5 Δ (per lens) due to the significant change in thickness profile required and potential sequellae related to corneal hypoxia. Consequently, spectacles with prism may be required in some cases to be worn in conjunction with scleral lenses. Given the high degree of stability required to maintain the orientation of the prism during lens wear, particularly for horizontal deviations, the majority of isolated cases reported in the literature involve lenses manufactured with a customised haptic based on impression molding.

3.6. Reverse geometry designs

Oblate, or reverse geometry, back surface designs incorporate a central BOZR that is flatter than the adjacent peripheral curve (i.e. the opposite of a conventional prolate back surface design). Unlike conventional prolate back surface designs, which may be most appropriate for regular or keratoconic corneae, oblate designs are often indicated in post-surgical cases where the central cornea is significantly flatter centrally compared to the periphery (e.g. corneal refractive surgery for myopia, radial keratotomy, and in some post-penetrating keratoplasties [85–88]). In these cases a reverse geometry design more closely aligns with the shape of a surgically altered cornea and allows for relatively uniform and lower clearance of both the central and mid-peripheral cornea, while a conventional back surface design may yield mid-peripheral bearing and require a significant increase in sagittal depth, and therefore excessive central clearance, to clear the mid-periphery. This may adversely affect oxygen transmission, lens stability, centration, and induce a prismatic effect from the post-lens tear layer if the corneal apex or cone is not centred. However, oblate back surface designs may also be fitted to prolate corneae. For example, in advanced corneal ectasias, fitting a reverse geometry design may reduce the need for a steeper BOZR, and the convexity of the post-lens tear layer, resulting in a less minus (or more plus) powered scleral lens. This will alter image magnification, and also has advantages for oxygen transmission for myopic corrections [89]. Currently, no studies have examined the optical or visual benefits of prolate and oblate back surface lens designs. Therefore, it remains unclear if there are significant visual benefits in some or all corneal shapes fitted with reverse geometry lenses, and if the optical benefits relate to a more uniformly distributed post-lens tear layer and therefore potentially less oedema, improved lens centration, or a reduction in image minification.

Gemoules and Morris [86] examined the optical outcomes and visual performance in ten highly symptomatic patients who had undergone corneal surgery (PRK, LASIK and penetrating keratoplasty) and were fitted primarily with reverse geometry corneo-scleral lenses (85% of lenses) ranging from 13.4–15.0 mm in total diameter. These patients had minimal post-operative refractive error (mean < 1 D spherical equivalent), but experienced glare, starbursts, ghosting or monocular polyopia consistent with elevated levels of HOA's (mean spectacle acuity 6/7.5). Visual acuity with scleral contact lenses improved to 6/6 on average, but decreased in 15% of eyes. In these highly aberrated eyes, oblate back surface scleral contact lens correction significantly reduced the RMS values of HOA's by 65%, including spherical aberration by 82% and coma by 71%. While a prolate back surface scleral lens (or a corneal rigid lens [85]) may have reduced HOA's to a similar extent, a physiologically acceptable fit may not have been possible with a conventional design.

3.7. Contact lens telescopes

Since the 1930's, numerous methods which utilise a high minus scleral contact lens as the eyepiece of a low powered monocular Galilean refracting contact lens-spectacle telescope (in conjunction with a high plus powered spectacle lens objective) have been proposed [90,91] and utilised in clinical practice [92–94] to provide distance and near magnification for patients with low vision. The major advantages of such contact-spectacle lens telescopic systems is the improvement in cosmesis and conspicuity compared to traditional low vision aids [95,96]. Optically, such contact lens telescopic systems provide a substantially larger field of view in comparison to hand-held or spectacle mounted telescopes, however, the theoretical maximum magnification is limited to ~2x, primarily because the maximum separation between the principal planes of the contact lens eyepiece and spectacle lens objective is limited by the spectacle frame vertex distance. Since the movement of a high minus powered contact lens with a blink, relative to the fixed position of the spectacle lens objective, causes an apparent movement of the visual field, scleral lenses provide a very stable eyepiece.

Scleral lenses have also been utilised in reflecting telescopes, an approach which incorporates internal reflectors within the optic zone, and provides increased magnification and brightness, reduced weight and improved cosmesis (a high powered spectacle objective is not required) compared to refracting contact-spectacle lens telescopes. The optics of scleral lens reflecting telescopes have been described in detail elsewhere [95,97–99]. Briefly, the lens includes two orthogonally polarised independent optical paths; unmagnified (through a central horizontal polariser) and magnified through internal reflection (via a mid-peripheral vertical polariser) (Fig. 4). The polarisation state of spectacles worn over the lens is changed using liquid crystal elements, controlled by the wearer, to switch between the magnified and unmagnified paths. Providing adequate corneal oxygenation poses a significant design challenge for such lenses since the internal reflectors are encased within a PMMA core and surrounded by a gas permeable shell with a total lens thickness of more than 1600 μm [97]. Details regarding the corneal response during lens wear or long-term optical performance have not been published.

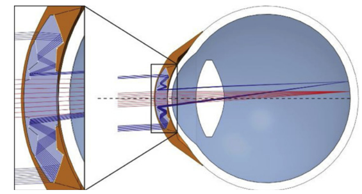

Fig. 4. Optical ray trace through the 1x (red) and 2.8× (blue) apertures of a reflecting telescope contact lens with zoomed inset showing the internally reflected optical path. The optical axis is shown as a dotted line. Reproduced with permission of The Optical Society (OSA) from: G.M. Schuster, A. Arianpour, S. Cookson, A. Zhang, L. Hendrik, T. O'Brien, A. Alvarez, J.E. Ford, Wink-controlled polarization-switched telescopic contact lenses, Appl Opt 54(32) (2015) 9597-605.

4. Lens specific issues

4.1. Manufacturing tolerances

The current International Standard dimensional and optical tolerances for scleral and corneal gas permeable (GP) lenses are summarised in Tables 1 and 2 [100], which have remained largely unchanged for scleral lenses over the past thirty years. It should be noted that while the optical tolerances are identical for corneal gas permeable and scleral lenses, for BOZR, total diameter, and centre thickness parameters, these particular dimensional tolerances are 2-5x greater for scleral lenses compared to corneal GP lenses. A centre lens thickness tolerance of ± 100 μm is significant (compared to ± 20 μm for corneal lenses), since for scleral lenses with labelled centre thicknesses ranging from 170 to 420 μm for example [89], a ~20–60% variation from the labelled value would be still be considered within the manufacturing tolerance. This may have potential optical implications with respect to lens flexure or warpage, and estimating oxygen permeability.

4.2. Wettability

Wettability indicates how a liquid spreads over a surface and can be quantified by measuring the contact angle formed between a drop of liquid and the lens surface, with a lower contact angle associated with improved wettability. Poor lens wettability can significantly compromise patient comfort, visual quality and stability, and is dependent

Table 1
Dimensional manufacturing tolerances for corneal gas permeable (GP) and scleral contact lenses from the International Standard ISO 18369-2:2017 Ophthalmic optics - Contact lenses (Part 2: Tolerances) [100].

Dimension (mm)	Tolerance	
	GP corneal contact lens	Scleral contact lens
Back optic zone radius	± 0.05	± 0.10
Back optic zone radii (toroidal surfaces)[a]		
$0 < \Delta r \le 0.2$	± 0.05	± 0.12
$0.2 < \Delta r \le 0.4$	± 0.06	± 0.13
$0.4 < \Delta r \le 0.6$	± 0.07	± 0.15
$\Delta r > 0.6$	± 0.09	± 0.17
Back and front peripheral radius	± 0.10	± 0.10
Back scleral radius (preformed)		± 0.10
Back and front optic zone diameter	± 0.20	± 0.20
Primary optic diameter		± 0.20
Back peripheral diameter	± 0.20	± 0.20
Total diameter	± 0.10	± 0.25
Bifocal segment height	−0.10 to 0.20	−0.10 to 0.20
Centre thickness	± 0.02	± 0.10

Δr denotes the difference between the back optic zone radii between the two principal meridians.

[a] Tolerance applies to each principal meridian.

Table 2
Optical manufacturing tolerances for rigid contact lenses from the International Standard ISO 18369 – 2:2017 Ophthalmic optics - Contact lenses (Part 2: Tolerances) [100].

Dimension	Tolerance
Labelled back vertex power (weaker meridian) (D)	
$\|BVP\| \leq 5.00$	± 0.12
$5.00 < \|BVP\| \leq 10.00$	± 0.18
$10.00 < \|BVP\| \leq 15.00$	± 0.25
$15.00 < \|BVP\| \leq 20.00$	± 0.37
$\|BVP\| > 20.00$	± 0.50
Optical centration (sclerals only, maximum error) (mm)	0.50
Cylinder power (D)	
≤2.00	± 0.25
< 2.00 to ≤4.00	± 0.37
< 4.00	± 0.50
Cylinder axis (degrees)	± 5

upon a number of factors including the contact lens material (the contact angle and surface treatments or coating), the patient's ocular surface and tear film, lens cleaning procedures, and potential exposure to contaminants [101].

Poor wettability observed at the initial lens delivery may be caused by laboratory related issues such as over-polishing or the adherence of residual substances from the manufacturing process, or handling throughout shipment or in-office [102]. Additionally, patients with ocular surface disease or eyelid anomalies such as ocular rosacea, meibomian gland dysfunction, Sjögren syndrome, graft versus host disease, or lid wiper epitheliopathy may be predisposed to poor lens wettability, and should be treated prior to and during scleral lens wear as required. If poor wettability persists despite the active treatment of eyelid and ocular surface disease, personal hygiene and lens care and maintenance procedures should be revisited (investigating any potential contaminants that may have come into contact with the lens surface such as make up, hair products, soaps) and solution compatibility also considered. Plasma treatment or a polyethylene glycol-based polymer coating (Hydra-PEG) to render the lens surfaces more hydrophilic may assist with recalcitrant cases of poorly wetting lenses, however, the efficacy of these treatments will vary over time and between patients. Other lens surface anomalies such as significant scratches, deposits and crazing may also affect lens wettability, and overall visual performance, and affected lenses which cannot be remedied through in office cleaning or polishing should be replaced (as for corneal rigid lenses).

While a small number of studies have investigated the influence of different corneal rigid lens material properties upon lens wettability or tear film surface quality in-vivo [103,104], only one study has specifically investigated scleral lenses wettability (tear film surface quality scores measured with the lens in-situ using high-speed videokeratoscopy) [105]. On average, scleral lens tear film surface quality was similar at both lens delivery shortly after insertion and one month later following 8 h of lens wear (~3% decrease) in a cohort of keratoconic patients using a hydrogen peroxide care system. Given the significant differences between corneal rigid lenses and sclerals lenses with respect to lens diameter and depth, surface area and movement, and the vastly different interaction with the bulbar and tarsal conjunctiva during lens wear, future studies directly comparing the in-vivo tear film surface quality between these two lens modalities may provide useful information regarding longer-term visual performance.

4.3. Flexure and warpage

It is well known that spherical corneal rigid lenses may flex on the eye, and the extent of this flexure is influenced by the BOZR fitting relationship [106,107], lens diameter [108], material Dk [109], and thickness [110]. Lens flexure may also be observed during scleral lens wear and can typically be visualised or quantified using over-keratometry or videokeratoscopy of the anterior scleral lens surface (Fig. 5), however, flexure may also generate scleral lens back surface toricity that alters the power of the post-lens tear layer. Since scleral lenses rest entirely upon the sclera and overlying tissues, the magnitude of lens flexure is governed by scleral rather than corneal toricity. Vincent et al. [50] observed that decreasing scleral lens centre thickness from 350 μm to 150 μm, a common approach used in clinical practice in an attempt to improve oxygen transmission to the cornea, did not result in a significant increase in flexure, unless scleral toricity was greater than 200 μm (i.e. the greatest scleral height difference between perpendicular meridians at a 15 mm chord).

To minimise scleral lens flexure the centre or junctional thickness can be increased, or the scleral landing zone may be customised using a toric, quadrant specific or impression derived haptic. If residual astigmatism persists, despite optimising lens thickness and centration, and landing zone alignment, a front surface toric may be indicated if lens warpage has also been excluded. As stated earlier, front surface toric corrections should only be considered if residual astigmatic error is visually significant and consistent in orientation and magnitude with repeated testing.

Lens warpage refers to persistent unwanted front or back surface toricity (with respect to the tolerances outlined in Table 1), measured in-vitro, which may arise due to the lens manufacturing process or

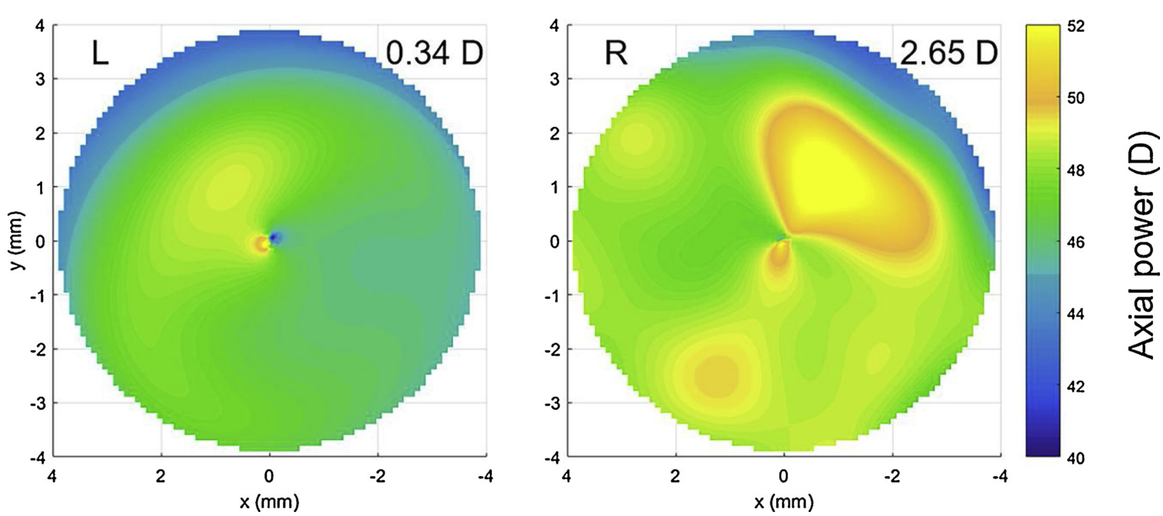

Fig. 5. Anterior surface axial power over-topography maps obtained during wear of two scleral lenses using Scheimpflug imaging from the same individual. The left lens displays minimal flexure (0.34 D averaged across the central 6 mm), while the right lens displays significant residual astigmatism greater than 2.5 D.

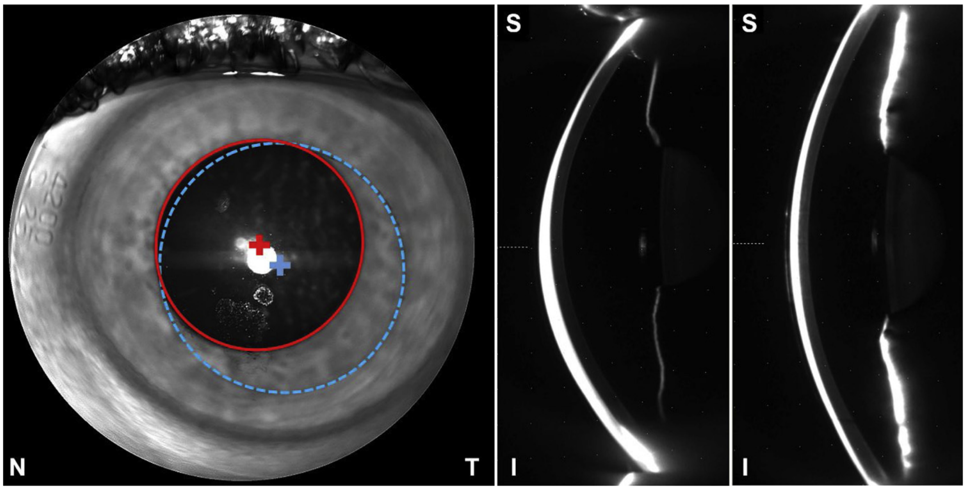

Fig. 6. Examples of scleral lens decentration. Left image: En-face scanning laser ophthalmoscope image of a scleral lens (8 mm optic zone diameter, blue line) on a left eye (6.5 mm pupil diameter, red line) exhibiting inferior (~0.65 mm) and temporal (~0.62 mm) decentration (blue cross) relative to the pupil centre (red cross). Middle image: Scheimpflug imaging of the post-lens tear layer with sodium fluorescein (white band) demonstrating the base down prismatic effect associated with inferior lens decentration (i.e. a thicker post-lens tear layer inferiorly compared to superiorly). Right image: Scheimpflug imaging of a centred scleral lens displaying a relatively uniform and symmetrical (plano powered "alignment/on-k fit") post-lens tear layer thickness along the vertical meridian.

gradually over time due to lens wear and routine handling. Lens warpage can be assessed and quantified using a radiuscope or in-vitro keratometry or videokeratoscopy and may manifest as reduced acuity during lens wear, which improves with a cylindrical over-refraction. Vertometry may not be appropriate to investigate potential warpage since a spherical rigid lens that is approximately equally warped on the front and back surface will still display a spherical BVP. Clinically, lens warpage may also be confirmed by refitting a patient using a known non-warped diagnostic trial lens to see if visual acuity improves. Vincent et al. [50] examined the influence of centre lens thickness (150, 250 and 350 μm) upon miniscleral lens warpage (based on changes in-vitro front surface toricity) over time in a short-term study and observed no significant differences between the lenses and minimal warpage (< 0.05 D). However, warpage associated with different lens designs and longer wearing times may vary significantly. For example, Cho et al. [111] reported a slight flattening of the BOZR (mean ~0.015 mm) for high Dk corneal rigid lenses over a simulated handling period of 9 months.

4.4. Lens material and parameters

Differences in the physical characteristics, chemical structure and composition of rigid lens materials may also influence the optical quality and visual performance of a contact lens. Dominguez-Vicent et al. [112] recently assessed the in-vitro optical quality of corneal rigid lenses (BVP -3.00 D, BOZR 7.90 mm, total diameter of 9.60 mm, and center thickness 190 μm) manufactured in four different Boston contact lens materials (ES, EO, XO, and XO_2) using a modified interferometer. Statistically significant differences were observed between the different lens materials over a 3 mm diameter, but the magnitude of variation was not clinically significant (largest difference in HOA RMS < 0.01 μm). For a 6 mm analysis diameter, the largest difference in HOA RMS between materials approached 0.1 μm, which could be considered clinically significant. The Boston ES material displayed the best optical quality across a range of metrics. This particular material is recommended for corneal rigid lens daily wear, but is not suitable for scleral lens wear due to its low Dk of 18 (and has a maximum button size of 12.7 mm) [113]. Importantly, no clinically significant optical differences were observed between the XO and XO_2 materials, which are often used for larger diameter rigid lenses (e.g. on average the HO RMS differed by only 0.006 μm between these two high Dk materials).

In a follow-up study, Dominguez-Vicent et al. [114] applied the same interferometry technique to assess the optical quality and refractive power profile of scleral lenses of varying diameter (14.4 and 16.6 mm) and BVP (up to ± 3.75 D) while controlling for BOZR (7.8 mm). Across a 6 mm central diameter, the BVP varied by up to 0.40 D, however there was no systematic pattern of variation observed with respect to lens diameter or BVP. Interestingly, 30% of the lenses examined were outside the BVP manufacturing tolerance listed in Table 2 (difference between the nominal and measured BVP > 0.12 D, range −0.50 to +0.30 D), however, the measurement of the BVP in this study was not consistent with the recommended measurement standards [115]. Regarding the optical quality of the lenses with respect to lens diameter, over a 3 mm analysis diameter, minimal differences were observed between the 14.4 and 16.6 mm lenses when averaged across all BVP's (a difference of 0.3% for HOA RMS and < 2% for the visual Strehl ratio). However, larger differences were observed over a 6 mm analysis diameter, with a poorer optical quality observed for the 16.6 mm compared to the 14.4 mm lenses (a 38% increase in HOA RMS and a 12% reduction in the visual Strehl ratio averaged across all BVP's). This may be due to differences in the thickness profile outside the central 3 mm and towards the edge of the optic zone for lenses of different diameters [38,89].

While these in-vitro studies provide some insights into the factors potentially affecting the optical quality of scleral contact lenses, the results are difficult to translate directly to clinical practice since numerous other variables influence the overall visual performance during scleral lens wear such as the age of the lens, surface wettability, lens centration and flexure, and the composition of the post-lens tear layer. In addition, small differences in various lens parameters, within the ISO manufacturing tolerances (Tables 1 and 2), or the repeatability of the specific interferometric technique used in these studies may contribute to some of the observed differences in optical quality between lens designs or materials [112,114].

5. The lens fit

5.1. Decentration

It is well established that tilt or decentration of rigid contact lenses induce residual astigmatism and HOA's [48,49]. Scleral lenses often decentre during lens wear; typically temporally due to the elevated and flatter sclera in the nasal compared to the temporal quadrant, and inferiorly due to gravitational and eyelid forces. Decentration of the optic zone relative to the pupil centre due to lens translation may induce an unwanted prismatic effect (both vertically and horizontally), and HOA's that are not neutralised by the post-lens tear layer (Fig. 6). A non-uniform settling of the lens on eye may also induce a prismatic effect (e.g. the optic zone is relatively centred but there is greater lens settling superiorly compared to inferiorly) (Fig. 6). The reliable measurement of scleral lens decentration is challenging and requires en-face imaging and markings on the scleral lens [72,77] or high resolution anterior segment OCT imaging [116] and customised software to quantify lens translation. However, Vincent and Collins [117] recently proposed a topography based method to quantify decentration relative to the pupil centre which may be a simpler approach that can be utilised in clinical practice.

While induced prism will not affect visual acuity, it may adversely affect binocularity, particularly in unilateral scleral lens wearers. The magnitude of prism theoretically induced during scleral lens wear can be estimated using Bennett's equation [40] which calculates the optical effect of both the decentred contact lens and the anterior surface of the fluid reservoir. The theoretical magnitude of prism induced (P, in prism dioptres) is given by

$$P = c\left[\frac{F_{CL}}{10} + \frac{33}{r_2} - \frac{33}{r_s}\right]$$

where c is the magnitude of lens decentration, F_{CL} is the BVP of the contact lens in air, r_2 is the BOZR of the scleral lens, r_s is the radius of curvature of the anterior sclera (with all distances in mm). Given that the refractive indices of various saline solutions typically only vary to the third decimal place (n ∼1.33) [118], the primary modifiable determinants of the magnitude of prism induced during scleral lens wear are; the BOZR and BVP of the lens and the magnitude of decentration.

Fig. 7 shows the theoretical magnitude of prism induced as a function of lens decentration for a range of BVP's (controlling for BOZR) (A), and for a range of BOZR (controlling for BVP) (B) (using a refractive index of saline of 1.33 and r_s of 13.12 mm [119]). Increasing levels of induced prism are associated with greater lens decentration, steeper BOZR (when controlling for BVP), and increasing hyperopia/decreasing myopia (when controlling for BOZR). The magnitude of prism induced as a function of lens decentration for a suite of scleral lenses contained within a diagnostic fitting set is included in Fig. 7C to display the relationship for typical BOZR/BVP combinations. As a clinical rule of thumb (for this particular diagnostic fitting set), the amount of prism induced is approximately double the decentration, however, this approximation becomes less reliable for larger amounts of lens decentration (i.e. 2 ± 0.50 Δ for 1 mm decentration and 6 ± 1.5 Δ for 3 mm decentration).

Vincent et al. [116] calculated that only a small amount of prism was induced during short-term wear relative to the pupil centre 0.01 ± 0.16 Δ base out and 0.50 ± 0.19 Δ base down (maximum prism induced 1.35 Δ base out, 1.53 Δ base down), due to minimal lens decentration (average 0.01 mm temporally and 0.24 mm inferiorly) and the predominantly minus powered lenses used in the study. Prismatic effects due to lens decentration are of most concern in unilateral corrections for aphakia or high hyperopia due to the lens mass, which may induce diplopia (typically vertical) or prevent fusion or comfortable binocular vision due to a significant latent heterophoria or poor fusional reserves [39].

Lens decentration may also introduce unwanted HOA's, typically horizontal or vertical coma. Additional comatic aberrations may not be visually significant in a standard scleral lens correction if the decentration is minimal, however, decentration is problematic for wavefront guided lenses designed to correct residual HOA's that are not neutralised by the post-lens tear layer [72,75]. Good centration is particularly critical for aspheric contact lenses, potentially more so than spherical front surface lenses. For example, modelled over a 5 mm pupil diameter, a +6 D rigid lens with an aspheric front surface (Q = -0.24 to minimise spherical aberration) fitted to a spherical cornea, that decentres by 1 mm induces -0.30 DS/-0.56 DC residual astigmatism, and -0.66 DS/-1.25 DC for 1.5 mm displacement [120].

In order to minimise lens decentration and resultant unwanted prism or HOA's, potential solutions include reducing the lens thickness or mass, reducing the total lens diameter or fitting a customised back surface haptic, or decentring the optic zone. For prismatic effects specifically, other options include incorporating prism into the scleral lens

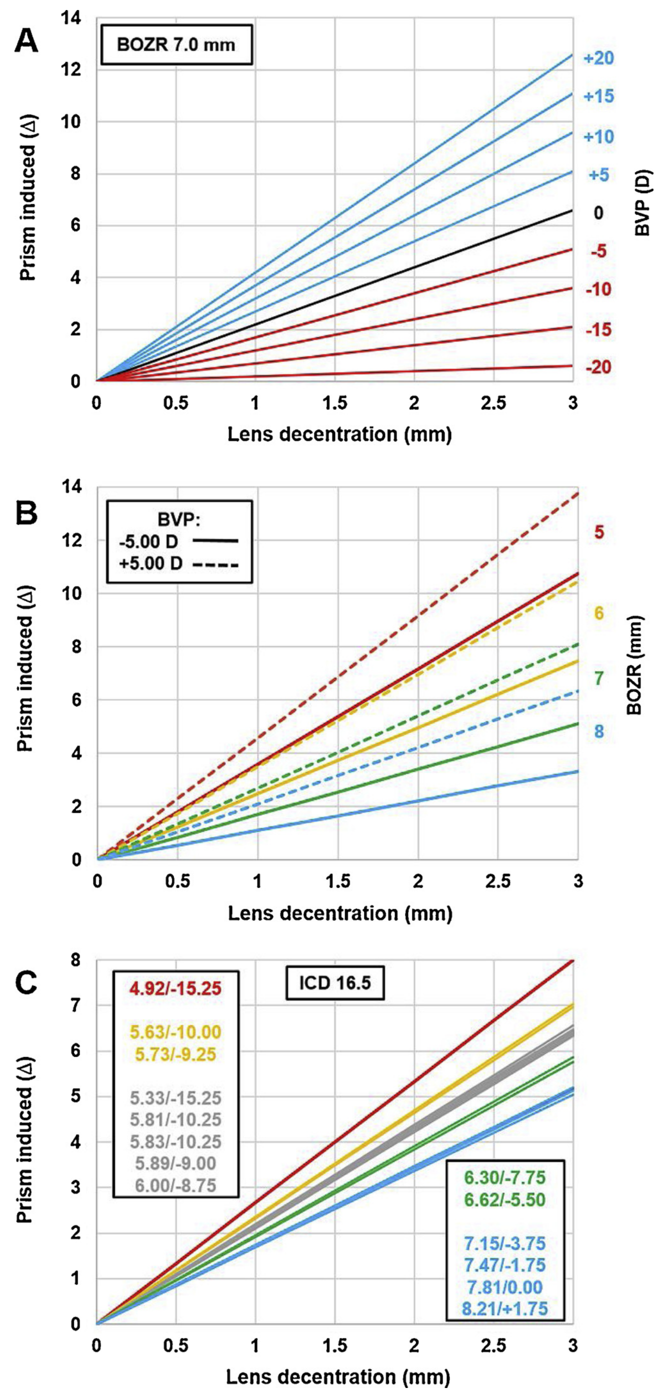

Fig. 7. The theoretical relationship between scleral lens decentration and the magnitude of prism induced. (A) The effect of back vertex power (± 20 D) upon prism induced for a fixed back optic zone radius of 7.00 mm. (B) The effect of back optic zone radius (5–8 mm) upon prism induced for fixed back vertex powers of ± 5 D. (C) The effect of lens decentration upon prism induced for a typical range of scleral lens back optic zone radius and back vertex power combinations (4.92 mm/-15.25 D to 8.21 mm/+1.75 D) from an Irregular Corneal Design (ICD 16.5) trial lens kit (y-axis scale differs in C). Note: all calculations used an anterior scleral radius of 13.12 mm and refractive index of the post-lens tear layer of 1.33. Back vertex power (BVP), back optic zone radius (BOZR), Irregular Corneal Design (ICD).

or over spectacles, altering the BOZR to create a plano powered post-lens tear layer, or in unilateral lens wearers, fitting the fellow eye with a scleral lens so there is some (typically vertical) prism induced in both eyes which will eliminate or reduce the interocular prismatic

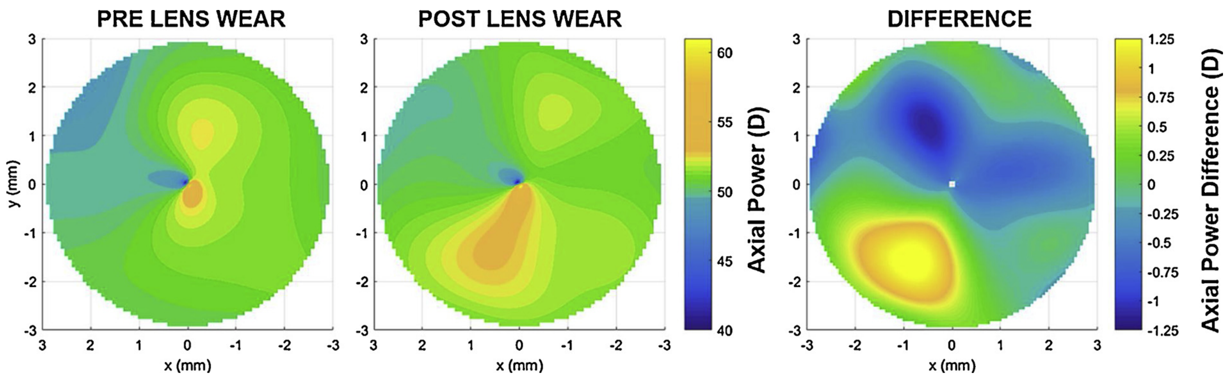

Fig. 8. An example of changes observed in the optics of the anterior corneal surface curvature of one individual following three hours of miniscleral lens wear. The pre and post lens wear axial power maps display the corneal topography immediately before lens insertion and after lens removal and the difference map highlights a region of central and superior corneal flattening and inferior corneal steepening. Averaged over the central 6 mm the sphero-cylindrical refractive change induced was $+0.48/-0.65 \times 150$.

imbalance.

5.2. Transient changes in corneal optics

The magnitude and persistence of changes in corneal optics induced by any type of contact lens are important considerations when evaluating corneal stability with respect to the progression of keratoconus, and consequently the indication for collagen cross linking, or obtaining accurate biometric data for intraocular lens calculations. While optimal fitting scleral lenses do not bear on the cornea, a small number of studies have documented that scleral lens wear results in anterior surface flattening (which may result in an underestimation of disease progression) and alterations in the HOA profile which may affect visual quality following lens removal (increased spectacle blur).

In non-keratoconic corneae, scleral lenses have been reported to induce ~0.10 mm of anterior surface flattening on average in the central or superior cornea, following 3–8 h of wear [18,28,29] (Fig. 8). A similar magnitude of flattening up to ~0.2 mm on average has also been reported following 8 h of scleral lens wear in keratoconic corneae (both with and without intracorneal ring segments [ICRS]), although the location of corneal flattening varied substantially; primarily superiorly and nasally in keratoconic eyes and inferiorly in those with ICRS (i.e. the location of the implants) [30]. Soeters et al. [31] also observed that immediately following lens removal the global mean central keratometry values were 0.5–1.1 D flatter compared to baseline values obtained after 1–2 weeks without lens wear (18–22 mm diameter lenses). Importantly, in all of these studies the scleral lenses were appropriately fitted with adequate corneal clearance, and in non-keratoconic eyes 50% of subjects demonstrated an increase in anterior surface corneal cylinder of > 0.25 D and 40% displayed an increase of 0.50 D or more [28]. Only one study has examined the recovery of such scleral lens induced changes in corneal optics [18]. The central anterior surface curvature had returned to baseline levels after 3 h of lens removal and the change in anterior surface corneal sphero-cylinder had reduced by half. Minimal changes in posterior corneal curvature have been observed immediately following lens removal [18,20], however a slight flattening may occur as the cornea de-swells from mild corneal oedema [18]. This change in posterior corneal curvature alone would have minimal impact on visual quality, unless significant corneal oedema was present.

A small number of studies have also described more subtle and complex changes in the anterior corneal surface shape or optics following scleral lens removal by converting the corneal elevation data to a wavefront [18,28,30]. In non-keratoconic corneae, no significant changes in anterior corneal HOA's were observed following 3 h of lens wear (6 mm analysis diameter) [18]. However, horizontal and vertical coma and spherical aberration varied significantly following 8 h of lens wear (by up to 0.2 µm over an 8 mm corneal diameter) [28]. In keratoconic eyes, a significant increase in spherical aberration has been reported after 8 h of lens wear (6 mm diameter) and an increase in vertical coma in keratoconic eyes with ICRS observed over the central 4 mm only [30]. Together, these studies suggest that changes in anterior corneal HOA's following scleral lens wear are typically modest changes in spherical aberration and coma (≤0.2 µm for individual Zernike terms), however, the magnitude of the observed change is dependent upon the pupil size or corneal diameter over which the corneal wavefront is analysed and potentially the duration of lens wear. While changes in the anterior corneal shape during lens wear will be partially neutralised by the post-lens tear layer, following lens removal these changes may compound spectacle blur or adversely affect vision particularly for patients with larger pupils. While the magnitude of the corneal changes observed in normal and keratoconic eyes appear relatively similar, the optical changes induced in biomechanically altered corneae following surgeries such as LASIK, radial keratotomy or penetrating keratoplasty are unknown.

Practitioners should be cognisant that topography captured shortly after scleral lens removal may mask subtle corneal steepening (i.e. disease progression or regression following corneal collagen cross-linking of up to ~1 D). Relying upon measurements of corneal thickness immediately after lens removal to estimate disease progression via corneal thinning may also be misleading since high Dk scleral lenses induce up to 2% corneal swelling in young healthy eyes (i.e. a pachymetry increase of ~ ≥10 µm) [17–20,121]. Currently, the exact cause of these changes in corneal optics following lens wear remains unknown. Since scleral lenses vault the cornea, the typically observed flattening is not a result of mechanical contact, but rather may be a consequence of pressure within a sealed system, low level corneal oedema, or compression forces or mechanical stress within the scleral landing zone that is transferred to the adjacent limbus [122,123]. Greater corneal changes following scleral lens wear have been observed in Asian compared to Caucasian eyes [28] which suggests that limbal anatomy [124] or eyelid morphometry may also play a role.

6. The post-lens tear layer

6.1. Air bubbles

The presence of unwanted air bubbles within the post-lens tear layer is a common issue that arises during the scleral lens fitting process. The formation of air bubbles may be due to improper lens application (typically insufficient filling of the lens bowl with saline, or excessive loss of saline during insertion), or a non-optimal lens haptic fitting relationship with the underlying sclera which allows external tears and air to enter the reservoir. For a sealed scleral lens system, small mobile bubbles, of less than 2–3 mm in diameter, may be acceptable, since they will not cause significant corneal desiccation, often reduce in size during lens settling, and do not adversely affect vision. This is the desired effect when fitting fenestrated lenses. Larger and immobile bubbles due to the lens fit must be managed prior to undertaking long-term lens wear due to potential physiological complications associated with persistent corneal dehydration such as chronic epithelial staining and dellen formation. This may require the use of a customised haptic or further reduction in apical clearance for fenestrated lenses. Optically, an air bubble in the post-lens tear layer that traverses the line of sight will adversely affect vision since the anterior corneal surface is no longer neutralised, or may induce monocular diplopia if the bubble covers only a portion of the pupil.

6.2. Debris (midday fogging)

The accumulation of debris composed primarily of mucous and lipid, or inflammatory mediators [125] within the post-lens tear layer (so called "midday fogging") is unique to the scleral lens modality [126]. Since most modern scleral lenses are sealed or semi-sealed systems, there is minimal or no tear exchange after lens settling [17]. This is in stark contrast to the constant turnover of the substantially thinner post-lens tear layer during corneal rigid lens wear. Debris may accumulate rapidly within minutes of insertion and is observed in around one third of scleral lens wearers once per day [127]. Reservoir debris may reduce the number of consecutive hours a scleral lens can be worn as affected patients must remove, rinse, refill, and reinsert their lenses to eliminate the debris if vision or comfort is affected.

A small number of studies have attempted to quantify the extent of post-lens tear layer debris (turbidity) and its impact upon vision. In a retrospective chart review of children recently fitted with PROSE lenses (85% of eyes affected by Steven Johnson's syndrome or vernal keratoconjunctivitis), Rathi et al. [128] observed a reduction in visual acuity of 1–7 lines in 70% of eyes after four hours of lens wear which improved following lens removal and reinsertion. This reduction in visual acuity was attributed to significant post-lens tear layer debris associated with the ocular surface disease in this particular cohort of patients.

In a cohort of adults with keratoconus (with and without ICRS) and no ocular surface disease, Carracedo et al. [129] also observed a reduction in high contrast visual acuity and contrast sensitivity after 6–9 h of scleral lens wear; a mean reduction of ~1 line in keratoconics without ICRS and a reduction of 2–3 letters in patients with ICRS. Two metrics derived from OCT imaging were used to quantify post-lens tear layer debris; "turbidity" (i.e. the number of non-optically transparent particles/mm^2) and the "turbid tear layer area" (i.e. the percentage area of the post-lens tear layer containing debris). Both parameters increased significantly following lens wear, with turbidity increasing ~8 fold (from 100 to over 800 particles/mm^2) and the turbid tear layer area increasing by a factor of 30 (from 0.36 to 10.68%). Significant positive correlations were observed between both OCT derived debris metrics and the visual acuity measured prior to lens removal (r values ~0.5), while no relationship was found between turbidity and initial apical clearance. Other factors that may influence visual acuity over the course of the day such as lens wettability and centration were not considered in this study. Schornack and Nau [130] utilised Scheimpflug imaging to quantify central reservoir turbidity which doubled following two hours of lens wear in healthy scleral lens neophytes (the optical density of the post-lens tear layer increased from ~5 to 10%). The impact upon visual acuity was not assessed, however, lens diameter, lens settling and corneal oedema were not associated with the extent of debris. These studies confirm that post-lens tear layer debris increases during short-term scleral lens wear and suggest that the quantity of debris explains approximately 50% of the variance in end of day visual acuity.

A number of clinical approaches have been utilised to minimise the visual impact of post-lens tear layer debris and increase the duration of uninterrupted lens wearing time including; aggressively treating eyelid and ocular surface disorders, adding a fluid more viscous than saline to the lens bowl, minimising initial apical clearance, and most importantly, improving the alignment of the landing zone with the underlying sclera to minimise the potential passage of external tears and debris into the reservoir. However, more research is required into the aetiology of reservoir debris, its effect on vision and optimal treatment strategies since there is limited evidence that tear inflow rates [131], initial apical clearance [129], or the extent of lens settling [130] play a significant role.

6.3. Thickness (apical clearance)

Unlike corneal rigid contact lenses, with an optimal central corneal clearance of ~10 µm centrally with ~60 to 90 µm of edge lift [132], for sealed scleral lenses the thickness of the central post-lens tear layer is substantially greater (e.g. clearance values may extend up to 600–1800 µm [133,134]) and varies with practitioner fitting philosophy, the back surface design of the lens, corneal shape and elevation, and the duration of lens wear. While optimal visual acuity can be achieved with significant apical clearance, excessive post-lens tear layer thickness has been associated with sub-optimal visual outcomes due to air bubble formation, debris accumulation, and the potential image magnification effects discussed earlier.

Traditionally for corneal rigid lenses, the power of the post-lens tear layer is calculated as the sum of the power of its front and back surfaces in air, disregarding the minimal thickness of the post-lens tear layer (i.e. the thin lens formula). However, this approach may be inappropriate for scleral lenses due to the thicker post-lens tear layer and consequently the thick lens formula should be applied. Fig. 9 displays the theoretical change in the power of the post-lens tear layer with increasing central corneal clearance for two extreme examples; a steep cornea (4.5 mm) fitted with a high minus lens (-15.25 D) and a flat

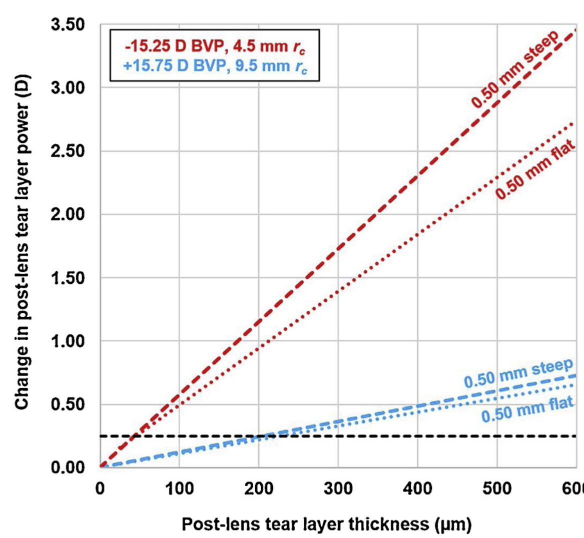

Fig. 9. Theoretical modelling of the influence of the post-lens tear layer thickness upon the change in the power of the post-lens tear layer for two extreme examples; an eye with a 4.5 mm anterior corneal radius of curvature fitted with a -15.25 D scleral lens (red) and an eye with a 9.5 mm anterior corneal radius of curvature fitted with a +15.75 D scleral lens (blue). The effect of the lens fitting relationship between the anterior corneal radius of curvature and the back optic zone radius is also illustrated (dashed lines denote the BOZR fitted 0.50 mm steep and dotted lines denote the BOZR fitted 0.50 mm flat). In these two examples, a change in the post-lens tear layer power of 0.25 D would occur with a ~50 µm change in the post-lens tear layer thickness for the −15.25 D lens/4.5 mm cornea and a ~200 µm change for the +15.75 D lens/9.5 mm cornea.

cornea (9.5 mm) fitted with a high plus lens (+15.75 D), both with the BOZR ± 0.50 mm steeper or flatter than alignment. These particular examples highlight that the theoretical power of the post-lens tear layer increases (becomes more positive and would manifest as a minus over refraction) with increasing clearance, and is also influenced by the BVP of the contact lens (i.e. the vergence of light entering the post-lens tear layer), and the fitting relationship (i.e. a steep or flat fitting BOZR). In these examples, every additional 100 µm of clearance results in ~0.12 to 0.50 D additional plus power. Consequently, clinical axioms often applied when modifying a scleral lens fit do not account for the thickness of the post-lens tear layer, and should only be considered approximations.

6.4. Dynamic thinning (lens settling)

A number of studies have used anterior segment OCT imaging to quantify the change in central corneal clearance over the course of a day or week of scleral lens wear [38]. Over the course of the day, a non-linear exponential decay is typically observed, with the majority of lens settling occurring within four hours after lens insertion (70–90% of the settling observed after 8 h of lens wear is observed within 2–4 h) [16,116,135]. However, a large degree of interocular and inter-patient variability has been reported, and some studies show more settling with smaller diameter lenses and greater initial clearance. Few studies have examined the optical effect of the change in the post-lens tear layer. Vincent et al. [116] calculated the theoretical change in the power of the post-lens tear layer based on the thick lens formula and reported minimal change over an 8 h period (76 ± 8 µm of settling, −0.12 ± 0.01 D reduction in post-lens tear layer power) and Bray et al. [136] measured similar clinically insignificant optical changes over the course of the day (83 ± 22 µm of settling, −0.13 ± 0.30 D reduction). However, these studies only included eyes with normal corneae and therefore could be fitted without the need for lenses with a steep BOZR. However, based on the examples shown in Fig. 9, changes in central clearance over the course of the day may result in clinically significant changes in the power of the post-lens tear layer with even a modest amount of lens settling of 50–100 µm. Therefore, it is recommended that over-refractions and lens assessments during the fitting process be conducted after a reasonable period of lens wear (e.g. 2 h), however, the time to stabilisation will vary slightly with lens design and the individual eye treated.

6.5. Refractive index

The post-lens tear layer is a combination of both the natural tear film (Gullstrand's refractive index of 1.336) and the solution used to fill the scleral lens bowl, typically preservative free saline (refractive index 1.3347–1.3348 [118]). However, in some instances, more viscous products such as artificial tears are used to minimise the formation of air bubbles and reservoir debris (refractive index up to ~1.34 [137]). The traditional lacrimal lens theory uses the keratometer's assumed corneal refractive index of 1.3375 for the post-lens tear layer, similar to the assumed refractive index of the tear film. Fig. 10 displays the discrepancy between the theoretical power of the post-lens tear layer (using the traditional refractive index of 1.3375) and published refractive indices for the natural tears (1.336), preservative free saline (1.3348) and artificial tears (1.34), assuming a negligible post-lens tear layer thickness. For a range of steep and flat fitting lenses (±0.5 mm) on a steeper (6.5 mm) and flatter cornea (8.5 mm), the variations in the power of the post-lens tear layer are negligible (all < 0.05 D).

However, if the post-lens tear layer thickness is taken into account (using the thick lens formula) (Fig. 11), the variation between the theoretical power of the post-lens tear layer using the traditional and presumed actual refractive index of the reservoir fluid increases with more apical clearance, steeper lens fits, steeper corneae, and more viscous tear substitutes (higher refractive index). Therefore, to accurately model or predict the combined refractive power of the scleral lens and post-lens tear layer in combination, requires knowledge of the apical clearance and refractive index of the fluid within the reservoir, both of which may change during lens wear due to lens settling and tear exchange or mixing respectively.

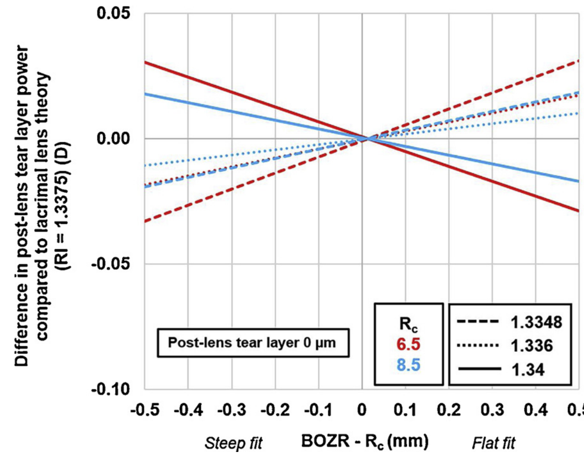

Fig. 10. The difference in the theoretical power of the post-lens tear layer when using the traditional lacrimal lens theory (tear fluid refractive index of 1.3375) and other published refractive indices (natural tears 1.336, preservative free saline, and artificial tears 1.34) as a function of lens fit (BOZR 0.50 mm flatter or steeper than the central cornea) for a relatively steep (6.5 mm) and flat cornea (8.5 mm), assuming a negligible post-lens tear layer thickness.

7. Conclusion

The optical principles of small and large diameter rigid contact lenses are identical with respect to the neutralisation of anterior corneal surface irregularities. However, the fitting characteristics of scleral lenses means that the thin lens optics traditionally applied to corneal rigid lenses may be inaccurate in certain clinical scenarios based on theoretical modelling. Dynamic changes within the post-lens tear layer which are not typically encountered during corneal rigid lens wear, such as a reduction in apical clearance and reservoir debris or air bubbles, may also alter optical performance. Similarly, suction or tear fluid forces upon the cornea and adjacent to the limbus are also unique to scleral lenses and may explain the changes in anterior corneal shape and optics observed immediately after lens removal, despite sufficient corneal vault. While scleral lenses with a spherical haptic are prone to infero-temporal decentration, which can induce residual astigmatism, coma, and prismatic effects, a well-centred scleral contact lens provides an extremely stable lens platform upon which front surface optical corrections can be applied to correct internal lower and HOA's to improve visual outcomes in diseased or surgically altered eyes. Scleral contact lenses can provide exceptional visual acuity for patients with complex corneal shapes which otherwise cannot be achieved with a smaller diameter rigid lens; however, practitioners should be aware of their unique differences in comparison to corneal lenses which can lead to altered optical performance.

Declarations of interest

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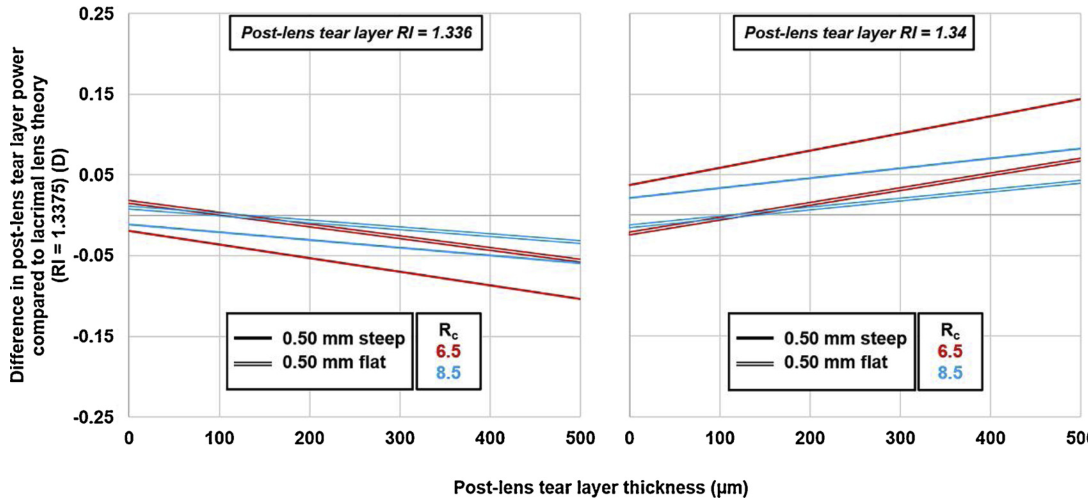

Fig. 11. The difference in the theoretical power of the post-lens tear layer when using the traditional lacrimal lens theory (tear fluid refractive index of 1.3375) and other known refractive indices (natural tears 1.336 and artificial tears 1.34) as a function of apical clearance (using the thick lens formula). Examples are provided using a relatively steep (6.5 mm) and flat cornea (8.5 mm) with ± 0.50 mm steeper/flatter back optic zone radii. The difference in the post-lens tear layer power increases with more apical clearance, steeper lens fits, steeper corneae, and more viscous tear substitutes (lower refractive index).

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