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Review article

Potential contraindications to scleral lens wear

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ABSTRACT

Research and reviews have resulted in clear indications for scleral lens (SL) wear. Those indications include visual rehabilitation; therapeutic use in managing ocular surface diseases, lid and orbit disorders; and refractive correction to enhance visual quality, comfort and quality of life. In some cases, the use of SLs may be contraindicated: the presence of low endothelial cell density; Fuchs' endothelial corneal dystrophy; glaucoma (because of the risk of an increase in intraocular pressure and the existence and location of draining devices and blebs); or overnight wear.

While the literature provides an extensive description of the indications for scleral lens wear, the authors recognize that there is no paper reporting the contraindications to their use. The aim of this review is to illustrate the conditions for which SL wear is potentially contraindicated or requires caution. Improved knowledge of SL limits should reduce the risk of adverse events and increase the likelihood of fitting success.

1. Introduction

The benefits of scleral lenses (SLs) have been well established in the literature since descriptions of glass-blown shells in the late 1800s [1–6]. SLs are fit for therapeutic use [1–3] and visual improvement [3,2–6]. The first successful fitting of polymethyl methacrylate (PMMA) SLs was reported in 1939 [7]. However, complications related to hypoxia, such as neovascularization and corneal edema, were important limitations to SL use until the latter part of the 20th century [8,9].

High oxygen permeability (Dk) of rigid contact lens materials renewed interest in the use of SLs. In 1983, Ezekiel first described the successful use of gas-permeable SLs, which significantly reduced complications from corneal hypoxia [10]. Other pioneers reported the success of gas-permeable SLs for post-operative refractive correction and for keratoconus [9,11,12]. Since the 1990s, indications for SLs have been improved and refined [9–124]. Yet the authors are not aware of current literature that clearly defines the contraindications to SL use.

The goal of this review is to describe the conditions for which SL use is potentially contraindicated or requires caution. Awareness of potential contraindications can prevent unnecessarily high patient expectations that would arise by initiating a SL fitting and having to discontinue their eventual use and can reduce the risk of adverse events.

2. Method of literature search criteria

The literature reviewed was from PubMed on the 25th February 2018, using the following keywords, separately and in combination: scleral contact lens, irregular cornea, ocular surface diseases, indications, management, contraindications, complications, endothelial cells, glaucoma, intraocular pressure, overnight wear. The search identified 112 papers on indications for SL use, 8 on intraocular pressure during SL lens wear, 4 on overnight wear of SLs. Articles were reviewed and clinical indications and potential contraindications for SL wear are summarized respectively in Tables 1 and 2.

3. Indications

A large number of publications summarize the indications for SLs. As with early scleral shells, the main indication for modern SLs is corneal irregularity [9–63,120,121,123,124]. Other reports describe the benefits of SLs for managing ocular surface diseases [11,13,16,17,19,23,34,43,47,63–108]. Additionally, SLs are a viable therapeutic option for lid or orbital disorders and for refractive correction in otherwise normal, healthy eyes, and as drug delivery devices [9–11,13,34,39,40,42,58,64,105,109–122].

SLs are a good option to enhance visual quality and comfort [16,30,60,123], and hence quality of life [32,123,125,126]. In a retrospective review, 18.7% of all SL patients who presented between

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Table 1
Indications for scleral lens use.

Irregular cornea	
Primary corneal ectasias	Keratoconus [9–43,52,58,60,120,127]
	Pellucid-marginal degeneration [13,34,35,43–46,63,66,120]
	Keratoglobus [13,33,43,47,120]
Post-keratoplasty	Penetrating keratoplasty (PK) [9,11,16–20,25,34,39–41,48–52,58–60,66,120,124]
	Anterior lamellar keratoplasty (ALK) [13,17,18,34,51,60,120]
Post-refractive surgery	Post LASIK [13,34,53–57,97,120]
	Post LASEK [120]
	Post PRK [11,63,120]
	Post RK [61,63,120]
Post-other surgeries	Pterygium surgery [120]
Corneal scarring	Herpes simplex keratitis [13,120]
	Other keratitis [13,34,120]
	Trauma [10,13,34,67,120,121,125]
Ocular surface diseases	
Keratitis sicca	Sjögren's syndrome [13,16,17,34,64,66,70,75,83,93,97,118,120]
	Neurotrophic keratopathy [34,63,64,82,83,90,93,109,118,120]
	Following irradiation [13,64,84,120]
	Acne rosacea [64]
	Chemical burns [64]
	Undifferentiated dry eye [64,69,93]
Cicatrizing conjunctivitis	Stevens-Johnson syndrome [13,34,40,63,64,71–74,84,93,97,106,120]
	Ocular cicatricial pemphigoid [13,34,64,83,84,88,93,100,120]
Corneal dystrophies and degenerations	Salzmann's nodular degeneration [43,102–104,120]
	Terrien's marginal degeneration [43,47,120]
	Recurrent corneal erosion [17,70,91,93,101]
	Lattice corneal dystrophy [64]
	Granular dystrophy [64]
Exposure keratopathy	Exophthalmos (Grave's disease) [64,83,90,92,93,109,120]
	Nerve palsies [11,13,34,63,84,99,118,120]
	Post eyelid surgery [84,117,120]
	Acoustic neuroma resection [11,13,84,120]
Graft versus host disease [13,17,34,70,75–80,88,93,94,96,97,110,120]	
Atopic keratoconjunctivitis [13,107,120]	
Congenital corneal hypoanesthesia [120]	
Symblepharon [120]	
Limbal stem cell deficiency [11,13,34,63,71,72,77,86,88,106]	
Vernal keratopathy [81,119]	
Persistent epithelial defects [23,64–66,84,91,93,104,105,108,120,144,269–271]	
Lid/orbit disorders	
Lid surgery [110]	
Facial trauma [112]	
Dermatochalasis [120]	
Crouzon syndrome [13,120]	
Goldenhar syndrome [13]	
Bulbous atrophy [120]	
Ptosis [9,13,120,122]	
Trichiasis [13,84,120]	
Ectropion [120]	
Entropion [120]	
Eyelid coloboma [120]	
Refractive correction and normal cornea	
Myopia [9,10,13,34,120]	
Hyperopia [10,13,34,39,120]	
Astigmatism [11,13,34,39,120]	
Anisometropia [13,120]	
Presbyopia [13,34,120]	
Pseudophakia [13]	
Aphakia [9,11,13,34,120]	
Cornea plana [120]	
Strabismus [119]	
Low vision [13]	
Nystagmus [13,113,120]	
Sports [120]	
Work environments [120]	
Drug delivery [64,105,112,115–117]	

Table 2
Conditions for which SL wear is potentially contraindicated or needs caution.

Corneal endothelial abnormalities	Endothelial cell density
	Fuch's endothelial corneal dystrophy
Glaucoma	Intraocular pressure
	Location of drainage devices
	Blebs
Overnight wear	

1999 and 2003 had undergone corneal transplants and achieved 20/20 or 20/25 vision with their SLs [16]. DeLoss et al. showed that even eyes with advanced keratoconus may benefit from SLs and that the visual outcome for stage four ectasia was better and more rapid with SL correction than with keratoplasty [124]. A recent study demonstrated the successful long-term treatment with SLs in severe keratoconus that otherwise would have led to transplant surgery [127]. The authors of that study concluded that SLs reduce the need for corneal transplantation in severe keratoconus [127].

4. Potential contraindications to the use of scleral lenses

4.1. Corneal endothelial abnormalities

4.1.1. Endothelial cell density

The major concern with SLs is their use in cases with reduced or low endothelial cell density (ECD). Reduction of ECD may be related to age [128–137], diabetes [138–142], contact lens wear [143–154], ophthalmic surgeries [155–160], or dry eye [161].

At birth, the endothelial layer is regular and uniform. It comprises about 500,000 cells, with a density of about 4500 cells/mm^2 [128,129], although variation is large (2987 to 5632 cells/mm^2) [130,131]. The endothelium undergoes quantitative and qualitative changes related to aging [131–146]. Those changes include a decrease in cell density to 1000–2000 cells/mm^2 [131–137] (Table 3).

It is controversial whether ECD is altered in diabetes. Some studies that investigated central corneal thickness and morphologic characteristics of the corneal endothelium in diabetic patients have reported lower ECD than in non-diabetic controls [138–142]. However, others studies have observed ECD similar to that in non-diabetics [162–170]. Leem et al. found lower ECD in diabetic contact lens wearers than in diabetic non-wearers [138]. In contrast, O'Donnell and Efron found that endothelial cell characteristics among diabetic soft lens wearers were similar to age-matched non-diabetic subjects wearing soft contact lenses [170].

Studies results vary on the effects of contact lens use on endothelium cell density [143–155]. Studies have reported that both rigid and soft contact lenses can contribute to a decline in cell density above and beyond the expected age-related decline [147–151]. Hollingsworth and Efron reported that ECD was unaffected by rigid gas-permeable (RGP) lens wear [152]. Other studies observed that reduced ECD in the central cornea is a consequence of a small redistribution of endothelial cells from the central to the peripheral cornea, rather than a true loss of

Table 3
Relation between endothelial cell density and age (source: Edelhauser, 2006; Niederer, 2007).

AGE	CELL DENSITY (cell/mm^2)
10-19	2900–3500
20-29	2600–3400
30-39	2400–3200
40-49	2300–3100
50-59	2100–2900
60-69	2000–2800
70-79	1800–2600
80-89	1500–2300

cells [153,154]. Studies observing contact lens-related endothelial cell loss may have examined only the central corneal endothelium and could not exclude a possibly increased cell density in the mid-peripheral cornea due to cell redistribution. Wiffen et al. hypothesized that such redistribution may reverse itself if contact lenses are discontinued [153]. Consistent with this hypothesis, ECD remains unchanged during the use of soft and corneal RGP contact lenses [171].

Reduction in ECD may also be associated with surgery of the vitreous or retina, glaucoma repair, cataract or keratoplasty [155–160]. The Cornea Donor Study Investigator Group measured ECD five years after successful penetrating keratoplasty (PK) and found cell loss of 70% [172]. Five year Descemet stripping automated endothelial keratoplasty (DSAEK) cell loss was 53% [173]. Cross-sectional and longitudinal analyses have shown that median endothelial cell loss after Descemet membrane endothelial keratoplasty (DMEK) was 26%–27% at one month, increasing to 39% at five years [174]. Another longitudinal study found that the median cumulative endothelial cell loss ten years after DSAEK was 71% [175] and was comparable to the 76% after PK [158].

Previous research suggests that 15–31% of patients undergoing PK may develop postoperative astigmatism greater than 5 diopters [176–179]. The astigmatism can be irregular and associated with higher-order aberrations and consequent visual problems [180]. Patients with corneal transplants have obtained good vision with SLs with an average of ten hours or more wearing time in 59% patients [16]. Severinsky et al. described prolonged and successful SL wear in PK patients. Only 6% of eyes had demonstrated periodic episodes of transient corneal edema. Discontinuing SL wear resulted in spontaneous resolution of the mild edema [50]. The authors also urge practitioners to be aware of ectasia recurrence when fitting corneal transplants in patients in the second or third decades of their lives [50]. In their retrospective study, hypertonic saline (5% NaCl) may be used to accelerate the recovery of the edematous cornea [181]. When the edema persists, topical 5% NaCl solution can be instilled during the removal and reinsertion procedure [50].

Dry eye disease (DED) may also lead to a reduced ECD. Kheirkhah et al. showed a significantly lower ECD in a DED group compared to that of the control group [161]. The authors observed significant correlations between the reduction in endothelial cells and the severity of DED as determined by symptoms and signs. Although the mechanism underlying this association is unclear, the authors hypothesize that the lower ECD may be attributable to reduced corneal nerves in DED [161].

Few studies have reported the effects of SL wear on the corneal endothelium. A minimum of 400–700 cell/mm^2 appears necessary for maintaining corneal health and transparency (Fig. 1). If ECD declines below this limit, corneal edema may ensue [170,182].

However, normal cell density alone is no guarantee of corneal health. Endothelial cells vary in size. The coefficient of variation (COV) of cell size is calculated by dividing the standard deviation of the cell area in a particular field by the mean of that area. A high COV denotes wide variation in cell size, referred to as polymegethism. Endothelial cells may also vary in shape (referred to as polymorphism). A normal endothelium is very uniform; all cells are similar in size and typically hexagonal in shape. Endothelial cells may, however, show 3–9 sides [171]. A corneal endothelium with a proportion of hexagonally-shaped cell < 50% indicates a clinically significant polymorphism [183]. The modification of the endothelium may be related to age [184,185], injury [186], chronic solar radiation [187], ptosis [188], endothelial guttatae [189], intraocular surgery [190], keratoconus [191], systemic disease [138–142] or contact lens wear [153,154,192,193]. High COV and polymorphism are generally the first signs of physiological stress of the corneal endothelium [183]. It is therefore important to evaluate the cell structure by counting the total number of cells, while considering COV, hexagonal cells and polymorphic cells in a particular area. Cell density of 1000 cells/mm^2 with high COV may be a contraindication to SLs, whereas a density of 700 cells/mm^2 with a low COV and at least 50% hexagonal cells may not contraindicate SLs [194].

Careful documentation (including photodocumentation), baseline measurements and endothelial cell assessment are essential prior to SL fitting. If low ECD is suspected, it is crucial to differentiate the effects of aging, systemic diseases or ocular surgeries [171]; to evaluate the ECD in the global cornea; and to assess COV and polymorphism.

In case of keratoplasty surgery and compromised transplanted corneas, prior to SL fitting, the graft should be assessed also with sodium fluorescein to determine the presence of any pre-existing abnormalities such as edema, compromised endothelial function [195] or corneal staining [196]. An evaluation after 4–6 h of SL wear is recommended to assess adverse events. To avoid subclinical corneal edema, oxygen delivery should be optimized by using a thinner lens, which reduces post-lens tear reservoir thickness, and high-Dk lens material [197–200]. If the graft becomes edematous, the patient may experience hazy vision and see a rainbow pattern around light sources, known as Sattler's veil [196,201]. When corneal edema occurs, fenestrated SLs, which provide oxygen to the ocular surface without compromising normal physiology [27], may be a remedy in these cases. Fenestration holes are typically 0.5–1.0 mm in diameter and placed in the part of the lens overlying the

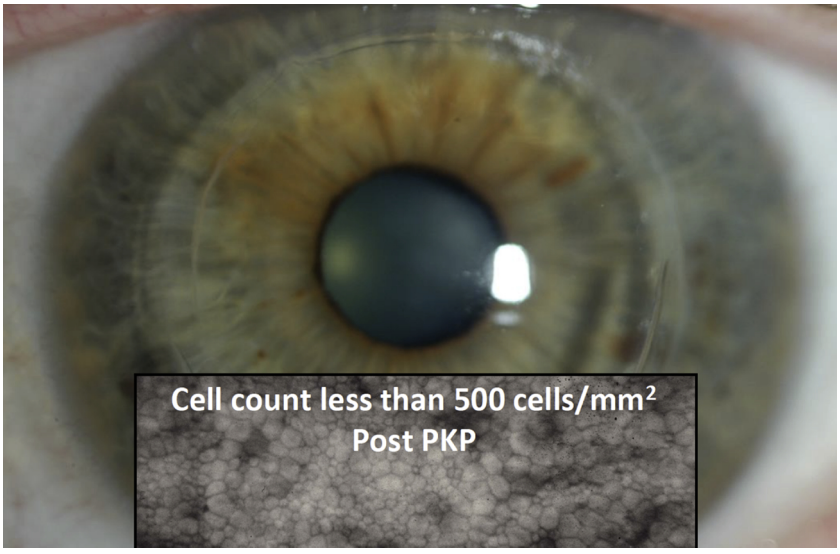

Fig. 1. Endothelial cell density after PKP about 500 cells/mm^2. Image courtesy of Maria Walker.

limbus. Johns reported a patient with an ECD of 745 cells/mm^2 who developed epithelial edema after four hours of SL wear. The patient was able to wear the lens uninterrupted for 16 h without edema after a fenestration was inserted [202]. Also, reduced hours of SL wear may be a good option [196,201] and SLs with peripheral channels, to allow for tear exchange, may be indicated.

The significant polymegethism and polymorphism are correlated with loss of endothelial cell function. It is not clear whether the barrier function or pump mechanism of the endothelium, or both, is altered. Several mechanisms by which the endothelial barrier and pump functions may be altered by contact lens wear have been suggested [203,204]. Studies, monitoring endothelial health and function during SL wear, at several intervals may focus on hypoxia, lens hygiene, lens environment, levels of inflammatory mediators in the tear film, adenosine triphosphate levels, altered calcium homeostasis, pH shift, lactate accumulation, and carbon dioxide elevation.

The authors recommend specialized examinations that can help to assess and monitor corneal health before and after SL wear. Specular or confocal microscopy can visualize, analyze and document the corneal endothelium. Global pachymetry can be particularly helpful in monitoring corneal thickness, an increase in which suggests corneal edema. Ocular coherence tomography (OCT) of the anterior segment allows the evaluation of all the structures of the cornea, including Descemet's membrane (DM). Anterior segment photography prior to and following SL wear is valuable to monitor ocular surface alteration.

4.1.2. Fuchs' endothelial corneal dystrophy

Fuchs' endothelial corneal dystrophy (FECD) is characterized by the morphological change of the hexagonal mosaic, accelerated reduction in ECD, and aberrant deposition of extracellular matrix (ECM) in the form of guttatae, which is manifested by thickening of DM [205]. Endothelial cells secrete and deposit ECM proteins that form the DM. A normal DM contains collagen type VIII, collagen type IV (chains α1–α2), and fibronectin on its stromal side and entactin, laminin, perlecan, and collagen type IV (chains α3–α6) on its endothelial side [206,207]. Reactive production of ECM may represent a defensive mechanism of endothelium threatened by foreign cells, tissues or materials [208].

Referring to Bergmanson, the presence of central guttatae and endothelial pigment are not sufficient to qualify as FECD. A positive diagnosis of FECD requires the presence of corneal edema [209]. At the early stage of the disease, mild stromal edema can be observed clinically using the biomicroscope. At a more advanced stage when the endothelium is compromised, the stromal edema increases, and epithelial edema may be evident. Epithelial edema causes painful bullae, which may produce irregular astigmatism, corneal swelling and severely reduced vision. SL wear may exacerbate preexisting corneal edema, because oxygen transmissibility through the SL may be lower than with other contact lens modalities, since it depends on the lens system as well as the fluid reservoir behind the lens [210]. Tear permeability has a Dk value of approximately 80×10^{-11} Fatt Dk units, which is relatively low compared to that of some high Dk materials, which may range from 100×10^{-11} Fatt Dk units to 163×10^{-11} Fatt Dk units [211].

As mentioned above, the structure of the endothelium should be evaluated before fitting a SL in patients with FECD. Yet a patient with FECD who then undergoes a corneal transplant may be a good candidate for SLs [201]. Selective replacement of the deteriorated endothelium with techniques of endothelial keratoplasty (DSAEK and DMEK) is now the most commonly performed procedure, having surpassed penetrating keratoplasty (PKP). DSAEK is the most commonly used technique in the United States, although the number of DMEK surgeries is increasing [212].

Conversely, when FECD causes bullous keratopathy, recurrent erosions, or extreme discomfort, and if surgical procedures are contraindicated, patients can wear soft bandage contact lenses to reduce the pain and smooth the irregular corneal surface from the broken epithelial bullae [209]. However, fitting soft contact lenses in these cases increases the risk of infections [209]. Studies are required to evaluate the outcomes of therapeutic SL wear instead of soft bandage contact lenses in this advanced disease process. The SLs may be fenestrated or with peripheral channels to allow for tear exchange.

4.2. Glaucoma

Glaucoma is a heterogeneous group of diseases characterized by cupping of the optic disc and visual-field damage [213]. The main factors for development and progression of glaucoma are age [214–216], intraocular pressure too high in relation to the pressure sensitivity of the optic disc [217,218], ethnic origin [219,220], positive family history, stage of disease and high myopia [221,222].

The treatment of acute angle closure differs profoundly from that of open angle glaucoma. In acute angle closure, IOP is lowered first, using drops, miotics being the first choice. An alternative may be laser iridoplasty. Also, a peripheral laser iridotomy may be performed, creating a small hole in the peripheral iris to form a pathway for aqueous humour flow between the posterior chamber and anterior chamber [213]. To further lower IOP, post-iridotomy procedures similar to those used to treat open-angle glaucoma can be attempted. Those procedures including trabeculectomy or lens extraction with the implantation of glaucoma drainage implants [213].

Reduced IOP in open-angle glaucoma can be achieved with drug therapy, laser therapy, or surgery. Topical drug choice depends on costs, adverse effects, and dosing schedules. If the target IOP is not achieved, laser therapy to the trabecular meshwork is indicated. If the IOP lowering effect is not adequate, surgical procedures such as trabeculectomy should be considered [213].

SL wear in patients with glaucoma may be challenging, because of the effect of the SL on IOP and the interaction of the lens with the drainage device and with blebs that develop after surgery. Glaucoma can also result from corneal transplantation [223,224], making the SL fitting more complicated. Topical medications for the treatment of glaucoma can cause corneal toxicity or decompensation [225,226], creating the need for a SL for both treatment and visual rehabilitation.

4.2.1. Intraocular pressure

SLs are designed to rest on the conjunctival tissue overlying the sclera and to create a vault over the entire cornea and limbus. Unlike soft lenses, SLs compress and settle into conjunctival tissue [227–229]. While blinking, the pressure generated by the eyelids may push the lens further into the conjunctiva. This pressure may also penetrate to deeper structures (such as drainage channels and episcleral veins) and increase resistance to aqueous humor flow out of the eye [228]. The total diameter of a SL could potentially contribute to the SL settling [227–230]. Because small-diameter SLs (14.0–16.5 mm in diameter) generally have limited haptic widths and contact the conjunctiva across a relatively small area closer to the limbus than do larger-diameter SLs ($\geq$18.0 mm in diameter), they may even compress Schlemm's canal, drainage channels, or episcleral veins, the structures responsible for aqueous humour outflow. Compression of these tissues could reduce aqueous humour outflow and consequently increase IOP [228]. Also referring to McMonnies' hypothesis, a SL fitting that closely matches the contours of the ocular globe might be more likely to settle tightly and increase IOP [230]. Lenses fitted tightly can narrow angles and cause inefficient aqueous drainage, thereby increasing IOP. A landing zone with a greater surface area could impede settling, because the weight of the lens is distributed over a greater area. Additionally, the composition of the ocular tissues varies as it transitions from the limbus (more compressible) to the bulbar conjunctiva (less compressible) [230]. Apart from lens fit tightness, any IOP elevation associated with SL wear may also vary with individual patient characteristics. Eyes with reduced scleral thickness and/or rigidity may be more easily applanated at

zones of tight SL bearing [231,232]. Other causes for increased IOP may be related to disruption of the angle and trabecular meshwork anatomy [231], and to suction forces beneath the SL [233].

The measurement of IOP through soft lenses may be achieved without removing the lens [234–240], but that is impossible with a SL in place [228]. These challenges in measurement methodology have not been sufficiently investigated. [241]. A case series in which IOP was measured using a transpalpebral scleral tonometer (Diaton, BiCom Inc.) illustrates the inconsistency in measuring IOP during SL wear [241]. The authors suggested measuring IOP via episcleral venous blood flow or via 24-hour monitoring devices.

Variation in IOP during SL wear was investigated as early as in 1951 [242]. The authors measured IOP in 33 subjects using Schiötz tonometry following short-term wear (25 min) of SLs made of glass. They found an increased IOP (+ 2 mmHg up to + 30 mmHg) in 25 subjects, while in two subjects, the pressure remained stable, and in five subjects, the IOP decreased compared to baseline values. Authors associated the IOP increase to the wear of SLs with narrow haptics responsible for aqueous vein compression and reported a rapid reduction in the pressure after lens removal [242].

Recently, different reports examined IOP changes following modern high Dk SL wear showing contradictory results. Nau et al. reported no effect of wearing small-diameter SLs (15 mm total diameter) for two hours on IOP in 29 healthy young adults [228]. A pneumatonometer (Model 30 Classic; Reichert, Inc; Buffalo, New York) was used to measure IOP at the central cornea and adjacent to the lens edge on the peripheral conjunctiva/sclera, both before and during lens wear. Immediately after removing the SL, mean central IOP in the study eye was not different from mean central IOP in the control eye or in the SL eye before lens wear. Nor were differences in IOP measured peripherally after two hours of lens wear [228]. Vincent et al. conducted two experiments in which IOP was measured before and after SL wear (16.50 mm total diameter) [233]. In the first experiment, the Ocular Response Analyzer was used to measure IOP after three hours of SL wear; in the second, a Non-Contact Tonometer was used to measure IOP after eight hours of SL wear. Although these studies were too small to produce statistically significant results, the authors observed a non-significant decrease in IOP following SL wear. They concluded that appropriately-fitted modern SLs do not substantially elevate IOP in the short term, despite superficial tissue compression near the scleral spur [233].

In contrast, increase in IOP was found following scleral lens removal and persisting up to eight hours later for two out of five subjects while wearing scleral lenses 16.5 mm in diameter [243]. Similarly, Aitseabomo et al. recorded an elevation in IOP of 5.81 ± 1.62 mmHg on nine patients wearing a 15.8 mm scleral lens on one eye for eight hours [244]. Pressure was measured using the iCare tonometer just after lens removal. This device, however, does not take corneal central thickness in account. Also, in another cases study, the IOP in all 14 normal subjects fitted with two different scleral lens designs ranging in diameter from 14.6 to 15.2 mm increased by an average of 5.5 mmHg after eight hours of scleral lens wear [245]. IOP measurements were taken with both the Diaton and Goldmann. A latest study conducted by Michaud and colleagues confirmed these findings observing a mean increase in IOP of 5 mmHg after five hours of scleral lens wear. In that study, transpalpebral pressure was measured using a Diaton tonometer. The patients studied had a large variability in response; some had an increase in IOP of 10 mmHg, some of 17 mmHg. Yet the difference in IOP did not depend on the size of the SL and disappeared within seconds following SL removal [246].

None of the results reviewed above can be generalized to patients with glaucoma or ocular hypertension, since no studies have assessed changes in IOP associated with SL wear in these patients [228]. Such patients may be more susceptible to lens wear, because even slight obstructions to conventional outflow may increase IOP [228]. It is therefore not recommended to fit SLs for simple refractive errors in patients with glaucoma or ocular hypertension. In the presence of ocular diseases, or of corneal irregularities in patients with glaucoma, large-diameter SLs with a wider haptic may be preferred, as such lenses land further from the limbus and may therefore not interfere with aqueous outflow [233]. Frequent follow-up is strongly recommended. As some young healthy adults display a small increase in IOP during or following SL wear, those with ocular hypertension or glaucoma should be monitored carefully [233]. SLs are also contraindicated in patients with other baropathic diseases, such as axial myopia and keratoconus [230].

Further well-designed studies are necessary to accurately evaluate SL wear in patients with glaucoma, with more ideal technology, at several intervals [247] and taking into consideration not only IOP, but also the diagnosis of open- vs closed-angle glaucoma, age, stage, different scleral and conjunctival properties, visual-field damage, ethnic origin, ametropia, the presence of ocular surface disease or corneal toxicity, decompensation from topical ocular and systemic medications, and different scleral lens designs (small vs large diameters) and fitting. Additional studies are also required for cases in which glaucoma develops after corneal transplantation and in patients who have undergone glaucoma surgery.

4.2.2. Location of drainage devices

Caution is advised in fitting SLs in patients with glaucoma filtration devices or glaucoma drainage implants located near the limbus [248] (Fig. 2). The placement of these devices varies according to the surgeon and the ocular anatomy. The glaucoma drainage device can be placed in the anterior chamber, in the limbal area, or the fornix, or posteriorly via a pars plana insertion [248]. The presence of a glaucoma drainage device may not necessarily contraindicate SL wear. However, the presence of such a device can create problems if it comes into contact with the SL [248]. SL fitting is usually easier if the device is fornix-based. Pars plana glaucoma tube insertion may be a better alternative to the conventional anterior chamber placement. A proper tube and patch positioning reduces interference with the SL and allows for continued lens wear [249]. The risk associated with wearing a SL is blockage of the underlying tube-shunt. This may alter the intended function of the device [249]. Some cases of SL wear can lead to erosion of the conjunctiva overlying the tube, requiring surgical revision [248,249]. In order to avoid touching the device, the diameter of the SL can be decreased to 1400–1500 mm. Creating a lens notch or and/or an area of increased elevation (by adding a focal vault at the lens edge) can help resolve the issues created by the device. A lens notch is contoured to the edge of the lens at a specific location (Fig. 3). In order for the notch to stay in this specific location, the SL needs to be rotationally stabilized by using toricity in the landing zone, a prism ballast, or a double-thin zone design. Localized areas of increased elevation can be created by lathing the specific part of the lens overlying the glaucoma filtration device. This helps to reduce bearing over the device and thus limits contact. A rotationally stable lens is necessitated in that case as well. Choosing a customized or molded/impression SL design may be a good alternative [250].

It is important to communicate with the glaucoma specialist to ensure that the eye is healed and can sustain SL wear. In addition to checking the SL fit and ocular surface health at follow-up visits, IOP should also be measured regularly [251]. Regular follow-up is essential to the long-term successful fitting of SL wear in patients with glaucoma drainage devices [250].

The role of SLs in the management of complex ocular disorders continues to expand. A history of glaucoma surgery does not preclude successful fitting of SLs for patients with corneal irregularities and/or ocular surface disease in whom all other options for treatment have been exhausted. Technological innovations in the design and modification of SLs have led to successful fitting of eyes with limbal anomalies resulting from glaucoma surgery [250].

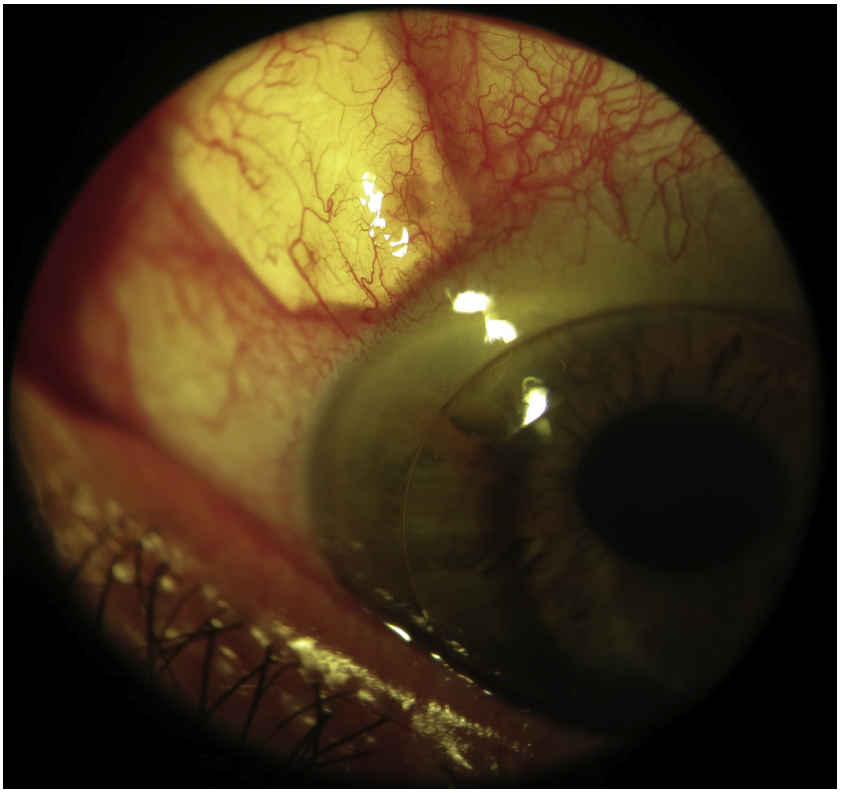

Fig. 2. Glaucoma drainage device with an overlying scleral patch that may indicate a contraindication for scleral lens use. This eye is fit with a corneal RGP lens. Image courtesy of Karen Lee.

4.2.3. Blebs

Surgical procedures to lower IOP significantly change the ocular surface and conjunctiva through the intentional creation of a conjunctival bleb. This bulbar conjunctival elevation at the surgical site is the result of the new drainage route, which allows aqueous humour to drain from the anterior chamber into the subconjunctiva [252]. The elevation and location of the bleb varies widely among patients and with the type of surgery. Fornix-based flaps experienced bleb leaks in 65% of patients after trabeculectomy, while limbus-based flaps showed bleb leaks in 24% [253].

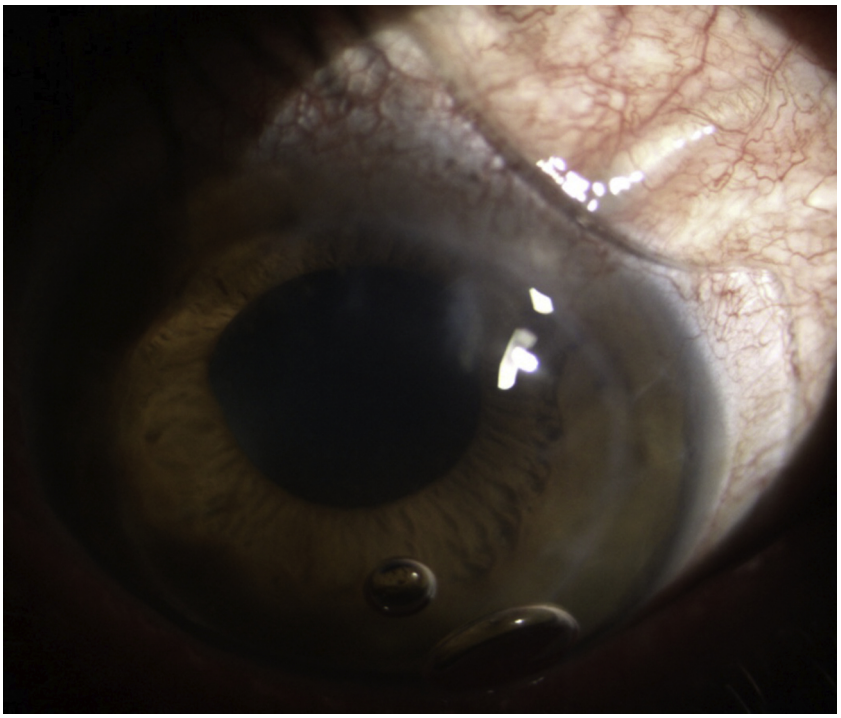

Fig. 3. Tube shunt residing close to the limbus necessitating a notch in the scleral lens to avoid the interaction between the lens periphery and the glaucoma drainage device. Image courtesy of Tom Arnold.

Analogous to drainage devices, blebs should be considered as limitations and challenges to fitting, rather than contraindications. These scleral obstacles may present a problem in patients who need SLs for irregular astigmatism or high ametropia, because the rigid SL will not drape over the bleb as a soft lens would. For blebs that are proximal to the limbus, mechanical friction between the SL and the bleb can cause tissue erosion and bleb leakage. Moreover, a SL may compress the bleb and lead to a reduction in functionality, resulting in increased IOP. The lens should be modified to avoid interaction with the bleb; notches can be beveled into a SL to enable it to bypass the bleb. SLs are designed to be fit without movement, so adverse physiological consequences are unlikely to occur. Notches that are less than 4 mm deep into the lens will usually not affect fit; however, anything more may cause air bubbles to form underneath the lens [254]. Measurements and photographs will help the laboratory position and create the notch. Corneoscleral topography is also very useful for the laboratory. Another option is a localized area of clearance or vault over the lens. Small-diameter SLs are recommended, because they allow for smaller notches; customized SL design or with a molded/impression technique may also be helpful [250,254].

4.3. Overnight wear

Continuous wear should be differentiated from overnight wear. Continuous wear is defined as a lens applied for a period of time without removal. Overnight wear refers to wearing the lens for a period of time while the eyes are closed but removed when the eyes are opened; the lenses may be cleaned regularly [255].

Overnight wear of SLs is not generally recommended, partly because the effects on corneal health are unknown. SLs are frequently applied on ocular surfaces with diseases. Several studies on soft lenses have shown that corneas with compromised ocular surfaces are more susceptible to microbial keratitis (MK) [65,256–260]. An intact tear film is essential to avoid MK [261]. Also blinking helps to prevent microbial binding to the ocular surface [262].

All types of contact lenses disrupt the normal physiology of the tear film. Soft contact lenses induce a thin post-lens tear film and less post-lens tear exchange than corneal RGP lenses. This is one reason why soft lenses are associated with the highest risk of MK [262]. A normal corneal RGP lens allows a thicker post-lens tear film than a soft lens, but a reverse geometry RGP produces a thinner post-lens tear film centrally and is associated with a moderate risk of MK, lower than that of soft lenses but higher than that of normal corneal RGP lenses [263,264]. Corneal RGP lenses provide additional oxygen to the cornea through the lid-activated pump, which provides a tear exchange of post-lens tear fluid between 10 and 30% per blink [265,266]. Compared to soft and corneal RGP lenses, SLs provide the thickest post-lens fluid reservoir. However, the challenge in SL wear is the limited tear exchange rate of 0.2% per minute once the lens is settled, which means that it takes more than eight hours to replace the fluid underneath the lens [267]. SL continuous wear may sometimes be required, however, as in patients with severe challenges in lens handling and/or ocular surface diseases necessitating constant SL wear [65,83,84,255,268–271].

A further concern of overnight wear of SLs is corneal swelling. This issue has been investigated by Smith et al. in four patients with normal eyes. SLs with a thickness of 800 μm and a clearance of 200–300 μm were fitted for nighttime wear. Corneal swelling occurred in three subjects, ranging from 4.9 to 10.2% [255]. This rate of edema is greater than that induced by daytime wear, which has been reported at 3.2% [272]. The fourth subject agreed to participate in the study despite showing a daytime wear swelling in excess of 5%; he developed even greater overnight swelling: almost 17.5%. The authors highlighted insufficient knowledge on the corneal implications of overnight wear of SLs and a general reluctance to wearing SLs overnight [255], despite success in the treatment of such ocular diseases as chronic epithelial defects corneal exposure [65], trichiasis, post-radiation keratopathy, post-surgical lid defects, Stevens-Johnson disease, and keratinized lid margins [65,83,84,255,268–271].

A recent three-case series of SL overnight wear reported persistent epithelial defects, but with resolution of the defects and improvement in best-corrected visual acuity after 2–4 weeks of SL wear [269]. These cases again demonstrate the efficacy and the safety of these lenses, but caution against overnight use unless a patient cannot be treated with other forms of contact lenses. Overnight use of SLs should not be considered for visual rehabilitation alone [255].

Nonetheless, the use of SL as overnight orthokeratology treatment has been reported for almost ten years. Practitioners fitting these lenses have observed no ocular complications for that indication [273–278].

5. Discussion and conclusion

Studies of SL wearers have reported a significant improvement in quality of life for patients who failed to wear or were intolerant to corneal RGP lenses [32,124]. SLs are beneficial for visual rehabilitation, ocular surface disease management, and pain relief. In some severe conditions, SLs represent a last resort treatment.

While the literature review showed a wide number of papers describing the indications for SL use, there is a lack of published reports on the contraindications. Referring to clinical experience, in some cases, SL wear may be contraindicated or requires attention. In this review, the authors provide guidelines how to proceed with caution in some conditions: significant corneal endothelial abnormalities, glaucoma or following glaucoma surgery, and overnight wear.

Fitting a SL in patients with significant corneal endothelial anomalies requires caution. When applying a SL in compromised corneas, an evaluation after 4–6 hours of SL wear is crucial. An initial reduced wearing schedule, about 4–6 waking hours, is recommended. If at the following visits there is no evidence of complications, the wearing schedule may be gradually increased. If corneal edema occurs, fenestrated SLs or SLs with peripheral channels, which allow tear exchange and more oxygen to the cornea, may be a remedy.

It is not recommended to fit simple refractive errors in patients with glaucoma or ocular hypertension, since the effect of SL wear on IOP in these patients is unknown. In glaucoma patients, a SL with a wide haptic may be preferred [233]. Also customized or molded/impression SL design may be a good alternative.

SL wear in cases with glaucoma filtration devices, glaucoma drainage implants positioned near the limbus, or blebs, necessitates particular attention because the lens may alter the intended function of the drainage implants. A small diameter SL 1400–1500 mm may be indicated to avoid the interaction with the device and the conjunctival irregularity. A notch, an increased elevation in the periphery of the lens, a customized lens, or an impression technique may be suggested.

Likewise, SL overnight wear should not be prescribed only for visual rehabilitation and may be considered when patients cannot be treated with other modalities [255].

Careful examination and documentation are essential prior to SL fitting, especially in patients that present potential contraindication to SL wear: specular or confocal microscopy to visualize the corneal endothelium and to assess cell density, COV, and polymorphism, in the central and peripheral cornea, differentiating the effects of aging, systemic diseases or ocular surgery; global pachimetry to monitor the corneal thickness and the ensue of corneal edema; OCT to evaluate all the corneal structures; biomicroscopy to evaluate with fluorescein the presence of previous anomalies; and photodocumentation prior to and following SL fitting to monitor ocular surface changes. Co-management with corneal and/or glaucoma specialists is fundamental to verify the eye health and to ensure the continued lens wear.

Other relative contraindications include any psychological intolerance to the placement of a foreign body in the eye, inability to follow instructions for cleaning, storage, maintenance and asepsis of the SLs, poor personal hygiene (hands and nails) cost, inability to understand

the risks associated with contact lens use pronounced difficulties with insertion and removal, and persistent overnight wear. These contraindications, nonetheless, can often be reduced or eliminated [252]. A few patients have difficulty, however, and despair after repeated unsuccessful attempts [279]. These difficulties are more likely in the very young or very old [280]. Most patients, even those with small palpebral apertures, learn to be proficient in applying and removing their SLs. Since application and removal procedures seem to be an achievable goal, further training sessions may be necessary. Many videos are widely available online or can be made available by contact lens practitioners and manufacturers to help patients learn and improve these skills. Patients also vary in their expectations, from doubtful to unrealistically optimistic. The limits and challenges of SL fitting should be clearly described and clarified to patients with unrealistic expectations. Otherwise, overall satisfaction will be compromised, leading to abandoning SL wear. Practitioners should select the proper candidates for SL wear. Patients who cannot benefit from SLs may request them but will be extremely disappointed after using them.

In many cases SL wear is extremely beneficial. When benefits outweigh the risks, careful documentation and achievable baseline measurements, photography, and other ocular examinations are helpful, and frequent follow-ups should be scheduled. Lens designs may require fenestrations, peripheral channels, notches, peripheral elevations, a localized vault, customization, or impression techniques. A deeper understanding of the contraindications associated with SLs will reduce complications related to their use and increase the likelihood of success among patients in whom SL wear is unavoidable.

Declarations of interest

None.

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