CLEAR MEDICAL USE OF CONTACT LENSES

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Abbreviations

BCVA: Best-corrected visual acuity
BSCL: Bandage soft contact lens
cGVHD: Chronic Graft-versus-host Disease
CXL: Corneal Collagen Cross-linking
EDTA: Ethylenediamine-tetraacetic Acid
FDA: Food and Drug Administration (US)
IATS: Infant Aphakia Treatment Study
IOP: Intraocular pressure
ICRS: Intracorneal Ring Segments
LASEK: Laser Epithelial Keratomileusis
LASIK: Laser-assisted in situ Keratomileusis
LSCD: Limbal stem cell deficiency
MK: Microbial keratitis
NEI-VFQ-25: National Eye Institute Visual Function Questionnaire (25 item)
NSAID: Nonsteroidal anti-inflammatory drug
OSDI: Ocular surface disease index
PED: Persistent epithelial defect
PK: Penetrating keratoplasty
PMD: Pellucid marginal degeneration
PMMA: Polymethyl methacrylate
PRK: Photorefractive keratectomy
PROSE: Prosthetic Replacement of the Ocular Surface Ecosystem
QOL: Quality of Life
RCES: Recurrent Corneal Erosion Syndrome
SiHy: Silicone hydrogel
SLK: Superior limbic keratoconjunctivitis
SJS: Stevens-Johnson Syndrome
TFOS DEWS II: Tear Film and Ocular Surface Dry Eye Workshop II

Abstract

The medical use of contact lenses is a solution for many complex ocular conditions, including high refractive error, irregular astigmatism, primary and secondary corneal ectasia, disfiguring disease, and ocular surface disease. The development of highly oxygen permeable soft and rigid materials has extended the suitability of contact lenses for such applications. There is consistent evidence that bandage soft contact lenses, particularly silicone hydrogel lenses, improve epithelial healing and reduce pain in persistent epithelial defects, after trauma or surgery, and in corneal dystrophies. Drug delivery applications of contact lens hold promise for improving topical therapy. Modern scleral lens practice has achieved great success for both visual rehabilitation and therapeutic applications, including those requiring retention of a tear reservoir or protection from an adverse environment. This report offers a practical and relevant summary of the current evidence for the medical use of contact lenses for all eye care professionals including optometrists, ophthalmologists, opticians, and orthoptists. Topics covered include indications for use in both acute and chronic conditions, lens selection, patient selection, wear and care regimens, and recommended aftercare schedules. Prevention, presentation, and management of complications of medical use are reviewed.

1 Introduction

Clinicians have long appreciated that contact lenses play a role in the care of patients with ophthalmic disease. Contact lenses therefore have a medical use, in addition to their use for correction of refractive error. This medical use has evolved over decades alongside advances in contact lens materials and design. Appreciation of the role a lens might play in stabilising the ocular surface, neutralising refractive error, and improving visual function, combined with awareness of potential complications and how to avoid them, has yielded vast experience and a body of literature on the medical use of contact lenses.

Statements on the quality of evidence are based on the approach discussed in the CLEAR Evidence-based Practice Report [1].

1.1 Definition of Medical Contact Lenses

The literature search conducted to create this report failed to find a field-wide, accepted definition for medical contact lenses. After discussion and consensus, the following definition for medical contact lenses has been adopted by the subcommittee on Medical Use Contact Lenses:

Medical Contact Lenses are any type of contact lens that is worn for the primary purpose of treating an underlying disease state or complicated refractive status. Medical contact lenses may or may not correct refractive error. Medical contact lenses are prescribed for reasons other than the cosmetic purpose of eliminating the need for spectacles. There is no universally accepted definition for medical contact lenses, but in some countries, some insurance companies set requirements as to the condition or diagnosis (e.g., cornea ectasia, unilateral aphakia) or degree of refractive error (e.g. high myopia) before a coverage or reimbursement is granted. Because of this, requirements and definitions can vary from nation to nation based on the structure of healthcare in the respective country.

1.1.1 Regulatory bodies, labelling, and "therapeutic" lenses

In the United States (US), mass produced contact lenses are regulated by the US Food and Drug Administration (FDA). The first (hydrogel) soft CL was approved by the US FDA in 1971 as a new drug [2,3]. Contact lenses were later reclassified by the US FDA as Class III medical devices (high risk) in 1976 when the Medical Device Amendment was passed. Later regulatory revisions have since reclassified daily wear soft lenses and rigid corneal lenses as Class II medical devices (moderate to high risk), while overnight and myopia management contact lenses, are considered Class III medical devices [4]. The European Medicines Agency of the European Union, the Australian Therapeutic Goods Administration in Australia, the Drug Controller General of India, and the National Medical Products Administration in China perform a similar function and have similar classification systems for regulating medical devices [4].

National regulatory bodies take guidance from the International Organisation for Standardization when creating their policies. This body has specifically set international industry standards that are broadly recognised by regulatory agencies throughout the world for lens and care product labelling [2]. They have also set efficacy standards for the care systems needed to maintain contact lenses [5]. Professional organisations likewise provide best practice guidance to clinicians, and they provide feedback to the above regulatory bodies when new policies are being set [6].

While any CL might be used medically or as a therapeutic or bandage CL, some contact lenses are labelled for use as a bandage lens or with a therapeutic indication for use.

1.1.2 Clinical definitions

Contact lenses are used for numerous medical purposes that include, but are not limited to, treating patients with corneal ectasia, ocular surface disease, after ocular surgery and in the setting of high refractive error [7]. The authors

recommend the following set of definitions to be adopted by the community for medical use of contact lenses.

- **Therapeutic or Bandage Contact Lenses** are lenses that are used for the treatment of ocular discomfort or to support the cornea during healing after surgery or when the cornea is being treated for an underlying disease state or to protect the cornea from the environment or mechanical interaction with the lids.

- **Rehabilitative Contact Lenses** are lenses that are prescribed for conditions that prevent a patient from achieving adequate visual function with spectacles because of high, irregular, or asymmetric refractive error. Partially or completely occlusive lenses that improve function or cosmesis after trauma, surgery, or stroke also fall into this category.

1.2 Lens types used for medical purposes

It is widely accepted that Müller described the first CL for correcting refractive error in the late 1880s [8], but concurrently, in 1888, Fick described what may be the first medical use of contact lenses in his report of the improvement of vision in patients with keratoconus [9]. Müller's lenses, which were scleral lenses made of glass and used to correct his own high myopia, unfortunately induced corneal oedema and ocular pain because they were impermeable to oxygen. Because of this, they could only be worn for short periods of time. Polymethyl methacrylate (PMMA) corneal lenses were used on a therapeutic basis as early as the late 1950s and early 1960s [10,11]. Oxygen impermeable PMMA contact lenses have largely been replaced by rigid lens materials, which are used on a therapeutic basis in corneal and scleral lenses [12–15].

The soft contact lens market emerged in the early 1970s with the creation of cross-linked hydrogel polymers and the introduction of hydrogel contact lenses [16–22]. Hydrogel contact lenses inherently lacked the ability to transmit enough oxygen to

the cornea in order to avoid corneal hypoxia during overnight wear [16], which propelled the creation of the much more oxygen permeable silicone and then silicone hydrogel (SiHy) contact lenses [23–25]. There was hope that SiHy contact lenses would reduce the rate of microbial keratitis (MK) associated with overnight night CL wear. Post-market experience reveals that infection rates are similar between SiHy and hydrogel contact lenses [26,27], While hydrogel contact lenses are still labelled and used in some countries for overnight wear and as therapeutic or bandage lenses, it is generally only SiHy lenses that currently carry therapeutic or bandage indications for use. The following is a discussion on how these material properties, modes of wear, and innovation in design might affect the choice of lens for medical use of contact lenses.

1.2.1 Hydrogel/Silicone Hydrogel

The first US FDA approved soft contact lens was a conventional hydrogel lens (Soflens) developed by Bausch and Lomb [16]. Conventional hydrogel contact lenses fail to meet the criteria (87.0 Dk/t) set forth by Holden and Mertz to provide the cornea with enough oxygen to avoid excess corneal swelling during overnight wear [28], a limitation to their use (see CLEAR Complications Report [30]). Eventually, this challenge of hypoxia was circumvented by the release of the first silicone hydrogel contact lens (PureVision) by Bausch & Lomb with reports of improved performance compared to hydrogel lenses for both cosmetic [23] and broad therapeutic use [31]. While silicone hydrogel contact lenses have a reduced likelihood of corneal hypoxia [32–35], they have failed to address many of the other issues that are problematic for CL wearers [36].

Furthermore, the literature currently lacks well-controlled studies related to these materials being used specifically for medical purposes. One of the first reports on therapeutic soft was published in 1971 [16]. That study described the use of the Soflens for treating 45 patients with corneal disease (corneal oedema, dry eyes, corneal ulcers, and advanced corneal conditions such as keratoconus). They found hydrogel contact lenses were an effective bandage lens for reducing

external ocular discomfort. Early evidence in a study with 278 participants demonstrated that hydrogel contact lenses were effective therapeutic lenses for treating about half of participants with acute or chronic corneal diseases [20]. In a prospective study, 91% of the adult participants (n = 70) found benefit from wearing silicone hydrogel contact lenses for therapeutic purposes for conditions such as bullous keratopathy and post-operative corneal epitheliopathy [37]. Similarly, silicone hydrogel contact lenses can be beneficial post-LASEK [38], and a prospective study found that SiHy lenses (n = 29) are safe and effective for children for therapeutic purposes for conditions such as corneal burns or wounds [39]. Similarly, a multicentre study reported general success of a senofilcon A lens as bandage lens for a range of therapeutic indications [40]. These data fail to provide clear evidence with regards to selecting a hydrogel or silicone hydrogel contact lens for medical use. Similarly, disposable soft contact lens that are replaced on a daily, bi-weekly, or monthly basis are now readily available, though there is no clear evidence for selecting one wear schedule over another for medical purposes [41].

1.2.2 Specialty soft lenses

Standard, commercially available soft contact lenses are typically between 13.8 mm and 14.5 mm in diameter. There are two special types of soft lenses that have medical use: large diameter hydrogel soft lenses and custom toric hydrogel or SiHy lenses.

Large diameter hydrogel soft contact lenses are available for off the shelf use in eyes with larger corneal diameters and can be used for medical purposes such as bleb leak or when there is poor retention of typical diameter lenses due to exposure, ocular surface disease or unusual corneal or scleral topography. The sub-committee on Medical Use Contact Lenses acknowledges that there are off the shelf large diameter contact lenses (e.g., Kontur, Hydrolens, Eye-58) and that these are in widespread use in the locales in which they are marketed. However, no primary references related to these contact lenses were identified during the

preparation of this report, and because of this, more investigation on this topic is needed. A randomised, crossover study with 25 patients who wore a well-fitted optimum diameter soft contact lenses or a soft lens that was 1.2 mm larger in successive trials were examined to determine if excessively large lens would have a negative impact on the ocular surface [42]. While the larger lens did not fit as well, there was no difference in ocular comfort between the groups and there was minimal difference in ocular signs. This work will help to inform futures studies as to which parameters of custom soft contact lens fit are critical for success in diseased eyes.

Current literature suggests good long-term tolerance of custom soft contact lenses. A review of 11 charts from patients who began wearing their custom soft contact lenses between 1982 and 1984 found that 7 out of these 11 patients were still wearing their lenses in 1986 [43]. A study that enrolled 105 patients who had astigmatism and who were empirically fitted with the Igel Rx toric soft lens, found that 74% of the enrolled subjects were able to wear the contact lens full-time and that 89% of enrolled subjects were able to achieve vision that was within one line of their best-corrected visual acuity [44]. A more recent 12-month prospective study with the Kerasoft® iC (custom soft) contact lens in a group of 43 patients who had a variety of irregular corneal conditions found that, at 12 months, 84% of the subjects were still wearing these lenses with the majority achieving good vision and comfort [45].

1.2.3 Rigid corneal lenses

While rigid corneal lenses make poor choices as therapeutic contact lenses for ocular surface disease because of their mobility, small diameter and associated tear film instability, rigid corneal lenses have been used for decades for visual rehabilitation [25,46–48]. Rigid corneal lenses may be particularly useful in patients with high refractive error or aphakia because the lenses needed to correct these conditions would be thick to meet power requirements, limiting oxygen transmission through the lens [48]. Rigid corneal lenses allow for greater access

to atmospheric oxygen than any soft lens which covers the cornea beyond the limbus. Additionally, rigid corneal lenses allow for much greater tear exchange compared to scleral lenses, especially a sealed one, so atmospheric oxygen should be more available to the cornea with this approach [49,50], just as a SiHy lens is likely to allow for better tear exchange than a sealed scleral lens [51]. Rigid corneal lenses are useful in the visual rehabilitation of corneal scars because their capacity to neutralise any corneal irregularity outweighs any worsening of straylight [52]. Nevertheless, the prescribing of rigid corneal lenses has lost some favour for cosmetic purposes and for corneal disease cases in recent years because of the challenges associated with fitting this modality and because many patients find scleral lenses more comfortable [53]. Some wearers of rigid corneal lenses however, report corneal lenses to be more comfortable than scleral lenses and chose to continue with them, suggesting that this modality remains an option for management of disease [54].

1.2.4 Hybrid lenses

A hybrid lens is a contact lens that has a central rigid corneal lens for providing clear vision which is fused to a soft contact lens skirt intended to help with lens stability and comfort. The utility of early hybrid lenses was limited due to low oxygen transmission contributing to corneal neovascularisation and breakage at the lens skirt junction [55]. Recently, a number of low quality evidence reports, which are fully described in sections 4.1.1 (keratoconus) and 4.2.1 (penetrating keratoplasty), suggest that hybrid lenses are useful in treating patients with irregular corneas (e.g. keratoconus) and with history of surgical interventions (e.g., keratoplasty) [56–60].

1.2.5. Piggyback lenses

A piggyback lens system, which is a rigid lens worn on top of a soft lens can be used for medical purposes when surgery, trauma, or disease results in irregular astigmatism or high power requirements, such that a rigid corneal lens is not tolerated [61]. Because of the combined thickness of two lenses on the eye, the

issue of adequate oxygen transmission is critical to consider in selection of each lens [62]. Many parameters can be manipulated along with adoption of innovations in lenses and materials, to improve comfort, vision, and physiological function [63–65].

1.2.6 Scleral lenses

Scleral lenses were not only the first contact lens, but they were also the first contact lenses used for therapeutic purposes [11,66,67]. Scleral lenses are large diameter contact lenses, initially impression moulded [68,69] and then lathed, that completely vault the cornea and land on the sclera/episclera and overlying conjunctiva [15,70]. Scleral lenses enclose a fluid reservoir that is filled with preservative free sterile saline, creating a tear lens between the ocular surface and the contact lens. This feature neutralises the majority of anterior corneal aberrations, provides lubrication and support of the ocular surface, as well as protection from exposure and/or external mechanical irritation from the lids/lashes. Scleral lenses can play a therapeutic role in ocular surface disease and in the visual rehabilitation of corneal ectasia and irregular astigmatism [71] (see CLEAR Sclerals report [72]).

Scleral lenses have important medical uses as bandage lenses for comfort, as therapeutic lenses for supporting the surface, and in improvement in vision in the setting of disease. There is a large body of evidence on the use of scleral lenses for visual rehabilitation in conditions characterised by irregular astigmatism, to be reviewed in section 4 below. Over 20 years ago, there emerged low quality evidence studies that supported prescribing scleral lenses as therapeutic contact lenses for patients who have severe dry eye. A study of 11 subjects found that 91% had better visual acuity and symptomatic improvement while wearing modern scleral lenses [73]. A retrospective chart review including 49 patients who were fitted with scleral lenses for ocular surface diseases, such as Stevens-Johnson syndrome, with dry eye symptoms [74], found that fitting these patients with scleral lenses resulted in 82% having substantial improvements in ocular surface

symptoms and 92% having improvements in visual function and quality of life. Another retrospective chart review evaluated 48 patients who were fitted with scleral lenses after failure with other modalities [75]. The authors found that, while not all patients could wear scleral lenses (10.4%) due to mostly handling issues, 81% of their included subjects had improvements in ocular surface symptoms, similar to the findings of Romero-Rangel et al. Similarly, Jacobs and Rosenthal performed a chart review of 33 patients fitted with scleral lenses for ocular surface disease who were subsequently contacted to complete a survey related to ocular surface symptoms. They found that 97%, 94%, and 97% of their subjects had improvements in pain, photophobia, and quality of life, respectively [76]. The same group reported significant improvement in visual function as measured by NEI VFQ-25 in a 2006 cohort of 100 patients with ectasia, irregular astigmatism, and ocular surface disease [77]. Consistent with these reports of broad utility, a survey of 292 practitioners revealed that scleral lens wear improves vision and reduces corneal staining in their patients [78]. In a study of corneal nerve structure and function in 20 patients fitted with a fluid filled scleral lens, patients with a distorted cornea had significantly reduced basal tear production and increased corneal sensation after long-term wear of the scleral lens, whereas patients with ocular surface disease did not show any changes in tear production or corneal sensation [79].

2 Bandage lenses in the acute setting

2.1 After keratorefractive procedures

Bandage soft contact lenses (BSCLs) were incorporated into the post-operative regimen following surface ablation procedures to attenuate post-operative pain, reduce the need for topical and/or systemic analgesia, to provide the regenerating epithelium protection from shear stress induced by blinking, and promote re-epithelialisation. SiHy lens resulted in faster corneal reepithelialisation and reduced patient discomfort in comparison to a hydrogel lens [80]. As discussed in the subsequent section, lens fitting has also been suggested to be important for achieving optimal pain control and epithelial healing [81]. Drawbacks to the use of

BSCLs in the acute setting are the same as for other CL uses, specifically the potential for infection. In a retrospective study across six military centres for kerato-refractive surgery, 25,337 eyes that underwent photorefractive keratectomy (PRK)were identified [82], in which BSCL is standard part of post-operative regimen. Only five eyes in that cohort developed MK, four of which were culture positive for *Staphylococcus*, a common inhabitant of the normal skin microbiota.

2.1.1 Photorefractive keratectomy (PRK)

Numerous prospective studies provide strong evidence to support the use of BSCLs immediately following PRK. PRK is a procedure in which the corneal epithelium is removed, followed by ablation of the anterior limiting membrane and the stroma using the excimer laser, to alter corneal shape and thus refractive power. In almost all studies, ocular discomfort is assessed using validated subjective questionnaires. To mitigate pain and promote re-epithelialisation, BSCLs are usually worn for three to five days [83,84]. Reports of the additive use of BSCLs along with topical anaesthetic agents, topical nonsteroidal anti-inflammatory (NSAID) eye drops, or both, after PRK [85,86]. Both studies found that patients treated with both topical agents and BSCLs experienced less pain than patients treated with both agents and no lens, supporting the practice of using BSCLs following PRK. More recently, an evaluation of the use of BSCLs soaked in 0.45% ketorolac [87] found that the use of the ketorolac-soaked lens significantly reduced postoperative pain.

Despite the theoretical benefits of increased oxygen transmissibility with silicone hydrogel lenses, medium quality evidence studies are equivocal as far as the superiority of silicone hydrogels to hydrogels. In a prospective study of 100 patients randomised to either a silicone hydrogel or hydrogel lens, the silicone hydrogel lens outperformed its hydrogel competitor [80]. However, a subsequent study's retrospective analysis of epithelial healing after PRK in 206 patients did not find a difference in the rate of re-epithelialisation [83]. While patient-reported pain levels

and the frequency of haze were higher with the hydrogel lens, more infiltrates were seen with wear of the silicone hydrogel lens [83].

While more recent studies have primarily used silicone hydrogel lenses, there are very few comparative controlled studies that support the use of a specific silicone hydrogel lens after PRK. Available evidence suggests that second and third generation silicone hydrogel lenses may confer some advantages in terms of pain and discomfort; however, re-epithelialisation is unchanged. The data reporting and comparing various SiHy lenses after PRK are summarised in **Table 1**.

Table 1: Summary of prospective published studies (all case control or cohort studies) comparing the efficacy of various silicone hydrogel contact lenses after PRK.

Author, Year	Study design	Number of patients (n)	Materials compared	Study outcomes
Grentzelos et al., 2009 [88]	Randomised, Contralateral	44	Lotrafilcon A Lotrafilcon B	No differences in re-epithelialisation
Razmjoo et al., 2012 [84]	Randomised, Contralateral	44	Senofilcon A Lotrafilcon A	Pain and discomfort lowest with senofilcon A, no difference in epithelial healing
Plaka et al., 2013 [89]	Non-randomised Contralateral	47	Lotrafilcon B Asmofilcon A	Faster epithelial healing with asmofilcon in first 3 days; no other differences noted
Taylor et al., 2014 [90]	Randomised, Contralateral	45	Senofilcon A Balafilcon A Lotrafilcon A	Pain levels highest with balafilcon A > lotrafilcon A > senofilcon A
Mukherjee et al., 2015 [91]	Randomised, Contralateral	24	Comfilcon A Senofilcon A	A reduction in pain with wear of the senofilcon A lens; no

				difference in epithelial healing
Eliaçik et al., 2015 [92]	Randomised, Contralateral	21	Lotrafilcon B Comfilcon A	No difference in overall healing rate, size of epithelial defect through postop day 3 and discomfort were both reduced with comfilcon A
Mohammadpour et al. 2015 [93]	Randomised, Contralateral	60	Balafilcon A Lotrafilcon A	Less pain with lotrafilcon A; Foreign body sensation with balafilcon A
Mohammadpour et., 2018 [94]	Randomised, Contralateral	60	Lotrafilcon B Comfilcon A	No differences in pain or ocular discomfort
Yuksel et al., 2019 [95]	Randomised, Contralateral	34	Samfilcon A Lotrafilcon B	Some differences in healing and pain on postop day 2; no differences between lens types by postop day 3
Duru et al., 2020 [96]	Randomised, Contralateral	43	Senofilcon A Lotrafilcon B	Less pain and tearing over first 48 hours postop with senofilcon A, no difference in epithelial healing
Bagherian et al., 2020 [97]	Randomised, Contralateral	45	Both generations of balafilcon A	No difference in epithelial healing, second generation lenses tended to have increased deposits

Duru et al., 2020 [98]	Randomised, Contralateral	37	Balafilcon A Samfilcon A	Better comfort with samfilcon A, no differences in epithelial healing

Two medium quality evidence studies have reported on the efficacy of investigational silicone shields following PRK. The first study concluded that the investigational device had a relatively good margin of safety, however no comparator BSCL was used [99]. A subsequent study included the use of a comparator lens and found an improvement in visual recovery with the silicone shield; however, ocular discomfort was greater compared to the BSCL and no statistical differences were noted in epithelial healing [100].

The efficacy of sutureless cryopreserved amniotic membrane placed at the time of the procedure on epithelial healing compared to BSCL after PRK found that the amniotic membrane was not superior to a BSCL in the promotion of epithelial healing after PRK [101]. Similarly, a cohort study found that the use of sutureless amniotic membrane was not more effective than BSCLs in preventing haze after PRK [102]. In a similar study, the use of cultured human allogeneic epidermal keratinocyte onlays as a method to promote healing and reduce pain was compared to BSCL wear [103]. Patients were randomised into one of three treatment groups with the cultured human allogeneic epidermal keratinocyte onlays with BSCL, with amniotic membrane and a BSCL, or a group with BSCL alone. Study findings demonstrated that a shorter duration of lens wear was required for the group treated with the amniotic membrane, but no other differences were noted.

Lens fitting is also an important determinant for managing postoperative pain in PRK. In a prospective study, 140 patients were fitted with a silicone hydrogel lens available in two base curves: 8.4 mm and 8.8 mm [104]. The relationship between the lens base curve and anterior corneal curvature impacted comfort, with corneas with a postoperative keratometry (K) value of less than 38 dioptres (8.8 mm) having

better pain outcomes when wearing the 8.8 mm base curve, whereas steeper corneas with a postop K value greater than 42 dioptres (8.04 mm) did better with the 8.4 mm lens [104]. Misalignment between the base curve of the contact lens and corneal curvature was a factor driving premature lens loss. This study highlights that lens fit, as opposed to lens material or Dk, warrants consideration and study in the selection of BSCL after PRK.

To further investigate the parameters associated with BSCL wear and pain control, a prospective study examined the timing of BSCL removal in 260 eyes of 130 patients, removing the lens either on day 4 or day 7 post-operatively [105]. They found no differences in pain between the two groups, although interestingly, the group in which the BSCL was removed on day 4 post-op had an increase in the frequency of complications, including filamentary keratitis, corneal erosion, and haze. This finding suggests that longer postoperative lens wear was associated with fewer complications. Visual recovery at one month was also improved in the seven-day BSCL group, although this change was not evident at three months.

A prospective study examined if the temperature of the irrigating solution and BSCL had an effect on post-PRK pain, with one group receiving chilled (2-5°C) balanced salt solution and a chilled BSCL, while the other group received the solution and BSCL at room temperature (21-23°C) [106]. No difference in post-operative pain measures were noted between the two groups.

2.1.2 Laser assisted *in situ* keratomileusis (LASIK)

LASIK is a procedure in which a corneal flap is cut using a blade or femto-laser under which an excimer laser is used to ablate corneal stroma, reshaping the cornea and altering its optical power. There is insufficient evidence to support the routine use of BSCLs following LASIK. A controlled study of the use of hydrogel BSCLs after LASIK in 200 myopic eye found that the majority of patients did not experience better postoperative comfort from the application of a BSCL after LASIK, nor did the BSCL protect from the occurrence of microstriae [107]. Another

study compared the use of BSCLs to no lens wear immediately following LASIK and reported that 29% of patients were intolerant to BSCLs, necessitating removal at one hour [108]. The authors concluded that BSCL wear was effective for up to four hours after LASIK to decrease symptoms, while flap oedema and the presence of mucoid secretions were limitations of overnight wear. In terms of pain control, a prospective investigation of the efficacy of BSCLs after LASIK compared to topical medications on the first postoperative day [109] concluded that the use of topical medications was superior to the BSCL in terms of pain control and visual acuity. Additionally, patients preferred not wearing a BSCL.

The use of BSCLs after LASIK can alter corneal topography and increase corneal oedema, reducing uncorrected distance visual acuity [110]. The mechanism for this was both an increase in corneal asphericity, likely due to the mechanical pressure of the CL, and corneal flap oedema. The authors speculated that the oedema in the flap was due to preservatives in the topical medications. The finding of oedema in the flap was consistent with that reported by another group [108].

Some beneficial effects of BSCLs on wound healing after LASIK have been reported. A prospective, randomised study evaluated the effect of a BSCL on fibrosis at the flap margin with 41 patients (82 eyes) fitted with a BSCL in one eye but not in the contralateral, control eye [111]. Pain and photophobia were milder in the eyes fitted with a BSCL than those with no BSCL, however the BSCL was associated with a foreign body sensation. While the BSCL did appear to improve healing at the flap margin, there were no differences in any of the other outcome measures at six months.

Evidence supporting the use of BSCLs for the prevention of epithelial ingrowth is equivocal based on three retrospective reports in the literature. The largest of these evaluated 16,702 eyes in 12,485 patients over a ten-year period who

underwent an enhancement [112]. No differences were found in visual acuity or the rate of epithelial ingrowth between eyes that did or did not receive BSCL. The second, much smaller study also looked at the rate of epithelial ingrowth following an enhancement [113]. While the authors reported a potential trend towards an increase in epithelial ingrowth in the BSCL group, the study groups were small and there were no statistical differences reported. A third earlier study retrospectively evaluated the rate of epithelial ingrowth after LASIK included 783 eyes over a three-year study period, including eyes undergoing primary procedure and 108 undergoing enhancement [114]. All eyes were given a BSCL for the first day after surgery. In this cohort, only three eyes developed epithelial ingrowth Due to the small number of cases reported, the authors concluded that extensive cleaning of the stromal interface during surgery combined with BSCLs may decrease the rate of epithelial ingrowth, although there was no control group with no lens for comparison.

Only one report was found on the use of BSCLs in epi-LASIK [115]. This prospective study evaluated the effects of two different base curves (8.4 mm and 8.8 mm) on the corneal epithelium and postoperative pain. Twenty-seven patients were fitted with both base curves in a contralateral fashion. There were no differences in any of the outcome measures, except for uncorrected distance visual acuity, with a statistically significant improvement with the 8.8 mm base curve on day four postop visit that was no longer evident by day seven. Similarly, a significantly significant improvement in uncorrected visual acuity was noted with the 8.8 mm base curve lens in patients with higher levels of myopia preoperatively and keratometry measurements of ≥ 43 dioptres at day four post op but was no longer significant at day seven.

There is medium quality evidence supporting the use of BSCLs in the management of post-LASIK complications. In a report of 5,896 eyes that had LASIK using a microkeratome, 95 eyes had intra-operative epithelial damage [116]. BSCLs were used to treat epithelial defects that were larger than three mm in size. All of these

eyes healed in 1-3 days; 3 eyes with 4-5mm defect were left with visually symptomatic irregular or against-the-rule astigmatism that was successfully treated with transepithelial phototherapeutic keratectomy. Another report of 5,566 eyes that underwent LASIK using a microkeratome evaluated over a one-year period eight eyes that had recurrent epithelial loosening [117]. Lubrication and BSCLs were used in 4 eyes with the remaining 4 requiring anterior stromal puncture plus wear of BSCL for 1 month for resolution of symptoms. Additionally, a case of blunt trauma leading to a corneal flap dehiscence in a 32-year-old man with a history of LASIK was successfully treated with a BSCL [118].

No differences were found in the incidence of corneal epithelial ingrowth and in visual outcomes after enhancement by flap lift when comparing those that were fitted in a BSCL after the procedure to those who were not [112]. Additionally, bacterial contaminants on used bandage lenses after LASIK or PRK have been characterised, but have not necessarily been associated with complications as usually only ocular commensal microorganisms are isolated [119–122]

2.1.3 Laser epithelial keratomileusis (LASEK)

LASEK is a procedure in which an “epithelium only” flap is created under which the stromal ablation is performed. Only four studies to date have evaluated the use of BSCLs following LASEK. One study demonstrated that SiHy BSCLs were well tolerated and effective in patients undergoing LASEK, however it is important to note that no comparator lens or control group were used [38]. Two other research groups later compared the use of hydrogel and SiHy lenses after LASEK. Both groups concluded that SiHy lenses were superior to hydrogels as BSCLs after LASEK [123]. In the final study, the efficacy of two different generations of SiHy lenses were evaluated [124]. Greater discomfort and an increase in deposits on the lens surface were found with wear of a first-generation silicone hydrogel compared to the second-generation lens material. Whether the advantage is based on oxygen transmission, modulus, tendency to deposits, or another material feature remains unknown.

2.1.4 Phototherapeutic keratectomy (PTK)

PTK is a procedure in which epithelial debridement and excimer laser ablation are used to treat anterior corneal disease including corneal dystrophies and scarring. Most evidence supporting the use of BSCLs after PTK ablation comes from prior work evaluating their use after PRK. A small case series investigating the use of BSCLs after PTK on patients with recurrent corneal erosions reported that eight eyes presented with erosions secondary to bullous keratopathy and all patients responded well to PTK with BSCLs [125] In a small case series on the use of PTK in children, five eyes from five children (six to eight years of age) with superficial anterior scarring were treated to prevent the development of amblyopia [126]. All eyes were fitted with BSCLs postoperatively along with topical antibiotics, steroids, and artificial tears. Four eyes showed an improvement in best corrected visual acuity. There was no mention of the specific BSCL that was used.

2.2 Corneal Collagen Crosslinking (CXL)

BSCLs are standard practice in CXL with epithelium removal (epi-off) to promote epithelial healing and reduce postoperative pain [127,128]. The only studies addressing the effects of BSCLs following CXL are focused on the risk of infection, which remains very low (0.0017%-0.71%) [129,130]. The use of steroids and a BSCL was the largest risk factor identified for infection after surgery [129]. Rates of infection were higher than in PRK for reasons unknown, however it is speculated that the increased incidence of atopy among patients with keratoconus may be contributory.

One of the few studies to evaluate the use of BSCLs on pain control and re-epithelialisation after CXL examined the use of balafilcon A and hioxifilcon A lens materials, and reported that the epithelium underwent complete healing by day three with no differences in pain [131]. Collagen shields have also been tested for their efficacy in managing epithelial defects after CXL [132]. In a prospective study, all epithelial defects were fully healed by day four, with complete re-

epithelialisation at one month. While the authors demonstrated that the collagen shield was effective, there was no comparator BSCL or non-treated control.

2.3 Ethylenediamine-tetraacetic acid (EDTA) chelation

For patients with band keratopathy, the corneal epithelium is removed by mechanical debridement and the cornea is then treated with EDTA to remove calcium deposits located within the anterior stroma and anterior limiting lamela membrane. Historically, either a BSCL is inserted or the eye is patched after the procedure. In recent years, there has been a shift towards increased BSCL use. Evidence supporting the efficacy of BSCL after EDTA chelation is scant. In a small cohort, 19% ethanol was used to detach the epithelium to prevent the development of a post-procedure corneal abrasion and the clinical experience of three patients fitted with silicone hydrogel BSCL for one to two weeks following the procedure was described [133]. In this small cohort, the BSCL was very effective in reducing postoperative pain. A retrospective study evaluated 89 cases that were all fitted with a BSCL postop and focused on the recurrence of disease; however, no mention of the BSCL type or impact of the BSCL on procedural outcomes or ocular discomfort were noted [134].

2.4 Persistent epithelial defects (PED)

Corneal epithelial defects are classified as PEDs when they are non-responsive to treatment after two weeks [135]. PEDs can occur from a myriad of aetiologies. These include iatrogenic (e.g. toxic keratitis secondary to chronic use of medications containing benzalkonium chloride), surgical complications, neurotrophic keratopathy, ocular surface disease, infection, and trauma [136]. Importantly, if the epithelial defect is not properly treated, it can progress to ulceration and/or scarring. Past treatments involved pressure patching along with antibiotics and cycloplegics. BSCLs are now considered a standard therapy and are used as part of a conservative management approach, along with lubrication, punctal occlusion, and epithelial debridement [136,137]. The BSCL protects from damage from the eyelid that may contribute to mechanical erosions, thus aiding in

epithelial healing. BSCLs are superior to pressure patching because the eye can be monitored without removal. Soft contact lenses are routinely used in these cases since standard rigid corneal lenses are small, move too much, and are too abrasive for a PED. Drawbacks to using BSCLs for PEDs include lens displacement and risk of microbial keratitis [46].

Medium quality evidence exists to support the use of BSCLs in the treatment of PEDs. In a prospective study, all patients with PEDs following vitreoretinal surgery that showed no improvement after patching for two weeks were fitted with BSCLs, though the exact lens type not specified [138]. Patients were then treated with topical 1% indomethacin or artificial tears. No differences in epithelial staining were noted between the groups, but pain was reduced in patients that used both the topical NSAID and BSCL. It was noted that NSAID use was associated with the development of fine stromal opacities which resolved over time.

Early prospective study of a balafilcon A lens in an overnight wear modality of 3-90 days for therapeutic indications including PEDs found that 15 of 19 patients with PEDs demonstrated complete healing and BSCLs were well tolerated; however, of note, two eyes did develop MK [139]. A similar study used the lotrafilcon A lens, also in an overnight wear modality for 3 days to 13 months, as a BSCL for a variety of ocular surface diseases, including four PEDs [140]. All PEDs were successfully healed with good tolerance and comfort of the BSCL and without sight-threatening complications or vision loss. Due to the successful study outcome, the authors theorised that the benefit of the longer wear schedule was advantageous as it reduced the risk of epithelial damage associated with more frequent replacement.

A retrospective review compared the use of a porcine collagen shield (Bausch &Lomb, Rochester, NY) worn for 24 hours to a standard hydrogel BSCL for PEDs [141]. Patients that wore the BSCLs had complete re-epithelialisation, whereas no healing was evident in patients wearing the collagen shield. In a small case series

examining the use of a topical regenerative agent and a BSCL for the treatment of PEDs, all eyes and PEDs fully healed within three weeks with said treatment [142]. Large diameter BSCLs have also been used following allogenic simple limbal epithelial transplantation for the treatment of PEDs with successful re-epithelialisation in 93% of eyes [143]. In this case series, all patients wore BSCLs, thus no control group was included.

There is only weak evidence supports the successful use of BSCLs in conjunction with autologous serum eye drops. The first evaluation of the therapeutic efficacy of this treatment was in a small case series on six eyes with PEDs due to various aetiologies [144]. All eyes resolved without complications and BSCLs were well tolerated, despite reports of white protein deposition on the BSCL surface. More recently, the efficacy of autologous serum and BSCLs for the therapeutic management of PEDs was studied [145] and all twenty-one eyes that received 20% autologous serum along with a silicone hydrogel BSCL demonstrated complete re-epithelialisation without recurrence during a 3 month follow-up period. A retrospective evaluation of 12 eyes with PEDs due to previous infectious events were similarly treated with complete resolution of the PED [146].

While soft contact lenses are mostly used as BSCLs for the treatment of PEDs, published studies support the use of scleral lenses for the management of longstanding cases, even those that have failed with prior treatment. The first report regarding the use of scleral lenses for the treatment of PEDs found that scleral lenses promoted re-epithelialisation of the defect in a majority of cases, however four eyes (29%) developed microbial keratitis [147]. A later report by Lim et al. evaluated clinical outcomes for PEDs treated with the Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) device, with daily cleaning and replenishment as well as the use of a prophylactic, non-preserved antibiotic in the reservoir [148]. Unlike the prior study, most eyes had complete re-epithelialisation with no adverse events with the prophylactic antibiotic treatment. Other studies report success with the PROSE device for the treatment of PEDs

and recurrent corneal erosion syndrome secondary to multiple aetiologies [149–151]. Interestingly, in one study, all were patients that had failed to heal with wear of a silicone hydrogel BSCL [149].

2.5 Corneal abrasions and recurrent corneal erosion syndrome (RCES)

RCES is a painful condition that often occurs upon awakening as a result of nocturnal drying. In addition to pain, hyperaemia, tearing, photophobia, and blurry vision are often present. BSCLs are routinely used in patients with RCES to protect the damaged epithelium and facilitate re-epithelialisation. They also help to mitigate pain. A 2018 Cochrane review of interventions for RCES found benefit of therapeutic contact lens over lubricant with no adverse effects, based on one study, (detailed below), using a modern lens that met criteria for inclusion in the review [152]. The ideal BSCL for treating RCES would have high oxygen transmissibility and a flat base curve [153]. The preference towards the use of a flat base curve suggests that the mechanical contact from the flat lens is superior to a tight lens, although there is little evidence in the BSCL literature to support this and thus represents an area where further studies are needed. The primary risk of using BSCLs in patients with RCES remains infection, which is increased if steroids are used to help suppress inflammation [153,154]. The largest retrospective study to evaluate BSCLs compared to other treatment modalities for RCES spanned an eight-year period [155]. During that time, 104 patients were evaluated and full re-epithelialisation was seen in all eyes wearing BSCLs. A randomized controlled trial (RCT) study also compared treatment with either ocular lubricants or a BSCL for patients with RCES [156]. After three months, 71.4% and 73.3% of patients in the BSCL group and ocular lubricant group, respectively, showed complete re-epithelialisation. They further reported that wear of the BSCL enhanced the rate of re-epithelialisation. A report on the impact of long term overnight wear of the BSCL in patients with RCES found that 75% of these patients had no further recurrences when followed over one year [157].

A retrospective analysis of the efficacy of a silicone hydrogel BSCL across three different clinical sites concluded that the lens was effective at managing patients with RCES [40]. No controls or comparators were used in this study.

There is medium quality evidence to support the use of BSCLs for traumatic corneal abrasions. The first report on this topic was in 1987, which compared the use of BSCLs to patching in patients with abrasions greater than four mm^2 in size [158]. Overall, patients wearing BSCLs healed faster and experienced less pain. In studies using BSCLs combined with a topical NSAID to treat RCES, successful re-epithelialisation and a significant reduction in pain were reported [159,160]. In addition, patients wearing a BSCL were able to resume normal activities earlier than the patched group [160]. However, at the same time, evidence emerged to suggest that pressure patch offers no advantage in the treatment of corneal abrasion, suggesting that the CL studies did not use the appropriate control group [161].

A retrospective examination of all patients that presented with traumatic, non-infected corneal erosions over a five-year period found that, despite a large variation in defect size, all eyes wearing a BSCL re-epithelialised between one and three days [162]. In agreement with these studies, a smaller retrospective study examined patients with traumatic corneal abrasions that presented to one of several U.S. military battalion aid stations [163]. Successful re-epithelialisation with the BSCL was achieved in 87% of patients.

A later report on the efficacy of the same silicone hydrogel BSCL compared to patching for the treatment of traumatic erosions showed that patients wearing BSCL had less pain than those that were patched [164]. The authors point out that the pressure patch had to be removed for the instillation of topical medications and was replaced at home by family members or the patient. Thus, the strength of the pressure patch may have varied and contributed to the differences reported.

2.6 Over-tissue adhesive (glue) for corneal perforations and lacerations

Fibrin and cyanoacrylate tissue adhesive are sometimes used in patients with corneal perforation. Depending on the size of the perforation and location within the cornea, tissue adhesive along with a BSCL may be sufficient to avoid the need for surgical intervention to stabilize the globe, with cyanoacrylate adhesive more effective than fibrin for larger perforations. The application of a BSCL is essential, as the surface of the adhesive is rough and may be dislodged by squeezing or blink [165–167]. There are numerous case reports/series that reported on the use of tissue glue with BSCLs [168–172]. Unfortunately, there is little detail or data as far as the optimal lens materials or fitting parameters to use in such of cases.

2.7 Over-amniotic membrane – frozen, dried

BSCLs have been used over amniotic membranes to promote retention. Many case studies and reviews report on the efficacy of amniotic membranes for the treatment of severe corneal epithelial defects, with and without stromal ulceration, and mention the use of BSCLs as part of their treatment protocols, but no studies have examined the benefits of their inclusion [173–177].

Only two studies were identified that support the use of BSCLs for the retention of amniotic membranes. An evaluation of the use of amniotic membranes for the treatment of epithelial defects due to surgery or unresponsive PEDs found that BSCLs were successfully used in 5 of 20 patients to maintain membrane position when the membrane only covered the cornea [178]. The use of the BSCL increased retention time of the membrane and four of the five eyes re-epithelialised. A subsequent study in the UK investigated the efficacy of amniotic membrane transplantation with and without a BSCL [179], and whilst there was a fairly high failure rate with the amniotic membrane, the application of a BSCL immediately post-operatively increased their likelihood of success.

2.8 Post-operative use for comfort and healing

There is moderate quality evidence for the use of BSCLs after phacoemulsification, penetrating keratoplasty, ptosis repair, and pterygium surgery.

2.8.1 Phacoemulsification

There are two recent cohort studies that report on the use of BSCLs after cataract surgery. In a comparison of clinical signs and symptoms of dry eye after phacoemulsification performed after retrobulbar block, those who wore BSCLs for 1 week had reduced signs and symptoms of dry eye when compared to those who wore an eye pad on the first day, at all evaluated time points (1 week, 1 month, 3 months) [180]. Another study examined the effects of BSCL wear after phacoemulsification on dry eye symptoms in patients with mild meibomian gland dysfunction [181]. Dry eye symptoms were improved with BSCL use for 1 week versus no lens, with a statistically significant decrease in OSDI and subjective symptom scores at day 7 and day 14 post-op. No statistically significant difference was seen at day 1, day 30, and day 90 post-op.

2.8.2 Penetrating keratoplasty

BSCLs have been used after penetrating keratoplasty to enhance re-epithelialisation, prevent suture irritation, smooth irregularities in the wound margin, and to act as a tamponade for wound leaks since the mid-1970's [182–185]. In a randomised prospective study, 14 of 26 patients that underwent either deep anterior lamellar keratoplasty or penetrating keratoplasty were fitted with BSCLs and compared to a no lens control group [186]. No differences in any of the outcome measures were found between these two groups. The authors went on to speculate that postoperative pain may not be a factor due to damaged nerve endings as a result of keratoplasty, and thus BSCLs would not be beneficial for pain management in this setting. Moreover, in healthy patients, epithelialisation is usually complete approximately two days post-grafting. Unless the patient had an abnormal wound healing response or impaired tear secretion, BSCLs may not enhance healing. Other proposed factors that may influence the success of the

BSCL are the health status of the donor and recipient corneas, surgical parameters, and postoperative therapeutic regimens used.

A retrospective study designed to examine the frequency of PEDs after penetrating keratoplasty found that, of 11 eyes that were initially treated with a BCL (either a silicone hydrogel or scleral lens), four eyes were successfully healed in the first two weeks [187]. The remaining eyes needed additional treatment due to lagophthalmos or mechanical restriction.

2.8.3 Ptosis repair

A prospective report of 30 patients undergoing bilateral ptosis repair using a contralateral eye design found that the eye wearing the BSCL experienced less pain and ocular discomfort [188]. A RCT of 30 eyes in 30 children undergoing surgery for congenital blepharoptosis found better tear film breakup time, tear meniscus height and less fluorescein staining, supporting a conclusion that BSCL wear after surgery was beneficial to protect the ocular surface [189]. The use of a BSCL was reported as beneficial in prevention of epithelial breakdown that occurred in two cases where surgical intervention was required to treat exposure keratopathy after blepharoplasty [190]

2.8.4 Pterygium surgery

The use of BSCLs following pterygium surgery is equivocal. A comparison of the effects of BSCLs after pterygium surgery on re-epithelialisation and pain in 39 eyes (20 eyes randomised to the BSCL group, 19 to the no lens control group) found BSCL use significantly reduced pain and enhanced epithelial healing [191]. In a prospective study, pain, discomfort, and sleep quality during the initial 24 hours after pterygium surgery were compared between subjects using BSCLs versus subjects who were patching [192]. Interestingly, pain levels were worse and sleep quality was decreased in the BSCL group. Thus, the authors concluded that, despite certain drawbacks, patching is superior to BSCLs after pterygium surgery. Another comparison of the use of BSCL wear versus patching on pain levels after

pterygium removal reported an increase photophobia in the BSCL group on the day of surgery, but no other differences were found for any of the remaining outcome measures [193].

Another investigation of the efficacy of BSCLs compared to patching for pain control and re-epithelialisation was performed in 30 eyes, and, in contrast to previous studies, found that BSCL wear improved both pain and rate of re-epithelialisation when compared to patching over the first three post-operative days [194]. Similarly, a study of "scleral" design large diameter (18.0, 18.5, and 19.0mm) hydrogel lens after pterygium surgery reported that symptoms were less intense for patients who wore a lens compared to patients who wore no lens [195], with the larger diameter a plausible explanation for discordance with other studies.

2.8.5 Intracorneal ring segments.

There is limited evidence that BSCLs can be worn after implantation of intracorneal ring segments to aid recovery and comfort [196–199].

2.9 Bleb leaks, perforations, and trauma

There is medium quality evidence, for the use of BSCLs for the treatment of bleb leaks following trabeculectomy and in setting of wound leaks, trauma, and perforations.

2.9.1 Bleb leaks

BSCLs can be used for both early and late post-trabeculectomy bleb leaks. It is suggested that early bleb leaks occur within the first two months after surgery and are seen in up to 30% of patients, whereas an older study suggests that the rate may be even higher (up to 56%) in patients who undergo a fornix-based as opposed to a limbal-based procedure [200,201]. Late bleb leaks occur more than two months after surgery and are usually associated with the use of antimetabolites [202,203]. For small bleb leaks located close to the limbus, a soft

contact lens can be used as a tamponade. A BSCL also facilitates re-epithelialisation over the wound margin. For optimal results, BSCLs need to cover the superior conjunctiva, with a minimum of two to three mm above the limbus. The fit must be checked 30 minutes after insertion to confirm that no air bubble is present and that there is adequate coverage and proper movement. The size of the lens needed depends on corneal diameter, which may vary depending on race [204]. Complications from BSCL use for bleb leaks include displacement of the contact lens under the conjunctival incision or irritation of the wound margin, which can further increase the leak and risk of endophthalmitis.

The earliest report on the use of BSCLs for complications after trabeculectomy was in 1990 with subjects fitted with a 20.5 mm overall diameter Xylofilcon B lens [205]. The BSCLs were effective for deepening postoperative shallow chambers within 5 days in 5 of 5 patients; bleb leaks presenting days to months after surgery closed in 8 of 10 patients after a mean of 2.2 months of wear. More recently, a prospective evaluation of the safety and efficacy of BSCLs following trabeculectomy was reported in 200 eyes, divided into two groups (one group that wore a contact lens after surgery and a no lens control). At one year, success rates, defined as achievement of optimal intraocular pressure (IOP), were higher for patients that wore BSCLs [206].

The remaining studies are retrospective and case series. A retrospective analysis of early bleb leaks following trabeculectomy using mitomycin C included a mix of both fornix- and limbal-based procedures and found that 13 of the 27 bleb leaks reported were treated with bandage lenses with resolution within 1 week [200]. However, no specific analysis was done to determine the efficacy of BSCLs. An evaluation of 19 eyes with early bleb leaks after fornix-based trabeculectomy reported that the mean CL wear time to heal bleb leaks was 24 days [207]. The authors concluded that BSCLs for the use of bleb leaks were effective, although no control group was included.

A study of 11 patients with early bleb leaks in a Chinese cohort fitted with SiHy Balafilcon A BSCLs with 2 mm of coverage superior to the limbus concluded that BSCLs were effective for treating bleb leaks after fornix-based procedures [208]. BSCLs of 18 mm diameter worn for 2 weeks were reported as useful to ensure healing of residual bleb leaks in a report of sutureless revision of overhanging filtering blebs [209].

The use of hyperdry amniotic membrane patching along with tissue adhesive for bleb leaks and perforations was evaluated in a prospective study of five eyes, two with bleb leaks and three with perforations due to diabetes, herpetic infection, and trauma. Application of 2-octyl-cyanoacrylate glue to the epithelial side of the amniotic membrane and a hydrogel BSCL were used. All five cases had complete healing [210]. Finally, an unusual case reported ischaemic necrosis of the conjunctiva and an early bleb leak in a 27-year-old male patient one week after trabeculectomy. The leak was successfully treated with a 15.5 mm hydrogel BSCL and IOP was stable throughout a two-year follow up period [211].

A small case series consisting of seven patients treated for late bleb leaks with BSCL reported only one patient healed with the use of a BSCL [212].

2.9.2 Perforations

A series of corneal perforations and ulcerations in Sjøgren syndrome patients were successfully treated with soft contact lenses [213]. There is a single report of management of acute hydrops with perforation with BSCL [214].

2.9.3 Trauma

There is long history of use of bandage contact lens in penetrating wounds of the cornea [215]. Additionally, topical pilocarpine can be used as an adjunct to free incarcerated iris [216].

3 Contact lenses for chronic disease

3.1 Ocular surface disease

The history of use of contact lenses in the management of ocular surface disease is described earlier in this report (see Section 1.2.1). There are several conditions in which the experience and literature is substantial, warranting detailed consideration.

3.1.1 Chronic Graft versus Host Disease

Ocular involvement in chronic graft versus host disease (cGVHD) after either bone marrow transplantation and haematopoietic stem cell transplantation, has been reported to be between 40-60%, with a higher incidence after bone marrow transplantation (~60%) [217–219]. Ocular manifestations include keratoconjunctivitis sicca (most prevalent), inflammatory signs in the conjunctiva (chemosis, oedema, pseudo-membrane formation [acute GVHD only]), chronic blepharitis, meibomian gland atrophy and dysfunction, and lid fibrosis and atrophy with keratinisation sometimes leading to entropion or ectropion [218–221]. Corneal epithelial manifestations include punctate erosions, filamentary keratitis, and epithelial defects. At times, the immunocompromised state of these patients can lead to ocular infections and ulcerations that result in corneal melts and visual loss [218,220]. More recently, superior limbic keratoconjunctivitis (SLK) has also been reported as a manifestation of ocular cGVHD [217,221–223]

The first reports on the use of contact lenses as a therapeutic option in the management of ocular cGVHD were published in the 1970s and these continue to be published to date. While all these reports focus on the therapeutic use of contact lenses in the management of cGVHD, it is important to highlight that, despite the reported benefits of contact lenses, the overall treatment approach for ocular cGVHD is multimodal [217,218,221,223,224]. In addition to the therapeutic use of contact lenses, treatment and management often include a combination of some or most of the following: preservative free artificial tears, autologous serum tears,

punctal plugs, topical cyclosporine, topical steroids, topical tacrolimus, oral tetracyclines, and moisture chamber goggles.

Although conventional wisdom is that soft contact lenses are “contra-indicated” or problematic in eyes that are dry, an early study on the benefits of soft contact lenses in the treatment and management of keratoconjunctivitis sicca reported good tolerance and visual benefits [67]. This was later substantiated for cGVHD, particularly in a well-designed prospective, interventional case series that studied patients with moderate to severe dry eye signs and symptoms from cGVHD [225]. In this study, an inclusion criterion was a minimum score of 50 on the Ocular Surface Disease Index (OSDI) survey, a widely accepted subjective evaluation of symptoms. With planned overnight wear of a lotrafilcon A silicone hydrogel lens (Focus NIGHT & DAY, CIBA Vision, GA), there was improvement in visual acuity and OSDI scores at 1-week and 1-month. Dry eye signs (Schirmer’s, tear breakup time, and corneal staining) remained unchanged compared to baseline and there were no adverse effects. No patients were on topical steroid or cyclosporine A and no prophylactic antibiotics were used.

In a substantially larger clinical trial of multiple soft lenses, outcomes of soft lens wear in cGVHD were reported at 3 months in the 19 patients recruited. Patients were prescribed prophylactic antibiotic drops (ofloxacin, 0.3% ophthalmic solution or moxifloxacin, 0.5% ophthalmic solution, 4x daily) while wearing soft lenses. Lenses were worn in a continuous manner for up to a month and replaced every 2-4 weeks. Disposable hydrogel or SiHy soft contact lenses ranging from 14-18 mm in size were used, including PureVision (Bausch & Lomb, Rochester, NY), SofLens 38 (Bausch & Lomb), Flexlens (Ideal Optics, Duluth, GA) and Kontur (Kontur Kontact Lens, Hercules, CA). No adverse events were noted, and there was improvement in both visual acuity and objective measures in ~50% of the patients [226]. Similarly, a retrospective, non-comparative study examined the effect of 3 different types of silicone hydrogels in the treatment and management of cGVHD and found similar outcomes, with resolution of objective clinical signs in

~55% of the subjects [227]. Minimal adverse events were reported other than 2 infectious events, a *Pseudomonas* keratitis and herpetic keratitis, the latter which was not believed to be related to contact lens wear. Additional therapeutic benefits of soft contact lenses in cGVHD include the ability to heal persistent epithelial defects [223] and to manage superior limbic keratoconjunctivitis-like inflammation [222].

Most of the studies reporting on the therapeutic use of contact lenses for the treatment and management of ocular cGVHD focus on the use of scleral lenses [14,76,221,222,227–234]. Although the therapeutic benefits of scleral lenses were reported as early as the 1970s, a large retrospective case series in 2005[14,67] analysed 875 eyes of 538 patients fitted with fluid-ventilated, gas-permeable scleral lenses (PROSE, BostonSight, Needham, MA) during an 18-year period [14]. In this cohort, ocular cGVHD was present in 50 eyes. Of the 50 eyes, four presented with PEDs, which were all healed with overnight wear of scleral lenses and were subsequently transitioned to daily wear, with one exception that failed secondary to a leaky descemetocele. There was improvement in comfort and vision in forty-nine eyes. Two years later, the impact of this fluid ventilated scleral lens (PROSE, BostonSight, Needham, MA) in 9 patients with cGVHD was reported [235]. Aside from improvement in symptoms, signs, and vision, there was a mean improvement in OSDI scores from 81 to 12 (85% improvement; 1-23 months). Similarly, there was a substantial positive impact on pain, photophobia, and quality of life (QOL) in an interventional case series of 33 consecutive patients with cGVHD using a ventilated scleral lens (PROSE, BostonSight, Needham, MA), with 97% of patients reporting improvement on QOL [76].

An improvement in vision and clinical signs was reported by others with other scleral lenses soon after, including paediatric patients with ocular cGVHD [228,234,236]. **Table 2** summarises the literature on the effect of scleral lens treatment and management on QOL, visual function, and dry eye symptoms in patients with ocular cGVHD. Although only one study was prospective and the

remainder are retrospective case series, the weight of evidence suggests that scleral lenses are beneficial as far as improving visual function, OSDI, and/or QOL in cGVHD.

Table 2: Studies reporting on the results of validated QOL measures, visual function measures, and dry eye symptom assessments when scleral lenses were used in the treatment and management of ocular cGVHD.

Report	Type of Study	Validated PRO measure	Results
Takahide et. al.[235]	Prospective n=9	OSDI	Median OSDI improved from 81 to 21 in 2 weeks, improvement to median of 12 at time of last contact (median 8 months later)
Jacobs and Rosenthal[76]	Retrospective, n=33	QOL	73% reported highest improvement level for QOL
Theophanous et. al.[232]	Retrospective, n=40	OSDI	Of the remaining 29 patients (8 patients died and 3 discontinued wear), average OSDI scores improved from 72.6 ± 20.1 to 21.1 ± 14.9 (P < .0001)
Rossi et. al.[231]	Retrospective, n=16	OSDI NEI VFQ-25	OSDI score improved from 92.1 ± 11.3 to 23.5 ± 11.2 (P = 0.002) NEI VFQ-25 improved from 41.3 ± 7 to 83.1 ± 15.9 (P = 0.003), 6 months after scleral lens fitting
Deloss et. al. [237]	Retrospective, n=18 (main PROSE centre)	NEI VFQ-25 /VFQ-SRGH	Improvement of 30 points (P<0.001) in NEI VFQ-25 and 13 (P=0.0456) in VFQ-SRGH, comparing baseline to 6-month follow-up
	n=6 (network PROSE sites)		Improvement of 41 points (P<0.001) in NEI

			VFQ-25 and 20 (P=0.0041) in VFQ-SRGH, comparing baseline to 6-month follow-up
La Porta Weber et. al.[238]	Retrospective n=2	OSDI/SF-36v2	Significant improvements in OSDI and SF-36v2 at 12 months compared to baseline (both P < .001)
Magro et. al.[239]	Retrospective, n=60	OSDI	Significant improvement in mean OSDI at 2 months compared to baseline (86 vs 30, P<0.001),

n – number of patients; PRO – Patient reported outcome; OSDI – Ocular Surface Disease Index; QOL – Quality of life; NEI VFQ-25 – National Eye Institute Visual Function Questionnaire; VFQ-SRGH - Visual Function Questionnaire Self-Reported General Health; SF-36v2 – Short Form-36 Health Survey

Reports on the long-term benefit and effectiveness of scleral lenses in management of ocular cGVHD found a 90% continuation rate of scleral lens wear at 32 months and a 75% continuation rate at 5 years in the cGVHD subgroup, with the latter being the only study reporting on outcomes more than 3 years after initiation of scleral lens wear [240,241]. Benefits have also been reported in the management of SLK secondary to ocular cGVHD [222], stabilisation of a descemetocele [242], and management of cGVHD patients after cataract extraction [243].

While there are reported improvements in clinical signs with the use of scleral lenses, there were no changes in the expression of inflammatory biomarkers was observed in a conjunctival impression cytology study, pre- and post-scleral lens wear [233]. Additionally, no changes in tear production, corneal sensation, or the corneal nerve plexus were noted after long-term wear [244].

There are reports of scleral lens dropout in a small minority of patients for various reasons including accumulation of lens debris in the lens reservoir and/or on the front surface of the lens [241,245]. A single case report describes a cGVHD patient that required overnight wear of PROSE scleral lenses in order to heal bilateral PEDs, with a wearing schedule that alternated between 2 pairs of lenses, each worn for 12 hours and then disinfected prior to next use [230]. Patients wearing PROSE medical contact lenses because of ocular surface disease were less likely to continue wearing the device at 5 years than those wearing PROSE contact lenses because of an irregular ocular surface (64% versus 84%, p=0.01) [241]. Subgroup analysis indicated that, out of the patients with ocular surface disease, those with cGVHD had the highest rate of success (75%) and patients with improved vision at 6 months were less likely to have discontinued wear of PROSE lenses at 5 years [241].

3.1.2 Sjøgren syndrome

Sjøgren syndrome is an autoimmune condition characterised by lymphocytic infiltration of the salivary and lacrimal glands, resulting in symptoms of dry eye and dry mouth [246,247].

Similar to the TFOS International Dry Eye Workshop (TFOS DEWS II) report, a consensus on clinical guidelines for the management of dry eye disease in Sjogren's syndrome was created in 2015 by a panel of experts who reviewed and analysed contemporary published literature on the topic [248]. This review created criteria for staging of the disease, along with including recommended treatment options depending on staging of severity. When reviewing and discussing the role of therapeutic contact lenses, it referred to the TFOS DEWS II report criteria, ranking the use of lenses as a stage III treatment along with autologous serum tears and permanent punctal occlusion, indicated for use if stage I and II treatments were inadequate [248,249].

Evidence is largely limited to case seris regarding the therapeutic use of contact lenses in Sjøgren syndrome. The first report found in the literature discussing the benefits of contact lenses specifically to manage the ocular manifestations of Sjøgren syndrome was published in 1948 [250]. In 1971, another report was published on the successful use of soft contact lenses in Sjøgren syndrome patients [18]. In 2011, a case report demonstrated the successful management of a patient with Sjøgren syndrome for over 25 years with contact lenses [251]. The patient initially started with rigid corneal lenses and later switched to soft lenses. The use of hydroxypropyl cellulose ophthalmic inserts were later required for continued success [251]. Another early report focused on the management of sequalae from Sjøgren syndrome and reported on a series of corneal perforations and ulcerations successfully treated with soft contact lenses in Sjøgren syndrome [213].

A RCT compared the efficacy of silicone hydrogel contact lenses and autologous serum tears in the management of dry eye associated with Sjøgren syndrome [252]. Of the total of 36 eyes, 19 eyes were placed in the BSCLs group. The study found that SiHy contact lenses were more effective than autologous serum tears, as demonstrated by improvements in visual acuity, OSDI scores, and corneal staining scores.

While there is evidence of management success with soft contact lenses, there are various case series and cohort studies that report either complications from BSCLs in Sjøgren syndrome patients or a failure of soft lenses to provide adequate corneal protection [223,253–258]. A cohort study of 69 consecutive microbial keratitis cases in various ocular surface diseases found 20 cases corresponding to 17 Sjøgren syndrome patients, nine of which were associated with soft contact lens use. Of note, most of the causative organisms responsible for microbial keratitis in Sjøgren syndrome were Gram positive bacteria [254].

Most studies regarding scleral lenses and their potential benefits in the management of the ocular sequalae of Sjøgren syndrome are case series or cohort designs. Even though there are some reports from as early as the 1970's reporting on the benefit of scleral lenses for the treatment and management of dry eye disease [67,259,260], none specifically report on the benefits of dry eye signs and symptoms associated with Sjøgren syndrome. In 1992, a case series reported on the use of scleral lenses for ocular surface disease and dry eye [73]. While most patients could be fitted with good comfort, and wearing time of at least eight hours, it is notable that the 2 patients (3 eyes) that failed scleral lens fitting, likely because of suction complications, had Sjøgren syndrome. The lenses were 22 to 23.5 mm in diameter and were fitted with minimal central and limbal clearance. A more recent case series that reported on scleral lens fitting failure in this patient population was part of a prospective interventional case series, where patients of moderate to severe dry eye were fitted with mini-scleral lenses. The one patient with Sjøgren syndrome in the cohort did not end up wearing the lenses for unspecified reasons [261]. A prospective interventional case series of 41 eyes fitted with a scleral lens (Esclera), 11 of which had dry eye associated with Sjøgren, reported both improvement in symptoms and quality of life, based on OSDI and Short-Form Health Survey (SF-36v2) scores, respectively; however, data for Sjogren's patients was not analysed separately [238].

There are numerous case series that describe the successful management of dry eye patients, including those with Sjøgren syndrome, with fluid-ventilated scleral lenses [14,74,147,262–264]. There is a single case report of polymicrobial and microbial keratitis in a Sjøgren patient in association with scleral lens use [265]. The patient was using a topical steroid at the time and the authors did not share any information about the cleaning and disinfection protocol used by the patient, nor were care practices taken into consideration in the discussion as a potential contributing factor [265].

Interestingly, even though there is medium quality evidence (from case series and cohort studies) of improvement in symptoms and QOL with scleral lenses in patients with Sjogren's, a cohort based impression cytology study found that the inflammatory response in a Sjøgren patient actually increased with scleral lens wear. In this study, an increase in the HLA inflammatory marker was noted after 12 months of scleral lens wear, with the percentage of Sjogren's patients exhibiting the marker increasing from 11% to 67% [233]. These results warrant further study into the role of inflammation in success or failure of scleral lenses in Sjøgren syndrome.

3.1.3 Stevens-Johnson syndrome (SJS)

Early reports on the therapeutic use of soft contact lenses to treat SJS described moderate to poor outcomes [20,253,266–268]. Of these, a report from 1971 discussed outcomes of more than 200 patients fitted in soft contact lenses, including SJS patients, and reported that soft lenses were not indicated for SJS, given the poor outcomes [253]. In a series of 278 patients with corneal disease, 18 of which fell into the dry eye disease category and 5 of which had SJS, 58% of the patients were successful with soft lenses though one had a microbial keratitis complication [20]. These findings were later supported by a cohort study from 1984 which found that more severe SJS cases were prone to microbial keratitis and poor outcomes [269]. Another study showed that the use of BSCLs was prevalent in SJS cases that developed MK and found Gram-positive cocci present in the majority of cases, with Gram-negative bacilli less commonly noted [254].

With the advent of new soft contact lens materials, some case series report on complications, e.g., tight lens syndrome [270], while other such studies have reported on successful management outcomes [271–273]. It is worth mentioning that most of the latter studies report the benefit of soft lenses in managing secondary sequelae or complications that arise from SJS versus primary ocular symptoms and signs.

Based on the evidence found in the literature, SJS patients benefit more from scleral lenses than other contact lens options. These benefits have been reported as early as the late 1960s in case reports [260,274,275]. A study from 1966 reported on the successful outcome of flush-fitting scleral lenses (moulded lenses that conform to the cornea and sclera) [274], which was soon followed by reports of SJS patients managed with this same type of scleral lens design and fitting approach [67,275]. In a case series on moulded PMMA lenses used for a range of indications including Stevens-Johnson syndrome, no serious complications were reported [13].

With the advent of materials with increased oxygen permeability, an increase in use of scleral lenses as a therapeutic option to treat and manage ocular manifestations of SJS became evident, with an increase in studies published in literature from the 1990s and into the 21st century. Most studies provide low quality of evidence. Recent reviews of current ophthalmological treatment strategies for SJS and Toxic Epidermal Necrolysis highlight scleral lenses as a treatment modality to be considered in sub-acute and chronic disease in this patient population [276,277].

One of the first reports on the benefits of fluid-ventilated scleral lenses in chronic SJS was published in 1998 [12]. The same group, shortly thereafter, reported for the first time on the impact these lenses can have on the QOL in this patient population. While this study analysed various ocular surface diseases, SJS was by far the predominant disease category, with 54 out of 76 eyes having SJS (71%) [74]. A vast majority (92%) of patients reported an improvement in QOL secondary to decreased pain and photophobia with scleral lens wear. The impact on QOL in SJS has been studied with validated and standardised questionnaires. It is interesting to note that OSDI outcomes were very similar for this patient population in two different research groups. Each group found that OSDI scores improved from ~70 to ~30 (76 to 37 and 70 to 37, respectively) in cohorts of 39 and 16 patients, using two different scleral lens designs [278,279]. Improvement in visual

function, as assessed by the NEI VFQ-25 questionnaire, was reported by one of these groups [278] and several years later by another group reporting on a series of 167 eyes with SJS fitted with a PROSE device [280]. In contrast, another report found no improvement in visual function with a corneo-scleral lens in SJS, indicating that a corneoscleral lens, as opposed to a scleral lens, may be problematic for a fragile ocular surface [281]. Various other case series have been published reporting on successful patient outcomes with scleral lenses [282–284]. One particularly beneficial application of scleral lenses in this patient population (and other conditions) is in the treatment and management of persistent epithelial defects [14,74,147,148,285].

There are several reports on the use of scleral lenses in children with chronic sequelae of SJS [236,244,286]. Although fitting children and teens with pain and photophobia can be challenging, Wang et al. reported success in fitting two thirds of children with SJS, including children as young as 4 years of age [244]. A recent cohort study, which included 568 eyes from 284 children with chronic sequelae of SJS, compared outcomes between conservative therapy (lubricant and topical agents) and definitive therapy (PROSE treatment, mucous membrane grafting, limbal transplantation, and keratoprosthesis) [287]. At 5 years, in eyes with lid-related keratopathy, mucous membrane grafting was significantly more effective than PROSE, although both were significantly better than conservative therapy; the combination of mucous membrane grafting followed by PROSE provided the best results as far as preventing the development or progression of keratopathy.

A recent association between SJS and subsequent development of ectasia has been made in various case series [288–291]. These studies highlight an important consideration that the visual potential of patients with SJS may be significantly impacted not only by superficial keratopathy and opacification but also by the visual consequences of corneal ectasia. Clinicians should keep this association in mind when addressing reduced visual acuity in SJS patients. SJS patients may

benefit from front surface eccentricity, and perhaps higher order aberration correction, in scleral lenses as do other patients with ectasia [292].

3.1.4 Over keratoprosthesis

The role of a contact lens over a keratoprosthesis is to maintain hydration and to protect the corneal tissue that surrounds the anterior plate of the keratoprosthesis, which is prone to desiccation, epithelial breakdown, dellen formation, and corneal melt [293]. A cohort study of a small series of patients (n=19) from 2002 found that soft contact lenses were protective against desiccation [294]. In 2016, another cohort study of the outcomes in 92 patients (103 eyes) at 12, 24 and 36 months, demonstrated, via multivariate analysis, that eyes that had soft contact lenses removed or lost and not replaced were more likely to develop complications [295] A lstudy found that a standard 16 mm hydrogel soft lens yielded a satisfactory fit in only 30% of a small series of 16 patients [296]

While soft contact lenses provide a therapeutic role, complications do arise related to the overnight wear that is typically necessary in the setting of keratoprostheses. These complications can include development of deposits on the front surface, keratolysis [297], and microbial keratitis [298–303]. Several case series have reported on surface deposits on soft contact lenses compromising visual acuity [293,304–306]. Optic zones composed of rigid corneal lens materials may help reduce the amount of surface deposits (hybrid or large diameter rigid lenses) [305]. In a prospective, non-randomised study, the use of topical *N*-acetylcysteine in conjunction with soft lenses was evaluated and a 20% decrease in protein deposition was reported when compared to using no agent [307].

A Lretrospective study found that 67% of eyes fitted with BSCLs over keratoprostheses had positive surveillance cultures of their BSCLs. The growth of 15 or more colonies of coagulase-negative staphylococcus occurred only in patients not on prophylactic vancomycin [308]. A surveillance study found that eyes implanted with a keratoprosthesis, many of which were on prophylactic

antibiotics and wearing a BSCL, were more likely to have bacterial growth upon culture of conjunctival swabs compared to the fellow eye [300]. A cohort study from 2018 compared the effects of prophylactic use of vancomycin and linezolid in the formation of biofilm on soft lenses worn by patients with the Boston Type I keratoprosthesis for 1 month [303]. The study found that not only was there no infection reported in any of the treated eyes, but also the rate of biofilm formation decreased with the topical use of either vancomycin and linezolid.

The emergence of fungal infection or resistant bacteria is a concern with long term prophylactic use of antibiotics with keratoprostheses. A study evaluated 182 patients (202 eyes) and reported 4 definite and 1 probable fungal infections (3 endophthalmitis and 2 keratitis) yielding a low incidence of 0.009 fungal infections per patient-year in the setting of keratoprostheses with BSCL [302]. uthors Others suggestthat risk may be higher in fungal endemic areas, warranting antifungal prophylaxis [301]. A cohort study reported that 50% of the subjects with keratoprostheses who were treated prophylactically developed resistance to fourth-generation fluoroquinolones [299]. A single case series found that the addition of 5% povidone-iodine to a daily prophylactic fluoroquinolone prevented infectious complications and fungal colonisation in patients sampled at intervals of several months [309].

3.1.5 Atopic keratoconjunctivitis / Allergy

Atopic keratoconjunctivitis and vernal keratoconjunctivitis are bilateral, chronic allergic conditions affecting the eyelids and ocular surface. In its advanced form, atopic keratoconjunctivitis has potentially blinding sequelae and is characterised by decreased tear production, lid margin keratinisation and significantly scarred lid surfaces that can easily and repeatedly damage the vulnerable corneal surface. Vernal keratoconjunctivitis is characterised by tarsal papillae, Horner-Trantas dots, and superficial punctate keratopathy.

The use of therapeutic scleral lenses for dermatological-associated disorders was initially proposed in 2005 in a study which reported reduced pain and photophobia and improved vision in four eyes fitted for indications of atopic keratoconjunctivitis [14]. A case series of 6 patients (10 eyes) with advanced disease demonstrated that atopic keratoconjunctivitis can be very successfully managed with therapeutic wear of scleral lenses [310]. In that series, all patients were able to wear lenses during daytime hours for more than one year and observed improvements in visual acuity, conjunctival hyperaemia, chemosis, and corneal epithelial defects [310]. Therapeutic scleral lenses have also been successfully prescribed to manage four patients with vernal keratoconjunctivitis and associated keratoconus (5 eyes) and limbal stem cell deficiency (LSCD) (2 eyes) [311].

3.1.6 Superior limbic keratoconjunctivitis/filamentary keratitis

Filamentary keratitis is a chronic, recurrent disorder of the cornea (and rarely the conjunctiva) characterised by the presence of fine strands of degenerated epithelial cells and mucous attached at one or both ends to the ocular surface [312–314]. Filamentary keratitis is frequently observed in severe diseases of the ocular surface including aqueous deficient dry eye, allergic conjunctivitis, viral keratitis, exposure keratitis, post ocular surgery or trauma, and in association with autoimmune diseases [313]. Filamentary keratitis often does not respond well to conventional lubricant therapy [315]. The management of filamentary keratitis can involve medical contact lenses, typically in severely symptomatic refractory cases where other treatments (e.g. mucolytics, topical steroids) have failed. In the case of filamentary keratitis, the rationale for medical contact lenses would be to provide pain relief and promote epithelial healing. Contact lenses protect the cornea from frictional forces of the lids and prevent stimulation of exposed or vulnerable epithelial nerve endings, providing immediate pain relief. At the same time, the post-lens tear film provides a stable interface under which epithelial cells can safely migrate and filamentous keratopathy can heal [314].

SLK has been described as a disease characterised by inflammation of the upper palpebral and superior bulbar conjunctiva, staining of the superior conjunctiva, keratinisation of the superior limbus, and corneal and conjunctival filaments [222,316]. The pathogenesis of SLK remains unclear, however, it is known to be associated with conditions such as thyroid eye disease and tight upper lids. SLK may be caused by repeated microtrauma between the tarsal and superior palpebral conjunctiva, and medical contact lenses would thus protect the limbus from the action of the upper eyelid during blink [317]. Completed resolution of SLK and prevention of recurrences have been reported with use of BSCLs, as long as the lens remains in place [318,319]. In a report of two SLK cases, rapid resolution of symptoms was noted with use of unilateral SiHy contact lenses in the worse eye as quickly as one hour after lens instillation, although the mechanism of bilateral symptomatic relief with unilateral lens wear remained unexplained [319]. SLK-like inflammation has been described in ocular cGVHD in a case series of 13 patients (26 eyes) [222]. All 26 eyes showed superior conjunctival injection and staining and filamentary keratitis in 11 eyes. All were initially treated with conservative treatment alone (lubrication, topical cyclosporine A, topical corticosteroids, punctal occlusion, serum tears). This conservative treatment failed for 16 eyes; lenses were used with success in 12 eyes, with the remaining 4 eyes requiring a scleral lens to resolve signs and symptoms, suggesting that scleral lenses may provide more significant protection of the superior cornea from the overriding palpebral conjunctiva than BSCLs in cases of advanced disease [74,222].

The first few successful reports of the medical use of soft lenses occurred in cases of filamentary keratitis secondary to brain stem injury [320]. In a series of seven patients, bandage SiHy contact lenses (balafilcon A) were used for the acute management of symptomatic filamentary keratitis associated with adenoviral keratoconjunctivitis, with filaments disappearing by the next day [321]. The first successful resolution of filamentary keratitis of all eyes fitted with therapeutic scleral lenses was reported in 2005 [14]. A single case report of a patient with filamentary keratitis successfully treated with scleral lenses later showed that

significant reduction of filaments was observed after only 3 hours of lens wear on the first day, and complete absence of filaments was confirmed following 6 hours of scleral lens wear on the second day [322]. Similarly, a patient with debilitating filamentary keratitis secondary to cGVHD was successfully fitted with scleral lenses and the filaments completely disappeared during the first day of wear with no further episodes of filamentary keratitis developing over the next 6 months [323].

3.1.7 Mucous membrane pemphigoid

Mucous membrane pemphigoid is a group of rare autoimmune disorders characterised by blistering lesions that affect the mucous membranes of the body. In the context of the eyes, this is known as ocular cicatricial pemphigoid. Clinical manifestations of the disease can include nonspecific chronic conjunctivitis (in mild disease), symblepharon, exposure keratopathy, and trichiasis. Treatment with scleral lenses has been described in the literature for cases of mucous membrane pemphigoid/ocular cicatricial pemphigoid, including those with persistent epithelial defects where therapeutic soft lenses failed to fully heal the epithelium [14,74,324,325]. One case was managed with overnight wear of scleral lenses, with instructions to remove the lenses twice daily for instillation of topical medication and for cleaning and disinfection [324]. In this case, the increased risk for complications such as corneal oedema and microbial keratitis (see section below) associated with overnight wear was weighed against the immense likely benefit of providing the continuous protection of the ocular surface required for adequate healing; ultimately the treatment was successful with healing of the epithelial defect, improved vision, and stable management over a reported 17 month follow up period. Another case was successfully refitted with a mini-scleral contact lens during waking hours and a soft lens of unspecified material at night [325]. Such a strategy may be less successful in allowing persistent epithelial defects to heal but may help to minimise the overnight corneal swelling.

3.1.8 Aniridia

Aniridia is a rare congenital abnormality characterised by the partial or complete absence of the iris, caused principally by heterozygous mutation in the paired box 6 (PAX6) gene responsible for normal ocular development [326,327]. Associated corneal abnormalities occur in up to 90% of patients with aniridia and include progressive LSCD and conjunctivalisation of the cornea, causing recurrent epithelial breakdown and stromal scarring [327]. A single case report was found where long term use of a soft hydrogel therapeutic lens with concurrent topical prophylactic antibiotic and topical corticosteroid drops helped to resolve a persistent epithelial defect post penetrating keratoplasty [328]. Three eyes with aniridia and associated LSCD and/or persistent epithelial defects were fitted with daily or planned overnight wear (48- or 72-hour intervals) scleral lenses in a large case series, although outcomes were not reported [14]. Subsequently, successful long term (3 and 5 year) management of LSCD and persistent epithelial defects associated with aniridic keratopathy was described in a case report where a 30-year-old female was fitted sequentially with daily wear scleral lenses (PROSE, BostonSight, Needham MA), minimizing scar formation and allowing for optimal visual acuity to be maintained [329]. It remains unclear whether the use of a contact lens alters the course of disease in aniridic keratopathy. It may be that support of the surface with a therapeutic contact lens, before the onset of LSCD and epithelial defects, may maximize visual acuity and delay sight threatening corneal breakdown and opacification.

3.1.9 Limbal Stem Cell Deficiency (LSCD) – a paradox

LSCD is a hereditary (e.g. ectodermal dysplasia, aniridia) or acquired (e.g. chemical injury, drugs, multiple surgeries at the limbus, contact lens, Stevens-Johnson syndrome, mucous membrane pemphigoid) multifactorial disease of the ocular surface [330]. Maintenance of a healthy cornea requires functioning limbal stem cells which serve as a barrier to prevent encroachment of the transparent cornea by the conjunctival epithelial cells [331]. LSCD can be partial (involving some but not all of the limbus) or total. Clinically, LSCD manifests as an abnormally staining corneal surface, whorl-like epitheliopathy, superficial vascularisation,

recurrent or persistent epithelial defects, scarring, ulceration, and opacification. Symptoms are variable and progressive and can include decreased vision, photophobia, tearing, redness, and pain [330].

Whilst therapeutic (soft and rigid corneal) lens wear plays a role in the management of visual deficit and breakdown in LSCD, LSCD paradoxically can be a result of soft lens wear, with up to 15% of LSCD cases attributed to contact lens use. Soft lens wear is thought to induce LSCD either from chronic long term mechanical friction on the limbus, from hypoxia, and through toxicity from use of preserved storage and disinfection solutions, or through a combination of these mechanisms [332–337]. Please refer to the CLEAR Complications Report [30] and LSCD.

Conservative measures such as preservative-free ocular lubricants, topical steroid and other anti-inflammatory treatments, and lens cessation will sometimes may fail in the management of LSCD [338]. Scleral lenses warrant consideration as a therapeutic option for patients with LSCD, including those with soft lens induced disease. There is limited quality evidence that large diameter scleral lenses are useful in the setting of LSCD related to cGVHD, and may be the treatment of choice when there is longstanding superior limbic keratoconjunctivitis [222]. Use of customized large diameter scleral lenses for treatment of LSCD including a case associated with Stevens-Johnson syndrome has also been reported [284]. LSCD has also been described in the setting of ocular cGVHD in two of 13 patients (3 of 26 eyes) where SLK was left untreated for some time [222]. These authors recommend that large-diameter scleral lenses are the treatment of choice for patients with advanced LSCD. Surgical intervention including limbal stem cell transplantation may be required over the long term if conservative measures fail [338,339].There is emerging consensus among cornea specialists that specialized rigid scleral contact lenses can stabilize the ocular surface in patients with LSCD and that such lenses play a role in medical management prior to consideration of surgical intervention [340]. Best practices have yet to be established as to lens

diameter, central and peripheral clearance, optic and haptic thickness, width of landing zone, and wear and care regimens for scleral lenses in the setting of LSCD, so clinicians are advised to proceed with extreme caution given that hypoxia, mechanical insult, and solution toxicity can occur with any lens type and contribute to LSCD. We concur with the authors of the Global Consensus on the Management of Limbal Stem Cell Deficiency [340], that close monitoring of patients with LSCD during the use of therapeutic contact lenses is absolutely essential.

See CLEAR Future Report [341] for the use of contact lenses in stem cell transplantation.

3.2 Exposure keratopathy

Contact lenses have long been a treatment option for patients with exposure keratopathy (also called exposure keratitis, although inflammation is not the primary process), with the aim of providing a protective barrier and maintaining continued lubrication at the cornea. The earliest recorded scleral shell, made in 1887 by an artificial eye manufacturer, was a protective device for a patient who had eyelid damage which had left the cornea exposed [342]. The potential use of BSCLs in such applications was identified soon after their introduction [17].

There is a large body of evidence supportive of the use of scleral lenses in the management of exposure keratopathy, usually within larger case series reviewing all scleral lens use in a specific institution. Exposure keratopathy cases were among those described in early reports of scleral lens use for ocular surface disease [14,15,73–75,240,262,343,344]. There is evidence that overnight scleral lens wear can be a safe and effective treatment for exposure keratopathy [285] and in the treatment of persistent epithelial defects in which exposure may be contributory [148], although further research into appropriate wearing schedules is required. The risks and benefits of overnight wear should be carefully considered before recommendation as these products are labelled for daytime use only.

Where lens wear for a continuous period is indicated, consideration should be given to appropriate wear and care regimens such as a two lens regimen with one lens being worn for 12 hours while another is disinfected [324].

Case reports and small series regarding the use of scleral lenses for exposure, in some instances associated with neurotrophic keratopathy, have emerged [345–347]. Since that time, higher level evidence has emerged from a larger series (18 eyes in 29 patients) reporting the effectiveness of PROSE scleral lenses in patients with exposure keratopathy who failed with conventional therapy, serving as an alternative to lid surgery [348]. In an important cohort study of 53 eyes in 45 patients with postsurgical lagophthalmos and exposure keratopathy, treatment with a scleral lens was compared to the usual standard of care, and a scleral lens gave rapid, substantial and sustained visual improvement, often from a worse starting point, than eyes in the standard of care group [349]. There are reports of scleral lens use for exposure keratopathy of specific aetiology; thermal injury [350,351], Graves' disease [352], craniofacial trauma [353], acoustic neuroma [354], facial palsy [284,355], post neurosurgery [356] and whilst awaiting eyelid reconstruction [357]. All studies reported that the use of scleral lenses gave positive results based on their outcomes, including improved visual acuity, ocular comfort, and clinical findings. One report noted a patient preference for treatment with a scleral lens over other strategies such as tarsorrhaphy [345].

Success with BSCL use is described, but it should be noted that patients with exposure keratopathy, particularly when combined with neurotrophic keratopathy, will be at greater risk of soft contact lens complications than healthy patients [358]. Soft lenses should be used with caution and after consideration of the risks and benefits. Pain relief has been reported in three cases and soft contact lenses have been used in one paediatric case [39,40]. Soft lenses have been used to aid recovery from exposure related complications such as corneal perforation [359], corneal ulceration [360], and where surgical intervention was required to treat exposure keratopathy after blepharoplasty [190].

A randomised pilot trial in sedated, critically ill patients found that patients wearing BSCLs replaced every four days showed no progression of exposure keratopathy and healing of keratitis in patients with initial signs. This was found to be equivalent to the use of punctal plugs and was favourable to the regular use of ocular lubricants [361]

Of the many papers reporting on strategies for management of exposure, including large reviews, relatively few mention contact lenses, suggesting that contact lenses are an overlooked management option.

3.3 Neurotrophic keratopathy

Neurotrophic keratopathy (also called neurotrophic keratitis, although inflammation is not the primary process) is a degenerative condition caused by impairment of trigeminal nerve function characterised by reduced corneal sensation, persistent corneal epithelial defects, ulcers and perforation. Contact lens therapies aim to prevent progression of corneal damage and to promote epithelial healing [362]. Review articles tentatively propose the use of contact lenses in neurotrophic keratopathy but warn of possible secondary infection or sterile hypopyon [362–365]. A thorough review has suggested, that contact lenses should be used with 'extreme caution' as the reduced corneal sensation reduces 'alarm' signals for infection [366], and Baenninger advocates the use of prophylactic non-preserved antibiotic eye drops alongside contact lens use [367].

If used with appropriate caution, BSCLs [31,37,368,369] and scleral lenses worn daily [14,284,345,347,370,371] or overnight with daily removal and disinfection [148], have been used successfully to aid epithelial recovery where other treatments had seen only partial success or failure, although the number of cases presented is small.

Soft contact lenses significantly reduced the recovery time for “neurogenic” corneal ulcers from an average of 47 days to 11 days in a cohort of 20 patients, 10 of whom were fitted with a SiHy lens. No complications were reported in the contact lens group, whereas patients in the non-contact lens group showed significant complications associated with progression of their underlying condition [369].

The largest scleral lens case series presented 34 eyes that were fitted with the Boston PROSE device after unsuccessful treatment with BSCLs. In all cases the integrity of the cornea was restored and maintained [14]. The use of scleral lenses in paediatric cases has also proven to be successful. In one study, 17 eyes of 12 patients fitted for corneal anaesthetic conditions over a ten-year period noted no infections, though one patient developed transient corneal oedema that did not affect long term lens wear [236]. In a smaller series of six eyes of five patients, similar results were found [372].

It is appropriate for authors to advocate caution when fitting contact lenses in cases of neurotrophic keratopathy as both soft [358] and scleral [373] lenses treated without due care have led to unwanted complications. A safety driven rationale of avoiding steroids or preservatives in the tear reservoir has been recommended, as well as moving to daytime only wear and discontinuing prophylactic antibiotics as soon as re-epithelialisation is complete [147,148].

The recent development of contact lens carriers for amniotic membrane has added another treatment option [366].

3.4 Corneal Dystrophy – Reis-Buckler, Meesmann, Epithelial Basement Membrane Dystrophy, and others

Most cases of contact lens fitting for corneal dystrophy aim to reduce symptoms of discomfort or improve visual acuity in an irregular cornea. There are some cases in which fitting a contact lens can slow the condition or aid resolution of symptomatic episode. The current knowledge in the field reviewed providing

insight into each corneal dystrophy and the methods and rationale for contact lens management [374]. Most evidence, such as for Meesmann corneal dystrophy, [375] are only from case reports.

Corneal dystrophies are associated with recurrent corneal erosion syndrome (RCES) [376]. Epithelial basement membrane dystrophy has been reported as the leading non-traumatic cause of RCES [377,378]. The role of contact lenses in the management of RCES is detailed in section 2.5 above.

Meesmann corneal dystrophy causes corneal microcysts that can lead to recurrent erosions. In severe cases, corneal distortion and irregular astigmatism are thought to be related to subepithelial scarring from persistent recurrent erosions [379]. Resolution of microcysts associated with Meesmann corneal dystrophy has been reported in three patients using soft contact lenses, with a hypothesis that the hypoxia induced by the presence of a CL caused a change in corneal metabolism [380]. This is opposed to the usual understanding that corneal hypoxia induces microcystic change [381]. A case report suggests that high modulus SiHy lenses may offer advantage in the management of epithelial defects in the setting of Messman dystrophy [382]. A reduction of corneal opacities caused by Lisch corneal dystrophy has been reported in two patients who wore daily soft contact lenses, and progression was noted on cessation of wear [383]. In a retrospective cohort study of 40 eyes of 20 patients with gelatinous drop-like corneal dystrophy, overnight wear soft contact lenses slowed the progression of corneal opacities and delayed surgery [384].

Posterior polymorphous corneal dystrophy causes corneal distortion that is very similar to that caused by keratoconus in 37% of cases. In 86% of cases, it is associated with zinc finger e-box binding homeobox 1 (ZEB1) genetic mutation [385]. Contact lens fitting for posterior polymorphous corneal dystrophy is only for optical correction purposes, with one case of a successful fitting of a rigid corneal

lens reported in literature [386]. In this, as with most other corneal dystrophies, the use of contact lenses is incidental for refractive purposes.

3.5 Bullous keratopathy

Bullous keratopathy is a result of corneal endothelial failure and corneal oedema leading to epithelial bullae, which can cause pain when ruptured. Historically, flush fitting scleral “shell” lenses have been reported to be useful for bullous keratopathy [11,248,259,275]. Moreover, soft contact lenses emerged as a therapeutic option for bullous keratopathy in the 1970s, with several large case series reporting favourable outcomes [19,67,387–390]. Twenty four hour wear was established as the preferred wear schedule in order to provide adequate protection whilst sleeping [391]. A contact lens prevents the mechanical effects of eyelid trauma and bullae rupture [392]. With modern cataract surgical technique and then advances in lamellar keratoplasty, symptomatic bullous keratopathy is now rarely encountered. A small number of bullous keratopathy cases can be found in reports of the therapeutic use of SiHy lenses. Considerable or complete pain relief with no adverse events has been reported in small case series (maximum of 7 eyes) when using Balafilcon lenses [31,393] and in larger series (max 47 eyes) using Lotrafilcon A lenses [37,140,394–396].

A well-constructed prospective comparative study of 22 patients that compared two SiHy and one conventional hydrogel materials [397] concluded that SiHys are a safe and effective alternative to conventional hydrogels in management of bullous keratopathy. Silicone hydrogels were shown to outperform conventional hydrogel lenses in patient comfort, with no significant differences in pain relief, lens fitting or deposit build up (medium quality of evidence).

There was concern that wearing a BSCL would increase the risk of corneal ulceration in cases of bullous keratopathy. A large early study of 278 patients showed positive outcomes when using BSCL with concurrent antibiotic therapy to mitigate this risk [20]. However, these results were not replicated, and in a series

of 918 patients the use of topical antibiotics increased the risk of ulceration in patients who were concurrently treated with steroid and BSCL [398]. It is worth noting this series covered therapeutic use prior to the introduction of SiHy lenses and also included topical steroid use. Although the advent of SiHy lenses has not reduced rates of microbial keratitis in general, there have been no reports to explore this in the setting of therapeutic use for bullous keratopathy, in part because prevalence of this condition decreased with improved cataract surgical techniques. One experience with 74 patients (102 intervals of use) treated with SiHy bandage SCL for ocular surface disease found no cases of MK in their ten patients with bullous keratopathy [399].

There is a paucity of recent evidence regarding the use of antibiotics with BSCLs for bullous keratopathy, though a survey of 52 consultant ophthalmologists found that only 42.3% prescribe prophylactic antibiotics when using BSCLs, with the most common indication noted as “pain relief (e.g. bullous keratopathy or current erosion syndrome)” [400].

In a prospective case series of 47 patients with primary or secondary bullous keratopathy fitted with SiHy therapeutic lenses, a decrease in limbal neovascularisation was noted in 32 (68%) patients [401], although there was no control group fitted with hydrogel lenses; thus, superiority to hydrogel lenses in that regard has not been demonstrated.

4 Contact lenses for visual rehabilitation that cannot be achieved with spectacles.

4.1 Due to disease

4.1.1 Keratoconus

Contact lenses have been considered as the primary mode of treatment for the vast majority of patients with keratoconus (65-97% of patients) [402–406] and the successful fitting and use of contact lenses in this patient group has been reported

to significantly lower the risk of undergoing keratoplasty [407]. There are four groups of lenses which have been included in this review: rigid corneal, large-diameter rigid or scleral contact lenses including PROSE, hybrid, and customised SiHy lenses.

Rigid corneal lenses have been considered the gold-standard correction in patients with keratoconus due to the superior visual correction provided by the rigid, regular front surface of the lens (when compared to soft lenses that mould to the irregular shape of keratoconic corneas) [408–413]. When fitted with rigid corneal lenses, the number of eyes with 20/40 or better-corrected vision increased to 88-95% [414,415]. This is particularly meaningful as a visual acuity of worse than 20/40 has been associated with reduced QOL [416]. Additionally, a significant difference in best corrected vision with rigid corneal lenses versus spectacles has been noted with a visual improvement of 0.3logMAR [417]. Rigid corneal lenses provide superior visual performance and a more significant reduction of 3rd-order aberrations compared to standard toric soft contact lenses [418]. Binocular resolution and stereoacuity also improve from spectacles to rigid corneal lenses in bilateral keratoconus [419]. Nonetheless, visual performance and optical quality do not appear to improve commensurately with the sophistication of contact lens design [420,421]. Furthermore, rigid corneal lens wear has been associated with a 2-fold increase in the risk of scarring; additionally, among rigid corneal lens wearers, the flatness of the fit was significantly associated with incident scarring [422,423]. However for more advanced disease with steep keratometric values of more than 52 dioptres (6.50 mm), rigid corneal lenses may not guarantee a relatively good score in vision-related QOL [424].

Hybrid contact lenses may provide improvement in terms of vision and comfort when compared to rigid corneal lenses [58,59]. In a retrospective chart review of 54 rigid corneal lens wearers with irregular corneas who were refitted into a hybrid contact lens (SynergEyes, Carlsbad, CA), hybrid contact lenses improved visual acuity on average four lines over the patients' spectacles and 79.5% of patients

found their hybrid lenses more comfortable than their habitual rigid corneal lenses [56]. Other studies comparing the ClearKone hybrid to rigid corneal lenses, confirmed the superior comfort with the hybrid and similar acuity compared to the rigid corneal lenses [57–59]. Nevertheless, in a randomised study of 50 patients comparing hybrid (SynergEyes) to soft contact lenses found that soft lenses were still more comfortable than hybrid lenses although visual acuity was better with the hybrid lenses [425]. There is a single report of use of a hybrid lens in a 9 year old with bilateral keratoconus to facilitate participation in sporting activities [426].

Piggyback lens systems offer lens stabilisation and centration, as well as reduction of mechanical trauma from rigid lenses in keratoconic patients, while also potentially increasing tolerance to contact lenses. A case series found improvement in visual acuity with a piggyback system when compared to habitual rigid corneal lens correction and that many patients could return to wear of the rigid corneal lens alone after several months of piggyback wear [427]. Soft contact lenses with power -1.50 and -3.00D provide a flatter anterior surface and thus, might be more suitable for piggy-back lens fitting [428] Further, use of negative powered soft lenses (-6.00 or -3.00) in piggyback fitting reduced rigid corneal lens power without impacting VA in patients with keratoconus [429].

Customised SiHy contact lenses have been evaluated in several studies. There was no statistically significant difference between best-corrected visual acuity (BCVA) with these lenses compared to their rigid corneal counterparts with different designs. In one study, two cohorts with similar pre-fitting characteristics (mean keratometry 46.34 D (7.28 mm) vs 47.75 D (7.07 mm) and best spectacle-corrected visual acuity [BSCVA] Log MAR 0.33 vs 0.4) were compared, and the outcome BCVAs were similar [430]. Additionally, in studies comparing visual outcomes between soft designs and rigid corneal lenses in mild to moderate keratoconus, no statistically significant difference in vision was found when comparing the two modalities [45,430,431]. In moderate to advanced keratoconus, one study found a mean increase in visual acuity of 3.6 ± 1.8 Snellen lines between

BCVA with spectacles and BCVA with the Toris K (SwissLens, Prilly, Switzerland) specialty soft contact lens [432]. Similar results were found in another study with the Toris K lens [433]. Rigid corneal and SiHy contact lenses for keratoconus have a similar impact on QOL [434,435]. One of the limitations of these studies is limited representation of severely advanced KCN in the populations evaluated.

Scleral lenses form a heterogeneous group that encompasses corneo-scleral, mini-scleral as well as full scleral designs. Compared with rigid corneal lenses, scleral lenses do not provide any improvements in terms of BCVA but do provide improved comfort in well-designed studies [54,436]. Most previous lcohort studies assessed contact lens performance via BCVA and wear time in keratoconus patients with good outcomes and safety profiles, regardless of diameter and fitting approaches (**Table 3**) [434,437–443]. Scleral lenses can also provide satisfactory visual acuity after corneal hydrops in keratoconus [444]. In a prospective crossover study of rigid corneal, specialty rigid corneal, specialty soft and scleral contact lenses in a small number of subjects with early, moderate and advanced keratoconus, visual performance and optical quality did not improve commensurately with the sophistication of lens design across disease severity. The authors conclude that non-visual factors like quality of the lens fitting, wearing comfort and cost may therefore drive the selection of lens type in keratoconus more than the performance efficacy of these lenses [420].

Scleral corneal lenses have led to a decreased need for corneal transplants in severe keratometry (defined as max keratometry ≥ 70 D [4.82mm]) [445]. This is consistent with another report that patients successfully using rigid corneal lenses have one-third the risk of undergoing keratoplasty, while those using scleral lenses have one-fifth the risk [407]. In a study with 36 keratoconic patients fitted in PROSE scleral lenses and 37 undergoing keratoplasty, those fitted in PROSE had faster achievement of visual improvement, a better mean visual acuity, even amongst the Amsler-Krumeich stage 4 keratoconus group [446]. However, the group that underwent keratoplasty did have more severe ectasia than those in the PROSE

group. Similarly, success was also reported by Baran et al. in their cohort of 89 eyes fitted with PROSE scleral lenses where all eyes were successfully fitted, despite very steep keratometry [439]. A case series showed improvement in BCVA and reduction of central opacity with PROSE for reduced vision and central opacity as a complication of four decades of PMMA, rigid, low-Dk hybrid and piggyback contact lens wear [447].

There are still very few studies that address the fitting of keratoconic corneas after CXL. One study found that rigid corneal lenses had a greater improvement in BCVA post-CXL in those corneas with a central cone rather than other cone locations [448]. A study of habitual scleral lenses wearers who continued wearing lenses after CXL found no significant change in BCVA, wearing time, and subjective tolerance one year after the procedure [449]. However, practitioners should consider that one study reported additional changes in corneal shape with scleral lens wear after CXL which may mask signs of progression of keratoconus [450].

Table 3: Recent reports (all cohort studies) of corneo-scleral and scleral lenses in keratoconus.

Author	Length of Wear Per Day (hr)	BCVAwith the Lens (Log MAR)	Mean Total Diameter (mm)	Contact Lens Design	Sample Size (eyes)
Kim et al., 2017 [437]	10.1± 2.3	0.10 ± 0.11	15.80	MSD	38
Montalt et al., 2018 [438]	13.44 ± 2.08	0.00 ± 0.14	13.00	Scleracon	27
Baran et al., 2012 [439]	Not reported	0.09 ± 0.15	Not reported	PROSE	89

Arumugam et al., 2014 [440]	Not reported	0.23±0.30	19.15±0.56	PROSE	85
Ortenberg et al., 2013 [441]	10.00	0.20±0.14	18.50	Microlens Scleral	105
Lee et al., 2013 [434]	Not reported	0.079±0.10	Not reported	PROSE	45
Suarez et al., 2018 [442]	9.2±2.8	0.20±0.14	16.50	ICD	10
Fernández-Velázquez, 2019 [443]	12.19±1.96	-0.02±0.10	15.00	ALEXA ES	46

4.1.2 Pellucid Marginal Degeneration (PMD)

It is worth mentioning that the diagnostic differentiation of PMD from keratoconus by topography is complex and clouds any analysis of treatment of either [451,452]. This might not be critical if dealing only with the overall refractive status of the eye but might be more critical with the study of the role of intracorneal ring segments (ICRS), and perhaps also the role of contact lenses.

Seventy-five eyes out of 85 eyes (88.2%) with PMD were managed non-surgically with contact lenses (51.8%) or spectacles (36.4%) in a case series study [453]. These rates are comparable with a cohort study with 30 eyes, which found that 88.8% of the eyes were managed non-surgically [454]. A retrospective study of patients fitted with a customised SiHy contact lens found comparable wearing time and improvement in visual acuity with the lens when compared to the BSCVA in patients with keratoconus and PMD [430].

Significant improvement in visual acuity was also seen with PROSE wear in a level case series of 20 eyes in 12 of 19 patients with PMD [455]. In another case series of 24 eyes in 12 patients with PMD in which half successfully wore the study lens, concluded that a scleral contact lens with 16.5 or 17mm diameter can be used successfully [456]. There is the conventional wisdom that a corneal rigid lens will move to the steepest quadrant, and with inferior steepening characteristic of PMD. Rigid corneal lenses will be unstable and fail. This recent evidence suggests that scleral lenses are a useful option as alternative to penetrating keratoplasty which may be considered higher risk due to likely need for a large, decentred graft.

4.1.3 Keratoglobus / Brittle Cornea Syndrome

Keratoglobus is a bilateral ectatic disorder of the cornea, principally characterised by a globular protrusion of the cornea associated with diffuse thinning from limbus to limbus [457]. Other ophthalmic features might include extreme corneal thinning, irregular corneal astigmatism, high myopia, blue sclera, and retinal detachment [458]. There are no specific studies or literature on contact lens fitting in cases of keratoglobus. In one case series, two paediatric patients and two adults with keratoglobus were fitted with PROSE scleral lenses with varying results, with one patient developing hydrops and another patient having successful wear without incident over a 3 year follow-up [459].

4.1.4 Irregular astigmatism from infection, trauma, dystrophy or degeneration

Rigid corneal lenses can be considered for visual rehabilitation in scarred corneas and with corneal opacities after trauma or infection [52,460–462]. More recently, semi-scleral contact lenses provide excellent visual acuity and comfort in patients with such irregular corneas [441,463]. Moreover, PROSE scleral lens treatment had a positive impact on visual acuity for a wide range of corneal irregularities, suggesting that PROSE lenses, and perhaps any scleral lens, may offer improvements in visual acuity without surgical intervention [464]. However, patients with lower endothelial cell counts or with Fuchs' dystrophy were more likely to fail treatment with PROSE [245].

4.2 Irregular astigmatism after to surgery

4.2.1 Penetrating keratoplasty (PK)

Refractive error that cannot be corrected via spectacles after PK is often successfully corrected with contact lenses [465]. Indications for contact lens fitting typically include visual rehabilitation for the correction of irregular astigmatism or anisometropia following surgery [75,466,467]. In addition to improvement of visual acuity, contrast sensitivity is also enhanced with use of rigid corneal lenses after PK [468]. In patients with keratoconus that proceed to PK, between 31% and 56% return to contact lens wear after surgery [469–471].

A variety of lens types have been fitted after PK for both visual rehabilitation and therapeutic uses. There are many case series and case reports that document successful visual and physiological results with all available lens types. These reports are considered low level evidence, and many of them also appear to test (and promote) a single lens design with no comparison group. Beginning with hydrogels, these have been used for visual purposes [472] or as BSCLs [466,473]. Soft disposable contact lenses have been used to treat persistent epithelial defects, wound leak, and dry eye after keratoplasty [473]. Hydrophilic lenses have also been used as a corneal stent to realign the graft-host interface for cases of partial wound dehiscence [474]. Rigid corneal lenses have a long track record of use after PK for visual rehabilitation in traditional spherical or bitoric designs

[467,475], or larger diameter intralimbal lenses [469,476,477]. Success with hybrid lenses has been described after PK with new [56,60] and older generation designs [478–480]. Specifically, rigid corneal lens intolerant PK patients had an 80% success when refitted with modern hybrid lens designs [56]. A case series with 20 patients who had undergone keratoplasty and were unable to achieve adequate vision in spectacles were fitted with hybrid UltraHealth (SynergEyes, Inc., Carlsbad, CA, USA) contact lenses [60]. The authors found that all patients in their study could be fitted with the hybrid contact lens, with the lens providing good ocular comfort and BCVA of 0.05 logMAR or better in 80% of the subjects. Lastly, scleral lens use as an option for visual rehabilitation after PK has dominated the literature in the past 2 decades [481–488], with these studies documenting good success after between 3 months and 9 years after fitting. Three of 31 patients (~10%) fitted with scleral lenses post-PK discontinued due to discomfort over a period of 3 years or more [486].

Prior to the widespread use of scleral lenses, various case series in the literature documented fitting techniques and success rates specific to various rigid corneal lens designs. These include the use of traditional spherical [489], intralimbal [477], reverse geometry oblate [490,491], bispheric [492], keratoconic prolate, and bitoric lenses [493,494]. Interestingly, very few fitting algorithms are found in the literature. When photokeratoscopy and later videokeratography became available in the late 1980s, several authors reported fitting success in post-PK eyes by utilising specific topographic variables [495,496] or topographically-guided software [497]. One paper described a tricurve intralimbal design fitting approach to select the initial lens' base curve by using the videokeratography values over the elevated edges of the transplant wound [477].

Rigid corneal lenses generally do not disrupt corneal physiology, integrity or topography even when worn for many years after PK. A comparison of the endothelium of post-PK eyes fitted with rigid corneal lenses versus post-PK eyes that never wore contact lenses did not demonstrate any significant decreases in

endothelial cell density of the corneal grafts in the contact lens wearing group three years after fitting [498]. However, just as in CL wearers without a history of PK, lenses made of oxygen impermeable materials (PMMA) induce polymegethism and pleomorphism in PK eyes [499]. In a series of studies, corneal curvatures derived from topography, and corneal indices such as symmetry, remained stable after rigid corneal lens fitting [495,500,501]. In fact, well-centred rigid corneal lenses can increase the regularity and decrease the asymmetry of grafts [496,502].

Scleral lens fitting is a popular modern form of visual correction after PK, although scleral lenses have also been used to treat grafts with ocular surface disease such as filamentary keratitis [322]. Just as with corneal lens designs, low level evidence in the form of case series document successful lens fitting with mini-scleral designs [481–485], sclerals [75,484,486,487,503], and custom designs with asymmetric peripheries such as the PROSE lens [439].

Long term success with scleral lenses up to 9 years post-keratoplasty has been documented [486], but when lens discontinuation occurs it is typically due to difficulty with lens handling [484,485], economic considerations [485], or due to endothelial dysfunction and/or decompensation and subsequent graft oedema [245]. Interestingly, failure due to progression of ectasia at the graft-host interface and discontinuation on that basis has not been reported; in a cohort of PROSE patient fitted for ectasia including those with grafts, there was no eye that could not be fit due to extent of ectasia [439]. Progression can be addressed with increase of lens vault that is independent of haptic or optic base curves. Transient epithelial macrocysts have been described secondary to graft oedema, anatomical alterations within the cornea, and negative pressure behind the scleral lens; however, the macrocysts do not lead to further complications or prevent successful lens wear [284]. Scleral lens wear can induce graft oedema, perhaps related to design and fitting parameters [504,505], particularly in eyes with low endothelial cell count [245].

Microbial keratitis has been reported in contact lens users after PK but not at a concerning rate, and there is no evidence that the risk of MK is higher in CL wearers after PK than in other contact lens wearers. In fact, since most lenses fitted after PK are manufactured in rigid materials, the rate of MK is expected to be low, as rigid lenses have lower rate of infection compared to soft lenses [506,507]. Specific to post-PK scleral lens use, two case series reported instances of MK: 2 of 33 eyes in a series from Israel [486], and 1 of 27 eyes in a series from Brazil [483]. Moreover, there are several singular case reports of rare and atypical microbial infections in the post-PK cornea wearing a rigid lens, suggesting the lens was the vector for transmission [508–510]. See section 2.8.2. for information on PK eyes fitted with early generation BSCL in the early post-operative phase.

The older literature documents significant corneal neovascularisation with low Dk hydrogel lenses for aphakia and/or overnight wear after PK [511–514] or in with lower Dk rigid corneal lens wear [500]. Although graft rejection has been documented during both corneal [471] and scleral lens wear [484,486], allograft rejections are usually not attributed to the use of the contact lenses. Rejection and loss of endothelial reserve may preclude future contact lens wear [471,515,516], especially prior to the development of higher Dk materials. Rarely other adverse events of contact lens use can occur in post-PK eyes, such as inadvertently inducing complications such as wound dehiscence after rigid corneal lens removal via plunger (reported in one series of 3 patients) [517].

Similar considerations for lens use are relevant in other forms of corneal transplantation. Scleral lenses are also successfully fitted after deep anterior lamellar keratoplasty [485] and typically follow the same successes and barriers, with the exception of endothelial dysfunction in corneal transplant involving a donor endothelium.

4.2.2 LASIK / PRK

Contact lens options after LASIK and PRK range from soft hydrophilic lenses to corneoscleral lenses to highly customized scleral lenses [518,519]. Soft lenses are typically used when residual ametropia remains after the surgical procedure [520,521] or as BSCLs (see Sections 2.1.1 and 2.1.2).

Although rigid corneal lenses can be used to correct residual ametropia [521], the most common indication for fitting rigid lenses after PRK or LASIK is for the correction of optical aberrations and irregular astigmatism, which may or may not be related to ectasia. Most studies in the literature contribute low level evidence case reports and series. Although two case reports document successful use of a soft spherical [522] or toric lens [523] for post-LASIK ectasia, rigid corneal lenses are typically used since they decrease higher order aberrations in patients with visual complaints and irregular astigmatism [524–529].

The types of rigid corneal lenses fitted after LASIK and PRK range from simple tricurve designs to complex reverse geometry designs. Traditional and aspheric lens designs [530–532] as well as specialty lenses, often reverse geometry designs, are successful for ectasia and complications after LASIK, PRK and radial keratotomy [490,533–537]. For myopic photoablative procedures, the post-operative oblate shape produces a more difficult corneal contour to fit, since traditional rigid corneal lens nomograms for base curve selection and peripheral curve systems may not be appropriate. Some have advocated reverse geometry lens designs [490,524,528,534] although use of although successful use of same or only minimally flatter (0.1-0.2mm) aspheric rigid corneal lens than preoperatively has been reported with good centration attributed to the negative pressures created by the bearing of the periphery and excess central apical clearance [530]. Lathe cut SiHy lenses have been used in post-LASIK ectasia with good results in a case report [538] and limited case series [539]. New generation hybrid lenses have been successfully fitted after failed LASIK in case reports [540] and limited case series [56]. Additionally, there are several case reports for successful

corneoscleral [541] and scleral [542,543] lens fitting for post-LASIK ectasia. In larger case series, corneoscleral lenses have shown good success in fitting post-LASIK ectasia after 1 year of follow-up [518,544] and one series demonstrated that corneal biomechanical parameters increased after 1 year of corneoscleral lens use without adverse clinical effects [545].

Rigid corneal lenses can be used to improve visual acuity and reduce higher order aberrations after unsatisfactory refractive surgery outcomes, an effect that persists after the lens is removed due to moulding effect [546]. The same centre found that miniscleral lenses can reduce persistent optical symptoms in patients with good uncorrected acuity after corneal refractive surgery by reducing post-operative spherical aberration [547]. Full scleral lenses, including the custom PROSE [464,519] and the EyePrint Pro [284], have also been effective to treat post-refractive surgery complications including ectasia, optical aberrations, dry eye and neuralgia.

Several papers have been published on base curve selection using topographic data for fitting rigid corneal lens designs after LASIK and PRK [548–551]. For example, the power on the transition zone of the corneal topographic map, 0.2 mm outside the ablated refractive area, facilitated selection of the back-optic zone radius of a well fitted rigid cornea lens after LASIK [549]. Additionally, comparing axial and tangential anterior curvature maps, the average axial curvature 4.0 mm from the vertex normal or 2.0 mm from the vertex normal on tangential maps were best predictors of accurate spherical rigid corneal lens base curve selection after LASIK [548].

There are two case reports describing adverse effects with contact lenses after LASIK or PRK. Late-onset interface inflammation was reported after a patient slept in a cosmetic soft lens 18 months after LASIK [552] and crystalline keratopathy was reported in a corneoscleral lens wearer several years after LASIK [553].

4.2.3 Radial keratotomy

Radial keratotomy and astigmatic keratotomy are rarely performed today as stand-alone procedures for myopia and astigmatism, but they are still used in conjunction with other refractive and surgical techniques. Nonetheless, many patients that had radial keratotomy performed in the past 30-40 years still exist in the contact lens practice, as many of these patients are now presbyopic and suffer from over-correction [554], hyperopic drift [555], and diurnal variations [556] since their original procedure. From the Prospective Evaluation of Radial Keratotomy study, 58% of patients felt some type of optical correction was required 10 years postoperatively; 23% of patients had overcorrections or induced hyperopia greater than 1 dioptre, and 17% had under corrections or residual myopia greater than 1 dioptre [557].

Similar to the PK and LASIK/PRK fitting options above, the literature (mostly in the form of case series) documents a wide range of CL fitting options after radial keratotomy [558–560], which are considered more challenging to fit compared to nonsurgical eyes [561,562]. Soft lenses range from traditional daily disposable hydrogels [563] to conventional soft lenses [558,559]. Single case reports have described a high Dk lens compensating for diurnal fluctuations [556] or a prosthetic soft lens fitted after ruptured radial keratotomy incisions with iris damage [564]. Successful use of hybrid lenses has also been described in case series [559]

Rigid corneal lens use includes reverse geometry lenses [490,558,565], which are often orthokeratology-designed lenses but used for daily wear to better match the post-radial keratotomy oblate contour [546,566,567], or plateau designs fitted soon after radial keratotomy to manipulate the healing process and influence the refractive results [568]. Traditional prolate designs have also been used extensively [525,559] with various fitting algorithms proposed. Some early case series proposed fitting based on pre-operative keratometry readings [554]. In other series, empirical lens fitting based on flat post-operative keratometry readings has worked well, although the base curves of the final lenses were usually steeper than

the post-operative flat keratometry [569]. Using corneal topography, efficient base curve selection has been reported by selection of the lens base curve equal to the value 3.5-4.0 mm superior to the visual axis on an axial map [570]. When traditional corneal lenses are fitted after RK, or any myopic photoablation procedure which creates an oblate cornea, the contact lens vaults the flatter central cornea resulting in a plus powered lacrimal lens which must be compensated for with additional minus power in the lens [571]. Rigid corneal lenses also have a moulding effect that alters corneal power [572,573] and can improve vision temporarily after lens removal [546].

Successful scleral lenses use of various types has also been described [284,574–576]. Scleral lenses are currently the most popular option in the recent literature.

Historical complications associated with contact lens use after radial keratotomy that have been reported in the literature most often include superficial corneal neovascularisation along the incisions with low Dk soft lens wear [554,577] especially when the incisions reach the limbus [578].

4.2.4 Intra-corneal ring segments

Intra-corneal ring segments (ICRS) are flexible, crescent-shaped rings of polymethyl methacrylate inserted intrastromally into the peripheral cornea. The goal is to reduce refractive error by physically changing and flattening the shape of the cornea, and reduce corneal astigmatism. The US FDA first approved INTACS® (Addition Technology Inc.) intracorneal rings in 1999 to offer an alternative to contact lenses [579] and the use of ICRS to treat keratoconus and contact lens intolerance was first reported in 2000 [580,581].

Since then, numerous reports confirm that intrastromal corneal rings improve the tolerance of contact lenses in keratoconus [582–587], although one study found only a minor improvement [588]. Contact lenses are more straightforward to fit to a flatter and more regular cornea [198,588,589].

In 2007, the UK National Institute for Health and Clinical Excellence completed an overview of the insertion of ICRS for corneal disease, in particular keratoconus [198]. All patients who were contact lens-intolerant at baseline were able to use a contact lens after surgery [585], a finding confirmed by the Medical Advisory Secretariat [590].

Contact lenses are frequently required to achieve BCVA after the insertion of ICRS, especially with advanced keratoconus [199,583,584,587,591–594]. Various lens types and designs have been described for this indication, and various contact lens modalities have been found to be well tolerated after surgery, including disposable soft lenses, toric soft lenses [595], custom-made soft lenses [583,592,593,596,597], rigid corneal lenses [584,596], piggy-back lenses [587,591,592,596,598], corneo-scleral lenses [599,600] and scleral lenses [542,594,601], which were reported to be useful after other lens types had failed [601].

Contact lenses can improve visual function after implantation of ICRS by reducing higher order corneal aberrations including piggyback [587]; soft [597]; corneo-scleral [599]; and scleral designs [589,594].

Most reports of contact lens after ICRS are of a small number of cases with short follow-up. Low rates of injection and of staining from lens wear over ICRS are reported [593]; Montalt et al. report no adverse effects in 27 eyes of 27 patients with keratoconus fitted with corneo-scleral lenses after ICRS implantation and followed for 1 year [599]. Severe complications, including corneal neovascularisation and fungal infection (*Fusarium* sp.*)* have been reported [199], but there has been no systematic study or report on the issue. One study looked at the biomechanical impact of 1 year of corneo-scleral lens wear in normal patients, and in keratoconic patients with and without ICRS and found no

statistically significant effects on corneal viscoelastic properties in any of the groups [600].

Scleral lenses were tolerated by patients who could not wear other types of contact lenses after ICRS [601]. PRK can also be performed after INTACS to reduce the residual refractive error or reduce the astigmatism enough to improve tolerance [197].

4.2.5 High refractive error

The first reference to fitting contact lenses for high myopia was in 1889 by August Müller of Kiel in Germany who corrected his own 14 D of myopia with a scleral lens. Widespread adoption of corneal contact lenses yielded numerous reports of correction of high ametropia [602–605]. Generally, papers referring to high hypermetropia and astigmatism are generally incorporated into those for general ametropia or aphakia [488,602,604,606,607].

In patients with high astigmatism, empirical fitting of both rigid and soft lenses can provide equally good results which equate to the acuity of spectacles [608], with more recent reports that rigid corneal lenses improve vision compared to spectacles [609,610].

Fonda (1974) noted that Bennett (1963), quoting the calculations by J.L. Francis, showed that a contact lens gives 24% more magnification than a -20D spectacle lens at a back vertex distance of 12 mm [611]. Contact lenses therefore provide better acuity than spectacles for highly myopic refractive errors [612]. The reverse is true for high hypermetropes or aphakes. Also, more accommodation is required by myopes and less by hypermetropes when they transfer from spectacles to contact lenses [613]. Contact lenses also provide better contrast sensitivity than spectacles in higher prescriptions [614]. A high success rate was reported for rigid corneal lenses prescribed to be worn overnight for up to one month for high refractive errors, including myopia, hypermetropia and astigmatism [606].

Good results including stereopsis can be achieved treating myopic anisometropic amblyopia with contact lenses [604,605,615,616] with aniseikonia not a problem [617–619]. One study reported amblyopia only improved in eyes with a refractive error up to 9 dioptres [620].

Scleral lenses can be useful for high myopes and also high astigmats, in particular those with high astigmatism resulting from tilted grafts [488].

Rigid corneal contact lens correction of myopic refractive error, particular higher refractive error, may be associated with development of ptosis. The degree of ptosis was found to increase with higher degrees of myopia and longer duration of rigid corneal contact lens wear [621]. Ptosis may arise as an issue in unilateral wear or when there is high anisometropia.

When manufacturing high minus rigid corneal lenses, thinning the lenticular junction prevents excessive movement on blink [622]. The correction of soft CL spherical aberration is not beneficial to the majority of patients in practice [623]. See CLEAR Orthokeratology Report regarding the use of orthokeratology to slow myopia progression and reduce refractive error in high myopia [624].

4.2.6 Aphakia

Contact lenses have been the correction of choice for aphakia for many years. Starting in the 1940s, there were trials to correct aphakia with contact lenses, especially unilateral aphakia [625–628]. Continued reports have appeared in the literature over the decades and a review of aphakic lens fitting was written in 1979 [629]. Since aphakia is much less common now that intraocular lenses are the norm, most aphakic contact lenses required are for paediatric aphakia, aphakia following trauma, or ectopia lentis.

Over the years, rigid [606,630–633], soft [629,634–639], and scleral [488] lenses have been used successfully to correct aphakia.

Aphakic lens designs present certain challenges due to the large hyperopic refractive error being corrected. High plus power mandates high central thickness, which for any material, reduces oxygen transmission and increases theoretical risk of hypoxic complications such as neovascularisation, endothelial decompensation, and infection. High power lenses have mechanical issues related to their weight and to lid interactions as well as optical issues related to spherical aberration. The visual performance of two aspheric designs of soft aphakic lenses was compared to a spherical design, and the better of the two aspheric designs was assessed for mechanical and visual performance as well as physiological acceptance. Visual performance of all three lens types showed no significant difference and the mechanical performance of the aspheric lenses behaved more like low power lenses due to the reduced bulk and smooth profile of the lenses [637].

In 1967, a large rigid lens, the Apex lens, was designed to provide mechanical stability [630], and is the basis for more recent lens designs. More recently, a mini-scleral lens design has been successfully fitted for severe corneal irregularity and aphakia after trauma [640].

In the case of unilateral aphakia, aniseikonia can be a limitation to spectacle wear. For example, +20.00 D spectacle lens produces approximately 30% more magnification than a contact lens [613]. Dallos scleral lenses have been fitted in a group of unilaterally aphakic patients in an attempt to achieve binocular vision [626]. Unilateral aphakes fitted with PMMA contact lenses [641] and PMMA, soft and overnight wear soft lenses [642] were found to have gross binocular vision with some degree of aniseikonia.

Eighty percent of contact lens wearing unilateral aphakes demonstrated suppression in the aphakic eye [643]. A group of 24 patients with at least 2 years of disrupted binocular function after unilateral traumatic cataract or unilateral traumatic cataract followed by uncorrected aphakia had intractable diplopia when

the cataract was removed and the aphakia corrected with a contact or intraocular lens [644].

Hydrogel contact lenses have been fitted as an occlusive lens in the unoperated eye of unilateral aphakes in an attempt to treat dense amblyopia, either using a lens with a black opaque centre [645] or a high-plus lens [646]. Success was measured as the time the lens was worn, and four of 13 patients (nine of whom were aphakic) successfully wore the lens between 26 and 60 months, however, visual acuity was not measured as an outcome. Good compliance was achieved with 6/10. Additionally, diplopia was found to be a problem when only one eye was aphakic [644,647].

Traumatic aphakia is frequently accompanied by corneal irregularity and scarring, therefore rigid lenses provide the best chance of visual rehabilitation, despite comfort sometimes being an issue with monocular use of rigid lenses [631]. However, soft lenses can be fitted initially followed by refitting with rigid corneal lenses if adequate vision cannot be achieved with soft lenses [647]. Scleral lenses were a safe and effective option to improve vision with reasonable comfort [640]. In cases of traumatic aphakia with additional complaints of photophobia from traumatic aniridia, rigid corneal lenses made of fluorosilicone acrylate with a dark brown tint have been fitted with success and decreased photophobia [632].

Although initial reports on contact lenses for traumatic aphakia in children reported disappointing results [648], rigid lenses were used in unilateral traumatic aphakes with good results in children over 7 years old [649]. Subsequent to that, intraocular lenses produced better outcomes than contact lenses in traumatic aphakia [650]. Scleral lenses, bitoric corneal lenses, multifocal soft lenses, and hybrid lenses can also be used [651,652].

In some instances of ocular trauma, a combined procedure of cataract extraction and PK may be necessary. In these cases, the patients require a contact lens if

they do not have an intraocular lens inserted at the time of surgery. Overnight wear aphakic soft lenses have been used, but it was noted that this modality was frequently problematic and it was advised that sutures should be removed before fitting the lenses [513]. However, another report found the same lens modality gave successful results [512]. Rigid corneal lenses worn on an overnight wear basis may be useful for patients who were unsuccessful with soft lenses [653].

Other conditions that result in aphakia include patients with ectopia lentis and Marfan syndrome, which provide unique challenges when fitting contact lenses. Corneas are much flatter than average [654–656] and a larger than average horizontal visible iris diameter is common, along with a high level of myopia and astigmatism [657]. In one study, seven different contact lens modalities were used to fit patients with ectopia lentis; the authors noted that this group of patients included those who had not had lensectomy [658], and that aphakic contact lenses could be used if the native lens was sufficiently dislocated to create an aphakic axis within the pupil.

Contact lenses can be used to correct aphakic refractive error in patients with ectopia lentis, as modern methods of cataract extraction and IOL fixation in absence of capsular support have yet to be demonstrated as safe over decades of use and are associated with complications [659–661]. Improvement of BCVA with a contact lens has been reported to improve over one or more years [662].

The issue of overnight wear versus daily wear of contact lenses for aphakia has been given substantial consideration, including patient experience and risk of complications, as many patients are elderly and face challenges with daily lens insertion, removal, and care. Overnight wear was considered to give the best experience for aphakic patients using both rigid [606,636,638,663–665] and silicone elastomer lenses [666]. However, there was a high risk of problems and adverse events including MK and vision loss [636,638,663,665]. Low numbers of complications were found in daily wear aphakic rigid corneal lens wearers, which

included corneal punctate staining and contact lens-papillary conjunctivitis [631,632].

Only half (21/40) of aphakes fitted with overnight wear lenses were successful, with the risk of serious complication being six times greater compared to daily wear lenses (55% compared to 8.8%) [667]. Serious complications included MK, tight fit syndrome, corneal erosions, neovascularisation >2 mm, stromal oedema, and blepharoconjunctivitis [667]. In one study, corneal oedema was a problem with overnight wear, and three out of 150 patients lost their sight as a result of MK and hypopyon [629]. In a review of 100 aphakes fitted with overnight wear soft lenses, four patients developed major complications, three of whom were diabetic [668]. The authors advised that special consideration should be given when fitting diabetics with overnight wear aphakic lenses. Because of the higher risks in overnight wear, daily wear is preferable [669]. Higher rates of complications were found in overnight wear hydrophilic lens wearers [638,670], while there were less problems from daily wear rigid and soft lenses [647]. An examination of the endothelium of a group of unilateral aphakes noted that overnight wear of both rigid corneal and hydrogel lenses had a deleterious effect, presumably due to chronic hypoxia [669]. However, silicone elastomer contact lenses produced no effect on the corneal endothelium in a unilateral lens wearing group [666]. This was similar to earlier findings by Schoessler et al. for patients wearing lenses in both eyes [671].

4.2.7 Paediatric aphakia

Using hard lenses to fit babies after surgery for congenital cataracts was first mentioned in 1959 [672], with numerous other reports to follow [673–676]. Numerous reports of the use of rigid corneal lenses in young aphakes followed [677–681] as well as the use of scleral lenses [236,682]. Paediatric aphakic patients have been successfully fitted with soft lenses, in overnight and daily wear [679,683]. A silicone rubber material was reported to give sufficient oxygen for

overnight wear [684], and numerous reports of the use of Silsoft lenses for this indication followed [651,677,681,685–689].

In a cohort of 240 eyes in 184 patients, 22% of the 112 eyes fit with Silsoft lenses abandoned lens wear for a variety of reasons, with “dense amblyopia or retinoblastoma” reported as the most common reason [685]. No patients had contact lens complications with permanent visual sequelae. Recent evidence shows no visual advantage of IOLs over contact lens correction for infants and toddlers, with contact lenses yielding fewer adverse events such as visual axis opacities [690–694]. A report of corneal changes in children after unilateral cataract surgery in the Infant Aphakia Treatment Study (IATS) found endothelial cell density and central corneal thickness were less favourable for infants treated with aphakic contact lenses compared to those treated with intraocular lenses at the 5-year outcome examination, [695] but the long term implications remain unknown. In a secondary analysis, the IATS found that children who wore contact lenses for a larger amount of their waking hours in a day throughout the study period of 5 years had better visual outcomes, even after accounting for patching adherence [696].

As far as choice of lens type, overnight wear silicone elastomer lenses have been fitted up to ages 3-4 years and replaced with daily wear high water content lenses thereafter [687] with report of15% of eyes with complications, all without sequelae. Better vision with rigid corneal lenses compared to Silsoft lenses was reported in a cohort of patients with unilateral infant aphakia followed to 5 years of age [697]. In a study comparing overnight wear of silicone elastomer lenses (mostly 7-21 nights) with daily use of rigid corneal lenses, visual acuity data at 1 and 5 years of age failed to provide convincing evidence regarding which approach is the best option for managing infantile aphakia [697]. There was a trend toward better BCVA in the rigid corneal lens group, but this did not reach statistical significance, possibly due to small sample size of 57 infants. There is medium quality evidence that there are fewer adverse ocular events with the rigid corneal lenses, but more

lenses are lost. In one study, 22% had CL related adverse events with overnight wear Silsoft lenses, which was supported by the same percentage of patients in another study, who also developed adverse events, including corneal abrasion, bacterial keratitis and corneal opacity [686,697]. All but one wore overnight wear silicone elastomer lenses, and all resolved without sequelae. In the IATS group, 18% had adverse events, all of which resolved when the lenses were removed and treated with topical antibiotics [692]. Silsoft lenses were fitted and replaced at 3-monthly intervals in one study [687] that reported few complications below 3 years old, although 4/26 eyes (15%) had adverse events. It is worthwhile to note that approximately 6 lens changes were needed during the first year in a report on contact lens correction of unilateral nontraumatic paediatric aphakes [679]. Another study reported an average of approximately 9 lens changes and 21 visits in the first year in their practice, favouring the use of customisable soft hydrophilic lenses. Frequent lens loss, frequent need for replacement, and frequent visits represent a substantial commitment for all parties. An evidence based medicine report by the American Academy of Ophthalmology [681] reported that there was limited quality and amount of evidence that showed that silicone elastomer and rigid corneal lenses were effective for treating aphakia in children. They reported that data show that silicone elastomer lenses are easier to fit and have the wear and care advantage that they may be worn on an overnight wear basis. Their data found that although rigid corneal lenses must be removed every night and require a more customised fit, they are associated with fewer adverse events. Others report no cases of adverse events with daily wear rigid corneal lenses and [677,698,699]. A report on 16 eyes wearing rigid corneal lenses on a 1-week overnight wear basis found no observable increases in the rate of microbial infection [700]. Silicone elastomer is used frequently in the US but less commonly in other countries. Custom lathe cut SiHy lenses are an option elsewhere [651]. Overnight wear contact lenses were poorly tolerated in children with unilateral aphakia after radiation and cataract surgery in the setting of orbital rhabdomyosarcoma [701]. Special fitting and power considerations are needed for the small eyes of infants following congenital cataract surgery as they have

small, steep corneas [702]. Because it is not always possible to take keratometry measurements, the first lens used is fitted empirically according to expected corneal radius for the patient's age [703,704]; there is a rapid rate of corneal flattening during the first 18 months of life [651]. Corneal radius of a neonate is between 48.50 D (6.96 mm) and 47.00 D (7.18 mm) and corneal diameter is approximately 10mm; although, in one study of congenital cataracts, 57% were found to have microcornea [705–708]. Contact lenses were generally fitted within one month of surgery for a wide range of ages [677,679,685,686,688,700,703]. Hydrogel lenses with radii of 7.00 to 7.60 mm in infants and of 7.80 to 8.10 mm in children two years and older have been fitted [683]. Silsoft lenses were fitted with a 7.50 mm back-optic zone radius in patients up to the age of 1.5 years old, and by the age of 4 years, a back-optic zone radius of 7.90 mm was needed [687]. Lenses of diameter 7.50 mm or 7.70 mm have been fitted for the first 6 months, followed by flatter lenses of 7.7m0 m from 6-18 months, flattening further to 7.70 or 7.90mm for children over 18 months old [709]. In the IATS, 84% of patients were initially fitted with a 7.50 mm radius [697]. Rigid corneal lenses were fitted steeper than flattest K readings to 'give a grip' on small corneas [678]. The average radius was 46.75 D (7.20 mm). Saltarelli fitted Dyna Z Intralimbal lenses with an average base curve of 7.9 to 7.5 mm [700]. In the IATS study, the mean radius of rigid corneal lenses was 47.62 D (7.08 mm) up to the age of 12 months and flattened to 44.31 D (7.60 mm) by age 5 years [697].

Silicone elastomer lenses (Silsoft, Bausch & Lomb) are available in an 11.3mm diameter, used to fit young infants [710] and in 12.5mm for older children who need lower powers. Rigid corneal lenses are fitted as an intralimbal or paralimbal fitting. Complete corneal coverage is recommended to give better stability, with a diameter of 10.8-11.2 mm depending on corneal diameter [651]. Larger diameters can be fitted as can a range of small diameters, as small as 7.5-9.5 mm depending on corneal diameter. The mean diameter fitted in the IATS cohort was 9.4 mm [678,697,700].For soft and SiHy contact lenses, the total diameters should be 2.5-3.0 mm larger than the horizontal visible iris diameter for normal size eyes

[651,704] and 11-12 mm for microphthalmic eyes. Some microphthalmic eyes have been fitted with lenses of 10.5 mm or smaller diameter [651,704].

The power of aphakic lenses for infants and young children is much higher than in adults because the eyes are smaller with steeper corneas and shorter axial lengths. Mean lens powers used when fitting aphakic infants range from +21.36 to +29.60 D [677,683,686–689,699,711]. Lens power is estimated as this cannot be obtained directly from refraction in paediatric patients and can be significantly miscalculated with aphakic spectacle correction [689]. Some literature presents guidelines for calculating lens power either through using an equation or referencing a table of expected values [712–714].

Because infants generally look at close objects such as faces, food, and toys, the power is increased by 2-4 dioptres to provide a near focus to preclude refractive amblyopia [651,679,686,709].

5 Tinted, opaque, or prosthetic lenses

Contact lenses can be used to modify or enhance the appearance of an eye and improve vision in certain eye conditions such as in aniridia, trauma, diplopia, albinism or retinal disease. Depending on the tint applied, a contact lens can be translucent, semi opaque or completely opaque across all or part of the lens diameter.

- A Cosmetic Tinted Lens can be defined as a lens that is designed to beautify the appearance of a healthy eye, frequently used to create an effect of enlarging the iris and changing iris colour. These lenses are considered a fashion accessory [715].
- A Therapeutic Tinted Lens is used to treat an ocular disease or defect. They can be prescribed to reduce glare, photophobia, enhance colour vision and for occlusion therapy in amblyopia [715].

- A Prosthetic Tinted Lens is designed to improve cosmesis of an otherwise cosmetically abnormal eye. These lenses are typically used in congenital abnormalities, disfiguring disease, and penetrating trauma [715].

5.1 For photophobia (albinism, migraine, etc)

Centrally tinted soft contact lenses are available in a range of colours, tint densities and pupil options (Ultravision, Cantor and Nissel) and can be used to reduce photophobia in patients with various retinal conditions such as in retinitis pigmentosa, cone dystrophies, and albinism. Case reports and case series show a marked reduction in photophobia and improved daily QOL in adults and in children [716–722].

5.2 For glare (mydriasis, traumatic aniridia, coloboma etc)

Therapeutic tinted lens can be used to resolve glare for patients with pupils that are nonreactive or suffered traumatic injury [723]. In cases of traumatic aphakia with additional complaints of photophobia from traumatic aniridia, rigid corneal lenses made of fluorosilicone acrylate with a dark brown tint have been fitted [632]. Partially occlusive lenses with a clear pupil can offer relief to patients who complain of glare after peripheral iridotomy.

5.3 Colour-blindness

The use of red tinted lenses to enhance colour vision in patients with colour-blindness has been reported as early as 1988 [724]. Various contact lens systems such as X-Chrom lens or ChromaGen are available. Subjects with congenital colour vision deficiency wearing two types of tinted contact lenses (light red and dark red tints) improved on Ishihara plates, although the Farnsworth 100 hue test did not show any improvement with either lens [725]. An improvement on Ishihara plates with the ChromaGen contact lens, especially in deutan subjects, has been reported but again there was no significant effect on the Farnsworth lantern test performance. Subjects also reported enhanced colour perception with ChromaGen lenses, although significant difficulties with vision in dim light were apparent [726].

Despite widespread use of tinted contact lenses, there is still little evidence that supports their efficacy in enhancing colour perception (see CLEAR Future Report) [341].

5.4 Disfiguring disease

Visible abnormalities of the anterior ocular structures can be masked using printed, dyed or iris-painted prosthetic contact lenses (Ultravision, Cantor and Nissel). A retrospective analysis of 42 patients (48 eyes) for whom an iris-painted soft contact lens was prescribed reported that three tint patterns were used depending on the therapeutic purpose [727]. All tint patterns prescribed had the same tinted iris structure but differed in pupil type, either containing a solid black pupil, no pupil, or a clear pupil. The authors reported an improvement in BCVA in those patients wearing a clear-pupil prosthetic soft CL. However, 40% of wearers experienced complications, with the incidence higher in patients wearing the solid-pupil type. This may be because such patients had greater disturbance to the corneal barrier function and endothelial reserve at baseline and are thus more susceptible and/or that they were less sensitive to early symptoms of hypoxia or infection because of reduced vision. High satisfaction has been reported in 25 of 33 patients fitted with hand-painted cosmetic lenses for cosmetic purposes, finding a 76% satisfaction regarding lens comfort and 88% satisfaction regarding lens colour and appearance [728]. The diameter of most soft lenses are approximately 15 mm up to 22 mm (Cantor and Nissel). Hand painted scleral shells, made by taking ocular impressions, can be used with good cosmetic success, where the eye has become phthisical.

5.5 For amblyopia treatment

Opaque tinted contact lenses can be a potential alternative to amblyopia occlusive treatment in those patients who were patch-intolerant and failed with conventional therapies and in those with intractable diplopia. Several case series have reported the efficacy of using overnight and daily wear opaque contact lenses to treat

amblyopia in children and adults, suggesting that this approach is a useful alternative to improve compliance in occlusion therapy [645,729–733]. High-positive contact lenses for optical penalisation of the unoperated eye have also been used to treat strabismic amblyopia in unilateral aphakes [645,646]. One study in normally sighted patients suggests that modifying the size of the opaque pupil can allow different degrees of penalisation while potentially leaving peripheral fusion intact [734].

6 Nystagmus

The use of rigid corneal and soft contact lenses has been recommended over spectacles in nystagmus, however, published data is scarce and equivocal. Early studies have reported that contact lenses dampen ocular oscillation in nystagmus (presumably because they provide tactile feedback about the eye motion to the ocular motor system) and provide better visual acuity than spectacles, particularly in infantile nystagmus [735–738].

Some studies report improvements in visual acuity and eye movement and others show no changes or variable results [739–743]. These studies are mainly retrospective and small case series or reports. More recently, a randomised controlled trial assessed the use of rigid corneal and soft contact lenses in infantile nystagmus, reporting that neither lens type reduced nystagmus or improved best corrected visual acuity as compared to wearing spectacles [744].

A short term rebound phenomenon was reported in a 20-year-old female nystagmus patient who was fitted with a contact lens for a 90-minute trial session [745]. Upon removal of the contact lens, the patient experienced a short-term rebound phenomenon that included oscillopsia and dizziness. The authors hypothesised that relieving the dampening effect of contact lenses on congenital nystagmus might have induced the rebound phenomenon consisting of a transient increase in nystagmus intensity and/or changing the foveation period.

There is a lack of good-quality evidence studies in this field. Well-designed trials with standardised methodology are needed to establish the effectiveness of contact lenses in infantile nystagmus.

6.5 Ptosis

There is low quality evidence that scleral lenses can be useful in the management of ptosis of various aetiology, including ocular myopathy, complicated ptosis due to long term rigid corneal lens wear, phthisis bulbi, and myopathy from Kearns-Sayre syndrome [746,747]. The scleral lenses improved cosmesis, increased both the palpebral aperture and marginal reflex distance, and provided visual correction successfully for all patients [747].

7 Medical use of contact lenses with prophylactic antibiotics

Due to the potential risk of MK associated with overnight wear of therapeutic contact lenses, many practitioners prefer disposable contact lenses with high oxygen transmissibility materials, such as SiHy materials, along with prophylactic antibiotics (preferably preservative free). However, there is not strong evidence that directly addresses and supports this practice. A survey of 52 consultant ophthalmologists found that only 42.3% prescribe prophylactic antibiotics when they use bandage contact lenses [400]

While there are reports of MK despite the use of prophylactic antibiotics which might in turn cause toxicity and other complications, some authors believe the reported benefits surpass the reported complications [20,79,147,152,293,301,302,308].

Some studies do not report any episodes of MK with therapeutic contact lenses for various ocular surface disorders with or without prophylactic antibiotics [31,140,225,226,321]. Other studies show that the use of prophylactic antibiotics did not eliminate the risk of MK in patients treated with therapeutic SiHy contact lenses [139,399]. One study found an increased risk of MK when antibiotics were

used in association with therapeutic hydrogel lens and steroid for bullous keratopathy [398] (See section 3.5). It is conceivable that prolonged prophylactic antibiotic use during bandage contact lens wear could potentially lead to increased antibiotic resistance in pathogenic and changes to the microbiota of the eye, which may be of importance in the protection of the ocular surface.

When antibiotic prophylaxis is used concurrently with therapeutic lenses, the agent is sometimes rotated regularly to decrease the risk for development of microbial resistance, e.g. moxifloxacin 0.5%, followed by tobramycin 0.3%, followed by polymyxin B-trimethoprim for 1 month or ofloxacin 0.3% to sodium sulfacetamide 10% to levofloxacin 0.5% to polymyxin/trimethoprim [328,748].

There is substantial literature on the role of prophylactic antibiotics with therapeutic contact lens with keratoprostheses (see section 3.1.4), a clinical situation that warrants special consideration.

In a retrospective case study of patients with refractory persistent epithelial defects fitted with overnight wear scleral lenses with various prophylactic antibiotic regimens or none, MK occurred in 4 of 14 eyes analysed [147]. A more recent retrospective case series reported no cases of microbial keratitis in 20 eyes with persistent epithelial defects with a regimen incorporating overnight wear of scleral lenses with daily removal for cleaning and the addition of a preservative free fourth-generation fluoroquinolone antibiotic drop to the lens reservoir at time of insertion [148].

Most studies are inadequately powered and of insufficient quality to provide firm evidence to inform the development of management guidelines. Well-designed, masked, randomised, controlled trials are needed to establish the benefits of the use of prophylactic antibiotics treatment regimens along with therapeutic contact lenses.

8 Medical use of contact lens during therapy with other agents

This section summarises the *in vivo* reports describing the concurrent use of topical therapeutic agents with contact lenses. Contact lenses for drug delivery are under development and this is covered in the CLEAR Future Report [341].

8.1 Corticosteroids and NSAIDs

There is some concern about concurrent use of contact lenses with topical corticosteroids or NSAIDs because *in vitro* data suggest that topical corticosteroids and NSAIDs cause corneal toxicity [749], which could exacerbated by contact lenses because lenses may increase the retention time of the drugs. Only one study has investigated the combination of 1% prednisolone acetate and hydrogel contact lenses in rabbits [750]. In this study, lenses were soaked in 1% prednisolone acetate for 2 minutes prior to application. Eyes of the treated animals were compared to animals that received 1% prednisolone acetate drops without contact lenses. The cornea and aqueous humour were sampled, and data suggest that using these drugs concurrently with contact lenses enables more efficient drug delivery over a sustained amount of time to the ocular surface in an animal model. No reports were found at the time of this report related to the use of corticosteroids and NSAIDs, for treating animal or human disease, though these investigations would be welcomed because they have the potential to increase treatment efficacy and compliance. These data would likewise better help the community determine the safety of this practice.

8.2 Glaucoma medications

Glaucoma medications were among the first medications that were prescribed in combination with contact lenses. The active ingredients and preservatives within glaucoma medications are known to induce or exacerbate existing ocular surface disease [751]; therefore, concurrent use of glaucoma medications with lenses should be used with caution. Early work related to concurrent use of glaucoma medications with contact lense focused on using pilocarpine for the treatment of angle closure or primary open angle glaucoma. The studies found that contact

lenes enhanced reduction in the IOP with pilocarpine [752,753]. Hillman et al. likewise found that contact lenses soaked in pilocarpine were associated with reduced side effects seen with the systemic absorption of the drug compared to topically applied drops [753]. The use of pilocarpine however has diminished with the advent of more effective medications such as topical prostaglandin analogues, beta-adrenergic antagonists, alpha-adrenergic agonists, and carbonic anhydrase inhibitors [751]. The literature search performed for this report did not uncover any literature related to the concurrent use of these medications with contact lenses. See CLEAR Future Report for glaucoma drug delivery applications [341].

8.3 Autologous serum tears / other blood products

There are a growing number of reports within the literature that have used 20% to 50% autologous serum tears in combination with contact lenses for treating persistent epithelial defects (PEDs). A retrospective case review of five patients who had PEDs and were treated with 20% autologous serum tears and ocufilcon D contact lenses found that five of the six treated eyes resolved after a mean of 14.2 days; however, it took one patient about 90 days to fully recover [144]. This study reported no adverse events other than deposits on the lenses. In a prospective study of eight patients who were treated with 50% autologous serum tears and senofilcon A contact lenses, PEDs resolved in an average of 11.9 days [223]. In 12 patients who had a PED secondary to infectious keratitis, treated with balafilcon A contact lenses and 20% autologous serum tears there was a similar outcome [146]. In a prospective study of 21 patients, recalcitrant PEDs were successfully healed with BSCLs and 20% autologous serum tears [145]. A subgroup of subjects was randomised to continue the use of 20% autologous serum tears for an additional two weeks after PED resolution and BSCL removal while the other subjects discontinued autologous serum tear use after BSCL removal. Recurrence rates in PED were significantly decreased in those subjects who continued serum tears after BSCL removal [145]. In a prospective study of 40 Sjøgren Syndrome patients who were randomised to either 50% autologous serum tears or balafilcon A BSCLs, both groups had a significant improvement in OSDI

scores [252]. Of note, the BSCL group had better OSDI scores than the autologous serum tears group, likely because of the protection that the BSCLs offer from the external environment. While these results are promising, there is still a need for a randomised study that compares patients who are treated with BSCLs alone, autologous serum tears alone, or the combination of the two treatments to determine this treatment strategy's true effectiveness and safety.

8.4 Antibiotics

Antibiotics have been used in combination with contact lenses for prophylactic purposes after a corneal injury or in conjunction with surgical interventions [20,139,155]. When used for these purposes, practitioners typically directly apply the drops to a contact lens wearing eye [20,139,155]. While this practice is common, no well-controlled human studies have been reported in corneal disease. Nevertheless, lenses pre-soaked in gentamicin were able to provide an inhibitory concentration of gentamicin in the tear film of healthy human adults for up to three days [754]. Senofilcon A contact lenses soaked in gentamicin, kanamycin, tobramycin, ciprofloxacin, or ofloxacin were able to deliver antibiotics to the anterior chamber [755]. The aqueous fluid was sampled during surgery and in all cases contact lenses enhanced antibiotic concentrations within the anterior chamber. A similar conclusion was found in a rabbit study of tobramycin penetration of the cornea [756]. A rabbit animal model of *P. aeruginosa* corneal infection demonstrated that molecularly imprinted contact lenses delivered ciprofloxacin and produced a similar amount of corneal resolution during eight hours of treatment, comparable to topical eye drops [757]. While the above work is promising, well-controlled human studies still need to be conducted to determine if these therapeutic options are safe and effective when used for either preventative procedures such as cataract surgery or for treating bacterial keratitis.

9 Complications of medical use of contact lenses

For many of the indications in which medical contact lenses are used, the ocular surface is compromised and thus more vulnerable or prone to complications

including infection. Complications may in some instances be precipitated by the disease for which the therapeutic lenses were prescribed (see section 9.3 of CLEAR Complications Report) [30].

9.1. Microbial keratitis

The incidence and prevalence of MK in contact lenses worn for medical use is largely unknown. As with cosmetic wear, it is likely that soft medical lenses carry a higher risk, particularly when worn overnight [507,758]. These risks may also be reduced but not eliminated with concurrent use of prophylactic antibiotics, see section 7, above. Many patients with autoimmune and inflammatory diseases where medical contact lenses are indicated may also be receiving corticosteroid or immunosuppressive treatments locally or systematically (e.g. methotrexate, cyclosporine), potentially putting them at higher risk of developing an infection.

9.1.1 Microbial keratitis and BSCLs

Case reports of MK appeared in the early use of BSCLs in the setting of chronic ocular surface disease; it is notable that both of these cases were in teens with cGVHD, a 13-year-old girl with *Staphylococcus aureus* keratitis and a 14-year-old boy with *Pseudomonas aeruginosa* keratitis with cGVHD [219,759]. Microbial keratitis is sporadically reported when high oxygen transmissible SiHy lenses are worn therapeutically [227,760,761].

In a large retrospective review at a Chinese University Hospital, 6,188 patients (6,385 eyes) were fitted with SiHy contact lenses whilst using antibiotic prophylaxis over a 42-month period. Within this cohort, eight patients (0.13%) developed MK for an annualised incidence of 3.7 cases per 10,000 per year [762]. In a case series of 74 patients using medical SiHy contact lenses for 102 intervals of use, two patients (3 eyes) (2.7%) developed MK whilst on antibiotic prophylaxis [399]. Older age and keratoplasty were positive risk factors for MK in a large retrospective case review of patients fitted with medical contact lenses [762]. In a case series of 3 patients with epidermolysis bullosa treated with overnight wear BSCLs, several

episodes of MK occurred during the next 1 to 4 years, particularly when prophylaxis was not used [748]. The underlying disease and predisposition to infection might influence the decision for and choice of antibiotic prophylaxis.

Therapeutic soft lenses are routinely applied after refractive surgical procedures involving epithelial debridement or the creation of a corneal flap (e.g. PRK, LASIK, LASEK) to promote epithelial healing, preserve flap integrity, and relieve pain. Soft lenses are typically fitted immediately after surgery, for 3 to 4 days of continuous wear. Severe complications following refractive surgery are rarely reported, however, numerous low quality evidence publications involving single case report or case series following PRK, LASIK, and LASEK have been reported [256,763–768]. It can, however, be difficult to ascertain whether these complications are caused by wear of the therapeutic lens, by the surgical procedure, or by a combination of both. Severe complications of refractive surgery in young, healthy individuals can be particularly distressing when they occur in both eyes and have blinding consequences [769].

Concomitant use of topical antibiotics, ocular lubricants, and topical steroid or NSAID eyedrops is common in the setting of refractive surgery. Cases of MK after PRK where BSCLs were used without appropriate prophylactic antibiotics or with insufficient dosage, highlighted the risks involved in this practice [770,771]. A prospective randomised trial investigating standard postoperative PRK procedures with and without use of a BSCL demonstrated the effectiveness of these lenses in managing postoperative pain, but complications were observed [772]. One of 47 patients (2.1%) developed bacterial keratitis [773]. A large retrospective review of MK cases among 107,613 patients (204,586 eyes) who had undertaken LASIK at a single clinic in Spain suggested therapeutic lens usage is a significant risk factor for MK in those with intraoperative epithelial defects [774]. In another large retrospective review of infectious keratitis after PRK at six United States Army and Navy refractive surgery centres, five eyes from 25,337 PRK procedures developed MK during therapeutic lens wear in the first postoperative week [82]. Risk factors

of contact lens manipulation and working in a medical environment were identified [82].

Bacterial contaminants of worn bandage lenses after LASIK or PRK have been characterised, but these have not necessarily been associated with complications as usually only ocular commensal microorganisms have been isolated [119–122]. Microbial keratitis caused by unusual organisms are nevertheless occasionally reported. A case of bilateral fungal keratitis in a wearer of BSCLs after bilateral penetrating keratoplasty has been reported [256]. A case of severe unilateral methicillin-resistant *Staphylococcus aureus* keratitis 3 days after PRK has been reported [775]. Microbial keratitis after LASIK can be complicated by the location of the infection at the interface, making it more difficult to culture the organisms and preventing adequate penetration of the topical antibiotics [776].

9.1.2 Microbial keratitis and scleral lenses

A review of the literature in 2016 [777] described 11 cases of microbial keratitis associated with scleral lens wear published as retrospective case reports or case series over the previous 15 years [147,227,265,351,373,486,778]. For most of these, risk factors for infection were present including overnight wear, ocular surface disease, epithelial compromise, use of oral or topical corticosteroids, or poor compliance. Four cases of MK occurred in 13 complicated cases (14 eyes) with persistent epithelial defects fitted with scleral lenses on an overnight wear basis; as a result, it was suggested that conversion to daily wear of scleral lenses should occur as soon as the epithelial defects have resolved [147]. An explanation for this apparent high rate of infection was proposed [324]: patients were instructed to place one or two drops of medications in the scleral lens reservoir before topping off with sterile, non-preserved saline before lens insertion and the concentration of preservative or corticosteroids in the bowl of the scleral lens may have contributed to epithelial toxicity and local immunosuppression, leading to a higher rate of MK. A subsequent and larger series reported no cases of MK in an updated regimen that included daily lens removal and cleaning and the use of 1

drop of preservative-free moxifloxacin in the reservoir daily, with all other medications applied directly to the ocular surface prior to lens insertion or at the time of daily lens removal [779]. See CLEAR Sclerals Report for general discussion of scleral lenses [72].

9.2 Corneal Inflammatory Events

Episodes of acute red eye were first described by Zantos and Holden in overnight wearers of hydrogel lenses for the correction of low refractive errors [780], with similar complications reported during therapeutic lens wear [31,395,773]. A patient with ocular burns and a corneal epithelial defect treated with a therapeutic SiHy, worn on an overnight wear basis, developed sterile peripheral corneal infiltrates two weeks after initiation of treatment [31]. Cultures from corneal scrapings were negative but those from the bandage lens were positive for *Staphylococcus aureus*. Such inflammatory reactions associated with bacterial colonisation of the contact lens by *S. aureus* have previously been reported during overnight wear of soft lenses [781].

In a prospective randomised post-PRK trial, two of 47 patients (4.3%) developed corneal infiltrative events during therapeutic lens wear [773]. In a large retrospective review of infectious keratitis after PRK at six United States Army and Navy refractive surgery centres, among 25,337 PRK procedures there were 5 eyes in 5 patients with culture proven or clinically suspected microbial keratitis and 26 eyes developed corneal infiltrates (presumed to be sterile) in the first postoperative week during the period of therapeutic lens wear [82]. These latter cases improved with removal of the bandage lens and increasing of antibiotic coverage.

There is a single case report of recurrent acute red eye reaction in a keratoconic patient fitted with mini-scleral contact lenses [782]. Unilateral severe bulbar conjunctival and limbal hyperaemia, slightly swollen superior eyelid, diffuse infiltrates in the mid-peripheral cornea and minimal punctate corneal fluorescein

staining were noted with no corneal ulceration or other signs of corneal infection. The episodes were successfully managed with temporary cessation of contact lens wear, cold compresses, topical lubricants, and topical corticosteroids four times daily, followed by attention to improved lens hygiene.

9.3 Hypoxia with scleral lens wear

Complications commonly observed with traditional non-oxygen permeable scleral lenses included corneal oedema and neovascularisation [783]. Whilst hypoxia was a common complication of traditional scleral lenses made of glass and PMMA, the advent of modern rigid scleral lenses significantly shifted the complications profile. This shift was clearly illustrated in a retrospective analysis of 343 patients fitted with PMMA scleral lenses [344] and 85 patients who were refitted or newly fitted with rigid scleral lenses [783].

There is, however, little evidence that clinically significant levels of corneal oedema above 4.5% are induced by daily wear of well fitted modern scleral lenses [784]. Statistically but non-clinically significant corneal swelling of less than 2% following 8 hours of daily wear of scleral lenses was demonstrated in healthy young patients with no prior corneal transplantation [784]. Transient corneal oedema has been reported with modern rigid scleral lenses [73,486,504,785]. There is more scleral lens induced central corneal oedema in eyes after penetrating keratoplasty than in control eyes [505] with overnight wear [786] and during closed eye conditions [787]. Scleral lens wear is reported to alter curvature and pachymetry in patients with keratoconus [788].

Clinically significant corneal oedema in the setting of scleral lens wear has been successfully managed using a combination of lens refit, temporary lens discontinuation, and topical instillation of hypertonic saline [486,504]. Patients fitted with scleral lenses post-penetrating keratoplasty may have reduced endothelial counts and function and may require closer monitoring and attention to aspects of fit to improve oxygen availability [486,504,505]. Finally, modelling of

oedema levels suggest that overnight wear of scleral lenses may more easily yield clinically significant levels of oedema and should therefore be avoided or minimised as much as possible [789].

In a study evaluating the long-term success of the PROSE medical devices, ophthalmic complications (redness, corneal graft failure, elevated pressure, and opacification) were uncommon, accounting for 2.5% (3 of 121) of discontinuation at 5 years [241]. A 6.4% rate of failure among 125 patients that received PROSE medical devices over a 4-year period has been reported [245]. Patients with lower endothelial cell counts after penetrating keratoplasty or with Fuchs' dystrophy were more likely to fail treatment.

In a large retrospective study, patients who removed lenses during the day were reported to have better success as measured by total wearing time with scleral lenses (96% versus 52% success rate, respectively) [441]. For many patients, removal of the lenses during the day provides an opportunity to clear accumulated debris in the post-lens fluid reservoir and restore vision. Increased post-lens tear turbidity during scleral lens wear was demonstrated in a recent investigation of 26 keratoconic patients over eight hours of wear [790]. The composition of the particulates in the stagnant post lens tear film has not been fully characterised, though inflammatory leukocytes have recently been identified [791].

9.3.1 Epithelial bullae with medical use of scleral lens

Epithelial bullae are described as "oval shaped, fairly large (40 microns or larger) epithelial formations with indistinct borders that can coalesce into clusters and tend to be associated with chronic corneal oedema" [792]. It has been postulated that in the setting of scleral lenses, these epithelial bullae may form due to weakened connections in the basal corneal epithelium rather than a purely hypoxic mechanism [792]. In support of this, peripheral epithelial bullae described in a case series of 15 patients after only six hours of wear of small diameter scleral lenses were attributed to lens bearing and the resulting interaction between the lens and

the cornea [793]. In another case series, three patients fitted with scleral lenses for different indications (cGVHD, aniridia, and LSCD) each developed small transient epithelial bullae [792]. In all cases, these appearances were asymptomatic and transient; they flattened and disappeared immediately following scleral lens removal, although persistence of epithelial bullae for up to a week has been reported [792,793]. Conversely an epithelial bulla has been reported in a patient fitted post-penetrating keratoplasty during an episode of significant corneal oedema [504]. Practitioners should be alert to the possible development of epithelial bullae during scleral lens wear and note that these will on occasion best be detected while the scleral lens is still on the eye due to their possible transient nature.

9.4 Lens retention

There are many case reports of contact lenses retained asymptomatically in the upper fornix, but only one related to the use of a BSCL that was retained folded for six and a half years in the superior subtarsal space of an elderly patient with dry eye disease [794].

9.5 The challenge of concurrent vs. intercurrent disease

An intercurrent disease is one that has an impact on or is related to the safety, treatment efficacy or other relevant conditions but is not directly caused by the condition. For example, a patient fitted with a therapeutic lens for severe ocular surface disease may have an episode of MK or a patient fitted with a therapeutic lens for a PED may develop neovascularisation. In such cases it may be unclear whether the keratitis is an intercurrent event related to the ocular surface disease or the PED and unrelated to the use of therapeutic lenses, or whether therapeutic lens wear precipitated these complications. Complications may in some instances be precipitated by the disease for which the therapeutic lenses were prescribed. For example, corneal melt and perforation has been reported in patients with cGVHD wearing BSCLs, however, this complication is likely due to the immune-mediated disease rather than to therapeutic lens wear [795,796].

In the setting of therapeutic lens use, the risk of complications may therefore be high because of the abnormal ocular environment rather than because of the risks inherent with lens wear. In such instances, it may be tempting for practitioners and/or patients to attribute any or all complications to lens wear and thus temporarily or permanently end their use. Any complication, no matter its presumed cause, must of course be managed appropriately and this will often require use of topical antibiotic and/or anti-inflammatory medication; however, it must be remembered that therapeutic lenses often significantly improve the quality of life for those where their use is indicated. Practitioners should be encouraged to consider whether certain aspects of lens type, design, material, and wear and care regimen may be modified to mitigate the future risk of complications. For example, a switch to a higher oxygen permeable material or improvement in fluid ventilation in the case of a scleral lens, or reduction in wear time might help reduce the risk of progression of neovascularisation. Extra precautions may be warranted in order to minimise the risks such as more regular follow-up visits or use of topical prophylactic agents.

10 Patient instructions and education in wear and care

10.1 Insertion and removal

Many of the patient instructions that apply to refractive and cosmetic use of contact lenses are relevant in the context of medical use. For example, thorough handwashing prior to any insertion, removal, or manipulation of any contact lens is indicated. Handling of large diameter scleral lenses often poses significant challenges for patients. Insertion can be particularly difficult where the diameter of some scleral lenses is larger than the interpalpebral fissure. Patients should be instructed to fill the scleral reservoir with sterile, non-preserved saline before lens insertion, to avoid the formation of air bubbles. Family members may need to be taught insertion and removal [285], for example, when children or patients with poor acuity bilaterally are fitted. In a retrospective study of 49 patients fitted with

scleral lenses for chronic ocular surface disease, nine (18%) reported insertion difficulties and 16 reported (33%) difficulties during removal [74]. In another large retrospective study of 178 patients fitted with scleral lenses for a range of indications, 36% reported routinely needing more than one attempt to correctly insert their lenses [797]. In a one-year prospective study of scleral lens wear success, there was a reduction in number of attempts to achieve successful insertion and removal over 1 year of follow-up in the 73% who were wearing lenses at one year [798]. In a study evaluating the long-term success of the PROSE medical device, difficulty with insertion/removal was a reason for discontinuation of wear in the first year of wear for 3% of patients (accounting for 12.5% of discontinued patients at 5 years) [241]. The most frequently reported difficulty during lens insertion in successful wearers was a trapped air bubble behind the lens [797]. The need to establish a good tear fluid reservoir without significant spillage of saline during insertion also presents challenges for some patients.

Scleral lenses can be inserted by hand or with the help of rubber devices such as plungers (ventilated and non-ventilated), scleral cups, or rings Which stabilise the lens during preparation and insertion [799,800]. As with storage cases, plungers should be cleaned and disinfected after each use [800]. Stands that hold the plunger are also available for patients with motor deficits. A no-touch technique for insertion of a BSCL using a sterile Minims dropperette has also been described [801].

10.2 Wearing time

Many patients wearing therapeutic lenses are dependent on them for functional vision and/or comfort. Because of this, patients may choose to wear them all waking hours, potentially increasing risk of complications.

Several large retrospective reviews indicate that many patients fitted with daily wear scleral lenses for long term use are able to successfully wear these for 12 to 16 hours (range 3 to 19 hours) [74,228,486,488,797,802]. A large retrospective

study found an average of 10 hours or more wearing time in 59% (n=538) of patients [488]. In line with these findings, 650 practitioners in the Scleral Lenses in Current Ophthalmic Evaluation survey reported recommending wearing of scleral lenses for approximately 12 hours (range 2 to 19) [802]. In one retrospective large case series, patients fitted with scleral lenses for indications related to dry eye disease showed a shorter median wearing time (14 hours versus 16 hours per day) than those fitted for other indications such as keratoconus or penetrating keratoplasty [797]. Similarly, those wearing scleral lenses for keraconus had better "success," defined as wear of more than 10 hours per day, than those fitted after PK or for other reasons (72% of patients versus 50%, respectively) [441].

Overnight wear is sometimes indicated for successful medical use of contact lenses because the symptoms or complications that occur during or following sleep may be as bad as or worse than during the day [285,324]. Therapeutic hydrogel or SiHy are routinely used on an overnight wear basis without removal, knowing that oxygen requirements of the cornea are met and that the need for removal and reinsertion of the contact lenses is minimised. As discussed above, overnight wear of scleral lenses is made difficult by the likelihood of clinically significant corneal oedema and unacceptable accumulation of debris in the post lens tear film developing. Nevertheless, instances where the specific indication (e.g. persistent corneal erosions, trichiasis) make overnight use of scleral lenses a reasonable option for ocular surface disease have been reported [148,285]. In such cases, daily removal for cleaning and replenishment of the tear reservoir is advised.

10.3 Disinfection regimen

Traditional rigid lens care products including multipurpose solutions are sometimes recommended, but there is concern that use of multipurpose solution in hydrophilic materials or in the scleral lens reservoir might increase the risk of toxicity to the ocular surface [803]. This would be particularly problematic in patients that use lenses on a therapeutic basis for ocular surface disease or those that are prone to allergic and hypersensitivity reactions such as individuals with keratoconus. Also

of concern is the fact that a substantial percentage of eyecare practitioners (38%) reported that they recommended tap water for rinsing of scleral lenses. This is of concern, because the use of tap water to rinse contact lenses, and tap water exposure, have been associated with an increased risk of *Acanthamoeba* keratitis [802,804,805] and increased risk of any MK or infiltrative event.

10.4 Compliance

Poor compliance has consistently been shown to increase the risk of complications in soft contact lens wearers using lenses for the correction of low refractive errors [806]. It has been suggested that patients fitted with medical contact lenses may be more diligent with compliance, as these patients often have careful ocular hygiene needs related to their underlying condition [777]. Nevertheless, noncompliance with eyedrop usage (3 of 8 patients) and extending wearing time past 30 days (2 of 8 patients) were reported in cases of MK in wearers of BSCLs [762]. In a large retrospective review of 97 patients fitted with scleral lenses, 23% of patients who were strongly recommended to use unpreserved saline solution to fill the scleral still opted for preserved saline to decrease expenses [441].

Good compliance is particularly important for scleral lenses because of their sealed fit; any contamination of scleral lenses may expose the eye for the duration of wear time, with little opportunity for replenishment or tear exchange behind the lens. Compliance in the setting of medical contact lenses can be complicated by the complexity of the management needs of the underlying conditions and the lens regimen prescribed. For example, patients may often have to instill multiple topical agents (e.g. lubricants, prophylactic antibiotics, etc.). Those with prescribed topical medications should be told to remove lenses for cleaning and disinfection, and for drop instillation as required, appreciating that drops applied over the surface of a scleral lens will not have access to the cornea and anterior chamber as they would over a hydrophilic soft contact lens. Poor compliance due to misunderstanding practitioner instructions has been reported in a case of MK in a wearer of scleral lenses for neurotrophic keratopathy [373].

10.5 Follow-up schedule

In a large retrospective review of 6,188 patients (6,385 eyes) fitted with SiHy contact lenses for a broad range of medical purposes with antibiotic prophylaxis at a Chinese University Hospital, weekly follow-ups were scheduled [762]. Infection was identified in eight patients (0.13%) and they reported that three were non-compliant with their eye drops and two prolonged wear past 30 days. The authors advised close follow-up attention, although it is not clear if this is to monitor for infection or reinforce good compliance with prescribed medications and wear and care regimen. When contact lenses were used for the management of symptomatic filamentary keratitis in the setting of adenoviral keratoconjunctivitis (infection), follow ups were scheduled next day and every 3 days thereafter for as long as the therapeutic lens was in place [321].

When medical contact lenses are considered for use on an overnight wear schedule, patient education and follow-up are critical. The risk for the development of MK, possible perforation and vision loss should be explicitly discussed and patients should be advised to return immediately for early signs of infection.

With medical use of scleral lenses, follow-up visits should be scheduled after at least 5 to 6 hours of wear as it is important to assess the lens fit following complete lens settling and to examine the ocular physiology at maximum wear time.

10.6 Patient experience of medical use of contact lenses

In a retrospective review of 49 patients fitted with scleral lenses, 92% of patients reported improvement in their QOL related to daily activities such as reading, driving, watching television and working [74]. In a large retrospective study, 178 patients fitted with scleral lenses for a range of indications were on average satisfied with their correction (mean 4.3 on a 1 to 5 overall satisfaction scale). Ninety nine percent of wearers described their satisfaction as average or above with only 1% of wearers ranking it as very poor or poor [797]. There is evidence of

improvement in QOL measured with the NEI VFQ-25 when PROSE type medical contact lenses were worn across all diagnoses and in a study of scleral lenses in patients with Steven Johnson syndrome [77,278]. These studies found improved quality of life measured at 6 months. A related study by Shepard et al. found that the PROSE device was cost-effective and cost beneficial [807]. There was a sustained similar level of improvement in visual function at 5-years in a second PROSE cohort [241]. The change in NEI VFQ-25 score in this cohort was +19 points with 8-10 points generally considered to be clinically significant. Dramatic improvements in activities of daily living facilitated by use of medical lenses include the ability to drive once again [373].

In a case series of three patients with epidermolysis bullosa treated with overnight wear BSCLs, the families of two patients who experienced a severe complication secondary to medical contact lens usage (i.e. MK) stated without hesitation that "their child's QOL was substantially improved with BSCLs, and that the risk of vision loss from infection was outweighed by the significant improvement in perceived quality of life" [748].

11 Summary

The medical use of contact lenses is well documented from initial reports of contact lenses in the late 19th century to the 21st century. The development of rigid gas permeable materials improved physiologic compatibility for the management of ectasia and astigmatism, aphakia, and high refractive error with corneal lenses. Further advances in materials and manufacturing have allowed for the use of scleral lenses in the management of these conditions and in the management of ocular surface disease. Meanwhile, soft contact lenses were recognised early for their potential as bandage lenses, relieving symptoms and promoting healing; they are used in this capacity to this day. Contact lenses are not simply cosmetic alternative to spectacles. They play an important role in the management of disease, particularly for less common conditions for which there are no good medical or surgical options. All eye care providers: ophthalmologists, optometrists,

orthoptists and opticians alike, should be aware of advances in the medical use of contact lenses. Although this work aims to be an exhaustive review of the evidence in literature regarding the medical use of contact lenses, it is likely that much information, such as complications, are under reported. Continued investigation and innovation to increase awareness and utilisation as well as to reduce complications is warranted.

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