Review Article

Scleral lenses and PROSE: indications, complications, and future challenges

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ABSTRACT

Background: Scleral lenses (SLs) and prosthetic replacement of the ocular surface environment (PROSE) are the same device, designed to enhance the optical quality of irregular surfaces or ectatic corneas. They also improve the corneal surface epithelium and the ocular surface microenvironment for patients with severe ocular surface diseases, including dry eye. This review aims to provide a comprehensive overview of the indications for SL/PROSE, as well as an exhaustive analysis of the corresponding complications, their possible remedies, and future challenges in this rapidly evolving field of ophthalmology.

Methods: We conducted a review of the English language literature on the indications and complications of SL/PROSE devices using the following website search engines: National Library of Medicine's PubMed, Google Scholar, EMBASE, Web of Science, and Scopus for articles in English published from inception up to July 2025. The following scientific reports were considered for analysis: systematic reviews and meta-analyses, randomized controlled trials, cohort studies, case-control series, case reports, editorials, and short communications.

Results: Research and development in SL/PROSE have made significant strides, broadening its applications, improving structural materials and designs, and adapting it to benefit a diverse range of patients facing numerous pathologies. These include keratoconus, post-refractive surgery ectasia, corneal transplantation, severe dry eye, and chronic cicatrizing ocular surface disorders, among many others. For patients suffering from these emerging pathologies, apart from medical therapy and surgical procedures there are limited treatment options. Currently, SL/PROSE offer a less invasive potential solution for many of these challenging conditions, raising hope and motivation within the field of corneal and ocular surface disease. However, they are not without potential complications, which differ significantly from those associated with soft contact lenses and rigid gas-permeable contact lenses. The most frequently reported SL/PROSE complications relate to improper lens adaptation and patients' handling.

Conclusions: While much of the existing literature has focused on the benefits and applications of SL/PROSE devices, the potential complications associated with their use have received less attention and aren't as widely explored.

KEYWORDS

sclera, contact lens, contact lens solution, extended-wear contact lenses, PROSE, sequelae, rigid contact lenses, hydrophilic contact lenses

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INTRODUCTION

The first documented attempt to correct ocular optical imperfections and treat ocular conditions using a scleral contact lens, commonly referred to as a "shell," dates back to 1887. This innovative approach was introduced by Friedrich A. and Albert C. Muller, who created a glass shell for a patient who had undergone eyelid removal due to cancer [1]. Significant advancement in scleral lenses (SLs) is observed since 1983, following the introduction of gas-permeable polymers made of silicone hydrogels, whose high oxygen permeability and resistance make them suitable for extended wear, and fluorosilicone acrylates, which combine the oxygen-permeability of silicone with the wettability and deposit resistance of fluorinated monomers, resulting in improved comfort and vision. Among the most popular materials are Hexafocon-A (Boston XO) and Hexafocon-B (Boston XO2) [2, 3].

Since then, research and development in this field have transformed patient care for visual rehabilitation, particularly in complex cases where traditional glasses or soft contact lenses (SCLs) are ineffective [2]. SLs have also proven essential in treating severe ocular surface disorders, especially those associated with extreme dryness and various conditions that result in irregular or scarred corneal surfaces. This application is often referred to as the prosthetic replacement of the ocular surface ecosystem (PROSE) [4, 5].

Additionally, SLs have transformed the management of visual rehabilitation for common corneal conditions such as keratoconus, ectasia following photorefractive keratectomy (PRK) or laser in situ keratomileusis (LASIK) surgery, irregular astigmatism, and paracentral or peripheral leukomas that exhibit scarring and surface irregularities due to various infections (e.g., herpetic stromal keratitis) and inflammatory ocular surface disorders (e.g., Stevens-Johnson syndrome) [3, 6–8]. Due to their application, many high-risk corneal procedures, including deep anterior lamellar keratoplasty and penetrating keratoplasty, are avoided in favor of a less invasive and less risky remedy [9–12].

The complications associated with contact lenses can vary significantly based on risk factors such as lens material and design, as well as patients' handling and hygiene practices. SCLs are more susceptible to frequent and severe ocular surface complications which may include infectious keratitis, giant papillary conjunctivitis, peripheral corneal vascularization, and dry eye [13–15]. SLs and PROSE devices are associated in the literature with fewer and less severe complications compared to SCLs. For example, daily overwear of SLs may lead to symptoms like perilimbal redness, ciliary injection, and discomfort [7, 16]. These issues are much less severe than the complications associated with SCLs, which can include perilimbal pannus or vascularization, as well as peripheral nummular sterile or infectious infiltrates accompanied by epithelial defects due to overuse-related hypoxia [17, 18]. There are preventive measures and therapeutic alternatives to address these issues [19, 20].

The adaptation and use of SLs and PROSE devices are not exempt of certain limitations and potential complications. This review aims to present an overview of the most common and significant complications associated with the adaptation of these devices, depending on their intended use, fitting process, and wear habits. Additionally, we offer preventive measures and therapeutic alternatives to address these issues.

METHODS

We searched the National Library of Medicine's PubMed/MEDLINE, Google Scholar, EMBASE, Web of Science, and Scopus databases for articles in English published from inception up to July 2025. All types of scientific reports were considered for analysis, including systematic reviews and meta-analyses, randomized controlled trials (RCTs), cohort studies, case-control series, case reports, editorials, and short communications. Search terms used included "scleral contact lens," "prosthetic replacement of the ocular surface ecosystem," "PROSE," "scleral contact lens complications," "scleral lens fitting," "scleral lens wear," "lens vault," "scleral zone". Abstracts were screened for relevance, and references were cross-checked for relevant publications.

RESULTS and DISCUSSION

1. Terminology

1.1. Scleral Lenses

SLs are large-diameter (14.5 mm–24.0 mm), rigid (silicon acrylate, fluorosilicone acrylate, and polymethyl methacrylate), gas-permeable contact lenses that are designed to vault over the cornea, creating a space between the lens and the cornea (fluid reservoir) to finally rest on the perilimbal sclera. Their design permits the optical correction of multi-curve irregular corneas (ectasia) and other surface irregularities [21, 22]. Due to their design, SLs provide improved comfort by not touching the cornea, thanks to a moisture chamber effect that allows for sharp and clear vision related to its

regular anterior curvature and fluid-filled space between the lens and the anterior irregular cornea. Additionally, SLs offer excellent stability because of their large diameter and the vacuum created when they are applied [22].

1.2. Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE)

PROSE device refers to an SL that serves both optical and therapeutic purposes [23]. Although it provides visual benefits, its primary function is to treat severe dry eye and various ocular surface disorders such as Sjogren's syndrome, graft-versus-host disease (GvHD), Stevens-Johnson syndrome (SJS), ocular mucous membrane pemphigoid (OMMP), and neurotropic keratopathy (NK) by creating a barrier between the cornea and the external environment and by protecting the ocular surface from friction and rubbing caused by the eyelid [24–26]. The high-humidity and wetting environment provided creates a stable moisture chamber that allows the corneal epithelium to repair and heal effectively [27, 28]. Today, the PROSE device has become an essential resource in the interventional management of many severe ocular surface disorders [25, 28, 29].

2. Benefits and Disadvantages of SL/PROSE Applications

2.1. Benefits

There are significant optical and corneal epithelial healing benefits associated with the use of SL/PROSE devices. From an optical and visual perspective, SLs provide nearly perfect and stable vision, effectively correcting visual distortions, overlapping images, glare, and dazzle—issues often caused by keratoconus and an irregular corneal surface [10, 11]. As mentioned, SLs have transformed the visual rehabilitation approach for advanced keratoconus, other corneal ectasias, and irregular astigmatism. They help reduce or eliminate the need for partial or total corneal transplantation, along with the associated risks and postoperative care required to achieve successful visual outcomes [12, 21, 30].

In terms of epithelial healing and restoring the ocular surface, PROSE devices can relieve severe dry eye and repair epithelial defects, ulcerations, and degenerative or scarred changes on the corneal surface. This makes PROSE one of the most popular and effective therapeutic options for conditions such as GvHD, severe Sjogren's syndrome, and SJS/toxic epidermal necrolysis (TEN) syndrome, among many severe ocular surface diseases [24, 26, 31, 32].

2.2. Disadvantages

In contrast, SL/PROSE devices are expensive and may not be affordable for certain patients. Additionally, they are not always covered by insurance, particularly when applied as an optical correction device; this makes them unavailable for a large population that needs them [1, 2]. On the other hand, children, the elderly, and physically disabled patients may not be capable of applying them if they are unable to handle the lenses properly. Finally, their adaptation requires an expert and experienced contact lens specialist, which is not always available everywhere; the procedure is time-consuming and requires patience, endurance, and a strong will to succeed [6, 7, 13].

3. Indications for SL/PROSE

3.1. Visual Rehabilitation Indications:

3.1.1 Primary Visual Rehabilitation

SLs have been used since their introduction as a primary method for visual rehabilitation in patients with high refractive errors, especially in cases involving significant irregular astigmatism [1, 33]. Irregular astigmatism presents a considerable challenge for correction using spectacles or conventional SCLs, often requiring advanced visual rehabilitation techniques like SLs. By resting on the surface of the cornea and creating a smooth, regular anterior optical interface through a fluid reservoir, SLs effectively compensate for corneal irregularities (Table 1). This design offers superior visual correction compared to SCLs or standard rigid gas permeable contact lenses (RGP-CLs), resulting in significantly improved visual acuity and increased patient comfort [1]. However, the application of SLs in healthy individuals requires further investigation.

3.1.2. Difficulty Wearing Alternative Contact Lenses

The use of traditional contact lenses in patients with irregular astigmatism and underlying ocular surface diseases often presents challenges such as discomfort, poor tolerance, and dissatisfaction due to inadequate visual outcomes. In such cases, SLs offer a valuable alternative, providing better visual correction while significantly enhancing lens comfort and protecting the ocular surface [34]. SLs can be effectively fitted for patients who cannot tolerate traditional SCLs or RGP-CLs due to issues like poor lens stability, discomfort, or insufficient optical correction. They offer improved comfort and visual rehabilitation [2]. SLs are successfully used by individuals participating in water sports, where wearing traditional contact lenses is not advisable due to the higher risks of lens displacement and microbial contamination. SLs

provide enhanced stability and create a sealed fluid reservoir, thus offering more reliable vision correction and improved ocular safety in aquatic environments [2].

3.1.3 Corneal Ectatic Disorders

3.1.3.1 Keratoconus

Keratoconus is the most common primary ectatic disorder of the cornea. It is characterized as a bilateral and asymmetric disease that leads to progressive thinning and steepening of the cornea. These changes result in irregular astigmatism and a decline in visual acuity. The Global Consensus on Keratoconus and Ectatic Diseases recommends the use of SLs for visual rehabilitation in patients with keratoconus who do not achieve satisfactory vision with spectacles or SCLs (Table 1). Keratoconus consistently emerges in the literature as the most common indication for SL fitting [35]. Early studies, such as Pullum et al., identified keratoconus as the predominant diagnosis in patient cohorts using SLs [36]. More recent data confirm a rising trend in SL prescriptions over the past two decades, with keratoconus remaining the leading indication, especially among younger patients [37]. Additionally, keratoconus represents the largest single indication for SL use across published reports [1].

Keratoconus causes abnormal corneal curvature, making traditional contact lens fitting challenging. SLs are proven to be more effective because they can vault over the irregular surface of the cornea, providing a customizable fit that other lens types cannot offer [9, 10]. While treatments like corneal cross-linking aim to enhance corneal biomechanics, visual rehabilitation often starts with traditional RGP-CLs. In more advanced keratoconus cases, SLs are preferred due to their superior comfort, stability, and ability to improve vision by compensating for corneal irregularities [1].

SLs play a vital role in the visual rehabilitation of patients with keratoconus. In an initial study by Schornack and Patel, 52 eyes diagnosed with keratoconus were fitted with SLs, resulting in a significant increase in visual acuity from a mean of 20/40 to 20/20 after lens fitting [38]. Carracedo et al. showed a statistically significant improvement in best-corrected visual acuity (BCVA), visual comfort, and high-contrast sensitivity following the use of SLs [39]. Hadimani et al. reported similar positive outcomes in a cohort of 28 eyes fitted with SLs, with a significant increase in visual acuity from a mean of 0.47 logarithm of the minimum angle of resolution (logMAR) to 0.03 logMAR, along with notable improvements in National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) quality of life scores [40].

Table 1. Ophthalmic indications for scleral lenses and prosthetic replacement of the ocular surface environment devices

SL [3, 10, 12, 37, 42, 44, 53, 56, 61, 70, 71, 77]	**PROSE** [5, 6, 24, 26, 28, 62, 63, 66, 69, 70]
Primary Visual Rehabilitation	**Corneal Scarring**
Difficulty Wearing Traditional Contact Lenses	**Ocular Trauma**
Cornea Ectatic Diseases	Direct Ocular Trauma
Keratoconus	Chemical Burns
Pellucid Marginal Degeneration	**Ocular Surface Protection and Restoration**
Pellucid Marginal Degeneration	Persistent Epithelial Defect
Post Refractive Surgery Ectasia	Keratoprostesis Protection
Keratoglobus	Corneal Neovascularization
Corneal Dystrophies	**Ocular Surface Disease**
Post Surgical Visual Rehabilitation	Severe Dry Eye Disease
Post Refractive Surgery	Keratoconjuntivitis Sicca
Post Corneal Collagen Cross Linking	Atopic Keratoconjuntivitis
Post Radial Keratotomy	Vernal Keratoconjuntivitis
Corneal Transplantation	Stevens-Johnson Syndrome
Astigmatism Management	Ocular Graft-vs-Host Disease
Aphakia	Sjogren Syndrome
Dry Eye Disease	Ocular Cicatricial Pemphigoid
	Neurotrophic Keratopathy
	Recurrent Corneal Erosions
	Limbal Stem Cell Deficiency
	Keratitis-Ichtosys-Deafness Syndrome
	Pain Management
	Neuropathic Corneal Pain

Abbreviations: PROSE, prosthetic replacement of the ocular surface environment; SL, scleral contact lens.

Historically, corneal transplantation, including lamellar procedures, was often necessary for patients with advanced keratoconus who could not achieve satisfactory visual acuity with conservative treatments. However, the introduction and increased use of corneal cross-linking (CXL) and specialty SLs for visual rehabilitation have shifted the focus toward more conservative, non-surgical management approaches [30]. In a retrospective cohort analysis involving 2806 eyes, Ling et al. found that the use of SLs, particularly RGP-CLs, significantly reduced the risk of requiring keratoplasty, showing a hazard ratio of 0.19 when compared to patients who did not use contact lenses [41]. Similarly, Koppen et al. successfully managed 51 patients with advanced keratoconus using SLs, avoiding corneal transplantation in 40 of those cases. This demonstrates the effectiveness of SLs in providing long-term visual rehabilitation and delaying the need for surgical intervention for most patients [30].

SLs provide an effective method for visual rehabilitation by vaulting over the cornea. They offer a customizable fit that enhances both comfort and vision, particularly in advanced stages of eye disease. Clinical studies consistently show significant improvements in visual acuity and quality of life for individuals who wear them [3].

3.1.3.2. Pellucid Marginal Degeneration

Pellucid marginal degeneration (PMD) is a bilateral, non-inflammatory condition characterized by thinning of the inferior cornea. Contact lenses are essential for visual rehabilitation in patients with PMD. After fitting 19 patients with PMD using SL/PROSE, Rathi et al. reported an improvement of more than two lines in visual acuity [11]. Similarly, Asena et al. reported on 24 eyes with PMD fitted with SLs ranging 16.5–17 mm in diameter, noting that three patients ultimately stopped using the lenses due to intolerance [42].

3.1.3.3 Post-Refractive Surgery Ectasia

Refractive surgery has made significant advancements over the past few decades, particularly in terms of techniques, equipment, and screening methods to identify suitable candidates for the procedure. However, despite improvements in parameters and safety measures it is still possible to develop ectasia following refractive surgery [2, 34]. SLs are recommended for treating residual refractive errors or secondary ectasia that may arise after refractive surgery (Table 1). These lenses provide several benefits due to changes in corneal biomechanics and anatomy. Most notably, because SLs do not come into contact with the corneal surface, they offer increased safety by reducing the risk of complications such as flap dislocation or corneal warpage. Additionally, SLs can be designed in various geometrical shapes, which can help accommodate changes in corneal shape resulting from refractive surgery [1].

Dry eye disease (DED) is a common issue following refractive surgery due to changes in the corneal subbasal nerve plexus, which can lead to dry eyes and reduced corneal sensitivity [43]. The inherent protective design of SLs along with their ability to hold a reservoir of fluid provide an effective therapeutic option for managing dry eye symptoms after such surgeries. In a retrospective case series, Marty et al. fitted 35 eyes post-refractive surgery with SLs and observed significant improvement in BCVA, with a mean change from 0.33 to 0.08 logMAR [44]. Patients experienced notable reductions in their Ocular Surface Disease Index (OSDI) scores, indicating symptomatic relief. Objective assessments of corneal aberrations showed marked improvements in the objective scatter index and higher-order aberrations, highlighting the multifaceted benefits of SLs in this context [44].

3.1.3.4 Keratoglobus

Keratoglobus is characterized for being a bilateral ectatic disorder with protrusion of the cornea and diffuse thinning [33]. In a small case series, four patients with keratoglobus were fitted with SLs, resulting in variable outcomes, including one case of acute corneal hydrops [33, 45].

3.1.4 Corneal Dystrophies

Corneal dystrophies are a group of inherited, bilateral diseases that typically progress over time. These conditions often lead to accumulation of material in various layers of the cornea. Their classification is usually based on the depth within the cornea, and they can produce a wide range of symptoms depending on their presentation [46]. SLs are used in the management of corneal dystrophies to address issues such as corneal opacification and recurrent epithelial erosions, which are commonly associated with anterior corneal dystrophies. In a case series by Pullum et al., patients with lattice corneal dystrophy successfully fitted with SLs demonstrated improved visual function and better symptom control [47]. Similarly, Visser et al. reported positive outcomes in patients with corneal dystrophy, noting improvements in visual acuity and patient satisfaction [48]. Contact lenses have been effectively utilized in treating recurrent corneal erosion (RCE) stemming from epithelial dystrophies [49].

3.2 Post-Surgical Visual Rehabilitation

3.2.1 Post-Corneal Refractive Surgery

SLs are typically used to manage post-corneal refractive surgery ectasia, but they can also benefit patients who have residual refractive error or experience prolonged healing of the corneal surface after these procedures [1]. Since refractive surgery often leads to DED, SL/PROSE can offer extra therapeutic advantages by protecting the ocular surface, promoting the healing of the epithelium, and relieving dry eye symptoms [1].

3.2.2 Post-Corneal Collagen Cross-linking (CXL)

CXL is commonly recommended for managing keratoconus, as it helps halt disease progression by improving the biomechanical stability of the cornea. This is achieved by strengthening the bonds between collagen fibrils [35]. The procedure typically involves removal of the corneal epithelium to allow better penetration of riboflavin into the corneal stroma before activating it with UV light [50].

During the healing phase of the epithelium, patients may experience temporary visual distortions. This phenomenon can also occur, albeit to a lesser degree, in patients who undergo transepithelial (epithelium-sparing) CXL techniques. In a prospective study, Visser et al. [51] assessed patients who wore SLs before and after the CXL procedure. They found that while there were no significant changes in visual acuity or daily wear time of the lenses before and after the procedure, 61% of the eyes required adjustments to the fit of the contact lenses due to post-procedure changes in corneal biomechanics and shape [1, 51].

3.2.3 Post-Radial Keratotomy (RK) and Incisional Refractive Surgery

RK is a surgical procedure designed to correct myopia by creating radial incisions in the cornea, which helps flatten its central curvature [52]. This method was developed before the introduction of laser-based refractive procedures and has largely been replaced by these more precise and predictable techniques. While RK typically yielded good short-term results, it was often associated with long-term complications such as vision fluctuations, hypermetropic shifts, induced irregular astigmatism, and weakening of the cornea [52].

SLs have been used to enhance visual acuity in patients who have undergone RK (Table 1). Due to the irregularities in their corneal surfaces, traditional contact lenses and glasses may not effectively improve vision for these patients. SLs have emerged as a viable option for addressing the irregular astigmatism often seen after RK [3]. In a case series involving 23 patients successfully fitted with SLs, it was found that the best corrected contact lens vision was significantly better than their best spectacle-corrected vision. This demonstrates that SLs can be an effective solution for treating irregular astigmatism resulting from RK [53].

3.2.4 Corneal Transplantation

Corneal transplantation is a crucial surgical procedure for treating diseased or scarred corneas. Over the past few decades, the technique has significantly advanced with the development of lamellar transplantation and, more recently, femtosecond-assisted corneal transplantation. However, visual rehabilitation remains a challenge in the postsurgical care of these patients [3, 54]. Suturing of corneal grafts often leads to notable astigmatism due to altered corneal curvature, which can delay visual recovery and negatively impact visual outcomes for months after surgery [3, 55]. Additionally, abnormalities in corneal curvature can complicate contact lens fitting, resulting in issues such as poor fit, ejection, and decentration. Typically, SLs are fitted after the removal of sutures is complete, although early fitting can still be attempted with remaining sutures [56].

SLs have shown significant improvements in visual rehabilitation for patients who have undergone corneal transplantation, regardless of the surgical technique used—be it penetrating keratoplasty or lamellar transplantation methods like Descemet membrane endothelial keratoplasty or deep anterior lamellar keratoplasty [56] (Table 1). Severinsky et al. found that 82% of eyes fitted with SLs achieved a visual acuity of 0.5 logMAR (equivalent to 20/63) or better after keratoplasty [57]. Similarly, Barnett et al. reported that among 48 eyes fitted with SLs following penetrating keratoplasty, 91.7% achieved functional vision of 20/40 or better [58]. These findings emphasize the effectiveness of SLs in visual rehabilitation post-corneal transplantation [57, 58].

While corneal transplantation is a fundamental procedure for treating some diseased corneas, postoperative visual rehabilitation can often be adversely affected by induced astigmatism and changes in corneal curvature. However, SLs have proven to be effective in enhancing visual outcomes across various transplant techniques, providing significant improvements in visual acuity that contribute to better patient recovery and an improved quality of life [55–58].

3.2.5 Management of High or Irregular Astigmatism

Astigmatism is typically the most prevalent cause of reduced visual acuity following penetrating keratoplasty, and often persists even after sutures are removed [59]. Irregular astigmatism is the primary reason for fitting SLs in patients who have undergone corneal transplantation, followed by increased graft toricity, which is often described as more than 5

diopters after the procedure [57]. A retrospective case series conducted by Rocha et al. demonstrated the effectiveness of mini SLs in managing post-transplant patients. In this cohort, 40.7% of eyes exhibited irregular astigmatism, while 37% had high astigmatism exceeding 5 diopters. After fitting with SLs, patients experienced significant visual improvement, with 96.3% of eyes achieving a contact lens-corrected visual acuity of ≥ 0.3 logMAR [59].

3.2.6 Aphakia Correction

SLs have been used effectively for visual rehabilitation in patients with aphakia to manage the high refractive errors commonly associated with this condition [60]. Several case reports have documented successful outcomes in correcting aphakia using SLs. While other contact lens options are often preferred for managing aphakia, SLs have proven to be an effective alternative, providing adequate visual rehabilitation for select patients [36]. Additionally, SLs are utilized for correcting aphakia in pediatric patients following congenital cataract surgery. A retrospective study showed that around 76% of children fitted with SLs achieved a visual acuity of 20/40 or better, although the overall visual outcomes were influenced by a prevalence of strabismus and amblyopia [61].

4. PROSE Device Indications

4.1.1 Corneal Scarring

Corneal scarring can result from various causes, including trauma, infections, and iatrogenic factors. This scarring leads to tissue loss and fibrotic remodeling, which often result in irregularities on the corneal surface, irregular astigmatism, and opacification of the visual axis. Such corneal pathologic responses can significantly impair visual acuity [1]. Although SLs are highly effective in regularizing the altered corneal surface and neutralizing irregular astigmatism, challenges remain in addressing visual axis opacification, which can hinder optimal visual rehabilitation [1].

In a case series involving four patients with corneal opacification, Cressey et al. reported substantial visual improvement following the use of PROSE, including two pediatric cases [62]. Despite the significant corneal opacity, all patients showed notable gains in visual acuity after starting PROSE therapy [62]. A case series by Liao et al. demonstrated the beneficial effects of PROSE in patients with corneal opacifications and scarring resulting from SJS [63]. Both patients in this series experienced significant visual improvements and partial clearing of corneal opacification after using PROSE [63]. These findings highlight the potential of PROSE to enhance visual rehabilitation for patients suffering from corneal scarring and opacities by providing a stable and regularized optical surface [62, 63] (Table 1).

4.2. Ocular Trauma

4.2.1 Direct Ocular Trauma

Ocular trauma can result in chronic changes to the corneal surface, conjunctiva, and intraocular structures. The severity and nature of the resulting conditions depend on the mechanism and extent of the injury. Such traumatic events often lead to persistent epithelial defects (PEDs), corneal scarring, irregular astigmatism, and surface irregularities, all of which can significantly impair visual function and the stability of the ocular surface [64].

While SLs are not typically the first-line treatment for managing acute ocular trauma, they have proven to be valuable during the rehabilitation phase, particularly for visual restoration and the treatment of PEDs. The liquid reservoir provided by SL/PROSE devices acts as a fluid bandage, protecting the corneal surface from mechanical trauma caused by eyelids, reducing evaporative loss, and promoting epithelial healing [64–67].

4.2.2. Chemical Burns

Chemical burns from both acid and alkaline sources can cause severe damage to the ocular surface, leading to PEDs, significant inflammation, and limbal stem cell deficiency (LSCD) [68]. In the chronic phase, SLs have proven to be valuable therapeutic tools for managing chemical burns, especially in cases complicated by PEDs and eyelid abnormalities [69]. By creating a stable tear reservoir, they protect the ocular surface, reduce evaporative loss, and promote epithelial healing. They also enhance visual function in patients with corneal irregularities and scarring. Their use can alleviate debilitating symptoms like pain and photophobia, and may help delay or reduce the necessity for surgical intervention in selected cases [66, 69].

4.3 Ocular Surface Protection and Restoration

4.3.1 Persistent Epithelial Defects (PEDs)

A corneal epithelial defect is classified as persistent when it does not heal within two weeks, despite receiving appropriate conventional medical treatment. These defects are often secondary to severe ocular surface diseases and are typically associated with some degree of LSCD [70]. PEDs most commonly occur in the context of underlying conditions such as ocular GvHD, SJS, the aftermath of chemical burns, and neurotrophic keratopathy. These conditions disrupt the

normal regenerative capacity of the corneal epithelium, leading to impaired healing [6].

The PROSE device has been used as a therapeutic option for PED (Table 1). It promotes healing by protecting the corneal epithelium, maintaining lubrication through its fluid reservoir, and providing high oxygen permeability. This creates an optimal environment for epithelial regeneration while ensuring ocular surface stability and patient comfort [70]. Additionally, PROSE can serve as an effective mechanism for drug delivery to aid in the resolution of the epithelial defect [71]. Lim et al. used overnight PROSE wear in combination with prophylactic fluoroquinolone therapy to treat 20 eyes with PED resulting from severe ocular surface disease. Epithelial closure was achieved in 85% of the eyes, with most demonstrating complete re-epithelialization within seven days of fitting [32].

Rosenthal et al. [72] examined the use of SLs for treating PED that was resistant to autologous serum, amniotic membrane grafts, and tarsorrhaphy. This approach involved using prophylactic antibiotics and corticosteroids within the fluid reservoir during SL wear. Despite these precautions, microbial keratitis developed in 4 out of 14 eyes, highlighting the potential infectious risks associated with extended use of SLs in this vulnerable patient population [72]. Overall, SL/PROSE devices are valuable therapeutic options for managing PED resistance to conventional medical treatments. They offer mechanical protection and a stable lubricating environment, plus promote epithelial healing in eyes with severe ocular surface disease.

4.3.2 Keratoprosthesis Protection

Artificial keratoprosthesis (KPro) is a synthetic corneal implant designed to restore vision in patients who are not suitable candidates for corneal transplantation, often due to severe ocular surface disease. The PROSE device has been used as a protective measure for patients with Boston KPro type 1, helping to manage the underlying ocular surface environment and improve outcomes. In a retrospective case series, Asghari et al. fitted four patients with Boston KPro type 1 using PROSE devices, which demonstrated the potential benefits of this approach in protecting and rehabilitating the ocular surface [73]. Patients with underlying ocular surface disease who had previously struggled to tolerate bandage SCLs reported significantly improved comfort and wearability after being fitted with PROSE. Furthermore, the use of PROSE led to notable improvements in visual acuity compared to their prior experiences with bandage soft lenses [73].

4.3.3 Corneal Neovascularization Treatment

Corneal vascularization is a common anomalous pathway of corneal repair shared by many severe corneal and ocular surface diseases. This pathological change can lead to opacification and a reduction in corneal transparency, which alters the structure of the epithelium and can ultimately result in significant vision impairment, especially when the visual axis is affected [74]. Various therapeutic strategies have been utilized to combat severe corneal neovascularization, one of which involves the PROSE device as a sustained antiangiogenic drug delivery system for the ocular surface [75, 76]. A retrospective case series of 13 patients with corneal neovascularization caused by different ocular surface disorders, such as SJS and ocular GvHD, found that 92% of cases exhibited regression of corneal neovascularization. Additionally, 77% of these patients experienced significant improvement in visual acuity after receiving bevacizumab treatment for a median duration of six months while under a PROSE vault [5].

4.4 Ocular Surface Disease

4.4.1 Severe Dry Eye Disease (DED) / Keratoconjunctivitis Sicca (KCS)

DED is one of the most common ophthalmologic complaints worldwide. Severe dry eye is a chronic condition that affects individuals of all ages and can significantly impair quality of life due to persistent discomfort, visual disturbances, and damage to the ocular surface [71]. It is uncommon to fit patients with SLs for DED when their cornea and ocular surface are otherwise healthy, yet usage of SLs is increasing because of the benefits they offer. Their inert shape can protect the cornea from external factors, help prevent desiccation, and mitigate the mechanical effects of blinking [71, 77] (Table 1). A retrospective study found that nonspecific DED was the leading reason for fitting SLs among patients with ocular surface disorders, following a thorough evaluation by a cornea specialist. Most of these patients reported rapid and significant relief from symptoms soon after being fitted with the lenses, demonstrating the effectiveness of SLs in managing ocular surface discomfort [78]. In another study, 41 eyes from patients with moderate-to-severe DED and poor responsiveness to medical treatments were fitted with SLs. Significant reductions in tear hyperosmolarity and improvements in OSDI scores were observed at 6 and 12 months of SL use, with no statistically significant changes in tear break-up time, Schirmer test results, meibomian gland dysfunction, or other ocular surface parameters [79]. However, while SLs can effectively manage the symptoms of dryness, they do not address the underlying causes of DED [77].

4.4.2 Atopic Keratoconjunctivitis (AKC) and Vernal Keratoconjunctivitis (VKC)

AKC and VKC are bilateral and chronic allergic conditions that affect the ocular surface. If left untreated, these conditions can lead to severe visual impairment and long-term changes to the ocular surface. Use of SCLs for managing four eyes with AKC showed significant improvements in ocular discomfort, including better pain control, reduced photophobia, and enhanced visual acuity [33, 67]. Subsequent studies using RGP-CLs in advanced cases of AKC also indicated improvements in visual acuity, hyperemia, chemosis, and a reduction in epithelial defects [80]. Although the role of SL in treating VKC has not been extensively studied, there are previous cases where SL was used to manage four patients with VKC and associated keratoconus. In those instances, patients noted improvements in vision with no reported side effects [33, 81].

4.4.3. Stevens-Johnson Syndrome (SJS)

SJS is a severe hypersensitivity reaction, mostly triggered by medications, that affects the skin and mucous membranes. On the ocular surface, SJS leads to significant inflammation and progressive scarring of the conjunctiva, resulting in considerable morbidity [26]. Chronic changes that follow can result in severe dry eye and LSCD, which can further damage the ocular surface and impede corneal healing. Additionally, long-term alterations of the eyelids, such as keratinization of the lid margin, may result in lid-wiper epitheliopathy. Other complications, including trichiasis and cicatricial entropion, contribute to corneal injury and worsen ocular surface instability [71]. The inert material used in SL/PROSE devices, along with their fluid reservoirs, has proven effective for managing ocular SJS (Table 1). Furthermore, the use of SLs in SJS is consistently recommended in various comprehensive disease overviews and treatment guidelines [1].

PROSE devices can aid in the healing of the ocular surface while also protecting against mechanical trauma caused by eyelid abnormalities. PROSE likewise improves visual function in patients with severe ocular surface disease by masking corneal irregularities and maintaining a stable refractive surface [69]. In a retrospective study of patients fitted with PROSE, all participants showed significant improvements in visual acuity after using the device; there was also a marked reduction in OSDI scores following the fitting of PROSE, indicating substantial symptomatic relief and an enhanced quality of life [26]. DED is a common complication in patients with SJS, often leading to chronic discomfort and visual impairment. The use of PROSE has proven effective in alleviating DED symptoms in patients with SJS by improving ocular surface lubrication, reducing exposure-related damage, and enhancing visual function [82]. However, fitting and removing PROSE lenses in patients with SJS can still present challenges due to changes in the eyelids.

4.4.4 Ocular Graft-vs-Host Disease (GvHD)

Ocular GvHD affects patients who have undergone allogeneic hematopoietic stem cell transplantation. In this condition, the donor's immune system reacts against the recipient's tissues, causing inflammation, fibrosis, and ocular surface disease. Evidence suggests that the use of SL/PROSE devices can effectively manage chronic GvHD. Multiple case series have shown significant improvements in patient-reported outcomes, including OSDI scores, vision-related quality of life questionnaires, and Visual Functioning Questionnaire scores after fitting with SLs [24, 83–86]. Using PROSE in cases of GvHD is particularly beneficial for managing the underlying LSCD. It helps relieve the signs and symptoms of epithelial injury and severe dry eye while also enhancing visual acuity. By providing a stable, lubricating environment, PROSE protects the compromised ocular surface and promotes epithelial healing [25, 33].

4.4.5 Sjogren's Syndrome

Sjogren's syndrome is a multi-systemic autoimmune disease characterized by the infiltration of lymphocytes into the salivary and lacrimal glands, leading to reduced production of saliva and tears. Ocular involvement typically presents as severe aqueous-deficient dry eye, causing persistent discomfort and damage to the ocular surface. SL/PROSE devices have been utilized in managing Sjogren's syndrome, particularly for addressing the severe dry eye symptoms. These options provide a stable, lubricated environment that protects the ocular surface and enhances patient comfort [71]. Current guidelines recommend the use of SLs in managing Sjogren's-related dry eye in patients with moderate-to-severe symptoms. This is due to the lenses' capacity to maintain a continuous aqueous reservoir while avoiding direct contact with the corneal surface. This design offers adequate lubrication and protection for the compromised ocular surface, ultimately improving comfort and visual function [87].

4.4.6 Ocular Mucous Membrane Pemphigoid (OMMP)

OMMP is a relatively rare autoimmune bullous mucocutaneous disorder characterized by chronic inflammatory scarring of mucous membranes, including the ocular surface. This condition can lead to progressive scarring and complications that threaten vision. In managing OMMP, SL/PROSE has been utilized, especially in cases that do not

respond to conventional SCLs or where PEDs are unresponsive to standard medical treatments. PROSE provides protection for the ocular surface plus aids in visual rehabilitation [88, 89].

4.4.7 Neurotrophic Keratopathy (NK)

NK is a condition characterized by reduced or absent corneal sensitivity due to dysfunction of the trigeminal nerve. This leads to impaired epithelial healing and decreased corneal sensation. The disruption in corneal innervation can result in PEDs and, in advanced stages, may progress to corneal ulceration and perforation [90]. Bandage soft contact lenses have long been used as a therapeutic option to protect the corneal epithelium, facilitate the healing of epithelial defects, and prevent serious, sight-threatening complications—but caution is advised, as abuse and overuse of these lenses may have side effects [33]. PROSE devices, on the other hand, have proven to be valuable in reestablishing homeostasis of the ocular surface in NK. They provide a stable, protective, and lubricated environment that promotes epithelial healing, especially in cases where defects are resistant to conventional therapies [91]. The unique tear reservoir created by PROSE establishes a continuously hydrated microenvironment over the corneal epithelium, promoting epithelial stability and regeneration. In patients with NK, this sustained ocular surface protection can significantly reduce the frequency of epithelial breakdown and, in selected cases, may delay or eliminate the need for surgical intervention. Additionally, the consistent lubrication provided by PROSE devices helps alleviate ocular discomfort while supporting visual rehabilitation [92].

4.4.8 Exposure Keratopathy (EK)

EK is a clinical syndrome characterized by absent, incomplete, or inadequate blinking and eyelid closure, leading to the loss of the tear film and subsequent corneal damage [93]. Patients with EK are especially vulnerable to various corneal injuries, including superficial punctate keratopathy, epithelial defects, neovascularization, corneal melting, and perforation [71]. SL/PROSE devices were among the earliest therapeutic interventions introduced for managing EK (Table 1). These lenses provide multiple protective mechanisms for the ocular surface, primarily by maintaining a stable, hydrated environment that counteracts the progressive dryness associated with EK. Acting as a dynamic liquid bandage, the fluid reservoir beneath the lens promotes epithelial healing and helps prevent further damage to the surface [94]. However, although they have been helpful in alleviating symptoms related to EK, caution is advised when using SLs for nighttime wear [95]. Chahal et al. highlighted the beneficial role of SLs in managing EK resulting from surgical procedures performed by oculoplastic surgeons. All patients fitted with SLs showed significant improvement in fluorescein staining, and the vast majority experienced at least a one-line improvement in visual acuity. Still, visual gains were limited in cases of preexisting corneal scarring [96].

PROSE is demonstrated to improve visual acuity compared to topical treatments and tarsorrhaphy in case series, and has been effective in treating PEDs in patients with EK [93, 97]. SLs have been utilized in severe cases of EK too. In one reported instance involving a patient with extensive facial chemical burns, SL therapy was employed to protect an exposed keratoprosthesis, acting as a crucial barrier that preserved the integrity of the ocular surface in an otherwise highly compromised situation [98].

4.4.9 Recurrent Corneal Erosions

RCE is a common condition, often caused by underlying diseases, previous injuries, or dystrophy of the basal lamina. It is characterized by frequent erosions of the corneal epithelium, which can occur spontaneously and lead to symptoms such as pain, blurred vision, and photophobia [49]. Contact lens patching has been used to reduce corneal erosions and encourage epithelial healing [49], and is generally recommended for cases that do not respond to traditional bandage SCL therapy [49]. In a case series involving nine patients with PED or RCE that were unresponsive to bandage SCLs and standard medical treatments, PROSE achieved complete epithelial closure in all cases. However, eight of these patients experienced a recurrence of epithelial defects after discontinuing use of PROSE, highlighting the potential need for continued lens wear in some situations [99].

4.5 *Limbal Stem Cell Deficiency*

The corneal epithelium, supported by limbal epithelial stem cells, plays a crucial role in forming a protective barrier against environmental threats and maintaining corneal transparency, which is vital for good vision. Damage or loss of these stem cells results in various corneal epithelial disorders, collectively known as LSCD. As mentioned, SLs offer significant therapeutic benefits for LSCD caused by conditions like SJS and GvHD. However, their use in LSCD related to prolonged wear of bandage SCLs is more contentious due to the risk of corneal hypoxia, particularly in eyes where limbal function is already compromised [33]. While the use of large-diameter SLs is widely recommended for managing LSCD to enhance ocular surface coverage and protection, there is no established consensus on the optimal lens diameters

or solution protocols tailored specifically for this condition [33].

4.5.1 Keratitis Ichthyosis Deafness Syndrome

Keratitis ichthyosis deafness (KID) syndrome is a rare condition characterized by mutations in GJB2 gene encoding for conexin-26 [100]. Ocular manifestations include corneal neovascularization, thickening of the eyelids, keratinization, keratoconjunctivitis sicca, and recurrent corneal epithelial defects due to total LSCD. A recent case series described two patients—one child and one adult—who experienced severe KID syndrome. Both were fitted with PROSE to enhance visual clarity, improve comfort, and manage recurrent corneal erosions over an extended period, which spanned 1–7 years [101].

4.*6. Pain Management*

4.*6.1. Neuropathic Corneal Pain*

Neuropathic corneal pain (NCP) is characterized by eye pain caused by abnormal or dysfunctional activity of the corneal nerves. This condition presents with symptoms such as burning, discomfort, and sensitivity to light (photophobia). Importantly, these symptoms can persist even with standard treatments for dry eye, suggesting that the underlying issue is neuropathic rather than simply related to the ocular surface [102]. PROSE provides effective protection for the cornea against external environmental factors, which often leads to quick relief from pain and marked improvement in photophobia symptoms [71, 103]. Additionally, SLs are particularly beneficial in minimizing exacerbating factors, such as friction caused by blinking and dryness of the ocular surface [104].

5. Contraindications

Like other contact lenses, the SL/PROSE device has both relative and absolute contraindications that depend on the context of its use and patients' eye condition and their ability to handle and wear it [3].

5.1. Extended and Overnight Wear

In terms of usage context, and like most contact lenses—except for those designed for orthokeratology, which is a controversial topic—overnight wear is considered an absolute contraindication for the SL/PROSE device [105, 106]. This is primarily due to its very low oxygen permeability when the eyelids are closed, which creates significant corneal hypoxic stress. Such stress disrupts the cornea's metabolism and particularly harms epithelial and endothelial cells. These cells have a high metabolic rate because they are involved in functions such as replication, repair, and maintenance of the corneal epithelial barrier, as well as maintaining corneal clarity due to their constant and permanent dehydrated state facilitated by the endothelial ion exchange pump [106–108]. Regarding the latter, a pre-existing low endothelial cell density, as seen in e.g. aged patients, diabetes mellitus, previous contact lens wear, Fuchs endothelial corneal dystrophy, primary corneal guttae, and conditions related to surgical trauma including cataract surgery, glaucoma-filtering procedures and valve implantations, vitrectomy and retinopexy with silicone oil or vitreous endothelial touch in aphakia or pseudophakia, and corneal transplantation, are also considered relative or absolute contraindications for wearing an SL/PROSE device, depending on the severity of the condition [106, 109–113].

One potential risk of wearing SL overnight is microbial keratitis, which is more commonly associated with SCL use [10, 114]. An intact tear film is crucial to prevent microbial keratitis [115]. Additionally, blinking helps prevent microbes from adhering to the ocular surface [114]. In the case of SLs, while they create a thick fluid reservoir behind the lens, the limited tear exchange rate (just 0.2%/minute) once the lens is in place poses a challenge. It takes more than eight hours to completely replace the fluid underneath the lens [116]. This risk may be heightened for patients with severe ocular surface disorders such as DED; they may need to wear SLs continuously, including overnight [32, 95].

5.2. Glaucoma and Ocular Hypertension

Pre-existing glaucoma may be another relative contraindication for wearing SL/PROSE devices. The compression of episcleral veins or deformation of tissue in Schlemm's canal beneath the landing zone of the SL could lead to elevated intraocular pressure (IOP). This effect may be particularly noticeable during blinking, as the eyelid exerts pressure on the conjunctiva and inner structures, including the drainage channels and episcleral veins; this increases resistance to the outflow of aqueous humor. There are documented cases of high IOP with an average increase of 5 mmHg after a few hours of SL wear [117]. According to McMonnies' hypothesis, an SL that closely conforms to the shape of the eye is more likely to fit tightly and increase intraocular pressure (IOP) [118]. A larger surface landing zone area can help prevent this issue because it distributes the weight of the lens over a wider area. Additionally, the composition of ocular tissues changes as it moves from the limbus (more compressible) to the bulbar conjunctiva (less compressible) [118]. Hence eyes with reduced scleral thickness or rigidity may be more susceptible to applanation in areas where there is

tight SL contact [119, 120]. Other factors that can lead to increased IOP include disruptions in the anatomy of the angle and trabecular meshwork, as well as suction forces acting beneath the SL [119, 121]. However, such findings cannot be generalized to all patients with glaucoma or ocular hypertension: so far no studies have assessed changes in IOP associated with SL wear in these patients [119, 122]. Nevertheless, it is wise not to fit SLs for simple refractive errors in patients with glaucoma or ocular hypertension; in those cases with severe ocular surface disease or corneal irregularities, large-diameter SLs with a wider haptic (≥18.0 mm) are preferred, as such lenses sit further from the limbus, thereby reducing the possibility of interfering with aqueous outflow [121].

Another potential issue with SL fitting may occur in patients who have undergone glaucoma surgery, particularly those with filtering procedures or valve drainage implants. These devices are typically located near the limbus and may interfere with or come into direct contact with the SL, leading to various complications. Glaucoma drainage devices can be positioned in the anterior chamber, in the limbal area, in the fornix, or posteriorly through a pars plana insertion [123]. Fitting SLs is generally easier and safer when the drainage device is in the fornix. Pars plana tube insertion is a preferable option compared to traditional anterior chamber placement. Using a reinforced scleral patch or another material over the tube at the limbal area can minimize interference with the SL, allowing for continued lens wear [124]. However, there are risks associated with wearing SLs, including blockage of the underlying tube shunt or erosion of the conjunctiva over the tube [123, 124]. To avoid contact with the tube, it is recommended to reduce the SL diameter to between 14.0–15.0 mm, or to create a lens notch and/or an area of increased elevation by adding a focal vault at the lens edge. A lens notch is specifically contoured at a designated location on the lens. To maintain this notch in the correct position, the SL is stabilized using a prism ballast, toricity in the landing zone, or a double-thin zone design. Elevating the part of the lens that overlaps the glaucoma filtration device can help reduce pressure on it and limit contact. For this purpose, a rotationally stable lens is essential. Opting for a customized or molded/impression SL design is a good alternative [1].

6. Complications

6.1 Device-Related Issues

6.1.1 Handling Errors

Proper handling of SLs is crucial for achieving successful and long-lasting wear. This can pose significant challenges, especially for first-time users and those with neuromuscular or anatomical limitations (Table 2). Conditions such as essential tremor, finger deformities, and peripheral neuropathy can greatly hinder a patient's ability to apply and remove lenses effectively [1].

As the indications for SLs expand to include patients with anatomically normal corneas, driven by the desire for superior optics and improved visual stability, there is a growing focus on developing reduced-diameter lens designs. These lenses are generally easier to handle and more cost-effective, and may simplify the fitting process. However, for patients with corneal irregularities or ocular surface diseases larger-diameter lenses are still necessary to achieve complete corneal vaulting and provide adequate support for the ocular surface [1].

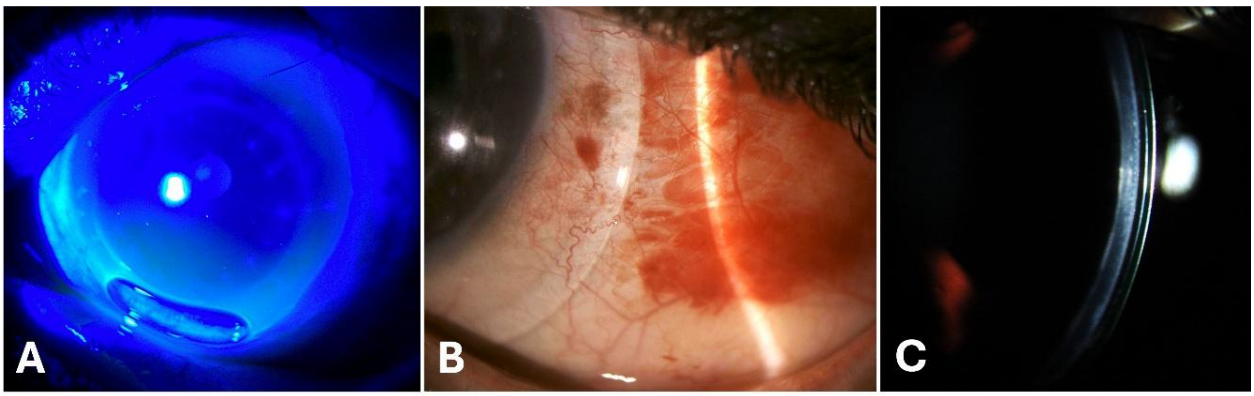

Figure 1. Complications derived from SL/PROSE use. (A) Inferior air entrapment observed in a patient with irregular astigmatism resulting from radial and astigmatic keratotomy and improper lens application. (B) Hyposphagma (subconjunctival hemorrhage) provoked during difficult lens removal. (C) Lens settling after three months of SL use for keratoconus, showing a narrower vault space.

Advances in SL technology, including enhanced customization options for sagittal depth, edge profile, and overall diameter, offer clinicians greater flexibility in optimizing visual outcomes and improving ease of handling [3].

Air entrapment during lens application is a common complication related to handling. These air bubbles often occur due to incomplete filling of the lens bowl with sterile saline or improper positioning of the eyelids during insertion (Figure 1A). It can lead to decentration when using the application device or fingertips. Clinically, this issue manifests as localized corneal desiccation, often seen in a ring-like pattern after lens removal, and can be easily detected with fluorescein staining [122].

The literature consistently highlights the complexity of handling SLs as a significant factor contributing to lens discontinuation, especially when compared to conventional RGP-CLs [58, 125]. In a prospective study involving 36 patients, Abou Samra et al. found that 11.1% (n = 4) faced considerable challenges with lens handling [126]. Each of these patients received personalized re-training and was recommended using a suction holder to aid with lens insertion and removal. This approach led to improved compliance and allowed for continued lens wear [126].

6.1.2. Insertion and Removal Difficulties

Difficulties with lens handling remains one of the primary reasons for SL discontinuation, with dropout rates of 25%–49% reported in the literature [36, 127, 128]. Insertion and removal challenges represent the most frequently cited cause [129]. This issue is particularly relevant in patients with limited hand function, essential tremor, or congenital or acquired digital deformities, where standard application techniques may be inadequate (Table 2). Reduced uncorrected visual acuity during the insertion process can further complicate lens use by increasing the likelihood of confusion between care products, including cleaning agents, preservative-free filling solutions, and disinfection systems [1].

The mechanical demands associated with SL wear, such as the need for midday removal and reinsertion in response to debris accumulation within the tear reservoir or the formation of anterior surface deposits, may further hinder patient adherence [34]. These factors highlight the importance of patient education, integration of appropriate application and removal devices, and consistent follow-up to support long-term lens tolerance and success [19, 31].

To address these challenges, a variety of assistive devices have been developed to facilitate SL insertion. The See Green Lens Inserter is one such tool designed to improve visualization during lens insertion. It features an integrated LED light that illuminates the SL insertion plunger from below, enhancing the user's ability to detect air bubbles and verify lens centration before application [130]. This device is particularly beneficial for patients with low vision or reduced ambient lighting during handling. Another helpful tool is the EZI Scleral Lens Applicator, which offers a stable platform for lens insertion with one finger [131]. The design enables users to mount the applicator securely, allowing for steady lens placement with reduced risk of spills or misalignment. These tools have expanded accessibility to SLs for patients who might otherwise be unable to manage lens-handling independently.

Similarly, a range of plunger devices are available to facilitate SL removal. Worth noting is a common miscalculation involving positioning the device too close to the center of the lens, which can create excessive surface tension and hinder successful dislodgement. This often leads to complications such as conjunctival blanching, impingement, hemorrhage, and corneal or conjunctival staining, factors that may contribute to significant ocular discomfort and reduced lens tolerance [1, 122] (Figure 1B).

Table 2. Classification of SL/PROSE complications

Device Related Issue s [122, 130, 134, 135, 153, 198, 215]	**Ocular Surface Complicaciones [168, 175, 178, 179, 182, 191, 201]**
Handling errors	Epithelial bogging
Insertion and removal difficulties	Corneal edema
Lens settling	Bullae
Mechanism and magnitude of settling	Hydrops
Blanching	Infiltrates
Compression of glaucoma draining device	Microbial keratitis
Increased clearance	Giant papillary conjunctivitis
	Cornea neovascularization
Visual and Optical Complications [170, 193, 203, 206, 208]	Toxic keratopathy
Asthenopia and visual adaptation	Conjunctival impression
Haze and halos	Conjunctival prolapse
Midday fogging	

6.1.3 Lens Settling

SLs are designed to vault the cornea and rest on the bulbar conjunctiva and Tenon's capsule. However, due to the soft and compressible nature of these supporting tissues, SLs undergo a well-documented phenomenon known as *settling*—a gradual decrease in the post-lens tear reservoir over time (Figure 1C). This phenomenon occurs as the lens sinks into the ocular surface structures, effectively reducing the sagittal depth of the fluid reservoir [60, 132, 133].

6.1.3.1 Mechanism and Magnitude of Settling

Although the exact mechanisms responsible for SL settling are not yet fully understood, tissue compression beneath the haptic zone is widely believed to play a central role [133]. Several factors, including lens design, total diameter, material thickness, duration of wear, and individual patient anatomy influence the degree of lens settling. Additional variables such as eyelid pressure and initial apical clearance may also contribute, though their precise roles are yet to be fully characterized [133, 134].

The literature reports a wide range of settling values for SLs. In a case series study involving keratoconic eyes, Esen et al. found that the average settling of SLs after one month of wear was 146 μm, with values ranging from 106–186 μm [135]. Courey and Michaud observed a mean reduction of 70 ± 9.8 μm following six hours of wear [136]. Otchere et al. found a mean clearance loss of 34 ± 48 μm after just one hour [134]; this aligns with the broader literature, which indicates that approximately 70% of SL settling occurs within the first 2–4 hours of wear [133, 134]. Differences in settling have also been documented across various lens designs. Kauffman et al. compared the short-term settling behavior of three different SLs (Onefit P&A™, Mini-Scleral Design (MSD)™, Jupiter™ lenses), finding statistically significant differences in both amount and rate of settling; this demonstrates that design and diameter variations influence the settling values, ranging from 88–133 μm [133].

Another study evaluated the settling time characteristics by measuring the post-lens tear thickness (PoLTT) at the center of the pupil using anterior segment-optical coherence tomography (OCT). The study focused on a conventional SL (diameter = 15.6 mm, thickness = 300 μm, made from Boston XO material). The findings indicated that the amount of lens settling was greater at the dispensing visit than after three months, with an average difference of 28 ± 63 μm. The study concluded that practitioners could estimate lens-settling in individual cases by using a prediction model based on the PoLTT measured 30 minutes after the lenses were first worn [132].

6.1.3.2 Clinical Implications

The clinical implications of lens settling are quite complex. A significant concern is that a decrease in the post-lens tear reservoir over time may lead to unintended corneal or limbal bearing if insufficient initial clearance is provided. This situation can result in patient discomfort, conjunctival impingement, epithelial compromise, or even central touch in advanced cases of keratoconus or post-surgical eyes [137, 138]. Therefore, fitting protocols should account for expected settling, with recommendations suggesting that the initial apical clearance be overestimated by 100–200 μm, depending on lens diameter and design [139, 140].

Although the refractive impact of SL settling is generally considered minimal, changes in lens position and sagittal depth can theoretically influence the effectiveness of the lens-tear reservoir system. In a cohort study involving 16 patients, Bray et al. reported an average refractive shift of approximately 0.25 diopters following lens settling. However, they did not account for all potential variables that may affect vergence through the post-lens tear film [141]. While this shift may be clinically insignificant in many cases, the refractive implications of lens settling should not be entirely dismissed—especially for patients with high refractive errors or those requiring precise visual outcomes.

Importantly, when assessing central clearance during the diagnostic evaluation of lenses clinicians must document the time elapsed since the lens was applied. Measurements taken too early, before significant settling occurs, can lead to an overestimation of the final vault, increasing the risk of corneal contact during regular wear [132, 134].

6.1.4 Blanching

Conjunctival blanching refers to the localized whitening of the superficial blood vessels in the bulbar conjunctiva and is a common complication associated with SL wear. This phenomenon occurs when excessive pressure from the lens landing zone compresses the conjunctival blood vessels, restricting local blood flow [142]. Blanching acts as a clinical indicator of compression at the interface between the scleral lens and the ocular surface. It may also be accompanied by adjacent hyperemia, which is typically observed at the limbus or just outside the edge of the lens [1].

The presentation of conjunctival blanching can be either circumferential or sectorial and may affect the inner or outer edge of the landing zone of the lens (Figure 2A). A detailed slit-lamp examination is crucial to identify the location and severity of the blanching, as this data is essential for making appropriate modifications to the lens design [142]. In

cases of compression-induced blanching, practitioners should consider flattening the peripheral curves of the lens or using toric or quadrant-specific landing zones to adjust for scleral asymmetry [122, 143, 144].

It is important to note that the human sclera has anatomical irregularities; it tends to be steeper temporally than nasally, and there is increased asymmetry near the regions where the extraocular muscles attach. To mitigate localized pressure and enhance lens alignment, using smaller-diameter scleral lenses or designs with customized toric haptics may be beneficial [145, 146].

In cases where blanching occurs during lens wear and rebound hyperemia is observed after lens removal, mechanical compression should be considered the primary cause [1]. If lens removal is performed without complications and hyperemia appears in the previously blanched area, this further supports the diagnosis of pressure-induced vascular occlusion. However, some patients may display a hypersensitive conjunctival response, resulting in injection even with minimal manipulation. This can complicate the interpretation of findings after lens removal [1].

Persistent redness of the conjunctiva and discomfort related to blanching may lead to shorter daily wear times for SLs and, in some instances, can result in the development of intolerance to these lenses [147]. It is estimated that around 10% of SL users eventually stop using them due to ocular discomfort, much of which may be caused by unrecognized or unresolved mechanical complications, including issues like vascular compression [57, 129].

Recognizing and managing conjunctival blanching promptly is crucial for enhancing patient comfort, preventing long-term complications, and optimizing the retention of scleral lenses. A key strategy to address this device-related issue is designing the landing zone to better match the unique contour of the individual's sclera [143–147].

6.1.5 Compression of Glaucoma Drainage Devices and Filtering Blebs

Fitting SLs in eyes that have undergone glaucoma surgery demands an elaborated approach. The presence of glaucoma drainage devices (GDDs) or filtering blebs, while not absolute contraindications for wearing lenses, introduces anatomical and functional complexities that necessitate careful planning. This is essential to avoid mechanical interference, compromise of the ocular surface, and potential disruption of surgical outcomes [105, 123, 124].

6.1.5.1 Glaucoma Drainage Devices

GDDs can be positioned in various anatomical locations, with the anterior chamber being the most common site. Alternatively, they can be placed in the ciliary sulcus or through the pars plana, depending on the patient's ocular condition and the chosen surgical technique [123, 124]. From an SL-fitting standpoint, pars plana placement tends to be more favorable, as it positions the tube posterior to the SL landing zone, thereby minimizing the risk of direct interaction [124, 148]. However, pars plana placement requires a prior vitrectomy, which may not be suitable for all patients. If pars plana placement is not feasible, positioning the device in the ciliary sulcus of pseudophakic eyes is a potential alternative [149, 150].

Anterior chamber tube placement presents a greater fitting challenge. Depending on the position of the implant, the SL landing zone may remain unaltered if adequate clearance is available approximately 3–4 mm from the limbus [124].

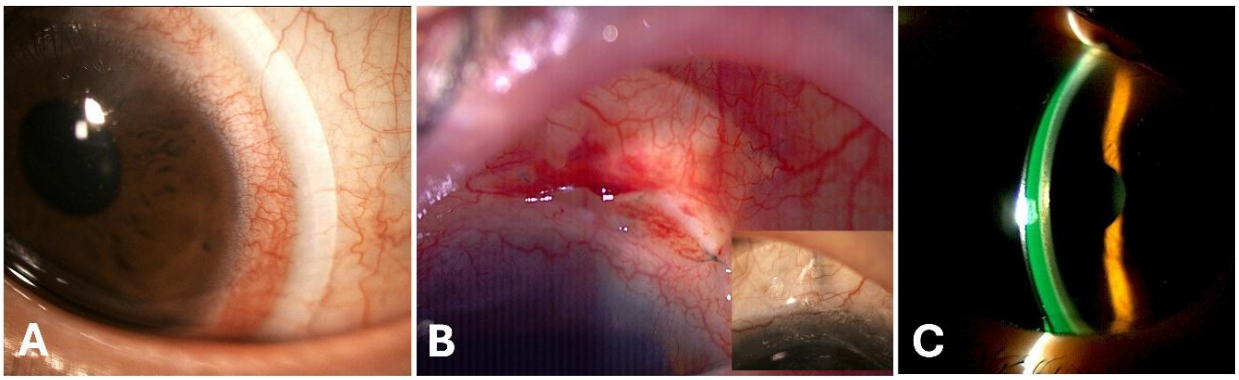

Figure 2. Complications derived from SL/PROSE device-related issues. (A) Conjunctival blanching due to a steep scleral landing. (B) Postoperative image of a scleral patch due to Ahmed tube exposure caused by PROSE device conjunctival erosion in a patient with severe Sjogren´s dry eye (inlet showing long-term surgical resolution). (C) Excessive central clearance due to high vault, causing corneal hypoxia and visual fluctuation.

It is crucial to ensure proper tube orientation and adequate coverage, often using a scleral graft. This helps reduce frictional contact and minimizes the risk of erosion or breakdown of the conjunctiva [124]. Additionally, mechanical compression of the tube by the SL can obstruct aqueous outflow, potentially leading to increased intraocular pressure or disrupted function of the shunt [124, 151]. Furthermore, interactions at the tube site may result in thinning of the adjacent conjunctiva, erosion, and in some cases tube exposure that requires surgical intervention (Figure 2B) [123, 151].

To reduce mechanical stress, several lens design strategies have proven effective. These include decreasing lens diameter, applying focal vaults or relief zones over the tube, and customizing the landing zone using toric or impression-based designs [1, 105, 152]. Notched or scalloped haptic designs are also described in the literature as successful methods for offloading pressure from GDDs [123, 153, 154]. In addition, long intrascleral tunnels with or without a patch graft positioned further posteriorly may help lower erosion risk [124, 155].

In complex anterior segment cases or eyes with corneal grafts, pars plana tube placement remains the preferred method when feasible, as it offers a more predictable fit for SL wear [148–150].

6.1.5.2 Filtering Blebs

Filtering blebs, particularly those resulting from trabeculectomy, present significant challenges when fitting SLs. The location and shape of these blebs often vary based on the surgeon's technique; leaks from the bleb occur more frequently in fornix-based flaps (65%) compared to limbus-based flaps (24%) [156]. Since SLs do not conform to elevated tissue as SCLs do, applying mechanical pressure on a bleb can lead to erosion, leakage, reduced filtration, and increased intraocular pressure [105].

While filtering blebs are not a strict contraindication for lens fitting, they do complicate the process. Modifying the lens geometry—such as adding a notch or creating focal vaulting at the lens edge—can allow the lens to bypass or clear the bleb [105, 153, 154]. Generally, notches < 4 mm in depth are well tolerated. However, deeper notches may cause air bubble formation beneath the lens, potentially compromising both vision and comfort [153].

Other important factors to consider include the risk of inflammation caused by mechanical interactions with vascularized or scarred tissue, especially in patients who have previously received treatment with antimetabolites like mitomycin C [157, 158]. Because of this potential risk, careful lens care and hygiene are crucial to minimize the chances of blebitis or endophthalmitis, concerns that are common across all types of contact lens use [151].

6.1.5.3 Clinical Considerations and Recommendations

Although fitting SLs can be challenging after glaucoma surgery, several reports show that successful outcomes can be achieved with appropriately modified lenses. For example, Tanhehco et al. described five patients who had previously undergone glaucoma surgeries, such as GDDs and trabeculectomies, and were successfully fitted with SLs. This success was achieved by customizing the vaults and landing zones of the lenses [123]. The unique design of SLs has proven effective in accommodating complex anatomical features due to their ability to conform to irregular ocular surfaces [3, 34]. When fitting a SL in the presence of glaucoma filtration devices or blebs, it is essential to avoid mechanical interaction through design modifications, select smaller-diameter lenses to permit more localized clearance or notching, consider posterior tube placement or fornix-based bleb configurations during surgery to optimize future lens compatibility, and monitor closely for signs of inflammation, conjunctival compromise, or bleb/device dysfunction [154].

6.1.6 Increased Clearance

Achieving proper corneal clearance is essential for a successful fit of SLs. Inadequate clearance can compromise the corneal epithelium mechanically, while excessive clearance can lead to reduced oxygen delivery to the cornea, lens instability, and difficulties with application [3] (Table 2).

It is well understood that both the lens material and the fluid reservoir beneath the lens limit the oxygen available to the cornea. SLs are made from high oxygen permeability (Dk) materials, typically ranging from 88–140 cm^2/s. However, their significant thickness—often between 250–500 μm and even higher—can hinder oxygen transmissibility (Dk/t) [159, 160].

Additionally, the tear reservoir beneath the lens has a Dk of approximately 80 cm^2/s, further contributing to this oxygen barrier [161]. Although it has been suggested that dissolved oxygen within the reservoir may help with corneal oxygenation, this contribution is insufficient to offset the effects of excessive clearance [1]. An optimal scleral lens fit should maintain a balance between adequate corneal clearance and minimal fluid reservoir thickness to ensure acceptable oxygen transmission [162].

Excessive central clearance, particularly when it exceeds 500 μm after lens application, is linked to several complications (Figure 2C); these include decreased optical quality due to increased vault, accumulation of debris in the

post-lens tear reservoir, heightened negative pressure beneath the lens, and, ultimately, corneal hypoxia and swelling [81, 159, 163]. The equation for Dk/t demonstrates that an increase in the thickness of either the lens or the fluid layer reduces the oxygen available to the cornea [160].

Moreover, excessive clearance, especially in the limbal region, can distort the sagittal profile of the optic zone, causing it to shift forward and increasing the interaction with the upper lid. This mechanical effect can result in the lens being displaced inferiorly, leading to decentration [1, 164, 165]. The greater the vault, the more the pressure from the upper lid pushes the lens downward, resulting in optical misalignment and discomfort.

Lens decentration is a common issue observed in SL wearers who have increased clearance, often resulting in an inferior-temporal shift. This displacement can lead to uneven distribution of the fluid reservoir, causing localized thinning in the superior-nasal quadrant. Optical decentration can introduce aberrations, unwanted prismatic effects, and inconsistent visual quality, all of which can reduce patient comfort and satisfaction [165].

After the lens has settled, excessive clearance may persist, compromising oxygen transmission and potentially leading to complications related to hypoxia [166–168]. In addition to hypoxia, high vaults may degrade visual acuity and cause visual disturbances, such as the "fishbowl effect". Furthermore, when combined with a narrow or misaligned landing zone, excessive clearance increases the risk of air bubbles forming beneath the lens [122, 169]. Central clearance of SLs exceeding 500 μm may be associated with a higher incidence of midday fogging, a common complaint among SL wearers, characterized by debris accumulating in the post-lens fluid reservoir [170].

6.2 Ocular Surface Complications.

6.2.1 Corneal Epithelial Bogging

Corneal epithelial bogging is a complication characterized by irregularities on the corneal epithelial surface observed after removal of an SL. It is defined by positive fluorescein staining of the cornea or negative staining in the limbus, presenting as elevated lesions in the corneal epithelium with a swollen, waterlogged appearance that may be related to mechanical stress applied on the ocular surface secondary to SL wear [171]. Walker et al. noted that this condition may occur due to prolonged exposure of the corneal epithelium to a non-nutritious saline solution while wearing SLs [19]. The exact pathophysiology of epithelial bogging is still unknown; however, it is believed to involve epithelial edema, alterations in tear film osmolarity, or loss of the glycocalyx layer, which leads to inadequate wetting of the ocular surface and/or accumulation of devitalized epithelial cells. This accumulation may occur due to the absence of normal eyelid shearing forces that typically compress the epithelium [19, 172]. Current evidence indicates that epithelial bogging does not result in long-term adverse effects on corneal health [19].

Management of epithelial bogging includes periodical removal of the scleral lens during the day, followed by thorough rinsing and reapplication. This approach may help minimize the condition. Modifying the lens design when necessary may enhance corneal health [142].

6.2.2 Corneal Edema

Induced SL corneal edema refers to the swelling of the cornea due to fluid accumulation, primarily caused by hypoxia while wearing scleral lenses (Figure 3A). Hypoxia triggers anaerobic metabolic processes, resulting in changes to lactate and bicarbonate ion concentrations in the endothelial layer. These alterations affect the cornea's ability to uptake water through membrane osmotic transport and the active ion pump, leading to swelling [110, 111].

SLs, due to their larger size, thickness, and material properties, can significantly reduce oxygen transport to the cornea (Table 2). The increased thickness of the tear film behind the SL raises diffusion resistance, further limiting oxygen supply to the cornea [112, 113]. Lower oxygen transmissibility of the lens exacerbates hypoxia and increases the risk of corneal edema. Additionally, reduced carbon dioxide permeability can alter bicarbonate ion concentrations, impacting corneal hydration and swelling. Wearing scleral lenses while the eyes are closed significantly increases corneal edema because it reduces oxygen supply from the palpebral conjunctiva [110, 111, 173]. Corneal edema is assessed by measuring the increase in central corneal thickness compared to baseline values. OCT is the optimal measurement method, although a Scheimpflug camera or an ultrasound pachymeter can also be useful [110]. To manage hypoxia caused by scleral contact lenses, it is essential to reduce corneal and limbal clearance to enhance oxygen delivery. Switching to materials with higher Dk and using thinner lenses (<220 μm) can improve oxygen flow. Proper lens fitting is crucial to avoid excessive clearance, with an optimal thickness of around 150 μm, as excessive clearance can worsen hypoxia. Patients with compromised endothelial layers require careful monitoring, since a low cell density (less than 800 cells/mm²) increases the risk of complications [122]. Fenestrated lenses can improve oxygen exchange, helping to strike a balance between lens fitting and adequate oxygen supply to the cornea [174].

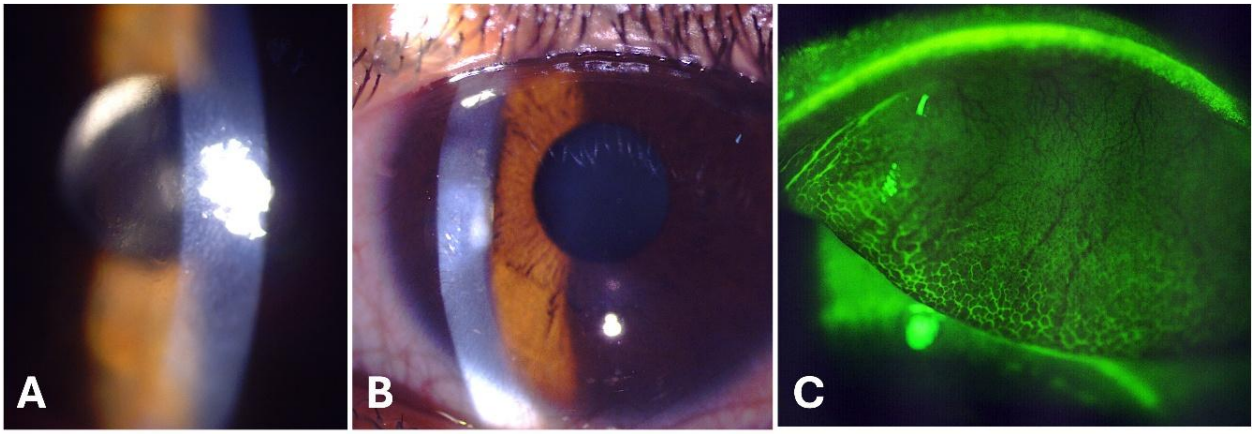

Figure 3. Ocular surface complications from SL/PROSE. (A) Generalized corneal stromal edema in a patient with severe irregular astigmatism after penetrating keratoplasty while wearing an SL. (B) Sterile stromal infiltrate accompanied by localized corneal edema and a small epithelial defect due to excessive use of the SL. (C) Giant papillary conjunctivitis in a longtime SL wearer complaining of red eye, ocular irritation, and lens intolerance.

6.2.3 Corneal Bullae

Corneal epithelial bullae are fluid-filled blisters that form within the corneal epithelium, particularly near the basal layer. These bullae are characterized by their oval shape, sizes ≥40 μm, and tendency to cluster together. They can be distinguished from other corneal conditions, such as epithelial vacuoles or microcysts, by their appearance under marginal transillumination, which reveals unreversed illumination due to their fluid or gaseous contents [175].

In the context of wearing SL/PROSE devices, corneal epithelial bullae are thought to develop due to mechanical compression between the lens and the cornea. This compression weakens the tight junctions between epithelial cells, leading to fluid accumulation. The pathogenic mechanism behind the formation of these bullae is also significantly influenced by hypoxia. PROSE devices are often fitted with higher clearances, which are associated with corneal hypoxia and reduced fluid exchange beneath the lens [175]. Bullae are usually detected as areas of negative staining when fluorescein dye is applied and are commonly found in regions where contact lenses induce corneal compression, particularly near the limbus. While hypoxia and other factors can play a role, mechanical trauma is considered the primary cause of these bullae [176].

Isozaki et al. [175] identified various underlying medical conditions, such as GvHD, traumatic ruptured globe, and LSCD-associated DED, that can lead to transient epithelial bullae formation after wearing large-diameter PROSE devices. Despite these differing causes, the corneal manifestations observed were similar—characterized by large, transparent, and irregular epithelial formations with distinct borders, typical of bullae [175]. Anterior segment OCT imaging is an effective tool for accurately identifying the separation of the corneal epithelium at the level of the basement membrane and Bowman's layer. This imaging technique can also provide details about the depth, diameter, and irregular borders of the bullae, as well as any debris present within the fluid chamber of the SL [175].

To manage corneal epithelial bullae it is crucial to immediately discontinue the use of SLs to prevent further mechanical interaction and hypoxia, and allow the cornea to heal. Epithelial bullae typically resolve spontaneously, although recovery can take at least a week. Lubricating eye drops can be applied to alleviate dryness and support the healing process. If SLs are to be reintroduced, it is important to follow proper fitting protocols to avoid excessive vault space, corneal bearing, and compression. Follow-up appointments should be scheduled to ensure complete resolution of the bullae, and patients should be educated on the importance of reporting any symptoms such as discomfort or redness during lens wear [175, 176].

6.2.4 Corneal Hydrops

Corneal hydrops is a condition characterized by sudden swelling of the cornea due to a break or detachment in Descemet's membrane, which leads to rapid stromal and epithelial edema (Table 2). This condition is commonly associated with advanced keratoconus and other ectasias and has been reported in SL wearers [45, 177]. Potential contributing factors could be implied, like extreme corneal thinning and steepening, mechanical stress or trauma during SL insertion and removal, SL-induced negative pressure, and hypoxic stress, especially in eyes with low endothelial cell density. It is well-known that SLs create a physical barrier effect that reduces oxygen availability to the highly metabolic corneal epithelium [110]. Such reduction can disrupt the impermeability of the epithelial barrier, leading to stromal

edema, which in turn can place additional metabolic and mechanical stress on Descemet's membrane. In an already vulnerable cornea, the increased chronic stress resulting from habitual and prolonged SL wear may contribute to the development of corneal hydrops. In this case, stromal edema serves as an inciting factor, rather than merely a consequence of the traditional Descemet membrane break caused by progressive stromal thinning or protrusion of the ectasia [11, 45].

Acute corneal hydrops has been reported as part of the natural history of post-penetrating keratoplasty corneas for keratoconus, even in the absence of contact lens use. However, in a case series two of the hydrops episodes occurred shortly after SL refitting, raising the possibility of an association [178].

6.2.5 Corneal Infiltrates

A corneal infiltrate appears as a greyish or white area within the corneal stroma or epithelium, caused by the accumulation of inflammatory cells. This condition is typically associated with infections, hypoxia, irritation (such as trauma), or inflammatory immune responses (Figure 3B). While a corneal infiltrate may be asymptomatic, it often leads to other complications, including red eye, vasodilation, and increased capillary permeability. Patients may experience symptoms like discomfort, scratchiness, mild sensation of a foreign body, pain, photophobia, and tearing [13, 179, 180].

Corneal infiltrates are rarely observed in the context of SL use. When they do occur, it is often as a protective reaction to chemical, physical, and biological agents deemed foreign and harmful to the body. Potential causes include overnight lens wear and poor patient compliance. The use of fluorescein dye can be helpful for detecting positive staining of the cornea [3, 108, 181].

6.2.6 Microbial Keratitis

Microbial keratitis is a corneal infection caused by bacteria, viruses, fungi, or protozoa. This condition is a significant cause of blindness in both developing and developed countries. When associated with scleral contact lenses, microbial keratitis can result from various corneal environmental conditions [182]. Corneas affected by ocular surface diseases, such as neurotrophic keratitis and impairment in the epithelium, basal lamina, and tear film, have weakened natural defenses and are therefore more susceptible to infections [183]. Poor compliance with lens care—e.g. improper cleaning, storing lenses in contaminated cases, or using non-sterile solutions—greatly increases the risk of microbial keratitis [114]. While SLs create a thick tear reservoir, they also have a reduced rate of tear exchange, which can promote microbial growth. Studies have linked the extended wear of SL to an increased risk of microbial keratitis [72, 114, 184]. Certain preservatives found in contact lens solutions can lead to contamination if not handled properly. Furthermore, PEDs make individuals more vulnerable to microbial infections due to impaired defense mechanisms [32, 72].

Treatment varies depending on the specific microorganism causing the infection. For bacterial keratitis, commonly used medications include fluoroquinolones such as ciprofloxacin and moxifloxacin, as well as fortified antibiotics [185]. In cases of fungal keratitis, treatment options consist of natamycin, voriconazole, or amphotericin, with the potential addition of oral antifungals in severe cases [186]. Acanthamoeba keratitis is typically treated with biguanides, including poly-hexa-methylene biguanide and chlorhexidine, as well as diamidines like propamidine and hexamidine [187].

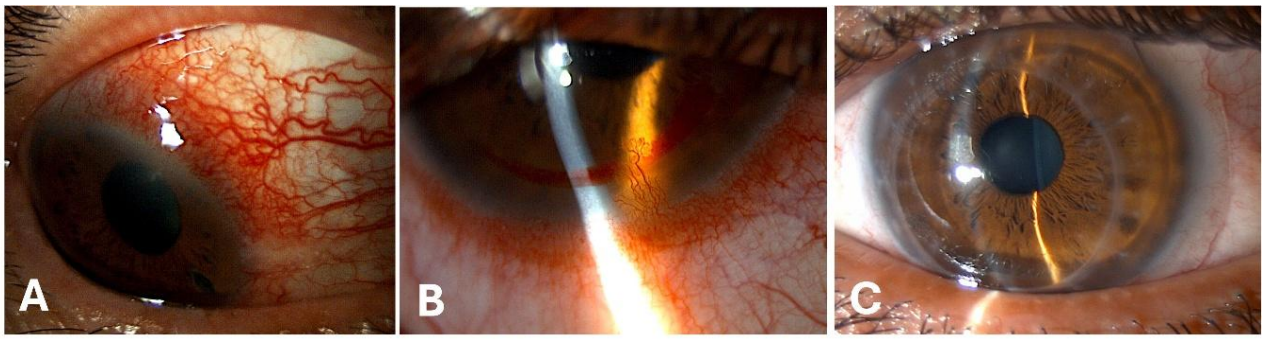

Figure 4. (A) Prominent limbal corneal vascularization observed in a patient with a tight-fitting lens that settled excessively after keratoconus corneal transplantation. (B). Extensive inferior corneal vascularization with intrastromal hemorrhage through the inferior edge of the transplant interface. (C) Three months after receiving corticosteroid and anti-angiogenic (anti-VEGF) treatment, along with refitting a looser SL, the vascularization disappeared.

6.2.7 Giant Papillary Conjunctivitis

Giant papillary conjunctivitis (GPC) is an allergic condition affecting the upper tarsal conjunctiva and characterized by the development of papillae larger than 1.0 mm (Figure 3C). Common symptoms include itching, redness, mucus discharge, discomfort from contact lenses, and excessive vertical lens movement. GPC can occur with any type of contact lens, but it is particularly prevalent among SCLs [188, 189]. It may arise in individuals with ocular prostheses, exposed sutures, or other foreign bodies in the eye. Symptoms typically progress gradually, often linked to prolonged lens wear and/or infrequent replacement of daily or disposable lenses. In the later stages of the condition, patients often find it intolerable to wear their lenses [188].

SLs cause GPC through constant and frequent eyelid blinking and lens movement, which irritates the superior tarsal conjunctiva (Table 2). Cell debris and proteins deposit on the lens surface, acting as antigenic stimuli that trigger an immune and/or foreign body reaction [190]. Treatment consists of discontinuing lens wear, improving lens hygiene, changing the lens material, and refitting a new lens. Topical surface corticosteroids, such as 0.2% loteprednol and dual-action anti-allergic drugs like 0.2% olopatadine or 0.05% ketotifen, along with preservative-free lubricant eye drops, can be used to manage inflammation and symptoms. For severe or refractory cases, immunomodulatory therapies including 0.03% tacrolimus or 0.05% cyclosporine-A can be considered [188, 190].

6.2.8 Corneal Vascularization

Corneal vascularization is an abnormal growth of new blood vessels from the limbal vascular plexus into the cornea, resulting from SL wear. It is typically associated with prolonged corneal hypoxia, inflammation, infection, trauma, poor lens compliance, and use of poorly fitted lenses including limbal bearing (Figure 4A). Corneal vascularization may also arise from SL overwear or extended wear [95, 122]; as it progresses, the risk of corneal opacification increases, which can threaten the patient's vision [1, 191]. Superficial blood vessels are generally linked to hypoxia, while deeper and larger vessels may indicate inflammation, possibly related to an underlying disease [36]. Depending on the severity of corneal vascularization, patients may experience no symptoms or may report reduced vision as the clarity of the cornea diminishes. Clinically, the presence of blood vessels extending into the cornea will be observed [19, 192].

The use of older poly-methyl-methacrylate materials in SLs can contribute to corneal vascularization. Refitting patients with modern materials that have higher oxygen permeability can enhance corneal health and reduce hypoxia. This approach is shown to reverse corneal vascularization in some cases. Additionally, maximizing corneal oxygenation by using highly oxygen-permeable materials and optimizing the thickness of the lens and the post-lens tear reservoir can help prevent a hypoxic corneal state, which may lead to vascularization. Pressure from limbal bearing or a tight scleral landing zone can also trigger the development of vascularization (Figure 4B). Therefore, it is essential to adjust the lenses to minimize such mechanical stressors [3, 19, 108, 193] (Figure 4C).

6.2.9 Toxic Keratopathy

Toxic keratopathy is caused by acute or chronic exposure to toxic substances such as ophthalmic drugs, environmental agents, or chemicals [194]. Preservative-free saline or preservative-free artificial tears are commonly agreed upon as the ideal options for SL filling; however, patients may forget or encounter instances where they use various multiple-purpose contact lens solutions or preserved artificial tears, giving rise to toxic epitheliopathy. Such toxic keratopathy can also occur in patients who use more viscous RGP-CL solutions to store their SLs in and are not thoroughly rinsing the SL chamber prior to application [195]. Corneal toxicity can range from mild sensitivity reactions to more severe chemical burns, depending upon the offending agent. Mild reactions are often asymptomatic, while more severe cases can result in ocular surface damage characterized by eye redness, irritation, pain, photophobia, and blurred vision. Signs can vary from mild and uniform diffused superficial punctate epitheliopathy to severe corneal melting and perforation (Figure 5A). Common causes are preservatives in medications and contact lens solutions, topical anesthetics, antibiotics, antivirals, and glaucoma medications [191]. Management of toxic keratopathy consists in stopping the insulting agent and switching to preservative-free solutions. In more severe cases, soft surface corticosteroids may be needed along with epithelial healing promoters, like Trehalose, Dexpanthenol, or blood derivates. Identification of the offending agent and its pH will drive the course of management [19, 196, 197].

6.2.10 Conjunctival Impression/Compression Ring

A conjunctival impression or compression ring is a visible indentation on the conjunctival tissue that occurs after removal of an SL (Table 2). This indentation is caused by the mechanical pressure applied by the lens in the area where it rests against the conjunctiva [198].

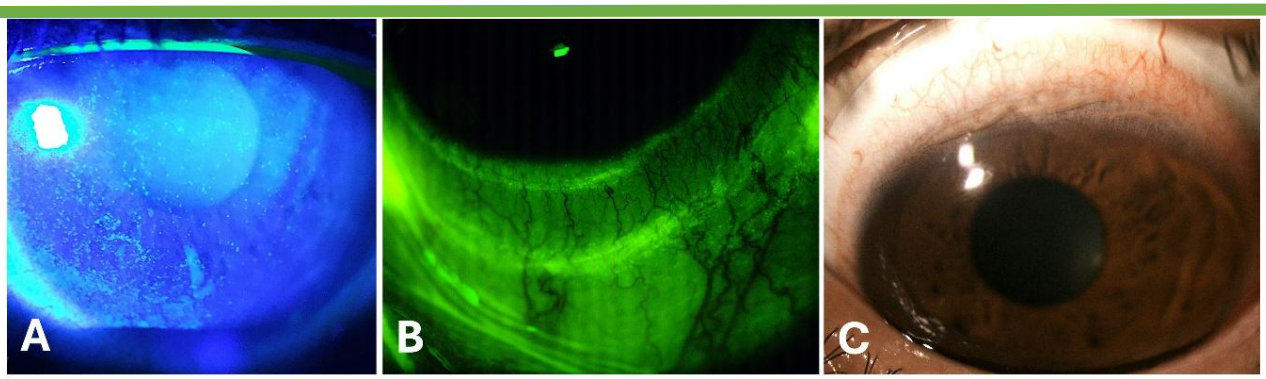

Figure 5. Ocular surface complications associated with SL/PROSE. (A) Toxic keratopathy characterized by irregular fluorescein staining of the epithelium and diffuse punctate keratitis seen with extended use of SLs. (B) A fluorescein-stained conjunctival compression ring is visible at the limbus, indicating a tight fit of the SL. (C) Subtle conjunctival prolapse at the upper limbus observed in a patient with advanced keratoconus under the scleral lens.

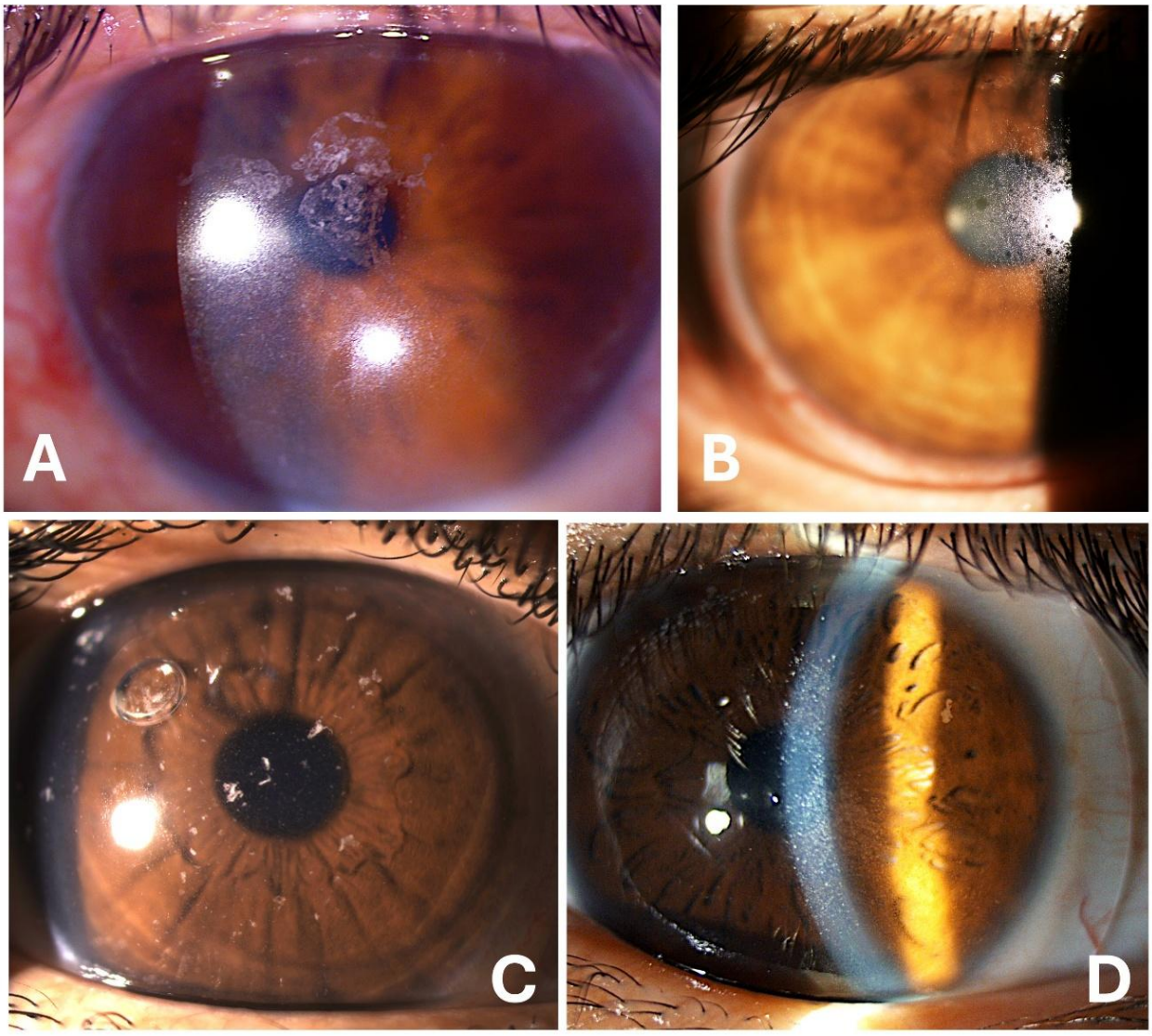

Figure 6. Visual and optical complications. (A) Central deposition of mucoproteins on the SL after extended wear due to severe dry eye disease. (B) Excessive protein accumulation in the pupillary area of a keratoconus soft lens wearer. (C) Typical midday fogging, characterized by large particles accumulated in the tear reservoir between the posterior surface of the lens and the corneal surface after six hours of SL use. (D) Extensive collection of small particulate waste in the SL vault, leading to blurred vision and discomfort after a few hours of wear.

Compression of the conjunctiva can lead to thinning or flattening of the tissue in the affected area. Interestingly, this change can be observed even without any signs of conjunctival blanching or staining and is generally considered a benign condition, as it typically resolves within a few hours of removing the lens [198]. However, compression can decrease blood flow to the area, potentially resulting in conjunctival hyperemia or scleral blanching; this may lead to discomfort, decreased lens tolerance, and reduced effectiveness of the lens (Figure 5B). Clinical signs of this condition include visible impressions from the lens on the conjunctiva, corneal or limbal edema, and increases in intraocular pressure. Compression may also affect corneal clearance or cause the lens to decenter, particularly along the horizontal meridian. To minimize discomfort and prevent compression, adjustments to lens parameters such as sagittal depth, landing zone radius, and central corneal clearance may be necessary [198, 199]. If the lens-fitting relationship is too steep for an extended period, resulting in conjunctival hypertrophy, it is advisable to prescribe a surface corticosteroid and discontinue lens wear. Once the condition improves, refit the patient, paying special attention to aligning the lens correctly over the affected area. As options, consider using a large-diameter lens to cover the affected tissue or a small-diameter lens to avoid it [66, 198–200].

To address the fitting issues, keep these recommendations in mind [1, 19, 57, 94]:

1. If there is compression at the lens edge, consider flattening it.
2. If the compression occurs inside the lens edge, steepen the design.
3. If there is a symmetric meridian of compression, add a toric haptic.
4. If there is an asymmetric meridian or quadrant of compression, use a quadrant-specific design.
5. If focal compression is due to a specific pathology, consider elevating the peripheral edge, decreasing the lens diameter, or notching it.

6.2.11 Conjunctival Prolapse (Hypertrophy)

Conjunctival prolapse occurs when there is a thickening, enlargement, or redundancy of the limbal conjunctiva, causing it to be drawn into the transition or limbal zone under an SL (Figure 5C). This happens due to sectoral haptic impingement, which occurs when the edge of the lens is too steep, pinching the conjunctiva and obstructing its blood supply [1, 165, 201]. This condition is more commonly seen in older patients with naturally looser conjunctival tissue, but can affect individuals of any age. Symptoms typically arise after lens removal and may lead to intolerance when the lens is used again. While conjunctival prolapse is generally a benign finding, it can become problematic. If a significant amount of conjunctival tissue is drawn into the SL vault, it can interfere with vision and may require intervention [2, 201]. To mitigate this issue, options such as flattening the lens edge, adjusting the base curve, or modifying the transition zone and landing zone can be considered. Decreasing limbal clearance helps reduce the opposing pressure that draws the tissue into that area, thus alleviating the problem, improving lens tolerance, and preventing long-term damage to the tissue [201]. In addition, anti-inflammatory treatments—e.g. cyclosporine-A, lifitegrast, topical corticosteroid pulses, amniotic membrane transplantation—can help tighten the conjunctival tissue. In cases of excessive conjunctivochalasis, a surgical conjunctivoplasty may be necessary [106, 201].

6.3 Visual and Optical Complications

6.3.1 Asthenopia and Visual Adaptation

Although ophthalmologists and optometrists primarily use Snellen visual acuity to assess visual performance, it is important to consider additional metrics such as high- and low-contrast visual acuity, night vision, and aberrometry. In terms of aberrometry, conventional SLs correct approximately 60–65% of high-order aberrations (HOAs) [202]. However, the remaining uncorrected HOAs can lead to decreased patient satisfaction and a further decline in vision-related quality of life [203]. Additionally, inferior decentration of the SL, caused by factors like gravity and eyelid morphology, can create an asymmetric fluid reservoir. This asymmetry may result in a base-down prismatic effect, contributing to the presence of additional HOAs [204].

6.3.2 Haze and Halos

Haze and halos are relatively common complications experienced by approximately 10% of SL wearers [129]. Common causes of these issues include improper lens fitting, corneal edema resulting from hypoxia, lens deposits, lens-induced HOAs, and tear film instability [60, 204]. Clinically significant corneal edema occurs more frequently in patients with ocular surface diseases and among those using non-fenestrated SLs with high Dk values. Potential solutions to address these problems include use of fenestrated SLs, which enhance tear exchange and oxygen delivery; reduction of wearing time; and minimizing lens and fluid reservoir thickness [60].

6.3.3 Midday Fogging

Midday fogging is a complication that affects 26–46% of SL users [60] (Table 2). The primary symptom is often described as a "hazy view" or "looking through fog", which necessitates periodic lens removal, refilling with fresh solution, and reapplication [205] (Figure 6A–D). This phenomenon is believed to result from debris on the ocular surface, such as leukocytes, lipids, and external tear film debris, accumulating in the fluid reservoir [60, 205]. Several factors have been proposed as causes of midday fogging, including poor alignment in the landing zone, increased central corneal clearance, the properties of the lens and contact lens solution, and underlying ocular surface disease [60]. Fogt et al. found that lens diameter, haptic design, lens material, storage and filling solution, and lens coating accounted for 28% of the variance related to midday fogging. However, none of these factors were statistically significant on their own [205]. A recent unmasked trial demonstrated a statistically significant improvement in comfort and subjective visual acuity when using a filling solution that mimics the composition of tears and maintains the pH of the normal ocular surface [206].

7. Strengths and Limitations of the review

This comprehensive review offers an in-depth overview of the current literature on the most common complications associated with the adaptation and usage of SCL/PROSE devices. As these complications are directly linked to the various indications for wearing these types of lenses, we felt it was crucial to explore and discuss the different situations in which an SCL/PROSE device can be applied to patients. This area of ophthalmology is currently expanding; as it develops, the broader range of indications will likely lead to new and varied complications that will need to be addressed. This context underscores the importance of this review.

We have also identified significant limitations, particularly the lack of sufficient and conclusive information in the current literature. There is a need for large sample sizes and well-designed randomized clinical trials to obtain stronger evidence regarding the complications associated with adapting to and wearing SCL/PROSE devices. These limitations hindered our ability to draw solid conclusions from the analyzed material. On a positive side, we envision an immense opportunity for further research and development in this field, both in the immediate term and in the future, with potential new indications and improved detection and understanding of potential complications for their prevention or effective management.

8. Future Directions and Challenges

8.1 Increasing Long-term SL Wearability

Studies with extended follow-ups show that approximately 27% of individuals discontinue wearing SLs [25, 207]. Common reasons include lack of motivation, insufficient visual improvement, discomfort or intolerance, and complications related to the ocular surface, such as corneal edema, limbal or conjunctival hyperemia, graft rejection, and corneal neovascularization. Ortenberg et al. found that patients who took short breaks every 4 to 5 hours during continuous wear experienced significantly longer wear durations [207].

Adequate central corneal clearance—the space between the posterior surface of the SL and the cornea—is necessary to optimize oxygen flow to the cornea and maintain comfort [208]. Insufficient clearance can lead to excessive pressure on the cornea, resulting in a condition known as "corneal touch". Conversely, too much clearance can cause an unstable fit, leading to visual distortion and discomfort. Otchere and colleagues demonstrated that measuring corneal sagittal height using anterior segment OCT is an effective method for determining the lens/cornea relationship, resulting in better visual outcomes [208]. Future studies are needed to enhance current fitting strategies and improve long-term SL wearability.

8.2. Optimizing the Tear Exchange Rate Under the Lens Vault

Some users of SL/PROSE devices experience severe conjunctival hyperemia and lens intolerance after wearing them for just a few hours. This can lead to corneal edema [111]. The tear exchange functionality of SL/PROSE lenses enhances the oxygen supply to the cornea, which helps reduce corneal edema, particularly in cases with compromised endothelial cells. It also minimizes the buildup of tear film debris and metabolic byproducts between the cornea and the lens [159]. Achieving an optimal fit for SL/PROSE lenses that promotes effective tear exchange requires a careful balance. The goal is to create a lens fit that facilitates fluid exchange while minimizing debris accumulation. This can be accomplished by optimizing the apical and limbal clearance of the lens, as well as ensuring proper haptic alignment. Additionally, the material and thickness of the lens should be considered [200, 209]. If there are no fitting issues, small fenestrations or

channels can be incorporated into the haptic design to prevent suction in these specific cases. These openings enhance tear and oxygen circulation, potentially alleviating problems such as fogging and suction-related discomfort that are often associated with traditional sealed SL. Furthermore, fenestrations can simplify lens removal and may reduce conjunctival compression [210].

8.3 Costs and Accessibility

SLs are significantly more expensive than RGP and SCLs. The cost of fitting may also represent a barrier for patients. Although there is strong evidence highlighting the visual benefits, comfort, and improvements in quality of life associated with SL wear, the financial aspect remains unclear [211, 212]. Balaji et al. analyzed the costs and benefits of specialty contact lenses in 212 patients with irregular corneas and ocular surface diseases. For SL users, the total median cost was USD 1321. However, when the total gains in productivity for all patients wearing SLs were divided by the costs, the resulting benefit-to-cost ratio was 119:1, equating to USD 6 5058 in benefits [211]. The visual function score, measured with the NEI-VFQ 25, improved significantly from 58.6 to 85. While SLs have been shown to be cost-beneficial and cost-effective, the out-of-pocket expenses are prohibitive for many patients. Therefore, it is crucial for health and government policymakers to address this issue to enhance the affordability of SLs for low-income individuals [211].

8.4 Facilitating Application and Removal

SL users face more challenges with lens handling compared to RGP-CL users, with difficulties reported by 63% of SL users versus 40% of RGP-CL users. These difficulties are among the primary reasons for discontinuation of use [212]. There are many publicly available resources to help patients with SL education, like YouTube videos from the Scleral Lens Education Society and the guidelines on "Healthy Scleral Lens Habits" provided by the Association of Optometric Contact Lens Educators [60].

8.5. Improving Lens Hygiene

Solutions intended for SL applications must be preservative-free due to their prolonged contact with the cornea. It is also advisable to use multipurpose solutions for nightly disinfection to help prevent the spread of infections [213]. Although a multidose preservative-free saline bottle can remain sterile for a time after being opened, factors such as bottle design, patient hygiene and compliance, and the discard schedule can all affect its sterility. Sweeney et al. demonstrated significant bacterial contamination, exceeding 10^5 colony-forming units /mL, in preservative-free saline in multidose 500-ml bottles with flat necks and wide openings after just one week of use. In contrast, bottles with raised necks and pinhole openings showed contamination after four weeks. The bacteria found were primarily Gram-negative bacilli [214]. A recent study reported a 63% prevalence of microbial contamination among 4-ounce multidose, pH-balanced, buffered preservative-free sterile saline solutions, which are commonly used to clean contact lenses [213]. Despite this contamination, none of the 35 patients involved in the study developed microbial keratitis. For patients at higher risk of microbial keratitis, such as those with severe ocular surface diseases, it may be prudent to use smaller 2-ounce bottles or single-use preservative-free saline vials to reduce the risk of contamination [213].

CONCLUSIONS

The complications associated with SL/PROSE differ from those seen with SCL and RGP-CLs in many ways. SCLs are more susceptible to infectious keratitis and allergic reactions (GPC). Other complications related to extended wear include lens intolerance, chronic red eye, and dryness. In contrast, RGP-CL wear rarely associates with infections and allergies but frequently induces high sensitivity to bright lights and airflow, along with decreased lens tolerance, especially in steep corneas and keratoconus. On the other hand, SL/PROSE may face unique complications primarily related to fitting issues, including discomfort from tight lenses, persistent red eye, blurred vision due to hypoxia-caused subtle corneal edema, mid-day fogging, irritation from pinguecula, and erosions of glaucoma valve tubes. Fortunately, these issues are infrequently reported and do not appear to significantly impact the indications or use of SL/PROSE. We are optimistic about the future of SL/PROSE. Advances in lens research design and improved biocompatibility of complex polymer materials should make SL fitting easier and enhance patient adaptability for even the most complicated cases.

ETHICAL DECLARATIONS

Ethical approval: This study was a narrative review, and no ethical approval was required.

Conflict of interest: None.

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