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## The Ocular Surface

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Several lifestyle choices made by contact lens wearers can have adverse consequences on ocular health. These include being non-adherent to contact lens care, sleeping in lenses, ill-advised purchasing options, not seeing an eyecare professional for regular aftercare visits, wearing lenses when feeling unwell, wearing lenses too soon after various forms of ophthalmic surgery, and wearing lenses when engaged in risky behaviors (e.g., when using tobacco, alcohol or recreational drugs). Those with a pre-existing compromised ocular surface may find that contact lens wear exacerbates ocular disease morbidity. Conversely, contact lenses may have various therapeutic benefits. The coronavirus disease-2019 (COVID-19) pandemic impinged upon the lifestyle of contact lens wearers, introducing challenges such as mask-associated dry eye, contact lens discomfort with increased use of digital devices, inadvertent exposure to hand sanitizers, and reduced use of lenses. Wearing contact lenses in challenging environments, such as in the presence of dust and noxious chemicals, or where there is the possibility of ocular trauma (e.g., sport or working with tools) can be problematic, although in some instances lenses can be protective. Contact lenses can be worn for sport, theatre, at high altitude, driving at night, in the military and in space, and special considerations are required when prescribing in such situations to ensure successful outcomes. A systematic review and meta-analysis, incorporated within the review, identified that the influence of lifestyle factors on soft contact lens dropout remains poorly understood, and is an area in need of further research. Overall, this report investigated lifestyle-related choices made by clinicians and contact lens wearers and discovered that when appropriate lifestyle choices are made, contact lens wear can enhance the quality of life of wearers.

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## 1. Introduction

Contact lenses have the capacity to enhance the lifestyle of individuals, primarily for the correction of refractive errors, but also for many other reasons including medical indications or certain forms of eye protection. The decision by eyecare practitioners to prescribe, or individuals to choose, whether to wear contact lenses as an optical correction will be governed by several lifestyle factors that influence choices for contact lens wear, such as ocular and systemic health, the anticipated types of activities in which the wearer will be engaged, the intended frequency of lens wear, and the environments in which lenses are likely to be worn. Clinicians also have the option to prescribe contact lenses for a variety of medical applications.

For those wearing contact lenses, numerous factors will govern wearing success, as judged by the quality of vision, ocular comfort, utility of lens wear and convenience. The presence of pre-existing ocular or systemic medical conditions will influence the types of contact lenses fitted and the recommended pattern of lens use. Those engaged in risky practices, such as being non-compliant with lens wear and care instructions, wearing lenses when ill or using tobacco, alcohol or recreational drugs, may suffer from various forms of contact lens-associated ocular compromise that could limit, or result in the cessation of, lens wear. Wearing contact lenses in challenging atmospheric or work environments is potentially problematic, but in certain circumstances may confer protection.

The coronavirus disease-2019 (COVID-19) pandemic, in addition to posing numerous social and behavioral constraints upon society, has also introduced challenges for contact lens wearers. Those restricted to working from home through choice or enforced lockdown might be engaged in more near vision activities, such as increased use of digital devices, requiring altered refractive considerations. Other untoward factors such as mask-associated dry eye [1-4] and the potential for inadvertent injury from hand sanitizers entering the eye have also been described [5,6].

This report was conducted as part of the Tear Film & Ocular Surface Society (TFOS; www.tearfilm.org) Workshop 'A Lifestyle Epidemic: Ocular Surface Disease', which was undertaken to establish the direct and indirect impacts that everyday lifestyle choices and challenges have on ocular surface health. For the purpose of this Workshop, the 'Ocular Surface' is defined as the cornea, limbus, conjunctiva, eyelids and eyelashes, lacrimal apparatus and tear film, along with their associated glands and muscular, vascular, lymphatic and neural support. 'Ocular Surface Disease' includes established diseases affecting any of the listed structures, as well as etiologically related perturbations and responses associated with these diseases. Disease is considered from an etiological perspective, to include infection, inflammation, allergy, trauma, neoplasia, dysfunction, degeneration and inherited conditions. Methods used to evaluate clinical evidence in this report, including the description of systematic review evidence, are described in the TFOS Lifestyle -Evidence Quality Report [7].

This manuscript will consider a wide variety of factors, with the aim of providing a holistic map of: (a) factors that impact the choice of whether to wear contact lenses, and (b) factors that impact the success or otherwise of those who elect to wear contact lenses. This information is summarized in a narrative style review that, wherever possible, refers to outcomes from high-quality systematic review (Level I) evidence. In alignment with the other TFOS Lifestyle Workshop reports, the Evidence Quality Subcommittee provided a comprehensive database of appraised Level 1 evidence judged to be of potential relevance, which was factored into the writing of the report [7]. In addition, a systematic review is presented that used rigorous methodology to investigate a focused research question, considered of clinical importance by the subcommittee members, relating to identifying the lifestyle factors that may impact soft contact lens dropout.

## 2. Contact lens choices that may impact the ocular surface

### 2.1. Patient choice of contact lenses

Since August Müller's self-experiments with glass contact lenses for his high myopia correction in 1889 [8], significant advances in lens designs and materials have led to a wide number of reasons to choose contact lenses over spectacles (Table 1).

Improved cosmesis, social factors and convenience are the most cited reasons for choosing contact lenses over spectacles as the primary form of vision correction [9-12], with contact lens wearers being relatively happier with their appearance [13] and more likely to appreciate their vision correction [14,15]. In addition, children and teenagers have reported better peer perception with contact lenses compared to that when wearing spectacles [14,15].

The reduction, or cessation, of contact lens wear during the COVID-19 pandemic due to the decrease in social interaction and hence a reported lack of need, further highlights the importance of cosmesis [16-19]. Contact lenses provide a series of vision and ocular protection-related advantages, making them a highly suitable choice during many sports and in some professions. Contact lens wearers report greater satisfaction and performance during physical activities [14,15] and gym time [13] than spectacle wearers. Cosmetic contact lenses enhance or change the eye colour, or enlarge the iris appearance, and are particularly popular in lens wearers with or without a vision correction requirement in Asia [20-22].

Overall, contact lens wearers are primarily young and female [22], and the majority of lenses (86%) fitted in 2021 were single vision lenses [22]. In 2021, nearly 50% of all contact lenses prescribed worldwide were daily disposable lenses, although there are significant differences between countries in their prescribing patterns [22]. The benefits of daily disposable lenses include greater convenience, no need for a care system with an associated decreased risk of solution toxicity, easy access to spare lenses, and potentially better vision satisfaction and improved comfort [23,24]. Originally introduced for primarily overnight wear due to their high oxygen transmissibility, silicone hydrogel lenses are now used mainly on a daily wear basis and accounted for 74% of all soft

Table 1

Reasons for selecting contact lens wear rather than spectacles.

	Reasons for selecting contact lens wear
General/	Cosmesis (including disfigured eyes) [9–12]
Social	Convenience [9,11,12]
Psychological	Greater happiness with own appearance compared to glasses [13]
	Greater likelihood to like vision correction [14,15]
	Enhanced peer perception [14,15]
Visual	Wider field of view compared to spectacles [11,264,667]
	Better depth perception compared to spectacles [667]
	Fewer minification/magnification issues compared to spectacles
	[667]
	Reduced aberration and distortions compared to spectacles [667]
	Reduced reflections and glare compared to spectacles [264]
	Vision not affected by rain, fog, or snow [465]
	Anisometropic amblyopia treatment [668]
Workplace <sup>a</sup>	Ocular chemical protection [465]
	Preferred vision correction during face mask usage due to greater
	comfort on ears, easier breathing, less heat, less fogging [264]
	Improved fit of a respirator [465]
	Occupational requirements to avoid spectacles for reasons of safety
	(armed forces; police, etc.)
	Occupational requirements to avoid spectacles for reasons of
	cosmesis (TV presenters; actors, etc.)
Therapeutic	Bandage lens
	Drug delivery
	Therapeutic lens for chronic diseases
	Vision correction that cannot be achieved with spectacles
	Therapeutic tinted or cosmetic lenses

<sup>a</sup> Wear of contact lenses must be considered in addition to appropriate personal protection equipment. contact lens fits worldwide in 2021 [22]. On average, contact lens wearers wear their lenses approximately six days per week, but frequency is dependent on wearer age and sex, as well as lens type and design [25,26].

Approximately 3% of all lens fits in 2021 were orthokeratology designs [22], with considerable differences between countries [27]. Orthokeratology lenses are specially designed rigid lenses, worn overnight to reshape the cornea to temporarily reduce refractive error, allowing for lens-free days. A high proportion of orthokeratology lenses are fitted to children with the intent of modulating their myopia progression (i.e., for myopia control) [28,29]. The mechanisms and use of orthokeratology, including their role in myopia control in children, have been reviewed previously [28,30,31]. The significant increase in myopia worldwide has led to an increase in prescribing of both soft and rigid contact lenses to children [32]. In recent years, many soft contact lenses for myopia control have been brought to market and in 2021, 2% of all soft contact lenses were prescribed for myopia control [26].

While contact lenses are worn primarily for cosmesis and correction of ametropia, they play an important role as therapeutic and rehabilitative lenses (see Section 3.2.1).

## 2.1.1. Market penetration and fit success

It has been estimated that over 140 million people wear contact lenses, representing approximately 2% of the population of the world [33]. The global market size was \$7.84 billion (USD) in 2020, and is projected to grow at a compound annual growth rate of 5%–7.5% per year [34]. Reasons for growth include an increase in the numbers of myopes globally and presbyopes wishing to wear contact lenses, as well as an increased uptake of contact lenses in developing countries [35,36]. In addition to the increase in lenses fitted to correct refractive errors, for therapeutic reasons and cosmetic contact lenses, it is likely that lenses with other functions will enter the market [37]. Future contact lenses may be used to deliver pharmaceuticals to the ocular surface (with one lens already approved in certain markets [38,39]), detect ocular surface and systemic diseases, change their shape to correct presbyopia, project digital information to the eye, or provide augmented reality experiences [37].

In 2021, soft contact lenses accounted for 86% of all lens fits. Of those, 45% were spherical lenses, 32% toric and 14% multifocal contact lenses [22]. When considering only spherical and toric lenses, in many markets, toric lenses were fitted in more than 40% of cases, which reflects the prevalence of ametropes with astigmatism of  $\geq$ 0.75D [22,40]. Modern toric lenses are relatively simple and rapid to fit, with average lens fit times under 25 min, often successfully upon the first attempt (>84%), with a high success rate after one month of lens wear [41,42]. Additionally, they provide prescription coverage for up to 96% of potential wearers in frequent replacement modalities [40].

When considering presbyopic contact lens wearers only, in 2021, 49% were fitted with multifocal lenses, 11% with monovision and 40% with single vision lenses [22]. Despite the wide variety of optical designs for multifocal contact lenses [43], there remains hesitation among practitioners to fit multifocal contact lenses due to concerns regarding the time to fit the lenses and limits in fit success [44]. It has been found that 43% of multifocal contact lens neophytes discontinued lens wear after 1 year due to inadequately corrected vision [45].

#### 2.1.2. Discontinuation from contact lens wear

Contact lens wear discontinuation rates remain at around 25% over a two to three year period, although this estimate varies depending on the definition of 'discontinuation', in addition to the country being considered [46]. Ocular discomfort is the most cited reason for lens discontinuation in established contact lens wearers [33,46-49]. Other reasons include inconvenience and cost [33,48,50], and poor vision [48,50]. In newly fitted contact lens wearers, discontinuation rates are similar to those in established contact lens wearers, but vary with lens type, with higher discontinuation rates in multifocal wearers. The main reasons for

discontinuation in neophytes are poor vision, discomfort, lens handling, and loss of interest [45,51]. New wearers of single vision lenses discontinued primarily due to comfort (35%) and handling (33%) issues, whereas multifocal lens wearers mainly discontinued due to vision (73%). Shorter tear film breakup time after three months of contact lens wear discontinuation, greater likelihood of dry eye diagnosis, meibomian gland plugging and worse meibum quality have been observed more often in individuals who drop out of contact lens wear when compared to age- and sex-matched successful lens wearers [52,53]. A systematic review on reasons for dropout of contact lens wear is provided in Section 4.

Driven by cosmesis, convenience and resolution of discomfort, most lapsed wearers will resume contact lens wear [33,47]. Evaluating contact lens refits in lapsed contact lens wearers showed high fit success with new lenses and a high retention rate after a six-month period, highlighting the importance of follow-up visits and offering alternative lens wear solutions. The COVID-19 pandemic reduced the ability of people to socialize and attend work in person. The use of face masks to protect from the virus has resulted in an increase in dry eye reports, often referred to as 'mask-associated dry eye' [1,3,4]. During the pandemic, many lens wearers discontinued or reduced lens wear, primarily due to a perceived lack of need, as well as increased eye dryness with mask use [16-18,54,55].

### 2.2. Clinician choice of contact lenses

Successful contact lens wear has been defined as being able to comfortably wear contact lenses for at least 12 h per day for at least six days per week, with vision comparable to that obtained while wearing spectacles [56]. The choices that practitioners make with respect to the contact lenses they prescribe and the manner in which patients then opt to use those lenses, ultimately impacts the performance of the lenses in terms of comfort, vision, wearing time, safety and almost certainly the likelihood that the patient will cease lens wear and become another "dropout" statistic [57].

The section below provides an overview of factors that impact contact lens success. For a more in-depth review of major factors contributing to contact lens success and dropouts the reader is recommended to review previous publications discussing this topic [33,52,57].

## 2.2.1. Impact of contact lenses on signs and symptoms of ocular surface disease

Placement of a contact lens onto the ocular surface leads to compartmentalization of the tear film into a pre-lens and post-lens tear film, thereby disrupting its structure and stability [58]. A reduction in tear film breakup time, thinning of the lipid layer, and increase in tear evaporation rate have been associated with ocular discomfort during contact lens wear [58,59].

There has been debate about the impact of contact lenses on meibomian gland structure, atrophy and function. Recent reviews have concluded that contact lens wear may impact certain aspects of meibomian gland function [29,59,60]. A recent narrative review [60] suggested that information from the majority of studies lends support to the notion that contact lens wear does affect normal meibomian gland morphology and could potentially impact comfortable wear, although this latter finding remains more equivocal. Comparisons between only contact lens wearers suggest that the severity of meibomian gland alterations depend upon the duration of wear and type of lens worn as well as their modulus of elasticity. In some of these studies, patients who had worn contact lenses for longer periods of time showed about a two-fold greater meibomian gland dropout or alteration than those who had worn them for shorter periods. In terms of material elasticity, wearers of high modulus lenses showed higher meibomian gland loss than those wearing low modulus materials and non-lens wearers, respectively [61]. With respect to lens type, wearers of rigid corneal lenses demonstrated a 34-80% greater meibomian gland loss than wearers of soft lenses and non-wearers [62,63]. Rigid lenses may have a greater predisposition to meibomian gland loss, possibly due to friction associated with the mechanical interaction with the lens or their impact on blinking [63]. Worse meibum quality, reduced secretion, meibomian gland plugging and presence of foam at the meibomian gland orifice are associated with contact lens discomfort and a proactive approach should be taken to facilitate early management of meibomian gland dysfunction (MGD) [52,59].

A reduction in lubrication has been associated with increased friction between the ocular surface and contact lens. Increased friction between the lid wiper and contact lens is considered a primary reason for lid wiper epitheliopathy [29,64]. Despite greater lid wiper epitheliopathy in some contact lens wearers, the impact of contact lens wear on lid wiper epitheliopathy and the effect of this condition on ocular discomfort remain equivocal [29]. Increased friction between the bulbar conjunctiva and eyelids leads to increased shearing forces during blinking, which are possibly linked to the development of lid-parallel conjunctival folds [65]. These are small folds on the conjunctiva, primarily in the 4 and 8 o'clock area, that increase with years of lens wear. This condition has been associated with ocular discomfort and considered as a predictor for contact lens-induced dry eye [29].

Increased friction during blinking caused by poor conjunctival lubrication and a greater exposure area has been suggested as the cause of conjunctival staining outside the lens edge. Bulbar conjunctival staining due to exposure has been linked to dry eye symptoms during contact lens wear [66,67]. Bulbar staining around the lens edge has been found to be associated with the lens edge design, with an inverse relationship between staining and comfort [29].

Corneal fluorescein staining due to contact lenses can be broadly categorized into desiccation, trauma and toxicity staining [29]. Contact lens deposition, daily wear time and contact lens material have been shown to affect corneal staining, but at this time no clear relationship between corneal staining and ocular symptoms has been demonstrated [68].

### 2.2.2. Impact of lens wear modality and compliance on wearer success

A recent narrative review paper has addressed the fact that soft contact lenses differ in their performance, and that patient success is linked to a myriad of factors relating to the surface and bulk properties of the lens material, in addition to their design, fit and frequency of replacement [69]. These factors will be briefly discussed below; however, interested readers are directed to more extensive reviews for further detail [44,69-75]. Based on a meta-analysis of cohort studies and randomized trials, there is a statistically significant, two-fold (2.18 risk ratio, P < 0.05) higher risk of corneal inflammatory events in users of silicone hydrogel lenses when worn for up to 30 days of planned overnight wear (mean: 14.4; 95% confidence intervals (CI): 4.3-48.2 infiltrates per eye-years) compared to low oxygen permeability planned overnight wear lenses worn for 7 days without removal (mean: 7.7; 95% CI: 2.2-26.7 infiltrates per eye-years), but this effect could not be definitively linked to lens material because of the confounding impact of wear duration [76].

2.2.2.1. Replacement modality. The vast majority of prescribed contemporary soft contact lenses are replaced every four weeks or less, with a growing number of wearers using daily disposable lenses, which now account for approximately 50% of all soft lens fits globally [22]. There is no doubt that daily disposable lenses provide greater convenience and help to minimize complications associated with lens cases and solutions [77-82], including solution induced corneal staining [59]. They exhibit a lower incidence of inflammatory complications [59] and while the incidence of microbial keratitis appears to be similar to that seen with reusable lenses, the severity of the disease is reduced and the eventual outcome in terms of visual acuity appears to be improved [59, 83,84].

2.2.2.2. Impact of non-compliance. Also sometimes referred to as 'non-adherence', non-compliance to advice from practitioners on appropriate contact lens wear and care is rife among lens wearers. It is estimated that almost 100% of contact lens wearers will, at some point in time, exhibit at least one contact lens hygiene risk behavior [85], with some publications suggesting that over 80% of patients will be non-compliant with a behavior that will put them at risk of developing a serious complication [86].

Two separate surveys reviewed nine contact lens wear and care recommendations that eye care practitioners reported discussing with their patients, and the authors compared this with the recall of contact lens wearers regarding these same factors [87]. The majority of eye care practitioners reported sharing recommendations 'always' or 'most of the time' at every patient visit, and especially at initial visits and visits related to contact lens complications. Of the nine recommendations for safe contact lens wear and care, eye care practitioners most often recommended complying with the recommended lens replacement schedules (85% of the time), not sleeping in contact lenses (79%) and not 'topping off' their contact lens solutions (64%), whereby wearers add fresh solution to the remaining solution in their case rather than pouring away used solution and only using fresh solution each night. However, one third of contact lens wearers recalled never having heard any lens wear and care recommendations, fewer than half recalled hearing their eye care practitioner recommend not sleeping in lenses at their last visit, and only one in five recalled being told to avoid 'topping off' their contact lens solutions [87]. Clearly, there is a substantial mismatch between what practitioners believe they discuss at patient visits and what wearers hear, potentially resulting in not following important advice.

2.2.2.1. Non-compliance with wear modality. A high proportion of contact lens wearers nap or sleep in their contact lenses (in some studies >50%) [85,86,88-90] and numerous prior publications confirm that this is a significant risk factor for both sight threatening microbial keratitis [44,91-94] and non-infectious infiltrative keratitis (also termed sterile keratitis) [59,92,95]. Overnight wear of contact lenses increases the risk of microbial keratitis by between three to ten times, compared with daily lens wear [59,95].

2.2.2.2.2. Non-compliance with replacement frequency. Lack of compliance with replacing contact lenses at their appropriate replacement frequency is well documented [33,78,88,89,96-98], with approximately 10% of wearers in North America over-wearing their daily disposable lenses, 50% not complying with two-week replacement lenses and 30% over-wearing lenses that should be replaced every month [88]. This finding of daily disposable and monthly wearers being more likely to replace their lenses on time is consistent with that of other researchers [90,98], with some reports describing how long some wearers of both daily disposable and reusable lenses can stretch their use beyond the recommended replacement time [78,89]. Reports exist of wearers replacing their two week and monthly replacement lenses as far out as 10 weeks or more [78], and of daily disposable wearers often not replacing them after two days of wear, with a very small percentage wearing them for up to 20 days [89].

Of note, in some cases this non-compliance is actually encouraged by the prescribing eye care practitioner [88,89], calling into question whether this issue is considered clinically relevant by practitioners. In some cases this relates to the eye care practitioner suggesting that two-weekly replacement lenses could be replaced after one month, or that two-weekly replacement means that they should be replaced after "14 wears of the lens", which for a part-time wearer could mean the lenses are replaced after several months. Review of the literature strongly suggests that this non-compliant behavior with replacement schedule should be discouraged, as extending lens wear beyond the recommended time-frame can result in reduced comfort and vision [89, 99], longer intervals between eye examinations [96], reduced use of appropriate lens care [96], an increased rate of non-serious, non-vision threatening complications [97,98] and an increased rate of vision threatening keratitis [100]. It is worth noting that in situations where eye care practitioners are recommending replacement of the contact lenses beyond the approved replacement period that this is essentially an off-label recommendation, potentially making the practitioners, rather than the manufacturers, liable for any adverse consequences.

Non-replacement of daily disposable contact lenses [85,88,89,96,98] is particularly concerning, as patients prescribed such lenses are typically not provided with disinfection instructions prior to reapplying their lenses. This may result in wearers storing their lenses in inappropriate solutions, such as tap water [85,101] or blister-pack saline [102], with the significant risk of severe complications such as microbial keratitis associated with this behavior [103].

2.2.2.3. Using expired lenses and/or solutions. Several reviews exist on the topic of non-compliance with care systems and their impact on successful contact lens wear [77,78,80-82,98,104]. A further issue to consider with respect to non-compliance relates to the potential risk to contact lens wearers of using lenses or solutions beyond their expiry date.

All contact lenses and solutions are manufactured with an expiry date clearly visible on the packaging. Once opened, lenses should be used immediately and either disposed of upon removal if a daily disposable product, or disinfected prior to reapplication of lenses if a reusable product. The expiration date for soft contact lenses relates to the autoclave date post-manufacture and the ability of the packaging material to maintain that sterility over time, and thus the expiration date primarily relates to the packaging integrity [105] and also the stability of lens parameters (e.g. base curve, diameter) for the lens material over time. In contrast, rigid lenses that are not packaged in conditioning or blister-pack solutions do not have an expiration date.

Once contact lens solutions are opened, they should be replaced within a set time, as recommended by the manufacturer. Guidance pertaining to the appropriate time that a care product should be discarded once opened is provided by the International Standards Organization [106,107], and these discard dates vary between 30 and 90 days. While the bottle remains sealed, sterility is rarely an issue with respect to shelf-life/expiration dating. However, given the wide variety of components contained within the solution [82,108] it is possible that they may change over time and component breakdown could yield substances that may prove deleterious to the ocular surface, especially from the biocides and chelating agents. In addition, there may be changes in pH or viscosity over extended periods of time that impact the compatibility or comfort of the solution once placed on the ocular surface. However, empirical research is required to establish if these hypotheses are accurate.

Thus, while there exists a theoretical risk of microbial keratitis or altered comfort due to contamination of expired products, no peerreviewed evidence exists concerning this issue with contemporary products. However, there are many publications discussing microbial contamination of saline products [109,110], contamination of care products once opened [111], contamination of products that have been open for many months [79] and contact lens cases [77]. It is therefore prudent to avoid using unopened expired products, although further work is required to determine if this is truly a risk factor for severe complications or reduced comfort.

2.2.2.2.4. Re-use of contact lens disinfecting solutions. One situation where re-use of multipurpose disinfecting solution has been associated with an increased risk of microbial keratitis was with the increased incidence of corneal infection caused by *Fusarium*. On May 15<sup>th</sup>, 2006, the Food and Drug Administration (FDA) released a statement announcing that Bausch and Lomb had globally recalled their solution, ReNu MoistureLoc (Bausch and Lomb, Rochester, NY, USA) [112]. This followed epidemiological evidence that this solution was linked to an increase in microbial keratitis rates of between five to 13 times, caused by *Fusarium* sp [100,112].

Subsequent to the recall, it has been shown that non-compliance with the use of ReNu MoistureLoc, i.e. re-use of the solution three or more times, 'topping off' the solution, drying the solution in the case or using disinfection times significantly less than those recommended by the manufacturer, was likely to have affected its anti-fungal activity [113-115]. It was probably the combination of the novel ingredients in the product (including the disinfecting agents and a cellulose polymer) and non-compliance by users that brought about this increase in *Fusa-rium* keratitis and the demise of this solution. 'Topping off' contact lens solutions has been found to increase the chance of developing microbial keratitis (not just fungal keratitis) by about 2.25x (odds ratio) [116].

2.2.2.2.5. Non-compliance with lens case replacement and hygiene advice. Non-compliance with instructions for maintaining the hygiene of contact lenses storage cases, such as replacing cases at least every three months and air-drying cases between use, is reported to range from 41% for not replacing cases to 26% for not air-drying cases [117]. Inappropriate hygiene management of contact lens storage cases for the disinfection and storage of daily wear lenses when not being worn has been shown to be a risk factor for developing microbial keratitis [77, 104,118,119]. Recommended hygiene measures for these products are regular replacement (at least every three months) and air-drying of the cases when not in use [77,120]. Poor storage case hygiene practices (i.e., irregular replacement and no air drying) has been associated with a 3.7x (odds ratio) increased risk of developing any case of microbial keratitis and a 6.42x (odds ratio) increased risk of developing moderate to severe keratitis during daily wear of contact lenses [84]. The population attributable risk for lens case hygiene practice was 62% [84]. In other words, based on these findings, if daily wear contact lens wearers used the recommended replacement schedule for lens cases and air dried them between every use, there would be an expected reduction in severe microbial keratitis of over 60% during daily wear of soft lenses. Another study has shown that people who never use a new contact lens case are 3.4x (odds ratio) more likely to develop microbial keratitis, and that those people who clean their lens cases at least every second day or use contact lens disinfecting solutions to clean cases are approximately half as likely to develop microbial keratitis [116].

A study of non-infectious corneal inflammatory events in a university population found that relative to people who never replaced their contact lens cases, those who replaced their lens case at least every three months were 4.4x (odds ratio) less likely to experience a corneal inflammatory event; for those who replaced their lens case every four to six months, the chance was 2.9x (odds ratio) less than for those who never replaced their cases [121]. Similarly, another study found that replacing a contact lens case less frequently than every six months was associated with a 7.69x (adjusted odds ratio) risk of developing corneal inflammatory events compared to replacing cases at least every two months [122].

Contact lens storage cases are associated with frequent microbial contamination [111,119,123]. Lens storage cases are most frequently contaminated with Gram-positive bacteria, followed by Gram-negative organisms and then fungi [123]. The disinfection solution type can affect the frequency and profile of microbes found in the storage case [123]. Also, the use of lens cases from different manufacturers to the manufacturers of multipurpose disinfecting solutions being used by contact lens wearers (i.e., a solution and lens case mismatch) results in great numbers of microbes being isolated from cases [120]. Compliance with instructions for lens and lens case hygiene reduces the microbial contamination of cases [124]. Greater numbers of microbes in lens cases are associated with failure to wash hands or only washing hands in tap water compared to washing with soap and water, not drying cases between use, and greater than two years compared to two or more years lens wear experience [120]. The use of tap water to clean contact lens cases has been associated with greater numbers of Gram-negative bacteria in the lens cases [81]. The amount of bacterial contamination of cases is greater in patients diagnosed as having contact lens-related microbial keratitis [125]. Also, the microbial contamination of contact lens cases has been correlated with the causative microbes isolated from corneas of contact lens-related microbial keratitis [118,126].

Several simple steps to avoid or minimize lens storage case contamination include soaking lens cases in disinfecting solution for the minimum time recommended [127], not using tap water to rinse cases, not 'topping off' disinfecting solution in the lens case, and giving careful consideration to where and how the lens case is stored during lens wear [78,119,123]. Air-drying the lens case by placing it face down is suggested, but this procedure alone cannot be relied upon to prevent microbial growth [127]. Replacing the cases after three or fewer months of use reduces contamination [124].

To minimize microbial build-up, mechanical rubbing and rinsing the contact lens storage case, along with wiping the lens case with tissue to dislodge bacterial biofilm and reduce nutrients that may promote bacterial growth, is recommended [127]. Silver-impregnated lens cases have been used and appear to result in less contamination when the lens case lids are recapped. Otherwise, recapping lids should be discouraged during the air-drying process [127]. Reinforcing case hygiene procedures, and the risks of not following these procedures, resulted in reduced contamination of lens cases in wearers of orthokeratology lenses in one study [128], but not in another [129], possibly due to differences in the reinforcement protocols. It is interesting that in a study from the United States of America, contact lens wearers who had previously experienced a contact lens-related complication were significantly more likely to replace their lens case [130], suggesting that discussions with contact lens wearers can help improve lens case hygiene in certain circumstances, especially where wearers are afraid of experiencing further complications.

There is currently no simple, fool-proof method of caring for contact lenses and storage cases suitable for home use and travel. Inconsistent and often inadequate contact lens and storage case hygiene recommendations remain an issue amongst various regulatory and advisory bodies [131]. Therefore, frequent and regular disposal of lens cases to prevent microbial colonization is strongly recommended [78,123,127,131].

2.2.2.3. Deposits. Interaction between a contact lens material and the tear film occurs rapidly, and deposition of both protein and lipid can be demonstrated within minutes to a few hours of exposure to tear film components [132-135]. The uptake of these various tear film proteins and lipids are complex, vary depending upon the charge, size and hydrophobicity of the tear film component and the chemical composition, water content, ionic charge, pore size and hydrophobicity of the contact lens material. These concepts are covered in greater detail elsewhere [136-143]. In general, protein deposition occurs to a greater extent on hydrogel materials (especially the deposition of positively charged lysozyme with a negatively charged lens material, such as etafilcon A) and lipid deposition occurs to a greater extent on more hydrophobic materials such as Food and Drug Administration group II hydrogels and silicone hydrogels [44,138,140,142].

While it would seem intuitive to assume that reduced lens deposition would be beneficial to successful lens wear, to date little evidence exists to support this concept for the periods of time that contemporary materials are worn prior to replacement occurring [70]. Indeed, it would appear that it is the state of the tear film contaminant rather than its amount that is clinically relevant. Increased subjective contact lens comfort has been correlated with a higher proportion of active, rather than denatured, lysozyme deposited in daily disposable wear of etafilcon A lenses, with the quantity of lysozyme being unrelated to lens performance [144]. The amount of extracted lipocalin or keratin-1 from silicone hydrogel lenses was higher (two times greater) in wearers who reported mild to moderate symptoms of ocular dryness, but not contact lens discomfort [145]. Lipid deposition has been reported to be higher in asymptomatic wearers of silicone hydrogel senofilcon A lenses compared to symptomatic wearers [146], suggesting that deposition of certain lipids may have a positive impact on lens comfort.

Overall, to date, the clinical relevance of low levels of deposition, within the four weeks or less that most contemporary lenses are replaced, remains equivocal. However, it is accepted that tear film deposition is reduced for lens materials replaced on a daily basis [147-149] and given their high level of clinical performance [24, 150-154] these very low levels of deposition may potentially be involved in increased comfort. More work is required to confirm this supposition and, if so, the underlying etiology.

### 2.2.3. Impact of lens care solutions on wearer success

The choice of contact lens care solution and the correct use of the system has been suggested to have a substantial impact on the success of lens wear and lens comfort. Interestingly, despite their long history of safety and efficacy, hydrogen peroxide-based systems are much less frequently prescribed than their multipurpose solution counterparts [26]. The apparent ease of use and convenience of multipurpose solutions have made them the more popular choice for contact lens disinfection [155]. Peroxide-based systems exhibit their anti-microbial effectiveness through the production of free radicals, while multipurpose solution systems rely on the presence of charged components, which interact electrostatically with, and disrupt, microbial cell membranes [108]. With appropriate neutralization, the risks associated with the use of peroxide-based systems are relatively minimal, while multipurpose solutions can be associated with an increase in the incidence of complications such as corneal staining, although the clinical impact of this staining remains unknown [25,156-158].

In the mid-2000's there were two recalls of multipurpose disinfecting solutions that highlighted the impact of compliance and solution formulations on the risk of microbial keratitis. The first of these was the recall of ReNu MoistureLoc™ (Bausch and Lomb, USA) [112], which is further discussed in Section 2.2.2.2.4. This followed epidemiological evidence that this solution was linked to an increased risk (five to 13 times) of microbial keratitis caused by Fusarium sp [100,112]. The risk associated with using this solution appeared to be associated with re-use of the solution or not removing all the solution from lens cases prior to 'topping off' the solution and going through a cycle of disinfection. The second worldwide solution recall was for Complete MoisturePlus<sup>TM</sup> (Advanced Medical Optics, USA) multipurpose disinfecting solution in 2007, which was associated with an increased risk of Acanthamoeba keratitis [159,160]. This solution (in particular the excipient, propylene glycol, perhaps in conjunction with buffering systems containing potassium chloride) promoted the development of cysts of Acanthamoeba spp. [161], protecting the amoeba from the disinfectants.

Since these recalls, there have been reports of associations of other multipurpose disinfecting solutions with a risk of developing keratitis. Complete Comfort Plus (Advanced Medical Optics, USA) has been associated with a 7.16x (odds ratio) increased risk, compared to other brands of contact lens disinfectants, of developing moderate-to-severe keratitis during daily wear of hydrogel or silicone hydrogel contact lenses [162]. The population attributable risk associated with the use of this solution and microbial keratitis was 35.1% [162]. In another study, the use of Oxipol disinfection (an oxychlorite complex composed of sodium chloride and hydrogen peroxide; Sauflon, Pharmaceuticals Ltd) was associated with a 4.74x (odds ratio) greater risk of developing *Acanthamoeba* keratitis compared to disinfecting solutions containing polyhexanide [163].

Some [164], but not all [165,166], clinical trials comparing the use of one-step hydrogen peroxide solutions to multipurpose contact lens disinfecting solutions have reported that multipurpose disinfecting solutions are associated with a greater risk of developing corneal inflammatory events during lens wear. This apparent discrepancy may be due to the types of multipurpose disinfecting solutions used by participants in the various trials, the trial designs or the definition of corneal inflammatory events.

In a 2013 study, patients using hydrogen peroxide-based contact lens disinfection systems reported significantly better comfort compared with those using multipurpose solution systems [167,168]. Since the hydrogen peroxide-based systems do not typically contain preservatives,

which have been implicated in dry eye disease and contact lens associated dry eye, it may be that the increased comfort was the result of the lack of preservatives in the system [169]. As a result of these and other similar reports, peroxide-based systems are preferred among some eye care practitioners [170]. A study suggested that the incidence of complications between the two disinfection systems was similar, although subjective comfort was found to be better in patients using peroxide-based cleaning regimens [171]. Another study found similar levels of comfort when comparing four different multipurpose solutions with a peroxide-based system [172]. However, the stability of the tear film can decrease with the use of any contact lens cleaning system [173].

In general, there is little reported difference in the extent of lid wiper epitheliopathy between the use of different multipurpose solution or peroxide solutions. There was a significant decrease in lid wiper epitheliopathy in some patients wearing galyfilcon A contact lenses and using a multipurpose disinfecting solution compared with a one-step hydrogen peroxide solution, but the clinical significance of this finding is uncertain [174]. Similarly, there does not seem to be a relationship between solution compliance, including rub versus no rub protocols and 'topping off' solutions, and the incidence or development of dry eye disease.

Given the complexity of multipurpose contact lens disinfecting solutions, which are designed to perform a myriad of functions, including cleaning, rinsing, disinfection and wetting, it is not surprising that interactions with different contact lens materials vary [75,175]. The different contact lens materials can take up and release many of these components onto the ocular surface [176]. Preservatives, for example, may be taken up by contact lens materials and subsequently released from the material, conferring antimicrobial activity [177,178]. However, the potential impact on eye comfort or secondary complications were not reported in these studies.

One of the suggested treatments for contact lens induced dry eye involves the incorporation of wetting agents in lens care solutions, specifically hyaluronic acid [179-183]. For patients affected by contact lens discomfort and contact lens induced dry eye, a change in lens care products, specifically avoiding those containing polyhexamethylene biguanide [184], may be appropriate [59]. Overall, more research is needed to develop evidence-based recommendations for safe, effective contact lens care.

### 3. Lifestyle choices that impact contact lens performance

## 3.1. Supply chain and lens types

### 3.1.1. Choosing to buy lenses through unregulated supply outlets

Contact lens supply channels that fall outside of government regulatory control and circumvent the involvement of an eye care practitioner are described as 'unregulated supply outlets' [185]. Unregulated supply outlets include: "over-the-counter" outlets [185] such as beauty salons [186,187], supermarkets [188], optical shops [96,186], pharmacies [186], flea markets [189,190], night markets [187], discount stores [96] and costume shops [190]; internet retailers [185,191]; borrowed or shared lenses [185,187]; and automated vending machines [192]. Contact lenses can be acquired without a valid prescription from many of these unregulated sources, and therefore wear and contact lens care is often undertaken without adequate supervision [185]. Access to contact lenses through such unregulated supply outlets is jurisdiction dependent.

The proportion of contact lens wearers who purchase contact lenses from unregulated supply outlets is substantial. Reports indicate that up to 23% of contact lens wearers purchase from the internet [96,191, 193-196], 21% from discount stores [96], 11% from pharmacies [186] and half of Malaysian school children purchased lenses from unlicensed vendors [187]. During the COVID-19 pandemic, the proportion of contact lenses purchased over the internet doubled [16], but it remains to be seen whether this change in consumer behavior will be retained post-pandemic.

Online shopping is convenient and can be initiated anywhere and anytime [193], while combining the benefits of home delivery and the potential for significant discounts [188,191,197] due to low operational costs [188]. However, contact lens purchase from unregulated outlets, particularly internet purchase of lenses, has been shown to carry increased risk of contact lens-related eye problems [198], including significant sight threatening adverse events [84,199-202].

Patients with serious and significant contact lens-related corneal inflammatory events are more likely to have purchased contact lenses on the internet compared to patients presenting with other non-serious and significant events [201]. This may be due to the lack of verification of acceptable contact lens fitting, and education regarding general hygiene practices and lens disinfection [199,200]. In addition, the frequency of eye examinations is lower among those who purchase contact lenses online [96,191,195,203] or in retail stores [191]. Also, those who purchase online are more likely to forget their contact lens aftercare schedule [193]. Supply of contact lenses without the supervision of an eye care practitioner also leads to delays in seeking professional help and treatment when problems are encountered [185,199,202].

Significant associations between poor contact lens hygiene and compliance behaviors, and purchase from unregulated outlets, has been reported amongst university students in Thailand [204] and India [205]. However, a study of older contact lens wearers in the United States of America showed no difference in compliance behaviors, including the recommended replacement of contact lenses, handwashing, and contact lens and storage case care, based on purchase location [195].

Internet purchasers report being too busy, juggling too many things and having too little time [191]. Those who purchase from unregulated supply outlets also have their contact lens fitting checked less frequently, and are less likely to check that their contact lens prescription is current prior to lens purchase [191].

## 3.1.2. Choosing not to see an eyecare professional for regular aftercare visits

Regular contact lens aftercare check-ups and eye health examinations are important, as more than half of asymptomatic contact lens wearers presenting for routine comprehensive eye examinations are diagnosed with ocular complications and/or systemic disease [206]. Amongst wearers who purchase contact lenses through the internet, follow-up eye examination frequency is less than that recommended, with 40% not having attended a follow-up examination in the previous year [194]. In fact, more than half (56%) of university student contact lens wearers in India reported not attending the recommended aftercare visits [205].

Reasons for not seeing an eye care practitioner include being 'time poor' [191], running out of contact lens supply, resulting in purchase of a different lens without trial fitting [207], forgetting the aftercare schedule [193], claiming that no aftercare advice was given [208], and the belief that they are competent lens wearers [209]. In a survey of contact lens wearers aged 18–30 years in South Africa, approximately one third believed that regular aftercare visits to their eye care practitioner should be optional [209]. Less than half of non-ophthalmic healthcare workers in Turkey comply with follow-up visits according to the recommendations of their ophthalmologists [210].

Low compliance rates were also reported for contact lens-wearing medical doctors in a Nepali eye hospital (46.2%), but were no different to age-matched subjects with no medical background (43.6%) [211]. In contrast, compliance rates with follow-up visits amongst ophthalmologists and lay public wearers in the contact lens clinic of an Education and Research Hospital in Turkey, was very high at 88% [210], and may be attributed to contact lens education being more focused in a contact lens clinic than in a general eye hospital.

Online purchasing lacks personal interaction [197]; however, improving the quality of the interpersonal communication skills of contact lens practitioners could enhance compliance with contact lens

care and maintenance among lens wearers [212]. Health-conscious consumers prefer to have their eyes examined by an eye care practitioner, and perceive that the inconvenience is worth mitigating the risk of problems [197]. Face-to-face consultations offer the advantage of tailoring advice to individual contact lens wearers and potentially preventing severe complications from occurring [199]. Therefore, it is worthwhile educating contact lens wearers as to the benefits and safeguards when lenses are dispensed and followed up by trained professionals, a scenario which does not exist when contact lenses are purchased online or through mail-order outlets [207].

## 3.1.3. Choosing telemedicine over in-person exams

Telehealth, or the provision of healthcare remotely by means of telecommunications technology, is a useful tool in ophthalmic care for the diagnosis and formulation of treatment plans for a variety of ocular diseases [213]. However, contact lens practice is not a discipline which easily lends itself to telehealth, since examination of the ocular surface at high magnification and assessment of the contact lens fit are central to clinical decision making in contact lens practice, for screening at-risk patients and to detect asymptomatic pathologies [214]. Prior to the COVID-19 pandemic, only a single report (from over two decades ago) on the use of tele-consultation to evaluate the acceptability of rigid gas-permeable contact lens fits had been published [215].

A recent paper offered the following suggestions to enable eye care practitioners to adapt to providing remote contact lens services during the COVID-19 pandemic: focus history-taking on key contact lensrelated symptoms, such as pain, redness and glare, to help identify the presence and determine the urgency of anterior segment disease; enhance contact lens wearer compliance via text (SMS) messages, written or verbal information via videos or increasing awareness of lens care phone apps; and consider at-home vision screening tools and selfimaging of the anterior eye, although current limitations of digital photographs and ocular illumination, whereby subtle changes are less discernible, need to be addressed [216].

A survey of primary care optometrists based in the United Kingdom, who provided consultations during the national lockdown following the COVID-19 pandemic in 2020, showed that contact lens-related problems were reported less frequently than vision-related problems for both remote and face-to-face consultations [216]. While this could be related to the challenges associated with providing contact lens telehealth services described above, given the frequency of contact lens-related problems reported was similar amongst remote and essential/emergency face-to-face consultations, this may also be attributable to the substantial reduction in contact lens wear in those living in lockdown (working from home and/or self-isolating) during the COVID-19 pandemic.

In the United Kingdom, 72% of patients wore their lenses less often during lockdown [18], which was similar to the 67% rate reported in Spain [55]. In Jordan, 38.8% of wearers ceased lens wear entirely during the COVID-19 pandemic [16]. The most cited reasons were the same for each of these studies and pertained to a decreased need for contact lenses due to reduced social and outdoor activities, as well as work outside the home. These findings reinforce the association of contact lens wear with cosmesis.

Information regarding telehealth contact lens services is currently very limited, and consequently, the effect on the success of contact lens wear is largely unknown. Further work to improve at-home anterior eye imaging capabilities is needed to advance the provision of contact lens telehealth services. This could provide a solution for enhancing convenience in accessing eyecare services, and reducing complications associated with a lack of adequate supervision of contact lens wear. However, the challenges of providing physical fitting of contact lenses and verifying the acceptability of the fit remain.

## 3.1.4. Choosing to buy the least expensive contact lenses/care products In Japan, contact lens price was the highest determining factor that

motivated patients to purchase contact lenses (38.0%), and this was approximately equal to the recommendation of a doctor/eye care professional/staff (37.6%) [194]. Contact lens cost was the primary reason for discontinuation of lens wear in 6% of presbyopic contact lens wearers in a university setting in the United States of America [217], while cost was a barrier to contact lens wear in 19.1% of spectacle wearers in Ghana [218]. On the contrary, female university students in Saudi Arabia did not consider cost a hindrance to wearing contact lenses [219], and in Turkey, while the majority of soft contact lens wearers considered the price of contact lenses to be acceptable (69.8%), 30.2% of habitual lens wearers considered contact lenses to be expensive [220].

Amongst daily disposable lens wearers in Canada, the most commonly cited reason for patients wearing their lenses longer than the recommended replacement frequency, was "to save money" [88]; in the United States of America, this was the second most commonly cited reason [221]. Forty-four percent (44%) of contact lens wearers in a university population in Jordan used their lenses for longer than the recommended replacement schedule, which was attributed to financial considerations, as students typically have limited income [16]. Thirty-five percent (35%) of daily disposable contact lens wearers in Italy reported reusing their contact lenses to save money [222].

Rising prices have also driven the growth in online purchase of contact lenses in Europe [188,203] and the purchase of cosmetic contact lenses in Thailand [223]. This is important to consider, given that the purchase of contact lenses by patients from unregulated supply outlets, and cosmetic contact lens wear, are associated with an increased risk of severe contact lens complications (see Sections 3.1.1 and 3.1.5).

Comprehensive cost-per-wear modeling, which takes into account professional fees, lenses and lens care solutions over 12 months, has been conducted for both Australia [224] and the United Kingdom [225]. If cost is a driver for lens replacement frequency, then the modeling suggests that daily disposable lenses are more cost effective for part-time wear, and reusable lenses for full-time wear [224,225]. These findings, along with other factors, such as risk profile for complications and convenience, should be considered by eye care practitioners during contact lens selection and fitting, particularly for young wearers, where cost is likely to have a greater impact on lens wear.

Contact lens wearers attempt to reduce costs by purchasing online or extending the recommended replacement frequency. However, these behaviors are associated with an increased risk of severe contact lensrelated complications, which also carry a separate and significant financial burden [226]. Few studies have investigated the effect of purchasing less expensive contact lens disinfection solutions. Sheard et al. [227] reported that varying the cost of contact lens solutions did not appear to impact compliance in the use of these products; the vast majority of patients still used the original recommended solutions [228]. Given that contact lens care products in developed countries are well regulated by national authorities to meet standards for safety and efficacy, switching to cheaper solutions is unlikely to pose any significant additional risks, but as different combinations of contact lenses and solutions may reduce lens comfort or increase ocular surface staining [229,230], such actions should be undertaken in consultation with an eye care practitioner.

### 3.1.5. Choosing to wear colored or 'party/novelty' contact lenses

Cosmetic contact lenses, also known as costume or decorative contact lenses, are any type of colored contact lens that are intended to change the appearance of the eyes, and which may or may not contain a refractive correction [223]. Cosmetic contact lens wearers are influenced by fashion [231], are more likely to be young, have a shorter period of lens wearing experience [232,233] and be female [232]. It was estimated a decade ago, that cosmetic contact lenses made up about 30% of the contact lens market in Southeast Asian countries [231]. Cosmetic contact lenses are frequently dispensed without a prescription in numerous countries, and education about lens care and handling is deficient in most wearers [233]. Cosmetic contact lens wear has frequently been associated with sight-threatening microbial keratitis [189,190,200,234] including a higher rate of *Acanthamoeba* keratitis [232]. Colored contact lenses with pigments printed on the surface also showed higher bacterial adherence compared to transparent (non-colored) contact lenses [235], although one review has shown no difference in the frequency of complications between wearers of colored contact lenses and transparent contact lenses [198]. The need to protect this often young, vulnerable group of wearers from developing serious ocular complications has been recognized [231]. Regulating the supply of non-prescription cosmetic contact lenses has successfully reduced the rate of adverse events in the United States of America and United Kingdom [185], and is an important first step towards improving education and supervision of contact lens wear.

### 3.1.6. Conclusions

Contact lens wearers who purchase their lenses from unregulated supply outlets appear to do so primarily to save time. It is not surprising then, that these contact lens wearers also present less frequently for eye examinations. However, given the increased risk of serious contact lensrelated complications associated with the purchase of lenses from unregulated outlets, including cosmetic contact lens suppliers, which remain unregulated in many countries, convenience needs to be balanced against safety. Strategies to ensure the provision of adequate lens wear hygiene and safety education, and ongoing care and connection with an eye care practitioner are needed, particularly for young adults, who are generally less compliant with respect to lens wear hygiene and replacement frequency [86,236-238].

Further development of tele-eyecare services might assist in this space, but greater consistency in regulatory oversight globally is also warranted. Currently, to save on costs, contact lens wearers tend to replace their lenses less frequently than indicated, purchase their lenses online, or discontinue from lens wear. Cost-per-wear modeling can assist eye care practitioners to select the most cost-effective options for contact lens wearers and reduce the chances of patients potentially electing to purchase online, potentially triggering the vicious cycle of complications associated with unregulated lens supply.

## 3.2. Health and aging factors

### 3.2.1. Medical indications for contact lenses

As well as being used for optical purposes, contact lenses have a number of medical applications which can have benefits for the ocular surface in many situations [239]. The main benefits of medical contact lenses are relief of pain, accelerating re-epithelization, corneal sealing, mechanical protection of the cornea, visual improvement, and facilitating binocularity. A complete review of these functions is outside the scope of this report and has been recently published in the Contact Lenses Evidence-Based Academic Report on the Medical Use of Contact Lenses [198]. The major limitations of medical contact lenses are increasing susceptibility of the lens wearer to infection or lens loss in patients with corneal irregularity [239,240].

### 3.2.2. Potential complications for contact lens wearers during the pandemic

The novel coronavirus has been detected in the tears and conjunctival epithelium of severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) positive patients, so the possibility that SARS-CoV-2 can also infect the ocular tissue cannot be discounted [241,242], although the risk appears to be very low [243,244]. Ocular complications post-vaccination for SARS-CoV-2, whilst very rare, have included optic neuritis, diplopia and cranial nerve palsies [245,246].

The prevalence of ocular manifestation in COVID-19 patients was estimated to be 11.03% (95% CI: 5.7–17.7%) in a recent systematic review involving data from 8219 patients, with the most common manifestation being conjunctivitis or dry eye/foreign body sensation [247]. On that basis, approximately one out of 10 COVID-19 patients could report ocular surface symptoms. There is emerging evidence that so-called "long COVID" is associated with a loss of corneal epithelial nerves and an increased density of immune cells in the cornea [248], which may have implications for contact lens wear in the longer term.

3.2.2.1. Choosing to wear lenses during the COVID-19 pandemic. The global use of contact lenses is increasing due to their ease of availability, capacity to improve vision, convenience of use in sporting and other activities, and general enhancement of quality of life [249,250]. At the beginning of the COVID-19 pandemic, a considerable number of media reports speculated that contact lens wear was unsafe [251], and that wearers of contact lenses were at a higher risk of contracting COVID-19 as they touched their eyes more often; it was therefore suggested that contact lens wearers should stop wearing lenses and revert to spectacle wear [252]. However, based on the evidence to date, practitioners can assure their patients that they can keep wearing contact lenses, and that there is no scientific evidence to suggest contact lens wearers have an increased risk of contracting COVID-19 compared with spectacle wearers [253-255]. Three recent publications have shown that oxidizing systems based on hydrogen peroxide or povidone-iodine are very effective at killing coronavirus strains, and appear to be more effective than systems based on other disinfectants unless a 'rub and rinse' step is incorporated [256-258]. Contact lens wearers must continue to practice safe lens wear and hygienic lens care habits, advice that remains the same as that provided prior to the pandemic [253]. As hands remain a possible vector for spreading microbes through contact lenses, hand hygiene should be followed before both application and removal of contact lenses to reduce the risk of contracting the virus.

It is advisable that patients with an active COVID-19 infection do not wear contact lenses [253,254]. The patient should revert to spectacle lens wear and when fully recovered may recommence wear with a new pair of contact lenses [253,259]. Previously worn soft contact lenses should be immediately disposed of, as should any remaining disinfecting solutions and contact lens cases that the patient was using. To date, little pandemic-specific information exists with respect to the cleaning and disinfection of rigid lenses, but recent reports of the ability of oxidative disinfection systems to eliminate coronavirus variants [256-258] would suggest that disinfection in either hydrogen peroxide or povidone-iodine based systems should be adequate to permit their safe reuse.

3.2.2.2. Mask-associated dry eye and chalazion. Despite great pharmacological advances and the development of vaccines, face masks and shields remain important for providing barrier protection from the COVID-19 virus. Ocular complications that have been associated with face mask use include an increased chance of developing a chalazion [260,261], and the diagnosis of dry eye appears to be increasing, although this has yet to be formally described in the literature [262, 263]. Dry eye due to mask wear has been termed 'mask-associated dry eye' [1,3,4].

The use of face masks reduces the spread of exhaled air. If masks are poorly fitted, this exhaled air moves upwards, creating an air current across the cornea. This may lead to faster evaporation of the tear film, resulting in the production of dry spots on the ocular surface, eye irritation, and discomfort [2]. Mask-associated dry eye can worsen dry eye symptoms in contact lens wearers [54], who often have a lower-quality pre-corneal tear film [262]. A contrary view is that mask wear does not adversely impact ocular comfort during contact lens wear and that patients prefer to wear contact lenses over spectacles when using a mask, as this avoids spectacle fogging [264]. Eye care practitioners should be aware of the possibility of this cause of dry eye, and educate patients to appropriately fit their face masks so that exhaled air does not go directly into the eyes, given the importance of mask wearing in controlling spread of the virus [265]. Other societal-focused factors related to the ocular surface and the influence of the COVID-19 pandemic are discussed in the TFOS Lifestyle: Impact of societal challenges on the ocular surface report [266].

*3.2.2.3.* Increased digital screen time. The time spent on digital devices increased by more than 2 h daily during the COVID-19 pandemic [54]. The amount of online education [267] and use of social media platforms also increased. Using artificial tear products to lubricate the eyes can help reduce ocular surface symptoms, as can reducing the use of air conditioning and taking longer and/or more frequent breaks from the use of digital devices [265]. Further details are included in the *TFOS* Lifestyle: Impact of the digital environment on the ocular surface report [268].

*3.2.2.4. Reduced use of contact lenses.* During the COVID-19 pandemic the use of contact lenses and the daily number of hours of lens wear decreased compared with before the pandemic, as reported in studies conducted in the United Kingdom, Ireland, Spain, Portugal, Jordan, China, Australia, Saudi Arabia and online [16,18,19,54,55,264, 269-272]. The most common reason given was that contact lenses were needed to a lesser extent when spending more time at home [18,54,269, 271,272]. Fear of infection with SARS-CoV-2 accounted for only a small proportion of people (4–28%) discontinuing contact lens wear [18,54, 269,272].

In Jordan, the majority (73%) of respondents reported that they had less frequently contacted their eye care practitioner, and 12% of them reported using the internet to purchase contact lenses during the COVID-19 pandemic compared to 6% before the pandemic [269]. There are differences in contact lens prescribers' information that is provided to wearers regarding the impact of the pandemic on their contact lens wear. Two Spanish studies highlight these differences, with most wearers (88%) in one study reporting that no professional had offered them information related to contact lens wear and COVID-19 nor had they sought it on their own (82%) [271]), whereas the other study reported that just over half (54%) of the contact lens wearers had received specific instructions regarding contact lens wear and COVID-19, mostly about handwashing (93%) and storage case hygiene (49%) [17]. Whilst contact lens wearers appear to be more frequently washing their hands during the pandemic [269], inadequate hand washing was still occurring, along with using shared towels to dry hands rather than single use paper towels [17,19,55]. In addition, non-compliance with other hygiene instructions has continued to occur during the COVID-19 pandemic, with 42% of people never rinsing their contact lenses, 30-54% of people never rubbing their lenses before soaking, and 24-26% of people showering in lenses [19,55,271]. Contact lens wearers also continued 'topping off' lens care solutions in cases 'frequently' or 'occasionally' (18-67%), did not clean their storage cases regularly ( $\geq$ 82%), used tap water to rinse their lens cases (19–46%), or replaced lens cases less frequently than monthly even though new lens cases are often provided free of charge with new bottles of disinfecting solution (≥47%) [19,55].

3.2.2.5. Exposure to hand sanitizer. People have reported a change in their handwashing routine during the pandemic. The majority self-reported that they were compliant with handwashing prior to applying and removing contact lenses, using soap and water [55]. Although hand sanitizers contain between 60 and 90% alcohol and are highly effective at killing a broad spectrum of microbes, they are not recommended for use before applying or removing contact lenses as they may transfer to the lenses and subsequently onto the ocular surface, potentially resulting in ocular burns [5,6]. If there is no other choice and the hands are not clean, sanitizer may be used, but the patient should be advised to wait several minutes until the alcohol evaporates. Eye drops or saline solution should then be applied to the fingers used for contact lens handling, and the contact lenses should be rinsed again to ensure that no sanitizer remains [273].

Eye care practitioners should continue to educate contact lens wearers to minimize the chance of developing contact lens complications during the pandemic, or when sick, in general. Advice includes handwashing for at least 20 s before contact lens handling; drying hands with single use paper towels; including a rub-and-rinse step for reusable lenses; lens storage case cleaning; regular (at least daily) renewal of solutions in the lens case; avoidance of water exposure; and when to cease lens wear during the pandemic [55].

The available evidence suggests the safety of contact lens wear has not altered due to the COVID-19 pandemic. Appropriate hygiene considerations for contact lens wear and care should be no different from pre-COVID practices [253]. Information concerning this novel coronavirus is evolving at a rapid rate and eye care practitioners must continue to monitor the literature for new findings [253].

### 3.2.3. Choosing to wear contact lenses when unwell

An understudied area of contact lens wear involves what to do when a wearer is ill with a viral upper respiratory infection, such as the common cold or influenza. The evidence related to the risk of developing microbial keratitis in those who are unwell was determined to be inconclusive in a recent review by the American Academy of Optometry Microbial Keratitis Think Tank [274]. In contrast, evidence exists of a potential link between being unwell and occurrences of corneal inflammatory events associated with contact lens wear [275].

Upper respiratory tract infection has been linked to corneal inflammatory events associated with contact lenses colonized by *Haemophilus influenzae* or *Streptococcus pneumoniae* [276,277]. Furthermore, a case control study of contact lens wearers using hydrogel or silicone hydrogel lenses on daily or planned overnight wear schedules found a 3.45x (odds ratio) chance of developing a corneal infiltrate if wearers had cold or flu-like symptoms in the previous week [122]. Upper respiratory infection can also be associated with conjunctivitis or keratoconjunctivitis. For these reasons, it is advisable to pause contact lens wear until the respiratory infection has resolved and the ocular surface is clear. In addition, certain infections can sequentially involve the contralateral eye, such as with adenovirus, which further warrants cessation of contact lens wear.

In a study of an outbreak of conjunctivitis among university students in the United States of America, contact lens wear was associated with conjunctivitis and with bilateral disease, whereas spectacle wear was protective [278]. It was hypothesized that wearing spectacles created a barrier to droplet transmission of the virus or that persons wearing glasses touch their eyes less frequently than those who do not [278].

Adenovirus conjunctivitis is of particular interest in eye care because of its highly transmissible nature, including via fomites, and potential for vision-threatening epidemic keratoconjunctivitis. It is the most common ocular viral infection [279]. Mainstays in the management of adenovirus include frequent hand washing, use of separate towels, and avoidance of close contact with others during the period of contagion, which ranges from seven to 14 days from the onset of symptoms in the second eye, if involved [280]. Some cases of adenovirus conjunctivitis can benefit from the use of povidone iodine and/or topical steroids to reduce symptoms and scarring [281]. Close follow-up is warranted in patients being treated with topical corticosteroid drugs. Although most patients present with follicular conjunctivitis, adenovirus infections may also lead to corneal epithelial defects, edema, filaments and infiltrates, and conjunctival membranes. Bandage contact lenses may be useful in this situation to promote healing of the cornea and symptom resolution, along with prophylactic topical antibiotics to prevent secondary infections [282].

Patients who wear contact lenses should be counseled to seek medical evaluation even if they think it is "just pink eye", to rule-out more serious infections that require intervention beyond the cessation of contact lens wear. Optimal timing of safe return to contact lens wear requires additional study. Based on the established management protocols for other disease entities, such as papillary conjunctivitis, a gradual resumption of contact lens wear once the eye is no longer inflamed may be most sensible. A new contact lens storage case and lens should be used upon return to wear. 3.2.4. Choosing to wear contact lenses when suffering from ocular allergies

Seasonal allergic conjunctivitis and perennial allergic conjunctivitis are the most common forms of allergic eye diseases [283]. Approximately 20% of the population suffer from allergic conjunctivitis, with stark differences between regions and increasing prevalence worldwide [284,285]. Seasonal allergic conjunctivitis, which accounts for 90% of all allergic eye disease, is triggered by pollen and outside mold, and is season dependent. In contrast, perennial allergic conjunctivitis, which accounts for about 5% of all allergic eye diseases, is a chronic condition, typically occurring year-around and is caused by allergens found indoors, such as dust mites, animal dander, mold and insects.

Typical symptoms of seasonal allergic conjunctivitis include itching, burning, tearing, conjunctival hyperemia, chemosis, and eyelid edema, with milder symptoms in perennial allergic conjunctivitis [286]. The pharmaceutical management of allergic eye diseases has been extensively reviewed and includes topical antihistamines, mast cell stabilizers, dual-acting agents (antihistamine and mast cell stabilizer), vasoconstrictors, calcineurin inhibitors, non-steroidal anti-inflammatory drugs, corticosteroids (including intra-nasal), as well as systemic antihistamines and allergen-specific immunotherapy [284, 287-291]. Despite ocular symptoms and advice to cease lens wear, many contact lens wearers look for ways to comfortably wear contact lenses. Several studies have demonstrated the potential benefits of daily disposable contact lenses in patients with allergic conjunctivitis [292-294]. Studies showed that during wear of daily disposable lenses, participants experienced less ocular symptoms [293], better comfort [292], and showed improved clinical signs (i.e., reduced bulbar redness, corneal staining, palpebral redness and roughness) [292] compared to wear of a new set of their habitual re-useable lenses. A study using an environmental exposure chamber and two different types of daily disposable contact lenses (nelfilcon A and etafilcon A) confirmed the positive effects of daily disposable contact lenses on symptoms and clinical signs, compared to the naked eye, highlighting that the barrier function and lens surface moisture contribute to the observed benefits [294].

Recent work has focused on antihistamine releasing contact lenses [38,39,295,296]. Wear of the antihistamine (ketotifen) releasing contact lenses was reported to lead to significantly lower ocular itch scores, both after 15 min and 12 h of lens wear [38], with no differences in corneal staining between test and control (non-antihistamine) lenses [39]. In 2021, Japan was the first country to approve prescription of these contact lenses, followed soon after by Canada and the United States of America.

# 3.2.5. Choosing to wear contact lenses while having systemic disease or using systemic drugs

Systemic diseases, such as diabetes mellitus and thyroid disease that have ocular surface manifestations, can complicate successful contact lens wear. People aged 65 years of age with diabetes have a prevalence of dry eye of 15%–33% [297], which is broadly equivalent to that seen in the general population. Dry eye has been reported in up to 85% of patients with thyroid eye disease and is the most frequent cause of ocular discomfort in this population [298].

Individuals with diabetes can have an abnormal corneal epithelium, with prolonged wound healing, reduced corneal sensation, reduced corneal oxygen consumption, abnormalities of the corneal endothelium, and an increased risk of infection [299,300]. To date, very few studies have evaluated the potential for adverse events in individuals with diabetes wearing contact lenses [301-303]; more studies are needed to evaluate if contact lens wear does indeed provide a risk of any sort to the cornea in people living with diabetes. Clinicians fitting contact lenses to the patients with diabetes need to carefully consider the duration of disease, the level of glycemic control, the presence of retinopathy and the patient's overall health [300]. It is currently considered reasonable to fit contact lenses to patients with controlled disease, who have been counseled on the potential additional risks inherent to diabetes, and who

are monitored carefully by their eye care practitioner [299].

Systemic medications can cause or exacerbate dry eye, and secondarily, make contact lens wear challenging [304,305]. This is covered in more detail in the *TFOS Lifestyle: Impact of elective medications and procedures on the ocular surface* report [306]. Common offenders include anticholinergic agents, which include antidepressants, antipsychotics, antihistamines, and medications for Parkinson's disease. The use of antihypertensives (beta-blockers and angiotensin-converting enzyme inhibitors), antiarrhythmics and isotretinoin can also negatively impact the ocular surface [307].

The type and severity of the underlying disease can also impact the ability to wear contact lenses. Optimization of the underlying systemic disease is paramount. It is important to optimize the ocular surface for all contact lens wearers, but even more so in those with underlying systemic disease [308]. Topical lubricants, anti-inflammatory medications, punctal plugs, eyelid positioning and hygiene all play a role in maintaining a healthy ocular surface [309]. The mode of contact lens wear, care, and lens design and materials are also of greater relevance for these patients. For those patients who cannot tolerate standard contact lenses, the availability of specialty scleral lenses continues to grow and offer both refractive and therapeutic benefits. Some systemic diseases benefit from the therapeutic application of contact lenses, such as with scleral lenses and bandage contact lenses [198] (also Sections 3.2.1 and 3.6.1).

### 3.2.6. Choosing to wear contact lenses when using topical ocular drugs

To avoid preservative-toxicity, any topical medications used during soft contact lens wear should ideally be non-preserved whenever possible, to avoid their uptake and consequent release onto the ocular surface. Benzalkonium-preserved eye drops should be avoided in soft contact lens wear as lens uptake and subsequent release of the benzalkonium preservative into the tear film can result in significant damage to the ocular surface [177,310-314]. Recent reports have suggested that high molecular weight preservatives found in contact lens solutions and various ocular lubricants, may be safe to use with soft contact lenses, as their uptake and release are reduced compared with older, low molecular weight preservatives [177,314,315]. Various non-preserved artificial tear formulations have been reported to improve ocular comfort in contact lens wearers, with no known superiority of one formulation over the other [315]. In the presence of soft contact lenses, interaction of topical drop formulations with the ocular surface is unpredictable, with resultant uncertain therapeutic efficacy. Other concerns are the risk of development of contact lens surface deposits or discoloration, particularly with soft lenses [316]. Therefore, patients are advised to instill therapeutic eye drops before the contact lens is applied, or after it is removed for the day, a concept that also holds true for scleral lenses [317-319].

While wearing bandage contact lenses overnight for medical indications, such as in the case of ocular surface disease or following corneal/ocular surface surgical procedures, preserved drug formulations may be used under close supervision if there are no non-preserved formulations available [239,320].

### 3.2.7. Effect of age of wearers and years of contact lens wear

Children (aged eight to 12 years) and teenagers (aged 13–17 years) report significant improvements not only in vision, but also appearance, satisfaction, ability to perform activities and peer perception during contact lens wear [14]. In a study of children aged eight to 11 years, those wearing contact lenses reported that their self-perceived physical appearance, athletic competence, and social acceptance were higher, relative to a group wearing spectacles [321]. Children (aged eight to 14 years) wearing soft hydrogel or silicone hydrogel contact lenses were less likely to report contact lens dryness, as defined by a positive score on the Contact Lens Dry Eye Questionnaire [322], than an adult population (mean  $\pm$  standard deviation age: 30.9  $\pm$  10.8 years) [323].

Patient age and length of contact lens wear have an impact on the

ocular surface and continued success with contact lens wear. The prevalence of dry eye disease in patients aged over 50 years is between 5% and 35% [324]. The ratio of central to mid-peripheral corneal epithelial immune cells increases with age from 15 to 35 years for both contact lens wearers and non-lens wearers, but soft contact lens wearers were reported to exhibit a higher density of corneal epithelial dendritic cells than non-lens wearers [325].

Meibomian gland atrophy increases with age, and prolonged duration of contact lens wear has also been associated with a decrease in the number of functional meibomian glands [326]. It has also been suggested that contact lens wear accelerates age-related changes in the meibomian glands [62].

In patients who have worn contact lenses for many years, severe limbal stem cell deficiency is a serious, but rare occurrence. A case series has been published of 18 eyes with severe limbal stem cell deficiency, following on average of 14 years daily usage of 10 or more hours of contact lens [327]; however, many of these patients also had other ocular complications, including severe MGD, rosacea, low serum vitamin A levels, and other confounders which may have contributed to the limbal stem cell loss. A full account of contact lens-induced limbal stem cell deficiency is beyond the scope of this report, but further information can be found in a narrative review [328].

As the field of myopia control grows, the impact of starting contact lens wear at a younger age on the ocular surface and cornea is of increasing interest. In 2019, the first soft contact lens with a specific labeling for myopia control was approved by the United States Food and Drug Administration (MiSight®, CooperVision Inc., USA). It is a daily disposable, hydrogel lens indicated for children aged eight to 12 years. Orthokeratology for myopia management in children has gained popularity, although the majority of these lenses are approved for use by the Food and Drug Administration to correct myopic refractive error in nondiseased adult eyes; these devices are therefore used 'off-label' for this purpose in children [329]. A rigid orthokeratology lens (Acuvue Abiliti Overnight Therapeutic Lenses, Johnson & Johnson, USA) has recently received approval from the United States Food and Drug Administration for myopia control.

There are growing data to suggest the safety of contact lens wear in young children. A clinical trial of 240 children (aged seven to 14 years) wearing silicone hydrogel contact lenses on a daily wear basis found an incidence rate of 14.2 per 100 patient-years for all adverse events, with contact lens-induced papillary conjunctivitis being the most common event and the incidence of significant corneal inflammatory events being 1.3 per 100 patient-years [330]. The incidence of corneal inflammatory events was approximately equal to that seen in studies of adult contact lens wearers [331]. Poor comfort resulted in 8.3% of children discontinuing lens wear during the study [330]. A three-year investigation of adverse events related to contact lens wear in 294 children aged seven to 11 years demonstrated that 74.8% encountered at least one adverse event [332]. Of the 432 adverse events, 75.2% were ocular, and 24.8% non-ocular. Contact lens wear was judged to be 'probably' or 'definitely' related to 60.6% of the ocular, and 2.8% of the non-ocular, adverse events. None of the ocular adverse events were serious or severe, or caused permanent contact lens discontinuation. The corneal inflammatory events amounted to 185 cases per 10,000 patient-years of contact lens wear. The incidence of moderate ocular adverse events that were 'probably' or 'definitely' related to contact lens wear was 405 cases per 10,000 patient-years of contact lens wear [332].

The eyelid and conjunctival microbiota of children (aged eight to 14 years) wearing soft hydrogel lenses for two years comprised what is considered a normal ocular microbiota, did not change over time [333], and was similar to other reports of the microbes from contact lenses of adults [334]. A recent study reported that ocular health and safety examined by biomicroscopy of 144 children fitted with a soft hydrogel daily disposable contact lens and followed for six years was similar to pre-lens wear, suggesting that children of this age can successfully wear daily disposable hydrogel contact lenses with minimal impact on ocular

surface physiology [154].

The Infant Aphakia Treatment Study [335] followed children who underwent cataract extraction, with or without intraocular lens implantation, between the ages of one and six months, and found that the subset of children that continued contact lens wear to age 10.5 years had the best visual outcomes; however, the study did not report on ocular surface status. There was no difference in self-reported contact lens-related adverse events, problems with compliance, wearing time or ocular health in children who had worn contact lenses for at least 10 years, but were fitted at 12 years or younger versus similarly long-term wearers who were fitted at age 13 years or older [336]; similarly, no differences between the two groups was noted from a subset that underwent slit lamp biomicroscopy and specular microscopy [336].

The Contact Lens Assessment in Youth (CLAY) study on people aged from eight to 33 years [164] found that inflammatory adverse events associated with contact lens wear tended to peak in incidence between 13 and 25 years of age. Another study from the same CLAY research group found that the risk of having an adverse event that interrupted contact lens wear was less at 10 years of age compared to those aged 20, and also at 30 years of age compared to 20 years [337]. In both of these studies, planned overnight wear of lenses was identified as a risk factor for adverse events, and another study found that overnight wear of contact lenses peaked in those aged 18-25 years, and was significantly lower in people aged 26 years or older [237]. Studies in people aged under 18 years and wearing orthokeratology lenses to control the development of myopia have estimated the rate of microbial keratitis to be 4.9 to 5.3 per 10,000 patient years [338], or 13.9 per 10,000 patient years [339]; the latter estimate is approximately equal to the numbers reported for adults wearing soft contact lenses on a planned, overnight wear basis [340], suggesting no increased risk of microbial keratitis during planned overnight wear of lenses in children.

### 3.2.8. Handling issues and their impact on contact lens success

Younger and older age have been considered to impact successful and safe contact lens wear due to factors such as manual dexterity and comprehension capacity. Children as young as eight years of age are capable of understanding contact lens care processes [14] and have no issues handling daily disposable contact lenses [341]. This may be related to greater parental supervision and financial resources to purchase lenses and care products for younger children.

At the other end of the spectrum, older wearers are more likely to have other comorbidities, such as dry eye disease, poor vision, arthritis and dementia, which can make it difficult to wear and care for contact lenses. Highly oxygen permeable soft contact lenses were developed to address patients who struggled with handling aphakic contact lenses following cataract surgery [342]. With the advent of modern intraocular lenses, less attention has been given to contact lens wear in the older population.

#### 3.2.9. Choosing to wear a contact lens after cosmetic (aesthetic) treatments

The choice to wear contact lenses after cosmetic surgery or treatments may be purely cosmetic or it may be driven by the optical and lifestyle advantages conferred by contact lenses. Furthermore, patients who undergo refractive surgery or intraocular surgery may have residual refractive error that they wish to correct with contact lenses rather than spectacles.

3.2.9.1. After PRK, LASIK and small incision lenticule extraction. Patients who undergo photorefractive keratectomy (PRK), laser-assisted in-situ keratomileusis (LASIK) and small incision lenticule extraction may opt for contact lens wear to correct any residual error not amenable to enhancement; correct residual myopia in the near eye when monovision is chosen for activities in which stereo distance vision is a high priority; enable monovision, if the full distance correction was chosen for surgical correction; or to change eye color. Generally, patients and their

clinicians will choose soft contact lenses in these situations. It would normally be considered reasonable to return to the same contact lens and material, in a different refractive power, if the patient successfully wore contact lenses prior to the ocular surgery. However, the fit of the contact lens may no longer be appropriate if there is substantial change in the corneal apical curvature.

As discussed in further detail in the *TFOS Lifestyle: Impact of elective medications and procedures on the ocular surface* report [306], LASIK, due to acute disruption of the corneal stromal and epithelial sub-basal nerves, is associated with ocular dryness symptoms; 60% of patients are symptomatic at one month postoperative, when there is still evidence of reduced basal tear secretion [343]. Typically, ocular irritation may persist for up to six months, and ocular surface staining may not return to baseline levels until 12 months [344] or beyond. PRK and small incision lenticule extraction (SMILE) have a lower risk of postoperative dry eye than LASIK [345,346]. It is prudent to defer contact lens wear until the postoperative course of topical medical therapy is complete, and until after the eye has recovered from any surgically-induced aqueous tear deficiency, typically after approximately three to four weeks.

It is generally advisable that patients who have undergone refractive surgery and return to contact lens wear, or who are refit into different lenses, should be reviewed at more frequent follow-up visits as they may be more prone to complications related to dryness or inflammation, with neovascularization to the flap or incision site a possible concern.

*3.2.9.2. After radial keratotomy.* Contact lens wear after radial keratotomy presents numerous challenges [347-349]. The corneal incisions can develop epithelial plugs and may be subject to inflammatory events and ulceration. The incisions may be prone to neovascularization, especially if they are located at or close to the limbus. Eyes that have undergone radial keratotomy may have irregular astigmatism and be prone to fluctuation in corneal power over the course of the day. A higher modulus soft contact lens may reduce these optical challenges, although no evidence to confirm this is available. Scleral lenses are a useful option for addressing the optical challenges of eyes that have undergone prior refractive surgery [350-352]. Further discussion of the impact of keratotomies on the ocular surface is also provided in the *TFOS Lifestyle: Impact of elective medications and procedures on the ocular surface* report [306].

3.2.9.3. After intraocular surgery. Any eye that has undergone intraocular surgery, such as cataract extraction, vitrectomy for floaters or retinal detachment, or intraocular contact lens insertion for high refractive error, may have compromised corneal endothelial function, particularly if the surgery was prolonged, if there were intraoperative complications, or if there was postoperative elevation of intraocular pressure [353-356]. Any contact lens, particularly those with lower oxygen permeability or increased thickness due to the nature of the refractive power requirements, may exacerbate or trigger corneal edema in patients with endothelial compromise [357-360]. Ideally, the surgeon should be consulted as to if, and when, contact lens wear is advisable. Assessment of the corneal endothelium, via confocal or specular microscopy, might be warranted for eyes with suspected endothelial dysfunction. A highly oxygen permeable lens, and limited wearing time, may allow for contact lens wear in cases in which spectacle correction is not an option.

3.2.9.4. Contact lenses for colour change. Where contact lenses are available in a limited range of materials and parameters, such as colored lenses for eye color change, it may be more difficult to achieve a comfortable fit after refractive surgery. Poor oxygen permeability and a lack of availability in daily disposable replacement frequency [361] necessitate closer patient follow-up due to the risk of corneal neovascularization at the surgical flap or incision site. A similar approach

applies to any eye with a history of inflammatory episodes, infiltrates, ulcers, or neovascularization, or any eye with a compromised corneal endothelium from conditions such as trauma, surgery, or Fuchs' dystrophy. Further details are also provided in the *TFOS Lifestyle: Impact of elective medications and procedures on the ocular surface* report [306].

3.2.9.5. After cosmetic blepharoplasty. Patients who wear contact lenses should seek the advice of their surgeon as to when it is advisable to resume contact lens wear after eyelid surgery. Any tugging on or traction of the eyelids in the process of contact lens application or removal may disrupt sutures or interfere with healing. Further details are provided in the *TFOS Lifestyle: Impact of elective medications and procedures on the ocular surface* report [306].

Any time the eyelid configuration or contour is modified, it is possible that a well-fitting and comfortable contact lens before surgery may no longer be possible. A reasonable approach, but publications to support it are currently lacking, may be to resume contact lens wear on a limited basis and increase to a preoperative schedule, as tolerated. Refitting into a different contact lens design may be required if comfort or lens retention is an issue.

3.2.9.6. After botulinum toxin injection. Botulinum toxin injections in the periocular region reduce muscle tone but are unlikely to cause problems with contact lens instability or comfort unless there is a resultant short-term ptosis. However, no studies to date have evaluated this hypothesis. This topic is covered in further detail in the *TFOS Lifestyle: Impact of cosmetics on the ocular surface* report [362].

3.2.9.7. With concurrent use of cosmetic topical drops. Numerous agents are now available that are approved for use in, or near, the eyes for cosmetic purposes, with further details included in *TFOS Lifestyle: Impact of cosmetics on the ocular surface* report [362]. These agents include bimatoprost 0.03% (Latisse, Allergan, USA) for increasing the growth of eye lashes, brimonidine tartrate 0.025% (Lumify, Bausch + Lomb, USA) to relieve redness of the eye due to minor eye irritations, oxymetazoline hydrochloride 0.1% (UPNEEQ, RVL pharmaceuticals, USA) for acquired blepharoptosis, and pilocarpine hydrochloride 1.25% (VUITY, AbbVie, USA) for the management of presbyopia.

Not all cosmetic products provide the rationale behind the advice provided, but typically recommend waiting 10–15 min after eye drop application before applying contact lenses. Labeling for the Latisse product states that *"benzalkonium chloride in Latisse may be absorbed by and cause discoloration in contact lenses"*, thus providing an appropriate rationale for leaving some time after its use before contact lens wear commences.

# 3.2.10. Impact of co-existing ocular surface disease on successful contact lens wear

Contact lens wearers with ocular surface disease may face additional challenges. They may have problems with eye discomfort, ocular redness, and/or deposits on the contact lenses, interfering with both comfort and vision.

Contact lens discomfort was defined by the 2013 TFOS International Workshop on Contact Lens Discomfort [363] as "a condition characterized by episodic or persistent adverse ocular sensations related to lens wear, either with or without visual disturbance, resulting from reduced compatibility between the contact lens and the ocular environment, which can lead to decreased wearing time and discontinuation". Patient-reported outcome 'instruments' (questionnaires) are increasingly available to eye care practitioners. Instruments aiming to specifically measure contact lens discomfort have been developed, however very few appear to have been psychometrically tested [165,364-366] to the appropriate degree. A recent systematic search for validated tools to evaluate patient-reported outcomes of long-term contact lens wearers yielded only four available instruments (the Pediatric Refractive Error Profile, the Ocular Surface Disease Index, the pain or comfort subscale of the National Eye Institute Visual Function Questionnaire, and the Contact Lens Dry Eye Questionnaire), which had been used in contact lens wearing myopes [249].

The terms "contact lens-induced dry eye" (CLIDE – defined as the existence of signs and symptoms of dry eye during contact lens wear, whereby such signs and symptoms did not exist prior to contact lens wear) and "contact lens-associated dry eye" (CLADE – defined as the existence of signs and symptoms of dry eye during contact lens wear) have been proposed to assist ongoing interpretation of the literature [304]. However, these terms have not been widely adopted and the term 'contact lens discomfort' is often used, based on symptoms alone. More research is needed to determine whether contact lenses can induce dry eye (both signs and symptoms) in contact lens wearers who had no ocular surface disease prior to wear, and if so, what is the timescale and risk factors for this process.

3.2.10.1. Reduction in performance related to pre-existing disease. Common sense suggests that pre-existing ocular surface disease should be treated to minimize any signs and symptoms that might be confounded with problems associated with contact lens wear itself. This strategy is elucidated in the 2013 TFOS International Workshop on Contact Lens Discomfort [33]. The management of ocular surface disease is beyond the scope of this report. There are no data on contact lens discontinuation rates in patients with treated versus untreated ocular surface disease. The therapeutic use of contact lenses in the setting of ocular surface is covered in detail in the 2021 Contact Lens Evidence-based Academic Report on Medical Use of Contact Lenses [198], and is briefly reviewed in Sections 3.2.1 and 3.2.9 of the present report.

3.2.10.2. Reduction in ocular surface performance related to aging. It is generally appreciated that with increasing age, the function of the ocular surface declines in association with a reduction in secretions of the various tear film components, reduction in sensation, and altered mucosal immune responses [367-369]. Ocular Demodex is frequently observed in the eyelashes of older age patients, and is a possible causative agent of blepharitis [370,371]. What might be considered a clinically significant infestation with Demodex when found in evelashes of contact lens wearers remains uncertain. However, one report did show that increased amounts of Demodex were found in patients who had ceased lens wear, compared with a control group of successful wearers [372], and another showed that contact lens wearers appeared to exhibit higher numbers of ocular Demodex [373], although further work on this topic is warranted. With increased lifespan and activities into the later decades of life, these factors might contribute to issues with contact lens tolerance, and lead to lens dropout. Clinical experience suggests there is less dropout of rigid corneal lens wearers in midlife and later years than there is among soft contact lens wearers, although this has never been formally studied. Years of contact lens wear and aging factors are addressed in more detail in Section 3.2.7.

*3.2.10.3.* The microbiome. The gut microbiome may be linked to dry eye through alterations in immune homeostasis, in Sjögren's syndrome, in particular [374-377]. The ocular microbiome, with its relatively low diversity of microorganisms, has been the subject of various recent studies [378-381]. As yet, there is no evidence that variation in the gut or ocular microbiomes is related to contact lens discontinuation. Further details on this topic can be found in the *TFOS Lifestyle: Impact of nutrition on the ocular surface* report [382].

3.2.10.4. Management approaches to enhance contact lens wear in symptomatic patients. The TFOS International Workshop on Contact Lens Discomfort report [363] advised that options for patients who have contact lens discomfort or intolerance include: modifications by way of lens choice, mode of wear, and care; addressing modifiable patient risk factors; treating underlying disease; improving the ocular environment; and modifying the general environment. It further concluded that the use of topical artificial tears and wetting agents, oral essential fatty acids, punctal occlusion and topical medications (e.g., azithromycin, cyclosporine A) may be beneficial, along with avoiding adverse environments (e.g., aircraft cabins) and altering blinking behavior. All these approaches have been used in the treatment of patients with dry eye disease or MGD [383] and may be useful adjuncts in reducing contact lens discomfort, although further evidence of their specific efficacy in the context of contact lens wear is required [384]. New topical artificial tears preparations are increasingly available in multidose, sterile, preservative-free formats and many of these may provide additional benefits in the setting of contact lens discomfort [385-388].

Cochrane systematic reviews and meta-analyses on the use of cyclosporin A, artificial tears, punctal occlusion and serum eye drops for dry eye disease suggest that reports of the impact of each of these is inconsistent or inconclusive [389-392]; none studied effects on contact lens discomfort or dropout specifically. Eyelid hygiene treatments may be able to provide symptomatic relief for blepharitis and MGD, but the effectiveness of other treatments for MGD such as topical corticosteroids, intense pulsed light, and oral antibiotics remains inconclusive [393-396]. The 2013 Contact Lens Discomfort Workshop report on Management and Therapy [397] concluded that the effects of cyclosporin A on contact lens discomfort are contradictory. The authors concluded that overall, the balance of evidence somewhat suggested that punctal occlusion can reduce contact lens discomfort, and that silicone plug occlusion is more likely to be more effective than dissolvable types. Similarly, it was concluded that occlusion of the puncta in both the upper and lower eyelids was likely to be beneficial, in preference to occluding the lower eyelid alone. Cochrane and systematic reviews and meta-analyses on the use of oral omega-3 fatty acid supplementation indicate that this may be an effective treatment for dry eye disease [398-400]. In a randomized, controlled trial, oral omega-6 fatty acid supplementation was found to be helpful for reducing contact lens discomfort [401], and oral omega-3 fatty acid treatment may alleviate dry eye symptoms and improve lens comfort and cytological changes in contact lens wearers [402]. A randomized controlled trial, involving 72 adults with contact lens discomfort, assessed the efficacy of various anti-inflammatory approaches, comprising a topical corticosteroid, as well as oral omega-3 fatty acid supplements, relative to an oral olive oil placebo, for modulating the inflammatory changes associated with contact lens discomfort [403]. Contact lens discomfort was attenuated by oral long-chain omega-3 supplementation for 12 weeks. Acute (two-week) topical corticosteroids and longer-term (12-week) oral omega-3 fatty acid supplementation reduced tear levels of the proinflammatory cytokines interleukin-17A and interleukin-6, demonstrating parallels in modulating ocular inflammation in lens wearers with these approaches.

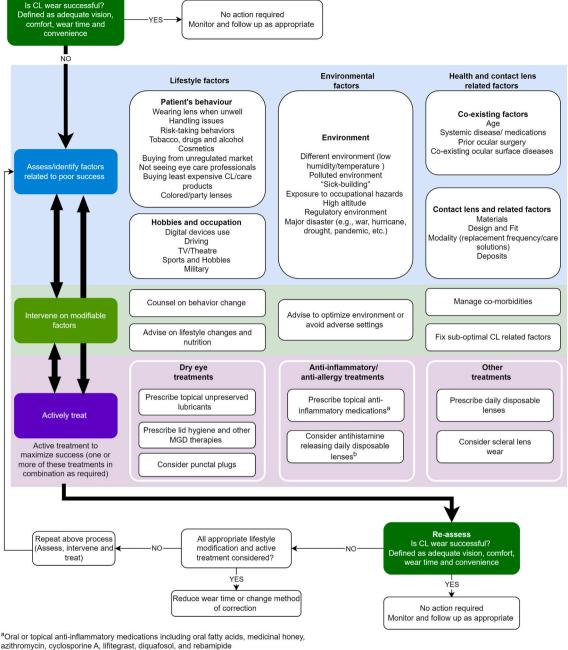
Novel therapeutic agents, including topical antibacterial honey, liftegrast 5%, diquafosol 3% and rebamipide 2%, have been proposed for the management of contact lens discomfort [404-408]. It is hoped that the effectiveness of many of these preparations will be confirmed in appropriately conducted, randomized controlled trials in future research.

The subcommittee of the present report created a summary of current management strategies for contact lens discomfort (Fig. 1), which they considered a reasonable approach to addressing problems with contact lens wear in the setting of ocular surface disease, dry eye disease, or contact lens intolerance, based on currently available evidence.

### 3.3. Environmental factors

## 3.3.1. Choosing to wear contact lenses in 'non-standard' environments

The impact of humidity and/or temperature levels on contact lens wear has been assessed in a variety of studies, including wearing contact lenses on aircrafts [409,410], when using digital devices [411-413] and



<sup>b</sup>In those with ocular allergies

Fig. 1. Summary of potential management strategies for contact lens discomfort

Although recommendations displayed in this Figure are informed by evidence, the level and strength of this evidence can vary and are not equal for each approach. The reader is referred to the main body of the text for more information on this.

evaluation in environmental chambers [414-416]. However, many of these studies were carried out using contact lens types and materials that are used less often today or are no longer available.

Low humidity appears to be a particularly challenging environment for the ocular surface, especially for contact lens wearers. Symptom reports among people using visual display terminals are more prevalent among contact lens wearers and females [413,417,418]. Contact lens wear in environments with air conditioning and heating has also been studied [419], and it was concluded that scratchiness was the only symptom with a significantly higher prevalence among contact lens wearers compared to non-lens wearers.

In a review of travelers with eye disease, one of the main exacerbating risk factors was exposure to a low humidity environment [420]. Observations of contact lens wearing patients in Australia with severe contact lens related microbial keratitis found that this was more likely to occur in warmer, humid regions, as compared with smaller, more peripheral corneal lesions, which were more common in cooler climates [421]. An *in vitro* study demonstrated that lower room humidity seems to increase contact lens material dehydration, which is further accelerated by the presence of airflow [422]. The levels of several tear film inflammatory mediators during contact lens wear differs depending on room humidity [423].

Other research groups have evaluated the impact of temperature on contact lens diameter and modulus, comparing these parameters at room temperature with those found at eye temperature [424,425]. Increased use of digital devices, especially in air conditioned

environments, and with associated reduced eye blink efficiency, may contribute to dry eye symptoms among contact lens wearers [426]. Further details are included in the *TFOS Lifestyle: Impact of the digital environment on the ocular surface* report [268].

Symptomatic contact lens wearers have higher corneal cold detection sensitivity, and report greater intensity and irritation sensations of the cornea at stimulus detection than asymptomatic lens wearers [427].

Exposing soft contact lens wearers to an environmental chamber at different air temperatures and relative humidity showed that decreasing air temperature and relative humidity results in a thinner pre-lens tear film, less stable tear film and increased ocular dryness [428]. Non-lens wearers were fitted with two different soft contact lenses to observe the effect of the exposure to a controlled adverse chamber environment. This study revealed marked tear film instability, higher tear osmolarity and increased tear evaporation, with dry eye and visual symptomatology in non-adapted hydrogel lens wearers, suggesting that silicone hydrogel lenses may be a better choice for those who live and work in cool, low-humidity and windy conditions [415]. In contrast, soft contact lens dehydration was unaffected by environmental extremes (arid, temperate and arctic conditions), observed using an environmental chamber [416].

The predominant factor in many of the above studies may be contact lens dehydration due to low humidity, which is also impacted by airflow and temperature. In summary, lifestyle choices resulting in changed environmental conditions may impact contact lens comfort, but further work is required on this topic.

#### 3.3.2. Choosing to wear contact lenses in environments that are polluted

Only a few studies have observed the impact of pollution on contact lens wear. An evaluation of the influence of air pollution, specifically sulfur dioxide levels, on tear film pH found a negative correlation between sulfur dioxide and tear pH, suggesting that an atmosphere with a high concentration of oxidizing agents exerts an appreciable influence on tear pH changes [429]. In individuals who spent about 8 h each day in different levels of sulfur dioxide, problems associated with contact lens wear increased with higher levels of sulfur dioxide [429].

Air pollution can have a wide range of effects, from no symptoms to chronic eye discomfort and irritation [430]. It was suggested that the effects of air pollution in many indoor and outdoor environments are often overlooked when eye care practitioners perform clinical examinations on patients [430]. Nevertheless, there are significant correlations between eye irritants and symptoms [410,431,432]. Ocular discomfort could be an indicator of poor indoor air quality [431]. A recent study reported that the least comfortable environments, as related contact lens wear, are those that are dusty, polluted or smoky, but comfort significantly improved when refitting the hydrogel contact lens wearers in this study into silicone hydrogel lenses [433]. Brief passive exposure to cigarette smoke is associated with adverse effects on the ocular surface, including decreased tear film stability and damage to the ocular surface epithelia [434].

Air pollution in urban and metropolitan areas, as well as indoors, may impact ocular surface health, including the epithelium and the tear film, and contact lens comfort [414]. Relevant factors include the levels of ozone, sulfur dioxide, carbon dioxide, nitrogen dioxide and passive cigarette smoke in the air [410,414,429]. However, one study failed to observe significant differences in ocular comfort while wearing contact lenses when exposed to moderate-to-severe air pollution [435]. The impact of global warming on ocular health, the tear film and contact lens comfort has not been studied.

## 3.3.3. "Sick-building syndrome" and contact lens wear

Office employees can suffer from ocular discomfort [436], perhaps as a component of so-called 'sick-building syndrome'. This term has been used to describe an increasingly common pattern of symptoms seen in workers in modern office buildings [437]. The main cause of sick-building syndrome may be due to the recycling of air in rooms, traffic noise, poor lighting and the effects of buildings located in polluted metropolitan areas [438]. However, sick-building syndrome is poorly defined. Symptoms are mainly allergy-like and include nasal, ocular and mucous membrane irritation, dry skin, respiratory symptoms and general symptoms, including fatigue, lethargy, headaches and fever [439, 440].

As sick-building syndrome is a source of ocular discomfort [431], it may also impact contact lens wear. However, it may be hypothesized that wearing contact lenses, which intrinsically challenges the ocular surface (e.g., in even patients with mild dry eye disease), may accelerate the signs and symptoms of sick-building syndrome. Poor air quality, low humidity and airflow may all play a role. With the relatively rare exception of some comments on sick-building syndrome in relation to contact lens wear [431], evidence of a direct link is lacking, and this is an area for further research. However, in non-contact lens wearers, the most prevalent symptoms in sick-building syndrome are eye irritation and non-specific, upper respiratory symptoms [440]. In conclusion, the office working environments can, in some cases, be challenging for contact lens wearers and can compromise ocular health.

## 3.3.4. Challenging environments

In virtually all challenging environments, reported ocular comfort improved significantly two weeks after changing patients from a habitual hydrogel to a silicone hydrogel contact lens [433]. However, the study design employed, in which patients were simply refit into a new lens type, is highly susceptible to bias. Of note, is that for the environments examined, wearers were the least comfortable in dusty, polluted or smoky environments, and were most comfortable while reading or using a computer [433].

### 3.4. Occupation, sports and recreation

### 3.4.1. Choosing to wear contact lenses when using digital devices

As discussed in the TFOS Lifestyle: Impact of the digital environment on the ocular surface report [268], there is growing global dependence on digital devices [441,442]. Digital device use is ubiquitous, with estimates that there are more than 4.66 billion active internet users worldwide, which is more than 50% of the global population [441]. In digital device users, there is a reduction in eye blink frequency and amplitude, which has been associated with visual complaints that include eye strain, dry eyes, burning, irritation and blurry vision [441]. A systematic review and meta-analysis of dry eye disease in those using digital devices concluded that their high global prevalence estimate of 49.5% lacked reliability; they highlighted an urgent need for common diagnostic criteria to be developed in this area in order for appropriate preventative action to be taken [443]. Despite 89% of soft contact lens wearers reporting eye fatigue more than once per month, and 60% more than once per week, of a comprehensive list of ocular symptoms, including eye strain/pain, dryness and tired eyes, only the frequency and severity of eye dryness and irritation were significant factors in soft contact lens wearers (n = 602) compared to non-wearers (n = 127) [412].

For both the sub-classification and management of dry eye disease and contact lens discomfort, blinking serves as an important clinical metric [444-446]. Contact lens wearers are more predisposed to incomplete blinking when using digital devices [447] or reading a book [448], and the frequency and completeness of the blink are altered [29]. Adequate contact lens wettability requires an adequate blink rate to be maintained. During contact lens wear, blinking promotes the even spread of the tear film over the lens surface, aiding lens surface wettability [75]. Tasks that require high cognitive demand [449], computer use [450], and reading on smart phones [451] may be associated with a decline in the blink rate and completeness, and thus an anticipated reduction in tear film stability.

Contact lenses may also be used to evaluate blinking. A blink sensor in a contact lens can continuously monitor blink dynamics while a person undertakes activities in any setting, not just a clinical setting [37]. The commercially available SENSIMED Triggerfish lens (Sensimed AG, Switzerland) that indirectly estimates intraocular pressure is able to observe basic blinking characteristics during lens wear, due to a spike in resistance associated with blinking [452]. Limitations that may interfere with natural blinking dynamics with the Triggerfish contact lens are its thickness and modulus, and the invasive nature of its external antennae [37].

A contact lens blink detection monitoring system has been depicted, whereby an electronic system is incorporated into an ophthalmic lens [453]. The blink detection algorithm in the system controller samples light on the eye to determine when an eyelid is open or closed to determine the frequency and completeness of eyelid blinking. At the time of publication, this idea remains conceptual only.

As highlighted in the *TFOS Lifestyle: Impact of the digital environment* on the ocular surface report [268], wearing the fully optimized refractive correction for the device screen distance is a key digital eye strain management strategy; this has been demonstrated in patients with astigmatism, who were able to read smaller digitally presented print sizes more comfortably when corrected with toric contact lenses. compared to with their mean spherical equivalent lens power [454].

## 3.4.2. Choosing to wear lenses when driving

Driving is an activity with high visual demands that can impact safety if a visual disruption occurs. In an immersive driving simulator, correction of low to moderate astigmatism with toric contact lenses compared to an aspherical equivalent, improved tactical driving skills, such as steering, speed management and braking [455].

In some individuals, contact lenses for presbyopia can adversely impact visual performance when driving [456-458]. A study of 13 contact lens wearers found that daytime driving performance with a monovision correction was not affected compared to the performance with the habitual correction of the subject [458]. Conversely, under night driving conditions, multiple visual performance parameters were adversely affected with monovision compared to single vision contact lenses or progressive addition spectacles [456].

Multifocal contact lens wearers may experience visual ghosting and blur, especially at night when their pupils enlarge in low light conditions [459,460]. Night driving sign legibility also may be affected in multifocal contact lens wearers who have not adapted [456]. A visual adaptation period of up to 15 days may be needed for individuals to acclimatize to multifocal contact lenses [461].

A driving simulator study [462] compared sign identification distances and driving performance metrics in 19 participants with presbyopia wearing multifocal contact lenses and progressive addition lens spectacles. There was no statistical difference in sign identification distance between the two groups for signs located 32.0 m (m) or 51.4 m from the side of the road. However, there was a significant difference in signs positioned 70.2 m from the road, favoring the use of progressive addition lens spectacles.

Although there are multiple studies involving wearers of contact lenses in an aviation environment (see Section 3.4.8), the literature is lacking for contact lens wearing drivers of cars in challenging situations, such as fog, rain, or other adverse conditions. Data are also deficient for those whose occupation is driving, such as long-distance truck drivers. More studies on the topic of driving performance, especially in adverse conditions and when wearing modern multifocal contact lens designs, are warranted.

## 3.4.3. Choosing to wear contact lenses when potentially exposed to occupational hazards

Studies on contact lenses in the industrial workplace date back more than 50 years. Various authors have referred to "urban legends", such as corneal ulcers attributed to an arc flash that fused a polymethyl methacrylate contact lens to the cornea of a welder; however, the corneal pathology was subsequently attributed to contact lens overwear after the accident [463-465]. Additional personal protective equipment was initially imposed for contact lens wearers, but since the 1980s, contact lenses have not been considered to increase the risks of corneal injury while arc welding [465,466].

Other potential industrial occupational hazards are chemical fumes, vapors and aerosol droplets. With some exceptions, no additional personal protective equipment is suggested for contact lens wearers [465, 466]. If workers are non-compliant with their standard personal protective equipment, contact lenses can, in some instances, provide additional protection [463,465,467] due to the lens forming an effective shield over the cornea. However, such protection will not be conferred if noxious substances are able to absorb or diffuse through the lens [465, 468].

The frequency of reported ocular irritation from fumes by firefighters is reduced with contact lens wear [469], and similar protection has been reported in the case of police being exposed to tear gas in the absence of a gas mask [470]. A well-known observation is the protective effect of contact lenses against the tearing that occurs when allyl-disulfides are released when an onion is cut [465]. Clearly, the possible protection depends on the chemical species and concentration, the exposure time, and the contact lens material and thickness. Alkalis are considered more corrosive than acids [465,468], and it is advised that contact lenses should not be worn when working with caustic solutions, including acrylonitrile, 1,3-butadiene, ethylene oxide, methylene chloride, or 4, 4'methylene dianiline [465,467].

In the event of an accident, any noxious chemical contacting the eye should be removed immediately and the eye thoroughly irrigated without delay. The contact lens is frequently flushed out during irrigation or can be subsequently removed [465,467]. Exposure to infectious aerosol droplets in hospital units can be a serious occupational hazard, possibly resulting in ocular infections including keratitis [471].

Soft contact lenses have been recommended in the industrial workplace for protection against foreign bodies, due to their greater corneal conformity and wider diameter than rigid corneal lenses [465,468]. The temperature of solutions entering the eye in the workplace can be problematic, although the risks of ocular damage appear to be unrelated to contact lens wear [465]. For example, direct corneal exposure to water at 80 °C can result in corneal burns, whereas hot air of a similar temperature will not necessarily be harmful [465,468].

### 3.4.4. Choosing to wear contact lenses for television or theatre

Eyes play a fundamental role in the world of communication and contact lenses are often preferred to spectacles for those engaged in communication activities. Prior to participation in stage productions or television appearances, make-up is often applied to the face and around the eyes. Certain eye cosmetics may adhere to contact lenses and alter their properties, especially for more hydrophobic silicone hydrogels [472-476]. For further details please refer to the *TFOS Lifestyle: Impact of cosmetics on the ocular surface* report [362].

In addition to contact lenses for the correction of ametropia, colored contact lenses have been used by actors since the 1930s (e.g., Marilyn Monroe was myopic and used colored contact lenses [477]). The types of complications associated with cosmetic and conventional contact lenses are similar, but the risk of infection is greater with cosmetic lenses, especially when obtained from unregulated suppliers [87,233,235,478]. Color pigments and lower lens wettability, associated with higher lens surface roughness, may result in higher bacterial adherence [75,235, 479-481]. If cosmetic contact lenses are worn occasionally, the lack of frequent solution replacement may reduce the antimicrobial efficacy [478,481,482]. Corneal changes and loss of visual acuity have been reported after wearing cosmetic contact lenses [483,484].

### 3.4.5. Choosing to wear contact lenses for sport

During sports activities, contact lenses are often preferred to spectacles because of comfort, convenience and avoiding the potential restriction of peripheral vision with spectacles. In sport, the object of interest is often in several gaze directions, or in a direction other than primary gaze (such as in upgaze, from a crouched cycling position), which means that contact lens centration and stability is critical. A 'sport-specific' contact lens can be prescribed for sports use, typically with a larger than normal diameter to improve lens stability in the various gaze positions and with rapid saccadic movements [485,486].

Contact lens loss is another concern during sports. To prevent this, well-fitted, large diameter soft lenses are recommended [487]. The risk of accidental lens loss during sporting activities is greater with rigid corneal lenses due to the generally smaller diameter and lower ocular conformance of this lens type.

An important consideration during sports and leisure activities is the avoidance of ocular trauma. Protective eyewear during such activities often takes the form of goggles and shields [488]. For example, regardless of contact lens use, ocular injury can be inflicted by a bungee-jumping cord [489]. In this case, intraocular hemorrhages and retinal detachment due to the rapid acceleration/deceleration may occur [489]. In some cases, contact lenses can provide partial protection by absorbing energy, such as in the case of trauma from a field hockey stick that resulted in minimal corneal damage, even though the rigid corneal lens being worn was fractured [490].

Many people opt to swim in contact lenses. Water polo players who wear contact lenses show higher corneal and conjunctival damage compared with lens wearers not playing this sport, often due to finger and fingernail involvement [491]. Amoebae have been detected in 41% of pool water samples examined [492]. After swimming in a chlorinated pool, soft contact lenses can accumulate bacteria, principally *Staphylococcus epidermidis* [493]. No significant differences have been found in this regard between silicone hydrogel and hydrogel contact lenses [494]. More microorganisms are found on contact lenses when goggles are not worn in aqueous environments [495]. Water exposure during contact lens wear, for example swimming or showering in contact lenses or rinsing lenses with water, is a risk factor for corneal inflammatory events [122], as well as microbial keratitis during contact lens wear [496].

When scuba diving [497], increased pressure underwater (1 bar for each 10 m additional depth) causes more dissolved gases to enter tissues. These gases may be expelled during the ascent, producing bubbles under the contact lens, resulting in blurry vision, especially with rigid contact lenses [494].

Some sports are played at low temperatures, in windy environments, and at high altitudes. Sports conducted in mountainous regions may be associated with increased exposure to ultra-violet radiation, which can cause photokeratitis [498] and altered accommodative responses [499]. An updated systematic review of the evidence in this area would prove useful. Irradiance increases 9% per 1000 m of altitude at the wavelength of 370 nm, and even more at 300 nm [500]. Ground reflection, especially from snow or ice, also increases in the mountains. Ocular phototoxicity in mountaineer guides has been found to be more common than in people living in non-mountainous areas [501]. Ultra-violet radiation-blocking soft contact lenses cover and protect the anterior corneal surface, and the adjacent limbal and conjunctival stem cells beneath the lens [499,502-505]. However, the use of such lenses should be combined with methods to protect the eyelids and other parts of the anterior ocular structures, such as ultra-violet blocking sunglasses [502].

### 3.4.6. Choosing to wear contact lenses for hobbies requiring elevated gaze

When an elevated gaze position is required, contact lenses can provide a wider field of view compared to spectacles, reduced aberrations and annoying reflections, especially for those with high refractive errors. Nonetheless, some athletes and hobbyists, such as shooters, prefer spectacles because of purported vision instability with contact lenses. For example, prolonged intervals between eye blinks can occur in aiming sports, as required to achieve alignment with a target. During these intervals, contact lens movement and drying can produce visual fluctuations [506]. If contact lenses are worn for such aiming sports, a

tighter contact lens fit may limit lens movement on the eye.

Tinted contact lenses have been developed to improve visual perception, such as amber lenses for dynamic sports and grey-green lenses to enhance environmental details when engaged in water surface sports, such as kayaking, surfing, windsurfing or kiteboarding. Tinted contact lenses have the potential to improve or degrade visual performance, depending on the environment, the specific spectral transmission properties of the filter, and the visual status of the wearer [507-512].

### 3.4.7. Choosing to wear contact lenses in the military

Contact lens-related microbial keratitis has been reported to occur in a deployed military setting more frequently than in a civilian setting, particularly during the Summer [513]. In the military, eye problems can affect ocular comfort and health, but also safety. For example, in an airline accident in 1996, the probable cause was assumed to be the misperception of the runway by the pilot due to the use of monovision contact lenses [514]. Conversely, in the 1980s, contact lenses were recommended for use on army attack helicopters, due to the incompatibility of an electro-optical display with spectacles [515]. Contact lenses can also obviate the use of spectacles so that a better seal can be obtained between a mask and the face when using respirators, although some symptoms of eye dryness may occur. However, protection by contact lenses was not found for free fall parachutists whose goggles came off, as they still experienced corneal freezing and desiccation keratitis [516].

The main difficulties experienced with contact lenses by Royal Air Force aircrew were reported to be cloudy vision, dry eye, photophobia, red eyes, excessive mucus formation, contact lens movement, itching and grittiness [517]. However, no contact lens-related flight safety incidents were reported over a twelve-month period, compared with five percent of incidents related to spectacles [517]. Further work using more modern contact lens materials and replacement frequencies is warranted.

Contact lenses have been found to provide some protection from mechanical trauma, for example in an *in vitro* study on porcine eyes exposed to iron filings suspended in a high-speed air jet generated by a gun [490]. Rigid corneal contact lenses have a greater propensity for trapping foreign bodies underneath the lens, compared to soft lenses [465,469].

Non-visible lasers represent a possible hazard in the military environment. A contact lens-based protection system has been proposed by incorporating gold nanoshells in soft contact lenses [518].

### 3.4.8. Choosing to wear contact lenses at high altitude

Atmospheric humidity decreases with latitude and with altitude, to half of that at sea-level at 2000 m and less than 10% at 5000 m. Decreased tear production and accelerated tear evaporation have been reported in windy and dry environments, regardless of contact lens use, and wrap-around spectacles have been recommended as an appropriate alternative [519-522].

Some protection provided by contact lenses from wind-driven ice and snow can be inferred from experiments exposing rabbits to winds while wearing rigid corneal contact lenses [523]. Dry rigid contact lenses can fracture [524]. Of note, is that fracture rates rose from 8% to 83% if rigid lenses were stored wet at -7 °C, as opposed to being stored dry [525].

In airplanes at 11,000 m cruise altitude, the interior pressure corresponds to the outdoor pressure at 2000–3000 m, with variations depending on factors such as the air handling system, the time elapsed since take-off and the extent of airplane crowding [526,527]. Below 10% relative humidity, contact lenses dry out and the radius of curvature decreases [465]. Ocular discomfort and possible ocular surface epithelial disruption have been reported in such environments with very thin contact lenses [528,529]. The secretion of tear inflammatory mediators has been found to depend on environmental humidity and the

## type of contact lens worn [423].

Open and closed eyes at sea-level are exposed to an oxygen pressure of 155 mmHg and 50–60 mmHg, respectively [530,531]. Oxygen pressure decreases to ~80 mmHg at 5500 m and ~50 mmHg (similar to that measured during sleep at sea-level) at the summit of Mount Everest [532]. On a typical airplane flight, the cabin oxygen pressure (~120 mmHg [526,527]) corresponds to the open-air value at 2000–3000 m. Various estimates of the minimum corneal surface critical oxygen pressure to avoid corneal dysfunction have been reported, such as 20 mmHg [533-535], 100 mmHg [536-538] and 130–150 mmHg [539, 540]. These differing estimates can be attributed to the investigated clinical effect, experimental methodology and variability among individuals.

Based on the assumed critical oxygen pressure and the oxygen pressure of a specific environment, values for the contact lens oxygen transmissibility to avoid corneal dysfunction can also be deduced. A slight difference is found between rigid corneal and soft contact lenses, with the former showing a better exchange of oxygenated tears under the contact lens during blinking [541,542]. Although symptoms of ocular dryness and discomfort during soft contact lens wear are often attributed to lens dehydration, a review concluded that these symptoms are possibly related to an inflammatory response due to hypoxia [543].

The difficulties inherent in maintaining hygienic contact lens practices when mountaineering are compounded by possible freezing of contact lenses and disinfection solutions [524]. Wearing the same contact lens for longer periods than recommended in such environments increases the risks of adverse ocular events [525]. However, in a cross-sectional survey involving 159 contact lens wearing respondents, 78% reported no critical problems with their contact lenses during high-altitude trekking in Nepal [524]. Although highly oxygen transmissible contact lenses that provide sufficient oxygen for overnight wear might be considered appropriate for this high-altitude environment, many of those surveyed were unaware of the existence of contact lenses that can be worn overnight [524].

A questionnaire on eye comfort evaluated some of the conditions in an aircraft that may influence ocular comfort of flight attendants [409]. Of the 774 flight attendants who responded, 95% reported some eye discomfort when on board an aircraft. Both contact lens wearers and non-wearers reported similar eye problems. Ocular injection and dry eyes were the most common problems. Smoking was the most noticeable factor to cause ocular symptoms, which has now ceased on aircraft. The authors implied that since air passengers are exposed to the same aircraft conditions as the attendants, they probably would manifest similar eye problems. However, there is a lack of literature on this topic.

A study of 44 helicopter pilots in the United States Army undertook flying duties wearing extended-wear soft and rigid contact lenses for periods ranging from six months to two years [544]. Contact lens related problems did not ground any of the pilots; 86% were reportedly successful with contact lens wear, and the wear of lenses overnight was perceived to favorably impact job performance.

Contact lenses can be worn in space. In 2019, 78% of members of the United States of America Astronaut Corps were ametropic, and 40% used contact lenses [545]. Caution is recommended when wearing contact lens in a weightless environment in space due to floating objects and particulate matter. Before applying contact lenses, benzalkonium chloride-based products are preferred to alcohol-based products for hand cleaning [545]. Systems that require fluids to settle in the bottom of a lens case are not recommended. When using eye drops, a squeezable vial is required to obtain a solution globule as weightlessness prevents drop formation.

Contact lenses have been observed to maintain their position on the cornea under high acceleration, with maximum decentration of two to 3 mm (mm) above +5G [546,547]. At the same acceleration, contact lens wear did not produce any corneal complications.

Vision was found to be reduced with both contact lenses and spectacles following space flights [545-547]. Decreased near vision, due to a 0.50 to 1.75 D hyperopic shift, has been reported in astronauts following their return to earth after six months of space flight [545,548]. Decreased choroidal drainage in weightless conditions may contribute to this shift as it could result in choroidal expansion, causing a short-ening of the macula-lens distance, as well as a rise in intraocular pressure [545,548].

Changes have been reported in free volume gaps in the polymeric structure of soft contact lenses exposed to ionizing radiation [549]. Space travellers are extensively exposed to solar ionizing radiation, as well as galactic cosmic radiation arising from outside the solar system. The possible development of the space flight sector requires an improved understanding of the risk of space radiation to contact lens performance to develop appropriate strategies for future missions.

### 3.5. Other non-compliant and risky behaviors

Numerous accessory devices may be used by individuals who wear contact lenses. Devices to assist in applying and removing contact lenses, such as tweezers and plungers/suction cups, can serve as a nidus for microbial contamination and produce unwanted side effects [111,124, 550-552]. Patients who wear rigid corneal or scleral contact lenses following successful corneal graft procedures are at some risk for traumatic complications from these devices. Reports of serious injury have been cited when patients use plungers or other lens removal devices inappropriately. Suction cup devices can exert sufficient force to cause significant trauma to corneal transplants when used incorrectly [553]. Appropriate warnings and in-office training to lens wearers using these devices are essential to ensure safe and effective wear, and should include highlighting the need for employing good hygiene practices. Washing with soap and water, and replacing these supplementary devices on a frequent basis are recommended, but no data exists on what that frequency should be.

The safety of contact lens wear should be a shared responsibility among the lens wearer, lens manufacturer and the eye care provider caring for the patient. Unfortunately, practitioners who see a higher volume of contact lens wearers have a higher tendency to possess risktaking personalities [554]. Fortunately, the increased risk-taking behavior does not appear to affect the perceived importance and type of advice given to contact lens wearers [554].

Compliance practices and risk-taking behaviors among lens wearers have been investigated extensively [17,80,82,85,86,129,130,236,238, 554-557]. Higher risk-taking personalities among lens wearers are associated with poorer compliance and appear to be a better predictor of compliance than age, gender, and practitioner perception [236]. The United States Center for Disease Control and Prevention has surveyed contact lens wearers to assess the prevalence of contact lens hygiene-related risk behaviors [85,86]. An exceedingly high number (approximately 99%) [85] of those surveyed reported at least one contact lens hygiene risk behavior [80,130]. About one-third of those patients reported experiencing a red eye or painful response in the past while wearing contact lenses [85].

Sleeping or napping in contact lenses was a frequently reported behavior and results in a heightened risk of corneal infection [85,86]. Although some contact lenses have been approved by the United States Food and Drug Administration for sleeping or napping, overnight wear of any lens type increases the risk for eye infection in a dose-related fashion [85,86,111]. Additional risky behaviors include not adhering to recommended contact lens and storage case replacement schedules, wearing lenses longer than recommended [238], and 'topping off' disinfecting solutions in the lens storage case (which reduces the effectiveness of the disinfecting solution) [85,86].

The morbidity and cost related to poor contact lens care compliance is a cause for concern. Nearly one million healthcare visits for keratitis (inflammation of the cornea) or other contact lens-related complications occur annually in the United States of America, at an estimated cost of \$175 million [85]. Targeted prevention messages, including age-targeted messages, aimed at contact lens wear safety have been employed. These messages are provided with the intent of minimizing the risk of infection and other contact lens related complications. The prevention messages are shaped around lifestyle changes [86], and have included keeping all water away from the contact lens and its storage case [103,104,496,557,558], discarding used disinfection solution and avoiding 'topping off' solution in the case, adhering to recommended lens replacement schedules, cleaning with fresh solution daily, and replacing the lens case at least every three months [85,127]. Overall, existing healthcare communication strategies known to influence contact lens wearing behavior can be applied to communication efforts focusing on hygiene behaviors of specific populations [86].

As part of their prevention campaign, the United States Center for Disease Control and Prevention has provided travel tips for people who wear contact lenses [559]. Lens wearers should carry an up-to-date contact lens and spectacle prescription, replace their case every three months prior to travel, and pack back-up supplies including a contact lens case, contact lenses, glasses, and lens care disinfecting solution. Specifically, wearing contact lenses while camping may pose additional risks, especially since fresh water for hand washing may not be available and wearing lenses overnight increases the risk for infection. While use of hand sanitizer may be considered, overall, glasses appear to be the best option for camping.

Contact lens compliance, particularly in terms of handwashing and storage case hygiene, was reportedly poor during the prolonged COVID-19 lockdown [17]. Patient-practitioner communication strategies to curtail the possibility of ocular transmission and lens complications is important [129].

The effectiveness of compliance campaigns has been encouraging. An example of an effective health promotion campaign is evident in the anti-smoking campaign, where the messaging cost \$325 million, but was estimated to have saved \$1.9 billion in healthcare costs in the United States [274]. Systematic reviews of modifiable risk factors in contact lens wear are needed. Reach and engagement metrics of the various campaigns by the Center for Disease Control and Prevention have been assessed and show encouraging results in modifying lifestyles to minimize the risk for contact lens related eye infections [274].

### 3.5.1. Tobacco, marijuana, and vaping use in contact lens wear

Smoking tobacco cigarettes has been associated with numerous adverse effects to the eye, such as cataracts, macular degeneration, glaucoma, Graves' disease, and more specifically to the ocular surface [162,275,434,560-567]. Contact lens wearers may choose to smoke tobacco or marijuana, or elect to use electronic cigarettes (vape) while wearing their lenses. There are multiple means through which smoking may impart adverse effects in this group of contact lens wearers, including through lens contamination.

Research suggests that there are striking similarities between the composition of marijuana and tobacco smoke [560]. Sixty-nine common compounds that cause negative health effects through carcinogenic, mutagenic, teratogenic or other toxic mechanisms have been identified [560].

Ocular surface changes from smoking tobacco and marijuana can have lasting effects and impact ocular comfort, thus impeding successful contact lens wear [275]. Reported ocular surface changes related to smoking cigarettes include faster tear evaporation rates and tear lipid layer abnormalities, which may result from conjunctival squamous cell metaplasia and goblet cell loss [566]. Some of these changes cause smokers to experience excessive tearing and decreased tear film stability [566], resulting in decreased tear lysozyme concentrations [566]. In addition, the chronic irritative effects of smoking may have a profound overall effect on the ocular surface defenses of contact lens wearers [566].

Passive exposure to tobacco or marijuana smoke has been shown to cause unwanted and adverse ocular surface changes, as evidenced by an increase in tear film evaporation, oxidation of tear lipids, slowing of tear film spread time, increase of tear interleukin-6 concentration, and damage to the ocular surface epithelium (measured using increased vital staining scores) [560]. The acute effects of e-cigarette use (vaping) does not seem to impact corneal epithelial thickness and non-invasive keratography tear break-up time after mild exposure [568]. However, the long-term adverse effects of vaping on contact lens wear are yet to be studied.

Smoking has been shown to increase the risk for corneal infiltrative events between 1.4 and 2.7 times in contact lens wearers [162,275,561, 567], most likely as a result of lens contamination; although, overall these patients may be also more likely to engage in other risky behaviors [567]. The reported adverse effects of smoking may be due to toxins, increased pathogens in the microbiota of patients or changes in their mucus membranes [567]. Tobacco smoke contains certain substances of microbiologic origin, such as ergosterol (fungal membrane lipid) and lipopolysaccharide (in the outer membrane of Gram-negative bacteria), that can be potential drivers of inflammation [569,570]. For the reasons mentioned above, the mechanisms of this relationship are considered partly causal and partly confounding [567].

An increase in corneal staining in smokers [275,567] has been frequently reported, along with a heightened awareness of the potential risk of microbial keratitis [162,275,434,567]. Smokers are about three times more likely to develop microbial keratitis than non-smokers [162]. Additional concerns for patients who smoke center around impaired wound healing [434,565].

Lifestyle counseling for smokers, including its impact on contact lens wear (as relevant), is warranted. Future research may (or may not) show similar ocular surface changes with smoking marijuana and vaping, which may warrant admonition of smoking of any type for contact lens wearers [563,571]. Eye care providers should continue to ask patients if they smoke, and if they do, educate them not only on the overall health risks related to smoking, but the potential risks for reduced contact lens comfort, increased corneal inflammation [569] and even an elevated risk of microbial keratitis [162,567,570].

The mechanism by which smoking affects the ocular surface and the potential for adverse reactions, such as corneal inflammatory events or microbial keratitis, is a potential topic for further research. For example, does smoking affect microbial product adherence to contact lens surfaces? Can microbial products be transferred from the fingers of smokers to their contact lenses? Is there an increase in *Pseudomonas aeruginosa* corneal infections in smokers and if so, why? Further information can be found in the *TFOS Lifestyle: Impact of societal challenges on the ocular surface* report [266], and the *TFOS Lifestyle: Impact of lifestyle challenges on the ocular surface* report [572].

## 3.5.2. Contact lens wear while under the influence of drugs/substance abuse and alcohol intake

Consumption of alcohol and its direct effect on the ocular surface appears to be related to the quantity consumed [573]. Heavy alcohol intake alters tear film function, with an increase in osmolarity measures and disturbed cytokine production [568,573]. Ocular surface epithelial degradation (impression cytology scores) in men who are heavy drinkers has been reported and these changes were found to exacerbate signs and symptoms in patients with pre-existing ocular surface disease [568, 573-575]. Peripheral neuropathy induced by alcohol abuse may mask the prevalence of dry eye symptoms among heavy drinkers, leading to an underestimation of dry eye disease prevalence in this population [576, 577].

Severe corneal melting and corneal perforation can occur with drug and alcohol abuse. Known alcohol or drug users with corneal melting should be evaluated for vitamin A deficiency as a possible cause, especially in contact lens wearers [576].

Cocaine hydrochloride is a powerful neuro-stimulating substance that has been abused for hundreds of years [578,579]. Atypical keratopathy (i.e., corneal epithelial disruption and stromal ulceration) with reduced corneal sensation should prompt the eye care practitioner to investigate social habits, including possible substance abuse [578,579]. The potential exists for diagnostic confusion between a contact lens-related complication and another predisposing keratopathy, since a lens-related complication may mimic the keratopathy related to drug abuse (i.e., crack keratopathy) [578,579]. Duration and frequency of drug abuse are major risk factors for developing cocaine-induced neurotrophic keratitis [578,579]. Secondary corneal infections are possible (fungal or bacterial) [579]. A complete ocular evaluation that includes corneal sensitivity testing should be planned as part of the clinical management of anyone addicted to cocaine [578,579]. It would be prudent to cease contact lens wear until drug abuse rehabilitation is successful.

# 3.5.3. Contact lens wear and exposure to cosmetics, eyelash extensions and tattooing

Clinical evidence suggests that the use of soaps, lotions, and cosmetics can affect contact lens comfort and contribute to contact lens related dryness [33]. Adverse effects of eye cosmetics have been reported, including cutaneous changes (allergic reactions), and pigmentation collection on the conjunctiva and in the lacrimal system [313, 580-582]. Skin anti-aging products, such as creams applied around the eye, may contain retinoids that can have a negative effect on the meibomian glands [313,472,580-582], contributing to dry eye complaints.

Eye shadow, eyeliner, mascara, and cleansers to remove makeup, contain oil ingredients and preservatives (often benzalkonium chloride and formaldehyde) to avoid microbial growth [313,582,583]. Influence testing of benzalkonium chloride and formaldehyde on the morphology, survival and proliferation, and signaling ability, of immortalized human cells (corneal, conjunctival and meibomian gland epithelial cells) found these cosmetic preservatives exert many toxic effects on cells of the ocular surface and adnexa [313]. Exposure to these agents at concentrations approved for human use can lead to cellular atrophy and death within hours of exposure [313]. Another study found additional cosmetic preservatives (methylparaben, phenoxyethanol, and chlorphenesin) harmful to human meibomian gland cells [582]. Contact lens wearers may use different types of eye makeup multiple times per day, which can accumulate and potentially affect ocular surface health and cause ocular discomfort [313,582].

Contact lens parameter changes have been noted when certain cosmetics interact with contact lens materials. Alterations to the base curve of contact lenses composed of different materials were reported to show the greatest parameter variation from baseline [472]. Makeup removers and mascaras changed lens parameters to varying degrees, and may directly affect the on-eye fitting relationship, and even the overall performance of the contact lens [472]. Eye creams were noted to have minimal, insignificant effects on contact lens parameters [472]. Deformation and contact lens swell of silicone hydrogel materials will occur with the use of cosmetic and cleansing products; therefore, a warning seems prudent when prescribing contact lenses to cosmetic users [472].

Cosmetic enhancements (i.e., permanent and semi-permanent procedures) are widely employed today, including eyelash extensions, tattooing and dyeing. These procedures are associated with a variety of ocular adverse events [583-586]. These adverse reactions associated with the use of cosmetics, eyelash enhancements and aesthetic procedures are important to contact lens wearers since they can directly affect the ocular surface and adnexa. Knowledge of the possible direct and indirect adverse effects associated with these enhancements that can impact ocular health and visual outcomes is important. Eyecare providers need to be familiar with the cosmetic products used and the aesthetic procedures employed today to adequately educate lens wearers about the potential adverse effects [583,585]. Failure to treat these adverse reactions can lead not only to lens-related adverse reactions, but to the potential for more serious ocular complications.

The cosmetic industry needs to consider measures to improve upon the safety of current products, by making their products more compatible with the ocular surface, thereby improving comfort for contact lens wearers. Further details on these topics can be found in the *TFOS Lifestyle Reports on Cosmetics and Elective Medications and Procedures* [306,362].

### 3.6. Potential future uses of contact lenses

Potential future uses of contact lenses include drug-delivery by contact lenses and smart contact lenses that may potentially be used in the diagnosis and treatment of various ocular and systemic conditions [37].

### 3.6.1. Contact lenses for ocular drug delivery

Ocular drug delivery is traditionally achieved using eye drops. However, low bioavailability, preservative toxicity and patient noncompliance may become problematic, particularly for eye drops requiring frequent dosing or when dealing with chronic eye diseases, in which compliance may reduce over time. Since the main reasons for low bioavailability include variable penetration through the cornea, high tear turnover rates, blinking, and nasolacrimal drainage, various means of increasing the residence time of ophthalmic drugs on the ocular surface have been investigated [587,588].

Contact lenses have been suggested as vehicles to deliver therapeutics, in an attempt to address limitations in both the bioavailability of, and patient compliance with, topical therapies. In this approach, the instilled therapeutic is partially shielded from the tear film turnover, increasing its pre-corneal residence time, and thereby improving bioavailability up to 10 times more than that achieved with eye drop formulations [587,588]. Furthermore, with drug-releasing contact lenses, the use of preservatives is not required. These contact lenses have been suggested also to provide more accurate dosing of medications compared to eye drops, with more consistent release that would not be affected by the dexterity of the patient [589]. Delivery of drugs with the use of contact lenses may also decrease conjunctival drug absorption, resulting in smaller amounts of drug entering the systemic circulation, and minimizing systemic adverse effects [587,588].

The simplest method for incorporating drugs into contact lenses is by immersing them in concentrated solutions of the active ingredient. However, this approach leads to uncontrolled, excessively rapid release. To achieve controlled sustained release, a series of modifications need to be performed to the contact lens materials, while maintaining basic lens properties such as oxygen permeability, transparency, comfort, water content, pH, and its mechanical and ionic properties [37,587,588,590]. These modifications include the incorporation of polymeric nanoparticles, microemulsions, micelles, liposomes, diffusion barriers (e.g., vitamin E) and sophisticated loading techniques such as molecular imprinting, ion ligand polymeric systems, drug-loaded films, or supercritical fluid technology [37,587,588,590].

Although research on drug-releasing contact lenses appears promising and one such lens has recently been approved in several countries [38,39], there are currently limited clinical and commercial options available, due to various technological challenges inherent to the process. Such challenges include compatibility of the physicochemical properties of the drug with that of the contact lens material; stability of the chemical during contact lens processing/manufacturing or over time in the packaging solution; achievement of zero-order release kinetics with variable powers; avoidance of drug release during the post-manufacturing monomer extraction step; protein adherence; drug release during storage; and considerations relating to cost-benefit [37, 587,588,590,591]. Furthermore, corneal toxicity is a concern with prolonged exposure to pharmaceuticals, although that appears to not be an issue with a recently commercialized anti-allergy contact lens [39]. As such, attaining drug release kinetics on the eye that are comparable to that demonstrated in vitro, and maintaining ocular surface homeostasis simultaneously, remains challenging at the present time [37].

3.6.2. Drug-releasing contact lenses to manage allergic eye disease

Worldwide, the prevalence of allergic diseases is on the rise, probably owing to problems such as an increase in global temperatures, extreme weather events and air pollution [592]. Given that allergic conjunctivitis can be aggravated by contact lens use and patients with allergic conjunctivitis are usually advised to avoid using lenses during the allergy seasons, daily disposable contact lenses that can prevent or treat allergic conjunctivitis by eluting antihistamine drugs are currently being studied extensively. This approach is hoped to avoid washout of anti-allergy drops from the ocular surface that occurs with rapid tear film turnover. This approach has the potential to improve drug retention time and bioavailability, avoiding possible contact lens damage due to eye rubbing, stopping further allergen deposition on the lens surface, limiting preservative toxicity, and limiting compliance problems with chronic eyedrop instillation [38,593]. As such, contact lens wearers with allergies may not need to revert to spectacles during allergy seasons, with reliable daily allergy relief that lasts for as many hours as they would typically wear their contact lenses.

As described in Section 3.2.4, there has been a particular focus on the development of antihistamine releasing contact lenses [38,39,295,296]. Recently, a contact lens-based drug delivery system for therapeutic delivery of the antihistamine ketotifen was tested in two parallel, conjunctival allergen challenge-based, multicentre, randomized, placebo-controlled trials involving 244 participants [38]. In these two clinical studies, etafilcon A lenses with 19 µg of ketotifen were well tolerated, and achieved a clinically and statistically significant reduction in mean ocular itching scores compared to etafilcon A lenses with no added drug, both at 15 min and 12 h after lens application on the eye [38]. Incorporation of the drug into the lens was not observed to have any structural, optical, or refractive adverse effect on the contact lens. Other antihistamines such as epinastine and olopatadine are also being studied for possible contact lens delivery [296,594].

### 3.6.2.1. Drug-releasing contact lenses to manage various ocular diseases.

Contact lenses have also been studied for the topical delivery of various agents, including ocular lubricants (polyvinylpyrrolidone, hyaluronic acid, hydroxypropyl methylcellulose); cyclosporine A and dexamethasone in patients with dry eye disease; antibiotics in bacterial keratitis; antifungals in fungal keratitis; chlorhexidine in acanthamoeba keratitis; antivirals in herpetic keratitis; corticosteroids in the treatment of dry eye/post-surgical prophylaxis/uveitis/inflammation-induced corneal neovascularization; antiglaucoma agents; roscovitine in retinoblastoma; and cysteamine in cystinosis [37,588,590,591]. The fluid reservoir beneath scleral lenses has been used for the delivery of bevacizumab (1%) to decrease corneal neovascularization [595], and, in a retrospective case series, scleral lenses in combination with platelet rich growth factor eye drops were found to decrease ocular surface symptoms in patients with recalcitrant ocular surface disease [596]. Myopia management has become a major area of research, with topical atropine being one of the most extensively studied therapeutic agents for slowing myopia progression. As there may be a complimentary benefit of adding atropine to the optical effects afforded by certain contact lens designs, investigators have reported on loading commercially available spherical and multifocal soft contact lenses with agents that include atropine and pirenzepine [597,598].

### 3.6.3. Other potential future uses of contact lenses

Another potential application of contact lenses are as "smart lenses" that can sense and monitor biochemical or biophysical changes in tear fluid, ocular surface temperature, intraocular pressure and/or pH value [37]. These sensors may have a future role in detecting ocular diseases, optimizing pharmaceutical treatments, and monitoring treatment efficacy in point-of-care settings [599-601]. Interested readers are referred to recent reviews on this topic for more details [37,587,602-604].

The previously described contact lens sensor with a silicone-based

contact lens for continuous intraocular pressure measurement (see Section 3.4.1) [605] has been reported to be safe and well-tolerated in healthy and glaucomatous eyes, but its high cost along with difficulties in clinical interpretation of its data, have been significant limitations [606]. Other cost-effective contact lens technologies with relative simplicity, providing faster measurements, are currently being studied to monitor intraocular pressure [606]. Smart contact lenses that can monitor tear glucose levels, using various approaches, have also been described. Glucose monitors based on spectral or electrochemical methods, fluorescence-based approaches or glucose-sensitive hydrogels have been reported [37,600,601,607]. Due to a variety of limitations, including a lag period between changes in blood glucose and tear glucose levels, in addition to relatively high cost, commercialization of a glucose-sensing contact lens is yet to occur.

Experiments are currently ongoing to identify and quantify other potential biomarkers present in the tear film that could be the target of smart contact lenses, enabling point-of-care diagnostics [37,590,592, 599-601]. Temperature-sensing, reactive oxygen species-sensing, blood oxygen/pulse rate-sensing and pH/electrolyte/osmolarity-sensing smart contact lenses, as well as a contact lens-based blink monitoring system, have been developed for use in dry eye disease [37]. Cortisol-sensing contact lenses that can detect tear-film cortisol concentrations as low as 10 pg/ml have been described [608]. Soft contact lenses have also been suggested as analyte-scavengers to possibly help as an adjunct in the treatment of several diseases, with examples including methods to remove excessive reactive oxygen species on the ocular surface [609].

New contact lens ideas for optical enhancements include contact lenses with customized optics for eyes with increased aberrations, such as in wearers affected by keratoconus; accommodative contact lenses for presbyopia correction, or electronic contact lenses to decrease myopia progression [37]. Contact lens telescopes have been studied as low-vision aids, for "augmented vision" [610] and they may also be used to improve subjective color perception in individuals with color blindness [611].

In summary, contact lenses appear to be promising devices for ocular anterior and posterior segment drug delivery, and are emerging tools for addressing unmet clinical needs in ocular diagnosis and therapeutics. Long-term comfort, adverse effects and/or toxicity need to be studied further for better understanding and implementation of these advanced technologies.

### 3.7. Impact of stress, depression and physical inactivity

A search of the literature failed to find any direct reports of the possible impact of stress, depression or physical inactivity on contact lens wear. There are reports of people with dry eye disease reporting greater levels of stress and depression [612-614], and given the known link between dry eye disease and reduced contact lens comfort, then it is plausible that there could be a link with contact lens discomfort and stress or depression. Given the increased reports of these conditions during the COVID-19 pandemic, this is a potential area for future contact lens research.

### 3.8. Impact of contact lens wear on 'quality-of-life'

Improved visual acuity and cosmesis are the major benefits that contact lenses provide for all age groups, from infants through to the elderly [615-617]. Although ocular dryness related symptoms are not uncommon with contact lens wear and may impact both short- and long-term lens wear, in general, contact lens wear results in a better quality-of-life than spectacles, in adults, children and the elderly [249].

In recent years, the proportion of pediatric contact lens fits has increased, and the average age of a first contact lens fit has decreased due to the availability of daily disposable soft and overnight orthokeratology contact lens modalities, and an increased interest in myopia management [32]. In teenagers aged 12–19 years, favorable effects of wearing daily disposable contact lens on quality-of-life measures [15] as well as self-esteem have been reported [15]. Myopia control studies have provided further long-term data on the effects of contact lens wear on patient-reported outcomes in children and teenagers. Children who wore orthokeratology lenses were reported to be more self-confident, more willing to try new things, and more active in participating in sports and entertainment, resulting in a further increase in the total time spent pursuing outdoor activities [249,618,619]. While further studies evaluating quality-of-life outcomes of combination protocols for myopia management, and physiological response and adverse events with long-term contact lens wear are needed, the available evidence has highlighted better quality-of-life outcomes with contact lenses than spectacles in children. A recent study reported minimal physiological complications over a six year period in children wearing a hydrogel, daily disposable contact lens approved for myopia control [154].

Since keratoconus is a chronic disease that typically develops during a period of life where significant physical, cognitive and psychosocial development occurs, the disease has also been reported to have a negative impact on vision-related quality-of-life and the psychosocial life of patients [620]. Management of keratoconus varies with the stage of disease. Corneal collagen cross-linking can stiffen the cornea and halt progression to more severe disease [621]. Nevertheless, contact lenses are often an effective means of visual rehabilitation in many patients with keratoconus, and visual correction, with various types of contact lenses. Contact lens correction has been associated with major improvements in quality-of-life, independent of disease severity, visual improvement or occasional ocular discomfort symptoms [622-626].

### 3.9. Impact of contact lens wear on the environment

Contact lens products represent a form of medical plastics, and plastics are known to pose significant ecological and human health risks. The increased popularity of daily disposable contact lenses has resulted in more contact lenses and blister-packs being used, and discarded [627]. Despite the widespread use globally of daily disposable contact lenses, environmentally friendly disposal options for contact lenses have recently become available from several vendors. Flushing of contact lenses down the drain was reported to render them dangerous for the environment, since biological wastewater treatment was ineffective in breaking down these polymers [628].

The contact lens industry has taken steps towards end-of-life options for contact lenses, aiming for greater sustainability across all areas of the product life cycle, including manufacturing sites becoming powered from renewable sources [627]. At the time of fitting, eye care practitioners may play an important role in informing patients about proper disposal and recycling options available locally for contact lenses and associated care products. The collaborative efforts of manufacturers, and environmentally conscious eye care practitioners and consumers, will further reduce contact lens waste and help to better preserve the environment. Discussions around the appropriate disposal of contact lenses and their packaging are ongoing.

## 4. Systematic review: associations between lifestyle factors and soft contact lens dropout

Since their introduction to the market in the 1970s, the growth of soft contact lenses has been plagued by stubbornly high rates of contact lens dropout. The major reasons reported by wearers for ceasing contact lens wear have included poor vision, discomfort, problems with lens handling and disinterest [45,48,51,52,57,629]. Many contact lens studies also report significant rates of participant loss to follow-up.

The aim of this systematic review was to investigate associations between behavioral and environmental lifestyle factors, and the frequency of soft contact lens dropouts. The intent was to provide useful findings for clinicians, contact lens wearers and industry, and to inform future research directions.

### 4.1. Methods

The review protocol was prospectively registered on PROSPERO (CRD42022297616) and is reported according to the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) statement. See also the *TFOS Lifestyle - Evidence Quality Report* [7] for a description of the methodological approach for the systematic review.

## 4.1.1. Search method

Medline Ovid, Embase Ovid, and CINAHL electronic databases were searched from inception to 14 December 2021. Complete search strategies are provided in Appendix A. In addition, the reference lists of included studies were screened to identify any potential studies that were not captured in the searches.

## 4.1.2. Eligibility criteria

4.1.2.1. Study design. Study designs eligible for inclusion were randomized controlled trials, and retrospective or prospective cohort studies that compared exposures to lifestyle factors between study groups or linked exposures to contact lens dropout. Only studies in English were included. Conference abstracts, case reports, case series, and non-systematic reviews were ineligible for inclusion. The initial intent was to also include non-randomized studies of interventions, casecontrol, and qualitative studies; however, after reviewing eligible fulltext publications, in recognition of the sufficient number of randomized controlled trials and cohort studies identified, only the randomized controlled trial and cohort study designs were included at the data extraction stage.

4.1.2.2. Participants. Studies evaluating contact lens wear in children or adults compared to a control population within the same study, as well as inception cohorts of soft lens wearers without a control population, were eligible for inclusion. The conceptualization of a cohort study proposed by Mathes and Pieper was applied, whereby studies without a comparison group could be retained as cohort studies, as long as participants were sampled on the basis of exposure (contact lens wear) and the occurrence of outcomes (dropout) was assessed during a specified follow-up period [630].

The initial intent was to retain articles with all contact lens wear schedules. However, after reviewing eligible full-text publications, in recognition of the sufficient number of studies identified, only those studies that required participants to wear contact lenses during waking hours, and did not allow participants to wear lenses during sleep, were included at the data extraction stage.

The analysis considered studies involving soft contact lenses of any material (e.g., hydrogel, silicone hydrogel) or design (e.g., spherical, toric, multifocal). Studies where the intervention may have included rigid lenses, or those where contact lenses were prescribed for medical reasons (e.g., aphakia), were excluded.

### 4.1.3. Outcome measures

The outcome of interest was contact lens dropout, defined as permanent cessation of contact lens use for any reason and at any time point. Dropout was reported as a dropout rate, a retention rate, or an odds ratio with 95% CI, depending on the study.

### 4.1.4. Study selection

Citations retrieved from the electronic databases were collated into an EndNote library. After removal of duplicates, the library was imported into Covidence (Veritas Health Innovation, Melbourne, Australia). Three systematic review authors (IJ; MW; KB) undertook various phases of the review.

Two of the three review authors independently performed title/abstract screening; studies judged as 'eligible' or 'potentially eligible' progressed to full-text screening. Two review authors independently screened the full texts and decided whether to 'include' or 'exclude' studies, based on the eligibility criteria. For all articles excluded at the full-text screening stage, the reason(s) for exclusions were recorded. Discrepancies were resolved by discussion and consensus.

### 4.1.5. Data extraction and management

Two review authors independently extracted the predefined key study data from eligible studies; discrepancies were resolved by discussion and consensus. The following data were extracted: article details, study date and setting; study methods (design); numbers and characteristics of participants within each study group (age, gender); refractive error type; sources of funding; and conflicts of interest.

### 4.1.6. Risk of bias assessment

Risk of bias tools appropriate to the study design were used, comprising Cochrane RoB-2 tool for randomized controlled trials and the Newcastle Ottawa scale for cohort studies. Two review authors independently performed the assessments; discrepancies were resolved by discussion. The risk of bias plot for randomized controlled trials was created using robvis [631]. For risk of bias assessment of cohort studies, three months was selected as an adequate minimum follow-up period for the outcome of interest, and a 20% lost to follow-up rate as the maximum loss that would be unlikely to introduce bias.

## 4.1.7. Primary and secondary outcomes

The pre-specified primary outcome was incidence of contact lens

dropout. Secondary outcomes related to the reason(s) for dropouts. Primary and secondary outcome data were extracted as the rate(s) of contact lens dropout, and the timing and reason(s) for discontinuation, for the intervention and comparator groups. All outcomes were considered for any length of follow-up. The 95% CI of the dropout rates were calculated without continuity correction using online software (available at: http://vassarstats.net/prop1.html).

### 4.1.8. Data analysis

Meta-analyses were performed using Cochrane Review Manager software [632], when at least two studies reported data in a consistent format, and a pooled analysis was deemed clinically appropriate; for example, studies where the intervention, comparator and the clinical population were similar.

Clinical and methodological heterogeneity were assessed by evaluating the study design, participant characteristics and intervention type. Statistical heterogeneity was quantified using the I-squared ( $I^2$ ) statistic, which describes the percentage of variation across studies that is due to heterogeneity, rather than chance. An  $I^2$  statistic >60% and Chi-squared test *P* value < 0.10 defined significant heterogeneity [633]. If there was only one study with relevant data, or data pooling was not appropriate, such as in the presence of significant heterogeneity, a narrative summary of the key findings was provided.

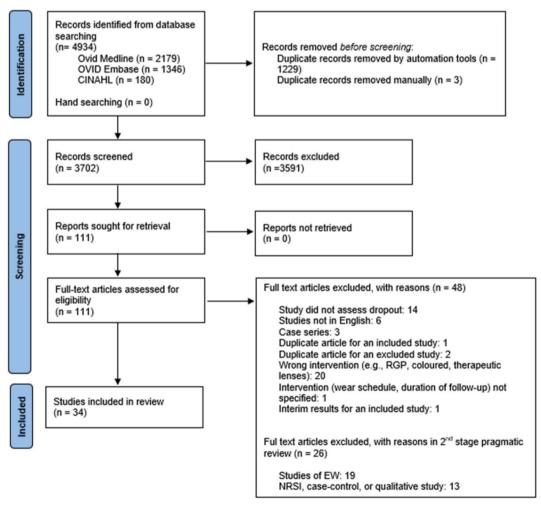


Fig. 2. Flow diagram of studies included in the systematic review.

### 4.2. Results

### 4.2.1. Characteristics of included studies

The electronic database searches yielded 4934 citations (Fig. 2). After removing duplicates (n = 1232), title and abstract screening was performed on 3702 citations. Of these, 111 citations underwent full-text screening, and 34 studies (15 randomized control trials and 19 cohort studies) met the pre-specified eligibility criteria and were included. A list of studies excluded at the full-text review stage, and the primary reason for exclusion, is summarized in Appendix B.

All 34 studies were full-text articles published between 1988 and 2021; their key characteristics are summarized in Table 2 for randomized controlled trials, and Table 3 for cohort studies.

## 4.2.2. Randomized controlled trials

The 15 randomized controlled trial were conducted in seven countries: United States of America (n = 4) [634-637], United Kingdom (n = 3) [15,41,638], Canada (n = 2) [639,640], China (n = 2) [330,641], Spain (n = 2) [642,643], Australia (n = 1) [644], and India (n = 1) [645]. Twelve studies used a parallel-arm design, and three trials [634, 637,640] were crossover studies.

The exposure(s) evaluated involved contact lens wear in all groups or arms of the study for 11 of 15 randomized controlled trials [41,330, 634-637,639-642,644]. Seven studies compared contact lens designs or materials [41,330,635,637,640,642,644], two studies compared lens replacement schedules [636,639], one study compared lens care regimens [641], and one study compared daily soft contact lens wear to orthokeratology [634]. The remaining four studies evaluated contact lens wear relative to spectacle or no lens wear [15,638,643,645]. The contact lenses evaluated were spherical in design for nine of 15 randomized controlled trials [15,634-636,638,639,641,644,645]. Two studies evaluated myopia control contact lenses [330,643], three studies evaluated multifocal lens designs for presbyopia [637,640,642], and one study evaluated toric lens designs [41]. All contact lenses to correct presbyopia were grouped under the single umbrella term of multifocal soft contact lenses, without distinguishing between the various possible contact lens designs to correct presbyopia (e.g., concentric, diffractive, aspheric, extended depth of focus, etc.). Contact lenses evaluated were hydrogels in eight studies [15,634-637,639,643,645], silicone hydrogels in four studies [330,638,640,641], and a combination of hydrogel and silicone hydrogels in three studies [41,642,644].

In total, 2164 participants were enrolled across the 15 studies, with individual study sample sizes ranging from 40 to 282 participants. Eleven studies [15,41,330,635,636,638-640,642,644,645] reported the sex distribution of recruited or completed participants; female (n = 1070), male (n = 732). Eight studies enrolled adult participants aged 18 years and over [41,634-636,638,639,641,644]. One study enrolled participants aged 16–35 years [645]. Three studies enrolled older aged adults with presbyopia [637,640,642]. Three studies enrolled children [330,643] or teenagers [15].

Six randomized controlled trials recruited neophyte participants with no contact lens wearing experience [15,330,638,639,643,645], four studies recruited existing experienced contact lens wearers [635,636,640, 642], and three studies enrolled participants comprising a combination of neophyte and experienced lens wearers [634,641,644]. One study recruited previous contact lens dropouts, as well as participants that were current and new to contact lens wear [41]. One study did not specify whether participants had any previous contact lens experience prior to enrolling [637]. Ten of the 15 clinical trials recruited participants with myopia [330,634-636,638,639,641,643-645]. Two studies recruited participants with myopia or hyperopia [15,642], one study recruited participants with astigmatism [41] and two studies recruited individuals with presbyopia [637,640]. Other study-level characteristics are summarized in Table 2.

### 4.2.3. Cohort studies

The 19 cohort studies were conducted in eight countries: United States of America (n = 8) [341,646-652], Canada (n = 2) [653,654], United Kingdom (n = 2) [301,655], Australia (n = 1) [459], China (n = 1) [656], Finland (n = 1) [657], Portugal (n = 1) [658], Netherlands (n = 1) [659], Singapore (n = 1) [660], and one multi-site study was conducted in four countries (Canada, Portugal, Singapore and United Kingdom) [154].

The type of exposures for cohort studies involved contact lens wear of spherical [154,301,341,646,650,654-656,658,660], myopia control [154,656], toric [647,660], multifocal [459,648,649,651-653,659] and unspecified [657] lens designs. Contact lenses evaluated were silicone hydrogels in three studies [654-656], both hydrogels and silicone hydrogels in one study [656] and hydrogel lenses only in the remaining cohort studies.

In total, 5074 participants were enrolled across the 19 studies; individual study sample sizes ranged from 10 to 3066 participants. Fifteen studies [154,301,341,459,646,648-652,654,655,657-660] reported the sex distribution of the recruited or completed participants; female (n = 3088), male (n = 1207). Five studies enrolled 902 children aged eight to 16 years [154,341,654,656,660]. Three studies enrolled both children aged 11 years and older [650,658] or teenagers aged 14 years and older [657] and adults. Three studies enrolled adult participants less than 50 years of age [301,646,655], four studies enrolled older adults with presbyopia [651-653,659], and another study did not specify participant age [647].

Six studies recruited neophyte participants who had never worn contact lenses [154,653,654,656,657,660], three studies recruited existing experienced contact lens wearers [646,649,650], seven studies enrolled a combination of neophyte and experienced participants [301, 459,648,652,655,658,659], and three studies did not provide this information [341,647,651]. Nine of 19 studies recruited participants with myopia [154,301,341,646,654-657,660], one study recruited participants with myopia or hyperopia [658], one study recruited participants with astigmatism [647], seven studies recruited participants with presbyopia [459,648,649,651-653,659], and one study did not specify the refractive error profile of the participants involved [650]. Other study-level characteristics of the cohort studies are summarized in Table 3.

## 4.2.4. Risk of bias or quality assessment in included randomized controlled trials

None of the randomized controlled trials were judged to be at low risk of bias across all the domains assessed; 10 trials were considered to have overall high risk of bias (67%) and those remaining were judged to have some concerns (Fig. 3).

4.2.4.1. Randomization and allocation (selection bias). Eight (53%) and three (20%) of the included 15 randomized controlled trials were judged to have unclear or high risk of bias with regard to either proper random sequence generation or appropriate concealment, respectively. Other trials were judged to be at low risk for both domains.

4.2.4.2. Masking (performance bias and detection bias). Fourteen of 15 randomized controlled trials were judged to be at high risk of performance bias (40%), detection bias (7%), or both (47%). Six trials were described as open label, where participants and clinicians were aware of which intervention each group was receiving [41,641,644] or no information was provided with regards to masking [330,636,640]. In four trials, participants and the clinicians who assessed them could not be masked due to the inherent differences between the interventions (e.g., soft lens versus orthokeratology, soft lens versus spectacle wear, soft multifocal lens versus single vision distance or soft lens combined with reading glasses) [15,634,637,643]. In four trials described as investigator-masked, study personnel were masked by involving a

## Table 2

Characteristics of the randomized controlled trials included in the systematic review.

Study ID	Country	Setting	Age, years	Female,n/N (%)	Population	Lens Material (Type)	Wear Schedule,	Study	CL Dropou	t	CL Dropout reasons	Study funding sources
			mean $\pm$ SD (range)				Replacement Schedule, Care regimen	duration	n/N (%)	Comparator n/N (%)		
Parallel-arm de	sign											
Diec 2012 [645]	Australia	University clinic	$\begin{array}{c} 29.0\pm10.7/\\ 29.9\pm12.0/\\ 31.0\pm13.8\end{array}$	66/120 (55%)	Experienced, neophytes Myopes	Etafilcon A (H)/ Narafilcon A (SH)/ Senofilcon A (SH)	DW, DD, none	3 months	0/40 (0%), 6/40 (15% 1/40 (2.5% Overall: 7/	)/	Discomfort x 2 AE x 2 Vision x 1 Revocation of consent x 1 Protocol violation x 1	Alcon, BHVI Institute
Ma 2017 <sup>a</sup> [642]	China	Research Centre	Unknown	Unknown/162	Experienced, neophytes Myopes	Balafilcon A (SH) <sup>a</sup>	DW, Monthly, Complete MPS; Hydron Aqua- shining moist; Baoshining; Weicon Fresh; Weicon 2000 MPS	3 months	8/32 (25%) 7/33 (21%) 10/31 (32°) 6/32 (19%) 5/34 (15%) Overall: 36	)/ %)/ )/	Not specified	Brien Holden Vision Technology (Guangzhou) Co Ltd, China
Morgan 2013# [639]	United Kingdom	Research institute	$26.5 \pm 7.4 / \\ 26.5 \pm 8.1$	19/38 (50%)/ 16/36 (44%)	Neophytes Myopes	Narafilcon A (SH)/No lens wear#		12 months	15/38 (39.5%) 2-week: 7/38 (18.4%) 1-month: 9/38 (23.7%) 3-month: 9/38 (23.7%) 6-month: 14/38 (36.8%) 9-month: 15/38	6/36 (16.7%) #	Vision ×7 LTFU ×2 Handling x 1 AE x 1 Disinterest x 1 Others x 2 Disconfort x 1 <u>No lens wear#</u> Others x 3 Protocol violation ×1 LTFU x 1 Relocated x 1	Johnson & Johnson Vision Care
Nason 1994** [637]	United States	Private practice	32.1 (18–53)/ 31.2 (18–50)	52/72 (72%)/ 100/127 (79%)	Experienced Myopes	Etafilcon A (H)/ Unknown (H)	DW, DD, none/DW, not specified, unknown	1-year	7/72 (10%)	15/127 (12%) :/177 (12.4%)	$\begin{tabular}{lllllllllllllllllllllllllllllllllll$	Johnson & Johnson Vision Care
Novillo-Díaz 2018 [643]	Spain	Private practice	$\begin{array}{l} 50.44 \pm 5.18 / \\ 47.96 \pm 5.03 / \\ 47.98 \pm 5.19 \\ \text{Overall:} \\ 48.79 \pm 5.13 \end{array}$	41/50 (82%)/ 39/50 (78%)/ 40/50 (80%) Overall:	Experienced Presbyopes	Methafilcon IV (H, MFCN)/Comfilcon A (SH, MFCD)/ Lotrafilcon B (SH, MFCN)	DW, unknown	3 months	34/50 (689 17/50 (349 12/50 (249 Overall: 63 1-week:	%)	Methafilcon IV MFCN: Vision ×24 Discomfort ×6 LTFU ×4	None declared

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Study ID	Country	Setting	Age, years	Female,n/N (%)	Population	Lens Material (Type)	Wear Schedule,	Study	CL Dropout	:	CL Dropout reasons	Study funding sources	
			mean $\pm$ SD (range)				Replacement Schedule, Care regimen	duration	n/N (%)	Comparator n/N (%)			
				120/150 (80%)					1-month: 34/50 (68% 17/50 (34% 12/50 (24%	6) 6) /150 (27%) 6) 6)	Comfileon A MFCD: Vision ×11 Discomfort ×4 LTFU ×2 Lotrafileon B MFCN: Vision ×8 Discomfort ×3 LTFU ×1 Overall: Vision x 43 Discomfort x 13 LTFU x 7		
Plowright 2015# [15]	United Kingdom	Not specified	$16.2 \pm 1.8/$ $16.3 \pm 2.0$ Overall: (13–19)	32/57 (56%)/ 31/53 (58%)	Neophytes Myopes, hyperopes	Nelfilcon A (H)/ Spectacle wear#	DW, DD, none	6 months	10/57 (18%) Week 4: 8/57 (14%) Month 3: 10/57 (18%)	3/53 (6%)# Week 4: 3/53 (6%) Month 3: 3/53 (6%)	Discomfort $\times 4$ Handling $\times 2$ Disinterest $\times 1$ AE $\times 1$ LTFU $\times 1$ Others $\times 1$ Spectacle# Disinterest $\times 2$ LTFU $\times 1$	Alcon Research Ltd	
Pomeda 2018 # [644]	Spain	Not specified	$\begin{array}{c} 10.94 \pm 1.24 / \\ 10.12 \pm 1.38 \end{array}$		Neophytes Myopes	Omafilcon A (H, MC)/Spectacle wear#	DW, DD, none	2 years	5/46 (11%) 1 year 1/46 (2%)	0/33 (0%) 1 year 0/33 (0%)	Disinterest $\times 4$ Relocated $\times 1$	CooperVision S.L. Spain	
Pritchard 1996 [640]	Canada	University clinic	$31 \pm 7/28 \pm 7/$ 29 ± 7 Overall: 30 ± 7	21/37 (57% %)/24/41 (59%)/19/41 (46%) Overall: 64/119 (54%)	Neophytes Myopes	Polymacon (H)	DW, Monthly, Renu MPS/ DW, 3-monthly, Renu MPS/ DW, none, n/a	2 years	13/37 (35% 9/41 (22%) 8/41 (20%) Overall: 30	)	Discomfort ×8 Disinterest ×5 Vision ×5 LTFU ×5 Relocated ×4 Others ×2	Bausch & Lomb (Internation Division)	
Sankaridurg 2003 [646]	India	Hospital	22 ± 4 (16–35)/ 22 ± 4 (16–35)	47/139 (34%)/32/142 (23%)	Neophytes Myopes	Etafilcon A (H)/ Spectacle wear#	DW, DD, none	12 months	46/139 (33%) 1 week: 6/139 (4%) 1 month: 14/139 (10%) 3 months: 25/139 (18%) 6 months: 39/139 (28%) 9 months: 41/139 (29%) 12 months: 46/139 (33%)	24/142 (17%) # 1 week: 4/142 (3%) 1 month: 11/142 (8%) 3 months: 16/ 142 (11%) 6 months: 18/ 142 (13%) 9 months: 19/ 142 (13%) 12 months: 21/142 (15%)	Disinterest $\times 3$ Other $\times 4$ Discomfort $\times 3$ Protocol violation $\times 2$ Relocated $\times 2$ Handling $\times 1$ <u>Spectacle#</u> LTFU $\times 19$ Disinterest $\times 2$ Protocol violation $\times 2$	Johnson & Johnson Vision Care; Hyderabad Eye Research Foundation, India; Optometric Vision Research Foundation, Australia	

Study ID	Country	Setting	Age, years	Female,n/N (%)	Population	Lens Material (Type)	Wear Schedule,	Study	CL Dropou	t	CL Dropout reasons	Study funding sources
			mean $\pm$ SD (range)				Replacement Schedule, Care regimen	duration	n/N (%)	Comparator n/N (%)		
Sankaridurg 2013 [330]	China	Hospital	10.9 ± 1.8 (7–14)	118/240 (49%)	Neophytes Myopes	Lotrafilcon B (SH)/ Lotrafilcon B designs I, II, III (SH, MC)	DW, monthly, AO SEPT or Clear Care	2 years	70/240 (29 1 month: 1 3 months: 6 months: 9 months: 12 months: 15 months: 18 months: 21 months:	1% 15% 18% 20% 51/240 (23%) 25% 27%	Disinterest $\times 25$ Discomfort $\times 24$ Others $\times 7$ Relocated $\times 6$ LTFU $\times 5$ Handling $\times 2$ Allergy $\times 1$	Brien Holden Vision Institute; Vision Co-operative Research Centre, Sydney
Sulley 2013 [41]	United Kingdom	Private practice	$37 \pm 11.8/$ $39 \pm 10/$ $32 \pm 12.3$	47/67 (70%) 54/72 (75%) 28/61 (46%) Overall: 130/200 (65%)	Astigmats Experienced, previous dropouts, neophytes	Etafilcon A (H, toric)/ Senofilcon A (SH, toric)	DW, DD, none/DW, 2-week, Opti-Free Replenish or AO Sept Plus	1-month	4/67 (6%) 4/72 (6%) 10/61 (14%) Overall: 18/200 (8%) 1 week: 2/67 (3%) 2/72 (3%) 5/61 (5%) Overall: 9/ 200 (4.5%)	8/109 (7%) DD 8/89 (9%) 2- week	Discomfort ×7 Vision ×4 Handling ×2 LTFU ×1 Others ×3	Johnson & Johnson Vision Care
Walker 2007 [636]	United States	Private practice	$\begin{array}{c} 27.8 \pm 6.2 \\ (18  39) / 27.8 \pm 6 \\ (18  39) \end{array}$	107/141 (76%)/101/ 141 (72%)	Experienced Myopes	Etafilcon A (H)/ Nelfilcon A (H)	DW, DD, none/DW, DD, none	1 week	1/141 (0.7 5/141 (3.5 Overall: 6/	%)	Unknown $\times 3$ Lens fit $\times 1$ Discomfort $\times 1$ Cost $\times 1$	Johnson & Johnson Vision Care
Crossover des Harris 1991 [638]	<b>ign</b> United States	Unknown	52.5 § (44–67)	Unknown/40	Presbyopes	Unknown (H, MF)/ Unknown (H, Sph)	DW, not specified, unknown/DW, not specified, unknown	8 weeks	8/40 (20%)	Not specified	Vision ×5 Handling ×2 Relocated ×1	None declared
Lipson 2005 ## [635]	United States	University clinic	29.5 ± 6.9 (18–40)	Unknown/81	Experienced, neophytes Myopes	Ocufilcon D (H)/ Paflufocon B or Boston XO##	DW, 2-week, unknown/ Overnight, n/a, unknown	8 weeks	8/81 (9.9%)	10/81 (12.3%)##	Others x 5 Handling x 1 Discomfort x 1 Othokeratology## Others x 5 Vision x 3 Handling x 1	Paragon Vision Sciences; Ocular Sciences, Inc.; Art Optical Contact Lens Inc.
Woods 2015 ** [641]	Canada	Research Centre	52 (43–66)	35/49 (71%)	Experienced Presbyopes	Lotrafilcon B (SH, MF)/Lotrafilcon B (SH, Sph)	DW, not specified, Clear Care	1 month	1/50 (2%)		AE ×1	CIBA Vision

<sup>a</sup> Intervention = one of five randomly assigned MPS care regimen; § Demographic characteristics of discontinued participants not provided. # Comparator = no lens or spectacle wear; \*\* Demographic characteristics of discontinued participants not provided; ## Comparator = overnight RGP orthokeratology wear.

Abbreviations: AE, adverse event; CL, contact lens; DD, daily disposable; DW, daily wear; H, hydrogel; LTFU, lost to follow up, MC, myopia control, MFCD, multifocal centre distance; MFCN, multifocal centre near; MPS,

multipurpose solution; SH, silicone hydrogel.

second examiner who performed relevant clinical assessments once the intervention (e.g., contact lens or spectacles) was applied or removed [638,639,642,645]. One of these trials was considered at risk of detection bias as it was unclear whether study personnel could remain truly masked to inherent differences in the appearance of the contact lenses (e.g., stiffness, diameter, color, or surface markings) [642]. One trial where participants were masked to the intervention by over-labeling of the lens packaging was judged to be at unclear risk for performance bias due to the intervention unlikely to be truly masked due to differences in the shape of lens packaging [635].

4.2.4.3. Incomplete outcome data (attrition bias). One randomized controlled trial was judged to have high risk of bias due to reporting of incomplete outcome data on contact lens dropout reasons [641]. One trial was judged to have a high risk of bias due to participants who were unable to complete the intervention having been more likely to be excluded from the comparative control [637]. One trial was judged to have an uncertain risk of bias due to incomplete outcome data reporting at certain study visits (e.g., between dispensing and the one week follow-up) [636]. The remaining 12 trials were assessed as having low risk of bias in this domain.

4.2.4.4. Selective reporting (reporting bias). Seven randomized controlled trials were judged to be at unclear risk of selective reporting bias because of the lack of availability of pre-specified analysis intentions [41,330,634,635,641,644,645]. The other eight trials were considered at low risk in this domain.

4.2.4.5. Other bias: source of funding. Eleven of the 15 trials were considered to be at high risk of bias due to potential conflict of interests, as reported by the authors [15,41,634-636,638-640,643-645]. Three trials were judged to have unclear risk of bias due to lack of information [642] or insufficient information being disclosed [330,637,641].

### 4.2.5. Risk of bias or quality assessment in included cohort studies

Fig. 4 summarizes the risk of bias assessments for cohort studies. Of the 19 cohort studies, four studies were judged to have a high risk of bias using the Newcastle-Ottawa tool, as they were given a total of two [647, 652,653] or three [648] out of nine stars. The domain with the highest risk of bias was comparability of cohorts, where, with the exception of one prospective cohort study [301], all other inception cohorts scored poorly (Fig. 4). The domain with the overall lowest risk of bias was outcome, where 17 of 19 studies scored two out of three stars, or better.

Nine of 19 cohort studies were judged to be at high risk of bias due to potential conflicts of interest, as reported by the study authors [154,301, 341,646,650,654,655,658,660]. Cohort studies judged to be at low risk of bias included those that reported no commercial funding sources [459,656,657]. Seven cohort studies were judged to have unclear risk of bias due to the lack of information disclosed [647-649,651-653,659].

### 4.3. Contact lens dropout

Very few of the 34 eligible studies in this systematic review reported on the study participant behaviors or environmental exposures associated with contact lens dropout, as defined to be of primary interest in the systematic review protocol. One study reported on lens adherence [656] and one on allergy [657]. As a result, the presented analyses focus primarily on rates of contact lens dropout.

## 4.3.1. Primary outcome

Four randomized controlled trials reported on dropout, where a group wearing contact lenses was compared to study participants wearing spectacles or who had no refractive error. Higher discontinuation rates occurred among participants assigned to contact lens wear, relative to those not wearing lenses (18% vs 6%; 39.5% vs 16.7%; 11%

vs 0%; 33% vs 17%) at both six month [15] and 12 month [638,643, 645] follow-up time points.

Pooling comparable data from four randomized controlled trials [15, 330,638,643], with follow-up periods ranging from six months to two years, there was a significantly higher risk of participant dropout in contact lens wearers compared to spectacle lens wearers (Fig. 5; four studies; 544 participants; relative risk: 2.16; 95% CI 1.50 to 3.11; P = 0.0001). The follow-up period ranged from six months [15] to two years [330,638,643]. Of the four studies, two included adult participants [330,638] and the other two included children [15,643].

## 4.3.2. Additional outcomes

4.3.2.1. Dropout by lens type and population. One randomized controlled trial and six cohort studies, reporting on wear of multifocal contact lenses, reported variable participant dropout rates, comprising 72% at one month [653], 42% at three months [642], 20%–24% at six months [649,659], and 26%–54% at one year [459,648,652] of follow-up. Two cross-over, randomized controlled trials comparing multifocal contact lenses to single vision distance correction with over-reading spectacles and to monovision contact lenses either did not report dropouts in the comparator group [637], or did not attribute dropout to either the multifocal or the comparator group [640].

Two trials and one cohort study reporting on wear of myopia control contact lenses by children found dropout rates of 11% [643], 29% [330] and 43% [656], respectively, at two years follow-up; another cohort study reporting on myopia control contact lenses worn by children for six years reported a dropout rate of 36% [154].

One randomized controlled trial and one cohort study involving participants with astigmatism wearing toric contact lenses reported dropout rates of 4.5% at one month [41], and 18% at 26.6 months of follow-up [647].

Two cohort studies reporting on wear of spherical contact lenses by adults had dropout rates of 2% [650] and 4.4% [658], in daily disposable and frequent replacement lens wearers respectively, at four weeks of follow-up. A similar dropout rate of 4.3% was reported in a randomized controlled trial, of one week duration, involving daily disposable lenses [635]. A cross-over trial found a dropout rate of 9.9% at four weeks in the frequent replacement arm of the study [634]. Two trials and one cohort study reported dropout rates of 5.8% [644], 22.2% [641] and 5.9% [646] at three months of follow-up. Another randomized controlled trial and cohort study found rates of 11% [636] and 23% [301] at 12 months of follow-up. Another cohort study found rates of 7.9% at 1.7 years [657], and a trial and cohort study found rates of 25% [639] and 29% [655] at two years of follow-up, respectively.

Three cohort studies reporting on wear of spherical contact lenses by children found dropout rates of 9.5% [654], 10% [660], and 17% [341] at a three month follow-up time point.

One study reported comparative dropout rates in neophyte and experienced cohorts of multifocal contact lens wearers at 12 months (67% versus 42%) [459]. Two trials that involved neophyte, spherical contact lens wearers reported dropout rates of 39.5% [638] and 33% [645], whereas a randomized controlled trial that involved experienced wearers only, reported lower dropout rates of 11% [636].

An analysis was performed to consider potential differences in dropout rates reported in randomized controlled trials involving contact lens wearers at a time-point of 30 days of follow-up, relative to >30 days of follow-up. Pooling data from three studies [15,330,638] was not deemed appropriate due to high statistical heterogeneity ( $I^2 = 79\%$ , P = 0.009), in the presence of divergent study effects, as two studies reported no inter-condition difference [15,638], whereas in one study [330] the dropout rate was higher among participants at the >30 day follow-up time-point (Fig. 6). The follow-up periods were six months [15] and 12 months [330,638]. Of the three studies, two included adult participants [330,638] and one included children [15].

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Study ID	Country	Setting	Age, years mean $\pm$ SD (range)	Female, n/ N (%)	Population	Lens Material (Type)	Wear Schedule, Replacement Schedule, Care regimen	Study duration	CL Dropout n/ N (%)	CL Dropout reasons	Study funding sources
Cohort - Prosp											
Back 1992 [459]	Australia	Research Institute	$58 \pm 6$ (neophytes) $57 \pm 5$ (experienced) (47–70)	61/108 (56%)	Neophytes Experienced Presbyopes	Polymacon (H, MF)	DW, not specified, unknown	12 months	58/108 (54%) Neophytes: 34/ 51 (67%) Experienced: 24/57 (42%) 1-week: Neophytes 35% Experienced 20% 1 month: Neophytes 44% Experienced 25% 3 months: Neophytes 59% Experienced 38%	Vision ×35 Handling ×6 Others ×6 Discomfort ×4 Disinterest ×4 AE ×3	Optometric Vision Research Foundation of Australia
Bierly 1995 [649]	United States	Not specified	51.5 (40–68)	Unknown/ 30	Neophytes Experienced Presbyopes	Hefilcon A (H, MF)	DW, not specified, unknown	1 year	14/30 (47%)	§§ Vision ×19 Handling x 3 Discomfort ×2 LTFU ×1	None declared
Brenner 1994 [650]	United States	Not specified	49.1 (40–70)	17/25 (68%)	Experienced Presbyopes	Polymacon (H, MF) Hefilcon A (H, MF)	DW, not specified, unknown	6 months	6/25 (24%) 2 weeks: 2/25 (8%)	Disinterest x 3 Unknown ×2 Others x 1	None declared
Fahmy 2010 [651]	United States	Not specified	28.1 ± 9.1 (11–46)	61/83 (74%)	Experienced Symptomatic	Nelfilcon A (H)	DW, DD, none	4 weeks	2/83 (2%) 1 week 2/83 (2%) 2 weeks 2/83 (2%) 3 weeks 2/83 (2%)	Lens fit ×1 Discomfort ×1	CIBA Vision
Guillon 2012 [656]	United Kingdom	Research Institute	$29.2 \pm 9.5$	64/90 (71%)	Experienced Non-wearers §§§ Myopes	Senofilcon A (SH)	DW, 2 week, biguanide MPS or polyquad MPS or polyhexanide MPS or hydrogen peroxide-based solution	2-years	26/90 (29%) Experienced 16/58 (28%) Non wearers 10/32 (31%)	LTFU $\times 16$ Others $\times 6$ Discomfort $\times 2$ Lens fit x 1 Vision $\times 1$	Johnson & Johnson Vision Care
Josephson 1988 [654]	Canada	Private practice	Unknown	Unknown/ 81	Neophytes Presbyopes	Bufilcon A (H, MF)	DW, not specified, unknown	4 weeks	58/81 (72%) 35/81 (43%) fitting	Vision $\times 57$ Others $\times 1$	None declared
Kari 1992 [658]	Finland	Private practice	20 (14–40)	64/76 (84%)	Neophytes Myopes	Not specified (H)	DW, yearly, not specified	1.7 years (0.3–4.2)	6/76 (7.9%)	Discomfort ×6	The Eye Foundatio The Allergy Research Foundation, Helsinki, Finland
Key 1996 [652]	United States	Private practice	50 (40–73)	171/215 (80%)	Presbyopes	Methafilcon A (H, MF)	DW, not specified, unknown	3-months	87/215 (40%) 1-month 36/215 (17%)	LTFU ×16 Not specified otherwise	Sunsoft Corporation (for 2nd author KM
Li 2009 [661]	Singapore	Research Institute	9.8±0.9 (8–11)	37/59 (62%)	Neophytes Myopes Astigmats	Etafilcon A (H)	DW, DD, none	3 months	6/59 (10%)	Handling $\times 4$ Lens fit $\times 1$ AE $\times 1$	Johnson & Johnson Vision Care

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Table	3 (	(continued)
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Study ID	Country	Setting	Age, years mean $\pm$ SD (range)	Female, n/ N (%)	Population	Lens Material (Type)	Wear Schedule, Replacement Schedule, Care regimen	Study duration	CL Dropout n/ N (%)	CL Dropout reasons	Study funding sources
Malet 2002 [659]	France	Private practice	$30 \pm 8.5$ (11–59)	2303/3066 (75%)	Neophytes Experienced Myopes Hyperopes	Etafilcon A (H)	DW, 2-week, PHMB MPS	4 weeks	134/3066 (4.4%)	Others ×54 LTFU ×50 Unknown ×9	Johnson & Johnsor Vision Care; Allergan, France, S. A.S.
Nason 1993 [647]	United States	Not specified	$32.5 \pm 6.7^{a}$ (21–49)	39/ 48 <sup>ª</sup> (76%)	Experienced Myopes	Etafilcon A (H)	DW, 2-week, PHMB MPS	3-months	3/51 (5.9%)	Lens fit $\times 1$ AE $\times 1$ Protocol violation $\times 1$	Johnson & Johnson Vision Care
O'Donnell 2001 [301]	United Kingdom	Research Institute	Diabetics: $34 \pm 13$ Non-diabetics: $31 \pm 11$	24/40 (60%) 19/40 (48%)	Neophytes Experienced Myopes	Etafilcon A (H)	DW, 2-week, MPS	12-months	18/80 (23%) 11/40 (28%) diabetics 7/40 (18%) non-diabetics	Discomfort ×6 AE ×5 Disinterest ×3 Handling x 2 LTFU ×1 Relocated ×1	Johnson & Johnsor Vision Care; Bausch & Lomb, Inc.
Paquette 2015 [655]	Canada	University clinic	Unknown (8-16)	101/179 (56%)	Neophytes Myopes	Lotrafilcon B (SH)	DW, monthly, hydrogen peroxide-based solution	3-months	17/179 (9.5%) Dispensing: 12/ 179 (6.7%) 1-week: 16/ 179 (8.9%)	Ineligible ×8 Handling ×7 Disinterest ×1 Discomfort ×1	Alcon Research, Lto
Shapiro 1994 [653]	United States	Not specified	Unknown (40–67)	84/100 (84%)	Presbyopes Neophytes Experienced	Hefilcon A (H, MF)	DW, not specified, MPS	1-year	26/100 (26%) hefilcon A	Discomfort ×1 Not specified otherwise	None declared
Walline 2004 [341]	United States	University clinic	10.6 ± 1.5 (8–13)	7/12 (58%)	Myopes	Etafilcon A (H)	DW, DD, none	3-months	2/12 (17%) 1-week: 1/12 (8%) 1-month: 1/12 (8%)	Handling $\times 1$ Relocated $\times 1$	Johnson & Johnsor Vision Care
Weng 2021 [657]	China	University clinic	Unknown (8-13)	Unknown/ 508	Neophytes Myopes	Somofilcon A designs I, II (SH, MC) Etafilcon A designs III, IV (H, MC) Somofilcon A (SH)	DW, DD, none/ DW, DD, none/ DW, DD, none/ DW, DD, none/ DW, DD, none	24-months	47/103 (46%) 44/101 (44%) 43/98 (43%) 46/104 (44%) 38/102 (37%) Overall: 218/ 508 (43%) 1-month: 28/103 (27%) 25/101 (25%) 25/98 (26%) 30/104 (29%) 21/102 (21%) Overall: 129/ 508 (25%)	Others ×84 Discomfort ×55 Disinterest ×29 Handling ×23 LTFU ×22 Relocated ×9 Vision ×3	Brien Holden Visio Institute, Sydney
Woods 2021 ** [154]	United Kingdom, Canada, Portugal, Singapore	Not specified	10.1 ± 1.4 (8–12)	69/144 (48%)	Neophytes Myopes	Omafilcon A (H, MC)/Omafilcon A (H)	DW, DD, none/DW, DD, none	6 years	52/144 (36%) Dispensing: 9/ 144 (6%) 1-month: 14/ 144 (9.7%) Year 1: 22/144 (15%) Year 2: 27/144 (19%) Year 3: 35/144 (24%)	Disinterest $\times$ 12 Lens fit $\times$ 7 Vision $\times$ 7 Handling $\times$ 6 Discomfort $\times$ 5 Relocated $\times$ 5 LTFU $\times$ 4 AE $\times$ 3 Protocol violation $\times$ 3	CooperVision Inc.

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Study ID	Country	Setting	Age, years mean ± SD (range)	Female, n/ N (%)	Population	Lens Material (Type)	Wear Schedule, Replacement Schedule, Care regimen	Study duration	CL Dropout n/ N (%)	CL Dropout reasons	Study funding sources
									Year 4: 44/144 (31%) Year 5: 46/144 (32%)		
Zandvoort 1993 [660]	Netherlands	University clinic	$52 \pm 5$ (46–61)	8/10 (80%)	Presbyopes Neophytes Experienced	Unknown (H, MF)	DW, not specified, unknown 6 months	6 months	2/10 (20%)	Vision $\times 2$	None declared
Cohort - Retrospective Maltzman United ( 1989 [648]	ospective United States	Not specified	Unknown	Unknown/ 160***	Astigmats	Not specified (H, Not specified toric)	Not specified	26.6 months (4- 51)	18/100 (18%)***	Not specified	None declared
Abbreviations	AF adverse event	• CI contact le	Abhreviatione: AF_adverse event: CI_contact lene: DD_daily dismoshle: DW_	able DW dail	v wear H hvdro	rel·1 TELL lost to follo	daily wear: H. hydrored: I. TEH   Act to follow in: MC - monia control: ME - miltifocal: MDS - multiniurnose solution: DHMR - nolohevamethylane	(LC) AE multiforal	· MDS multimurv	nointion esc	· DHN

Demographic characteristics of discontinued participants not provided. § Demographic characteristics of 347 of 531 participants who responded to at least one questionnaire. \*\*RCT (years 1–3) followed by prospective biguanide; SH, silicone hydrogel.

inception cohort (years 4–6). §§ Some participants gave more than one reason for discontinuation. \*\*\* Data was available by eye and not by person; 100 of 160 eyes only with accurate follow-up data available. §§ Non wearers defined as previously failed contact lens wearers (who had discontinued contact lens wear due to unacceptable performance or who wore their contact lenses not more than 1 day per week due to an unsatisfactory performance) OR neophytes The Ocular Surface 29 (2023) 175-219

4.3.2.2. Reasons for contact lens dropout. Overall, lens discomfort was the most frequently reported reason for dropout in many (nine of 34) studies [15,41,301,636,639,642,644,656,657]. In six of eight studies involving participants wearing multifocal lenses for presbyopia correction, the most frequent reason was vision quality [459,637,642,648,653,659]. Other reasons participants discontinued study participation were disinterest with contact lens wear (n = 4) [154,330,643,649], 'other' reasons (n = 4) [634, 640,656,658], lost to follow up (n = 3) [645,651,655], unknown reasons (n = 3) [635,647,652], lens handling (n = 1) [660], or ineligibility (n = 1) [654]. In one study, three participants discontinued, one each due to the contact lens fit, an adverse event or a protocol violation [646]. In another study, two participants dropped out, one each due to lens fit or discomfort [650]. In another study, two participants discontinued, one each due to lens handling or participant relocation [341].

### 4.4. Discussion

This is the first systematic review to investigate what is known about the association between lifestyle factors and soft contact lens dropout. Those lifestyles factors of interest included patient behaviors (e.g., contact lens handling abilities, wear schedule, adherence, patient motivation. occupation, etc.) and environmental exposures (e.g., climate, temperature, health status, allergies, pollution, water exposure, air conditioning, wind, wildfires, etc.). Other than wear schedule, very few of the 34 eligible studies reported on the patient behaviors and/or environmental exposures listed as lifestyle factors of interest in the systematic review protocol. The exclusion of studies that allowed participants to wear lenses during sleep precluded investigations on the possible effect of wear schedule on contact lens dropout. Many cohort studies that specifically aimed to estimate the incidence of contact lens dropout, and the risk factors associated with wear failure, were excluded because of the inclusion of other types of contact lenses (e.g., rigid, cosmetic) in the study population [45,51,661,662]. Case-control and cross-sectional studies not included in this systematic review that could have reported on the lifestyle factors of interest [52,372,663,664] would also often have been excluded due to the inclusion of other types of lens wearers in the study population [48,217,629]. Recent evidence-based summaries of the contact lens field have highlighted the need for distinct evaluations of specialty, soft and rigid lenses, including an assessment of their rate of dropout and associated factors [59,74].

The present review demonstrated that participants wearing contact lenses for the correction of their refractive error were approximately twice as likely to discontinue from a clinical trial or cohort study than those wearing spectacles. Analysis of dropout rates over time could not be conducted due to significant heterogeneity among the included randomized controlled trials. Whilst lens discomfort was the most frequently reported reason for dropout in many studies, vision quality was a frequent cause of discontinuation in studies involving participants with presbyopia wearing multifocal contact lenses.

All soft contact lenses were associated with dropouts, no matter the lens type, study design, or study population. In randomized controlled trials, allocation to a soft contact lens intervention was found to increase the chances of participant dropout compared to a spectacle correction or no lens wear. Discomfort with contact lens wear was commonly reported as a dropout reason in both randomized trials and cohort studies. An exception to this was those studies involving multifocal contact lenses among study participants with presbyopia, where vision was frequently reported as a reason for discontinuation, rather than discomfort; although this finding should be interpreted in the context of those studies being judged to have a high [637,648,652,653] or unclear [459, 642,649,659] risk of bias.

Based on risk of bias assessments, one study was judged to be of overall high quality, indicating minimal risk of bias, in a cohort study evaluating contact lens wear in participants with diabetes [301]. All other studies were assessed to be of fair, poor or unsatisfactory quality, or having serious risk of bias, as determined by the appropriate risk of

						of bias						
		D1	D2	D3	D4	D5	D6	D7	Overall			
	Diec	-	-	X	+	+	-		×			
	Harris	-	X	X	X	X	+	-	×			
	Lipson	+	+	X	X	+	-	X	X			
	Ма	+	-	X	-	×	-	-	X			
	Morgan	+	-	X	+	+	+	X	-			
	Nason 1994	×	-	X	X	-	+	X	X			
	Novillo-Diaz	+	+	-	-	+	+	-	-			
Study	Plowright	+	-	X	-	+	+	X	X			
	Pritchard	-	+	X	+	+	+	X	-			
	Ruiz-Pomeda	+	+	X	×	+	+	X	X			
	Sankaridurg 2013	+	-	X	×	+	-	-	X			
	Sankaridurg 2003	+	+	X	-	+	-	X	-			
	Sulley	+	-	X	X	+	-	X	X			
	Walker	+	-	-	×	+	-	X	-			
	Woods 2015	+	×	X	×	+	+	X	X			
		D1: Sequ	J	udgement								
		D2: Allocation Concealment D3: Masking participants personnel D4: Masking assessors										
		D5: Incomplete outcome data D6: Selective reporting										
			sources b						+ Low			

Fig. 3. Risk of bias judgement for randomized controlled trials included in the systematic review, evaluated using the Cochrane RoB-2 tool.

bias tool for the study design [7]. Common reasons for downgrading the assessment outcomes were due to randomized controlled trials not masking participants, personnel and investigator/outcome assessor(s), cohort studies enrolling selected populations or not providing a description of the derivation of the cohort, and uncertainty or lack of information regarding how the exposure and/or outcome were assessed. A further consideration is that of the 34 included studies, 30 were considered at medium to high risk of bias due to declared industry funding or unclear funding sources. There is a possibility that this may influence the design, reporting and publication of research findings [665,666]. To minimize the risk of bias in future research, studies should be double-masked, wherever possible, and clearly pre-define the criteria for discontinuation from the study and the classification of contact lens dropouts, to enable greater certainty in analysis.

The generalizability of the findings reported within this systematic review is uncertain. Of the 34 included studies, most were conducted outside eye care practices, instead being performed in university clinics and research centers, where patients were often formally enrolled in clinical trials, testing investigational products. The population of patients participating in these trials may differ from the general contact lens wearing population. The high frequency of contact lens dropout reasons relating to 'disinterest' and 'lost to follow-up' may indicate the potential negative impact of trial participation on dropout rates. The time and commitment required to participate in a clinical trial may negatively impact on continuation of contact lens wear, rather than necessarily reflect the nature of contact lens wear in itself. In the future, population studies are required to more clearly ascertain true contact lens dropout rates in the field, outside of the clinical trial setting, as well as the overlay of lifestyle and behavioral factors on lens discontinuation.

### 4.5. Systematic review conclusions

A need exists for research to specifically examine the lifestyle factors associated with soft contact lens dropout, with a consideration of factors that might influence such dropouts (e.g., type of lens design, participant age, lens modality, etc.). It is recommended that population studies be conducted, ensuring that participants and assessors remain masked (to the extent it is feasible), and that clear pre-defined clinical and classification criteria are formulated to capture the nature of contact lens dropouts.

		SELECT	ION		COMPARABILITY		OUTCOME		
				Demonstration					
				that outcome of			Was follow-up		1
		Selection of the		interest was not			long enough for	Adequacy of	1
	<b>Representativeness of</b>	non exposed	Ascertainment of	present at start of	<b>Comparability of</b>	Ascertainment	outcomes to	follow up of	Total score
Study	the exposed cohort	cohort	exposure	study	cohorts	of outcome	occur	cohorts	(out of 9)
Back			*	*		*	*	*	5
Bierly						★	*	*	3
Brenner				*		*	*	*	4
Fahmy	★		*	*		★		*	5
Guillon			*	*			*	*	4
Josephson	· .			*		★			2
Kari	× .			*			*	*	4
Key	★		*	*			*		4
u			*	*		*	*	×	5
Malet	★		*	*		★		*	5
Maltzman			*				*		2
Nason 1993			*	*		★	*	*	5
O'Donnell	★	*	*	*	*	*	*	*	8
Paquette			*	*		★	*	*	5
Shapiro				*			*		2
Walline			*	*		*	*	*	5
Weng	★		*	*		★	*	*	6
Woods 2021	*		*	*		★	*	*	6
Zandvoort	<b>★</b>			*			*	*	4

Fig. 4. Risk of bias judgements for cohort studies included in the systematic review, evaluated using the Newcastle Ottawa tool A maximum of one star for each numbered item within the 'Selection' and 'Outcome' categories can be awarded. A maximum of two stars can be awarded for 'Comparability', making a sum total of a possible 9 stars.

	Contact lens w	earers	Spectacle w	earers		<b>Risk Ratio</b>	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% Cl
Morgan 2013	15	38	6	36	19.3%	2.37 [1.03, 5.43]	
Plowright 2015	10	57	3	53	8.7%	3.10 [0.90, 10.65]	
Pomeda 2018	5	46	0	33	1.6%	7.96 [0.46, 139.12]	
Sankaridurg 2003	46	139	24	142	70.4%	1.96 [1.27, 3.02]	<b></b>
Total (95% CI)		280		264	100.0%	2.16 [1.50, 3.11]	•
Total events	76		33				
Heterogeneity: Tau <sup>2</sup> :	$= 0.00; Chi^2 = 1.4$	41, df = 3	$B (P = 0.70); I^2$	= 0%			
Test for overall effect	z = 4.15 (P < 0)	.0001)					0.001 0.1 1 10 1000 Favours contact lens Favours spectacle lens

Fig. 5. Forest plot of comparison: Contact lens vs. spectacle wearers for study discontinuation in randomized controlled trials included in the systematic review. Follow-up periods ranged from six months to two years.

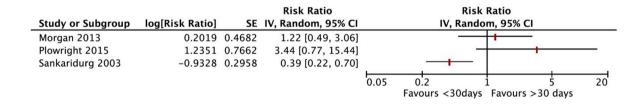


Fig. 6. Forest plot of comparison: 30 day vs. >30 day follow-up period for contact lens dropout in randomized controlled trials included in the systematic review. Follow-up periods ranged from six to 12 months.

## 5. Conclusions

When informed choices are made, contact lenses can enhance the ocular well-being and overall lifestyle of those who require refractive correction, medical treatment or eye protection. Such choices must be underpinned by knowledge based upon evidence derived from the ophthalmic literature; this review has summarized this evidence base. Ocular conditions that contraindicate the use of contact lenses have been reviewed, as well as those conditions that may benefit from contact lens wear. Systemic conditions that may adversely impact contact lens wear have also been discussed.

Examination of the literature resulted in an appreciation of the fact that several areas of study lack high quality evidence and would benefit from further exploration. These areas include determining the measures that should be taken when contact lens wearers are unwell with an upper respiratory tract infection, the impact of ocular surface disease on contact lens success (especially in older and naive wearers), and the impact of various environmental factors as well as mental health, stress and depression on contact lens performance with contemporary lens materials and modalities.

The COVID-19 pandemic has heightened awareness of the importance of hygiene during contact lens wear and has introduced new potential risks that could impact the success of contact lenses, including inadvertently introducing sanitizing products into the eye and maskassociated dry eye. Contact lenses can continue to be worn safely during the COVID-19 pandemic, especially if lens wearers make efforts to mitigate the risky situations described above. Contact lens wear should be ceased when unwell with systemic infections, including with COVID-

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Lifestyle choices can impact the success and safety of contact lens wear. The avoidance of risky behaviors such as sleeping in lenses, failing to comply with instructions from the eye care provider, failing to attend for regular aftercare visits, purchasing contact lenses and solutions from unregulated vendors, wearing or sharing 'party' lenses, and using tobacco, alcohol or recreational drugs, can all increase the risk of adverse consequences. These adverse effects can range from dissatisfaction with contact lens wear to serious ocular compromise and permanent loss of vision. Strategies to ensure provision of adequate hygiene, safety education and ongoing connection with an eye care practitioner are needed, particularly for young adults who are often less compliant with respect to contact lens hygiene. Further development of tele-optometry services may help in this regard.

Consideration of the physical, work and atmospheric environment in which contact lenses are worn can inform practitioners and lens wearers of whether lenses should be worn, and if so what lens type, care system, wear frequency and pattern of lens wear is most appropriate. Such issues have been considered in detail in this review and can serve as a guide to assist eye care practitioners in optimizing the contact lens wearing experience for individual patients, to enhance their lifestyle in terms of optical refraction, ocular health, eye safety, convenience and utility.

With respect to contact lens dropout, much further work is required to acquire high quality data that will provide information on the lifestyle factors that can result in the discontinuation of lens wear, which continues to occur in approximately 25% of wearers over a two to three year period. The major known factors for contact lens dropout are discomfort, lens handling difficulties, and vision issues. Of note is the finding from the systematic report within this report, that many of the highquality studies that have reported on lens dropout are randomized controlled trials. However, whether these represent the most appropriate means to determine the factors that influence dropout in the 'real world' remains a point of debate. Randomized controlled trials are typically short-term evaluations, in well-defined study populations, rather than examinations of patient wearing trends over extended periods of time. Perhaps surveys embedded within clinical practices or longitudinal web-based surveys might be a more accurate way of obtaining generalizable data on the reasons behind contact lens dropouts.

Finally, growing evidence demonstrates that daily disposable lenses provide many advantages over reusable contact lenses, including increased convenience, enhanced adherence to lens replacement, reduced ocular inflammatory complications and avoidance of the many complications linked to contact lens storage cases. The potential role of contemporary daily disposable lenses in overcoming a number of lifestyle challenges highlighted in this review are worthy of further study.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jtos.2023.04.010.

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