Review article

All soft contact lenses are not created equal

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Short title: Contact lens are not equal

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ABSTRACT

Soft contact lenses that have been prescribed by eye care practitioners are sometimes substituted for alternative lenses by unqualified, unregulated and sometimeseven fully regulated lens suppliers, in the mistaken belief that there is essentially no difference between different soft lens types. This review considers the implications of inappropriately substituting soft contact lens types in terms of (a) lens properties: surface treatment, internal wetting agents, material, total diameter, back optic zone radius, thickness, edge profile, back surface design, optical design, power, colour (tint) and ultraviolet protection; and (b) lens usage: wearing modality (daily versus overnight wear)

and replacement frequency. Potential aspects of patient dissatisfaction and adverse events when prescribed soft lenses are substituted for lenses with different properties or intended usage are considered. Substitution of 15 of the 16 lens properties considered (i.e. except for back surface design) was found to be related to at least one – and as many as six – potential sources of patient dissatisfaction and adverse ocular events. Contact lens are medical devices which are prescribed and fitted; they should never be substituted for another lens type in the absence of a new prescription further to a full finalised fitting, for the simple reason that all soft contact lenses are not created equal. A substituted lens may have properties that result in undesirable consequences in respect of the vision, ocular health, comfort and cosmetic appearance, and may be incompatible with the lifestyle of the patient.

1. Introduction

The adapted title of this paper is a paraphrase of, and antithetic to, a famous pronouncement that is part of the sentence in the US Declaration of Independence – penned in 1776 during the beginning of the American Revolution – that reads, "We hold these truths to be self-evident, that all men are created equal ...". That all soft contact lenses are *not* created equal is self-evident to all qualified eye care practitioners; apparently, however, this notion is *not* self-evident to many non-ophthalmic-qualified commercial lens suppliers, regulatory and governmental agencies (such as the United States Federal Trade Commission) or members of the public, where the desire to deliver choice of product at the point of purchase seemingly takes priority over the regulated clinically-driven prescribing process.

There is an established evidence base for the way in which contact lenses are prescribed by eye care practitioners [1], who have had sufficient professional training and experience qualifying them to fit these Class II and III (United States) or Class IIa and Class IIb (European Union/United Kingdom) medical devices [2]. Contact lenses with appropriate surface treatments and/or internal wetting agents must be selected to be compatible with assessed features of the anterior ocular anatomy and physiology of the lens wearer [3]. Lens bulk material properties such as oxygen permeability, water content, and modulus are chosen to achieve satisfactory lens comfort and ocular health, commensurate with the ability of patients to handle lenses. The physical dimensions of the lens must be chosen carefully to ensure that the lens fits appropriately on the eye, with an appropriate level of corneal coverage and blink-induced movement commensurate with good comfort, eye health and stable vision [1].

Contact lenses need to be of an appropriate optical design for the correction of ametropia or presbyopia, as required for a specific patient, and must have the correct optical power for the visual tasks that the patient will undertake [4]. Coloured lenses can be prescribed to improve handling, or enhance/alter cosmetic appearance. Ultraviolet light blocking lenses may be prescribed as a ubiquitous prophylactic measure, or more specifically for patients who anticipate excessive ultraviolet light exposure. For patients who choose to routinely or sporadically sleep in soft lenses, high oxygen transmissible silicone hydrogel lenses are routinely prescribed. The choice of lens

replacement frequency is made by weighing up a number of factors, including the ocular response to lens wear, lifestyle considerations and affordability [1].

All the above considerations are taken into account by a qualified eye care practitioner to ensure that an appropriate contact lens is prescribed for a given patient, with respect to visual, ocular, lifestyle and affordability considerations. It is therefore of concern that contact lenses purchased from an unregulated supply outlet such as a convenience store, on-line portal or through telephone ordering [5], may be exchanged for lenses with different properties (a practice which is known as 'substitution'). As well, some *regulated* suppliers are known to encourage unsupervised switching of brands. It is often the case that the supplier fails to understand – or does understand but chooses to ignore – the truism that "all soft contact lenses are *not* created equal". This problem of soft contact lens substitution appears to be rife around the world.

In the USA, the Contact Lens Rule of the Federal Trade Commission [6], which is currently under review, requires contact lens prescribers to release contact lens prescriptions at the end of contact lens fitting and to document this release, among other stipulations. The Rule also allows sellers to substitute contact lenses for "private label" lenses if the substitute lenses are made by the same manufacturer and are identical to the prescribed lenses. This rule is intended to ensure that patients receive the exact lenses prescribed to them by their eye care practitioner, regardless of where they choose to purchase.

However, in June 2020, the Federal Trade Commissioner made concerning statements that were not based upon medical/scientific criteria; in particular, it was suggested that the US Food and Drug Administration should study the "therapeutic interchangeability of different kinds of lenses for common ocular ailments, such as nearsightedness [7]." Notwithstanding the desire to implement consumer protections, such an edict fails to recognize the regulation of contact lenses as medical devices.

One report has documented 70 cases of ocular complications in people obtaining contact lenses via unregulated sources [5]. These problems may have arisen due to some combination of lens substitution, and absent or erroneous lens care advice, during the transaction process; it is not

straightforward to untangle the relative contribution of these two potential factors. This means that the present authors are unaware of any *direct* evidence in the literature demonstrating adverse ocular effects or other unwanted consequences of contact lens *substitution*. This is not surprising as the consequences will often take time to occur and substitution is unlikely to be reported to the attending eye care practitioner.

The aim of this review, therefore, is to demonstrate from first principles, and from evidence in the contact lens literature, why all contact lenses are not the same, and to consider the potential consequences of inappropriate lens substitution. This aim will be approached by considering specific material, design, optical and other properties of contact lenses, evaluating the reasons why these properties might be appropriate for a given lens wearer, and highlighting potential problems and difficulties that lens wearers are likely to experience when wearing contact lenses *other* than those which have been specifically prescribed for them. The discussion is restricted to soft contact lenses, as anecdotally, the issue of improper lens substitution almost exclusively relates to this lens type.

2. Physico-chemical properties

2.1. Surface treatment and internal wetting agents

The commercialisation of silicone hydrogel lenses in the late 1990s brought with it challenges to how lens materials remain wettable and resist deposition of tear components (especially lipid and denatured protein) due to the presence of relatively hydrophobic siloxane species [8, 9]. To make the surfaces of silicone hydrogel lens materials hydrophilic and more wettable, they were either surface treated, or internal wetting agents such as polyvinyl pyrrolidone were incorporated within the material [10-12]. These concepts have been extended to hydrogel lenses [13] and more recent developments have included the development of "water gradient technologies" [14], in which high water content hydrogel surfaces have been situated on the outer side of a silicone hydrogel core, providing the improved wettability afforded by a more hydrophilic hydrogel interface with the oxygen transport benefits of a silicone hydrogel.

Solution interactions are driven by a complex series of factors related to the surface and bulk properties of contact lens materials and the charge, size and hydrophobic nature of solution

preservatives and other components [15-17]. These interactions can be impacted by surface treatments and result in corneal staining [18-20], with an associated impact on the development of corneal infiltrates [21-23] and an adverse impact on lens comfort and vision [18, 20, 24, 25].

Levels of corneal staining appear to vary significantly across the range of combinations of available contact lens materials (and solution brands) [20]. Should a patient, who is using a particular prescribed lens and care system with no observed corneal staining, be substituted with a lens material with different surface properties, then an increase in solution-induced corneal staining could occur. Corneal staining with daily disposable lenses can also differ between materials, with water gradient materials demonstrating lower levels of staining than some other daily disposable lens materials [26, 27].

The incorporation of an internal wetting agent has been associated with an increase in the quality of vision, likely due to an improvement in lens surface wettability [13, 28]. Two studies have demonstrated the strong influence of vision on reported contact lens comfort [29, 30], suggesting that any reduction in quality of vision, for whatever reason, could also result in a reduction in perceived lens comfort, increasing the likelihood of lens dissatisfaction and subsequent drop-out [31]. Comfort responses for silicone hydrogel materials with internal wetting agents have been shown to be advantageous for previously symptomatic wearers [32] and in challenging environments [33, 34], which may not occur with materials without these polymeric components. Comfort responses for daily disposable lens materials with varying surface properties can also differ markedly [35-38], and a patient inappropriately substituted with a different material for daily disposability could notice a detriment in lens performance.

Surface properties impact the coefficient of friction of soft lens materials [39-41], which has been linked with comfort [42-44]. A patient prescribed a lens material with different surface properties may notice a reduction in lens comfort and performance, especially towards the end of the day. Anecdotal reports exist of some wearers struggling to remove lenses that have extremely lubricious surfaces, as their fingers are unable to easily “grasp” the lens and break the lens adhesion forces between the ocular surface and the lens material. The adhesion force between the back surface of the lens and the front surface of the cornea is impacted by the surface properties of the material

[45]; a patient who, via inappropriate substitution, is provided with a material that is more difficult to remove could be negatively impacted by this. Given the known relationship between lens handling and dropout from lens wear [46, 47], this issue could potentially result in patients unnecessarily ceasing lens wear.

In summary, surface treatments and the presence of internal wetting agents can negatively impact vision, comfort and handling; lead to the development of corneal staining and infiltrates; compromise overall satisfaction with lens wear; and potentially result in discontinuation from lens wear. Thus, contact lenses with differing surface properties should never be substituted unless the patient undergoes an appropriate trial period and receives subsequent follow-up with an eye care practitioner.

2.2. Surface deposition and tear film absorption

Contact lens induced papillary conjunctivitis can occur as a delayed type IV hypersensitivity reaction to denatured protein that accumulates on the surface of contact lenses [48]. Although visible deposits on the surface of contact lenses worn for many months or years can reduce vision [49], there is no evidence to suggest that reduced vision is an issue with contemporary contact lenses that are replaced monthly or more frequently [50].

Interaction occurs between contact lens materials and the tear film at a molecular level. Tear film proteins, for example lysozyme, will deposit on both hydrogels and silicone hydrogel lenses, although the kinetics, total amount, and proportion that is denatured varies significantly by material [51, 52]. These differences exist not only between the broad categories of hydrogels and silicone hydrogels, but also within these groups; for example, significant differences exist in lysozyme uptake between FDA Group II and Group IV hydrogels [51]. Furthermore, there are correlations between higher amounts of keratin or lipocalin on silicone hydrogel lenses and the sensation of dryness during lens wear [53]. Lipid deposition also varies, being material-dependent and higher in silicone hydrogel than hydrogel lenses. Total uptake on silicone hydrogel lenses increases over time and especially when higher concentrations of lipid are present in the tear film [54].

While these differences are well described *in vitro*, it is relevant to understand if they impact clinical performance, and some evidence is available to suggest an association with subjective comfort. One study has shown that increases in clinically assessed lens deposition is associated with increases in corneal staining [55]. A correlation has been reported between increased subjective contact lens comfort and a higher proportion of active, rather than denatured, lysozyme deposited in daily disposable wear of etafilcon A lenses [56]. Lipid deposition has been reported to be significantly higher in asymptomatic wearers of silicone hydrogel senofilcon A lenses compared to symptomatic wearers [57], suggesting that certain lipids may have a positive impact upon their interaction with some lens materials.

In conclusion, switching material types will impact contact lens deposition, which can have deleterious effects on lens performance.

3. Material

3.1 Oxygen permeability

The most obvious difference present when considering material choice in soft lens fitting exists between the broad material groups of hydrogels and silicone hydrogels, driven clinically by the difference in oxygen permeability between them [58, 59].

The introduction of first-generation silicone hydrogel lenses with their significantly increased oxygen transmissibility [58, 59] was intended to reduce the complications associated with overnight wear, the most serious of which is microbial keratitis. While silicone hydrogel materials are widely accepted to have eliminated hypoxia-related clinical changes, particularly in daily wear [60-62], the incidence of microbial keratitis remains similar between hydrogel and silicone hydrogel lenses [63-66].

Corneal neovascularisation can be the result of extended exposure to hypoxic conditions and was noted to occur with thick hydrogel lenses [67]. However, a recent extensive review of utilisation of the hydrogel etafilcon A material concluded there have been very few reported cases of corneal vascularisation with current-generation hydrogel or silicone hydrogel lenses used for cosmetic daily wear [68]. While this finding suggests contemporary mid-water content hydrogel lenses are

not likely to produce significant neovascularisation, it is important to understand that this represents the average, rather than an individual, response. The corneal swelling response to overnight wear of contact lenses varies significantly between individuals [69] and is not possible to predict. Oxygen transmissibility through hydrogel contact lenses can also be significantly impacted by lens design; for example, high prescriptions, toric and multifocal designs can have thick zones that restrict the transmission of oxygen [70-72].

Inappropriate substitution of a prescribed high oxygen transmissibility lens for a lower oxygen transmissibility lens can result in hypoxic ocular complications and even microbial keratitis if the patient intends wearing lenses overnight.

3.2. Water content

For hydrogel contact lenses, there is a direct relationship between water content (W) and oxygen permeability (Dk), as given by the equation [59]:

$$Dk = 1.67^{0.039W}$$

Therefore, if a practitioner is seeking to alleviate hypoxic complications of hydrogel lens wear, higher water content lenses are prescribed, or better still, silicone hydrogel lenses, which have a much higher oxygen performance [58]. In such instances, improper substitution of a prescribed high water content hydrogel lens with a low water content hydrogel lens could result in hypoxic ocular complications.

There is an inverse relationship between lens water content and modulus of elasticity (stiffness) for both hydrogel and silicone hydrogel lens categories, whereby higher water content lenses have a lower modulus [73]. For hydrogel lenses, the ‘trade off’ in lens performance is that, while a higher water content lens will have a higher oxygen performance and may be more comfortable [73], it may be more susceptible to physical damage [74]. Hence, for lenses of similar design and power, higher water content hydrogel lenses may pose problems for some patients with poor manual dexterity, as such lenses are more ‘floppy’ and may be more difficult to insert into the eye,

i.e. they do not ‘sit proud’ on the tip of the finger as do lower water content hydrogel lenses with a relatively higher modulus.

In view of the above considerations, improper substitution of a low water content lens for a high water content lens could pose lens handling problems for a patient, especially for one with compromised manual dexterity. Handling difficulties of this type are associated with discontinuation of contact lens wear [75] and as such, is a noteworthy clinical issue.

3.3 Modulus of elasticity

Modulus of elasticity is described as the amount a material deforms when stress is applied to it. Incorporation of siloxane groups increases the modulus of elasticity of silicone hydrogels compared to hydrogels [8], with the highest moduli of elasticity associated with first generation silicone hydrogels. Complications of a mechanical nature have been reported with some silicone hydrogel materials, including superior epithelial arcuate lesions, extensive mucin ball formation and contact lens induced papillary conjunctivitis [76-78]. Mucin balls result from shear forces created by the mechanical interaction between the contact lens and ocular surface, with early mucin ball formation in overnight wear correlated with an increased risk of corneal infiltrative events [79]. However, the longer-term, repeated presence of mucin balls appears protective from corneal infiltrative event development [79, 80].

There is no consistent trend for one material type being more comfortable than another, and similar comfort performance, on average, has been found for both hydrogel and silicone hydrogel contact lenses [73, 75, 81, 82], with comfort scores for daily disposable contact lenses comparing well to no lens wear [83].

Data on dropout from different contact lens materials is equivocal, with greater dropout being reported in both hydrogel [75] and silicone hydrogel materials [47], although it should be noted that the hydrogel lens study [75] surveyed the experience of *established* wearers, while the silicone hydrogel lens chart review [47] was concerned with dropout among *newly fitted* wearers. Across several surveys, it appears that the introduction of silicone hydrogel materials has not significantly reduced dropout rates [75, 84, 85].

In conclusion, inappropriate substitution of lenses with different modulus of elasticity values can lead to a compromises in lens handleability, ocular discomfort and mechanically-induced adverse ocular reactions.

4. Physical design

Soft contact lenses have a variety of design parameters that should be considered as they may relate to the ultimate success of the lens wearer, including the total diameter, back optic zone radius, thickness (centre and edge), and back surface and edge profiles, amongst others. Although there may be some prescriber choice in parameters, such as total diameter and back optic zone radius, other design parameters are inherent to specific commercial products and cannot be altered by the practitioner during the fitting process.

Lens fitting characteristics are dependent not just on the lens design, but also on its interaction with the anatomy of an individual. Therefore, lens fit cannot be predicted by lens parameters alone. This means that testing of a lens before a final prescribing decision is confirmed is essential and a different lens, even of the same parameters, will not necessarily have an equivalent fit [86]. Consideration of contact lens design elements as they relate to clinically relevant issues is important in order to optimize contact lens designs and improve the on-eye performance and wearing experience for the patient.

4.1. Total diameter

Of all the properties evaluated in this paper, diameter is one that is most likely to cause to dissatisfaction through inappropriate switching. Contemporary soft lens designs typically range in total diameter from approximately 13.8mm to 14.5mm, to ensure the lens extends beyond the limbus. Decreasing the total diameter of a soft lens (while maintaining a constant back optic zone radius) may lead to a decrease in sagittal depth (effectively flatter), and more on-eye movement. Looser fitting soft lenses are generally less comfortable than tighter fitting lenses and may be associated with more bulbar and limbal hyperaemia [87, 88]. However, adequate on-eye movement is also important to improve tear exchange (including removal of any post-lens debris) and

minimize paralimbal conjunctival staining, given that the conjunctiva is flatter than the central cornea [89].

On-eye diameters can vary widely even if the labelled diameters are similar [90, 91]. High water content hydrogel contact lenses have been shown to reduce in total diameter over one day of wear, in addition to exhibiting reduced on-eye movement [92]. Such effects can only be ascertained by trial lens fitting and prescribing of a lens of suitable stabilised diameter [93].

Although typically seen in overnight wear, a tighter fitting lens can be associated with contact lens peripheral ulcers [94].

In conclusion, inappropriate substitution of lenses of different total diameter can adversely impact lens comfort and tear exchange dynamics, and result in ocular compromise such as limbal and bulbar hyperaemia and the development of contact lens peripheral ulcers.

4.2. Back optic zone radius

The effects of changes in back optic zone radius on comfort have been assessed in a series of small, clinic-based studies. Substantial changes in the back optic zone radius also affect on-eye fitting characteristics such as lens movement, whereby a flatter back optic zone radius can be associated with a looser fitting lens. One of the effects of changing lens back optic zone radius is to change on-eye lens diameter due to the difference in surface area. For a 0.4 mm change in back optic zone radius, it is necessary to change diameter by 0.2 mm to maintain similar on-eye diameter (arclength). When changing lens diameter, a change in back optic zone radius of 0.2 mm is required to maintain similar tightness of fit [95].

As noted above, looser fitting lenses are generally associated with reduced lens comfort and may be associated with inflammatory complications such as contact lens peripheral ulcers [96]. However, there appears to be some inconsistency in the literature regarding changes in back optic zone radius and lens comfort. One study evaluating thick, low water content hydrogels demonstrated that a rather large change in back optic zone radius of 0.95mm was required to affect comfort [97]. Another study of mid-water content hydrogels showed that flattening of 0.6mm led

to a decrease in comfort [98]. In another study of high water content hydrogel lenses, varying back surface curvature had no significant effect on comfort [99].

Improper substitution of back optic zone radius can negatively impact comfort (for large changes), adversely affect lens fitting characteristics, and lead to adverse ocular reactions.

4.3. Thickness

Contact lens thickness is important as it relates to handling of contact lenses, in addition to other considerations such as oxygen transmissibility. Variation in thickness due to power differences of soft hydrogel lenses is associated with a significant impact on central and peripheral oxygen transmissibility that must be considered when fitting high plus and minus power lenses [100].

Thick lenses with reduced oxygen transmissibility are associated with increased bacterial binding to the corneal epithelium, increased limbal hyperemia, corneal vascularization, reduced corneal sensitivity and corneal swelling [60, 100-105]. Thicker hydrogel lenses have less initial comfort than thinner hydrogel lenses [106].

As a result of the above considerations – for hydrogel lenses in particular – inappropriate substitution of a thinner lens for a thicker lens can result in reduced comfort and hypoxic ocular complications.

4.4. Edge profile

Mass-produced soft contact lenses typically have one of several types of edge profiles, and some of these may have an impact on fitting, comfort and/or ocular surface health [107-111]. One study showed that hydrogel lenses with a greater edge thickness were associated with more movement than hydrogel lenses with a thinner edge [99]. For silicone hydrogel lenses, a thin, knife-edge design has been shown to be associated with greater comfort than alternative chisel and round edge designs [111]. However, the knife edge design is also associated with increased conjunctival staining [111, 112].

Lid wiper epitheliopathy is associated with contact lens wear (specifically symptomatic contact lens wear), presumably due to the palpebral conjunctival interaction with the contact lens surface and edge [113], although further work is required to understand its aetiology in relation to lens edge design and its relationship with contact lens discomfort [3].

Improper substitution of lenses with different edge profiles can therefore compromise patient comfort and lead to mechanically-induced adverse ocular reactions.

4.5. Back surface design

The back surface of hydrogel lenses can be designed with a series of curves to better fit the peripherally flattening cornea and sclera. A lens may have a monocurve or bicurve design, or take on an aspheric back surface geometry. For high water content hydrogels, one study varied the back surface design using a monocurve, bicurve and aspheric profile [99]; the results as they related to their impact on comfort were equivocal. Therefore, there does not appear to be evidence of negative consequences due to substitution of lenses with different back surface designs.

5. Optics

5.1. Optical design

The optical designs of spherical, aspheric, toric and multifocal contact lenses vary in power profile [4]. Multifocal lenses can have annular power zones of different widths and power sequences; employ diffractive optics; or use multiple higher order spherical aberrations to extend the depth of focus or rotationally asymmetric optics [4, 114]. Optical interventions for reducing the progress of myopia in children utilise multifocal optics, but with the aim to induce peripheral myopic defocus [115], which has been shown to attenuate eye growth [116].

Multifocal contact lenses using a similar optical design markedly differ in optical profile for a particular distance refractive correction and stated near addition [117]; hence, receiving a different multifocal optical design than that prescribed could affect visual performance and patient satisfaction [114, 118]. Therefore, the lens brand name needs to be stipulated in a formal/legal prescription to correctly identify the lens optical design that has been prescribed, to optimise the visual needs of the patient. This result cannot be predicted without a lens wearing trial performed

by a qualified eye care practitioner [119, 120]. For example, a patient wearing an inappropriately substituted multifocal contact lens for night-time driving, may have a reduced legibility at distance for street signs and increased fixation times [121].

An early presbyope receiving an inappropriately substituted monofocal contact lens may experience symptoms of soreness, eyestrain, tired eyes, or headaches with near work [122]. In addition, poor vision is a factor associated with patients dropping out of lens wear [46], resulting in them missing out on the benefits that they sought from adopting this modality of refractive correction.

A young myope not receiving the myopia control contact lens optics they have been prescribed would be of serious concern and could result in their eye length increasing unchecked [115] leading to an increased risk of retinal pathology in the long term [46, 123].

Toric and multifocal lenses tend to be more expensive than their spherical lens equivalents [124] and may therefore be less affordable for some patients. This situation lends itself to inappropriate substitution of prescribed toric or multifocal lenses for less expensive spherical lenses, therefore depriving the lens wearer of a proper solution to their visual requirements.

To summarise, there is evidence of clinically significant issues of receiving inappropriately substituted optical design, including reduced driving safety, ocular discomfort, a higher likelihood of dropping out of lens wear and, in the case of myopia management, the potential to induce increased risk of visual impairment from retinal pathology in later life.

5.2. Power

It is perhaps self-evident that dioptric power is the major attribute of a contact lens and a feature which necessarily should be included on any contact lens specification. Each 0.25D of positive optical blur in an experimental setting is associated with approximately a one line reduction in logMAR visual acuity [125]. This supports the optometric convention of measuring refractive error and prescribing vision correction devices to 0.25D increments. Other researchers have reported on

the visual benefit of prescribing soft toric contact lenses to even those with moderate astigmatism, underlining the need for cylinder power, and associated axis, to be appropriately noted [126, 127].

Although lens power does not appear to be associated with the incidence or severity of microbial keratitis, higher minus powers have been associated with an increased incidence of corneal infiltrative events in some reports [128, 129] although not all [130]. Other adverse events also appear to be linked to the power of a contact lens. For example, there is a higher likelihood of corneal neovascularisation in wearers using hydrogel lenses of -9.00DS and greater [131]; this finding presumably relates to reduced oxygen supply to the peripheral cornea during the use of lenses which are relatively thick in that region [103].

Both superior epithelial arcuate lesions and papillary conjunctivitis are considered to be associated with the mechanical/physical presence of a soft contact lens at the ocular surface [77, 132]. As such, a connection with lens thickness (and therefore, lens power) might be anticipated, but a clear link between lens power and these adverse events is not apparent in the literature. An indirect link may be present for corneal staining [133].

Dehydration and corneal erosions have been historically attributed to very thin hydrogel lens designs [134, 135]. More recent reports described increased staining in patients using soft lenses greater than -5.00DS [130], but in these cases, the level of staining generally would not be considered to be clinically significant.

There is reasonable evidence for an association between the form of the edge, which necessarily varies with lens power, and wearer comfort [111]. As well, higher lens powers are associated with increased lens comfort [136, 137].

Some other clinically relevant aspects of contact lens wear are related to contact lens power. Lens handling is generally considered to be easier with high minus lenses, due to their increased bulk, although this issue has received little direct attention in the literature [137]. Rates of drop-out are clearly greater in patients using lenses in the low plus power range (annual retention of 57% for new soft lens wearers) compared to all other lens powers (70-90%) [46]. However, lens costs are

not generally related to spherical lens power. There appears to be no evidence to associate wearer compliance with contact lens power.

In conclusion, inappropriate substitution of lens power, especially if there are significant differences between the prescribed and substituted lenses, could compromise vision and comfort, and in hydrogel lens wearers can potentially induce hypoxic ocular complications.

6. Colour (tint)

6.1. Coloured lenses for cosmetic enhancement

Many patients have a desire to cosmetically change their eye colour appearance using contact lenses. This can be achieved by wearing lenses that have colouring agents embedded within, or applied to the surface, of a contact lens, typically outside the pupillary zone, which is left clear. Limbal accent tints are also popular, especially across Asia [138].

Coloured tinted contact lenses significantly increase ocular aberrations and decrease optical quality and contrast sensitivity, as the pigment-free optical zone diameter decreases, resulting in the lens wearer noticing a perceived decrease in visual function [139]. Others have also reported a reduction in optical quality with tinted lenses under certain lighting conditions [140, 141]. The potential for such problems can be assessed by observing the relationship between the diameter of the pigment-free zone of the contact lens in relation to the diameter of the pupil of the eye at various levels of illumination.

Although tinted contact lenses are generally safe when prescribed by a qualified eye care practitioner and when the patient is fully compliant with lens wear and care instructions [138], the surface tints of some products have been shown to alter the physical characteristics of the lenses, such as increasing surface roughness at a microscopic level [142]. In such cases, there might be an increased susceptibility to bacterial adhesion on the contact lens surface, which in turn could increase susceptibility to microbial keratitis [142] and cases of resulting infection have been documented [143].

It is axiomatic that if a patient is supplied with a substituted coloured contact lens comprised of a different tint to that expected, the desired cosmetic benefit could be lost, resulting in patient dissatisfaction.

6.2. Prophylactic or therapeutic tints for protection from ultraviolet light

Contact lenses can be supplied that are designed to protect some parts of the eye (cornea and internal ocular structures) from excessive ultra-violet light [144, 145]. The use of ultra-violet-blocking contact lenses greatly increases the time the wearer can be exposed to solar radiation before a toxic ocular dose is reached. While lenses with ultra-violet-blocking agents are generally prescribed as a prophylactic measure, the substitution of such a lens with one that does not contain ultra-violet-blocking agents may be problematic for a patient who was specifically prescribed contact lenses with ultra-violet protection for a given reason, such as engaging in outdoor occupations or sporting activities.

7. Lens wear

7.1. Modality

Soft contact lenses can be worn either only during the day (termed daily wear) or during the day and night. The wear schedule for lenses worn during the day and night and reused, formerly called extended or continuous wear, has recently been defined as planned or sporadic overnight wear [1]. Lenses can also be worn during the day, then disposed of, and a new lens worn the next day (termed daily disposable wear).

In a randomized cross-over clinical trial assessing wearer preference when using etafilcon A contact lenses on a daily disposable or overnight basis (with lenses being replaced each week and the seventh night being without lens wear), 65% of participants (31/50) preferred the overnight modality of wear [146]. This preference was associated with convenience of lens wear [146]. Previous studies in the 1990s [147] also found that people preferred overnight wear lenses due to convenience. This preference for overnight wear occurs despite there being no difference in comfort responses between daily disposable and overnight wear [148], or even an increased level of discomfort in the morning during overnight wear [146].

The repeated handling of daily disposable lenses was one of the issues raised as a concern that was mitigated by overnight wear [146]. These data point to a high probability of contact lenses being used on an overnight wear basis even though overnight wear is associated with higher levels of adverse events. The risks associated with overnight wear are the main reason [147] that prescriptions for overnight wear soft lenses has remained low [149, 150].

The most serious issue with contact lenses being worn on an overnight wear scheduled is the risk of corneal infections. Wearing silicone hydrogel or hydrogel soft lenses on an overnight wear schedule increases the risk of corneal infection (microbial keratitis) by approximately 10 times [151]. Whilst more nights of overnight wear increases the risk, even one night of overnight wear increases the risk by 2.4 to 3.6 times compared to daily wear [152].

Overnight wear is associated with an increase in the concentration of the metalloproteinase MMP-9 in tears [153]. This may be associated with the increased risk (14 to 66 times) during overnight wear of developing corneal erosions [154], which are also associated with the risk of developing microbial keratitis [154]. Wearing lenses on an overnight wear schedule also increases the risk of any corneal inflammatory event, not just infection [155-157].

Even as far back as 1990, it was understood that the risks associated with overnight wear could only be mitigated by good patient-clinician interactions [158]. Such interactions educate and encourage patients to (a) follow the proper lens wear regimen; (b) observe appropriate lens care routines: (c) follow the proper lens disposal regimen; (d) monitor the appearance, visual acuity, and well-being of their eyes; and (e) immediately report any irregularities or changes in ocular status to their eye care practitioner [158].

Another issue with lens modality that may be confused by unregulated or unqualified lens suppliers is the difference between daily *disposable* and daily *wear* lenses. Daily disposable lenses may not have been tested for compatibility with disinfecting solutions used during daily wear. This may result in ocular changes such as corneal staining as a result of uptake and release of disinfecting solutions by the daily disposable materials [15, 16]. Further, daily disposable lenses may not be

sufficiently robust to withstand multiple uses and so potentially rip or be physically damaged in other ways during use.

If a patient is inappropriately substituted an intended daily wear lens with a lens designed for planned or sporadic overnight wear, and the patient does not receive proper instructions of the precautions to be taken when sleeping in lenses instructions – early signs and symptoms of ocular distress may be dismissed or overlooked, which could lead to serious microbial keratitis.

7.2. Replacement frequency

A number of aspects of the clinical performance of a soft contact lens are influenced by the frequency with which the lenses are replaced. The two forms of daily wear lens usage which have typically been compared are 'daily disposable', where a lens is worn for some or all of the waking hours of day and then discarded, and 'reusable', where a lens is stored in a disinfection solution (generally overnight) between each wearing period, with the lens discarded on a two-weekly or monthly basis.

The key safety metric of contact lens wear is the incidence of microbial keratitis. In one carefully executed case control study, this measure has been reported to be statistically significantly greater in daily disposable wearers compared with reusable wearers [66], although other work has found rates of microbial keratitis to be similar for these two modalities of wear [63, 65]. In fact, daily disposable lenses are associated with infections which tend to be less severe [65] and which have a lower likelihood of both vision loss and culture-positive infections [159]. Daily disposable lenses are associated with a very low absolute rate of corneal infiltrative events, including one report of zero symptomatic corneal infiltrative events in 470 wearer-years of a hydrogel daily disposable lens [160]. Such adverse events are about 3X [161] or 12X [128] more likely to occur in association with reusable lenses. Furthermore, it appears there are no differences when reusable lenses are replaced on a two-weekly or monthly cycle [161]. Such findings may relate to a lower sub-clinical corneal and conjunctival inflammatory response with daily disposable compared to reusable lenses [162].

There is no evidence for replacement frequency being associated with corneal neovascularisation or superior epithelial arcuate lesions, presumably because these responses to contact lens wear principally relate to oxygen transmissibility [3] and bulk mechanical material properties (especially early silicone hydrogels) [163], respectively, rather than surface deposition or other traits which might vary with replacement interval. On the other hand, there are reports of greater levels of corneal staining with less frequent soft lens replacement [133] and reduced papillary conjunctivitis when daily disposable lenses are worn compared to reusable lenses, perhaps due to lower levels of protein deposition on the lens surface acting as an antigen [164].

There is little evidence of visual performance being related to frequency of lens replacement. From a rather theoretical and historical standpoint, the development of extreme levels of deposition of the contact lens surface over time has been reported to diminish visual acuity [49]; however, such surface changes are rarely seen now as almost all soft lenses are prescribed to be replaced monthly or more frequently [150, 165]. Interestingly, one report has demonstrated better 'visual discrimination' with reusable lenses compared to daily disposable lenses, which was attributed to the surface action of the wetting agents in the solutions in which the reusable lenses were stored [166].

Research findings on the association between contact lens discomfort and frequency of lens replacement are equivocal. No such link was found in a cross-sectional study of over 2,000 wearers in the United States and the United Kingdom [167]. In another large-scale study of 360 lens wearers in the United States, replacement schedule was not found to be associated with lens comfort [168]. Subjective comfort was better for senofilcon A lenses worn on a daily disposable basis rather than re-used with a range of four different solutions for a three-month period [169]. The daily disposable lenses were associated with the best comfort scores, out-performing two of the four reusable lens groups to a statistically significant degree [169].

Rates of drop-outs are similar for daily disposable and reusable soft contact lenses. Retention rates of 77% have been reported for both lens types after one year of use in new wearers [47]. Other researchers have also failed to find a difference for this metric [170]. No differences in lens handling are apparent for these two replacement options.

Compliance is associated with lens replacement interval, primarily because of the lack of a requirement for contact lens solutions with daily disposable lenses. There were 1.5 missed compliance behaviours on average each day (from seven keratitis-related behaviours studied) for daily disposable wearers, compared with 3.5 missed behaviours for patients wearing reusable lenses [171].

Lens cost is closely related to frequency of lens replacement. A British 2010 'cost per wear' model demonstrated that the overall cost of a monthly or two weekly replaced soft spherical lens (including professional consultation fees and solution costs) was around £6 per wear if only worn once per week. This value fell significantly to about £1 per wear when worn seven days per week. By contrast, daily disposable lenses show a much less dramatic difference, from £4 per wear for use only once per week to about £1.50 per week for full time usage (seven days per week). The "cross-over point" – at which the cost per wear of daily disposables and reusables is very similar – was three days per week [124].

Inappropriate substitution of lenses of different replacement frequency may therefore adversely impact lens affordability. Inappropriate substitution of daily disposable lenses for reusable lenses can compromise ocular health if unaccompanied by proper lens care advice and supply of the required lens care solutions. Such a substitution would also increase the risk of developing corneal infiltrative events.

8. Conclusions

Given the wide range of parameters and properties few soft contact lenses are identical in their clinical performance. The consequences of inappropriate substitution of soft contact lenses can vary from physical or visual discomfort to significant physiological complications.

The key properties of soft contact lenses are summarised in Table 1, along with likely adverse consequences of substituting the desired/prescribed lens type with an alternative lens with different properties (likely associations indicated by black dots). Table 1 can be used to predict possible

sources of patient dissatisfaction and adverse events, in respect of various lens properties, when the prescribed lenses are substituted for an alternative lens type.

It is evident from Table 1 that lens substitution can result in at least one potential aspect of patient dissatisfaction and adverse event for each of the lens properties that can be specified on a contact lens prescription, with the single exception of back surface design. That is to say, almost all forms of soft lens substitution are associated with between one and six aspects of potential patient dissatisfaction and adverse events.

As a result of the way soft contact lenses are packaged and distributed, the 16 lens properties documented in Table 1 are not mutually exclusive. That is, most of the 16 lens properties of a specific lens type/brand supplied by a specific lens manufacturer will be fixed, and only a limited number of properties of such a lens may be available in different parameters, such as lens power, total diameter, back optic zone radius and replacement frequency. Nevertheless, a qualified eye care practitioner would be aware of all of the properties relevant to a given lens, even if they are fixed, and will be mindful of the ocular impact of all relevant properties when selecting the most appropriate lens for a patient. Thus, the absence of choice in respect of some contact lens properties does not imply that lenses can be freely interchanged in the absence of oversight from a qualified eye care practitioner.

It is in the best interests of contact lens wearers that the intended contact lenses are prescribed and fitted and that lenses are never substituted for another lens type without prior consultation with an eye care practitioner, for the simple reason that all soft contact lenses are *not* created equal, and a different lens may have properties unsuited to the patient. If a prescribed contact lens is to be substituted with a different lens, this decision should only be made by a qualified eye care practitioner who has full knowledge of the properties of the lenses involved and the ocular characteristics, lifestyle patterns and expectations of the patient. In this way, the practitioner can weigh up the benefits of any given instance of lens substitution against the downsides of any potential altered lens behaviour, risks of an adverse ocular response, or other sources of patient dissatisfaction.

Table 1.

Properties of a substituted soft contact lens which may result in patient dissatisfaction and adverse events (black dots indicate likely associations).

Property of substituted lens	Possible aspects of patient dissatisfaction and adverse events								
	Reduced vision	Discomfort	Handling problems	Adverse ocular response[a]	Microbial keratitis	Unaffordability	Inconvenience	Unsatisfactory cosmetic appearance	Failure to arrest myopia
Surface treatment	●	●	●	●					
Internal wetting agent	●	●		●					
Oxygen permeability		●		●	●[b]				
Water content		●	●	●	●				
Modulus		●	●	●					
Total diameter		●		●					
Back optic zone radius		●		●					
Thickness		●	●	●	●				
Edge profile		●		●					
Back surface design									
Optical design	●	●				●[c]			●[d]
Power	●		●	●					●[d]
Colour (tint)	●				●			●	
UV protection				●					
Wearing modality[e]		●	●	●	●		●		
Replacement frequency		●		●	●	●	●		

[a]Excluding microbial keratitis
[b]Severity of the condition
[c]Should toric/multifocal lenses be required
[d]Myopia control (or 'myopia management') lenses
[e]Overnight versus daily wear

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