CLEAR EVIDENCE BASED CONTACT LENS PRACTICE

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Running Title

CLEAR Evidence-based Practice Report

Abbreviations

CIE	Corneal infiltrative event
ECP	Eye care practitioner
CLDEQ	Contact Lens Dry Eye Questionnaire

HEMA	2-hydroxyethyl methacrylate
HVID	Horizontal visible iris diameter
LIPCOF	Lid-parallel conjunctival folds
LWE	Lid wiper epitheliopathy
MDPS	Multipurpose disinfecting solution
OCT	Optical coherence tomography
OSDI	Ocular Surface Disease Index
VPA	Vertical palpebral aperture

Evidence-based contact lens practice involves finding, appraising and applying research findings as the basis for patient management decisions. These decisions should be informed by the strength of the research study designs that address the question, as well as by the experience of the practitioner and the preferences and environment of the patient. This reports reviews and summarises the published research evidence that is available to inform soft and rigid contact lens history and symptoms taking, anterior eye health examination (including the optimised use of ophthalmic dyes, grading scales, imaging techniques and lid eversion), considerations for contact lens selection (including the ocular surface measurements required to select the most appropriate lens parameter, lens modality and material selection), evaluation of lens fit, prescribing (teaching self-application and removal, adaptation, care regimen and cleaning instructions, as well as minimising risks of lens wear through encouraging compliance) and an aftercare routine.

Evidence-based practice has developed from evidence-based medicine, a term first introduced in the early 1990s for medical students to help with clinical decision-making using the most appropriate evidence [1] and then to describe the new approach when teaching medicine [2]. Evidence-based medicine is defined as the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients"[3] and the "process of finding, appraising and using contemporaneous research findings as the basis for medical decisions"[4]. Evidence-based practice involves integrating the best available, and clinically relevant, scientific research evidence with a clinician's expertise, the practice context and individual patient values (Figure 1). This considers the patient experience, importance of prognostic markers and the efficacy and safety of various treatment or management options. While appraising the latest knowledge and the validity of data, it may also identify key questions that are currently unanswered and highlight potential areas for future research.

Figure 1: Three fundamental elements in Evidence-Based Practice

Evaluating scientific research findings and using them to make the best clinical decision for patients is a key aim with evidence-based practice and an important part of contact lens practice. The commonly cited hierarchical evidence model (Figure 2) aims to assist healthcare providers categorise the quality of evidence from different sources, from systematic reviews and randomised controlled clinical trials through to case reports and expert opinion. The levels within the hierarchy have been challenged [5]; it has been suggested there may be overlap based on clinical

applicability, and that the 'critical appraisal' levels of the hierarchy pyramid should be separated as they are limited by the difference in methodology and statistics in the studies they combine [5]. It is also important to recognise that individual studies within a given level of the hierarchy (such as randomised controlled clinical trials) may differ in their 'quality', due to differences in risk of bias and internal validity. Formal risk of bias tools exist to assist clinicians with appraising the quality of an individual study rather than simply relying on the evidence level [6].

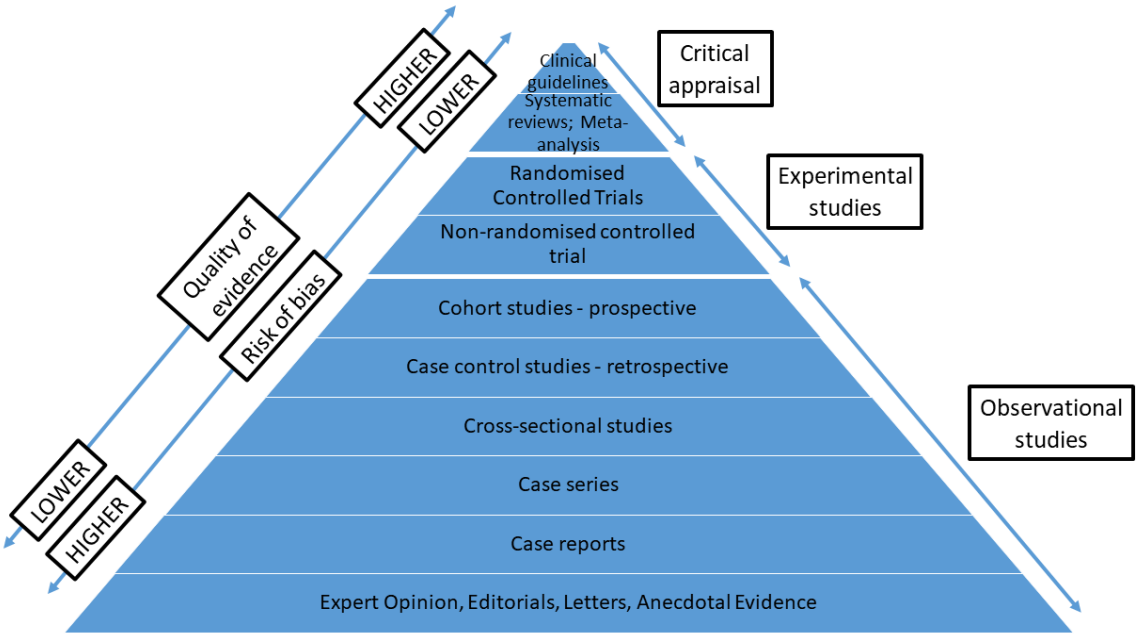

Figure 2 – Hierarchy of Clinical Scientific Evidence (animal model/*in vitro* evidence not included). Adapted from Murad et al., (2016) [5].

In a PubMed search performed on January 2, 2021 (https://pubmed.ncbi.nlm.nih.gov/), "evidence-based medicine" provided 203,167 search results and "evidence based practice" 152,188; when the term "contact lens or "contact lenses" was added (AND operator), the potential data sources were limited to just 65 results. However, much of the evidence relevant to contact lens practice is from clinical studies designed to test a specific hypothesis, ideally with the least bias and greatest precision. Study designs vary, ranging from randomised controlled clinical trials to retrospective case control studies, providing a range in the quality of evidence. The research question can influence the most appropriate study design; for example a randomised controlled clinical trial may be the best approach

to study a clinical intervention, whereas a prospective cohort study may be employed to assess an aetiological question. Potential bias can be minimised by masking (researcher and/or the participants), randomisation (between treatment(s) and/or a control) and statistical analysis methods (such as accounting for within-participant associations such as the synergy between eyes). Some contact lens research employs study designs not explicitly described in hierarchical models or common in general medicine; cross-over, contralateral and monadic designs are important to understand the clinical performance of different brands of lenses and care products (Table 1).

Table 1: Study designs commonly seen in contact lens and care product research

Study design	Description	Strengths	Limitations
		Sequencing	
Parallel	Each participant receives only one product Group comparison (test versus control) or matched pairs	Shorter, simpler and easier to run Less complicated analysis No carry-over effect No need for washout period Reflects 'real world'	Requires larger sample size Cannot determine 'within participant' vs 'between participant' variability Comparison between participant groups Cannot derive 'preference'
Cross over	Repeated measures - participant receive at least two products over different periods (one may be a control); all participants receive same number of "treatment" options and for same number of periods	Determine 'within participant' and 'between participant' variability Comparison of treatments undertaken within each participant Assesses effect of first treatment on second (carry-over) with higher order designs Smaller sample size	Consider carry-over effect May need wash-out period Analysis can be complex Longer to run
Contralateral	Direct comparison within participant at same time i.e. different lenses in each eye	Speed (vs cross over) Smaller sample size (vs parallel) Well controlled variables	Could switch lenses between eyes Not 'real life' Sympathetic effect Assumes eyes have similar characteristics Assume participants can reliably distinguish outcomes between eyes
		Eyes	
Bilateral	Comparison within subjects; different	Reflects 'real life' experience	Larger sample size;

	time points or between participants		Contact lenses/care products experienced at different time points
Monocular	Participants wear one product	Stand-alone product performance & wearer acceptance; "real world"	No comparison
		Comparison	
Observational	Effect of treatment in a population Analytical or descriptive (case report or series). Retrospective or prospective including registries	"Real world" Non-interventional Low resources Cohort, case control or cross-sectional study	No control, randomisation or masking, so prone to bias Hard to determine causality
Controlled trials	Interventional study with a control group for comparison	Hypothesis tested – determine causality	High resources Hard if outcome being studied is rare
Comparison trial	Intervention study with no control group	Able to compare efficacy/safety directly	Potential bias in terms of the comparison product and measures assessed

Systematic reviews such as those developed with Cochrane (www.cochranelibrary.com), seek to collate, appraise and synthesise evidence that fits pre-specified eligibility criteria to answer a specific research question. The aim is to minimise bias by using explicit, systematic methods that are documented in advance with a published protocol [7]. An analysis of 1,016 Cochrane health related reviews found the intervention under review to be beneficial in 44%, was likely to be harmful in 7% and in 49% the evidence supported neither benefit nor harm; by far the majority of reviews (96%) recommended further research [8]. To date, the only Cochrane systematic review conducted in the field of contact lenses is on interventions to slow the progression of myopia in children [9]. While Cochrane reviews are regularly updated, it is important to consider studies that may have been published since the cut-off date of the last review when considering the benefit of a new treatment and that they only generally consider randomised controlled clinical trials. In recent years, a number of international, consensus-building workshops that inform elements of contact lens practice such as dry eye therapies and management options [TFOS DEWS II][10], meibomian gland dysfunction [TFOS Meibomian Gland Dysfunction workshop][11] and contact lens discomfort [TFOS Contact Lens Discomfort workshop][12], and a critical review of the evidence on myopia control [International Myopia Institute reports][13]. Other recently published work on

evidence-based practice in the contact lens field include tear film assessment [14], meibomian gland dysfunction management options [15] and myopia control [16].

The quality of evidence from case reports may be low, particularly for rare diseases, but in the absence of higher level evidence they can demonstrate how a management option can work for an individual patient, the clinical relevance in practice and the critical thinking over the time-course of a case [17]. Publishing atypical cases can be of interest to ECPs, and case series can be of clinical interest. The information can be linked to clinical questions to help improve patient outcomes on when and how to manage certain cases and the potential prognosis. This can be useful when considering the potential time to obtain high-quality evidence from longitudinal studies for certain treatments; it has been estimated that there is an average 17-year lag between initial clinical research and the translation of that evidence into routine clinical practice in medicine [18]. Case reports also highlight potential gaps in the evidence, giving direction and context to possible future research and can be very useful such as in the context of the potential utility of new materials, care systems and optical designs in the specific case of contact lenses. .

1.2.2 Patient values and preferences

Patients should be involved in their own care and decisions that determine their management. There has been a growing interest in using structured validated questionnaires to quantify patient reported outcomes to understand the perspective of the patient, quantify quality-of-life impact or benefits, and understand their experience related to contact lens wear rather than an ECP recording their perception of satisfaction [19-21]. Patient-reported experience questionnaires have also been promoted [22]. However, this approach has been limited mainly to meet a research purpose, and not as a routine clinical procedure. While ECPs are expected to routinely consider patient needs in a clinical practice setting to tailor their evidence informed decisions, they are often not encouraged or well prepared to elicit and discuss them [23]. Understanding patient needs involves skills and various competencies so to help embrace this more in practice, training should include communication and critical thinking skills to help with clinical decision making.

1.2.3 Clinical judgement

For ECPs to apply evidence-based practice in their contact lens practice, they need to be trained in its implementation and to be lifelong, independent learners. While it

is likely that few ECPs conduct their own literature searches or critically appraise research evidence, systematic reviews and peer-reviewed journal articles that appraise and summarise the literature can help provide the latest evidence. Keeping up to date can be supported by attending evidence focused clinical conferences and continuing education programs. While clinical trials can show whether an intervention is efficacious and/or safe (on average and in a particular population), they do not answer whether it will work in an individual patient to the same extent. Having reviewed the evidence and its relevance, ECPs need to exercise careful clinical judgment and critical thinking, having reviewed the subjective and objective contact lens performance, during fitting and aftercare, to ensure the management is effective and safe, and discuss the options with their patient.

1.2.4 Proactive lens fitting

Evidence-based practice can be employed by ECPs to help maximise the likelihood of success for lens wearers, maintain satisfaction with lens wear, retain wearers and grow their contact lens practice. With neophyte lens wearers, ECPs should ensure that handling, vision and comfort are optimised on fitting and routinely check wearer satisfaction and anterior eye health to help retain them in lens wear [24, 25]. Established lens wearers lapse mostly due to comfort-related problems, and these tend to be product (material or care system) or ECP-related (competency or lack of encouragement) rather than being due to patient-specific problems [26, 27]. The majority can be successfully refitted and so EBP can be employed in these cases to review the evidence, consider the patient needs and apply clinical expertise to find alternative options. Evidence-based practice can also be employed to help ECPs grow their wearer base; research shows that introducing contact lenses to non-wearers prior to spectacle dispensing is well received and encourages many to trial contact lenses in addition to optimising the dispensing process [28].

2.0 History and symptoms: considerations for lens wear

A discussion of history and symptoms are essential to an efficient practice, highlighting issues requiring further investigation such as health, lifestyle and environment features that inform lens type or wearing frequency. The questions asked should allow efficient examination of the key issues and elicit all relevant information to inform clinical decision making and patient advice.

2.1 Reason for visit

Cosmesis, especially on social occasions, is one of the major motivators why people with refractive error decide to wear contact lenses, together with the benefits they provide in optics and performing certain activities such as sports. In two qualitative studies, contact lens wearers reported being more confident and less conscious about their appearance in social functions such as weddings and parties than spectacle wearers [29, 30]. Social acceptance scores are higher in myopic children wearing contact lenses compared to the those wearing spectacles [31].

2.2 Patient age

Contact lenses can slow the progression of myopia in children [32]. For presbyopes, contact lenses can provide clear vision at distance and near with natural head movements [33]. The risk of corneal infiltrative events (CIEs) has been found to be higher in young adults <30 [34-36] as well as those >50 years of age [34], hence daily disposables might be considered to reduce this risk. Conversely, use of soft contact lenses in young patients aged 8 to 15 years has been associated with a lower risk of CIEs compared with teens and young adults (15-25 years) [37].(Table 2).(see CLEAR Complications Report) [38].

A further age-related consideration is the increased prevalence of meibomian gland dysfunction,[39, 40] dry eye disease,[41-43] and changes to the tear film that occur with age[44-47]. Although this information does not direct the clinician to a specific recommendation for contact lens material or modality, it should prompt careful assessment of tear film quantity, quality and ocular surface condition during the clinical examination.

2.3 Ocular health

2.3.1 Ocular symptoms

The commonly reported ocular symptoms in contact lens wearers include dryness, scratchy or watery sensations, irritation, blurry vision, light sensitivity, eye soreness, sandy or grittiness and burning sensations. [29, 48, 49] In established wearers, use of the Contact Lens Dry Eye Questionnaire (CLDEQ-8) provides a validated quantification of ocular symptoms when contact lenses are worn, with a score of ≥12 points proposed to identify soft contact lens wearers who may be experiencing suboptimal lens wear and could likely benefit from clinical management of their contact lens-related symptoms [50]. Further, the CLDEQ-8 can be used to monitor the response to any contact lens intervention, with a difference in score of three

being established as the size of change representing a 'clinically important difference'[50]. The Standardized Patient Evaluation of Eye Dryness (SPEED) questionnaire has also been validated for use in contact lens wearers [51]. Neophyte lens wearers who are symptomatic before lens fitting are more likely to drop out from lens wear than those who are asymptomatic [52-54](Table 2).

A recent study showed the importance of a routine clinical examination even in asymptomatic contact lens wearers. More than half (52%) of the 202 wearers had at least one diagnosed complication: 70% had contact lens-related complications (such as meibomian gland dysfunction, conjunctival injection, corneal staining and contact lens papillary conjunctivitis); 54% were diagnosed with non-contact lens related ocular health issues; and 4% showed signs of undiagnosed systemic disease.[55]

Table 2: Summary of evidence available for ocular history, age, general health and medication, which can help to inform successful contact lens fitting

Author, Year	History and symptom area	Relevance to contact lens recommendation
Ocular history		
Glasson et al, 2003[52]	Baseline symptoms	Modified McMonnies questionnaire: tolerant wearers report on average 1 vs 3 descriptive symptoms in intolerant wearers
Pult et al, 2009[53]	Baseline symptoms	OSDI score: asymptomatic 4.0 ± 5.7 vs 14.5 ± 9.7 for symptomatic wearers
Best et al, 2013[54]	Baseline symptoms	OSDI score: successful wearers 7.6 ± 10.2 vs 12.2 ± 9.2 for unsuccessful wearers
Chalmers et al, 2016[50]	Existing contact lens wearer symptoms	CLDEQ-8 score ≥12 suggests clinical management of symptoms necessary
McNally et al, 2003[36] Richdale et al, 2016[56]	Corneal infiltrative events	History of CIE associated with 4-6x increased risk of future CIE
Hayes et al, 2003[57] Wolffsohn et al, 2011[58]	Seasonal ocular allergies	Ocular signs and symptoms of seasonal allergy significantly reduced when hydrogel daily disposable lenses worn compared to the exposed ocular surface
Nijm et al, 2013[59] Zhu et al, 2018[60]	Blepharitis	Increased bacterial bioburden on lid margin
Tarkowski et al, 2015 [61]	*Demodex* presence	Associated with contact lens wear drop out

Age		
Chalmers et al, 2007[34] Chalmers et al, 2010[35] [62] McNally et al, 2003[36]	Young age	Increased risk of CIE: <25 years old 1.75x [34] and 2.61x [35]; aged 18-29 2.2x[36]
Chalmers et al, 2007[34]	Older age	Increased risk of CIE: >50 years, 2.04x[34]
General health		
Keay et al, 2009[63] Sankaridurg et al, 1996[64]	Health conditions	Thyroid disease and self-reported poor health more common in microbial keratitis cases than controls;[63] 154x increased risk of CLARE in patients positive for *Haemophilus influenzae*.[64]
McNally et al, 2003[36] Efron et al, 2005[65] Morgan et al, 2005[66] Stapleton et al, 2008[67] Radford et al, 2009[68] Stapleton et al, 2012[69] Richdale et al 2016[56]	Smoking	Current or former smoker associated with 1.4-2.7x increased risk of CIE or microbial keratitis in comparison to non-smokers
Medication		
Gomes et al, 2017[70]	Systemic and topical medications that can impact on the tear film and hence successful contact lens wear	Analgesics, anaesthetics, anticholinergics, antihypertensives, antileprosy, antimalarial, antineoplastic, anxiolytic/hypnotic, chelator/calcium regulator, depressant, herbal and vitamins, hormones, neurotoxins, sedatives, antiglaucoma, mast cell stabilizer/antihistamines, antivirals, decongestants, preservatives, non-steroid anti-inflammatories etc

2.3.2 Ocular history

History of previous CIEs is associated with a 4-6x increased risk of future CIE in contact lens wearers [36, 56]. Around one-quarter of contact lens wearers treated for microbial keratitis reported a previous event requiring care [63].

Past ocular surgery can impact corneal topography and leave scarring [71, 72].

Seasonal allergic conjunctivitis results in uncomfortable, itchy, red eyes. Use of daily disposable hydrogel lenses has been shown to reduce ocular symptoms compared

to the exposed ocular surface,[57, 58] possibly by acting as a barrier to antigens such as pollen.

Both Staphylococcal blepharitis and *Demodex* blepharitis have been associated with increased bacterial bioburden on the lid margin,[59, 60] which is a risk factor for CIEs [73-76]. Increased numbers of *Demodex* are seen in contact lens wear compared to age-matched non-wearers,[77] and in contact lens drop outs compared to asymptomatic lens wearers [61]. Changes in bacterial microbiome are described in the pathogenesis of meibomian gland dysfunction [78] and increased numbers and diversity of bacteria have been recovered in meibomian gland dysfunction,[79] although studies have not necessarily found these can be correlated with symptoms, or with significant differences compared to controls [80, 81]. A history of these conditions and dry eye/ocular surface disease is relevant to enable the clinician to check if there is a need to manage the pathology prior to fitting contact lenses, and, for conditions that increase the presence of bacteria on the lid margin.

2.4 General health

Certain ocular sequelae of diabetes are relevant to contact lens wear, including the presence of ocular surface disease, recurrent corneal erosions or reduced corneal sensitivity; however, providing these contraindications are absent, a patient with diabetes can still achieve successful contact lens wear [82]. Similar considerations apply to patients diagnosed with the human immunodeficiency virus (HIV) which can make them more susceptible to infection along with a number of potentially associated ocular pathologies [83]. In addition, they have a higher rate of meibomian gland drop-out [84]. Ensuring that the patient is making an informed choice about contact lens wear and understands the need to remain compliant to safe handling, wear and care practices is of particular importance in these two patient groups.

In a large case series, both thyroid disease and self-reported poor health were more common in wearers with contact lens related microbial keratitis compared to age-matched controls, with the authors concluding that ECPs should consider recommending daily disposables as a lower risk lens wear schedule in these cohorts.[63] Poor health is also relevant for current contact lens wearers, with inflammatory responses such as contact lens-associated red eye (CLARE) 154x more likely to develop in subjects positive for *Haemophilus influenzae*.[64]

Poor health, specifically upper respiratory tract infections, is a factor in contact lens associated corneal infiltrates and illness during the past week was a significant risk

factor for developing a CIE with soft contact lenses, and so advising against lens wear is prudent advice, particularly for overnight wear [56, 64]. Debate continues on the presence of receptors for Severe Acute Respiratory Coronavirus-2 (SARS-CoV-2) on the ocular surface, although risk of infection via this route is thought to be low [85].

2.5 Medication

A number of systemic medications can cause ocular surface changes leading to dryness symptoms by decreasing tear production, altering nerve input and reflex secretion, inflammatory effects on secretory glands, or direct irritation through their secretion into tears.[86] Examples include non-steroidal anti-inflammatories (NSAIDs), diuretics, antidepressants, antihistamines and hormone replacement therapy.[70] ECPs should check the side effects of medication used, prompting a thorough evaluation of tear film quantity and quality along with careful assessment of the ocular surface.

Application of topical ocular medications, such as for glaucoma management, is also important to consider. Whilst not a direct contraindication for contact lens wear, patients will need counselling about the timing, dosing and applying contact lenses. This is especially relevant for preparations preserved with benzalkonium chloride, which is known to cause signs and symptoms of ocular surface disease.[87, 88] Additional topical medications associated with the potential to induce dry eye symptoms are antihistamines and decongestants.[70]

2.6 Family history

There are many systemic and ocular conditions for which family history may be of critical importance. This includes inherited conditions, such as keratoconus and corneal dystrophies [89-91]. For young patients, parental history of myopia increases the risk of myopia developing in the child.[92] For these patients, contact lens fitting can be supplemented with advice and recommendations on myopia management strategies such as myopia control contact lenses, potential pharmaceutical options and environmental considerations, such as time outdoors and time on close work and near digital devices [32] (see CLEAR Orthokeratology Report) [93]. Diabetes has a genetic element [94] and can impact contact lens wear (section 2.4).

2.7 Influence of lifestyle/occupation on lens wear

Patients' engagement in hobbies or recreational activities such as playing video games for a long time may cause contact lens discomfort [29, 30, 95]. Similarly,

family and living conditions may impact on contact lens compliance and hygiene [96]. Wearing spectacles to play contact sports can cause injuries so soft contact lenses are a good form of refractive correction for these individuals [97]. Swimming while wearing contact lenses is generally not recommended [98], but spectacles are also not a good option for water sports, so the disposal of contact lenses after swimming and/or the use of well fitted goggles over the contact lenses can reduce the bioburden and related risks [99]. Driving has high visual demands and contact lenses for presbyopia can adversely impact performance in some individuals [100-102], so it is important to ascertain whether a patient will be driving in the contact lenses prescribed. Correction of even low levels of astigmatism should be considered to optimise driving performance [103].

History taking should include questions on smoking and alcohol consumption as they may be associated with contact lens discomfort.[48, 104] Smoking, either a current or past history, is associated with a 1.4-2.7 times increased risk of CIE or microbial keratits,[36, 56, 65-69] which, if reported during the patient history, can help inform the wear modality, avoiding overnight wear and consideration of daily disposables (Table 2).

It is also important that history-taking includes questions on use of eye cosmetics [105]. The use of face and eye creams around the eyes is of concern since constituents such as retinol may damage meibomian glands resulting in dry eye [106]. Similarly, pigments in eyeliners, mascara and eye shadows can disrupt the flow of meibum from the glands, deposit on the contact lenses, and cause ocular irritation.[105, 107, 108] Chemical substances in eyeliners can cause inflammation in eye lids and the fibrotic changes may lead to clogged meibomian gland orifices.[108] Eyelash growth products, such as those containing prostaglandin analogues and false eyelashes, may also cause ocular discomfort [105]. Identification of patient needs and epectations, and delivery of relevant and accessible patient education is important to achieve successful contact lens wear.

2.8 Influence of environment on successful lens wear

Certain work-environments are challenging for contact lens care. Office workers who work prolonged hours at video display terminals should be encouraged to take breaks, as both contact lens and computer use are associated with tear film instability [95, 109-111]. Environmental factors such as air pollution, wind, low humidity, high room temperature, dust, smoke, and high altitude may impact contact

lens wear [30, 112, 113]. Exposure to wind, dust, fumes and water splashes has been linked with an in increased risk of CIE [114]. Use of safety glasses over contact lenses and frequent replacement modalities has been suggested for dusty environments [63]. Conversely, in some industrial settings, contact lenses have been shown to protect from mechanical injuries from high-speed particles striking the eye [115, 116].

Windy or air-conditioned environments can cause evaporative stress on the tear film [117]. Continuous exposure to cold temperature affects the lipid layer of the tear film leading to dry eye [118], whereas, increased temperature leads to contact lens discomfort due to increased tear evaporation [48]. Similarly, low humidity decreases tear production and increases evaporation, leading to ocular surface disorders [48, 117, 119]. Low humidity and increased blink-interval while concentrating on visual tasks may cause ocular dryness in pilots, with those wearing contact lenses, significantly more likely to report use of eye drops than non-lens wearers [120]. However, contact lenses are well tolerated by flight crews [121]. There is limited evidence that lens material choice may help to reduce these effects [122]. In addition, ultraviolet light can damage ocular surface cells [123] and contact lens materials offer varying levels of protection [124]. Water contamination of contact lenses can cause infection and infiltrates [125] and loss of vision (section 6.7.2.7). Therefore, work-environments and potential hazards to contact lens wear should be discussed during history-taking.

3 Anterior Eye Examination

A thorough examination of the anterior eye is required prior to fitting contact lenses and at each aftercare visit. The assessment requires a combination of different slit lamp biomicroscopy techniques [126] to evaluate the fit of the contact lens (section 5), anterior eye anatomy (see CLEAR Anatomy Report and CLEAR Material Impact Report) [127, 128] and the health of the eye, and the use of ophthalmic dyes to monitor the eye for contact lens complications (section 7.4 and see CLEAR Complications Report) [38]. The least invasive tests in terms of illumination intensity, lid manipulation and dye application, should be performed first.

3.1 Ocular surface topography

Corneal topography can change with ocular pathology (such as keratoconus) (see CLEAR Medical Uses Report) [129] and affects lens fit – more so for rigid corneal

lenses (section 4.1). Central corneal radii over a 2-3mm radius can be quantified by conventional keratometry, which measures the separation of reflected pair(s) of mires [130]. A fuller profile of the shape of the cornea can be gained by video topography where the separation of placido disc rings reflected from the smooth tear film surface across the corneal surface are analysed (hence the need to ask the patient to blink a few seconds before image capture). The limitation of the extent of the analysed area from shadows of the ocular adnexa can be minimised by 'stitching' together topographies captured in different positions of gaze [131]. Fluorescein dye (section 3.5.1) can be applied to the ocular surface to allow image analysis of reflected light to extend onto the sclera [132, 133]. Raster scanning, in the form of measuring the shape of a slit of light as it passes across the cornea, can be used to assess anterior and posterior surface shape of the cornea as well as scleral shape with techniques such as scanning-slit, Scheimpflug cameras or Optical Coherence Tomography (OCT) [134-136].

3.2 Slit lamp biomicroscopy

Standard anterior eye viewing is conducted using a slit lamp biomicroscope. Different illumination and observation techniques are used to optimize the visibility of the features of the anterior segment of the eye and contact lens [126]. The smallest features of interest, such as microcysts, typically require 16-25x magnification [137] and corneal endothelial cell imaging 40x. The cornea should be scanned for signs of physiological compromise (section 7.4) and hyperaemia should be assessed [138]. Slit lamp biomicroscopes combined with commercial digital imaging systems adapted to the slit lamp biomicroscope, including use of smartphone cameras mounted to the eye pieces, may enhance patient record keeping and management. Appropriate database and image manipulation software is available, as well as automated intelligence systems to grade images [126].

3.2.1 Tear film

The tear film is an essential component in contact lens wearing comfort [139] and can impact contact lens drop out (section 7.3 and see CLEAR Maintenance Report and CLEAR Anatomy Report) [127, 140]. Consequently, an appropriate examination of the tear film, the ocular surface and quantification of symptoms, is vital in contact lens fitting and aftercare [14, 141]. The tear film should be observed in its natural appearance with non-invasive techniques [142], such as using cold light illumination

(section 3.6.1). The pre-lens tear film can also be observed to assess the *in vivo* wettability which is affected by lens deposition [139] and by the lens material and surface characteristics (see CLEAR Maintenance Report) [140].

3.3 Grading scales and photography

Detailed and accurate record keeping is a necessity in contact lens practice. A worldwide survey of ECPs reported that 84.5% use a grading scale to record the anterior eye health of their contact lens patients [138], with ECPs preferring to use either the Efron or Cornea and Contact Lens Research Unit / Institute Eye Research grading scales [138, 143].

There are two main approaches to generating clinical grading scales: illustrated (artist-rendered drawings) and photographs of eyes. Illustrated scales can systematically represent the severity of a feature using the same magnification and angle-of-view [144], but may lack the realism of a photographic scale. Some scales combine these approaches with a photograph of a healthy eye overlaid with the different severities of the feature of interest [138].

Images are typically presented to represent grades 0 to 4. While it is suggested that clinical action is needed for grades >2, this depends on the feature being observed and associated signs and symptoms. In theory ECPs should use these images to interpolate to 0.1 grade increments to enhance sensitivity [145]; however in practice 0.5 steps appear to the most appropriate grade increment [146]. Digital presentation of grading scales allow image morphing between grades, but this does not seem to improve grading variability [147]. A change in grading >1 unit is typically considered clinically significant [148]. Due to differences between grading scales [144, 149], it is important that clinicians specify which grading scale they use [138]. Reference to a visible grading scale at every visit to record blepharitis, meibomian gland dysfunction, bulbar and limbal hyperemia, corneal neovascularisation and palpebral conjunctival redness under white light and palpebral roughness with fluorescein (section 3.4.1) in recommended [138]. Corneal and conjunctival staining observation recording was also recommended, but a sketch with a description of depth was advocated rather than multiple grading scales scores to record type, size, location and depth [138].

Objective grading from digital images has the potential to decrease the variability of subjective rating, but relies on good quality imaging [150-152]. Although anterior eye

digital imaging (from a digital slit lamp or even a smartphone) is not commonly utilised in clinical practices [138], the resulting images or movie clips can accurately reflect anterior eye characteristics. As well as allowing changes in physiology and pathology to be more precisely tracked over time, grading scale images and digital images/videos are also useful education tools to help explain ocular changes to patients during contact lens aftercare appointments and keep them fully informed.

3.4 Lid eversion

Eyelid eversion is a necessary component of the contact lens fitting and aftercare process to assess the eye for complications (see CLEAR Complications Report) [38]. The procedure must be quick and comfortable for the patient, while also permitting the clinician to view a large area of the palpebral conjunctiva. The optimal device for everting the upper lid is a finger-shaped everter made of silicone rubber [153]. The silicone rubber everter was rated as comfortable as using the ECP's index finger to evert the lid, as fast as using a cotton bud, and exposed the largest amount of palpebral conjunctiva [153]. To evert the upper lid, instruct the patient to look down, and then lift up the upper eyelid to separate the base of the lashes while stretching the lid forward [153]. Clinicians need to avoid causing iatrogenic staining of the lid wiper area when everting the lids (section 3.4.2.2). Double lid eversion is useful when there is a history of a lost or displaced contact lens [154-157]. The lower lid can be everted by placing a cotton wool bud along the lower eyelid margin, rotating towards the eye and pressing inwards or using a curved ended plastic tool to press just below the lower lid margin [153].

3.4.1 Palpebral conjunctiva

The palpebral conjunctiva must be evaluated for redness and papillae/follicles at each visit (see CLEAR Anatomy Report) [127]. The grading of palpebral roughness is significantly higher when assessed with fluorescein and blue light rather than under white light [158]. The authors recommend to first evert the upper and lower eyelid to examine the hyperemia at the slit lamp with white light before instilling fluorescein [158]; however pragmatically, as multiple eversion of the lid can induce staining [159, 160] if fluorescein is instilled before lid eversion, the ECP can assess redness with white light and switch to blue light and insert a yellow filter to observe roughness. More advanced clinical techniques, such as confocal microscopy [161-

163] and OCT [164], have also been used to examine the palpebral conjunctiva, but are not routinely employed in clinical practice.

3.4.2 Lid margin

The lid margins should be examined to identify anterior blepharitis [142], meibomian gland dysfunction [165], lid-parallel conjunctival folds and lid-wiper epitheliopathy [11, 78, 166] (see CLEAR Anatomy Report) [127].

3.4.2.1 Lid-parallel conjunctival folds (LIPCOF)

LIPCOF are small folds in the inferior-temporal and inferior-nasal bulbar conjunctiva, which are aligned parallel to the lower lid [167] (see CLEAR ANATOMY Report) [127]. LIPCOF are visible with a slit-lamp biomicroscope and white light at magnifications of 18x [53, 167] to 25x [168]. Additional techniques used to investigate LIPCOF include Scheimpflug imaging [169] and optical coherence tomography [170-172]. Although the aetiology of LIPCOF is unknown, they are a fair [173] to significant [167] predictor of contact lens discomfort. The majority of studies comparing symptomatic and asymptomatic soft contact lens wearers have found increased grades of LIPCOF in symptomatic wearers [167, 173, 174].

3.4.2.2 Lid wiper epitheliopathy (LWE)

The full extent of lid wiper staining (see CLEAR Material Impact Report and CLEAR Anatomy Report) [127, 128] is visible after either instilling two drops of lissamine green or two drops of fluorescein one-minute apart, although these dyes have not been directly compared [175]. The TFOS DEWS II Diagnostic Methodology report recommends using two separate strips of lissamine dye wet with two drops of saline [142]. Care should be taken to not touch the lid margin prior to instilling the dye [176] and when everting the lids to avoid inducing staining. The upper lid should only be everted once to avoid increasing the amount of staining [159, 160]. The optimal viewing time for lissamine green is 1 to 5 minutes after the second drop has been instilled, while viewing LWE with fluorescein requires waiting 3 to 5 minutes before staining can be assessed [175]. LWE is viewed at 16x magnification [177] with diffuse white light for lissamine green or blue light and a yellow barrier filter if fluorescein has been instilled [178]. Grading scales have been developed based on the length and width (relative to the lid), but objective analysis is more accurate and sensitive [179]. LWE has been reported to be one of the significant predictors of contact lens-induced dry eye [167]. However, a 2016 meta-analysis was unable to find a relationship between LWE and the ‘contact lens user experience’ score [178]

and a 2018 study did not find LWE to be a significant predictor of contact lens discomfort [173].

3.5 Ocular surface damage

Physiological damage to the ocular surface is revealed by ophthalmic dyes [142]. Use of strips are preferred over Minims (Bausch & Lomb U.K Limited) because they are sterile [180] and less expensive [181]. The strip should be applied flat and at the temporal canthus to avoid damage to the tissues under observation [142].

3.5.1 Sodium fluorescein

Fluorescein allows visualisation of the tear film and is used in rigid corneal (section 5.2.4) and scleral lens fitting (see CLEAR Scleral Report) [182]. Fluorescein also penetrates the corneal epithelium when the epithelial surface has been disrupted [183]. If excess fluorescein is instilled, the stimulated molecules collide, reducing the fluorescence, hence the recommended technique is to place a drop of saline onto the paper strip, then shake the strip to remove the excess liquid [180, 184]. To optimally observe the fluorescence, a blue light with a peak of around 495 nm should be used in conjunction with a yellow (around 500 nm) cut-off filter to remove the residual reflected blue light. Traditionally cobalt blue glass was used, but this has a wavelength approximately of 460nm [180]. The optimal time to assess corneal staining is between 1 to 3 minutes [142] after the dye has been instilled.

3.5.2 Rose bengal

Rose bengal was initially reported to stain dead or degenerated cells and mucus [185, 186]. More recent work has described rose bengal to be toxic [187, 188] and stains healthy cells [188]. Although there is a lack of information regarding the comfort of ophthalmic strips [189], 1% to 10% rose bengal causes stinging [186, 190], irritation [191] and discomfort [190-192]. Due to its adverse effects, use of rose bengal use has generally been replaced by lissamine green.

3.5.3 Lissamine green

Lissamine green stains dead or degenerated cells and mucus on the cornea and conjunctiva [193]. Although not available in all countries, lissamine green is the dye of choice to assess conjunctival and lid margin staining [142]. To apply the dye, a strip of lissamine green should be wet with saline and the drop kept on the strip for a minimum of 5 seconds. With the patient looking up, the lower eyelid should be pulled down and slightly temporal, and a drop placed into the inferior cul-de-sac [142]. Optimal viewing is with white light 1 to 4 minutes after dye instillation [142, 194]. A

red barrier filter, such as a Hoya 25A [195, 196] or Kodak Wratten 92 [196], can be used to enhance contrast of the staining. It is important to recognize that the amount of staining produced by lissamine green strips can significantly differ depending on the manufacturer [159].

3.6 Other Anterior Eye Imaging Techniques

3.6.1 Cold light illumination

A cold light source usually refers to a light external to a microscope that allows diffuse illumination without marked thermal impact on the sample. It can be used to observe the stability of the tear film (usually in the form of a placido pattern), the tear meniscus and the lipid thickness (through interferometric patterns)[197]. Instruments can be used as stand-alone, some with digital imaging and objective software analysis [198], or in conjunction with a slit lamp biomicroscope for control and magnification. Alternatively, placido discs of video topographers can be used as a cold light source to evaluate tear film [199, 200].

3.6.2 Meibography

Meibography enables the evaluation of the morphology of the meibomian glands (see CLEAR Anatomy Report) [127]. The traditional technique was transillumination of the meibomian glands by placing a light source behind the everted lid [201]; direct illumination with infrared light is non-contact and more comfortable [202, 203]. Standalone or multifunctional instruments have been on the market since 2011 [204]. Contact lens wear may affect the meibomian glands and therefore documenting and monitoring their appearance would seem appropriate [166, 205-208] (see CLEAR Complications Report) [38].

3.6.3 Specular microscopy

Specular reflections arise from light which is reflected from the interfaces of materials with different indices of refraction. This occurs when the angle of incidence is equal to the angle of reflection. Thus, the difference between the index of refraction between the corneal endothelium and the aqueous produces a specular reflection which allows the cell morphology to be observed and photographed. Factors such as number of cells per unit area as well as cell shape may give the clinician further information in terms of contact lens induced endothelial cell loss [209]. This technique is rarely used in clinical practice. The technique can be set up with a slit lamp biomicroscope observed using 40x magnification, but the field of view is generally limited compared to dedicated instrumentation.

3.6.4 Confocal microscopy

Confocal microscopy is an optical imaging technique for increasing optical resolution and contrast of an image by means of a point illumination and conjugate pinhole to block out-of-focus light. A sensitive sensor is needed due to the reduction in light. Capturing multiple two-dimensional images at different depths in the living human cornea enables the reconstruction of three-dimensional structures at up to ~500x magnification [126]. However, contact with the corneal surface (usually with a gel medium) is required so it is not commonly used in clinical practice, but can be used to aid the diagnosis of fungal and *Acanthamoeba* keratitis [210] and observe the nerves of the body without biopsy which is useful in monitoring patients with diabetes [211].

3.6.5 Optical coherence tomography (OCT)

OCT involves splitting a beam of light, with one branch reflected off a reference mirror while the other is passed through the optics of the eye, before being recombined. The interference fringes provides A-scan information on the depth of the structures with an axial resolution as low as 2μm [212]. Time domain which relies on the mechanical movement of the reference mirror; spectral or Fourier domain OCT extracts spectral information by distributing different optical frequencies onto a detector stripe via a dispersive element; and swept source OCT where the spectrum is either filtered or generated in single successive frequency steps and reconstructed before Fourier-transformation. Instruments designed for posterior segment imaging (typically with about a 830 nm wavelength) can image the anterior eye with the addition of a objective lens, but have a reduced penetration depth compared to a dedicated anterior segment OCT (typically with a central wavelength ~1310nm)[212]. Anterior segment imaging includes the tear meniscus [213], post-lens and pre-lens tear film [214] (although the resolution for this is questionable), contact lenses fitting [215], LIPCOF [171], conjunctival folds [216], epithelial, stromal and total corneal thickness, and the ocular surface curvature [217].

4 Lens selection

Orthokeratology, scleral lenses and medical use of contact lenses have been covered in accompanying reports, so the following sections focus on soft and rigid corneal lenses (see CLEAR Orthokeratology Report and CLEAR Medical Uses

Report) [93, 129]. Direct evidence based on a patient’s history, refractive error and ocular health that informs lens selection is summarised in Table 3.

Table 3: Direct evidence to inform soft and rigid corneal lens selection. *Advise* represents strong evidence (multiple well designed studies with similar findings); *Consider* indicates there is some (possibly conflicting) evidence.

CATEGORY		FACTOR	EVIDENCE	SOFT	RIGID CORNEAL
Patient Information	Common health conditions, past treatments/ surgeries (excluding immediate post-op), and current medication	Diabetes Mellitus	**SOFT:** ↓ Corneal endothelial function in low Dk CLs [218] ↑ CL-induced complications including corneal erosions with extended wear [82, 219] **RIGID CORNEAL:** ↑ Tear exchange, ↓ toxins and pathogens trapped beneath or bound to the lens. Also ↑ epithelial fragility causing corneal erosions [82]	Consider high Dk Hydrogel or SiH Consider DW [220] or DD [221]	Epithelial fragility might contraindicate [222] Consider ScCL in case of neurotrophic keratopathy [182, 223]
		Hormone Replacement Therapy (HRT)	**GENERAL:** ↓ Lacrimal function, ↑ dry eye depending on type and dose of hormone intake [224]	Consider low water content Hydrogel, or SiH in aqueous-deficiency	Unknown
		Thyroid dysfunction (hyper- and hypo-)	**GENERAL:** ↑ Exposure keratitis, incomplete blinking, ↑ evaporative and aqueous deficiency dry eye [225, 226] ↑ Superior eyelid tightness and mobility of bulbar conjunctiva [227]	See HRT in case of aqueous deficiency.	Unknown
		Stevens-Johnson syndrome, or Sjøgren syndrome	**SOFT:** ↑ Ocular comfort and ↑ VA with bandage lens vs autologous serum in Sjøgren syndrome [228]	Consider SiH overnight wear	Unknown Consider ScCL in advanced stages [129, 182, 223]
		Post refractive surgery	**SOFT:** ↑ Comfort, vision and ↓ symptoms with low modulus or newer lens designs [229] for corneal healing **RIGID CORNEAL:** ↑ VA, ↓ higher-order aberrations,[230] ↓ corneal irregularities, ↓ anisometropia for refractive error correction [231]	Advise DD or frequent replacement soft lenses	Advise rigid corneal or reverse geometry lenses when corneal irregularities are present Consider ScCL or hybrid with particularly severe corneal irregularities [182, 223, 232]

	Post keratoplasty or cross-linking (CXL)	**SOFT:** Extend use of therapeutic bandage lens if prolonged ↓ epithelial healing [233] Optical designs for irregular astigmatism (see *Keratoconus*) [233] **RIGID CORNEAL:** ↑ VA after CXL [234] ↑ VA and good tolerance in post keratoplasty with (large diameter) rigid corneal lenses [235, 236] ↑ VA and good tolerance in post keratoplasty with reverse-geometry lenses [237]	Consider SiHy overnight wear bandage, reverse geometry hydrogel or hydrogel toric lenses [238]	Advise rigid corneal or reverse geometry lenses post keratoplasty Advise rigid corneal lens after CXL Consider ScCL or hybrid in advanced stages [182, 239]
Seasonal allergy		**SOFT:** Antigens bind to biofilm, ↑ signs and symptoms [58, 240] ↑ Comfort and ↓ symptoms in allergic conjunctivitis (AC) with hydrogel DD [57, 58]	Advise DD. Consider hydrogel material in atopic keratoconjunctivitis.	Provide greater tolerance to giant papillary conjunctivitis compared to soft lenses (Ortiz-Toquero et al., 2017) Consider ScCL in advanced atopic keratoconjunctivitis [182, 241]
Ocular History	Reoccurrence corneal complications (for example corneal erosion, MK)	**SOFT:** Possibly ↑ chance of recurrence [63, 242, 243]	Advise DD for Herpes Simplex, MK, corneal erosion. Consider short-term SiHy bandage lens for pain relief and ↑ corneal integrity [129]	Unknown
	Keratoconus and corneal surface irregularities	**SOFT:** ↑ Ocular comfort and ↑ VA with specialty soft CLs [129] **RIGID CORNEAL:** ↑ VA in early keratoconus, good comfort, but risk of corneal scarring resulting in ↓ VA. ↑ VA in corneal irregularities [129]	Advise customised soft or different modality in moderate to severe cases [129]	Advise rigid corneal lenses for early keratoconus and corneal irregularities Consider ScCL or hybrid lenses in advanced cases [239]

		Binocular vision	**GENERAL:** ↓ Aniseikonia in with CLs, improving BV status [244] Possibly ↓ risk of sensory adaptations (such as suppression) in children with anisometropia [245]	Consider soft CLs	Consider rigid corneal lenses
	Hygiene habits	Smoking/ vaping	**SOFT:** ↑ Risk of MK in smokers [246-248] ↑ Risk of CIE in smokers [34, 66, 74] Passive smoke may affect tear evaporation and staining in CL wearers [104]	Consider DD [249]	Unknown
		Poor hygiene	**SOFT:** ↑ Discomfort and infection/ CIE risk, and ↓ vision due to build-up of deposits [250, 251]	Advise DD, or peroxide based solution with reusable lenses [252, 253]	Unknown
	Environment/ occupation	Increased levels of dust, wind, fumes, temperature, near or computer work Low relative humidity	**SOFT:** ↑ Discomfort due to dehydration of CL, dry eye symptoms and ↑ tear inflammatory mediators [139]. Little known on longitudinal direct exposures [254]	Advise low water content, SiHy, water gradient [255-257].	ScCL may be indicated rather than rigid corneal lenses to prevent foreign bodies getting beneath the lens, but no academic evidence to support
	Age	Safety in those <18 years	**SOFT:** No ↑ CL complications in children vs adults; for DW, overnight wear, Hydrogel, SiHy, and myopia control [258, 259]	Consider DD soft CL	Unknown
Refractive indications	Astigmatism	Corneal and lenticular astigmatism	**RIGID CORNEAL:** ↑ VA and quality of vision in irregular and corneal astigmatism.[260, 261] Front toric rigid corneal lenses in case of residual astigmatism [262]	Prescribe total refractive astigmatism (≥0.75D)[263-266]	Advise rigid corneal lenses (Front or Bi-toric in case of residual astigmatism)
	Presbyopia		**SOFT:** ↑ stereopsis if fully corrected vs mono-vision [33] ↑ Retention if fully corrected, not mono-vision [24, 25] **RIGID CORNEAL:** ↑ near VA with bifocal and multifocal rigid corneal lenses and ↑ binocular contrast sensitivity [267]	Advise multifocal soft lens	Advise rigid corneal lenses

	Myopia progression	**SOFT:** ↓ Myopia progression with DD concentric rings around CD-zone [268, 269], soft bifocal and multifocal designs [270], and Extended Depth Of Focus [271]. Higher near addition ↓ progression [272] **RIGID CORNEAL:** no effect of rigid corneal lens wear on myopia progression in children [273, 274]	Advise on-label soft lens.	Advise ortho-k, not rigid corneal lens [93]
Ocular Surface Health	Moderate to severe dry eye signs and symptoms	**SOFT:** ↑ Tear stability with bandage lens [275]. ↑ Ocular surface staining after 6 months SiH CL wear [24, 54]	Consider SiHy overnight wear bandage lens for severe DED	Provide greater tolerance compared to soft lenses [276] Advise ScCL in moderate to severe dry eye disease [223]

CL contact lens, DD daily disposable, ScCL scleral contact lens, CLPC contact lens-induced papillary conjunctivitis, MSE mean spherical equivalent, CD centre distance, SiHy silicone hydrogel, DED dry eye disease, VA visual acuity, MK microbial keratitis

4.1 Ocular surface measurements

4.1.1 Feature dimensions

4.1.1.1 Horizontal Visible Iris Diameter (HVID)

The Horizontal Visible Iris Diameter (HVID - also referred to in the literature as the corneal diameter or white-to-white and limbal-to-limbal) is the distance between the nasal and temporal limbus and is recorded in millimetres (to 1 decimal place to account for the accuracy of ruler measurement). The HVID is used to estimate the ideal diameter of a contact lens. HVID can be measured manually (ruler or slit lamp graticule), or with the use of imaging techniques such as topography or OCT including manual or automated analysis software. HVID varies significantly depending on the methodology used, whereby the true diameter is generally underestimated by subjective enface observation [217, 277]. Using objective measurement techniques, the HVID in adults is on average 11.8 ± 0.5mm, ranging between 10 and 14mm [278]. It is adult size by age 4 [279] and slightly decreases with age (by 0.2mm between aged 10 and 80 years)[280]. Corneal diameters have also been reported to vary with sex, ethnicity and culture. For example, Far East Asian origin corneas are significantly smaller (11.2-11.6mm) than Caucasian origin corneas (11.8-11.9mm)[278] and males may have larger HVIDs compared to females [26, 278].

There is little published evidence which informs lens diameter choice. Interaction of the lens edge with the limbal area is thought to potentially cause mechanical damage from the change in surface curvature, although this is less than was previously envisaged except for perhaps nasally [217]. The limbal region also marks the end of the corneal avascular area and location of the ocular stem cells, so mechanical insult from a lens edge is best avoided [281].

4.1.1.2 Vertical Palpebral Aperture (VPA)

The distance of the fissure between the superior and inferior eye lid margins measured at the pupil centre in primary gaze is known as the vertical palpebral aperture (VPA). Similar to HVID, the VPA can be measured subjectively or objectively. On average, the VPA is 9.7 ± 1.2mm, ranging between 9.1 and 10.8mm [282]. VPA is significantly smaller in eyes of Asian ethnic origin (9.6 ± 1.2mm) compared to other races (10.8 ± 1.3mm) [283], while the VPA in females is on average 0.7mm smaller compared to males [284]. There is no scentific literature

suggesting VPA is relevant to contact lens fitting. It is not related to ocular surface disease or dry eye [285].

4.1.1.3 Pupil size

The size of the pupil is measured in normal room illumination as well as dim (mesopic) light to improve the ECPs understanding of the influence of lens geometry and optical power distribution on visual outcomes. In a dark examination room, the ECP is able to replicate dim illumination conditions by using a ruler in combination with a Burton lamp or instead measure photopic and mesopic light conditions using an objective imaging technique (such as topographer or pupillometer). The average normal pupil size in adults varies from 2.0-7.0mm in diameter in bright light to 4.0-8.5mm in the dark [286]. Pupils are also smaller when accommodating and converging on a near target [287]. Age and refractive status also affect pupil size, whereby presbyopes and hyperopes usually present smaller pupil sizes than average [288, 289]. Knowledge of the pupil size has been shown to be essential for the successful fitting of bifocal contact lenses [290] and should affect the performance of multifocal contact lenses [291], although this has not been found to be the case in practice [292]. Pupil size is a valuable measurement for corneal GP lens fittings to prevent glare and haloes when the pupil is larger than the back optic zone diameter.

4.1.1.4 Corneal Shape

Measurements of the ocular surface shape (section 3.1) should be conducted prior to lens fitting to gain information on the shape of the ocular surface [293]. A topography map can be used to determine if the astigmatic component of the refractive error is corneal, if it is regular or irregular and how far it extends to the peripheral cornea. This information will help to determine whether a soft toric or rigid corneal lens would be best suited, in addition to the correct diameter size and peripheral curve for rigid corneal lenses [294-296]. Corneal topography alone does not inform soft lens fit as this is dependent on the sagittal height of the cornea and lens (see sections 5.1.2 and 5.1.3); however it is required for base curve selection for rigid corneal lens types, especially with complex corneal shapes [297]. Following lens wear, measurements of the ocular surface are valuable to visualise and assess how the lens affects the shape of the ocular surface [298]. In addition, long-term rigid corneal lens wearers may benefit from ocular surface shape analysis to determine if there are any signs of corneal warpage [299].

On average, there are no significant differences in corneal curvature between East Asian and White eyes, but greater asphericity (more prolate shape factor) in the vertical meridian (flatter in the horizontal meridian); they have smaller vertical palpebral apertures, horizontal fissures and HVIDs [300-302]. With increasing myopia, East Asian corneas show increasing prolate asphericity and steeper curvature, as well as greater inclination (or obliquity) of the eyelids [300, 301]. Corneas from White are thicker than African races, but have a smaller temporal corneo-iridial angle [303].

4.2 Modality and material selection

4.2.1 Soft contact lenses

There is a wide choice of soft contact lens materials, which can be categorised as hydrogel or silicone hydrogel. Selection is based on their differing oxygen permeability (related to silicone and water content), hydrophobicity (related to silicone content, wetting agents and surface modifications), modulus (related to silicone and water content) and susceptibility to deposition (related to ionicity)[304] (see CLEAR Material Impact Report) [128]. The coefficient of friction, but more so the lens surface lubricity, principally affect comfort [305, 306], but the role of lens surface wettability is less clear [307] (see CLEAR Maintenance Report) [140]. Contact lens modality includes daily wear or overnight wear. While regulatory terminology denoted ‘extended’ wear as 7 days and 6 nights and ‘continuous’ wear as up to 30 days and 29 nights [308], these definitions overlap and are used interchangeably in the literature. Research suggests that there are no marked differences between these modalities [309]. Hence the terminology ‘overnight wear’ is more appropriate for clinical use, with an indication whether it is ‘sporadic’ or ‘planned’. Lens choice for planned overnight wear or for the many patients that nap in their lenses [310, 311] should be within the regulatory indication for the lens, noting this can vary between regions and napping should be treated as a form of overnight wear. It is well established that overnight wear significantly increased the chance of contact lens-induced complications including microbial keratitis [312]. However, similar rates of microbial keratitis have been found between silicone-hydrogel and hydrogel materials [313], with around a 2x increased risk of CIEs in reusable silicone-hydrogels compared to reusable hydrogel lenses [37, 68, 249]. Daily replacement of lenses during overnight wear reduced mechanical

complications from 5.2% to 0.8% if replaced in the morning, but not at night, so evening handling and application of lenses appears to increase the risk of complications [314]. Daily disposable use reduces the risk of CIEs [249, 315], the severity of microbial keratits infection [67, 316] and ocular allergic symptoms [57, 58] compared to daily wear of soft reusable contact lenses. Comfort of reusable lenses can be modulated by the material-care solution combination [317] and is improved with more frequent replacement of soft lenses [318].

4.2.2 Rigid corneal lenses

Rigid corneal lenses generally provide excellent visual acuity and contrast sensitivity, and are generally more effective in correction of high corneal astigmatism compared to soft lenses [276, 319]. There is also evidence that rigid corneal lenses are better tolerated by patients with dry eye or papillary conjunctivitis compared to soft contact lenses [276]. A lower number of contact lens related complications and serious complications such as microbial keratitis are observed in rigid corneal lenses compared to soft contact lenses [67, 276, 320] (see CLEAR Complications Report) [38]. Despite these advantages of rigid corneal lenses, only around 10 percent of wearers use rigid corneal lenses [321], which is most likely due to initial discomfort and adaptation, and the time required to successfully fit and manage rigid corneal lens wearers [276, 322]. They are not suitable for part-time wear, but there has been an increase in their use for myopia control using orthokeratology (see CLEAR Orthokeratology Report) [93]. The majority of current rigid corneal lenses are made of silicone-acrylate or fluorosilicone-acrylate, which allow for increased oxygen transmission through the lens material compared to the polymethylmethacrylate (PMMA) rigid lenses used in the past.

4.3 Lens parameter selection

4.3.1 Soft lenses

Base curve: Traditionally, central keratometry readings have been used to select the base curve of a soft contact lens, with a value of 0.3 to 1.0 mm added to account for the flattening of the cornea towards the periphery, but the relationship between these two parameters is not linear [323, 324]. Ideally the lenses sagittal height should be matched to corneal sagittal height (see sections 5.1.2 and 5.1.3)[325]. Until these values are more widely available, the limited available base curves of mass produced soft contact lenses can be used successfully for around 75% to 90% of eyes, with the rest needing a custom-designed lens [325, 326].

Total Diameter: Ideally HVID+≥2mm (section 4.1.1.1). The limbal width is reported to be about 1.5-2.0 mm (see CLEAR Anatomy Report) [127] and the visible HVID is about 1 mm smaller than the corneal width [217]. For soft lenses, fitting with a 1.2 or 2.4mm (tightness was compensated by a 0.6mm change in base curve) overlap onto the sclera made no difference to comfort, physiology or lens movement [327]. Hence HVID + ≥2mm would seem appropriate for a soft contact lens. The majority of spherical soft lenses are manufactured in diameters between 14.0 to 14.5mm; consequently, the choice of non-custom lenses is very much dependent on availability.

Back Vertex Power (F): A trial frame/phoropter prescription in the spectacle plane (F_{spec}) needs to be converted to a corneal plane prescription where:

$$F_{contact\ lens} = \frac{F_{spec}}{(1 - (back\ vertex\ distance[m]\ x\ F_{spec})}$$

Both meridians of the cornea need to be considered separately (sphere and sphere + cylinder) and recombined. At a typical 12mm back vertex distance, prescriptions <4D make ≤0.18D difference and hence F_{spec} can be used. If a spherical lens is to be fitted, the mean spherical equivalent powered contact lens should be prescribed. However, visual quality is noticeably improved with toric correction compared to a spherical equivalent even for low levels of astigmatism (≥0.75 D)[263-266] so a toric lens should be trialled.

For presbyopes, lens fitting guides use the trial frame/phoropter selected near addition to inform lens selection. Optimisation is described in section 5.1.7. Monovision works well for many early presbyopes, but stereopsis is impaired (section 6.3)[33].

4.3.2 Rigid corneal lenses

Base curve: Rigid corneal lenses should be fitted to create an alignment fit in at least one meridian which distributes the weight of the lens over a larger area of the cornea and forms a tear fluid layer mathematically calculated to be 10 to 25 µm between the back surface of the lens and the anterior surface of the cornea [328, 329]. Back optic zone radius selection depends on the asphericity and eccentricity of the cornea, and manufacturing guidelines should be followed for initial lens selection.

Total Diameter: Interaction with the limbal area should be minimised (sections 4.1.1.1 and 4.3.1), hence HVID minus 2mm would seem appropriate for a rigid

corneal lens. There is some evidence that larger diameter rigid corneal are more comfortable for adapted wearers [330], but do not aid the adaptation process [331].

Back Vertex Power: A trial frame/phoropter prescription needs to be converted to a corneal plane prescription (section 4.3.1), but the tear film will reduce the corneal astigmatism (~0.25D for every 0.05mm difference in curvature between the corneal meridians), hence only the spherical component in negative cylindrical form needs to be inputted into the formula. Lenticular astigmatism needs to be corrected with front surface toricity (with stabilisation if no back surface toricity) and back surface toricity is used to prevent rigid corneal lenses from rocking on more toroidal corneas, causing discomfort [265]. Back surface torics induce astigmatism due to the refractive index difference between the lens material and the tear film, of approximately the toricity of the back surface of the contact lens multiplied by 0.28 (for a lens refractive index of 1.43 [fluorosilicone acrylate]) or 0.47 (for a lens refractive index of 1.49 [polymethyl methacrylate]) [332]. In minus cylinder form the orientation of the induced astigmatism is the same as the flatter meridian of the back surface of the contact lens (i.e. the flatter corneal meridian). This induced astigmatism can be useful if the corneal astigmatism is lower than refractive astigmatism as it minimizes residual (internal) astigmatism. However, when corneal astigmatism is greater than refractive astigmatism, the induced astigmatism will increase the residual astigmatism which may require correction using a front surface toric.

For presbyopes, the same considerations as with soft lenses should be considered, but translating lens designs are also an option [33]. Empirical fitting (designing the lens parameters based on corneal topography) reduced the need to use trial lenses, even for more complex lens designs [261].

5. Evaluation of Lens fitting

5.1. Soft contact lenses:

5.1.1. Physiological and Optical Impact of poor lens fitting

Contact lenses are designed to approximately align with the ocular surface which varies in shape and regularity between individuals. Poor fitting soft lenses have been shown to have a negative impact on ocular physiology and has been linked to contact lens drop out [333]. Reduced lens movement or increasing tightness are associated with improved comfort; increased lens-induced paralimbal conjunctival

staining and indentation, considered to be associated with contact lens fit or edge design, are also linked with better comfort [307]. Greater fluorescein staining has been observed with both loose and tight fitting lenses and higher levels of bulbar and limbal hyperaemia occur with loose fitting lenses [334]. Focal limbal cell deficiency can rarely occur with contact lens wear [335], but whether this is due to limbal interaction with the lens edge has not been established. It is widely believed that adequate tear interchange beneath a contact lens enhances gas exchange at the corneal surface, reduces friction and removes trapped debris, inflammatory cells and other tear components that would otherwise accumulate under the lens [336]. Decentration of the lens affects the optical correction's aberrations projected onto the retina [337], but lens misalignment with the optical axis has little effect with spherical optical designs [338] (see CLEAR Optics Report) [339].

5.1.2. Modelling of lens movement

The post-lens tear film has been shown to be the major determinant of lens movement [340, 341], with gradual post-lens tear film expulsion accounting for the initial decrease in lens mobility [342]. During blinking, the eyelid pressure over the lens causes it to stretch to conform to the shape of the eye, generating a suction pressure (or hydrodynamic squeeze) [343-345]. Modelling suggests this pressure is greater for steeper, thicker and lower water content contact lenses, but that the relationship is not linear [343]. However, tear exchange under a soft lens is limited to about 0.7 to 1.8 % per blink [336, 346]. Tear mixing has been reported to differ with the amount of lens movement, but there is only one abstract on the topic [347]. Kikkawa described a model in which a soft contact lens was conceptualised as a series of concentric elastic rubber bands, progressively stretching and flexing to accommodate changes in peripheral ocular curvature [348]. More recently, an ellipto-conical corneal modelling of soft lens fit showed closer concordance with actual measurements than an elliptical model and estimated an edge strain of 2.7% for a standard 8.6 mm base curve, 14. 2mm diameter lens on an average eye, with edge strain <0 % being too loose and >6 % being too tight [326, 349]. This modelling showed that theoretical success rates for one base curve would be 61-90% with not much improvement from a second base-curve [350]. Increasing lens diameter to >2 mm more than the HVID does not negatively impact the eye if the base curve is adjusted to keep the sag the same [327]. The sagittal height (sag) of a lens is the displacement along the optic axis, of the surface from the vertex, at a specified

distance (Figure 3). The sag of commercial mass produced lenses ranges from 3450 to 3907 µm [294] and the sagittal height of the healthy cornea has been found to be 3180 µm (range 2740-3750 µm) or at a chord length of 15mm, 3740 µm (range 3230-4100 µm)[324].

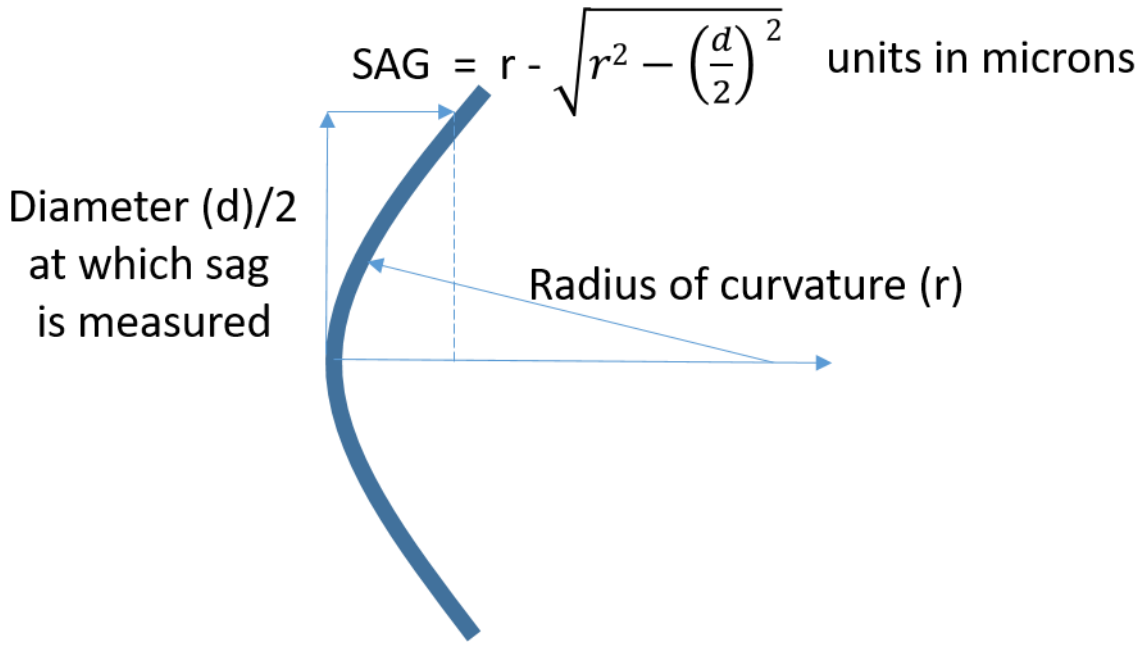

Figure 3: Sagittal height of a contact lens

5.1.3. Ocular characteristics affecting lens movement

Factors that predict centration, movement and tightness (principally palpebral aperture, horizontal visible iris diameter, spherical refraction and upper lid angle) vary with ethnicity, but only account for ~10 % of the observed variation [301]. Keratometry alone and in conjunction with corneal topography over the corneal area only weakly predict lens fit characteristics [295, 324]. Quantifying the corneo-scleral junction profile increased the variance accounted for by lens fit up to 24% with the palpebral aperture, scleral radius, corneal sagittal height and differences in the horizontal corneo-scleral junction angles being associated with increased lens tightness as assessed using the push-up test [324]. The larger the HVID, the looser the lens fit [351]. The palpebral aperture and lid orientation, as well as the strength of the spherical power, affects rotational stability of a toric lens [26, 301, 351].

5.1.4. Effect of lens material /design on lens fitting

Hydrogel material lens movement does not appear to be greatly influenced by water content or other material properties [332], although it is affected by the method of manufacture, with lathe cut HEMA lenses centering lower and spin cast lenses moving less than lathe or cast moulded HEMA lenses [352]. Contact lens movement and ocular surface indentation are influenced by lens edge design and mid-peripheral shape profile [353]. Soft lens edge design affects conjunctival indentation and lens movement [353, 354]. Conjunctival epithelial flaps have been found to occur in first generation, high modulus, silicone hydrogel contact lens wear [355]. Silicone hydrogels generally display less decentration and greater movement on push-up recovery than HEMA lenses [281]. While it is not clear whether back surface shape of lenses affects their movement, less movement is associated with more stable lens orientation and a slower recovery speed of soft toric lenses [26].

5.1.5. When to assess lens fitting

Studies have shown a decrease in lens movement over the initial 10–15 min post-application, but it increases again during the day, equating to the movement measured 5-20 min after application for hydrogel lenses [352, 356, 357], but 10-20 minutes after application for silicone-hydrogel lenses [357]; hence 10 minutes after application, seems an appropriate time to assess lens fitting.

5.1.6. How to assess and record lens fitting

Subjective grading of soft lens fitting has traditionally lacked standardisation and often was limited to descriptive terms such as ‘good’ or ‘poor’ [281]. In clinical studies, more systematic approaches have been adopted such as grading decentration relative to the limbus (lens displays a difference in overlap ≤1:2 or >1:2 at any point on either side of the cornea) and inadequate coverage (limbal exposure with extreme eye movement/primary gaze, with or without blink) on a 3 point scale, and movement and push-up tightness on a 5 point ‘acceptability’ scale, but not based on any evidence. When over 2000 evaluations of soft contact lens fitting from previous studies were analysed [358], the push-up test was the most accurate predictor of ECP determined acceptable lens fit. Assessment of post-blink movement (in primary gaze) was a sensitive indicator of tight fitting, but not loose fitting, lenses. Horizontal lag showed better sensitivity in assessing loose fits, whereas upgaze lag showed better sensitivity for tight lens fits. Lens decentration increased with loose fits, but was of no predictive value in identifying tight fitting lenses. The outcomes of this subjective assessment were largely supported by a subsequent prospective

study [281]; using objective lens movement analysis, the primary predictive measures of overall lens mobility on the ocular surface were: post-blink movement in up-gaze (“B” with ideal values being 0.25-0.50mm – post-blink movement in primary gaze was less diagnostic), horizontal lag (“L” a change in overlap of the lens onto the limbus of 50-100% [0.5-1.0mm] being ideal – vertical lag was less diagnostic) and push-up recovery speed (“P” a 2-4mm/s or non-sluggish, visible recovery being ideal, with ease of push-up less diagnostic)[281]. The authors demonstrated that a simple 3 point (+, o, -) scale was adequate to grade these characteristics clinically. This approach, combined with a comfort score (0 [poor] to 10 [can’t feel]) and a fitting cross (on which decentration and corneal incursions with the limbus) could be recorded quickly in clinical practice to describe lens fit (Figure 4). Using the soft lens assessment scheme, regardless of lens material, a poor movement on blink (B^-) or push-up (P^-) at least 10 min after application, is an unacceptable fit [357]. As lens movement is principally driven by lens sag rather than just base curve or diameter (section 5.1.2), for a cornea with a near average topography, a brand with a more appropriate sag can be selected, whereas if the corneal sag is more extreme, a custom-made lens should be considered [325].

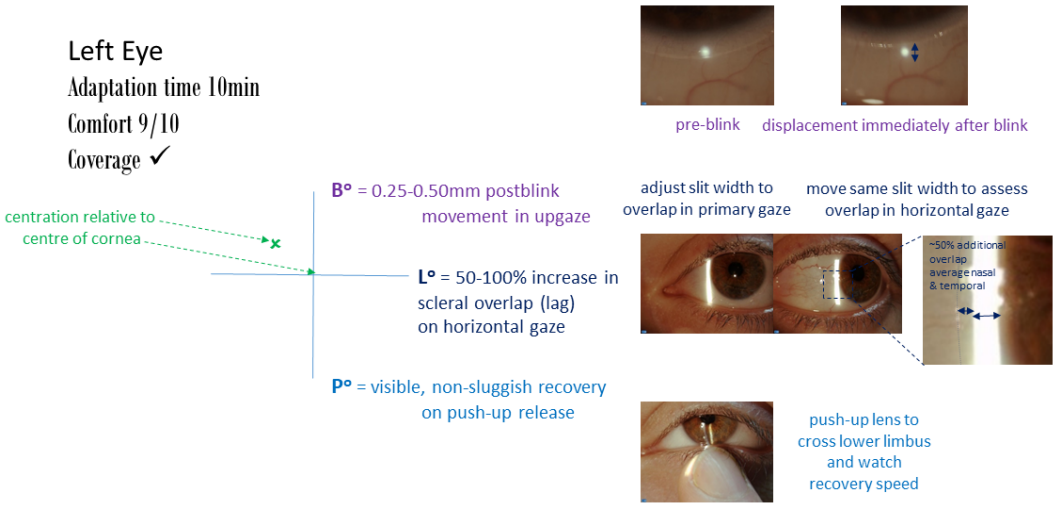

Figure 4: Example of using the soft lens fit scheme to describe a comfortable lens (score 9 out of 10) 10 minutes after application [281], which adequately covers

the cornea, is decentred superior-nasal and whose movement post-blink, horizontal excursion lag and push up recovery speed are optimal.

If a soft toric lens fits well, the orientation of the etched marking should then be assessed, by estimation relative to the known orientation differences between the marks on the lens or rotating a thin slit projected by a slit lamp biomicroscope to align with the lens orientation marks and reading the axis from the protractor [266]. The marks indicate how the lens orientates relative to the lens design rather than the axis of the cylindrical component, which is largely due to the dynamic interaction between the lid anatomy and the lens thickness profile (often referred to as the melon seed effect). Rotation of the lens design can be compensated by the lens ordered (such as Clockwise Add, Anticlockwise Subtract – CAAS), but the rotation of the lens design on a particular eye should stay the same. Rotating the lens with a finger can be used to assess how well the lens re-orientates, which will affect lens performance; hence rotational stability should be assessed as this can affect visual quality and is impact by factors such as eyelid anatomy [351, 359, 360].

5.1.7. Assessment of visual performance with contact lenses

Little research has been conducted on the optimal clinical assessment of visual performance when wearing contact lenses in practice. Aspheric lens designs change the aberrations of light entering the eye, but do not seem to affect visual performance [361, 362] (see CLEAR Optics Report) [339]. Toric and multifocal soft lens wearers have a higher risk of dropping out of lens wear than spherical design wearers so ECPs should ensure that patients wearing these lens designs are happy with the visual performance on dispensing and within the first couple of months of wear [24]. Even corneal astigmatism as low as 0.75 D can impact visual performance [266] and despite some adaptation occurring to reduce this effect with time [265], the difference in visual quality with a toric compared to the mean spherical equivalent should be demonstrated.

For monovision and multifocal lenses, it is traditional to optimise the prescription (most positive powered prescription giving the best distance visual acuity in the dominant eye and adjusting the positive power in the non-dominant eye for best vision at the patients preferred working distance)[363, 364], but there is no research evidence to support this approach. Eye dominance varies with technique used to assess it [101, 365] and the distance of the task [366], but sensory dominance (the

eye in which a +1.50D add impacts binocular distance viewing the most being the dominant eye) most closely matches the presbyopic correction technique and is therefore recommended [101]. Assessing [367] and predicting the visual performance of complex optical designs based on baseline clinical objective measures [292], such as multifocals, with standard visual acuity tests has been suggested to be inadequate. Therefore it is recommended that an assessment of visual performance and patient reported outcomes is undertaken using real-world tasks that the individual typically performs, once the power has been optimised with a spherical over-refraction. In most cases soft contact lenses conform to the corneal surface, but this is not true for high-powered lenses [368], where the on-eye lens effect may be different than anticipated and require correction through over-refraction. Due to the competing images inherent from multifocal lens designs, assessment of contrast sensitivity and glare may be appropriate as well as visual acuity at critical working distances [33].

5.1.8. Future techniques to assess soft lens fitting

Objective techniques for measuring soft lens centration, lag, post-blink movement and push-up recovery speed from image analysis of slit-lamp video, improving on subjective assessment (which tends to underestimate the true values), have been developed [369]. Centration and movement, as well as the lens interaction with the conjunctiva can also be measured reliably by OCT [353, 370].

5.2. Rigid corneal lenses

5.2.1. Physiological and Optical Impact of poor lens fit

The rationale for the need for lens mobility and centration is covered in section 5.1.1. Suboptimal lens fit affects lens comfort [371] and can cause 3- and 9-o'clock staining [372] and corneal warpage [373, 374]. The tear layer between the contact lens and cornea reduces the friction between the surfaces, avoiding significant mechanical interaction. Although the impact of rigid corneal lens mobility on ocular physiology has not been systematically researched, flat fitting lenses result in more adherence with overnight wear [375].

5.2.2. Ocular characteristics affecting lens movement

Unlike soft contact lenses, rigid corneal lens movement is not influenced by lens stretch, but rather by the conformity of the shape profile between the corneal surface and the lens back surface. Gravity also plays a part, so the further back the centre of gravity, the more stable a lens will be [376]. Knowledge of the eccentricity value from

videokeratography allows a better prediction of the base curve to cornea relationship than is provided by only a central corneal measurement; fitting lenses based on the latter resulted in a slightly too steep fit [377]. The palpebral aperture (and the associated tear meniscus height) has also been noted to affect the optimal subjective lens diameter and curvature, but not in a predicable way [378]. Unfortunately, there can be significant variations in lens fit within the tolerances of rigid corneal lens manufacture [379].

5.2.3. When to assess lens fitting

Although the stability of fluorescein intensity can start to decline in as little as 45 seconds post fluorescein instillation, the diagnostic pattern of alignment, steep or flat fit is seen in each meridian by subjective observation from about 30 s to 3 min; hence this is the most appropriate time window to evaluate this element of rigid corneal lens fitting in clinical practice [380].

5.2.4. How to assess lens fitting

Evaluation of rigid corneal lens fit with fluorescein has occurred since the 1930's [381] and the fluorescence is proportional to thickness for low concentrations [382]. Lack of visible fluorescence is thought to indicate the tear layer at that point is <20bμm, so there is close alignment or contact with the cornea [382]. In addition to the fluorescein pattern, other characteristics have been proposed to be important to optimise rigid corneal lens fitting such as centration and coverage, lid attachment and surface wettability [383]. However, there is little evidence in the academic literature as to how these parameters independently contribute to comfortable rigid corneal lens wear with minimal impact on ocular physiology. Unlike soft lenses (see section 5.1.2), there are no studies modelling how lens design, material and anterior eye parameters influence lens movement. Compared to soft lenses, the fit is dynamic with lens movement across the ocular surface and the resulting tear exchange an order of magnitude larger [336, 384].

A scheme to record rigid corneal lens fit has been developed and evaluated based on consensus between 35 experienced contact lens ECPs around the world [385]. Lens design details were recorded together with settling time, discomfort, dynamic centration ("L" if the lens crosses the limbus, "P" if the lens edge encroaches on the pupil, or "C" if the lens remains mobile within the cornea), lens movement on blink using a +2 to -2 scale, and the primary fluorescein pattern (when the lens is centred on the cornea) recording fluorescein intensity on a +2 to -2 scale in the 2 principal

meridians in the central, mid-peripheral and edge zone. This scheme has a number of limitations such as using a different comfort scale compared to soft lens schemes (5-point discomfort vs 10-point comfort scale), fluorescein intensities from alignment (0) to a hard landing touch (-2) are not visible to the human eye and the edge 'intensity' is observed more as a fluorescein edge band width. Hence the authors propose a revision on this scheme with regards to the rating scale for comfort and assessment of fluorescein patterns[#] (Figure 5):

1 Comfort[#]
- rating 0 (extreme discomfort) to 10 (no lens sensation)

2 Coverage
- +2 (width of limbus)
- +1 (~0.5mm smaller than HVID)
- 0 (~1.0mm smaller than HVID)
- -1 (~1.5mm smaller than HVID)
- -2 (≥2.0mm smaller than HVID)

3 Centration
- L (crosses limbus)
- P (crosses pupil in dim light conditions)
- C (contained within limbus)

4 Movement inter-blink
- +2 (>2mm)
- +1 (1.6-2mm)
- 0 (1.1-1.5mm)
- -1 (0.5-1.0mm)
- -2 (<0.5mm)

5 Primary fluorescein pattern (PFP i.e. with the lens centred) in the principal meridians
- [#]Conformity with the Cornea *(where the lens is landing and where it is standing off the cornea).*
    i. +2 (steep)
    ii. +1 (slightly steep)
    iii. 0 (alignment)
    iv. -1 (slightly flat)

v. -2 (flat)

- #Edge width in the principal meridians
  i. +2 (>2mm)
  ii. +1 (~1.5mm band)
  iii. 0 (~1mm band)
  iv. -1 (~0.5mm band)
  v. -2 (no visible band)

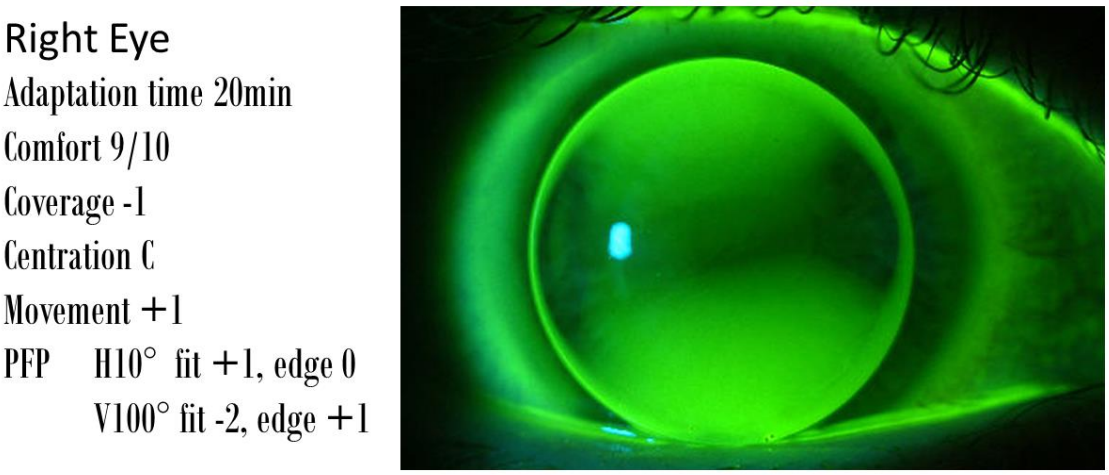

Figure 5: Example of using the rigid corneal lens fit scheme to describe a comfortable rigid corneal lens 20 minutes after application: corneal coverage is 1.5mm smaller than the HVID; does not cross the limbus or expose the pupil; moves 1.6-2.0mm between blinks; is slightly steep in the horizontal meridian (the principal meridian being at 10°) with the lens landing at 3 and 9 o'clock and an edge band of ~1mm; it is flat in the vertical meridian with an edge band of ~1.5mm.

5.2.5. Optimising success

Symptomatology related with dryness and discomfort, during the first 10 days of lens adaptation, may help the clinician to predict who will potentially fail to adapt to rigid corneal lens wear [386]. If presented with genuine interest and a positive and realistic attitude, patients are more likely to succeed in rigid corneal lens wear during

the initial critical period [387]. There is some evidence that larger lenses are more comfortable for adapted wearers [330], but not during adaptation [331].
The minimum parameter change required to observe a clinically significant difference in fluorescein pattern or lens fit on average corneas [388] are presented in Table 4.

Table 4. Minimum parameter change required to observe a clinically significant difference in fluorescein pattern or lens fit on average corneas [388].

Lens parameter	Minimum change required (mm)
Base curve	0.1 (0.50 D)
Overall diameter	0.4
Back optic zone diameter	0.3
Secondary curve radius	0.3
Peripheral curve radius	0.5
Centre thickness (high Dk)	0.02

5.2.6. Assessment of visual performance with contact lenses

Corneal topography can show effects of a decentred lens, which can impact visual performance [373]. The alignment of the back surface of the lens with the cornea can be checked by over-refraction as the tear film shape under the lens creates a ‘liquid lens’ of approximately 0.25 D for a 0.05 mm difference in curvature between the lens back surface and the cornea [373].

5.2.7. Future techniques to assess rigid corneal lens fitting

Topography rigid corneal lens fitting systems have been shown to have ~77 % first success rate and decreased chair-time [388]. Semi-automated measurement of rigid corneal lens movement with a Smartphone has also been demonstrated [389].More advanced instrumentation such as Scheimpflug imaging combined with machine learning conforms well to the fitting decisions made by experts [390] and computer algorithms can achieve 89 % sensitivity and 94 % specificity to predict the evaluation of lens fit by clinicians [391]. However, despite some positive reports [392], 2D spectral domain OCT is less sensitive at detecting apical clearance than the observation of fluorescein pattern [393]. 3D printing of ocular surface models has been utilised to support the teaching of rigid corneal lens fitting [394].

6 Prescribing

6.1 Teaching self-application/removal

Despite poor lens handling being cited as a key contributor to drop our from contact lens wear [24, 25], there is a general lack of evidence underpinning current patient training practices. Conventional clinical practices advocate that a patient demonstrate application and removal of a contact lens a minimum of 3 times prior to dispensing [395], but the origins of this arbitrary figure are unclear. In addition to contact lens drop out, poor lens handling holds the potential to increase risk of contact lens complications; for example, aggressive application and removal of lenses is believed to be directly related to the development of aponeurotic blepharoptosis in soft as well as rigid lens wearers [396]. Additionally, there are multiple reports of ocular lens retention, including instances where lenses have been retained in the eye over many years [154, 155, 397, 398]. Such cases underline the need for better patient education. Nails should be short and artificial nails avoided to reduce bacterial load [399], although there is no evidence in the academic literature of mechanical trauma from nails in contact lens application or removal. While ECPs may provide relevant advice, this is sometimes limited to verbal advice only, and poorly recalled by patients [400]. Poor retention of information may be further compounded by patient anxiety, which is believed to increase during periods of 'communicative interaction' with the clinician [401]. Thus, verbal instructions should ideally be supported with written information [400].

6.1.1 Lens handling amongst children and teenagers

In a survey of adolescents [402], approximately 55 % identified lens application as a key concern when considering contact lens wear. Of those fitted with contact lenses, lens application was reported to be perceived as one of the most difficult procedures, though (soft) lens removal was perceived to be one of the easiest tasks [403]. Yet despite concerns, adolescents are generally successful contact lens wearers; with one report demonstrating that teenagers were able to handle soft contact lenses with the same confidence as spectacles [404].

At the time of dispensing, almost 75% of children surveyed (aged 11- 13 years) felt they needed additional practice with lens handling, but at 6 months this figure had reduced to 13.5% [403]. In a more recent survey of soft and rigid corneal contact lens wearing children, more than 90% reported they either 'usually didn't' or 'never' experienced problems with contact lens application or removal 6 months after fitting,

although 13% of rigid corneal, but no soft contact lens wearers reported difficulties with application after 3 years of wear [405].

An important consideration for optometric practices, when fitting children and teenagers, may be chair time invested in training patients to apply and remove lenses, but the differences seem to be minimal; training times did not change with age in one study [406] , whereas another found teenagers (13-17 years) took, on average, 15 minutes less chair time than younger children (8-12 years)[395].

6.1.2 Lens application and removal

Various devices have been proposed to help with the handling of contact lenses, such as variants of the ubiquitous rubber suction device used for rigid corneal lenses. Most approaches, including those commonly used in clinical practice, suffer from a lack of peer-reviewed evidence. There are no reports in the academic literature of corneal abrasions resulting from lens application or removal. Thus, the safety profile of each approach must rely upon anecdotal evidence and clinical experience. Application and removal are not, of course, the sole aspects of contact lens handling. Patients need to know how to check if a lens is inside out, check for damage, check the expiration date and both understand and adhere to instructions regarding hand hygiene [407], compliance with lens wear and care such as care systems, case cleaning, instructions about sleeping in lenses and no water exposure [408]. Consideration may also need to be given to dexterity issues and disabilities, such as training of patients / carers. The published evidence base for contact lens application and removal is limited. Given lens handling is a key aspect in successful contact lens wear, future research ought to address how this process may be optimised.

6.2 Lens adaptation

To optimise contact lens success, clinicians should provide adaptation advice prior to dispensing contact lenses. There are two key elements to sensory adaptation: neural (such as visual adaptation) and physical (such as lid sensation; lens awareness). However, other factors such as visible changes to ocular physiology [27, 409] or patient personality type and motivation [410] may also influence contact lens acceptance.

Conventional practice has been for neophytes to be advised to gradually build up lens wearing time, based largely on the low oxygen permeability of early lens materials. Recent work [411] has refuted this advice by demonstrating that modern

soft daily disposable lenses can be worn successfully despite the omission of any adaptation period.

Adaptation to soft contact lenses is generally considered to be easier than with rigid lenses [412], with soft lenses associated with better comfort [413], although neophyte soft contact lens wearers may still find lenses less comfortable than those who are adapted wearers [414]. Rigid corneal lenses are often associated with poorer initial comfort [386, 415, 416] and longer adaptation times. One study reported that neophyte rigid corneal lens wearers require 1 week of daily wear or 1 night of overnight wear to achieve a successful level of comfort, similar to that found with soft (experienced and neophytes) and experienced rigid corneal lens wearers [417]. However, other studies suggest on average 2-3 weeks adaptation is required [386, 418]. Identifying a potentially successful rigid lens wearer is challenging, but visual analogue scores [418] and the Pain Sensitivity Questionnaire [419] have been found to help, whereas lid sensitivity did not [419]. Anaesthetic use during rigid lens fitting appointments can improve initial comfort [387, 415], reduce drop outs [387] and reduce anxiety [415], but a survey of UK ECPs (n=451) found less than 1.5 % used anaesthetic regularly and less than one-third (30.3 %) considered it clinically acceptable to do so [420].

6.3 Presbyopia

6.3.1 Multifocal contact lenses

Multifocal lens wearers will initially need to adapt to the optical power profile of the contact lens and may complain of problems such as ghosting and blur, particularly at night when their pupils enlarge [421, 422]. Unadapted wear of multifocal contact lenses may impact sign legibility during night driving [100]. Poor vision is a common reason for discontinuation of multifocal lenses [24, 25, 421, 423-425], but initial changes to vision do not necessarily translate into longer-term problems [426]. An initial visual adaptation period of up to 15 days may be required to help patients acclimate to multifocal lenses [363].

Subjective measures (subjective perceived distance vision and lower subjective loss of contrast) and an absence of astigmatism could act as predictors of presbyopic contact lens success [427]. However, a randomised crossover trial of four commercially available presbyopic contact lenses and monovision, found that pre and post lens wear visual performance, ocular physiology, pupil size, ocular

aberrations, lifestyle and personality were poor indicators of the patient's preferred lens [292].

6.3.2 Monovision

The rate of successful monovision wear is estimated at approximately 60 to 70% [101, 428, 429]. While stereopsis is disrupted [363, 430-432], and is generally worse than with multifocal contact lenses [363, 431], it is not considered a significant cause of failure [428]. Nevertheless, the binocular rivalry and image suppression associated with monovision may require a period of cortical adaptation [433, 434]. Disruption to stereopsis with monovision has been attributed to changes in gait [435]. Thus, ECPs may wish to consider warning patients of such risks and to perhaps exercise caution fitting those who may have pre-existing mobility issues. Problems with vision may become more noticeable for specific occupational tasks such as those involving intermediate working distances [101]. There is also potential for monovision to decompensate existing heterophoria [101], thus it is prudent to make binocular vision assessment part of the contact lens fitting process.

A small (n=13) cohort study showed daytime driving performance with monovision to be unaffected when compared to performance with the participant's habitual correction [102]. However, under night driving conditions a number of visual performance parameters are adversely affected with monovision when compared to single vision lenses or progressive addition spectacles [100].

Other indicators which could help maximise successful monovision fitting and identify ideal candidates include stereoacuity reduction of less than 50 seconds of arc, distance esophoric shifts of less than 0.6 prism dioptres [430]; fitting presbyopes with lower than a +2.50D add [436]; consideration of occupational factors and exercising flexibility when selecting the near add power [429].

6.4 Astigmatism

Astigmatism can be corrected with toric soft lenses with a range of stabilisation methods or rigid corneal lenses. Some prism ballasted toric soft lenses can have vertical prism in the central optic zone. Clinicians should exercise particular care when fitting unilateral astigmats to avoid inducing or exacerbating any existing vertical heterophoria [437, 438], although the potential clinical impact of the differences in vertical prism has not been demonstrated.

6.5 Aspheric Optics

While the optical aberrations of the eye can be altered by fitting contact lenses with aspheric optics, the benefits are minor [439] (see CLEAR Optics Report) [339]. Aspheric lens designs are less effective than toric lenses for correcting low astigmats [440].

6.6 Care regimen

Decisions regarding solution choice may not be governed by efficacy alone (see CLEAR Maintenance Report, CLEAR Material Impact Report and CLEAR Complications Report) [38, 128, 140]. Factors affecting ease of use and comfort (such as solution pH, tonicity, osmolarity and wetting agents) may also be considered. Multipurpose disinfecting solutions (MPDS) are the most commonly prescribed care regimen for reusable soft contact lenses [441-445]. In the mid-2000s, ECP and consumer confidence in MPDS was adversely affected by global product recalls with a subsequent decline in MPDS prescribing [442, 446, 447]. Such doubts seem to have subsided and a recent global survey reported worldwide MPDS prescribing in 2019 as 89 % for reusable lenses [445]. Despite the low prevalence of adoption, one-step hydrogen peroxide cleaning systems tend to promote more favourable compliance, efficacy, comfort and ocular surface outcomes for a wide range of contact lens-wearing patients, avoiding exposure of the eye to preservatives and should be considered by ECPs as a first-line as well as a troubleshooting option for patients [448]. Studies have shown a decreased risk of corneal infiltrative events and/or solution induced staining [37, 449] and a reduction in lid papillae [450] with hydrogen peroxide compared to MPDS. Longer comfortable wearing times have also been reported by silicone hydrogel wearers using hydrogen peroxide compared to MPDS [252]. Older generation polyhexamethylene biguanide-based solutions and some high water lens materials caused solution-induced transient (peak after ~2 hours) corneal staining and discomfort [451]. High water ionic or early generation silicone hydrogel lens materials benefit from solutions with enhanced wetting agents, as may patients with dry eye, ocular surface disease or who report contact lens discomfort [451]. Clinicians should also be aware that lens parameters may be affected through cleaning and immersion of lenses in some contact lens solutions [452].

6.6.1 Cleaning instruction

While the early 2000s saw marketing campaigns claiming ‘no rub’ MPDS, opinion has since shifted [453] and the need for mechanical rubbing to loosen viable organisms from the lens surface established [454]. While the incidence of complications with rigid corneal lenses is lower than with soft contact lenses and much less research has been conducted on them, the risk factors seem to be the same and hence the same compliance issues should be emphasised [455].

Contact lens case contamination is common [456-458], occurs rapidly, and can persist despite the use of multipurpose or hydrogen peroxide-based systems [456]. Diversity of lens case contaminants may be greater than that of the lens [459] and provide an ideal environment for the development of biofilm. Despite clear guidance that tap water should not be used, a recent survey found 24% of ECPs (n=8/33) recommended boiled/warm water for case cleaning [400]. Although many modern soft lens solutions can help inhibit biofilm in storage cases [460, 461], the most effective methods of case cleaning incorporate manual rubbing or wiping [462-464] and once clean, at least in the case of polypropylene cases, air drying.

Contamination of lens cases can be significantly lowered by air drying cases face down rather than face up and by avoiding storage in humid environments such as bathrooms [465]. In some instances, these steps may not be specified by manufacturer instructions [463, 466] thus will need to be outlined separately to patients.

Guidance from professional bodies and solution manufacturers with respect to lens case maintenance may be contradictory [467]; lens case replacement advice varies between 1 to 3 months and few mention the need to rub and store cases face down. Further efforts to minimise case contamination may be achieved by use of non-ridged cases [468] and possibly cylindrical cases [469]. Promising outcomes in limiting biofilm formation have also been reported, through incorporation of various compounds into the materials of polypropylene contact lens cases [470-472], but additional testing is needed to establish their biocompatibility and safety.

6.7 Minimising risks of lens wear (compliance)

Contact lens non-compliance is common, but differs depending on patient demographics [310, 473, 474], psychological traits [475] and contact lens modality [476]. Each non-compliant behaviour carries a corresponding risk for developing ocular complications [477], which may range from minor asymptomatic signs,

compromised comfort and visual experience, to serious sight threatening infections (see CLEAR Complications Report) [38]. Prescribing daily disposable reduced the reliance on some of these compliance steps.

A lack of patient awareness may underlie non-compliant behaviours; there are discrepancies between information ECPs believe to have provided patients versus that which patients recall receiving [400]. A small survey showed the majority of ECPs only provided patients with verbal information during follow-up visits [400]; thus, ECPs could be missing opportunities to reinforce key messages about compliance. Other factors may include financial constraints, purchase of service schemes and environmental influences [27, 96, 478].

6.7.1 Non-modifiable variables

Better compliance has generally been reported in females compared to young males, though this is not always the case [310, 473, 479]. Age does not appear to be a factor in compliance [206, 311, 475, 479-488]. Various studies have also reported on inter-country differences in compliance and its associated risk with Acanthamoeba keratitis development [473, 474] which may be associated with modifiable factors such as water storage and legal requirements, but also to differences in ECP guidance [474].

6.7.2 Modifiable factors

6.7.2.1 Poor handwashing

An absence of proper hand washing can increase the likelihood of contact lens infections by about 4.5 times [477]. Despite the risks, up to about 50-60% of lens wearers admit to a lack of proper hand washing [484, 487]. However, better compliance has been reported for specific population groups such as health care workers (by 70-100%), [479, 488, 489]. Unfortunately there is minimal evidence that education strategies improve handwashing [407]

6.7.2.2 Sleeping in contact lenses

Regular, non-prescribed, overnight wear is estimated to increase the risk of contact lens related infection by about 4 times [477]. While many studies report high compliance (>90%) with respect to sleeping and lens wear,[480, 486, 488], others have found non-compliance of approximately 30% or more [489, 490]. The risk of sleeping or napping in contact lenses may also be affected by environmental influences such as when travelling or having consumed alcohol [96].

6.7.2.3 Improper use of solution

Topping up cases with fresh solution presents about a 2.5 times increase in risk of contact lens related infections [477]. Several studies estimate 10-35 % of lens wearers top up solutions [311, 480, 484, 487, 490, 491]. Risk of infection may also stem from the use of expired lens care products [492, 493].

6.7.2.4 Extending lens use beyond the replacement interval

There are, of course, differences in the reported compliance rates for lens replacement, but the general consensus remains that compliance is better with daily disposable lenses [310]. Nevertheless, one report showed about 9 % of daily wearers failed to adhere to replacement schedules [310, 494]. The main reasons for lens reuse were to save money or that the patient had run out of lenses [310]. Previously, tracking contact lens orders was suggested as a means of monitoring contact replacement frequency [495], but with the advent of online purchasing and changes in consumer laws, the usefulness of such approaches may be somewhat reduced. Extended use of lenses beyond their recommended replacement frequency leads to a higher rate of corneal abrasions [496]..

6.7.2.5 Inadequate case cleaning

Inadequate case cleaning can increase the risk of a contact lens related infection by about 4 times [477]. The steps for correct case care are outlined in section 6.6.1. Not only is poor case cleaning common [466, 485, 489], but a study found two-thirds of individuals used tap water to clean cases [311]. Poor cleaning may be further compounded by a lack of regular case replacement [311, 490, 492]. Poor case care could, in part, be attributed to the mixed messages delivered by ECPs [400], professional and regulatory bodies and manufacturers [467].

6.7.2.6 Failure to rub and rinse lenses

Rubbing lenses followed by rinsing helps to loosen microorganisms and is considered more effective than rinsing alone [454, 497, 498]. Failure to rub and rinse may increase risk of a contact lens infection by about 3.5 times [477].

6.7.2.7 Use of tap water and water sports

Use of tap water, swimming and water based sporting activities, and showering/bathing with contact lenses have been associated with increased risk of ocular complications, and of particular concern is the increased risk of Acanthamoeba keratitis [499, 500] [125, 501, 502]. Despite its sight threatening potential, showering with lenses appears to be a common occurrence with estimates

ranging between 29-86 % [485, 489, 503, 504]. Swimming with lenses is also common, estimates range from 25-68 % [489, 490, 492, 503, 504].
Rigid corneal lens wearers are considered more likely to use water for lens storage and rinsing [503], but complications can still arise [455]. Unfortunately tap water is also used by some individuals for case cleaning (see section 6.7.2.5) and there are other ways tap water can be introduced into the eye; for example, more than 50 % of teenagers surveyed admitted to wearing lenses they had dropped in the sink [492]. It has been suggested that discrepancies in guidance and the use of water imagery in contact lens marketing may be a source of confusion for some patients [125]. A “no-water” infographic on contact lens cases improves overall water-contact behaviours and reduced storage case endotoxin (a toxin of Gram-negative bacteria, also called lipopolysccharide) [505].

6.8 Online purchasing

The frequency of eye examinations is lower amongst individuals who purchase lenses exclusively online or via the internet/telephone, although the lack of regular eye examinations does not necessarily translate into an increased risk of non-compliance [504, 506]. However, within some demographics there appears to be a growing number of self-taught contact lens wearers [504], who may be at higher risk of non-compliance. Unregulated purchasing behaviour of contact lenses is associated with ocular complications such as a higher rate of infection and microbial keratitis [67, 507, 508].

7. Aftercare

7.1. Frequency

A comprehensive recent review [477] recommended routine aftercare visits every 24 months for soft daily disposable, every 12 months for soft daily reusable and rigid daily wear, and every 6 months for soft and rigid overnight wear. However, they noted these recommendations may need to be adjusted when rapid rates of refractive change are anticipated, such as every 6 months for progressive myopes and every 12 months for advancing presbyopes. The frequency of follow-up (in-person or planned telephone follow-up by practice staff) for new lens wearers should be more frequent due to the rapid drop out from lens wear that can occur over the first 2 months after fitting [24]. Telehealth approaches can be used to remotely triage

complications, but current technology does not allow an adequate assessment of anterior eye health [509].

7.2. Routine

Aftercare visits should focus on changes in experience from previous visits, but also review any changes in environment, work/hobbies and health that could impact future lens wear (Table 5)[510]. Lens brand and care system recall is generally poor, but is much enhanced using photo-prompts [476]. At least in the past, the use of fluorescein in aftercare appointments across European countries has been poor with little valid justification [511]. The tear film should be examined as its homeostasis can be affected by many factors including ageing, so may lead to discomfort and the need to review contact lens factors even after a period of successful lens wear [512]. Lid eversion is also required to inspect the palpebral conjunctiva [153].

7.3. Optimising compliance / minimising drop out

The principal reasons for discontinuation of lens wear are reported as discomfort, dryness, lens awareness, red eyes, vision related problems and lens handling [25, 27, 333, 409, 416, 513, 514]. Vision related factors affecting discontinuation may be more common amongst specific lens types such as new toric and multifocal lens wearers or low prescriptions [25]. Compliance is essential for minimising the risk of complications and drop out from lens wear. Compliance may be worse in young males [473] and those with higher risk-taking propensity [475]. Ocular symptoms should be carefully assessed (section 2.3.1) and improved if possible [141]. Key issues linked to contact lens complications or infections include water contact with lenses, sleeping in lenses, improper case care and cleaning, failure to wash hands, wearing lenses beyond the recommended modality duration and not including a rub and rinse step prior to storage of lenses [125, 251, 473, 476]. Although swimming while wearing contact lenses is not recommended [98], disposal of lenses after swimming and/or the use of goggles may help to reduce the bioburden of swimming in contact lenses if wearers decide to wear them for water sports [99].

Not remembering instructions is a common justification given for non-compliance [515]. Information may not be retained at the initial visit due to anxiety, when learning retention rates are low (but better if physical practice

is involved) and will vary according to a patient's education / cognitive level; patient compliance may also be affected by conflicting advice from others after the visit through social influence [408, 516].

Many strategies to improve compliance have been proposed; some have not formally been tested, such as providing written rationale for the lens care measures suggested [408, 517] or promoting the gain from performing an action such as improved vision and comfort from replacing lenses when scheduled (gain-framed) rather than advising that they might experience poor vision and discomfort if the patient is non-compliant (loss-framed). This "Prospect Theory" approach has been successful in smoking compliance [518]. Of those studied, the strategies employed have generally not been successful, such as the implementation of a regular review exercise [519], combining written and oral instructions [482] (although this can improve case cleaning compliance [520], intense instruction [521] and reduced cost care products (although re-instruction enhances compliance [522]. Even having a significant health condition does not appear to affect patient compliance [523]. However, compliance is significantly better in those prescribed with daily disposable lenses [473], perhaps due to less complex requirements.

7.4. Managing complications

Complications resulting from modern contact lens wear relate to hypoxia (microcysts and vacuoles, folds, striae, oedema, corneal thinning, neovascularisation, endothelial blebs and polymegethism, warpage), mechanical (such as blink rate/completeness, ptosis, meibomian gland dysfunction, dry eye, lid wiper epitheliopathy, an acute red eye, papillary conjunctivitis, staining, corneal warpage), toxic (papillary conjunctivitis, staining) or microbial (such as infiltrates and microbial keratitis) aetiologies [524] (see CLEAR Complications Report) [38]. Temporarily discontinuing lens wear should be considered to allow the ocular surface to heal before refitting lenses.

7.4.1. Vision

Vision is a key aspect of refractive correction and is related to contact lens drop out [25]. A reduction in visual quality between blinks could be due to dry eye (manage the dry eye disease and consider non-preserved lubricants [525]) or poor lens wettability (consider lens material and cleaning regimen). Optimal visual correction may require toric or presbyopic lens corrections

(section 5.1.7) and rigid corneal lenses should be considered for irregular corneas (see CLEAR Medical Uses Report) [129].

7.4.2. **Discomfort**

Discomfort can result from infection, exposure to toxins and mechanical interaction with a lens (see sections 7.4.4 to 7.4.6). Once the lens fit is optimised, management options include: changing or eliminating the care solution/system; adjusting the replacement frequency; changing the lens material and/or design; dry eye management including tear film and dietary supplementation; reviewing medication; and improving the environment [141].

7.4.3. **Hypoxic complications**

Hypoxic complications of lens wear are largely overcome by fitting silicone-hydrogel materials [477] and daily disposable lenses [255], although lens diameter and movement will contribute for rigid corneal lenses (see section 5.2.1).

7.4.4. **Mechanical complications**

Mechanical problems can be addressed by selecting a lens material with a lower modulus and enhanced surface lubricity properties, ensuring safe application and removal techniques and optimising lens fit (especially the interaction between the lens and lid margin for a rigid corneal lens) [305, 306, 526]. Tear supplementation, enhancing the environment and treating any ocular surface disease (including meibomian gland dysfunction and blepharitis) should also be considered [141] along with reviewing lens handling (section 6.1).

7.4.5. **Toxicity issues**

Toxic or hypersensitivity complications can be reduced by careful matching of lens and care solution properties, changing to a solution with a different preservative, changing to daily disposable contact lenses and/or managing allergies [58, 451].

7.4.6. **Microbial complications**

Microbial complications are largely related to compliance (see section 7.3), not sleeping/napping with lenses in-situ and are less common with daily disposable soft or rigid corneal lens wear [527, 528]. The use of daily

disposable lenses and improved storage case hygiene may limit more severe keratitis [67, 69, 529]. Hand hygiene and lens handling procedures should be reviewed, as poor hygiene has been associated with increased bacterial bioburden on lenses [407, 481], which in turn can result in a higher risk of corneal inflammatory events [74-76]. In the future, tear film biomarkers may help predict patients that are likely to have microbial complications with contact lens wear [530].

Table 5: Recommended aftercare routine

Update

- The date of last full eye examination and aftercare
- Reason for visit - any issues with lens wear / precipitating factors
- Comfortable and average wearing time
- Any changes in health or medication
- Any changes in work/hobbies, driving or environment
- Spare spectacle visual correction in case of eye infection or systemic viral infection [531]
- Any challenges with compliance such as napping or swimming/showering in lenses; case cleaning for frequent replacement soft and rigid corneal lens wearers

Current Aspects

- How long have the lenses been worn today and age of current lenses
- Check lens and care system brand
- Ask patient to demonstrate cleaning regimen; observe case cleanliness
- Vision with contact lenses and over refraction
- Check lens fitting (sections 5.1.6 and 5.2.4) and wettability/deposition
- Observe patient washing and drying hands
- Observe patient removing lens
- Check anterior eye health and documentation with a slit-lamp biomicroscope [138]
    - Tear film assessment
    - Lid eversion [153] to inspect palpebral conjunctiva
    - Corneal staining with fluorescein illuminated with an appropriate blue light and observed through a yellow band-pass filter [180]
- Corneal topography if needed (rigid corneal lens wearer, unexplained changes in vision/or prescription etc)
- Explore history and symptoms further if necessary
- Manage complications (see section 7.4)
- Consider upgrading/optimising lens (material, design or replacement frequency) and/or care system
- Observe patient reapplying lens (if appropriate)

Reiterate

- Reason for visit and how issues have been addressed
- Reteach lens application and removal if necessary
    - Compliance [310]
    - Hand washing with soap and dry hands
    - Replace lenses when scheduled
    - Sleeping in contact lenses
    - Inappropriate lens purchase and supply
    - Exposure of lenses to tap water (including showering and swimming)
    - Failure to clean and replace lens cases regularly
    - Inappropriate use of care systems
    - Potential future vision changes if approaching presbyopia
    - Children/young adults – myopia progression rates, learning to drive etc
    - Follow ECP recommendations for lens wear if unwell with flu/cold symptoms
- Next aftercare and eye examination dates

Conclusions

This report on evidence-based practice has reviewed the current literature on contact lenses that informs contemporary clinical practice, from taking history and symptoms and the anterior eye examination, to prescribings lenses and evaluating fitting along with subsequent aftercare. The report has identified areas where more research might be needed to optimise the success, satisfaction and safety of contact lens wearers. While evidence-based practice is regarded as the gold standard for clinical practice, there are some limitations. For example, trial designs may not be relevant for all management situations, individuals can vary from population norms, statistical differences are not always clinically meaningful, and a patient's environment and values need to be considered. However, ECPs owe a duty of care to their patients to apply an evidence-based approach in order to provide the best outcomes on the safe wear and care of contact lenses, informed by credible, scientific data.

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