# Contact Lens Evidence-based Academic Reports (CLEAR)

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Since contact lenses were invented in 1887, innovations have included advances in optical design, material, care systems, wear modality, lens size, lens shape and applications. Over 19,000 peer reviewed academic papers on the contact lenses have been published. The Contact Lens Evidence-based Academic Reports (CLEAR) follow the exemplary work of organisations such as the Tear Film and Ocular Surface Society dry eye[1], meibomian gland disease [2], contact lens discomfort [3] and dry eye II [4] workshops and the International Myopia Institute white papers on myopia control [5] in collating and appraising the academic literature in an ocular field of interest. CLEAR represent the work of nearly 100 multidisciplinary experts in the field, who set out to critically review, synthesise and summarise the research evidence on contact lenses to date; this serves to inform both clinical practice, manufacturing innovation and future research directions.

**The Process**

CLEAR was conceived by James Wolffsohn in June 2019 and the British Contact Lens Association (BCLA) executive committee gave their backing in September 2019. Philip Morgan was elected as executive vice-chair and the name for the initiative, report topics and leading experts as chairs (Table 1) were agreed with Cheryl Donnelly, the then Chief Executive Officer of the BCLA. Sponsors were sought to cover the costs of production and publication, but had no input concerning the scope or content of the reports.

Interested clinicians and scientists were invited to apply to working groups and experts in the field (identified by the BCLA and report chairs) were selected to contribute to one of the reports that best fitted their area of expertise and/or practice. An inclusive approach was adopted, while limiting the number of participants from any one research group or company on any single report to ensure a balanced representation.

The report committees, led by their chair, developed an outline of the subtopics to be covered in their report in January and February 2020 and these were reviewed in March to minimise gaps and overlap. The chairs allocated the subsections of their report to members of their committee and writing commenced in April; these were returned to chairs by the end of May to collate and review. This version was reviewed and edited by all committee members by August 2020. From August to September the refined reports were sent to all CLEAR members for review. Their comments were sent back to chairs for addressing (in a similar fashion, but more extensively than would occur through a typical peer review academic journal process) by November 2020. Simultaneously, a medical illustrator was commissioned to draw the necessary original artwork for the reports. The harmonisers (Table 1) met (virtually due to COVID-19) to agree on the standardisation of terminology, abbreviations, formatting, remaining areas of report overlap and abstract development. The finalised reports were submitted to the BCLA's journal Contact Lens and Anterior Eye in January 2021.

| **CLEAR Report** | **Chair** | **Harmoniser** |
|---|---|---|
| Anatomy and physiology of the anterior eye[6] | Laura Downie | James Wolffsohn |
| Contact lenses wettability, cleaning, disinfection and interactions with tears [7] | Mark Willcox | Lyndon Jones |
| Effect of contact lens materials and designs on the anatomy and physiology of the eye [8] | Philip Morgan | Mark Willcox |
| Contact lens optics [9] | Kathryn Richdale | Philip Morgan |
| Orthokeratology [10] | Stephen Vincent | Lyndon Jones |
| Scleral lenses [11] | Melissa Barnett | Philip Morgan |
| Medical use of contact lenses [12] | Deborah Jacobs | Fiona Stapleton |
| Contact lens complications [13] | Fiona Stapleton | James Wolffsohn |
| Evidence-based contact lens practice [14] | James Wolffsohn | Fiona Stapleton |
| Contact lens technologies of the future [15] | Lyndon Jones | Mark Willcox |

Evidence-based practice can be defined as the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients"[16]. It involves integrating the best available, and clinically relevant, scientific research evidence with a clinician's expertise and an individual patient's values and environment (see CLEAR Evidence-based Practice Report) [14]. Evaluating scientific research findings and using them to make the best clinical decision for patients is a key aim of all evidence-based practice, including fitting and managing contact lenses. The quality of research evidence generally comes from the study design [14]. Formal risk of bias tools also exist to assist clinicians with appraising the quality of an individual study rather than simply relying on the evidence level [17].

Larger cohort studies are considered more informative than expert opinion, case reports or case series and are generally used for epidemiological studies. For management decisions, randomised controlled trials are considered to provide the highest level of evidence-basis; they limit unconscious bias through masking (ideally of the participants and clinical researchers) as to which treatment they are getting and randomise participants to treatment and control (or placebo) options. Systematic reviews, collate, appraise and synthesise evidence from multiple papers that fit pre-specified eligibility criteria, to answer a specific research question. Hence they are generally considered a higher level of evidence than individual research papers and are often used to inform professional clinical guidelines, which interpret and contextualise their finding to guide and regulate clinical practice. A number of international, evidence-based reviews that inform elements of contact lens practice have been conducted recently, based on a consensus-building workshop approach [5, 18-20].

Individual studies within a given level of the hierarchy level (such as Randomised Controlled Trials) may differ in their 'quality', due to differences in their study design, tests performed, cohort selection and participant numbers. Some contact lens research employs study designs that are not explicitly described in hierarchical models of research quality or common in general medicine; these include cross-over, contralateral and monadic designs which are often used to understand the clinical performance of different lenses and care products [14]. While systems for rating the level of evidence of individual papers or hypotheses have been developed, they are not robust enough to

systematically apply [21], hence the approach taken in CLEAR is to present summaries of the research findings and to critically appraise the evidence on relevant topics.

**Approach to terminology**

Inconsistent terminologies have developed within the field of contact lenses that can be confusing to students, clinicians, researchers and other stakeholders. Several anatomical terms, named after individuals, such as Bowman's and Descemet's membrane, have been renamed the anterior and posterior limiting membrane by the Federative Committee on Anatomical Terminology (FCAT)[22] and these have been adopted by CLEAR. Whilst the FCAT also renamed 'Meibomian glands' as 'tarsal glands', this terminology does not logically follow other terms in the field. Meibomian glands produce meibum, however the term tarsal is only attributed to a single plate that is not the sole location of the glands; lacrimal glands are named after the secretion they produce and not their location. Hence, 'meibomian' gland terminology, also used in the dry eye disease literature, has been retained in the CLEAR reports. Likewise, tarsal conjunctiva is a region of the palpebral conjunctiva rather than an appropriate term to describe this tissue on the underside of the eyelids.

The term rigid gas permeable lenses (RGP) was developed to differentiate the first oxygen-permeable hard/rigid lenses from earlier oxygen impermeable materials, such as poly methyl methacrylate. In more recent times, this has been truncated to simply 'gas permeable' or 'GP' by some authors as 'rigid' was felt to suggest to potential patients that these lenses would cause discomfort [23]. However, all modern contact lenses (soft or rigid) are 'gas permeable' and scleral lenses are also RGPs, yet the term is generally used to describe exclusively corneal lenses. Hence, a poll of CLEAR members was conducted and 62% were in favour of adopting a change in terminology to 'corneal lens', 18% against (mainly as they felt soft lenses also 'landed' on the cornea) and the rest (21%) were equivocal. Since their 'rigidity' is a key feature of the optical and health benefits of these lenses, the term 'rigid corneal lens' was adopted throughout CLEAR. Scleral lens terminology has recently been redefined [24] and CLEAR has accepted this approach, and thus all rigid lenses that vault the cornea are termed 'scleral lenses'. While regulatory terminology denoted extended wear as 7 days and 6 nights, and continuous wear as up to 30 days and 29 nights [25], these definitions overlap and are used interchangeably in the literature. Research suggests that there are no marked clinical differences between these modalities [26]. Hence the terminology 'planned' or 'sporadic' 'overnight wear' is more appropriate for clinical use and has been adopted in these reports.

The CLEAR harmonisers carefully considered the use of abbreviations throughout the reports, using the principles articulated in Cochrane reviews [27] that they should be used sparingly and only if they are widely known across the broad readership, are used frequently and enhance readability. Two word abbreviations were only adopted where the abbreviation is used more commonly than the words they represent. It is hoped this general list of terms will assist standardisation in future publications in the field and to support new ECPs. Standard unit and country abbreviations are not articulated in full due to these being commonly accepted terms.

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| BAK | Benzalkonium chloride |
| BOZR/BOZD | Back optic Zone Radius/Diameter |
| CIE | Corneal infiltrative event |
| CLD | Contact lens discomfort |
| CLIDE | Contact lens induced dry eye |
| CLPC | Contact lens-induced papillary conjunctivitis |
| Dk/t | Oxygen permeability/transmissibility |
| ECP | Eye care practitioner |
| EDOF | Extended depth of focus |
| EDTA | Ethylenediaminetetraacetic Acid |
| HEMA | 2-hydroxyethyl methacrylate |
| HPMC | Hydroxypropyl methylcellulose |
| HVID | Horizontal visible iris diameter |
| LIPCOF | Lid-parallel conjunctival folds |
| LWE | Lid wiper epitheliopathy |
| MGD | Meibomian gland dysfunction |
| MK | Microbial keratitis |
| MPDS | Multipurpose disinfecting solution |
| PEG | Polyethylene glycol |
| PHMB | Polyhexamethylene biguanide |
| PMMA | Polymethyl methacrylate |
| PoLTF | Post-lens tear film |
| PVA | Polyvinyl alcohol |
| PVP | Polyvinyl pyrrolidone |
| SICS | Solution induced corneal staining |
| SiHy | Silicone-hydrogel soft contact lens |
| VPA | Vertical palpebral aperture |

## CLEAR

The collaboration between experts in the field of contact lenses and the anterior eye has been inspiring and productive, despite the enforced 'virtual' nature of the interactions. These reports bring together the evidence, and consensus where this was lacking, to inform clinical practice, identifying areas where further research is needed and determining where there are opportunities for new innovations from industry.


## Acknowledgements

The CLEAR initiative was facilitated by the BCLA, with financial support by way of Educational Grants for collaboration, publication and dissemination provided by Alcon and CooperVision.


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