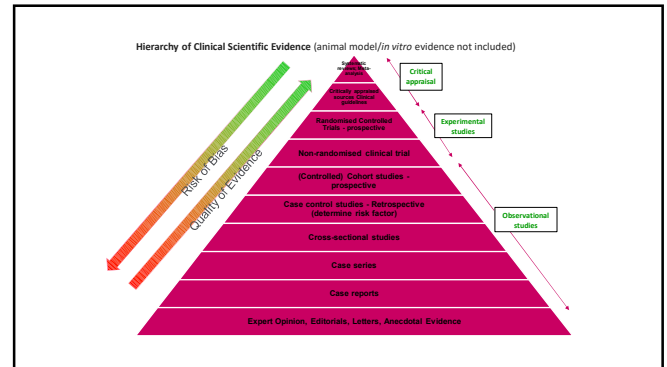


Aston University  
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## Safety & Compliance Speciality Soft Lenses

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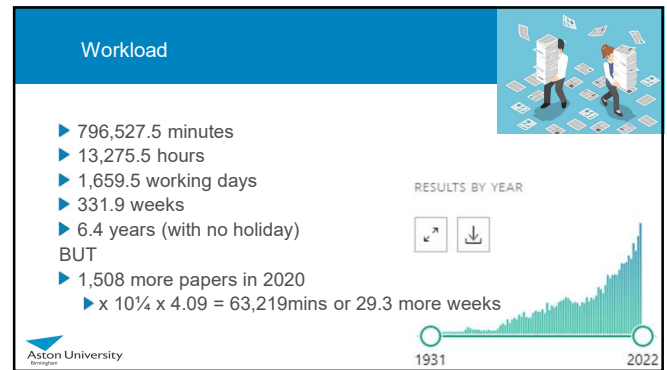
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~19,000 papers X average length 10¼ pages  
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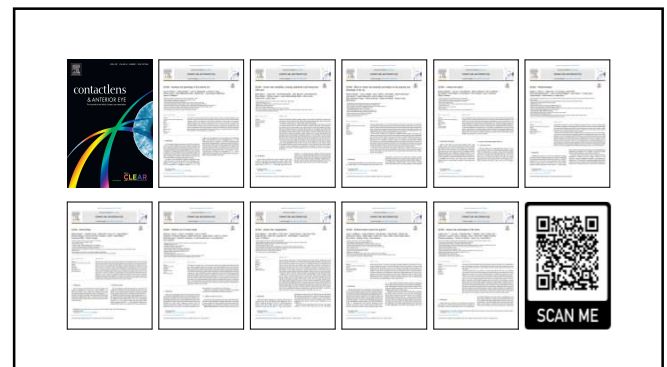
BCLA  
**CLEAR**  
GLOBAL Contact Lens Evidence-based Academic Report

Executive Chair: James Wolffsohn  
Executive Vice-Chair: Philip Morgan

- Anatomy and physiology of the anterior eye -
- Biochemistry of lens materials, coating, comfort drops and solutions -
- Effect of lens materials/design on the anatomy and physiology of the eye -
- Orthokeratology -
- Scleral lenses -
- Contact lens complications -
- Medical use of contact lenses -
- Contact lens optics -
- Future applications of contact lenses -
- Evidence based contact lens practice -

Dr Laura Downie  
Prof Mark Willcox  
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Professor Pauline Cho  
Dr Melissa Barnett  
Professor Fiona Stapleton  
Assoc Prof Debbie Jacobs  
Dr Kathryn Richdale  
Professor Lyndon Jones  
Professor James Wolffsohn

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## Complications with bandage soft lenses

- Very few reports
- How do you differentiate complication from pathological eye
- Risk vs benefit
- Duty of care to provide best practice from knowledge of optimal management of normals

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## CLEAR Clinical guidelines

<https://bcla.org.uk/common/Uploaded%20files/CLEAR/BCLA%20CLEAR%20summary.pdf>



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## Implications for Clinical Practice

[illegible]

### 1. History & symptoms: considerations for wear

This initial step is essential to help inform lens recommendation, assess likelihood of success and the presence of factors for complications. It should include: reasons for wear, lifestyle, hobbies, current spectacle prescription, ocular and systemic health information, medications, past contact lens use.

### What is known

- **Wearing** can impact the chance of achieving successful, comfortable contact lens wear. Identification of which can inform patient counseling, lens recommendation and management of any co-existing pathology.
  - Baseline symptoms of ocular discomfort without lens wear; best reviewed in conjunction with tear quantity and quality measures<sup>2A</sup>
  - Medications that can impact the tear film see: **CLEAR** Interventions based on clinical evidence
  - Presence of Demodex (associated with higher dropout)<sup>3</sup>
- Presence of risk factors for corneal infiltrative events (CIEs) can inform recommendation of daily disposable, rather than reusable contact lenses<sup>4</sup>. These are:
  - Patient age (<25 years; >50 years), prior history of CIEs, increased lid margin bioburden from blepharitis or MGD, certain health conditions (thyroid disease, self-reported poor health), history of smoking, poor hygiene

### What is not known

Other than consideration of oxygen transmissibility for high refractive error or overnight wear, little evidence is available to

## 2. Anterior eye exam

This is required prior to fitting contact lenses and at each aftercare visit and should include: assessment of anterior eye physiology and tear film using slit lamp biomicroscope and diagnostic dyes, plus ocular topography.<sup>10</sup> Digital image capture should be considered to enhance record keeping, grading, management, and patient education.<sup>10</sup>

### What is known

- Video topography provides a more complete profile than keratometry alone and is recommended as a baseline measure to determine whether the eye could be fit with standard (commercial) lenses, to detect conditions such as keratoconus and is required when fitting ortho-K
- A grading scale should be referred to at every visit, for key metrics such as bulbar, limbal and palpebral hyperaemia and palpebral roughness (best imaged with fluorescein instilled), along with recording via appropriate diagrams, the extent of conjunctival conjunctivitis
- Test order should be from least-to-most invasive, starting with the tear film, and finishing with addition of diagnostic dyes, lid eversion and meibum assessment

### What is not known

- Aetiology of lid-parallel conjunctival folds (LIPCOF) remains unknown; model proposed of increased friction between the eyelid and ocular surface or contact lens.<sup>11</sup> They are considered a fair to significant predictor of contact lens discomfort<sup>20</sup>
- A relationship has not been established between lid wiper epitheliopathy (LWE) and contact lens discomfort<sup>12</sup>



- Conjunctival damage and LWE are best viewed 1-5 mins post 2 drops from 2 paper strips installation of lissamine green retained on the strip for at least 5 secs to increase the concentration. If using fluorescein, wait 3-5 minutes before viewing. Care should always be taken to avoid touching the upper lid wiper area while evert the lid

### 3. Lens selection

Lens selection depends on many factors. Desired wearing schedule and refractive status can inform the type of contact lens as summarised in table 1. Cosmesis, as an alternative to spectacles, is the most common reason to wear lenses, but in some cases medical need may drive their use, with reasons including high refractive error, irregular astigmatism and ocular surface disease.<sup>6</sup>

**CLEAR** Medical use of contact lenses

- What is known for soft lens selection
  - Corneal topography alone does not inform soft lens fit because fit is dependent on the sagittal height of the cornea and the corneal and non-produced soft lens curves (back optic zone radii, BOZR) can fit only 75-90% of eyes<sup>10</sup>
  - Comfort can be affected by the coefficient of friction, and more so by the lubricity of material,<sup>14,15</sup> and is not linked to increased oxygen transmissibility<sup>16</sup>
  - Daily disposable use reduces OIE risk,<sup>14,17</sup> severity of microbial keratitis (MK),<sup>18,19</sup> and ocular allergy symptoms<sup>20</sup> compared to reusable soft contact lenses
  - For MF fit sensory decisions should be determined to inform initial lens selection, and manufacturers report high MF fit success when lens fitting guides are followed

### What is known for RCI selection

- Compared to soft lenses, RCLs may be better tolerated by patients with dry eye or papillary conjunctivitis,<sup>22</sup> and fewer contact lens-related complications occur with RCLs
- Corneal topography (typically keratometry) is used for BOZR selection
- Some evidence shows that larger diameter RCLs are more comfortable for adapted wearers,<sup>23</sup> but do not aid the adaptation process

See Scleral and Orthokeratology report

**CLEAR** Clinical Issues      **CLEAR** Collaboration/Technology

[illegible]

### What is not known

- Very little evidence published that informs lens diameter choice although it is thought important to avoid mechanical insult of the limbal area by the lens edge
- There is no literature suggesting vertical palpebral aperture (VPA) is relevant to contact lens fitting
- Past work has not been shown clearly to affect the performance of multifocal soft contact lenses<sup>14</sup>
- Key point: There is no clear association between wettability and comfort. The exact role of interactions between material, tear film and solutions, and whether biocompatibility can be improved by altering them remains debatable<sup>15</sup>

Table 3

[illegible]


[illegible]

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4. Evaluation of fitting
  - Accurate assessment of lens fit is a crucial step in any contact lens examination because poor fitting lenses can impact optical performance and comfort performance which in turn is associated with drop out. soft lens fit should be accurate assessed after 10 mins (figure 2), along with measures of visual performance.
- What is known for soft lenses
  - Assess rotational position and stability of toric lenses
  - MFR: Vision assessment is recommended using real-world tasks. Predicting visual performance of complex optical designs (MFR) with theoretical visual acuity tests have been questioned to be inadequate. Over MFR design does not work for all patients, and initial fit performance may not predict long-term performance.
  - Toric and MFR designs perform well visually, with little difference in high contrast distance vision with some soft MFR compared to single vision lenses **CLEAR** (see next slide)
- What is known for RCLs
  - Optimum window for observation of fluorescein pattern is 30 seconds to 3 minutes post-installation
  - Revised scheme for standardised observation of RCLs proposed that includes rating subjective comfort, and grading lens coverage, centration, movement and fluorescein fitting pattern<sup>26</sup>

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## Care Regimen



**Contact Lens and Solution Type**



**CLEAR - Contact lens versatility, cleaning, disinfection and immersion with CLEAR**

**Black Widow™ - Super Dry™ - Vision Maintenance® - Aqua-Maintenance® - Clear Care® - Clear Care Rewet™ - Vision Maintenance Rewet™ - Vision Maintenance Rewet Plus™ - Hydro Eye™ - Optima™**

- ▶ Choice not governed by efficacy alone [Willox et al., 2002]
  - ▶ Also ease of use and comfort (e.g. solution pH, tonicity, osmolality and wetting agents)
- ▶ Multipurpose disinfecting solutions (MPDS) most commonly prescribed (~89%)<sup>[441–445]</sup>, despite mid-2000s recalls <sup>[442,446,447]</sup>
- ▶ One-step hydrogen peroxide cleaning systems promote more favourable compliance, efficacy, comfort and ocular surface outcomes, avoiding exposure to preservatives <sup>[448]</sup> - decreased risk CIEs/SICS <sup>[37,449]</sup>, reduced lid papillae <sup>[450]</sup> and longer SiHy comfortable wearing times <sup>[252]</sup>; more than troubleshooting??
- ▶ Older generation polyhexamethylene biguanide-based solutions and some high water lens materials caused SICS (peak after ~2 h) and discomfort <sup>[451]</sup>
- ▶ High water ionic or early generation SiHy benefit from solutions with enhanced wetting agents, as do patients with dry eye, ocular surface disease or CLD <sup>[451]</sup>

Lens parameters may be affected through cleaning and immersion of lenses <sup>[452]</sup>

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## Care Regimen

- ▶ Rub and rinse essential [454]
- ▶ Case contamination is common [456–458], occurs rapidly, and can persist despite the use of MPDS/ hydrogen peroxide-based systems [456]. Diversity may be greater than that of lenses [459]
- ▶ Many modern soft lens solutions help inhibit biofilm in storage cases [460,461], and most effective case cleaning incorporate manual rubbing or wiping [462–464] and once clean, at least in the case of polypropylene cases, air drying (upside down) in non-humid environment [465]
- ▶ Tap water avoidance still needs promoting despite guidance from professional bodies and manufacturers contradictory on replacement freq & need to rub [467].
- ▶ Future improvements: non-ridged [468] / cylindrical cases [469]; limiting biofilm formation with compounds embedded into polypropylene CL cases [470–472]

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## Minimising Risks (compliance)

- ▶ Non-compliance common, but differs with patient demographics [310,473,474], psychological traits [475] and contact lens modality [476].
- ▶ Related complication risks also vary [477] (Stapleton et al., 2021)
- ▶ DD reduced reliance on some compliance steps.
- ▶ Discrepancies between information ECPs believe to have provided patients versus that which they recall receiving [400].
- ▶ Other factors include financial constraints, purchase of service schemes and environmental influences [27,96,478].
- ▶ **Non-modifiable variables**
  - ▶ Generally female sex [310,473,479], but not age [206,311,475,479–488]
  - ▶ Country (Acanthamoeba keratitis) [473,474] due to water storage and legal requirements, but also ECP guidance [474].



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## Minimising Risks (compliance)

**BRIGHT EYES  
COMPLETE YOUR LOOK  
DON'T OVERLOOK**  
Healthy contact lens wear and care

- **Modifiable factors**
  - Poor handwashing: ~4.5x [477], but ~50–60% admit to failures [484,487]. Better in health care workers (by 70–100%) [479,488,489], minimal evidence education strategies improve [497]
  - Overnight wear: ~4x [477]
  - Improper use of solution: ~2.5x (topping up) [477], 10–35% of wearers top up [311,480,484,487,490,491]. Also expired lens care products [492,493]
  - Extending lens use beyond the replacement interval – DD better, but ~9% of daily wearers reuse [310,494] to save money or had run out of lenses [310]
  - Inadequate case cleaning: ~4x [477]. Common [466,485,489] & 2/3<sup>rd</sup>s use tap water [311] Compounded by lack of regular case replacement [311,490,492]
  - Failure to rub and rinse lenses: ~3.5x [477]
  - Use of tap water and water sports: risk of Acanthamoeba keratitis [499,500,125,501,502] – no water graphic improves [505]
  - Online purchasing: not conclusive [504,506], but unregulated purchasing behaviour associated with ocular complications [67,507,508]

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## Which strategy leads to better compliance?

1. providing written rationale for lens care measures suggested
2. promoting gain from performing action e.g. improved vision/ comfort
3. regular review exercise
4. combining written and oral instructions
5. intense instruction
6. re-instruction
7. reduced cost care products

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## Which strategy leads to better compliance?

1. providing written rationale for lens care measures suggested [408,517] ✗
2. promoting gain from performing action e.g. improved vision/ comfort [518] ✗
3. regular review exercise [519] ✗
4. combining written and oral instructions [482] ✗
  - although this can improve case cleaning compliance [520]
5. intense instruction [521] ✗
6. re-instruction [522] ✓
7. reduced cost care products ✗

Note: Even having a significant health condition does not appear to affect patient compliance [523].

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## 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 [130]
  - 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 wearers, 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 [510]
    - Handwashing 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 the cold symptoms
  - Next aftercare and eye examination dates

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## Managing Complications

## Relate to

- ▶ hypoxia (microcysts and vacuoles, folds, striae, oedema, corneal thinning, neovascularisation, endothelial blebs and polymegathism, warpage) ⇒ **SiHy, DD**
- ▶ mechanical (such as blink rate/completeness, ptosis, meibomian gland dysfunction, dry eye, LWE, an acute red eye, papillary conjunctivitis, staining, corneal warpage) ⇒ **modulus, lubricity, tear film [handling]**
- ▶ toxic (papillary conjunctivitis, staining) ⇒ **solution/material match, DD, allergy management**
- ▶ microbial (such as infiltrates and microbial keratitis) ⇒ **compliance (sleeping/napping, hygiene), DD**

Temporarily discontinue to allow healing

Vision optimisation

CLD results from infection, exposure to toxins and mechanical [141] ⇒

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## Practical Conclusions

- ▶ Best practice from the evidence-base
  - ▶ Anterior eye assessment
  - ▶ Lens selection
- ▶ Optimise lens
  - ▶ material
    - ▶ Oxygen permeability
    - ▶ Modulus
    - ▶ Lubricity
  - ▶ Modality
    - ▶ DD
    - ▶ Planned overnight
  - ▶ Solution
    - ▶ Avoid water – remind with stickers
  - ▶ Case
- ▶ Detailed instruction
- ▶ Reinstruction

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