UK OPHTHALMOLOGY ALLIANCE

How to choose an intraocular lens (IOL) in an NHS eye unit.

Information for theatre managers, clinicians and procurement staff

Making the right choice on which IOL to use requires a multidisciplinary team effort and a methodology for assessing and deciding based on factors such as cost, safety, outcomes, and usability as well as surgeon preferences. Some units will have very expert and experienced consultant cataract surgeons who have a great deal of knowledge about how to assess lenses. Others may not be certain how to approach this. Non clinicians may have very little prior knowledge in this area. Lens suppliers will all have features of their lens which they feel make them superior to other products and it can be confusing and difficult to know how underpinned by robust evidence all the claims are. This handbook provides staff with some of the things to consider when undertaking this decision, with tips from UKOA members and stakeholders who have experience in this process. It uses expert consensus views from UK cataract surgeons to try to address areas of uncertainty. What units want and what individual surgeons want, and their approach, can vary, so this document does not try to restrict your decisions or tell you which IOL to choose. We hope it will help you improve your own decision making process by sharing knowledge, experience and ideas.

Some basics for non surgeons

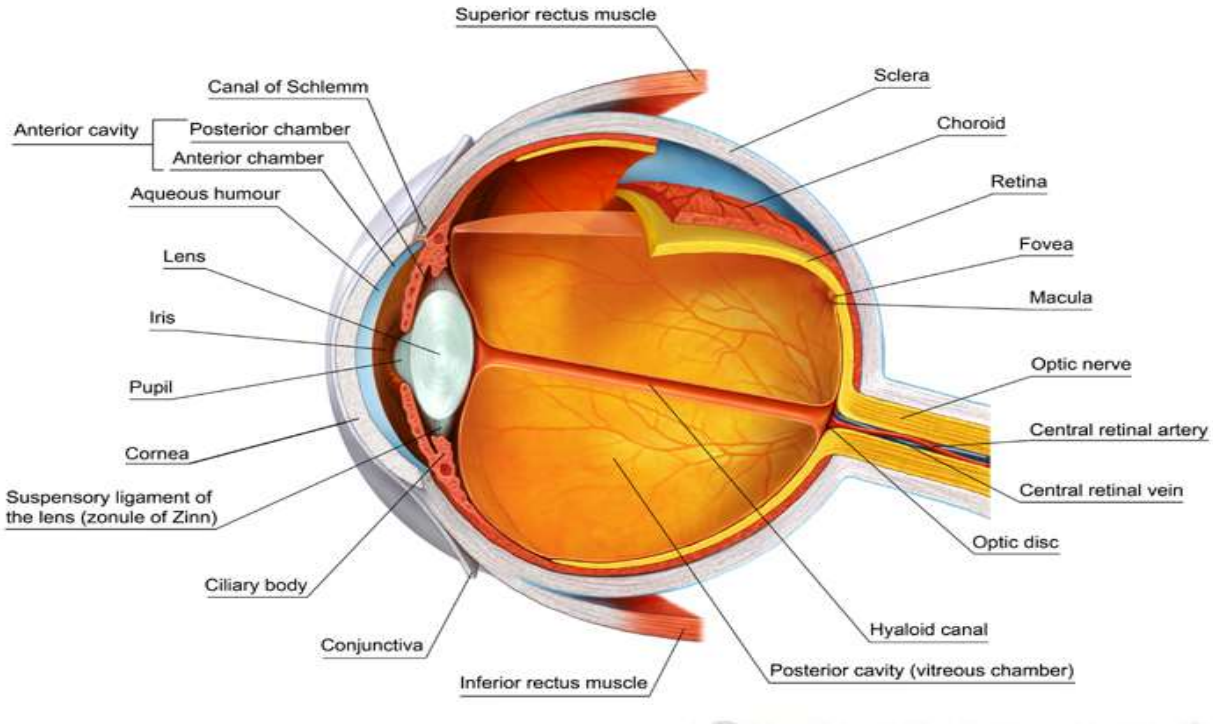
Cataract is a clouding of the natural clear focusing lens inside the eye, usually associated with age but there are other causes e.g. diabetes, drugs, and trauma. Symptoms of cataracts include blurred vision, glare, double vision and difficulties driving at night. Cataract is diagnosed by a visible loss of transparency or opacity by a clinician on a slit lamp.

A cataract is usually operated on only when the patient decides their symptoms warrant the risks associated with the surgery. >90% are done under local anaesthetic. The principles of cataract surgery are to remove the cloudy lens and to replace the lost focusing power of the eye with an artificial lens or intraocular lens implant (IOL) which is inserted into the space where the original lens sat.

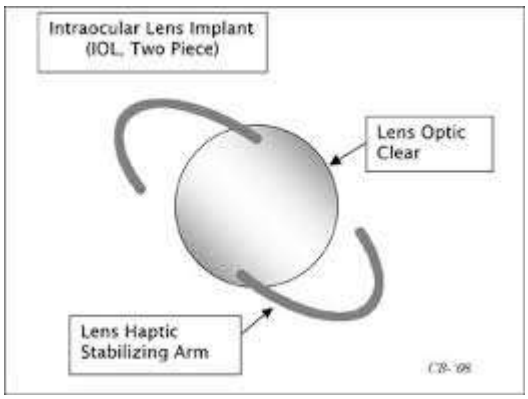
The standard cataract operation involves the phacoemulsification of the lens, in which the lens is removed with instruments including an ultrasound probe, which emulsifies (liquidises) the lens. The lens is reached via an incision (wound) at the edge of the clear part of the wall of the eye (cornea) and a small opening (capsulotomy, capsulorrhexis) in the anterior lens capsule (capsular bag), which is a thin, transparent film which surrounds the lens. Every effort is made to not rupture the posterior capsule (posterior capsular rupture, PCR, commonest complication) and to prevent the vitreous jelly behind it from coming forward (vitreous loss), as these interfere with inserting and keeping in place the artificial IOL, may require more surgical intervention and increase the risk of postoperative complications such as retinal problems. Standard IOLs need to be supported by an intact and stable capsule and go into the posterior chamber (PC) of the eye behind the iris and in the capsular bag: “in the bag” or “PC” IOLs. If there is not a stable and intact capsule, options include:

- lenses that can go into the ciliary sulcus, the space between the capsule and the iris
- lens that sit in the anterior chamber resting on the iris (anterior chamber or AC lenses)
- lenses that sit in the anterior chamber and clip onto the iris (iris clip lenses)

- lenses where no other support exists that are sutured into place.



Lenses are usually made up of a central round focussing element called the optic, and small legs for support and to keep the lens in place, called haptics. The same lenses come in a whole range of different powers, to allow patients a choice of IOL to optimise their focus and therefore the sharpness of their sight. Which lens is correct for each patient is determined by measurements of the patient's eye and calculation of which lens gives which focus (biometry), and the surgeon choses the right power IOL for a patient based on their knowledge and what the patient wants postoperatively. Most patients choose to be corrected for distance vision and usually require reading glasses. Some prefer to be corrected for near, and wear low power glasses for distance (usually short-sighted people). Note that it is possible to fit a distance vision IOL in one eye and a near vision IOL in the other, so called monovision, but many find it difficult to tolerate



Finally, in anything from 1.5-10% of patients, over time the clarity of the posterior capsule supporting the lens may reduce, known as posterior capsular opacification (PCO) or in layman's terms an "after

cataract". This causes symptoms similar to the original cataract. If symptomatic enough and the patient accepts a small risk of complications, this is treated by YAG laser capsulotomy, a minor procedure performed in clini,c where a small clear opening is made in the opaque capsule to restore vision clarity.

Should you have one "usual" or "default" lens

Many units now aim to have a "standard" IOL for in-the-capsular-bag use in most of their straightforward cases. Having one usual IOL, as opposed to multiple different IOLs, or different IOLs for different surgeons, within the same unit, may decrease the risk of a wrong IOL never event because things are more standardised. In addition, prices for IOLs, like any consumable, are usually lower the more you buy at once (volume discount) so financially it often makes more sense to buy a large number of one IOL rather than a small numbers of many IOLs.

You will need to have a plan for what IOLs you will use for cases which are complex, unusual or suffer complications. (see below) Depending on what IOL you choose, for some of the complex (e.g. sulcus IOL) cases you may be able to use your default lens.

Choosing your "standard" IOL

What does NICE say?

The NICE adult cataract guideline 2017 has a large section on lens design which is worth reading if you are not an expert in these things. Much of the evidence is either not high quality randomised controlled trial (RCT) data or has a fairly small number of study participants, and the amount of robust evidence is quite limited. Little was recommended in terms of which is the best IOL material, shape, design, colour etc.

They did however recommend:
Do not offer multifocal intraocular lenses for people having cataract surgery [in the NHS].

What sort of things are desired features in an IOL?

1. Cost. Low cost is usually on everyone's list as a desirable.

2. There are some features that are to do with practicalities, convenience and efficiency: Such IOL features can make it potentially easier, more convenient and faster to do the surgery, they may allow one IOL to be suitable for a wider range of patients, reducing the different types of lens required in stock etc.:

- Easy to handle (folding, implantation)
- Quicker and easier – preloaded injectable
- Wide range powers including minus powers
- Potential to use in sulcus.

3. There are some features to do with safety and outcomes:

- Non rigid (foldable, injectable) for routine small incision cataract surgery a given, as smaller incisions are desired for rapid visual rehabilitation, no stitches and reduced astigmatism.
- Low degree postop inflammation ("biologically inert", "uveal biocompatibility")
- Low incidence of posterior capsular opacity = PCO ("capsular biocompatibility")
- Very low incidence lens spoilage or opacification
- Safe and smooth to insert/inject
- Fit through smaller incisions (reduced astigmatism)
- Toric IOLs (correct astigmatism)
- Minimal visual unwanted effects or limitations (glare, reflections, dark spots or edges, poor contrast) especially in dim light
- Predictable refractive outcomes
- Stability of position.

All these features are not mutually exclusive

The difficulty is being certain how to match the desired outcomes above to the material and design of the IOL with certainty, compounded by the numerous permutations and combinations of features, including whether measured outcomes such as contract sensitivity, lens glistenings, depth of focus, small changes in lens position, and small differences in optic aberrations really matter in terms of real life visual function, quality of life (QoL) and visual satisfaction for patients. This is quite controversial and, for most of these issues, NICE stated only that "Please note: the recommendations around lens design and material have been removed to allow for further consideration".

Many surgeons feel that most IOLs in established UK use are very good and much of the choice may be preference.

What sort of physical features or properties do IOLs have? Do we know if they matter?
Here is the long list of features of IOLs with some analysis of how this might affect performance and outcomes. These features are not all mutually exclusive.

1. Focus

Monofocal IOLs are by far and away the most commonly used IOLs in the NHS. Monofocal lenses have one focal point, in other words they will correct your vision for one distance. Most patients choose to be corrected for distance vision and usually require reading glasses. Some prefer to be corrected for near, and wear low power glasses for distance (usually short-sighted people). Note that it is possible to fit a distance vision IOL in one eye and a near vision IOL in the other, so called monovision, but many find it difficult to tolerate.

Toric lenses correct astigmatism, which helps free patients up from post-op distance glasses. They may be more expensive to buy, require more detailed IOL biometry and calculations, and need to be carefully positioned in the eye; sometimes this positioning needs surgical adjustment postop – therefore they may take up more theatre time or require more procedures. Some NHS units are using toric lenses for patients with significant astigmatism if the price is reasonable.

Multifocal – these IOLs attempt to correct for both distance and near. They are usually more expensive, dependent on very good IOL positioning, and can be associated with unwanted visual effects such as glare. They are not recommended for NHS use by NICE.

2. Insertion

Previously IOLs were made of rigid material and required a large incision in the eye with sutures. With modern phacoemulsification this is only used for complex cases or those with intraoperative complications. Now all standard IOLs are flexible so that they can be folded up and inserted through a small wound which does not need stitches and which leads to less post-op astigmatism and more rapid visual recovery.

Flexible IOLs may require some handling by surgical or scrub staff to fold into a smaller configuration. This can be done using IOL forceps to manually fold and then insert the lens, which can be quite fiddly; or introducing the lens into an injector (single use or multiuse) where it folds up and can be injected; however, more and more IOLs now come preloaded ready to inject, which saves time and effort. This seems to be becoming the norm for suppliers and users.

3. Lens insertion size:

Lens insertion size determines the size of the wound required and varies from about 1.8mm to 3.2mm. In general, the lower the wound size the less astigmatism. However, surgeons we asked stated that in their view anything less than 2.2-2.4mm may not offer much extra practical benefit, at least from experience so far.

4. Material

The original material of the previously used non foldable lenses is PMMA that is rigid plastic. These are not “standard” IOLS as stated above. For the rest of the features we will omit the rigid IOLs.

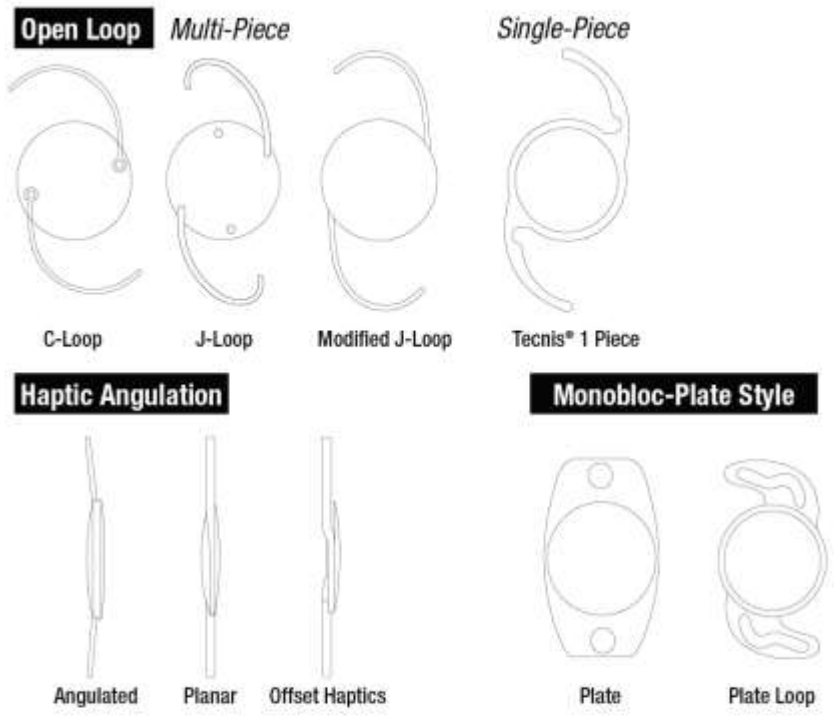
For modern flexible IOLs, the following materials are used:

- Hydrophobic (water repelling) acrylic. This is the commonest IOL material and is thought to offer:
    - Suitable for preloaded insertion
    - controlled unfolding (very slightly slows down the procedure but potentially less likely to open in uncontrolled and potentially risky manner)
    - good “memory” – haptics tend to remain in same position which helps with lens centralisation and stability
    - can get inclusions (small opacities) in the central lens part (optic) over time
    - more prone to dysphotopsias, that is unwanted effect of seeing light or dark patches in field of vision
    - lower incidence of posterior capsular opacification (PCO) but may be due to the material allowing a sharper edge shape (“profile”)
    - possibly causes more inflammatory reactions, leading to anterior chamber flare (cloudy fluid) and cellular deposits on the lens, than silicone.

- Hydrophilic (water attracting) acrylic “hydrogel”. This material is thought to offer:
    - Suitable for preloading
    - Increased rates of PCO but may be due to rounder edge profile and may therefore potentially be offset with better edge design
    - Rapid unfolding(slightly speeds up the procedure but potentially more likely to open in uncontrolled and potentially risky manner)
    - Less inflammation
    - Rare cases of calcification of optic have occurred which spoils the lens and may require lens exchange.
- Silicone. This material is the least commonly used now and is thought to offer:
    - Not suitable for preloaded insertion
    - Minimal PCO
    - Minimal inflammation.

5. Design

- 1-piece. All in one IOL with no “joins” between optics and haptics. Better for injecting as less likely to be damaged – suitable for preloaded insertion. Not suitable for the sulcus.
- 3-piece. Haptics made of a different material (can be prolene, PMMA, PVDF orpolyimide material) and attached to optic. Not suitable for preloaded/injectable. Possibly more risks of malposition (decentration). Leg shape can be C loop, J loop (better for sulcus), modified J loop – these variations may not be particularly important in routine cases for in the bag implantation. Suitable for the sulcus if large and ideally C loop haptics
- Plate haptic:. More likely to develop PCO. Not suitable for sulcus
- Plate loop. Not suitable for sulcus.



From ASCRS: Intraocular Lens Materials and Design.
http://phaco.ascrs.org/sites/phaco.ascrs.org/files/textbooks/Achieving%20Excellence%20in%20Cataract%20Surgery%20-%20Chapter%2012.pdf

6. Haptic configuration.

- Planar
- Angulated: said to ↓ PCO but this is not considered proven; must not put IOL in wrong way around.
- Offset: said to ↓ PCO but this is not considered proven.

7. Edge

- Square/sharp edge: reduces PCO but may increase dysphotopisa (edge glare)
- Round edge - increases PCO
- Round anterior, sharp posterior - may offer the best of both worlds for PCO?

8. Blue light filter

- None (although all IOLs have some degree)
- Blue blocking /yellow: Said to protect retina including if have early AMD, but the evidence for this is not robust. Can affect colour contrast and give a different colour effect therefore if use, should probably be used in both eyes. Probably offers no real advantage.

9. Optics – most of our experts felt these elements offered little advantage.

- Biconvex
- Asymmetric biconvex (back relatively flat) - must not put lens in wrong way around
- Aspheric - neutral spherical aberration or reduce SA, increase contract sensitivity in dim light/when pupil bigger.

10. Length i.e. overall length of IOL including haptics (note the average capsular bag size is 10-11mm but need a bigger IOL for the sulcus)

- 10.5mm, 11mm, 12, 12.5mm
- 13mm and more is suitable for sulcus

11. Size of optic

5.75-6.5mm, optic size may not matter unless IOL in the sulcus. There is some evidence that 6mm optics have less PCO.

12. Power range and steps

Ideally have wide range for every patient including minus powers to +35D

Ideally have as wide a range as possible covered by +0.5D steps rather than +1D steps.

Making sense of all these permutations and combinations - What did the UKOA say?

Our expert group used their knowledge of the evidence and their consensus views from experience to try to determine the relative importance of these features and here is what they concluded:

Hard outcomes – in the ideal world there would be ongoing collection and analysis nationally of outcomes per patient, tracked and linked over different providers if patients move from unit to unit, which could then be matched against different IOL features and models to determine whether they were linked with the key measurable outcomes including:

- Posterior capsular rupture
- Rates of YAG laser capsulotomy for PCO
- Refractive outcomes
- Explantation (removal/replacement) rates
- Spoilage/wastage during operation
- Surgery times/efficiency
- PROMs QoL measures
- Other postop complications especially inflammatory & cystoid macular oedema.

This is not possible currently. It is hoped that developments of the RCOphth NOD national cataract audit will develop to incorporate some of these, at least in patients who remain in the same units. The UKOA will work with NHSI/GIRFT and the national ophthalmology procurement team (national category tower) to pursue systems to procure nationally against these outcomes collected routinely at a national level.

Key IOL Features **-** In the absence of the ability to measure the above outcomes nationally, the group rated features in terms of what they felt were the important priorities for "standard" IOLs: which are likely to influence the above outcomes:

1. **Most important**

- Lens must not fail (become spoiled or opaque) after implantation
- Wide range powers including minus powers and at least half powers
- Low degree postop inflammation (biologically inert, uveal biocompatibility) note difficult to audit/evidence
- Accurate tolerances for actual lens power (i.e. a 20D lens lies somewhere between 19.90-20.10D and not 19.6-20.4) note extremes of range it is accepted tend to have much wider tolerance, e.g. above 30D may have tolerance of 1D
- Safe to implant (non-explosive entry, easy to see haptics, haptics not razor-sharp and not overly rigid, tongue of injector cannot capture or suck up iris). Lens is easy to centre, stable in capsular bag
- Very very low incidence lens spoilage (haptics do not snap/crimp on insertion, optic does not crack on implantation, no jamming)
- IOL size 2.4mm or less

2. **Next most important**

- Easy to handle and implant (preloaded – this saves time, reduces training needs and reduces number of IOLs dropped on to floor which means 1 piece), injected not folded.
- Square edge to reduce PCO
- Hydrophobic acrylic material to reduce PCO
- Easy to explant without damaging posterior capsule (i.e. no terminal bulbs or barbs on haptics, no loop haptics that can snag capsule once lens has fibrosed into bag).

3. Less important

- Asphericity and other optics– no definitive published data to suggest this is an advantage but those who have to remove IOLs from unhappy patients felt this is important.
- Dysphotopsia rate – this is negligible with modern lenses and difficult to measure anyway but again more important to those who remove IOLs from unhappy patients.
- Haptic angulation only in terms of not mattering if put in IOL wrong way around.

Probably not important

- Low glistenings
- Toric– nice to have not crucial and only for certain cases
- Blue light filter
- Size of optic
- Length – some evidence larger may be more stable but not proven. Only matters for sulcus lens.

Non standard IOLs - Lenses required for complicated or complex cases

This accounts for about 5% of all cataract cases. The expert group felt that rather than try to get standard lenses that also can be used for complex e.g. the sulcus, it was better to have a separate bank of lenses as they are less suitable for general high-turnover use or for routine cataracts

The choice of lenses for complex surgery should be dealt with and advised by experienced cataract surgeons and should not be used in tendering for mainstream lenses.

There need to be 3-piece lenses for sulcus implantation available, e.g. if poor capsular support or posterior capsule rupture. These need sufficient posterior vault to avoid iris chafing, and a total diameter (at least 13mm) with C loop haptics large enough to fit in sulcus without decentering

There were differences in opinion for anterior chamber intraocular lenses; some think these should be iris-enclavated lenses as these were felt to be very stable in the long-term; others feel iris enclavation not desirable and one stated "*Most experienced surgeons who have implanted high numbers of these have given them up due to rate of dislocation, blood/aqueous barrier breakdown and pupil issues*" with 4 point fixation Kelman-style AC lenses preferable and stable as long as they are correctly sized (white to white + 1mm).

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Approaching the procurement process for IOLs

Trusts will have procurement staff and devices/equipment staff (EBME electrical and biomedical engineering) who are expert in this area and need to be involved from the very beginning of any process to ensure you are compliant with the rules and get the best IOLs for the best price. In addition, your trust may have device standardisation rules (eg only certain models and specifications allowed) you need to adhere to. In addition, trusts usually have a procurement or equipment policy to refer to.

Involve:

- Clinical lead for ophthalmology
- Ophthalmic service managers
- Theatre managers
- Theatre senior nursing
- Consultant ophthalmic surgeons ideally including someone with a lot of knowledge of cataract surgery and IOLs
- Finance
- Procurement team

See UKOA Procurement Guide for full details

UKOA, December 2018.

With thanks to the UKOA National Cataract Expert Working Group:

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