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Consultation Document

Patient Information: phakic intraocular lens (PIOL) implantation

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1 What is phakic intraocular lens (PIOL) implantation?

- 1.1 Lenses that are implanted into the eye to correct vision without taking out the natural lens are called phakic intraocular lenses (PIOLs). PIOLs are made of clear synthetic plastic and sit either just in front of, or just behind, the pupil – a bit like building your contact lenses into your eyes.
- 1.2 PIOL implantation is effective in treating high spectacle prescriptions, and is widely used to treat younger patients who are not suitable for laser eye surgery.
- 1.3 The commonest type of PIOL implanted in the UK and worldwide is the Visian ICL (intraocular collamer lens). This is a soft flexible implant designed to sit just behind the pupil and in front of the natural lens. You cannot see or feel ICLs after implantation, and you do not need to clean them.
- 1.4 The other main type of PIOL is the Artisan/Verisyse PIOL, which clips onto the iris just in front of the pupil and is sometimes visible as a glint in the eye.
- 1.5 If you are suitable for PIOL implantation, your surgeon will discuss which type is the best option for you.

2 What are the benefits?

- 2.1 PIOLs are highly effective at treating both high spectacle prescriptions and astigmatism. For most patients, vision after PIOL surgery is similar to vision in contact lenses before surgery without the discomfort and limitations on activity.
- 2.2 Spectacles may still be required for some activities after treatment, particularly reading in older patients, but these will be a low prescription and relatively inexpensive.
- 2.3 Over 95% of patients are satisfied with the outcome of surgery, and many describe it as life changing. Although PIOL implantation is often bracketed with cosmetic surgery procedures, the benefits are primarily functional. It is designed to make you less dependent on spectacles and contact lenses, helping you to lead an active lifestyle more easily.
- 2.4 Short sight and astigmatism normally stabilize in the late teens or early 20s, but natural prescription changes can occur at any stage in life. So laser vision correction is sometimes needed to enhance distance vision in the years after PIOL implantation.

3 How much does PIOL implantation cost?

- 3.1 Surgery to correct the need for spectacles or contact lenses is not available as an NHS procedure and is not covered by private health insurance schemes.
- 3.2 Your clinic should be clear from the outset about the total cost of the procedure. Follow up clinic visits and treatment for any problems resulting from surgery are usually included in this cost for up to six months after surgery. Vision stabilizes quickly after PIOL implantation, but problems resulting from PIOL implantation, cataract in particular, may occur many years later.
- 3.3 Most clinics do not accept an open-ended liability and will charge for additional treatment relating to natural prescription changes or a new problem with eye health.

4 Who is suitable for PIOL implantation?

- 4.1 Young patients who are unsuitable for laser vision correction are often offered PIOL implantation. This is because PIOLs can correct a wider range of spectacle prescriptions than laser vision correction, and may be a safer option if you have pre-existing cornea or eye surface problems.
- 4.2 You need to be over 18 years of age and have a stable spectacle prescription. This is normally defined as no change greater than 0.5 units (0.5D) in the last two years.
- 4.3 The range of spectacle prescriptions that can be treated effectively is approximately:
 - Up to -17.00D of myopia or short sight
 - Up to +10.00D of hyperopia or long sight
 - Up to ± 4.50 D of astigmatism
- 4.4 Supplementary laser vision correction can be used to extend this range for suitable patients with very high prescriptions in a combination treatment that is commonly called BIOPTICS.
- 4.5 You may not be suitable for ICL implantation if you have other problems with vision including cataracts, glaucoma, or recurrent inflammation in the eye (uveitis). You also need to have enough room in the front of the eye to fit the PIOL safely. This is normally determined by a scan of the eye at your initial consultation.

5 What are the alternatives?

Vision correction surgery alternatives

- 5.1 PIOL implantation is one of three main categories of operations to correct vision. The other two are laser vision correction and refractive lens exchange (RLE).
 - Laser vision correction does not require a lens implant, and works by altering the curvature and focusing power of the front surface of the eye.

- RLE is identical to modern cataract surgery, and works by replacing the natural lens with a lens implant.

5.2 Laser vision correction is generally preferred if you have a lower spectacle prescription. This is because there are very few longer-term risks associated with laser vision correction; whereas problems including cataract can occur many years after PIOL implantation.

5.3 Older patients with a high spectacle prescription are more at risk of getting a cataract after PIOL implantation, and they have already lost most of the flexibility of focus provided by the natural lens. So after 50 years of age, RLE is the usually the best option if you are unsuitable for laser vision correction.

Alternative PIOLs

5.4 Different types of PIOL have a different safety profile. Of the two main types now available (ICL and Artisan/Verysise), most surgeons now prefer the ICL because it is easy to implant through a small entry into the eye and it has a very good long-term safety record. Sizing can be an issue for the ICL, and some ICLs need to be replaced soon after the initial operation. Iris clip lenses (Artisan/Verysise) have the advantage that one size fits all, but annual eye health monitoring is required after implantation and some lenses need to be removed in the years after implantation to avoid later problems.

Continuing in spectacles or contact lenses

5.5 PIOL implantation is elective. This means you can choose to proceed with it at any time, or not at all. The alternative is staying in spectacles or contact lenses.

5.6 Spectacles are risk free but can be expensive and very limiting in terms of the range of activities, particularly sport, that you can participate in if you have a higher prescription.

5.7 Contact lenses provide good all-round vision. They do not mist over during sport and will help you to be more active; but they can be inconvenient when travelling, make water sports more difficult, and should not be worn whilst showering, swimming or during sleep. Contact lens wear is sometimes associated with eye surface discomfort, and may be complicated by sight threatening infection.

5.8 The risks and benefits of PIOL implantation should be balanced against those for continued contact lens wear, since this is the main alternative for active people considering sight correction surgery.

6 How is PIOL implantation performed?

6.1 PIOL implantation is performed using eye-drop anaesthetic supplemented by an injection in the back of your hand to relax you if required. Anaesthetic may also be washed around the back of the eye to prevent excessive eye movement. A spring clip holding the eyelids apart allows you to blink safely during surgery.

- 6.2 Your surgeon will be looking through a microscope to perform the surgery. You will be lying down under a surgical tent with fresh air coming in underneath. A sticky plastic drape covers the skin around the eye and sticks the eyelashes out of the way.
- 6.3 Some centres offer surgery for both eyes on the same day. More commonly, second eye surgery is delayed for a week or longer to ensure that the recovery in the first eye is progressing well and, for ICLs, that sizing in the first eye is correct. The surgery typically takes about 20 minutes per eye. You can return home on the same day as surgery.
- 6.4 Strong pupil dilating drugs are given as drops or a using a pellet placed under the lower eyelid to prepare the eye for surgery.
- 6.5 Essential steps in surgery are:
- *Entry points* - formation of small self-sealing entry points in the front of the eye at the junction of the white of the eye and the cornea.
 - *PIOL insertion* - injection of the PIOL and unfolding into position using a supporting gel to fill the front of the eye. Sometimes a small bypass drainage hole is formed in the iris at this point, but this additional stage is no longer required for (v4c) ICLs in myopic patients.
 - *Wash out and refilling* - washout of the supporting gel and refilling with fluid and antibiotics. Sutured closure of the eye is often required for Artisan/Verysise PIOLs.

7 What are the risks?

- 7.1 In all forms of eye surgery, problems can occur during the operation or afterwards in the healing period. Problems can result in permanent, serious *loss of vision* (vision worse than the driving standard in the affected eye that cannot be corrected with spectacles or contact lenses). More commonly, problems can be corrected with changes in medication or *additional surgery*. Typically, these additional operations feel like the original surgery and have a similar recovery period.
- 7.2 Different types of PIOL have different associated risks. Your surgeon will ensure that you are given clear advice relevant to the lens type that is recommended.

Loss of vision

- 7.3 Permanent, serious loss of vision is very uncommon after ICL implantation. Causes include damage to the nerve at the back of the eye caused by a sudden rise in fluid pressure within the eye after surgery, and damage to the retina caused by infection or retinal detachment. Sudden pressure rises are much less common with the newer v4c ICL used for treating myopic patients. The v4c ICL allows natural fluid flow through the pupil and does not require a bypass drainage hole in the iris. If pressure rises do still occur, it is normally because of incomplete removal of supporting gel – a problem that can be fixed relatively easily with further washout. All patients with high levels of short sight have a higher risk of retinal detachment. This risk is not increased by ICL implantation, which does not involve surgery to the back compartment of the eye. Infection rates after ICL implantation are very low

(approximately one in 6000). Complete loss of vision can occur after any operation involving the inside of the eye; but this is rare after ICL implantation.

- 7.4 Although fluid pressure rises and infection can occur after Artisan/Verisyse PIOL implantation, the risk of problems leading to visual loss generally relates to later complications, particularly corneal waterlogging. These problems can often be spotted at an early stage and may be partially or completely intercepted by PIOL removal.
- 7.5 Annual review with your eye surgeon for life is normally recommended after Artisan/Verisyse PIOL implantation, whereas a standard optometric eye health check once a year is sufficient after ICL implantation for which the main long-term risk is cataract formation.

Additional surgery

- 7.6 Cataracts may occur earlier in life than they would have done otherwise after all types of PIOL implantation. Cataract surgery can normally be combined with PIOL removal if necessary, and substitution of a new lens implant during cataract surgery helps to minimize any additional requirement for spectacles. In other words, PIOL implantation does not stop you having successful cataract surgery or RLE later in life if this is required.
- 7.7 Statistical techniques are used to size ICL implants. These are imperfect and in approximately one case in 40, the ICL needs to be replaced with a lens of a different size in order to get the best fit in the eye. A minor rotation of the position of an ICL implant is also sometimes required after surgery to optimize the correction of astigmatism. For Artisan/Verisyse PIOLs, sizing is not a problem, since once size fits all. But repositioning procedures are sometimes required after the initial implantation.
- 7.8 PIOLs can be removed if they are causing problems. This usually means that your vision and eye health will be the same as it was before PIOL implantation. But not all problems caused by PIOLs can be corrected by removing them, and additional treatment may be required even after PIOL removal.
- 7.9 ICL removal is uncommon unless you require cataract surgery or an ICL of a different size.
- 7.10 Artesan/Verisyse PIOLs are sometimes removed to prevent further deterioration in the eye health if it looks like the risk of corneal waterlogging is increasing or if there are persistent problems with eye inflammation.

Risks of contact lens wear

- 7.11 Continuing in contact lenses is often the main alternative for people considering sight correction surgery. If you follow the right safety advice, contact lens wear is low risk; but approximately one in 3000 wearers each year will develop a serious corneal infection.
- 7.12 To minimize this risk, you should not swim or shower in contact lenses, and should not wash them in tap water. Sleeping in contact lenses, including those designed for

overnight wear, increases the risk of infection significantly. Soft, daily disposable lenses are safer than non-disposable lenses.

8 What are the side effects?

- 8.1 Side effects are problems which most patients experience to some degree after surgery. They normally improve with time, but do not always resolve completely.

Vision

- 8.2 It is normal to experience some light scatter side effects in the early period after PIOL implantation, particularly if you have treatment for a very high spectacle prescription. These can take a variety of forms including glare, halos, starbursts and ghost images. Increased flare from oncoming car headlights is a common symptom, and night driving may be difficult at first. Visual side effects are usually mild and improve within a few months. PIOLs can be removed if visual side effects persist, but this is rarely required.

Eye comfort

- 8.3 Some eye surface discomfort is common in the early months after most forms of eye surgery. This is usually mild after PIOL implantation, and highly variable – often affecting one eye more than the other. Treatment and prevention are based on making sure your eye surface is healthy before and after surgery. Lubricant eye drops can be helpful, and can be taken safely in addition to your other medication when required. For patients with a normal eye surface prior to surgery, lasting problems are unusual.

Eye appearance

- 8.4 Red blotches are often visible on the white of the eye after any form of eye surgery. These are called subconjunctival haemorrhages, and are caused by a small leak of blood under the mucous membrane covering the white part of eye wall. Although they can be quite unsightly, red blotches are temporary, and do not affect eye health; but they can take up to six weeks to go away completely.
- 8.5 ICLs are not visible. But you may be aware of a glint in the eye caused by a reflection from the lens after Artisan/Verysise PIOL implantation.

9 Will PIOL implantation affect my future eye health care?

- 9.1 If you develop a new eye health problem in later life, PIOL implantation should not prevent you having successful treatment. Common eye health problems like glaucoma, diabetic retinopathy, and age related macular degeneration can be monitored and treated as normal after PIOL implantation.
- 9.2 If cataract surgery is required after PIOL implantation, as explained above, the PIOL will have to be removed as part of the cataract procedure. ICLs can be removed safely through a normal cataract entry incision, whereas Artesan/Verysise PIOL removal may require a larger entry. Some of the advantages of keyhole cataract

surgery (no sutures, rapid recovery and less need for spectacles) are reduced if a larger entry into the eye is required.

10 How can I reduce the risk of problems?

- 10.1 Most patients have PIOL implantation under local anaesthetic. You can eat and drink normally before surgery, and should take any regular medication as usual.
- 10.2 Most surgeons work with an anaesthetist to monitor your health during surgery and optimize your comfort, administering sedation where necessary. Keep your breathing calm, stay as relaxed as you can, and try to keep your head still after the surgeon has positioned it comfortably.
- 10.3 You can help your surgeon apply the drape and stick your eyelashes out of the way by opening both your eyes wide at the beginning of surgery. Blinking is no problem after the draping is complete. Just look straight up ahead to the bright operating light with both eyes open, but blink when you need to. Looking up to the bright microscope light helps to keep your eyes in the best position.
- 10.4 Your surgeon will talk you through the procedure, encouraging you at every stage. Let your surgeon know if you feel any discomfort, and tell your surgeon if you need to cough, sneeze or take a break.
- 10.5 A clear plastic shield is normally taped over your eye at the end of surgery for protection on the way home. Nursing staff will show you how to wear the eye shield at night (normally for one week after PIOL implantation).
- 10.6 You can wash and shower normally from day one after surgery. Most surgeons recommend no swimming for a week and no contact sports for a month. Non contact sports such as gym and jogging can be resumed from day one after surgery.
- 10.7 Set a smart phone reminder and use the antibiotic and anti-inflammatory drops as prescribed to help the eyes to heal well. It is good to leave at least two minutes between different types of eye drop so that they each absorb well before the next drop is applied. If you miss the first time or you are not sure, applying a second eye drop is no problem.
- 10.8 Some variability of vision and comfort is normal in the early weeks after PIOL implantation, and patience is required. But discomfort is usually mild, and vision normally recovers substantially within two to three days once the pupil dilating drugs have worn off.
- 10.9 Report to your surgeon or an eye casualty department without delay if you have increasing aching pain, light sensitivity, redness, blur after surgery.
- 10.10 You may not be aware of a problem that requires treatment in the healing phase. So make sure you attend your review appointments even if your eyes feel good.

11 Glossary

ICI	Intralocular Collamer Lens
LASEK	Laser-Assisted Subepithelial Keratomileusis
LASIK	Laser Assisted In Situ Keratomileusis
PIOL	Phakic Intraocular Lenses
PRK	Photorefractive Keratectomy
RLE	Refractive Lens Exchange
SMILE	Small Incision Lenticule Extraction
TransPRK	Transepithelial Photorefractive Keratectomy