

Patient Information Phakic Intraocular Lens Implantation





Contents

What is phakic intraocular lens (PIOL) implantation?	3
What are the benefits?	3
Who is suitable for PIOL implantation?	4
What are the alternatives?	4
Vision correction surgery alternatives	4
Alternative PIOLs	4
Continuing in glasses or contact lenses	4
How is PIOL implantation performed?	5
Loss of vision	5
Additional surgery	6
Risks of contact lens wear	6
What are the side effects?	6
Vision	6
Eye comfort	6
Eye appearance	6
Will PIOL implantation affect my future eye health care?	7
How can I reduce the risk of problems?	7
How much does PIOL implantation cost?8	8

What is phakic intraocular lens (PIOL) implantation?

Lenses that are implanted into the eye to correct vision without taking out the natural lens are call phakic intraocular lenses (PIOLs). PIOLs are made of clear synthetic plastic. They sit either just in front of, or just behind, the pupil – a bit like building your contact lenses into your eyes.

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.

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 in the eye. You cannot see or feel ICLs after implantation, and you do not need to clean them. The other main type of PIOL is the Artisan/Verysise PIOL. This PIOL clips onto the iris just in front of the pupil, and is sometimes visible as a glint in the eye. Like ICLs, you cannot feel Artisan/Verysise PIOLs after implantation, and you do not need to clean them.

If you are suitable for PIOL implantation, your surgeon will discuss which type is the best option for you.

What are the benefits?

PIOLs are highly effective at treating both high glasses 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.

Glasses may still be required for some activities after treatment, particularly reading in older patients, but these will be a low prescription and relatively inexpensive.

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 mainly functional. It is designed to make you less dependent on glasses and contact lenses, helping you to lead an active lifestyle more easily. 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.

Who is suitable for PIOL implantation?

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.

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 2 years.

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 ±4.50D of astigmatism

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. You may not be suitable for PIOL implantation if you have other problems with your eye health 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.

What are the alternatives?

Vision correction surgery alternatives

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.

Laser vision correction is generally preferred if you have a lower glasses 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.

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 in the eye. So after about 50 years of age, RLE is the usually the best option if you are unsuitable for laser vision correction.

Your surgeon will advise on your best treatment options after reviewing your test measurements and your eye health

Alternative PIOLs

Different types of PIOL have a different safety profile. Of the two main types now available (ICL and Artisan/ Verysise), the ICL is easy to implant through a small entry into the eye and 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.

Continuing in glasses or contact lenses

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 glasses or contact lenses

Glasses 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.

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.

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 vision correction surgery

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How is PIOL implantation performed?

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.

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.

Strong pupil dilating drugs are given as drops or a using a pellet placed under the lower eyelid to prepare the eye for surgery.

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 newer (v4c and later) ICLs in myopic patients

What are the risks?

• 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

Some centres offer surgery for both eyes on the same day. More commonly, second eye surgery is delayed for a day 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

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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 glasses 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.

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

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

Although fluid pressure rises and infection can occur after Artisan/Verysise PIOL implantation, the risk of problems leading to visual loss generally relates to later complications, particularly corneal clouding. These problems can often be spotted at an early stage and may be partially or completely intercepted by PIOL removal.

Annual review with your eye surgeon for life is normally recommended after Artisan/Verysise 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

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 glasses. In other words, PIOL implantation does not stop you having successful cataract surgery or RLE later in life if this is required.

Statistical techniques are used to size ICL implants. The size prediction is sometimes incorrect, and in approximately 1 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 optimise the correction of astigmatism. For Artisan/Verysise PIOLs, sizing is not a problem, since once size fits all. But repositioning procedures are sometimes required after the initial implantation.

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. ICL removal is uncommon unless you require cataract surgery or an ICL of a different size.

Artesan/Verysise PIOLs are sometimes removed to prevent further deterioration in the eye health if it looks like the risk of corneal clouding is increasing or if there are persistent problems with eye inflammation.

Risks of contact lens wear

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 1 in 3000 wearers each year will develop a serious corneal infection.

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.

What are the side effects?

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

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.

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Eye comfort

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

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.

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.

Will PIOL implantation affect my future eye health care?

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.

If cataract surgery is required after PIOL implantation, 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 glasses) are reduced if a larger entry into the eye is required.

How can I reduce the risk of problems?

Most patients have PIOL implantation under local anaesthetic. You can eat and drink normally before surgery, and should take any regular medication as usual.

Most surgeons work with an anaesthetist to monitor your health and optimise your comfort during surgery, 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.

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.

Your surgeon will talk you through the procedure, encouraging you at every stage

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Let your surgeon know if you feel any discomfort, and tell your surgeon if you need to cough, sneeze or take a break.

A clear plastic shield is normally taped over your eye at the end of surgery for protection on the way home. Nursing staff will provide aftercare information and show you how to wear the eye shield at night (normally for 1 week after PIOL implantation).

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. Your surgeon will advise you when it is safe to start driving again. Typically this is within a few days of surgery.

Set a reminder and use the antibiotic and antiinflammatory 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.

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.

Report to your surgeon or an eye casualty department without delay if you have increasing aching pain, light sensitivity, redness, blur after surgery.

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

How much does PIOL implantation cost?

Surgery to correct the need for glasses or contact lenses is not available as an NHS procedure and is not covered by private health insurance schemes.

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 12 months after surgery. Vision stabilizes quickly after PIOL implantation, but problems resulting from PIOL implantation, cataract in particular, may occur many years later. 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.

Refractive Surgery Glossary of Terms

Accommodation the reflex by which the eye brings a near object into focus by changing the shape of the natural lens. The *natural lens* gets less flexible with age, and powers of accommodation diminish. This affects reading vision and the ability to compensate for *hyperopia*.

Artisan/Verysise PIOL this is a type of *PIOL* that is clipped on to the *iris* during implantation. PIOLs are a commonly used alternative to *laser vision correction* for younger patients.

Astigmatism irregular defocus, or an eye that is 'more rugby ball shaped than football shaped.' The first number in your prescription for glasses describes the amount of long or short sight. The second number describes the amount of astigmatism. Most of us have at least some astigmatism, and a small amount can even help extend the range of activities you can do without reading glasses when you get older.

Biometry this test involves measurement of the eye and a set of calculations (biometry formulae) that help determine the right focusing power for an *IOL* before *cataract surgery* or *RLE*.

Binocular vision this is vision measured with the two eyes open.

Cataract when the *natural lens* gets misty enough to make vision hazy, it is called a cataract.

Cataract surgery this is surgery to replace the natural lens with an *IOL*. Cataract surgery is identical to *RLE* but is performed in patients who cannot see clearly despite using glasses or contact lenses with the main aim of restoring clear vision.

Conjunctiva the membrane covering the white of the eye. The conjunctiva produces mucus to help spread the watery *tear film* over the eye surface.

Cornea the clear part of the eye wall at the front of the eye. Two thirds of the focusing power of the eye is in the cornea.

Corneal epithelium the corneal skin layer

Corneal topography this is a scan that maps the surface curvature of the cornea.

D or **Dioptre** a unit for measuring the refractive power of a lens.

Excimer laser this type of laser removes tissue by non-thermal vapourisation (photoablation). Excimer lasers are extremely accurate and do not damage the surrounding tissues. They are used in *LASIK* and *surface laser treatments (PRK, LASEK and TransPRK)*.

Femtosecond laser this type of laser is designed to cut any 3D shape in clear eye tissues such as the *natural lens* or the *cornea* with a high degree of accuracy. They work by creating a 3D pattern of tiny gas bubbles, which is traced through the target tissue at high speed. Femtosecond lasers are used in *LASIK*, *SMILE*, and increasingly in *RLE* and *Cataract surgery*.

Floaters floating shadows cast on the retina by opacities in the *vitreous*. Most of us are aware of *floaters* in some lighting conditions.

Glaucoma this is a condition in which the optic nerve is gradually damaged causing the visual field to contract. Left untreated, patients with glaucoma may develop 'tunnel vision.' Glaucoma is often associated with a higher than normal *intraocular pressure*, and treatment is centred on drugs or surgery to lower the intraocular pressure.

Hyperopia long sight. People with hyperopia typically have good vision as young adults. As they get older, they find themselves reliant on glasses for reading, and then for the distance vision too. Younger people are able to compensate for hyperopia by *accommodation*. The amount of hyperopia is shown by a positive number in your spectacle prescription.

ICL (intraocular collamer lens) this is the most commonly used type of *PIOL*. It is implanted behind the *iris* and vaults over the *natural lens* – a bit like a contact lens implanted in the eye. ICL implantation is a commonly used alternative to *laser vision correction* in younger patients.

IOL (intraocular lens) IOLs are small synthetic lens implants that are used to replace the natural lens in cataract surgery and RLE.

Intraocular pressure (IOP) this is the pressure of fluid within the eye. It is often measured with a puff of air in routine eye checks or (more accurately) with a yellow drop and a blue light.

Iris this is the coloured part of the eye behind the cornea that expands and contracts in response to light to dilate or constrict the pupil.

LASEK (laser assisted sub-epithelial keratectomy) this is a form of *surface laser treatment* in which the corneal skin layer is soaked with dilute alcohol to loosen it before removal.

Laser vision correction correction of sight using *excimer* and/or *femtosecond* lasers to alter the curvature and focusing power of the cornea.

LASIK (laser in situ keratomileusis) this is the commonest form of laser vision correction in which a thin protective flap is created using a femtosecond laser. The protective flap is moved aside by the surgeon before optical reshaping of the cornea using an excimer laser. The flap is then replaced, and adheres without stitches, keeping the corneal skin layer intact and giving a fast visual recovery.

Meibomian glands the specialized oil glands in the eyelids that pump out a stabilizing layer of oil each time we blink that floats on top of the watery layer of the *tear film*. Inflammation of the eyelid margins upsetting this layer (blepharitis or meibomitis) is one of the commonest reasons for eye discomfort.

Micromonovision this is the name often given to the strategy of aiming for a clearer distance focus in one eye and a clearer focus at arms' length in the other. Input from the two eyes combines to extend the range of focus for patients in the reading glasses age group undergoing vision correction surgery.

Monofocal IOL an IOL with one clear point of focus. These are the lenses most commonly used in standard cataract surgery. They have fewer optical side effects than multifocal lenses, but glasses are normally required for at least some activities after implantation.

Multifocal IOL an IOL with more than one point of clear focus. Multifocal IOLs are often used in RLE in order to help increase freedom from glasses in the near range as well as providing good distance vision.

Myopia short sight. People with myopia are able to see up close but not in the distance. They typically first need glasses as school age children. The amount of myopia is shown as a negative number in your spectacle prescription.

Natural Lens the natural lens sits just behind the pupil and is suspended by a trampoline like array of microligaments from the ciliary muscle, which contracts during *accommodation*. The natural lens accounts for one third of the focusing power of the eye and is the flexible element of focus. The natural lens gets less flexible with age. It also becomes less clear as we get older. If the natural lens gets misty enough to make vision hazy, it is called a *cataract*.

Phacoemulsification this is the standard technique for liquefying the natural lens in *cataract surgery* and *RLE*. Ultrasound energy delivered from the tip of a fine, hollow probe liquefies the lens. Fluid is washed continuously into the eye around the probe, and the liquefied lens material is sucked away. Where previously the natural lens had to be shelled out like a pea, phacoemulsification allows it to be removed through a tiny, key-hole entry into the eye. This development revolutionised modern cataract surgery. *Femtosecond lasers* are now commonly used to break the lens up into small fragments before phacoemulsification.

Posterior capsule opacification (PCO) in *cataract* surgery and *RLE*, the *IOL* is implanted within the capsule of the natural lens. This thin, clear membrane then shrink-wraps the IOL and stabilises it in the natural position in the eye. As part of this healing up process, the membrane often goes misty, causing gradual loss of vision after surgery. This is posterior capsule opacification (PCO). It can be treated successfully with a one-off minor laser procedure called *YAG capsulotomy*.

Presbyopia age related loss of reading vision and the ability to focus on a near object without help from glasses.

PIOL (phakic intraocular lens) an eye that still has the natural lens in place is described as 'phakic.' PIOLs are small, synthetic lenses that are implanted in the eye without taking the natural lens out. PIOL implantation is an alternative to laser vision correction for younger patients.

Posterior vitreous detachment (PVD) as we age, the vitreous shrinks and will often peel off the back of the eye. For some of us, this event passes unnoticed. In others, a new shower of floaters will prompt them to attend for an eye examination. Doctors examining patients after a PVD look carefully for any abnormal attachment of the gel to the retina which could lead to a retinal detachment.

PRK (photorefractive keratectomy) this is a form of *surface laser treatment* in which preparatory removal of the corneal skin layer is done by the surgeon.

Refraction this is the test that is done to determine the numbers in your spectacle prescription and the amount of *myopia*, *hyperopia* or *astigmatism*.

Refractive surgery this is another name for vision correction surgery or surgery to reduce the need for glasses and contact lenses.

Retina the carpet of light sensitive cells lining the back of the eye, which is sometimes described as 'the film in the camera.' Images are focused on the retina by the *cornea*, the *natural lens*. Information from the retina is fed through the *optic nerve* to the visual areas of the brain.

Retinal detachment the retina sometimes detaches from the eye wall and its blood supply. Urgent surgery is then required to re-attach the retina in order to prevent visual loss. Patients with high myopia are more likely to get a retinal detachment. Retinal detachments are also more common in the early years after cataract surgery or RLE. Warning signs are a sudden change in vision with field loss (a dark shadow in part of the visual field); flashing lights (arcs of light – even with the eyes closed); and a sudden new shower of *floaters*. **RLE (refractive lens exchange)** this is surgery to replace the natural lens with an *IOL*. RLE is identical to cataract surgery but is performed in patients who can see clearly if they wear glasses or contact lenses. The aim of RLE is to help people to see clearly for more activities without glasses or contact lenses.

SMILE (small incision lenticule extraction) this is a form of *laser vision correction* in which a lens shaped piece of corneal tissue is marked out using a femtosecond laser and removed surgically through a small incision.

Surface laser treatment a collective term for *PRK*, *LASEK*, *TransPRK* and other similar forms of *laser vision correction* in which optical reshaping of the cornea is performed on the corneal surface after removal of the corneal skin layer.

TransPRK (transepithelial PRK) this is a form of *surface laser treatment* in which the corneal skin layer is removed by the laser itself.

Tear film a multilayered wet film covering the front of the eye, which is essential for vision and comfort. A layer of mucus produced by specialized cells in the *conjunctiva* helps the watery layer of the tear film to spread over the eye. The watery layer is stabilized between blinks by an oily layer that forms a thin film (a bit like petrol floating on water) and acts to prevent localized evaporation. The oily layer is pumped out from specialized glands in the eyelids called *meibomian glands* each time we blink. **Visual acuity** this is the main measurement of how well we can see and is tested by asking you to read down a chart which has smaller letters on each line. The lower you can read, the better your visual acuity is. Measurements are expressed as a fraction. If your visual acuity is 6/6 (normal) then you can see at 6 meters what a normally sighted person can see at 6 meters. If your vision is 6/9 you can see at 6 meters what a normally sighted person can see from 9 meters away et cetera. In the USA, the same measurement is made in feet, with 6 meters being roughly 20 feet. Many people are familiar with the American definition of normal '20/20' vision. This is the same as 6/6 vision in the UK measurement.

Vitreous this is the gel filling the back of the eye. It tends to shrink as we age and accumulates wrinkles and opacities that cast floating shadows (*floaters*) on the retina.

Wavefront scan this is an optical map of your eye used to guide modern *excimer laser* treatments.

YAG capsulotomy a one-off minor laser procedure used to treat *posterior capsule opacification* (PCO).

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