

INFORMED CONSENT FOR LENS IMPLANT SURGERY

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THE LUCK VISION

PARTNERSHIP

What is 'Informed Consent'?

Informed consent is a process in which a doctor or health professional works in partnership with a person to give them information about a proposed course of treatment, presented in a manner that they can understand. This then allows that person to weigh up that information and make an informed decision about whether to accept or refuse treatment.

It has some important elements, including an explanation of the nature of the procedure, reasonable alternatives to the proposed intervention, and the risks and benefits involved.

Informed consent is not a 'waiver' or a 'disclaimer'. It's best thought of as a record or confirmation that someone considering a course of treatment or an intervention has all the information that they require to make a decision, and has had a chance to have all their questions answered to their satisfaction.

This booklet has been designed for that purpose - to help make sure that you have had all the information you need to make a decision about whether or not you wish to undergo lens implant surgery (sometimes called refractive lens exchange or clear lens extraction) to correct your vision. It is not designed or intended to replace a consultation with Mr. Luck, and should also be read together with the booklet about lens implant surgery.

If you any questions or concerns arising from this information, please contact Mr. Luck.

All the booklets are downloadable from www.jonathanluck.com.

At the bottom of each page there is a box for you to initial indicating that you have read and understood the contents, and there is a declaration at the end of the document for you to sign. Please bring the signed form with you on the day of surgery or send it to Mr. Luck at the Circle Hospital. Please keep a copy for your own records (you can download a copy from www.jonathanluck.com).

Initials:

“This surgery involves the removal of the natural lens of my eye, even though there may be no or minimal cataract. The natural lens will be replaced with an artificial implant called an intraocular lens in order to attempt to correct my longsightedness, shortsightedness, presbyopia and/or astigmatism, to improve my unaided natural vision and thereby reduce my dependency on glasses or contact lenses, previously required to correct my vision”.

For both:

“I will undergo (or have already undergone) a complete eye examination should I decide to have the surgery. This examination will include measurement of my vision with and without glasses (visual acuity), measurement of the pressure inside my eye (tonometry), measurement of the curvature of my cornea (keratometry), measurement of the length of my eye (axial length), intraocular lens calculation to determine the best estimate of the proper power of the implanted lens, microscopic examination of the front part of my eye (slit-lamp examination), and examination of the retina of my eye with my pupil dilated (ophthalmoscopy).

Should I decide to proceed with surgery, I will have a local anaesthetic administered by Mr. Luck immediately beforehand. The natural lens in my eye will then be removed by gently breaking it into small pieces with a vibrating/aspirating probe (phacoemulsification) through a small incision in my eye. After my natural lens is removed, the artificial lens of the power determined during my pre-operative examination will then be placed inside my eye. The incision required to perform this operation is usually self-sealing, but it may occasionally require closure with very fine stitches (sutures) which will be removed a month or two after surgery.

Mr. Luck will examine my eye a few days after surgery to ensure all is well. During the immediate recovery period, I will place drops in my eyes for 2 to 4 weeks, according to the instructions provided. Glasses or contact lenses may still be required either for further improvement in my distance vision, reading vision, or both. I should be able to resume my normal activities within 2 or 3 days, and I should expect stable vision within 2 to 4 weeks, at which time glasses or contact lenses, if required, may be prescribed by my Optician”.

Initials:

Risks and possible complications of surgery

During surgery:

a) A tear in the posterior capsule of the lens. This thin cellophane-like membrane is left intact to support the lens implant. It is very delicate, and sometimes is torn during surgery. The risk of this happening is very low (approximately 1 in 500). This can make lens implantation more difficult, and may necessitate the use of a different style of lens implant. Occasionally, a decision may be made to postpone lens implantation to allow the eye to recover, and a second procedure to implant the lens is then required. Rarely, a fragment of the natural lens may drop through the tear into the vitreous jelly at the back of the eye. Further specialised surgery would then be required to complete the operation.

b) Damage to the lens implant on insertion. The lens implants are delicate, and rarely the lens itself or one of its supporting legs is damaged during the insertion process. If the damage is minor the lens can be left in-situ, but if significant, it would then have to be immediately exchanged for a new lens. This is usually straightforward, but further complications may occur.

c) Bleeding at the back of the eye may occur, and can result in loss of vision, but is extremely rare.

After surgery:

a) Infection (which if serious can lead to complete loss of vision). We are obsessive about reducing this risk that is extremely rare (about 1 in every 1000 cases).

b) Swelling in the central area of the retina (called cystoid macular oedema). This usually improves with time. We use a special post-operative drop (Bromfenac) that has been shown to markedly reduce the risk of this problem occurring, but the overall incidence is between 1-2%.

c) Clouding of the cornea (corneal oedema) - the clear part of the front of the eye. This is very rarely significant and usually temporary, but if severe could eventually require a corneal transplant.

d) Detachment of the retina (patients with high degrees of shortsightedness [myopia] have an increased risk of retinal detachment compared with the general population. Cataract or lens surgery increases this risk, but only slightly. Most retinal detachments can be repaired, but some patients will lose vision as a result.

e) Increased astigmatism (causing blurring of vision). Astigmatism is where the eye is shaped more like a rugby ball than a football. Mr. Luck always tries to reduce your astigmatism (people have differing amounts) and if necessary will use toric lenses to achieve this. Sometimes there is residual astigmatism in the eye that may require a further procedure(s) to achieve the best results, although if this is easily correctable with glasses then that may be advised.

Initials:

g) Decentration or malposition of the intraocular lens, which may provide unwanted images and increased glare (rare, but usually requires further corrective surgery).

h) Increased pressure in the eye (glaucoma). This is rare – lens surgery usually lowers the pressure within the eye.

i) Visual side-effects. Sometimes patients may notice bright or dark shadows in their peripheral vision after surgery. These effects usually improve with time, but on rare occasions may require further treatment.

Residual spectacle error

Although the accuracy of intraocular lens calculations is quite satisfactory for normal sized eyes, these calculations can be less accurate for unusually long or short eyes. The best available calculation formula will be used to evaluate the power of the lens to be implanted. In the event of a minor amount of residual myopia, hyperopia and/or astigmatism, the vision can usually be corrected by a glasses prescription, which should be considerably weaker than the patient's original prescription. A large amount of residual myopia, hyperopia, and/or astigmatism error may be corrected by a stronger pair of glasses, laser surgery, contact lenses, exchange of the implant or the insertion of a second 'piggyback' implant in another operation. Any such remedial surgery required in the first year will be covered by the initial payment; no extra costs will be incurred (laser surgery is no longer offered by Circle, and in the extremely unlikely event of this being necessary post-operatively, the patient will have to bear the extra expense involved).

Since only one eye will undergo surgery at a time the patient may, depending on the refractive error, experience a period of imbalance between the two eyes (anisometropia). This usually cannot be corrected with spectacles because of the marked difference in the prescription needed for each eye, so the patient will either temporarily have to wear a contact lens in the non-operated eye or will have to function with only one clear eye for distance vision. In the absence of complications, surgery in the second eye can usually be scheduled within one to four weeks following first eye surgery.

Posterior capsular opacification

As part of lens implant surgery, the front part of the capsule (the membrane enclosing the lens) is opened and the natural lens is removed, with the back part of the capsule left in place to support the intraocular lens. Many months or even years after the surgery this capsule remnant may become cloudy and cause blurry or poor vision. This cloudy remnant is called capsular opacity or posterior capsular fibrosis. The way to make the vision clear again is with a laser capsulotomy, which simply means making an opening in the back of the capsule with a laser. This is a painless out-patient procedure that takes just a few minutes.

Most patients don't have any after-effects, but complications can occur. These include raised internal eye pressure, retinal tears or detachment, especially in myopic patients, and rarely, dislocation or movement of the lens implant. Laser capsulotomy is performed as a medically necessary procedure and is therefore usually covered by medical insurance.

Initials:

Monofocal lens implants:

One definite disadvantage of having the clear lens removed, especially in a patient less than 45-50 years of age, is the loss of the near focusing power of the eye (accommodation). A standard monofocal lens implant has a single focus, and even with an accurate intraocular lens calculation targeted to correct the eye's distance vision, close vision without spectacles will be blurred, and the patient will require spectacles for close and intermediate vision.

It may be possible to deliberately correct one eye for close vision instead of distance. This would allow the patient to read without glasses, even though the eye would then be short-sighted and require a corrective lens for distance vision. This combination of a distance eye with a reading eye is called 'monovision'.

This strategy is regularly successfully used by Mr. Luck for suitable patients, but requires careful discussion. If the monovision outcome is not tolerated by the patient, which is extremely unusual, then the eye that is short-sighted may require further surgery to correct the vision and balance it up with the other eye.

An alternative method of achieving both acceptable distance and near vision after surgery is to use a multifocal lens (see below).

Multifocal lens implants:

Multifocal lens implants are made of the same materials and have the same basic design as many of the monofocal lenses, but in addition to providing clear vision at far distances, they can also provide good focus for a range of near distances, such as the computer monitor and reading.

They can have some side effects; these may include halos and glare, especially around bright light sources such as car headlights at night. A small percentage of people will find these troubling; most report a decrease in these symptoms in time and/or they grow accustomed to them. A loss of contrast may also be noted, which can affect the quality of vision at night and in low light conditions. Sometimes patients with multifocal lenses implanted find this difficult to describe, but just report that their vision isn't as good as they had hoped, despite there being little or no refractive (spectacle) error.

If these side effects are severe enough (bearing in mind a lot of these issues disappear with time) then the multifocal lens may have to be removed and a monofocal lens inserted in its place (a lens exchange). This is usually a straightforward process, but complications can occur. In the rare event that this is required, Mr. Luck will discuss the procedure with you in detail.

Initials:

Non-surgical alternatives:

The non-surgical alternative to lens implant surgery is to wear spectacles or contact lenses. Although there are essentially no risks to wearing glasses, the quality of vision with strong longsighted or shortsighted glasses is not normal because of a magnified or minified image and a slight decrease in peripheral vision caused by the thickness of the lenses at the edge. Although contact lenses provide higher quality and more normal vision, they have a slight risk of complications, especially if they are worn overnight. The risks of contact lenses include: infection, (which can rarely cause loss of vision if the infection involves the cornea), allergies (giant papillary conjunctivitis, or GPC, which can make wearing the lenses impossible), and mild irritation and discomfort. Contact lenses or glasses are non-surgical, extremely accurate, permit easy changes in prescription and also allows the eye to retain its focusing power for near vision before age 45.

Surgical alternatives (including lasers):

If you are having lens implant surgery in order to reduce your reliance on glasses, there are several other procedures for the correction of farsightedness, nearsightedness and astigmatism.

Excimer laser treatment:

The excimer laser is capable of reshaping the cornea. It can be used to correct low to moderate amounts of hyperopia, myopia and astigmatism through PRK (photorefractive keratectomy) or LASIK (laser in-situ keratomileusis) procedures.

LASIK, the most commonly performed of these alternatives, is an operation that combines the creation of a corneal flap with an instrument called a microkeratome, or a femtosecond laser, and the removal of corneal tissue with the laser. LASIK has been found to be quite successful and relatively safe for the correction of moderate and high myopia, up to about -10.00 dioptres. LASIK can be complicated by problems with accuracy and quality of vision, especially at night, when attempting high corrections. Dry eyes can also be an issue afterwards.

As the eye ages, the natural lens continues to change, and patients undergoing laser may find that after some years their prescription alters.

The advantage to laser procedures is retaining the under 45 year old patient's natural near focusing power, and there is no incision into the inside of the eye.

If Mr. Luck thinks that you would be better served by having a laser procedure, then he will inform you either prior to or during the consultation.

Initials:

Additional information

Should a second surgical procedure be required within the one-year follow up period, i.e. replacement or repositioning of my intraocular lens, I understand that there will be no additional fees payable.

Should a second surgical procedure be required after the one-year follow-up period, i.e. YAG laser capsulotomy, I understand there will be additional fees from my surgeon and the Hospital.

I consent to the photographing or televising of the operation(s) or procedure to be performed for medical, scientific or educational purposes, provided that my identity is not revealed, and I consent to the admittance of observers to the operating room for purposes of advancing medical education.

I acknowledge that no guarantee has been given by anyone as to the results of the procedure.

I understand that my identity will be kept confidential in any reports or journal articles. I give permission for medical data concerning my operation and any subsequent treatment to be submitted for publication.

I also understand that it is impossible for my doctor to inform me about every conceivable complication that may occur and therefore any unforeseen risks.

The consent form given to me comprises eight (8) pages and I have been given a copy to keep. I am aware that there could also be unforeseen risks and that I must assume that if I suffer injury I will only receive compensation to which I am entitled to receive under law. In other words, I shall be in the same position as I would be if I were receiving normal clinical management.

I have carefully read and understand the information presented in this form and consent to have refractive lens exchange (clear lens replacement) performed. I have had the opportunity to ask questions and have had them answered to my satisfaction. I have been fully informed of my right to receive a copy of this signed and dated consent form. I am therefore making an informed decision in giving my permission to have lens implant surgery performed on my:

Right eye

Left eye

Both eyes

Patient Name:

Patient Signature:

Surgeon Signature:

Date:

Patient notes:

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