



Cataract and Refractive Lens Exchange (RLE) Surgery Informed Consent Document

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**It's a wonderful world.
We'll help you see it that way.**

OpticalExpress

Cataract and refractive lens exchange (RLE) surgery Informed consent document

This document is a legal document. You need to sign it to give the surgeon your written permission to treat you. It is important that you bring this document with you on the day of your treatment. If you do not understand anything in this document, please ask us for more information.

Patient's name:

Patient's central ID:

Eye to be treated: Right eye Left eye

Informed consent

Background information

We aim to work in partnership with our patients to make the right clinical decisions. In this document we tell you about the benefits, potential risks and alternative treatment or vision correction options to refractive lens exchange (RLE) surgery.

At Optical Express we believe that by complying with the requirements of the applicable regulatory bodies, such as the General Medical Council (GMC) in relation to refractive surgery, working collaboratively with our International Medical Advisory Board (IMAB) and by only working with highly skilled and experienced surgeons and multi-disciplinary support teams we can deliver refractive surgery safely.

This document along with the other information that you received at and during your consultations, is designed to make sure that you fully consider the benefits and potential risks of the surgery you have been scheduled for and make an informed decision in accordance with the General Medical Council's 'Good Medical Practice' and 'Consent: patients and doctors making decisions together' guidance.

Please initial each point below to confirm that you understand the information.

Your surgeon will decide whether you are suitable for treatment after carrying out a careful examination, discussing the treatment with you and considering your optometrist's opinion. The surgeon's decision will be based on your individual needs.

You may wish to tell your GP that you are considering cataract or RLE surgery, as they can give you independent medical advice.

If you have any questions about your treatment, you should ask your surgeon before you sign this document.

Write your initials here:

Before your treatment you must tell your surgeon if any of the following applies.

- You have any general health conditions, including back problems or claustrophobia or other psychological conditions (including a history of anxiety or depression).
- You are taking or using any medications, eye drops or supplements, including vitamins or nutritional supplements you have bought 'over the counter' without a prescription.
- Your current or planned occupation prevents you from having a multifocal lens implant, any type of lens surgery or laser eye surgery.

It is vital that you have fully and accurately filled in the health and lifestyle questionnaire you received at your pre-treatment consultation before you meet your surgeon for treatment.

The information in this document is extremely important as it will help your surgeon to decide whether or not you are suitable for the treatment.

I have read and understood this section and have met all the conditions.

Write your initials here:

General information

The cataract surgery procedure

Cataracts develop when the natural lens inside your eye becomes cloudy, making it difficult for you to see well enough to carry out your usual daily activities. While cataract surgery is elective, a cataract cannot be corrected with medications, glasses, contact lenses or laser eye surgery. The purpose of this procedure is to replace the cloudy lens (cataract) with

a clear lens implant inside your eye to restore your vision that you have lost due to the cataract. Another benefit of this procedure is that it could reduce your need for glasses or contact lenses, if you previously needed these. Modern day cataract surgery is identical to RLE surgery.

I understand the above and all of my questions have been answered.

Write your initials here:

Refractive Lens Exchange

RLE is a procedure to correct vision. Patients can choose to have this treatment if they want to reduce the need to wear glasses or contact lenses. RLE corrects vision by replacing the natural lens in the eye with a new lens of a given focusing power. The procedure is explained in more detail in the information you received at the consultation. RLE is identical to modern day cataract surgery.

There is a significant amount of medical evidence that shows RLE procedures are extremely safe and effective. However, it is not possible to absolutely guarantee that RLE surgery will improve your vision or that you may not need other types of treatment to improve your vision.

RLE surgery involves replacing the eye's natural lens with an artificial lens implant into the eye. We select the power of the new lens as accurately as we reasonably can using very sophisticated technology, to reduce or correct short-sightedness, long-sightedness or astigmatism. However, because healing patterns can be unpredictable and because of other surgical factors, we may not achieve the result we are aiming for after one or several treatments, even with the correct lens power. So, even after treatment, you may still need additional vision correction in the form of glasses, contact lenses, laser eye surgery or further lens replacement surgery, to achieve the best vision possible. Dependent on the lens type selected up to 7% of patients that have a primary procedure will go on to have a secondary procedure, such as laser eye surgery, within the first twelve months. Any future surgery is of course subject to suitability. With some types of Intraocular Lens (IOL) less than 2% require additional vision correction after the primary procedure to drive legally and with multifocal IOLs less than 5% require additional vision correction to perform daily regular reading tasks, such as viewing a newspaper.

Although we confirmed that your prescription was stable at the time of your consultation, it is still possible for you to develop further short-sightedness, long sightedness or astigmatism over the time after treatment, even if the treatment is successful in correcting your vision.

RLE surgery will not correct other causes of poor vision such as amblyopia (lazy eye), vitreous opacities (floaters), glaucoma, diabetes, age related macular degeneration or any other retinal or optic nerve conditions. As a result of the RLE procedure being identical to modern day cataract surgery, you will not develop a cataract as a follow-on to it being performed. By opting for treatment at an early stage you are reducing the risk of a complication developing during the procedure.

After having RLE surgery, it is possible that you may develop eye conditions that are unrelated to, and not caused by or prevented by, RLE surgery, such as glaucoma, age-related macular degeneration and other conditions of the retina.

I understand the above and all of my questions have been answered.

Write your initials here:

All-laser (femtosecond) surgery

Femtosecond lasers can now be used in cataract and RLE surgery, and their role is to help with or replace several parts of the manual cataract or RLE surgery.

The possible benefits of using the laser include the potential to be more precise and consistent. The laser can also assist the surgeon in making the surgery safer. In turn, this aims to improve your clinical outcome. Traditionally, the surgeon uses a surgical blade to make the incisions in the front window of the eye known as the cornea, and uses other special instruments to make the circular incision in the outer layer of the cataract or clear lens. This procedure is known as a 'capsulotomy'. The surgeon then uses a high-powered ultrasound phacoemulsification device to break up the natural lens and remove it from the eye. The possible benefits of using the laser include the ability to make more precise and consistent incisions in the cornea, a more circular and centred capsulotomy, and to soften the cataract before it is removed so less ultrasound energy is needed with the phacoemulsification device. It is also possible to make accurate incisions in the cornea (known as 'astigmatic keratotomy' or AK) to reduce astigmatism.

Using the laser does not take away the risk of complications during or after surgery, which include decentration of the corneal or capsulotomy incisions, incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure.

Most people treated with the laser, report temporary small, red spots on the sclera (the white of the eye) after treatment.

In some people, the red spots covered a larger area of the sclera, and this is called a 'subconjunctival haemorrhage'. The people who reported these effects also reported that the effects usually went away within seven days.

I understand the above and all of my questions have been answered.

Write your initials here:

Comfort during your procedure

Just before surgery, we will give you a local anaesthetic to numb the eye and we will give you drops to dilate the pupil. The majority of patients report no discomfort at all during the procedure itself. During surgery you will be in a comfortable lying position and a member of the surgery team will be by your side offering you reassurance. The surgery itself will only take approximately ten minutes per eye.

There are risks associated with the use of anaesthetic, including a squint or 'lazy eye' and droopy eyelids, which resolve in the longer term in many cases. Other complications including enlarged pupils, partial or complete blindness and cardiac and respiratory problems are extremely rare.

For patients who are anxious we can give you a mild sedative to help you relax. Patients who are given a sedative are cared for by a medical specialist from administration of the sedative until discharge.

I understand the above and all of my questions have been answered.

Write your initials here:

Monofocal lens surgery

As part of your lens surgery you can have a monofocal (single focus) lens implant to correct your vision at one distance, typically for far vision, and wear glasses, for example, for close-up work. The aim of this approach is that you are left with excellent distance vision with both eyes.

The disadvantage is that you will need to wear glasses, typically for intermediate and near vision tasks such as reading a newspaper or restaurant menu, viewing a computer screen or mobile device, or applying make-up.

I understand the above and all of my questions have been answered.

Write your initials here:

Presbyopia

When we are young, our eyes can focus at all distances, from very distant objects to very near objects (like an auto-focus camera). This ability to focus weakens throughout life due to natural ageing of the eye. From about the age of 40, this loss of near focus begins to affect our ability to read and see close-up things clearly. This weakening continues until we are about 60 years old, at which time we have almost no ability to change focus.

The loss of ability to focus results in the need for near vision glasses, even for people who have previously had excellent distance and near vision without glasses. This process (called 'presbyopia' or 'dysfunctional lens syndrome') happens in everyone.

People with presbyopia usually need bifocal, varifocal or separate reading glasses to see clearly at close range. If you are short-sighted, you can compensate for this loss of near focus simply by taking your glasses off or your contact lenses out. If you are short-sighted and choose to have both eyes treated to give you the best distance vision, you will lose the ability to compensate for your loss of near focus.

The most important thing to remember is that if you have presbyopia and choose to have both eyes treated to give you the best distance vision, you will need to wear glasses for most near-vision activities after treatment, not just reading. This includes most close-up tasks that you can touch with arm's length, such as using a computer, looking at your mobile phone, applying make-up, reading a menu and so on.

Monofocal monovision lens surgery

An alternative method of treatment for patients with presbyopia utilising monofocal lenses is a technique called 'monovision', where a single-focus lens for best distance vision is implanted in one eye and a single-focus lens for the best near vision is implanted in the other eye. The possible advantage of this technique is that it gives you a better range of vision and reduces the need for glasses.

The combination of a distance eye and a reading eye may allow you to see clearly at both far and near distances without glasses. Monovision has been used successfully for many contact lens wearers and for patients who have had laser eye surgery.

It can also take some time for your eyes to adapt to the new lenses and you may still need glasses for certain tasks. Judgement of depth may not be as good as when both eyes are focused for best distance vision. If your eyes do not adapt, it may be necessary for you to have further treatment.

I understand the above and all of my questions have been answered.

Write your initials here:

Multifocal (prebyopia correcting) lens surgery

Multifocal lenses (including Extended Depth of Focus or EDOF IOLs) are an advanced form of intraocular lens technology. They can provide good distance, intermediate and near vision using multiple optical powers in the same lens. This can improve your intermediate and near vision and reduce your need to rely on glasses for intermediate or near viewing, although it is possible that it will not restore all of the ability to focus at near or intermediate distances.

A possible disadvantage of this type of lens can be glare, starbursts or 'halos' around lights in situations with low lighting such as at night, and this may make driving at night more difficult. It is known and accepted that the overwhelming majority of patients adapt to or overcome these symptoms with time.

If you do have these symptoms following your treatment, you could consider a lens exchange where the lens is removed and replaced with a different design of lens such as a single focus lens. This additional treatment will present further surgical risks and will result in a change in your distance vision, intermediate vision and near vision. Approximately 1 in 600 (0.17%) primary procedures where our most frequently used multifocal IOL is implanted will be followed on by a lens exchange procedure.

I understand the above and all of my questions have been answered.

Write your initials here:

Complications and side effects

During the first few days after your treatment, including on the day of your surgery, you may have varying degrees of pain and discomfort, feel as though there is something in your eye and your eye may be sensitive to light. It is common for your eyes to water, and your eyelids may look red and swollen.

There may also be differences in the quality of your vision. If you have any discomfort, we will give you eye drops to use, if necessary. Analgesics can be used by patients and are generally very effective in providing relief.

I understand the above and all of my questions have been answered.

Write your initials here:

Following RLE surgery, there is the risk that you could develop a condition called posterior capsule opacification (PCO). Although the natural lens is removed during surgery, the capsule surrounding the back of the lens is left intact to support the lens implant. It is possible for the capsule to become cloudy and reduce your vision during the months or even years following your surgery. The incidence of this condition developing based on Optical Express data is 4%. However, if this happens, vision can be successfully and quickly restored using a specialised laser called a YAG laser. This procedure takes only minutes to carry out, is not painful and produces almost immediate improvement in vision.

In rare cases, RLE surgery can lead to a complication. An infection can develop within the eye (endophthalmitis - incidence less than 0.01% at Optical Express) or on the outer surface of the eye (microbial keratitis – incidence of less than 0.01% procedures after RLE surgery). Other rare complications include swelling of or abrasions on the cornea, bleeding inside the eye, damage to the capsule that supports the lens, intraocular lens opacification, displacement or dislocation of the lens implant, remnants of the natural lens being left inside the eye resulting in inflammation, complications of the retina to include swelling in the central area of the retina known as the macula or a retinal detachment, vitreous opacities or floaters, wound leak, elevated eye pressure (IOP), glaucoma, droopy eyelids or double vision. Complications can occur, however, their incidence following RLE surgery is exceptionally low. The majority of patients experience no complication as a follow-on to their RLE procedure.

It is impossible to list every complication which could arise from RLE surgery. While extremely rare, it is reported in peer review literature that RLE surgery may result in blindness, or even the loss of an eye. We have not told you about all potential risks and complications that are considered to be extremely rare or which have not previously been reported. Also, there may be long-term effects that we do not yet know about or cannot expect at the current time, even though intraocular lenses have been implanted for over 80 years in the human eyes.

Neither cataract nor RLE surgery is reversible (the natural lens cannot be put back in your eye), though where deemed to be clinically necessary a lens exchange procedure can be performed, where the implanted IOL is removed and replaced with another. Quality of vision side effects such as glare, starbursts or 'halos' around lights or symptoms of dry eye, can develop after surgery but their associated symptoms tend to dissipate or resolve in the medium to long term in the majority of patients.

I understand the above and all of my questions have been answered.

Write your initials here:

After your procedure

We recommend that you do not travel alone for at least two hours after your eye surgery, even if you are travelling a route you know well or for a week after your eye surgery where you are travelling a route you do not know well. We cannot predict how you will feel after your eye surgery, and whether you will be able to safely use transport (either public transport or your own transport). For example, you may feel drowsy or disorientated, or have restricted vision.

I understand that if I decide to travel on my own following the treatment, this is at my own risk.

I agree to follow the aftercare advice you give me relating to protecting my eyes and I will take my medications, including my antibiotic and anti-inflammatory drops, as prescribed.

Due to the position of the lens within the eye, I understand it is important that my eye health is checked every year.

I understand the above and all of my questions have been answered.

Write your initials here:

Treating both eyes

You can choose to have Cataract or RLE surgery carried out on both eyes on the same day. Alternatively you may prefer, or be recommended to have surgery carried out on separate days.

I choose to have Cataract or RLE surgery carried out

Both eyes on the same day

Each eye individually

I understand the above and all of my questions have been answered.

Write your initials here:

Patient consent

Your surgeon will help you with the choices in this section. I give my consent to having the following treatment. (Tick the appropriate box.)

I choose to have the following cataract or RLE surgery:

Implant a multifocal lens: Right eye Left eye

Implant a monofocal lens: Right eye Left eye

I elect to have **monofocal lenses** to correct:

Distance vision Right eye Left eye

Near vision Right eye Left eye

I consent to my surgeon making the choice as to whether he/she uses a femtosecond laser and/or traditional (manual) surgery technique during my procedure.

Write your initials here:

Use of medical information

I give permission for you to use information relating to my treatment to help you provide my treatment, review my treatment, give me advice about additional treatment, carry out any additional treatment, and manage your business properly, for example to allow you to keep accurate records and for quality-control purposes.

Write your initials here:

I give permission for you to use information relating to my treatment for research purposes, for statistical analysis, in connection with academic and scientific papers, presentations and other publications, and for marketing purposes. I understand that the information relating to my treatment will not reveal my identity.

Write your initials here:

I understand that Optical Express may receive my medical records, including, but not be limited to, reports, charts, medical history and record entries by different doctors or healthcare professionals, photographs, findings, ophthalmic (eye) or other scans, radiographs (x-rays), prescriptions, diagnosis, medical testing, test results, billing, and other treatment records in my doctor's possession ("Medical Records") to the extent necessary for treatment, determination of clinical management plans, customer service, and billing. My Medical Records will only be shared with third parties if this is covered by my consent or otherwise permitted by the applicable law. Optical Express may also use this information for internal educational and internal data review and analysis purposes.

I will not, nor shall anyone on my behalf seek legal, equitable or monetary damages or remedies for such disclosure. I acknowledge that use of my Medical Records is without compensation and that I will not nor shall anyone on my behalf have any right of approval, claim of compensation, or seek or obtain legal, equitable or monetary damages or remedies arising out of any use such that comply with the terms of this Consent.

Write your initials here:

Patient declaration

Further to my consultation with my optometrist I have taken part in a discussion with a second clinician who also discussed with me the risks, benefits and alternatives to laser eye surgery.

I received my cataract and RLE terms and conditions and informed consent documents more than 24 hours before my surgery.

I confirm that I have not been placed under any pressure and I do not feel obliged to have treatment. I understand that the decision whether to go ahead with cataract or RLE surgery (whichever applies) is mine alone, and should be based on the information I have received in this document and during my pre-treatment consultation.

I confirm that all my questions have been answered, and I am satisfied with the answers. I understand that cataract or RLE surgery is an elective procedure (which means that I can choose whether or not to have this procedure). I understand that there are other ways to correct vision, some which involve surgery and some which do not, but I also understand that there are currently no other effective ways to correct or restore lost vision that is caused by cataracts. The risks and benefits of treatment have been thoroughly explained to me.

I give my consent to go ahead with surgery.

Write your initials here:

Confirmation of declaration

Please confirm you want to go ahead with the surgery by writing the following statement in the box below.

‘Having considered the information I received at my pre-treatment consultation and the information in this document, and discussed the risks, side effects, possible outcomes and benefits of treatment with my optometrist, second clinician and surgeon, I am happy to go ahead with the surgery. I understand I am under no obligation to do so.’

Your signature:

Your full name (print):

Your date of birth:

Date of your pre-treatment consultation:

Date of your signature:

Witness declaration

Witness’s signature:

Witness’s full name (print):

Witness’s date of birth:

Date of witness’s signature:

Surgeon declaration

I have discussed the intended procedure with the patient. I am satisfied that the patient has read this informed consent document, and understands it and the risks and benefits of, and alternatives to, the treatment. The patient has told me that I have answered all their questions to their satisfaction. The patient has also told me they are willing to accept the risks associated with the intended treatment, and voluntarily agrees to have cataract or RLE surgery.

I agree to accept this patient on the above terms and provide treatment as set out in this document.

Surgeon’s signature:

Surgeon’s full name (print):

Date of surgeon’s signature:

Surgeon’s status (please tick as appropriate):
Employee of Optical Express Independent practitioner

Notes:

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