



Laser Eye Surgery (iLASIK, LASEK, iDesign iLASIK and iDesign LASEK) Informed Consent Document

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

OpticalExpress

Laser eye surgery (iLASIK, LASEK, iDesign iLASIK and iDesign LASEK) 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 (or eyes) to be treated: Right eye Left eye **Both eyes to be treated on the same day:**

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 laser eye 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 safely deliver refractive surgery.

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 for which you have been scheduled and make an informed decision in accordance with guidance such as 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 make a final decision on whether or not you are suitable for treatment after carrying out a careful and thorough examination, discussing all aspects of the treatment with you and considering your optometrist's opinion. The surgeon's decision will be based on your individual needs.

Your Surgeon may elect to postpone your procedure to a future day should they believe that additional diagnostic tests or additional medical specialist support is required to allow delivery of your treatment.

You may wish to tell your GP that you are considering laser eye 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 and understand this is a very important decision. We are always happy for patients to call us or attend the clinic for further clarification.

I have read and understood the points discussed in this section.

Write your initials here:

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

- You have any general health conditions, including back problems, claustrophobia or other psychological conditions (including any 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 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 treatment.

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

Write your initials here:

General information

There are two types of laser procedures used to correct vision: LASIK (laser in situ keratomileusis) and LASEK (laser epithelial keratomileusis). They are both intended to reduce or eliminate the need for you to wear glasses or contact lenses. The effects of both types of laser procedures are permanent and cannot be reversed.

The main difference between the two types of laser procedures is that LASIK treats the inner layers of the cornea whereas LASEK treats the outer layers (near to the surface).

Both procedures are explained in more detail in the information you received at your pre-treatment consultation.

The results of the LASIK and LASEK procedures are equally effective. Most of the risks and side effects are also similar, but there are some characteristics that are unique to each procedure.

LASEK involves gently moving the outer protective layer of the eye (the 'epithelium'), using a diluted alcohol solution (ethanol 18%). This protective epithelium regenerates (grows back), typically within three to four days after your treatment. Ethanol is used routinely and safely in this way for LASEK procedures worldwide. However, ethanol is not licensed for use as an eye drop and by signing this informed consent document you are also agreeing to ethanol being used during your treatment.

In line with industry standards in the case of LASEK, if you have a moderate or high prescription, your surgeon may decide to use an anti-haze agent (mitomycin C) during your treatment, to reduce the risk of you developing corneal haze (frosty or hazy vision). Mitomycin C has been used for many years in ophthalmic surgery, but is not licensed for this use. By signing this informed consent document you are also agreeing to mitomycin C eye drops being used during your procedure should your surgeon believe their use is in your best interests.

I understand that anaesthetic eye drops are used during the procedure to reduce any sensation and a lid holder (speculum) is used to prevent my eyelids from closing. In rare cases (less than 0.05%), this may slightly alter the position of the eyelids in the short to long term after the treatment.

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

Write your initials here:

Medical Evidence and Outcomes

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

Due to potential variances in healing patterns and other aspects of surgery, we may not fully achieve the desired result from the treatment you are scheduled for, after a single procedure. There is a low risk that you could still be short-sighted, long-sighted or have astigmatism and may need to wear glasses or contact lenses, or have more surgery. More than 98% of patients do not require any further treatment. Up to 2% of patients that have a primary procedure will go on to have a secondary procedure within the first twelve months. Less than 0.3% of patients will require additional vision correction to drive legally after their primary procedure.

Laser enhancement surgery may be possible when your prescription is stable, there is enough corneal tissue available and there are no medical reasons why further laser eye surgery could not be safely carried out. We normally consider laser enhancement surgery three to six months after your initial laser eye surgery procedure.

Although we confirmed that your prescription was stable at the time of your pre-treatment consultation, it is still possible for you to naturally develop further short-sightedness, long-sightedness or astigmatism over time after treatment, even if the treatment is successful in correcting your vision. The majority of patients will have no change in their vision, with their prescription remaining stable in the long term.

Laser eye surgery will not correct other causes of poor vision such as amblyopia ('lazy eye'), glaucoma, diabetes or age-related macular degeneration.

I understand that, after having laser eye surgery, it is possible that in the future I may develop eye conditions that are unrelated to, and not caused by, laser eye surgery, such as glaucoma, eye muscle imbalances, cataracts, 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:

Presbyopia / Monovision

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 to 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 off your glasses or taking out your contact lenses. 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 within arm's length, such as using a computer, looking at your mobile phone, applying make-up, reading a menu and so on.

An alternative method of treatment for patients with presbyopia is a technique called 'monovision', where one eye is treated to give you the best possible distance vision, and the other eye is treated to give you the best possible near vision.

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.

It can also take some time for your eyes to adapt to monovision and you may still need glasses for certain tasks. 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:

Wavefront iDesign technology

There is more information about wavefront treatment in the information you received at your pre-treatment consultation. Wavefront treatment is a more advanced laser technique for correcting vision. It is safer and can provide better results by correcting both your prescription and subtle visual imperfections in the eye. Studies have shown that wavefront treatment reduces the risk of night glare and increases your chances of achieving better-quality vision.

Wavefront treatment has the same surgical and healing risks as the other treatments described in this document. iDesign technology is an advanced technology used to further improve the clinical outcomes of wavefront treatment.

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

Write your initials here:

Alternatives to laser eye surgery

Laser eye surgery is an elective procedure. This means you can choose whether or not to have it.

There are other ways to correct your vision, some of which involve surgery and some which do not, including glasses, contact lenses, refractive lens exchange and another type of lens surgery, which may be able to help your condition.

It is important to put the recommended procedure into context. A range of potential complications can occur with all forms of vision correction, including contact lenses. The risk of developing an eye infection associated with daily wear soft contact lenses is around four times greater per year of wear than for example LASIK. With extended wear lenses, the risk is around twenty times greater. These contact lens associated risks of infection are greater than the risk of infection associated with laser eye surgery. In addition, contact lenses are a single use plastic and, in a disposable format, carry a significant environmental risk. In respect of glasses, these carry risks associated with trauma and falls, which ultimately can lead to serious health concerns.

You have received this document because we have recommended laser eye surgery as the best procedure to meet the goals you have identified during your consultation. However, if you would like more information about other treatment options, please ask us.

I understand that there are alternatives to laser eye surgery. I understand that laser eye surgery is an elective procedure and that I do not have to have treatment.

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

Write your initials here:

Development of cataract

Cataract develops when the natural lens inside your eye becomes discoloured and cloudy and reduces your vision. Patients aged 60 or older have a higher risk of developing cataracts than younger patients. This is a natural ageing process that happens in everyone, but progresses at different rates in different people. It is impossible to predict the age at which cataracts will begin to affect your vision. Some people never get to a point where cataracts affect their vision.

Laser eye surgery does not cause cataracts or affect the process of cataracts forming. It is possible that you could develop cataracts as part of the natural ageing process, after having laser eye surgery, even if there were no signs of cataracts at your pre-treatment consultation.

The treatment for cataracts is cataract surgery. This is a surgical procedure during which the natural cloudy lens is replaced with a clear artificial lens that is implanted inside the eye.

Because the risk of cataracts increases when you reach the age of 60, it is important to understand that there is an alternative treatment to laser eye surgery which also prevents cataracts. The treatment is called 'refractive lens exchange' (RLE), and is a form of intraocular lens (IOL) surgery.

The advantages of RLE are that it will permanently correct your vision (like laser eye surgery) and it will prevent you from developing cataracts later in life. Like all forms of medical procedures and vision correction solutions there are some potential risks as well as advantages.

I understand the issues relating to cataracts, and that RLE is an alternative to laser eye surgery. All of my questions have been answered. I would like to go ahead with laser eye surgery, which is the procedure that has been recommended for me, instead of RLE surgery.

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 experience 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. We will give you eye drops to use if you have any discomfort. 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:

In the case of LASIK treatment, there is a small risk of complication during the part of the treatment that involves creating a protective flap from the tissue in your eye.

When we are creating the flap, gentle suction is needed to stop your eye from moving. It is possible for suction to be lost during this step of the treatment and this carries an incidence of 0.05%. If this happens, it may result in blurred vision or delayed recovery (or both) which will be temporary, and we may need to postpone the rest of your treatment until your eye has fully recovered. The majority of patients go on to have treatment, either on the same day or on a day in the future.

Possible complications from creating the protective flap, and the healing process, include flap displacement (where the protective corneal flap has moved and is not in the correct position), corneal wrinkles, corneal abrasion (scratch), corneal scarring or irregularities and epithelial ingrowth (which is where surface cells grow underneath the protective flap) – the incidence of these complications is 0.173% or less.

Another possible complication is diffuse lamellar keratitis (DLK). DLK is inflammation which can produce corneal haze, scarring, blurred vision or delayed recovery. DLK can generally be managed as part of your routine aftercare, and it very rarely causes long-term problems with vision – the incidence of moderate DLK is 0.112%. Severe DLK carries an incidence of 0.003%

Another possible complication is central toxic keratopathy (CTK), which is a more severe form of DLK. CTK is very rare. It can lead to scarring, long-sightedness, irregularity in the surface of the cornea and, like the other possible complications, can result in a reduction in the quality of your vision.

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

Write your initials here:

In a small percentage of patients, haze or scar tissue may form on the cornea following LASEK treatment – incidence 0.120%. All patients receive a mild steroid eye drop to use for approximately one month following their treatment to reduce the risk of developing corneal haze.

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

Write your initials here:

Dry eye is a condition that some patients may have before treatment, especially people who wear contact lenses. Dry eye is a common symptom early in the healing process and you may experience it following laser eye surgery, even if you have not had it before.

Dry eye can be caused by factors external to the treatment. Air conditioning, increased use of computers and mobile devices and general health medications are some examples of un-associated factors that can cause dry eye and the associated symptoms. Nearly 9 in every 10 dry eye cases suffered by patients today are evaporative in nature. The number one cause of evaporative dry eye is a condition called meibomian gland dysfunction (MGD). This condition is associated with the eyelids and is not caused by laser eye surgery.

Most dry eye symptoms, which may include differences in the quality of your vision, can be managed with artificial tears, ointments and other treatments and will usually disappear gradually over the first few months following your surgery.

However, in a small percentage of patients the dry eye symptoms may not fully disappear and will need long-term treatment.

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

Write your initials here:

Night-vision disturbance such as glare and 'halos', double vision or seeing 'ghosts' around things are common immediately after laser eye surgery. In most cases, these symptoms gradually disappear over a period of weeks or months following the treatment. In rare cases, night-vision problems may last for longer periods or could be permanent.

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

Write your initials here:

Infection of the cornea can result in scarring, or a permanent reduction in, or loss of, uncorrected and corrected vision.

However, the risk of severe corneal infection that could also affect the inner eye is very low (0.0046% with LASIK and 0.013% with LASEK). The risks are greater with contact lenses.

Corneal infection develops rarely, either as a result of the way a patient's eyes heal, a surgical complication or due to unrelated issues.

Corneal infection can slow your recovery and we may recommend further treatment. Corneal infection can affect the level, quality and sharpness of the vision that can be achieved through further treatment. This means that if your vision can be corrected to 6/6 (or 20/20) with glasses or contact lenses before treatment, it may not be possible to correct it to the same level after your treatment if you have a corneal infection.

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

Write your initials here:

Keratoconus is a condition that can result in a weakening of the inner layers of the cornea, and may need to be corrected with a special contact lens or surgery, including corneal cross-linking or even a corneal transplant. This condition affects approximately 1 in 2,000 people (0.05%) in the general population, regardless of whether or not they have had laser eye surgery. Ectasia is the name given to a very similar, even identical, condition that sometimes develops after laser eye surgery, particularly LASIK surgery. The risk of ectasia after laser eye surgery is lower than the risk of keratoconus in the general population as a result of the diagnostic screening tests we carry out during your pre-treatment consultation which can identify risk factors for keratoconus or ectasia in many patients. It is not known whether ectasia is a unique condition associated with, or caused by, laser eye surgery, or if it is simply that keratoconus had not yet developed at the time of treatment, but would have developed anyway, whether a patient has had laser eye surgery or not. Either way, ectasia following laser eye surgery is rare. If you do have ectasia, you could need further treatment, similar to that described above for keratoconus, and it may result in a permanent reduction in the quality of your vision.

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

Write your initials here:

Most published scientific literature shows that laser eye surgery is safe and effective in patients with stable or well-controlled autoimmune conditions. If you have an autoimmune disorder, it is important to understand that you may be at an increased risk of complications compared with patients who do not have autoimmune disorders.

Patients who have certain types of autoimmune conditions, even before laser eye surgery, can sometimes experience eye and vision problems ranging from mild dryness to a breakdown or thinning of the cornea (the front of the eye).

This thinning condition is very uncommon, but it can lead to discomfort and reduced vision, and may need long-term medical treatment. In very rare cases these conditions may mean that you need more surgery. It is not known whether having laser eye surgery means you are more likely to develop these conditions.

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

Write your initials here:

Posterior Vitreous Detachment (PVD) is a condition that can occur whether or not you have had laser eye surgery. There is low level evidence that laser eye surgery may hasten the onset of this naturally occurring event. PVD can cause vitreous opacities (floaters) and other conditions of the retina.

It is impossible to list every complication which could arise from laser eye surgery. We have not told you about risks and complications that are considered to be unforeseeable or extremely rare, or which have not previously been reported. Also, there may be long-term effects that we do not yet know or cannot expect at the current time.

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 use transport safely (either public transport or your own transport). For example, you may feel drowsy, 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.

To achieve the best result and reduce the risks, I agree to follow the medication regime the surgeon or optometrist prescribes and the aftercare routine described in the information documents.

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.

It is important that your eye health is checked every two years (unless recommended otherwise by a clinician after discharge) and the thickness of certain layers of the outer surface of the eye (known as the cornea) is measured.

I acknowledge your recommendation and agree to have bi-annual (two yearly) eye examinations, unless recommended otherwise by a clinician after discharge. 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 iLASIK or LASEK surgery to improve:

Distance vision Right eye Left eye

Near vision Right eye Left eye

I choose to have laser eye surgery with iDesign: Yes No

Write your initials here:

Use of personal information

I understand personal information relating to my treatment will be used 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 understand information relating to my treatment will be used for research purposes and statistical analysis, in connection with academic and scientific papers, presentations and other publications. I understand that information relating to my treatment and used for these purposes will not reveal my identity.

Write your initials here:

I understand that Optical Express may receive my medical records, including, but not 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 confirm that I have taken enough time to carefully and thoroughly read and understand the information in this document and the other information I received during my pre-treatment consultation.

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 laser eye surgery 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 laser eye 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. 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 laser eye 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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