

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

Informed consent

Background information

We aim to tell you about the risks, benefits and alternative treatment options of laser eye surgery.

It is important for you to understand that there are risks with any type of surgery. This informed consent document, along with the information you received at your pre-treatment consultation, is designed to make sure that you can fully consider the risks and benefits of the surgery that you have been scheduled for and make an informed decision on whether or not to go ahead with the treatment.

We are giving you all this information before your treatment so that you have enough time to consider all aspects of your treatment before your surgery.

The information in this document applies to all types of laser eye surgery.

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.

Please 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

The purpose of this part of the document is to confirm that you have understood all of the information you have received and to keep a record of your decision to go ahead with the treatment.

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

Write your initials here:

I understand that my surgeon will be registered with the General Medical Council. I understand I should visit www.gmc-uk.org for the benefits this offers me. I also understand my surgeon may be an independent practitioner using facilities you have provided.

You will tell me whether my surgeon is an Optical Express surgeon or an independent practitioner at the end of this document.

I am aware of the facts stated above.

Write your initials here:

I understand that my surgeon may decide to change the type of procedure I have if a different surgical approach would be safer or would provide a better outcome.

Write your initials here:

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

- You have any eye problems including amblyopia (lazy eye), strabismus (muscle imbalance which can cause double vision), severe dry eyes or any recurrent (keeps coming back), residual (an after-effect of another condition) or active eye conditions.
- You are a carrier of methicillin-resistant staphylococcus aureus (MRSA) or have been exposed to MRSA.
- You have any general health conditions, including back problems, claustrophobia or other psychological conditions (including any history of anxiety or depression).
- You have any implants, including a pacemaker, defibrillator, insulin pump or any other implanted device.
- You are allergic to any medication or latex.
- 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.
- You have had an eye injury or eye surgery in the past.
- You are pregnant, breastfeeding or could possibly be pregnant.

It is vital that you have fully and accurately filled in the health 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 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 (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.

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

Write your initials here:

LASEK involves creating a 'flap' of 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 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 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.

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

Write your initials here:

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, this may slightly alter the position of the eyelids in the short to long term after the treatment.

Write your initials here:

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.

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

Write your initials here:

I understand that 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 I may develop eye conditions that are unrelated to, and not caused by, laser eye surgery, such as glaucoma, eye muscle imbalances, cataracts, vitreous opacities (floaters), age-related macular degeneration and other conditions of the retina.

I may need more surgery to treat these conditions.

I understand that laser eye surgery does not increase or reduce my chance of developing these eye conditions in the future, or other conditions where there is no known cause.

Write your initials here:

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

Write your initials here:

I understand that I may still need to wear glasses or contact lenses after laser eye surgery or that I may need further treatment to achieve the best result possible.

Write your initials here:

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. 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 you are about 60 years old, at which time you have almost no ability to change focus. The loss of ability to focus results in the need for reading glasses, even for people who have previously had excellent distance and near vision without glasses. This process (called 'presbyopia') 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, such as using a computer, looking at your mobile phone, applying make-up, reading a menu and so on.

I have read and understand this section. I understand the issues of presbyopia, loss of ability to read and focus, and the need for glasses. I understand that if I have presbyopia and choose to have my distance vision corrected in both eyes, I will need to wear glasses for most near-vision activities after having laser eye surgery.

Write your initials here:

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 advantage of this technique is a better range of vision and you are less likely to need glasses after your treatment.

This 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.

Possible disadvantages may include reduced overall quality of vision and a reduced ability of both eyes to work together to help with depth of vision (depth perception).

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 that if I choose to be treated using the 'monovision' technique, my depth perception and overall quality of vision may be reduced, and that I still may need glasses for certain tasks. I understand that with the 'monovision' technique my eyes can take time to adapt to monovision and I may need further treatment if my eyes struggle to adapt.

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 treatment described in this document. iDesign technology is an advanced technology used to improve 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 which involve surgery and some which do not, including glasses, contact lenses and lens surgery, which may be able to help with your condition.

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 pre-treatment 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.

Write your initials here:

Cataracts develop 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 once you reach age 60, it is important to understand that there is another treatment that can be used instead of laser eye surgery which also prevents cataracts. The treatment is called 'natural lens replacement' (NLR), and is a form of intraocular lens (IOL) surgery.

The advantages of NLR are that it will permanently correct your vision (like laser eye surgery) and that it will prevent you from developing cataracts later in life. Some disadvantages of NLR include different risks, because the procedure involves surgery inside the eye, and the possibility that you may still need a laser procedure or other treatment to 'fine tune' your vision after NLR.

Your refractive optometrist or surgeon will discuss NLR with you if you would like more information.

For most patients laser eye surgery is still the best option, but it is important that you understand that NLR can be an alternative.

I understand the issues relating to cataracts, and that NLR is an alternative to laser eye surgery. All of my questions have been answered. I would like to go ahead with laser eye surgery instead of NLR surgery.

Write your initials here:

Possible risks, complications and desired results

Due to uncertainties 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.

So, even after laser eye surgery you could still be short-sighted, long-sighted or have astigmatism and may need to wear glasses or contact lenses or have more surgery. Your eyes may also go back towards their original prescription.

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.

Although laser enhancement treatment is generally very effective, there are extra risks involved, and we cannot guarantee we will achieve the result we are aiming for. We normally consider laser enhancement surgery three to six months after your initial laser eye surgery procedure.

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

Write your initials here:

Laser eye surgery is not reversible. The results of surgery cannot be guaranteed and you may need further treatment or surgery (or both) to achieve a result you are happy with.

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

Write your initials here:

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.

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. It is possible for the flap to be too thin or too thick, or for it to be created only partially or without a hinge.

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. If this happens it may result in blurred vision or delayed recovery (or both), and we may need to postpone the rest of your treatment until your eye has fully recovered.

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).

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 rarely causes long-term problems with vision. Another possible complication is central toxic keratopathy (CTK), which is a more severe form of DLK. CTK is very rare, and is not well understood. 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. 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. Some patients (depending on their prescription) will also receive mitomycin C drops during surgery, as described earlier in these terms and conditions.

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 haven't had it before.

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. Patients at greatest risk of dry eye include those with long-standing dry eye symptoms, women aged over 40 and people who are long-sighted.

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. The risk of night-vision disturbance is higher in patients who had a high prescription before their treatment.

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 (less than 1 in 5,000). Corneal infection develops rarely, either as a result of the way a patient's eyes heal, or 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 in the general population, regardless of whether they have had laser eye surgery. Ectasia is the name given to a very similar, possibly 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 because 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 had 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:

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.

Most published scientific literature shows that laser eye surgery is safe and effective in patients with stable or well-controlled autoimmune conditions. However, there is no universal agreement within the scientific community on this topic. 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.

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

Write your initials here:

Conditions of the retina (the back of the eye) that develop in patients who have not had laser eye surgery, such as detached retina or bleeding, have also been reported in patients who have had laser eye surgery, although this is rare. It is not known for certain whether laser eye surgery affects the chance of these conditions, or if it is simply a coincidence when they develop after laser eye surgery.

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

Write your initials here:

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:

We do not recommend that you 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.

Write your initials here:

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.

Write your initials here:

It is important that your eye health is checked every two years and the thickness of certain layers of the outer surface of the eye (known as the cornea) is measured.

I understand the above, acknowledge your recommendation and agree to have yearly eye examinations.

Write your initials here:

Same-day treatment of both eyes

The benefits of having both eyes treated on the same day include convenience, balanced vision, improved depth perception and less night glare. It is widely accepted as safe and medically appropriate to do this. For an initial procedure, most patients choose to have both eyes treated together.

Although complications relating to treating both eyes at the same time is extremely rare, the result could severely reduce your vision and cause disability. You may choose to have only one eye treated at a time if you prefer.

Enhancement treatment is usually carried out on only one eye at a time, but could also be done on both eyes on the same day.

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

Write your initials here:

Laser eye surgery enhancement treatment

A small percentage of patients (approximately 5%) choose to have further treatment after laser eye treatment to achieve the best possible vision.

Your surgeon may recommend this. This treatment is called enhancement treatment and typically is carried out three to nine months after the initial treatment. Enhancement treatment has the same benefits and risks outlined in this document, plus the following increased risks.

In the case of LASIK, these increased risks include epithelial ingrowth (where cells from the outer layer of the cornea, known as the epithelium, curl round under the protective flap created during surgery), ectasia if the LASIK flap is lifted or IOL displacement if the enhancement treatment is carried out after an IOL implant. There may be scarring of the cornea if enhancement treatment is carried out after radial keratotomy (RK).

In the case of LASEK, these increased risks include corneal haze, or corneal scarring if the enhancement treatment is carried out after RK or LASIK.

I understand that enhancement treatment carries all of the risks of laser eye surgery treatment, plus the extra risks listed above.

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 laser eye surgery treatment:

Initial surgery Right eye Left eye

Laser enhancement surgery Right eye Left eye

I choose to have iLASIK or LASEK surgery to improve:

Near vision Right eye Left eye

Distance vision Right eye Left eye

I choose to have both eyes treated on the same day:

Yes No

I choose to have laser eye surgery with iDesign:

Both eyes Yes No

Right eye only Yes No

Left eye only Yes No

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 on additional treatment, carry out any such 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:

Patient declaration

We advise you to take enough time to carefully and thoroughly read and understand the information in this document, and the other information you receive during your pre-treatment consultation. If you have not read or understood all of this information, please let us know and do not go ahead with the treatment.

At my consultation my optometrist discussed the risks, benefits and alternatives to laser eye surgery with me.

Write your initials here:

At my consultation I watched the laser eye surgery consent video which explained the risks and benefits of, and alternatives to, laser eye surgery and emphasised the importance of this informed consent document.

Write your initials here:

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 I have had enough time to read this document and the other documents in the patient information folder, including the terms and conditions document, which I received at 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 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: