

PATIENT INFORMATION SHEET **Laser assisted versus standard** **ultrasound cataract surgery**



A Randomised Comparison of Femtosecond Laser Assisted vs Standard Phacoemulsification Cataract Surgery for Adults with Visually Significant Cataract

1. We invite you to take part in a research study

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Discuss it with friends, relatives and your GP if you wish. You are free to decide whether or not to take part, this will not affect the care you get from your own doctors. Ask us if there is anything that is not clear or if you would like more information.

2. What is the purpose of the study?

We are comparing 2 ways of performing cataract surgery. These are standard ultrasound (phacoemulsification) cataract surgery and laser assisted (semi-automated) cataract surgery. The standard cataract technique relies on the surgeon performing a series of steps, including use of a hand-held ultrasound probe to break up the cataract. With laser assisted cataract surgery a laser automatically performs approximately half of the steps, including the breaking up of the cataract. An ultrasound probe is still used to remove pieces that have been broken by the laser.

We already know these steps can be performed more precisely, reliably and faster by a laser than by hand. We want to find out if this results in better outcomes and fewer complications. The newer method of cataract surgery is not normally available on the NHS. We will compare the two types of surgery by looking at measurements of vision, including quality of life questionnaires, complication rates and cost.

3. Why I am being asked to take part?

You have been invited to take part because you have a cataract that could be operated on using either the standard method or the laser assisted method. We are looking for 808 patients in total.

4. Do I have to take part?

It is entirely up to you to decide if you want to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive. If you decide not to take part, your cataract operation will, in all likelihood, be performed by the standard ultrasound method. If you have private medical insurance, you should inform your insurance company.

5. What will happen to me if I take part?

If you wish to take part, you will have a number of additional measurements of your eye health and vision. Some of these tests are standard NHS tests that may be requested by your surgeon if you are not in the study. All are non-contact tests; there is no discomfort or risk to your eye from the measurements. They are:

- Measuring your vision using a more detailed vision chart
- Checking your glasses prescription
- Measuring the shape of the front of your eye
- Measuring the health of the inner corneal layer (clear window at front of eye)

We will also ask you to fill out a few questionnaires while you are in clinic. The additional time for the research tests is approximately 1.5 hours, and can be done either after your clinic appointment or on a later day if you would prefer.

If you are found to be suitable for the study, you will be randomly allocated to have laser assisted cataract surgery or cataract surgery using the standard ultrasound technique. If you need to have cataract surgery on both your eyes, you will be offered the same technique for the second eye.

When we don't know which way of treating patients is best, we need to compare them fairly. We put people into 2 groups and give one group the new treatment and the other the standard treatment. The results are then compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). The decision as to which group you will be put in will be made by a computer, and neither you nor your surgeon will choose which treatment you receive.

You will be sent a letter confirming the time and date of your cataract surgery.

Photographs or recordings of your eye operation which are part of standard care, may be taken for analysis and/ or use in publications or presentations. You will not

be identifiable from these images as they are close ups of your eye and will not include your face.

After your surgery, you will need to attend clinic for two research appointments in addition to any appointments related to your standard NHS care. The first research appointment is 3 months after surgery and the second at 1 year after your cataract surgery. At these research appointments we will repeat the measurements of your eye health and vision, and you will again be asked to complete some more questionnaires. Each of these visits will last approximately 1.5 hours. You can stop taking part in the study at any time; however we ask that you only take part if you think you will be able to attend both the 3 month and 1 year research appointments.

We will ask you to provide us with 'best alternative contact details' for a relative, carer or friend who you give permission for us to contact if we cannot get in touch with you.

6. What does laser assisted cataract surgery involve?

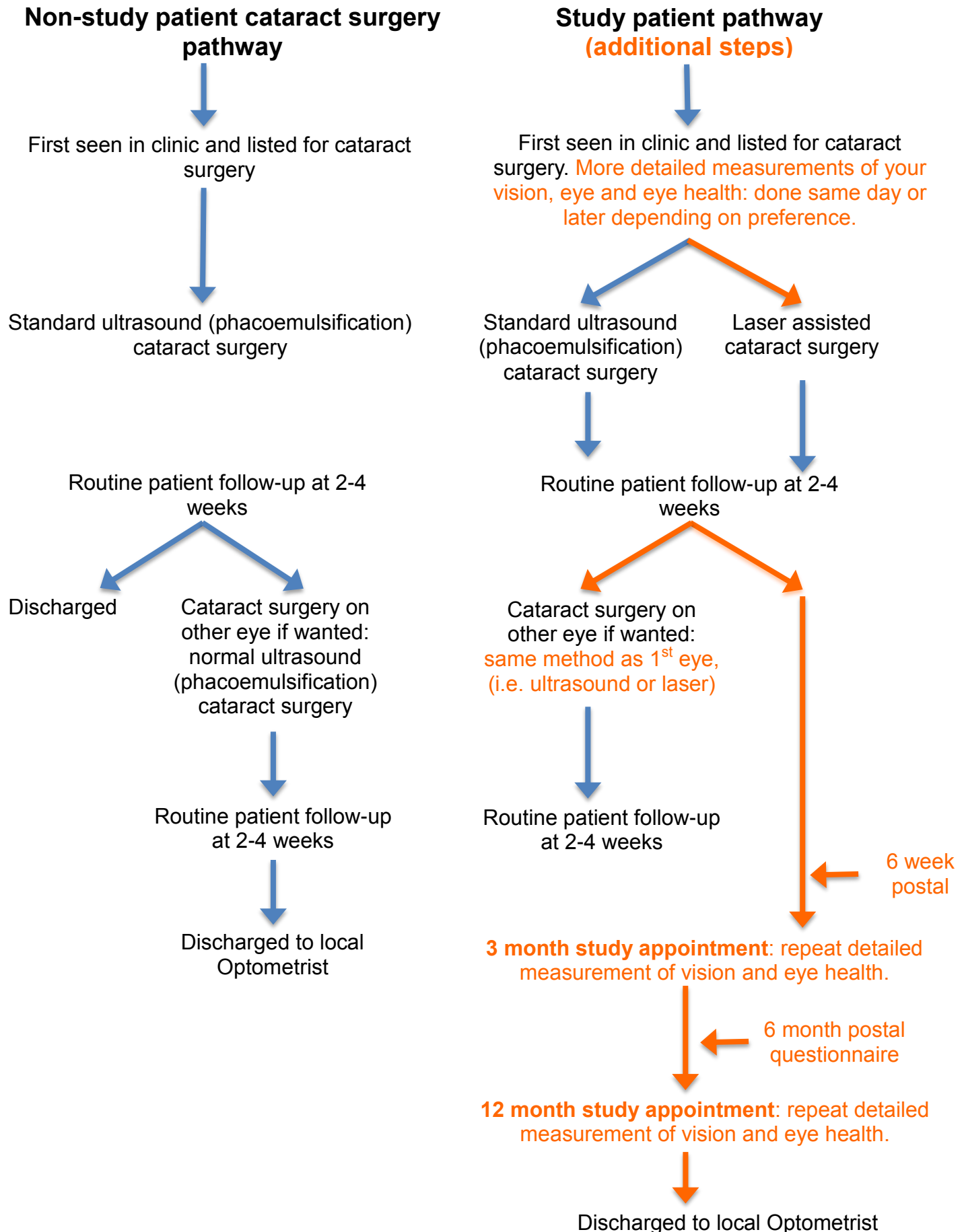
If you are randomised to the laser assisted cataract surgery, the only difference is you will have the laser treatment done immediately before the rest of your cataract operation. This is done in a separate room to the operating theatre and involves you lying down under the laser for approximately 3 minutes. You will need to keep still just like in the operating theatre and anaesthetic eye drops will be used to numb the eye. The laser treatment is not painful and patients describe it as seeing lots of different lights.

7. Do you do any extra tests if I take part?

All patients in the study will have special measurements made of their eye health and vision. All of these are non-contact tests and do not harm your eye in any way. These take approximately 1.5 hours and are in addition to the standard NHS pre-operative assessment that you would have. After your cataract surgery, you will undergo standard NHS post-operative care but will be asked to attend 2 additional study appointments as explained in section 5 above.

We will also ask you to complete some questionnaires during the study. You will be given these questionnaires to complete while at the hospital at your first visit and at the 2 research study appointments. We will also post you questionnaires to complete 6 weeks and 6 months after your surgery.

8. Study Summary Flowchart



9. When do I find out which treatment I will receive?

If you want to know which treatment you will receive, you can ask your surgeon on the day of your cataract surgery.

10. What are the possible disadvantages or risks of taking part?

We do not anticipate any risks to taking part in the study beyond those associated with standard cataract surgery.

The risks and potential side effects of cataract surgery are detailed in your hospital's Cataract Surgery Information booklet, which you have already been given and are summarized below.

Studies to date on laser cataract surgery have reported no overall difference in serious complications when compared to standard ultrasound (phacoemulsification) cataract surgery. Serious complications for both types of surgery are uncommon, but if they do occur they can permanently damage your eye and your vision.

For cataract surgery done by either study method, there is an average:

- One in a thousand risk of severe and permanent visual loss
- One in a hundred risk of requiring additional surgery to rectify a problem
- One in twenty risk of less serious complications, which may require further treatment at the time of surgery or following the operation
- One in ten risk of laser treatment at some time in the future for opacity of the capsule behind the implant
- There is virtually no risk to the other eye

11. What are the potential benefits of taking part?

We cannot promise that taking part in the study will benefit you, however by taking part you will be helping us find out how laser assisted cataract surgery compares to the current, standard method. The results of the study will help to plan cataract services offered by the NHS.

12. What happens when the study stops?

Once the study stops, all patients will have access to further treatment or further assessments as part of normal NHS care.

13. What will happen if I don't want to carry on with the study?

If a patient withdraws from a clinical study it can affect how the results are analysed, so we ask you to think carefully about participating in the study and attending for all visits before you agree to take part. However, you are free to withdraw from study follow up at any time without giving a reason. Your study information already collected will be used unless you tell us that you do not wish this. You should still attend any routine NHS appointments to monitor your vision and eye health.

14. What if there is a problem?

If you have complications relating to your cataract surgery, you will be looked after in exactly the same way as NHS patients not taking part in the study. You will be given a clear explanation of the problem and the treatment required. With patience, most problems occurring after cataract surgery can be corrected without affecting the final visual result. Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your study doctor, please make the claim in writing to Mr Mark Wilkins who is the Chief Investigator for the study and is based at Moorfields Eye Hospital NHS Foundation Trust. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of legal action initially, and you should consult a lawyer about this. Participants may also be able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of University College London or another party.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated by members of staff or about any problems you may have experienced from taking part in this study, the normal NHS complaints mechanisms are available to you. Please ask your study doctor if you would like more information on this. Details can also be obtained from the Department of Health website: <http://www.dh.gov.uk>".

15. Will my taking part in the study be kept confidential?

Yes. The records obtained while you are in this study will remain strictly confidential at all times, and will be held securely on paper and electronically at your treating hospital. Information relating to your cataract surgery will be transferred electronically to University College London to enable analysis of the study results, under the provisions of the 1998 Data Protection Act,

Your records will be available to people authorised to work on the study but may also need to be made available to people authorised by the Research Sponsor, for example members of the Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All of these people will have a duty of confidentiality to you as a research participant. Your details will not be passed to anyone who is not involved in the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it. If you withdraw from the study, unless you object, your data will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice (GCP) guidelines your data will be securely archived for a minimum of 5 years once the study is complete. They will then be destroyed in line with the NHS and GCP standards for such procedures.

16. Will my GP be informed of my involvement?

With your consent, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study. If there are any changes in your health requirements as a result of taking part in the study, your GP will again be informed.

17. Expenses and payments

We will be able to offer you a contribution towards your travel expenses for the two additional study appointments (at 3 and 12 months following surgery). You will not receive any other payment for being included in the study.

18. What will happen to any samples I give?

There are no samples taken as part of this study.

19. Will any genetic tests be done?

No genetic tests will be performed as part of this study.

20. What will happen to the results of the research study?

The results of the study will be available after it finishes and will be published in a medical journal and presented at scientific conferences. The data will be anonymous and none of the patients involved in the study will be identified in any report. Should you wish to see the results, please ask your study doctor.

21. Who is organising and funding the research?

This research is being funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme.

22. What if new information becomes available during the study?

Sometimes new information becomes available about treatments that are being studied. If this happens, we will tell you about it and discuss whether you want to, or should, continue in the study. If you decide to withdraw, we will make arrangements for your follow-up care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. If the study is stopped for any reason, you will be told why and your continuing care will be arranged.

23. Who has reviewed the study?

Patient and public groups have been involved in reviewing all stages of the research. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study was given favorable ethical opinion for conduct in the NHS by City Road and Hampstead Research Ethics Committee.

24. Further information and contact details

If you have any questions at any time, please ask either your study nurse or study doctor. If you require any further information or have any concerns please contact:

Name: Alexa King

Tel. Number: 0207 566 2117

Emergency Contact Number: 020 7566 2089


**National Institute for
Health Research**