ÖZEL ESKİŞEHİR GÖZ SAĞLIĞI VE HASTALIKLARI DAL MERKEZİ

INFORMED CONSENT FOR CATARACT SURGERY WHEN A PREMIUM IOL IS IMPLANTED, DURING REFRACTIVE LENS EXCHANGE SURGERY, OR TO TREAT ASTIGMATISM

Patient Name Surname :
File Number :
Education :
Job :
State of mind : ……

BARCODE

GENERAL INFORMATION

This information is given to you to help you make an informed decision about having cataract and/or lens implant surgery. Once you have read this **Informed Consent**, you are encouraged to ask any questions you may still have about the procedure. It is impossible to list all of the possible risks and complications associated with surgery. Risks and complications that are considered to be unforeseeable, remote, or commonly known may not be specifically discussed in this consent.

AN OVERVIEW OF CATARACT AND LENS IMPLANT SURGERY

Diagnosis: A cataract occurs when the natural lens of the eye becomes cloudy. The normal natural lens is clear, and helps focus light on the retina in the back of the eye. When cataract develops, it blocks and scatters light, cause reducing the quality of vision. Cataracts are part of the normal aging process. Most people over age 50 will have some degree of cataract, although some patients develop cataract at an earlier age or even at birth. Certain diseases (such as diabetes) or medications (such as steroids) cause faster the development of cataracts. Smoking, poor nutrition, and excessive exposure to ultraviolet light or radiation can also increase the risk of cataract.

Cataract Surgery: During cataract surgery, the cloudy natural lens of the eye is removed. In almost all cases, the cataract is replaced with a clear artificial lens, called an **intraocular lens implant (IOL)**, which is placed permanently inside the eye at the same time the cataract is removed. IOLs are available in different sizes, powers, materials, and designs, and must be selected by the surgeon depending on the needs of the eye.

An IOL can be inserted later as a separate procedure after a cataract is removed. This may require a different type of IOL than is used if one is placed at the time the cataract is removed.

EXAMINATIONS PRIOR TO SURGERY

If you agree to have the surgery, you will undergo a complete eye examination by your surgeon. This will include an examination to determine your glasses prescription (refraction), measurement of your vision with and without glasses (visual acuity), measurement of the pressures inside your eye (tonometry), measurement of the curvature of your cornea (keratometry), laser and/or, ultrasonic measurement of the length of your eye (axial length), intraocular lens calculation (biometry) to determine the best estimate of the proper power of the implanted IOL, microscopic examination of the front part of your eye (slit-lamp examination), and examination of the retina of your eye with your pupils dilated. Other tests such as Endothelial Cell Counts and OCT evaluation of the retina help to plan the surgery. Not all tests are covered by insurance.

HOW DOES SURGERY WITH THE LASER DIFFER FROM TRADITIONAL SURGERY TO REMOVE THE LENS? WHAT ARE THE POSSIBLE BENEFITS?

Traditionally, the eye surgeon uses blades to create the incisions in the cornea (the front window of the eye), and other special instruments to create the capsulotomy (the circular incision in the outer layer of the cataract or clear lens). The surgeon also uses a phacoemulsification device that utilizes ultrasound power to break up the lens and remove it from the eye. Make precise and consistent incisions in the cornea, a more circular and centered capsulotomy, and to pre-soften the cataract so less ultrasound energy is necessary with the phacoemulsification device.

HOW IS THE LASER USED TO TREAT ASTIGMATISM?

Patients with astigmatism have several choices for the reduction of astigmatism. Nonsurgical options for astigmatism correction include glasses and contact lenses. Surgical correction of astigmatism can be achieved through a toric intraocular lens, a limbal relaxing incision (LRI) made manually with a blade. Refractive surgery such as LASIK or PRK can also treat astigmatism. The shape and size of incisions made with the laser may be more precise.

WHAT ARE THE COMPLICATIONS ASSOCIATED?

There are risks and complications with this procedure. They include but are not limited to the following.

General risks:

- Infection can occur, requiring antibiotics and further treatment.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs such as Warfarin, Asprin, Clopidogrel (Plavix or Iscover) or Dipyridamole (Persantin or Asasantin).
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs.

Specific risks:

- A cloudy cornea which may or may not settle. This may require further surgery.
- An acute inflammatory reaction causing pain. This may need further treatment.
- A fragment of the cataract may fall into the back of the eye. This may require further surgery. •Infection of the eye which could cause loss of vision or loss of the eye.
- Glaucoma (eye disease). This may need further treatment.
- Macular oedema (collection of fluid); and retinal haemorrhage (bleed). This usually settles with time.
- Retinal detachment may occur. This will require further treatment.
- Any of these complications may occur but these complications are now rare.
- Any of these complications may permanently damage sight.
- Any of these complications may involve a second operation being necessary.

ALTERNATIVES TO CATARACT SURGERY

In the early stages, a change in glasses and attention to better lighting can sometimes improve the vision enough to delay surgery. Except in unusual circumstances, there is little danger to the eye from delaying cataract surgery, except that the vision will remain impaired until the cataract is removed. If delayed, surgery can usually be done later with a good chance of success. However, cataracts do not go away without surgery, and will get worse with time.

It is possible to remove the cataract and not insert an IOL. In this situation, strong glasses or a contact lens are usually required to focus. If glasses are used, the lenses may be very thick, and can cause distorted or double vision or visual imbalance. Contact lenses may not be tolerated by some individuals, and may be difficult to handle, insert, and remove. Because of these problems, an IOL is recommended for almost all cataract surgery patients today.

MORE INFORMATION ABOUT INTRAOCULAR LENS BIOMETRY

While biometry, the method used to calculate the power of the IOL, is very accurate majority of patients, the final result may be different from what was planned. As the eye heals, the IOL can shift very slightly toward the front or the back of the eye. The amount of this shift is not the same in everyone, and it may cause different vision than predicted. Patients who are highly nearsighted or highly farsighted have greatest risk of differences between planned and actual outcomes. Patients who have had LASIK or other refractive surgeries are especially difficult to measure precisely. If the eye's visual power after surgery is considerably different than what was planned, surgical adjustment is usually possible.

DOCTOR NOTE: ……
……

THE PROCEDURE AND POST-OPERATIVE CARE

Surgery: Surgery is typically performed as an outpatient, using eye drops and/or ointments for anesthesia. In the majority of cases, injections or stitches are not needed, depending on how your eye responds before and during surgery.

Post-Operative Care: You will be given instructions on post-operative care. You will also be given a schedule for follow-up appointments. If you are unclear about any instructions, please ask. In most cases you will be able to resume most normal activities immediately, but should keep the eye clean and dry and avoid bumping or pushing on the eye during the initial healing. Time off work will vary, depending on your job duties and speed of visual recovery. Blurr vision during healing is normal. Glasses, if needed, can be prescribed any time after surgery, but this is usually not done for 2-3 weeks.

YAG Laser Capsulotomy: After cataract surgery, it is very common to eventually develop some haze behind the IOL. This forms a film that can make the vision worsen again, much like when the cataract was present. This can happen a few months, or many years, after cataract surgery. When this interferes with vision, it can be cleared with a YAG laser. This procedure, called a

YAG Laser Capsulotomy, is usually done in the office, takes just a few minutes, is painless, and usually restores the vision to the way it was initially after cataract surgery. After procedure use medication for 10 days.

PATIENT'S ACCEPTANCE OF RISKS

Patient consent

I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- There is no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

DOCTOR NOTE: ……
……

I have reviewed all five (5) pages of this Informed Consent. The cataract and/or lens implant surgery has been explained to me in terms that I understand. I have been informed about the possible benefits, risks, and contraindications associated with the surgery. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to my questions. I understand that no guarantee of a particular outcome has been given, and that my vision could become better or worse following surgery.

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- If my ophthalmologist has informed me that if I have a high degree of hyperopic (farsightedness) and/or that the axial length of my eye is short, I am at increases risk for a rare complication known as nanophthalmic choroidal effusion. This complication could result in difficulties completing the surgery and implanting a lens, or other problems.
- If my ophthalmologist has informed me that if I have a high degree of myopia (nearsightedness) and/or that the axial length of my eye is long, I am at increased risk for a retinal detachment, whether or not I have surgery. Retinal detachments can lead to vision loss or blindness. Recent studies indicate that risk doesn't increased by the surgery, although an older study using different techniques did find an increased risk.
- I authorize the physicians and other health care personnel involved in performing my cataract surgery and pre- and post-operative care to share with one another any information relating to my health, my vision, or my surgery that they deem relevant to providing me with care. I give my permission for Dr. …….. to use my photograph for display or promotion.

DOCTOR NOTE: ……

……

I understand that it is impossible for the doctor who inform me of every possible complication that may occur. By signing below, I agree that my doctor has answered all of my questions, that I have been offered a copy of this consent form, and that I understand and accept the risks, benefits, and alternatives of _____ surgery.

I wish to have a _____ operation with cataract surgery on my _____ Right eye _____ Left eye

PATIENT'S NOTE:……

Date : …./…./……
Hour : ….:….

PATIENT:
Name-Surname : ...…..…….....
Signature :

Patient's Parent/ Legal Guardian (mother and father)/ Translater

Name-Surname	:	...…..……......	Name-Surname	:	...…..……......
Signature	:		Signature	:	

DOCTOR- Ophthalmologist:
Name-Surname : ...…….....

stamp

Signature :