

TAILORED EYES

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FEMTOSECOND LASER TREATMENT AND ASTIGMATISM TREATMENT FOR CATARACT SURGERY INFORMED CONSENT

This consent form is designed to educate you about the various options available. It is intended to make you better informed about the risks, benefits, and alternatives of femtosecond laser cataract surgery and to help you decide if you would like to proceed with the surgery. If you have any questions or do not understand the information, please discuss with your eye surgeon prior to signing.

OVERVIEW OF FEMTOSECOND LASERS

A femtosecond laser is a medical device that can be used to perform various steps in many different eye surgeries. It is approved by the Food and Drug Administration (FDA) to perform some of the steps of cataract surgery (approved use). It is also used to perform some of the steps of clear lens extraction or refractive lens exchange (RLE), and to make arcuate incisions in the cornea (AK) to reduce astigmatism (depending on the laser these may be off-label uses). There are benefits and risks associated with the use of the laser, and there are additional costs. This section provides information to help you decide if you would like your ophthalmologist to use a femtosecond laser to perform parts of your eye surgery.

FEMTOSECOND LASER CATARACT VS TRADITIONAL CATARACT SURGERY

In traditional cataract surgery, the ophthalmologist does all of the steps of the surgery by hand. A basic overview steps in cataract surgery include: making incisions in the eye with a keratome or a diamond blade, making a circular opening in the support structure that holds the cataract in the eye (a capsulotomy), breaking the cataract into little pieces with ultrasound waves and vacuuming it from the eye (phacoemulsification), and implanting a new intraocular lens in the eye.

In femtosecond laser cataract surgery, some of the steps of the surgery are done by the laser rather than by hand. To accomplish these steps the femtosecond laser uses an imaging guidance system and a laser cutting system. The femtosecond laser can make precise incisions in the eye, can make a more circular and centered capsulotomy, and can pre-soften the cataract breaking it into tiny fragments. Using the femtosecond laser may reduce the amount of ultrasound energy needed to remove the cataract and improve the precision of some of the steps of the surgery.

If Medicare insurance is paying for your cataract surgery, these steps are considered part of the covered portion of the cataract surgery procedure and are included in the fee, whether created by hand-held instruments or the laser. There is no clear policy on these issues from other health insurers.

Unlike the cutting function, the imaging function of the laser is not part of routine cataract surgery. The imaging system helps assure proper centration of a premium or toric lens in the eye to maximize the visual outcome and benefit of the premium lens. Because imaging is not part of routine cataract surgery, it is not covered by Medicare or any other insurer and is not included in the fee. As such, the fee for using the femtosecond laser is the responsibility of the patient.

Refractive lens exchange (RLE or CLE) is not covered by Medicare or other insurance companies, so the fee for a femtosecond laser refractive operation may be greater.

LASER TREATMENT OF 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 done with a toric intraocular lens, a limbal relaxing incision (LRI) made manually with a blade, or an arcuate incision made with the femtosecond laser (AK). 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 than those made by hand. Any attempt at astigmatism reduction could result in over- or under-correction, in which case glasses, contact lenses, or another procedure may be needed. None of the methods of reducing astigmatism are perfect or completely predictable, but all are designed to help reduce the amount of astigmatism present.

Medicare does not pay for the surgical correction of astigmatism. If you choose a toric IOL, you may be asked to pay the difference between the cost of a standard monofocal IOL and the toric IOL. If you choose astigmatism treatment with an LRI or AK (by hand or with the femtosecond laser), or other refractive surgery, you will be responsible for the fees associated with it.

RISKS ASSOCIATED WITH FEMTOSECOND LASER AND ASTIGMATISM CORRECTION

This information is an overview of some of the risks associated with femtosecond laser surgery. Use of the laser may increase the total time needed to complete the surgery, and you may need to have the procedure performed in two different rooms at the surgery center. Use of the femtosecond laser may lead to complications, which include but are not limited to: decentration of the corneal or capsulotomy incisions; an incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure; anterior capsular tear; posterior capsular tear with lens/lens fragment dislocation into the vitreous; corneal abrasion or defect; pain; infection; bleeding; damage to intraocular or extraocular structures; anterior chamber fluid leakage; anterior chamber collapse; and elevated eye pressure.

In the case of an interrupted or incomplete corneal incision, the laser can be recentered and the incisions repeated at a different location, or the incisions can be completed by hand. In the case of an incomplete or interrupted capsulotomy, the procedure may be repeated and completed using a slightly larger diameter or the surgeon may elect to complete the procedure by hand. In the case of an incomplete or interrupted fragmentation, the procedure can be repeated after recenteration or the surgeon may elect to complete fragmentation by hand with conventional phacoemulsification treatment. In the case of loss of lens fragments into the vitreous, a separate procedure called a vitrectomy may be necessary to remove the vitreous and lens fragments. If a full vitrectomy is needed, you may need to be referred to a retina specialist for surgical evaluation and management.

The risks of a Limbal Relaxing Incision (LRI) or Astigmatic Keratectomy (AK), if performed in conjunction with cataract surgery are similar to those for cataract surgery, but also include perforation of the cornea, damage to the iris, increased astigmatism, and scarring, and loss of vision. Astigmatism correction, done by hand or by the femtosecond laser, may not fully correct the astigmatism and may result in under-correction or over-correction of your astigmatism. Rarely, your astigmatism may be made worse by the procedure or you could develop irregular astigmatism or corneal ectasia (warping). The final vision outcome may be different from what you and your doctor anticipated. You may need to wear glasses, contacts, or another surgical procedure may be needed to improve the vision.

If a complication happens during surgery, your surgeon may need to perform another surgery right away to treat it. Your surgeon may discover a new condition or problem for the first time during the surgery. Your surgeon may need to change the plan for surgery to treat this problem or condition right away.

OTHER RISKS

Depending on the type of anesthesia used, other risks are possible. Local (eye block) anesthesia may damage the retina, damage the optic nerve or may lead to: bleeding in or behind the eye, double vision, permanent vision loss, perforation of the eye, a droopy eyelid, interference with the circulation of the blood vessels in the retina, respiratory depression, and hypotension. Useful vision can be permanently lost and in rare cases complications may include cardiopulmonary complications, coma, and death.

If you have **OTHER KNOWN MEDICAL CONDITIONS**, such as heart disease, history of heart failure, or lung disease such as Asthma or Chronic Obstructive Pulmonary Disease, or if you are **TAKING MEDICATIONS** such as Coumadin (a blood thinner) **OR OTHER SUPPLEMENTS OR VITAMINS**, tell your ophthalmologist so that you can minimize the risk of additional complications during and after surgery.

I understand that there may be other unexpected risks or complications that can occur that were not listed in the consent form or discussed by the doctor. I also understand that during the course of the proposed operation unforeseen conditions may be revealed that require the performance of additional procedures, and I authorize such procedures to be performed. I further acknowledge that no guarantees or promises have been made to me concerning the results of any procedure or treatment. I understand that there is no guarantee that femtosecond laser surgery will improve my vision and that in some cases complications may occur weeks, months, or even years later.

PATIENT CONSENT AND ACCEPTANCE OF RISKS

I have had ample opportunity to read this consent form (or this consent form has been read to me), ask questions of my surgeon, and have been offered a copy of this consent form to take home. I voluntarily give my authorization and consent to the performance of the procedure(s) described above by my physician and/or his associates, assisted by hospital or surgery center personnel and other trained persons.

_____ I am aware of the recognized specific risks related to Limbal Relaxing Incision (LRI) or Astigmatic Keratectomy (AK) for Astigmatism Reduction are those that are described in this form, and I understand that any of these risks could result in loss of vision, blindness or loss of the eye, and may require me to undergo further surgery. Furthermore, the LRI or AK may not fully correct or may over correct the astigmatism, and glasses, contacts, or another surgical procedure may be needed to correct the vision.

In signing this informed consent for femtosecond laser cataract surgery and/or astigmatism correction surgery, I am stating that:

_____ I have been offered a copy of this consent to take home and it has been fully explained to me

_____ I have filled in all the blank spaces

_____ My ophthalmologist has answered all my questions and I fully understand the possible risks, benefits, alternatives, and complications of femtosecond laser cataract surgery and astigmatism correction.

_____ I have read this consent document or someone has read it to me

The consent form was read to me by _____ (name).

I consent to have Dr. Steven Kane perform Femtosecond Laser Cataract Surgery and/or Astigmatism

Correction on my _____ RIGHT EYE or _____ LEFT EYE.

Patient's signature (or person authorized to sign for patient)

Date

Print patient's name