



CURRENT STUDIES – CATARACT SURGERY

The COAST Study

(COmparison of ASpheric Toric & non-toric aphakic intraocular lenses)

WHAT IS THE COAST STUDY?

This is a research study to examine the safety and effectiveness of an investigational aspheric, Toric intraocular (this intraocular lens is not yet approved by the FDA).

WHAT IS A CATARACT?

A cataract is a clouding of the normally clear, natural crystalline lens in your eye. Aging is the most common cause of cataracts. Other causes include eye trauma, heredity, diabetes, and even some medications. Common cataract symptoms include poor night vision, sensitivity to light, a blurring of vision and a fading or yellowing of colors. Over time, the cataract may grow larger and cloud more of the lens, making it more difficult to see clearly. If you are visually limited from performing your daily activities from cataracts, then you may be a candidate for cataract surgery. When your eye doctor determines it is appropriate, cataract surgery with an intraocular lens implant will be suggested.

WHAT IS ASTIGMATISM?

Astigmatism is a vision condition that causes blurred vision, usually due to an irregularly shaped cornea, the clear front cover of the eye. An irregular shaped cornea prevents light from focusing properly on the retina, the light-sensitive surface at the back of the eye. As a result, vision becomes blurred at any distance.

WHAT TO EXPECT AS A SUBJECT IN THE COAST STUDY

This study is intended for individuals who have astigmatism and are already planning on having cataract surgery with intraocular lens implantation. The study requires no additional surgical procedures but it does require some additional testing that is painless and non-invasive. Compensation for participation in this study is available which includes reduction of some surgical costs.

Study Overview

This study involves research sponsored by HOYA Surgical Optics, Inc.

There are two arms of this study:

- A) Participants with mild-moderate astigmatism may be enrolled in one arm of this study and will undergo cataract surgery and implantation of either an investigational toric intraocular

lens (which corrects astigmatism) or a standard, FDA-approved intraocular lens (non-toric intraocular lens) which does not correct astigmatism. The choice of which participants will receive toric or non-toric intraocular lenses will be made using a randomization plan.

- B) Participants with more severe astigmatism may be eligible to be enrolled in the other arm of this study. All of these participants will undergo cataract surgery and implantation of a investigational toric intraocular lens (which corrects astigmatism).

Summary of the Procedure

In this study, the cataract will be removed using standard surgical procedures. Participants who volunteer for this study will be randomly chosen to have either the toric intraocular lens or the non-toric intraocular lens implanted into the eye after the natural lens has been removed. The surgeon's standard postoperative procedures will be followed along with testing to determine the position of the intraocular lens in your eye.

AM I A CANDIDATE FOR THE STUDY?

You may be eligible if you:

- Are 60 years of age or older and have some astigmatism
- Are planning to have cataract surgery with IOL implantation
- Are willing and able to participate in follow-up examinations for 12 months

You may not be eligible if you have:

- Experienced previous serious eye problems, infections, injuries or surgeries in the operative eye
- Experienced serious systemic disease
- Elevated intraocular pressure in either eye
- Poor vision potential in both eyes

There are other criteria for qualifying for the study. Please check with Our Staff for full details.

Visit Requirement

- An evaluation to determine eligibility is required
- Surgery must occur at our Mt. Dora or Stonecrest location, and all exams must be done at Mt. Dora or Stonecrest
- Five postoperative examinations are required over a span of one year at: day 1, 1 week, 1 month, 6 months, and 1 year

IS THERE AN ALTERNATIVE TREATMENT

Yes. At Mid Florida Eye Center, we already use FDA-approved toric intraocular lenses in patients with astigmatism. However, there is an extra charge to you for procedures with those intraocular lenses.

If you are interested in finding out more about your eligibility for this study, please contact Our Staff and we will be happy to talk with you in more detail to determine if you qualify.

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