Do You Need Cataract Surgery?

If so, you may be eligible to participate in a study to further evaluate the safety of an FDA approved intraocular lens (IOL), the RxSight Light Adjustable Lens (LAL). The LAL allows your eye doctor to adjust the power of the lens after it has been implanted in your eye to improve distance vision.

Read on to learn more about this study.

RxSIGHT®

LIGHT ADJUSTABLE LENS

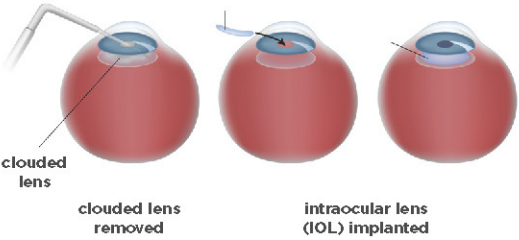
What You Need to Know About Cataracts and Cataract Surgery

What is a cataract?

A cataract is a cloudy area in the normally clear lens of your eye, causing things to look blurry, hazy, or less colorful. Most cataracts are related to the natural aging process and, over time, can lead to vision loss and blindness.

How are cataracts treated?

The only treatment for cataracts is surgery. Your eye doctor will likely recommend surgery when a cataract interferes with your usual activities, such as reading and driving. Cataract surgery is the most common procedure in the world and is very safe and routine.



What is an intraocular lens?

During cataract surgery, your cloudy lens is removed and replaced with a clear artificial lens. This lens is called an intraocular lens (IOL). The IOL is permanent and intended to last for life.

What is the Light Adjustable Lens™?
The Light Adjustable Lens is the only IOL available that can be adjusted after your eye has healed from surgery. This optimization may help enhance distance vision after your cataract surgery.

You should discuss all IOL options with your study doctor.

How Does the Light Adjustable Lens Work?

The Light Adjustable Lens is made of a special photosensitive material that changes the shape and power of your implanted lens in response to ultraviolet (UV) light. After your eye has healed from surgery, you will return to the clinic to have your vision tested. Based on the results of your exam, your implanted Light Adjustable Lens is exposed to light treatments.

UV Light Exposure **Modified Shape**

The light treatment is designed to provide your eye with improved distance vision. The potential benefit of the Light Adjustable Lens is the ability to see far away, without the need for glasses or contact lenses.

What is the Purpose of This Study?

The purpose of this clinical study is to further evaluate the safety of the FDA approved Light Adjustable Lens and Light Delivery Device. The results obtained with the Light Adjustable Lens will be compared to the results obtained with another commercially available IOL that some participants in the study will receive.

What Will Happen if I Choose to Participate in This Study?

During this study, you will be randomly assigned to have one of your eyes implanted with the IOL called the RxSight Light Adjustable Lens, or implanted with a commercially available monofocal IOL made by another manufacturer. You have an approximately 66% chance of being assigned to receive the LAL and a 33% chance of receiving the commercially available monofocal IOL. Only one of your eyes will be implanted as part of your study participation.

If you receive the Light Adjustable Lens, the special lens is adjusted after surgery using a device called the Light Delivery Device to try to permanently give your eyes the ability to see far away, without glasses or contact lenses.

If you receive the commercially available monofocal IOL, this IOL can not be adjusted once it is implanted in your eye and will not be able to correct your astigmatism. You will likely have to wear glasses to correct your astigmatism for optimal distance vision.

Evaluation Schedule

After surgery to implant your IOL, you will need to return to the study doctor's office per the evaluation schedule for 6 months. You may be required to return to the clinic 12 months after surgery or for additional visit(s) if your study doctor decides it is necessary. Each study visit may last between 2 to 4 hours.

What Else Should I Consider Before Deciding to Participate in This Study?

Possible Outcomes

The potential benefit to individuals receiving the Light Adjustable Lens is the ability to see far away, without the need for glasses or contact lenses.

Protective Glasses

If you are chosen to receive the Light Adjustable Lens, you will be instructed to wear special UV blocking glasses following surgery until 24 hours after the final light treatment is completed (up to 7 weeks, depending on timing of the light treatment schedule).

This eyewear protects your Light Adjustable Lens from exposure to UV light, which can change the power of the lenses prior to the light treatments being completed.

What Do I Need to Know About Study Costs and Payment for Participation?

Cataract Surgery Costs

Study-related exams and procedures, including implant of the lens and follow-up care, may be provided to you at little or no cost. However, please talk to your study doctor about any costs that may be associated with your participation in this study.

Payment for Participation

You will be paid for your participation in the study, up to a maximum of $450. The payment is based upon the following schedule of after surgery exam visits: $150 at week 3 visit, $150 at month 1-2 visit, and $150 at month 6 visit.

What Are the Potential Risks of Participating in This Study?

There are risks associated with cataract surgery and IOL implantation regardless of the type of IOL you have implanted. There is a small chance that your vision could be made worse or that you may require additional surgery as a result of a complication.

For individuals receiving the Light Adjustable Lens, the light treatments will expose the eye to UV light. There is a potential risk for UV-induced damage to the eye, including the cornea and retina. It is also possible that the desired results of the surgery may not be obtained or may not last.

A complete list of risks can be found in the study informed consent. You should discuss these potential risks with your study doctor.

Informed Consent

Before you decide to participate or not to participate in this study, it is important to understand all of the potential risks and benefits of the surgery and what participation in the study would mean for you. Please read the Information and Consent Form and discuss the study with your doctor.

Participation in this study is voluntary and you are free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care you will receive.

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