



Current Studies

Cornea Research Foundation of America - 2007 Studies

The Foundation conducts a minimum of 12 studies annually related to treating vision problems and especially focuses on corneal transplant, corneal disease, intraocular lens surgeries, and refractive surgery.

I. FDA Clinical Trials of Investigational Drugs and Devices

Artificial Iris

Background

Some people are missing the colored part of the eye, called the iris, either because it failed to form properly before they were born, or because they were hit in the eye at some point and the iris was damaged. The iris helps regulate the amount of light entering the eye, so people who are missing all or part of their iris are extremely light sensitive and have poorer vision than normal people.

Purpose

The purpose of this multi-center study is to evaluate an artificial iris that can be implanted inside the eye to help improve vision by reducing the amount of light entering the eye. The artificial iris is available in blue, brown or green colors, so it can also help provide a more normal eye appearance.

Participation

We have consistently led enrollment in this study, which started in 2002, and we now have over 100 study participants at our site.

Impact

The results of this study will be presented to the United States Food and Drug Administration to seek approval for the sale of this implant in the United States.

Glaucoma Gold Micro-shunt

Background

Some people get high pressure inside their eyes that cannot be adequately controlled with use of eye drops, so they need to have a drainage device implanted to help remove fluid and lower their eye pressure. The traditional drainage devices drain fluid to the surface of the eye where a blister, called a "bleb" forms. This bleb sometimes develops complications, such as infection. A Spanish surgeon recently developed a tiny new drainage device that drains fluid to the space behind the eye, so it doesn't cause a bleb to form. This device is made of ultra-thin 24-karat gold.

Purpose

We were invited to participate in a multi-site clinical trial to compare this device with a traditional type of drainage device. Study participants are randomized to receive the new device or a traditional device. The data will be submitted to the U.S. FDA to seek marketing approval for the gold micro-shunt in the United States.

Participation

We were the first U.S. site to enroll a patient in this study and have now enrolled nine patients. We will continue to study these patients for two years after their surgery.

Impact

Approximately 1% of the U.S. population suffers from glaucoma and could potentially benefit from a device that reduces eye pressure with fewer complications.

Verisyse Lens

Background

Some young people are so extremely near-sighted that they may have difficulty fully participating in sports and other normal activities.

Purpose

The purpose of this study was to evaluate a small lens that can be placed in the front part of the eye to provide excellent distance vision. Participants retained the natural lens in the back of their eye to allow them to focus up close as well as at a distance.

Participation

We enrolled 55 patients in this multi-center study, which began in 1998 and was recently completed in 2007. All study participants had the lens implanted in both eyes.

Impact

The results of the study led to FDA approval of this lens for use in the United States.

Veriflex Lens

Background

The U.S. FDA recently approved the earlier Verisyse lens to correct extreme near-sightedness in young people. This is a rigid lens that must be implanted through a relatively large incision. Recently, a foldable version of this lens was developed for insertion through a small incision. The smaller incision helps speed the healing process.

Purpose

The purpose of this study is to compare the new foldable lens with the rigid lens, which has already received FDA approval.

Participation

In March 2007, we enrolled the first patient in this multi-center study and hosted the training session for the other sites. We have now enrolled five patients and hope to enroll up to 30 patients over the next year. Patients will be followed for three years.

Blue-Blocker Lens

Background

As people age the natural lens in the back of eye becomes cloudy; this is called a “cataract.” The cataract can be removed and replaced with a small plastic lens, called an IOL. People’s natural lenses filter harmful ultraviolet and high-energy blue light, which can damage the retina. The IOLs that replace the natural lens usually filter ultraviolet light, but most do not filter high-energy blue light.

Purpose

The purpose of this multi-center study is to evaluate a new IOL that filters high-energy blue light as well as ultraviolet light.

Participation

We enrolled 43 patients in this study which began in 2004. The study will end this year after all patients have completed their three year examinations.

Impact

The results of the study will be presented to the FDA to seek approval for use of this lens in the United States.

Implant to Prevent Graft Rejection in High Risk Patients

Background

Cornea transplants are the most common and most successful form of solid tissue transplant, and over 30,000 are performed each year in the United States. Sometimes the body recognizes that the transplanted tissue is “foreign” and begins to attack it. This process is called “graft rejection” and it is a leading cause of graft failure. Certain characteristics cause some patients to have a particularly high risk of rejecting their graft.

Purpose

The purpose of this study is to evaluate a new slow-release drug implant that can be placed near the graft to release anti-rejection medication over a one year period.

Participation

We enrolled the first patient in this multi-center study which began in March, 2007. We have enrolled three patients so far and will follow each of them for a three year period. We hope to enroll at least 10 patients by the end of this year.

Impact

A slow-release drug implant could help reduce the risk of graft rejection for high-risk patients and minimize their dependence on eye drops.

Implant to Prevent Repeated Graft Rejection

Background

If someone begins to reject a transplanted cornea, it is often possible to save the graft with use of frequent doses of anti-rejection medication. However, anyone who has had one rejection episode is at increased risk of experiencing another.

Purpose

The purpose of this study is to evaluate a new slow-release drug implant to help prevent recurrence of graft rejection.

Participation

We enrolled the first patient in this multi-center study which began in March 2007 and we provided a surgical training video to be used by the other 31 sites in the United States, Europe and India.

Impact

The results of this study will be presented to the U.S. FDA and may result in the first approval of a drug to prevent cornea transplant rejection.

II. Other Clinical Studies

Genetics of Fuchs' Dystrophy

Background

The cornea is the clear window that covers the center of the eye. Unfortunately, as some people get older, their cornea becomes cloudy because of a condition known as Fuchs' dystrophy. We don't know what causes this condition. It seems to run in families, so we think it may have a genetic basis.

Purpose

The purpose of this study, sponsored by the National Eye Institute, is to identify the genes involved in Fuchs' dystrophy so we can figure out why this condition occurs and develop ways to prevent its progression.

Participation

Over 30 sites around the United States are participating in this study, which began in late 2005. The goal is to enroll at least 500 families during a three year period. We have consistently led enrollment, and have enrolled over 40 families at our site.

Impact

Patients with Fuchs' dystrophy have been very excited to help us find out what causes this condition and hopefully find a cure before their children and grandchildren become affected by it!

Cornea Donor Study

Background

Surgeons have generally assumed that it is best to give a cornea transplant recipient a donor cornea that is of similar age or younger. However, the supply of young organ donors is limited.

Purpose

To determine whether transplant outcomes are similar if the donor was older than 60 years compared with younger than 60 years.

Impact

If corneal surgeons were confident of obtaining excellent outcomes with older donor corneas, it could greatly increase the supply of donor tissue.

Participation

This multi-center study, sponsored by the National Institute of Health, began in 2000 and we enrolled 12 participants. We originally planned to follow these patients for five years, but the study period was recently extended to 10 years.

Donor Graft Preparation Study

Background

The use of small-incision transplants, known as DSEK, has grown exponentially over the past two years and now accounts for approximately 40% of the transplants performed in the United States. The donor tissue needs to be thinly sliced for this procedure, but many surgeons cannot justify the significant expense of purchasing the necessary equipment. Therefore, several eye banks have purchased the equipment to provide pre-cut donor tissue to their surgeons.

Purpose

We designed a study to evaluate whether the pre-cut tissue provided outcomes similar to surgeon-cut tissue.

Participation

In 2006, we enrolled 40 patients in this study. These patients were randomized to receive either pre-cut or surgeon-cut tissue for their transplant procedure. We are tracking the outcomes in these patients for one year.

Impact

We have found that pre-cut tissue provides outcomes similar to surgeon-cut tissue. Pre-cut tissue is now becoming more widely available, allowing more surgeons to perform the procedure so that more patients can benefit from it.

Comparison of Eye Pressure Measurement Techniques in Transplanted Eyes

Background

As people get older, some will develop high pressure inside their eye. If left untreated, this can damage their optic nerve and permanently rob them of vision. Therefore, it is important for patients to have their eye pressure checked on a regular basis. The standard method of measuring eye pressure in normal eyes is influenced by corneal thickness. Small incision transplants increase corneal thickness, often far beyond the normal range, and it was not clear what effect this might have on eye pressure readings.

Purpose

We undertook this study to compare three different ways of measuring eye pressure, including the standard method, along with a newer method that is supposed to be less sensitive to corneal thickness.

Impact

The findings from this study will help doctors more accurately track eye pressure changes in patients who have had small incision cornea transplants.

Participation

This study was conducted and completed in May 2007. Thirty eight small incision transplant recipients came in for an eye examination along with pressure measurements using three different methods.

Results

The results showed good agreement between the pressure readings taken using three different methods and indicated that the pressure readings were not significantly influenced by the increased corneal thickness from the small incision transplant.

Accuracy of Eye Pressure Measurements after Small-incision Transplants

Background

As people get older, some will develop high pressure inside their eye. If left untreated, this can damage their optic nerve and permanently rob them of vision. Therefore, it is important for patients to have their eye pressure checked on a regular basis. The standard method of measuring eye pressure in normal eyes is influenced by corneal thickness. Small incision transplants increase corneal thickness, often far beyond the normal range, and it was not clear what effect this might have on eye pressure readings.

Purpose

We undertook this study to determine whether eye pressure readings changed significantly after people had a small incision transplant procedure.

Accuracy of Eye Pressure Measurements after Small-incision Transplants Con't

Participation

We reviewed the records of 450 patients who had small incision transplants performed at our center over a three year period.

Impact

We found that eye pressure readings did not change significantly after the transplant, so doctors can continue to use their normal criteria to determine if a transplant patient may be developing glaucoma.

Cell Loss after Small Incision Transplants

Background

The cells lining the inner surface of the cornea do not usually divide or regenerate so as cells are lost over time, they are not replaced. Cell loss is usually more rapid in transplanted corneas compared with eyes that have not had surgery, and excessive cell loss is one of the primary causes of transplant failure.

Purpose

The purpose of this study was to compare the rate of cell loss after a small-incision transplant with the rate of cell loss experienced after a standard full-thickness transplant. We also wanted to identify factors that increase or decrease cell loss after transplantation.

Participation

We reviewed the records of 750 patients who had a small-incision transplant procedure performed at our center over the past 3.5 years.

Impact

We discovered that use of specific surgical instruments and techniques help minimize cell loss with small-incision transplants. This knowledge can help doctors provide longer-lasting transplants.

Risk Factors for Rejection after Small Incision Transplants

Background

Rejection is a principal reason that traditional full-thickness transplants sometimes fail, and we have a good understanding of what to expect in terms of risk factors and frequency. However, small-incision transplants are relatively new, and little is known about the relative risk of rejection with this type of graft.

Purpose

The purpose of this study was to characterize the signs, symptoms and frequency of graft rejection with small incision transplants and to determine what factors might increase or decrease the risk of rejection.

Risk Factors for Rejection after Small Incision Transplants con't

Participation

We reviewed the records of 750 patients who had a small incision transplant performed at our center during the past 3.5 years.

Impact

Our findings will help doctors know how to recognize graft rejection and reduce its incidence with the newer transplant procedure.

Culturing Cell Sheets for Transplants

Background

Donor corneas are in short supply around the world so many people who could benefit from a transplant are not able to have one.

Purpose

The purpose of this study is to develop methods to multiply precious cells from a single donor cornea and grow them into sheets which could be transplanted to restore peoples' sight.

Impact

This study could help alleviate the chronic worldwide shortage of suitable donor corneas and restore sight to countless people.

Cataract Medication Comparison

Background

After having cataract surgery, patients use antibiotic eye drops to prevent infection, in addition to steroidal and non-steroidal eye drops to control inflammation. Two companies make slightly different versions of these three types of eye drops. We were invited to participate in a multi-center study to determine whether visual outcomes and the extent of inflammation are similar or different with the two different company's eye drops. Each site was asked to enroll 20 participants who would be randomized to receive one set of eye drops or the other. We recently completed enrollment and our last three patients each have one more visit to complete.

Purpose: We are trying to determine which set of medications will provide patients with the best possible vision and minimize inflammation after cataract surgery.

Participation

We began enrolling patients in this study in the summer of 2006 and are completing the study one year later. We queried patients who had signed up for cataract surgery if they were interested in participating. Only patients who did not have any other eye problems and who wanted to have a single-focus lens implanted were invited to participate in order to simplify the data analysis.

Impact

Two out of every three people will need to have cataract surgery at some point in their lives, so our findings from this study could potentially improve the outcomes of cataract surgery for a very large segment of the population.