MORE THAN 600 EYES TREATED IN FDA LASIK STUDY

The Cornea Research Foundation of America is monitoring results of more than 600 eyes that have been treated with LASIK (laser-assisted in situ keratomileusis). LASIK is the latest refractive surgery available to correct distance vision and lessen the need for glasses and contacts.

The FDA granted Corneal Consultants of Indiana an Investigational Device Exemption (IDE) last spring to test the safety and effectiveness of a new excimer laser, the KERACOR 116 (Chiron) excimer laser, for correction of myopia (-0.25 D to -30.0 D) and/or astigmatism (up to 6.0 D). To our knowledge, it is the most comprehensive excimer laser study given full approval. While two other excimer lasers have already been approved, we believe this laser offers advantages over the other lasers.

"Without the IDE process,"

Dr. Price said, "no new devices or machines could be approved in this country. The only way to have surgery with investigational devices is to be part of the IDE process."

The Foundation supplies the necessary support and experience to monitor and comply with the strict regulatory requirements of this study. The study will close when 450 patients (or 900 eyes) have been enrolled. Trish Harrington, study coordinator, adds "We are over half way there! So far, patient compliance has been very good."

Once the study is closed, results will be submitted for approval. Experts will review the data to ensure that the laser is safe and effective for the surgeries indicated. If approved, Chiron's KERACOR 116 excimer laser would be the newest excimer laser on the market.
Answers to frequently asked questions about LASIK and Corneal Transplants (Penetrating Keratoplasty or PKP)

LASIK (Laser-Assisted In Situ Keratomileusis)

1. When can I go back to work?
This will vary depending on your type of job and how fast you heal. Some people return to work the next day, while for others it may be several days before they are ready to resume normal activities.

2. If I only get one eye done, how will I manage until I get the other eye done?
Your options are to wear nothing and use your newly operated eye to see or to wear your glasses but remove the lens from the operated side. Many patients prefer to have both eyes operated on at the same time.

3. What will I feel and see during surgery?
You shouldn’t have any definite pain. You will feel pressure from the surgeon’s hands and instruments. You will see several different lights (white and red) which are used to help you concentrate and to help the surgeon see what he is doing.

4. Is there pain after surgery?
Once the numbing drops wear off (1/2- one hour after surgery), you may have tearing, irritation and sensitivity to light. Make sure you take your pain medication and try to take a nap. After a few hours most people have minimal or no discomfort.

Corneal Transplant
(also known as Penetrating Keratoplasty - PKP)

1. Why can’t you perform a transplant using a laser? A corneal transplant is a surgical procedure that requires physically removing a diseased cornea and replacing it with a healthy new cornea. This can only be done with surgical instruments. At this time corneal transplant surgery cannot be done with a laser beam which can only reshape or shave tissue.

2. Where do you get donor tissue, and does it have to be matched to the eye? An eye bank retrieves, evaluates and distributes eyes donated for corneal transplantation, research and education. To promote patient safety, the eye banks extensively test all donated eyes, including tests for hepatitis and AIDS, and donor medical histories are evaluated based on strict Eye Bank Association of America Medical Standards. Since the cornea is unique in that it has no blood vessels, the transplant tissue does not have to be matched.
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A PERSONAL PERSPECTIVE ON LASIK SURGERY
by Manuel Chaknis, M.D.

Count me as one of the few, the proud — no, not a Marine..., but an ophthalmologist who has undergone refractive surgery.

It took only three months into my fellowship at Corneal Consultants of Indiana to make a personal decision about refractive surgery. After seeing many patients undergo successful refractive surgery, I too decided to “take the plunge.” And today I can proudly say I am a previous glasses and contact lens wearer.

Having worn glasses for nearsightedness since third grade and eventually changing to contact lenses in college, I found glasses and contacts to be interfering with many of the activities and sports, like football and tennis, I enjoyed in my free time.

On November 1, 1996, I had very successful LASIK surgery at the Price-Whitson Center for Refractive Surgery, and I am extremely happy with my results. I was changed from someone dependent on glasses to someone with “visual freedom.”

What I experienced is an example of today’s “cutting edge” technology available in the field of ophthalmology.

The Cornea Research Foundation of America has been instrumental in evaluating new refractive procedures as well as successfully implementing the very latest instruments to provide patients with the best potential for excellent vision. Refractive surgery is now a readily available, successful and lifestyle-changing procedure.

The proof is in the pudding — just ask this ophthalmologist.

Answers to frequently asked questions (continued from page 2)

Corneal Transplants

3. When will I see better? You should begin to see somewhat better soon after the surgery, but it can take up to a year and a half to completely heal, have the stitches removed, and have additional incisions made in the transplant for any residual astigmatism and to optimize your visual acuity.

4. Why do I have to take drops (e.g., FML)? After transplant surgery, topical corticosteroid drops are used to prevent the body from rejecting the donor cornea. Those with corneal transplants are lucky because only eye drops are needed to prevent rejection. After other transplants, like kidneys and hearts, strong systemic medications are needed to prevent rejection.
At its October 1996 meeting, the Board of Directors of the Cornea Research Foundation of America elected five new members.

The new board members include Joan Lane, from Columbia City; Robert F. Nagan, M.D., retired surgeon; Bill Grube, Calumet Lubricants Co.; Tom Godby, Godby Heating and Air; and Pat Chastain, Indiana Water Company.

The Cornea Research Foundation of America brings to the people of Indiana a level of investigation and treatment of eye diseases and visual defects otherwise not available.

Without the work of the Foundation, there would be no long-term analysis on how patients do after corneal transplant surgery and what both physicians and patients can do to try and improve results. Our long-term study of data on corneal transplants patients is the only one of its kind in the United States.

As a not-for-profit organization, the Foundation depends entirely on financial contributions to continue our mission to restore and preserve vision through research, fundraising and planning efforts.

Several of our Board members have experienced what many of you have — a threatened loss of vision — and they live with it every day of their lives, as you do; so they know first hand how important their task is to improve the quality of life for all.