

**FACTS YOU NEED TO KNOW ABOUT PHOTOREFRACTIVE KERATECTOMY
(PRK) SURGERY FOR THE CORRECTION OF -1.50 TO -7.00 DIOPTERS OF
NEARSIGHTEDNESS AND UP TO 4.50 DIOPTERS OF ASTIGMATISM
WITH THE BAUSCH AND LOMB SURGICAL
KERACOR 116 EXCIMER LASER SYSTEM**

PATIENT INFORMATION BOOKLET

Please read this entire booklet. Discuss its content with your doctor so that all your questions are answered to your satisfaction. Ask any questions you may have before you agree to the surgery.

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TABLE OF CONTENTS

	<u>PAGE</u>
INTRODUCTION.....	3
HOW THE EYE FUNCTIONS.....	3
Focusing with Your Eye.....	3
Checking Your Focus.....	4
The Nearsighted Eye.....	4
WHAT IS PHOTOREFRACTIVE KERATECTOMY (PRK)?.....	5
Benefits.....	5
Risks.....	5
During the First Week Following Surgery.....	6
For the First Two to Six Months Following Surgery.....	6
One Year or More After Surgery.....	6
Early Complications.....	7
Long-term Complications.....	7
Contraindications.....	8
Warnings.....	8
Precautions.....	8
ARE YOU A GOOD CANDIDATE FOR PRK?.....	9
WHAT YOU NEED TO KNOW ABOUT THE SURGERY.....	9
Before the Surgery.....	9
The Day of Surgery.....	9
Immediately After the Surgery.....	10
First Days After Surgery.....	10
QUESTIONS TO ASK YOUR DOCTOR.....	11
SUMMARY OF IMPORTANT INFORMATION.....	12
PATIENT ASSISTANCE INFORMATION.....	13
INDEX.....	14

INTRODUCTION

This booklet contains information to help you decide whether or not to have Photorefractive Keratectomy (PRK) laser surgery for the correction of nearsightedness. Glasses, contact lenses, or the refractive surgical procedure known as radial keratotomy (RK) also correct nearsightedness. PRK, using the Bausch and Lomb Surgical excimer laser system, is a completely different type of surgery than RK.

If you are nearsighted in both eyes, it may be necessary to have both eyes treated with PRK. Sometimes, it is better to have PRK done on only one eye. Talk with your doctor about whether it would be better to treat one eye or both eyes.

Please read this booklet completely and discuss your questions with your doctor. Only your eye care professional can determine whether or not you are a suitable candidate. Some jobs, such as military pilots, have vision requirements that RK and PRK presently cannot meet.

HOW THE EYE FUNCTIONS

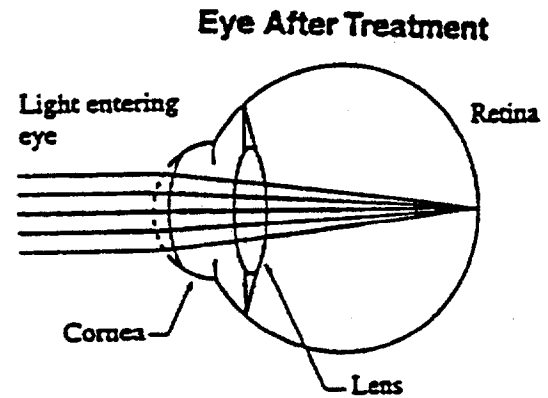
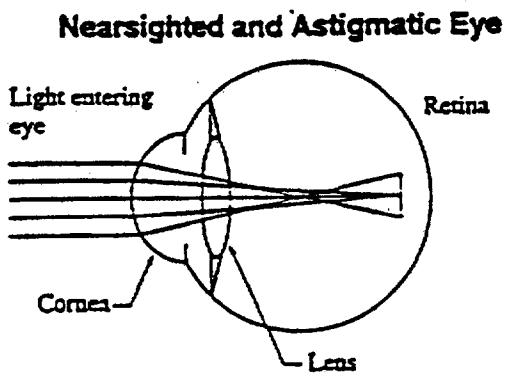
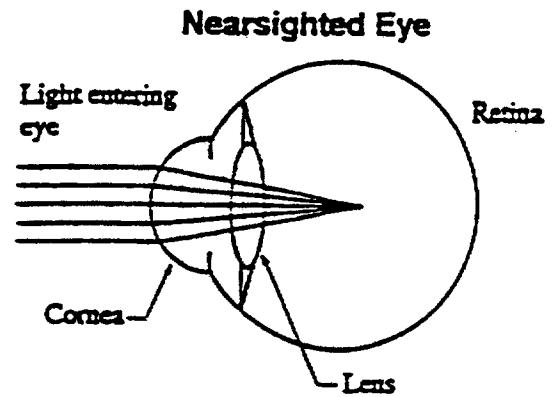
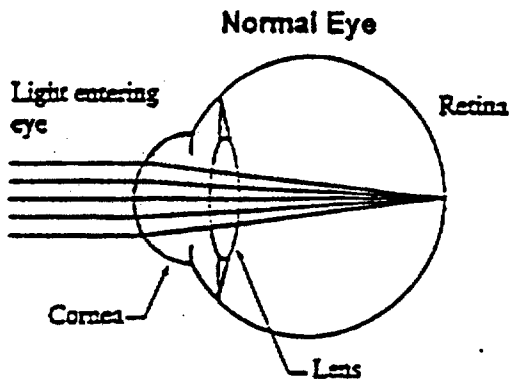
Your eye focuses light to form images or "pictures" much like a camera. Your eye changes the images into electrical signals and sends them to the brain. If your eye is out of focus, what you see is blurred.

The cornea at the front of the eye bends the light toward your retina. The clear tissue of the cornea is responsible for two-thirds of the focusing power of the eye. The lens within the eye finishes the job of focusing the light onto your retina.

Focusing with Your Eye

The eye focuses light by bending all light rays to meet at a single point. If it works perfectly, a sharp image of the object you look at will be focused exactly on the retina. You will see a clear image. However, if the light focuses either in front of or behind the retina, the image you see will be blurred. Depending on where the image focuses, you will be nearsighted, farsighted, or astigmatic.

The shape of the cornea determines the focusing power of the eye. The more sharply curved the cornea, the more that light rays are bent. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. If the cornea is curved too much, the image focuses in front of the retina and the eye is nearsighted. If the cornea is irregularly shaped (like a football rather than a basketball), it is called astigmatic.



Checking Your Focus

Your doctor checks where your eye focuses light. When your vision is corrected, a lens or a combination of lenses is added to move the point where the light focuses so that the focal point strikes your retina perfectly. Good focus depends on the shape and size of your eyeball, the shape of your cornea, and the power of your natural lens.

The Nearsighted Eye

One in four people in North America are nearsighted. They see near objects clearly, but distant objects are blurry. Light rays focus in front of the retina instead of directly on it. Nearsightedness tends to run in families. It usually starts in childhood and stabilizes in the late teens or early adulthood. It can be corrected by glasses, contact lenses, or refractive surgery.

Glasses and contact lenses can be adjusted if vision changes over time. Changes due to refractive surgery are usually permanent and cannot be undone if vision or focus changes. If

your vision changes or the initial surgery is not completely successful (which occurred in 14.3% of the cases treated in the Bausch and Lomb Surgical clinical studies). additional treatments may be performed to try to improve your results. In the Bausch and Lomb Surgical studies 12.1% of eyes did not have a successful outcome following a single retreatment procedure.

WHAT IS PHOTOREFRACTIVE KERATECTOMY (PRK)?

PRK is a surgical treatment for nearsightedness. An excimer laser is used to flatten the front surface of the cornea. It removes small amounts of tissue with ultraviolet light. This is different from RK. In RK, a surgical knife is used to make deep cuts around the center of the cornea.

An excimer laser is a machine that produces and aims a powerful beam of ultraviolet light. The excimer laser produces a brief, intense pulse that lasts only a few billionths of a second. Each pulse removes a microscopic amount of tissue from the surface of the cornea. It produces little heat and leaves the tissue beneath unchanged.

PRK surgery is performed on one eye at a time. The second eye can be treated if all goes well with the first eye. Laser surgery on the second eye is usually done three months after surgery on the first eye.

In the U.S. clinical studies of the KERACOR 116 Excimer Laser System, 44.6% of all treated eyes could see 20/20 or better without glasses after a single PRK procedure, and 85.7% could see 20/40 or better. Although vision without glasses improved for all eyes, some patients still needed glasses or contact lenses after PRK. PRK does not eliminate the need for reading glasses. It is possible that you may need reading glasses after laser surgery even if you did NOT wear them before.

Benefits

PRK surgery, performed with the KERACOR 116 Excimer Laser System, is effective in reducing nearsightedness of -1.50 to -7.00 diopters with astigmatism of up to 4.50 diopters.

PRK may reduce overall nearsightedness while reducing or eliminating dependency on contact lenses or glasses.

PRK surgery, performed with the KERACOR 116 Excimer Laser System, is a reasonably safe and effective alternate way to correct nearsightedness.

Risks

To get the best possible vision, you may need to have additional PRK surgery if your initial surgery results are not satisfactory.

In addition, it is possible that PRK surgery may result in a decrease in your best corrected vision compared to before you had the surgery.

PRK surgery may cause visual problems or symptoms that you did not have before the surgery, or may make such pre-existing problems or symptoms worse following the surgery.

There is a risk of infection of the cornea or other parts of the eye as a result of the PRK surgery due to removal of tissue from the front surface of the eye as part of the procedure.

During the first week following surgery

- Pain and discomfort may last for up to 7 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You may be sensitive to bright lights.

For the first two to six months following surgery

- The pressure in your eye may increase due to use of anti-inflammatory medications. When you stop the medication or use other drug therapy, the pressure goes back to normal.
- Your cornea may become hazy or cloudy enough to affect your vision. This haze disappears over time. Some patients continue to experience haze over two to three years.

One year or more after surgery

The Bausch and Lomb Surgical clinical studies showed that for the following problems more than 1% of patients reported that they were worse after the surgery than before the surgery:

	<u>Better</u>	<u>No change</u>	<u>Worse</u>
Night driving difficulties	14.6%	46.6%	38.9%
Glare	7.5%	61.8%	30.7%
Halos around lights	6.5%	65.7%	27.8%
Light sensitivity	15.2%	65.5%	19.3%
Gritty feeling	3.4%	81.1%	15.6%
Pain	2.5%	87.1%	10.4%
Burning	5.5%	85.1%	9.4%
Blurry vision	1.3%	89.4%	9.2%
Headaches	12.7%	78.7%	8.5%
Redness	8.9%	83.1%	8.0%
Dry eye	1.7%	90.5%	7.9%
Tearing	3.2%	90.6%	6.2%
Double vision	0.0%	97.5%	2.5%
Ghost images	0.2%	98.5%	1.3%
Itching	0.5%	98.3%	1.2%
Astigmatism	0.0%	98.8%	1.2%

The studies also showed that certain vision-threatening events happened 1.0% or less of the time at one year or more after PRK surgery:

- Losing a significant amount of vision even with glasses
- Farsightedness caused by the surgery
- Problems with the eye's natural lens such as cataract, opacity, or cloudiness
- Corneal haze that clouded vision
- Infection of the cornea
- Swelling of the cornea
- Detachment of the retina

During the clinical trials of PRK, less than 1% of patients reported the following long-term effects of their PRK:

Infection or inflammation of the outside layer of the eyeball, itching, discomfort, drooping of the eyelids, reading difficulty, eyestrain, mattering of the eyes, swelling of the eye, and variations in vision.

During the Bausch and Lomb Surgical clinical trials, doctors reported the following complications:

Early complications (during the first few weeks after PRK)

Pain (first 24 to 48 hours), corneal swelling, cloudy vision, defect in the outer layer of the cornea, feeling that something is in your eye, shadow images, light sensitivity, tearing, redness, itching and scratchiness, burning, dryness, headache and enlarged pupil.

The normal healing process following PRK surgery can result in the above complications.

Long-term complications (one year or more after surgery)

These occurred in more than 1% of patients who were in the Bausch and Lomb Surgical clinical trials. These complications continued even after early discomfort ended:

- Glare from bright lights, such as car headlights or streetlights. This occurred in 5.7% of patients.
- Decrease in sharpness of vision, even with glasses. This occurred in 3.7% of patients.
- Halos around lights. This occurred in 3.5% of patients.
- Difficulty with driving at night. This occurred in 2.9% of patients.
- Feeling that something is in the eye. This occurred in 1.4% of patients.
- Sensitivity to bright lights. This occurred in 1.4% of patients.
- Eye discomfort or pain. This occurred in 1.1% of patients.
- Clouding of the cornea. This occurred in 1.1% of patients.

Contraindications

You should NOT have PRK surgery if:

- You have collagen, vascular, autoimmune, or immunodeficiency disease (e.g., lupus or AIDS)
- You are pregnant or nursing
- You show signs of keratoconus (a corneal disease)
- You have a tendency to form scars
- You are taking Accutane (isotretinoin) for acne treatment or Cordarone (amiodarone hydrochloride) for controlling normal heart rhythm.

Warnings

Discuss with your doctor if:

- Your nearsightedness is changing
- You are diabetic or have severe allergies
- You have had *Herpes simplex* or *Herpes zoster* infections.

Precautions

The safety and effectiveness of the KERACOR 116 Excimer Laser System have NOT been established in:

- Eyes with progressive nearsightedness or astigmatism
- Eyes with disease or abnormal corneas (scars, infections, etc.)
- Eyes with previous surgery or injury to the center of the cornea where PRK will be performed
- Eyes with abnormal blood vessels within 1.0 mm of the center of the eye where PRK will be performed
- Patients under 18 years of age
- Patients taking hormone replacement therapy or antihistamines
- Patients taking sumatriptan (Imitrex) for migraine headaches.

Although it has not been studied, you may find it more difficult than usual to see in poor lighting conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.

ARE YOU A GOOD CANDIDATE FOR PRK?

If you are considering PRK, you must:

- Be 18 years of age or older.
- Have healthy eyes free from retinal problems, corneal scars, and any eye disease.
- Have nearsightedness within the range of treatment: -1.50 to -7.00 diopters of nearsightedness with up to 4.50 diopters of astigmatism.
- Have written proof that the change in your vision is either one-half diopter or less per year for at least one year before your pre-surgery exam.
- Be fully informed about the risks and benefits of PRK as compared to other treatments for nearsightedness.

WHAT YOU NEED TO KNOW ABOUT THE SURGERY

Before the Surgery

If you are interested in PRK, you will need a pre-surgical examination to determine if your eye is healthy and suitable for PRK. The exam includes a physical and eye history. Both eyes will be checked. Your cornea will be mapped by computer to determine if it is smooth and properly shaped.

WARNING: If you wear contact lenses, the doctor will ask you to stop wearing them two to four weeks before your exam. Failure to do this may produce poor surgical results.

Before surgery, talk to your doctor about any medicine you take. Also discuss whether or not you should eat and drink just before surgery. You should arrange to have someone drive you home after surgery and to your next doctor's appointment. You should not drive until your doctor gives you permission.

The Day of Surgery

Before the actual surgery, you will be given the opportunity to hear the sounds the laser makes so that you will be prepared for the noise during surgery. You will be given some numbing drops in the eye that will be treated. When you go into the room that contains the laser system, you will see a large machine that has a computer screen, a surgeon's chair and a patient bed. You will be asked to lie down on the bed. You will lay face up toward the laser's microscope and the ceiling. Your eye may be numbed with more drops. The eye not having surgery may be covered with a temporary shield.

The surgery takes about 10-20 minutes overall. The use of the laser, however, lasts only about 15 to 40 seconds. The doctor will place a small spring-like device between your eyelids to hold them open.

When the surgery begins, the surgeon will use a small instrument to remove the outer layer of the cornea. The doctor will then reposition your head under the microscope. You will be asked to look directly at the red light. Try to keep both eyes open without squinting. This makes it easier to keep looking at the red light. You will then hear the noise the laser makes.

WARNING: It is very important that you keep looking directly at the red light, even if the light fades or dims. Your results depend on how well you look directly at this red light throughout the treatment.

Immediately after the surgery

After the surgery, your doctor will put some medicated drops or ointment into your eye. Your doctor may apply a patch or soft disposable contact lens to your eye for protection and comfort.

Numbing drops make the surgery painless. When these drops wear off, your eye may hurt for one to three days. Most patients describe the pain as moderate to severe. Your doctor may prescribe pain medicine to make you more comfortable. Do not rub or touch your treated eye for the first three to five days after surgery.

First days after surgery

The patch or contact lens is usually removed the next day. You may be mildly sensitive to light and glare. Wearing sunglasses may make you more comfortable. You may also have the feeling that something is in your eye. This happens while the outer layer of your cornea grows back.

Your vision should stabilize within several weeks. Some patients report small changes in vision such as improvement or worsening. These changes may occur up to six months or more after surgery.

You may see a haze or cloudiness in the cornea following surgery. It usually does not affect your vision. This haze tends to decrease over time. It usually disappears completely by 12 to 24 months after the surgery.

Use any prescribed drops and lubricants as directed by your doctor. Your surgical results depend on carefully following your doctor's directions.

QUESTIONS TO ASK YOUR DOCTOR

- What are the other options for correcting nearsightedness?
- Will I have to limit my activities after the treatment? If yes, for how long?
- What are the benefits of PRK for my level of nearsightedness?
- What vision can I expect in the first few months after surgery?
- If PRK does not correct my vision, could my vision be worse than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses if I still need them after PRK?
- How is PRK likely to affect my need to use glasses or contact lenses as I get older?
- Will my cornea heal differently if I injure it after having PRK?
- Should I have PRK surgery in my other eye?
- How long will I have to wait before I can have PRK surgery on my other eye?
- What vision problems will I experience if I have PRK only in one eye?

Discuss the cost of surgery and follow-up care with your doctor. Most health insurance policies do not cover excimer laser treatment for vision correction.

SUMMARY OF IMPORTANT INFORMATION

- PRK is permanent. Once performed, it is not reversible.
- PRK does **NOT** eliminate the need for reading glasses, even if you have never worn them.
- Your vision must be stable for at least one year before PRK surgery. You will need written proof that your nearsightedness has changed less than 0.50 diopters.
- Pregnant and nursing women should wait to have the surgery.
- You would not be a good candidate if you have any medical condition that makes wound healing difficult.
- The PRK treatment may cause you discomfort.
- The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks, before you agree to the treatment.
- PRK is not a laser version of radial keratotomy (RK). These operations are completely different from each other.
- Some alternatives to PRK include glasses, contact lenses, and RK.
- Some jobs, such as military pilots, have vision requirements that RK or PRK do not presently meet.
- Before considering PRK you should:

Have a complete eye examination

Talk with one or more eye care professionals about the potential benefits of PRK and the complications, risks, and time required for healing.

PATIENT ASSISTANCE INFORMATION

PRIMARY EYE CARE PROFESSIONAL

Name:
Address:
Telephone Number:

PRK DOCTOR

Name:
Address:
Telephone Number:

LOCATION WHERE TREATMENT WAS DONE

Name:
Address:
Telephone Number:

LASER MANUFACTURER

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INDEX

A

Activities, 11
Additional laser treatments, 5
Age, patient, 8, 9
Allergies, 8
Alternatives, 12
Astigmatism, 5, 8, 9

B

Benefits, 5
Blurry vision, 6
Burning, 6

C

Candidate, suitable, 3
Cataract, 7
Cloudiness, 7, 10
Complications, 7, 12
Contact lenses, 3, 4, 5, 9, 11, 12
Contraindications, 8
Cornea, 3, 4, 5, 6, 7, 8, 9, 10, 11
 defect, 7
Cost, 11

D

Diabetes, 8
Diopter, 5, 9, 12
Discomfort, 6, 7, 12
Diseases, contraindications, 8
Double vision, 6
Driving, 7
Drooping, eyelid, 7
Dry eye, 6

E

Examination, pre-surgical, 9
Excimer laser, 3, 5, 8, 11
Eyestrain, 7

F

Farsighted, 3, 7
Focus, 3, 4,

G

Glare, 6, 7, 8, 10
Glasses, 3, 4, 5, 7, 10, 11, 12

Gritty feeling. 6

H

Halos, around lights. 6, 7
Haze. 6, 7, 10
Headache, 7, 8
Healing. 7, 12
Heredity, nearsightedness. 4
Herpes. 8

I

Infection, 6, 7, 8
Inflammation, 7
Insurance coverage, 11
Itching, 6, 7

J

Jobs, vision requirements, 3, 12

K

Keratoconus. 8

L

Length, surgery, 9
Lens, 3, 4, 7
Light sensitivity, 6, 7
Lighting conditions, vision in, 8
Long-term effects, 7

M

Medications, 6, 8, 9, 10
 Accutane, 8
 anti-inflammatory, 6
 Cordarone, 8
 Imitrex, 8
 lubricant, 10
 numbing drops, 9, 10
 ointment, 10
 pain, 10

N

Nearsighted, 3, 4, 5, 8, 9, 11, 12
Noise, during surgery, 9, 10
Nursing, 8, 12

P

Pain. 6. 7. 10
Photorefractive keratectomy (PRK). 3. 5
Precautions. 8
Pregnancy. 8. 12
Pressure, intraocular. 6
Problems. 6. 7. 9. 11
Pupil. 7

R

Radial keratotomy (RK). 3. 5. 12
Reading difficulty. 7
Redness. 7
Refractive surgery. 4
 permanence. 4
Results, clinical. 5. 9. 10
Retina. 3. 4. 7. 9
Risks. 5. 9. 12
Rubbing eye. 10

S

Safety. 8
Scars. 8. 9
Scratchiness. 7
Second eye. treatment of. 5
Shadow images. 7
Stabilization, vision. 4. 10
Success. 5
Sunglasses. 10
Swelling. 7

T

Tearing. 6. 7
Touching eye. 10
Treating both eyes. 3

V

Vision, sharpness. 7
Vision, variations in. 7

W

Wound healing. 12