Information for the U.S. Market

PRK for Myopia (Nearsightedness)

Surgical laser treatment for nearsighted patients with spherical correction from -0.75 to -13.0 diopters and having less than or equal to 0.75 diopters of astigmatism.

Introduction

- How the eye functions -

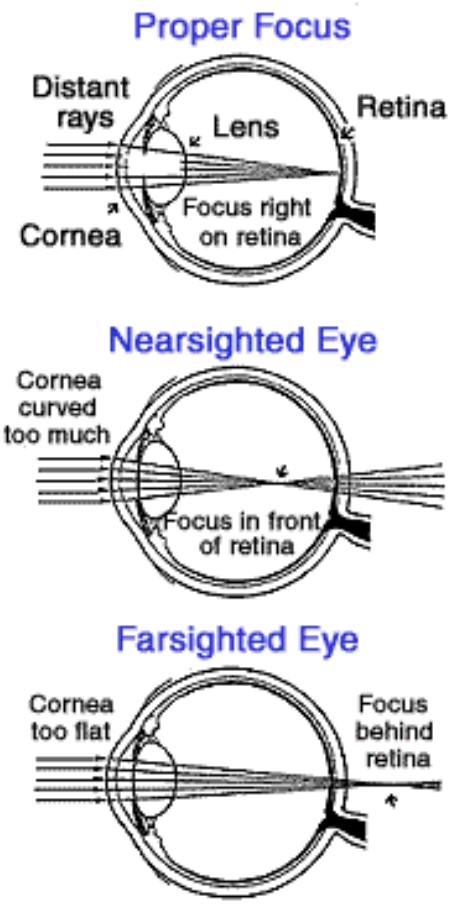
Please read all the information for patients if you are thinking about having Photorefractive Keratectomy (PRK) laser surgery to correct nearsightedness (myopia) without treatment for any astigmatism. The options for correction of myopia now include glasses, contact lenses, and different kinds of refractive surgery such as radial keratotomy (RK), automated lamellar keratoplasty, excimer laser in situ keratomileusis (LASIK), and PRK using excimer lasers, including the Nidek EC-5000 Excimer Laser System.

This information can help you make an informed decision when selecting a method to correct your nearsightedness. If both of your eyes are nearsighted, your doctor may recommend PRK surgery for both eyes to achieve satisfactory vision. However, there are cases where it is better to reshape the cornea on only one eye.

Please read the rest of the information for patients completely. Discuss any questions you may have with your doctor in order to decide if PRK is the right choice for you. Only a trained and certified practitioner can

determine whether or not you are a suitable candidate for PRK. You should be aware that a small percentage of patients treated with excimer lasers experience permanent vision reduction. The goal of PRK is to reduce your need for glasses or contact lenses by changing the shape of the cornea through PRK laser surgery.

How the Eye Functions



The cornea and lens of the eye focus light like a camera lens to form an image on the retina at the back of the eye. The cornea, where light first enters the front of the eye, provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. Normally, in relatively young persons (i.e., less than 50 years of age) the lens of the eye can adjust its focusing power somewhat, so you can see objects clearly both near and far away.

The eye focuses light by refracting all light rays to meet at a single point. If the focusing process works perfectly, a sharp image of the object you are looking at will be focused exactly on the retina and you will see a clear image. However, if the light focuses either in front of or behind the retina, the image on the retina (and the image you see) will be blurred, and you are said to have a refractive error. Refractive errors are not diseases, but are common variations observed in human beings across the world.

There are three main types of refractive error. The are called nearsightedness (myopia), farsightedness (hyperopia) and astigmatism. The amount of refractive error present in the eye is measured in units called "diopters." When your eye cannot focus correctly, it is said to have one of the main refractive errors: myopia or hyperopia.

Myopia usually starts in childhood and typically stabilizes in the late teens or early adulthood. The tendency to develop myopia also runs in families. Myopia can change from a very mild to a very strong nearsighted effect. The range of treatment with the Nidek EC-5000 covers a large part of that range.

Hyperopia is also very common, and is especially problematic in older persons who have difficulty in focusing on objects up close. Astigmatism occurs when the refractive error is stronger in a particular direction. Astigmatism may occur with either myopia or hyperopia. The Nidek EC-5000 is not approved for treating either astigmatism or hyperopia.

The following pictures emphasize the role of the cornea in determining the focusing power of the eye. They show that the more sharply the cornea is curved, the more the light rays are bent. If the cornea is curved too much, the image focuses in front of the retina and the eye is nearsighted. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. When the cornea shape is just right the image from a distant object is focused exactly on the retina. This proper focus for distance vision is called emmetropia.

Good focus depends on three factors, the overall shape and size of your eye, the shape of the cornea, and your lens power. During a regular eye examination, your doctor checks your vision to determine where the eye focuses light relative to your retina. When your doctor adjusts your vision with different lenses, he correctly focuses light on the retina.

Myopia is the most common refractive condition observed in North America and affects about 25% of the population. Myopic individuals see near objects clearly, but distant objects are blurry. Nearsightedness can be corrected by any method that reduces the total refractive power of the eye, and includes the use of glasses, contact lenses and refractive surgery. With glasses or contacts, changes in your vision that occur slowly over time can be corrected by simply adjusting the lens prescription of your glasses or contacts. Refractive surgery, on the other hand, produces changes that are permanent and cannot be undone or easily modified if your vision changes or if the initial surgery is not successful (4.8% of initial surgeries were found to be greater than 2.0D from intended correction at 6 months after surgery.)

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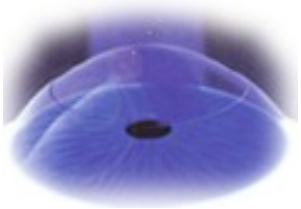
PRK for Myopia

What is PRK?

PRK is laser surgery to correct nearsightedness (myopia). An excimer laser beam is used to flatten the front of the cornea. The laser beam removes microscopic amounts of tissue from the front of the cornea, precisely reshaping the cornea.



The excimer laser produces a beam of ultraviolet light in a series of rapid pulses. Each pulse lasts only a few billionths of a second and removes a microscopic amount of tissue by evaporating it. Excimer laser light does not penetrate the eye and leaves other eye structures (iris, lens and retina) undisturbed. The laser produces very little heat and is controlled by the doctor during the operation.

Prior to PRK, some anesthetic drops are placed on the eye to numb it. Your doctor then begins the PRK procedure by gently removing the outer layer of cells from the cornea where the laser treatment will be used. These cells are usually scraped away using a scalpel or other surgical tool. This part usually takes a couple minutes. After that, your doctor uses the laser beam to complete the PRK procedure. The laser treatment usually lasts only about 15-40 seconds. This procedure is performed on one eye at a time even if both are to be treated. If all goes well with the first eye, and your vision stabilizes without complications or adverse reactions, then the second eye can be treated later. PRK laser surgery on the second eye is usually done three months after the first eye, if needed.

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PRK for Myopia

Contraindications, Warnings & Precautions

Contraindications

You should not have PRK surgery if:

- You have collagen vascular, autoimmune or immunodeficiency diseases (for example: rheumatoid arthritis, lupus or AIDS).
- You are pregnant or nursing.
- You show signs of keratoconus (corneal disease).
- You are taking prescription medications that affect corneal healing or your refraction. You should discuss all medications you take, even over-the-counter medications, with your eye doctor.

Warnings

Discuss with your doctor if:

- Your nearsightedness is changing. If your vision is unstable, then you should not be treated.
- You have severe allergies. Your medications may have to change before or after your eye surgery.
- You have been diagnosed with ocular Herpes simplex or ocular Herpes zoster. Herpes are viral infections. Laser treatment may reactivate the infection.
- You have nystagmus (uncontrolled eye movements) or another condition that prevents a steady gaze. You need to be able to keep your eyes still during treatment.

Precautions

The safety and effectiveness of the Nidek EC-5000 Excimer Laser has NOT been established in:

- Eyes with disease or corneal abnormality (for example: scar, infection, corneal dystrophies, etc.).
- Eyes with previous surgery or injury to the center of the cornea where PRK will be performed.
- Patients under 21 years of age.
- Patients over the long term (more than 2 years after the surgery).

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Risks & Benefits

Risks

Laser PRK is surgical procedure involving your eyes and has potentially serious risks. You should consider and discuss with your doctor the risks that are noted here. These are based on clinical experience with PRK cases and the possibilities that doctors believe should be considered for this kind of eye surgery.
See the information listed below for details on risks of complications and adverse events.

- Although the effects of PRK on visual performance under poor lighting conditions have not been determined, it is possible that you will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night. These effects have been reported as being more common in persons with large pupils. It is possible that these may be permanent effects.

- The first week following surgery: The following complications have been reported up to several weeks following PRK treatment. They are associated with the normal healing process after treatment and include:
  - Discomfort (60.2% of cases, including mild to moderate pain, pressure, scratchiness, burning sensation, and dryness) may last for up to 3 days after surgery, for which your eye doctor can provide medications.
  - The feeling that something is in your eye (14.9% of cases).
  - Blurred vision (7.2% of cases) and tearing or watery eyes (5.2% of cases) may occur as the cornea heals.
  - Sensitivity to bright lights (3.5% of cases).

- The first two or six months following surgery:
    - Your intraocular pressure may increase due to use of steroid or anti-inflammatory medications (0.7% of eyes had a significant elevation in intraocular pressure). This is usually resolved by drug therapy or by stopping the use of steroid or anti-inflammatory medication.
    - Your cornea may become hazy or cloudy enough to affect your vision (2.2% of eyes had mild or moderate haze at 6 months after surgery, 0.5% with significant loss of vision). This haze typically disappears over time, but some patients continue to experience a small amount of haze over 1-2 years.
    - An increase in fluctuation of vision (34.1% pre-operatively vs. 48.1% post operatively).
    - Glare (26.9% pre-operatively vs. 34.4% post-operatively).
    - Difficulty in night driving (23.5% pre-operatively vs. 48.0% post-operatively).
    - Increased sensitivity to bright light (0.3% at 1 month, not reported at later periods).
    - More than one diopter worsening (regression) of nearsightedness compared to their best result by 6 months (6.3%).

  NOTE: You should contact your doctor if you notice any pain or change or loss of vision in the eye.

- More than one year after surgery: Nidek clinical studies showed that at one or more years after PRK surgery the following vision-threatening events happened less than approximately 1% of the time:
    - Too large a correction (causing farsightedness more than +2.0D).
    - Losing a significant amount (more than 2 lines lost) of vision even with glasses.
    - Corneal haze (that causes significant loss of vision).

If the results of the surgery are not satisfactory, you many need to have additional PRK surgery in the same eye.

Benefits

- PRK surgery, as performed with the Nidek EC-5000 Excimer Laser, is effective in reducing nearsightedness between -0.75 and -13.0 diopters in patients with less than or equal to 0.75 diopters of astigmatism (84.8% of treated eyes were within 1.0 diopter of intended correction at 6 months).
- PRK may reduce overall nearsightedness (91.3% significantly improved uncorrected vision to the level of 20/40 or better at 6 months).
- PRK may reduce or eliminate dependency upon contact lenses or glasses (60.6% could see 20/20 or better without glasses or contacts at 6 months).
- PRK should be considered a permanent surgical procedure.

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PRK for Myopia

Are you a good candidate for PRK?

- Why PRK may not be right for you -

If you are considering PRK, you must:

- Be at least 21 years of age.
- Have healthy eyes which are free from eye disease or corneal abnormality (for example: scar, infection, etc.).
- Have nearsightedness (myopia) between -0.75 to -13.0 diopters with less than or equal to 0.75 diopters of astigmatism.
- Be sure your eye doctor has satisfactory evidence that your refraction has been stable over the past year (not changed by more than 0.5 diopters if your treatment is for less than 7.0 diopters, or by more than 1.0 diopter if your treatment is for more than 7.0 diopters).
- Be informed of PRK risks and benefits as compared to other available treatments for nearsightedness (myopia).
- Be willing to sign an informed consent form, as provided by your eye care professional.

Why PRK may not be right for you

- **If you expect perfect results.** No surgical procedure can assure you perfect results or can guarantee that you expectations will be met.

- **If you expect perfect vision under all conditions.** At night, eyes that have been reshaped by refractive procedures such as PRK may experience haze and a variety of visual effects. The PRK procedure only

reshapes the central portion of the cornea and does not reshape the entire cornea. As a result, when the pupil of the eye dilates under low light conditions it opens past the boundaries of the treated area producing unwanted changes in vision. You may find that you will need to wear corrective lenses to drive at night. In addition, PRK does not eliminate the need for reading glasses. In some patients, reading glasses may be required after treatment even if they were not worn before treatment. If the thought of occasionally wearing eyewear is uncomfortable, then PRK may not be right for you.

- **If you expect an instant change in vision.** The visual results are not instant, particularly for patients with more than 4 diopters of myopia. It may take up to three months, sometimes longer, for the shape of the cornea to stabilize following surgery. You must be patient and be willing to wait until the healing process finishes. You may also be asked to temporarily wear corrective lenses.

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PRK for Myopia

Before & the day of surgery

Before the surgery

If you are interested in having PRK, you will need to have a pre-surgical examination to determine if your eye is healthy and suitable for PRK. This will include a complete eye history, and a thorough examination of both eyes. In addition, computerized mapping of your cornea will be done to determine if it is smooth and properly shaped.

> **Warning**
> If you wear contact lenses, it is very important to stop wearing them 2-4 weeks before the evaluation. Failure to do this can produce poor surgical results.

Before the surgery, please tell your doctor well in advance whether you take any medications or have any allergies. Also, talk with your doctor about whether you can eat or drink immediately before the surgery. You should also arrange for transportation, since you must not drive immediately after the surgery. You can resume driving only after receiving permission from your doctor.

The day of surgery

Before the surgery, anesthetic (numbing) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up at a microscope that will deliver the laser light to your cornea. An instrument will be placed between your eyelids to hold them open during the surgery. For protection and comfort, a temporary shield will cover the eye not having surgery.

- Your doctor may perform a brief practice treatment so you can hear and

smell what the laser will be like during the treatment.

- Using a small instrument, the surgeon begins the procedure by removing the outermost layer of the cornea. Next, the doctor repositions your head in the chair, and refocuses the microscope on your cornea. You will then be asked to look directly at a blinking light. Relax the muscles of your face and forehead and try to keep both eyes open without squinting. As you continue to look at the blinking light, small amounts of tissue will be removed from your cornea using the Nidek EC-5000 Excimer Laser.

Precaution

It is very important that you keep looking at the blinking light during the procedure, even if the light fades or becomes dim. Your surgical results depends upon your looking at this blinking light throughout the treatment.

- You will be using the laser less than 1 minute. However, the entire surgical procedure takes about 10 to 15 minutes.
- After the laser surgery is complete, some drops or ointment will be placed into your eye. Then it will be covered and patched for your protection and comfort. The surgery itself is painless because of the numbing actions of the anesthetic drops that were applied to your eye at the beginning of the procedure.
- After 45-60 minutes, the anesthetic will wear off and your eye may hurt for 1-3 days. Most patients describe this pain as moderate to severe. Do NOT rub your eyes for the first 3 to 5 days. Rubbing your eyes can damage the cornea and will delay healing. Your doctor can prescribe pain medication to make you more comfortable during this brief time after the surgery.

Warning

Your doctor will monitor you for any side effects if topical steroids were used. The possible side effects from prolonged use of topical steroids are ocular hypertension.

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The first days after surgery

In your doctor's office, your eye patch will be removed the following day. You will be mildly sensitive to light and have the feeling that something is in your eye for the first few days. Sunglasses may make you more comfortable during this time.

- Your vision should become stable within the first several weeks after surgery. Some patients may experience some small changes (for example, improvement or worsening of their vision). These changes may occur up to six months or more after surgery.

- A haze or cloudiness is typically seen in the cornea following surgery, but usually does not affect your vision. This haze tends to decrease over time and usually disappears completely over a 1-2 year period.

Important
Use the anti-inflammatory eye drops and lubricants as directed by your doctor. Your surgical results depend upon your following your doctor's directions.

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Questions to ask your doctor

You may want to ask the following questions to help you decide if PRK is right for you:

- What other options are available for correcting my nearsightedness?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of PRK for my amount of nearsightedness?
- What quality of vision can I expect in the first few months after surgery?
- If PRK does not correct my vision, what is the possibility that my glasses would need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after PRK if I need them?
- How is PRK likely to affect my need to wear glasses or contact lenses as I get older?
- Is it likely I will need reading glasses sooner than later?
- Will my cornea heal differently if injured 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 might I experience if I have PRK only on one eye?

Discuss the cost of surgery and follow-up care requirements with your doctor, as laser treatment is not covered by most health insurance policies.

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Self-Test

Are you an informed and educated patient?
Take the test below and see if you can correctly answer these questions after reading this information for patients.

1. Excimer laser refractive surgery is risk free.
   ○ True ○ False
2. Excimer laser surgery use pulses of invisible light.
   ○ True ○ False
3. It doesn't matter if I wear my contact lenses when my doctor told me not to.
   ○ True ○ False
4. The laser does all the work; I just have to lie on the chair and close my eyes.
   ○ True ○ False
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.
   ○ True ○ False
6. I may need reading glasses after laser surgery.
   ○ True ○ False
7. There is a risk that I may lose some vision after laser surgery.

○ True ○ False

8. It doesn't matter if I am pregnant.

○ True ○ False

9. If I have an auto-immune disease, I am still a good candidate for PRK.

○ True ○ False

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Summary of Important Information

- PRK is a permanent operation to the cornea; it cannot be reversed.
- Alternatives to PRK include glasses, contact lenses and RK.
- PRK is not a laser version of radial keratotomy (RK); they are completely different from one another.
- Some occupations, such as pilots, do not accept applicants who have had any refractive surgery.
- Refractive error must be stable (within ±0.5 diopters if your treatment is for less than 7.0 diopters, or within ±1.0 diopters if more) for at least one year before surgery.
- The following risks of PRK surgery should be noted:
  - transient complications: discomfort (24-48 hours), corneal swelling, blurred vision, feeling something in the eye, shadow images, light sensitivity, tearing, and pupil enlargement. These problems are common (over 60% of cases report one or more of these complications) and may last up to several weeks.
  - adverse events beyond the first few months: night vision difficulty (48% at 6 months); elevation of intraocular pressure (0.7% at 6 months); cloudy cornea affecting vision (0.3% at 6 months with mild to moderate haze reducing vision); overcorrection by more than 2.0 diopters (2.0% at 6 months, 0.6% at 12 months); under correction or nearsighted by more than 2.0 diopters (2.3% at 6 months, 3.4% at 12 months); loss of best vision that can be achieved with glasses (1.2% at 6 months); ghost images (1.3% at 6 months); and, glare (34.4% at 6 months, compared to 9.2% before

surgery).

- The following benefits of PRK surgery should be noted:
  - Nearsightedness may be reduced so that the amount of time contact lenses or glasses are used during the day is reduced or eliminated.
  - PRK may be an alternative to glasses in some patients who are intolerant of contact lenses.
  - Another alternative to correct nearsightedness.

- Patients considering PRK surgery should:
  - Discuss fully with one or more ophthalmic surgeons the complications of PRK surgery, the risks and the time required for healing, and have a complete eye examination before making a final decision.
  - Read both the Patient Information Booklet (same contents with this information for patients pages) and the Informed Consent Document (ICD) provided by your doctor carefully before signing the ICD.

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Summary Tables

Summary of Key Safety and Efficacy Variables at 6 months after Surgery	
Efficacy Variables	
Visual acuity without glasses or contacts:	
20/20 or better	60.6%
20/40 or better	91.3%
Treated eyes within range of target correction:	
±0.50 diopters	62.2%
±1.00 diopters	84.8%
±2.00 diopters	95.2%
Safety Variables	
• Visual acuity with glasses being 20/40 or worse:	0.5%
• Loss of more than 2 lines on vision chart with glasses on:	0.5%
• Visual acuity with glasses on is worse than 20/25 when better than 20/20 before surgery:	2.1%
• Increase in astigmatism by more than 2.0 diopters:	0.2%

Complications and Adverse Events		
Description	Immediate Post-op to 1 Month	At 6 Months

Complications-		
Discomfort:	60.2%	0.0%
Haze (trace to moderate):	18.5%	10.5%
Foreign body sensation:	14.9%	0.0%
Blurry/cloudy vision:	7.2%*	0.0%
Tearing/watery eyes:	5.2%	0.0%
Photophobia:	3.5%	0.0%
Ghost/double images:	1.2%	0.0%
Corneal edema:	0.4%	0.0%
Recurrent erosions:	0.0%	0.0%
Adverse events-		
Persistent corneal defect:	0.4%	0.0%
Corneal infiltrate:	0.3%	10.5%
Elevated intraocular pressure (relative or absolute):	0.2%	0.7%
Loss of visual acuity after 6 months:	----	1.2%
Late onset haze with decreased vision:	----	0.3%
Retinal accidents/detach:	0.0%	0.0%

*Percentage taken from consistent follow-up cohort (n=556); all other complications and adverse event data from all available eyes (n=940).

NOTE: Because of the relatively small (n=21) sample size of myopia treatments exceeding -10.0 diopters, the clinical study may have been unable to detect other complications and/or adverse events that occurred at lower rates in patients in this high refractive error range.

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