

# FTC FACTS for Consumers

## VISION CORRECTION PROCEDURES



**I**f you're among the 68 million Americans who are nearsighted, you probably wear glasses or contact lenses to improve your distance vision. You also may hear a lot about Radial Keratotomy (RK) and Photorefractive Keratectomy (PRK) — surgical procedures that treat your vision problem — and Orthokeratology (Ortho-K), a non-surgical procedure that claims to improve your vision by changing the shape of your cornea.

Don't throw away your glasses or contact lenses just yet. The Federal Trade Commission (FTC) cautions that RK, PRK, and Ortho-K are not always short cuts to perfect vision, although some advertising and promotional materials for the procedures may suggest otherwise.



## The RK and PRK Surgical Procedures

RK and PRK reduce nearsightedness by altering the shape of the cornea. In RK, the surgeon uses a diamond knife to make incisions in the cornea in a radial or spoke-like pattern. This causes the cornea's curvature to flatten, changing the way it focuses light on the retina. In PRK, the surgeon uses a computer-controlled excimer laser to sculpt the surface of the cornea, changing its shape and the way light is "refracted" to the retina.

RK and PRK are outpatient surgical procedures. They are not used to treat people who have trouble seeing near objects — those who are farsighted — or people who need reading glasses as a result of the aging process — those who are presbyopic.

Some surgeons who perform RK schedule two operations, allowing one eye to stabilize before operating on the second. The U.S. Food and Drug Administration (FDA) recommends a three-month waiting period between PRK operations. Many RK patients and a small percentage of PRK patients also need or want additional surgery — usually called an "enhancement" — to fine-tune the results of the initial operation. Neither RK nor PRK is considered medically necessary, because the operation is performed on a healthy organ. As a result, the surgery usually is not covered by health insurance.



## The Ortho-K Non-Surgical Procedure

Ortho-K is defined as a procedure that involves fitting the patient with a series of rigid contact lenses in an attempt to reshape the cornea to improve vision. The last set of lenses become "retainers" that the patient wears for a limited time each day to maintain the new corneal shape. Some eye care provid-

ers use special names, such as "precise corneal molding" (PCM) or "controlled kerato-refraction" (CKR), to refer to their method of performing Ortho-K.

Published results of four controlled clinical studies conducted in the 1970's and 1980's showed that some contact lens wearers experienced changes in their nearsightedness after several months of contact lens wear. However, the studies show that any reduction in nearsightedness that may be achieved is temporary. In fact, the patient's nearsightedness returns to its original level when that patient stops wearing contact lenses. It also is not possible to predict who might respond positively to this procedure and by how much. Some practitioners claim that newer techniques achieve better results than what the four studies showed. However, there is no scientific evidence to back this up. It is very important to know that the FDA, which regulates contact lenses as medical devices, has not approved any specific contact lenses designed especially for Ortho-K.



## Seeing Through Claims

Even with 20/20 vision, it can be **difficult to read between the lines in promotional literature.** If you or someone you care about is considering RK, PRK, or Ortho-K, here is some information to help you evaluate some of the claims about these procedures. Among the claims you may see or hear are:

### *No more glasses or contact lenses!*

One claim about refractive surgery is that you'll never need glasses or contact lenses again. This claim is FALSE for most people. The truth is that for a variety of reasons, you still may need corrective lenses after RK and PRK. Like any surgical procedure, refractive surgery is not 100 percent predictable. RK and PRK surgery may result in overcorrection,

which renders you farsighted, or undercorrection, which leaves you nearsighted. And almost everyone who undergoes RK or PRK surgery eventually will need reading glasses.

What's more, studies have shown that a number of patients who undergo RK surgery to treat their nearsightedness may become farsighted and need corrective lenses for close vision because of a *hyperopic shift* — a gradual but continuing shift toward farsightedness. Some doctors deliberately undercorrect, leaving patients with residual nearsightedness after RK surgery to compensate for any slow drift toward farsightedness. In recent years, RK equipment and techniques have developed and surgical results have improved. Nevertheless, studies assessing RK surgery continue to document an ongoing need for corrective lenses after surgery for a significant number of patients.

The FDA recently approved two laser systems as safe and effective for performing PRK on adult patients with *mild to moderate* nearsightedness and mild astigmatism. In clinical studies that were submitted as part of the FDA approval process for one of the laser systems, about five percent of patients followed after surgery still needed corrective lenses often for distance vision, and up to 15 percent needed corrective lenses occasionally for distance vision. Those who wore reading glasses for near vision before the surgery still needed them afterward. In addition, there were indications that some patients who did not need reading glasses before surgery might need them afterward or earlier in life than they might have had they never had the surgery.

*The claim that you won't need glasses or contact lenses following the Ortho-K procedure also is false.* Even if Ortho-K helps reduce some of your nearsightedness, you must wear

contact lenses at least part of the day to maintain the reduction. You might be told that you only have to wear “retainer lenses” at night, freeing you from contact lenses during the day. But no controlled study has been conducted to test the hypothesis that retainer lenses worn at night on a limited basis can stabilize the shape of the cornea. More importantly, overnight use of contact lenses is associated with greater risk of complications. The immediate and long-term health risks of Ortho-K performed in combination with overnight wear are unknown.

### ***Permanent, stable, or predictable long-term results!***

Although research on RK surgery has identified a shift toward farsightedness in a significant number of patients, new RK techniques are being studied to determine whether they result in more stable vision. One technique, known as “mini-RK,” uses shorter and fewer incisions. It may provide more stable vision for people with a *low degree* of myopia only. Research on this technique continues.

One possible effect of PRK surgery may be a return to some degree of nearsightedness. Studies of the long-term effects of PRK are being conducted to determine whether vision remains stable over long periods of time.

Studies indicate that while Ortho-K can alter the corneal curvature, it is not possible to predict who will respond favorably to Ortho-K, by how much, and for how long. With lens removal, it is not possible to predict when unaided vision is at its best. The reason: unaided vision fluctuates.

### ***95 percent of patients achieve 20/40 vision or better!***

You may have read or heard claims that a high percentage of PRK patients achieve unaided 20/40 vision or better. Although 20/40 vision may be enough to pass a driver's license eye test in

# Facts for Consumers

most states, you still may need or choose to wear corrective lenses for distance vision, particularly at night. A 95 percent chance for unaided 20/40 vision or better does not mean that you have a 95 percent chance of never wearing glasses or contacts again.

In addition, you may have read testimonials from consumers who claim they've achieved unaided 20/20 or 20/40 vision with the Ortho-K procedure. These results are not typical or permanent. Ortho-K can reduce nearsightedness by a small amount, but most people who are nearsighted need more reduction to achieve unaided 20/20 or 20/40 vision.

You may read other claims about the safety and effectiveness of the surgical procedures as well. Keep in mind that no surgical procedure is risk-free. In rare instances, RK and PRK may result in serious complications, like loss of vision or infection. In addition, there are several potential side-effects. For example, after RK surgery, patients may experience fluctuating vision, a weakened cornea, halos around lights, increased sensitivity to light and glare, and temporary pain. Clinical studies submitted to the FDA by one laser manufacturer reported that those who have PRK surgery may experience pain 24 to 48 hours after surgery. In addition, other side-effects occurred within six months after surgery, including corneal haze, loss of best vision achieved with glasses, minor glare, and mild halos around images.

## For More Information

For more information about possible benefits, limitations, side-effects, and complications of vision-correction options, consult your eye doctor. Remember to ask your eye doctor about his or her experience with these procedures.

You also may contact the National Eye Institute, Building 31 Room 6A32, 31 Center Drive MSC 2510, Bethesda, MD 20892-2510, (301) 496-5248, and your local office of the U.S. Food and Drug Administration.

In addition, you may contact the Federal Trade Commission. The FTC is not authorized to intervene in individual cases, but the information you provide may indicate a pattern of possible law violations requiring action by the Commission. The FTC works for the consumer to prevent fraudulent, deceptive and unfair business practices in the marketplace and to provide information to help consumers spot, stop and avoid them. To file a complaint, or to get free information on any of 150 consumer topics, call toll-free, **1-877-FTC-HELP** (1-877-382-4357), or use the complaint form at [www.ftc.gov](http://www.ftc.gov). The FTC enters Internet, telemarketing, and other fraud-related complaints into **Consumer Sentinel**, a secure, online database available to hundreds of civil and criminal law enforcement agencies worldwide.



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