

Wang Vision Institute
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The purpose of this consent for is to educate you on the Phototherapeutic Keratectomy (PTK) and Photorefractive Keratectomy (PRK) procedure. It is not intended to scare you, or deter you from surgery, but to inform you of the risks and benefits. It may contain words that you do not understand. Please ask the doctor or the staff to explain any words or information that you do not clearly understand. The surgeon will review your chart before you come in for your procedure and again when you arrive.

OVERVIEW OF THE PROCEDURE

PTK/PRK is performed as an outpatient procedure. Anesthetic (numbing) eye drops are placed in the eye immediately prior to surgery in order to minimize pain during the procedure. In some cases, a mild sedative pill may be administered to reduce apprehension prior to surgery. The eyelid is cleansed and held open using a special instrument. A patch generally covers the other eye during the treatment.

When performing Phototherapeutic Keratectomy (PTK), the goal is to recreate a healthier corneal surface, to remove scars and/or treat corneal dystrophies and other irregularities. The refractive error is **not treated** in this procedure, and it is medical rather than elective.

When performing Photorefractive Keratectomy (PRK), the goal is to reshape the cornea to correct the refractive error such that the dependence upon glasses and/or contacts is lessened. This is an elective procedure. The purpose of PRK is to reduce your refractive error such that you are visually comfortable without glasses. We cannot however guarantee that you will not have to wear glasses or contact lenses either some or all of the time to achieve your best corrected vision. Even if your uncorrected vision is significantly better than it was before surgery, you may still require glasses or contact lenses either full or part time in order to see well for distance tasks (such as driving or golf). Additionally, you may, depending on your age, need to wear reading glasses after PRK. This is still true if you choose to have monovision correction.

In either case, the surface epithelium is removed and the ultraviolet laser is used to reshape the corneal surface. The treatment phase is usually over in less than one-minute. Then antibiotic drops are applied and a contact lens is placed on the eye.

Pain and blurred vision can be a concern until the surface heals in about 3 days and eyedrops are used for the first week. The patient is examined the next day and as needed for the next few days until the corneal surface heals. Then the contact lens is removed. Subsequent follow-up visits will be determined by the doctor according to your progress, but typically occur within the first 3 months. Additional visits may be scheduled according to your doctor's recommendation.

Best vision, may take several weeks or months to achieve. Because the patient is blurry, light sensitive, and may have taken a light sedative, the patient will not be allowed to drive themselves home. Surgery will not be performed unless a driver is present (or other arrangements have been made).

In order to minimize the risk of infection and postoperative discomfort, as well as maximize the visual results of the PRK/PTK procedure, it is important that the patient complies faithfully with the medication dosage and schedule. Medications are usually necessary for only a few days. We recommend the usage of artificial tears frequently – every 15 minutes for the first week, then even 30 minutes for the second week to alleviate dry eye symptoms common after PRK/PTK.

Although the vast majority of patients report markedly improved uncorrected vision quite soon after PRK/PTK, an individual patient's best vision may not be realized for several weeks or months later. Delayed visual recovery following PRK/PTK may be a result of, among other factors, dryness, surface defects, or haze/scarring.

Patients who do not experience full correction may opt to wear glasses, contact lenses or could possibly have additional refractive surgery (either PRK/PTK or other procedures). The need for enhancements (re-operation of PRK/PTK or other procedures) for low-to-moderate nearsightedness has been less than 10%. Generally, re-operation will not be performed for at least three months following the original procedures.

PRESBYOPIA

If both eyes are corrected for distance, glasses for reading will be needed sometime after the age of forty. This condition, known as "presbyopia", occurs as a result of the natural aging process of the lens inside the eye. Without surgery, presbyopia results in the need for bifocals. After surgery, if the distance vision is good, near vision will be blurry and magnifiers will be needed.

One approach to address the issue of presbyopia is called "monovision" and involves intentionally under-correcting one eye in order to leave a small amount of nearsightedness. The result is for this eye to have good uncorrected near vision (but somewhat blurred distance vision) while the fully corrected eye will have good distance vision (and somewhat blurred near vision). However, not everyone can successfully adjust to monovision. Even successful monovision PRK/PTK patients may require glasses for specific tasks (e.g. driving at night and reading small print in dim lighting). Also, it is important to note that the need for reading correction progresses as we age; if the need overcomes the degree of residual nearsightedness left in the "reading" eye in a monovision procedure, reading glasses may become necessary. We will demonstrate this for patients over 40 during the evaluation. Patients interested in monovision may benefit from a trial with contact lenses prior to surgery.

CONTRAINDICATIONS

PRK/PTK should not be performed on persons:

1. Who are immune-compromised or on drugs or therapy which suppress the immune system
2. With signs of kerataconus (steepening of the cornea)
3. With a previous history of keloid formation
4. Who are pregnant, nursing or expecting to become pregnant within six months following the PRK/PTK procedure
5. With residual, recurrent, or active ocular disease(s) or abnormality except for myopia (or hyperopia or astigmatism) in either eye
6. With active or residual disease(s) likely to affect wound healing capability
7. With unstable or uncontrolled diabetes
8. With progressive myopia (or hyperopia)

9. With heart disease
10. With drug interactions

If you know that you have any of these conditions, you should inform your physician. In addition, if you have any other concerns or possible conditions, which might affect your decision to undertake PRK/PTK surgery, you should discuss them with your physician.

RISKS, COMPLICATIONS, AND SIDE EFFECTS OF PRK/PTK:

What follows is a discussion of the most common side effects of PRK/PTK. It is impossible to include all conceivable side effects, risks, and complications of the surgery. It is also possible that there are side effects not known to us at this time.

Pain: Due to the removal of the corneal epithelium, there may be significant discomfort following PRK/PTK, some may feel discomfort or pain for several hours immediately after surgery. Occasionally, analgesics may be necessary. Pain or tenderness of the eyelids resulting from the instrument used to keep the lids open during surgery may occur. If you have postoperative discomfort or if pain increases or extends beyond 48 hours, you should report this immediately to the medical staff.

Loss of best-corrected vision: This may occur with infections, scarring, or due to poor healing. It may be permanent.

Light Sensitivity: Light sensitivity following PRK/PTK is quite common. This sensitivity, though mild in degree and usually most intense for the first 48 hours or slightly longer, may necessitate the use of sunglasses.

Blurred Vision: Your vision may be somewhat blurred in the early postoperative period, particularly in the first 48-72 hours, and this may interfere with functions such as driving, working and hobbies. The actual level of vision necessary for people to comfortably function is quite individual and varies with individual healing. Therefore it is impossible to precisely predict when your vision will be good enough for you to feel comfortable.

Tearing: Tearing commonly occurs after PRK/PTK, but is usually limited to the first 24-48 hours after surgery. In rare cases, tearing may be so profuse as to blur vision and interfere with functions such as driving.

Sedation-related: Many patients feel more comfortable taking a light sedative prior to the PRK/PTK procedure. If you receive sedation you may not feel sufficiently comfortable to drive or operate machinery for 24 hours after surgery.

Under correction and regression: While the introduction of the excimer laser has improved the accuracy of refractive surgery, variations in the individual biology of wound healing (as well as other factors) from patient to patient mean that PRK/PTK is not a 100% accurate procedure. It is not possible to accurately predict how your eyes will respond to the treatment. While our goal is provide you with the vision we demonstrate in the office, you may be left with a residual refractive error (nearsightedness, farsightedness, astigmatism, or some combination). In fact, mild nearsightedness may be preferable because of the “protection” it may offer against the need to wear glasses or contact lenses. Should you desire an enhancement (or “touch up procedure”), this cannot be completed until your vision is stable, a fair amount of healing has occurred, and it is medically safe to proceed. These conditions are typically met 3-6 months after the procedure.

Glare, halos and night vision problems: Mild glare, halos, shadows, or “ghosting images” are not uncommon immediately after surgery. In most patients these will slowly return to normal over time. Driving at night is always more difficult than driving in daylight, and some patients request glasses for night driving. In rare cases, they may be severe and glasses may not improve them.

Infection: Infection is a potential complication following PRK/PTK surgery. In order to minimize the risk of post-operative infection, it is critical that you use the medications and preservative-free artificial tears precisely as your doctor recommends following your surgery. Should infection occur in the cornea following PRK/PTK, a potentially lengthy course of treatment may be necessary. This may include invasive laboratory tests, special medications requiring frequent usage, multiple doctor visits, and hospitalization. Infections may result in corneal scarring, perforation, spread of infection to outside the eye, and loss of vision. Since health care workers are thought to be at higher risk for such infections, it is recommended that our patients in the health care field minimize their exposure to potentially infective situations. If you have had infections in the past, please let your doctor know prior to surgery.

Corneal Scarring: Corneal scarring or haze if necessary may occur after PRK/PTK. If it occurs, there may be a permanent loss in vision. Not complying with the post-operative medication regime increases the risk for scarring.

Loss of Best-corrected Vision: This may occur with healing complications, infections, scarring or due to poor healing. It may be permanent. Irregularities in corneal shape may result from PRK/PTK, and in rare cases, undetected keratoconus can be exacerbated (made worse) by the procedure. In cases of corneal irregularities PRK is preferred over LASIK for safety.

Ptosis: Droopy of the upper eyelid is a rare occurrence following PRK/PTK. The cause is not fully understood. Generally, it is mild in degree and resolves spontaneously over the several months.

Cataracts: PRK/PTK has not been directly and conclusively associated with the development of cataracts. A cataract is an opacification of the lens within the eye that develops slowly over time. They are commonly found at an early stage in anyone over 50 years of age. Prolonged use of post-operative medications may increase the risk of cataracts.

Retinal Detachment: PRK/PTK has not been directly and conclusively associated with retinal detachments. Nearsighted individuals are at higher risk for having a spontaneous detachment or other retinal complication than the general population, and this may occur at any time unrelated to your PRK/PTK procedure.

Specific Occupations: Having refractive surgery, including PRK/PTK, could conceivably disqualify you from some professions (particularly military) and it is your responsibility to investigate any requirements and/or exclusion criteria for any profession and/or sport/hobby in which you are interested.

Pregnancy: If you are pregnant or breastfeeding, you should not undergo PRK/PTK. We require three months pass after delivery and/or cessation of breastfeeding prior to surgery. If you are able to become pregnant, you must agree to use birth control for at

least one month after surgery, and possibly up to three months, because this is when the majority of healing takes place.

In addition to the above mentioned, it is possible to experience unknown or as yet unreported complications following PRK/PTK, in spite of the fact that we have nearly 50 years experience with lamellar refractive surgery and nearly a decade of experience with excimer refractive surgery. As noted above, complications can occur after PRK and it is conceivable that, if severe enough, these may cause partial loss of vision or even blindness or may require prolonged treatment and/or further surgery.

ALTERNATIVES TO PTK

PTK is a surgical treatment of corneal surface irregularities and/or scarring. Treatment options may include:

- Regular and liberal use of artificial tears
- Stomal Puncture – tiny punctures into the deep cornea to improve adherence of overlying tissue
- Contact lenses

ALTERNATIVES TO PRK

PRK is an elective procedure. There are alternatives to PRK. These include:

- Glasses
- Contact lenses
- Radial keratotomy (RK) – surgical alternative where the surgeon makes cuts on the cornea to change your refractive error
- Photorefractive Keratectomy (PRK) -- surgical alternative where the surgeon gently removes the epithelium of the cornea and uses the excimer laser to resurface the eye
- Conductive keratoplasty (CK) and Laser Thermal Keratoplasty (LTK) – surgical alternative for patients requiring correction of small amounts of hyperopia using small burns in the corneal periphery

If you have any questions at any time during this process, please feel free to call **651/321-8881** and our technicians and doctors will be happy to assist you.

CONSENT

In signing this consent form for PTK/PRK, I state that I have read this document completely or that it has been read in full to me, and that I understand its content and purpose. I understand that no warranty or guarantee is being made to me regarding my outcome, the effectiveness or the safety of PTK/PRK. I further state that I have no questions regarding surgery and my questions have been answered to my satisfaction.

_____ I have read and understand the information presented in this consent form.

_____ I hereby give permission for Dr. Ming Wang to perform PTK/PRK on my eye(s). By signing this form, I have not waived any of my legal rights, which I otherwise would have as a participant in a research study.

_____ I am willing to accept the fact that I may need glasses or contact lenses or further surgery following PTK/PRK to achieve my best possible level of vision.

_____ I understand that 20/20 vision is not guaranteed. My healing may be variable, and I understand that Dr. Wang and his staff have no control over my body's healing ability. My healing may affect my final result.

_____ I understand that dry eye is a side effect of PTK/PRK, which although it is rare, may not resolve.

_____ I understand that night glare may increase after PTK/PRK surgery.

_____ I understand that if both eyes are corrected for distance vision, I will require reading glasses.

_____ I understand that even with monovision, I may still need reading glasses for some tasks.

Uncommonly, a patient might experience a corneal complication, such as severe infection, corneal scarring or other problems that would require consultation and treatment to another specialist. If this situation arises, I understand that I am financially responsible for those consultations and treatments. I understand that prescription eye drops and oral medications, along with post-operative optical appliances such as contact lenses and glasses are also my financial responsibility.

I am making an informed decision in giving my permission to have PRK/PTK performed on:

(please circle your choice) Both eyes Right eye Left eye

I understand that I may receive a copy of this consent form if I request it.

Patient's signature

Date

Witness's signature

Date

Doctor's signature

Date