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Consent for LASIK to Correct Nearsightedness, Farsightedness and/or Astigmatism

INTRODUCTION

This information is offered to assist you in making an informed decision about having **LASIK** for the purpose of vision correction. LASIK is an abbreviation for **L**aser-**A**ssisted **I**n-Situ **K**eratomileusis, and describes a procedure combining the use of a **microkeratome** with a computer-controlled, computer guided **excimer laser**. LASIK is a surgical treatment to correct **refractive errors** of the eye including **nearsightedness, farsightedness and/or astigmatism**, LASIK represents one of several treatment options for this purpose. In LASIK, the microkeratome is used to create a thin flap of outer corneal tissue, which is opened like the cover of a book. Next, the excimer laser is used to optically 'sculpt' the underlying corneal tissue, reshaping it and thereby reducing or eliminating the refractive error. The flap is then returned to its original position, without sutures. In the US, ophthalmic surgeons receive special training in order use the excimer laser and perform LASIK.

LASIK is an elective procedure. The choice whether to have LASIK or not is completely up to you. You could continue wearing contact lenses or glasses and, thus corrected, retain excellent vision. LASIK, like any surgery, presents some risks, which are outlined here. You should understand that there may be other risks not known to your doctor which may become known later. Despite the best of care, complications and side-effects may occur; should this happen in your case, the visual result might be affected, even to the extent of making your vision worse.

ALTERNATIVES TO LASIK

If you decide not to have LASIK, there are other methods of correcting your vision. Non-surgical alternatives include **eyeglasses** and **contact lenses**. Surgical methods of correcting vision include photorefractive keratectomy ("**PRK**," also sometimes called "**LASEK**"), cataract-style surgery with intraocular lens ("**IOL**") implantation, phakic lens implantation ("**PLI**") without removal of the eyes natural lens, radial keratotomy ("**RK**"), astigmatic keratotomy ("**AK**"), and/or conductive keratoplasty ("**CK**"). PRK was the first surgery technique developed specifically for use with the excimer laser. In PRK the lining cells covering the cornea are removed, and laser treatment is applied to the collagen layer of tissue just beneath, without using a microkeratome to make a flap. PRK has been shown to be safe, accurate, and as effective as LASIK over the long term; but can cause pain, discomfort, glare, light sensitivity, and slower return of clear vision in the short term. LASIK may be preferable to PRK for correction of very high refractive errors, if the tissue thickness is adequate to allow creation of the LASIK flap and the laser sculpting treatment. Certain long-term consequences may adversely affect eyes that have had PRK that do not occur after LASIK. RK and AK are older, less precise, less stable methods of vision correction that do not use the excimer laser. CK is a relatively new technique, appropriate only for treatment of mild farsightedness, that works by creating "controlled" shrinkage of collagen in a ring pattern in the mid-periphery of the cornea, thereby steepening curvature. The effects of CK have been shown to decrease or diminish over time ("regression"). Intraocular lens implantation (very safe, highly effective, and routinely performed in conjunction with cataract removal) can correct refractive errors but since the natural lens of the eye is removed, the eye loses the ability to adjust for close focus. In PLI surgery the natural lens is retained and a new artificial lens is placed in front of this tissue. PLI surgery has been shown to be safe and effective for extremely high myopia, but LASIK is felt to be safer for low to moderate amounts of correction.

PATIENT CONSENT

In giving my permission for the performance of LASIK, I understand that Dr. Devgan will use a microkeratome to create a superficial corneal 'flap' and the underlying corneal tissue will be treated with an excimer laser programmed to correct my refractive error. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure:

VISION THREATENING COMPLICATIONS

1. I understand that other very rare complications threatening vision can occur including, but not limited to, corneal perforation, corneal thinning (ectasia), corneal swelling, severe infection, retinal detachment, hemorrhage in the retina or inside the eye, venous and arterial blockage of the retina, cataract formation, total blindness, and even loss of my eye.
2. Uncontrolled corneal thinning and shape change (collectively and/or separately referred to as "ectasia") may occur after refractive surgery in very rare cases. Ectasia can worsen with time and can lead to a reduction in visual acuity. In some cases, ectasia may be associated with keratoconus ("KC") or a related corneal disorder. KC is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative corneal surface contour appearance (also called corneal topography) and thickness. Since KC may occur on its own, there is no absolute test that will ensure a patient will not develop it following laser vision correction. Severe KC or ectasia may need to be treated by corneal transplant, while mild keratoconus can be corrected by glasses or contact lenses.
3. On extremely rare occasions, instead of the microkeratome making a flap, a thin 'cap' of the front corneal surface could be cut off, and very rarely could be lost. If preserved, this tissue could be put back on the eye after the laser treatment, possibly using sutures. It is also possible that the incision could result in an incomplete flap, or a flap that is too thin. If this happens, the laser treatment might have to be postponed until the cornea can heal sufficiently to create a new, complete flap.

NON-VISION-THREATENING SIDE EFFECTS

1. There may be increased sensitivity to light, glare, and fluctuation in the sharpness of vision after LASIK. These conditions usually only occur during the early healing and stabilization period (typically the first 1-3 months after LASIK), but they may be permanent.
2. On very rare occasions the flap can heal imperfectly, due to inflammation or wrinkling, and such irregular healing could result in visual distortion. This would mean that your best vision after LASIK might not be as clear or sharp as it was before LASIK.

If such vision distortion is severe, a partial (lamellar) or complete corneal transplant might be necessary to repair the problem and restore the vision.

3. The microkeratome or excimer laser could malfunction, requiring the procedure to be halted before completion. Depending on the type of malfunction, this may or may not be accompanied by temporary vision change, but permanent vision loss is unlikely.
4. Overcorrection could occur, causing you to become farsighted (if originally nearsighted) and this farsightedness could be either permanent or treatable. Overcorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time. If farsighted before treatment, overcorrection would cause one to become nearsighted. Overcorrection, undercorrection, or imperfect correction is amenable to "enhancement," wherein the original flap is lifted and additional laser treatment is rendered.
5. At night you may notice glare, flare or halo effect around lights. This condition usually diminishes with time, but could be permanent. Vision may not seem as sharp at night as during the day, and you may need to wear glasses at night.
6. The visual correction from LASIK may or may not be perfect. It is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later. "Refractive drift" describes the slow change in correction required for optimum vision over time, due to growth of the eye and other factors, which can cause one's prescription to change slightly from year to year. Since refractive drift is known to occur before LASIK or other corrective surgery, it should be anticipated that this will occur after such surgery as well.
7. I may not get a 100% perfect correction from the first LASIK procedure. I may benefit from an enhancement or touch-up procedure, including more laser treatment, or from use of glasses or contact lenses after LASIK. The sharpness of vision I initially gain from LASIK could also regress.
8. I understand that there is an increased risk of eye irritation related to drying of the corneal surface following LASIK. This condition may be temporary or, on rare occasions, permanent; and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.
9. After LASIK, the eyes may be more fragile to direct trauma. Evidence has shown that the corneal flap incision will not be as strong as the cornea originally was at that site. The treated eye, therefore, is somewhat more vulnerable to injury, for at least 1 year after LASIK. It would be advisable to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, fingernail or other object injuring the eye may exist.
10. There is a natural tendency of the eyelids to droop with age, and eye surgery may hasten this process.
11. Temporary glasses either for distance or reading may be necessary while healing occurs, and more than one pair of glasses may be needed.
12. I may notice some pain or foreign body sensation, particularly during the first 24 hours after surgery.
13. The long-term effects of LASIK beyond ten years presently are unknown. Unforeseen complications or side effects could occur.
14. I will be given a mild sedative in preparation for LASIK. I understand I must not drive after LASIK until at least the next morning, and in any case not until I feel my vision is adequate for safe driving.
15. I understand that if I currently need reading glasses, I will still likely need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have LASIK. If I choose "monovision" (correcting one eye for distance and one for near) I may experience some visual imbalance, and some impairment of depth perception.
16. Even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable unless it is unwise or unsafe. Enhancements are generally performed 3 months or more after the first surgery. The original flap can usually be lifted, eliminating risks associated with repeat microkeratome use. Rarely, a new flap is required, incurring slightly greater risk. In order to perform an enhancement surgery, there must be adequate tissue remaining. Dr. Devgan will assess the benefits and risks of enhancement surgery if appropriate, and will discuss these matters with you.
17. With any surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors. Since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

Information about LASIK has been presented to me in detail in this document and elsewhere, and has been explained to me by Dr. Devgan and the staff at LA Sight. All my questions have been answered to my satisfaction. I desire and voluntarily consent to LASIK surgery on:

_____Right Eye _____Left Eye _____Both Eye

I give permission to videotape or photograph my procedure, for purposes of education, research, or training of other health care professionals. I also give permission for Dr. Devgan to use data about my procedure and subsequent treatment to further understand LASIK, but that my name and personal information will be kept confidential.

Signature Date Witness Date