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## **CONSENT FOR BILATERAL SIMULTANEOUS LASIK and PRK**

### **Introduction**

In the United States, the FDA considers LASIK to be a practice of medicine issue between a doctor and a patient. As such, LASIK becomes an “off label” use of an approved excimer laser. Overall, the LASIK procedure has not received FDA approval as only a limited number of sites using specific lasers have applied for approval. A LASIK procedure has become a common procedure worldwide for many refractive surgery patients. The FDA does recommend a minimum of three months between the treatment of the first and second eye with PRK, but there is no recommendation made about LASIK. In both PRK and LASIK, the second eye may be treated sooner than three months after the first eye, or even at the same time; however, there may be risks associated with simultaneous treatment that are not present when the eyes are treated on different days. **If you elect to have surgery performed on both eyes at the same time, you should understand both the possible advantages and disadvantages of your decision.**

### **The advantages of having LASIK or PRK performed on each eye at a separate time are:**

**Safety:** You will not experience the risk of developing an infection in both eyes at the same time, which although very rare, could lead to significant loss of vision in both eyes. Since the pressure in the eye is increased significantly for a short time during the LASIK procedure, there is a very remote possibility of internal bleeding or damage to the retina, which could lead to significant loss of vision or even blindness. Should this happen to both eyes, the consequences could of course be devastating. The pressure in the eye is not increased in PRK, so this is not a potential complication for PRK.

It is also possible to develop a delayed cloudiness in the cornea or even corneal scarring which is not visible immediately after the procedure. Although this is uncommon and generally clears with time, it can result in significant loss of vision for a prolonged period of time. Should this occur in both eyes at the same time, carrying out normal daily activities could be difficult.

**Accuracy:** The doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye, increasing the likelihood of a better outcome in the second eye.

**Visual Recovery:** Although most LASIK and PRK patients experience a rapid recovery in their vision, the recovery can at times be delayed. If the eyes are operated separately, you can function with the fellow eye while the first eye fully recovers. This is especially true if you are able to wear a contact lens in the unoperated eye. You will not be able to wear this lens for days to weeks (depending on the type of lens) prior to having the procedure on your second eye.

**Satisfaction:** You will be given the opportunity to determine whether the LASIK or PRK procedure has produced satisfactory visual results without loss of vision or other uncommon undesirable side effects such as glare, ghost images, or increased light sensitivity. If you are over age 40, you will have an opportunity to experience the change in your close vision, which results from the correction of your nearsightedness. This could influence your decision on whether or not to fully correct your other eye to maintain some degree of close vision without the need for glasses (monovision).

**The disadvantages of having LASIK or PRK performed on each eye at a separate time are:**

**Convenience:** It may be inconvenient for you to have each eye treated at separate visits. This will necessitate two periods of recovery from the laser surgery and may require additional time away from work.

**Visual Recovery:** There will be a potential period of imbalance in vision between your two eyes. This is especially important when you are unable to wear a contact lens in your unoperated eye. It is usually not possible to wear glasses with no correction in the operated eye and your usual corrective lens for your unoperated eye because it produces a strong sense of imbalance, dizziness, and a form of double vision (or ghosting).

**Cost:** Additional time off work may be necessary if the eyes are treated on different days.

**The advantages of having LASIK or PRK performed on both eyes at the same time are:**

**Convenience:** It may be more convenient to have both eyes treated during the same visit.

**Visual Recovery:** The balance in vision between two eyes will usually be restored more rapidly. This is especially true if you are unable to wear a contact lens in your unoperated eye.

**Cost:** When both eyes are treated at the same time, it is most likely that less work will be missed, both for the surgery and recovery time.

**The risks of having LASIK or PRK performed on both eyes at the same time are:**

**Safety:** The risks of infection, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage are very rare but potentially devastating. If these serious but rare complications occur in one eye, they may also occur in the other. Should any of these complications happen, you could experience significant loss of vision or even temporary or permanent legal blindness.

**Accuracy:** By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye. Therefore, if there is an over-correction or under-correction in one eye, chances are it will happen in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye will also require a retreatment.

**Visual Recovery:** LASIK and PRK patients generally experience rapid visual recovery. Some patients, however, can experience delayed visual recovery and experience symptoms such as blurred vision, night glare, or ghost images. There is no way of predicting how long your eyes will take to heal, and some of these complications can result in prolonged recovery of normal vision. Blurred vision may rarely continue for several weeks in both eyes, which could make driving difficult or dangerous and could interfere with your ability to work. The healing corneal flap is most susceptible to trauma during the first several weeks after surgery. Should both flaps become accidentally displaced, significant visual loss in both eyes may result.

**Satisfaction:** Both eyes tend to experience similar side effects. If you experience undesirable side effects such as glare, ghost images, increased light sensitivity, or corneal haze in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated.

**Consent Statement:**

I have read and understand the above risks and benefits of bilateral simultaneous LASIK and/or PRK, and I understand that this summary does not include every possible risk, benefit, and complication that can result from bilateral simultaneous LASIK and/or PRK. Dr. Goodman has answered all of my questions about the LASIK/PRK procedure.

     **I WISH to have both eyes treated during the same treatment session** if Dr. Goodman determines that the treatment in the first eye appeared to be technically satisfactory.

The reason(s) I wish to have both eyes treated at the same time are:

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     **I DO NOT WISH to have both eyes treated during the same treatment session.**

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_