# Shealy Eye Laser Center SBK Thin Flap LASIK

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**INFORMED CONSENT FOR LASER INTRASTROMAL KERATOMILEUSIS (LASIK)**

**INTRODUCTION:**

This information is being provided to you so that you can make an informed decision about the use of a device known as a microkeratome. The microkeratome when used with an excimer laser to correct an eye prescription is known as Laser Assisted Intrastomal Keratomileusis or LASIK. LASIK is one of a number of alternatives for correcting nearsightedness, farsightedness, astigmatism, and near vision problems. In LASIK, the microkeratome is used to create a flap of corneal tissue. The flap then is opened like the page of a book to expose tissue just below the corneas surface, leaving a hinge, but in 1 in 500 there is no hinge. Thin flap LASIK or SBK (Sub-Bowmans Keratomileusis) extends the range patient prescriptions that can be treated, decreases the incidence of post operative dry eye, and accelerates the visual recovery process to a 24 hour time period. A predictable creation of a thin planar 100-micron flap is achieved with a smoother exposed corneal flap bed to apply the laser allowing excellent high quality visual outcomes, greater patient comfort in the first five hours, and better bio-mechanical corneal stability. We chose this advanced form of flap creation for our patients in 2008. We feel that this system offers many advantages over femtosecond flap creation laser technology.

Next, the excimer laser is used to remove ultra-thin layers from the cornea to reshape it to reduce refractive error. There are two types of lasers, one which is better at removing astigmatism (toric lasers) and spherical lasers (non-toric lasers) which are used to treat farsightedness and nearsightedness primarily. Each laser system has an optimal use in terms of range of prescriptions treatable. Finally, the flap is returned to its original position, without sutures. Dr. Shealy did many successful cases before the hinge was invented, so this is usually not a problem when the cap is free (no hinge). This experience has been collaborated with Dr. Steve Hollis as Dr. Shealy and he have performed 138,000 eye surgeries together.

LASIK is an elective procedure: There is no emergency condition or other reason that requires that you have LASIK performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. The procedure, from which LASIK evolved, Keratomileusis, has been around for 50 years and it is logical to assume that problems that would have come in the future for LASIK would have been seen with Keratomileusis, since they are similar procedures. 1.3 million LASIK procedures were performed in the US in 2007 and with no loss of an eye or blindness.

**WAVEFRONT CORRECTIONS** (Called custom by some companies): This is exciting technology finally approved after a 7-year wait by our FDA. It allows correction of errors not treatable with glasses, because they are irregular. It is necessary in 2 to 5% of patients to improve vision. It becomes less reliable after 45 years of age because of lens changes in the eye (cataract). It has still not been approved for high minus or farsightedness.

**TOPOGRAPHY GUIDED CORRECTIONS:** Our Nidek laser has finally gotten approval for this procedure. In my opinion, this is more valuable than Wavefront correction, since it is not distorted by lens changes (cataract), or by previous corneal scars from previous procedures. We may add this technology to our Nidek laser in the future in order to give the best care. We will do Wavefront on patients under 45 years of age with normal lens on inspection by the doctor. Extreme errors are best corrected with the Allegretto with standard LASIK. We might do topography-guided treatments on patients over 45, or all patients that are hyperopic in the future as we are waiting on the FDA.

## ALTERNATIVES TO LASIK

If you decide not to have LASIK, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. These alternatives include, among others, eyeglasses, contact lenses and other refractive surgical procedures.

## PATIENT UNDERSTANDING-BEFORE CONSENT

In giving my permission for LASIK, I understand the following: The long-term risks and effects of LASIK are unknown. I have received **no guarantee** as to the success of my particular case. I understand that the following risks are associated with the procedure:

1. ______________ (INITIALS) I understand that the microkeratome or excimer laser could **malfunction**, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this can usually be treated and is not accompanied by long-term visual loss.

2. ______________ (INITIALS) I understand that in using the microkeratome, instead of making a flap, an entire portion of the cornea could be removed. In Dr. Shealy's experience these free flaps are rarely a problem. It is also possible that the flap incision could result in an **incomplete flap, or a flap** that is too thin. If this happens, it is likely that the laser part of the procedure will have to be postponed until the cornea has a chance to heal sufficiently to create the flap again.

3. ______________ (INITIALS) I understand that **irregular healing of the flap** could result in a distorted cornea. This would mean that glasses or contacts might not correct my vision to the level before undergoing LASIK. This is rare but on occasion has happened.

4. ______________ (INITIALS) I understand that Dr. Shealy **prefers monovision to offset** presbyopia in those patients who desire such, and has used this in 6,000 cataract patient eyes operated previously. In most of his refractive patients he has used monovision routinely in patients

over age 42, as he has had monovision refractive surgery performed in his own eyes in 1994. Almost all adapt to this within 6 weeks. A small percent will say that they see better in the distance when the near eye is covered, as they are getting interference. If the patient does not adapt, less than 1% of the time, they are re-corrected for distance in the near eye and wear drug store reading glasses for near. Over 50% of laservision correction ophthalmologists at a recent Wavelight user meeting in 2008, practice monovision.

5. ________________ (INITIALS) I understand that **mild or severe infection** is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye. Dr. Shealy has not seen a loss of the eye in the 38,000 cases he has done.

6. ________________ (INITIALS) I understand that other **very rare complications threatening** vision include, but are not limited to, corneal swelling, corneal thinning (ectasia), retinal detachment, hemorrhage, venous and arterial blockage. These occur with or without LASIK and may not be directly caused by this procedure.

## NON-VISION THREATENING SIDE EFFECTS

1. ________________ (INITIALS) I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent. Dr. Shealy thinks that the Allegretto Wavelight Laser actually reduces glare in most patients having glare with glasses or contacts. Most patients seemed to tolerate these problems even with the old lasers.

2. ________________ (INITIALS) I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the LASIK procedure. These symptoms may be temporary or, on rare occasion, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid. Typically, LASIK increases the symptoms of dry eyes for 6 months.

3. ________________ (INITIALS) I understand that an **overcorrection or under correction** could occur, causing me to become farsighted or nearsighted or increase my astigmatism. Small amounts of tissue are removed with each procedure, so these minor problems may be treated with a touchup.

4. ________________ (INITIALS) After refractive surgery, a certain number of patients **experience glare, starburst or halo effect around lights, or other low-light** vision problems that may interfere with the ability to drive at night or see well in dim light. Although there are several possible causes for these difficulties, the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I

may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate. These risks in relation to my particular pupil size and amount of correction have been discussed with me. Dr. Shealy has not seen any patients with severe glare at night since using the Wavelight Allegretto Laser.

5. ________________ (INITIALS) I understand that **I may not get a full correction** from my LASIK procedure and this may require future enhancement procedures, such as more laser treatment or the use of glasses or contact lenses.

6. ________________ (INITIALS) I understand that, after LASIK, the eye may be more fragile to trauma from impact. Evidence has shown that, as with any scar, the corneal incision will not be as strong as the cornea originally was at that site. I understand that the treated eye, therefore, is somewhat **more vulnerable to all varieties of injuries**, at least for the first year following LASIK. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.

7. ________________ (INITIALS) I understand that there may be pain or a foreign body sensation, particularly during the first 12 hours after surgery.

8. ________________ (INITIALS) I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.

9. ________________ (INITIALS) I understand that visual acuity I initially gain from LASIK could regress, and that my vision may go partially back to a level that may require glasses or contact lens use to see clearly. Dr. Shealy has not seen a tendency for patients to need additional surgery at 10 years.

10. ________________ (INITIALS) I understand that the correction that I can expect to gain from **LASIK may not be perfect**. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all time, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purpose requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.

11. ________________ (INITIALS) I understand that I may be given medication in conjunction with the procedure. I therefore, understand that I must not drive the day of surgery and not until I am certain that my vision is adequate for driving.

12. ________________ (INITIALS) I understand that if I currently need reading glasses, Dr. Shealy usually uses monovision on all patients over 40 years of age. In his experience 99% adapt by 6 weeks and do not need reading glasses. 1% are retreated after 6 weeks and need drug store readers.

13. ________________ (INITIALS) I understand that, 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.

14. ________________ (INITIALS) In some cases **when there is a difficulty in making a flap, PRK** or photorefractive keratectomy, of the exact same prescription is done on the surface, on top of the intended flap. Dr. Shealy will need permission to switch to PRK if it is better for the patient. It is his experience that the results are the same with either procedure, and by proceeding it is possible to keep you from having the procedure later.

15. _______________ (INITIALS) I understand that Surface Epi-Laser treatment is preferred after previous radial keratotomy and for thin corneas less than 500 microns, and any time a person is subjected to a blow to the eye as an occupation.

16. _______________ (INITIALS) If no laser is applied after thin-flap LASIK with imperfect flap formation, thick-flap LASIK at a greater depth of 130 to 160 microns may be performed because the laser should be applied to a smooth intrastromal or suprastromal bed.

**FOR PRESYOPIC PATIENTS** (Those requiring a separate Rx for reading, typically over 40 years of age): The option of monovision has been discussed. _______________ (INITIALS)

**PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING**

The details of the procedure know as SBK-LASIK/and surface LASER VISION CORRECTION has been presented to me in detail in this document. Dr. Shealy will answer my entire question to my satisfaction. I therefore consent to SBK-LASIK/and surface LASER VISION on my:

___________ Right eye _______________ Left eye ____________ Both Eyes

Patient Signature ________________________ Date __________________

Witness Name ___________________________ Date ________________

I have been offered a copy of this consent form: (please initial) ____________________