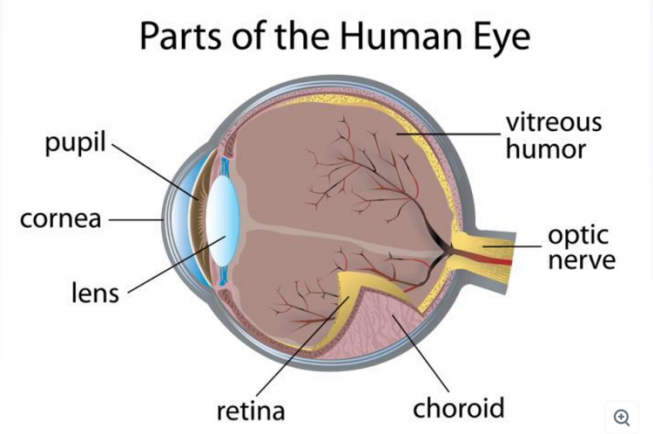
Laser Vision Correction (LVC) Informed Consent

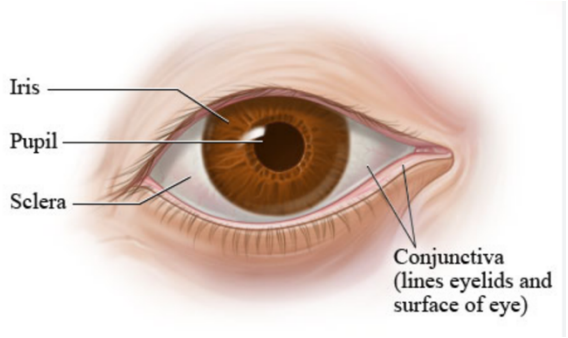
Including Sub-Bowman's Keratomileusis (SBK) and Photorefractive Keratectomy (PRK)

The following information is intended to help you make an informed decision about having laser vision correction (LVC) at Brinton Vision in the form of either sub-Bowman keratomileusis (SBK), formally known as laser assisted in situ keratomileusis (LASIK), or photorefractive keratectomy (PRK). Take as much time as you need to make a decision about signing this form. You are encouraged to ask questions and have them answered to your satisfaction before you give your permission to have the procedure. Every surgery has risks as well as benefits and each person must evaluate this risk/benefit ratio for themselves in light of the information previously presented and the information which follows.

It is impossible to list all risks and complications associated with these proposed procedures or any other surgery. As with all vision correction procedures, there may be long-term effects not yet known or anticipated at the present time.

Spectacles and contact lenses are the most common methods of correcting nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. When handled properly and tolerated well, they can be good alternatives to LVC. Refractive surgery is continually evolving, and other refractive procedures may be available as an alternative to laser vision correction.





1. AN OVERVIEW OF THE PROCEDURE

SBK Procedure

SBK is a version of LASIK. SBK permanently changes the shape of the cornea. The procedure is performed using a topical anesthetic (drops in the eye). The procedure involves separating a thin layer of corneal tissue, known as a corneal flap, with a femtosecond laser (an extremely precise laser with ultrashort pulses). The flap is folded back and the light from an excimer laser is used to reshape the cornea by removing ultra-thin layers of corneal tissue. The flap is returned to its original position for healing in place. The removal of thin layers of tissue causes the center of the cornea to flatten in the case of nearsightedness, steepen in the case of farsightedness, or become more rounded in the case of astigmatism, all resulting in a change of the focusing power of the cornea.

I have read and understood this page. Patient initials _____

PRK Procedure
Photorefractive keratectomy permanently changes the shape of the cornea. The procedure is performed using a topical anesthetic (drops on the eye). Photorefractive keratectomy can differ in the way the surgeon prepares the epithelium (the top layer of the cornea) to be removed before the laser is used. The light from an excimer laser is used to reshape the cornea by removing ultra-thin layers of corneal tissue. A contact lens is temporarily placed on the cornea for comfort. The removal of thin layers of tissue causes the center of the cornea to flatten in the case of nearsightedness, steepen in the case of farsightedness, or become more rounded in the case of astigmatism, all resulting in a change of the focusing power of the cornea.

Limits of Laser Vision Correction
Although the goal of LVC is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, this result is not guaranteed. Additional procedures (enhancements), spectacles (including for distance, intermediate, and/or up close), or contact lenses may be required to achieve adequate vision even after your procedure. LVC can correct eye prescription but does not prevent aging of the eye known as presbyopia, which occurs in most people after age forty. Consequently, even after an LVC procedure, whether you are nearsighted, farsighted, or have astigmatism, you may still need glasses due to the aging of your eyes. Even if you do not currently need reading glasses you may need them in the future. In addition, LVC will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration, retinal tear, or retinal detachment.

2. GENERAL CONTRAINDICATIONS OF LVC
The treatment should not be performed on persons with uncontrolled vascular disease; with uncontrolled autoimmune disease; who are immune-compromised or on drugs or therapy that strongly suppress the immune system; with residual, recurrent, or active ocular disease(s) or abnormality except for myopia, hyperopia, or astigmatism in either eye; with active or residual disease(s) likely to affect wound-healing capability; with unstable or uncontrolled diabetes; with progressive myopia or hyperopia; with uncontrolled glaucoma; with inadequate corneal thickness; or as advised by your physician.

If you know that you have any of these conditions, you should inform your physician. In addition, if you have other concerns or possible conditions that might affect your decision to undertake this procedure, you should discuss these with your physician prior to completing this informed consent.

3. GENERAL RISKS OF LVC
The risks of your procedure include, but are not limited to:

Loss of vision
LVC can possibly cause loss of best-corrected vision. This can be due to infection (internal or external), scarring, or other causes. Unless successfully controlled by antibiotics, steroids, or other necessary treatment, it could even cause loss of the infected eye. Vision loss can be due to the cornea healing with an irregular surface, which could cause astigmatism and make wearing glasses or contact lenses necessary. Irregular cornea healing could result in an uneven corneal surface so

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that glare, distorted vision, or "ghosting" may occur. This may or may not be correctable by spectacles or contact lenses.

Visual side effects
Other complications and conditions that can occur after LVC, any one of which may be incapacitating for some time and may not completely go away, include: increased risk for dry eyes; anisometropia (difference in power between the two eyes); aniseikonia (difference in image size between the two eyes); double vision; hazy vision; fluctuating vision during the day and from day to day; increased or decreased sensitivity to light; and glare and halos around lights. These conditions may be transient or lasting and may affect your ability to drive or perform other tasks.

Overcorrection or Undercorrection
LVC may not give you the result you desired. It is also possible that your eye may be overcorrected to the point of becoming farsighted (by over treating myopia) or nearsighted (by over treating hyperopia). It is possible that as the eye ages your vision results could change over time. In some cases additional laser (enhancement) could be effective and necessary in correcting vision.

Keratoconus
Keratoconus is a bilateral (both eyes) non-inflammatory corneal ectasia (weakening) with an incidence estimated to be approximately one per one thousand in the general population. Despite intensive clinical and laboratory investigation, the etiology (cause) of keratoconus remains unclear. Clinical studies provide strong indications of a major role for a genetic etiology. The age of onset for keratoconus ranges from infancy to the early 50s. LVC procedures remove corneal tissue that may influence the onset and/or progression of keratoconus in individuals predisposed to the condition. The treatment of keratoconus could require other surgical procedures which may include corneal crosslinking or transplant.

Other Risks
Other reported complications include corneal ulcer formation; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); ptosis (droopy eyelid); corneal swelling; contact lens intolerance; progressive corneal thinning (ectasia); retinal detachment; and hemorrhage. Complications could arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. It is possible that due to laser malfunction the procedure may need to be stopped prior to completion and completed on another day. There are potential complications due to medications or drug reactions that may involve other parts of your body. Since it is impossible to state all potential risks of a surgical procedure and because there are differences in the way individuals heal and respond to a procedure, this form does not provide a comprehensive listing of every problem.

Later-discovered Complications
You should be aware that other complications may occur that have not yet been reported. Long term results may reveal additional risks and complications. Whether or not you have LVC, you should have yearly check-ups to assess the condition of your eyes.

I have read and understood this page. Patient initials _____

Pain and Discomfort
It is common to experience discomfort or pain in the eye postoperatively and a physician may need to prescribe medication for this pain.

Employment Risk
While LVC is commonly performed in various branches of the US military, you should be aware that having LVC before receiving permission from a commanding officer or supervisor at your intended place of employment could potentially disqualify you from some professions, including with commercial aviation, military, and certain law enforcement agencies.

4. RISKS OF NOT UNDERGOING LVC

The risks of not having the procedure are limited to those associated with your current visual condition. These include but are not limited to the dangers that may be associated with losing glasses or contact lenses, the risks of corneal distortion and/or infection from wearing contact lenses, and the risks of trauma to the eye caused by breakage of plastic spectacles or contact lenses in the eye.

5. ADDITIONAL PROCEDURE-SPECIFIC RISKS

Specific Risks of SBK
Specific risks of SBK include those related to the corneal flap created during the procedure. These include but are not limited to: loss of the corneal flap; damage to the corneal flap; corneal flap decentration; a flap that is too small, too thin, or not smooth, resulting in cancellation of the surgery; wrinkling of the flap necessitating lifting and smoothing the flap; epithelial ingrowth (surface cells growing underneath the corneal flap); infection involving the flap; and inflammation or interface fluid syndromes under the flap including diffuse lamellar keratitis or pressure-induced stromal keratitis. Sutures may also be required which could induce astigmatism.

Specific Risks of PRK
Specific risks of PRK include delayed healing resulting in delayed improvement of vision. Post-treatment medications may lead to an increase in inner eye pressure and glaucoma. The correction of high degrees of nearsightedness (or myopia) with PRK is associated with a higher chance of corneal scarring or "haze." This corneal haze may occur years after the original procedure and can result in decreased vision. In 1997, a medication called Mitomycin-C (MMC) was introduced to treat patients who developed this condition. It is anticipated that, with the use of MMC, the likelihood of developing haze will be minimized. MMC is an antibiotic that has been used in the medical field for a number of decades. It has been used as an anti-cancer drug because it can stop the overgrowth of certain types of cells such as those seen in tumors, and also those cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980s to prevent scarring after a variety of eye procedures, such as glaucoma filtration and pterygium surgeries. MMC is commonly used today by laser vision correction surgeons to reduce the risk of corneal haze after PRK, even though this is considered "off-label" use of an FDA-approved medication. Dr. Brinton's technique uses a low dose (0.02%) of MMC delivered to the central cornea for approximately forty seconds. While this technique is designed to minimize the chance of complications after PRK surgery, possible toxicity and/or corneal haze cannot be eliminated.

6. PRE-TREATMENT PRECAUTIONS

I have read and understood this page. Patient initials _____

Pregnancy
Pregnancy may affect your healing process, and some medications may pose a risk to an unborn or nursing child. If you are pregnant or trying to become pregnant, you should notify your physician prior to your procedure.

Pacemaker/Internal Defibrillator
The laser could adversely affect the function of your pacemaker/internal defibrillator. You should inform your physician prior to your procedure if you have a pacemaker/internal defibrillator. Your cardiologist will have to release you to have the procedure.

Taking medications and allergies
You should inform your physician of any medications or supplements you are taking in order to account for the risk of allergic reactions, drug reactions, and other potential complications during the LVC procedure and subsequent treatment.

7. POST-TREATMENT PRECAUTIONS
Eye Protection
Avoid exposing the eye to water, such as in a pool, hot tub, river, lake, or ocean. You should protect your eyes and avoid eye rubbing. It is advisable to wear protective eye wear when engaging in contact sports such as boxing or racquet sports such as squash or racquetball where a fist or small projectile may contact the eye.

Operating Motor Vehicles
After your procedure, you may experience starburst-like images or "halos" around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. You may not drive on the day of your surgery and will need to arrange for a driver to take you home following your LVC procedure. SBK patients may drive the next day once you are certain that your vision is adequate. PRK patients may drive after we remove your contact lens and clear you for driving, usually on postoperative day four.

Pain and Discomfort
The amount of pain and discomfort experienced after LVC varies with the individual. You should expect that the eye will be painful and sore to some extent after the procedure. Vision may be blurry, and you may experience some redness and/or corneal edema (swelling of the cornea). Some patients report the sensation of a foreign object in the eye, itching, or dryness of the eye. A contact lens may temporarily be placed on the eye to help decrease discomfort.

Off Label Use
Using the laser for your treatment may be "off label" if your treatment falls outside the Food and Drug Administration (FDA) approved use and range for the laser. Physicians are permitted to access "off-label" uses and ranges as a practice of medicine. A Patient Information Booklet that further outlines details of FDA approval is available in paper form upon request, can be accessed at fda.gov, or can be accessed by clicking the corresponding link on our company's LASIK web page.

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8. ALTERNATIVES TO LASER VISION CORRECTION

LVC is an elective procedure, and you may decide not to have this operation at all. Alternatives to your planned form of LVC include:

- Eyeglasses/spectacles
- Hard and soft contact lenses
- Orthokeratology. A system of wearing a sequential series of flatter-than-normal hard contact lenses overnight that flatten the cornea.
- Intrastromal corneal ring segments (INTACS). Plastic segments inserted into channels created in the middle layer of the cornea. They are intended for the reduction or elimination of low amounts of myopia in patients by flattening the central corneal curvature. These segments can be surgically removed if/when needed.
- Astigmatic keratotomy (AK). Used to help people with astigmatism, an uneven curvature of the cornea. One or more surgical incisions are made in the peripheral cornea. The purpose is to relax areas where the cornea is too steep to obtain a more spherical (rounded) shape.
- Radial keratotomy (RK). A surgical procedure in which tiny spoke-like incisions are made in a "radial" pattern around the cornea. These cuts in the cornea flatten the corneal curvature for low to moderate levels of nearsightedness. This procedure is infrequently used.
- Conductive keratoplasty (CK). Uses radio frequency to warm and shrink corneal tissue. The treatment spots are placed in a circular pattern in the periphery. A tightening effect occurs which steepens the central corneal curvature. The procedure is indicated for low degrees of hyperopia and presbyopia.
- Phakic intraocular lens (phakic IOL). An artificial lens surgically placed inside the eye, added in front of the natural lens. The lens is used to neutralize moderate to high amounts of myopia. The phakic IOL can be surgically removed if/when needed.
- Refractive lens exchange (RLE). Involves surgically removing the natural lens within the eye and replacing it with an artificial intraocular lens implant (IOL).

Alternatives include forms of LVC other than your planned procedure, including:

- Laser assisted in situ keratomileusis (LASIK) - a surgical procedure in which a flap is created by a microkeratome (a surgical blade) or with a laser. The corneal flap with LASIK is thicker than that created during the SBK. Similar to SBK, the corneal flap is folded back and the excimer laser removes tissue from the inner corneal layers.
- Sub-bowman keratomileusis (SBK), a form of LASIK
- Photorefractive keratectomy (PRK)
- Small incision lenticule extraction (SMILE)

9. CONVERSION TO PRK WHEN SBK IS PLANNED

Your surgeon could decide during the procedure that switching to PRK would be in your best interest due to your anatomy or other factors. By signing below, you are consenting to allow Dr. Brinton to perform PRK instead of LASIK if he decides it would be in your best interest.

10. PRESBYOPIA AND BLENDED VISION

Blended vision is an option that will help treat the effects of presbyopia, or natural aging changes that occur over age forty. Blended vision does not stop the natural aging process of the lens. Testing will be performed to determine your dominant eye. If you choose to have blended vision, often, though not always, the dominant eye is targeted for far distance vision and the non-dominant eye is targeted for near reading or intermediate computer-length vision. The brain usually adapts to

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each eye focusing at a different distance as the eyes heal, but the exact time will vary from patient to patient. Glasses, including so-called "glovebox glasses," may be required to fully correct both eyes for distance, such as for night driving, and/or for near vision.

11. PATIENT STATEMENT

By signing this form, I am stating that I have read all pages of my Treatment Instructions and this Informed Consent (or these documents have been read to me). LVC has been explained to me in terms that I understand. I have been informed about the possible benefits, complications, risks, consequences, and contraindications associated with LVC. I understand that it is impossible for my doctor to inform me of every complication that may occur, and that there may be unforeseen risks. Although these documents contain medical terms which I may not completely understand, I have been given the opportunity to ask questions of Dr. Brinton and have received satisfactory answers to any questions I have asked. I understand that medicine and surgery are not exact sciences, that no guarantee of a particular outcome was given, and that my vision could become better or worse following treatment. I understand that I may receive a copy of my signed consent form today on my request.

My decision to undertake LVC was made without threat or coercion of any kind. I understand that LVC is an elective procedure and is not medically required to preserve my life or health. I understand that my myopia, hyperopia, and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of vision correction surgery. While it is hoped that LVC will reduce or eliminate my dependence on glasses or contact lenses, I understand that the correction obtained may not fully accomplish this and that additional correction with glasses or contact lenses may be needed.

I understand that the improved vision I expect to gain from LVC may not be perfect. I understand that it is not realistic to expect that this procedure will give perfect vision, under all circumstances, for life.

I consent to the administration of anesthesia and other medications as recommended by Dr. Brinton and understand that certain risks attend all anesthetics and medications.

I understand that my postoperative medical care will be performed by Dr. Brinton and/or his associates. Alternatively, I may choose to have my postoperative care provided by another qualified eye care professional.

I authorize the physicians, medical/surgical technicians, and other health care personnel involved in performing my LVC procedure and in providing my preoperative and postoperative care to share with one another any information relating to my health, my vision, or my LVC procedure that they deem relevant to providing me with care. I understand that my eye and health information will be entered into an electronic medical record database system. My physician may use this database to analyze preoperative and postoperative information and aid in the development of optimized outcomes. I give my permission for medical data concerning my operation and subsequent treatment to be use in clinical teaching. I give permission to photography and videography of my surgery for teaching purposes. I consent to the admittance of observers in the operating room.

I have read and understood this page. Patient initials _____

I release Brinton Vision from responsibility for loss or damage to money, jewelry, electronic devices, or other personal effects that I bring to the facility, even if such loss is caused by negligence.

I agree to arrange for someone to drive me home after my procedure and to refrain from driving myself until I am comfortable with both my day and night vision. I have fully informed the operating physician and health care professionals about my medical history and use of prescription medications, supplements, over-the-counter medications, or other drugs.

Neither Dr. Brinton nor any of his employees or representatives have made oral statements to me that are inconsistent with the information stated in this consent form. I have not taken any pre-operative medications prior to reading, understanding, and signing this Informed Consent document.

Patient to initial **ONE** option below – I consent to have laser vision correction performed on:

_____ my right eye

_____ my left eye

_____ both of my eyes

Patient name	Patient signature	Date
Witness name	Witness signature	Date

Surgeon statement: All questions regarding the procedure were answered to the patient's satisfaction prior to surgery. The patient verbally acknowledged to me their understanding of the risks, benefits, and alternatives explained in this Informed Consent.

Jason P. Brinton, MD (surgeon)	Date

I have read and understood this page. Patient initials _____