

Important Information

CONDUCTIVE KERATOPLASTY (Also Known as CK) FOR THE CORRECTION OF HYPEROPIA (FARSIGHTEDNESS) AND/OR PRESBYOPIA (NEED FOR READING GLASSES AFTER 40) AND/OR ASTIGMATISM “ON-LABEL USE” and “OFF LABEL USE”

The procedure

Using radiofrequency (RF) energy, CK can change how the eye focuses light by reshaping the cornea. After the doctor has applied a topical anesthetic (eye drops), controlled RF energy is applied in a circular pattern to shrink the corneal tissue. This pattern is applied in the periphery of your cornea and therefore minimizes interference with your line of sight (i.e., pupil). A device called a "speculum" holds your eye open during the procedure.

Once finished, you don't have to wear a patch and can usually return to work or normal activities the next day. Vision generally begins improving in about a week's time. As with other procedures, the level of improved vision may be temporary.

CK is labeled by the FDA for patients with farsightedness, or hyperopia, a condition in which the eye is too flat. CK modifies the topographical (surface) curvature, making it steeper and therefore improving vision. CK is used off-label for the correction of astigmatism or Presbyopia.

Risks and complications

CK is associated with a nominal amount of surgery-related complications. Some people who have had CK have experienced side effects that have impaired their vision for a few days after the procedure. Although these risks are relatively rare, they should be taken into consideration by anyone considering the CK procedure. Some side effects include:

- Discomfort and/or foreign body sensation
- Glare
- Halos
- Overcorrection

All patients considering vision correction should undergo a complete examination by a doctor prior to the procedure.

The doctor can give you the complete list of indications and contraindications and determine if CK is right for you.

Presbyopic Indications

Approval of the premarket FDA approval application supplement for CK is for the temporary induction of myopia (-1.00 D to -2.00 D) to improve near vision in the non-dominant eye of presbyopic hyperopes or presbyopic emmetropes, via spherical hyperopic treatment of 1.00 D to 2.25 D, in patients 40 years of age or greater with a documented stability of refraction for the prior 12 months, as demonstrated by a change of < 0.50 D in spherical and cylindrical components of the manifest refraction, and with ≤ 0.75 D of cycloplegic refractive cylinder and with a successful preoperative trial of monovision or history of monovision wear (i.e., dominant eye corrected for distance vision and non-dominant eye corrected for near vision).

CK is an elective procedure with the alternatives including, but not limited to, reading glasses, bifocal eyeglasses, multifocal contact lenses, monovision contact lens wear, or other refractive surgeries.

Approval of this application is based on a clinical trial of 150 patients treated for near vision in their non-dominant eye, with the other eye treated for distance vision in 38 of the patients. Of all eyes, 148 near vision treatments were available for analysis at 3 months, 146 eyes were available for analysis at 6 months, 94 eyes were available for analysis at 9 months, and 77 eyes were available for analysis at 12 months. Accountability was 99% at 3 months, 97% at 6 months, 97% at 9 months, and 96% at 12 months. The data analysis was based on the refractive data at all follow-up examination time points (1 month, 3, 6, 9, and 12 months). At 6 months, this analysis showed that 83% (67/81) eyes were corrected to (J3) 20/40 and 23% (19/81) were corrected to (J1+) 20/20 or better visual acuity without spectacles or contact lenses.

The study showed that all the adverse events occurred at low rates (< 1%).

Long-term risks of CK for improvement of near vision have not been determined. The safety and effectiveness of re-treatment procedures with CK or other refractive surgical devices have not been established.

Hyperopic Indications

CK is FDA approved for the temporary reduction of spherical hyperopia in patients who have 0.75 D to 3.25 D of cycloplegic spherical hyperopia, less than or equal to 0.75 D of refractive astigmatism (minus cylinder format), and a cycloplegic spherical equivalent of +0.75 D to +3.00 D. Patients must be 40 years of age or greater with a documented stability of refraction for the prior 12 months, as demonstrated by a change of less than 0.50 D in spherical and cylindrical components of manifest refraction. The magnitude of correction with this treatment diminishes over time, with some patients retaining some or all of their intended refractive correction.

CK[®] is an elective procedure with the alternatives including, but not limited to, eyeglasses, contact lenses, photorefractive keratotomy (PRK), laser *in situ* keratomileusis (LASIK), or laser thermal keratoplasty (LTK).

Approval of this application is based on a clinical trial of 401 eyes (233 primary and 168 secondary). Of all eyes treated, 358 eyes were available for analysis at 3 months, 352 eyes were available for analysis at 6 months, 350 eyes were available for analysis at 9 months, and 344 eyes were available for analysis at 12 months. Accountability was 99% at 3 months, 97% at 6 months, 96% at 9 months, and 99% at 12 months.

The data analysis was based on the refractive at all follow-up examination time points (1 month, 3, 6, 9, and 12 months). At 12 months, this analysis showed that 318/344 (92%) eyes were corrected to 20/40 or better and 191/344 (56%) were corrected to 20/20 or better visual acuity without spectacles or contact lenses.

The study showed that all adverse events occurred at low rates (<1%).

Long-term risks of CK[®] for hyperopia have not been determined. The safety and effectiveness of re-treatment procedures with CK[®] or other refractive surgical devices have not been established.

ADDITIONAL GENERAL INFORMATION:

The following information is intended to help you make an informed decision about having Conductive Keratoplasty (CK) to improve your vision.

The FDA approved **Conductive keratoplasty**, also called CK for hyperopia and presbyopia. The surgery is designed to change the focus of your eye by changing the shape of the cornea. Changing the focus of the cornea by changing the shape of the cornea is called refractive surgery. CK is designed to reduce low to moderate hyperopia (farsightedness). When is used for astigmatism, selected spots are applied to the cornea to change its shape in a selective manner. CK for astigmatism and after prior surgical procedures is considered “off label” (not FDA approved for astigmatism and/or keratoconus).

You and your surgeon may make a decision for a same day retreatment or immediate enhancement if your hyperopia is greater than +2.50 diopters. You and your surgeon may make a decision to utilize even if you are not at least 40 years old. You and your surgeon may make a decision to utilize to reduce the need for reading glasses a condition known as presbyopia. You and your surgeon may make a decision to utilize only one treatment zone at either 6mm or 7mm. You and your surgeon may make a decision to utilize CK after previous eye surgery. You and your surgeon may make a decision to utilize this procedure to help reduce astigmatism. CK for the treatment of the above reasons is an "off label" use of an approved medical device. Your surgeon is not precluded from using CK for these treatments if the surgeon and the patient are in agreement.

DIAGNOSIS:

You have been diagnosed with astigmatism, keratoconus, or hyperopia (farsightedness) with or without presbyopia (“aging eyes”: the need for reading glasses or the need for reading magnification) or presbyopia.

ANTICIPATED BENEFIT:

This procedure has been shown to improve vision in patients so that they either can see and function without glasses or contact lenses, or provide patients with the ability to see well with thinner glasses or contact lenses.

CK PROCEDURE DESCRIBED:

Before the conductive thermokeratoplasty (CK) surgery, anesthetic drops will be placed in the eye which has been selected for treatment. Due to the use of the anesthetic drops, there is expected to be little to no discomfort during this surgery. You will be laying down under a microscope. There is a blinking red light inside the microscope for you to stare at. When everything is ready, you will hear a series of beeps. The gentle heat generated by the probe interaction with the cornea causes the tissue to shrink. This surgery will change the shape of the cornea. The CK surgery itself should take no more than a few minutes to perform, although you will probably be under the microscope for about 10 to 15 minutes. After the procedure, you can expect the eye to feel irritated to a degree for the first few days after the procedure. You will receive prescription eye drops to improve comfort during this period.

You will need to return to the office for periodic evaluations following your surgery. Expect your vision to fluctuate during the healing process. The FDA study showed that most of the fluctuation will occur during the first 3 months of healing, but small vision changes can occur up to 18 months following the procedure. Initially you should notice an improvement in your near vision. As your eyes heal your distance vision will improve over the following months with a reduction in the near vision.

LIMITS OF CK:

Although the goal of CK 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, spectacles or contact lenses may be required to achieve adequate vision during or after the healing phase. CK does not correct the condition known as presbyopia (aging of the eye) which occurs in most people around the age of 40 as the lens of the eye changes. CK does not change the normal aging process of the lens but, will change the focusing power of the cornea to help with your near vision.

Presbyopia requires individuals around the age 40 and older to wear reading glasses for close-up work or to wear bifocals so that they can focus for up-close work and far work. If you presently need reading glasses or bifocals for up-close work, you may need them afterwards to varying degrees. If you do not wear reading glasses or bifocals now you may still need to wear glasses for reading after the surgery or at a later age. The CK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachment. CK is intended to be used for the temporary reduction of hyperopia.

RISKS AND CONTRAINDICATIONS:

Contraindications: This 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 suppress the immune system
- who are pregnant or nursing
- with residual, recurrent, or active ocular disease(s) or abnormality except for myopia, hyperopia, or presbyopia 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

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

Risks: As with all forms of surgery there are risks and the results cannot be guaranteed. The risks of the CK surgery include, but are not limited to:

- **Loss of Vision:** CK surgery 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 that distorted vision or “ghosting” occurs. This may not be correctable by glasses or contact lenses.
- **Visual Side Effects:** Other complications and conditions that can occur with CK surgery include: anisometropia (difference in power between the two eyes); aniseikonia (difference in image size between the two eyes); double vision, hazy vision; induced astigmatism; fluctuating vision during the day and from day to day; increased or decreased sensitivity to light that may be incapacitating for some time and may not completely go away; glare and halo around lights, which may not completely go away. The most common visual symptom associated with this procedure is light sensitivity; this usually resolves within the first few weeks after treatment.
- **Overcorrection or Undercorrection:** It may be that the CK surgery will not give the desired result. Some surgery result in the eye in being undercorrected. If this occurs, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. It is also possible that your eye may be overcorrected to the point of becoming nearsighted. It is possible that your initial results could have late healing or changes that occur over time. In some, but not all cases, re-treatment, glasses or contact lenses could be effective in correcting vision. In addition, it is also possible that the change in your prescription (vision) from CK may return to what it was before the treatment. If you do require a retreatment with CK, there will be no charge if the retreatment is performed within the first year after the primary CK procedure was performed.
- **Employment Risk:** You should be aware that having this surgery may affect future employment opportunities with certain military or law enforcement agencies or airline companies. This procedure may impair your ability to perform your job.

- **Other Risks:** The CK treatment spots will be visible for the first few days because there are small round hazy areas where the cornea was heated. These spots will gradually fade and are only visible with the microscope in about 3 months. Other possible complications include: scarring; infection (of the surface of the eye); extended inflammation; ulceration or perforation (holes) of the cornea; ptosis (droopy eyelid); corneal swelling; new or increased floaters; retinal detachment; retinal hemorrhage; contact lens intolerance. There are also potential complications due to reactions from anesthesia and medications that may involve other parts of your body. The laser may need to be aborted during or prior to the surgery. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. Since it is impossible to state all potential risks of any surgery or procedure, this form may not provide a comprehensive listing of every conceivable problem.
- **Later-Discovered Complications:** CK is a relatively new surgery, there may be long-term effects not yet known or anticipated at the present time. It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. Risks and complications that are considered to be unforeseeable, remote, or unknown are not discussed. You should be aware that other complications may occur that have not yet been reported. Longer term results may reveal additional risks and complications. After the procedure, you should continue to have routine check ups to assess the condition of your eyes.
- **Risks of Not Undergoing CK:** The risks of not having the surgery 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.
- **Complex Cataract Surgery:** At the point you develop cataracts you will need more complex testing and calculations for the selection of a lens to use during the cataract procedure. This procedure can make the selection of a lens less accurate than for patients who have not had any previous surgery. It will be important to return to this office for cataract surgery or be sure to have the surgeon who performs your surgery be made aware of having undergone this procedure.

ALTERNATIVES TO CK

CK is purely an elective surgery, and you may decide not to have this surgery at all.

Non-surgical alternatives include:

- Eyeglasses/Spectacles
- Contact Lenses
- Nothing
- Orthokeratology

Surgical alternatives include:

- Photorefractive Keratectomy Surgery (PRK)
- Laser in Situ Keratomileusis (LASIK)
- Automated Lamellar Keratoplasty (ALK)
- Hexagonal Keratotomy Surgery (HK)
- Clear Lens Extraction (CLE)

You may wish to discuss these options with your physician.

Pre- and Post-Treatment Care

Before the CK Surgery

- **Pregnancy:** Pregnancy could adversely affect your treatment result since your refractive error can fluctuate during pregnancy; In addition, pregnancy may affect your healing process, and some medications may pose a risk to an unborn or nursing child. If you are pregnant, you should not undergo the CK procedure until after the pregnancy. If you become pregnant in the one month following treatment, you should notify your eye doctor immediately.
- **Taking medications and allergies:** You should inform your physician of any medications you may be taking in order to account for the risk of allergic reactions, drug reactions, and other potential complications during the CK surgery and subsequent treatment.

Post-Treatment Precautions:

- **Eye Protection:** Avoid exposing the eye to tap water in the bath or shower, as such nonsterile water may expose the eye to increased risks of infection. Wear sunglasses during the first day after having surgery. Avoid rubbing the eye the eye may be more tender.
- **Operating Motor Vehicles:** After CK, in order to operate motor vehicles, glasses, contact lenses, eye drops, or other measures may be needed. After surgery, you may experience 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. Driving should only be done when you are certain that your vision is adequate. On the day of the CK surgery and for your 1 day postoperative appointment, you should arrange to have a driver.
- **Pain and Discomfort:** The amount of pain and discomfort that can be expected soon after the CK procedure varies with the individual. You should expect that the eye will be sore to some extent after the surgery. 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.

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for information on LTK

Important Information

HOLMIUM LASER THERMAL KERATOPLASTY (LTK) FOR THE CORRECTION OF HYPEROPIA (FARSIGHTEDNESS) AND/OR PRESBYOPIA (NEED FOR READING GLASSES AFTER 40) “ON-LABEL USE” and “OFF LABEL USE”

GENERAL INFORMATION:

The following information is intended to help you make an informed decision about having Laser Thermal Keratoplasty (LTK) to improve your vision.

On June 30, 2000, the FDA approved the Sunrise Hyperion™ Holmium Laser Corneal Shaping System for the “on-label use” for the reduction of hyperopia in patients of at least the age of 40 with up to +2.50 diopters of hyperopia. This laser is designed to perform a surgery called **laser thermokeratoplasty**, also called "LTK". The LTK surgery is designed to change the focus of your eye by changing the shape of the cornea. Changing the focus of the cornea by changing the shape of the cornea is called refractive surgery. LTK is designed to reduce low to moderate hyperopia (farsightedness).

You and your surgeon may make a decision for a same day retreatment or immediate enhancement if your hyperopia is greater than +2.50 diopters. You and your surgeon may make a decision to utilize LTK even if you are not at least 40 years old. You and your surgeon may make a decision to utilize LTK to reduce the need for reading glasses a condition known as presbyopia. You and your surgeon may make a decision to utilize only one treatment zone at either 6mm or 7mm. You and your surgeon may make a decision to utilize LTK after previous corneal surgery. Instead, LTK for the treatment of the above reasons is considered an unregulated or "off label" use of an approved medical device. Your surgeon is not precluded from using LTK for these treatments if he and the patient are in agreement.

DIAGNOSIS:

You have been diagnosed with hyperopia (farsightedness) with or without presbyopia (“aging eyes”: the need for reading glasses or the need for reading magnification) or presbyopia.

ANTICIPATED BENEFIT:

This procedure has been shown to improve vision in patients so that they either can see and function without glasses or contact lenses, or provide patients with the ability to see well with thinner glasses or contact lenses.

LTK PROCEDURE DESCRIBED:

Before the laser thermokeratoplasty (LTK) surgery, anesthetic drops will be placed in the eye which has been selected for treatment. Due to the use of the anesthetic drops, there is expected to be little to no discomfort during this surgery. You will be seated at a slit-lamp (an instrument your doctor uses to look into your eye) and asked to place your chin in a chin rest. There is a blinking green/yellow light inside the laser for you to stare at. When everything is ready, you will hear a series of clicks as the laser makes a pattern of tiny dots in the periphery of your cornea at 6mm and/or 7mm. You may “hear” sounds during the laser treatment. The gentle heat generated by the laser interaction with the cornea causes the tissue to shrink. This surgery will change the shape of the cornea. The LTK surgery itself should take no more than a few seconds to perform, although you will probably be seated in front of the laser for about 10 to 15 minutes. (The laser will be deactivated the entire time, except for the actual treatment.) After the procedure, you can expect the eye to feel irritated to a degree for the first few days after the procedure. You will receive prescription eye drops to improve comfort during this period.

You will need to return to the office for periodic evaluations following your surgery. Expect your vision to fluctuate during the healing process. The FDA study showed that most of the fluctuation will occur during the first 3 months of healing, but small vision changes can occur up to 18 months following the procedure. Initially you should notice an improvement in your near vision. As your eyes heal your distance vision will improve over the following months with a reduction in the near vision.

LIMITS OF LTK:

Although the goal of LTK 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, spectacles or contact lenses may be required to achieve adequate vision during or after the healing phase. LTK does not correct the condition known as presbyopia (aging of the eye) which occurs in most people around the age of 40 as the lens of the eye changes. LTK does not change the normal aging process of the lens but, will change the focusing power of the cornea to help with your near vision. Presbyopia requires individuals around the age 40 and older to wear reading glasses for close-up work or to wear bifocals so that they can focus for up-close work and far work. If you presently need reading

glasses or bifocals for up-close work, you may need them afterwards to varying degrees. If you do not wear reading glasses or bifocals now you may still need to wear glasses for reading after the surgery or at a later age. The LTK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachment. LTK is intended to be used for the temporary reduction of hyperopia.

RISKS AND CONTRAINDICATIONS:

Contraindications: This 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 suppress the immune system
- who are pregnant or nursing
- with residual, recurrent, or active ocular disease(s) or abnormality except for myopia, hyperopia, or presbyopia 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

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

Risks: As with all forms of surgery there are risks and the results cannot be guaranteed. The risks of the LTK surgery include, but are not limited to:

- **Loss of Vision:** LTK surgery 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 that distorted vision or “ghosting” occurs. This may not be correctable by glasses or contact lenses.
- **Visual Side Effects:** Other complications and conditions that can occur with LTK surgery include: anisometropia (difference in power between the two eyes); aniseikonia (difference in image size between the two eyes); double vision, hazy vision; induced astigmatism; fluctuating vision during the day and from day to day; increased or decreased sensitivity to light that may be incapacitating for some time and may not completely go away; glare and halo around lights, which may not completely go away. The most common visual symptom associated with this procedure is light sensitivity; this usually resolves within the first few weeks after treatment.
- **Overcorrection or Undercorrection:** It may be that the LTK surgery will not give the desired result. Some surgery result in the eye in being undercorrected. If this occurs, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. It is also possible that your eye may be overcorrected to the point of becoming nearsighted. It is possible that your initial results could have late healing or changes that occur over time. In some, but not all cases, re-treatment, glasses or contact lenses could be effective in correcting vision. In addition, it is also possible that the change in your prescription (vision) from LTK may return to what it was before the treatment. If you do require a retreatment with LTK, there will be no charge if the retreatment is performed within the first year after the primary LTK procedure was performed.
- **Other Risks:** The LTK treatment spots will be visible for the first few days because there are small round hazy areas where the cornea was heated. These spots will gradually fade and are only visible with the microscope in about 3 months. Other possible complications include: scarring; infection (of the surface of the eye); extended inflammation; ulceration or perforation (holes) of the cornea; ptosis (droopy eyelid); corneal swelling; new or increased floaters; retinal detachment; retinal hemorrhage; contact lens intolerance. There are also potential complications due to reactions from anesthesia and medications that may involve other parts of your body. The laser may need to be aborted during or prior to the surgery. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. Since it is impossible to state all potential risks of any surgery or procedure, this form may not provide a comprehensive listing of every conceivable problem.
- **Complex Cataract Surgery:** At the point you develop cataracts you will need more complex testing and calculations for the selection of a lens to use during the cataract procedure. This procedure can make the selection of a lens less accurate than for patients who have not had any previous surgery. It will be important to return to this office for cataract surgery or be sure to have the surgeon who performs your surgery be made aware of having undergone this procedure.

- **Later-Discovered Complications:** LTK is a relatively new surgery, there may be long-term effects not yet known or anticipated at the present time. It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. Risks and complications that are considered to be unforeseeable, remote, or unknown are not discussed. You should be aware that other complications may occur that have not yet been reported. Longer term results may reveal additional risks and complications. After the procedure, you should continue to have routine check ups to assess the condition of your eyes.
- **Employment Risk:** You should be aware that having this surgery may affect future employment opportunities with certain military or law enforcement agencies or airline companies. This procedure may impair your ability to perform your job.
- **Risks of Not Undergoing LTK:** The risks of not having the surgery 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.

ALTERNATIVES TO LTK

LTK is purely an elective surgery, and you may decide not to have this surgery at all.

Non-surgical alternatives include:

- Eyeglasses/Spectacles
- Contact Lenses
- Nothing
- Orthokeratology

Surgical alternatives include:

- Photorefractive Keratectomy Surgery (PRK)
- Laser in Situ Keratomileusis (LASIK)
- Automated Lamellar Keratoplasty (ALK)
- Hexagonal Keratotomy Surgery (HK)
- Clear Lens Extraction (CLE)

You may wish to discuss these options with your physician.

Pre- and Post-Treatment Care

Before the LTK Surgery

- **Pregnancy:** Pregnancy could adversely affect your treatment result since your refractive error can fluctuate during pregnancy; In addition, pregnancy may affect your healing process, and some medications may pose a risk to an unborn or nursing child. If you are pregnant, you should not undergo the LTK procedure until after the pregnancy. If you become pregnant in the three (3) months following treatment, you should notify your eye doctor immediately.
- **Taking medications and allergies:** You should inform your physician of any medications you may be taking in order to account for the risk of allergic reactions, drug reactions, and other potential complications during the LTK surgery and subsequent treatment.
- **Contact lens wearers:** Patients who wear gas-permeable or hard contact lenses must completely stop wearing such lenses at least 3 weeks prior to the surgery. (This period may be longer for some patients.) Patients who wear soft contact lenses must completely stop wearing their soft contact lenses at least 3 days prior to the surgery.

Post-Treatment Precautions:

- **Eye Protection:** Avoid exposing the eye to tap water in the bath or shower, as such nonsterile water may expose the eye to increased risks of infection. Wear sunglasses during the first day after having surgery. Avoid rubbing the eye the eye may be more tender.
- **Operating Motor Vehicles:** After LTK, in order to operate motor vehicles, glasses, contact lenses, eye drops, or other measures may be needed. After surgery, you may experience 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. Driving should only be done when you are certain that your vision is adequate. On the day of the LTK surgery and for your 1 day postoperative appointment, you should arrange to have a driver.
- **Pain and Discomfort:** The amount of pain and discomfort that can be expected soon after the LTK procedure varies with the individual. You should expect that the eye will be sore to some extent after the surgery. 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.