Patient Assistance Information

Primary Eye Care Professional

Name: _____

Address: _____

Phone: _____

PRK or LASIK Doctor

Name: _____

Address: _____

Phone: _____

Treatment Location

Name: _____

Address: _____

Phone: _____

Laser Manufacturer:

VISX, Incorporated
3400 Central Expressway
Santa Clara, CA 95051
U.S.A.
Tel: 408.733.2020

Facts You Need to Know About Photorefractive Keratectomy (PRK) and Laser Assisted In Situ Keratomileusis (LASIK) Surgery

Patient Information Booklet

PRK:

Nearsighted Patients (-1.0 to -12.0 diopters) or
Nearsighted Patients (0 to -12.0 diopters) with
0.75 to 4.0 Diopters of Astigmatism
Farsighted Patients (+1.0 to +6.0 diopters) with
no more than 1.0 Diopter of Refractive Astigmatism

LASIK:

Nearsighted Patients (0 to -14.0 diopters) with or without
-0.50 to -5.0 Diopters of Astigmatism

Please read this entire booklet. Discuss its contents with your doctor so that all your questions are answered to your satisfaction. Ask any questions you may have before you agree to the surgery.

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3400 Central Expressway
Santa Clara, CA 95051-0703
U.S.A.
Tel: 408.733.2020

Table of Contents

Glossary

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions you may have about these terms.

Antibiotic Medication: a drug used to treat or prevent infection.

Anti-inflammatory Medication: a drug that reduces redness and swelling associated with inflammation. May be a corticosteroid, or a nonsteroidal anti-inflammatory drug.

Astigmatism: The cornea and lens focus light rays at multiple points at differing distances from the retina. The multiple focal points result in blurred distance and/or near vision.

Automated Lamellar Keratectomy (ALK): a type of surgery used to correct vision by removing a cap of cornea using a microkeratome (an automated instrument), reshaping or flattening the cap of cornea, and then replacing the cap on the corneal bed.

Cataract: an opacity or clouding of the lens inside the eye that can cause a loss of vision.

Collagen Vascular Disease: a condition that may result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis.

Contraindications: any special condition that results in the treatment being inadvisable.

Cornea: the clear front surface of the eye. Surgery such as PRK and LASIK reshape or flatten this surface to correct vision.

Corneal Epithelium: the top layer of the cornea. The doctor removes this layer during PRK surgery. The epithelium then grows back a few days after PRK surgery.

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Corneal Haze: a cloudiness of the cornea that may occur after PRK and LASIK.

Corneal Ulcer: an infection of the cornea that may result in a loss of vision.

Diopter: a unit used to measure the amount of myopia, hyperopia, or astigmatism of any eye.

Farsightedness: The cornea and lens focus light rays from near objects beyond the retina, causing images of near objects to appear blurry. Hyperopia is another term for farsightedness.

Glaucoma: a condition usually associated with high eye pressure. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

Halos: circular flares or rings of light that may appear around a headlight or other lighted object.

Herpes Simplex: a type of infection caused by a virus that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body.

Herpes Zoster: a type of infection caused by a virus that can recur. Vesicles appear on only one side of the body.

Highly Nearsighted: nearsightedness between -6 diopters and -12 diopters.

Hyperopia: The cornea and lens focus light rays from near objects beyond the retina, causing images of near objects to appear blurry. Farsightedness is another term for hyperopia.

Immunodeficiency Disease: a condition that alters the body's ability to heal. An example is AIDS.

Intraocular Pressure (IOP): fluid pressure inside the eye. Your doctor measures the pressure inside the eye with a tonometer.

Keratoconus: a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs.

LASIK: a type of surgery used to correct vision by raising a flap of cornea using a microkeratome (an automated instrument), then reshaping the cornea underneath using an excimer laser, and then replacing the flap on the corneal bed.

Lens: a structure inside the eye that helps to focus light onto the back of the eye.

Mildly Nearsighted: nearsightedness between -1.0 diopters and -6.0 diopters.

Moderately Farsighted: farsightedness between +1.0 diopters and +4.0 diopters.

Myopia: The cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Nearsightedness is another term for myopia.

Nearsightedness: The cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Myopia is another term for nearsightedness.

Ocular Hypertension: an increase in the pressure inside the eye.

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the cornea using an excimer laser.

Radial Keratotomy (RK): a type of surgery used to correct vision by flattening the cornea with a scalpel.

Re-epithelialization: regrowth of the top layer of the cornea. The epithelium is removed before the PRK treatment and usually grows back within a few days after the treatment.

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Regression: a decrease in the amount of vision correction after PRK or LASIK surgery.

Retina: the back surface of the eye. The retina takes focused light and transfers it to the brain.

Introduction

The information in this booklet is to help you decide whether to have Photorefractive Keratectomy (PRK) or Laser Assisted In Situ Keratomileusis (LASIK) laser surgery. PRK may be used to correct or partly correct your nearsightedness (myopia) and/or astigmatism or farsightedness (hyperopia). LASIK may be used to correct or partly correct your nearsightedness and/or astigmatism. Some other ways to correct nearsightedness, farsightedness, and astigmatism are glasses, contact lenses, and other kinds of refractive surgery such as radial keratotomy (RK) or automated lamellar keratectomy (ALK). PRK and LASIK are completely different from RK and ALK.

If both of your eyes are nearsighted and/or astigmatic, your doctor may recommend PRK or LASIK surgery for both eyes. If both of your eyes are farsighted, your doctor may recommend PRK surgery for both eyes. However, sometimes it is better to have PRK or LASIK done on only one eye. Talk with your doctor about whether it would be better to treat one or both of your eyes.

Please read this booklet completely. Discuss any questions with your doctor before you decide if PRK or LASIK is right for you. Only an eye care professional trained and certified in PRK and LASIK can determine whether you are a suitable candidate. Some people, such as military pilots, have job-related vision requirements that cannot be met by having RK, ALK, PRK, or LASIK.

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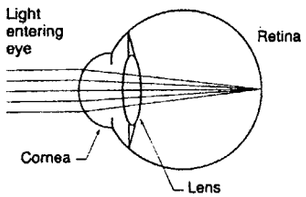
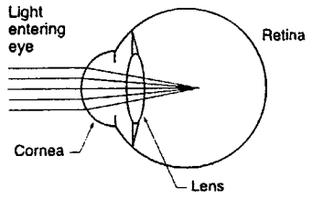
How the Eye Functions

The cornea and lens of the eye focus light like a camera lens to form an image on the retina at the back of the eye. The cornea, where light first enters the front of the eye, provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred. This condition is called nearsightedness, or myopia. Myopia usually starts in childhood and gets progressively worse through adolescence. It usually stops changing by the late teens, but it can sometimes continue to get worse into the mid-twenties. In astigmatism the image does not come to a point focus on the retina, but there are at least two points of focus that are differing distances from the retina.

Normal Eye

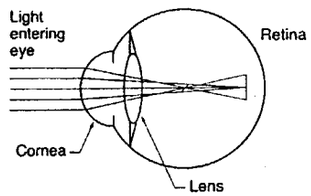


Nearsighted Eye

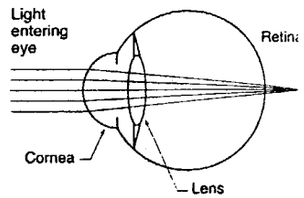


In farsightedness the image focuses beyond the retina. In our youth, the innate accommodating (focusing) power of the eyes often compensates for farsightedness. But as we age, our eyes become less able to accommodate. For this reason, farsightedness most commonly becomes a problem later in life. Many farsighted eyes do not need correction until the individuals reach their forties or fifties.

Nearsighted and Astigmatic Eye

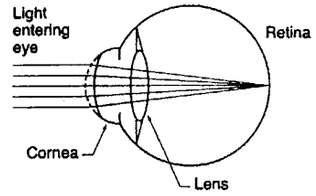


Farsighted Eye



Nearsightedness can be corrected by any method that reduces the total refractive power of the eye. Astigmatism correction makes all of the rays of light focus at the same distance so that they all fall right on the retina. Eyeglasses and contact lenses do this by putting in front of the eye "negative" lenses that are thicker at the edge than in the center. PRK and LASIK correct nearsightedness by flattening the central part of the cornea, and correct astigmatism by flattening the central cornea by different amounts at different orientations to correct for the uneven focus of the rays of light.

Eye After Treatment



Farsightedness can be corrected by any method that increases the total refractive power of the eye. Eyeglasses and contact lenses do this by putting in front of the eye "positive" lenses that are thicker in the center than

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at the edge. PRK does it by making the central part of the cornea more steeply curved.

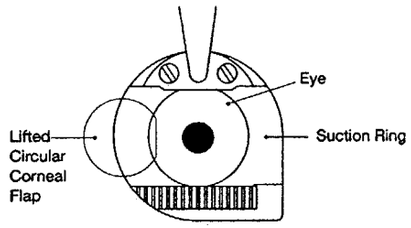
During a regular eye examination, your doctor uses lenses to measure your nearsightedness, astigmatism, or farsightedness in units called diopters. The VISX STAR S2™ Excimer Laser System is approved for PRK treatments in correcting eyes with up to 12 diopters of nearsightedness and from 0.75 to 4.0 diopters of astigmatism. For farsightedness, the system is approved for correcting eyes with up to 6.0 diopters of farsightedness and no more than 1.0 diopter of astigmatism. No astigmatism is corrected with a hyperopia treatment. The VISX STAR S2™ Excimer Laser System is also approved for LASIK treatment in correcting eyes with up to 14 diopters of nearsightedness and between 0.5 and 5.0 diopters of astigmatism.

What are PRK and LASIK?

PRK is laser surgery to correct nearsightedness (myopia), nearsightedness with astigmatism, or farsightedness (hyperopia). For nearsightedness with or without astigmatism, an excimer laser beam is used to flatten the front of the cornea. The laser beam removes small amounts of tissue from the front of the cornea. For farsightedness, the excimer laser beam is used to steepen the front of the cornea. To do this, the laser beam removes small amounts of tissue from a ring-shaped area around the center of the cornea. PRK and LASIK differ from RK, which uses a knife to make deep cuts around the center of the cornea.

LASIK is laser surgery to correct nearsightedness with or without astigmatism. The surgery is similar to PRK, but does not treat or alter the front surface of the cornea. The doctor uses an instrument called a microkeratome to create a circular flap of corneal tissue. The flap is then lifted from the cornea while the doctor uses the excimer laser to remove small amounts of underlying tissue from the exposed cornea. The corneal flap is then repositioned and the eye is covered with an eye patch.

View of Microkeratome on Eye



An excimer laser produces a powerful beam of ultraviolet light. The laser is controlled by the doctor. It produces a series of rapid pulses that removes small amounts of corneal tissue. Excimer laser light does not penetrate the eye and leaves other eye structures (iris, lens, retina) undisturbed.

Benefits

- PRK surgery, as performed with the VISX STAR S2, is effective in reducing nearsightedness between 0 and -12.0 diopters and/or astigmatism between -0.75 and -4.0 diopters.
- LASIK surgery, as performed with the VISX STAR S2, is effective in reducing nearsightedness between 0 and -14.0 diopters and/or astigmatism between -0.5 and -5.0 diopters.
- PRK or LASIK surgery may reduce overall nearsightedness and astigmatism, while also reducing or eliminating dependency upon contact lenses or glasses.
- PRK surgery, as performed with the VISX STAR S2, is effective in reducing farsightedness between +1.0 and +6.0 diopters with no more than 1.0 diopter of refractive astigmatism.

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Risks

As with any surgical procedure there are risks associated with PRK and LASIK surgery. It is important to discuss these risks with your doctor before you make the decision to have the surgery. If the results of the surgery are not satisfactory, you may need to have additional PRK or LASIK surgery in the same eye.

The First Week Following Surgery

- Pain and discomfort may last for up to 3 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You will be sensitive to bright lights.

The First Two To Six Months Following Surgery

- Your intraocular pressure may increase due to use of anti-inflammatory medications. This is usually resolved by drug therapy or by stopping the anti-inflammatory medication.
- Your cornea may become hazy or cloudy enough to affect your vision. This haze typically disappears over time, but some patients may continue to experience haze for up to 2 years before it disappears.

One or More Years After Surgery

Some patients report visual complaints at one or more years after surgery. These problems are discussed in detail later in this booklet (see the section titled Long-Term Post-Treatment Safety Problems).

Contraindications

You should **NOT** have PRK or LASIK surgery if:

- You have collagen vascular, autoimmune, or immunodeficiency diseases (for example, lupus or AIDS).
- You are pregnant or nursing.
- You show signs of keratoconus (corneal disease).

- You are taking one or both of the following medications:
  - — Accutane (isotretinoin).
  - — Cordarone (amiodarone hydrochloride).

Warnings

Discuss with your doctor if:

- Your nearsightedness, astigmatism, or farsightedness is changing.
- You are diabetic or have severe allergies.
- You have a history of Herpes simplex or Herpes zoster of the eye.
- Your treatment result might not be as good with higher corrections of nearsightedness and/or astigmatism.

Precautions

The PRK clinical trials included only 21 out of 200 eyes with nearsightedness between 10 and 12 diopters and 13 out of 275 eyes with farsightedness between 4 and 6 diopters. These populations may not have been sufficient to determine the level of effectiveness and complication rate for patients with severe nearsightedness and severe farsightedness.

If you have more than +4.0 D of farsightedness, you may be at a greater risk of regression of correction.

The effects of PRK or LASIK on visual performance under poor lighting conditions have not been determined. Following PRK or LASIK treatment, you may find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. If you are under age 30 or have a large pupil size and have PRK or LASIK treatment of astigmatism, you will be more likely to experience problems with your vision under poor lighting conditions.

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The safety and effectiveness of the VISX STAR S2 Excimer Laser System have **NOT** been established:

- In eyes with corneal disease or abnormality (for example, scar, infection, etc.).
- In eyes with previous surgery or injury to the center of the cornea where PRK or LASIK will be performed.
- For hyperopia (farsightedness) treatment of patients with refractions less than +1.0 D.
- In eyes with progressive nearsightedness, astigmatism, or farsightedness.
- In eyes with abnormal blood vessels within 1.0 mm of the cornea area where PRK or LASIK will be performed.
- In patients under 18 years of age for mild nearsightedness and under 21 years of age for high nearsightedness with or without astigmatism and farsightedness.
- In patients over the long term. (For PRK surgery: 3 years for nearsightedness, more than 1 year for highly nearsightedness with or without astigmatism, or 1 year for farsightedness. For LASIK surgery: 6 months for nearsightedness with or without astigmatism.)
- In patients who are taking sumatriptan (Imitrex) for migraine.
- In patients who have a tendency to form scars.
- For PRK treatments greater than -12.0 D of nearsightedness, up to -4.0 D of astigmatism, or +6.0 D of farsightedness.
- For LASIK treatments greater than -14.0 D of nearsightedness and/or up to -5.0 D of astigmatism.
- In patients taking hormone replacement therapy or antihistamines who may experience delayed re-epithelialization of the cornea following surgery.
- In patients who have had prior incisional refractive surgery.

Are You a Good Candidate for PRK or LASIK?

If you are considering PRK or LASIK, you must:

- Be at least 18 years of age for PRK treatment of mild nearsightedness or 21 years of age for PRK treatment of moderate farsightedness.
- Be at least 21 years of age for PRK or at least 18 years of age for LASIK treatment of high nearsightedness with or without astigmatism.
- Have healthy eyes that are free from eye disease or corneal abnormality (for example, scar, infection, etc.).
- Have nearsightedness (myopia) up to -12.0 diopters and/or between -0.75 and -4.0 diopters of astigmatism, or have farsightedness (hyperopia) between +1.0 and +6.0 diopters with no more than 1.0 diopter of refractive astigmatism for PRK treatment.
- Have nearsightedness up to -14.0 diopters and between -0.5 and -5.0 diopters of astigmatism for LASIK treatment.
- Have documented evidence that your refraction did not change by more than 0.50 diopter during the year before your pre-operative examination.
- Be informed of PRK or LASIK risks and benefits as compared to other available treatments for nearsightedness (myopia) with or without astigmatism and farsightedness (hyperopia).
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be able to keep your eye accurately on the fixation light for the entire PRK or LASIK procedure.
- Be willing to sign an informed consent form, if provided by your eye care professional.

Before the Surgery

If you are interested in having PRK or LASIK, you will need to have a pre-surgical examination to determine if your eye is healthy and suitable fo

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PRK or LASIK. This will include a complete physical and eye history, and thorough examination of both eyes. In addition, computerized mapping of your cornea will be done to determine if it is smooth and properly shaped.

WARNING:

If you wear contact lenses, it is very important to stop wearing them 2 – 4 weeks for the doctor to obtain a stable eye measurement. Failure to do this might produce less than perfect laser vision corrections.

Before the surgery, please tell your doctor whether you take any medications or have any allergies. Also, talk with your doctor about eating or drinking immediately before the surgery. You should also arrange for transportation, since you must not drive immediately after the surgery. You may resume driving only after receiving permission from your doctor.

The Day of Surgery

Before the surgery you will be asked to listen to the sounds of the treatment so that you will be prepared for the noise the laser makes during surgery. Anesthetic (numbing) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up at a microscope that will deliver the laser light to your cornea. An instrument will be placed between your eyelids to hold them open during the surgery. There will also be a temporary shield covering the eye not having surgery.

The PRK surgery begins with removal of the epithelium, the top layer of the cornea. This is done either with the laser or with a small spatula.

The LASIK surgery begins with the placement of a suction ring which elevates the pressure in the eye. The vision in the eye will go black as the suction increases the pressure in the eye. The movement of the microkeratome in the track of the suction ring cuts a circular corneal flap. This flap of tissue will be lifted by the doctor after the suction is released.

Vision will return to the eye after the suction is released.

For both PRK and LASIK surgery, the doctor will then reposition your head in the chair and refocus the microscope. You will be asked to look directly at a blinking red light. Try to keep both eyes open without squinting, as this makes it easier to keep looking at the blinking red light. Small amounts of tissue will then be removed from your cornea using the VISX STAR S2 Excimer Laser.

PRECAUTION:

It is very important that you keep looking at the blinking red light during the procedure, even if the light fades or becomes dim. You need to concentrate on looking at this red, blinking light throughout the treatment to prevent the laser vision correction from being off target.

You will be under the laser less than 1 minute and, overall, the surgery takes about 10 minutes.

After the laser surgery is complete, some eye drops and a bandage contact lens or a patch will be placed on your eye. The surgery is painless because of the anesthetic drops.

When the anesthetic drops wear off (about 45 to 60 minutes), your eye may hurt for 1 to 3 days. Most patients describe this pain as moderate to severe. To promote healing and to lessen the risk of infection, do **NOT** rub your eyes for the first 3 to 5 **days** after PRK surgery and for 3 to 5 **months** after LASIK surgery. Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery.

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IMPORTANT:

Your doctor will monitor you for any side effects if topical steroids were used. Possible side effects of prolonged topical steroid use are ocular hypertension, glaucoma, or cataract formation.

After Surgery

You will be mildly sensitive to light and have the feeling that something is in your eye for the first few days. Sunglasses may make you more comfortable during this time.

Your vision should become stable within the first several weeks after surgery. However, you may experience some small changes (for example, improvement or worsening of your vision). These changes may occur up to six months or more after surgery.

A haze or cloudiness is typically seen in the cornea following surgery, but usually does not affect your vision. This haze typically disappears over time, but some patients may continue to experience haze for up to 2 years before it disappears.

IMPORTANT:

Use the anti-inflammatory eye drops and lubricants as directed by your doctor. Your laser vision correction results depend upon your following your doctor's directions.

Results from Clinical Studies

The clinical study results of the VISX STAR Excimer Laser System were:

A. PRK surgery: without the help of glasses (results at 12 months after surgery)

- 94% mildly nearsighted eyes could see 20/40 or better
- 91% mildly nearsighted eyes with astigmatism could see 20/40 or better
- 90% highly nearsighted eyes with or without astigmatism could see 20/40 or better
- 95% moderately farsighted eyes could see 20/40 or better

B. PRK surgery: with the help of glasses* (results at 12 months after surgery)

- 99% mildly nearsighted eyes could see 20/40 or better
- 98% mildly nearsighted eyes with astigmatism could see 20/40 or better
- 99% highly nearsighted eyes with or without astigmatism could see 20/40 or better
- 99% moderately farsighted eyes could see 20/40 or better

C. LASIK surgery: without the help of glasses (results at 6 months after surgery)

- 97% highly nearsighted eyes with or without astigmatism could see 20/40 or better

D. LASIK surgery: with the help of glasses (results at 6 months after surgery)

- 99% highly nearsighted eyes with or without astigmatism could see 20/40 or better

Even though their vision without glasses improved, some patients still needed glasses or contact lenses after PRK or LASIK. PRK or LASIK does not eliminate the need for reading glasses.

NOTE: You may need reading glasses after laser surgery even if you did not wear them before.

* Data collected from eyes that could see 20/20 or better with glasses before surgery.

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Long-Term Post-Treatment Safety Problems

The following is a list of the adverse events and complications that occurred at approximately 1 year after PRK treatment in patients who were **mildly nearsighted (MN), mildly nearsighted with astigmatism (MNA), highly nearsighted with or without astigmatism (HN), or moderately farsighted (MF):**

Problems	PRK			
	MN (%)	MNA (%)	HN (%)	MF (%)
Worsening of Best Spectacle Corrected Vision: Significant (loss of more than 2 lines of vision on a vision chart) worsening of vision in the operated eye with the help of glasses	0.4	3.5	2.5	0
Overcorrection: May need to be corrected with glasses, contact lenses, or additional laser vision correction				
By more than 1 diopter	1.2	1.2	5.1	2.6
By more than 2 diopters	0.2	1.2	1.9	0
Increase in Astigmatism: Uneven curving of the cornea of 1 or more diopters that may distort vision and require corrective glasses or contact lenses	3.1	NA*	NA	0.9
Double/Ghost Images: Shadows or ghost images around objects, judged by the patient after surgery compared to vision before surgery:				
Somewhat Worse	0.6	1.1	NA	5.2
Much Worse	1.0	4.3	NA	0.9
Sensitivity to Bright Lights: Difficulty tolerating bright lights, judged by the patient after surgery compared to vision before surgery:				
Somewhat Worse	3.7	6.5	NA	6.1
Much Worse	1.6	6.5	NA	0.9
Difficulty with Night Vision: Difficulty performing visual tasks in low light or at night that are performed without difficulty during the day, judged by the patient after surgery compared to vision before surgery:				
Somewhat Worse	2.7	9.8	NA	4.3
Much Worse	2.5	8.7	NA	1.7

*Not available.

The following is a list of the adverse events and complications that occurred in LASIK patients at approximately 3 months after treatment.

LASIK Patient Findings (All Eyes)		
Visual Findings	Percent of Patients Reporting	
	Before LASIK Surgery	3 Months After LASIK Surgery
No Glare	6%	4%
Severe Glare	9%	6%
No Halo	12%	6%
Severe Halo	9%	4%
No Visual Fluctuations	17%	11%
Severe Visual Fluctuations	4%	2%

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Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if PRK or LASIK is right for you:

- What other options are available for correcting my nearsightedness (with or without astigmatism) or farsightedness?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of PRK for my amount of nearsightedness (with or without astigmatism) or farsightedness?
- What are the benefits of LASIK for my amount of nearsightedness (with or without astigmatism)?
- What vision can I expect in the first few months after surgery?
- If PRK or LASIK does not correct my vision, what is the possibility that my glasses will need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after PRK or LASIK if I need them?
- How is PRK or LASIK likely to affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having PRK or LASIK?
- Should I have PRK or LASIK surgery in my other eye?
- How long will I have to wait before I can have surgery on my other eye?
- What vision problems might I experience if I have PRK or LASIK only on one eye?

Discuss the cost of surgery and follow-up care requirements with your doctor, as laser treatment is not covered by most health insurance policies.

Self-Test

Are You an Informed and Educated Patient?

Take the test below and see if you can correctly answer these questions after reading this booklet.

	TRUE	FALSE
1. Excimer laser refractive surgery is risk free.	[ ]	[ ]
2. Excimer laser surgery is the same as radial keratotomy (RK).	[ ]	[ ]
3. It doesn't matter if I wear my contact lenses when my doctor told me not to.	[ ]	[ ]
4. The laser does all the work; I just have to lie on the chair.	[ ]	[ ]
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.	[ ]	[ ]
6. I may need reading glasses after laser surgery.	[ ]	[ ]
7. There is a risk that I may lose some vision after laser surgery.	[ ]	[ ]
8. It doesn't matter if I am pregnant.	[ ]	[ ]
9. If I have an autoimmune disease, I am still a good candidate for PRK or LASIK.	[ ]	[ ]

Answers to SELF-TEST are found on page 23.

Summary of Important Information

- PRK and LASIK are permanent operations to the cornea and are irreversible.
- PRK and LASIK do not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least one year before PRK or LASIK surgery. You will need written evidence that your nearsightedness and/or astigmatism or farsightedness has changed less than 0.50 diopters.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- PRK and LASIK surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks before you agree to the surgery.
- PRK and LASIK are not laser versions of radial keratotomy (RK) or automated lamellar keratectomy (ALK). PRK and LASIK are completely different from RK and ALK.
- Alternatives to PRK and LASIK include, but are not limited to, glasses, contact lenses, RK, and ALK.
- Some people, such as military pilots, have job-related vision requirements that cannot be met by having RK, ALK, PRK, or LASIK.
- Before considering PRK or LASIK surgery you should:
  a. Have a complete eye examination.
  b. Talk with one or more eye care professionals about the potential benefits of PRK or LASIK surgery, and the compiications, risks, and time required for healing.

Answers to Self-Test Questions:

1. False (see Risks on page 10); **2.** False (see What are PRK and LASIK? on page 8); **3.** False (see Before The Surgery on page 13); **4.** False (see The Day of Surgery on page 14); **5.** True (see Benefits on page 9); **6.** True (see What are PRK and LASIK? on page 8); **7.** True (see Risks on page 10); **8.** False (see Contraindications on page 10); **9.** False (see Contraindications on page 10).

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VISX STAR S2™
Excimer Laser System

Photorefractive Keratectomy (PRK)

Laser Assisted In Situ Keratomileusis (LASIK)

Professional Use Information

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical management and treatment of refractive errors.

This document provides information concerning the intended clinical use of the VISX STAR S2™ Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the VISX STAR S2™ Excimer Laser System Operator's Manual.

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

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Revision Record — Professional Use Information 0030-2305			
Revision	Description	Date	ECN #
A	LASIK Information added	11/19/99	7077

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General Warnings

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical treatment and management of refractive errors.

Performance of procedures, use of controls, or any other adjustments other than those specified herein may result in a hazardous condition.

Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol.

All patients must be given the opportunity to read and understand the Patient Information Booklet and to have all their questions answered to their satisfaction before giving consent for Photorefractive Keratectomy (PRK) or Laser Assisted In Situ Keratomileusis (LASIK) surgery.

GAS HANDLING: High-pressure gas cylinders are contained in a protected compartment within the VISX STAR S2™ Excimer Laser System. Storage of additional cylinders and the replacement of used cylinders must be done in accordance with "Gas Safety" (Section 4.5) and "Gas Maintenance" (Section 12.1) and must comply with all applicable Occupational Safety and Health Administration (OSHA), local, and national requirements for gas safety.

The premix (argon/fluorine) gas mixture used in this laser system is highly toxic. VISX, Incorporated, recommends that anyone working with the gas cylinders: 1) be trained in the proper handling of toxic and compressed gases, 2) know the location of the emergency exhaust fan/room purifier switch, 3) have easy access to all required protective equipment, and 4) be familiar with safety procedures and Materials Safety Data Sheets (MSDS) provided by the site's safety officer. Gas discharge into the atmosphere may be evidenced by a sharp, penetrating odor and by eye, nose, and throat irritation.

SKIN AND EYE EXPOSURE: The VISX STAR S2 System contains a Class IV laser with an output at 193 nm, which is potentially hazardous to the skin and the surface layers of the cornea. This laser radiation will not enter the eye and poses no threat to retinal structures or the crystalline lens. The fixed optical system restricts the beam path, which is bounded by the operating table or the floor. Reflectivity from objects in operating rooms, including surgical instruments, is extremely low for 193 nm radiation.

The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam. All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance from the primary beam.

PRECAUTIONS: Carefully read all instructions prior to use.The laser beam is invisible. The user cannot tell if the laser is emitting radiation by looking for the beam. Observe all contraindications, warnings, and precautions noted in this manual. Failure to do so may result in patient and/or user complications. This laser system is not for use in mobile clinics. Device performance in a mobile clinic has not been tested.

ELECTROMAGNETIC FIELD (EMF): The thyratron emits an electromagnetic pulse which is shielded by the metal coverings of the VISX STAR S2 Excimer Laser System. This metal covering reduces the EMF below the limits set by applicable standards for electromagnetic compliance.

WARNING: The effects of electromagnetic emissions from the excimer laser system on other devices, such as cardiac pacemakers or implanted defibrillators, is unknown. Operation of the laser in proximity to such devices is not recommended.

AIRBORNE CONTAMINANTS: Airborne contaminants which are produced by the ablation process are captured in proximity to the cornea near the point of production and fed into an aspirator with a filter. This aspirator is designed to prevent any of the products of ablation from contaminating the surgical suite.

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1.0 Device Description

The VISX STAR S2 System is designed to create a superficial lamellar keratectomy on exposed corneal tissue. Corneal tissue is removed by a process known as Ablative Photodecomposition. Ablative Photodecomposition occurs when far-ultraviolet radiation reacts with organic molecules, resulting in the photochemical breakdown of the molecular bonds without a significant local thermal effect. The source of the far-ultraviolet photons is a high-efficiency, gas-discharge excimer laser that electronically excites a combination of argon and fluorine, producing an ultraviolet wavelength of 193 nm.

The VISX STAR S2 Excimer Laser System combines submicron precision of tissue removal by an excimer laser with a sophisticated computer controlled delivery system. Features and components of the VISX STAR S2 System include:

Excimer Laser
An argon-fluoride excimer laser module, with an output wavelength of 193 nm.

Gas Management System
A gas cabinet containing a working gas cylinder for laser operation; a gas cleaning system; a gas leak audio alarm with a sensor to detect fluorine (one part-per-million); a gas discharge system, using an activated charcoal filter to absorb fluorine; an emergency safety system using a positive-action solenoid safety valve, which automatically seals the premix cylinder in the event of a power failure; and a second charcoal scrubber to neutralize fluorine in case of a leak.

Laser Beam Delivery System
Beam shaping and homogenizing optics designed to produce a uniform, coaxial beam profile; a spatial integrator and beam rotator for temporal integration; and an iris diaphragm and rotating slit blades used to shape the beam.

Patient Management System
An operating microscope with reticle, used to observe a patient procedure and to facilitate accurate focus and laser beam alignment; a debris-removal system designed to evacuate the debris plume that occurs during ablation; a patient operating chair used to align the patient for treatment; a video camera and monitor used to record and monitor patient treatment; an illumination device used to illuminate the patient's eye for observation and treatment, and a fixation LED used by the patient to maintain proper alignment during treatment.

Computer Control
An IBM-compatible computer and video monitor; a computer keyboard with trackball for user interface; a printer; a VisionKey card driver; and system software.

VisionKey Card
A write-once-read-many (WORM) optical memory card designed to allow compilation, storage, and printout of essential patient data and procedural information.

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2.0 Indications, Contraindications, Warnings, Precautions, and Adverse Events

2.1 Indications for Use

Photorefractive Keratectomy (PRK) procedure using the VISX STAR S2 System is intended for use:

- in patients with documented evidence of a change in manifest refraction of less than or equal to 0.5 D (in both cylinder and sphere components) per year for at least one year prior to the date of pre-operative examination; and
- in patients 18 years of age or older in PRK treatments for the reduction or elimination of myopia (nearsightedness) of less than or equal to -6.0 D spherical equivalent at the corneal plane with less than or equal to -1.0 D of astigmatism; or
- in patients 21 years of age or older in PRK treatments for the reduction or elimination of myopia (nearsightedness) of between 0 and -12.0 D spherical myopia at the spectacle plane with up to -4.0 D of astigmatism; or
- in patients 21 years of age or older in PRK treatments of naturally occurring hyperopia between +1.0 and +6.0 D spherical equivalent, with no more than 1.0 D of refractive astigmatism.

Laser Assisted In Situ Keratomileusis (LASIK) procedure using the VISX STAR S2 System is intended for use:

- in patients 18 years of age or older in treatments for the reduction or elimination of myopia (nearsightedness) from 0 to -14.0 D with or without astigmatism from -0.50 to -5.0 D.

Caution must be used to calculate treatment in MINUS CYLINDER at the spectacle plane (vertex distance 12.5 mm) before entering the refraction into the laser in order to conform with the Indications for Use.

Refer to the preceding General Warnings section of this Professional Use Information Manual, in addition to the warnings and precautions found in this section.

2.2 Contraindications

PRK or LASIK surgery is contraindicated:

- in patients with collagen vascular, autoimmune or immunodeficiency diseases.
- in pregnant or nursing women.
- in patients with signs of keratoconus.
- in patients who are taking one or both of the following medications: isotretinoin (Accutane); amiodarone hydrochloride (Cordarone).

2.3 Warnings

- The decision to perform PRK or LASIK surgery in patients with systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease, or an immunocompromised status, should be approached cautiously. The safety and effectiveness of the VISX STAR S2 System has not been established in patients with these conditions.
- Neither PRK nor LASIK is recommended in patients with a history of ophthalmic *Herpes simplex* or *Herpes zoster.*
- Lower uncorrected visual acuity rates for 20/20 and 20/40 may be anticipated for higher degrees of correction of myopia and astigmatism.

2.4 Precautions

A. General

There is no safety and effectiveness information for PRK refractive treatments greater than -12.0 D of myopia or greater than -4.0 D of astigmatism.

To avoid corneal ectasia, the posterior 250 microns (μm) of corneal stroma should not be violated by the laser or the microkeratome.

Of the eyes treated in these (PRK) trials, only 21/200 (10.5%) of highly myopic eyes had myopia between 10 and 12 diopters and only 13/275 (4.7%) of hyperopic eyes had hyperopia between 4 and 6 diopters. These populations may not have been sufficient to determine the level of effectiveness or the complication rates for this refractive error range with the same reliability as for eyes with less severe refractive errors.

PRK patients with **+4.0 to +6.0 D of hyperopia** may be at a greater risk of regression of correction.

2.1% of hyperopic PRK patients with pre-operative Best Spectacle Corrected Visual Acuity (BSCVA) of 20/20 or better, had post-operative BSCVA of worse than 20/25, but not worse than 20/32.

Sufficient data were provided to evaluate treatment to -14.0 diopters of sphere and -5.0 diopters of cylinder; however, there were insufficient eyes treated with a combination of -12.0 diopters of sphere and -3.5 or higher diopters of myopic cylinder to determine the level of effectiveness or the complication rates for this refractive error range with the same reliability as for eyes with less severe refractive errors.

The effects of PRK or LASIK on visual performance under poor lighting conditions have not been determined. It is possible, following PRK or LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes.

Astigmatic patients between the ages of 21 and 30 should be reminded that, due to larger pupils, they are more likely than the over-30-year-old population to experience a degradation in visual performance under these conditions.

The safety and effectiveness of the VISX STAR S2 System have **NOT** been established:

- For PRK treatment of astigmatism in patients with refractive cylinder of less than 0.75 D.
- For PRK hyperopia treatment of patients with refractions less than +1.0 D.
- For LASIK and PRK in patients with progressive myopia, progressive astigmatism, ocular disease, corneal abnormality, previous corneal surgery, or trauma in the ablation zone.
- For LASIK and PRK in patients with corneal neovascularization within 1.0 mm of the ablation zone.
- For PRK in patients under 21 years of age with myopia greater than -6.0 D and astigmatism greater than -1.0 D.
- For PRK in patients under 18 years of age with myopia up to -6.0 D and astigmatism less than -1.0 D.
- For PRK in patients under 21 years of age with hyperopia between +1.0 and +6.0 D spherical equivalent, with no more than 1.0 D of astigmatism.
- For LASIK in patients under 18 years of age.
- Over the long term: More than 3 years after PRK surgery for low myopia; more than 1 year after PRK surgery for high myopia with astigmatism; 1 year after PRK surgery for hyperopia; or more than 6 months after LASIK surgery for myopia with or without astigmatism.
- For PRK in patients with a history of keloid formation.
- For PRK and LASIK in patients who are taking sumatriptan (Imitrex).

- For PRK in patients taking hormone replacement therapy or antihistamines who may have delayed re-epithelialization of the cornea following surgery.
- For LASIK in patients treated for myopia with or without astigmatism who have had prior incisional refractive surgery.
- For LASIK treatments greater than -14.0 D of myopia or -5.0 D of myopic astigmatism.

B. Patient Selection

Consideration should be given to the following in determining the appropriate patients for PRK or LASIK:

- Complete examination, including but not limited to, cycloplegic evaluation, must be performed. The lens must be evaluated, especially in the older patient, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Myopic patients will have a higher incidence of retinal pathology, and indirect ophthalmoscopy through a dilated pupil is essential.
- To obtain accurate refractive information, contact lens wearers must be examined after abstaining from contact lens use for at least 2 weeks for soft lenses and at least 3 weeks for hard lenses. Prior to treatment and after at least 3 weeks of contact lens abstinence, patients who wear rigid gas permeable or hard (PMMA) lenses must have 3 central keratometry readings and manifest refractions taken at 1 week intervals, the last 2 of which must not differ by more than 0.50 diopter in either meridian. All mires must be regular. Any patient with keratometry or a clinical picture that is suggestive of keratoconus is specifically contraindicated as described above.
- Glaucoma is more common in myopic patients than in the general population. Evaluation of the optic nerve and measurement of the intraocular pressure are necessary. If there are any concerns regarding the appearance of the optic nerve, a Humphrey 24-2 Fastpac or equivalent threshold test of the visual field should be performed. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should be used only with careful medical supervision or the patient should not undergo PRK or LASIK surgery.
- Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.
- Baseline evaluation of patients requesting refractive surgery should be performed within 30 days of the PRK or LASIK surgery.
- The patient should have the ability to tolerate local or topical anesthesia.
- The patient should have the ability to lie flat without difficulty.

- The patient should be able to fixate steadily and accurately for the duration of the PRK or LASIK procedure.
- The patient must be able to understand and give an informed consent.
- Patients must be clearly informed of all alternatives for the correction of myopia and/or astigmatism. These alternative corrections include but are not limited to spectacles, contact lenses, and other refractive surgeries such as radial keratotomy or automated lamellar keratoplasty.

C. Procedure

The output of the laser is potentially hazardous only to the skin and the surface layers of the cornea. This radiation has not been shown to pose a threat to retinal structures or the crystalline lens. The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam.

All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance to the primary beam.

D. Post-Procedure

PRK

A slit-lamp examination should be performed on a daily basis until re-epithelialization is complete. After re-epithelialization, the following examinations are recommended at a schedule of at least 1, 3, 6, and 12 months:

- Uncorrected Visual Acuity (UCVA or VA-sc).
- Manifest refraction with the Best Spectacle Corrected Visual Acuity (BSCVA or VA-cc).
- Intraocular pressure (IOP).
- Slit-lamp examination, including corneal clarity evaluation.
- Videokeratography at 6 months (sooner only if unanticipated events occur during the healing process).
- If topical steroids are used post-operatively, patients should be monitored for development of possible steroid side-effects, including but not limited to ocular hypertension, glaucoma, and/or cataract.

LASIK

The following post-operative examinations are recommended on day 1 or day 2, and at 1, 3, and 6 months:

- Uncorrected Distance Visual Acuity.
- Best Spectacle Corrected Distance Visual Acuity.
- Manifest refraction.
- Cycloplegic refraction, performed at least 30 minutes after instillation of 1 or 2 drops of Cyclogyl 1-2% at 3 months.
- Intraocular pressure (Goldmann applanation) at 3 months.
- Central keratometry at 3 and 6 months.
- Slit-lamp examination.
- Computerized corneal topography at 3 and 6 months.

2.5 PRK and LASIK Adverse Events

There was no patient death related to the use of the VISX STAR S2 System.

The following transient complications might be expected with patients undergoing the PRK procedure: pain (24-48 hours), foreign body sensation, tearing, photophobia, redness, itching/scratchiness, burning, dryness, headache, blurred vision, corneal swelling, and pupil enlargement.

Other adverse events that might be expected with patients undergoing the PRK procedure but have not been observed in the VISX clinical studies are corneal perforations, intraocular infections, hyphemas, hypopyon, post-treatment lens abnormalities with vision loss, significant overcorrections, persistent corneal decompensation/edema, or cystoid macular edema.

Adverse events that might be expected with patients undergoing the LASIK procedure are glare, halos, monocular diplopia/polyopia, surface irregularity associated with cap healing, irregular ablations, decentered ablations, foreign body sensation, corneal scarring, keratitis (infectious or sterile) with the possible sequelae of corneal ulceration or perforation, dellen formation, foreign bodies in the interlamellar interface, vitreoretinal hemorrhage, cataract, corneal decompensation, and tenderness to touch.

Excimer laser energy has the potential to induce micromechanical damage to endothelial cells, induce cataracts, and cause mutations. These effects have not been observed in any clinical use, nor have they been reproducible in various animal and *in vitro* test systems.

2.5.1 PRK Adverse Events

A. Low Myopia

Nine hundred and nine (909) eyes of 676 subjects were used for safety analyses. Five hundred and forty-two (542) eyes were followed for at least 24 months.

Adverse events for 1 month and later are presented in Table 2-1.

Table 2-1 — Low Myopia Adverse Events (PRK)
Eyes Treated with 6.0 mm Ablation Zone (n = 909)*

Adverse Event Description	3 to 6 M (n = 846)**		12 M (n = 520)**		≥ 24 M (n = 542)**	
	n	%	n	%	n	%
1. Loss ≥ 2 Lines of BSCVA	50	6.0◆	11	2.2	1	0.2
2. Pre-treatment BSCVA 20/20 or Better						
With Post-treatment BSCVA Worse than 20/25	52	6.4◆	10	2.1◆	7	1.3
With Post-treatment BSCVA Worse than 20/40	7	0.9	1	0.2	0	0
3. Overcorrection:						
>1 D	44	5.2	6	1.2	7	1.3
>2 D	9	1.1	1	0.2	3	0.6
4. Increase in Refractive Cylinder:						
≥ 1 D	46	5.5	16	3.1	16	3.0
≥ 2 D	3	0.4	0	0	0	0
5. Glare Testing: Abnormal (≥ 2 line loss in BSCVA with glare)	1	1.0◆	1	1.7◆	0	0
6. IOP Increase:						
> 5 to 10 mm Hg	61	7.3	9	1.8◆	19	3.6◆
>10 mm Hg	7	0.8	0	0	0	0
7. Corneal Haze ≥ Grade 2	11	1.3	3	0.6	1	0.2
8. Corneal Infection/Ulcer/Infiltrate	0	0	0	0	0	0
9. Corneal Decompensation/Edema	0	0	0	0	0	0
10. Lens Abnormality Post-treatment†	2	0.2	1	0.2	3	0.6
11. Secondary Surgical Intervention:						
Single Retreatments	1	0.1	22	4.2	2	0.4
Double Retreatments	0	0	0	0	0	0
Other Refractive Procedures	4	0.5	14	2.7	9	1.7
12. Subjective Patient Responses†† :						
"Double/Ghost Images" ††						
Somewhat Worse	14	1.7	3	0.6	4	0.7
Much Worse	9	1.1	5	1.0	3	0.6
"Sensitivity to Bright Lights" ‡,††						
Somewhat Worse	30	3.5	19	3.7	14	2.6
Much Worse	5	0.6	6	1.6	2	0.4
"Difficulty with Night Vision" ‡,††						
Somewhat Worse	29	3.4	14	2.7	11	2.0
Much Worse	12	1.4	13	2.5	10	1.8

* Last Observation - Post-retreatment data not included.

** For all adverse events, percentages are given as:

$$\frac{\text{number of eyes with at least one occurrence observed at the specified study visit}}{\text{number of eyes examined at the specified study visit}}$$

◆ These values were calculated using an (n) value slightly smaller than the (n) shown in the column heading due to missing measurements.

† Adverse Event #10: lens abnormality post-treatment counted by first occurrence.

†† Reflects patient responses obtained from subjective questionnaires.

‡ Results of questionnaire responses were not validated by glare testing in a clinical setting.

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B. High Myopia

Two hundred (200) eyes of 157 subjects were used for safety analyses. One hundred and fifty-six (156) eyes were followed for at least 12 months.

During clinical trials, no new issues of patient safety or effectiveness were identified in the greater than 10 diopter range of pre-operative myopia. Because of the low numbers of patients (10.5%, 21/200) with myopia between the 10 and 12 diopters treated in these trials, there may not have been a sufficient population to determine the level of effectiveness or the complication rates for this refractive error range.

Adverse events for visits 6 months and later are presented in Table 2-2.

Table 2-2 — High Myopia Adverse Events* (PRK) (n = 200)

Adverse Event Description	6M (n = 199)		12M (n = 156)	
	n	%	n	%
1. Loss of ≥ 2 lines BSCVA due to				
All Causes	17	8.5	9	5.8
Corneal Causes	15	7.5	8	5.1
2. Pre-treatment BSCVA 20/20 or Better with a				
Post-treatment BSCVA Worse than 20/25	14	7.0	7	4.5
Post-treatment BSCVA Worse than 20/40	0	0	2	1.3
3. IOP Increase**				
> 5 mm Hg from baseline	5	2.7	1	0.7
> 10 mm Hg from baseline	2	1.1	0	0
> 25 mm Hg	1	0.5	0	0
4. Corneal Haze†				
With loss of ≥ 2 lines BSCVA	7	3.5	2	1.3
With loss of > 2 lines BSCVA	4	2.0	2	1.3
5. Retreatments not for primary undercorrection	0	0	3	1.5

* Patient survey not conducted for subjective evaluations of vision after surgery.

** There is a lower "n" for IOP data due to missing values (6M n=185 and 12M n=148).

† There is a lower "n" for Haze data due to missing values (12M n=153).

C. Myopic Astigmatism

One hundred and sixteen (116) eyes of 71 subjects, treated at five U.S. centers, were used for safety analyses. Eighty-two (82) of these eyes were followed for at least 2 years.

Adverse events for visits 6 months and later are presented in Table 2-3. They are ordered by frequency at final visit.

Table 2-3 — Myopic Astigmatism Adverse Events (PRK) (n = 116)

Adverse Events	6 M (n = 108)		12 M (n = 92)		Final Visit‡ (n = 82)	
	n	%	n	%	n	%
1. Loss of ≥ 2 lines BSCVA						
Due to Any Cause	5	4.6	6	6.5	7	8.5*
Due to Corneal Causes	4	3.7	4	4.3	4	4.9*
2. Pre-treatment BSCVA 20/20 or Better						
With Post-treatment BSCVA						
Worse than 20/25	5	4.8	4	4.3	5	6.1
With Post-treatment BSCVA						
Worse than 20/40	0	0	2	2.2	0	0
3. Secondary Surgical Intervention						
Retreatments	0	0	4	4.3	5	6.1
4. IOP Increase						
> 5 to 10 mm Hg	8	7.4	2	2.2	2	2.4
>10 mm Hg	0	0	0	0	0	0
5. Corneal Haze ≥ Grade 2	2	1.9	4	4.3	1	1.2
6. Secondary Surgical Intervention						
Other Refractive Procedures	0	0	1	1.1	0	0
7. Subjective Patient Responses††:						
"Double/Ghost Images"††						
Somewhat Worse	5	4.6	1	1.1	5	6.1
Much Worse	1	0.9	4	4.3	0	0
"Sensitivity to Bright Lights"††						
Somewhat Worse	13	12.0	6	6.5	6	7.3
Much Worse	5	4.6	6	6.5	7	8.5
"Difficulty with Night Vision" ††						
Somewhat Worse	16	14.8	9	9.8	13	15.9
Much Worse	12	11.1	8	8.7	6	7.3

Percentages of safety outcomes are reported as:

$$\frac{\text{number of eyes with at least one occurrence observed/reported at the specified study visit}}{\text{number of eyes examined at the specified study visit}}$$

* Includes two eyes in one patient who had cataract formation upon enrollment and one eye of one patient who had a stroke; these losses of BSCVA were not attributed to corneal wound healing. **At no time did any eye lose BSCVA beyond 20/50 and at the Final Visit no eye was worse than 20/40-1.**

‡ The final visit occurred at 24 ± 3 months after treatment.

†† Reflects patient responses obtained from subjective questionnaires.

D. Hyperopia

One hundred and twenty-four (124) subjects, treated at eight U.S. centers were used for safety analyses. The subjects were followed for at least 12 months.

Adverse events are presented in Table 2-4.

Table 2-4 — Hyperopia Adverse Events (PRK)

Adverse Events*	6 M (n = 201)		12 M (n = 115)	
	n	%	n	%
1. Decrease in BSCVA:				
> 2 Lines	2	1.0	1	0.9
2 Lines	0	0	3	2.6
Worse than 20/40	0	0	1	0.9
2. Pre-treatment BSCVA 20/20 or Better with a				
Post-treatment BSCVA Worse than 20/25	0	0	2	2.1*
Post-treatment Worse than 20/40	0	0	0	0
3. Increase >2.0 D Cylinder	0	0	1	0.9
4. Corneal Haze ≥ Grade 2	0	0	1	0.9
5. IOP Increase				
> 5 to 10 mm Hg	1	0.5*	1	0.9*
> 10 mm Hg	0	0	0	0
6. Overcorrection >1.0 D	4	2.0	3	2.6
7. Subjective Patient Responses††				
"Double/Ghost Images"††				
Somewhat Worse	6	3.0	6	5.2
Much Worse	4	2.0	1	0.9
"Sensitivity to Bright Lights"**,††				
Somewhat Worse	11	5.5	7	6.1
Much Worse	1	0.5	1	0.9
"Difficulty with Night Vision"**,††				
Somewhat Worse	8	4.0	5	4.3
Much Worse	2	1.0	2	1.7

* The percentage of adverse events reported reflects the actual number of occurrences reported divided by the number of data points available for each visit. Therefore, the percent reported may differ from the apparent value due to missing data points.

** Extensive contrast sensitivity and glare testing under mesopic and photopic conditions did not yield any statistically significant losses, nor any losses that could be interpreted as clinically significant.

†† Reflects patient responses obtained from subjective questionnaires.

2.5.2 LASIK Adverse Events and Complications

A. Myopia With or Without Astigmatism

Twelve hundred and seventy-six (1276) eyes were used for safety analyses. Eight hundred and sixty-seven (867) eyes were followed for at least 6 months. The following Adverse Events (AEs) occurred at a rate of less than 1% at 6 months: Loss of 2 or more lines of BSCVA; BSCVA less than 20/40; increase of 2 D or more of cylinder; BSCVA less than 20/25 when the pre-operative eye was 20/20 or better; flap edema; interface epithelium; persistent staining; stromal edema; uncontrolled IOP; and wrinkling of the cap.

The following Adverse Events (AEs) did not occur: Corneal infiltrate or ulcer; melting of the flap; late onset of haze; retinal detachment; retinal vascular accidents.

Intra-operative complications are presented in Table 2-5.

Table 2-5 — LASIK Intra-Operative Complications (n = 1276)

Damage to Epithelium	**7 (0.5%)**
Epithelial Defect	**8 (0.6%)**
Free Cap	**54 (4.2%)**
Oval Keratectomy	**9 (0.7%)**
Small Flap	**2 (0.2%)**
Small Flap with Thin Flap	**1 (0.1%)**
Surgery Aborted: Inadequate Flap	**2 (0.2%)**
Thin Flap	**4 (0.3%)**

Patient Findings

Patients graded their glare, halo, and visual fluctuations complaints before and at 3 months post-operatively. Severe glare was reported in 9% of subjects pre-operatively while 6% of subjects complained of severe glare at 3 months post-operatively. Severe halos were reported in 9% of subjects pre-operatively while 4% of subjects complained of severe halos at 3 months post-operatively. Four percent of subjects reported severe fluctuations pre-operatively while 2% of subjects complained of severe fluctuations at 3 months post-operatively.

3.0 PRK and LASIK Clinical Results

3.1 PRK Clinical Results

3.1.1 Low Myopia

A prospective, non-randomized, unmasked, multicenter clinical study was conducted. The refractive inclusion criteria specified that the primary eye have myopia of 1.0 to 6.0 D spherical equivalent at the corneal plane with astigmatism less than or equal to 1 D.

Patients who exhibited any of the following conditions were excluded: keratoconus; active ocular disease likely to affect wound healing; unstable central keratometry readings with irregularly shaped mires or corneascope photographs with broken central rings; use of systemic medications likely to affect wound healing; and an immunocompromised status.

A. About the Study

Nine hundred and nine (909) eyes treated at 6.0 mm comprised the cohort of eyes used for safety evaluations. These 909 eyes were treated between May 1992 and May 1995. Efficacy evaluations were done on 480 eyes from the 909-eye cohort. These 480 eyes were treated between May 1992 and October 1993 at nine participating centers. The patients were evaluated pre-operatively, every 24 to 48 hours post-operatively until re-epithelialization, and at 1, 3, 6, 12, 18, and 24 months post-treatment.

Both pre- and post-operatively, the patients were asked whether they experienced any visual symptoms. Following surgery, satisfaction with the procedure was assessed periodically. Objective measurements included: uncorrected and best spectacle corrected visual acuity (UCVA and BSCVA), manifest refraction, keratometry, intraocular pressure (IOP), pachymetry, clinical assessment of corneal clarity (haze), the anterior chamber, vitreous, retina and lens, and assessment of complications or adverse events.

Additional post-operative evaluations were performed in subsets of subjects as follows: cycloplegic refraction, corneal topography, glare testing, contrast sensitivity, endothelial cell counts, and visual fields.

B. Patient Accountability

The cohort evaluated for safety was comprised of 909 eyes treated. The cohort evaluated for efficacy was comprised of 480 eyes representing the subset of eyes that met the inclusion criteria and completed ≥2 years of follow-up.

C. Data Analysis And Results

1) Pre-Operative Characteristics

Pre-operative characteristics are presented for 480 eyes treated with a 6.0 mm ablation zone and ≥2 years follow-up:

Table 3-1 — Pre-Operative UCVA (n = 480) *

20/100 or Worse		20/50 to 20/80		20/25 to 20/40	
n	%	n	%	n	%
454	94.6	24	5.0	2	0.4

* Percentages may not add to 100.0 due to rounding.

Table 3-2 — Low Myopia: Pre-Operative BSCVA (n = 480) *

20/40		20/30 to 20/25		20/20 or Better	
n	%	n	%	n	%
1	0.2	13	2.7	466	97.1

* Percentages may not add to 100.0 due to rounding.

Table 3-3 — Low Myopia: Pre-Operative Myopia/Spherical Equivalent (n = 480) *

1 to < 2 D		2 to < 3 D		3 to < 4 D		4 to < 5 D		5 to 6 D	
n	%	n	%	n	%	n	%	n	%
37	7.7	75	15.6	119	24.8	128	26.7	121	25.2

* Percentages may not add to 100.0 due to rounding.

2) Post-Operative Results

Table 3-4 represents a summary of efficacy data for 480 eyes treated and ≥2 years follow-up stratified by pre-treatment myopia. This table presents data based on the Last Observed (LO) data analysis. The LO analysis presents data from the initial treatment only; thus, data for eyes after retreatment are excluded.

Table 3-4 — Low Myopia: Efficacy > 2 Years Follow-up**
First Treatment Only (Last Observed) (n = 480)

Pre-treatment Myopia	1 to < 2 D (n = 37 Eyes)		2 to < 3 D (n = 75 Eyes)		3 to < 4 D (n = 119 Eyes)		4 to < 5 D (n = 128 Eyes)		5 to 6 D (n = 121 Eyes)		ALL (n = 480 Eyes)	
Efficacy Parameter	n	%	n	%	n	%	n	%	n	%	n	%
1. UCVA 20/20 or Better (Pre-treatment: n = 0)	26	70.3	51	68.0	66	55.5	77	60.2	60	49.6	280	58.3
2. UCVA 20/25 or Better (Pre-treatment: n = 0)	32	86.5	63	84.0	92	77.3	103	80.5	93	76.9	383	79.8
3. UCVA 20/40 or Better (Pre-treatment: n = 2)	35	94.6	72	96.0	110	92.4	121	94.5	112	92.6	450	93.8
4. Dev. From Intended Within ± 1 D	33	91.7‡	69	92.0	111	93.3	113	88.3	106	87.6	432*	90.2‡
5. Dev. From Intended ≤ 1 D (Not Overcorrected)	36	100.0‡	74	98.7	119	100.0	127	99.2	118	97.5	474*	99.0‡
6. Dev. From Intended ≥ -1 D (Not Undercorrected)	33	91.7‡	70	93.3	111	93.3	114	89.1	109	90.1	437*	91.2‡
7. Cases with BSCVA 20/20 or Better Pre-treatment and UCVA of 20/25 or Better AND a Spherical Equivalent Between -1.0 D and +0.5 D Post-treatment	30	85.7‡	61	82.4‡	86	74.8‡	95	76.0‡	87	75.7‡	359*†	77.4‡
8. Spherical Equivalent > +1 D	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	1*	0.2

* One patient did not stay to have refractive exam.

† 15 other eyes had pre-treatment BSCVA worse than 20/20.

** Follow-up based upon eyes treated on or before 10/20/93.

‡ These values were calculated using an (n) value slightly smaller than the (n) shown in the column heading due to missing measurements.

a) Uncorrected Visual Acuity (UCVA)

Table 3-5 shows the distribution of uncorrected visual acuity, pretreatment and post-treatment. Pre-operatively, 0.4% of eyes had a UCVA better than or equal to 20/40. At 1 month after treatment, 32.3% of the eyes had a UCVA of 20/20 or better and 89.7% were 20/40 or better. At 2 years or more post-treatment, 58.3% of the patients were 20/20 or better and 93.8% were 20/40 or better.

Table 3-5 — Low Myopia: Uncorrected Visual Acuity (UCVA) (n = 480)

Visual Acuity	Preop (n = 480)		1 M (n = 436)		3 M (n = 415)		6 M (n = 421)		12 M (n = 344)		18 M (n = 294)		≥ 24 M (n = 480)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
20/20 or Better	0	0.0	141	32.3	187	45.1	235	55.8	219	63.7	193	65.6	280	58.3
20/25 – 20/40	2	0.4	250	57.3	197	47.5	163	38.7	108	31.4	87	29.6	170	35.4
20/50 – 20/80	24	5.0	40	9.2	28	6.7	23	5.5	16	4.7	13	4.4	28	5.8
20/100 or Worse	454	94.6	5	1.1	3	0.7	0	0.0	1	0.3	1	0.3	2	0.4

b) Reduction of Myopia

In Table 3-6, the spherical equivalent data (based upon manifest refraction) demonstrates the reduction of myopia, with most cases near emmetropia (defined as a spherical equivalent within ± 1 D of intended) post-treatment. At 1 month post-treatment, 86.9% of the eyes were ± 1 D and at ≥24 months post-treatment this percentage had increased to 90.8%.

There is an initial hyperopic overshoot in some cases at 1 month post-treatment (10.6% of eyes had a spherical equivalent of ≥+1 D). However, there is a statistically significant decrease of this effect at 1 and 2 years post-treatment (1.2% and 0.4% of eyes, respectively, remained ≥+1 D).

Table 3-6 — Low Myopia: Reduction of Myopia (n = 480)

Spherical Equivalent	Preop (n = 480)		1 M (n = 434)		3 M (n = 411)		6 M (n = 419)		12 M (n = 342)		18 M (n = 294)		≥ 24 M (n = 479*)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Myopia ≥ 3 D	368	76.7	1	0.2	2	0.5	4	1.0	1	0.3	1	0.3	1	0.2
Myopia 2 – < 3 D	75	15.6	3	0.7	7	1.7	3	0.7	1	0.3	2	0.7	3	0.6
Myopia 1 – < 2 D	37	7.7	30	6.9	41	10.0	34	8.1	42	12.3	33	11.2	61	12.7
± 0.5 D	0	0.0	297	68.4	286	69.6	300	71.6	254	74.3	214	72.8	339	70.8
± 1 D	1	0.2	377	86.9	370	90.0	387	92.4	309	90.4	269	91.5	435	90.8
Hyperopia 1 – < 2 D	0	0.0	37	8.5	10	2.4	7	1.7	3	0.9	2	0.7	2	0.4
Hyperopia 2 – < 3 D	0	0.0	7	1.6	3	0.7	1	0.2	1	0.3	0	0.0	0	0.0
Hyperopia ≥ 3 D	0	0.0	2	0.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* One patient did not stay to have refractive exam.

c) Deviation from Intended Correction (Predictability of Outcome)

In Table 3-7, the predictability of outcome has been assessed as the extent of deviation from intended correction (i.e., difference between achieved correction and intended correction). The intended final refractive error may not have been plano in certain cases (i.e., intended undercorrection for monovision). The percent of cases within ± 0.5 D and ± 1 D, respectively, of attempted correction remains relatively stable throughout the 24-month period. At 2 or more years, 90.2% of cases were within ± 1 D of attempted correction.

Table 3-7 — Low Myopia: Deviation From Intended Correction (n = 480)

Diopter	1 M (n = 434)		3 M (n = 411)		6 M (n = 419)		12 M (n = 342)		18 M (n = 294)		≥ 24 M (n = 479*)	
	n	%	n	%	n	%	n	%	n	%	n	%
± 0.5	261	60.1	265	64.5	288	68.7	233	68.1	203	69.0	309	64.5
± 1	363	83.6	362	88.1	384	91.6	310	91.6	270	91.8	432	90.2

* One patient did not stay to have refractive exam.

3) Stability of Outcome

Stability of mean line improvement in UCVA and mean deviation from intended correction between the 12- to 18-month, 18- to 24-month, and 12- to 24-month time periods were assessed to evaluate stability of the visual and refractive outcome. There are no statistically significant differences in mean lines improved between any of the time periods assessed ($p>0.75$). Therefore, the mean line improvement in UCVA following treatment with the VISX STAR S2 System remains stable over the 12-, 18-, and 24-month periods. When all eyes evaluated at each visit are plotted, the curve is not statistically significantly different.

Stability of the mean spherical equivalent has been assessed at each of the 1-, 3-, 6-, 12-, 18-, and 24-month time points following initial treatment. Results of this analysis show that the mean pre-operative refractive error of -4.07 D was reduced to almost plano (0.08 D) at 1 month following treatment. At 3 months the mean myopia is 0.19 D and remains unchanged at 6, 12, 18, and 24 months. There is no statistically significant difference in the amount of myopia at each follow-up period ($p>0.15$).

Myopic shift (regression of effect) has also been assessed using the data available at pretreatment, 1, 3, 6, 12, 18, and 24 months. Myopic shift based on mean spherical equivalent over time during the follow-up period is not statistically significant ($p>0.15$). Although 43/247 eyes (17.4%) had a myopic shift of 0.5 D from 12 to 24 months, only 7/247 (2.8%) of those eyes had a myopic shift of ≥1 D.

4) Retreatments

Retreatment data are presented for the initial cohort of the 909 eyes treated with a 6.0 mm ablation zone. Patients were eligible for retreatment after 6 months of follow-up. Thirty-three eyes (3.6%) were retreated. The data analyses for retreatment are presented in Table 3-8 through Table 3-12.

Table 3-8 — Low Myopia: Summary of Retreatment (n = 909)

Reason for Retreatment	Number of Eyes	Percentage of Retreated Eyes (n = 33)	Percentage of All Eyes (n = 909)
Regression*	9	27.3	1.0
Undercorrection**	12	36.4	1.3
Regression w/Haze	5	15.2	0.6
Undercorrection w/ Regression and Haze †	3	9.1	0.3
Other: Decentered Ablation, Haze, Induced Cylinder	4	12.1	0.4
Total	33	100.0	3.6

* Regression: a myopic change in spherical equivalent of more than 0.5 D.

** Undercorrection: deviation from intended correction of ≤ 0.5 D.

† Haze: a grade of ≥1 at any time prior to retreatment.

Table 3-9 — Low Myopia: UCVA in Retreatment Cases (n = 33)*

	Pre-Treatment		Before Retreatment		After Retreatment	
UCVA	n	%	n	%	n	%
Better than 20/20	0	0.0	0	0.0	2	7.1
20/20 – 20/40	0	0.0	0	0.0	20	71.4
20/50 – 20/80	0	0.0	28	84.8	4	14.3
20/100 or worse	33	100.0	5	15.2	2	7.1
Total	33	100.0	33	100.0	28**	100.0

* Represents 33/909 (3.6%) of eyes requiring retreatment.

** 5 eyes did not have a visit ≥ 6 months after retreatment.

Table 3-10 — Low Myopia: BSCVA in Retreatment Cases (n = 33)*

BSCVA	Pre-Treatment		Before Retreatment		After Retreatment	
	n	%	n	%	n	%
Better than 20/20	4	12.1	2	6.1	4	14.8
20/20	27	81.8	21	63.6	18	66.7
20/25	2	6.1	5	15.2	4	14.8
20/30	0	0.0	4	12.1	0	0.0
20/40	0	0.0	0	0.0	1	3.7
20/50	0	0.0	1	3.0	0	0.0
Total	33	100.0	33	100.0	27**	100.0

* Represents 33/909 (3.6%) of eyes requiring retreatment.

** 5 eyes did not have visit ≥ 6 months after retreatment. One eye had missing BSCVA at the visit after retreatment.

Table 3-11 — Low Myopia: Spherical Equivalent in Retreatment Cases (n = 33)*

Spherical Equivalent	Pre-Treatment		Before Retreatment		After Retreatment	
	n	%	n	%	n	%
Myopia > 3 D	28	84.8	2	6.1	1	3.6
Myopia > 2 – 3 D	4	12.1	5	15.2	1	3.6
Myopia > 1 – 2 D	1	3.0	15	45.5	4	14.3
± 0.5 D	0	0.0	2	6.1	14	50.0
± 1 D	0	0.0	10	30.3	22	78.6
Hyperopia > +1 – +2 D	0	0.0	1	3.0	0	0.0
Total	33	100.0	33	100.0	28**	100.0

* Represents 33/909 (3.6%) of eyes requiring retreatment.

** 5 eyes did not have a visit ≥ 6 months after retreatment.

Table 3-12 — Low Myopia: Haze in Retreatment Cases (n = 33)*

Haze	Pre-Treatment		Before Retreatment		After Retreatment	
	n	%	n	%	n	%
0.0 – 0.5 Trace	33	100.0	28	84.8	25	92.6
1 – 1.5 Mild	0	0.0	3	9.1	1	3.7
2.0 Moderate	0	0.0	2	6.1	0	0.0
3.0 Severe	0	0.0	0	0.0	1	3.7
Total	33	100.0	33	100.0	27**	100.0

* Represents 33/909 (3.6%) of eyes requiring retreatment.

** 5 eyes did not have a visit ≥ 6 months after retreatment. One eye had missing Haze score at visit after retreatment.

5) Adverse Events

Refer to Table 2-1 in Section 2.5.

3.1.2 High Myopia

A prospective, non-randomized, unmasked, multicenter PRK clinical study was conducted. The refractive inclusion criteria specified that the primary eye have myopia of between -6.0 and -12.0 D spherical myopia at the spectacle plane (with a vertex distance of 12.5 mm), and concomitant reduction or elimination of astigmatism of up to 4.0 D at the spectacle plane (with a vertex distance of 12.5 mm) as determined by minus cylinder refraction. There were a total of 200 eyes treated (157 primary eyes and 43 fellow eyes). Patients who exhibited any of the following conditions were excluded: keratoconus; active ocular disease likely to affect wound healing; unstable central keratometry readings with irregularly shaped mires; use of systemic medications likely to affect wound healing; or patients with an immunocompromised status.

A. About the Study

Treated eyes were followed for at least 12 months. Analyses of results were performed for 6 months and 12 months visits. Effectiveness analyses included: reduction of astigmatism, vector analysis (intended versus achieved, residual cylinder), stability of correction over time, and uncorrected visual acuity. Safety analyses included: closely examining best spectacle corrected acuity losses of two or more lines ("significant losses"), slit lamp findings (e.g., haze), and IOP increases. Eyes with examinations at the 6-month and 12-month visits prior to retreatment are included in the effectiveness analyses. This approach is meant to present the data and not overstate effectiveness results. Safety issues are reported regardless of treatment or retreatment.

B. Patient Accountability

Two hundred (200) eyes of 157 subjects, treated at two international centers (one in Canada and one in England), were used for safety and effectiveness analyses. One hundred and fifty-six eyes out of 171 were available for follow-up visits at 12 months.

C. Data Analysis and Results

1) Pre-Operative Characteristics

Pre-operative characteristics for the 200 eyes are presented in Table 3-13.

Table 3-13 — High Myopia: Pre-Op Refractive Error Stratified by Diopter Sphere and Cylinder (n = 200)

Pre-Op Cylinder	Pre-Operative Sphere							
	6.1 to 7.0	7.1 to 8.0	8.1 to 9.0	9.1 to 10.0	10.1 to 11.0	11.1 to 12.0	Total	
	n = 87	n = 49	n = 27	n = 20	n = 10	n = 7	n	%
0.00	20	10	4	3	1	1	39	19.5
0.01 to 1.00	36	20	13	10	4	4	87	43.5
1.01 to 2.00	23	14	9	4	4	2	56	28.1
2.01 to 3.00	7	2	0	2	1	0	12	6.0
3.01 to 4.00	1	3	1	1	0	0	6	3.0

2) Post-Operative Results

a) Uncorrected Visual Acuity (UCVA)

At 12 months following treatment, 140/156 (89.7%) of eyes were 20/40 or better, 125/156 (80.1%) were 20/30 or better and 79/156 (50.6%) were 20/20 or better. No eye was worse than 20/200 unaided.

Table 3-14 presents a matrix that summarizes the post-operative uncorrected visual acuities of eyes treated stratified by pre-operative UCVA. While no eye was better than 20/200 pre-operatively, regardless of the pre-operative UCVA, the majority of eyes (88.9% at 6 months and 89.7% at 12 months) were 20/40 or better after treatment. This represents a substantial improvement in uncorrected visual acuity sustained over time.

Table 3-14 — High Myopia: Post-Operative UCVA Stratified by Pre-Operative UCVA

Pre-Op (n=200)		6 M (n = 199)				12 M (n =156)			
UCVA	n	< 20/20	20/20-25	20/30-40	> 20/40	< 20/20	20/20-25	20/30-40	> 20/40
20/200	6	1	4	0	1	1	3	1	1
20/400-600	50	9	26	10	5	8	24	10	3
≥ 20/800	144	23	67	37	16	15	48	30	12
Total	200	33 (16.7)	97 (48.7)	47 (23.6)	22 (11.1)	24 (15.4)	75 (48.1)	41 (26.3)	16 (10.3)

b) Best Spectacle Corrected Visual Acuity (BSCVA)

Best spectacle corrected visual acuity (BSCVA) was analyzed at the 6-month and 12-month visits. No eye was worse than 20/40 pre-treatment.

At the 12-month visit, 126/156 (80.8%) are 20/20 or better and 153/156 (98.1%) are 20/40 or better. Three eyes had a BSCVA that was worse than 20/40, although none was worse than 20/80. One of these eyes had progressive nuclear sclerosis which decreased the BSCVA from 20/20 to 20/80 (this patient later recovered BSCVA to 20/20 following lens extraction). The reduction of BSCVA in the other two eyes were attributed to an anomalous refraction and decentered ablation (which later recovered to 20/30) in one eye and an irregular astigmatism in the other eye (this eye was 20/40 at pre-op).

Table 3-15 — High Myopia: 12-Month BSCVA Stratified by Diopter of Pre-Operative Sphere (n = 156)

Post-Op	Pre-Operative Sphere							
	6.1 to 7.0	7.1 to 8.0	8.1 to 9.0	9.1 to 10.0	10.1 to 11.0	11.1 to 12.0	Total	
BSCVA	n = 71	n = 38	n = 20	n = 15	n = 7	n = 5	n	%
20/10-12	13	2	4	2	0	0	21	13.5
20/15-16	25	12	6	1	0	0	44	28.2
20/20	25	19	5	7	3	2	61	39.1
20/25	4	3	3	1	2	2	15	9.6
20/30	2	2	0	3	2	1	10	6.4
20/40	0	0	2	0	0	0	2	1.3
< 20/40	2**	0	0	1*	0	0	3	1.9

* 6885115-2 (20/40 to 20/60—due to irregular astigmatism)

** 0189 (20/16 to 20/60—due to an anomalous refraction and decentered ablation) and 9411-1 (20/20 to 20/60—due to progressive nuclear sclerosis)

Best spectacle corrected visual acuity was also assessed by the number of lines of visual acuity gained or lost compared to baseline. This analysis was conducted on data from the 6-month and 12-month data. Seventeen (17/199 or 8.5%) eyes lost 2 lines or more of BSCVA at 6 months post-op, though not one of these eyes had an acuity that was worse than 20/40. By 12 months, the number of eyes that lost 2 or more lines of BSCVA had diminished to nine eyes (9/156 or 5.8%) and four (4/156 or 2.6%) had lost more than 2 lines of BSCVA.

c) Reduction of Mean Spherical Equivalent

The mean spherical equivalent was reduced at all time periods examined. The mean pre-treatment manifest refractive spherical equivalent was -8.27 D. At 6 months -0.16 D was the mean spherical equivalent or a mean reduction of 8.11 D (a mean reduction of 98%). At 12 months the mean spherical equivalent was -0.25 D which represents a mean spherical equivalent reduction of 8.02 D (a mean reduction of 97%).

Table 3-16 — High Myopia: Mean Spherical Equivalent Over Time

	Pre Op (n = 200)	6 M (n = 199)	12 M (n = 156)
Mean	-8.27	-0.16	-0.25
Median	-7.88	0.00	-0.13
SD	1.47	1.12	1.02
Min	-12.00	-7.00	-4.25
Max	-6.25	3.00	2.50

3) Stability of Outcome

The stability of outcome is demonstrated by a change of 1 D or less in manifest spherical equivalent between the 6 and 12-month visits. Of the 200 eyes initially treated, 155 had both a 6 and 12-month refraction. Of these, there were 133/155 eyes (85.8%) that had a change of not more than 1 D of manifest spherical equivalent between the 6 and 12-month visit.

The reduction in spherical equivalent is stable and the difference between the 6 and 12-month values are not statistically significant ($p>0.05$).

4) Retreatments

Three eyes were retreated (3/200 or 1.5%) during the study during the initial 12 months after primary treatment. In each case retreatment resulted in visual recovery to at least the pre-operative level. Table 3-17 below summarizes the 3 retreatment cases that occurred during the 12-month follow-up period. Retreatment was performed to address post-operative irregular videokeratographic maps, regression and haze, and irregular astigmatism.

Table 3-17 — High Myopia: Re-Treatment Summary

	Pre-Treatment		Pre-Retreatment		Post-Retreatment at Last Visit	
Subject ID	UCVA	BSCVA	UCVA	BSCVA	UCVA	BSCVA
7491-2	800	20	200	40	100	15
7432834	800	20	400	40	200	20
9797-1	800	20	200	30	25	20

5) Refractive Cylinder Over Time

Table 3-18 — High Myopia: Observed Cylinder Over Time

	Pre-Op (n = 200)	6-Month (n = 199)	12-Month (n = 156)
Mean	-0.99	-0.43	-0.41
Median	-0.75	-0.25	-0.25
SD	0.85	0.56	0.56
Min	0.0	0.0	0.0
Max	4.00	4.00	3.25

6) Adverse Events

Refer to Table 2-2 in Section 2.5.

3.1.3 Myopic Astigmatism

A prospective, non-randomized, unmasked, multicenter clinical study was conducted. The refractive inclusion criteria specified that the primary eye have myopia of 1.0 to 6.0 D spherical equivalent with between -0.75 and -4.5 D of refractive astigmatism. There were a total of 116 eyes treated (71 primary eyes and 45 fellow eyes). Patients who exhibited any of the following conditions were excluded: keratoconus; active ocular disease likely to affect wound healing; unstable central keratometry readings with irregularly shaped mires; use of systemic medications likely to affect wound healing; or immunocompromised status.

A. About the Study

One hundred and sixteen (116) eyes were treated. These eyes were treated between August 1993 and June 1995. The patients were evaluated pre-operatively, every 24 to 48 hours post-operatively until re-epithelialization, and at 1, 3, 6, 12, and 21 months or later after-treatment. Eyes were analyzed for: reduction of astigmatism, vector analysis of intended versus achieved refractive correction, residual refractive cylinder, stability of refractive correction over time, and uncorrected visual acuity.

Additional parameters were analyzed by closely examining best spectacle visual acuity losses of two lines or more (significant losses), endothelial cell counts, contrast sensitivity results, glare results, patient subjective symptoms (e.g., worsening of double vision, sensitivity to bright lights, and night vision disturbances), clinical signs (e.g., haze), and IOP increases, in addition to the adverse events as reported by the investigators and monitored throughout the course of the study.

B. Patient Accountability

One hundred and sixteen (116) eyes of 71 subjects, treated at five centers in the United States, were used for safety and effectiveness analyses. Eighty-two eyes out of 91 were available for follow-up visits at 24 months or longer.

C. Data Analysis and Results

1) Pre-Operative Characteristics

Pre-operative characteristics for the 116 eyes are presented in Table 3-19.

Table 3-19 — Myopic Astigmatism: Cohort Pre-Operative Refractive Characteristics (n = 116)

Primary Eyes (n = 71)	Spherical Equivalent	Spherical Myopia	Astigmatism
Mean	-4.46 D	-3.64 D	-1.63 D
SD	1.39 D	1.47 D	0.74 D
Range	-1.75 – -6.63 D	-0.5 – -6.00 D	-0.75 – -4.00 D
Fellow Eyes (n = 45)			
Mean	-4.16 D	-3.33 D	-1.66
SD	1.45	1.59	0.65
Range	-1.38 – -6.50 D	0.00 – 5.75	-0.75 – -3.25 D
All Cohort Eyes (n = 116)			
Mean	-4.34 D	-3.52	-1.64 D
SD	1.41	1.52	0.71
Range	-1.38 – -6.63	0.00 – -6.00 D	-0.75 – -4.00 D

2) Post-Operative Results

The following table represents the number of eyes in which data were collected for the particular field at the indicated visit interval.

Table 3-20 — Myopic Astigmatism: Eyes Tested at Each Visit*

	Examined	Refracted	BSCVA	UCVA	Con Sen	Glare
Pre-Op	116	116	116	115	111	111
6 M	108	106	104	106	90	87
12 M	92	89	89	90	74	74
Final Visit	84	82	82	82	66	67

* Not all parameters were available for each patient at each examination.

a) Uncorrected Visual Acuity (UCVA)

Table 3-21 is a distribution of uncorrected visual acuities (UCVA) for the primary and fellow eyes stratified by pre-operative refractive cylinder (PE = primary eye, FE = fellow eye) at final visit. At the final visit 91.5% (75/82) of eyes treated attained 20/40 or better vision without correction and 81.7% (67/82) attained an uncorrected visual acuity of 20/30 or better. No eye was able to attain 20/40 uncorrected acuity pre-operatively.

Table 3-21 — Myopic Astigmatism: Final Visit UCVA of Cohort Eyes Stratified by Diopter of Pre-Operative Cylinder (n = 82*)

	0.75 – 1.0			1.1 – 2.0			2.1 – 3.0			3.1 – 4.0		
	PE	FE	All	PE	FE	All	PE	FE	All	PE	FE	All
≥ 20/20	6	6	12	11	7	18	2	1	3	0	0	0
< 20/20 – 20/30	7	1	8	13	6	19	2	4	6	1	0	1
< 20/30 – 20/40	2	0	2	1	3	4	0	1	1	1	0	1
< 20/40 – 20/50	0	1	1	2	0	2	0	1	1	0	0	0
< 20/50 – 20/60	0	0	0	0	0	0	0	0	0	0	0	0
< 20/60 – 20/70	0	0	0	0	0	0	0	0	0	0	0	0
< 20/70 – 20/100	0	1	1	1	0	1	0	1	1	0	0	0
< 20/100 – 20/200	0	0	0	0	0	0	0	0	0	0	0	0
< 20/200 – 20/800	0	0	0	0	0	0	0	0	0	0	0	0
CF or Worse	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	15	9	24	28	16	44	4	8	12	2	0	2

* UCVA data for 2 eyes were not available at this visit.

Table 3-22 — Myopic Astigmatism: Cylinder Magnitude and Axis (n = 116)

	6 M (n = 106)*	12 M (n = 89)**	Final Visit (n = 82) †
Sphere (SIRC/IRC)‡	3.18/3.27 97.2%	3.30/3.36 98.2%	3.22/3.31 97.3%
Cylinder (SIRC/IRC)‡	1.25/1.47 85.0%	1.18/1.43 82.5%	1.14/1.44 79.2%
Mean absolute vector axis error	7.2°	10.49°	11.5°
Mean vector magnitude error	-0.22 D	-0.25 D	-0.3 D

* The refractive data for 2 eyes are not available for this visit.

** The refractive data for 3 eyes are not available for this visit.

† The refractive data for 2 eyes are not available for this visit.

‡ Surgically Induced Refractive Change/Intended Refractive Change.

b) Reduction of Mean Spherical Equivalent

The mean spherical equivalent (S.E.) was reduced at all time periods examined (Table 3-23). Not all eyes were targeted for emmetropia; the mean target was -0.10D. The mean pretreatment manifest refractive S.E. was -4.34D. The mean S.E. was reduced by 92.9% at the final visit.

Table 3-23 — Myopic Astigmatism: Reduction of Mean Spherical Equivalent

	6 M (n = 106)*	12 M (n = 89)**	Final Visit (n = 82)†
Mean	4.06	4.15	4.03
Median	4.19	4.13	4.13
SD	1.72	1.60	1.64
Min	-0.88	0.88	0.00
Max	8.00	8.63	8.63

* The refractive data for 2 eyes are not available for this visit.

** The refractive data for 3 eyes are not available for this visit.

† The refractive data for 2 eyes are not available for this visit.

c) Deviation from Intended Correction (Predictability of Outcome)

The predictability of outcome has been assessed as the extent of deviation from intended correction (i.e., difference between achieved correction and intended correction) by considering mean reduction in spherical equivalent and cylinder over time. The intended final refractive error was not plano in all cases (i.e., intended undercorrection for monovision); the resultant mean intended result was reduced by 92.9% at the final visit. The reduction in absolute cylinder was 62% at the final visit.

Predictability of outcome was also examined by performing vector analyses of the refractive data from follow-up visits. Because astigmatic corrections have three components (sphere, cylinder, and axis), an accurate outcomes assessment can be obtained only with a vector analysis to determine the magnitude and direction of change. A summary of the results is included in Table 3-22.

3) Stability of Outcome

Stability of outcome is presented by assessment of UCVA, spherical equivalent refractive error, and refractive cylinder over time. Over the course of the study, a significant number of eyes (86.7%, 86.6%, and 91.5% at the 6-month, 12-month, and final visit, respectively) achieved and maintained uncorrected visual acuity of 20/40 or better. The mean reduction in spherical equivalent was 4.06 D (SD 1.72) at 6 months, 4.15 D (SD 1.60) at 12 months, and 4.03 D (SD 1.64) at the final visit. The mean pretreatment cylinder was -1.64 (SD 0.71). The mean observed cylinder was -0.55 D (SD 0.54) at the final visit. The reduction in absolute mean cylinder was 1.15 (SD 0.79) at 6 months, 1.08 (SD 0.81) at 12 months, and 1.05 (SD 0.73) at the final visit. This represents a 67%, 64%, and 62% reduction in cylinder at each time point, respectively.

4) Retreatments

Nine eyes were retreated (9/116 or 7.8%) during the study. The majority were retreated for initial undercorrection of refractive error.

Table 3-24 — Myopic Astigmatism: Retreatment Summary

Patient	Pre-Treatment		Pre-Retreatment		Post-Retreatment **	
	UCVA	BSCVA	UCVA	BSCVA	UCVA	BSCVA
1	80 – 2	25 + 3	50	20 – 2	25	20
2	400	20 – 2	80 + 4	25 *	60	20
3	CF	20	40	20	20	20
4	CF	25	50 + 3	25 – 1	25 – 3	25 – 1
5	400	12	50 – 2	15	30	20 – 3
6	CF	20	25 + 2	20	25 +1	20
7	80	20	50	20	30	20
8	200	15	20 – 1	15	30	15
9	125	10	50	15	30	15

* The data listing indicates this BSCVA to be 20/80+4 in error; the correct value is included for accuracy.

** Last visit available.

5) Cylinder Axis Shift

Table 3-25 — Myopic Astigmatism: Distribution of Axis Shift between Pre-Op and Final Visit Stratified by Pre-Op Cylinder (n = 82)*

Axis Shift (degrees)	0.75 – 1.0 (n = 24)	1.1 – 2.0 (n = 44)	2.1 – 3.0 (n = 12)	3.1 – 4.0 (n = 2)
0 – 15	21	33	9	2
16 – 30	1	7	2	0
31 – 45	1	2	0	0
46 – 60	1	1	0	0
61 – 75	0	0	0	0
76 – 90	0	1	1	0

* The refractive data for 2 eyes are not available for this visit.

6) Adverse Events

Refer to Table 2-3 in Section 2.5.

3.1.4 Hyperopia

A prospective, non-randomized, unmasked, multicenter PRK clinical study was conducted. The refractive inclusion criteria specified that the primary eye have hyperopia of between +1.0 and +4.0 D spherical equivalent and no more than 1.0 D of cycloplegic refraction. The difference between the manifest and cycloplegic refractions may be no more than 0.75 D. There were a total of 124 patients treated in the United States supplemented with clinical data from a Canadian study on refractive errors from +4.0 to +6.0 D. Patients who exhibited any of the following conditions were excluded: keratoconus; active ocular disease likely to affect wound healing; unstable central keratometry readings with irregularly shaped mires; use of systemic medications likely to affect wound healing; or immunocompromised status.

A. About the Study

Treated eyes were followed for at least 12 months. Analyses of results were performed for 1, 3, 6, 9, and 12 months visits. Effectiveness analyses included distance uncorrected visual acuity, uncorrected near acuity, refractive error, stability of outcome, and predictability of outcome.

Additional parameters were analyzed by examining absolute and relative best spectacle visual acuity over time, haze, intraocular pressure, induced astigmatism, contrast sensitivity, endothelial cell study, adverse events, and complications.

B. Patient Accountability

One hundred and twenty-four (124) eyes of 124 subjects treated at eight centers in the United States were used for safety and effectiveness analyses. One hundred and twenty-four eyes were available for follow-up visits at 12 months.

C. Data Analysis and Results

1) Visual Acuity

Table 3-26 presents the distance uncorrected visual acuity (UCVA) pre-operatively and at 1, 3, 6, 9, and 12 months post-operatively. Pre-operatively, 5.4% of eyes were 20/20 or better. This increased to 53.3%, 69.7%, and 63.9% post-operatively at 6, 9, and 12 months, respectively. While 17.9% of eyes were 20/40 or better pre-operatively, 96.0%, 98.0%, and 94.8% were 20/40 or better post-operatively at 6, 9, and 12 months, respectively.

Table 3-26 — Hyperopia: Uncorrected Visual Acuity (UCVA)

Visual Acuity	Pre-op (n = 166)		1 M (n = 166)		3 M (n = 158)		6 M (n = 150)		9 M (n = 99)		12 M (n = 97)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/20 or Better	9	5.4	22	13.3	52	32.9	80	53.3	69	69.7	62	63.9
20/25 or Better	13	7.8	44	26.5	96	60.8	110	73.3	84	84.8	78	80.4
20/32 or Better	20	12.0	79	47.6	126	79.7	135	90.0	93	93.9	91	93.8
20/40 or Better	29	17.5	100	60.2	139	88.0	144	96.0	97	98.0	92	94.8

Of hyperopic patients who were 20/20 or better pre-operatively and who were examined 12 months post-operatively, 9% lost more than one line of Best Spectacle Corrected Visual Acuity (BSCVA) and no eye was worse than 20/32. **Note:** It can be anticipated that there will be a small BSCVA loss on image minification.

2) Refractive Error

All investigators were instructed to use a full plus refracting technique to assure measurement of maximum manifest hyperopia without cycloplegia. Cycloplegia was performed on all patients pre-operatively to confirm the full plus refraction and to preclude any patient with a large amount of latent hyperopia from being treated. Cycloplegic refractions were repeated at the 6 and 12-month visits. Table 3-27 presents the mean manifest refraction spherical equivalent pre-operatively, and at 1, 3, 6, 9, and 12 months post-operatively.

Table 3-27 — Hyperopia: Manifest Refraction Spherical Equivalent Over Time All Eyes Targeted for Emmetropia

	Pre-Op	1 M	3 M	6 M	9 M	12 M
n	192	192	183	175	116*	115
Mean (D)	2.28	-0.86	-0.50	-0.18	0.00	0.11
SD	0.84	0.68	0.60	0.51	0.51	0.58
Min	0.38	-3.50	-2.88	-2.00	-1.50	-1.63
Max	4.00	1.00	1.00	1.38	1.75	2.25
Mean + 95% CI	2.40	-0.76	-0.41	-0.10	0.10	0.21
Mean - 95% CI	2.16	-0.95	-0.59	-0.25	-0.09	0.00

*One patient did not have a manifest refraction at this visit.

3) Stability of Outcome

Table 3-28 presents the mean change in manifest refraction spherical equivalent for all eyes that had 1, 3, 6, 9, and 12-month visits (n = 107). Between the 9 and the 12-month visits, there was a mean change of 0.11 ± 0.45 D and 104 eyes (97.2%) experienced a change of not more than 1.00 D.

Table 3-28 — Hyperopia: Refractive Stability: Mean of the Differences in MRSE All US Eyes With 1, 3, 6, 9, and 12-Month Visits (n = 107)

Mean Pre SE +2.47 D	1 and 3 M		3 and 6 M		6 and 9 M		9 and 12 M	
	n	%	n	%	n	%	n	%
≤ 1.00 D	87	81.3	98	91.6	102	95.3	104	97.2
Mean Difference	0.41		0.32		0.16		0.10	
SD	0.74		0.56		0.49		0.45	
95% CI	0.55 0.26		0.42 0.21		0.25 0.07		0.19 0.02	

In consideration of the unique accommodative patterns of hyperopic subjects, refractive stability was further analyzed as a function of corneal power stability and resultant non-corneal power variation. The mean of the two meridians measured by standard keratometry (Mean K) was analyzed for the pre-operative, 1, 3, 6, 9, and 12-month post-operative follow-up visits to demonstrate corneal stability. Total refractive change at these time points was examined through changes in mean refractive spherical equivalent (MRSE) in the same eyes.

Table 3-29 presents the mean change of the Mean K for all eyes having a target of emmetropia that had 1, 3, 6, 9, and 12-month data (n = 105). Between 1 and 3 month visits, there was a mean change of -0.55 ± 0.88 D; between 3 and 6 months, there was a mean change of -0.22 ± 0.69 D; between 6 and 9 months, there was a mean change of -0.11 ± 0.47 D; and between 9 and 12 months, there was a mean change of -0.03 ± 0.35 D.

Table 3-29 — Hyperopia: Refractive Stability: Mean of the Differences in Keratometry
All US Eyes With 1, 3, 6, 9, and 12-Month Visits (n = 105)

	1 and 3 M		3 and 6 M		6 and 9 M		9 and 12 M	
	n	(%)	n	(%)	n	(%)	n	(%)
≤ 1.00 D	78	74.3	90	85.7	97	92.4	105	100
Mean Difference	-0.54		-0.22		-0.11		-0.03	
SD	0.88		0.69		0.47		0.35	
95% CI	-0.38 -0.71		-0.09 -0.35		-0.02 -0.20		0.04 -0.09	

The stability of the keratometry means when compared to their corresponding manifest spherical equivalent means and the predictive value of age are most significant and indicate the role of accommodative variation as the most probable factor in the apparent instability of measurement of the refractive state. This supports the overall stability of the induced corneal change.

Table 3-30 presents a combination of eyes with pre-operative refractive errors between +1.00 D and +6.00 D (n = 145) from both the U.S. and Canadian studies that were treated identically and had follow-up visits at 3, 6, 9, and 12 months post-operatively.

Table 3-30 — Hyperopia: Refractive Stability: Mean of the Differences in MRSE
All Eyes (1 to 6 D) With Visits 3 to 12 Months (n = 145)

Mean Pre SE +2.54 D	3 to 6 M		6 to 9 M		9 to 12 M	
	n	%	n	%	n	%
≤ 1.00 D	134	92.4	140	96.6	142	97.9
Mean Difference	0.34		0.15		0.11	
SD	0.53		0.46		0.42	
95% CI	0.25 0.42		0.08 0.22		0.04 0.18	

4) Predictability of Outcome

Predictability of outcome was determined by comparing the intended MRSE with the achieved MRSE at each visit. Since target MRSE is not a factor in determining the accuracy of the procedure, all eyes were used in this analysis. Table 3-31 presents predictability of outcome as measured by post-operative manifest refraction spherical equivalent within ± 1.00 D and ± 0.50 D.

Table 3-31 — Hyperopia: Predictability of Outcome: Intended vs. Achieved (All Eyes)

	1 M (n = 222)		3 M (n = 213)		6 M (n = 201)		9 M* (n = 116)		12 M (n = 115)	
	n	%	n	%	n	%	n	%	n	%
Within 0.50 D	78	35.1	119	55.9	149	74.1	91	78.4	87	75.7
Within 1.00 D	144	64.9	172	80.8	182	90.5	111	95.7	106	92.2

*One eye did not have a refraction at this visit.

5) Adverse Events

Refer to Table 2-4 in Section 2.5.

3.2 LASIK Clinical Results

3.2.1 Myopia With or Without Astigmatism

A prospective, non-randomized, unmasked, multicenter clinical study was conducted. The refractive inclusion criteria specified that the patient have myopia of between 0 and -14.0 diopters with or without astigmatism of -0.25 to -6.00 diopters. A total of 1276 eyes were treated. Patients who exhibited any of the following conditions were excluded: anterior segment pathology; residual, recurrent, or active ocular disease; previous intraocular or corneal surgery in the operative eye; history of herpes keratitis; or autoimmune disease, systemic connective tissue diseases, or atopic syndrome.

A. About the Study

Treated eyes were followed for at least 3 months. Analyses of results were performed at 1, 3, and 6 months post-treatment. Effectiveness analyses included uncorrected visual acuity, accuracy of manifest refraction, stability, effectiveness of astigmatic correction, and vector analysis. Safety analyses included loss of 2 or more lines of best spectacle corrected visual acuity (BSCVA); best spectacle corrected visual acuity of 20/40 or worse; haze with loss of BSCVA; or induced manifest astigmatism.

B. Patient Accountability

Twelve hundred and seventy-six (1276) eyes were treated at 11 centers.

Table 3-32 — LASIK: Patient Accountability (n = 1276)

1 Day		3 M		6 M or Later	
%	n/N	%	n/N	%	n/N
99.0	1263/1276	81.5	1000/1227	89.3	1028/1151

C. Data Analysis and Results

1) Pre-Operative Characteristics

The mean age of the patients participating in this trial was 42.0 ± 9.8 years. Gender distribution was 43.2% male and 56.8% female. Mean amount of myopic sphere was 5.85 ± 2.8.Mean amount of myopic cylinder was 1.54 ± 0.77.

2) Post-Operative Results

Six months post-operative results stratified by diopter for spheres and spherocylinders at ≤ 7 D and > 7 D are found in Tables 3-33 through 3-44.

a) Uncorrected Visual Acuity (UCVA)

Table 3-33 shows that the UCVA target is exceeded at 6 months post-operative interval for all eyes ≤ 7 D. At 6 months, 97.0% (550/567) had a UCVA of 20/40 or better. For all eyes > 7 D, UCVA was 20/40 or better at 6 months in 91.7% (221/241).

Table 3-33 — LASIK: UCVA in Eyes Intended to be Fully Corrected (Plano Target)

All Eyes	≤ 7D	> 7 D
Efficacy Variables	% n/N	% n/N
UCVA 20/20 or better	58.6 332/567	43.6 105/241
UCVA 20/40 or better	97.0 550/567	91.7 221/241
MRSE +/- 0.50 D	77.8 455/585	60.6 157/259
MRSE +/- 1.00 D	94.4 552/585	82.2 213/259
MRSE +/- 2.00 D	99.8 584/585	96.9 251/259
Safety Variables		
Loss of ≥ 2 Lines BSCVA	0.5 3/590	0.4 1/260
BSCVA Worse than 20/40	0.2 1/590	0.8 2/260
Increase > 2 D Cylinder	0.0 0/131	0.0 0/53
BSCVA Worse than 20/25 if 20/20 or Better Pre-operatively	0.0 0/544	1.5 3/201

Table 3-34 — LASIK: 6-Month Post-Operative Results (≤ 7 D) for Spheres

Spheres	0 to <1.00 D	>1.00 to 2.00 D	>2.00 to 3.00 D	>3.00 to 4.00 D	>4.00 to 5.00 D	>5.00 to 6.00 D	>6.00 to 7.00 D	Cum. Total ≤ 7.00 D
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Efficacy Variables								
UCVA 20/20 or better*	1/1 (100)	7/8 (87.5)	15/18 (83.3)	11/16 (68.8)	15/27 (55.6)	16/26 (61.5)	12/17 (70.6)	77/113 (68.1)
UCVA 20/40 or better*	1/1 (100)	8/8 (100)	18/18 (100)	16/16 (100)	27/27 (100)	26/26 (100)	16/17 (94.1)	112/113 (99.1)
MRSE +/- 0.50 D	1/1 (100)	7/8 (87.5)	17/17 (100)	14/18 (77.8)	18/27 (66.7)	20/28 (71.4)	13/18 (72.2)	90/117 (76.9)
MRSE +/- 1.00 D	1/1 (100)	8/8 (100)	17/17 (100)	17/18 (94.4)	26/27 (96.3)	25/28 (89.3)	17/18 (94.4)	111/117 (94.9)
MRSE +/- 2.00 D	1/1 (100)	8/8 (100)	17/17 (100)	18/18 (100)	27/27 (100)	27/28 (96.4)	18/18 (100)	116/117 (99.1)
Safety Variables								
Loss of ≥ 2 Lines BSCVA	0/1 (0.0)	0/8 (0.0)	0/17 (0.0)	1/18 (5.6)	0/27 (0.0)	0/31 (0.0)	0/18 (0.0)	1/120 (0.8)
BSCVA Worse than 20/40	0/1 (0.0)	0/8 (0.0)	0/17 (0.0)	0/18 (0.0)	0/27 (0.0)	0/31 (0.0)	0/18 (0.0)	0/120 (0.0)
Increase > 2 D Cylinder†	0/1 (0.0)	0/9 (0.0)	0/20 (0.0)	0/19 (0.0)	0/29 (0.0)	0/35 (0.0)	0/18 (0.0)	0/131 (0.0)
BSCVA Worse than 20/25 if 20/20 or Better Preoperatively	0/1 (0.0)	0/8 (0.0)	0/17 (0.0)	0/18 (0.0)	0/26 (0.0)	0/28 (0.0)	0/17 (0.0)	0/115 (0.0)

*. For all eyes minus those intentionally undercorrected.

†. For eyes treated for spherical corrections only.

Table 3-35 — LASIK: 6-Month Post-Operative Results (≤ 7 D) for Spherocylinders

Spherocylinders	0 to <1.00 D	>1.00 to 2.00 D	>2.00 to 3.00 D	>3.00 to 4.00 D	>4.00 to 5.00 D	>5.00 to 6.00 D	>6.00 to 7.00 D	Cum. Total ≤ 7.00 D
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Efficacy Variables								
UCVA 20/20 or better*	5/8 (62.5)	23/39 (59.0)	30/58 (51.7)	58/89 (65.2)	54/84 (64.3)	37/82 (45.1)	48/94 (51.1)	255/454 (56.2)
UCVA 20/40 or better*	8/8 (100)	38/39 (97.4)	56/58 (96.6)	88/89 (98.9)	80/84 (95.2)	79/82 (96.3)	89/94 (94.7)	438/454 (96.5)
MRSE +/- 0.50 D	6/6 (100)	29/33 (87.9)	51/61 (83.6)	79/91 (86.8)	71/89 (79.8)	60/91 (65.9)	69/97 (71.1)	365/468 (78.0)
MRSE +/- 1.00 D	6/6 (100)	31/33 (93.9)	57/61 (93.4)	90/91 (98.9)	84/89 (94.4)	84/91 (92.3)	89/97 (91.8)	441/468 (94.2)
MRSE +/- 2.00 D	6/6 (100)	33/33 (100)	61/61 (100)	91/91 (100)	89/89 (100)	91/91 (100)	97/97 (100)	468/468 (100)
Safety Variables								
Loss of ≥ 2 Lines BSCVA	0/7 (0.0)	0/34 (0.0)	1/61 (1.6)	0/93 (0.0)	0/88 (0.0)	1/91 (1.1)	0/96 (0.0)	2/470 (0.4)
BSCVA Worse than 20/40	0/7 (0.0)	0/34 (0.0)	0/61 (0.0)	0/93 (0.0)	0/88 (0.0)	1/91 (1.1)	0/96 (0.0)	1/470 (0.2)
Increase > 2 D Cylinder†	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)
BSCVA Worse than 20/25 if 20/20 or Better Preoperatively	0/7 (0.0)	0/33 (0.0)	0/57 (0.0)	0/88 (0.0)	0/78 (0.0)	0/79 (0.0)	0/87 (0.0)	0/429 (0.0)

*. For all eyes minus those intentionally undercorrected.

†. For eyes treated for spherical corrections only.

Table 3-36 — LASIK: 6-Month Post-Operative Results (> 7 D) for Spheres

Spheres	>7.00 to 8.00 D	>8.00 to 9.00 D	>9.00 to 10.00 D	>10.00 to 11.00 D	>11.00 to 12.00 D	>12.00 to 13.00 D	>13.00 to 14.00 D	Cum. Total > 7.00 D
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Efficacy Variables								
UCVA 20/20 or better*	6/10 (60.0)	5/7 (71.4)	5/10 (50.0)	1/5 (20.0)	0/2 (0.0)	1/3 (33.3)	1/4 (25.0)	19/41 (46.3)
UCVA 20/40 or better*	10/10 (100)	5/7 (71.4)	10/10 (100)	4/5 (80.0)	2/2 (100)	3/3 (100)	4/4 (100)	38/41 (92.7)
MRSE +/- 0.50 D	12/15 (80.0)	3/7 (42.9)	6/9 (66.7)	0/6 (0.0)	1/2 (50.0)	2/3 (66.7)	2/5 (40.0)	26/47 (55.3)
MRSE +/- 1.00 D	13/15 (86.7)	5/7 (71.4)	8/9 (88.9)	5/6 (83.3)	1/2 (50.0)	3/3 (100)	5/5 (100)	40/47 (85.1)
MRSE +/- 2.00 D	15/15 (100)	7/7 (100)	9/9 (100)	5/6 (83.3)	2/2 (100)	3/3 (100)	5/5 (100)	46/47 (97.9)
Safety Variables								
Loss of ≥ 2 Lines BSCVA	0/15 (0.0)	0/7 (0.0)	0/9 (0.0)	0/6 (0.0)	0/2 (0.0)	0/3 (0.0)	0/5 (0.0)	0/47 (0.0)
BSCVA Worse than 20/40	0/15 (0.0)	1/7 (14.3)	0/9 (0.0)	1/6 (16.7)	0/2 (0.0)	0/3 (0.0)	0/5 (0.0)	2/47 (4.3)
Increase > 2 D Cylinder†	0/17 (0.0)	0/10 (0.0)	0/10 (0.0)	0/6 (0.0)	0/2 (0.0)	0/3 (0.0)	0/5 (0.0)	0/53 (0.0)
BSCVA Worse than 20/25 if 20/20 or Better Preoperatively	0/12 (0.0)	0/5 (0.0)	0/6 (0.0)	0/5 (0.0)	0/1 (0.0)	0/2 (0.0)	0/1 (0.0)	0/32 (0.0)

*. For all eyes minus those intentionally undercorrected.

†. For eyes treated for spherical corrections only.

Table 3-37 — LASIK: 6-Month Post-Operative Results (> 7 D) for Spherocylinders

Spherocylinders	>7.00 to 8.00 D	>8.00 to 9.00 D	>9.00 to 10.00 D	>10.00 to 11.00 D	>11.00 to 12.00 D	>12.00 to 13.00 D	>13.00 to 14.00 D	>14.00 to 15.00 D	Cum. Total > 7.00 D
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Efficacy Variables									
UCVA 20/20 or better*	23/57 (40.4)	24/60 (40.0)	18/41 (43.9)	12/25 (48.0)	2/4 (50.0)	3/5 (60.0)	4/7 (57.1)	0/1 (0.0)	86/200 (43.0)
UCVA 20/40 or better*	51/57 (89.5)	56/60 (93.3)	39/41 (95.1)	21/25 (84.0)	4/4 (100)	4/5 (80.0)	7/7 (100)	1/1 (100)	183/200 (91.5)
MRSE +/- 0.50 D	43/63 (68.3)	39/66 (59.1)	24/40 (60.0)	15/24 (62.5)	3/5 (60.0)	2/6 (33.3)	5/7 (71.4)	0/1 (0.0)	131/212 (61.8)
MRSE +/- 1.00 D	52/63 (82.5)	53/66 (80.3)	34/40 (85.0)	19/24 (79.2)	5/5 (100)	4/6 (66.7)	6/7 (85.7)	0/1 (0.0)	173/212 (81.6)
MRSE +/- 2.00 D	60/63 (95.2)	65/66 (98.5)	39/40 (97.5)	22/24 (91.7)	5/5 (100)	6/6 (100)	7/7 (100)	1/1 (100)	205/212 (96.7)
Safety Variables									
Loss of ≥ 2 Lines BSCVA	0/63 (0.0)	0/66 (0.0)	0/40 (0.0)	1/25 (4.0)	0/5 (0.0)	0/6 (0.0)	0/7 (0.0)	0/1 (0.0)	1/213 (0.5)
BSCVA Worse than 20/40	0/63 (0.0)	0/66 (0.0)	0/40 (0.0)	0/25 (0.0)	0/5 (0.0)	0/6 (0.0)	0/7 (0.0)	0/1 (0.0)	0/213 (0.0)
Increase > 2 D Cylinder†	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)
BSCVA Worse than 20/25 if 20/20 or Better Preoperatively	1/52 (1.9)	1/51 (2.0)	1/34 (2.9)	0/21 (0.0)	0/5 (0.0)	0/2 (0.0)	0/3 (0.0)	0/1 (0.0)	3/169 (1.8)

*. For all eyes minus those intentionally undercorrected.

†. For eyes treated for spherical corrections only.

b) Accuracy of Manifest Refraction

As shown in Table 3-38, for all eyes ≤ 7 D, at 3 months 93.1% (605/650) had an MRSE within ± 1.0 D of the attempted, while at 6 months 94.4% (552/585) had this result. Table 3-39 shows that for spheres, the rate is 92.5% (136/147) at 3 months, and 94.9% (111/117) at 6 months. Table 3-40 shows that for spherocylinders, the rate is 93.2% (469/503) at 3 months, and 94.2% (441/468) at 6 months.

Table 3-38 — LASIK: Accuracy of Manifest Refraction (Attempted vs. Achieved) — All Eyes

All Eyes	3 M				6 M			
	≤ 7 D		> 7 D		≤ 7 D		> 7 D	
	n/N	%	n/N	%	n/N	%	n/N	%
MRSE +/- 0.50 D	478/650	73.5	167/319	52.4	455/585	77.8	157/259	60.6
MRSE +/- 1.00 D	605/650	93.1	240/319	75.2	552/585	94.4	213/259	82.2
MRSE +/- 2.00 D	648/650	99.7	299/319	93.7	584/585	99.8	251/259	96.9
Not Reported	28/678	4.1	3/322	0.9	65/650	10.0	14/273	5.1
Total	678	100	322	100	650	100	273	100
Overcorrected >+ 1 D	12/650	1.8	13/319	4.1	8/585	1.4	15/259	5.8
Overcorrected >+ 2 D	0/650	0.0	0/319	0.0	0/585	0.0	3/259	1.2
Undercorrected < - 1 D	33/650	5.1	66/319	20.7	25/585	4.3	31/259	12.0
Undercorrected < - 2 D	2/650	0.3	20/319	6.3	1/585	0.2	5/259	1.9
Not Reported	28/678	4.1	3/322	0.9	65/650	10.0	14/273	5.1
Total	678	100	322	100	650	100	273	100

Table 3-39 — LASIK: Accuracy of Manifest Refraction (Attempted vs. Achieved) — Spheres

Spheres	3 M				6 M			
	≤ 7 D		> 7 D		≤ 7 D		> 7 D	
	n/N	%	n/N	%	n/N	%	n/N	%
MRSE +/- 0.50 D	115/147	78.2	36/68	52.9	90/117	76.9	26/47	55.3
MRSE +/- 1.00 D	136/147	92.5	52/68	76.5	111/117	94.9	40/47	85.1
MRSE +/- 2.00 D	146/147	99.3	63/68	92.6	116/117	99.1	46/47	97.9
Not Reported	5/152	3.3	1/69	1.4	14/131	10.7	6/53	11.3
Total	152	100	69	100	131	100	53	100
Overcorrected >+ 1 D	3/147	2.0	2/68	2.9	1/117	0.9	1/47	2.1
Overcorrected >+ 2 D	0/147	0.0	0/68	0.0	0/117	0.0	0/47	0.0
Undercorrected < - 1 D	8/147	5.4	14/68	20.6	5/117	4.3	6/47	12.8
Undercorrected < - 2 D	1/147	0.7	5/68	7.4	1/117	0.9	1/47	2.1
Not Reported	5/152	3.3	1/69	1.4	14/131	10.7	6/53	11.3
Total	152	100	69	100	131	100	53	100

Table 3-40 — LASIK: Accuracy of Manifest Refraction (Attempted vs. Achieved) — Spherocylinders

Spherocylinders	3 M				6 M			
	≤ 7 D		> 7 D		≤ 7 D		> 7 D	
	n/N	%	n/N	%	n/N	%	n/N	%
MRSE +/- 0.50 D	363/503	72.2	131/251	52.2	365/468	78.0	131/212	61.8
MRSE +/- 1.00 D	469/503	93.2	188/251	74.9	441/468	94.2	173/212	81.6
MRSE +/- 2.00 D	502/503	99.8	236/251	94.0	468/468	100	205/212	96.7
Not Reported	23/526	4.4	2/253	0.8	51/519	9.8	8/220	3.6
Total	526	100	253	100	519	100	220	100
Overcorrected >+ 1 D	9/503	1.8	11/251	4.4	7/468	1.5	14/212	6.6
Overcorrected >+ 2 D	0/503	0.0	0/251	0.0	0/468	0.0	3/212	1.4
Undercorrected < - 1 D	25/503	5.0	52/251	20.7	20/468	4.3	25/212	11.8
Undercorrected < - 2 D	1/503	0.2	15/251	6.0	0/468	0.0	4/212	1.9
Not Reported	23/526	4.4	2/253	0.8	51/519	9.8	8/220	3.6
Total	526	100	253	100	519	100	220	100

c) Astigmatic Correction

Table 3-41 shows that 95.9% (462/482) of the eyes with pre-operative cylinder less than 3.0 D had 1.0 D or less of cylinder at 3 months. For the eyes with greater than 3.0 D of cylinder pre-operatively, 88.9% (8/9) had 1.0 D or less of cylinder at 3 months. 96.5% (357/370) of the eyes with pre-operative cylinder less than 3.0 D had 1.0 D or less of cylinder at 6 months. For eyes with greater than 3.0 D of cylinder present pre-operatively, 100% (3/3) had 1.0 D of cylinder at 6 months.

Table 3-41 — Cylinder Efficacy

Cylinder Range	+/- 1.00 D at 3 M	+/- 1.00 D at 6 M
0 to 3 D	95.9%	96.5%
> 3 D	88.9%	100%

d) Vector Analysis

Table 3-42 is a summary of the vector analysis results for all eyes undergoing cylinder correction. The ratio of surgically induced refractive vector change (SIRC) to intended refractive vector change (IRC) indicates the ratio of the vector cylinder change induced compared with the targeted amount. A ratio of 1.0 would indicate that the surgical correction exactly matched the targeted correction. Smaller ratios indicate that the cylinder correction was less than planned, and ratios > 1.0 indicate a cylinder overcorrection. At 6 months, the mean ratio of SIRC/IRC was 1.03 ± 0.32 D. The minimum was 0.00 and the maximum was 2.81 D.

Table 3-42 — LASIK: Vector Analysis for All Eyes Undergoing Cylinder Correction; Results Reported at 6 Months (n = 510)

6 M Results (n = 510)					
	Preoperative	Postoperative	IRC	SIRC	SIRC/IRC
Mean	-1.54	-0.33	-1.47	-1.48	1.03
SD	0.77	0.43	0.71	0.75	0.32
Min	-4.75	-3.00	-4.50	-4.48	0.00
Max	-0.75	0.00	-0.56	0.00	2.81

3) Stability of Outcome

As shown in Table 3-43, using eyes seen at all follow-up exams (1, 3, and 6 months) shows that between 1 and 3 months, 93.6% (424/453) of all eyes experienced a change in MRSE of ≤ 1.00 D. In the ≤ -7 D group, the rate was 95.1% (294/309), and in the > -7 D group, the rate was 90.3% (130/144). For spheres ≤ -7 D, the rate was 95.8% (69/72), and for spherocylinders, the rate was 94.9% (225/237). For spheres > -7 D, the rate was 79.3% (23/29), and for sphereocylinders, 93.0% (107/115). Table 3-44 shows that between 3 and 6 months, for spheres in the ≤ 7 D group, the rate was 97.2% (70/72), and for spherocylinders, 95.8% (227/237). For spheres > 7 D, the rate was 93.1% (27/29), and for spherocylinders, 88.7% (102/115).

Table 3-43 — LASIK: Stability of Manifest Refraction with +/- 1.00 D (1 to 3 M)

From 1 to 3 M						
Full Cohort	**All Eyes**		**≤ 7 D**		**> 7 D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤ 1.00 D	424/453	93.6	294/309	95.1	130/144	90.3
Mean Difference	-0.05 D		-0.09 D		0.03 D	
SD	0.55 D		0.50 D		0.65 D	
95% CI	91.3% to 95.9%		92.7% to 97.5%		85.4% to 95.1%	
Spheres	**All Eyes**		**≤ 7 D**		**> 7 D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤ 1.00 D	92/101	91.1	69/72	95.8	23/29	79.3
Mean Difference	-0.02 D		-0.11 D		0.20 D	
SD	0.71 D		0.58 D		0.94 D	
95% CI	85.5 % to 96.6%		91.2% to 100.4%		64.6% to 94.1%	
Spherocylinders	**All Eyes**		**≤ 7 D**		**> 7 D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤ 1.00 D	332/352	94.3	225/237	94.9	107/115	93.0
Mean Difference	-0.06 D		-0.08 D		-0.02 D	
SD	0.50 D		0.47 D		0.56 D	
95% CI	91.9% to 96.7%		92.1 to 97.7%		88.4% to 97.7%	

Table 3-44 — LASIK: Stability of Manifest Refraction with +/- 1.00 D (3 to 6 M)

From 3 to 6 M						
Full Cohort	**All Eyes**		**≤ 7 D**		**> 7 D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤ 1.00 D	426/453	94.0	297/309	96.1	129/144	89.6
Mean Difference	-0.05 D		-0.04 D		-0.05 D	
SD	0.51 D		0.43 D		0.64 D	
95% CI	91.9% to 96.2%		94.0% to 98.3%		84.6% to 94.6%	
Spheres	**All Eyes**		**≤ 7 D**		**> 7 D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤ 1.00 D	97/101	96.0	70/72	97.2	27/29	93.1
Mean Difference	-0.08 D		-0.09 D		-0.06 D	
SD	0.44 D		0.39 D		0.55 D	
95% CI	92.2% to 99.8%		93.4% to 101.0%		83.9% to 102.3%	
Spherocylinders	**All Eyes**		**≤ 7 D**		**> 7 D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤ 1.00 D	329/352	93.5	227/237	95.8	102/115	88.7
Mean Difference	-0.04 D		-0.03 D		-0.05 D	
SD	0.53 D		0.45 D		0.67 D	
95% CI	90.9% to 96.0%		93.2% to 98.3%		82.9% to 94.5%	

4) Retreatments

One hundred and three eyes were retreated (103/1276 or 8.1%) for undercorrections.

5) Adverse Events

Refer to Table 2-5 in Section 2.5.2.

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4.0 Surgical Planning and Procedures

After reading this section, please refer to the procedures provided in Section 5.1, Step-By-Step Procedure, before proceeding with surgery.

4.1 Introduction

PRK and LASIK are procedures that use the energy of the excimer laser to create a superficial lamellar keratectomy of a shape designed to correct or ameliorate a specific refractive error. It is essential that the refractive information upon which this surgical procedure is based is accurate and is correctly transmitted to the laser. It is the sole responsibility of the operating doctor to ensure that the information for each individual patient is accurate. For LASIK nomogram considerations, please refer to Appendix A of the VISX STAR S2 System Operator's Manual.

4.2 Pre-Operative (Examination of the Patient)

A complete examination, including but not limited to cycloplegic evaluation, must be performed. The lens must be evaluated to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery, as these opacities may adversely affect the end surgical result. Direct and indirect ophthalmoscopy through a dilated pupil are essential. Evaluation of the optic nerve and measurement of IOP are necessary. If there are any concerns regarding the appearance of the optic nerve, a Humphrey 24-2 Fastpac or equivalent threshold test of the visual field should be performed. Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. Baseline evaluation of patients with myopia desiring refractive surgery should be performed within 30 days of PRK or LASIK surgery.

Patients who wear soft contact lenses must discontinue their use for at least 2 weeks, and those who wear gas permeable or hard lenses must discontinue their use for at least 3 weeks. Failure to do so will adversely affect the end surgical result.

4.3 Peri-Operative (Anesthesia and Analgesia)

Extensive clinical experience has shown that PRK and LASIK excimer surgery are well tolerated and rarely cause significant pain. For this reason, systemic sedatives and injected local anesthetics are not required. Topical anesthesia applied just before insertion of the lid speculum will provide adequate control of pain during the surgery. For those patients with a high degree of anxiety, appropriate medication may be given pre-operatively.

4.4 Removing the Epithelium for PRK or PTK

If you do not intend to remove the epithelium using the laser, do not select Epithelium from the treatment menu.

The TREAT button is disabled on the Epithelium page. To perform an epithelial procedure, you must first define a stromal treatment. When the programming is complete, press TREAT from the stromal (Refractive or Therapeutic) page to begin epithelium removal.

When the Hyperopia treatment is selected, the laser epithelium removal is disabled. You cannot combine the Hyperopia treatment with laser epithelial removal.

The system will always perform the epithelium treatment first if it is selected.

The surgeon may use one of three epithelial removal techniques:

- Laser only
- Partial laser removal (laser plus scraping) supplemented with surface scraping to ensure complete and uniform removal of the epithelial cells.
- Mechanical (no laser) removal.

4.4.1 Complete Laser Epithelial Removal

To perform complete laser epithelial removal the surgeon must be able to monitor the fluorescence. Ensure that your system is equipped with the necessary optics upgrade before proceeding.[1]

To ensure complete and uniform removal of the epithelial cells using only the laser, the surgeon should compensate for the central under-ablation of the plano beam by adding a spherical refractive component to the ablation. This spherical refractive ablation may be done either before or after the plano ablation. To ensure greater patient comfort and better surgeon monitoring of the procedure, the spherical ablation is typically done before the plano ablation. The surgeon may define a plano ablation of up to 100 µm, as well as associated spherical ablation of up to -2.00 D.

1. For ordering information, contact your VISX service or sales representative.

With smoothing, the ablation shape for epithelial removal is different. The formerly sharp ablation wall is replaced by a flared wall. The specified ablation diameter defines a region between the outer and inner diameters of this flared wall. It is therefore necessary to increase the margin on epithelial removal by at least 0.4 mm. If using Auto Diameter for laser epithelial removal, you should enter a margin of at least 0.4 mm. Also, it may be necessary to adjust the magnitude of the spherical component and the depth of the plano ablation for complete laser or laser-plus-scrape epithelial removal.

Complete laser and partial laser (laser-plus-scrape) epithelial removal may not be selected for hyperopia treatments.

- Set the sequence. Select Sphere or Plano from the Perform First box.

For instructions on setting a spherical default value, see Chapter 9, Entering Treatment Data and Printing Reports, in the VISX STAR S2 Operator's Manual.

- Go to the first stromal treatment page of your procedure (Therapeutic or Refractive).
- Press the **TREAT** button to begin epithelial removal. Monitor the Ablation Status screen as the treatment progresses.

When the epithelial ablation is complete the Ablation Status screen automatically resets for the therapeutic (PTK) or refractive (PRK) treatment. **AT THIS POINT** the surgeon has an option to proceed to the stromal treatment, or to remove more epithelium.

- To proceed to the stromal treatment:
  - — Lift the footswitch, then depress it.
- To remove more epithelium:
  - — Lift the footswitch, and be careful **NOT** to depress it at this time.

WARNING! If you need to remove more epithelium, it is critically important to refrain from depressing the footswitch at this point. If you depress the footswitch at this point, the stromal treatment will begin, and you will not be able to remove more epithelium.

  - — Select **CANCEL** from the ablation status screen; the program returns to the Epithelium page.
  - — Reprogram the amount of epithelial ablation desired.

If no additional spherical ablation is desired, be sure to reprogram the spherical portion of the ablation to 0. Additional spherical ablation is subject to a total epithelial sphere limit of -2.00 D. There is no limitation on the total epithelium plano pulses.

— Re-select the desired Refractive (PRK) or Therapeutic (PTK) page and select TREAT. The system will prompt with **Repeat epithelium ablation?**

— Select YES, and repeat the epithelial removal process. You may repeat the process as many times as you need to, subject to the parameters in the note above.

When ready to proceed to the stromal treatment:

- If pulses remain, lift footswitch, depress it, select SKIP.
- If no pulses remain, lift footswitch, depress it; stromal treatment begins.

4.4.2 Partial Laser Epithelial Removal (Laser-Plus-Scrape) Technique

The surgeon uses this technique to compensate for the central under-ablation of the plano beam by manually scraping away residual epithelial tissue.

With smoothing, the ablation shape for epithelial removal is different. The formerly sharp ablation wall is replaced by a flared wall. The specified ablation diameter defines a region between the outer and inner diameters of this flared wall. It is therefore necessary to increase the margin on epithelial removal by at least 0.4 mm. If using Auto Diameter for laser epithelial removal, you should enter a margin of at least 0.4 mm. Also, it may be necessary to adjust the magnitude of the spherical component and the depth of the plano ablation for complete laser or laser-plus-scrape epithelial removal.

Complete laser and partial laser (laser-plus-scrape) epithelial removal may not be selected for hyperopia treatments.

- Set plano to the desired depth.
- Set sphere to 0.0.
- Treat with laser.
- Manually remove residual epithelial elements, ensuring that Bowman's membrane is uniformly exposed.
- The laser automatically adjusts to match the diameter of the largest defined treatment zone plus a margin of 0.5 mm up to a total diameter of 6.5 mm (the mechanical limit).[1]

1. The epithelial ablation diameter may not extend beyond 6.5 mm.

4.4.3 Mechanical Epithelial Removal

Remove the epithelium using a blunt instrument such as a Paton spatula. The region of epithelial removal should be at least 6.4 mm in diameter for systems with smoothing and at least 6.0 mm in diameter for systems without smoothing. Once the stromal bed is cleaned of debris, saturate a non-fragmenting sterile sponge, squeeze out, and wipe over the ablation bed.

4.4.4 Examples of Epithelial Removal Treatments

A. Example 1: Sphere Plus Plano Trans-Epithelial Removal

In this laser-epithelial-removal technique, the surgeon monitors the progress of the epithelial removal and gauges its completeness by observing the pattern of the blue fluorescence, which is produced during epithelial ablation.

- To perform this treatment use a combination of plano and spherical ablations.
  - — Enter a spherical value for the initial ablation.
  - — Enter plano depth for the second ablation.
  - — Select Sphere from the Perform First menu.
  - — Complete the initial spherical component of the ablation.
  - — Plano ablation begins automatically.
  - — Monitor the epithelial fluorescence during the plano portion of the treatment.
  - — When all the fluorescence disappears, lift the footswitch to end the treatment.
- Skip any remaining plano pulses.

Observe the pattern of the dissipating fluorescence for these characteristics to judge the accuracy of the spherical value.

- Spherical value correct: Fluorescence disappears from the entire area almost all at once, indicating a uniform ablation.
- Spherical value too small: Fluorescence first disappears in a ring at the outer diameter of the ablated area, indicating a residual central epithelium. Additional sphere may be applied.
- Spherical value too large: Fluorescence disappears from the center of the ablated area first, indicating a residual peripheral epithelium. Additional plano PTK may be applied.

B. Example 2: Plano Plus Sphere Trans-Epithelial Removal

Values entered may be similar to those in the first example, but the plano portion of the procedure is performed first.

- Monitor the fluorescence during the plano portion.
- Lift the footswitch when the fluorescence just begins to disappear in a ring at the outer diameter.
- Select **SKIP** to proceed to the spherical portion of the procedure.
- Complete the spherical portion of the treatment.

On completion, the program automatically proceeds to the stromal treatment page from which the epithelial removal was selected. Refer to Example 1 for fluorescence patterns.

C. Example 3: Laser Plus Scrape

- Set the spherical value to 0.
- Enter the desired plano depth (for example 45 µm).
- Treat until the desired depth is reached.
- Remove remaining epithelium mechanically.
- Alternatively, monitor the fluorescence as it dissipates from the outer epithelial ring.
- Skip remaining pulses.
- Depress footswitch and treat, or press CANCEL and do more epithelial removal.

D. Example 4: Mechanical

- Gently remove the epithelium using a blunt instrument such as a Paton spatula.
- The region of epithelial removal should be at least 6.4 mm in diameter when using smoothing systems and should be at least 6.0 mm in diameter when using systems without smoothing.
- Clean the stromal bed of debris.
- Saturate a non-fragmenting sponge with balanced sterile saline, squeeze it out, and wipe it over the ablation bed.
- Proceed to the Refractive (PRK) or Therapeutic (PTK) treatment.

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4.5 Post-Operative

A. Patching and Antibiotics

Following completion of the excimer laser surgery, appropriate medications and a bandage contact lens should be applied to the eye in a sterile manner. A steroidal medication may be included at the time of lens insert. Daily observation is required until re-epithelialization is complete, regardless of whether or not steroids are used.

B. Handling Complications

Delayed re-epithelialization of the ablated surface may be anticipated in some patients. It is essential that these patients be monitored on a daily basis with installation of antibiotics and maintenance of a firm patch. The doctor must remain alert to the possible development of corneal infiltrates, which will require appropriate diagnostic and therapeutic measures.

5.0 VISX STAR S2 Surgical Procedures

Before proceeding, please refer to the laser preparation and shut-down procedures presented in the VISX STAR S2 System Operator's Manual, Section 6.2, Turning System On and Off.

The VISX STAR S2 System contains a Class IV laser with an output at 193 nm, which is potentially hazardous to the skin and the surface layers of the cornea. This laser radiation will not enter the eye and poses no threat to retinal structures or the crystalline lens. However, the fixed optical system restricts the beam path, which is bounded by the operating table or the floor. Reflectivity from objects in operating rooms (including surgical instruments) is extremely low for 193 nm radiation.

The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam. All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if there is a possibility that healthcare personnel will approach closer than this distance from the primary beam.

The Professional Use Information Manual is to be used in conjunction with the VISX STAR S2 System Operator's Manual.

5.1 Step-by-Step Procedure — PRK and LASIK

Follow Steps 1 through 20 below to perform PRK or LASIK surgery. After Step 20, the PRK procedure continues with Steps 21 through 34. For LASIK, after performing Steps 1 through 20 below, go to Section 5.1.1 and follow the instructions.

1. Power ON the system.
2. Complete all daily calibrations, as described in the VISX STAR S2 System Operator's Manual, Chapter 8, Calibrating the System.
3. Prepare a VisionKey card with patient information and parameters for the PRK procedure as described in the Operator's Manual, Chapter 9, Entering Treatment Data and Printing Reports. This may be done in advance of treatment.

Ablate a spherical lens after every third ocular treatment to verify the calibration of the VISX STAR S2 System. Refer to the Operator's Manual, Chapter 8, Calibrating the System, for additional information on the calibration procedure.

4. Ensure that all persons in the operating room obey all safety regulations. Caution all attendees in the operating room against touching the laser, patient, or patient chair during the procedure. Movement of personnel in the operating room should be minimized during the procedure. It is recommended that all attendees, including the doctor, wear surgical masks and protective eyewear.

5. Allow the patient the opportunity to become familiar with the sounds of the laser during the calibration procedure.

6. Insert the VisionKey card into the card drive when prompted by the system software. Follow the system software prompts. If the card has been preprogrammed, verify that the card corresponds with the patient to be treated. Add any additional data to the Myopic MZ Treatment screen. For an unprogrammed VisionKey card, enter all necessary data and the planned surgery on the Myopic MZ Treatment screen.

The doctor has the option to perform a test of the patient's procedure parameters prior to the actual procedure. Refer to the Operator's Manual, Section 9.4, Treatment Verification. Confirm that the desired patient parameters are entered in the treatment fields, then fully depress the laser footswitch.

The patient's refraction should be entered into the system software at the spectacle plane, and the vertex distance carefully measured and entered. Accurate vertex distances are essential for the best surgical result. The importance of an accurate and thorough refractive and ophthalmological evaluation cannot be over-emphasized.

7. Power ON the video recorder.

8. Center the mechanical position of the chair using the guide marks found on the chair base.

9. Seat the patient and lower the patient chair backrest to a full reclining position while monitoring patient clearance. Ensure that the patient is comfortable.

10. Position the patient so the lateral canthus aligns to the mark on the headrest.

11. Place the vacuum pillow under the patient's head with the bottom portion of the "U" supporting the patient's neck. Assure that there is no head tilt or rotation present. This is accomplished by assuring that a line from the vertex of the chin through the nasion is parallel to the operating table.

12. Cover the untreated eye with an opaque shield that protects the eye and occludes vision. A post-operative surgical shield covered with electrical tape is suitable for this purpose. Instruct the patient to keep both eyes opened during the surgical procedure.

13. Monitor patient clearance while rotating the patient chair to the treatment position, then lock the patient chair in place by pressing the foot pedal in the

locked position. The chair must be fully rotated and the foot pedal locked for the laser to operate. Correct positioning is confirmed by the green status bar on the computer screen, which allows the procedure to continue.

If the patient chair is not in the treatment position and securely locked, the laser will not fire. Check the interlock message on the status screen.

14. Check the surgical parameters entered into the computer against the surgical plan and confirm that all interlocks are cleared. The accuracy of the entered data is the responsibility of the doctor.

15. Instruct the patient to remove earrings prior to using the vacuum pillow. Adjust the patient's head and vacuum pillow for comfort, angle, alignment, and stability. Connect the vacuum pillow suction tubing to the suction port located on the patient chair headrest. While keeping the patient properly aligned, conform the pillow shape to the patient's head, creating support under the occiput of the skull. This is more effective than creating lateral support for the head. Holding the pillow support against the occiput, power ON the suction pump switch, which is between the two (2) tilt knobs on the headrest. After several seconds, the pillow will harden and conform to the patient's head. This creates a comfortable, stable platform for the patient. Disconnect the tubing after the pillow has hardened.

16. Position the patient with the microscope set at low zoom magnification. When the cornea is visible in the microscope, focus the image of the cornea and increase the magnification. Refer to the Operator's Manual, Section 6.6, Focusing Instructions for the VISX STAR S2 System Microscope. Instruct the patient to begin fixating on the blinking red fixation light.

17. Move the patient so the microscope reticle is centered over the patient's pupil. Chair movement is controlled by the doctor's keypad. Refer to the Operator's Manual, Section 6.3.1, Preparing Chair for Patient, for information regarding chair movement.

The microscope oculars must be properly focused to accommodate the doctor's refraction. This will assure that the microscope focal plane and the laser focal plane are coincident.

18. Continually encourage the patient to maintain fixation on the blinking red fixation light throughout the procedure.

19. Verify that all color status bars are green in the procedure screen of the system software. If a yellow status bar is displayed, you may continue with the procedure; however, a condition exists that warrants attention as soon as

possible after completion of treatment. A red status bar will prevent system operation. Therefore, any interlock must be cleared prior to a treatment.

20. After verification of green system status bars, warn all attendees to stand clear of the laser, patient, and patient chair. Accidental bumping of the laser, patient, or patient chair during the surgery can cause de-centering of the treatment area. Movement in the operating room must be kept to a minimum during patient treatment.

To perform LASIK, skip now to Section 5.1.1, and follow the instructions. To perform PRK, continue by following Steps 21 through 34 below.

21. Insert a closed blade speculum into the eye to hold the eyelid open. If using mechanical epithelial removal, a 6.0 or 6.5 mm marker can be used, centered over the entrance pupil and gently depressed onto the epithelial surface. If the laser-scrape technique is to be used, then there is no need to mark the epithelium.

22. Epithelial removal is best performed using the ring illuminator, with the illumination on the lowest setting that allows good visualization of the epithelial surface while not causing the patient discomfort. This is accomplished by setting the ring illuminator on low power and gradually increasing illumination until the epithelial surface is comfortably in view. Visibility of the red blinking fixation light by the patient is facilitated by low operating illumination.

23. After confirming the pupillary centration of the 6.0 or 6.5 mm marker, mechanical removal is facilitated by placing one or two drops of anesthetic in the operative eye prior to commencing the surgical procedure. Many light, even strokes at a fixed site may be necessary to start the mechanical epithelial removal process. Avoid hard pressure that deforms the cornea. Use rapid, even strokes until the epithelium is completely removed. Mechanical epithelial removal can be accomplished with either a blunt spatula or a small blade such as a Beaver 64. If a sharp instrument is used, take care not to disrupt Bowman's membrane. If a patient has not had adequate pre-operative topical anesthesia, place a 6.0 mm anesthetic-soaked pledget on the cornea prior to removal of the epithelium. Remove the pledget after 60 seconds. If laser-scrape epithelial removal is to be used, place one or two drops of anesthetic in the operative eye prior to commencing the surgical procedure. The epithelial portion of the ablation should be set between 40 and 45 μm. The epithelium does not need to be mechanically marked if using the VISX STAR S2 system, as the reticle can be used to center the ablation over the entrance pupil. The reticle must be kept centered over the entrance pupil throughout the ablation of the epithelium. In the laser-scrape procedure, the foot pedal is depressed to complete the epithelial portion of the ablation, while the stromal portion is initiated only with a second foot depression. The

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epithelial portion of the ablation is a 6.0 mm PTK-type of ablation, while the stromal portion is PRK. After either mechanical removal or laser-scrape, the surface of the cornea must be wiped with a nonfragmenting sponge that has been soaked with balanced sterile saline and then squeezed so it is moist but not saturated. For more detailed instructions on laser epithelial removal, see Section 10.1.1 in the Operator's Manual, "Complete Laser Epithelial Removal."

There should be no epithelial cells in the 6.0 mm diameter treatment zone prior to laser initiation. Avoid adding fluids to the cornea after epithelial removal has begun. Position the head so the cornea is centered within the lid speculum. This minimizes the potential for tears to touch the corneal surface during surgery.

24. If, during the epithelial removal process, the surface of the cornea appears unevenly hydrated, wipe the area with a nonfragmenting sponge that has been soaked with balanced sterile saline and then squeezed so it is moist but not saturated.

25. Patients with nystagmus or poor fixation may require external fixation.

Keep the patient relaxed by explaining the process as you go along. Use the dimmest ring illumination intensity that allows the doctor to remove the epithelium. This low illumination is more comfortable for the patient. Use the oblique halogen illumination at its lowest intensity during laser ablation.

26. Just prior to surgery, verify that the pupil is centered in the reticle and the patient is fixating on the blinking red fixation light. Instruct the patient to maintain fixation on the blinking red fixation light at all times. Switch from the ring illumination to the lowest intensity of the oblique illumination.

27. Check the system focus and adjust the oblique illumination to the lowest intensity that allows monitoring of the pupil position during surgery. Depress the laser footswitch to initiate the procedure. The footswitch has two (2) positions. The first position powers ON the aspirator and pumps within the laser. The footswitch is only partially depressed in the first position. The second position allows the laser to fire and initiates the laser surgery. The footswitch is fully depressed in the second position. It is the doctor's responsibility to continually monitor the position of the patient's eye during the surgery to assure proper ablation centration.

Make sure all laser pulses have been fired. Check the Heads-Up Display to confirm treatment completion.

28. When the surgery is complete, remove the speculum and allow the patient to close the eye which has just undergone the laser surgery. Power OFF the microscope light and relieve the vacuum in the patient pillow.

The doctor may interrupt the procedure for any reason, at any time, by releasing the laser footswitch. This may be done if the patient should move and the treatment area becomes de-centered. The doctor then realigns the eye and continues the procedure by depressing the laser footswitch again. The procedure will automatically start from the point of interruption.

29. Lower the patient chair to its lowest position, then rotate the patient chair from under the laser while carefully monitoring patient clearance. Remove the eye shield from the untreated eye.

30. Place appropriate post-operative medications in the treated eye. Following application of medication, apply a firm pressure patch to the eye.

31. Raise the chair backrest to a sitting position. Assist the patient in putting on any spectacles, and escort him or her to a waiting area.

32. Ensure that the patient is given post-operative instructions. An analgesic may be given to the patient prior to leaving the facility.

33. Review post-operative instructions, confirm the first follow-up appointment, and discharge the patient when stable.

34. Clean the debris removal nozzle with isopropanol wipes and prepare the system for the next patient.

Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol.

Warn the patient about the hazards of driving immediately after surgery. The combination of analgesic and eye patch can be very dangerous.

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5.1.1 LASIK Procedure

Perform the following steps for LASIK after completing Steps 1 through 20 in Section 5.1.

1. The patient may be given a systemic medication (e.g., analgesic or sedative) at the physician's discretion before the procedure.
2. Perform a lid scrub with a topical surgical disinfectant.
3. Apply topical ophthalmic antibiotic agent to the operative eye.
4. Insert a new blade into the microkeratome. Test the microkeratome for suction, movement, and correct function.
5. Instill topical ophthalmic anesthetic to the operative eye.
6. Place a lid speculum into position.
7. Place the suction ring on the eye with a slight nasal displacement and apply suction. Perform tonometry to assure adequate suction. Place balanced saline solution (BSS) on the cornea and cut a flap with the microkeratome. Release the suction.
8. Using a forcep, displace the flap. Gently wipe the exposed corneal surface with an ophthalmic surgical sponge to ensure that the surgical area is free of epithelium and other debris. Remove fluid from the fornices with an ophthalmic surgical sponge.
9. Align the operative eye so that the reticle is centered on the entrance pupil while the patient views the blinking red fixation light. If the patient is unable to maintain fixation to the surgeon's satisfaction a fixation handpiece may be used to hold the eye.
10. Adjust and maintain the focus on the anterior corneal surface.
11. After ensuring that the reticle is centered over the patient's pupil and the patient is viewing the red fixation light, fully depress the foot pedal to perform the laser treatment. If necessary, stop the laser every 20 seconds and dry the cornea.

Keep the patient relaxed by explaining the process as you go along. Use the oblique halogen illumination at its lowest intensity during laser ablation.

12. The footswitch has two (2) positions. The first position powers ON the aspirator and pumps within the laser. The footswitch is only partially depressed in the first position. The second position allows the laser to fire and initiates the laser surgery. The footswitch is fully depressed in the second position. It is the doctor's responsibility to continually monitor the position of the patient's eye during the surgery to assure proper ablation centration.

Make sure all laser pulses have been fired. Check the Heads-Up Display to confirm treatment completion.

The doctor may interrupt the procedure for any reason, at any time, by releasing the laser footswitch. This may be done if the patient should move and the treatment area becomes de-centered. The doctor then realigns the eye and continues the procedure by depressing the laser footswitch again. The procedure will automatically start from the point of interruption.

13. Instill Ciloxan on the corneal bed and the flap, and replace the flap onto position. Irrigate underneath the flap and on top with BSS. Using a wet ophthalmic surgical sponge, gently stroke the flap into its original position. If necessary, use a dry ophthalmic surgical sponge to remove any excess moisture from the incision. Use pressure at the limbus to assure that the flap is re-adhered.

14. Move the patient away from the laser and apply topical ophthalmic medications to the cornea.

15. Print the laser treatment information.

16. Record the flap thickness, flap diameter, hinge diameter, hinge location, and environmental conditions (temperature and humidity).

17. If planned, and the first eye is without surgical complication, repeat this procedure on the fellow eye.

18. When the LASIK surgery is complete, remove the speculum and allow the patient to close the eye which has just undergone the laser surgery. Power OFF the microscope light and relieve the vacuum in the patient pillow.

19. Lower the patient chair to its lowest position, then rotate the patient chair from under the laser while carefully monitoring patient clearance. Remove the eye shield from the untreated eye.

20. Place appropriate post-operative medications in the treated eye. Following application of medication, apply a firm pressure patch to the eye.

21. Raise the chair backrest to a sitting position. Assist the patient in putting on any spectacles, and escort him or her to a waiting area.

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22. Ensure that the patient is given post-operative instructions. An analgesic may be given to the patient prior to leaving the facility.

23. Review post-operative instructions, confirm the first follow-up appointment, and discharge the patient when stable.

24. Clean the debris removal nozzle with isopropanol wipes and prepare the system for the next patient.

Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol.

Warn the patient about the hazards of driving immediately after surgery. The combination of analgesic and eye patch can be very dangerous.