

**Patient Information Booklet**

**Important Information About:  
LASIK Treatment for Farsightedness (Hyperopia)  
using the  
Nidek EC-5000 Excimer Laser System**

Surgical Laser Treatment for Vision Correction of Farsightedness (Hyperopia) from +0.5 to +5.0 D of sphere with or without astigmatic refractive errors from +0.5 to +2.0 D with manifest refraction spherical equivalent (MRSE) of +5.0 D or less

**PLEASE READ THIS ENTIRE BOOKLET**

Discuss its contents with your doctor so that all of your questions are answered to your satisfaction.

Ask any questions you may have before you agree to the surgery.

Ask your doctor about certain limitations in the range of correction. You may not qualify for treatment with certain amounts of farsightedness or astigmatism.

Distributed by:  
Nidek Incorporated  
47651 Westinghouse Drive  
Fremont, California 94539  
Phone: (510)-226-5700  
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## 1 INTRODUCTION

Please read this booklet if you are thinking about having a type of laser eye surgery, called Laser in situ Keratomileusis' (LASIK) to correct your vision for farsightedness (hyperopia) with or without astigmatism. Other ways to correct hyperopia and astigmatism include glasses, contact lenses, and other kinds of vision correction surgery such as photorefractive keratectomy (PRK) and conductive keratoplasty (CK).

This booklet is intended to help you decide how to correct your farsightedness. Please read this booklet completely. Discuss your questions with your doctor to decide if LASIK is the right choice for you. Only a trained and certified doctor can determine whether or not you are a suitable candidate for LASIK.

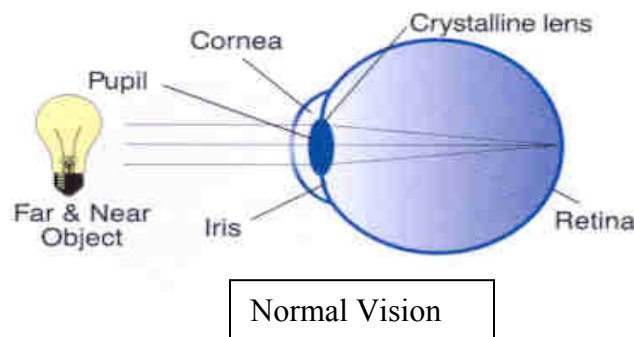
The goal of LASIK is to reduce your need for glasses or contact lenses by changing the shape of your cornea. However, LASIK does not always correct your vision perfectly. The laser may undercorrect or overcorrect your vision so that you still need glasses to see clearly. In some cases LASIK can make your vision permanently worse, so that you cannot even see clearly with glasses.

Both of your eyes may need correction. It is up to you and your doctor to decide if it is best for you to have surgery on both of your eyes or only on one.

## 2 HOW THE EYE WORKS

The cornea and lens of the eye work like a camera lens to form an image on the retina at the back of the eye. The sharpness of that image depends on the overall shape and size of your eye, the shape of the cornea, and the lens inside your eye.

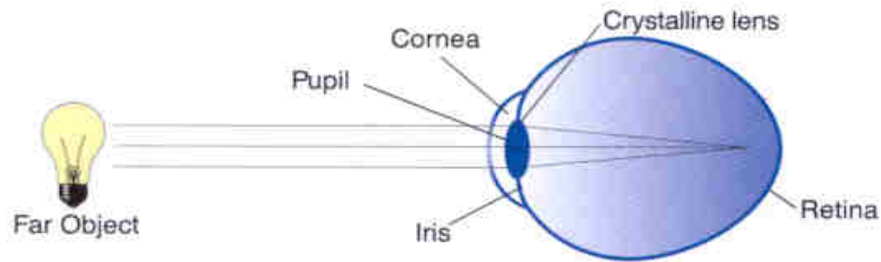
When light enters the eye, it passes first through the cornea, then the pupil, then through the lens, and finally to the retina, as shown in the drawing below. The cornea and the lens bend the light rays so that they focus, or come together at a single point on the retina.



When the light rays focus either in front or in back of the retina, the pictures that are formed on the retina are blurred and you are said to have a refractive error. Refractive

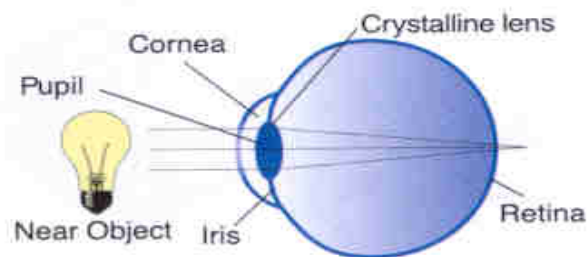
errors are common in people around the world. The three main types of refractive errors are nearsightedness (myopia), farsightedness (hyperopia), and astigmatism.

Nearsightedness occurs when the eye is too long. Nearsighted eyes can see clearly close up but distant objects look blurred because the images are focused in front of the retina. Nearsightedness can be corrected by glasses or contact lenses that move the image back onto the retina. Refractive surgery with a laser can also correct nearsightedness by removing tissue from the center of the cornea. This makes the cornea flatter so that the picture is in focus on the retina instead of in front of the retina.



Nearsightedness (Myopia)

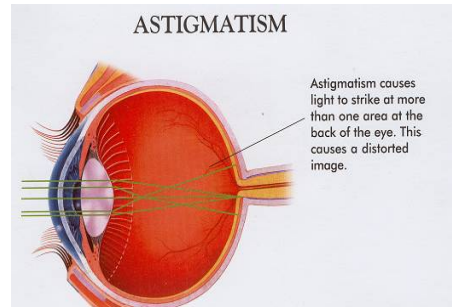
Farsightedness is the opposite of nearsightedness. The eye is too short and images are in focus behind the retina. Eyes that are farsighted have more difficulty seeing near objects than far away objects. The eye has the ability to adjust the shape of its lens to bring nearby objects into focus. This ability is called accommodation. How well the eye can accommodate, or adjust its focus from far to near objects also affects how well the farsighted eye can see far objects as well as near objects. Like nearsightedness, farsightedness can be corrected with glasses, contact lenses or laser surgery that moves the image to the retina. Laser surgery for the treatment of farsightedness removes more tissue in the outer edges of the cornea to make the cornea more curved so that images are in focus on the retina instead of behind the retina.



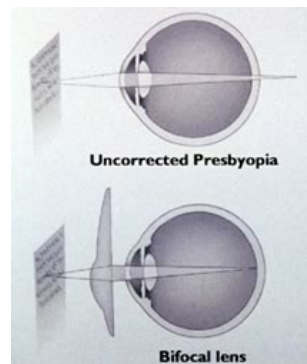
Farsightedness (Hyperopia)

An eye has astigmatism when the cornea is more curved in one direction than another. Some light rays focus in front of the retina and others focus behind it. Since the light rays are not all bent to a single point, the picture that is created on the retina is distorted

or fuzzy. Glasses, contact lenses, and laser surgery each use a cylinder shaped correction that is tilted at an angle to match the angle at which the cornea is curved the least. With the correction, the images focus onto the retina in a single point instead of in scattered points.



Presbyopia is a naturally occurring change in vision that happens as you age. After you reach the age of 40, the lens in the eye gradually becomes less elastic and begins to lose its ability to accommodate or change its focusing power from far to near objects. As a result, you may begin to have problems seeing objects that are near to you or reading small print at your normal reading distance as you grow older. Presbyopia can occur along with nearsightedness, farsightedness, and astigmatism. There is presently no treatment available that can restore accommodation in patients with presbyopia. However, presbyopia can be corrected by wearing reading glasses whenever you need to see objects that are close or to read or by wearing bifocal glasses or contact lenses that have additional correction placed in the lower segment of the glasses or contact lenses that you look through for reading or seeing near objects as shown in the diagram below.



The type of laser surgery you need depends on the type of refractive error your eye has. Your doctor detects whether you are nearsighted, farsighted, or have astigmatism by determining where the light rays focus on your retina during a regular eye examination. This is done by adjusting your vision with different lenses until the image you see is correctly focused on the retina. This procedure (called a manifest refraction) is used to determine whether you have nearsightedness, farsightedness, or astigmatism and the amount of each refractive error that is present in the eye. The amount of refractive error present in the eye is measured in units called "diopters." In North America, about 25% of the population is nearsighted and about 10% is farsighted.

It is important for you to understand that refractive surgery cannot be undone or easily changed if your vision changes or if the first surgery is not successful. With glasses or contacts, changes in your vision that occur slowly over time can be corrected by simply adjusting the lens prescription of your glasses or contacts. Nearsightedness, farsightedness, and astigmatism can range from very mild to very strong. The range of treatment with the Nidek EC-5000 Excimer Laser System to correct myopia or hyperopia with or without astigmatism covers a large part of that range. Whether you can have LASIK surgery will depend on the type and amount of refractive error that you have as well as other important information about your eyes.

### **3 WHAT IS LASIK?**

LASIK is laser surgery to reshape the cornea to correct near-sightedness (myopia) with or without astigmatism or farsightedness (hyperopia) with or without astigmatism. The laser fires a stream of up to 40 pulses of ultraviolet light per second. Each pulse lasts only a few billionths of a second. Each pulse removes a tiny amount of tissue by evaporating it. The pulses are placed in a pattern that makes the cornea either flatter (nearsightedness) or steeper (farsightedness). Excimer laser light does not penetrate the eye and does not harm the iris, lens, or retina. The laser produces very little heat and is controlled by the doctor during the operation.

Before starting the LASIK procedure, your doctor will place numbing drops on your eye to numb it. Your doctor will then cut a thin flap on the front of the cornea using a microkeratome or another laser designed to cut the flap. The doctor will then fold back this flap and expose the middle layer of the cornea where the laser treatment is performed. This part of the procedure usually takes a couple of minutes. The doctor then performs the LASIK procedure.

The laser treatment usually lasts about 15-40 seconds, depending on the type and amount of correction. During the procedure, you will be asked to look steadily at a light so that your eye does not move. After the laser treatment is complete, the doctor will fold the flap of cornea tissue back into place to complete the procedure.

This procedure is performed on one eye at a time. If all goes well with the first eye and you are having your second eye treated, the second eye may be treated on the same day or on a different day.

## **4 WHAT CAN LASIK SURGERY WITH THE NIDEK EC-5000 LASER SYSTEM FOR FARSIGHTEDNESS CORRECT?**

LASIK surgery with the Nidek EC-5000 Excimer Laser System can correct from +0.5 to +5.0 D of farsightedness with or without astigmatic refractive errors from +0.5 to +2.0 D with manifest refraction spherical equivalent (MRSE) of +5.0 D or less. MRSE is a way of calculating how much farsightedness and astigmatism together that your eye has. If you have farsightedness within this range, LASIK treatment with the EC-5000 may help you see objects that are far away more clearly without eyeglasses or contact lenses. The treatment may also help you see objects that are up close or improve your ability to read.

## **5 CLINICAL STUDY TO EVALUATE THE BENEFITS OF LASIK TREATMENT FOR FARSIGHTEDNESS**

A clinical study was conducted to determine the benefits and risks of treating farsightedness with or without astigmatism with the Nidek EC-5000 Excimer Laser System. In the study, 149 eyes were treated for farsightedness with astigmatism and 144 eyes were treated only for farsightedness. A total of 148 patients were enrolled and all but 3 patients had both eyes treated in the study. The study was conducted at six centers in the United States and one center in Mexico. Patients enrolled in the study were treated between December 2003 and December 2004. This booklet reports the outcomes for these patients through 1 year after they had LASIK surgery. Each of the tables lists the total number of eyes (N) that are included in each analysis, the number of eyes (n) out of the total number of eyes included in the analysis (n/N) that have the outcome that is reported, and the percentage (%) of eyes that have each outcome reported.

### **Demographics**

Table 1 presents the demographic information for the 148 patients enrolled in the study. Of these, 32% were male and 68% were female. Racial distribution consisted of 70% Caucasian, 28% Hispanic, 1% Black, and 1% Asian. The average age of all the patients was 49.5 years. The youngest patient was 23 years old and the oldest was 69.

TABLE 1 Clinical Study Patient Demographic Characteristics	
	% (n/N)
GENDER	
Male	32% (48/148)
Female	68% (100/148)
RACE	
Caucasian	70% (103/148)
Black	1% (2/148)
Asian	1% (2/148)
Hispanic	28% (42/148)
AGE	
Average	49.5 years
Standard Deviation	±8.9 years
Minimum	23 years
Maximum	69 years

## Vision Without Glasses After Treatment

A letter chart was used to measure how well patients in the study could see **without** the use of glasses or contact lens before and after the LASIK surgery. As shown in Table 2 below, at 1 month after the LASIK surgery 60% of the eyes could see 20/20 or better **without** any type of glasses or contact lenses and 99% of the eyes could see 20/40 or better. Most states require that you see at least 20/40 or better to obtain a driver's license without wearing glasses or contact lenses.

TABLE 2 Vision <u>Without</u> Glasses						
	PREOP	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
20/20 or better	6%	60%	56%	60%	61%	61%
20/25 or better	9%	84%	85%	86%	83%	82%
20/32 or better	15%	95%	96%	95%	95%	95%
20/40 or better	21%	99%	98%	99%	99%	99%

## Vision Without Glasses After Treatment Compared to Vision With Glasses Before Treatment

Table 3 compares how well patients were seeing without any glasses or contact lenses after their LASIK surgery compared to how well they were seeing with glasses or contact lenses before they had LASIK surgery. *At all post-op visits from 1 month onward, 75-79% of treated eyes had vision without glasses that was within 1 line of their vision with glasses or contact lenses before LASIK, and 20-24% of eyes had vision without glasses that was at least 2 lines worse than their vision with glasses or contact lenses before surgery.* At 12 months, 80% of the patients were seeing nearly as well (within 1 line or better) without glasses after the surgery as they did with their glasses before the surgery.

TABLE 3						
Vision <u>Without</u> Glasses after LASIK compared to Vision <u>With</u> Glasses Before LASIK						
	WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)
Vision <u>without</u> glasses after LASIK $\geq$ 2 lines ( $\geq$ 10 letters) better than vision <u>with</u> glasses before LASIK	2% (5/293)	3% (9/291)	1% (3/291)	1% (3/291)	1% (4/287)	1% (3/279)
Vision <u>without</u> glasses after LASIK within 1 line (5 letters) of vision <u>with</u> glasses before LASIK	70% (205/293)	77% (224/291)	78% (227/291)	75% (219/291)	75% (214/287)	79% (220/279)
Vision <u>without</u> glasses after LASIK $\geq$ 2 lines ( $\geq$ 10 letters) worse than vision <u>with</u> glasses before LASIK	28% (83/293)	20% (58/291)	21% (61/291)	24% (69/291)	24% (69/287)	20% (56/279)

## Changes in Quality of Vision Without Glasses After Treatment Compared to Vision With Glasses Before Treatment

Patients were asked to rate their visual symptoms before their LASIK surgery when using their glasses or contact lenses and after their LASIK surgery without using their glasses or contact lenses. Clinically significant changes in a symptom were considered to have occurred when there was a 10% or greater proportion of subjects that reported an improvement or worsening of a symptom. Using this criterion, there was a clinically significant improvement in night driving (12.4%) and difficulty reading (25.1%), and clinically significant worsening in dryness after LASIK (13.7%), as well as worsening of reading difficulty (10.3%), although this is offset by the number of patients with an improvement in their ability to read (25.1%).

<b>TABLE 4</b>			
<b>Change in Subjective Complaints between Baseline and 6 Months</b>			
<b>Symptom</b>	<b>Better than Baseline (2 or more grade change)</b>	<b>No Change from Baseline (0-1 grade change)</b>	<b>Worse than Baseline (2 or more grade change)</b>
	<b>% (n/N)</b>	<b>% (n/N)</b>	<b>% (n/N)</b>
LIGHT SENSITIVITY	7.9% (23/291)	89.3% (260/291)	2.7% (8/291)
DIFFICULT NIGHT DRIVING	12.4% (36/291)	85.2% (248/291)	2.4% (7/291)
DIFFICULTY READING	25.1% (73/291)	63.0% (186/291)	10.3% (30/291)
DOUBLE VISION	0.7% (2/291)	97.3% (283/291)	2.1% (6/291)
FLUCTUATION IN VISION	1.4% (4/291)	92.1% (268/291)	6.5% (19/291)
GLARE	8.6% (25/291)	90.0% (262/291)	1.4% (4/291)
HALOS	3.4% (10/291)	93.1% (271/291)	3.4% (10/291)
STARBURSTS	2.1% (6/291)	95.9% (279/291)	2.1% (6/291)
DRYNESS	2.7% (8/291)	83.5% (243/291)	13.7% (40/291)
PAIN	0.3% (1/291)	99.7% (290/291)	0% (0/291)
FOREIGN BODY	0.3% (1/291)	97.6% (284/291)	2.1% (6/291)

## **6 RISKS OF LASIK TREATMENT FOR FARSIGHTEDNESS**

LASIK is a laser surgical procedure involving your eyes and, like any surgical procedure, there are potentially serious risks. Your vision may not be perfect after LASIK surgery and you may need to have additional laser treatment in the same eye. You should consider these risks carefully and discuss them with your doctor before you decide to have LASIK surgery. You should also talk with your doctor about whether it would be better for you to have LASIK surgery in both of your eyes or only one eye.

The risks listed here are based on clinical experience with LASIK cases and the concerns that doctors believe should be considered for this kind of eye surgery. Some risks are related to the corneal flap and not to the laser treatment itself. Possible corneal flap complications could include, but are not limited to:

- Cutting an incomplete flap, irregularly shaped flap, or a flap that is completely free of the cornea;
- Not properly aligning the flap when it is replaced; or,
- Perforating the cornea during the flap cutting procedure.

Other possible corneal flap complications may not be listed here. If a flap complication occurs, you may need to postpone your LASIK surgery until the flap heals. A flap complication may also result in a corneal irregularity that permanently blurs your vision and prevents you from having LASIK surgery.

### **IMPORTANT**

You may need reading glasses after LASIK surgery even if you did not wear them before the surgery. You may not have perfect vision after the surgery. You may need to wear glasses or contact lenses for some activities after the laser surgery or you may need to have additional laser surgery to correct your vision.

## **Contraindications**

You should not have LASIK surgery if:

- You have collagen vascular, autoimmune or immunodeficiency diseases (for example: rheumatoid arthritis, lupus or AIDS). These conditions may result in scarring or poor healing after LASIK treatment resulting in reduced vision.
- You are pregnant or nursing. These conditions may affect your preoperative refraction, making it difficult to choose the correct amount of LASIK treatment.
- You show signs of thinning of the cornea (keratoconus). This condition can lead to serious cornea problems that require additional surgical repair and result in poor vision.
- You are taking the following medications: isotretinoin (Accutane®) or amiodarone hydrochloride (Cordaron®). These may affect your refractive outcome and possibly result in reduced vision after LASIK treatment.
- Your cornea is too thin to allow your doctor to properly cut a corneal flap. LASIK cannot be performed unless a corneal flap is created. You may be able to have other types of refractive surgery that do not require a corneal flap to perform the procedure.

## **Warnings**

Discuss with your doctor if:

- You have diabetes or connective tissue disease. These conditions may also involve your eyes. Eyes that have vision problems from these diseases may affect the accuracy of your refractive results.
- You have been diagnosed with ocular Herpes simplex or ocular Herpes zoster. Herpes are viral infections. Laser treatment may reactivate the infection.

You may have LASIK surgery if your doctor evaluates the severity of your condition and you and your doctor both agree that the benefit of having LASIK surgery is greater than the risk.

You should also be aware that your results may not be as good as those reported in the clinical study if you have more severe farsightedness or astigmatism.

## Precautions

The safety and effectiveness of the Nidek EC-5000 Excimer Laser were NOT evaluated in the farsightedness clinical study for the following conditions or situations. Therefore, the safety and effectiveness of performing LASIK is unknown if you have any of these conditions or situations:

- Your vision has changed in the past year. Treatment of unstable vision may affect the accuracy of your refractive results.
- Your eyes have large pupils (> 8mm diameter) in dim or dark light. You may have more problems driving at night if you have large pupils at night and you have LASIK surgery on your eyes.
- You have had other eye problems that could cause problems after the LASIK surgery, such as corneal ulcers, other surgery, scars, or injury to the area of cornea where LASIK will be performed. These types of problems can cause the surface of the cornea to be irregular and may affect the accuracy of your refractive results.
- You are taking medications that affect corneal healing or your vision, such as steroids, antimetabolites, and sumatriptan hydrochloride (Imitrex®). You should discuss all medications you take, even over-the-counter medications, with your eye doctor. Many medications can affect the way your cornea is changed by the laser and the way it heals after LASIK treatment. These may affect your refractive outcome and possibly result in reduced vision after LASIK treatment.
- You have severe allergies. Your medications may have to change before or after your eye surgery. These medications may change the wetness (moisture level) in your eye. If the medication changes the wetness of your eye, the accuracy of your refractive results may be affected.
- You have dry eyes that were not detected before you decided to have surgery or dry eyes that have not responded to treatment. Your doctor should evaluate you for dry eyes before surgery. Eye dryness may affect the accuracy of your refractive results and your comfort after the surgery may be affected. You may have dry eyes after LASIK surgery even if you did not have dry eyes before surgery.
- You have other eye diseases, such as glaucoma, high pressure in the eye, or diseases of the retina, that could cause you to have complications during or after the surgery.
- You have nystagmus (uncontrolled eye movements) or another condition that prevents a steady gaze. You need to be able to keep your eyes still during treatment. The accuracy of your refractive results will be affected if you can not keep your eyes still during treatment.
- Patients under 21 years of age.

If you have any of these conditions or situations, you may have LASIK surgery if your doctor evaluates the severity of your condition or situation and you and your doctor both agree that the benefit of having LASIK surgery is greater than the risk.

Although the effects of LASIK on visual performance under poor lighting conditions have not been determined, it is possible that you 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. These effects have been reported as being more common in persons with large pupils (over 6 mm). These effects may be permanent.

## Clinical Study to Evaluate Risks

The clinical study evaluated the safety of using the EC-5000 Excimer Laser System for the treatment of farsightedness with or without astigmatism.

## Vision With Glasses Before and After Treatment

Table 5 compares how well patients could see with glasses or contact lenses before and after their LASIK surgery. At 12 months, 27% of the patients saw 1 or 2 lines better with glasses than they did with glasses or contact lenses before surgery and more than half (57%) saw the same. One eye lost more than 2 lines (10 letters on the eye chart) of best corrected vision beginning at 6 months, but this reduction in vision was due to the development of a cataract that was not related to the LASIK surgery.

<b>TABLE 5</b>						
<b>Vision with Glasses After Treatment Compared to Before Treatment</b>						
	1 WEEK	1 MONTH	3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS
More than 2 Lines Worse	0%	0%	0%	<1%	<1%	<1%
2 Lines Worse	4%	<1%	1%	3%	3%	<1%
1 line Worse	23%	16%	16%	18%	17%	15%
Same Before and After	54%	57%	57%	53%	58%	57%
1 Line Better	16%	22%	21%	23%	19%	26%
2 lines Better	1%	3%	4%	2%	2%	1%
More than 2 lines Better	1%	1%	1%	0%	0%	0%

[NOTE: One line of vision is equal to seeing 5 letters and 2 lines of vision is equal to seeing 10 letters on the eye chart that is used to measure your vision.]

## Adverse Events and Complications

Some patients in the clinical study experienced adverse events or complications during the LASIK surgery procedure or after the LASIK treatment. These are listed in Table 6 below.

	Day of Surgery	Less than 1 Month	1 Month	3 Months	6 Months	9 Months	12 Months
Swelling of cornea		<1%	0%				
Defect in edge of flap	0%	0%	0%	<1%	0%	0%	0%
Cells growing under the flap	<1%	0%	0%	<1%	0.0%	0.0%	<1%
Feeling of something in the eye			1%	0%	0%	<1%	0.0
Pain in the eye			1.4%	0%	0%	0%	0%
Ghost or double images	0%	0%	0.7%	0%	0%	0%	0%
Microkeratome created irregular flap	<1%						
Inflammation of the cornea		4%	<1%	<1%	0%	0%	0%
Dry eyes requiring artificial tears			3%	<1%	1%	0%	0%
Vision with glasses is 2 or more lines worse than before treatment				1%	2%	2%	<1%

## Patient Symptoms after Farsighted LASIK Treatment Without Glasses Compared to Before LASIK Treatment With Glasses or Contact Lenses

Patients were asked to rate the following visual symptoms before and after the LASIK treatment. The occurrence of symptoms that were rated as none, mild, moderate, marked, or severe are presented in Table 7. Patient reports of light sensitivity, glare, night driving problems, and difficulty reading all improved after the LASIK treatment. Reports of dryness worsened after LASIK. Fluctuation in vision (changes throughout the day) and foreign body sensation (feeling of something in your eye) also worsened, which is expected since these symptoms commonly occur as a result of the eye dryness. Patients were not asked to rate their satisfaction with the LASIK surgery, nor did they record their use of glasses or contact lenses after the LASIK surgery, therefore, these outcomes were, not evaluated in the clinical study.

**TABLE 7**  
**Visual Symptoms Before and After LASIK**

QUESTION	VISIT	NONE	MILD	MODERATE	MARKED	SEVERE
LIGHT SENSITIVITY	SCREENING	71%	20%	6%	2%	1%
	POSTOP MONTH 6	73%	23%	3%	1%	0%
	POSTOP MONTH 12	79%	14%	5%	1%	1%
DIFFICULTY NIGHT DRIVING	SCREENING	68%	19%	9%	2%	1%
	POSTOP MONTH 6	84%	13%	3%	0%	9%
	POSTOP MONTH 12	80%	14%	5%	1%	0%
DIFFICULTY READING	SCREENING	50%	18%	21%	8%	3%
	POSTOP MONTH 6	53%	30%	10%	6%	1%
	POSTOP MONTH 12	47%	32%	14%	6%	1%
DOUBLE VISION	SCREENING	97%	2%	0%	0%	0%
	POSTOP MONTH 6	96%	2%	2%	0%	0%
	POSTOP MONTH 12	92%	7%	1%	0%	0%
FLUCTUATION IN VISION	SCREENING	87%	11%	2%	0%	0%
	POSTOP MONTH 6	64%	29%	5%	2%	0%
	POSTOP MONTH 12	74%	21%	4%	0%	1%
GLARE	SCREENING	79%	12%	6%	2%	1%
	POSTOP MONTH 6	78%	20%	2%	0%	0%
	POSTOP MONTH 12	80%	13%	5%	1%	0%
HALOS	SCREENING	88%	8%	3%	1%	1%
	POSTOP MONTH 6	81%	14%	3%	1%	0%
	POSTOP MONTH 12	84%	11%	4%	1%	0%
STARBURSTS	SCREENING	92%	5%	2%	1%	0%
	POSTOP MONTH 6	84%	14%	2%	0%	0%
	POSTOP MONTH 12	88%	8%	4%	0%	0%
DRYNESS <sup>1</sup>	SCREENING	76%	19%	3%	1%	1%
	POSTOP MONTH 1	32%	44%	21%	2%	1%
	POSTOP MONTH 6	46%	38%	12%	3%	1%
	POSTOP MONTH 12	55%	33%	7%	3%	1%
PAIN	SCREENING	99%	1%	0%	0%	0%
	POSTOP MONTH 6	95%	5%	0%	0%	0%
	POSTOP MONTH 12	97%	1%	1%	0%	0%
FOREIGN BODY	SCREENING	95%	5%	0%	0%	0%
	POSTOP MONTH 6	82%	16%	2%	0%	0%
	POSTOP MONTH 12	84%	12%	3%	1%	0%

<sup>1</sup> Clinically significant increase ( $\geq 10\%$ ) in the proportion of eyes reporting moderate to severe dry eye symptoms at 1 Month (24%) and 6 Months (16%) compared to baseline (5%).

## Accuracy of the Farsighted LASIK Treatment

With LASIK surgery, there is a risk that your vision will be corrected either too much or not enough. In the clinical study at 6 months after the LASIK surgery, 69% of all the eyes treated were within  $\pm 0.5$  D and 94% of the eyes were within  $\pm 1.0$  D of the attempted treatment. In the individual groups, 95% of the eyes treated for farsightedness only and 92% of the eyes treated for farsightedness with astigmatism achieved vision within  $\pm 1.0$  D of the attempted refraction. Eyes with this amount of remaining farsightedness can usually still see well enough to pass a driver's license test without correction. None of the eyes (0%) in the study had 2.0 D of farsightedness with or without astigmatism remaining after the LASIK surgery (undercorrected) and only one eye (<1%) was corrected by more than 2.0 D MRSE too much (overcorrected) at 6 months postoperatively. The subject with the overcorrected eye developed cataracts in both eyes, which became noticeable at the 6 month examination. Obtaining a reliable and accurate manifest refraction was difficult in this subject because of the cataracts.

The amount of farsightedness correction that was obtained at 6 months after the LASIK surgery is shown in Table 8 below for the different amounts of farsightedness that was treated in the study. At 6 months, the LASIK surgery corrected 91% of the farsightedness that was present before the surgery. The amount of correction achieved was better in those eyes that had more farsightedness before surgery (96.9% to 105.5% in those eyes with more than 2 diopters of farsightedness compared to 87.4% to 54.3% in those eyes with 2 diopters or less of farsightedness).

Farsightedness Group Before Surgery	0 – 1.0 D	>1.0 – 2.0 D	>2.0 – 3.0 D	>3.0 – 4.0 D	>4.0 – 5.0 D	>5.0D	Total
Eyes in each Farsightedness Group % (n/N)	8% 23/291	35% 103/291	30% 87/291	18% 52/291	6% 18/291	3% 8/291	100% 291/291
Average Amount of Farsightedness Before Surgery	0.75	1.50	2.43	3.37	4.53	5.5	2.35
Average Amount of Farsightedness at 6 Months After Surgery (Range)	0.30 (-1.00 – 0.75)	0.15 (-0.75 – .25)	0.03 (-2.25 – .50)	-0.13 (-3.25 – 1.25)	0.14 (-0.75 – 1.50)	-0.3 (-2.00 – .75)	0.06 (-3.25-1.50)
Average Percent Reduction in the Amount of Farsightedness at 6 Months (Range)	54.3% (-50.0 – 33.3)	87.4% (0.0 – 144.4)	96.9% (29.4 – 178.3)	101.5 (61.5 – 186.7)	98.4 (63.6 – 115.5)	105.5 (86.7 – 138.3)	91.2 (-50.0 – 233.3)

As shown in Table 9 below, the eyes treated for farsightedness with astigmatism that had smaller amounts of astigmatism (-1 D or less) before LASIK had an average of slightly more than half (51.1%) of the astigmatism treated at 6 months after the surgery. Those eyes that had larger amounts of astigmatism (>-1D to -2D) had about two-thirds (64%) of the astigmatism treated at 6 months after LASIK.

Astigmatism Group Before Surgery	0.5 – 1.0 D	>1.0 – 2.0 D	Total Range
Eyes in each Astigmatism Group % (n/N)	72% 99/137	28% 38/137	100% 137/137
Average Amount of Astigmatism Before Surgery	0.67 (0.50 – 1.00)	1.35 (1.125 – 1.875)	0.85 (0.50 – 1.875)
Average Amount of Astigmatism at 6 Months After Surgery (Range)	0.32 (0.0 – 1.25)	0.46 (0.0 – 1.50)	0.36 (0.0 – 1.50)
Average Percent Reduction in the Amount of Astigmatism at 6 Months (Range)	51.1% (-150% - 100%)	64.0% (-20% - 100%)	54.7% (-150% - 100%)

A patient with an eye that still has some farsightedness or astigmatism after the LASIK surgery may wish to have a second LASIK surgery, or retreatment, to improve the vision in that eye. None of the patients in the clinical study had a retreatment. The safety and effectiveness of retreatments is therefore unknown.

## **7 ARE YOU A GOOD CANDIDATE FOR FARSIGHTEDNESS LASIK SURGERY?**

If you are considering having LASIK treatment for your farsightedness with or without astigmatism performed with the Nidek EC-5000 laser, you must:

- Be at least 21 years of age and have farsightedness with or without astigmatism
- Have healthy eyes that have no eye disease or defects or problems with the cornea (e.g., scars, infection, thin cornea, etc.)
- Have documentation of your eye correction history that show your vision has been stable for the past year before you have your preoperative examination. Stable vision is considered to be a change in manifest refraction spherical equivalent (MRSE) not greater than  $\pm 0.5$  D in your required glasses or contact lens correction during the past year.
- Understand the risks and benefits of LASIK treatment for your farsightedness with or without astigmatism compared to other methods for correcting your vision.
- Be able to lie flat on your back without difficulty.
- Be able to gaze steadily at a light to keep your eye steady during the laser surgery.
- Be able to tolerate all of the medications (including the numbing drops) that will be used before, during, or after the LASIK surgery. If you have any allergies to any medications, please make sure you tell your doctor.
- Sign an informed consent form provided by your doctor or his/her staff that you agree to have the LASIK surgery and that you have been informed of and understand the risks and benefits of having the surgery.

## 8 WHAT CAN YOU EXPECT BEFORE LASIK SURGERY?

Before you have laser surgery to correct your vision, you will need to have a complete eye examination. Several tests and measurements will be performed to determine if your eyes are healthy and able to have the surgery. These tests and measurements also determine how much treatment your eyes will need to fully correct your vision. You will also be asked questions about your medical history and any medications you are taking. It is important for you to be truthful and honest with your doctor when you are answering these questions.

### WARNING

If you wear contact lenses, you must stop wearing them before the screening eye examination and must leave them out of your eyes until you have the LASIK surgery. Failure to do this could cause you to have poor results from your surgery or complications from the surgery.

The time you must stop wearing contact lenses before your initial examination depends upon the type of lens. Minimum times for stopping are:

- Soft lenses 3 days
- Soft, toric (astigmatism) lenses 14 days
- Hard gas permeable lenses 4 weeks

Your doctor may ask you to stop wearing your contact lenses for a longer period of time. You will also need to come back for a second visit before the surgery or be examined on the day of surgery to confirm that your vision has stabilized since you stopped using your contact lenses.

## 9 WHAT HAPPENS DURING THE LASIK SURGERY?

You will be taken into the laser room and asked to lie on your back in a reclining chair that is located under the part of the laser that shines the laser beam. Before the surgery, numbing (anesthetic) drops will be placed into the eye to be treated. An instrument will be placed between your eyelids to hold them open. A temporary shield usually covers the eye not having surgery. Surgical draping may be placed over your face, exposing only the eye to be treated, to keep the area around the eye as clean as possible. Your doctor may briefly fire the laser onto a piece of plastic so you can hear what the laser will sound like during the treatment.

If your corneal flap is being cut with a microkeratome, a suction ring will be placed on the eye to increase the pressure in the eye. Your vision will go black temporarily as the pressure is increased. The doctor will attach the microkeratome to the suction ring and cut the corneal flap. The doctor will then release the suction and your vision should no longer be black. The doctor will adjust your head to the correct position under the laser. The doctor will then lift the flap and fold it back, much like opening a hinged cabinet

door. This exposes the middle part of the cornea where the laser treatment will be performed.

The doctor will then focus the laser microscope on this middle part of your cornea. You will be asked to look directly at a blinking light and the laser treatment will begin. It is important for you to continue looking at the blinking light during the entire surgery. Relax the muscles of your face and forehead and try to keep both eyes open without squinting. As you continue to look at the blinking light, the laser pulses will be directed to the cornea and small amounts of tissue will be removed from your cornea.

**PRECAUTION**

It is very important that you keep looking at the blinking fixation light during the procedure, even if the light fades or becomes dim. The success of the treatment depends on you looking steadily at the light throughout the entire treatment.

After the laser surgery is complete, the doctor will fold the corneal flap back into place and smooth the surface. Some drops will be placed in your eye and the instrument holding your eye open and any surgical draping over your face will be removed. You will be allowed to stand up and will be taken to another area where you will wait for a short time to make sure there are no immediate problems from the surgery. Once your doctor checks your eye and determines everything is satisfactory, you will be allowed to go home. You should arrange to have someone drive you home after the surgery as driving immediately after having LASIK surgery is not recommended.

The surgery usually lasts 10 to 15 minutes from start to finish and you are only exposed to the laser beam for a minute or less. The surgery itself is painless because your eye was numbed with anesthetic drops before the start of the surgery. The numbing drops will wear off in about 30 to 60 minutes and your eye may hurt for 1 to 3 days. This is typically described as a “sandy sensation”. Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. It is important that you **DO NOT RUB** the eye for the first 5 days after the surgery. Rubbing the eye can damage the cornea, move the corneal flap, increase the risk of infection, and delay healing of the eye. You will be given instructions for the care of your eye after the surgery. It is important that you (and a family member) understand these instructions before you leave the surgery clinic.

## **10 WHAT CAN YOU EXPECT AFTER LASIK SURGERY**

The information below is provided to help you understand what to expect after you have LASIK surgery performed on one or both of your eyes. Sunglasses may make you more comfortable during the first few days after the surgery. Your doctor may give you a shield to place over your eye while you are sleeping to protect your eye from accidental injury. Your doctor may give you drops to use in your eyes after the surgery. It is important to use them as directed to promote healing and lessen the risk of infection in the treated eye.

### **IMPORTANT**

Use the lubricant (moistening) eyedrops and any prescribed eye medications (anti-inflammatory, antibiotic eyedrops) as directed by your doctor. Your results depend upon you following your doctor's instructions.

### **The first week following surgery:**

The following symptoms have been reported up to several weeks following LASIK treatment. Except for the symptoms related to flap complications, they are associated with the normal healing process after treatment and include:

- Discomfort (including mild to moderate pain, pressure, scratchiness, burning sensation, and dryness) may last for 1 to 3 days after surgery, for which your eye doctor can provide medications.
- The feeling that something is in your eye.
- Swelling of the cornea.
- A problem with healing of the corneal flap, including damage to the flap, loss or misalignment of the flap, or growth of cornea surface cells under the flap. If needed, the doctor may lift the flap to clean the inner layer of the cornea and reposition the flap to improve healing.
- Blurred vision and tearing or watery eyes may occur as the cornea and the flap heal.
- Sensitivity to bright lights.

### **The first one to six months following surgery:**

The following symptoms may occur during the first six months after LASIK surgery while your eye continues to heal:

- Eye dryness, which may be accompanied by a fluctuation in your vision or a feeling that something is in your eye

### **CAUTION**

You should contact your doctor if you notice any pain, sudden change, or loss of vision in the eye. Eye pain or sudden loss of vision can indicate a serious problem that requires immediate medical attention.

## **11 QUESTIONS TO ASK YOUR DOCTOR**

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

- What other options are available for correcting my farsightedness and astigmatism?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of LASIK for my amount of farsightedness and astigmatism correction?
- What quality of vision can I expect in the first few months after surgery?
- If LASIK does not correct my vision, what is the possibility that my glasses would need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after LASIK if I need them?
- How is 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 LASIK surgery?
- Should I have LASIK surgery in my other eye?
- How long will I have to wait before I can have LASIK surgery in my other eye?
- What vision problems might I have if I have LASIK surgery only on one eye?

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

## 12 SELF-TEST

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

- |   |  |                          |      |                          |       |
|---|--|--------------------------|------|--------------------------|-------|
| 1 | LASIK surgery is risk free.  | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 2 | It does not matter if I wear my contact lenses when my doctor told me not to.          | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 3 | The laser does all the work, I just have to lie on the chair and close my eyes.        | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 4 | After the surgery, there is a good chance that I will be less dependent on eyeglasses. | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 5 | I may need reading glasses after laser surgery.  | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 6 | There is a risk that I may lose some vision after laser surgery.                       | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 7 | It does not matter if I am pregnant.   | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 8 | If I have an autoimmune disease, I am still a good candidate for LASIK.                | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |

Answers to SELF-TEST are found in Section 14.

## 13 SUMMARY OF IMPORTANT INFORMATION

- LASIK is a permanent operation to the cornea that cannot be easily changed.
- LASIK may 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 LASIK. You will need documentation that your farsightedness with or without astigmatism has changed less than 1.0 diopter over the past year.
- Pregnant and nursing women should wait until they are not pregnant and not nursing to have LASIK surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- LASIK 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.
- Alternatives to LASIK for the correction of farsightedness with or without astigmatism include glasses, contact lenses, and PRK.
- Some people, such as military pilots, have job-related vision requirements that cannot be met by having LASIK.
- Before considering laser vision correction, you should:
  - Have a complete eye examination.
  - Talk with one or more eye care professionals about the potential benefits of laser refractive surgery and the complications, risks, and time required for healing.

## 14 ANSWERS TO SELF-TEST QUESTIONS

1. False (see Risks on page 11); 2. False (see Before Surgery on page 17); 3. False (see The During Surgery on page 18); 4. True (see Benefits on page 9); 5. True (see Risks on page 11); 6. True (see Risks on page 11); 7. False (see Warnings on page 12); 8. False (see Contraindications on page 11).

## 15 GLOSSARY

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

**Accommodation:** the ability of the eye to change its focus from distant objects to near objects.

**Acuity:** (see Visual Acuity)

**Antibiotic:** a drug used to treat or prevent infection. Usually administered as eye drops before and/or after refractive surgery.

**Anti-Inflammatory Drug:** a drug used to reduce or prevent inflammation. Usually administered as eye drops after refractive surgery.

**Astigmatism:** a refractive error in which the eye focuses more strongly in one orientation than another, so a beam of light focuses to two crossed lines, one in front of the other, instead of a point. For example, a hyperopic astigmatic eye might focus a horizontal line one diopter behind the retina and a vertical line three diopters behind the retina.

**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 systemic lupus erythematosus and rheumatoid arthritis.

**Contraindication:** any special condition for which the treatment is not allowed.

**Cornea:** the clear, front covering of the eye. The cornea is the first part of the eye that bends (or refracts) light rays and provides most of the focusing power.

**Diopter:** the unit of measurement of refractive power and refractive error. A negative diopter value signifies an eye with myopia and a positive diopter value signifies an eye with hyperopia.

**Dry Eye Syndrome:** a common condition that occurs when the eye does not produce enough tears to keep the eye moist and comfortable. Common symptoms of dry eye include pain, stinging, burning, scratchiness, and intermittent blurring of vision.

**Endothelium:** the inner layer of cells on the inside surface of the cornea.

**Epithelium:** The outermost layer of cells of the cornea and the eye's first defense against infection.

**Excimer Laser:** an ultraviolet light laser used in refractive surgery to remove corneal tissue.

**Farsightedness:** the common name for hyperopia.

**FDA:** the abbreviation for the Food and Drug Administration. The FDA is the United States governmental agency responsible for the evaluation and approval of medical devices.

**Femtosecond Laser:** a computer-controlled laser specially designed to create a corneal flap that is of precise dimensions and thickness.

**Ghost Image:** a fainter, displaced, second image of the object you are viewing.

**Glare:** scattered light in the eye that decreases vision.

**Halos:** rings around lights due to optical imperfections in or in front of the eyes.

**Haze:** corneal clouding that causes a sensation of looking through smoke or fog.

**Herpes (simplex or zoster):** a type of infection caused by a virus that can recur.

**Hyperopia:** the inability to see near objects as clearly as distant objects, and the need for accommodation to see distant objects clearly. Hyperopia occurs when the eye is too short and light rays focus behind the retina.

**Immunodeficiency Disease:** a condition that alters the body's ability to fight infection. An example is autoimmune deficiency disease (AIDS).

**Inflammation:** the body's reaction to trauma, infection, or a foreign substance, often associated with pain, heat, redness, swelling, and/or loss of function of the affected area.

**Informed Consent Form:** a document that describes and explains a medical or surgical treatment to prospective patients and discloses the risks, benefits, and alternatives to the treatment.

**In Situ:** a Latin term meaning "in place" or not removed.

**Intraocular Pressure:** fluid pressure inside the eye.

**Iris:** the colored ring of tissue behind the cornea and immediately in front of the lens.

**Keratotomy:** the surgical removal of corneal tissue.

**Keratitis:** inflammation of the cornea.

**Keratoconus:** a disorder characterized by an irregular corneal surface (cone-shaped), resulting in blurred and distorted images.

**Keratomileusis:** carving of the cornea to reshape it.

**Laser:** the acronym for “light amplification by stimulated emission of radiation.” A laser is an instrument that produces a powerful beam of light that can evaporate tissue.

**LASIK:** the acronym for “laser assisted in situ keratomileusis,” which refers to creating a flap in the cornea with a microkeratome or femtosecond laser and using a laser to reshape the underlying cornea.

**Lens:** a part of the eye that provides some focusing power. The lens is able to change shape allowing the eye to focus at different distances.

**Microkeratome:** a surgical device that is affixed to the eye by use of a vacuum ring. When secured, a very sharp blade cuts a layer of the cornea at a predetermined depth.

**Monovision:** the purposeful adjustment of one eye for near vision and the other eye for distance vision.

**Myopia:** the inability to see distant objects as clearly as near objects. In myopia, the eye is too long and light rays focus in front of the retina.

**Nearsightedness:** the common name for myopia.

**Ophthalmologist:** a medical doctor specializing in the diagnosis and medical or surgical treatment of visual disorders and eye disease.

**Optometrist:** a primary eye care provider who diagnoses, manages, and treats refractive errors and some disorders of the visual system and eye diseases.

**Overcorrection:** an outcome of refractive surgery where the achieved amount of correction is more than desired.

**PRK:** the acronym for photorefractive keratectomy, which is a procedure involving the removal of the surface layer of the cornea (epithelium) by scraping and use of a computer controlled excimer laser to reshape the cornea.

**Presbyopia:** a condition in which the eye has lost the ability to accommodate, or to maintain a clear image (focus) as objects are moved closer. Presbyopia is due to reduced elasticity of the lens with increasing age.

**Pupil:** the opening in the center of the iris that changes size to control the amount of light that enters the eye in response to changes in lighting. It gets larger in dim lighting conditions and gets smaller in brighter lighting conditions.

**Refract:** the bending of light as it passes from one medium into another.

**Refraction:** a test to determine the refractive power of the eye.

**Refractive Errors:** imperfections in the focusing power of the eye, for example, hyperopia, myopia, and astigmatism.

**Refractive Power:** the ability of an object, such as the eye, to bend light as light passes through it.

**Refractive Surgeon:** an ophthalmologist who specializes in performing surgery to correct refractive errors.

**Regression:** a decrease in the amount of vision correction that occurs over time after refractive surgery.

**Retina:** a layer of fine sensory tissue that lines the inside wall of the eye. The retina acts like the film in a camera to capture images, transforms the images into electrical signals, and sends the signals to the brain.

**Sclera:** the tough, white outer layer of the eyeball that, along with the cornea, protects the eyeball.

**Snellen Visual Acuity Chart:** one of the many charts used to measure vision. Snellen visual acuity is recorded as 20/xx (e.g., 20/20 is considered to be “normal” vision).

**Stroma:** the middle, thickest layer of tissue in the cornea. This is the area from which the laser removes tissue during a LASIK procedure.

**Undercorrection:** an outcome of refractive surgery where the achieved amount of correction is less than the intended amount.

**Visual Acuity:** the clearness of vision; the ability to distinguish details and shapes.