

WAVEFRONT-GUIDED LASIK INDICATIONS AND INTENDED USES:

The LADARVision®4000 Excimer Laser System is approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) for the reduction or elimination of myopia up to -7.00D with less than -0.50D of astigmatism at the spectacle plane; to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) for the reduction or elimination of myopic astigmatism up to -8.00D sphere with -0.50 to -4.00D cylinder and up to -8.00D spherical equivalent (SE) at the spectacle plane; to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) for the reduction or elimination of hyperopia and hyperopic astigmatism of +0.75D to less than +5.00D sphere with up to -3.00D cylinder (which has a magnitude less than or equal to the sphere in minus cylinder convention) and up to +5.00D cycloplegic spherical equivalent (SE) at the spectacle plane; to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) for the reduction or elimination of mixed astigmatism 1.00D to less than 5.00D cycloplegic cylinder magnitude at the spectacle plane, which is greater than the sphere magnitude, and the cylinder and sphere have opposite signs; in patients who are 21 years of age or older; and in patients with documented stability of refraction for the prior 12 months, as demonstrated by a change in sphere and cylinder of less than or equal to 0.50D in myopic, hyperopic and mixed astigmatic eyes and for a SE of up to -6.00D in myopic astigmatic eyes, and less than or equal to 0.75D for a SE greater than -6.00D in myopic astigmatic eyes.

For Wavefront-Guided LASIK Myopia

Note that the complete name for this ophthalmic laser is "LADARVision®4000 Excimer Laser System for wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments of myopia up to -7.00D with less than -0.50D of astigmatism at the spectacle plane". An acceptable alternate version of this official name is "wavefront-guided LASIK for correction of myopia". Wavefront-guided LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the application is based on a clinical trial of 426 eyes (264 primary and 162 secondary). Of all eyes treated, 426 were available for analysis of safety at 3 months, and 424 eyes were followed for 6 months. Accountability at 3 and 6 months was 100.0%. Of these eyes, 139 were evaluated for effectiveness with 100.0% accountability at both 3 and 6 months. The analysis of data from 139 total eyes treated and based on refractive data at 6 month follow-up examination, found that 98.6% (137/139) were corrected to 20/40 or better and 79.9% (111/139) were corrected to 20/20 or better visual acuity without spectacles or contact lenses.

For Wavefront-Guided LASIK Myopic Astigmatism

Note that the complete name for this ophthalmic laser is "LADARVision®4000 Excimer Laser System for wavefront-guided laser assisted in-situ keratomileusis (LASIK) for the reduction or elimination of myopic astigmatism up to -8.00D sphere with -0.50 to -4.00D cylinder and up to -8.00D SE at the spectacle plane." An acceptable alternate version of this official name is "wavefront-guided LASIK for correction of myopic astigmatism". Wavefront-guided LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the application is based on a clinical trial of 331 eyes (167 primary eyes and 164 secondary eyes). Of all eyes treated, 232 were evaluated for effectiveness with 100.0% accountability at 3 and 6 months, while all 331 eyes treated were evaluated for safety with 100.0% accountability at 3 and 6 months. The study found that of the 232 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 97.4% were corrected to 20/40 or better and 84.1% were corrected to 20/20 or better. The study showed that the 3 month stability time point that none of the 331 eyes in the entire cohort had lost ≥ 2 lines of best spectacle corrected visual acuity (BSCVA), had a BSCVA worse than 20/40, or had an increase of $>2.0D$ of cylinder magnitude. Although wavefront-guided LASIK treatment with the LADARVision®4000 Excimer Laser System is based on the measurement of the refractive error and wavefront aberrations of the human eye, including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher order aberrations through sixth order, in the clinical study for this PMA, the average higher-order aberrations did not decrease after CustomCornea® treatment.

For Wavefront-Guided LASIK Hyperopia and Hyperopic Astigmatism

Note that the complete name for this ophthalmic laser is "LADARVision®4000 Excimer Laser System for wavefront-guided (WFG) laser assisted in-situ keratomileusis (LASIK) treatment for the reduction or elimination of hyperopia and hyperopic astigmatism of +0.75D to less than +5.00D sphere with up to -3.00D cylinder (which has a magnitude less than or equal to the sphere in minus cylinder convention) and up to +5.00D cycloplegic spherical equivalent at the spectacle plane." An acceptable alternate version of this official name is "wavefront-guided LASIK for correction of hyperopia with or without astigmatism". Wavefront-guided LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the application is based on a clinical trial of 346 eyes. Of all eyes treated, 297 were evaluated for effectiveness with 100% availability at 3 months, 276 eyes with 92.9% availability at 6 months, and 138 eyes with 46.5% availability at 9 months. Accountability was 100% at 3 months, 99.3% at 6 months and 100% at 9 months. The study found that of the 276 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 95.3% were corrected to 20/40 or better, 80.8% were corrected to 20/25 or better and 59.1% were corrected to 20/20 or better without spectacles or contact lenses. The study showed that of the 320 eyes available for safety analysis at 6 months, no eyes lost more than 2 lines of best corrected vision that can be obtained with spectacles (BSCVA) and none of the eyes had BSCVA worse than 20/40. Although the LADARWave® CustomCornea® Wavefront System measures refractive error and wavefront aberrations of the human eye, including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher-order aberrations through sixth order, in the clinical study for this PMA, the average higher-order aberrations did not decrease after CustomCornea® treatment.

For Wavefront-Guided LASIK Mixed Astigmatism

Note that the complete name for this ophthalmic laser is "LADARVision®4000 Excimer Laser System for wavefront-guided (WFG) laser assisted in-situ keratomileusis (LASIK) treatment for the reduction or elimination of mixed astigmatism 1.00D to less than 5.00D cycloplegic cylinder magnitude at the spectacle plane, which is greater than the sphere magnitude, and the cylinder and sphere have opposite signs. An acceptable alternate version of this official name is "wavefront-guided LASIK for correction of mixed astigmatism". Wavefront-guided LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the application is based on a clinical trial of 110 eyes. All eyes were evaluated for effectiveness with 100% accountability at 1, 3, and 6 months, and 98.2% accountability at 9 months. The study found that of the 110 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 98.2% were corrected to 20/40 or better, 87.3% were corrected to 20/25 or better, and 63.6% were corrected to 20/20 or better without spectacles or contact lenses. The study showed that of the 110 eyes available for safety analysis at 6 months, no eyes lost more than 2 lines of best corrected vision that can be obtained with spectacles (BSCVA) and none of the eyes had BSCVA worse than 20/40. Although the LADARWave® CustomCornea® Wavefront System measures the refractive error and wavefront aberrations of the human eyes, including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher-order aberrations through sixth order, in the clinical study for this PMA, the average higher-order aberrations did not decrease after CustomCornea® treatment.

CONVENTIONAL PRK AND LASIK INDICATIONS AND INTENDED USES:

The LADARVision®4000 Excimer Laser System is approved to perform photorefractive keratectomy (PRK) for the correction of mild to moderate myopia between -1.00D to -10.00D with up to -4.00D of astigmatism; to perform laser in-situ keratomileusis (LASIK) for the correction of myopia less than -9.00D sphere and -0.50D to less than -3.00D of astigmatism at the spectacle plane; to perform laser in-situ keratomileusis (LASIK) treatments for the reduction or elimination of refractive error of less than or equal to +6.00D of sphere and -6.00D of cylinder at the spectacle plane (hyperopia with or without astigmatism and mixed astigmatism); in subjects who are 21 years of age or older; and in subjects with documented stability of refraction for the prior 12 months, as demonstrated by a change of less than or equal to 0.50D for myopic corrections up to -7.00D or hyperopic corrections up to +6.00D spherical equivalent, and less than or equal to -1.00D for myopic corrections greater than -7.00D spherical equivalent.

For Conventional PRK Myopia

Alternatives to PRK include: eyeglasses, contact lenses, LASIK, radial keratotomy, or automated lamellar keratoplasty. In studies of 604 eyes (417 myopic eyes; 187 eyes with myopic astigmatism) after final treatment with refractive data at 6 months, 95.9% and 95.2%, respectively, were corrected to 20/40 or better and 69.7% and 59.3%, respectively, were corrected to 20/20 or better without spectacles or contact lenses.

For Conventional LASIK Myopia

Note that the complete name for the device as approved is "the LADARVision®4000 Excimer Laser System for laser in-situ keratomileusis (LASIK) for the correction of myopia less than -9.00D sphere and -0.50D to less than -3.00D of astigmatism at the spectacle plane". An acceptable alternate version of this official name is "LASIK laser correction for nearsightedness with or without astigmatism". LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, PRK, radial keratotomy, astigmatic keratotomy or automated lamellar keratectomy. Approval of the application is based on a clinical trial of 347 eyes (186 primary and 161 secondary) of which 177 eyes were treated for spherical myopia and 170 for astigmatic myopia. Of all eyes treated, 330 eyes were available for analysis at 3 months, and 270 eyes were followed for six months. Accountability at 1 month was 97.4%; at 3 months accountability was 95.9%, and 94.4% at 6 months. The analysis of data from 347 total eyes treated and based on refractive data at 6 month follow-up examination, found that 93.7% (224/239) eyes were corrected to 20/40 or better and 56.9% (136/239) were corrected to 20/20 or better visual acuity without spectacles or contact lenses.

For Conventional LASIK Hyperopia

Note that the complete name of the device as approved is "the LADARVision®4000 Excimer Laser System for laser in-situ keratomileusis (LASIK) treatments of hyperopia with or without astigmatism and mixed astigmatism of less than or equal to +6.00D of sphere and -6.00D of cylinder at the spectacle plane." An acceptable alternate version of this official name is "LASIK laser correction for farsightedness with or without astigmatism." LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), or laser thermal keratoplasty (LTK). Approval of the application is based on a clinical trial of 360 eyes: 152 eyes were treated for hyperopia, 143 for astigmatic hyperopia, and 65 for mixed astigmatism. Of all eyes treated, 324 eyes were available for analysis at 6 months, and 265 eyes were followed for 9 months. Accountability at 3 months was 95.6%, at 6 months was 95.3%, and at 9 months was 90.4%. The analysis of refractive data at the 6 month stability time point found that 113 (93.4%) hyperopic eyes were 20/40 or better and 59 eyes (48.8%) were 20/20 or better without spectacles or contact lenses. In the astigmatic hyperopic eye group, 100 eyes (90.9%) were 20/40 or better and 41 eyes (37.3%) were 20/20 or better without spectacles or contact lenses. In the mixed astigmatic eye group, 50 eyes (92.6%) were 20/40 or better and 25 (46.3%) were 20/20 or better without spectacles or contact lenses.

CONTRAINDICATIONS:

Wavefront-guided LASIK, conventional LASIK and PRK are contraindicated in patients who: are pregnant or nursing; show signs of keratoconus; are taking the medications isotretinoin (*Accutane*®) or amiodarone hydrochloride (*Cordarone*®); or have autoimmune, collagen vascular, or immunodeficiency diseases.

WARNINGS:

Wavefront-guided LASIK, conventional LASIK and PRK are not recommended in patients who have diabetes, severe allergies, or a history of herpes simplex or herpes zoster keratitis. Wavefront-guided LASIK is not recommended in patients who have significant dry eye that is unresponsive to treatment. A minimum pre-operative pupillary dilation of 7.0 mm and a maximum dilation of 11.0 mm must be achieved and maintained in all patients throughout the refractive procedure to optimize tracking performance. For conventional LASIK treatment of hyperopia with or without astigmatism or mixed astigmatism, the microkeratome should create a flap large enough to allow for a treatment zone of 9.0 mm needed for this procedure.

PRECAUTIONS:

The safety and effectiveness of the LADARVision®4000 System for wavefront-guided LASIK, conventional LASIK and PRK have not been established in patients: with progressive myopia or unstable hyperopia, hyperopic astigmatism or mixed astigmatism; with ocular disease, corneal abnormality, previous corneal or intraocular surgery, trauma in the ablation zone, or history of glaucoma; with a residual posterior stromal corneal thickness less than 250 microns at the completion of the ablation; who are taking the medication Sumatriptin (*Imitrex*); under 21 years of age.

Eyes with prior intraocular or corneal surgery of any kind were excluded from clinical trials with the LADARVision® and LADARVision®4000 Systems. Safety and effectiveness, as well as tracking performance, have not been established for such eyes. Although the tracking system may acquire track in surgically altered eyes prior to ablation, the optics of the eye may change in the context of the ablation to potentially interfere with further tracking and compromise the completion of the ablation.

For Wavefront-guided LASIK

Pupil size should be evaluated under mesopic illumination conditions. Patients with large mesopic pupils ≥ 6.5 mm (optic zone size) should be advised of the potential for negative effects on vision after surgery, such as glare, halos, and nighttime driving difficulty. Preoperative evaluation for dry eye should be performed. Patients should be advised of the potential for dry eyes post-LASIK surgery. The physician's adjustment of defocus has not been studied, and its effects on the safety and effectiveness outcomes of this procedure are unknown.

For Wavefront-Guided LASIK Myopia

The safety and effectiveness of the LADARVision®4000 System for wavefront-guided LASIK myopia have not been established: in patients with prior history of refractive surgery; in patients over 65 years of age; over the long term (more than 6 months); for treatments greater than -7.00D of myopia combined with greater than or equal to -0.50D of astigmatism; for retreatment with wavefront-guided LASIK; and for treatment targets different from emmetropia (plano) in which the wavefront-calculated defocus (spherical term) has been adjusted. Additionally, this may negate the potential benefits of the wavefront-guided procedure to reduce higher-order aberrations. You should discuss with your patient the potential risks and benefits associated with treatment targets different from emmetropia. There were insufficient numbers of patients with a MRSE above -6D to determine the level of effectiveness or the complication rates of wavefront-guided LASIK myopia for this refractive error range with the same reliability as for eyes with lower refractive errors.

For Wavefront-Guided LASIK Myopic Astigmatism

The safety and effectiveness of the LADARVision®4000 System for wavefront-guided LASIK myopic astigmatism have not been established: over the long term (more than 6 months); for treatments of myopic astigmatism greater than -8.00D sphere combined with less than -0.50D cylinder or with greater than -4.00D cylinder and greater than -8.00D SE; for retreatment with wavefront-guided LASIK; and for treatment targets different from emmetropia (plano) in which the wavefront-calculated defocus (spherical term) has been adjusted. Additionally, this may negate the potential benefits of the wavefront-guided procedure to reduce higher-order aberrations. You should discuss with your patient the potential risks and benefits associated with treatment targets different from emmetropia. The safety and effectiveness of wavefront-guided LASIK for myopic astigmatism has ONLY been established for treatments that use an optical zone of 6.5 mm and an ablation zone of 9.0 mm.

For Wavefront-Guided LASIK Hyperopia and Hyperopic Astigmatism

The safety and effectiveness of the LADARVision®4000 System for wavefront-guided LASIK hyperopia and hyperopic astigmatism have not been established: in patients whose wavefront diameter is less than 6.50 mm; over the long term (more than 9 months); for treatments of hyperopia and hyperopic astigmatism of +5.00D or greater sphere combined with greater than -3.00D cylinder and greater than +5.00D SE by cycloplegic refraction; and for retreatment with wavefront-guided LASIK. The safety and effectiveness of wavefront-guided LASIK for hyperopia and hyperopic astigmatism has ONLY been established with an optical zone of 6.5 mm and an ablation zone of 9.0 mm.

For Wavefront-Guided LASIK Mixed Astigmatism

The safety and effectiveness of the LADARVision®4000 Excimer Laser System for wavefront-guided LASIK mixed astigmatism have not been established in patients whose wavefront diameter is less than 6.50 mm; over the long term (more than 9 months); for treatments of mixed astigmatism of less than 1.00D cycloplegic cylinder magnitude or 5.00D or greater cycloplegic cylinder magnitude at the spectacle plane; and for retreatment with wavefront-guided LASIK. The safety and effectiveness of wavefront-guided LASIK for mixed astigmatism has ONLY been established with an optical zone of 6.5 mm and an ablation zone of 9.0 mm.

¹Accutane Reg TM of Hoffmann-La Roche Inc.
²Imitrex Reg TM of Glaxo Group Limited

³Cordarone Reg TM of Sanofi-Aventis

For Conventional PRK Myopia

The safety and effectiveness of the LADARVision®4000 System for conventional PRK myopia have not been established: in patients with history of keloid formation; over the long term (more than 12 months); for treatment of astigmatism less than 0.50D; and for treatments greater than -10.00D of myopia combined with greater than -4.00D of astigmatism. In a contrast sensitivity study designed to assess the effects of PRK surgery using the LADARVision® System on how well patients can see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night, the percentage of patients showing clinically significant losses were 10.6% at 6 months and 6.6% at 12 months after surgery, and the percentages of patients showing clinically significant improvements were 5.9% at 6 months and 3.3% at 12 months after PRK surgery. In addition, U.S. clinical studies of PRK surgery using the LADARVision® System have shown that bandage contact lenses and non-steroidal anti-inflammatory drops used for pain management in the immediate postoperative period following PRK with this device are associated with sterile infiltrates (the rate of sterile infiltrates observed was 1.6%) and that overcorrections greater than +1D may be more likely to occur in older patients, at low room humidity and when attempting higher corrections.

For Conventional LASIK Myopia

The safety and effectiveness of the LADARVision®4000 System for conventional LASIK myopia have not been established: over the long term (more than 6 months); for treatment of astigmatism less than 0.50D; and for treatments greater than or equal to -9.00D of myopia combined with greater than or equal to -3.00D of astigmatism. The effects of conventional LASIK myopia on visual performance under poor lighting conditions have not been effectively determined. Following LASIK treatment, some patients 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.

For Conventional LASIK Hyperopia

The safety and effectiveness of the LADARVision®4000 System for conventional LASIK hyperopia have not been established: in patients who are non-Caucasian; over the long term (more than 9 months); for treatment of astigmatism less than 0.50D; for treatments greater than +6.00D of hyperopia or -6.00D of astigmatism; and for retreatments of hyperopia, hyperopic astigmatism or mixed astigmatism. Eyes with greater than 5.0D of hyperopia may have lower predictability of refractive outcome and improvement in uncorrected visual acuity than eyes with lower levels of hyperopia. Hyperopic astigmatism eyes with greater than 4.0D MRSE preoperatively may have lower predictability of refractive outcome and improvement in uncorrected visual acuity than eyes with lower levels of MRSE. These eyes may be more likely to experience a reduction of two lines in their best-corrected visual acuity and to require retreatment. Older patients and women on hormone replacement therapy may be less likely to achieve uncorrected visual acuity of 20/20 or better. The effects of LASIK on visual performance under poor lighting conditions have not been effectively determined. Following LASIK treatment, some patients 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.

ADVERSE EVENTS AND COMPLICATIONS:**For Wavefront-guided LASIK Myopia**

The clinical trials showed that the following adverse events occurred in at least 1% of the 426 eyes at any interval up to 6 months post-treatment: corneal edema 1 week to <1 month (1.9%); double/ghost images (2.1%); epithelium in the interface (3.3%); and diffuse lamellar keratitis (3.5%). Adverse events reported in <1% of the 426 eyes at any interval up to 6 months post-treatment included: recalcitrant diffuse lamellar keratitis with blepharitis (0.5%); foreign body sensation at ≥1 month (0.5%); striae (0.5%); miscreated flap related to microkeratome (0.2%); retinal horseshoe tear unrelated to device (0.2%); conjunctivitis (0.2%); epithelial defect by microkeratome (0.2%); focal inflammatory reaction in the interface (0.2%); and pain ≥1 month (0.2%). Long term risks of wavefront-guided LASIK for myopia beyond 6 months have not been studied.

The following subjective patient adverse events rated "significantly worse" occurred in at least 1% of 136 eyes in the effectiveness cohort at 6 months post-treatment: gritty feeling (1.5%); burning (1.5%); dryness (2.2%); and blurring of vision (2.9%). Subjective patient adverse events rated "significantly worse" in <1% of 136 eyes at 6 months post-treatment included: double vision (0.7%); fluctuation of vision (0.7%); and night driving difficulty (0.7%).

For Wavefront-guided LASIK Myopic Astigmatism

The clinical study showed that corneal edema occurred in 1.5% of the 331 eyes between 1 week and less than 1 month. There were no other adverse events or complications that occurred in 1% or more of the 331 eyes at any interval up to 6 months post-treatment. Long term risks of wavefront-guided LASIK for myopic astigmatism beyond 6 months have not been studied.

The following subjective patient symptoms were rated "significantly worse" in the postoperative uncorrected state relative to the preoperative spectacle-corrected state in more than 1% of eyes at 3 months: blurring of vision (1.3%), double vision (2.6%), dryness (2.2%), fluctuation of vision (2.2%), glare (1.7%), halos (1.3%), and night driving difficulty (1.7%).

For Wavefront-guided LASIK Hyperopia and Hyperopic Astigmatism

The clinical trials showed that the following adverse events or complications occurred in at least 1% of the 346 eyes at any post-treatment visit: epithelium in the interface (3.2%) and diffuse lamellar keratitis (DLK) in the operative eye (1.4%). Long term risks of wavefront-guided LASIK treatment of hyperopia with or without astigmatism beyond 9 months have not been studied.

The following subjective patient symptoms were rated "significantly worse" in the postoperative uncorrected state relative to the preoperative spectacle-corrected state in more than 1% of eyes at 6 months: dryness (1.1%), light sensitivity (4.0%), blurring of vision (2.9%), double vision (2.9%), fluctuation of vision (4.0%), glare (2.5%), halos (3.6%), and night driving difficulty (2.9%).

For Wavefront-guided LASIK Mixed Astigmatism

The clinical trials showed that the following adverse events or complications occurred in at least 1% of the 110 eyes at any post-treatment visit: grade ≥1 superficial punctate keratitis (SPK) (10.0%), epithelium in the interface (5.4%), diffuse lamellar keratitis (DLK) in the operative eye (4.5%), pain at one month or later (1.8%), and miscreated flap (related to the microkeratome) (1.8%). Long term risks of wavefront-guided LASIK treatment of mixed astigmatism beyond 9 months have not been studied.

The following subjective patient symptoms were rated "significantly worse" in the postoperative uncorrected state relative to the preoperative spectacle-corrected state in more than 1% of eyes at 6 months: blurring of vision (8.2%), fluctuation of vision (4.5%), halos (3.6%), night driving difficulty (3.6%), dryness (2.7%), light sensitivity (1.8%), and double vision (1.8%).

For Conventional PRK Myopia

The following adverse events and complications were reported during the course of the clinical trial: feeling of something in the eye (3.0% - spherical myopia; 2.4% - myopic astigmatism); double/ghost images (2.6% - spherical myopia; 6.2% - myopic astigmatism); peripheral epithelial defect (1.3% - spherical myopia; 0.5% - myopic astigmatism); pain (1.3% - spherical myopia; 1.9% - myopic astigmatism); halos/starbursts (0.0% - spherical myopia; 0.5% - myopic astigmatism); corneal infiltrates (1.6% combined cohort); increased intraocular pressure above 25mmHg (0.6% combined cohort); corneal ulcer (0.1% combined cohort); and retinal vascular accident (0.1% combined cohort). The loss of > 2 lines best spectacle corrected visual acuity (BSCVA) at 6 months was 0.5% for spherical myopia and 0.0% for myopia astigmatism, and pretreatment BSCVA 20/20 or better with post-treatment BSCVA worse than 20/25 was 0.5% for spherical myopia and 0.0% for myopia astigmatism. Other findings that occurred at a rate of < 0.3% (spherical myopia) included: corneal erosion; corneal abrasion (< 0.5% for astigmatism); scratchiness; pain; epithelial irregularity; corneal swelling; subconjunctival hemorrhage; light sensitivity; epithelial dots; iritis (< 0.5% for astigmatism); and ocular hypertension.

The following complications were reported by subjects: difficulty with night driving (4.3% - spherical myopia; 9.4% - myopic astigmatism); glare (1.7% - spherical myopia; 4.4% - myopic astigmatism); halos (2.3% - spherical myopia; 6.1% - myopic astigmatism); feeling of something in the eye (1.4% - spherical myopia; 0.0% - myopic astigmatism); fluctuation of vision (1.1% - spherical myopia; 3.8% - myopic astigmatism); blurring of vision (0.9% - spherical myopia; 2.2% - myopic astigmatism); light sensitivity (0.9% - spherical myopia; 0.5% - myopic astigmatism); headache (0.3% - spherical myopia; 0.5% - myopic astigmatism); double vision (0.3% - spherical myopia; 0.5% - myopic astigmatism); pain (0.3% - spherical myopia; 0.0% - myopic astigmatism); excessive tearing (0.3% - spherical myopia; 0.0% - myopic astigmatism); burning (0.3% - spherical myopia; 0.0% - myopic astigmatism).

For Conventional LASIK Myopia

The study showed that most adverse events and complications occurred in trace amounts (<1%). At 6 months post-treatment, the two events with ≥1% rate are interface debris at 4.2% (11/260) and superficial punctate keratitis at 2.3% (6/260). At 6 months post-treatment (n=260), adverse events or complications reported in <1% of eyes included: conjunctival injection (0.8%); corneal folds/striae/wrinkle (0.8%); fibrotic healing at flap edge (0.8%); oil droplets/sheen (0.8%); double/ghost images (0.4%); epithelial defect (0.4%); epithelium in the interface (0.4%); interface haze/opacity (0.4%). The following ocular findings were reported at 6 months at a rate of 0.8%: blepharitis, retinal vessel tortuosity, and lattice degeneration with floaters. Other adverse events and complications that were reported at intervals other than 6 months included: feeling of something in the eye, flap distortion, HSV dendrite, increase in intraocular pressure >10mmHg above baseline, induced astigmatism with flap decentration, misaligned flap, miscreated flap, peau d'orange, serous macular edema, and sterile interface inflammation. Long term (beyond 6 months) risks of LASIK for myopia and astigmatism have not been studied.

Subjects reported the following conditions at 6 months as "significantly worse" compared to before LASIK surgery: difficulty with night driving (5.7% - spherical myopia; 14.9% - myopic astigmatism); glare (2.8% - spherical myopia; 9.9% - myopic astigmatism); halos (3.5% - spherical myopia; 6.9% - myopic astigmatism); light sensitivity (2.8% - spherical myopia; 5.9% - myopic astigmatism); dryness (4.3% - spherical myopia; 3.0% - myopic astigmatism); fluctuation of vision (2.1% - spherical myopia; 2.0% - myopic astigmatism); blurring of vision (2.1% - spherical myopia; 1.0% - myopic astigmatism); redness (0.7% - spherical myopia; 1.0% myopic astigmatism); headache (0.7% - spherical myopia; 0.0% myopic astigmatism); and double vision (0.7% - spherical myopia; 0.0% - myopic astigmatism).

For Conventional LASIK Hyperopia

The study showed that at the 6 month stability time point, there was a loss of 2 lines of the best vision that can be obtained with spectacles in 5 (3.5%) hyperopic eyes, 7 (5.8%) hyperopic astigmatic eyes, and 1 (1.9%) mixed astigmatic eye. Most of the other adverse events and complications occurred with low frequencies (<1%). The four events with ≥1% rate were double/ghost images (1.5%), epithelium in the interface (1.5%), interface debris (1.5%), and superficial punctate keratitis (3.1%). At 6 months post-treatment (n=324), adverse events and complications reported in <1% of eyes included: isolated cells in interface (0.6%); corneal abrasion (0.3%); corneal opacities (0.3%); feeling of something in the eye (0.3%); iron line or ring (0.3%); and rolled flap edge with trace corneal melt (0.3%). Each of the following ocular findings was reported at 6 months at a rate of 0.6% or less: allergic conjunctivitis, vitreous floater, cotton wool spot, and drusen. Other adverse events or complications that were reported at intervals other than 6 months included: conjunctival injection, corneal infiltrate, corneal folds/striae/wrinkles, corneal swelling, epithelial defect, increase in intraocular pressure, intralaminar haze, irregular epithelium, lagophthalmos, misaligned flap, miscreated flap, pain, sterile interface inflammation, subconjunctival hemorrhage, trichiasis, and vacuoles. Long term (beyond 9 months) risks of LASIK for hyperopia, hyperopic astigmatism, and mixed astigmatism have not been studied.

Subjects reported the following conditions at 6 months as "significantly worse" compared to before LASIK surgery: night driving difficulty (2.3% - spherical hyperopia; 1.8% - hyperopic astigmatism; 7.5% - mixed astigmatism); fluctuation of vision (6.0% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); dryness (3.0% - spherical hyperopia; 5.3% - hyperopic astigmatism; 1.9% - mixed astigmatism); halos (2.3% - spherical hyperopia; 4.5% - hyperopic astigmatism; 0.0% - mixed astigmatism); blurring of vision (1.5% - spherical hyperopia; 1.8% - hyperopic astigmatism; 3.8% - mixed astigmatism); double vision (1.5% - spherical hyperopia; 3.6% - hyperopic astigmatism; 0.0% - mixed astigmatism); feeling of something in the eye (1.5% - spherical hyperopia; 2.7% - hyperopic astigmatism; 0.0% - mixed astigmatism); redness (0.8% - spherical hyperopia; 2.7% - hyperopic astigmatism; 0.0% - mixed astigmatism); light sensitivity (1.5% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); glare (0.8% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); burning (0.8% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); headache (0.0% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); and pain (0.8% - spherical hyperopia; 0.9% - hyperopic astigmatism; 0.0% - mixed astigmatism).

**FACTS YOU NEED TO KNOW ABOUT
LADARVision®
PHOTOREFRACTIVE KERATECTOMY (PRK) AND
LASER IN-SITU KERATOMILEUSIS (LASIK) SURGERY**

PATIENT INFORMATION BOOKLET

For

For Nearsightedness (Myopia): up to $-10.0D$ (PRK) or less than $-9.0D$ (LASIK)
With or Without Astigmatism: -0.50 to $-4D$ (PRK) or -0.50 to less than $-3.0D$ (LASIK)

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

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A. Glossary

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions that you may have about these terms. Your doctor can provide you with answers to your medical questions.

Astigmatism: a condition of the eye that results in blurred distance and/or near vision. The surfaces of the eye focus the light rays at different points inside the eye. The different points of focus create a blur of parts of objects you see.

Antibiotic Medication: a drug used to treat or prevent infection. Your doctor may prescribe this type of medication after surgery.

Anti-inflammatory Medication: a drug that reduces inflammation or the body's reaction to injury or disease. Surgery that alters the eye, such as PRK or LASIK, can also cause inflammation. Your doctor may prescribe this type of medication after surgery.

Autoimmune Disease: a condition in which the body attacks itself that may result in inflammation or swelling of parts of the body; such as muscles, joints, and blood vessels. Examples of this condition are multiple sclerosis and myasthenia gravis. If you have this type of condition, you should not have PRK or LASIK surgery.

Bandage Contact Lens: a soft contact lens placed on the cornea after surgery to cover the area that was treated with the laser.

Blepharitis: inflammation of the eyelid margins

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. If you have this type of condition, you should not have PRK or LASIK surgery.

Conjunctival Injection: increased redness of the blood vessels in the front of the eye

Contraindications: any special condition that results in the treatment not being recommended.

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

Corneal Abrasion: a scratch in the outer layer of the cornea often from an eye injury.

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.

Corneal Erosion: a defect in the outer layers of the cornea that may occur without injury.

Corneal Flap: a thin slice of tissue on the surface of the cornea made with a microkeratome at the beginning of the LASIK procedure. This flap is folded back before the laser is applied to the inner layers of the cornea.

Corneal Folds/Striae/Wrinkles: the temporary appearance of fine white lines in the back of the cornea as a result of corneal swelling.

Corneal Foreign Body: foreign debris in outer layer of the cornea.

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

Corneal Infiltrate: inflammation of the cornea.

Corneal Swelling: : an accumulation of fluid in the cornea that is not normally present. This condition is usually temporary with no significant effect on vision.

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 and astigmatism of an eye.

Epithelial Defect: a piece of the outer layer of the cornea that has torn off leaving a defect. This defect could occur anywhere on the surface of the cornea. This condition is usually temporary and may result in some discomfort or pain.

Epithelial Dots: small spots in the outer layer of the cornea, that have no effect on vision.

Epithelial Irregularity: an area of the outer layer of the cornea that is not smooth.

Epithelium in the Interface: this condition can occur after LASIK surgery when epithelial cells from the surface of the cornea move or grow underneath the corneal flap. This can result in loss of vision.

Excimer Laser: a type of laser used in PRK or LASIK that removes tissue from the cornea.

Fibrotic Healing of Flap Edge: slight scarring appearance of the edge of the corneal flap.

Flap Distortion: : irregular appearance of the corneal flap.

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. This symptom may occur after surgery.

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. You should discuss any history of this condition with your doctor before having PRK or LASIK surgery.

Herpes Zoster: a type of infection caused by a virus that can recur. This condition is a reactivation of the chicken pox virus as an adult. Vesicles appear on only one side of the body. You should discuss any history of this condition with your doctor before having PRK or LASIK surgery.

HSV Dendrite.: a branching treelike lesion in the cornea due to herpes simplex infection.

Immunodeficiency Disease: a condition that alters the body's ability to heal. An example is AIDS. If you have this type of condition, you should not have surgery.

Induced Astigmatism: the case when the eye has a greater amount of astigmatism after surgery than before surgery. This can happen if the corneal flap is created off-center (decentered flap) in LASIK.

Inflammation: the body's reaction to injury or disease. Surgery that alters the eye, such as PRK and LASIK, can also cause inflammation.

Interface debris: cellular and foreign material underneath the flap after LASIK surgery.

Interface haze/opacity: a cloudiness of the cornea underneath the flap, either diffuse or localized areas that may occur after LASIK.

Iritis: inflammation of the inside of the eye behind the cornea.

Keratoconus: a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs. If you have this type of condition, you should not have PRK or LASIK surgery.

Laser In-Situ Keratomileusis (LASIK): a procedure where a device called a microkeratome is used to surgically create a thin, hinged flap of corneal tissue. The flap is folded back, the laser is directed to the corneal surface exposed beneath the flap and the flap is brought back into place.

Lattice Degeneration: area of thinning in the back of the eye (retina), which is more common in nearsighted eyes and unrelated to surgery

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

Microkeratome: a surgical instrument used to cut a flap of corneal tissue as the first step in the LASIK procedure.

Misaligned Flap: the flap created with the microkeratome has not returned to its correct position after the ablation is complete. It is sometimes possible to reposition the flap.

Miscreated Flap: the flap created with the microkeratome was of poor quality (e.g. too small or irregular) and the laser ablation was not attempted. In this situation, a new flap can usually be created 3 months after the first attempt and LASIK surgery completed.

Monovision: optical correction of one eye so that it sees clearly in the distance and the other eye sees clearly up close.

Myopia: a condition of the eye that results in blurred distance vision. The cornea and lens focus light rays from distant objects in front of the retina. This incorrect focusing of light results in blurred images of objects at a distance.

Nearsightedness: another term for myopia. Nearsighted eyes see better at near than at a distance without glasses or contact lenses.

Nebula After Foreign Body Removal: area of haze in the outer layer of the cornea where foreign body was removed.

Non-Steroidal Anti-inflammatory Drug (NSAID): a type of drug that reduces inflammation or the body's reaction to injury or disease. Your doctor may prescribe this type of medication after surgery.

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

Oil droplets/sheen: oily appearance of the cornea

Overcorrection: too much correction after surgery that may cause blurred distance and/or near vision without glasses.

Peau d' orange: orange peel appearance of the cornea

Peripheral Epithelial Defect: a piece of the outer layer of the cornea that has torn off leaving a defect. This defect occurs in the periphery or outer part of the cornea.

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the surface of the cornea using an excimer laser. Tissue is removed from the outermost surface of the cornea just beneath the epithelium.

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

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

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

Retinal Vascular Accident: blockage of a blood vessel in the back of the eye.

Retinal Vessel Tortuosity: curving of blood vessels in the back of the eye unrelated to surgery

Serous Macular Edema: a sudden accumulation of fluid in the part of the retina responsible for central vision (macula) resulting in distortion of central vision.

Starbursts: flares of light seen around a lighted object that may appear like a star. This symptom is similar to halos and may occur after surgery.

Sterile Interface Inflammation: an inflammatory reaction underneath the corneal flap after LASIK surgery that is not due to bacteria. This condition may result in vision loss

Steroid Medication: a type of drug that reduces inflammation or the body's reaction to injury or disease. Your doctor may prescribe a steroid for use in the eye after surgery to modify the healing of the cornea. If you are taking this drug for a disease condition, you should not have PRK or LASIK surgery.

Subconjunctival Hemorrhage: an area of bleeding in the outer lining of the eye next to the cornea. This bleeding has no adverse effects and resolves on its own.

Superficial Punctate Keratitis (SPK): surface irritation in the outer layer of the cornea.

B. Introduction

Do you need to wear glasses or contact lenses to help you to see clearly in the distance? One option to see more clearly at a distance is to correct your vision with surgery. Some types of surgery correct vision by shaping the front surface of the eye, the cornea. Radial Keratotomy (RK) is one type of surgery that uses a scalpel to make fine cuts in the cornea. A more recent type of surgery is Photorefractive Keratectomy (PRK). PRK uses a laser instead of a scalpel to carefully shape the corneal surface. Another procedure, which uses the laser is called LASIK. In the LASIK procedure, the laser energy is applied to the inner layers of the cornea. PRK or LASIK may help you to see more clearly by partially or fully correcting vision.

The LADARVision[®] Excimer Laser System is a unique system that tracks all movements of the eye during surgery. Tracking movements of the eye allows the system to accurately place the laser beam. The system applies hundreds to thousands of laser beam pulses to the cornea to correct vision. Accurate placement of these laser beam pulses provides precise shaping of the cornea. The purpose of this booklet is to inform you about PRK and LASIK with the tracker-guided LADARVision[®] system. Please read this information carefully and discuss any questions with your doctor. It is important that you make an informed decision about PRK or LASIK with the help of your doctor.

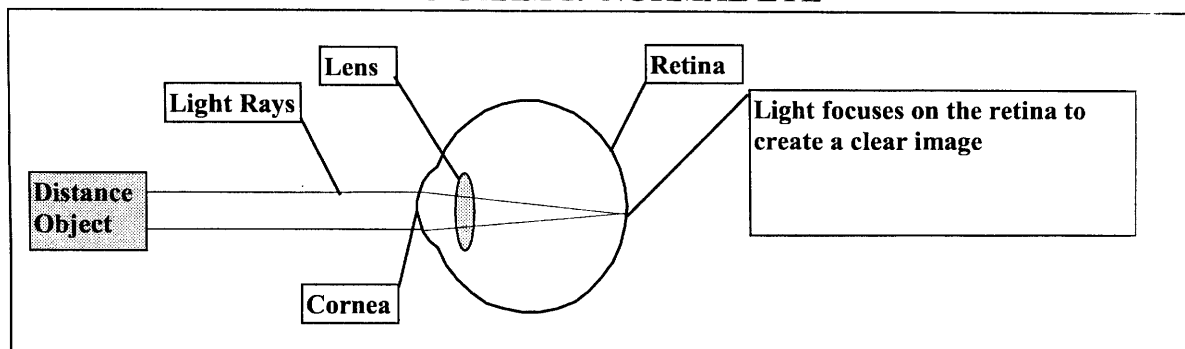
Although vision without glasses improved for all eyes, some people still needed glasses or contact lenses for some tasks after PRK or LASIK. PRK or LASIK does not eliminate the need for reading glasses. In addition, the vision requirements of some occupations, such as military pilots, cannot be met by having RK, PRK or LASIK.

NOTE: You may need reading glasses after PRK or LASIK even if you did not wear them before.

C. How Does PRK or LASIK Correct Myopia With or Without Astigmatism?

The human eye functions like a camera. The lens in a camera focuses light into images on to film. In the same way, the cornea and the lens inside the eye focus light into images on to the retina, the back surface of the eye (Diagram 1). Blurred vision occurs when the light does not focus precisely on the retina.

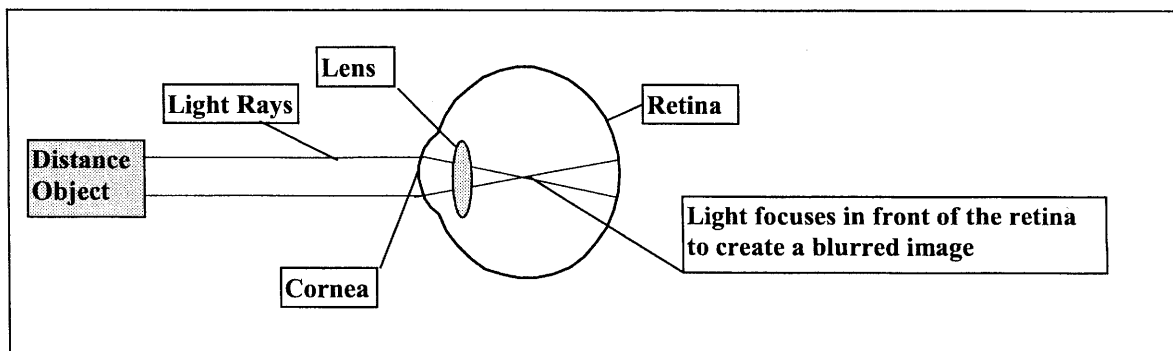
DIAGRAM 1: NORMAL EYE



Myopia (Nearsightedness) is a condition of the eye that results in blurred distance vision. The cornea and lens focus light rays from a distant object in front of the retina.

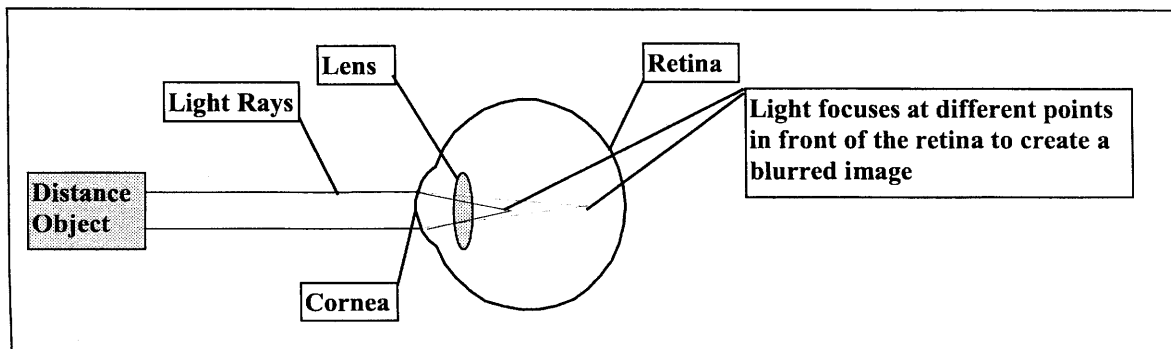
This incorrect focusing of light results in blurred images of objects at a distance. Diagram 2 shows how light focuses in front of the retina to cause a blurred image.

DIAGRAM 2: MYOPIA



Astigmatism is a condition of the eye that also results in blurred vision. In this case, the cornea and the lens focus the light rays at different points in front of the retina. The different points of focus create blur of parts of the images. For example, a person with astigmatism might confuse an “R” with a “P” or an “F” on a sign. This confusion about the letter occurs because only part of the letter is in focus. Diagram 3 shows how light rays focus at different points causing a blurred image.

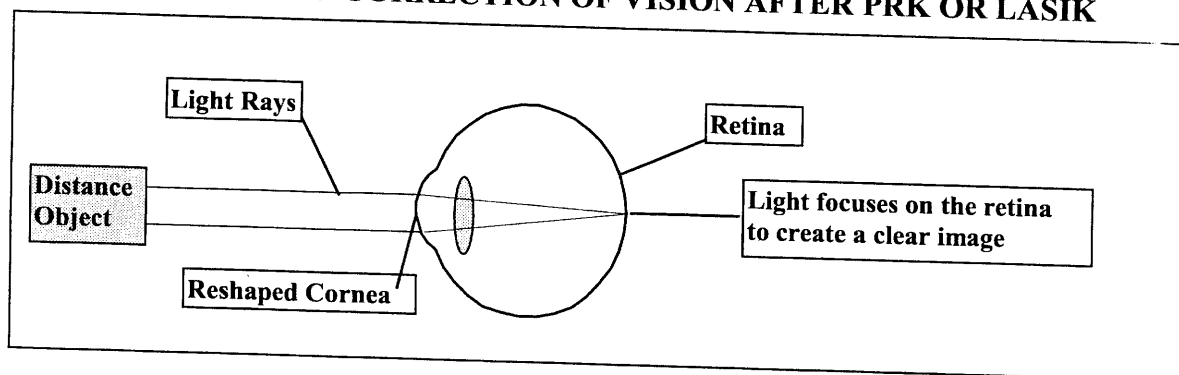
DIAGRAM 3: MYOPIA WITH ASTIGMATISM



Glasses and contact lenses help focus all of the light rays on to the retina. By focusing all of the light rays properly, the vision in the distance is clear. Another way to change the way the eye focuses light is to reshape the cornea. For treatment of myopia, flattening the center of the cornea helps to focus all of the light rays on to the retina to provide clear vision. PRK and LASIK flatten the cornea by removing a tiny amount of the tissue with a laser. An excimer laser is a type of laser used in PRK and in LASIK that removes tissue from the cornea. This type of laser reshapes the cornea without changing any other parts of the eye.

Diagram 5 shows how these procedures can reshape the cornea to provide clearer vision.

DIAGRAM 5: CORRECTION OF VISION AFTER PRK OR LASIK



The LADARVision[®] System incorporates an active eye tracking mechanism (LADARTracking), which compensates for eye movement during the surgery. The measurement speed of the LADARTracker (4000 measures/second) allows the system to detect eye movement and move the laser beam to compensate for this movement.

A very small laser beam is used to shape your cornea with this system. Therefore, precise shaping of the cornea depends on accurate placement of the laser beam. Without a system to track eye movements, any movement of the eye could affect the placement of the laser beam. Your eyes are constantly making fine eye movements even though you may not be aware of the movement. Many of these movements are beyond your control. In addition, you would not be able to hold your eye perfectly still even if you tried. By tracking all eye movements, the LADARVision[®] system maintains accurate placement of the laser beam.

Analysis of eye movement data gathered electronically during the surgical procedures of 554 eyes treated in the clinical study on myopia and astigmatism demonstrated that:

- All eyes moved during surgery.
- The LADARTracker compensated for this eye movement so that eyes with large movements and eyes with small movements had similar results.
- Active eye tracking with LADARTracking improves the accuracy of corneal shaping.

D. What Are Benefits Of PRK or LASIK?

Either PRK or LASIK may reduce overall nearsightedness. PRK or LASIK may also reduce or eliminate the need to wear glasses or contact lenses to see clearly.

- PRK surgery performed with the LADARVision® system is effective in reducing myopia between -1.0 and -10.0 Diopters. In patients with myopia, the LADARVision® system is effective in reducing astigmatism of up to 4 Diopters.
- LASIK surgery performed with the LADARVision system is effective in reducing myopia less than -9.0 Diopters. In patients with myopia, the LADARVision system is effective in reducing astigmatism of 0.50 Diopters to less than 3.0 Diopters.

The results listed in the following section are from U.S. clinical studies of the LADARVision® system for PRK and LASIK.

U.S. CLINICAL STUDY RESULTS AT 12 MONTHS AFTER PRK SURGERY			
	Mildly Nearsighted	Mildly Nearsighted with Astigmatism	Highly Nearsighted with and without Astigmatism
Visual Acuity 20/20 or better without glasses*	72.0%	61.7%	61.2%
Visual Acuity 20/25 or better without glasses*	88.7%	82.6%	76.9%
Visual Acuity 20/40 or better without glasses*	98.1%	97.4%	93.4%
Visual Acuity 20/20 or better with glasses	97.0%	94.1%	92.4%
Visual Acuity 20/40 or better with glasses	100%	100%	100%
Loss of more than 2 lines of visual acuity with glasses	0.3%	0.0%	0.0%

*not including eyes treated for monovision

U.S. CLINICAL STUDY RESULTS AT 6 MONTHS AFTER LASIK SURGERY				
	Eyes without astigmatism		Eyes with astigmatism	
	n/N	%	n/N	%
Visual Acuity 20/20 or better without glasses**	88/140	62.9%	47/89	52.8%
Visual Acuity 20/20 or better without glasses*	89/145	61.4%	47/94	50.0%
Visual Acuity 20/25 or better without glasses*	118/145	81.4%	69/94	73.4%
Visual Acuity 20/40 or better without glasses*	136/145	93.8%	88/94	93.6%
Visual Acuity 20/20 or better with glasses**	146/150	97.3%	88/98	89.8%
Visual Acuity 20/20 or better with glasses	148/155	95.5%	90/105	85.7%
Visual Acuity 20/40 or better with glasses	155/155	100.0%	105/105	100.0%
Loss of more than 2 lines of visual acuity with glasses	0/155	0.0%	0/105	0.0%

*Not including eyes treated for monovision

**If vision with glasses was 20/20 or better before surgery

E. Contraindications

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

- **You are pregnant or nursing**
- **You show signs of keratoconus** (This is a condition of the cornea that results in a change in the shape of the cornea.)
- **You are taking medications with ocular side effects** (for example, Isotretinoin (Accutane[®]) and Amiodarone hydrochloride (Cordarone[®]))
- **You have a collagen vascular, autoimmune, or immunodeficiency disease**
These are conditions that affect your immune response (your body's ability to heal), or result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of these diseases are AIDS, lupus, rheumatoid arthritis, multiple sclerosis and myasthenia gravis.

F. Warnings

Discuss with your doctor if:

- You are an insulin dependent diabetic
- You have severe allergies
- You have had a Herpes simplex or Herpes zoster infection that has affected your eyes

It will be necessary to use eye drops to enlarge your pupil to a certain size (7mm to 11mm) before surgery to optimize the tracker operation. This effect is only temporary.

G. Precautions

The safety and effectiveness of the LADARVision[®] system have **NOT** been established:

- In eyes with unstable or worsening myopia (nearsightedness)
- In eyes with disease or corneal condition (for example, scar, infection, etc.).
- In eyes with injury to the center of the cornea where PRK or LASIK will reshape the cornea
- In patients with a cornea that is too thin for the procedure to be completed safely
- In patients with a history of glaucoma (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision)
- In patients with a tendency to form scars (PRK only)
- In patients who are taking the medication Sumatriptan (Imitrex[®])
- In patients under 21 years of age
- For the treatment of astigmatism less than 0.50 Diopters
- In patients over the long term (more than 12 months for PRK; 6 months for LASIK)
- In eyes with previous corneal or intraocular surgery (for example, cataract surgery).
- For PRK refractive treatments greater than -10.0D of myopia combined with greater than -4.0D of astigmatism.
- For LASIK refractive treatments greater than or equal to -9.0D of myopia combined with greater than or equal to -3D of astigmatism.

The effects of LASIK on visual performance under poor lighting conditions have not been effectively determined. Following LASIK treatment, some patients may find it more difficult to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.

In a contrast sensitivity study designed to assess the effects of LADARVision PRK surgery on how well patients can see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night, the percentage of patients showing clinically significant losses were 10.6% at 6 months and 6.6% at 12 months after surgery, and the percentages of patients showing clinically significant improvements were 5.9% at 6 months and 3.3% at 12 months after PRK surgery.

In addition, U.S. clinical studies of the LADARVision® system have shown the following findings for PRK.

- Corneal infiltrates (inflammation) have been seen after PRK with the system in 1.6% of PRK eyes treated. All patients in the PRK study received bandage contact lenses and anti-inflammatory drops for pain management after surgery.
- Overcorrection of more than 1 Diopter with PRK has been associated with corrections of higher amounts of myopia, older patient age, and lower humidity in the laser room. An overcorrection is too much correction that may cause blurred distance and/or near vision without glasses.

H. What Are The Risks of PRK and of LASIK?

If the results of the surgery are not satisfactory, you may need to have additional PRK or LASIK surgery in the same eye.

PRK

The First Week Following PRK Surgery

- Pain and discomfort may last from 1 up to 3 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You will be sensitive to bright lights.
- You may have difficulty seeing in low light conditions (e.g. rain, snow, fog or glare).
- You will use antibiotic and anti-inflammatory drops in the first few days. You may also use a prescription drop and a bandage contact lens for management of pain in the first few days.

The First One To Six Months Following PRK Surgery

- The pressure inside your eye may increase. Anti-inflammatory medications prescribed by your doctor may cause an increase in pressure in the eye. Your doctor may need to treat a pressure increase with drug therapy or by stopping the anti-inflammatory medication. An increase in the eye pressure does not usually cause any symptoms. Therefore, it is essential that you see your doctor as directed to check for an increase in the eye pressure. A severe increase in eye pressure could cause eye pain or nausea. If you notice these symptoms, you should contact your doctor.

- Your cornea may become hazy or cloudy enough to affect your vision. Haze may occur as the cornea heals. The haze typically goes away over time. Some patients continue to have some haze over a longer period of time.
- You may notice glare, sensitivity to light and difficulty in driving at night.
- You should contact your doctor if you notice any pain or change or loss of vision in the eye.

One or More Years After Surgery

Some patients report visual complaints at one or more years after surgery. These problems are discussed in detail in the following section. In U.S. clinical studies of the LADARVision® system, the following events related to the surgery have occurred. These events may result in a loss of vision.

Summary of PRK Adverse Events¹ and Complications²

	Mildly Nearsighted (n=386)	Mildly Nearsighted with Astigmatism (n=144)	Highly Nearsighted with and without Astigmatism (n=148)
Corneal Infiltrates (inflammation) ¹	1.3%	2.1%	2.0%
IOP increase above 25 mmHg ¹	0.5%	0.7%	2.7%
Feeling of something in the eye ²	3.6%	7.6%	4.7%
Double or ghost images ²	2.1%	5.6%	8.8%
Peripheral epithelial defect ²	1.6%	1.4%	2.0%
Pain ²	2.1%	2.1%	2.0%
Other ²	3.9%	1.4%	4.1%

Other findings that occurred at a rate of less than or equal to 0.3% in all eyes treated (n=678) included:

- corneal edema (swelling in the cornea)
- corneal ulcer
- light sensitivity
- corneal erosion (a defect in the outer layer of the cornea that may recur)
- epithelial dots (small spots in the outer layer of the cornea with no adverse effects)
- epithelial irregularity (an area of the outer layer of the cornea that is not smooth)
- scratchiness (similar to a feeling of something in the eye)
- iritis (inflammation of the inside of the eye behind the cornea)
- ocular hypertension (an increase in the pressure inside the eye)
- subconjunctival hemorrhage (an area of bleeding in the outer lining of the eye next to the cornea. This bleeding has no adverse effects and resolves on its own.)
- superficial punctate keratitis (surface irritation in the outer layer of the cornea)
- corneal foreign body (foreign debris in the outer layer of the cornea)
- nebula after foreign body removal (area of haze in outer layer of the cornea where foreign body was removed)
- retinal vascular accident (blockage of a blood vessel in the back of the eye unrelated to the surgery)

Other findings that occurred at a rate of less than or equal to 1.0% in all eyes treated (n=678) included:

- corneal abrasion (a scratch in the outer layer of the cornea often from an eye injury)
- halos/starbursts (circular or star-shaped flares of light that may appear around a headlight or other lighted object)

Other events that did not occur in this study that could occur following PRK include significant corneal haze and loss of best corrected visual acuity.

U.S. clinical studies of the LADARVision® system have shown the following conditions may occur after PRK surgery. At 12 months or more after surgery, some patients noted on a questionnaire that these conditions were significantly worse than before surgery, as shown in the table below.

	Mildly Nearsighted	Mildly Nearsighted with Astigmatism	Highly Nearsighted with and without Astigmatism
Difficulty with night driving	2.1%	6.8%	9.4%
Glare	1.0%	1.7%	5.5%
Halos*	1.7%	3.4%	7.0%
Feeling of something in eye	0.0%	1.7%	2.3%
Fluctuation of vision	1.7%	0.0%	2.3%
Blurring of vision	0.3%	0.9%	2.3%
Light sensitivity	1.0%	0.0%	0.8%
Headache	0.0%	0.0%	0.0%
Double vision	0.7%	0.0%	1.6%
Pain	0.3%	0.9%	0.0%
Excessive tearing	0.0%	0.0%	0.0%
Burning	0.0%	0.0%	0.0%

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

LASIK

On the day of LASIK Surgery

- In clinical studies of the LADARVision® system for LASIK surgery, the following adverse event was reported on the day of surgery (n=325) at a rate of 0.3%: miscreated flap (e.g. too small or irregular) related to use of the microkeratome. In this situation, laser ablation is not attempted. A new flap can usually be created 3 months after the first attempt and LASIK surgery completed.

The First Week Following LASIK Surgery

- Pain, discomfort and a feeling of something in the eye may last from 1 up to 3 days after surgery.
- Blurred vision may be present for the first week as the corneal flap settles.
- Do not rub your eye as this may move the corneal flap. If you notice any sudden decrease in your vision, the corneal flap may have moved and you should contact your doctor immediately. The doctor may have to re-position the flap.
- Swelling of the eye may occur.
- You will use antibiotic and anti-inflammatory drops in the first few days. You may also use a prescription drop and a bandage contact lens for management of pain in the first few days.
- The pressure inside your eye may increase. Anti-inflammatory medications prescribed by your doctor may cause an increase in pressure in the eye. Your doctor may need to treat a pressure increase with drug therapy or by stopping the anti-inflammatory medication. An increase in the eye pressure does not usually cause any symptoms. Therefore, it is essential that you see your doctor as directed to check for an increase in the eye pressure. A severe increase in eye pressure could cause eye pain or nausea. If you notice these symptoms, you should contact your doctor.
- In clinical studies of the LADARVision® system for LASIK surgery, the following complications were reported within 1 week (n=313) at a rate of less than 1.0%: corneal folds/striae, epithelium in the interface, misaligned flap and sterile interface inflammation.

The First One Month Following LASIK Surgery

- You should contact your doctor if you notice any pain or change or loss of vision in the eye.
- You may notice glare, sensitivity to light and difficulty in driving at night.
- Your vision should become stable within the first few weeks after surgery. Some patients may experience some small changes in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after surgery.

In U.S. clinical studies of the LADARVision® system, the following adverse events and complications related to LASIK surgery have occurred at 1 month or later. These events may result in a loss of vision.

Summary of LASIK Adverse Events and Complications

	1 Month (n=316)		3 Months (n=310)		6 Months (n=260)		9 Months (n=111)	
	n/N	%	n/N	%	n/N	%	n/N	%
Induced astigmatism-flap decentration	1/316	0.3	1/310	0.3	0/260	0.0	0/111	0.0
Feeling of something in the eye	1/316	0.3	0/310	0.0	0/260	0.0	0/111	0.0
Double/ghost images	2/316	0.6	1/310	0.3	1/260	0.4	0/111	0.0
Epithelium in the interface	3/316	0.9	3/310	1.0	1/260	0.4	0/111	0.0
Sterile Interface Inflammation	2/316	0.6	2/310	0.6	0/260	0.0	0/111	0.0
Serous Macular Edema	0/316	0.0	0/310	0.0	0/260	0.0	1/111	0.9
Corneal Folds/Striae/Wrinkle	4/316	1.3	2/310	0.6	2/260	0.8	0/111	0.0
Interface debris	10/316	3.2	12/310	3.9	11/260	4.2	0/111	0.0
Interface haze/opacity	7/316	2.2	10/310	3.2	1/260	0.4	1/111	0.9
Superficial punctate keratitis (SPK)	15/316	4.7	8/310	2.6	6/260	2.3	3/111	2.7
Oil droplets/sheen	5/316	1.6	0/310	0.0	2/260	0.8	0/111	0.0
Flap distortion	1/316	0.3	0/310	0.0	0/260	0.0	0/111	0.0
Fibrotic healing at flap edge	0/316	0.0	3/310	1.0	2/260	0.8	0/111	0.0
Epithelial defect	0/316	0.0	0/310	0.0	1/260	0.4	0/111	0.0
Conjunctival injection	0/316	0.0	0/310	0.0	2/260	0.8	0/111	0.0

The following other adverse events and complications occurred at unscheduled visits at 1 month or later:

- IOP increase >10 mmHg above baseline (3 eyes): increase in the pressure in the eye
- HSV dendrite (1 eye): a branching tree-like lesion on the cornea due to herpes simplex infection
- corneal folds/striae/wrinkles (2 eyes): the temporary appearance of fine white lines in the back of the cornea as a result of corneal swelling
- interface haze/opacity (3 eyes): a cloudiness of the cornea underneath the flap, either diffuse or in localized areas
- superficial punctate keratitis (13 eyes): surface irritation in the outer layer of the cornea
- peau d' orange (2 eyes): orange peel corneal appearance that typically does not affect vision
- flap distortion (1 eye): irregular appearance of the corneal flap
- vacuoles (1 eye): small round areas of cellular debris that typically does not affect vision
- conjunctival injection (2 eyes): increased redness of the blood vessels in the front of the eye

The following ocular findings were reported at 6 months (n=260) at a rate of 0.8%: blepharitis, retinal vessel tortuosity, and lattice degeneration with floaters.

U.S. clinical studies of the LADARVision® system have shown the following conditions may occur after LASIK surgery. At 6 months after surgery, some patients noted these conditions were significantly worse than before surgery, as shown in the table below.

Subjective Responses	Eyes Without Astigmatism		Eyes With Astigmatism	
	n/N	%	n/N	%
Difficulty with night driving	8/140	5.7	15/101	14.9
Glare	4/141	2.8	10/101	9.9
Halos*	5/141	3.5	7/101	6.9
Light sensitivity	4/141	2.8	6/101	5.9
Dryness	6/141	4.3	3/101	3.0
Fluctuation of vision	3/141	2.1	2/101	2.0
Blurring of vision	3/141	2.1	1/101	1.0
Redness	1/141	0.7	2/101	1.0
Headache	1/141	0.7	0/101	0.0
Double vision	1/139	0.7	0/101	0.0
Pain	0/141	0.0	0/101	0.0
Excessive tearing	0/141	0.0	0/100	0.0
Burning	0/141	0.0	0/100	0.0
Feeling of something in eye	0/141	0.0	0/101	0.0

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

I. Are You A Good Candidate For PRK or LASIK ?

If you are considering PRK or LASIK, you must:

- Be at least 21 years of age
- Have healthy eyes that are free from eye disease or corneal condition (for example, scar, infection, etc.)
- Have myopia between 0 to -10.0 diopters with no more than 4.0 diopters of astigmatism for PRK or have myopia less than -9.0D with less than -3.0D of astigmatism for LASIK
- Have documented evidence that the change in your nearsightedness is less than or equal to 0.50 diopter per year for corrections up to 7D, and less than or equal to 0.75D for corrections greater than 7D.
 - at least one year prior to your pre-operative exam
- Be able to lie flat without difficulty
- Be able to constantly look at a blinking light during the PRK or LASIK procedure
- Be able to tolerate eye drops to numb your eye and enlarge your pupil
- Be informed of PRK or LASIK risks and benefits as compared to other available treatments for myopia
- Be willing to sign an Informed Consent Form, if provided by your eye care professional

J. What Should You Expect During PRK or LASIK Surgery?

PRK surgery is performed on one eye at a time. The second eye can be treated if all goes well and vision stabilizes in the first eye without complications or adverse reactions. Laser surgery of the second eye is usually done after the first eye if needed.

LASIK surgery can be performed one eye at a time or on both eyes during the same surgical session.

Before The Surgery

First, you will need to have a pre-operative examination if you have an interest in PRK or LASIK. This exam will help to determine if your eye is healthy and suitable for PRK or LASIK. This exam will include a complete medical and eye history, and a complete evaluation of both eyes. In addition, this examination will involve mapping your cornea with a computer to determine if it is smooth and properly shaped.

WARNING:

If you wear contact lenses, it is very important to stop wearing them at least 3 weeks before the evaluation. Failure to do this will produce poor surgical results.

Before the surgery, please tell your doctor if you take any medications or have any allergies. Also, talk with your doctor about eating or drinking right before the surgery. You should also arrange for transportation, since **you must not drive right after the surgery. Your doctor will inform you of when you can resume driving.**

The Day Of Surgery

Before the surgery, your doctor will ask you to lie on your back on the laser bed. The laser bed is a flat cushioned surface that does not recline or move. Your doctor will instruct you to watch a blinking light. Your doctor will take a picture of your eye to aid in determining the correct placement of the treatment on the cornea. Your doctor will not apply any laser pulses at this time. Your doctor will then put drops in your operative eye to dilate (enlarge) your pupil.

About 30-40 minutes later, your doctor will place anesthetic (numbing) drops into your eye. Your doctor will escort you back into the room with the laser. You will again lie on your back and look up at a microscope that will deliver the laser light to your cornea. Your doctor will place an instrument between your eyelids to hold them open during the surgery. A temporary shield will cover the eye not having surgery.

PRK surgery begins with removal of the outer layer of the cornea. Your doctor will remove this layer with a small spatula or a rotary brush. LASIK surgery begins with the creation of a corneal flap with a microkeratome. Then, your doctor will reposition your head and activate the tracker. Your doctor will ask you to look directly at a blinking light. The laser in the LADARVision[®] system will remove small amounts of tissue from your cornea. The tracker will follow eye movements and allow the laser to continue the treatment. Still, it is important to continue looking at the blinking light throughout the treatment.

You will be under the laser for several minutes. Overall, the surgery takes about 10 minutes. After the laser surgery is complete, your doctor will place some drops into your eye. For your eye protection and comfort, your doctor will cover your eye with a bandage contact lens in PRK. In some LASIK cases, a bandage contact lens is placed in your eye as well to help heal small abrasions. The surgery is painless because of the numbing drops. The numbing drops will wear off in about 45-60 minutes. After this time, your eye may hurt for 1 to 3 days.

WARNING:

Your doctor will monitor you for any side effects if you need to use topical steroids. Possible side effects of extended topical steroid use are: **ocular hypertension** (an increase in the eye pressure); **glaucoma** (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision); **cataract formation** (an opacity or clouding of the lens inside the eye that can cause a loss of vision).

The First Days After Surgery

If a bandage contact lens was applied to the eye after surgery, your doctor will remove the bandage contact lens on the day the surface of your eye has recovered. 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.

DO NOT rub your eyes for the first 3 to 5 days. You may be provided with a plastic shield for eye protection after LASIK for the first few days. Your doctor can also prescribe pain medication to make you more comfortable during this time after the surgery.

Your vision should become stable within the first few weeks after surgery. Some patients may experience some small changes in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after surgery.

A haze or cloudiness of the cornea will typically occur after PRK surgery. This haze usually does not affect vision. This haze tends to decrease over time and usually disappears completely over a 3 to 6 month period.

IMPORTANT:

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

K. 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 are my other options to correct my nearsightedness?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of PRK or LASIK for my amount of nearsightedness?
- 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 would 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 needs with your doctor. Most health insurance policies do not cover laser treatment.

L. 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 surgery is risk free.		
2. Excimer laser surgery is the same as Radial Keratotomy (RK).		
3. It does not matter if I wear my contact lenses when my doctor told me not to wear them.		
4. Since the LADARVision [®] system tracks my eye movements, I do not have to fixate on the blinking light.		
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 does not matter if I am pregnant.		
9. If I have an autoimmune disease, I am still a good candidate for PRK or LASIK.		

You can find the answers to Self-Test at the bottom of Page 26.

M. Summary Of Important Information?

- PRK or LASIK are permanent operations to the cornea and are irreversible.
- PRK or 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 has changed less than or equal to 0.50 Diopters.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You would not be a good candidate if you have collagen vascular or autoimmune diseases. If you have a condition that makes wound healing difficult, you would not be a good candidate.
- PRK or LASIK surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery. The sections on Benefits and Risks are especially important to read carefully.
- PRK or LASIK are not a laser version of Radial Keratotomy (RK). These surgeries are entirely different from each other.
- Alternatives to PRK or LASIK include, but are not limited to, glasses, contact lenses and RK.
- The vision requirements of some occupations, such as military pilots, cannot be met by having RK, 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 PRK or LASIK. This talk should include the potential benefits, risks, and complications of PRK or LASIK surgery. In addition, you should discuss the time needed for healing after PRK or LASIK.

Answers to Self-Test Questions:

1. False (see Risks on Page 16); 2. False (see Introduction on Page 10); 3. False (see Before the Surgery on Page 22); 4. False (see The Day of Surgery on Page 22); 5. True (see Benefits on Page 13); 6. True (see Introduction on Page 10); 7. True (see Risks on Page 16); 8. False (see Contraindications on Page 14); 9. False (see Contraindications on Page 14).

N. Patient Assistance Information?

To be completed by you or your Primary Eye Care Professional as a reference.

PRIMARY EYE CARE PROFESSIONAL

Name: _____

Address: _____

Phone: _____

PRK DOCTOR

Name: _____

Address: _____

Phone: _____

TREATMENT LOCATION

Name: _____

Address: _____

Phone: _____

LASER MANUFACTURER

Summit Autonomous, Inc. 2501 Discovery Drive, Suite 500 Orlando, FL 32826 U.S.A. Tel: (877)523-2784 Fax: (407) 384-1677
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**FACTS YOU NEED TO KNOW ABOUT
LADARVision®
LASER IN-SITU KERATOMILEUSIS (LASIK) SURGERY**

PATIENT INFORMATION BOOKLET

For:

For Farsightedness (Hyperopia) With or Without Astigmatism and Mixed Astigmatism
(Sphere up to +6.00D and Cylinder up to -6.00D)

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

Summit Autonomous Inc.
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A. Glossary

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions that you may have about these terms. Your doctor can provide you with answers to your medical questions.

Allergic Conjunctivitis: inflammation of the outer lining of the eye from an allergic reaction to the environment, such as hay fever.

Astigmatism: a condition of the eye that results in blurred distance and/or near vision. The surfaces of the eye focus the light rays at different points inside the eye. The different points of focus create a blur of parts of objects you see.

Antibiotic Medication: a drug used to treat or prevent infection. Your doctor may prescribe this type of medication after surgery.

Anti-inflammatory Medication: a drug that reduces inflammation or the body's reaction to injury or disease. Surgery that alters the eye, such as LASIK, can also cause inflammation. Your doctor may prescribe this type of medication after surgery.

Autoimmune Disease: a condition in which the body attacks itself that may result in inflammation or swelling of parts of the body; such as muscles, joints, and blood vessels. Examples of this condition are multiple sclerosis and myasthenia gravis. If you have this type of condition, you should not have LASIK surgery.

Bandage Contact Lens: a soft contact lens that may be placed on the cornea after surgery to cover the eye.

Cataract: an opacity, or clouding, of the lens inside the eye that can cause a loss of vision. This clouding tends to develop with older age and may affect different parts of the lens, which are categorized as nuclear sclerosis, cortical spoking, and posterior subcapsular cataract.

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. If you have this type of condition, you should not have LASIK surgery.

Conjunctiva: the outer lining of the eye that surrounds the cornea.

Conjunctival Injection: increased redness of the blood vessels in the front of the eye

Contraindications: any special condition that results in the treatment not being recommended.

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

Corneal Abrasion: a scratch in the outer layer of the cornea often from an eye injury.

Corneal Epithelium: the top layer of the cornea.

Corneal Flap: a thin slice of tissue on the surface of the cornea made with a microkeratome at the beginning of the LASIK procedure. This flap is folded back before the laser is applied to the inner layers of the cornea.

Corneal Folds/Striae/Wrinkles: the temporary appearance of fine white lines in the back of the cornea as a result of corneal swelling.

Corneal Infiltrate: inflammation of the cornea.

Corneal Opacities: cloudy areas in the cornea.

Corneal Swelling: an accumulation of fluid in the cornea that is not normally present. This condition is usually temporary with no significant effect on vision.

Cotton Wool Spot: a small area in the back of the eye (retina) with a cotton-like appearance that develops when there is a lack of blood supply to the area. This spot does not typically affect vision may be associated with several types of conditions, such as diabetes or high blood pressure.

Diopter: a unit used to measure the amount of myopia and astigmatism of an eye.

Drusen: small deposits of cellular material in the back of the eye (retina), which is more common in older age. These deposits often have no affect on vision but may result in vision loss if they occur in the area responsible for central vision (macula).

Epithelial Defect: a piece of the outer layer of the cornea that has torn off leaving a defect. This defect could occur anywhere on the surface of the cornea. This condition is usually temporary and may result in some discomfort or pain.

Epithelial Irregularity: an area of the outer layer of the cornea that is not smooth.

Epithelium in the Interface: this condition can occur after LASIK surgery when epithelial cells from the surface of the cornea move or grow underneath the corneal flap. This can result in loss of vision.

Excimer Laser: a type of laser used in LASIK that removes tissue from the cornea.

Farsightedness: Another term for hyperopia. Farsightedness eyes may see better at distance than at near without glasses or contact lenses but usually require correction for both distances.

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. This symptom may occur after LASIK surgery.

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. You should discuss any history of this condition with your doctor before having LASIK surgery.

Herpes Zoster: a type of infection caused by a virus that can recur. This condition is a reactivation of the chicken pox virus as an adult. Vesicles appear on only one side of the body. You should discuss any history of this condition with your doctor before having LASIK surgery.

Hyperopia: a condition of the eye that results in blurred distance and near vision. The cornea and lens focus light rays from distant and near objects behind the retina.

Hyperopic Astigmatism: a condition of the eye that results in blurred distance and near vision. The cornea and the lens focus the light rays at different points behind the retina.

Immunodeficiency Disease: a condition that alters the body's ability to heal. An example is AIDS. If you have this type of condition, you should not have surgery.

Inflammation: the body's reaction to injury or disease. Surgery that alters the eye, such as LASIK, can also cause inflammation.

Interface Debris: cellular and foreign material underneath the flap after LASIK surgery.

Intralamellar Haze: cloudiness underneath the corneal flap.

Iritis: inflammation of the inside of the eye behind the cornea.

Iron Line or Ring: a deposit of iron in the cornea that has no effect on vision.

Keratoconus: a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs. If you have this type of condition, you should not have LASIK surgery.

Lagophthalmos: failure to close eyes completely, which may result in irritation of the front of the eye due to dryness.

Laser In-Situ Keratomileusis (LASIK): a procedure where a device called a microkeratome is used to surgically create a thin, hinged flap of corneal tissue. The flap is folded back, the laser is directed to the corneal surface exposed beneath the flap and the flap is brought back into place.

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

MRSE (Manifest Refraction Spherical Equivalent): the amount of hyperopia and astigmatism calculated based on the glasses prescription.

Microkeratome: a surgical instrument used to cut a flap of corneal tissue as the first step in the LASIK procedure.

Misaligned Flap: the flap created with the microkeratome has not returned to its correct position after the ablation is complete. It is sometimes possible to reposition the flap.

Miscreated Flap: the flap created with the microkeratome was of poor quality (e.g. too small or irregular) and the laser ablation was not attempted. In this situation, a new flap can usually be created 3 months after the first attempt and LASIK surgery completed.

Mixed Astigmatism: a condition of the eye that results in blurred distance and near vision. The cornea and the lens focus the light rays at different points with one point focused in front of the retina and the other point focused behind the retina.

Monovision: optical correction of one eye so that it sees clearly in the distance and the other eye sees clearly up close.

Non-Steroidal Anti-inflammatory Drug (NSAID): a type of drug that reduces inflammation or the body's reaction to injury or disease. Your doctor may prescribe this type of medication after surgery.

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

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the surface of the cornea using an excimer laser. Tissue is removed from the outermost surface of the cornea just beneath the epithelium.

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

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

Sterile Interface Inflammation: an inflammatory reaction underneath the corneal flap after LASIK surgery that is not due to bacteria. This condition may result in loss of vision.

Steroid Medication: a type of drug that reduces inflammation or the body's reaction to injury or disease. Your doctor may prescribe a steroid for use in the eye after surgery to modify the healing of the cornea. If you are taking this drug for a disease condition, you should not have LASIK surgery.

Subconjunctival Hemorrhage : an area of bleeding in the outer lining of the eye next to the cornea. This bleeding has no adverse effects and resolves on its own.

Superficial Punctate Keratitis (SPK) : surface irritation in the outer layer of the cornea.

Trichiasis: misdirected eyelashes that may turn inward toward the eye.

Vacuoles: small round areas of cellular debris in the cornea that typically has no effect on vision.

Vitreous Floater: a strand or spot in the fluid inside the eye that may appear as floating spot in the vision. The appearance of floaters is normal and more common with age.

B. Introduction

Do you need to wear glasses or contact lenses to help you to see clearly? One option to see more clearly is to correct your vision with surgery. Some types of surgery correct vision by shaping the front surface of the eye, the cornea. A recent type of surgery that reshapes the cornea is Photorefractive Keratectomy (PRK). PRK uses a laser instead of a scalpel to carefully shape the corneal surface. Another procedure, which uses the laser is called Laser In-Situ Keratomileusis (LASIK). In the LASIK procedure, the laser energy is applied to the inner layers of the cornea. LASIK may help you to see more clearly by partially or fully correcting vision.

The LADARVision[®] Excimer Laser System is a unique system that tracks all movements of the eye during surgery. Tracking movements of the eye allows the system to accurately place the laser beam. The system applies hundreds to thousands of laser beam pulses to the cornea to correct vision. Accurate placement of these laser beam pulses provides precise shaping of the cornea. The purpose of this booklet is to inform you about LASIK with the tracker-guided LADARVision[®] system. Please read this information carefully and discuss any questions with your doctor. It is important that you make an informed decision about LASIK with the help of your doctor.

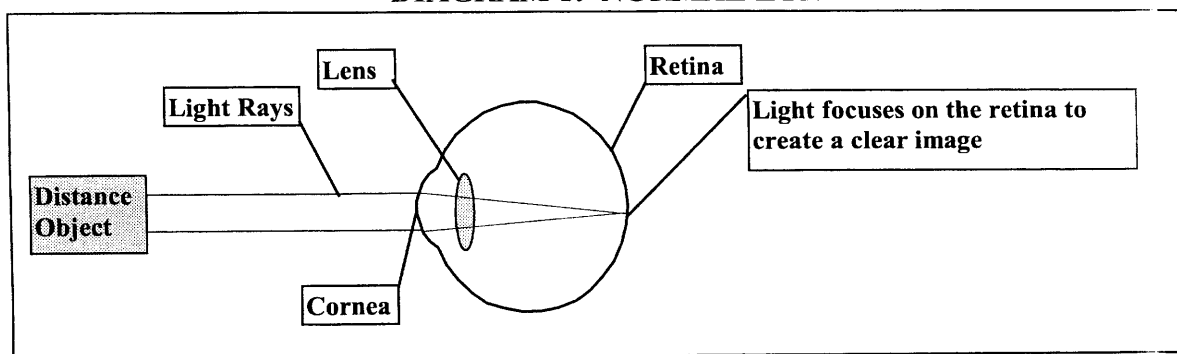
Although vision without glasses improved for all eyes, some people still needed glasses or contact lenses for some tasks after LASIK. LASIK does not eliminate the need for reading glasses. In addition, the vision requirements of some occupations, such as military pilots, cannot be met by having PRK or LASIK.

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

C. How Does LASIK Correct Hyperopia With or Without Astigmatism or Mixed Astigmatism?

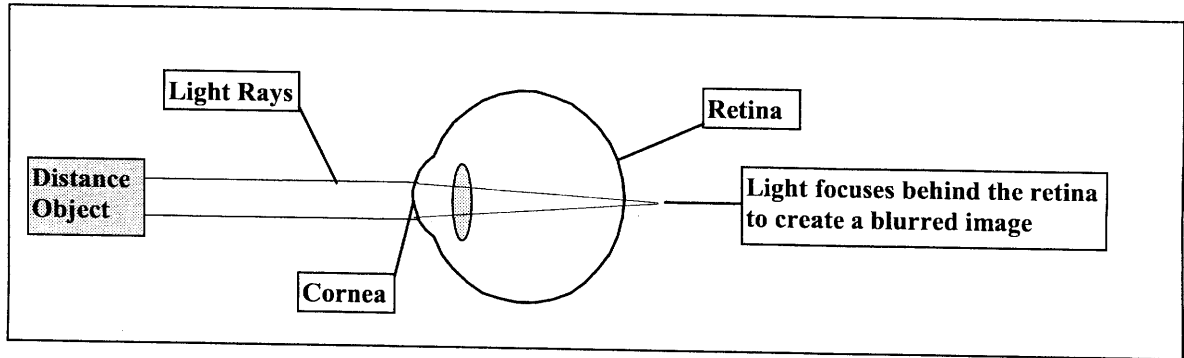
The human eye functions like a camera. The lens in a camera focuses light into images on to film. In the same way, the cornea and the lens inside the eye focus light into images on to the retina, the back surface of the eye (Diagram 1). Blurred vision occurs when the light does not focus precisely on the retina.

DIAGRAM 1: NORMAL EYE



Hyperopia (farsightedness) is a condition of the eye where people usually see better in the distance than near. The cornea and lens focus light rays from a distant and near object behind the retina. Diagram 2 shows how light from a distant object focuses behind the retina to cause a blurred image.

DIAGRAM 2: HYPEROPIA



Astigmatism is a condition of the eye that also results in blurred vision. In this case, the cornea and the lens focus the light rays at different points. In eyes with hyperopic astigmatism, both points focus behind the retina. In eyes with mixed astigmatism, one point focuses in front of the retina and the other point focuses behind the retina. The different points of focus create blur of parts of the images. For example, a person with astigmatism might confuse an “R” with a “P” or an “F” on a sign. This confusion about the letter occurs because only part of the letter is in focus. Diagrams 3 and 4 show how light rays focus at different points in an eye with astigmatism causing a blurred image.

DIAGRAM 3: HYPEROPIA WITH ASTIGMATISM

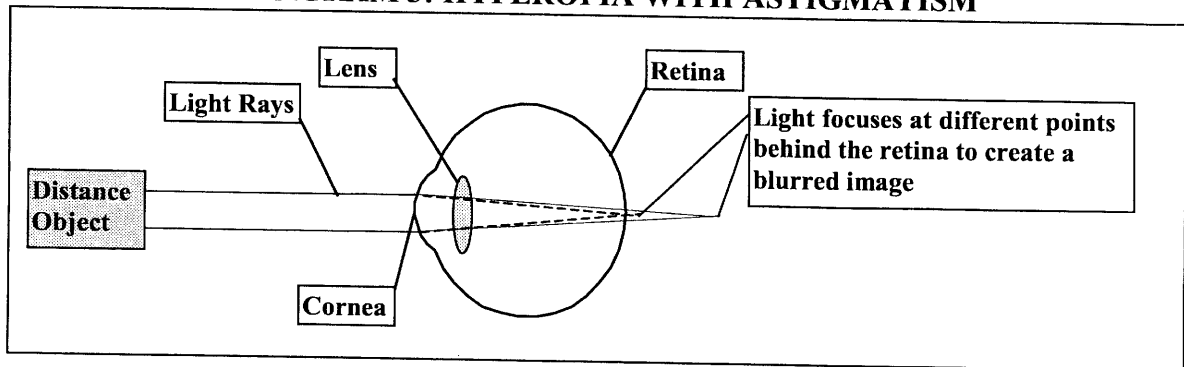
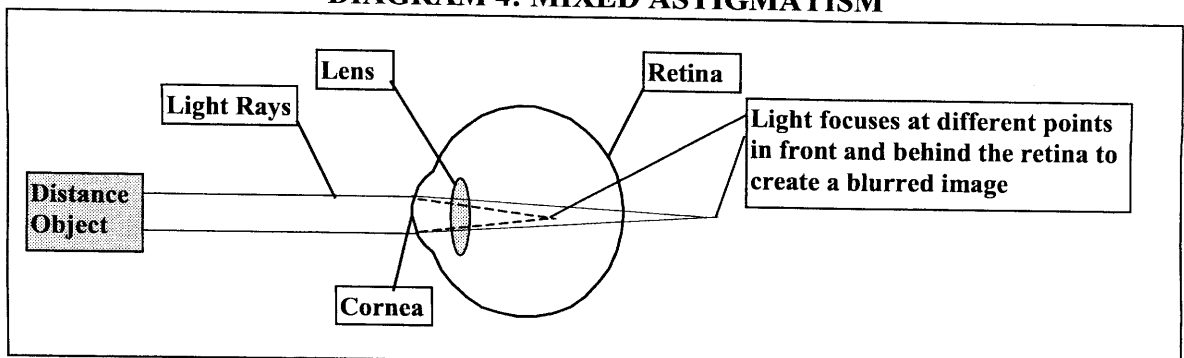
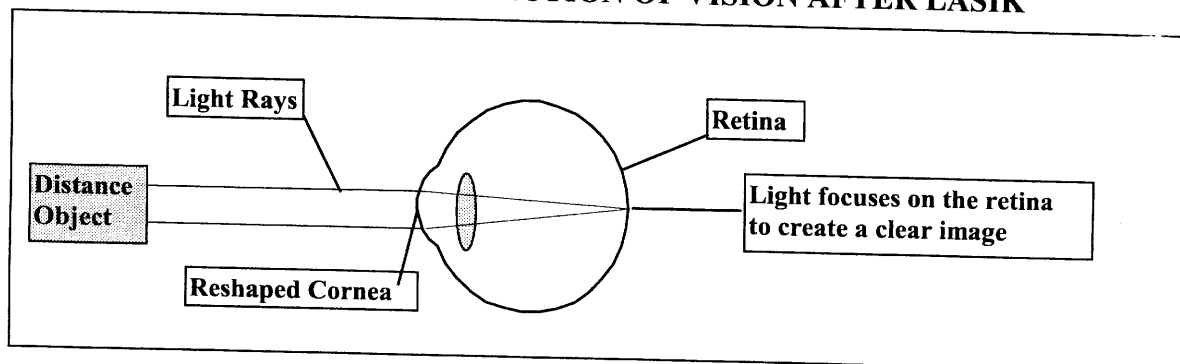


DIAGRAM 4: MIXED ASTIGMATISM



Glasses and contact lenses help focus all of the light rays on to the retina. By focusing all of the light rays properly, the vision in the distance is clear. Another way to change the way the eye focuses light is to reshape the cornea. For treatment of hyperopia, this is done by reshaping the periphery of the cornea. LASIK sculpts the cornea by removing a tiny amount of the tissue with a laser. An excimer laser is a type of laser used in LASIK that removes tissue from the cornea. This type of laser reshapes the cornea without changing any other parts of the eye. Diagram 5 shows how these LASIK can reshape the cornea to provide clearer vision.

DIAGRAM 5: CORRECTION OF VISION AFTER LASIK



The LADARVision[®] System incorporates an active eye tracking mechanism (LADARTracking), which compensates for eye movement during the surgery. The measurement speed of the LADARTracker (4000 measures/second) allows the system to detect eye movement and move the laser beam to compensate for this movement.

A very small laser beam is used to shape your cornea with this system. Therefore, precise shaping of the cornea depends on accurate placement of the laser beam. Without a system to track eye movements, any movement of the eye could affect the placement of the laser beam. Your eyes are constantly making fine eye movements even though you may not be aware of the movement. Many of these movements are beyond your control. In addition, you would not be able to hold your eye perfectly still even if you tried. By tracking all eye movements, the LADARVision[®] system maintains accurate placement of the laser beam.

Analysis of eye movement data gathered electronically during the surgical procedures of 554 eyes treated in the clinical study on myopia and astigmatism demonstrated that:

- All eyes moved during surgery.
- The LADARTracker compensated for this eye movement so that eyes with large movements and eyes with small movements had similar results.
- Active eye tracking with LADARTracking improves the accuracy of corneal shaping.

D. What Are the Benefits of LASIK?

LASIK may reduce overall farsightedness (hyperopia). LASIK may also reduce or eliminate the need to wear glasses or contact lenses to see clearly.

- LASIK surgery performed with the LADARVision® system is effective in reducing hyperopia between 0 and +6.0 Diopters. The LASIK procedure is also effective in correcting up to 6 Diopters of astigmatism in eyes with hyperopic or mixed astigmatism.

The results listed in the following section are from U.S. clinical studies of the LADARVision® system for LASIK. The clinical results are arranged by the type of condition: hyperopia without astigmatism, hyperopic astigmatism, and mixed astigmatism. It is important that you know which type of condition you have to determine which results represent your condition. Please discuss which type of condition you have with your doctor prior to reading this information.

Listed in the table below are the clinical results of vision with and without glasses at 6 months after surgery, which is the time point of stability of the refractive outcome of the procedure.

U.S. CLINICAL STUDY RESULTS AT 6 MONTHS AFTER LASIK SURGERY						
	Hyperopia without astigmatism		Hyperopic Astigmatism		Mixed Astigmatism	
	n/N	%	n/N	%	n/N	%
Visual Acuity 20/20 or better without glasses**	57/115	49.6	38/88	43.2	18/40	45.0
Visual Acuity 20/20 or better without glasses*	59/121	48.8	41/110	37.3	25/54	46.3
Visual Acuity 20/25 or better without glasses*	83/121	68.6	66/110	60.0	40/54	74.1
Visual Acuity 20/40 or better without glasses*	113/121	93.4	100/110	90.9	50/54	92.6
Visual Acuity 20/20 or better with glasses**	115/132	87.1	88/101	87.1	37/41	90.2
Visual Acuity 20/20 or better with glasses	121/141	85.8	94/124	75.8	47/56	83.9
Visual Acuity 20/40 or better with glasses	141/141	100	124/124	100	56/56	100
Loss of 2 lines of visual acuity with glasses	5/141	3.5	7/121	5.8	1/52	1.9
Loss of more than 2 lines of visual acuity with glasses	0/141	0.0	0/121	0.0	0/52	0.0

*Not including eyes treated for monovision

**If vision with glasses was 20/20 or better before surgery

At 6 months after surgery, patients completed a questionnaire for the following symptoms, which were rated as significantly better, better, unchanged, worse or significantly worse than before surgery. For information on the symptoms rated as worse or significantly worse, please refer to the section entitled “What are the risks of LASIK?” The table below displays the percentage of patients who rated the symptoms as unchanged, better or significantly better than before surgery. Note that this data reflects the percentage of patients who did not report worsening of these symptoms after surgery.

U.S. CLINICAL STUDY PATIENT QUESTIONNAIRE RESULTS AT 6 MONTHS						
Subjective responses rated as unchanged, better, or significantly better than before surgery						
	Hyperopia without astigmatism		Hyperopic Astigmatism		Mixed Astigmatism	
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%
Blurring of vision	132	88.6	111	82.9	53	88.7
Burning	133	97.0	113	90.3	53	92.5
Double vision	132	90.2	111	90.1	53	98.1
Dryness	132	80.3	113	77.0	53	75.6
Excessive tearing	132	98.5	111	98.2	52	100
Feeling of something in eye	133	93.2	113	92.0	53	94.3
Fluctuation of vision	133	78.2	111	77.5	53	88.7
Glare	133	77.5	113	79.6	53	77.4
Halos	132	84.8	111	74.8	53	73.6
Headache	132	97.0	110	95.5	53	96.2
Light sensitivity	133	72.2	112	76.8	53	79.2
Night driving difficulty	133	88.7	113	84.1	53	75.2
Pain	132	96.2	110	94.5	53	96.2
Quality of vision	132	95.5	115	94.8	53	94.3
Redness	133	88.0	112	92.0	53	96.2

Patients also reported on a questionnaire their satisfaction with their results at 6 months after surgery, which was rated as extremely satisfied, satisfied, not sure, unsatisfied or extremely unsatisfied, as shown in the table below.

U.S. CLINICAL STUDY PATIENT SATISFACTION RESULTS AT 6 MONTHS						
	Hyperopia without astigmatism		Hyperopic Astigmatism		Mixed Astigmatism	
	<i>N</i>	%	<i>N</i>	%	<i>n/N</i>	%
Extremely Satisfied	53/133	39.8	31/112	27.7	21/53	39.6
Satisfied	48/133	36.1	45/112	40.2	20/53	37.7
Not Sure	16/133	12.0	22/112	19.6	6/53	11.3
Unsatisfied	16/133	12.0	11/112	9.8	5/53	9.4
Extremely Unsatisfied	0/133	0.0	3/112	2.7	1/53	1.9

E. Contraindications

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

- **You are pregnant or nursing**
- **You show signs of keratoconus** (This is a condition of the cornea that results in a change in the shape of the cornea.)
- **You are taking medications with ocular side effects** (for example, Isotretinoin (Accutane[®]) and Amiodarone hydrochloride (Cordarone[®]))
- **You have a collagen vascular, autoimmune, or immunodeficiency disease**
These are conditions that affect your immune response (your body's ability to heal), or result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of these diseases are AIDS, lupus, rheumatoid arthritis, multiple sclerosis and myasthenia gravis.

F. Warnings

Discuss with your doctor if:

- You are an insulin dependent diabetic
- You have severe allergies
- You have had a Herpes simplex or Herpes zoster infection that has affected your eyes

It will be necessary to use eye drops to enlarge your pupil to a certain size (7mm to 11mm) before surgery to optimize the tracker operation. This effect is only temporary.

A microkeratome, used to create the corneal flap prior to laser treatment, should create a flap large enough to allow for a treatment zone of 9.0mm needed for this procedure.

G. Precautions

The safety and effectiveness of the LADARVision[®] system have **NOT** been established:

- In eyes with disease or corneal condition (for example, scar, infection, etc.)
- In eyes with previous surgery or injury to the center of the cornea where LASIK will reshape the cornea
- In patients with a cornea that is too thin for the procedure to be completed safely
- In patients with a history of glaucoma (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision)
- In patients who are taking the medication Sumatriptan (Imitrex[®])

- In patients under 21 years of age
- In patients over the long term (beyond 9 months)
- In eyes with previous corneal or intraocular surgery (for example, cataract surgery)
- In non-Caucasian patients
- For the treatment of astigmatism less than 0.50 Diopters
- For treatments greater than +6.0D of hyperopia or –6.0D of astigmatism
- For retreatments of hyperopia, hyperopic astigmatism or mixed astigmatism

Eye with greater than 5.0D of hyperopia may have lower predictability of refractive outcome and improvement in uncorrected visual acuity (vision without glasses or contact lenses) than eyes with lower levels of hyperopia.

Hyperopic astigmatism eyes with greater than 4.0D MRSE before surgery may have lower predictability of refractive outcome and improvement in uncorrected visual acuity (vision without glasses or contact lenses) than eyes with lower levels of MRSE. MRSE is the amount of hyperopic astigmatism calculated based on the glasses prescription. These eyes may be more likely to experience a reduction of two lines in their best corrected visual acuity (vision with glasses or contact lenses) and to require additional treatment (retreatment).

Older patients and women on hormone replacement therapy may be less likely to achieve uncorrected visual acuity (vision without glasses or contact lenses) of 20/20 or better.

The effects of LASIK on visual performance under poor lighting conditions have not been effectively determined. Following LASIK treatment, some patients may find it more difficult to see in conditions such as very dim light, rain, snow, fog, and glare from bright lights at night.

H. What Are the Risks of LASIK?

If the results of the surgery are not satisfactory, you may need to have additional LASIK surgery in the same eye.

On the day of LASIK Surgery

In clinical studies of the LADARVision® system for LASIK surgery, each of the following complications was reported on the day of surgery (n=360) at a rate of 0.3%: epithelial defect and misaligned flap. The following adverse event was reported on the day of surgery at a rate of 0.8%: miscreated flap related to use of the microkeratome. In the situation of a miscreated flap, laser ablation is not attempted. A new flap can usually be created 3 months after the first attempt and LASIK surgery completed.

The First Week Following LASIK Surgery

- Pain, discomfort and a feeling of something in the eye may last from 1 up to 3 days after surgery.
- Blurred vision may be present for the first week as the corneal flap settles. Best-corrected vision (vision with glasses or contact lenses) may be reduced in this early time period after surgery.
- Do not rub your eye as this may move the corneal flap. If you notice any sudden decrease in your vision, the corneal flap may have moved and you should contact your doctor immediately. The doctor may have to re-position the flap.
- Swelling of the eye may occur.
- You will use antibiotic and anti-inflammatory drops in the first few days. You may also use a prescription drop and a bandage contact lens for management of pain in the first few days.
- The pressure inside your eye may increase. Anti-inflammatory medications prescribed by your doctor may cause an increase in pressure in the eye. Your doctor may need to treat a pressure increase with drug therapy or by stopping the anti-inflammatory medication. An increase in the eye pressure does not usually cause any symptoms. Therefore, it is essential that you see your doctor as directed to check for an increase in the eye pressure. A severe increase in eye pressure could cause eye pain or nausea. If you notice these symptoms, you should contact your doctor.
- In clinical studies of the LADARVision® system for LASIK surgery, each of the following complications was reported at the 1 week visit (n=354) at a rate of 0.6% or less: corneal folds/striae, corneal swelling, epithelium in interface, and intralamellar haze. The complication of sterile interface inflammation was reported at 1 week at a rate of 2.0%. Each of the following adverse reactions was reported at 1 week at a rate of 0.8% or less: corneal infiltrate and increase in intraocular pressure.
- The following complications were reported only at unscheduled visits within the first two weeks after primary treatment or retreatment: corneal swelling (4 eyes), epithelium in the interface (1 eye), and sterile interface inflammation (2 eyes). In addition, one patient with a history of heart disease experienced a myocardial infarction (heart attack) two weeks after surgery, which was not related to the LASIK procedure or to the LADARVision system.

The First One Month Following LASIK Surgery

- You should contact your doctor if you notice any pain or change or loss of vision in the eye.
- You may notice glare, sensitivity to light and difficulty in driving at night.
- Your vision should become stable within the first few weeks after surgery. Some patients may experience some small changes in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after surgery.

In U.S. clinical studies of the LADARVision® system, the following adverse events and complications related to LASIK surgery have occurred at 1 month or later. These events may result in a loss of vision.

Summary of LASIK Adverse Events and Complications

	1 Month		3 Months		6 Months		9 Months	
	n/N	%	n/N	%	n/N	%	n/N	%
ADVERSE EVENTS								
Rolled flap edge with trace corneal melt	0/353	0.0	0/344	0.0	1/324	0.3	0/265	0.0
COMPLICATIONS								
Corneal abrasion	0/353	0.0	0/344	0.0	1/324	0.3	0/265	0.0
Corneal folds/Striae/Wrinkles	3/353	0.8	0/344	0.0	0/324	0.0	1/265	0.4
Corneal opacities	3/353	0.8	6/344	1.7	1/324	0.3	2/265	0.8
Double/ghost images	2/353	0.6	2/344	0.6	5/324	1.5	2/265	0.8
Epithelium in the interface	6/353	1.7	7/344	2.0	5/324	1.5	3/265	1.1
Feeling of something in the eye	2/353	0.6	2/344	0.6	1/324	0.3	0/265	0.0
Interface debris	10/353	2.8	7/344	2.0	5/324	1.5	1/265	0.4
Irregular epithelium	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Iron line or ring	0/353	0.0	0/344	0.0	1/324	0.3	2/265	0.8
Isolated cells in interface	0/353	0.0	1/344	0.3	2/324	0.6	1/265	0.4
Lagophthalmos	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Pain	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Sterile Interface Inflammation	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Superficial punctate keratitis (SPK)	20/353	5.7	17/344	4.9	10/324	3.1	14/265	5.3

The following other complications occurred at unscheduled visits at 1 month or later:

- superficial punctate keratitis (14 eyes)
- interface debris (8 eyes)
- corneal folds/striae/wrinkles (4 eyes)
- iron line/ring (3 eyes)
- corneal opacities (2 eyes)
- trichiasis (1 eye)
- subconjunctival hemorrhage (1 eye)
- conjunctival injection (1 eye)
- vacuoles (1 eye)

Each of the following ocular findings was reported at 6 months (n=265) at a rate of 0.6% or less: allergic conjunctivitis, vitreous floater, cotton wool spot, and drusen.

Lens findings (cataracts) were reported postoperatively in 14 eyes of 8 patients. All of these patients experienced lens changes due to age (range 59 to 73 years old). These findings included nuclear sclerosis, cortical spoking, and posterior subcapsular cataract. No eyes had a loss of more than 2 lines of best spectacle corrected visual acuity (with glasses). Only one eye had a related loss of 2 lines of best spectacle corrected visual acuity. All eyes had a last-reported best-corrected visual acuity of 20/32 or better.

The following other adverse events and complications occurred at 1 to 6 months after retreatment: epithelium in the interface (3 eyes) and double/ghost images (4 eyes.)

U.S. clinical studies of the LADARVision® system have shown the following symptoms may occur after LASIK surgery. At 6 months after surgery, patients noted on a questionnaire that these symptoms were worse or significantly worse than before surgery, as shown in the table below.

Subjective Symptoms at 6 Months

Subjective Responses	Hyperopia without astigmatism			Hyperopic Astigmatism			Mixed Astigmatism		
	<i>N</i>	Worse %	Significantly Worse %	<i>N</i>	Worse %	Significantly Worse %	<i>N</i>	Worse %	Significantly Worse %
Blurring of vision	132	9.8	1.5	111	15.3	1.8	53	7.5	3.8
Burning	133	2.3	0.8	113	8.0	1.8	53	7.5	0.0
Double vision	132	8.3	1.5	111	6.3	3.6	53	1.9	0.0
Dryness	132	16.7	3.0	113	17.7	5.3	53	24.5	1.9
Excessive tearing	132	1.5	0.0	111	1.8	0.0	52	0.0	0.0
Feeling of something in eye	133	5.3	1.5	113	5.3	2.7	53	5.7	0.0
Fluctuation of vision	133	15.8	6.0	111	20.7	1.8	53	11.3	0.0
Glare	133	21.8	0.8	113	18.6	1.8	53	22.6	0.0
Halos	132	12.9	2.3	111	20.7	4.5	53	26.4	0.0
Headache	132	3.0	0.0	110	2.7	1.8	53	3.8	0.0
Light sensitivity	133	26.3	1.5	112	21.4	1.8	53	20.8	0.0
Night driving difficulty	133	9.0	2.3	113	14.2	1.8	53	13.2	7.5
Pain	132	3.0	0.8	110	4.5	0.9	53	3.8	0.0
Quality of vision	132	4.5	0.0	115	5.2	0.0	53	1.9	3.8
Redness	133	11.3	0.8	112	5.4	2.7	53	3.8	0.0

I. Are You A Good Candidate for LASIK?

If you are considering LASIK, you must:

- Be at least 21 years of age
- Have healthy eyes that are free from eye disease or corneal condition (for example, scar, infection, etc.)
- Have hyperopia between 0 and +6.0D in combination with up to -6.0D of astigmatism
- Have documented evidence that the change in your farsightedness is less than or equal to 0.50 diopter per year for at least one year prior to your preoperative exam
- Be able to lie flat without difficulty
- Be able to constantly look at a blinking light during the LASIK procedure
- Be able to tolerate eye drops to numb your eye and enlarge your pupil
- Be informed of LASIK risks and benefits as compared to other available treatments for hyperopia
- Be willing to sign an Informed Consent Form, if provided by your eye care professional

J. What Should You Expect During LASIK Surgery?

LASIK surgery can be performed one eye at a time or on both eyes during the same surgical session.

Before The Surgery

First, you will need to have a pre-operative examination if you have an interest in LASIK. This exam will help to determine if your eye is healthy and suitable for LASIK. This exam will include a complete medical and eye history, and a complete evaluation of both eyes. In addition, this examination will involve mapping your cornea with a computer to determine if it is smooth and properly shaped.

WARNING:

If you wear contact lenses, it is very important to stop wearing them at least 3 weeks before the evaluation. Failure to do this will produce poor surgical results.

Before the surgery, please tell your doctor if you take any medications or have any allergies. Also, talk with your doctor about eating or drinking right before the surgery. You should also arrange for transportation, since **you must not drive right after the surgery. Your doctor will inform you of when you can resume driving.**

The Day of Surgery

Before the surgery, your doctor will ask you to lie on your back on the laser bed. The laser bed is a flat cushioned surface that does not recline or move. Your doctor will instruct you to watch a blinking light. Your doctor will take a picture of your eye to aid in determining the correct placement of the treatment on the cornea. Your doctor will not apply any laser pulses at this time. Your doctor will then put drops in your operative eye to dilate (enlarge) your pupil.

About 30-40 minutes later, your doctor will place anesthetic (numbing) drops into your eye. Your doctor will escort you back into the room with the laser. You will again lie on your back and look up at a microscope that will deliver the laser light to your cornea. Your doctor will place an instrument between your eyelids to hold them open during the surgery. A temporary shield will cover the eye not having surgery.

LASIK surgery begins with the creation of a corneal flap with a microkeratome. Then, your doctor will reposition your head and activate the tracker. Your doctor will ask you to look directly at a blinking light. The laser in the LADARVision[®] system will remove small amounts of tissue from your cornea. The tracker will follow eye movements and allow the laser to continue the treatment. Still, it is important to continue looking at the blinking light throughout the treatment.

You will be under the laser for several minutes. Overall, the surgery takes about 10 minutes. After the laser surgery is complete, your doctor will place some drops into your eye. In some LASIK cases, a bandage contact lens is placed in your eye as well to

help heal small abrasions. You may be provided with a plastic shield for eye protection after LASIK for the first few days. The surgery is painless because of the numbing drops. The numbing drops will wear off in about 45-60 minutes. After this time, your eye may hurt for 1 to 3 days.

WARNING:

Your doctor will monitor you for any side effects if you need to use topical steroids. Possible side effects of extended topical steroid use are: **ocular hypertension** (an increase in the eye pressure); **glaucoma** (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision); **cataract formation** (an opacity or clouding of the lens inside the eye that can cause a loss of vision).

The First Days After Surgery

If a bandage contact lens was applied to the eye after surgery, your doctor will remove the bandage contact lens on the day the surface of your eye has recovered. 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.

DO NOT rub your eyes for the first 3 to 5 days. You may be provided with a plastic shield for eye protection after LASIK for the first few days. Your doctor can also prescribe pain medication to make you more comfortable during this time after the surgery.

IMPORTANT:

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

Please refer to the section entitled "What are the risks of LASIK?" for information on the complications and adverse reactions that may occur in the first few weeks after surgery.

You may also experience blurred vision with or without glasses in the first week to one month after surgery. Some patients may experience a reduction in their best-corrected vision (with glasses) in the first week to one month as compared to before surgery, which tends to improve over the time. The following table displays the vision with and without glasses at one month for patients in the U.S. clinical study.

Some patients may experience some small changes or fluctuations in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after surgery. Your vision with and without glasses should become stable within the first few weeks after surgery. Please refer to the section entitled "What are the benefits of LASIK?" for information on visual outcomes in the clinical study at 6 months, the time point of stability of the refractive outcome of the procedure.

U.S. CLINICAL STUDY RESULTS AT 1 MONTH AFTER LASIK SURGERY						
	Hyperopia without astigmatism		Hyperopic Astigmatism		Mixed Astigmatism	
	n/N	%	n/N	%	n/N	%
Visual Acuity 20/20 or better without glasses**	45/118	38.1	33/101	32.7	20/46	43.5
Visual Acuity 20/20 or better without glasses*	46/124	37.1	34/124	27.4	23/61	37.7
Visual Acuity 20/25 or better without glasses*	74/124	59.7	52/124	41.9	33/61	54.1
Visual Acuity 20/40 or better without glasses*	114/124	91.9	104/124	83.9	55/61	90.2
Visual Acuity 20/20 or better with glasses**	104/138	75.4	82/114	71.9	37/48	77.0
Visual Acuity 20/20 or better with glasses	108/149	72.4	86/138	62.3	44/62	71.0
Visual Acuity 20/40 or better with glasses	149/149	100	137/138	99.3	62/62	100
Loss of 2 lines of visual acuity with glasses	14/149	9.4	16/135	11.9	1/58	1.7
Loss of more than 2 lines of visual acuity with glasses	3/149	2.0	3/135	2.2	1/58	1.7

*Not including eyes treated for monovision

**If vision with glasses was 20/20 or better before surgery

K. Questions To Ask Your Doctor

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

- Which type of refractive condition do I have: hyperopia without astigmatism, hyperopic astigmatism, or mixed astigmatism?
- What are my other options to correct my farsightedness (hyperopia)?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of LASIK for my amount of farsightedness (hyperopia)?
- What 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?
- Should I have 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 LASIK only on one eye?

Discuss the cost of surgery and follow-up care needs with your doctor. Most health insurance policies do not cover laser treatment.

L. 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 surgery is risk free.	<input type="checkbox"/>	<input type="checkbox"/>
2. It does not matter if I wear my contact lenses when my doctor told me not to wear them.	<input type="checkbox"/>	<input type="checkbox"/>
3. Since the LADARVision® system tracks my eye movements, I do not have to fixate on the blinking light.	<input type="checkbox"/>	<input type="checkbox"/>
4. After the surgery, there is a good chance that I will be less dependent on eyeglasses.	<input type="checkbox"/>	<input type="checkbox"/>
5. I may need reading glasses after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
6. There is a risk that I may lose some vision after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
7. It does not matter if I am pregnant.	<input type="checkbox"/>	<input type="checkbox"/>
8. If I have an autoimmune disease, I am still a good candidate for LASIK.	<input type="checkbox"/>	<input type="checkbox"/>

You can find the answers to Self-Test at the bottom of Page 25.

M. Summary Of Important Information

- LASIK is a permanent operation to the cornea and is irreversible.
- LASIK does not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least 1 year before LASIK surgery. You will need written evidence that your farsightedness has changed less than or equal to 0.50 D.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You would not be a good candidate if you have collagen vascular or autoimmune diseases. If you have a condition that makes wound healing difficult, you would not be a good candidate.
- LASIK surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery. The sections on Benefits and Risks are especially important to read carefully.
- Alternatives to LASIK include, but are not limited to, glasses and contact lenses.
- The vision requirements of some occupations, such as military pilots, cannot be met by having LASIK.
- Before considering LASIK surgery you should:
 - a. Have a complete eye examination.
 - b. Talk with one or more eye care professionals about LASIK. This talk should include the potential benefits, risks, and complications of LASIK surgery. In addition, you should discuss the time needed for healing after LASIK.
- If you are older or are a woman on hormone replacement therapy, you may be less likely than other patients to achieve a visual acuity of 20/20 or better without glasses or contact lenses.
- If you have hyperopia greater than 5.0D, your outcome may be less predictable and your visual acuity may be less likely to reach 20/20 or better without glasses or contact lenses.
- If you have hyperopic astigmatism greater than 4.0D MRSE before surgery (amount of hyperopic astigmatism based on your glasses prescription), your outcome may be less predictable and your visual acuity may be less likely to reach 20/20 or better without glasses or contact lenses. In addition, you may be more likely to experience a reduction of 2 lines of visual acuity with glasses or contact lenses. You may also be more likely to need additional treatment. The safety and effectiveness of retreatments has not yet been established.

Answers to Self-Test Questions:

1. False (see Risks on Page 16); 2. False (see Before the Surgery on Page 20); 3. False (see The Day of Surgery on Page 20); 4. True (see Benefits on Page 13); 5. True (see Introduction on Page 10); 6. True (see Risks on Page 16; also see The First Days After Surgery on Page 21); 7. False (see Contraindications on Page 15); 8. False (see Contraindications on Page 15).

N. Patient Assistance Information

To be completed by you or your Primary Eye Care Professional as a reference.

PRIMARY EYE CARE PROFESSIONAL

Name: _____

Address: _____

Phone: _____

LASIK DOCTOR

Name: _____

Address: _____

Phone: _____

TREATMENT LOCATION

Name: _____

Address: _____

Phone: _____

LASER MANUFACTURER

Summit Autonomous Inc. 2501 Discovery Drive, Suite 500 Orlando, FL 32826 U.S.A. Tel: (877) 523-2784 Fax: (407) 384-1677
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