

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 at 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 >2.0 D 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 93.2%, 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 Sumatriptan (*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.

*Accutane Reg TM of Hoffmann-La Roche Inc.

*Imitrex Reg TM of Glaxo Group Limited

*Cordarone 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 (0.6% - 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 myopic 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 $\geq 1\%$ 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 $\geq 1\%$ 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).