

# Ophthalmic Technology Assessment

## Wavefront-Guided LASIK for the Correction of Primary Myopia and Astigmatism

A Report by the American Academy of Ophthalmology

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**Objective:** To describe wavefront-guided (WFG) LASIK for the primary treatment of low to moderate levels of myopia and astigmatism and to examine the evidence on the safety and effectiveness of the procedure in comparison with conventional LASIK.

**Methods:** Literature searches conducted in 2004, 2005, 2006, and 2007 retrieved 209 unique references from the PubMed and Cochrane Library databases. The panel selected 65 articles to review, and of these, chose 45 articles that they considered to be of sufficient clinical relevance to submit to the panel methodologist for review. During the review and preparation of this assessment, an additional 2 articles were included. A level I rating was assigned to properly conducted, well-designed, randomized clinical trials; a level II rating was assigned to well-designed cohort and case-controlled studies; and a level III rating was assigned to case series, case reports, and poorly designed prospective and retrospective studies. In addition, studies that were conducted by laser manufacturers before device approval (premarket approval) were reviewed as a separate category of evidence.

**Results:** The assessment describes studies reporting results of WFG LASIK clinical trials, comparative trials, or both of WFG and conventional LASIK that were rated level II and level III. There were no studies rated as level I evidence. Four premarket approval studies conducted by 4 laser manufacturers were included in the assessment. The assessment did not compare study results or laser platforms because there were many variables, including the amount of follow-up, the use of different microkeratomes, and the level of preoperative myopia and astigmatism.

**Conclusions:** There is substantial level II and level III evidence that WFG LASIK is safe and effective for the correction of primary myopia or primary myopia and astigmatism and that there is a high level of patient satisfaction. Microkeratome and flap-related complications are not common but can occur with WFG LASIK, just as with conventional LASIK. The WFG procedure seems to have similar or better refractive accuracy and uncorrected visual acuity outcomes compared with conventional LASIK. Likewise, there is evidence of improved contrast sensitivity and fewer visual symptoms, such as glare and halos at night, compared with conventional LASIK. Even though the procedure is designed to measure and treat both lower- and higher-order aberrations (HOAs), the latter are generally increased after WFG LASIK. The reasons for the increase in HOA are likely multifactorial, but the increase typically is less than that induced by conventional LASIK. No long-term assessment of WFG LASIK was possible because of the relatively short follow-up (12 months or fewer) of most of the studies reviewed. *Ophthalmology* 2008;115:1249–1261 © 2008 by the American Academy of Ophthalmology.

The American Academy of Ophthalmology prepares Ophthalmic Technology Assessments to evaluate new and existing procedures, drugs, and diagnostic and screening tests. The goal of an assessment is to review systematically the

available research for clinical efficacy, effectiveness, and safety. After review by members of the Ophthalmic Technology Assessment Committee, other Academy committees, relevant subspecialty societies, and legal counsel, as-

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assessments are submitted to the Academy's Board of Trustees for consideration as official Academy statements.

## Background

Wavefront technology has been used in astronomy for a number of years to improve the image quality of telescopes. An example is the Hubble space-based telescope for which wavefront analysis was used to correct aberrations in reflecting mirrors as well as aberrations induced by the atmosphere, resulting in a significant improvement in image quality. This technology applied to the eye is a new and powerful tool for refractive surgery. It represents a paradigm shift in the way optical aberrations can be measured, described, and treated.

A clinical refraction, composed of sphere, cylinder, and axis, describes what are now termed *lower-order aberrations*. However, there are other types of optical aberrations in the visual pathway of the eye that can contribute to blur and visual symptoms such as coma and spherical aberration, which previously were referred to as *corneal irregularity* or *irregular astigmatism*. These other aberrations now are collectively called *higher-order aberrations* (HOAs). Wavefront technology can measure most of the lower- and higher-order aberrations of the eye.<sup>1</sup> The shape of the wavefront describes the total aberration of the eye. The shape can be described mathematically by Fourier transformation or, more commonly, by using a series of polynomials named after the physicist Fritz Zernike. Several Zernike polynomials represent aberrations common in clinical practice, in particular defocus (sphere) and astigmatism. Higher-order aberrations such as coma and spherical aberration are taking on clinical relevance as more is known about how they affect vision. The greater the number of polynomials used to recreate the wavefront is, the better the resolution of the overall wavefront. The total amount of HOA can be incorporated into a single number by computing the root mean square of the wavefront deviation after the sphere and cylinder components have been removed mathematically.

Wavefront-guided (WFG) LASIK, also called custom LASIK, is a variation of the surgery in which the excimer laser is instructed to ablate a sophisticated pattern based on measurements from an aberrometer. This is distinct from 3 other basic types of excimer laser treatment profiles: conventional, wavefront optimized, and topography guided. Conventional LASIK, also called *standard LASIK*, was the first profile to receive Food and Drug Administration (FDA) approval and still is used commonly today. Conventional LASIK applies a simple spherocylindrical correction based on the removal of tissue using Munnerlyn's equation.<sup>2</sup> It has been observed that conventional LASIK to treat myopia induces positive spherical aberration dependent on the amount of attempted correction.<sup>3</sup> Wavefront-optimized LASIK is a treatment profile designed to reduce or eliminate the induced spherical aberration of conventional LASIK.<sup>4</sup> The wavefront-optimized treatment is based on a spherocylindrical correction that is adjusted by an internal algorithm to remove additional tissue in the periphery of the ablation zone, thereby creating a more prolate corneal shape. Two

wavefront-optimized laser systems currently have FDA approval for the treatment of myopia and myopic astigmatism (Allegretto Wave Excimer Laser System; WaveLight AG, Erlangen, Germany; and MEL 80 Excimer Laser System; Carl Zeiss Meditec, Dublin, CA). Topography-guided LASIK uses information from both the corneal shape and the spherocylindrical correction to determine the excimer laser ablation profile.<sup>5</sup> Topography-guided LASIK is investigational in the United States because there are no FDA-approved indications. Wavefront-optimized and topography-guided LASIK are not included in this review because there is a lack of published comparative studies.

The goal of WFG LASIK is to achieve a more optically perfect ablation based on all of the optical aberrations measured with the wavefront aberrometer, not just sphere and cylinder. Achieving this goal depends on appropriate patient selection, high-quality wavefront data, successful surgery, and accurately predicting and managing the changes that occur during healing.

## Preoperative Evaluation

As with any surgical procedure, acquisition of comprehensive and reliable clinical data is required and patients should be screened thoroughly for any contraindications. The preoperative evaluation of WFG LASIK for the treatment of primary myopia and astigmatism is similar to that for conventional LASIK.<sup>6,7</sup> All of the preoperative elements of a conventional LASIK evaluation apply to a WFG LASIK evaluation, such as determining refractive stability and screening for dry eye. Key elements of a preoperative evaluation for WFG LASIK that are either different from those of a conventional procedure or that have particular importance to WFG LASIK are discussed. This is not meant to be a complete compendium of the preoperative WFG LASIK evaluation.

The aberrometer measurement is one of the most critical elements of the WFG LASIK procedure. The precision of the laser ablation depends on obtaining an accurate assessment of the aberrations of the eye. A variety of aberrometers currently is available, but those most commonly used for WFG LASIK are based on a Hartmann-Shack sensor. With these devices, light exiting the eye is divided by a lenslet array into a grid pattern for analysis. Each capture should be monitored carefully by assessing the lenslet pattern and dropout points. Transient dropout that varies between captures usually indicates a dry spot on the cornea, whereas an area of consistent dropout can indicate an opacity in the optical system. The captures should be repeated as needed to obtain high-quality images. The variability in the derived defocus (sphere) between captures is a useful tool to ensure accurate measurements. The size of the wavefront (cross-sectional area) is determined by the size of the entrance pupil. For systems that take measurements on an undilated pupil, the wavefront unit should be located in a dim room to allow a large pupil capture. A pupil size of 5 mm generally is accepted as the minimum. Low-strength tropicamide and phenylephrine have been used to increase the pupil size for the aberrometer capture, although there is concern about the potential shift in the pupil centroid for systems that do not

capture this information before dilation. Manufacturers have designed their wavefront units to minimize the tendency for a patient to accommodate (instrument myopia). Despite this, accommodation during a capture is always a concern and needs to be monitored and minimized in those laser systems that base their capture on a natural pupil. Checking the difference between the manifest and cycloplegic sphere and the wavefront-derived sphere is required. Laser systems that rely on a cycloplegic capture allow a large pupil capture without accommodation concern.

Depending on the laser system, an image (or series of images) is selected to calculate the ablation profile. Only the highest quality images should be used. There is often a difference between the objective wavefront-derived sphere and cylinder and the subjective manifest sphere and cylinder. This difference can be the result of the following factors: (1) the accuracy of the wavefront or manifest refraction, or both, (2) accommodation during either the wavefront capture or manifest refraction, or (3) the influence of HOAs on the manifest refraction.

Manufacturers provide guidance, and it is important to determine the acceptable differences between components of the manifest, cycloplegic, and wavefront refractions to assess acceptability of wavefront data and before proceeding with surgery.

If the difference between the wavefront and manifest refraction exceeds the guidelines, the following steps should be taken:

1. Repeat both; the wavefront capture or the manifest refraction may be even lower if the patient is accommodating on either of these tests.
2. Check the best spectacle refraction using the wavefront-derived sphere and cylinder. It is not unusual for the wavefront to measure cylinder more accurately, as demonstrated by an improvement in best-corrected vision.
3. Check the cycloplegic refraction.

If the deviation is greater than the above guidelines for the laser system, the patient may not be suitable for an WFG LASIK procedure.

After the most suitable wavefront image or composite is selected, an ablation profile is created within the aberrometer. This incorporates both lower-order aberrations (sphere and cylinder) and HOAs. The optical path deviation from the wavefront is converted into a pattern that can correct the aberrations on the corneal surface. The amount and location of stromal tissue to be removed is computed as a series of instructions to the excimer laser. The profile then is transferred to the laser via a floppy disk, USB memory key, or wireless connection.

Although the wavefront provides the treatment profile, including sphere and cylinder, a manifest refraction still is necessary. It is primarily used to assess the accuracy of the wavefront capture and to help determine refractive stability. This refraction should be push plus to eliminate accommodation as well as a careful determination of the astigmatism, typically using a Jackson cross cylinder. It is important to know the true refractive status of each patient to assess properly the wavefront data. It is also important to assess

and record visual acuity and to determine the preoperative and postoperative visual capability.

The measurement of central corneal thickness is an important element of the preoperative evaluation for LASIK and even more important for WFG procedures because WFG LASIK tends to remove more stromal tissue than conventional treatments. An estimated residual stromal bed is needed for surgical planning because it is one factor that may predict postoperative ectasia. It is computed by subtracting the anticipated flap thickness and maximum ablation depth from the central corneal thickness measurement. The minimal residual bed for LASIK remains controversial. Although 250  $\mu\text{m}$  generally is recognized as a minimum, many surgeons prefer to leave a stromal bed thicker than this to leave room for retreatment and because ectasia can occur with even thick residual stromal beds. To account for variations in actual flap thickness, many surgeons measure the stromal bed after the flap has been retracted to allow for a more precise determination of the residual bed.

The importance of pupillometry in the preoperative workup is controversial. Most studies of conventional LASIK have not shown a relationship between the diameter of the low-light pupil and disturbing visual symptoms after surgery.<sup>8,9</sup> Patients with larger pupils who undergo WFG LASIK seem to have no increase in symptoms and perhaps may have fewer symptoms. One of the most important benefits of WFG LASIK compared with conventional LASIK may be in low-light conditions when the pupil is dilated, because that is where a reduction, or less induction, of HOAs should be most apparent. Regardless of pupil size, it is important for potential patients to understand that there is a risk for night vision problems after surgery.

With increased public acceptance of LASIK and higher expectations of improved outcomes, it is imperative that patients have a realistic understanding of the goals, risks, and benefits of WFG LASIK. Wavefront-guided LASIK carries all of the risks of conventional LASIK, including sight-threatening complications such as microbial keratitis. The surgeon is responsible for obtaining the patient's informed consent before surgery.<sup>10</sup>

## Operative Technique

The WFG LASIK procedure is essentially the same as conventional LASIK surgery. The patient is prepared for the procedure, a microkeratome or femtosecond laser is used to create an epithelial and stromal flap, an excimer laser is applied to remove a precise amount of stromal tissue, and the flap is repositioned. Additional considerations for a custom procedure are described.

The alignment of the eye when measured by the aberrometer must match the alignment when the surgery is performed. As with astigmatism, most HOAs are not radially symmetric. Torsional misalignment, either cyclotorsion or head tilt, during surgery can result in undercorrection of the aberration or even in the induction of aberrations. Therefore, proper alignment is a critical component to correct HOAs surgically. It has been shown that eyes can undergo up to 9.5° of cyclorotation when a patient goes from a seated position measured on the aberrometer to lying under

the excimer laser.<sup>11</sup> In a study of 240 eyes, Swami et al<sup>12</sup> determined an average deviation from vertical to supine position of  $4.1 \pm 3.7^\circ$ ; 8% of eyes had a deviation of more than  $10^\circ$ . The authors reported that this degree of misalignment would result in a 14% and 35% undercorrection of astigmatism, respectively.

The most basic technique to ensure alignment is to mark the limbus, typically at the 3-o'clock and 9-o'clock position, immediately before surgery while the patient is seated. These marks are then used to align the head when the patient is lying under the laser. A more sophisticated system ensures that the eye alignment during aberrometry matches the alignment under the laser. Limbal marks are captured and recorded by the aberrometer immediately before surgery. An ablation profile then is computed. Under the laser, the same limbal marks are used to match the alignment manually to the wavefront image. The most recent technology advancement, iris registration, has automated the alignment process. Unique iris details are recorded by the aberrometer and are relayed to the laser. A camera and computer system in the laser records and matches iris detail to the aberrometer before the treatment. Cyclotorsional compensation is provided to align the ablation precisely at the start of the laser treatment.<sup>13</sup>

Proper centration of an ablation is important to ensure good outcomes. A mathematical model predicts that a decentration as little as 0.5 mm may result in debilitating visual symptoms.<sup>14</sup> Accurate centration is even more important when treating HOAs.<sup>14</sup> Centration is based on matching the aberrometer-derived ablation profile to either the limbus or pupil margin. The center of the pupil (pupil centroid) can change positions up to 0.7 mm as the pupil dilates or constricts.<sup>15</sup> For pupil-margin based laser systems, it is important to compensate for this centroid shift to avoid an ablation decentration. Iris recognition systems do this by using the limbus as a reference point.

Even with proper initial centration and alignment, eye movement during surgery can also have a deleterious effect on the outcome. Sophisticated eye trackers are used by all custom-capable excimer laser systems.<sup>16</sup> Most systems use an infrared camera to track the edge of the iris because of the contrast between the iris and pupil. A passive eye tracker monitors eye motion and interrupts the laser treatment if the eye movement exceeds a certain threshold. An active eye tracker drives a complex mirror system that directs the excimer laser beam onto the proper location on the cornea. Laser systems can use both methods, steering the laser if eye movements are slight but pausing the laser if movements are too great. This is important because active eye trackers do not account for the change in effective laser energy as the curvature of the cornea changes during movement or for the parallax error between the corneal and iris planes.<sup>17</sup> Therefore, despite having a properly working eye tracker, the surgeon needs to monitor centration and patient fixation continually during the procedure.

Surgical technique, local conditions (e.g., temperature and humidity), and patient characteristics (e.g., gender and age) are potential sources of variability in custom LASIK outcomes. Just as nomogram adjustments often are needed to fine tune the effectiveness of conventional LASIK, so,

too, adjustments may be needed to improve the efficacy of a custom treatment. This is accomplished by compiling and analyzing preoperative and postoperative refractive data on a reasonable number of patients. Commercially available software can be used to help determine a proper nomogram adjustment.

## Postoperative Management

The postoperative management of the custom LASIK patient is identical to conventional LASIK. Typically, the patient is prescribed an antibiotic and corticosteroid eye drop regimen during the perioperative period. Complications can occur, such as dry eye, microbial keratitis, diffuse lamellar keratitis, and epithelial ingrowth. As with any LASIK procedure, complications must be managed properly.

## Food and Drug Administration Status

Table 1 lists the excimer lasers and indications for LASIK that have been approved by the FDA for WFG correction of myopia and astigmatism.

## Resource Requirements

To perform WFG LASIK, a surgeon needs to be able to interpret the treatment plan derived from the aberrometer. A surgeon also needs to be trained to use a microkeratome or femtosecond laser keratome to create a corneal flap and to use the excimer laser to perform the refractive ablation. Each laser company requires that the surgeon successfully complete a course specific to each particular excimer laser.

Many surgeons who perform LASIK do not own an aberrometer, microkeratome, or excimer laser. The equipment typically is owned by a corporate laser center or a hospital. In some cases, a company will deliver an aberrometer, microkeratome set, mobile excimer laser, and technical staff to the surgeon so the surgery can be performed in his or her office. In these cases, the surgeon has minimal start-up costs to perform WFG LASIK. Surgeons who wish to have more control over the global fee the patient is charged can lease or buy their own equipment. An aberrometer costs approximately \$40 000 and an excimer laser costs \$250 000 to \$550 000. There can be an upgrade fee to perform WFG procedures using existing laser systems. Every manufacturer charges a fee to perform each WFG procedure.

## Questions for Assessment

Based on available literature, the focus of this assessment is to address the following questions:

1. What is the safety and effectiveness of WFG LASIK to correct primary myopia or primary myopia and astigmatism?

Table 1. Food and Drug Administration-Approved Excimer Lasers for Wavefront-Guided LASIK for Myopia and Astigmatism

Company and Model	Wavefront-Guided LASIK Indications for Myopia and Astigmatism
Alcon LADARVision 4000 (Fort Worth, TX)	Myopia up to -7.0 D with or without astigmatism less than 0.5 D (P970043/S10; 10/18/02) Myopic astigmatism up to -8.00 D sphere with -0.50 D to -4.00 D cylinder and up to -8.00 D SE at the spectacle plane (P970043/S15; 6/29/04)
Bausch & Lomb Surgical Technolas 217z (Rochester, NY)	Myopia up to -7.0 D with or without astigmatism up to -3.0 D (P99027/S6; 10/10/03)
AMO VISX Star S4 & WaveScan WaveFront System (Santa Clara, CA)	Myopia up to -6.0 D with or without astigmatism up to -3.0 D (P930016/S16; 5/23/03) Myopia from -6.0 to -11.0 D with or without astigmatism up to -3.0 D (P930016/S21; 8/30/05)
WaveLight (ALLEGRETTO WAVE) & WaveLight ALLEGRO Analyzer (WaveLight AG, Erlangen, Germany)	Myopia up to -7.0 D with up to -7.0 D of spherical component and up to 3.0 D astigmatic component (P020050/S4; 7/26/06)

D = diopters; SE = spherical equivalent.  
Source: <http://www.fda.gov/cdrh/lasik/lasers.htm>. Accessed March 26, 2008.

- How do the outcomes of WFG LASIK compare with the outcomes of conventional LASIK for the treatment of primary myopia or primary myopia and astigmatism?

## Description of Evidence

Literature searches without restrictions for date of publication were conducted in the PubMed and Cochrane Library databases on July 9, 2004, May 27, 2005, March 22, 2006, and May 8, 2007, using the key words *laser in situ keratomileusis*, *LASIK*, *wavefront*, *guided*, *ablation*, *coma*, *higher-order aberration*, and *cornea*. The PubMed database searches were limited to English language publications; there were no language restrictions in the Cochrane Library database. The searches retrieved 209 unique references.

Ophthalmic Technology Assessment Refractive Management/Intervention Panel members reviewed the literature searches and selected 65 articles to review in full text to consider their relevance to the assessment questions. Of these, panel members chose 45 articles that they considered to be of sufficient clinical relevance to submit to the panel methodologist for review. During the review and preparation of this article, an additional 2 articles were included. The methodologist rated the articles according to the strength of evidence. A level I rating was assigned to well-designed and well-conducted randomized clinical trials; a level II rating was assigned to well-designed case-control and cohort studies and poorly designed randomized studies; and a level III rating was assigned to case series, case reports, and poorly designed cohort and case-control studies.

Two randomized controlled trials of level I evidence quality were found.<sup>18,19</sup> One of these studied keratome performance rather than WFG ablation,<sup>18</sup> and the other studied photorefractive keratectomy rather than LASIK.<sup>19</sup> Nine randomized controlled trials were rated as level II evidence because of inadequate follow-up, low power, un-

certainty of randomization method, or lack of masking.<sup>20-28</sup> Two nonrandomized comparative trials<sup>29,30</sup> and 1 prospective individual cohort study<sup>31</sup> were rated as level II evidence. Thirty-three articles reviewed were graded as level III evidence and reported case series, experimental studies, and poor-quality prospective and retrospective studies. Most studies included in this assessment had relatively short follow-up, ranging from 1 week to 6 months.

Premarket approval (PMA) studies of WFG LASIK were deemed acceptable as a special category of evidence for this report. Although these studies were sponsored by laser manufacturers, they were large, multicenter series conducted for FDA approval.

## Published Results

The data from published studies and PMA reports reviewed indicate that WFG LASIK exceeds established guidelines for safety and effectiveness. It can result in better contrast sensitivity outcomes and less induction of HOAs than conventional LASIK (level II evidence).<sup>21-26,29,32</sup> Tables 2, 3, 4, and 5 summarize these studies, and specific findings are described below.

### Refractive Accuracy and Snellen Visual Outcomes

In the published studies assessed in this review (level II and III evidence), the mean preoperative manifest spherical equivalent (MSE) ranged from -3.16 to -7.30 diopters (D), as shown in Tables 3 and 4. The mean postoperative MSE ranged from 0.14 to -0.40 D, with 72% to 100% of these eyes being within 0.5 D of the intended postoperative target MSE. This refractive accuracy yielded an uncorrected visual acuity (UCVA) of at least 20/40 in nearly every study participant.<sup>21-26,29,32</sup> There was greater reported variation in attaining a UCVA of at least 20/20 (56% to 100%). One report<sup>33</sup> found that 69.3% of eyes had better postoperative UCVA than preoperative best spectacle-corrected visual

Table 2. Summary of Premarket Wavefront-Guided LASIK Results Submitted by Manufacturers to the Food and

Year Approved	Laser	Follow-up Reported (mos)	No. of Eyes Reported at 6 mos	Optical Zone (mm)	Ablation Zone (mm)	Preoperative Sphere (D), Range	Preoperative Cylinder (D), Range
2003	AMO VISX S4 & WaveScan WaveFront System (Santa Clara, CA)	12	277	6.0	8.0	0 to -6.0	0 to -3.0
2003	Bausch & Lomb Technolas 217z (Rochester, NY)	6	340	5.75-7.24	7.5-9.0	0 to -7.0	0 to -3.0
2004	Alcon LADARVision (Fort Worth, TX)	6	232	6.5	9.0	0 to -8.0	0 to -4.0
2006	WaveLight Allegretto with the Allegro analyzer (WaveLight AG, Erlangen, Germany)	6	166	6.5	9.0	0 to -7.0	0 to -3.0

D = diopters; NR = not reported.

acuity (BSCVA), whereas another study<sup>31</sup> did not find this type of improvement, and a third study found an improvement on one laser platform but not another.<sup>21</sup> Several articles compared outcomes of different WFG laser platforms at single institutions, but no major differences in outcomes were found.<sup>21,25,29,34</sup> One of these reports, a prospective randomized contralateral eye study, found that the major determinant of subjective patient satisfaction was the postoperative UCVA.<sup>25</sup> Although comparative studies provide useful snapshots in time, their relevance wanes as each platform undergoes technological advances.

Premarket approval results of 1015 eyes that underwent WFG LASIK with 6 months of follow-up using 1 of 4 systems (Alcon LADARVision 4000, Fort Worth, TX; AMO VISX Star S4 CustomVue, Santa Clara, CA; Bausch & Lomb Technolas 217z Zyoptix, Rochester, NY; WaveLight Allegretto, WaveLight AG, Erlangen, Germany) indicate a high level of refractive accuracy in the treatment of myopia and astigmatism (Table 2). The MSE was within 0.5 D of the intended target in 75.9% to 94.6% of eyes. The correction of cylinder also was accurate, with the reduction of absolute cylinder ranging from 64% to 80.7% and the vector analysis-derived correction ratio (surgically induced refractive correction to intended refractive correction) ranging from 1.0 to 1.15 after surgery (ideal = 1.0). Some of the variation among laser systems can be related to the preop-

erative level of myopia and astigmatism. A UCVA of 20/40 or better was achieved in 97.4% to 100% of eyes, and 84.1% to 93.9% of eyes obtained 20/20 or better UCVA at 6 months after surgery. The postoperative UCVA was the same or better than the preoperative BSCVA in 67.2% to 81.1% of eyes.

In reports that have compared the refractive accuracy of WFG and conventional LASIK, the results are mixed and do not indicate a clear advantage of WFG surgery. Some studies show an improved refractive outcome after WFG LASIK and others do not. Although most reports indicate better UCVA outcomes after a WFG procedure, the results also are mixed and understandably are dependent on the refractive outcome. Binder and Rosenshein<sup>30</sup> (level II evidence) found that the refractive and acuity differences between WFG and conventional LASIK were laser-platform specific. Patients generally preferred the WFG-treated eye over the eye treated with conventional LASIK in contralateral eye comparative studies.<sup>22,23</sup> Kim et al<sup>22</sup> performed a contralateral eye study of WFG and conventional LASIK in 24 subjects (level II evidence). At 3 months after surgery, more patients preferred the WFG-treated eye (n = 15) than the conventionally treated eye (n = 4), whereas 5 patients had no preference.

Refractive stability was assessed in the PMA studies using several different established criteria, such as the per-

Table 3. Reported Results of Selected Studies of Wavefront-

Author(s), Year	Level of Evidence	Laser	Follow-up (mos)	No. of Eyes	Preoperative Manifest Spherical Equivalent
Awwad et al, <sup>29</sup> 2004	II	LADARVision 4000	3	50	-3.59±1.54
		VISX S4	3	43	-3.62±1.46
Slade, <sup>25</sup> 2004 (industry-sponsored)	II	LADARVision 4000	1	25	-3.41
		VISX S4	1	25	-3.34
Durrie & Stahl, <sup>21</sup> 2004	II	LADARVision 4000	1	30	-4.66±1.73
		Technolas 217z	1	30	-4.38±1.71
Pop & Payette, <sup>32</sup> 2004	III	Nidek EC-5000 CATz	3	71	-4.40
Aizawa et al, <sup>31</sup> 2003	II	Technolas 217z	6	22	-7.30±2.72
Venter, <sup>39</sup> 2005	III	NIDEK EC-5000	6	93	-3.72±1.96

D = diopters; NR = not reported.

Drug Administration for the Treatment of Primary Myopia and Astigmatism (Level II Evidence)

Postoperative Manifest Spherical Equivalent within 0.5 D (%)	Cylinder Correction Ratio (Surgically Induced Refractive Correction/ Intended Refractive Correction)	Uncorrected Visual Acuity $\geq 20/20$ (%)	Uncorrected Visual Acuity $\geq$ Preoperative Best Spectacle-Corrected Visual Acuity (%)	Loss of Best Spectacle-Corrected Visual Acuity $\geq 2$ Lines (%)	Time to Stability (mos)
90.3	NR	93.9	NR	0	3
75.9	1.0	91.5	78	0.6	3
80.2	1.03	84.1	67.2	0	3
94.6	1.15	93.4	81.1	0	3

centage of eyes with a change of less than 1.0 D over a given interval and the confidence interval of the mean change in refraction. In all of these studies, WFG LASIK met refractive stability requirements by 3 months after surgery.

Retreatment rates were nearly universally absent from the literature, likely in part the result of the short duration of follow-up of the assessed studies. In PMA data, the retreatment rate for 2 laser systems was 2.7% and 3.4%. Otherwise, given the absence of data, it is difficult to predict the retreatment rate for WFG LASIK. One can infer that the eyes most likely to undergo enhancement procedures will be those that are more than 0.5 D from their intended target, have a UCVA less than 20/20, or both.

**Safety**

In the studies reviewed, no eye lost 2 or more lines of BSCVA at the final follow-up.<sup>21–26,29,32</sup> No reported eye had a BSCVA of worse than 20/40 or an increase in cylinder of more than 2.0 D at the final visit. The loss of 2 lines of BSCVA in PMA data for WFG LASIK at 6 or 12 months after surgery ranged from 0% to 0.6%, with no eye losing more than 2 lines of BSCVA. Together, this indicates preservation of best-corrected vision in WFG LASIK and a safety profile comparable with that of conventional LASIK.

Adverse events and complications reported in the PMA studies were rare and were related to the creation of the flap or postoperative flap problems. At any postoperative interval, the events included free cap (0.3%), poorly created flap (0.3%), flap striae (0.3%), epithelial defect (0.6%), epithelium in the interface (0.3%), and diffuse lamellar keratitis (0.9%).

**Patient Satisfaction and Visual Symptoms**

Subjective patient evaluation was reported in several studies using a variety of validated and nonvalidated questionnaires. In 1 PMA study (Bausch & Lomb Technolas), 99.7% of patients noted improved quality of vision at 6 months after surgery, 98.8% were moderately or very satisfied with their result, and 98.2% indicated they would choose LASIK again. In another premarket study (VISX CustomVue), the percentage of respondents who were satisfied or very satisfied with the quality of their vision 6 months after WFG LASIK increased from preoperative levels, especially with respect to night vision and night vision with glare. In one published report, 40% of patients rated their satisfaction significantly higher after WFG LASIK, and most of the remainder did not note any change.<sup>35</sup> Another study showed more than 90% of patients to be satisfied or extremely satisfied with their WFG LASIK procedure.<sup>25</sup>

Guided LASIK for Primary Myopia and Astigmatism

Postoperative Manifest Spherical Equivalent	Postoperative Manifest Spherical Equivalent $\pm 0.5$ D (%)	Uncorrected Visual Acuity $\geq 20/40$ (%)	Uncorrected Visual Acuity $\geq 20/20$ (%)	Loss of Best Spectacle-Corrected Visual Acuity of $\geq 2$ Lines (%)	Gain of Best Spectacle-Corrected Visual Acuity of $\geq 2$ Lines (%)
-0.03	98	NR	98	0	NR
0.03	95	NR	95	0	NR
-0.12 $\pm$ 0.31	92	100	76	0	NR
-0.40 $\pm$ 0.40	72	100	56	0	NR
0.01 $\pm$ 0.34	83	100	93	0	17
-0.04 $\pm$ 0.38	93	97	90	0	0
-0.07	85	100	92	0	NR
NR	77.3	96.5	77.9	0	4.5
-0.07 $\pm$ 0.27	92	100	88	0	4

Table 4. Reported Results of Selected Comparative Studies of Wavefront-Guided and

Author(s), Year	Level of Evidence	Laser	Procedure	Follow-up (mos)	No. of Eyes	Eye* Preference (%)
Lee et al, <sup>28</sup> 2006	II	VISX S4	C	6	92	NR
		VISX S4	W	6	104	NR
Vongthongsri et al, <sup>26</sup> 2002	II	Nidek EC-5000	C	1	11	NR
		Nidek EC-5000	W	1	11	NR
Awwad et al, <sup>34</sup> 2005 (industry-sponsored)	III	VISX S4	C	3	50	NR
		VISX S4	W	3	50	NR
		LADAR 4000	C	3	50	NR
		LADAR 4000	W	3	50	NR
Phusitphoykai et al, <sup>24</sup> 2003	II	Nidek EC-5000	C	6	10	NR
		Nidek EC-5000	W	6	10	NR
Nuijts et al, <sup>23</sup> 2002	II	Technolas 217z	C	6	6	33
		Technolas 217z	W	6	6	42
Kim et al, <sup>22</sup> 2004	II	Technolas 217z	C	3	24	17
		Technolas 217z	W	3	24	63
Arbelaez, <sup>20</sup> 2001	II	Nidek EC-5000	C	1wk	21	12.5
		Nidek EC-5000	W	1wk	12	62.5
Brint, <sup>27</sup> 2005 (industry-sponsored)	II	LADAR 4000	W	3	30	NR
		Allegretto Wave	O	3	30	NR
Carones et al, <sup>46</sup> 2005 (industry-sponsored)	III	LADAR 6000	C	3	28	NR
		LADAR 6000	W	3	46	NR
Caster et al, <sup>35</sup> 2005 (industry-sponsored)	III	LADAR 4000	C	3	20	NR
		LADAR 4000	W	3	87	NR

C = conventional; D = diopters; NR = not reported; O = optimized; W = wavefront-guided.

\*Contralateral eye studies.

†Uncorrected visual acuity results reported as mean logarithm of the minimum angle of resolution units  $\pm$  standard deviation.

The types of visual symptoms after WFG LASIK are similar to those after conventional LASIK and include glare, halos, and starburst. In WFG PMA studies, the most common visual symptoms at 6 months after surgery were glare, halos, night driving difficulty, and double vision, ranging from 0% to 7.1%. However, these symptoms occur less frequently after WFG LASIK. As reported by Lee et al<sup>28</sup> in a randomized clinical trial of 98 subjects, conventional LASIK had a higher percentage of patients (15.4%) who noted disturbing glare or halo symptoms compared with WFG LASIK (8.6%).

### Contrast Sensitivity

Contrast sensitivity results were reported in half of the published studies reviewed (Table 5). All of these studies reported either an improvement or no change in mean contrast sensitivity after surgery. In the studies that directly compared conventional LASIK with wavefront LASIK, WFG LASIK resulted in better mean postoperative contrast sensitivity (level II evidence).<sup>22,28</sup> This seems to be the case under photopic and mesopic testing conditions. Two studies compared different WFG laser systems and found that scotopic and mesopic contrast improved after WFG LASIK.<sup>21,25</sup> Pop and Payette<sup>32</sup> reported no loss of scotopic contrast sensitivity after wavefront LASIK using the NIDEK system (level II evidence; Nidek Inc, Fremont, CA). The results suggest that mean contrast sensitivity is either unchanged or improves after WFG LASIK.

Contrast sensitivity results were reported in all of the PMA studies. A clinically relevant change was defined as more than a 0.3-log unit change at 2 or more spatial frequencies. Nearly all patients (92.7% to 97.9%) who underwent surgery using either of 2 laser systems (Alcon LadarVision and Bausch & Lomb Zyoptix) had either no change or an improvement in mesopic contrast sensitivity. Analysis in the VISX PMA report demonstrated statistical improvement in contrast sensitivity for all 3 test conditions (dim with and without glare and bright without glare) at 1, 3, and 6 months after surgery. No mean loss of contrast sensitivity was reported in the WaveLight PMA report.

### Change in Higher-Order Aberrations

There is a growing awareness of the impact that HOAs have on the quality of vision, especially under low light conditions. Visual symptoms of glare, halos, and starburst have been correlated to HOAs.<sup>36,37</sup> Understanding surgically induced changes in HOAs is an important factor in assessing new technology. Table 5 lists changes in HOAs for selected comparative studies of WFG and conventional LASIK.

Published studies indicate that WFG LASIK generally increases HOA or results in a slight reduction.<sup>19,22,24,25,27,31-33,35,38,39</sup> The change in HOA after WFG LASIK has been related to both the preoperative myopia and level of HOA.<sup>27,39,40</sup> The higher the level of treated myopia is, the greater the increase in postoperative HOA. Eyes with relatively low preoperative HOA are associated



Non-Wavefront-Guided LASIK for Primary Myopia and Astigmatism

Preoperative Manifest Spherical Equivalent	Postoperative Manifest Spherical Equivalent	Postoperative Manifest Spherical Equivalent $\pm 0.5$ D (%)	Uncorrected Visual Acuity $\geq 20/20$ (%)	Loss of Best Spectacle-Corrected Visual Acuity of $\geq 2$ Lines (%)	Gain of Best Spectacle-Corrected Visual Acuity of $\geq 2$ Lines (%)
-3.97 $\pm$ 1.28	-0.34 $\pm$ 0.29	NR	78	0	NR
-4.08 $\pm$ 1.24	-0.44 $\pm$ 0.31	NR	74	0	NR
-5.30 $\pm$ 3.16	-0.55 $\pm$ 0.87	NR	45	0	NR
-5.60 $\pm$ 3.01	-0.09 $\pm$ 0.54	NR	82	0	NR
-4.26 $\pm$ 2.12	-0.11 $\pm$ 0.42	NR	0.18 $\pm$ 0.044 <sup>†</sup>	NR	NR
-3.59 $\pm$ 1.55	-0.14 $\pm$ 0.29	NR	-0.02 $\pm$ 0.07 <sup>†</sup>	NR	NR
-3.00 $\pm$ 1.49	-0.18 $\pm$ 0.46	NR	0.014 $\pm$ 0.067 <sup>†</sup>	NR	NR
-3.16 $\pm$ 1.63	-0.04 $\pm$ 0.24	NR	-0.034 $\pm$ 0.059 <sup>†</sup>	NR	NR
-7.18 $\pm$ 2.84	-0.21 $\pm$ 0.26	90	80	0	NR
-7.09 $\pm$ 3.32	+0.08 $\pm$ 0.32	100	100	0	NR
-4.35 $\pm$ 2.11	0.00 $\pm$ 0.21	92	83	0	8
-3.88 $\pm$ 1.92	-0.06 $\pm$ 0.41	92	67	0	16
NR	NR	NR	71	NR	NR
NR	NR	NR	67	NR	NR
-3.26	NR	NR	75	0	0
-3.33	NR	NR	75	0	25
-3.27	NR	93	80	NR	NR
-3.67	NR	90	90	NR	NR
-3.11	-0.04 $\pm$ 0.27	NR	92.9	0	>5
-4.53	0.14 $\pm$ 0.35	NR	97.8	0	>5
-3.62 $\pm$ 1.9	-0.42	NR	55	NR	NR
-3.62 $\pm$ 1.7	-0.16	NR	85	NR	NR

with an increase in HOA after surgery, whereas eyes with higher levels of HOA before surgery are associated with a reduction. Although a few studies found no significant difference in the preoperative to postoperative change in HOA between conventional and WFG LASIK, there is strong evidence that WFG results in less induction of HOA compared with conventional LASIK.<sup>22,24,26,27,35,38</sup>

The PMA studies also indicate that although there is a mean increase in HOA after WFG LASIK, it is less of an increase than after conventional LASIK. The LADARVision 4000 system showed an increase in root mean square HOA of 0.08  $\mu\text{m}$  6 months after surgery in the WFG LASIK group compared with an increase of 0.33  $\mu\text{m}$  in the conventional LASIK group (6.5-mm diameter analysis). There was a significant correlation between lower postoperative HOA and better low-contrast BSCVA. The PMA study for the Technolas 217z showed an increase in RMS HOA of 13% in the WFG group compared with an increase of 45% in a control conventional group at 6 months after surgery (6-mm diameter analysis). The PMA study of the Wavelight Allegretto system reported a mean postoperative HOA increase of 3% compared with a control group increase of 12% (6-mm diameter analysis). In this analysis, the change in HOA was related to the amount present before surgery. A mean preoperative HOA of less than 0.3  $\mu\text{m}$  was associated with a slight increase in postoperative HOA, whereas a preoperative HOA mean of more than 0.3  $\mu\text{m}$  was associated with a decrease in postoperative HOA.

## Conclusions

Wavefront-guided LASIK is a corneal refractive procedure that requires more resources and greater attention to detail compared with conventional LASIK. An aberrometer and compatible excimer laser as well as additional training are needed. In addition to a comprehensive preoperative examination, high-quality wavefront images over the low-light entrance pupil and consistency between manifest and wavefront refractions are important. As with conventional LASIK, proper caution must be observed with respect to corneal topography, central corneal thickness, and other measures of ocular health before surgery.

The preponderance of current literature demonstrates that WFG LASIK is both safe and effective. Compared with conventional LASIK, WFG surgery seems to result in improved outcomes. This is particularly true for contrast sensitivity, night vision, and visual symptoms. Although differences between WFG and conventional LASIK largely have been attributed to the WFG treatment in the studies reviewed, other factors such as optimized laser shot delivery profiles, larger treatment zones, better tracking devices, improved rotational alignment, or other device-specific properties may be responsible for some of these findings. Because details of some of these factors are proprietary, their roles could not be separated from those of WFG treatment itself. Long-term results of WFG LASIK also could not be assessed because of the

Table 5. Reported Contrast Sensitivity, Higher-Order Aberration Results, or Both of Selected Studies of

Author(s), Year	Level of Evidence	Laser	Procedure	Method of Contrast Measurement
Lee et al, <sup>28</sup> 2006	II	VISX S4	C	Pelli-Robson; glare meter
		VISX S4	W	Pelli-Robson; glare meter
Vongthongsri et al, <sup>26</sup> 2002	II	Nidek EC-5000	C	NR
		Nidek EC-5000	W	NR
Awwad et al, <sup>29</sup> 2004	II	LADARVision 4000	W	CSV-1000E (VectorVision, Dayton, OH)
		VISX S4	W	CSV-1000E
Slade, <sup>25</sup> 2004 (industry-sponsored)	II	LADARVision 4000	W	CSV-1000E
		VISX S4	W	CSV-1000E
Durrie & Stahl, <sup>21</sup> 2004	II	LADARVision 4000	W	Optec 3500 (Stereo Optical Co., Inc., Chicago, IL)
		Technolas 217z	W	Optec 3500
Phusitphoykai et al, <sup>24</sup> 2003	II	Nidek EC-5000	C	NR
		Nidek EC-5000	W	NR
Kim et al, <sup>22</sup> 2004	II	Technolas 217z	C	VCTS plates
		Technolas 217z	W	VCTS plates (Vistech Consultants, Dayton, OH)
Pop & Payette, <sup>32</sup> 2004	III	Nidek EC-5000 CATz	W	CSV-1000E
Aizawa et al, <sup>31</sup> 2003	II	Technolas 217z	W	NR
Brint, <sup>27</sup> 2005	II	LADARVision 4000	W	NR
		Allegretto Wave	O	NR
Carones et al, <sup>46</sup> 2005	III	LADAR 6000	C	NR
		LADAR 6000	W	NR
Caster et al, <sup>35</sup> 2005	III	LADARVision 4000	C	CSV-1000E
		LADARVision 4000	W	CSV-1000E
Venter, <sup>39</sup> 2005	III	NIDEK EC-5000	W	NR

C = conventional; cpd = cycle per degree; NR = not reported; O = optimized; VCTS = Vision Contrast Test System; W = wavefront-guided.

\*Postoperative to preoperative change.

relatively short follow-up (12 months or less) of reviewed studies.

## Future Research

On average, HOAs are higher after WFG LASIK than before surgery. Further improvement in results will require refinement of existing procedures as well as the development of new technology. Causes for surgically induced HOA include the ablation profile, imperfect alignment of the ablation to the wavefront, errors in eye tracking, variations in laser fluence and ablation rate, the microkeratome cut, postoperative epithelial thickness modulation, and stromal biomechanical shifts. Incomplete removal of preexisting aberration may be caused by errors in wavefront measurement, ablation design, and laser delivery. More studies are needed to assess the importance of these factors. Advances in laser technology such as iris registration may improve HOA outcomes. A Fourier transform-based ablation design may reconstruct the ocular wavefront more accurately and may result in better visual outcomes compared with Zernike reconstruction.<sup>41,42</sup> The use of improved mechanical microkeratomes or a femtosecond laser to create the LASIK flap also may reduce surgically induced HOA.<sup>18</sup>

A compelling therapeutic application of WFG LASIK is to treat visually significant HOAs that were induced by previous surgery. Even with existing technology, high levels of HOA can be reduced after WFG LASIK.<sup>43,44</sup> How-

ever, there are many issues and unanswered questions. There needs to be a better understanding of proper patient selection. Who are the best candidates? What are the treatment criteria? Highly aberrated eyes may exceed the dynamic range of the aberrometer. There must be sufficient resolution and accuracy of the wavefront capture to provide a pattern for treatment. Overlapping, dropped, or interpolated points in Hartmann Shack aberrometers are a concern. A hyperopic shift has been observed anecdotally after WFG LASIK for highly aberrated eyes that have very low refractive error. Surgeons should note the planned ablation depth for wavefront treatments in these eyes relative to the refractive error and should consider applying a spherical offset to counter the anticipated hyperopic shift. A better understanding of this phenomenon is needed. In addition, the predictability of HOA correction has not been addressed and needs study.

Zernike analysis is useful for separating HOAs (third-order and above) from lower-order aberrations (defocus and astigmatism). It also allows analysis of individual higher-order terms such as coma and spherical aberration, which are dominant after LASIK. For these reasons, Zernike analysis is indispensable in reporting ocular wavefront measurements; however, it has not been applied in a uniform manner in the ophthalmic literature. We make the following recommendations to help to standardize the reporting of wavefront data and to facilitate comparison between articles:

Wavefront-Guided LASIK and Contralateral Eye Conventional LASIK for Primary Myopia and Astigmatism

Change* in Contrast	Pupil Diameter Analyzed (mm)	Change* in Higher-Order Root Mean Square ( $\mu\text{m}$ )	Change* in Spherical Aberration Root Mean Square ( $\mu\text{m}$ )	Change* in Coma Root Mean Square ( $\mu\text{m}$ )
Reduced	NR	NR	NR	NR
No change from baseline; mesopic glare better than C		NR	NR	NR
NR	NR	-0.076	0.25	NR
NR	NR	-0.048	-0.35	NR
Scotopic better at all frequencies	NR	-0.03	0.06	0.06
Scotopic better at 3 cpd but worse at 6 cpd	NR	-0.03	0.02	0.03
Mesopic better at all frequencies	NR	NR	0.03	NR
Mesopic better at 12 cpd only	NR	NR	0.10	NR
NR	NR	NR	NR	NR
NR	NR	NR	NR	NR
NR	NR	Increased	Increased more	Increased
NR	NR	Increased	Increased less	No change
Photopic and mesopic contrast worse	5.0	0.203	Increased more	Increased more
Photopic and mesopic contrast better	5.0	0.164	Increased less	Increased less
No change in scotopic contrast	NR	0.07	NR	Increased
NR	5.0	NR	Increased	Increased
NR	6.0	Increased less	Increased	No change
NR	6.0	Increased more	Increased	No change
NR	6.0	Increased more	Increased	Increased more
NR	6.0	Increased less	Decreased	Increased less
No significant change in photopic or mesopic contrast	6.0	0.251	NR	NR
Mean photopic and mesopic contrast improved, but not statistically significant	6.0	0.117	NR	NR
NR	NR	19%	NR	NR

1. Use standard double-index notation and names for Zernike terms as adopted by the Optical Society of America.<sup>45</sup>
2. Use the root mean square magnitude to summarize all HOA and report it. Some articles single out one term (such as *coma*, *spherical aberration*, or *trefoil*) for statistical comparison. This would allow the author to choose only one number among many that support the favored conclusion.
3. Specify the diameter of the analytic zone. Among the reviewed articles, some adapted analytic zones of 4, 5, or 6 mm, whereas others did not specify the diameter. The diameter ideally should match the size of the low-light pupil to capture all visually relevant wavefront information. Adapting 1 standard diameter facilitates comparison between eyes. For wavefront measured through a pharmacologically dilated pupil, 6 mm has been proposed as a standard. A 4-mm zone may be too small. The same diameter must be used when comparing the magnitude of HOA, for example, before and after LASIK.
4. Perform vector analysis of surgically induced HOA. Most articles reported the magnitude (absolute or root mean square value) of HOA Zernike terms but not the sign (positive or negative). This omits useful information. For example, many reports showed that spherical aberration ( $Z_4^0$ ) increases after LASIK, but did not report whether it is prolate (negative) or oblate (positive). Vector analysis would provide this

information. The direction of the Zernike vector is given by the sign of the Zernike coefficients, which is provided in the output of most wavefront sensors.

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## Appendix

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