ARTICLE

# Wavefront-guided myopic laser in situ keratomileusis with a high-resolution Hartmann-Shack aberrometer and a new nomogram

*Robert K. Maloney, MD, MA(Oxon), Colman R. Kraff, MD, Stephen C. Coleman, MD*



**Purpose:** To evaluate visual, refractive, aberrometric, and patient-reported outcomes of wavefront-guided (WFG) myopic laser in situ keratomileusis (LASIK) using a high-resolution Hartmann-Shack aberrometer (iDesign Advanced WaveScan system) with a new nomogram and to determine whether the new nomogram resolved the mild undercorrection that occurs with the manufacturer's default settings.

**Setting:** Three private LASIK practices.

**Design:** Prospective, open-label, noncomparative, multicenter study.

**Methods:** One hundred ninety eyes of 95 patients underwent bilateral WFG LASIK for the correction of myopia or myopic astigmatism. A new nomogram was used, which effectively adjusted the wavefront-measured refraction sphere up or down to equal the manifest refraction sphere. Patients were followed up for 6 months.

**Results:** Eighty-four patients completed the final follow up. At 6 months, 162 (96.4%) of 168 eyes achieved monocular uncorrected distance visual acuity of 20/20 or better. No eye lost 2 or more lines of corrected distance visual acuity. The safety and efficacy indices were 1.12 and 1.09, respectively; 164 (98%) of 168 eyes had manifest refraction spherical equivalent within ±0.50 diopters (D) of emmetropia, and 154 (92%) of 168 eyes had residual manifest refractive astigmatism of 0.50 D or less. Fewer patients experienced burning, stinging, soreness, and irritation postoperatively than preoperatively. Eighty-one (96%) of 84 patients reported improved quality of life.

**Conclusions:** WFG myopic LASIK using a high-resolution Hartmann-Shack aberrometer and a new nomogram resolved the undercorrection with the manufacturer's default settings. The treatment was safe and effective with excellent visual and refractive outcomes, high patient satisfaction, and improved quality of life.

*J Cataract Refract Surg 2021; 47:847–854 Copyright © 2021 Published by Wolters Kluwer on behalf of ASCRS and ESCRS*

Conventional laser refractive surgery platforms can correct hyperopia, myopia, and astigmatism. Higher-order aberrations (HOAs), such as coma, spherical aberration, and trefoil, are typically induced by conventional laser in situ keratomileusis (LASIK) surgery, potentially leading to decreased quality of vision despite achieving 20/20 Snellen visual acuity.[1,2] Wavefront-guided (WFG) customized ablation treatments were designed to both correct spherocylindrical refractive errors and reduce preexisting ocular aberrations.[2] In practice, WFG treatments do not reduce preexisting HOAs but may have the benefit of inducing a smaller increase in HOAs than other methods.[3–7]

Safety and efficacy results have previously been reported with WFG LASIK treatments using a Hartmann-Shack aberrometer that measures up to 240 points over the pupil (WaveScan system, Johnson & Johnson).[1,8–12] A new system is commercially available that incorporates a high-resolution Hartmann-Shack aberrometer (iDesign Advanced WaveScan System, Johnson & Johnson Vision). This system captures up to 1257 points over the pupil, about 5 times the resolution of the previous system, and uses corneal topography to correct for the effect of angle of incidence on tissue ablation rates.[2,13–15]

One would expect that the newer system would produce better results for myopia and myopic astigmatism or results

Submitted: April 10, 2020 | Final revision submitted: November 3, 2020 | Accepted: November 23, 2020

From the Maloney-Shamie Vision Institute, Los Angeles, California (Maloney); Kraff Eye Institute, Chicago, Illinois (Kraff); Coleman Vision, Albuquerque, New Mexico (Coleman).

Supported by a grant from Johnson & Johnson Vision.

This manuscript describes off-label use of the Star S2/iDesign system.

Corresponding author: Robert K. Maloney, MD, MA(Oxon), Maloney-Shamie Vision Institute, 10921 Wilshire Boulevard, Suite 900, Los Angeles, CA.
Email: rm@maloneyshamie.com.



0886-3350/$ - see frontmatter
https://doi.org/10.1097/j.jcrs.0000000000000539

**Table 1. Baseline Clinical and Demographic Characteristics.**

| Parameter | Mean ± SD (range) |
|---|---|
| Age (y) | 30.4 ± 5.3 (18.6, 46.5) |
| Pupil size (mm) | |
| Photopic | 5.4 ± 0.9 (3.2, 8.5) |
| Scotopic | 6.6 ± 0.8 (4.0, 8.2) |
| MRSE (D) | −3.80 ± 1.90 (−8.38, −0.75) |
| Cylinder (D) | 0.87 ± 0.91 (−5.00, 0.00) |
| K readings (D) | |
| K1 | 43.70 ± 1.60 (40.10, 47.50) |
| K2 | 44.80 ± 1.70 (40.10, 47.50) |
| CCT (μm) | 570.8 ± 35.9 (484, 658) |
| M/F (%) | 63.2/36.8 |

CCT = central corneal thickness; K = keratometric

that at least were no worse than the older system. Yet, in the U.S. Food and Drug Administration (FDA) premarket approval (PMA) study of the older WaveScan system, 93% of 351 enrolled eyes achieved uncorrected distance visual acuity (UDVA) of 20/20 or better at 6 months (P930016/SO16 SSED, accessible at www.fda.gov). In the U.S. FDA PMA study of the newer iDesign system, only 83% of 334 enrolled eyes achieved UDVA of 20/20 or better (P930016/S044 SSED, accessible at www.fda.gov). Although the 2 trials are not directly comparable because the inclusion criteria were different, one contributor to the underperformance of the iDesign system in the PMA study was a systematic undercorrection of myopia. With the iDesign system, only 69% of eyes fell within ±0.50 diopters (D) of emmetropia at 6 months, because the mean manifest refraction spherical equivalent (MRSE) was −0.46 ± 0.42 D, significantly short of emmetropia. With the WaveScan system, 90% of eyes were within ±0.50 D of emmetropia at 6 months. It is clear that the manufacturer's default settings in the iDesign PMA study were not as accurate as the previous system. We undertook this investigator-initiated study to determine whether the iDesign system could produce superior results if a correcting nomogram were used.

## METHODS

This prospective open-label, noncomparative multicenter study was conducted at 3 sites in the United States (Kraff Eye Institute, Chicago, IL; Maloney-Shamie Vision Institute, Los Angeles, CA; and Coleman Vision, Albuquerque, NM). The 3 participating centers were each clinical investigative site for the iDesign FDA PMA. One hundred ninety eyes of 95 patients with myopia or myopic astigmatism were enrolled in the study. Written informed consent was obtained from all patients. The study was approved by an institutional review board (Alpha IRB, San Clemente, CA) and followed the tenets of the Declaration of Helsinki.

Eligible patients were healthy adults aged 18 years or older seeking bilateral LASIK surgery with a refractive goal of emmetropia both eyes. Subjects with myopic spherical equivalent up to −11.00 D with or without astigmatism up to −5.00 D in both eyes could be enrolled. Pupil diameter had to be between 4.0 and 9.5 mm in dim illumination to be included in the study. Soft and rigid gas-permeable contact lens wearers discontinued contact lens use at least 1 week and 3 weeks, respectively, before the preoperative examination.

Exclusion criteria included unstable refraction or corrected distance visual acuity (CDVA) of 20/25 or worse in either eye. Other exclusion criteria were as follows: evidence, in either eye, of keratoconus, abnormal corneal topography or any corneal pathology that was clinically significant in the assessment of the investigator; estimated residual corneal bed thickness less than 270 μm; history of severe ocular allergies; history of ocular herpes simplex/zoster; clinically significant lens opacity; moderate to severe dry eye; pregnancy or breastfeeding; use of isotretinoin within the past 6 months; use of amiodarone within the past 12 months; and use of systemic or nasal corticosteroids within the past 3 months. Patients undergoing monocular treatment or with a refractive goal other than emmetropia in each eye were excluded.

Subjects were examined preoperatively and at 1 day, 1 month, 3 months and 6 months postoperatively. CDVA and UDVA were measured on Early Treatment Diabetic Retinopathy Study (ETDRS) charts at 4 m. The iDesign Advanced WaveScan system was used to measure wavefront refraction, corneal topography, keratometry, pupil size and ocular aberrometry preoperatively and at 1 month and 6 months. In addition, patient satisfaction and overall incidence of photic phenomena were evaluated at baseline and 6 months postoperatively through a subjective patient questionnaire that was a modified version of the National Eye Institute Refractive Error Quality of Life (NEI-RQL)-42 and included questions about the frequency of visual disturbances.

### Nomogram

The wavefront map generated by the iDesign system was used to create an excimer laser treatment pattern. Using a proprietary algorithm, the iDesign system calculated an iDesign refraction from captured wavefront map. The sphere component of the iDesign refraction was intended to correct the eye to infinity. An option called sphere adjustment allowed the user to alter the amount of sphere correction in the treatment pattern by ±0.75 D. The manufacturer's default setting of the sphere adjustment is zero. It is this sphere adjustment that allows the user to incorporate a nomogram adjustment. Each patient had a sphere adjustment calculated as follows: First, the manifest refraction sphere was adjusted to an infinite lane length by adding the negative reciprocal of the lane length, in meters, to the measured manifest sphere. Then, the iDesign sphere correction was subtracted from the adjusted manifest refraction sphere to yield the

**Table 2. Visual and Refractive Outcomes.**

| Parameter | Preop | 3 mo postop | 6 mo postop |
|---|---|---|---|
| MRSE (D), mean ± SD | −3.83 ± 1.92 | 0.05 ± 0.25 | −0.01 ± 0.25 |
| MRSE, eyes within ±0.50 D of plano (%) | 0 | 98.3 | 98 |
| Eyes with manifest astigmatism ≤0.50 D (%) | 51 | 94.5 | 92 |
| Eyes with UDVA 20/20 or better (%) | 0 | 96.7 | 96.4 |
| Eyes with UDVA 20/16 or better (%) | 0 | 77.8 | 76.8 |
| Patients with binocular UDVA 20/20 or better (%) | 0 | 98.9 | 100 |
| Patients with binocular UDVA 20/16 or better (%) | 0 | 92.2 | 92.9 |

preop = preoperatively; postop = postoperatively

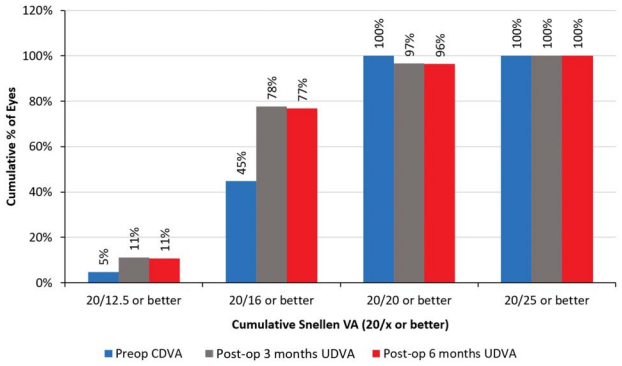


**Figure 1.** UDVA at 3 months and 6 months postoperatively compared with preoperative monocular CDVA. Postoperatively, 97% (3 months) and 96% (6 months) of eyes had UDVA 20/20 or better. All eyes (100%) had an UDVA of 20/25 or better at 3 months and 6 months postoperatively.

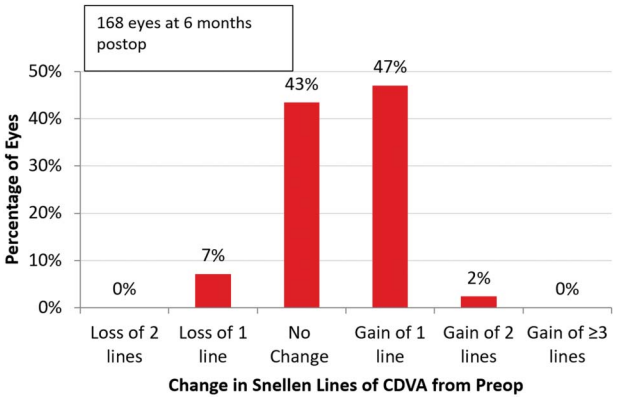


**Figure 2.** Change in lines of CDVA preoperatively to 6 months postoperatively: 49% of eyes showed a gain of 1 or more lines, and no eye lost 2 or more lines of CDVA.

sphere adjustment. For example, if the manifest refraction was −4.50 diopter sphere (DS) in a 4 m lane, then the adjusted manifest refraction sphere was −4.75 DS. If the iDesign calculated a sphere correction of −5.25 DS, then the difference between the iDesign sphere correction and the adjusted manifest refraction sphere is +0.50 D. A sphere adjustment of +0.50 D would be entered. This calculation had the effect of adjusting the iDesign sphere up or down to equal the adjusted manifest refraction sphere. The calculations were performed on the sphere, written in minus cylinder form and not the spherical equivalent. Cylinder correction was ignored for the purpose of this calculation but was always present to some degree or another in the calculated iDesign treatment because the treatment was calculated to the nearest 0.01 D. No adjustment to the cylinder correction was made. If the sphere adjustment fell outside the ±0.75 D range of the iDesign system at the time, the patient was excluded from the study. The iDesign system has a user option that does these calculations automatically after the manifest refraction is entered. Use of a nomogram with this or any other system is an off-label use.

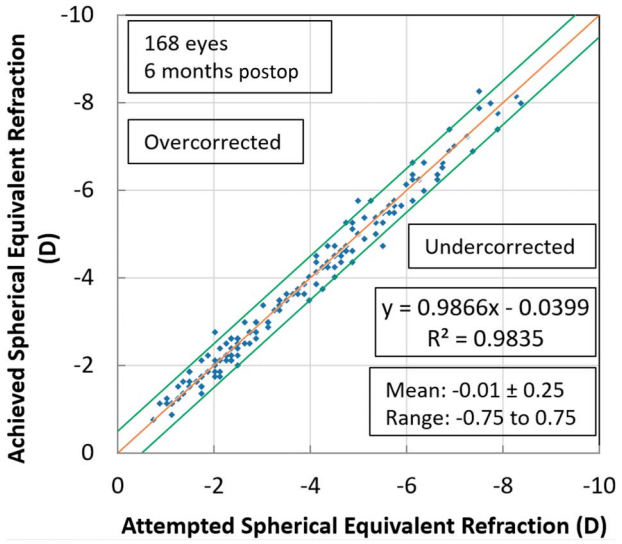


**Figure 3.** Comparison of attempted MRSE and achieved MRSE. The *green diagonal lines* enclose errors ≤0.50 D. MRSE = manifest refraction spherical equivalent

## Surgical Procedure

All subjects were treated with the iLASIK suite (Johnson and Johnson Vision), which includes the iDesign Advanced WaveScan aberrometer (version 1.3), the iFS femtosecond laser, and the Star S4 IR excimer laser. All surgeries were performed under topical anesthesia by one of the authors, each of whom is an experienced LASIK surgeon. Corneal flaps were hinged superiorly and were created with the femtosecond laser with an intended flap thickness of 90 to 120 μm and a flap diameter of 8.0 to 9.0 mm. WFG laser ablation was performed, with XYZ tracking in all eyes and torsional tracking based on iris registration when possible. Treatments were programmed in all cases with a 6.0 mm zone of wavefront correction and a total ablation zone of 8.0 mm. All eyes were targeted for emmetropia.

## Statistical Analysis

Clinical results were analyzed at 3 months and 6 months postoperatively. Statistical analysis was performed using SPSS Statistics for Windows software (SPSS, Inc.). Shapiro-Wilks test was used to check normality of the scaled data. For comparing preoperative and postoperative data, the paired *t* test was used for normally distributed data, and Wilcoxon signed-rank test was used for data that were not normally distributed. Although the calculation of the sphere adjustment involved adjusting the manifest refraction sphere for the optical difference between the lane length and infinity, no such adjustment was made to the sphere and spherical equivalent data reported in this study.

Statistic involving visual acuities were calculated by first converting the ETDRS vision to a logMAR equivalent and then performing any necessary calculations. At the end of the calculation, the logMAR equivalent was converted back to Snellen acuity for reporting in this study. The safety index was calculated as the ratio of mean postoperative CDVA to mean preoperative CDVA, and the efficacy index was calculated as the ratio of mean postoperative UDVA to mean preoperative CDVA.

# RESULTS

Ninety-seven patients were enrolled in the study. Two patients dropped out before LASIK was performed and were excluded from the results. Ninety-five patients were treated. At 3 months, 90 patients (95%) were available for analysis. Eighty-four patients (88%) with 168 eyes completed the final visit at 6 months. The preoperative patient characteristics are summarized in Table 1. No intraoperative complications occurred, nor were there any serious adverse events postoperatively.

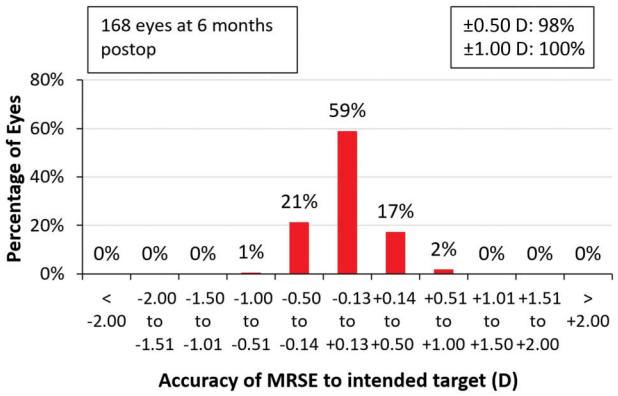


**Figure 4.** Accuracy of achieved MRSE: 98% eyes had an MRSE within ±0.50 D of emmetropia. MRSE = manifest refraction spherical equivalent

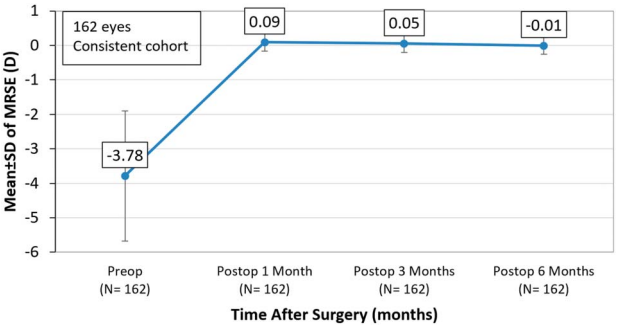


**Figure 5.** Stability of MRSE over time in a consistent cohort of eyes with follow-up at every visit: 6% of eyes changed more than 0.50 D between 3 and 6 months postoperatively. MRSE = manifest refraction spherical equivalent

## Visual Outcomes

The visual and refractive outcomes are summarized in Table 2. At 3 months postoperatively, 140 (78%) of 180 eyes showed 20/16 or better and 174 (97%) of 180 eyes showed 20/20 or better monocularly. At 6 months, these were 129 (77%) of 168 eyes and 162 (96%) of 168 eyes, respectively (Figure 1). All patients had binocular UDVA and CDVA of 20/20 or better 6 months postoperatively.

At 3 months and 6 months postoperatively, 96 (53%) of 180 eyes and 83 (49%) of 168 eyes gained 1 or more lines of CDVA, respectively, and 12 (6.7%) of 180 eyes and 12 (7.1%) of 168 eyes lost 1 line of CDVA, respectively. No eye lost 2 or more lines at either 3 months or 6 months postoperatively (Figure 2). At 6 months, mean monocular CDVA improved from −0.05 ± 0.06 logMAR (20/18 Snellen equivalent) preoperatively to −0.10 ± 0.06 logMAR (20/16 Snellen equivalent) postoperatively ($P < .001$). The safety and efficacy indices at 6 months postoperatively were 1.12 and 1.09, respectively.

## Refractive Outcomes

The MRSE within ±0.50 D of emmetropia was achieved in 177 (98.3%) of 180 eyes at 3 months and 164 (97.6%) of 168 eyes at 6 months (Figures 3 and 4). The mean MRSE improved from −3.83 ± 1.92 D at baseline to 0.05 ± 0.25 D at 3 months and −0.01 ± 0.25 D at 6 months postoperatively. Little change in mean MRSE occurred after 1 month: MRSE regressed by 0.04 D from 1 month to 3 months and by 0.06 D between 3 and 6 months (Figure 5). Between 3 and 6 months postoperatively, 9 (6%) of 162 eyes changed by more than 0.50 D.

The number of eyes with residual refractive cylinder of 0.50 D or less was 170 (94%) of 180 eyes and 154 (92%) of 168 eyes at 3 months and 6 months postoperatively, respectively (Figure 6). The Alpins method of astigmatism analysis was used to evaluate results in 147 eyes with preoperative refractive astigmatism of 0.25 D or more.[16] In all eyes, the target-induced astigmatism (TIA) was the preoperative manifest refractive astigmatism. Figure 7 shows TIA against surgically induced astigmatism (SIA)

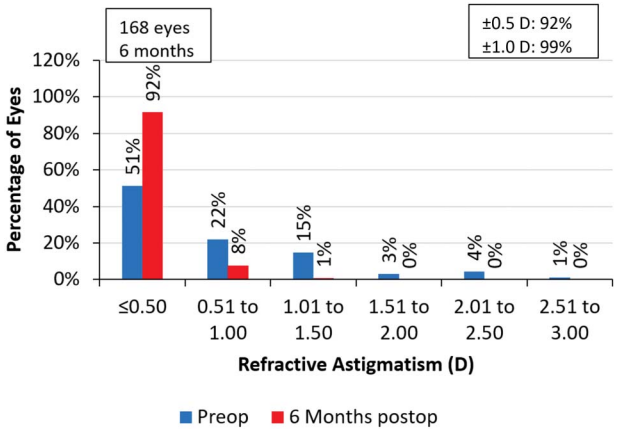


**Figure 6.** Comparison of refractive astigmatism from preoperatively to postoperatively. At 6 months postoperatively, 92% eyes had residual refractive cylinder of ±0.50 D or less, and 99% of eyes had ±1.00 D or less.

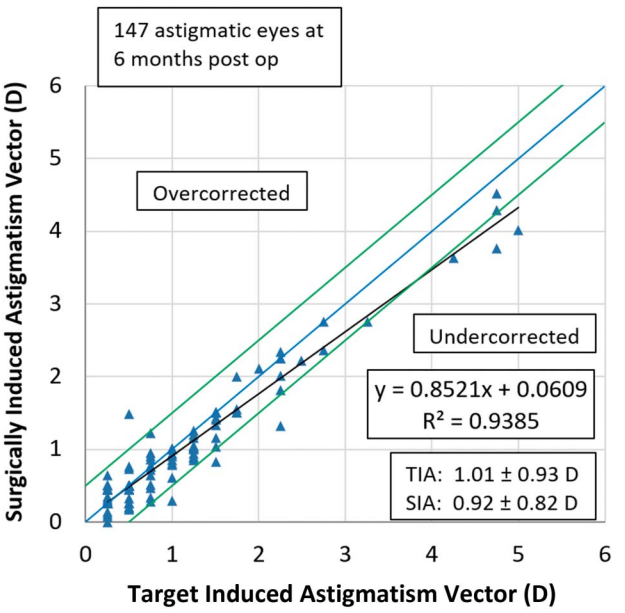


**Figure 7.** TIA vs SIA at 6 months. The *green diagonal lines* enclose errors of 0.50 D or less. The mean correction index was 0.97, with more highly astigmatic eyes somewhat undercorrected. SIA = surgically induced astigmatism; TIA = target induced astigmatism

**Table 3. Comparison of RMS HOAs at Baseline and 6 Months Postop.**

| Parameter | N | Mean ± SD | *P* value[a] |
|---|---|---|---|
| RMS HOA | 165 | 0.09 ± 0.04 | <.001 |
| 4 mm pupil preop | | | |
| 4 mm pupil postop 6 mo | 165 | 0.12 ± 0.07 | |
| 5 mm pupil preop | 157 | 0.17 ± 0.06 | <.001 |
| 5 mm pupil postop 6 mo | 157 | 0.23 ± 0.11 | |

HOA = higher-order aberrations; preop = preoperatively; postop = postoperatively; RMS = root mean square
[a]Wilcoxon signed-rank test.

at 6 months postoperatively. At 6 months, the magnitude of error (mean difference between SIA and TIA) was −0.09 ± 0.29 D, and the mean angle of error was −1.35 ± 38.13 degrees. The correction index (ratio of SIA and TIA) achieved was 0.97 ± 0.36. Eyes with manifest astigmatism of 3.00 D or more were somewhat undercorrected.

## Aberrometry Outcomes

Corneal aberrometry outcomes for both 4 mm and 5 mm pupils are summarized in Table 3. The mean root mean square HOAs showed a small but statistically significant increase from preoperatively to 6 months for both 4 mm and 5 mm pupils of 0.03 D and 0.06 D, respectively ($P <$ .001). The small increase in HOAs occurred despite the improvement in mean CDVA from preoperatively to 6 months postoperatively.

## Patient-Reported Outcomes

Patient-reported outcomes were determined using a questionnaire based on the NEI-RQL-42 that was administered preoperatively and 6 months after LASIK. Questions were added about the frequency of visual disturbances. The expanded questionnaire was not separately revalidated.

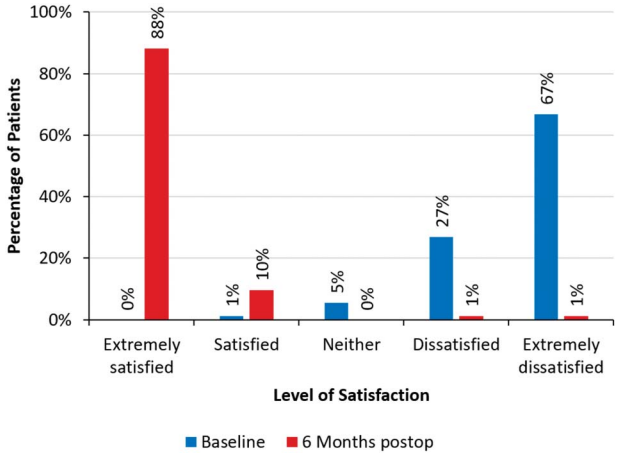


**Figure 8.** Patient satisfaction without spectacles or contact lenses: 98% of patients were satisfied or extremely satisfied with their uncorrected vision 6 months postoperatively.

Patients were asked about satisfaction with their vision before and after LASIK. In response to the question, "Over the last month, overall how satisfied are you with your vision without using prescription spectacles or contact lenses?", 82 (98%) of 84 patients were extremely satisfied or satisfied with their postoperative vision without spectacles or contact lenses (Figure 8).

To ascertain the incidence of photic phenomena, patients were asked a series of questions of the form, "Over the last month, how much difficulty have you had with your vision—overall due to X," where X was starburst, glare, halos, or double vision or ghost images. The percentage of patients experiencing glare, halos, starburst, or ghosting/double vision none of the time was lower at 6 months compared with that preoperatively, but the differences were not statistically significant (Figure 9).

Patients were asked a series of questions about symptoms that might be attributable to dryness. There was a decrease in the prevalence of patients experiencing soreness or

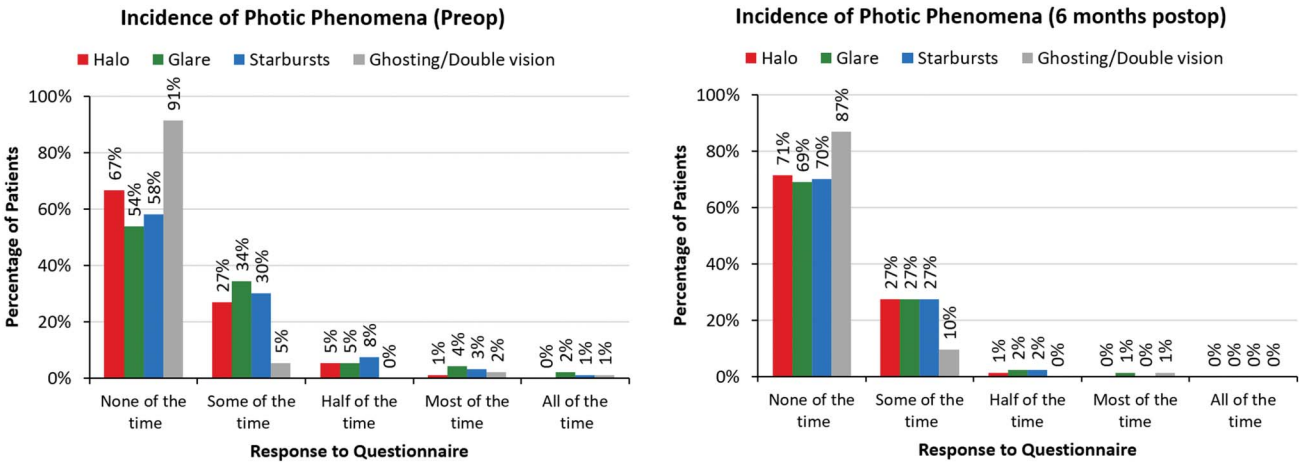


**Figure 9.** Patient-reported overall incidence of various photic phenomena preoperatively and 6 months postoperatively. There was an increase in the numerical percentage of patients experiencing no glare (54% vs 69%) and no halo (69% vs 71%) from preoperatively to 6 months postoperatively, but the differences were not statistically significant ($P$ = .061 and $P$ = .473, respectively).

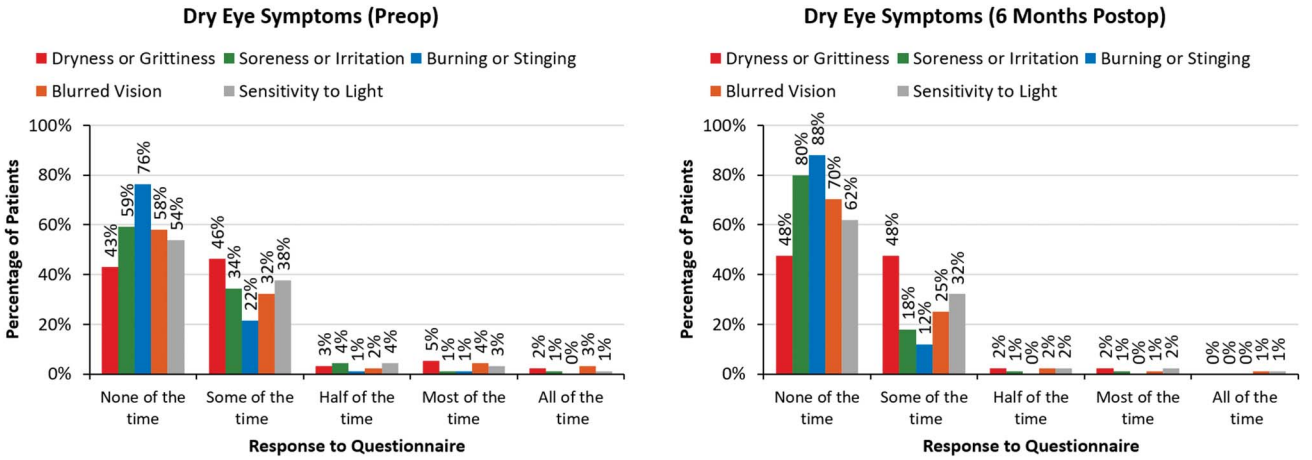


**Figure 10.** Patient-reported level of discomfort assessed through subjective patient questionnaire preoperatively and 6 months postoperatively. There was a decrease in the percentage of patients experiencing soreness or irritation ($P < .001$) and stinging or burning ($P = .021$) some of the time or more often from preoperatively to postoperatively. The other differences were not statistically significant.

irritation ($P < .001$) and burning or stinging ($P = .021$) some of the time or more often from preoperatively to 6 months postoperatively (Figure 10).

In response to the question, "Comparing your lifestyle prior to LASIK, has the quality of your life improved?" at 6 months, 81 (96%) of 84 patients reported great improvement or improvement in their quality of life postoperatively, and no patients reported a worse quality of life (Figure 11). Nearly, all patients (83/4 [99%]) would recommend the LASIK procedure to their friends and relatives.

## DISCUSSION

This study was undertaken to determine whether the iDesign system could produce superior results with a correcting nomogram. At 6 months postoperatively, 98% eyes were within ±0.50 D of emmetropia and 92% eyes had residual refractive cylinder within ±0.50 D. Monocular UDVA of 20/20 or better was achieved in 96% eyes and 20/16 or better vision in 77% at 6 months. Patients reported high satisfaction

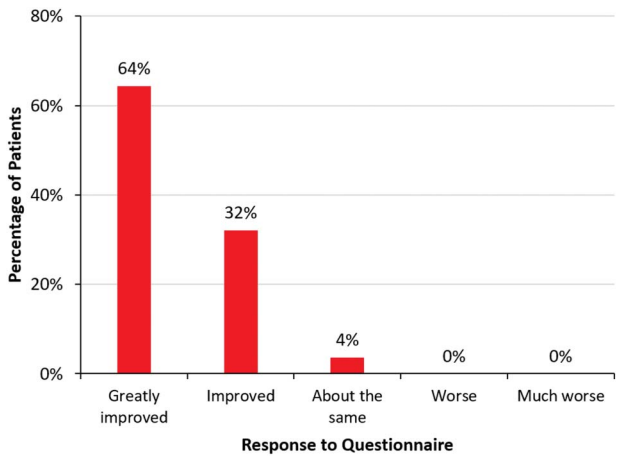


**Figure 11.** Perceived improvement in quality of life 6 months postoperatively: 96% patients reported improvement in their quality of life postoperatively.

(98%), reduced incidence of both photic phenomena and dry eye symptoms, and improved vision-related quality of life postoperatively. Nearly, all patients (99%) would recommend the procedure to their friends and relatives. This study supports the conclusion that WFG LASIK using this high-resolution Hartmann-Shack aberrometer is a safe and effective treatment for myopia and myopic astigmatism.

We undertook this study because the study leading to the U.S. FDA approval of this device achieved uncorrected acuity results that were inferior to the U.S. FDA study of its predecessor device, the WaveScan system, which used a lower-resolution aberrometer. In the U.S. FDA study of the iDesign system, the wavefront-measured sphere was used to treat each eye, even if it differed from the manifest refraction sphere (although a difference greater than 0.50 D was an exclusion criterion). An average undercorrection of 0.46 D resulted. The mean MRSE of −0.01 D at 6 months in this study indicates that the new nomogram produces a more accurate correction. The standard deviation (SD) of MRSE in this study was ±0.25 D, better than the ±0.42 D reported in the iDesign FDA study, suggesting that this nomogram also reduces the dispersion of the refractive outcomes. The nomogram does not adjust the astigmatism correction, but the close agreement of SIA to TIA indicates that no cylinder adjustment nomogram is needed, except possibly for high levels of preoperative astigmatism.

The nomogram presented in this study is not a table, as is traditional, but a method of calculation to determine an adjustment factor for the laser system. The calculation is simple: one takes the difference between the manifest sphere (for an infinite lane length) and the sphere calculated by the iDesign system. This difference is entered as the sphere adjustment factor. The practical effect is to cause the iDesign system to treat the manifest sphere instead of the iDesign sphere. We believe this works more effectively than relying on the iDesign sphere because patients sometimes accommodate during the wavefront measurement. This is similar to the approach taken by Subbaram and MacRae with the Zyoptix system (Bausch and Lomb, Inc.).[17]

When the study was performed, the iDesign system could only perform a sphere adjustment of ±0.75 D, so patients in which either eye required an adjustment outside of this range were excluded. This range has since been expanded in the United States to allow a sphere adjustment in the range −0.75 to +2.50 D. Because a statistically significant difference between manifest refraction sphere and iDesign sphere is usually caused by accommodation of the eye, this expanded range on the plus side allows for treatment of virtually all eyes with this nomogram. The nomogram is simple to use in practice: there is a user option in the iDesign system that does this nomogram calculation automatically.

Refractions were performed at 4 m on ETDRS charts. The mean MRSE was −0.01 D, suggesting optimal focus at 4 m on average. To optimize vision at infinity, a user may elect to add −0.25 D to the sphere adjustment to compensate for the 4 m distance at which refractions were performed.

One contributing factor to the difference between the iDesign and WaveScan FDA PMA studies is that the iDesign system was tested on a more challenging population than the WaveScan was. Eyes with a myopic spherical equivalent up to −12.00 D with cylinder up to −8.00 D could be enrolled in the iDesign study, whereas the WaveScan PMA study enrolled eyes only up to −6.00 D of sphere (written in minus cylinder form) with up to −3.00 D of cylinder. The mean preoperative myopia was −6.21 D in the iDesign study. Although mean preoperative MRSE was not reported for the WaveScan study, the median MRSE was between −3.00 and −4.00 D, so the WaveScan study enrolled a patient population with a lower level of myopia and astigmatism that, historically, has resulted in more predictable outcomes. The WaveScan PMA study did report UDVA stratified by preoperative MRSE, which allows comparison of the iDesign results with a similar population of WaveScan eyes. In the WaveScan PMA study, 72% of eyes with a preoperative MRSE between −5.00 and −6.00 D achieved 20/20 or better vision, a lower percentage than iDesign achieved overall in its PMA study.

In this study, a range of patient-reported outcomes were assessed. Nearly, all patients were satisfied with their postoperative vision. Patient satisfaction rate achieved in this study was similar to that previously reported in the Patient-Reported Outcomes with Laser In Situ Keratomileusis (PROWL) studies, which documented a satisfaction rate of 96% to 98% following LASIK.[18] Similar to the PROWL outcomes, we also found a modest reduction in the overall incidence of photic phenomena, including halo, glare, and starburst, and improvement in dry eye symptoms from baseline to 6 months.

WFG LASIK was originally developed with the intention of lowering postoperative HOAs. We observed a small (0.03 μm for a 4 mm pupil and 0.06 μm for a 5 mm pupil) but statistically significant increase in the mean root mean square HOAs from baseline to 6 months. Postoperative HOAs were still within the physiological range for normal, healthy populations.[19,20] The improvement in mean CDVA from preoperatively to 6 months postoperatively in the study population suggests that the small increase in HOAs had limited clinical significance because it did not impair quality of vision. Similar results have been observed in previously published studies that evaluated the aberrometry outcomes after high-resolution WFG LASIK.[2,13,19]

This prospective study, to our knowledge, is the first multicenter study of WFG LASIK with a commercially available high-resolution aberrometer to be reported. The refractive outcomes obtained in this study are comparable with or better than previously published studies of WFG LASIK with the iDesign system.[2,13–15,19,21–23] The SD of the MRSE at 6 months was 0.25 D, less than the SD of manifest refraction of 0.40 D.[24] In other words, this system and nomogram together produce laser corrections whose accuracy is largely limited by the accuracy of manifest refraction, suggesting that the laser engineering and the wavefront measurements create little variability in the outcome. It may be that this system and other modern laser systems are approaching a level of accuracy where further innovation in engineering is of limited value in improving refractive outcomes.

## Acknowledgements

Jan Beiting (Wordsmith Consulting, Cary, North Carolina) and Raman Bedi, MD (IrisARC–Analytics, Research & Consulting, Chandigarh, India) provided research, statistical, and editorial assistance in the preparation of this manuscript.

### WHAT WAS KNOWN

- Wavefront-guided (WFG) customized ablation treatments were developed to improve the refractive and visual outcomes of LASIK.
- The latest WFG system, the iDesign system, was approved by the U.S. Food and Drug Administration (FDA) with manufacturers default settings that produced a consistent undercorrection, resulting in only 83% of eyes achieving 20/20 or better vision in the U.S. FDA study.

### WHAT THIS PAPER ADDS

- In this prospective multicenter study, a new nomogram for the iDesign system using the manifest refraction sphere to guide the treatment improved mean manifest refraction spherical equivalent to −0.01 ± 0.25 D at 6 months and uncorrected vision to 20/20 or better in 96% of eyes.
- Patient reported outcomes, including glare, halos, starburst, and symptoms of dry eye, improved from preoperative to 6 months postoperatively.

## REFERENCES

1. Moshirfar M, Betts BS, Churgin DS, Hsu M, Neuffer M, Sikder S, Church D, Mifflin MD. A prospective, randomized, fellow eye comparison of WaveLight(R) Allegretto Wave (R) Eye-Q versus VISX CustomVue STAR S4 IR in laser in situ keratomileusis (LASIK): analysis of visual outcomes and higher order aberrations. Clin Ophthalmol 2011;5:1339–1347
2. Smadja D, De Castro T, Tellouck L, Tellouck J, Lecomte F, Touboul D, Paya C, Santhiago MR. Wavefront analysis after wavefront-guided myopic LASIK using a new generation aberrometer. J Refract Surg 2014;30:610–615
3. Al-Zeraid FM, Osuagwu UL. Induced higher-order aberrations after laser in situ keratomileusis (LASIK) performed with wavefront-guided IntraLase femtosecond laser in moderate to high astigmatism. BMC Ophthalmol 2016;16:29

4. He L, Liu A, Manche EE. Wavefront-guided versus wavefront-optimized laser in situ keratomileusis for patients with myopia: a prospective randomized contralateral eye study. Am J Ophthalmol 2014;157:1170–1178.e1171
5. Manche EE, Haw WW. Wavefront-guided laser in situ keratomileusis (LASIK) versus wavefront-guided photorefractive keratectomy (PRK): a prospective randomized eye-to-eye comparison (an American Ophthalmological Society thesis). Trans Am Ophthalmol Soc 2011;109:201–220
6. Sales CS, Manche EE. One-year outcomes from a prospective, randomized, eye-to-eye comparison of wavefront-guided and wavefront-optimized LASIK in myopes. Ophthalmology 2013;120:2396–2402
7. Ye MJ, Liu CY, Liao RF, Gu ZY, Zhao BY, Liao Y. SMILE and wavefront-guided LASIK out-compete other refractive surgeries in ameliorating the induction of high-order aberrations in anterior corneal surface. J Ophthalmol 2016;2016:8702162
8. Bababeygy SR, Zoumalan CI, Manche EE. Visual outcomes of wavefront-guided laser in situ keratomileusis in eyes with moderate or high myopia and compound myopic astigmatism. J Cataract Refract Surg 2008;34:21–27
9. Chen SP, Manche EE. Patient-reported vision-related quality of life after bilateral wavefront-guided laser in situ keratomileusis. J Cataract Refract Surg 2019;45:752–759
10. Jabbur NS, Kraff C, Visx Wavefront Study G. Wavefront-guided laser in situ keratomileusis using the WaveScan system for correction of low to moderate myopia with astigmatism: 6-month results in 277 eyes. J Cataract Refract Surg 2005;31:1493–1501
11. Perez-Straziota CE, Randleman JB, Stulting RD. Visual acuity and higher-order aberrations with wavefront-guided and wavefront-optimized laser in situ keratomileusis. J Cataract Refract Surg 2010;36:437–441
12. Schallhorn SC, Venter JA. One-month outcomes of wavefront-guided LASIK for low to moderate myopia with the VISX STAR S4 laser in 32,569 eyes. J Refract Surg 2009;25:S634–S641
13. Duran JA, Gutierrez E, Atienza R, Pinero DP. Vector analysis of astigmatic changes and optical quality outcomes after wavefront-guided laser in situ keratomileusis using a high-resolution aberrometer. J Cataract Refract Surg 2017;43:1515–1522
14. Smadja D, Santhiago MR, Tellouck J, De Castro T, Lecomte F, Mello GR, Touboul D. Safety and efficacy of wavefront-guided myopic laser in situ keratomileusis using a new wavefront sensor technology: first 100 cases. J Cataract Refract Surg 2015;41:1588–1593
15. Schallhorn S, Brown M, Venter J, Teenan D, Hettinger K, Yamamoto H. Early clinical outcomes of wavefront-guided myopic LASIK treatments using a new-generation hartmann-shack aberrometer. J Refract Surg 2014;30:14–21
16. Reinstein DZ, Archer TJ, Randleman JB. JRS standard for reporting astigmatism outcomes of refractive surgery. J Refract Surg 2014;30:654–659
17. Subbaram MV, MacRae SM. Customized LASIK treatment for myopia based on preoperative manifest refraction and higher order aberrometry: the Rochester nomogram. J Refract Surg 2007;23:435–441
18. Eydelman M, Hilmantel G, Tarver ME, Hofmeister EM, May J, Hammel K, Hays RD, Ferris F III. Symptoms and satisfaction of patients in the patient-reported outcomes with laser in situ keratomileusis (PROWL) studies. JAMA Ophthalmol 2017;135:13–22
19. Moussa S, Dexl AK, Krall EM, Arlt EM, Grabner G, Ruckhofer J. Visual, aberrometric, photic phenomena, and patient satisfaction after myopic wavefront-guided LASIK using a high-resolution aberrometer. Clin Ophthalmol 2016;10:2489–2496
20. Wang L, Koch DD. Ocular higher-order aberrations in individuals screened for refractive surgery. J Cataract Refract Surg 2003;29:1896–1903
21. Prakash G, Srivastava D, Suhail M. Femtosecond laser-assisted wavefront-guided LASIK using a newer generation aberrometer: 1-year results. J Refract Surg 2015;31:600–606
22. Schallhorn SC, Venter JA, Hannan SJ, Hettinger KA. Outcomes of wavefront-guided laser in situ keratomileusis using a new-generation Hartmann-Shack aberrometer in patients with high myopia. J Cataract Refract Surg 2015;41:1810–1819
23. Schallhorn SC, Venter JA, Hannan SJ, Hettinger KA. Clinical outcomes of wavefront-guided laser in situ keratomileusis to treat moderate-to-high astigmatism. Clin Ophthalmol 2015;9:1291–1298
24. Bullimore MA, Fusaro RE, Adams CW. The repeatability of automated and clinician refraction. Optom Vis Sci 1998;75:617–622


**Disclosures:** *R.K. Maloney, C.R. Kraff and S.C. Coleman are consultants to Johnson & Johnson Vision.*

**First author:**
Robert K. Maloney, MD, MA *(Oxon)*

*Maloney-Shamie Vision Institute, Los Angeles, California*