Prospective, randomized, fellow eye comparison of WaveLight® Allegretto Wave® Eye-Q versus VISX CustomVue™ STAR S4 IR™ in photorefractive keratectomy: analysis of visual outcomes and higher-order aberrations

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Background: The purpose of this study was to compare differences in visual outcomes, higher-order aberrations, contrast sensitivity, and dry eye in patients undergoing photorefractive keratectomy using wavefront-guided VISX CustomVue™ and wavefront-optimized WaveLight® Allegretto platforms.

Methods: In this randomized, prospective, single-masked, fellow-eye study, photorefractive keratectomy was performed on 46 eyes from 23 patients, with one eye randomized to WaveLight Allegretto, and the fellow eye receiving VISX CustomVue. Three-month postoperative outcome measures included uncorrected distance visual acuity, corrected distance visual acuity, refractive error, root mean square of total and grouped higher-order aberrations, contrast sensitivity, and Schirmer’s testing.

Results: Mean values for uncorrected distance visual acuity (logMAR) were −0.03 ± 0.07 and −0.06 ± 0.09 in the wavefront-optimized and wavefront-guided groups, respectively (P = 0.121). Uncorrected distance visual acuity of 20/20 or better was achieved in 91% of eyes receiving wavefront-guided photorefractive keratectomy, and 87% of eyes receiving wavefront-optimized photorefractive keratectomy, whereas uncorrected distance visual acuity of 20/15 was achieved in 35% of the wavefront-optimized group and 64% of the wavefront-guided group (P < 0.296). While root mean square of total higher-order aberration, coma, and trefoil tended to increase in the wavefront-optimized group (P = 0.091, P = 0.115, P = 0.459, respectively), only spherical aberration increased significantly (P = 0.014). Similar increases were found in wavefront-guided root mean square of total higher-order aberration (P = 0.091), coma (P = 0.403), trefoil (P = 0.603), and spherical aberration (P = 0.014). There was no significant difference in spherical aberration change when comparing the two platforms. The wavefront-guided group showed an increase in contrast sensitivity at 12 cycles per degree (P = 0.013).

Conclusion: Both VISX CustomVue and WaveLight Allegretto platforms performed equally in terms of visual acuity, safety, and predictability in photorefractive keratectomy. The wavefront-guided group showed slightly improved contrast sensitivity. Both lasers induced a comparable degree of statistically significant spherical aberration, and tended to increase other higher-order aberration measures as well.

Keywords: wavefront-guided, wavefront-optimized, photorefractive keratectomy

Introduction

Reoperation rates for primary conventional myopic photorefractive keratectomy surgery are reported to be between 16% and 20%.1-3 Conventional photorefractive
keratorefractive surgery. With the development of multiple wavefront-based platforms, it is important to ascertain if there are significant differences in visual outcomes and higher-order aberrations between specific wavefront-guided and wavefront-optimized lasers used in photorefractive keratectomy. Wavefront-guided laser ablations utilize preoperative wavefront aberrometer data to treat higher-order and lower-order aberrations. These data are strictly relied upon for the final treatment pattern. In contrast, wavefront-optimized laser ablations utilize preoperative refraction data for the treatment pattern. Wavefront-optimized platforms deliver more laser pulses to the periphery, which maintains the prolate structure of the cornea, and thereby minimizes higher-order aberrations.

Based on our most recent literature search using the PubMed keywords “wavefront”, “wavefront-guided”, “wavefront-optimized”, “photorefractive keratectomy”, “photorefractive keratectomy”, and “higher-order aberration”, there are no known published studies comparing wavefront-guided lasers with wavefront-optimized lasers in patients undergoing photorefractive keratectomy. However, laser in situ keratomileusis (LASIK) studies have compared these two lasers, with some studies suggesting an advantage to wavefront-guided platforms. and others showing no significant difference between the two. In this prospective, randomized, fellow-eye study, we compared the wavefront-guided VISX CustomVue platform (Abbott Medical Optics, Santa Ana, CA) with the wavefront-optimized WaveLight Allegretto platform (Alcon Inc, Hüningen, Switzerland) in the same patient undergoing photorefractive keratectomy, with respect to visual acuity, refractive error, higher-order aberrations, contrast sensitivity, and dry eye.

Methods and materials
This prospective, single-masked, randomized, fellow-eye study evaluated and compared the outcomes of photorefractive keratectomy performed in 23 patients (46 eyes) using the VISX CustomVue laser system and the WaveLight Allegretto laser system. Patients were recruited and enrolled at the John A Moran Eye Center, Department of Ophthalmology and Visual Science, University of Utah, between November 2010 and July 2011. All patients were older than 21 years.

The University of Utah Hospital institutional review board approved the research protocol in accordance with the tenets of the Declaration of Helsinki. All patients provided informed consent after they received an explanation of the procedure, including all risks and benefits. All patients had a preoperative discussion of relevant medical history, including history of herpetic eye disease and family history of keratoconus.

Patients were excluded if they had a history of clinically significant lens opacity, previous corneal or intraocular surgery, thin corneas, keratoconus, unstable refraction, amblyopia, or autoimmune disease, and also if they were pregnant or breastfeeding, or on immunosuppressive therapy. Patients desiring monovision were not included in the study.

Eligible patients were scheduled for bilateral photorefractive keratectomy and correction for distance in both eyes. The patients were randomly assigned (Research Randomizer software, Urbaniak, http:\www.randomizer.org) to treatment in one eye with the WaveLight Allegretto system (wavefront-optimized group), which utilizes the WaveLight® Allegretto 400 Hz Wave® Eye-Q Laser. The fellow eye was assigned treatment with the VISX CustomVue™ STAR S4 IR™ Excimer Laser with ActiveTrack™ iris registration (wavefront-guided group).

Soft contact lenses were discontinued 2 weeks before screening and rigid gas-permeable contact lenses were discontinued 6 weeks before screening. All patients had a preoperative examination including manifest refraction and cycloplegic refraction, uncorrected distance visual acuity, corrected distance visual acuity, tonometry, slit lamp examination, and dilated fundus evaluation. Corneal topography and thickness were measured using the Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany) and Humphrey Atlas (Carl Zeiss Meditec Inc, Jena, Germany) systems. Pupil size was measured in the dark using the Colvard pupilimeter (Oasis Medical Inc, Glendora, CA). Contrast sensitivity was performed using the VectorVision CSV-1000 (Dayton, OH) chart in controlled mesopic conditions (70 lux) at 3, 6, 12, and 18 cycles per degree (cpd). Schirmer’s testing evaluation for dry eye was measured in millimeters with topical anesthetic after 5 minutes. Manifest refraction and wavefront...
measurements were repeated on two separate visits to ensure refractive stability.

All eyes received five preoperative wavefront analyses using the VISX CustomVue WaveScan aberrometer v3.62 (Fourier) without pharmacologic intervention, under mesopic conditions, with a minimum pupil diameter of 6.0 mm. The emmetropic correction target was based on manifest refraction, topography, and wavefront analysis for the wavefront-guided group. For the wavefront-optimized group, the emmetropic correction target was based on topography and manifest refraction. Iris registration was obtained for eyes receiving wavefront-guided treatment. A physician-adjustment factor was used based on previously established Moran Laser Center wavefront-guided photorefractive keratectomy nomograms for the laser system used for surgery. The nomograms were generated using Datagraph-med Outcomes Analysis Software for Refractive Surgery (version 3.20a; Ingenieurbüro Pieger GmbH, Wendelstein, Germany).

Prior to laser treatment, ethanol diluted to 20% in sterile water was placed on the cornea in an 8.5 mm Camellin-style laser epithelial keratomileusis (LASEK) alcohol fixation well (Katena Products Inc, Denville, NJ) for 35 seconds. Epithelial removal was performed with a Sloane LASEK epithelial micro hoe (Katena Products Inc). For stromal ablation, a bandage contact lens (Softlens Plano T, Bausch and Lomb, Rochester, NY) was placed. All surgeries were performed by MM and MDM.

Postoperatively, one drop of gatifloxacin 0.3% (Allergan Inc, Irvine, CA), prednisolone acetate 1.0% (Allergan Inc), and ketorolac tromethamine 0.4% (Allergan Inc) was instilled. Ktorolac tromethamine 0.4% was administered four times a day for the first 72 hours and then discontinued. Gatifloxacin 0.3% and prednisolone acetate were continued four times a day for 1 week with a subsequent steroid taper over 2–3 months. Bandage contact lenses were removed upon complete epithelial healing, typically 3–5 days after surgery.

Data were collected at 1 day, 1 week, and 1 and 3 months after surgery. Uncorrected and corrected distance visual acuity were both recorded in Snellen notation and logarithm of the minimum angle of resolution (logMAR) format. Contrast sensitivity and Schirmer’s testing were performed. Higher-order aberrations, including root mean square of total higher-order aberration, coma Z(3,1), trefoil Z(3,3), and spherical aberration Z(4,0) were measured using the WaveScan aberrometer. Undiluted scans of both eyes were taken at 3 months postoperatively regardless of the wavefront platform used for treatment. The Quality of Life Impact of Refractive Correction (QIRC) survey instrument was used to record subjective outcomes, as previously described.

**Statistical analysis**

After the study was completed, the results were compiled and the data were unmasked for statistical analysis. Manifest refraction, refractive error, visual acuity, contrast sensitivity, higher-order aberation values for coma, trefoil, and sphere, and root mean square of higher-order aberration wavefront values were treated as continuous variables and analyzed for statistical significance using the Student’s t-test. A P value of 0.05 was considered statistically significant. Data analysis was performed using Microsoft Excel (Microsoft Corp, Redmond, WA).

**Results**

Twenty-three patients (46 eyes) with 3 months of follow-up were evaluated in this study. The study population consisted of 18 men and five women of mean age 31.4 ± 5.8 years, with no significant differences in preoperative corrected distance visual acuity and refraction (Table 1).

**Visual acuity**

Uncorrected and corrected distance visual acuity was not statistically different between the groups at 1 or 3 months (Table 2). At 3 months postoperatively, 20/15 uncorrected distance visual acuity was achieved in 35% of wavefront-optimized eyes and 64% of wavefront-guided eyes, and 20/20 uncorrected distance visual acuity was achieved by 87% and 91% of the eyes in both groups, respectively (Table 3).

**Safety, efficacy, and predictability**

At 3 months, 16 of 23 eyes (70%) in both groups maintained equal corrected distance visual acuity. Five eyes (22%) in the wavefront-optimized group and six eyes (26%) in the wavefront-guided group gained one line of corrected distance visual acuity. One eye in the wavefront-optimized group lost two lines. In each group, one eye lost one line of corrected distance visual acuity. In the wavefront-optimized group, the loss of vision was from residual astigmatism due to a central island. In the wavefront-guided group, the loss was due to irregular corneal epithelium secondary to superficial punctate keratopathy. No other eyes in the study population lost any lines of corrected distance visual acuity (P = 1.000, Table 3).
At 1 month, 20 eyes (87%) in the wavefront-optimized and 21 eyes (91%) in the wavefront-guided group were within ±0.50 diopters (D) of emmetropia. In addition, 16 eyes (70%) and 17 eyes (74%), respectively, were within ±0.25 D of emmetropia (P = 0.775). At 3 months, 20 eyes (87%) in the wavefront-optimized and 15 eyes (65%) in the wavefront-guided group were within ±0.50 D of emmetropia; 17 (74%) and 15 (65%), respectively, were within ±0.25 D (P = 1.000).

**Schirmer’s testing**

The preoperative average Schirmer’s test value for the wavefront-optimized group was 16.4 ± 9.43 mm and 15.9 ± 8.02 mm for the wavefront-guided group. At 1 month, the values were 16.2 ± 9.75 mm and 15.8 ± 8.38 mm for the wavefront-optimized and wavefront-guided groups, respectively. The 3-month postoperative values were 15.4 ± 8.89 mm for the wavefront-optimized and 15.7 ± 8.43 mm for the wavefront-guided group. There were no significant changes in Schirmer’s testing data between both groups before or after surgery (P ≥ 0.591).

**Contrast sensitivity**

There were no significant changes in wavefront-optimized contrast sensitivity (P ≥ 0.137). The wavefront-guided group showed a significant increase in contrast sensitivity at 12 cpd following surgery (P = 0.013), but no significant changes at 3 (P = 0.909), 6 (P = 0.458), or 18 cpd (P = 0.131, Figure 1).

**Higher-order aberrations**

Three months following surgical correction, 87% of patients in each group completed Custom WaveScan analysis. In

### Table 1 Preoperative group comparisons

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Platform</th>
<th>Allegretto (n = 23)</th>
<th>VISX (n = 23)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>31.4 ± 5.80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male/female</td>
<td></td>
<td>18/5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean logMAR CDVA</td>
<td></td>
<td>−0.06 ± 0.06 (−0.125 to 0.097)</td>
<td>−0.07 ± 0.06 (−0.125 to 0)</td>
<td>0.162</td>
</tr>
<tr>
<td>CDVA (20/x)</td>
<td></td>
<td>17.8 ± 2.95 (15 to 25)</td>
<td>17.2 ± 2.53 (15 to 20)</td>
<td>0.082</td>
</tr>
<tr>
<td>Spherical equivalent (D)</td>
<td></td>
<td>−3.26 ± 1.82 (−8.5 to 1.5)</td>
<td>−3.34 ± 1.75 (−8.5 to 1)</td>
<td>0.646</td>
</tr>
<tr>
<td>Sphere (D)</td>
<td></td>
<td>−3.49 ± 1.81 (−8.75 to 1.25)</td>
<td>−3.58 ± 1.76 (−8.75 to 2)</td>
<td>0.589</td>
</tr>
<tr>
<td>Cyclinder (D)</td>
<td></td>
<td>0.47 ± 0.35 (0 to 2.75)</td>
<td>0.48 ± 0.29 (0 to 1.25)</td>
<td>0.665</td>
</tr>
</tbody>
</table>

**Notes:** Values represented as mean standard deviation (range); *Student t test.

**Abbreviations:** UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; logMAR, logarithm of the minimum angle of resolution.

### Table 2 One month and 3-month visual acuity comparisons

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Postoperative month 1</th>
<th>Postoperative month 3</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDVA (LogMAR)</td>
<td>0.01 ± 0.15 (−0.301 to 0.176)</td>
<td>−0.03 ± 0.07 (−0.125 to 0.097)</td>
<td>0.743</td>
</tr>
<tr>
<td>UDVA (20/x)</td>
<td>22.6 ± 10.2 (10 to 60)</td>
<td>18.9 ± 3.36 (15 to 30)</td>
<td>0.186</td>
</tr>
<tr>
<td>CDVA (logMAR)</td>
<td>−0.10 ± 0.08 (−0.301 to 0.176)</td>
<td>−0.08 ± 0.07 (−0.125 to 0.097)</td>
<td>0.085</td>
</tr>
<tr>
<td>CDVA (20/x)</td>
<td>17.8 ± 4.96 (10 to 30)</td>
<td>16.3 ± 2.24 (15 to 20)</td>
<td>1.000</td>
</tr>
<tr>
<td>Spherical equivalent (D)</td>
<td>0.15 ± 0.43 (−0.5 to 1.5)</td>
<td>0.16 ± 0.28 (−0.375 to 0.625)</td>
<td>0.276</td>
</tr>
<tr>
<td>Sphere (D)</td>
<td>−0.02 ± 0.43 (−0.375 to 1.25)</td>
<td>0.00 ± 0.31 (−0.75 to 0.5)</td>
<td>0.714</td>
</tr>
<tr>
<td>Cyclinder (D)</td>
<td>0.34 ± 0.31 (0 to 1)</td>
<td>0.33 ± 0.27 (0 to 0.75)</td>
<td>0.732</td>
</tr>
</tbody>
</table>

**Notes:** Values represented as mean standard deviation (range); *Student t test.

**Abbreviations:** UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; logMAR, logarithm of the minimum angle of resolution.
the wavefront-optimized group, root mean square of total higher-order aberration ($P = 0.091$), coma ($P = 0.115$), and trefoil ($P = 0.459$) all showed an increasing trend 3 months postoperatively, with a statistically significant two-fold increase in spherical aberration ($P = 0.014$, Figure 2). In the wavefront-guided group, spherical aberration had a significant three-fold ($P = 0.014$) increase while root mean square of total higher-order aberration ($P = 0.113$), coma ($P = 0.403$), and trefoil ($P = 0.603$) increased, but without statistical significance (Figure 3). Although spherical aberration showed a statistically significant increase in both groups, there was no significant difference when comparing this change between the wavefront-guided and wavefront-optimized platforms ($P \geq 0.320$).

Quality of life
Mean QIRC values were obtained preoperatively and 3 months postoperatively (Figure 4). Postoperative mean QIRC increased by 31% over the preoperative mean QIRC ($P < 0.001$).

Complications
No intraoperative complications occurred in the study population. Observed complications included superficial punctate keratopathy leading to loss of one line of corrected distance visual acuity for a patient in the wavefront-guided group, and a central island leading to residual astigmatism and loss of one line of corrected distance visual acuity for a patient in the wavefront-optimized group.

![Figure 1](https://www.dovepress.com/)

**Figure 1** Comparison of contrast sensitivity between Allegretto and VisX laser platforms at 3, 6, 12, and 18 cycles per degree (cpd) preoperatively ($n = 21$) and at 3 months postoperatively ($n = 21$) using the Vectorvision CSV-1000E chart.

Note: *statistically significant ($P = 0.013$).
Discussion

There are numerous studies comparing wavefront-optimized and wavefront-guided platforms in LASIK, which have generally shown a lack of reproducible evidence favoring one platform over the other. To the best of our knowledge, this is the first reported study comparing these platforms in photorefractive keratectomy. The findings of our prospective, randomized, fellow-eye study support previous research that the VISX CustomVue wavefront-guided and the WaveLight Allegretto wavefront-optimized platforms are both effective and predictable in photorefractive keratectomy. Falavarjani et al showed that the wavefront-optimized Allegretto platform and a topography-guided platform had similar statistical outcomes. Bababeygy and Manche observed that the VISX CustomVue platform used in photorefractive keratectomy was both safe and effective for low-to-moderate and high myopia, as well as compound myopic astigmatism. In our study, there were no statistically significant differences in outcomes of uncorrected distance visual acuity, corrected distance visual acuity, root mean square of total higher-order aberration, or dry eye at 3 months postoperatively.

Our data showed a statistically significant increase in spherical aberration in both study platforms. However, when comparing the change induced by the wavefront-guided...
platform with the wavefront-optimized platform, there was no statistically significant difference. There was a nonstatistically significant increasing trend in all other higher-order aberration measures in both groups. Moshirfar et al also observed a trend similar to our results in their wavefront-guided photorefractive keratectomy vs LASIK study, showing postoperative increases in root mean square total higher-order aberration, coma, and spherical aberration for photorefractive keratectomy patients at 6 months. However, they also showed fewer induced higher-order aberrations in the photorefractive keratectomy group when compared with the LASIK group. Randleman et al compared wavefront-optimized photorefractive keratectomy and 3-month LASIK outcomes using the Allegretto platform, and, in contrast with our study, showed no significant induction of higher-order aberrations.16

The study showed a small statistically significant advantage exclusively at 12 cpd of contrast sensitivity for the VISX CustomVue platform. This supports other research, because Awwad et al compared two wavefront-guided platforms (VISX CustomVue and Alcon CustomCornea) in LASIK surgery, and reported statistically significant improvement in contrast sensitivity for both platforms.27 Although we are unsure of the reason for this improvement in contrast sensitivity in the wavefront-guided group, we speculate that it may be a benefit of the custom ablation pattern. Further follow-up is needed to determine if this outcome will be sustained.

For quality of life measures, we observed significant increases in ratings postoperatively. Because the QIRC does not separate ratings based on right eye outcomes and left eye outcomes, we were unable to compare VISX CustomVue with Allegretto WaveLight. However, Yu et al showed no significant difference in objective measurements on the QIRC questionnaire when comparing wavefront-guided with wavefront-optimized LASIK.28 We also administered a separate subjective survey; however, due to limited data, we were not able to derive conclusions from these data. Brief subjective surveys after LASIK have allowed for conclusions in previous literature,29 and we believe our 10-item survey instrument would benefit from a larger sample size.

Our study showed that one eye lost one line of corrected distance visual acuity in each of the study groups. The patient in the wavefront-optimized group was found to have residual astigmatism due to a central island. In the wavefront-guided group, the loss was determined to be due to irregular corneal epithelium secondary to superficial punctate keratopathy. Both patients have been treated with ocular lubricating agents and will be re-evaluated postoperatively at 6 months.

Limitations of the study include a small sample size and short-term follow-up. It is well known that final refractive and visual acuity outcomes in photorefractive keratectomy can take beyond 3 months to become established, although results are typically permanent and finalized at 6-month follow-up.30,31 Serrao et al recently concluded in their 6-year follow-up study that the higher-order aberrations after traditional photorefractive keratectomy stabilized after 1 year for myopia up to −9.00 D.32 Similarly, long-term analysis of wavefront photorefractive keratectomy can provide more information on stability of induced higher-order aberrations, which we hope to obtain in the future.

A potential limitation in comparing the VISX wavefront-guided platform with the Allegretto wavefront-optimized platform is the use of the VISX CustomVue WaveScan aberrometer to determine higher-order aberrations for both platforms. The WaveScan aberrometer is specifically designed for the STAR S4 platform. One may argue that the aberrometer (WaveLight® Analyzer, Alcon Inc) made for use with the Allegretto platform may have shown different results. However, use of a single aberrometer platform to compare various wavefront platforms has been documented in the literature.18,21 A final possible limitation is the exclusive use of Schirmer’s testing in our study to measure dry eye symptoms. Tear film stability, measured via dry eye symptoms and tear break-up time, may have enhanced our analysis on the impact of photorefractive keratectomy on the patients’ eyes.

In conclusion, there were no significant differences in visual acuity, refractive error, or dry eye between the wavefront-guided VISX CustomVue STAR S4 IR Excimer Laser with ActiveTrack iris registration and the
wavefront-optimized WaveLight Allegretto Wave Eye-Q Laser for photorefractive keratectomy. While not statistically significant, a greater percentage of patients in the wavefront-guided group achieved 20/15 uncorrected distance visual acuity. VISX CustomVue showed improved contrast sensitivity at 12 cpd. Both platforms induced spherical aberration after photorefractive keratectomy surgery at 3-month follow-up, and other higher-order aberration values had a tendency to increase as well. However, we observed no statistically significant difference between the changes in spherical aberration when comparing the two platforms. We feel that both lasers are equally effective in treating refractive errors in photorefractive keratectomy.

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Disclosure
The authors have no financial interests in any materials or products discussed in the manuscript or any other conflicts of interest to report in this work.

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