

Refractive Surgery Outcomes Comparison—All Wavefront-guided Versus a Decision Tree for Selecting Wavefront-guided or Wavefront-optimized

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Abstract

The purpose of this article is to compare refractive outcomes based on all wavefront-guided procedures versus a decision tree designed to assist with the selection of wavefront-guided or wavefront-optimized procedures. The setting was the The Laser Center, Greensboro. Twenty subjects were treated with a VISX CustomVue™ wavefront-guided refractive procedure in one eye and a WaveLight Allegretto procedure (wavefront-guided or optimized) in the contralateral eye. A decision tree was used to decide whether a wavefront-guided or wavefront-optimized procedure would be performed with the WaveLight system. The CustomVue eye was chosen at random. Visual acuity and refractive error were recorded pre-operatively and post-operatively. Subjective post-operative data included patient reported eye preference and post-operative glare and halos. The results were that one subject was lost to follow-up, leaving 19 subjects for analysis at three months. Of those subjects with data, 12 received wavefront-optimized treatment while seven subjects received a wavefront-guided treatment with the WaveLight laser. There were no significant differences in uncorrected visual acuity between the VISX and WaveLight groups at the one-day or six-month visits. At three months, 56 % of patients indicated no preference, with the remaining 44 % indicating a preference for the WaveLight-treated eye ($p < 0.05$). The patient reported outcomes showed a similar incidence of post-operative glare and halos reported between the two treatments. Results with the Allegretto Wave Eye-Q laser, using a decision tree to determine whether a wavefront-optimized or a wavefront-guided treatment would be performed, were equivalent to those achieved with the VISX Star S4 wavefront-guided procedure.

Keywords

Refractive surgery, laser in situ keratomileusis, wavefront-guided, wavefront-optimized, higher-order aberrations

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It has been almost 10 years since the first wavefront-guided laser refractive surgery procedure was approved in the US.¹ A number of laser systems now include the capability for wavefront-guided procedures. While clinical results have generally been equivalent or superior to conventional refractive surgery, the ability to correct measured higher-order aberrations (HOAs) has not been consistently demonstrated, particularly those aberrations of the fifth order and higher.² In most instances, HOAs are seen to increase post-surgery, though the increase in aberrations is generally lower than for conventional surgery. The aberration that shows the greatest difference in pre- and post-operative magnitude between conventional and wavefront-guided surgery is spherical aberration, primarily the result of a significant increase in spherical aberration with conventional surgery.³ Recognizing that the ability to measure HOAs appeared to exceed the ability to actually treat them, an alternative approach

was investigated. The aim was to reduce the potential induction of aberrations by the surgical procedure. A mathematical analysis of conventional ablation patterns showed that significant induction of spherical aberration could be expected, consistent with the clinical results of conventional surgery. A compensation algorithm was designed to reduce the induction of spherical aberration, resulting in what is now termed a wavefront-optimized ablation profile.⁴ As this modification of the ablation profile depended only on the intended spherocylindrical refraction, no wavefront measurement was required to perform the surgery. The wavefront-optimized profile is less sensitive to relative positioning errors—a wavefront-guided treatment must be precisely centered and rotationally aligned to match the measured wavefront to the intended treatment if any beneficial effect is to be realized.⁵ The study conducted to obtain the US Food and Drug Administration (FDA) label for wavefront-optimized

treatment showed that the visual acuity, contrast sensitivity and preoperative to post-operative aberration changes were similar between a wavefront-guided ablation profile and a wavefront-optimized ablation profile.⁶ The exception to this was in the case where measured pre-operative HOAs exceeded 0.3 μ root mean square (RMS). At that point, the wavefront-guided procedure appeared to provide a better surgical outcome. It is worth noting that only 17 % of the eyes in the study had pre-operative HOA magnitudes $\geq 0.3 \mu$ RMS.

The following study was designed to determine if a decision tree based on the criterion above would provide clinical results similar to those achieved by treating all patients with a wavefront-guided procedure.

Methods

This study was designed to compare results obtained using an excimer laser with wavefront-guided capability to a laser with both wavefront-optimized and wavefront-guided capability. The wavefront-guided system was a VISX Star S4 (Abbott Medical Optics Inc., Santa Ana, CA) with a WaveScan aberrometer (based on Shack-Hartmann principles). The wavefront-optimized/wavefront-guided system was a WaveLight Allegretto Wave Eye-Q laser (Alcon Laboratories, Inc., Fort Worth, TX) with a WaveLight Analyzer aberrometer (based on Tscherning principles). All subjects were prophylactically treated with a corticosteroid and a fluoroquinolone antibiotic four times daily for three days prior to surgery.

For the WaveLight system, a decision tree was developed to minimize the number of patients on whom a wavefront measurement would be required, and limit the number of patients with measured wavefronts who would undergo a wavefront-guided procedure. The primary driver for choosing wavefront-guided versus wavefront-optimized treatment was good pre-operative visual acuity, good night vision and good self-reported visual quality. All of these three were unlikely to be true if high pre-operative aberrations were present. If any of these conditions were not met a wavefront measurement was made, if possible. If total HOA RMS was $>0.3 \mu$ then a wavefront-guided procedure was performed. Otherwise a wavefront-optimized procedure was performed, or a topography-guided treatment if topography was atypical and a wavefront could not be measured. This decision tree is shown in *Figure 1*.

Institutional review board approval was applied for and obtained. A total of 20 subjects were planned for this study, all with normal eyes except for refractive error. Subjects served as their own controls so age and gender were the same between groups while refractive error was expected to be similar between groups. Eyes were randomly assigned to treatment for each subject with one eye receiving CustomVue wavefront-guided surgery and the contralateral eye receiving WaveLight surgery, either wavefront-guided or wavefront-optimized, as the decision tree indicated. A maximum of 12 eyes were enrolled in the wavefront-optimized group, so that a sufficient 'n' for analysis was obtained in the WaveLight wavefront-guided group.

Measures of interest were refractive error and uncorrected visual acuity. Subjects were also asked which eye they preferred, and were given a subjective questionnaire to fill out related to glare, halos, and other visual disturbances. Comparisons between groups were made

Figure 1: Decision Tree to Select Wavefront-optimized or Wavefront-guided Treatment

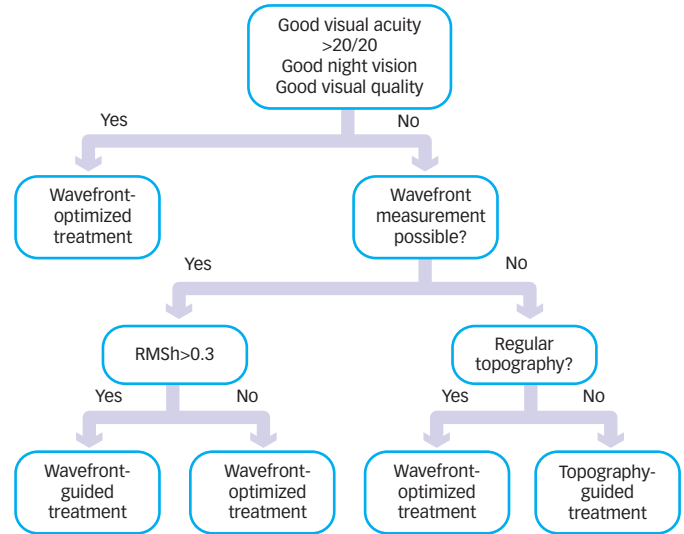


Table 1: Summary of Refractive Data over Time

	Pre-operative	One month	Three months	Six months
Visx	-4.44 D	-0.13 D	-0.12 D	-0.17 D
Range	(-6.75 to -1.00)	(-0.75 to 0.25)	(-0.50 to 0.50)	(-0.75 to 0.25)
Wavelight	-4.44 D	0.09 D	0.15 D	0.12 D
(Range)	(-6.75 to -1.00)	(-1.00 to 0.63)	(-0.50 to 0.75)	(-0.25 to 0.50)
Visx	-0.42 D	-0.03 D	-0.01 D	0.00 D
Range	(-2.50 to 0.00)	(-0.25 to 0.00)	(-0.25 to 0.00)	(0.00 to 0.00)
Wavelight	-0.44 D	-0.02 D	0.00 D	0.0 D
(Range)	(-2.50 to 0.00)	(-0.25 to 0.00)	(0.00 to 0.00)	(0.00 to 0.00)

using paired t-tests for parametric variables or analysis of variance if the three conditions were tested independently (wavefront-guided VISX, wavefront-guided WaveLight, wavefront-optimized WaveLight). In the case of non-parametric data a Wilcoxon matched pairs test was used. All tests were considered significant at $p<0.05$.

Results

Twenty subjects were recruited and treated in a four-month period. Surgery was performed using a superior hinge and an optical zone between 6.0 and 6.7 mm with flap creation using a femtosecond laser (IntraLase FS Laser, Abbott Medical Optics Inc., Santa Ana, CA). All surgeries were performed by one surgeon (KGS) and were uneventful. One subject was lost to follow-up at one week, leaving 19 subjects for analysis. Two additional subjects did not complete their six-month visit. Of those subjects with data, 12 received wavefront-optimized treatment while seven subjects received a wavefront-guided treatment with the WaveLight laser. All WaveLight wavefront-guided eyes had HOAs $>0.3 \mu$ RMS.

Average pre-operative sphere and cylinder were not significantly different between the VISX and WaveLight eyes ($p >0.9$). The maximum sphere treated was -6.75 D with a maximum cylinder of -2.50 D. *Table 1* shows the average refractive error (sphere, cylinder and the MRSE,

Figure 2: Uncorrected Vision on Post-operative Day 1

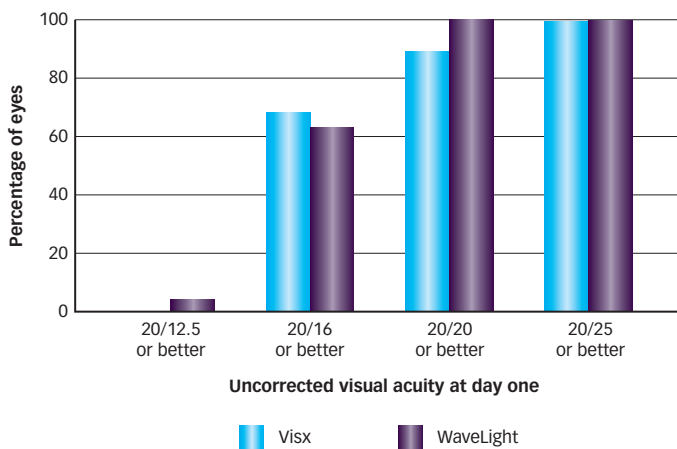
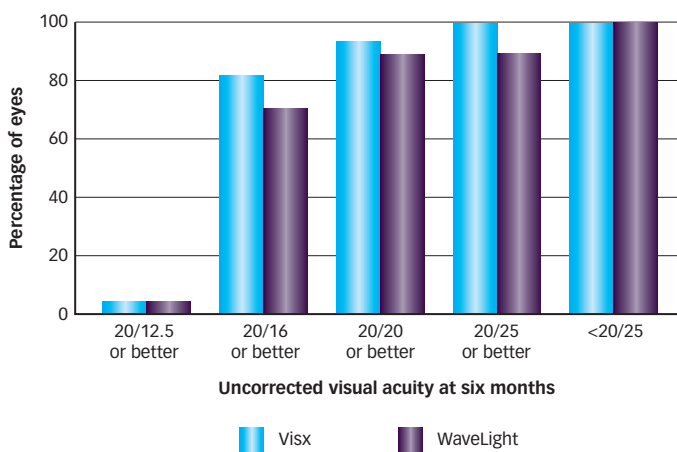


Figure 3: Uncorrected Visual Acuity at Six Months



the mean refraction spherical equivalent [MRSE]) results over time (pre-operative to six months post-operative). Post-operative refractive error was statistically significantly different ($p < 0.05$), but not clinically significant. The VISX-treated eyes had a mean spherical equivalent refraction of about -0.10 D while the WaveLight eyes had a mean spherical equivalent refraction around $+0.10$ D.

Figure 2 shows the percentage of eyes achieving a given level of uncorrected visual acuity one day after surgery. Two out of three eyes in both the VISX and Wavelight groups had 20/16 or better visual acuity on the day after surgery. There was no statistically significant difference between treatment groups at this time point. Figure 3 shows the percentage of eyes achieving a given level of uncorrected visual acuity at the six-month visit. Again, there was no statistically significant difference between treatments. More than two-thirds of subjects in each treatment group achieved an uncorrected visual acuity 20/16 or better. At six months, 15 of 17 subjects in each group had an uncorrected visual acuity better than, or equal to, their pre-operative best corrected acuity.

Subjects were questioned about their preference for one eye or the other at all post-operative visits. At one day post-operative, 57 % of subjects indicated no preference, with 21 % preferring the Wavelight eye

and 22 % preferring the VISX-treated eye. This was not significant ($p > 0.9$). At three months, 56 % of patients indicated no preference, with the remaining 44 % indicating a preference for the WaveLight-treated eye, a statistically significant difference (chi square test, $p < 0.05$).

The patient reported outcomes showed a similar incidence of post-operative glare and halos reported between the two treatments. The incidence and severity of glare and halos were reported to be higher than pre-operative levels in the early post-operative period but similar to, or lower than, pre-operative levels at the three-month and later visits, though differences were not statistically significant. The clarity of each eye at night was also reported as better at three months, but again the difference was not statistically significant.

Discussion

The results here demonstrate that a decision tree to select between a wavefront-guided or wavefront-optimized treatment algorithm for laser refractive surgery produces results that are equivalent to those achieved on an all wavefront-guided platform. On the first day post-operative, the 'wow' factor was achieved in both cases, with two of three eyes in either treatment groups achieving an uncorrected visual acuity of 20/16 or better.

The equivalence of clinical results allows surgeons to take advantage of the benefits of wavefront-optimized surgery. Of greatest benefit, perhaps, is that a high percentage of patients will be treated without the need for a wavefront measurement, based on their responses to the answers in the first box of the decision tree. Of the remainder who receive a wavefront measurement a significant percentage will have pre-operative HOAs $\leq 0.3 \mu$ —they will receive a wavefront-optimized treatment. Previous study results suggest that more than 80 % of patients will be suitable for wavefront-optimized treatment. The wavefront-optimized treatment removes any requirements for wavefront measurement and alignment of the measurement at the time of treatment, introducing significant time savings without any apparent compromise in clinical results.

As noted earlier, the WaveLight study submitted to obtain FDA approval for wavefront-optimized surgery showed that when pre-operative HOAs are high (e.g., > 0.35), wavefront-guided surgery provides a slightly better result. In some sense, this is a measure of the ability to correct pre-operative HOAs with wavefront-guided surgery. When HOAs are lower than 0.3μ RMS the noise in the wavefront-guided treatment, perhaps from centration or rotational alignment errors and measurement repeatability, is of a magnitude that makes a reduction in overall HOAs unlikely. When HOAs are higher than 0.3μ RMS, the noise is a smaller relative factor, and real reductions in pre-operative HOAs can be achieved. Conversely, because the wavefront-optimized treatment is designed to prevent the induction of HOAs, high levels of pre-operative aberrations will remain after surgery—no attempt is made to treat them.

There have been a number of other studies comparing refractive surgery results between wavefront-guided and wavefront-optimized procedures. Perez-Straziota et al. reported no significant differences in visual performance or HOAs between a wavefront-guided and a wavefront-optimized treatment group.⁷ An interesting observation by those authors was that 14 eyes scheduled for wavefront-guided treatment were treated with a wavefront-optimized procedure due

to wavefront measurement issues. This may be an advantage of wavefront-optimized procedures because there is no need for a pre-operative wavefront measurement to calculate the ablation profile.

MirafTAB et al. performed a contralateral study of wavefront-guided versus wavefront-optimized procedures and found an increase in all aberrations except trefoil after surgery, with no statistically significant difference in visual performance and no significant difference in HOAs (pre-operative, post-operative or change) between the two groups.⁸ Padmanabhan et al. performed a similar contralateral eye study. They reported a trend towards slightly better performance of wavefront-guided versus wavefront-optimized surgery but no significant differences were noted in the majority of visual and aberration measures.⁹ An important qualifier was that their wavefront analysis diameter was 7.0 mm and they state that the biggest differences in measurement occurred in the 6.5–7.5 mm zone. This is unlikely to affect patients with smaller pupils.

Yu et al. reported similar results to those above and found patient satisfaction rates equivalent between groups.¹⁰ George et al. reported on an early series of wavefront-optimized procedures relative to wavefront-guided procedures and found lower induction of spherical aberration with the wavefront-optimized procedure.¹¹

The meta-analysis by Fares et al. comparing wavefront-guided to conventional treatment included wavefront-optimized treatments in

the conventional group. There were no significant functional visual differences in the two groups, except when the pre-operative HOAs were high. They concluded that for patients with low RMS values, similar results were achieved with wavefront-guided and conventional/wavefront-optimized treatments.² A recent meta-analysis comparing wavefront-guided and wavefront-optimized laser in situ keratomileusis for myopia also found similar results in terms of efficacy, safety, and predictability with wavefront-guided treatment showing better post-operative aberration profile for patients who have pre-operative RMS HOAs $>0.3 \mu$.¹² These results are consistent with the findings here and provide further support for the decision tree implemented.

It should be noted that with the exception of the FDA trial data,⁶ wavefront-optimized versus wavefront-guided procedures in earlier studies (as in the present study) were often compared using different laser systems. Beam size, repetition rate, ablation pattern, and other system differences, including differences in wavefront measurement (e.g., Tscherning versus Shack-Hartmann principles) may contribute to some of the differences reported.

In summary, the results with the Allegretto Wave Eye-Q laser, using a decision tree to determine whether a wavefront-optimized or a wavefront-guided treatment would be performed, were equivalent to those achieved with the Visx Star S4 wavefront-guided procedure. ■

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