Wavefront-Optimized LASIK in High Myopic Patients-Retrospective Analyses

ADNAN EL-MARZOUKI, F.R.C.S.
The Department of Ophthalmology, Faculty of Medicine, King Abdel Aziz University, Saudi Arabia

Abstract

Purpose: To follow-up the visual and refractive outcomes of laser in situ keratomileusis (LASIK) to correct high myopia using Wavelight Allegretto Wave since 2001.

Setting: Eye Care Private Center, Jeddah, Saudi Arabia.

Methods: This retrospective study comprised 112 eyes of 65 high myopic patients having spherical refraction –8 diopters (D) or more, treated with LASIK Wavelight Allegretto Wave. Eyes were analyzed preoperatively and 1, 3, and 12 months postoperatively. Analyses were done on retrieved data from patient files.

Results: The mean patient age was 29.75 ± 7.31 years. Gender 42 Female: 23 Male. Seventy two eyes were evaluated at 3 months, 85 eyes at 6 months and 81 eyes at 12 months. All eyes have not been retreated during the study. The mean manifest refraction spherical equivalent MRSE was –8.67 ± 2.54 D preoperatively and –0.54 ± 0.64 D for 3 months, –0.64 ± 0.73 D for 6 months, and –0.7 ± 0.82 for 12 months postoperatively.

Eyes were distributed as 16 eyes, 35 eyes and 61 eyes to optical zones of 5.5mm, 6mm and 6.5mm respectively. Postoperatively 70 (62.5%) and 89 (79.46%) eyes were within ± 0.50D and ± 1.00D respectively of the intended correction. After 12 months follow-up 56 (50%) and 80 (71.43%) eyes remained within ±1.00D and ±0.50D respectively. The 6.5mm had achieved 44 (72.13%) and 57 (93.44%) eyes within ±1.00D and ±0.50D respectively after the 12 months. The 6.5mm was the highest efficacy and sustainability.

No records of postoperative ectasia or adverse events had been encountered.

Conclusion: Wavefront-Optimized technology might provide sustained efficacy in high myopic patients. The 6.5mm OZ had shown less regression and higher efficacy.

Key Words: Lasik – Wavelight Allegretto Wave – High myopic patients.

Correspondence to: Dr. Adnan El-Marzouki, The Department of Ophthalmology, Faculty of Medicine, King Abdel Aziz University, Saudi Arabia.

Introduction

IN 2003 LASIK Wavelight Allegretto Wave got the US FDA approval to be marketed in US [1-3]. The ALLEGRETTO WAVE Laser System consists of a combination of features including several internal energy control mechanisms and external test procedures to provide the right energy and fluence per laser pulse. The fast Eyetracker for determining eye position and a precise scanner motor for positioning the laser spot enable precise placement of every laser spot even when the eye is moving or having saccades. In addition, the Eyetracker offers an automatic centration of the ablation to avoid unintended decentration of the correction zone. The Gaussian shaped energy distribution within the laser beam and a small ablation spot of approximately 1mm assure the desired contour precision and high surface smoothness of the newly shaped corneal curvature [2].

Due to the small spot diameter used in the ALLEGRETTO WAVE, the excimer laser beam source is compact with low laser gas volume and minimal laser gas consumption.

During the treatment thousands of laser pulses have to be delivered to the cornea in a complex pattern. As the excimer laser is operated with a high repetition rate of 200 pulses per second, treatment times are short [2,3].

This new technology is thought to have the potential to provide better postoperative quality of vision in patients, especially in contrast sensitive conditions such as scotopic and mesopic vision, than older conventional excimer laser technology or wavefront-guided technologies? With the technological discovery of wavefront-optimized technology, ophthalmologists were able to quantify and potentially treat ocular higher order aberrations (HOAs) by excimer laser surgery [4]. Hence, the
The concept of wavefront-optimized ablation should improve the image and quality of the eye, improving patients' visual acuity, as can be observed with adaptive optics [9].

The experience of Wavelight with wavefront-optimized technology is relatively long in my private clinic in Saudi Arabia, compared to other countries where its use had been started in our center since 2000.

Patients and Methods

Study Design:
This retrospective single-surgeon study examined 112 eyes of 65 patients who were treated with LASIK Wavelight Allegretto Wave excimer laser.

Enrollment Criteria:
A group of patients with high myopia was retrospectively selected from a large group of myopic eyes consecutively treated with the wavefront-optimized platform. The inclusion criterion for patient selection was high myopic patients with spherical refraction more than –8 diopter. Patient underwent retreatment are excluded from this analysis.

Clinical outcome measures and follow-up:
In addition to general medical and ophthalmic histories and examination, preoperative measures included manifest refraction, Cylinder change, visual acuity, cycloplegic refraction, topography, pachymetry, pupil measurement and adverse events, the optical zone was set to the following values 5.5, 6 or 6.5.

The laser operated at a 200kHz treatment rate with fast correction rate 4 seconds per diopter. The spot size was 0.68mm (FWHM), with Gaussian beam profile. The Wavefront-optimized excimer laser treatment with the Wavefront OptimizedTM refractive treatments (WaveLight Standard) [6].

Postoperatively, patients were instructed to instill gatifloxacin 4 times daily for 4 days and prednisolone acetate 1% 4 times daily for 7 days. Postoperative follow-up examinations were at 1 day, 1 week, and 1, 3 and 12 months. The 1-, 3- and 12-month data are presented here [7].

Regularly the clinic is calling patients to remind them with their follow-up visits. This is mainly done after 6 and 12 months.

Statistical analysis:
Statistical package used was NCSS 7.1.8 version released April 2008 running on Widows Vista.

Statistical significance was calculated using the Student t-Test (p<.05). Data are expressed as means ± standard deviation. Ranges are expressed in 95% confidence interval C.I. Correlations were calculated using linear regression model. Visual acuity is measured using decimal scale.

Results

One hundred and twelve patients had been included in this retrospective analysis. 72 eyes were evaluated at 3 months, 85 eyes at 6 months and 81 eyes at 12 months. Patients received reminder calls to maintain high follow-up frequency. The mean patient age was 29.75 ± 7.31 yeas. Gender 42 Female: 23 Male. The baseline preoperative pachymetry was 552.52 ± 35.35 µm. Table 1 describes the optical variables pre-and post-operatively.

Predictability:
Twelve months postoperatively, the mean spherical correction in eyes was −0.7 ± 0.82D (95% C.I. range −0.88 to −0.52D) and the mean cylinder was 0.42 ± 0.16D (95% C.I. range 0.38 to 0.48). The mean MRSE was −0.7 ± 0.5 D (95% C.I range −0.88 to −0.52D).

Stability:
The MRSE stability with Wavefront optimized was found in all the included patients. Fig. (1) shows that patients had minimal change in their MRSE over the 12 month follow-up. Fig. (2) describes the stability of patients visual acuity.

Efficacy:
(Fig. 1 and Table 2) show all the results concerning MRSE, visual acuity and cylinder which direct indicators for efficacy. The impact of optical zone on efficacy is illustrated in (Table 2). The 6.5mm optical zone had shown greater efficacy and sustainability.

Safety:
All patients had clear records with no adverse event post-operatively or ectasia.

<table>
<thead>
<tr>
<th>Spherical refraction</th>
<th>Visual acuity (decimal scale)</th>
<th>Cylinder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>–8.67±2.54D</td>
<td>–1.23±0.89D</td>
</tr>
<tr>
<td>Postoperative (3 months)</td>
<td>–0.54±0.64D</td>
<td>0.84±0.25</td>
</tr>
<tr>
<td>Postoperative (6 months)</td>
<td>–0.64±0.73D</td>
<td>0.79±0.29</td>
</tr>
<tr>
<td>Postoperative (12 months)</td>
<td>–0.70±0.82D</td>
<td>0.72±0.28</td>
</tr>
</tbody>
</table>

Table (1): Summary of optical variables.
The efficacy using Wavefront-optimized technology with optical zones ranging 2.0 to 8.0mm had been proven in several clinical studies. The experience in this registry is important since all patients are below –8D myopic patients [1-6].

Patients had improved in terms of sustained spherical refraction, cylinder and visual acuity outcomes. This confirms findings of Stonecipher, et al. and other findings for the Wavefront-optimized technology [8].

This study represents my experience with Wavefront optimized technology comparing the efficacy and sustainability of different optical zones mainly 5.5mm, 6mm and 6.5mm in patients undergoing LASIK for first time and excluding the retreatment.

**Visual outcomes:**

Previous studies of LASIK (laser refractive surgery) for high myopia found that 46% to 78% of eyes achieved visual acuity of 20/40 (0.5 decimal scale) or better after six months of follow-up. [9-21]. The slightly lower postoperative BSCVA in this current study seems to be related to myopic regression and to some extent under correction.

Improvements in the nomograms regarding under correction and myopic regression have lead to a better efficacy after LASIK for high myopia. The overall BSCVA showed good stability during follow-up.

**Late complications:**

Previous studies demonstrated that corneal ectasia usually develops in the first two years after LASIK and identified high myopia, FFKC, low RSB, and multiple enhancements as risk factors for the development of ectasia [22-24]. Accordingly, in our study, I did not detect any case of ectasia over the 12 months follow-up.

**Optical zone:**

During the daily practice it was found that the 6.5mm optical zone is accurate, reliable and regression increases as optical zone gets smaller. My findings confirm that the 6.5mm is more effective and sustainable than smaller optical zones. (Table 2) showed that only 6 eyes had been regressed out of 1.00D after one year follow-up. The percentage patients kept within 1.00D are 83.61% confirms that 6.5mm OZ is more predictable, effective and sustainable. Because of the sample distribution where very few patients undertake optical zone

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Table (2): Number of eyes per each optical zone and their correction values of MRSE.

<table>
<thead>
<tr>
<th>Optical zone</th>
<th>3 Month postoperative number of eyes (%)</th>
<th>One year postoperative number of eyes (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5mm</td>
<td>8 (50%)</td>
<td>6 (37.5%)</td>
</tr>
<tr>
<td>6mm</td>
<td>18 (51.42%)</td>
<td>22 (62.86%)</td>
</tr>
<tr>
<td>6.5mm</td>
<td>44 (72.13%)</td>
<td>57 (93.44%)</td>
</tr>
<tr>
<td>Total (%)</td>
<td>112 (62.5%)</td>
<td>89 (79.46%)</td>
</tr>
</tbody>
</table>

Fig. (1): MRSE Change from 3 months to 12 months postoperative.

Fig. (2): Best corrected visual acuity during 3 and 12 months follow-up.
5.5mm, statistical testing is not feasible to check the probability comparing each optical zone. However the general overall trend is 71.43% of patients are within 1.00D after 12 months follow-up in all optical zones.

This registry had some limitation because of its retrospective nature, where patients might not attend the clinic on time. Other limitation would be the inability to involve patient in more sophisticated examination or testing, however this kind of retrospective registry is providing the real profiling of regular patient coming to our clinics.

Conclusion:

Wavefront-optimized technology might provide sustained efficacy in high myopic patients. The 6.5mm OZ had shown less regression and higher efficacy.

References


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