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*Original Article*

# CLINICAL OUTCOMES OF WAVEFRONT-GUIDED LASIK FOR LOW TO MODERATE MYOPIA: 6-MONTH FOLLOW-UP

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## Abstract

***Purpose:*** *To demonstrate the visual and refractive outcomes of wavefront -guided laser in situ keratomileusis 6 m postoperatively for low to moderate myopia in Assiut, Egypt.* ***Methods:*** *This prospective study took into account 39 eyes of 23 subjects treated with wavefront-guided LASIK who were available for evaluation at 6 months. All participants were subject to preoperative wavefront analysis, which was performed with a Hartmann-Shack aberrometer,* ***VISX WaveScan system.*** *The clinical outcomes of wavefront-guided LASIK were evaluated in terms of in terms of safety, efficacy, predictability, stability, complications, and preoperative and postoperative aberr-ations.* ***Results:*** *Following the 6 month benchmark 13 eyes had no change in best spectacle-corrected visual acuity and 25 gained 1 or more lines. Only one eye lost one line. The safety index was 1.15 and the efficacy index, 1.06.* ***94.9 % of*** *the eyes were within ± 0.50 diopter of emmetropia. Uncorrected visual acuity was 20/20 or better in 28 of the eyes. Supernormal vision (Best corrected visual acuity of 20/10 or better) was achieved in 32 of the eyes. There was a significant increase in Root mean Square, coma and spherical aberrations 6m. postoperatively. Trefoil aberration was significantly decreased. No complications have been observed, such as epithelial ingrowth, diffuse lamellar keratitis, or infection was observed and Trefoil was decreased.* ***Conclusion:*** *Wavefront-guided LASIK provides significant improvement of Best corrected visual acuity, and significant increase in Root mean Square and coma while trefoil was significantly decreased.*

**Keywords:** *Wavefront, LASIK, Myopia, LOAs, HOAs*

## 1. Introduction

Excimer laser refractive surgery is designed to reshape the cornea for refractive error corrections. Laser-assisted in situ kerat-omileusis (LASIK) is the most popular refractive procedure in use [1,2]. It can correct lower-order aberrations (LOAs) such as myopia, hyperopia and astigmat-ism , despite that some patients remained unsatisfied and troubled due to higher-order aberrations (HOAs), including halos, glare, and reduced contrast sensitivity [3]. High-order aberrations include third-order aberrations correspond to horizontal and vertical coma and triangular astigmatism with the base along the x- or y-axis (trefoil). Fourth-order aberrations include spherical aberration, tetrafoil, and secondary astigmatism. Fifth-tenth order aberrations are important only when the pupil is greatly dilated [4]. Root mean square (RMS) is defined as the deviation between the reference wavefront that comes from an ideal optic system and the wavefront that originates from a measured optical system. The unit used for wavefront aberration is microns or fractions of wavelength and is displayed as RMS [4]. Standard refractive procedures themselves are known to induce aberrations, and a significant increase was reported in HOAs after standard LASIK surgery that is correlated with a significant decrease in quality of vision, particularly under scotopic conditions [4]. Approximately, up to 30% of patients suffer from night vision problems such as glare and halos after LASIK [5] Preceding the invention of *Wavefront technology*, standard refractive surgery failed to address treatment for total HOAs of the eye. The development of *Wavefront technology* has provided a resolution to this obstacle. It has been rapidly adopted as a means of improving the quality of vision and possibly achieving perfect vision in every case [6]. Wavefront-guided LASIK aims to correct higher-order aberrations, as well as cases with irregular astigmatism, by preoperative wavefront analysis to determine the individual ablation pattern [7]. The femtosecond Laser may have advantages over the microkeratome in reducing HOA [8]. The basic concept of Wavefront-guided LASIK includes measurement of the wavefront aberrations with a wavefront analyzer as the Hartmann-Shack aberrometer and transfer of the measured wavefront aberrations into an adequate ablation pattern to be performed by a scanning-spot excimer laser [6]. The purpose of this study was to assess the visual and refractive outcomes of wavefront guided LASIK using VISX S4 excimer laser system 6 months postoperatively.

## 2. Patients and Methods

Wavefront-guided LASIK was done for 39 eyes of 23 patients during a period of 12 months in Roaya Vision centre, Assiut, Egypt, and were followed up for at least 6 months. The study included 16 females and 7 males. The mean age of them was 27.0 years ± 5.9 (SD) (range 20 to 45 years). The mean spherical equivalent (SE) refraction was -3.70 ± 1.43 diopters (D) (range -1.50 to -6.62 D) preoperatively.

Exclusion criteria included high myopia of more than -8.00 D, regular astigmatism of 2.0 D or higher, corneas with insufficient thickness for the surgery (less than 500 micron), corneal scars or previous corneal or intraocular surgery. We also excluded all patients with glaucoma, cataract, uveitis or any posterior segment abnormalities.

### 2.1. *Preoperative assessment*

The following examinations were performed preoperatively in all patients: slit lamp examination of the anterior segment, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA) using the decimal display , manifest subjective and objective refractions with the automatic refractor-keratometer (Nidek), cycloplegic subjective and objective refractions with instillation of cyclopentolate hydrochloride 1 %, intraocular pressure check (HaagStriet tonometer), corneal thickness with ultrasound pachymetry (SP-100, Tomey corporation), ophthalmoscopy, and corneal topography (Magellan Mapper, Nidek corporation). Wavefront analysis was done for every patient using the Hartmann-Shack aberrometer, (**VISX WaveScan system,** version 3.62 using Zernike analysis, Santa Clara, CA, USA) [6].

### 2.2. *Wavefront analysis*

**WaveScan WaveFront System** is a diagnostic instrument indicated for the automated measurement, analysis, and recording of refractive errors of the eye: including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher order aberrations through sixth order, as well as, displaying refractive data of the eye to assist in prescribing refractive correction [9]. This aberrometer is a Hartmann-Shack aberrometer that utilizes a diode laser with a wavelength of 780 nm with an automatic fogging, and measures about 180 data points within 6.0 mm pupil (255 points at 7.00 mm pupil). The function of the Hartmann-Shack sensor is to measure the refractive error of the eye by evaluating the deflection of rays emanating from a small beam of light projected onto the retina [1].

### 2.3. *Calculation of the wavefront-guided ablation*

Three readings of each eye were acquired in a low illumination with an undilated pupil. The best acquisition of the three readings that best match the manifest refraction was chosen for treatment. The information from the WaveScan was translated into a treatment plan and transferred into **VISX STAR S4 IR Excimer laser system** where a ***CustomVue treatment*** was performed. The maximum allowed ablation depth was calculated as the total corneal thickness (measured by ultrasonic pachymetry) minus the planned flap thickness (-160 um.) and minus the minimum allowed residual bed thickness of 300 um. The minimum optical zone was set at 6.0 mm, and the ablation zone (transition zone) was 8.0 mm. All eyes were targeted for emmetropia. There was no physician adjustment to the WaveScan refraction [4].

### 2.4. *Surgical technique*

Before starting surgery, The surgeon must confirm that the patient undergoing surgery is the correct patient by stating his name and date of birth and also, the surgeon must ensure that the refraction entered into the LASER machine is accurate [10]. Topical Anaethestic was used several times immediately before the surgery. Then, the Lieberman adjustable lid speculum is placed under the upper lid first then we asked the patient to look down and insert the speculum under the lower lid carefully to avoid touching the corneal epithelium [10]. The machine used in this study was VISX S4 excimer laser system (VISX Inc., 3400 Central Expressway Santa Clara, CA 95051-0703 USA) and the M2 automated microkeratome (Moria, France). All surgeries were performed by the same experienced surgeon. The wavefront data were transferred by USB drive from the VISX WaveScan (Zernike software) to the VISX S4 excimer laser system [11]. The Moria M2 automated microkeratome was used to create an 8.5-9.0 diameter corneal flap with a thickness of 130 μm with a superior hinge. The stromal bed was dried by tamponade (with a dry Weck sponge), being careful not to wipe which leaves more particulate matter. The patient was constantly reminded to look up at the center of the fixation light [10]. The mean optical zone diameter was 6.4 ± 0.4 mm (steps 6.0, 6.5, 7.0). The treatment zone diameter was up to 8.5 mm. The V1SX Star S4 laser machine utilizes the Variable Spot Size (VSS) technology with Variable Repetition Rate (VRR). Unlike other laser machines with fixed spot size, shape and repetition rate, the VISX Star S4 changes the beam diameter in a range from 0.65 mm up to 6.5 mm according to the pre-operative wavefront treatment profile of the patient. It also changes the beam shape and the repetition rate accordingly to meet the precise ablation profile which is needed in the wavefront-guided treatments. In addition, the laser machine has also an active 3D eye tracker to ensure the accuracy of the ablation profile [11]. To compensate for cyclotorsion that may happen when the patient lies flat under the laser machine, automated iris registration was activated for all customized eyes prior to treatment. Finally, the flap was repositioned, and the interface was washed with a balanced salt solution. After the operation, patients were instructed to instill antibiotic/steroid combination four times per day for 3 days, and then tapered over for two weeks and artificial tears fours per day for one month [11].

### 2.5. *Postoperative follow up*

At the postoperative examinations—1 day, 1 week, and 1, 3, and 6 months—the following assessments were performed: slit lamp examination of the anterior segment, UCVA, BSCVA, manifest subjective and objective refractions, and corneal topography. Wavescan was done at 1, 3 and 6 months to measure the higher order aberrations. The clinical outcomes of wavefront-guided LASIK were evaluated based on standard formats and criteria, Koch, et al. [1], Waring [2] for safety, efficacy, predictability, stability, complications, and preoperative and postoperative aberrations. Safety and efficacy indices, Koch et al. [1] are defined as the mean postoperative BSCVA/mean preoperative BSCVA and the mean postoperative UCVA/ mean preoperative BSCVA, respectively. The mean of the preoperative and 3 postoperative measurements were used in the analysis. Only 6-month data is presented.

## 3. Results

This study included Thirty-nine eyes (women to men ratio was 16:7), tab. (1). The mean age was 27.0 years ± 5.9 (SD) (range 20 to 45 years). The mean spherical equivalent (SE) refraction was -3.70 ± 1.43 diopters (D) (range -1.50 to -6.62 D) and the mean uncorrected visual acuity (UCVA) was 1.1103 ± 0.2447 preoperatively. The follow-up was of 6 months period for all patients.

**Table 1:** Demographic data

| | **n= 39 eyes** |
|---|---|
| **Sex:** Female/Male (No. (%)), Female to Male ratio | 16(69.6%)/7(30.4%), 2.29:1 |
| **Age (years):** Mean±SD, range | 27±5.9, 20 – 45 years |
| **Spherical equivalent:** Mean±SE, range | -3.7±1.43, (-1.5) – (-6.62) diopters |
| **UCVA:** Mean±SE | 1.1103±0.2447 |

***UCVA****: Uncorrected visual acuity*

### 3.1. *Safety*

The safety is how many lines of visual acuity the subject gained postoperatively. Table (2) & fig. (1) shows significant change in BSCVA (p 0.000*) from preoperatively (-0.002 ± 0.0873) to 6 months (-0.0770 ± 0.0559) postoperatively. Thirteen eyes (33.3%) had no change in BSCVA, and 25 (64.1%) gained 1 or more lines while only one eye (2.6%) lost one line in BCVA. The mean BSCVA was 1.01 preoperatively and 1.16 at 6 months.

**Table 2**: The change in BSCVA preoperatively to 6 months postoperatively

| | **No.** | **%** |
|---|---|---|
| **Lost 3 lines** | 0 | 0.0 |
| **Lost 2 lines** | 0 | 0.0 |
| **Lost 1 line** | 1 | 2.6 |
| **0** | 13 | 33.3 |
| **Gained 1 line** | 1 | 2.6 |
| **Gained 2 lines** | 19 | 48.7 |
| **Gained 3 lines** | 5 | 12.8 |
| **Total** | 39 | 100.0 |

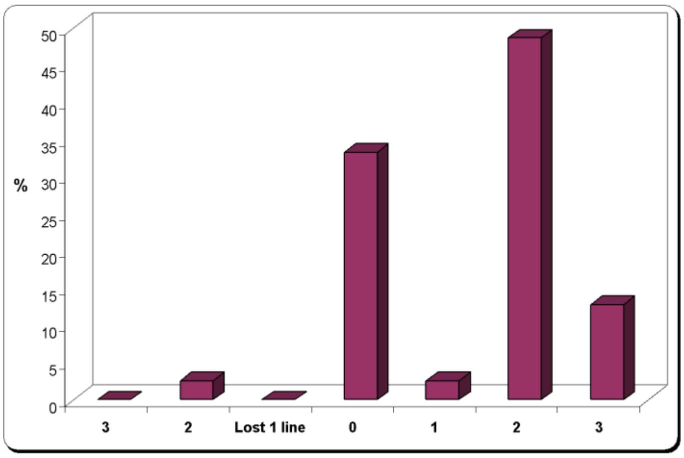


**Figure 1:** Change in BCVA (in decimals) preoperatively to 6 month postoperatively.

### 3.2. *Efficacy*

Figure (2) shows significant change in UCVA (p 0.000*). The mean UCVA was (1.1103 ± 0.2447) preoperatively and (-0.0490 ± 0.0624) at 6 months. The efficacy index was 1.06. An UCVA of 20/20 or better was achieved by 28 eyes (71.8 %) at 6 months postoperatively. Supernormal vision (BSCVA 20/10 or better) was achieved in 32 (82.1 %) eyes.

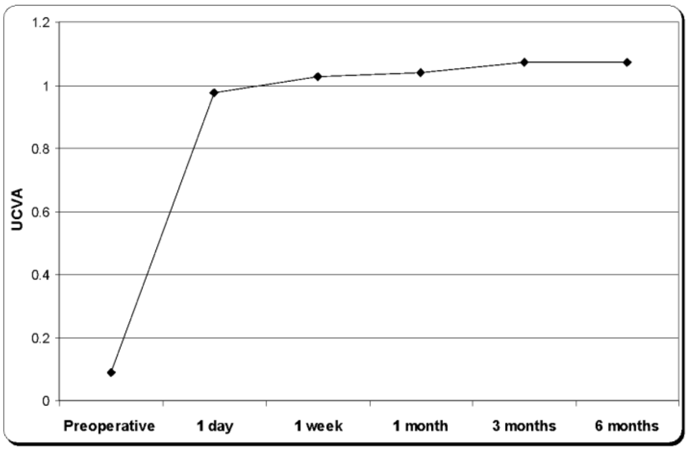


**Figure 2:** Change in UCVA (in decimals) preoperatively to 6 month postoperatively.

### 3.3. *Predictability*

Table (3) shows the number and percentage of eyes that were within ± 0.5 D of the expected SE refraction at 1, 3 and 6 month postoperatively. Figure (3) shows the attempted and achieved amounts of correction. The correlation between the attempted and achieved myopic correction was highly linear, with little under correction.

**Table 3:** The number and percentage of eyes that were within ± 0.5 D of the intended SE refraction at 1, 3 and 6 m.

| | (n= 39) | |
|---|---|---|
| | ***No.*** | ***%*** |
| **1 month:** | 35 | **89.7** |
| **3 months:** | 34 | **87.2** |
| **6 months:** | 37 | **94.9** |

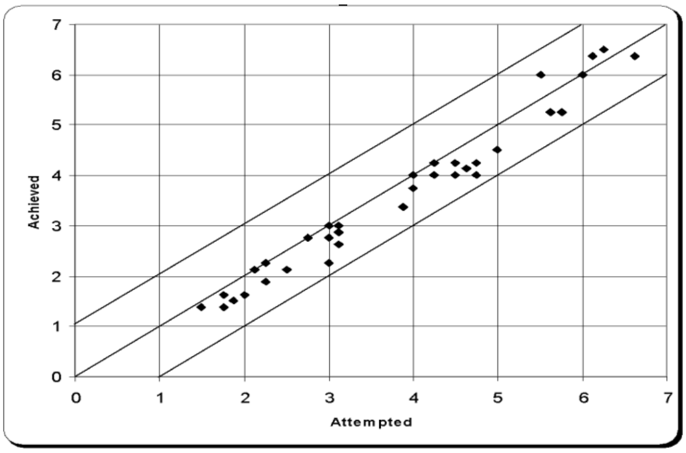


**Figure 3:** Predictability: The SE refractions are shown on the *x*-axis, the achieved myopic corrections on the *y*-axis, and predictability of 1.0 D in the lines.

### 3.4. *Stability*

The change in the subjective refraction is shown in fig. (4). The mean preoperative SE refraction was -3.70 ± 1.43 D. In 1 month, it was -0.24 ± 0.32 D. In 3 months, it was -0.23 ± 0.30 D. Finally at 6 months, it was -0.22 ± 0.27 D.

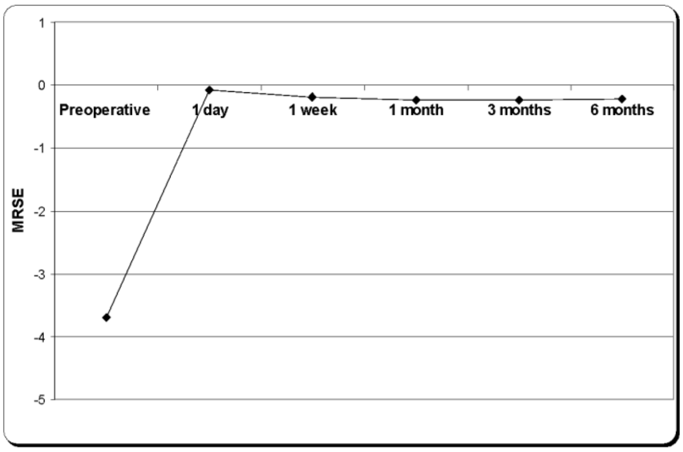


**Figure 4:** Stability of refraction (in diaopters) along the follow up period.

### 3.5. *Complications*

No complication such as epithelial ingrowth, diffuse lamellar keratitis, or infection was observed.

### 3.6. *Preoperative and Postoperative Aberrations*

WaveScan measurements were obtained preoperatively and at months 1, 3, and 6, figs. (5 & 6). The higher order aberrations over time (RMS, coma, trefoil, spherical aberration, Z42 and Z44) are summarized in tab. (4) and figs. (7-12). There was a significant increase in RMS, coma and spherical aberrations 6m postoperatively. Trefoil aberration was significantly decreased.

**Table 4:** The higher order aberrations (in micrometers) over time

| | Preoperative Mean ± SD | 1 month Mean ± SD | 3 months Mean ± SD | 6 months Mean ± SD | P-value |
|---|---|---|---|---|---|
| RMS | 0.38 ± 0.14 | 0.54 ± 0.20 | 0.55 ± 0.19 | 0.54 ± 0.20 | 0.000* |
| Coma | 0.22 ± 0.11 | 0.34 ± 0.19 | 0.34 ± 0.18 | 0.36 ± 0.19 | 0.001* |
| Trefoil | 0.18 ± 0.11 | 0.15 ± 0.09 | 0.14 ± 0.08 | 0.14 ± 0.07 | 0.028* |
| SPH | 0.03 ± 0.16 | 0.24 ± 0.21 | 0.27 ± 0.20 | 0.24 ± 0.19 | 0.000* |
| Z42 | 0.07 ± 0.05 | 0.09 ± 0.06 | 0.10 ± 0.06 | 0.10 ± 0.05 | 0.011* |
| Z44 | 0.07 ± 0.05 | 0.08 ± 0.05 | 0.09 ± 0.05 | 0.08 ± 0.04 | 0.135 |

***P- value****: * statistically significant*

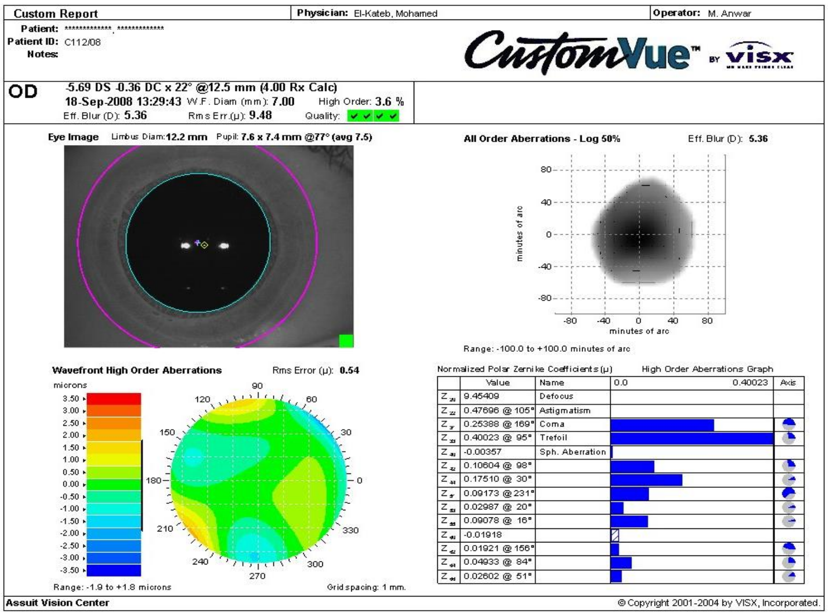


**Figure 5:** Example of HOAs preoperative

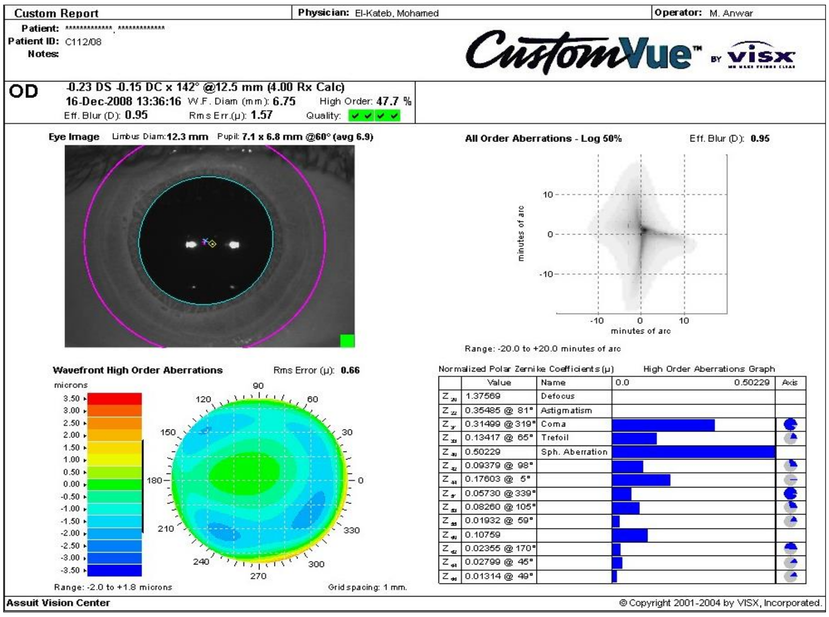


**Figure 6:** Example of HOAs postoperative

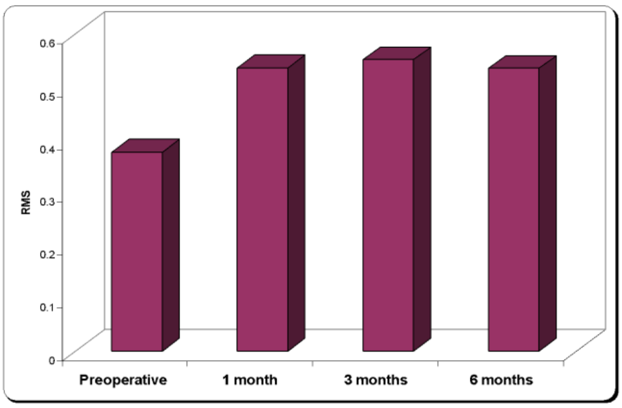


**Figure 7:** mean RMS

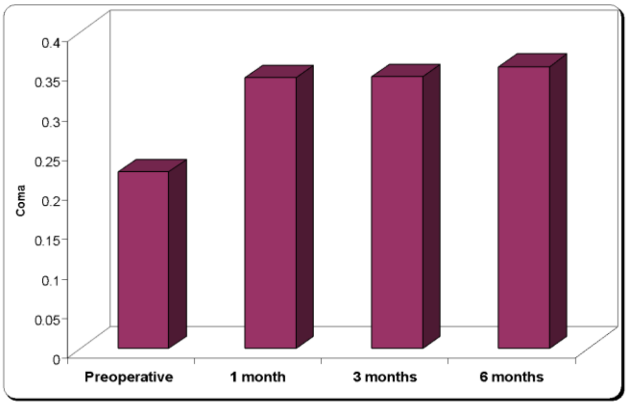


**Figure 8:** mean Coma

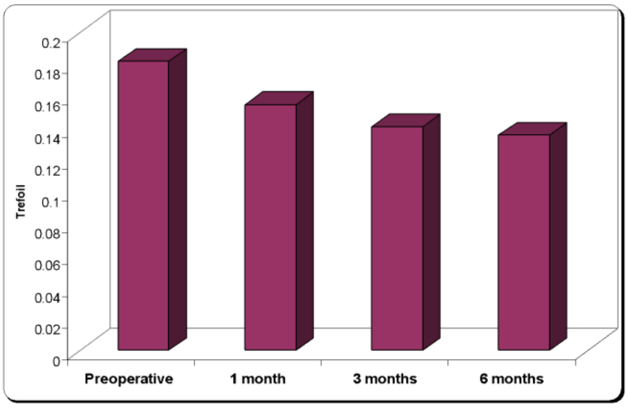


**Figure 9:** mean Trefoil

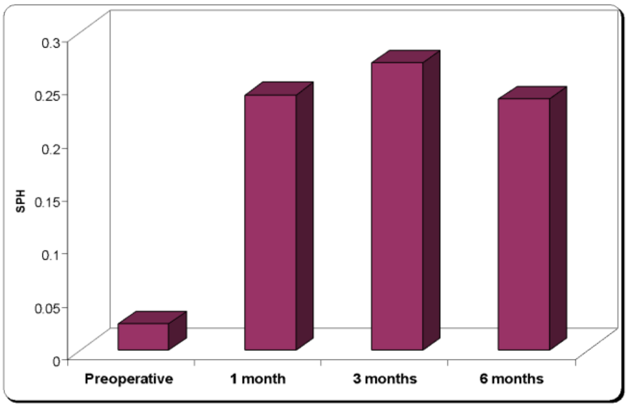


**Figure 10:** mean Spherical aberration

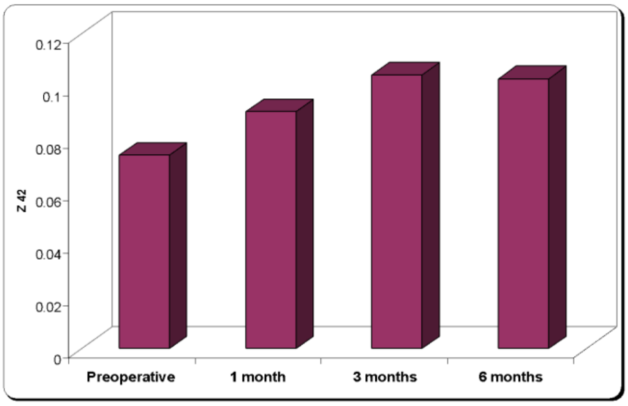


**Figure 11:** mean Spherical aberration

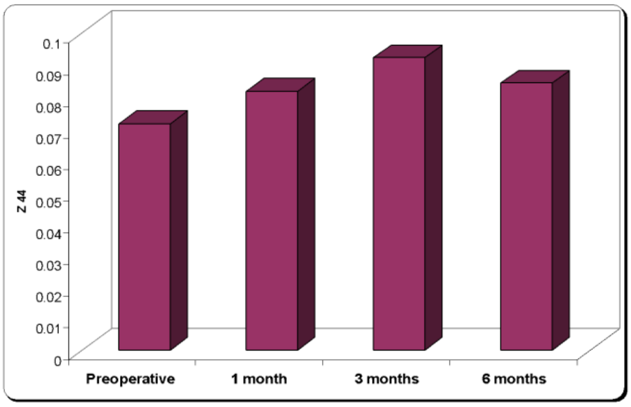


**Figure 12:** mean Z44

## 4. Discussion

One of the exciting frontiers of refractive surgeries is customized corneal ablation which reduces higher order aberration of the eye, in addition to eliminating sphero-cylinerical refractive error (lower order aberrations) [12,13]. To improve the quality of vision it is not necessary to completely remove all of the wavefront aberration of the eye but merely reduce it. Beyond sphero-cylindrical error (Zernike second order), most optical aberrations of the eye are contained in the Zerike third and fourth order terms and nearly all of the remainder resides in the fifth to eighth order terms [14,15]. Regarding safety, in the present study, BSCVA of 1.2 decimal or better was achieved in 32 eyes (82%) 6 months following LASIK procedure. The safety index was 1.15 which means improvement better than the preoperative level. This is consistent with the work done by Nuijts et al. [16] who achieved a safety index of 1.12 . In our study, we achieved excellent predictability (95%) with ± 0.5 d of spherical equivalent 6 months postoperatively. This result goes in accordance with the work done by Nuijts, et al. [16] and Kim, et al. [17] who used Zyoptix (Baush and Lomb) machine. Concerning stability, the current study showed a postoperative SE refraction of – 0.22 ± 0.27 D while Aizawa, et al. [5] overcome the hypermetropic shift by reducing the amount of correction by 10%. We noticed in our study increase in all HOAs except the trefoil aberration which decreased significantly. Also, there was no significant loss of BSCVA or a complication in any patient in this study. There are many studies comparing the outcomes of the Wavescan system and topography-guided ablation (TGA). Fala-varjani, et al. [18] compared Wavescan system ablation and TGA in eyes having low to moderate myopia with or without astigmatism that underwent topography-guided photorefractive keratectomy and reported the same corrected distance visual acuity testing (CDVA) and contrast sensitivity outcomes Jain, et al. [19] also stated that topography-guided LASIK and Wavescan system LASIK have excellent results with substantially equivalent outco-mes after myopic LASIK. On the contrary, Randleman, et al. [20] studied HOAs after wavefront-optimized photorefractive keratectomy and LASIK and found that wavefront-optimized excimer laser surgery did not induce any significant HOAs after LASIK. Wavefront guided LASIK takes into account pupil size. So that, we can treat subjects with large scotopic pupil size to avoid night glare and haloes after LASIK. Also, treatment with larger optical zones and transition zones may be possible since the entire corneal topo-graphy (not just the central cornea overlying the pupil) along with the wavefront in a dilated pupil are considered during treatment. We recommend a larger study with a bigger scale and a longer period of follow up to empower development of results.

## 5. Conclusions

*Wavefront-guided treatment of low and moderate myopia is safe, effective, predictable and gives good visual outcome especially in the early postoperative period. The results explained the patient satisfaction with the wavefront treated eyes. Along the six month of follow up there were still changes in the individual high order aberrations which means that these aberrations may change with time. We noticed significant increase in RMS and coma while trefoil was significantly decreased. We found that wavefront guided treatment of low and moderate myopia is safe, predictable and provides our patients with good night vision after surgery. A long-term follow-up and large population studies would be needed.*

## Abbreviations

**BSCVA**: Best Corrected Visual Acuity
**HOAs**: higher-order aberrations
**LASIK**: Laser-assisted in situ keratomileusis
**LOAs**: lower-order aberrations
**RMS**: Root mean Square


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