



SAFETY AND EFFICACY OF CORNEAL WAVEFRONT GUIDED LASER IN SITU KERATOMILIEUSIS IN MYOPIC ASTIGMATISM

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ABSTRACT

Back Ground: Laser in situ keratomelusus (LASIK) is a widely used refractive surgery technique. Corneal wavefront guided LASIK treatment is a newly evolving method to correct preexisting high order aberrations and also to reduce induction of further aberrations. This study is to assess the efficacy and safety of Corneal wavefront guided LASIK treatment in myopic astigmatism. **Methods:** This is a prospective study of 30 eyes of 16 patients who underwent Corneal

wavefront guided LASIK treatment. The pre operative and post operative one and three month data were collected and analyzed. **Results:** The post operative mean BSCVA at 1 month was 1.02 ± 0.2 and at 3 month was 1.02 ± 0.18 . The change in BSCVA at 1 month was 0.09 ± 0.22 and at 3 month was 0.10 ± 0.22 ($p < 0.001$). The change in RMS of 4th order HOA is 0.08 ± 0.01 D ($p < 0.001$). and that of the 5th order HOA is 0.02 ± 0.04 D ($p < 0.001$). **Conclusion:** Corneal wavefront guided LASIK treatment is safe and effective in treating patients with myopic astigmatism.

KEYWORDS: *Corneal wavefront, higher order aberrations, LASIK.*

INTRODUCTION

Corneal refractive surgery, laser in situ keratomileusis (LASIK) has been developed to correct refractive error using an excimer laser. Its safety and efficacy have been confirmed by many clinical studies.^[1] However, this procedure can increase ocular aberrations,^[2] leading to poor visual performance including halos,^[3] and reduction in low contrast visual acuity.^[4]

Also optical aberration may be the reason why visual acuity generally doesn't reach the retinal limit of vision which is of the order of 6/3 (20/10). Though the refractive outcomes have become increasingly accurate due to nomogram, laser algorithm adjustments, and the use of larger treatment zones, the focus has shifted to maintain or possibly increase the quality of vision. This target may be attained by addressing two issues: 1) the reduction of induced higher order aberration, and 2) the reduction of pre existing higher order aberrations. The concept of customized wavefront guided LASIK was proposed as a solution to reduce these ocular aberrations.^[5] Ocular wavefront guided treatment and corneal wavefront guided treatment are the two available platforms to address issues of higher order aberrations. There are mainly two differences between corneal topography guided and corneal wavefront guided treatment. One is that the conventional topographic elevation data are calculated from an ideal spherical cornea.^[5] But this ideal spherical cornea can have aberrations, indicating that treated cornea can still have aberrations particularly spherical aberration, even though the treated cornea resembles ideal cornea. In contrast corneal wavefront describes the optical error of cornea which is calculated from a spherical wavefront. So perfect focus can be achieved when the wavefront of the treated cornea resemble close to the spherical wavefront. Second difference is that the reference axis chosen by topography guided treatment is the optical axis and line of sight in the case of corneal wavefront guided ablation. Therefore cornea treated by topography guided ablation will be symmetric around the optical axis but not aberration free, whereas corneal wavefront guided LASIK will produce an aspheric surface which is aberration free.^[6] The dominant part of the total ocular aberration is the corneal component. Thus treatment of corneal aberration can improve the visual outcome of the subjects. Excellent correlation exists between induced total aberration and induced corneal aberration by laser treatment.^[7] The advantage of corneal wavefront guided ablation has some advantage over ocular wavefront guided ablation. Treating ocular aberration by ocular wave front analysis is influenced by the accommodation during measurement of aberrations. Pupil center shift is minimal in corneal wave front guided treatment compared to ocular wave front guided ablation since pupil dilation is not needed.

The aim of this study is to evaluate the clinical outcome of corneal wavefront laser in situ keratomileusis for the correction of myopic astigmatism. For this following objectives were undertaken - to determine the safety index with regard to visual acuity, the efficacy index with regard to visual acuity, and to measure the change in higher order aberration .

MATERIALS AND METHODS

The study was carried out in MES Medical College and its associated Al Salama Eye Hospital located in Perinthalmanna Malappuram district in Kerala state during the period of 24 months from July 2009 to July 2011. Institutional approval was granted by the Review Board. The study was an uncontrolled experimental trial in patients who came to the hospital for surgical refractive correction. All patients with myopic astigmatism were counseled for corneal wavefront guided treatment and those gave consent underwent surgery. Pre operative and post operative data comparison was done. We had enrolled 30 eyes of 16 patients who volunteered for undergoing refractive surgery for myopic astigmatism. The inclusion criteria were - patients with spherical equivalent $<4.00D$, patients with $<4.00D$ astigmatism, best spectacle corrected visual acuity better than or equal to 6/12 of snellen acuity. Exclusion criteria were - Eyes which had undergone previous refractive surgeries, Eyes which have undergone any ocular surgeries, Eyes with fundus lesion, Any eye with history of ocular disease that may have potentially unexpected effects on the outcome, Age of the patient above 35 yrs. The keratron Scout corneal topography system (Optikon 2000, Milan, Italy) is a videokeratoscope based topography system which measured the anterior corneal measurements. With the help of a computer software it analyzes the anterior corneal wavefront aberrations and expressed in zernicke polynomial upto 7th order HOA. The Optimized Refractive Keratometer (ORK) WAVEFRONT ANALYZER, is a unit that records aberrometry, fixed stimulus refraction, accommodation and keratometry. Higher order aberrations were measured using the WAVEFRONT ANALYZER, with the software, Complete Ophthalmic Analysis System (COAS) version 1.43.2, working on the principle of Hartmann-Shack aberrometer (Schwind Technologies, Germany). All patients were informed about the nature of the procedure and gave consent. Pre operative examination included - Uncorrected visual acuity with projected snellen chart, Best spectacle corrected visual acuity after subjective refraction, Cycloplegic refraction, Slit lamp examination, Schirmer's test, Ultrasonic pachymetry, Corneal topography with optikon keratron scout topography system, Wavefront aberrometry with ORK wavefront analyzer, and Dilated retinal examination. Anterior corneal data is obtained by the keratron Scout corneal topography system which also helps to analyze the anterior corneal wavefront aberrations. These wavefront aberrations are expressed in Zernicke polynomials. A skilled optometrist performed four examinations in the same eye at a time. The pupil size is maintained to be in scotopic condition (6-6.5mm). The patient was asked to blink lids before capturing the image. This helped to control tear film break and tear accumulation. The image is captured when

“very good” repeatability is reached. The best image with least artifact was chosen for analysis. The pupil margin shown on the map should be round as possible so that pupil center can be determined accurately. The software of the machine automatically detects the line of sight (line passing through the fixation target and exit pupil center. The software will produce a corneal wavefront map in reference to the surface determined by the equivalent sphere and reference axis by the line of sight. The HOA data obtained thus is combined with manifest refraction and linked to the ORK software of wavefront aberrometry. The ablation profile was calculated by ORK CAM software. All treatment were planned so as to have a residual stromal thickness of 300microns and then loaded to the ESIRIS laser system. All surgeries were performed by a senior, well experienced refractive surgeon of our Hospital. The laser machine is ESIRIS flying spot scanning excimer laser (software version 2.6.2; Schwind eye tech solutions GmbH, Kleinostheim, Germany) and has ORK software (version 2.1). This machine used has an eye tracking system with a frequency of 250Hz. Flap was created using Cariasso Pendular microkeratome which helps to take a uniform flap. Nasal hinge was used in all cases. The optical zone ablated was 6-6.5mm. The humidity and temperature were closely monitored during the procedure and maintained according to the instruction of the manufacturer. On the first post operative day detailed slit lamp examination was done to evaluate the position of flap and the interphase. Then patients were followed on first and third month. On every follow ups the following evaluations are done. Uncorrected visual acuity with projected snellen chart, Best spectacle corrected visual acuity after doing subjective refraction, Corneal topography with keratron scout topography system, Corneal wavefront aberrations measured from computer software of keratron. Pre operative HOA of 3rd order, 4th order and 5th order were compared with that of the 1st month and 3rd month follow up data. RMS (root-mean-square) of the measured components of HOA is taken to get an average value of each order of aberrations. Paired t –test used for testing statistical significance. A P-value of <0.001 is considered to be significant. Safety index was analyzed, which was calculated as the ratio of mean post operative BSCVA to pre operative BSCVA. Efficacy index was analyzed, which is calculated as the ratio of mean post operative UCVA to mean pre operative BSCVA.

RESULTS

The mean of pre operative uncorrected visual acuity in the study population was 11 ± 0.11 . 50% of eyes had UCVA less than 0.1 and 93.33% of eyes had UCVA less than 0.2. None of the eyes were better than 0.3. The mean pre operative best spectacle corrected visual acuity

(BSCVA) was 0.93 ± 0.22 . 20 eyes (66.67%) of subjects under study had BSCVA 1.0 or better. 26 eyes (86.67%) were better than or equal to 0.8. Four eyes (13.33%) had BSCVA less than 0.8. The mean pre operative refractive error of the population measured as mean of spherical equivalent was -3.01 ± 2.2 D. Twenty percent of the eyes under study had a spherical equivalent of < 2.00 D. (Chart 1). 43.33% of eyes had refractive error < 3.00 D. 56.67% of eyes had spherical equivalent of 3.00D or more and 20% had more than 4.00D. The post operative mean UCVA at 1 month was 0.92 ± 0.18 and at 3 month was 0.94 ± 0.18 . The change in UCVA at 1 month was 0.81 ± 0.2 D and at 3 month was 0.84 ± 0.2 D ($p < 0.001$). At 3 month follow up 53.33% of eye studied had UCVA of 1 or better. 83.3% had UCVA better than or equal to 0.9. 13.67 % had UCVA less than 0.9. Of all the eyes none the eyes were worse than 0.8. The post operative mean BSCVA at 1 month was 1.02 ± 0.2 and at 3 month was 1.02 ± 0.18 . The change in BSCVA at 1 month was 0.09 ± 0.22 and at 3 month was 0.10 ± 0.22 ($p < 0.001$). At 3 month follow up 16.67% of eyes under study had BSCVA of 1.2 or better. 93.33% of the eyes had BSCVA of 1 or better and 6.67 % had vision less than 1. None of the eyes had BSCVA less than 0.8. The mean refractive error measured as spherical equivalent 1 month after the surgery was -0.08 ± 0.40 D and after 3 months was -0.10 ± 0.40 D. The change in refractive error produced at 1 month was 2.93 ± 2.30 D and at 3 month was 2.91 ± 2.26 D ($p < 0.001$). At 3 month follow up 40% of the eyes under study had no refractive error. 53.33% of the eyes had refractive error of ± 0.25 D. Only 2 eyes (6.67%) had a refractive error of ± 0.5 D. none of the eyes had a refractive error more than 0.5D. BSCVA were unchanged in 15 eyes (50%). 15 eyes (50%) showed ≥ 1 line improvement. 7 (33%) eyes showed ≥ 2 line improvement and 2 eyes showed 3 line improvement. None of the eyes showed decrease in BSCVA. The safety index (ratio of mean post operative BSCVA to mean pre operative BSCVA) was 1.10. the efficacy index (ratio of post operative UCVA to pre operative BSCVA) was 1.01. The mean preoperative 3rd order HOA measured as RMS was 0.24 ± 0.20 D, mean of 4th order HOA RMS was 0.29 ± 0.14 D and mean of 5th order HOA RMS was 0.05 ± 0.04 . 46.67% of eyes had 3rd order RMS of < 0.2 D. 80% of the eyes had 4th order HOA RMS between 0.20D and 0.40D. All eyes had 5th order HOA RMS < 0.1 D of which 43.33% were < 0.05 D. (Table 1).

The change in RMS of 3rd order HOA at 1 month were $0.05 \text{D} \pm 0.30$ D ($p \text{ value} = 0.08$), that of 4th order HOA is 0.08 ± 0.01 D ($p < 0.001$). and that of the 5th order HOA is 0.02 ± 0.04 D ($p < 0.001$). There was no change in RMS between 1 month and 3 month follow ups. (Table 2 and Chart 2)

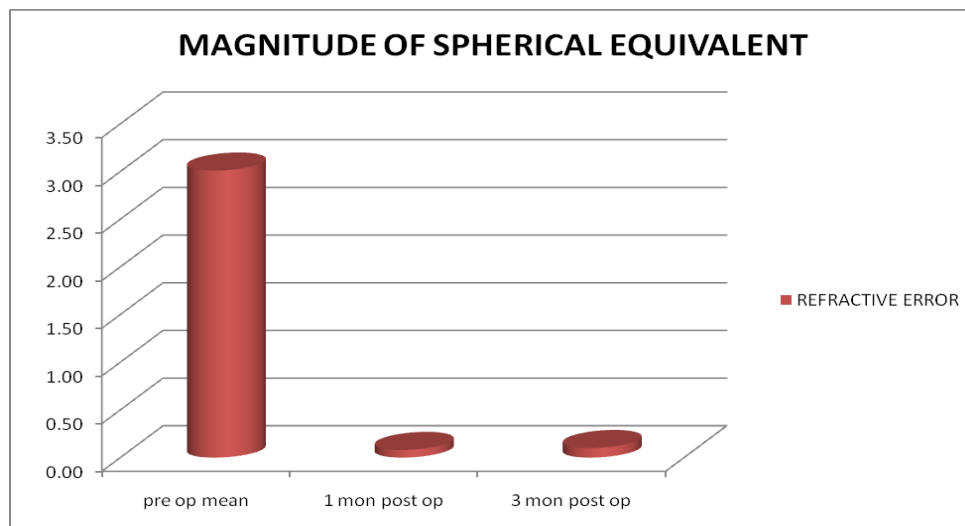


Chart 1: change in refractive error after surgery

Table-1: Distribution HOA in Study Population.

HOA	3rd order	4th order	5th order
<0.05	-	-	43.33
0.05 - 0.1	-	-	56.67
0.1 - 0.2	46.67	13.33	-
0.2 - 0.3	23.33	40.00	-
0.3 - 0.4	13.33	40.00	-
0.4 - 0.5	13.33	6.67	-

Table-2: Comparison of HOA at pre op, 1month and 3 month

	Pre op	1 month	3 month	P value
3rd HOA	0.24	0.29	0.29	0.08
4th HOA	0.29	0.37	0.37	0.000
5th HOA	0.05	0.07	0.07	0.000

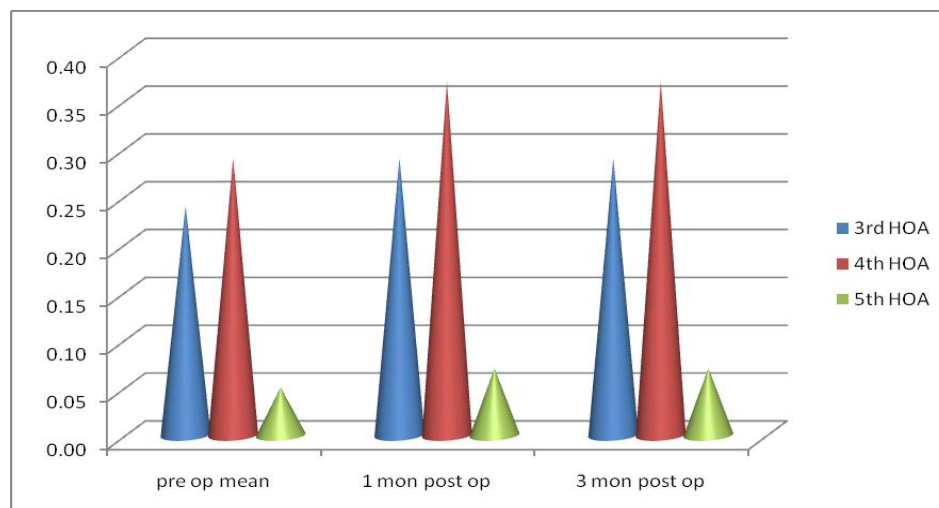


Chart 2: change in higher order aberration after surgery

DISCUSSION

Schallhorn S^[8] studied corneal higher order aberration induced by standard LASIK, which was higher than induced aberration in our study. It was also higher than values reported by Goldstone R^[9] who used ocular wavefront algorithm. In contrast our study demonstrated a decrease in higher order aberrations. These findings indicate that corneal wavefront optimized ablation is relatively efficient in reducing the increase of post operative aberrations. Corneal refractive procedures are currently widely applied to correct ametropia. A successful refractive procedure is gauged by many criteria like safety, efficacy, predictability, and long-term stability. Laser-assisted in-situ keratomileusis (LASIK) is presently the most widely performed refractive procedure, but it is not appropriate for all patients.^[10] Our study gives comparable results with Aslanides^[11] in improvement in uncorrected visual acuity and stable refractive corrections post operatively. There was no significant difference in the refractive values, higher order aberrations, best corrected and uncorrected visual acuities between one month and three month visits and the was the expected. There was no statistically significant difference in 3rd order aberrations pre and post operatively and the finding is consistent with the result of Aslanides.^[11]

CONCLUSION

In conclusion our findings indicate that there is significant change in the Visual Outcome of the patients after corneal wavefront guided Lasik treatment. There were significant change in HOA for 4th and 5th order aberrations but the change was insignificant for 3rd order HOA. Also this study proved that there was clinically a significant change in Visual Outcome of the patients after corneal wavefront guided Lasik treatment. It is also proved in the study that corneal wavefront guided LASIK treatment is safe and effective in treating myopia and myopic astigmatism. We would suggest that long term results are necessary to evaluate the duration of the change in the HOA. The need for pupillometer during pre op evaluation should be studied further. Indications and contra indications must be investigated. Hence many long term Randomized Control Trial should be done.

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