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CHANGES IN CORNEAL HIGHER ORDER ABERRATIONS (HOAS) AND ITS EFFECT ON QUALITY OF LIFE AFTER WAVEFRONT OPTIMIZED LASIK

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PURPOSE: To Measure the corneal Higher Order Aberrations and quality of life changes produced by Standard Laser in situ keratomileusis (LASIK) for Myopia.

SETTING: Nagri Eye Hospital and Research Foundation Trust, Ahmedabad, India

DESIGN: Prospective Clinical Experimental Study

METHODS: The study comprised 29 subjects with mean age group of 24.17 ± 3.81 SD years with myopia or myopic astigmatism. The manifest Refraction Spherical Equivalent [MRSE] mean was $-4.33D \pm 1.96SD$ (astigmatism of 0.0D to $-2.75D$). Corneal Higher order aberrations was measured preoperatively and 1, 3, 6 month post operatively with zeimer Galilei G4 Topographer. A validated questionnaire on post LASIK quality of life was introduced to selected subjects. Residual Manifest Refraction Spherical Equivalent [MRSE], uncorrected Distance Visual Acuity [UDVA] corneal Higher- Order Aberrations [HOAs] were analysed on 6 months postoperative follow up.

RESULT: The amount of corneal higher order aberrations increased with LASIK. Pre LASIK the Total root mean square, Spherical Aberration, Coma, Trefoil, Defocus and Astigmatism mean value were [mean (μm) \pm SD] 0.37 ± 0.45 , 0.04 ± 0.06 , 0.09 ± 0.11 , 0.05 ± 0.06 , 0.16 ± 0.19 , 0.34 ± 0.40 respectively and post LASIK mean were [mean (μm) \pm SD] 0.44 ± 0.52 , 0.11 ± 0.14 , 0.12 ± 0.16 , 0.09 ± 0.11 , 0.30 ± 0.39 , 0.27 ± 0.33 found ($p < .001$).

The UDVA was 0.0 Log MAR or better. Postoperative residual MRSE mean was $-0.09D \pm 0.16$ SD. After LASIK majority of subjects have found change for better, No difficulty in near intermediate and daily activities. In night Driving 51.72% had no difficulty & 41.37% had a little difficulty found. Starbursts or halos around the light seen by 41.37% most of the time and 31.03% some of the time, that make it difficult to see. Subjects were highly satisfied with Clarity of vision, working in outdoor and with mental status. Subjects were more happy with LASIK than previous glasses or contact lens correction.

CONCLUSION: Total Corneal Higher order Aberrations increasing after LASIK. Even With increasing corneal HOAs quality of life & visual outcome is maintained up to the requirements of subject's expectation level.

TITLE: Changes in Corneal Higher Order Aberrations (HOAs) and its effect on quality of life after wavefront optimized Lasik

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Introduction

In recent years, a number of possible surgical procedures in ophthalmology have offered prospective subjects an alternative to wear spectacles or contact lenses. Several laser and non laser refractive surgical procedures have been used to modify the shape of the cornea and correct myopia, hyperopia, astigmatism, and presbyopia. Introduction of the excimer laser to reshape the cornea has resulted in remarkable developments in the correction of these refractive errors. Combined with other advanced ophthalmic instruments, laser refractive eye surgery has resulted in a substantial increase in the safety, efficacy, and predictability of surgical outcomes. Laser *in situ* keratomileusis has become one of the most popular procedures for the reduction or elimination of myopic refractive errors and has emerged as the refractive corneal surgical procedure of choice for the correction of myopia.

Quality of life (QOL) refers to a multitude of subjective experiences important to people's lives. QOL assesses different dimensions that include physical status, functional abilities, psychological state and well-being, and social interaction. The physical status alludes to symptoms related to treatment, or results of surgery. The functional abilities refer to an individual's ability to perform daily activities; related to mobility and self-care. The psychological state describes the emotional status, perception of well-being, life satisfaction, and happiness. Negative and positive effects of surgery are assessed in this dimension. The negative effects include the level of anxiety, depression, guilty, and worry. As a result of the medical or surgical intervention, positive emotional states may produce improvement in the emotional functioning, such as joy, vigour, and hopefulness. The importance of quality of vision (QOV) along with quality of life (QOL) in medicine has been recently widely recognized.

We have conducted studies to quantitatively analyze factors related to QOV in post LASIK subjects. We have assessed QOL by use of validated questionnaires by NATIONAL EYE INSTITUTE REFRACTIVE ERROR QUALITY OF LIFE INSTRUMENT—425 (NEI RQL-42). NEI-RQL use traditional Likert scoring in which subjects response score for a selected set of items are summed to derive the overall score. Likert scoring assumes the value of each item represents equal difficulty, and it scores them equally. In addition, the linear response scale used for each item assumes uniform changes for that item.

HOA are present in all human eyes, but in normal, unoperated eyes HOAs are so minor that they are barely noticeable if at all. The cutting of a LASIK flap and ablation of corneal tissue creates an unnatural, irregular shape of the cornea which increases the higher order aberrations of the eye. Symptoms of HOA include starbursts, halos, double vision, multiple images and smeared vision. Irregular astigmatism can be a significant obstacle for achieving satisfactory QOV. Higher-order wavefront aberrations of the cornea were calculated by video keratography. Coma, spherical aberration and trefoil are the most common aberrations induced by LASIK. In this study; we evaluated correlation of post Lasik higher order aberration and their impact on quality of life.

Methodology:

A prospective comparative eye study included subjects having LASIK for the correction of myopia or myopic astigmatism at Laser Refractive Department, Ahmedabad, between June 2015 to March 2016. Subjects were enrolled after signing an informed consent form & the nature of surgery explained before the surgery. The study was approved by the local ethical committee and was performed in accordance with ethical standard. A prospective study comprised of 29 subjects (58 eyes) underwent LASIK for the treatment of myopia or myopic astigmatism. In all cases, bilateral LASIK was conducted and an optic zone of 6.5mm.

Inclusion criteria for the study were age 18 to 35 years, stable refractive error with -1.0D to -9.0D of spherical myopia, astigmatism between 0.00D to -2.75D, The manifest Refraction Spherical Equivalent [MRSE] mean was $-4.33D \pm 1.96SD$ and distance visual acuity correctable to 0.0 log Mar or better.

Exclusion criteria were presence of significant dry eye, anterior segment abnormalities (i.e., cataracts, corneal scarring, or neovascularization within 1 mm of intended ablation zone), basement membrane disease, history of recurrent corneal erosion, progressive or unstable myopia, estimated post-operative residual stromal bed thickness of less than 250µm, established or forme fruste keratoconus, macular or retinal disease, current use of systemic corticosteroid or immunosuppressive therapy, autoimmune disease, collagen vascular disease, Diabetes mellitus, pregnancy and lactation.

The preoperative Examination of each subject included uncorrected distance visual acuity (UCDVA) using a standard Snellen eye chart, corrected distance visual acuity (CDVA) (with spectacles), manifest Refraction, cycloplegic refraction with cyclopentolate 1.0%, post mydriatic testing at least 72 hours after cycloplegic refraction, intraocular pressure measurement, slit lamp biomicroscopy of anterior segment, dilated fundus evaluation, corneal topography with atlas 9000 corneal topographer, wavefront Report analysed by Schiømplog imaging with Ziemer Galilei G4. Contact lens users were asked to discontinue lens wear 2 weeks before screening for soft contact lenses and 6 weeks before rigid gas-permeable contact lenses. Manifest refraction and wavefront measurement were repeated at 2 visits to ensure refractive stability.

Eligible subjects were scheduled for bilateral wavefront -optimized Lasik. The correction target was based to manifest refraction, with emmetropia being the target in all subjects. Mechanical microkeratome used to create corneal flaps during study.

Postoperatively, the subjects were examined at 1 day, 1 week, 1 month, 3 months and 6 months. All post operative follow-up visits included measurement of UDVA, CDVA (if indicated), corneal wavefront report with Galilei G4 (dual Schiømplog) same as preoperatively.

For the assessment of vision-related QOL, National Eye Institute Visual Functioning Questionnaire 22 (NEI-VFQ 25) was translated into Gujarati. After the validation study, the influence of Lasik surgery on QOL was investigated. We have assessed QOL questioner postoperatively 6 months of Lasik. Subjects were requested to answer all questions on 4 Point response scale.

The aim of this study was to evaluate post Lasik corneal higher order aberrations & how LASIK affects QOL and to identify factors that may affect satisfaction after LASIK.

Result:

Statistical Analysis was done using Microsoft office software. The study comprised 29 subjects (58 Eyes). Below table shows mean values \pm SD ,Comparison of preoperative and 6 month-post operative corneal higher order Aberrations

	Pre Lasik	Post Lasik	P value
RMS	0.37 \pm 0.45	0.44 \pm 0.52	2.686E-12 ($<$ 0.01)
SA	0.04 \pm 0.06	0.11 \pm 0.14	7.15131E-16 ($<$ 0.01)
COMA	0.09 \pm 0.11	0.12 \pm 0.16	1.48E-05 ($<$ 0.01)
TREFOIL	0.05 \pm 0.06	0.09 \pm 0.11	0.000838 ($<$ 0.01)
DEFOCUS	0.16 \pm 0.19	0.30 \pm 0.39	2.58E-25 ($<$ 0.01)
ASTIGMATISM	0.34 \pm 0.40	0.27 \pm 0.33	0.007465 ($<$ 0.01)

Table:1

RMS=Total Root mean square. SA= spherical Aberration.SD= standard DeviationPre LASIK the Total root mean square, Spherical Aberration, Coma ,Trefoil, Defocus and Astigmatism mean value were [mean (μ m) \pm SD] 0.37 \pm 0.45, 0.04 \pm 0.06, 0.09 \pm 0.11, 0.05 \pm 0.06, 0.16 \pm 0.19, 0.34 \pm 0.40 respectively and post LASIK mean were [mean (μ m) \pm SD] 0.44 \pm 0.52, 0.11 \pm 0.14, 0.12 \pm 0.16, 0.09 \pm 0.11, 0.30 \pm 0.39, 0.27 \pm 0.33 found (p $<$.001).

Post Lasik ,86.2% found their life be with large difference for better. hobbies that require you to see well up close, such as cooking, fixing things around the house, sewing, using hand tools, or working with a computer 79.31% found No Difficulty. 62.06% had no difficulty in seeing because of changes in the clarity of their vision over the course of the day.96.55% had no difficulty in judging distances, like walking downstairs or parking car. 55.17% found no difficulty in dark adaptation. 93.10% had no difficulty in reading ordinary print in newspaper.82.75% had no difficulty in reading small print in a telephone book, on medicine bottle or on legal forms.51.72% had found no difficulty & 41.37% had a little difficulty in driving at night. 48.27% had no difficulty & 48.27% had a little difficulty in driving in difficult conditions such as, in bad weather, during rush hour, on the freeway , or in traffic.86.20% had no difficulty in taking part in active sport or other

outdoor activities. 99% had no need to wear glasses or bi-focal lenses or use a magnifier when they were reading something long, like a book, a magazine article, or the newspaper. 96.55% had no need to wear glasses or contacts when driving at night. 96.55% had no need to wear glasses or contacts at dusk, when it is starting to get dark. 41.37% had most of the time and 31.03% had some of the time seen starbursts or halos around the light that make it difficult to see. 51.72% had none of the time and 31.03% had some of the time experience pain or discomfort in and around their eyes. 27.58% had a very little dryness & 58.62% had don't felt dryness. 62.06% had never bothered by changes in the clarity of vision over the course of the day. 37.93% had occasionally worried and 31.03% had never worried about their eyesight after Lasik surgery. 62.06% had having perfectly clear vision & 24.13% had having pretty clear vision after LASIK surgery. 62.06% had completely satisfied & 34.48 % had somewhat satisfied after LASIK. 62.06% had completely dissatisfied in term of appearance with their glasses, contact lenses. 27.58% had tacking less part in active sports or outdoor activities after LASIK.

Discussion:

In the present study, we observed the changes in spherical aberration, coma, trefoil, defocus, Astigmatism & total root mean square of aberrations preoperative and 6 month post LASIK then evaluated the subjects' satisfaction about the daily visual functions & quality of life after LASIK through questionnaire.

Muhammad Siam Khan observed Effect of wavefront optimized LASIK on higher order aberrations in myopic subjects⁷. HOAs were measured with aberrometer (Wave light allegro analyzer version 1073) during preoperative assessment and one month after surgery. They found significantly increasing in the RMS of Total HOAs and Uncorrected visual acuity (UCVA) was improved to 0.00 or better in all 60 eyes after wavefront optimized LASIK.

Majid Moshirfar, MD, Joshua A. Schliesser compared visual outcomes between wavefront-guided photorefractive keratectomy (PRK) and wavefront-guided laser in situ keratomileusis (LASIK)⁸. found At 6 month The mean postoperative HOA root mean square was $0.45 \pm 0.13 \mu\text{m}$ in the PRK group and $0.59 \pm 0.22 \mu\text{m}$ in the LASIK group with the mean UDVA was $-0.03 \log\text{MAR} \pm 0.10$ [SD] (20/19) and $0.07 \pm 0.09 \log\text{MAR}$ (20/24), respectively.

David Smadja, MD; Marcony R. Santhiago⁶ analyzed the induced corneal higher order aberrations (HOAs) after wavefront-optimized ablation in sixty four eyes and concluded that The magnitude of the induced corneal HOAs was related to the amount of intended correction. Corneal wavefront profiles do not reflect the visual performance.

Although several clinical trial found increasing corneal higher order aberrations and better visual acuity after LASIK^{7,8,9,10,11,12}. In our study after LASIK the total Root mean square of corneal HOAs found $0.44 \mu\text{m} \pm 0.52 \text{SD}$ with The UDVA was 0.0 Log MAR or better. Postoperative residual MRSE mean was $-0.09\text{D} \pm 0.16\text{SD}$. We have similar results with several clinical trial^{7,8,9,10,11,12}. In this study with increasing corneal HOAs with better visual acuity 51.72% had found no difficulty & 41.37% had a little difficulty in driving at night and only 3.44% only have moderate difficulty at night and only 8.60% have seen halos around the light at night. Majority of subjects with life be with large difference with better, no difficulty in near and intermediate work, dark adaptation, outdoor activities. A large improvement in QOL after Lasik Refractive Surgery for myopia. Corneal wavefront profiles do not reflect the visual performance⁶. We have to observe ocular aberration also.

Conclusion:

Total Corneal Higher order Aberrations increasing after LASIK. Even With increasing corneal HOAs quality of life & visual outcome is maintained up to the requirements of subject's expectation level.

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