Original Article

# To evaluate efficacy and compare outcome of LASIK in myopia

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## Abstract

**Purpose:** To evaluate Visual outcome and compare results after LASIK in low to high myopic patients (-2 to -10D) and evaluate complications. **Materials and Methods:** In this prospective study, 100 patients (200 eyes) with myopia of -2 to -10D and cylinder less than -0.5 D were evaluated. Patients were grouped as MYOPIA between -2 TO -6 (Low Myopia – Group 1) AND -6 TO – 10 (High Myopia - Group 2). All LASIK procedures were performed with microkeratome (MORIA, FRANCE) and Excimer laser (STAR S4 IR, AMO VISC) according to the nomogram. At 3 months pre and post operative data was analysed and compared. **Discussion:** At 6 months follow up among treated patients 92 % achieved 6/6 vision in Group 1 and 88 % in Group 2. Most commonly seen complication was DRY EYES (32%), followed by GLARE (32 %), post operative loss of flap (1 %). Complications were more commonly seen in Group 2 but they were not statistically significant (P>0.05). **Conclusion:** The study supports the current evidence of efficacy and safety of LASIK as the treatment of choice in patients with low and high myopia (-2D to -10D).
**Keywords:** myopia.

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## INTRODUCTION

Refractive status is a complex variable, determined by the balance of the optical power of the cornea and the lens, and the axial length of the eye. Myopia is the refractive anomaly of the eye in which the conjugate focus of the retina is at some finite point in front of the eye, when the eye is not accommodating[1]." Myopia is a leading cause of refractory errors throughout the world with a varied prevalence among the geographical regions. With its increasing prevalence and earlier age-of-onset in recent birth cohorts, myopia now affects almost 33% of adults in the United States, and epidesmic proportions of adults from 85% to 90% in Asian cities[2]. Myopia depending on the severity can be classified into low to moderate degree of myopia (referred to as simple myopia-0.5 to -6.0 diopters) and high or pathological myopia (greater than 6.0 diopters)[3]." The interventions for the treatment of myopia include optical, pharmacological and surgical interventions. Of various surgical interventions, LASIK (laser in situ keratomileusis) is a most commonly performed surgery for moderate to high myopia patients. It is well recognized that LASIK surgery can correct refractive error and reduce dependence on eyeglasses or contact lenses[4]. The LASIK procedure has been proved to improve the quality of life of the patients and provide high patient satisfaction levels. Despite favorable outcome, LASIK can also result in postoperative complications like dry eye, keratitis, epithelial in growth, posterior chamber complications etc[5]. The safety and efficacy of LASIK in low to moderate myopia is supported by insufficient data in Indian scenario. With this background, this study was conducted to evaluate the outcome of LASIK in low to high myopia (-2 to -10 D) in Indian patients of a tertiary health center.

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## MATERIAL AND METHODS

This is a prospective hospital based observational study with patients being followed for the six months after the study enrollment. The study commenced after receiving the permission from the institutional ethics committee in full board review of the study protocol. The study comprised 200 eyes of 100 patients (50 men and 50 women with a mean age of 25.31 ± 3.26 years). Inclusion criteria were patients between the age of 20 and 40 years, low to high myopia (-2D to -10D) with the refractive error being stable for at least 1 year(defined as <0.5D of change over at least 1-year), low astigmatic error(less than 0.5D), Central corneal thickness (CCT) of more than 400 microns, Keratometric readings between 36 to 48 Diopters. Soft contact lens wearers were advised to stop wearing lenses 2 weeks before the examination and rigid contact lenses were advised to stop wearing lenses 1 month before the examination. Patients with severe dry eyes, adnexal diseases, conjuctival and corneal disorders and any ocular disorder that leads to impairment in the vision were excluded from study. Patients unwilling to provide the informed consent and any patient in the opinion of investigator, required immediate interventions in medical, surgical or ophthalmogical procedure were excluded. A standardized examination protocol was followed in all patients. Patients were examined preoperatively and postoperatively on 1-day, 1-week, 1-month, 3 month and at 6 months. Preoperative postoperative day 1, day 30 and 6 months data are reported here. Preoperative and 6 month postoperative examinations included measurement of uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA) (projector chart [feet system], Nidek Co. Ltd., Gamagori, Japans), noncycloplegic and cycloplegic refraction (VISUREF 100, Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany), and subjective refractions with a trial lens set. slit-lamp examination, keratometry, tonometry, pachymetry, placido disk-based computerized videokeratography, aberrometry (Wavescan Wavefront system ACV, AMO manufacturing USA,LLC) also noted. Dilated fundus examination was done for presence of peripheral retinal degeneration or breaks that may predispose to rhegmatogenous retinal detachment, which would be sealed by double frequency Nd-YAG laser photocoagulation prior to Lasik. All surgeries were performed by the same surgeon using topical anesthesia (proparacain 0.5%). The STAR S4 IR excimer laser (AMO Manufacturing, USA,LLC) was used for all treatments. The Moria M2 microkeratome (Moria Co., Antony, France) was used to create a nasally hinged flap with a 90 µm depth plate producing flap thickness of 90-120 µm. Antibiotic and steroid eye drops were instilled at the end of the procedure. Eyes were rechecked on slit lamp after 15 minutes to confirm the flap position and absence of debris under the flap. Patients were instructed to use topical prednisolone acetate suspension 1% four times daily tapered over 4 weeks, moxifloxacin hydrochloride ophthalmic solution 0.5% four times daily for 1 week and Unpreserved tear lubricants were used at least 4 times daily for 3 months. Patient asked to follow up as advised. Preoperative data (UCVA, BSCVA, manifest and cycloplegic refraction, minimum and maximum corneal keratometry, pachymetry), microkeratome-related intraoperative flap complications (incomplete flap, complete flap, buttonhole flap), postoperative flap complications (striae, diffuse lamellar keratitis, ectasia, epithelial ingrowth, flap dislocation, microbial keratitis), refractive outcome (UCVA, BCVA, manifest refraction, cycloplegic refraction), and results of enhancement (if performed) were extracted from each chart and analyzed using an Excel spreadsheet.

## RESULTS

The study cohort comprised 200 eyes of 100 patients who underwent LASIK. There were 50 males and 50 females. The mean age was 25.31 ± 3.26 years (range, 20 to 40 years). Table 1 describes the baseline characteristics of the study population. The mean preoperative spherical equivalent refraction was -3.82 ± 1.51 D for the right eye and -3.75 ± 1.6 D for the left eye (range, −2.00 D to −10 D). Mean preoperative cylindrical equivalent refraction was -0.17 ± 0.24D for the right eye and – 0.22 ± 0.18 D for the left eye. The mean preoperative intraocular pressure was 11.96 ± 1.12 in the right eye and 12.02 ± 1.21 in the left eye while the overall IOP was 11.99 ± 1.18 considering both the eyes at once.

**Table 1:**

| Sr No | Characteristic | Mean ± SD | Range (95% CL) Mean ± 2 SEM |
|---|---|---|---|
| 1 | Age | 25.31 ± 3.26 years | 24.66 to 25.96 years |
| | Gender: | | |
| 2. | Male | | N= 50 |
| | Female | | N= 50 |
| | Refractive Error(Diopters) | | |
| 3 | Right Eye | | |
| | | | -4.12 to -3.52 |

| | | | | |
|---|---|---|---|---|
| | Left Eye | Spherical | -3.82 ± 1.51 | -0.22 to -0.12 |
| | | Cylindrical | -0.17 ± 0.24 | -4.1 to -3.44 |
| | | Spherical | -3.75 ± 1.6 | -0.22 to -0.12 |
| | | Cylindrical | -0.17 ± 0.24 | |
| 4 | Intraocular pressure (mm of Hg) | Right Eye | 11.96 ± 1.12 | 11.74 to 12.18 |
| | | Left Eye | 12.02 ± 1.21 | 11.78 to 12.26 |
| | Topography: | | | |
| 5 | Right Eye | Ks | 43.92 ± 4.23 | 43.08 to 44.76 |
| | | Kf | 43.7 ± 1.43 | 43.42 to 43.99 |
| | Left Eye | Ks | 44.45 ± 1.72 | 44.11 to 44.79 |
| | | Kf | 43.73 ± 1.37 | 43.46 to 44.0 |

## VISUAL OUTCOMES

A comparison of preoperative best spectacle corrected visual acuity (BSCVA) and postoperative UCVA is provided in Table 2 and Table3. The baseline visual acuity recorded was with the best spectacle corrected vision. The visual acuity of the participants was expressed in terms of one eye as a unit and the results are shown in Table no 2. 83% (n=166) of the 200 eyes tested for a normal distant vision of 6/6. The remaining distribution in terms of BSCVA was 11.5% (n=23) for 6/9 vision, 3.5% (n=7) for 6/12 vision and 2% (n=4) for 6/18 vision. None of the patients had BSCVA worse than 6/18 at baseline. The patients were followed for 6 months with Preoperative and postoperative day 1, day 30 and 6 months data were reported. The unaided visual acuity was tested at each of these visits. The proportion of patient who acquired a 6/6 vision after the procedure was 65.5%, 76.3% and 83.1% in the consecutive three visits. The 83% of the patients who achieved 6/6 unaided visual acuity at 6 month is almost similar to the proportion of patients with BSCVA at the baseline.

**Table 2:**

| Sr. No | Unaided visual acuity | Postoperative | | |
|---|---|---|---|---|
| | | day 1 (n=200) | Day 30(n= 190) | 6 month (n=166) |
| 1 | 6/6 | 131 (65.5%) | 145 (76.3%) | 138 (83.1%) |
| 2 | 6/9 | 39 (19.5%) | 36 (18.9%) | 15 (9.04%) |
| 3 | 6/12 | 26 (13%) | 7 (3.7%) | 11 (6.6%) |
| 4 | 6/18 | 14 (07%) | 2 (0.1%) | 2 (1.2%) |
| 5 | 6/24 | 0 (0%) | 0 (0%) | 0 (0%) |

**Table 3:**

| Sr. No | Preoperative BSCVA | Number of eyes (Percentage) |
|---|---|---|
| 1 | 6/6 | 166 (83%) |
| 2 | 6/9 | 23 (11.5%) |
| 3 | 6/12 | 7 (3.5%) |
| 4 | 6/18 | 4 (2%) |
| 5 | 6/24 | 0 (0%) |

## REFRACTIVE OUTCOMES

The mean preoperative spherical equivalent refraction was -3.82 ± 1.51 D for the right eye and -3.75 ± 1.6 D for the left eye (range, −2.00 D to −10 D). We observed a mean correction of -3.68 ± 1.41D for the right eye and -3.62 ±1.42 for the left eye restoring the refractive error towards normal with a mean of -0.144 ± 0.25D for the right eye and -0.12 ± 0.24D for the left eye (table 4)

**Table 4:** Comparison of refractive errors in preoperative and postoperative visit on day 1 (Wilcoxon signed rank test for non parametric data. P value of less than 0.05 is considered significant.)

| Sr. No | Parameter | Preoperative Visit | Postoperative Day 1 | Mean Correction | P value |
|---|---|---|---|---|---|
| 1 | RE: Spherical | -3.82 ± 1.51 | -0.144 ± 0.25 | -3.68 ± 1.41 | <0.001 |
| | RE: Cylindrical | -0.17 ± 0.24 | 0.0 ± 0.0 | -0.17 ± 0.24 | <0.001 |
| 2 | LE: Spherical | -3.75 ± -1.6 | -0.12 ± 0.24 | -3.62 ±1.42 | <0.001 |
| | LE: Cylindrical | -0.17 ± 0.24 | 0.0 ± 0.0 | -0.17 ± 0.24 | <0.001 |

## ADVERSE EFFECTS

The safety of the procedure was evaluated by the number of the adverse effects and the integrity of the flap (table no 5). The most common adverse effect observed was dry eye which occurred in 32% (n=64%) of the eyes. Dry eye was followed in frequency by experience of glare by the patients in 19% (n=38) of the cases. Regression of myopia over 30 days was observed in 4 (2%) cases while the bacterial keratitis was observed in 1(0.5%) case. The incidence of lost flap was only in 1 case which contributes to a total of 0.5% of the study population. The proportion of patients with more than one adverse effects was 15%. The total number of patients who experienced any one adverse effect was 38%. There were no adverse effects which were serious and required immediate medical support. All the adverse events were treated as per the investigator's evaluation of them, aligned with the protocol of the Department of Ophthalmology at the institute.

**Table 5 :** Safety profile of postoperative period

| Sr. No. | Adverse Effect | No of eyes (Percentage) |
|---|---|---|
| 1 | Dry eye | 64 (32%) |
| 2 | Glare | 38 (19%) |
| 3 | Myopic regression | 4 (02%) |
| 4 | Bacterial keratitis | 1 (0.5%) |
| 5 | Lost flap | 1 (0.5%) |

## DISCUSSION

LASIK has become a very popular and favorite procedure in the field of surgical Ophthalmology supported by its predictability, safety and efficacy. Since the inception of LASIK and its progress through various clinical studies, LASIK has demonstrated excellent acceptability among the patients as well as the ophthalmologists. As with any surgical procedure, the complications can arise and the risk benefit assessment remains an important criteria while selecting the best procedure for the patients for a specific indication. This study was conducted to support the evolving literature of the LASIK's safety and efficacy in a tertiary health care setup. In our study of 100 patients (200 eyes), 92.1% of the patients remained with an unaided visual acuity of 6/9 or better. These patients did not require any further correction as the mean refractive error was very acceptable being in the range of 0.0 to -0.45 for the whole study population. These finding are in coherence with the results of a similar observational study by Iqbal *et al*[6] who reported 96.5% (n=386 out of 400) eyes reached an unaided visual acuity of 6/12 or better in a six month follow up period. Schallhorn *et al*[7] in 2009, reported achievement of 20/20 or better in 92% of eyes and 99% of 20/40 or better. Patients with bilateral vision correction with LASIK achieved 20/20 uncorrected binocular vision in 99% of the cases. Balazsi *et al* reported that at six months after LASIK, uncorrected visual acuity was 6/9 or better in 94.6% eyes[8]. The current study showed a higher percentage of patients (7%) with unaided visual acuity 6/12 or more. This could be because of the 13 patients who were lost to follow up at 6 month visit considering the fact that it was more likely for the very satisfied patients to be unavailable for the follow up and the patients with more severe refractive error ensured the follow up. The results of this study are consistent with the findings of our study and further support the achievement of a very acceptable binocular vision status in the patients of myopia even in the low myopia subgroup. The number of patients who achieved a low myopia was 100% and the efficacy of the procedure reflected in the success of maintaining a mean postoperative error of 0.0 to -0.45D. This shows an obvious benefit in all types of myopia in the current study and a minor postoperative error could indicate towards terminating the use of spectacles and contact lenses even in the patient of high myopia. The finding of the current study are consistent with reports form McDonald *et al* and supports the evidence of efficacy in Low to high myopia patients with a refractive error upto -10D[9]. The most common postoperative complication of LASIK was found to be dry eyes. Battat *et al*[10] and Benitez *et al*[11] have related this effect to decrease in corneal sensitivity and reduced tear production after the procedure. Many other factors like altered corneal shape and reduced tear film coverage also contribute to this complication. This can manifest as decreased sensation, fluctuations in vision and foreign body sensation by the patient. In current study, 19% of the patients reported the experience of glare especially during night driving. The incidence of glare was reported to be 28.5% by Iqbal *et al*[6] while Danasoury *et al*[12] reported 40% experienced glare after LASIK. Factors contributing to night driving problems include a postoperative decrease in contrast sensitivity and starburst and halos around lights at night[13]. The origin of these symptoms is multifactorial and includes aberrations at the edge of the ablation zone, irregular astigmatism, decentered ablations, and flap striae. The regression of myopia was reported higher in studies by Iqbal *et al*[6] and Chayet *et al*[14] who reported almost 7.5% patients with myopic regression. This incidence is more common in patients of high myopia and in the current study, 2% patients observed this adverse effect. Flaps may become displaced during the early or late postoperative period. The current study found this incidence in 1 of the 100 patients and the flap loss was found on the first day of the postoperative period. The incidence of flap loss can be easily prevented by careful evaluation of the patient and appropriate preoperative assessments which include corneal thickness. Late flap displacements are usually a result of direct trauma and can be prevented by education of the patient for the postoperative care[15]. Only one case of bacterial keratitis was reported in the current study and the incidence was of less serious nature and did not require any surgical intervention. The similar incidence (0.5%) was reported by Iqbal *et al*[6] for the bacterial keratitis. LASIK has been regarded as the most successful elective procedure because of its safety and efficacy profile. The current study supports this evidence by efficacy findings consistent with the literature for all degrees of myopia and a favorable adverse effects profile and offer a validated choice for the chronic spectacle or contact lens users.

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