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## Evaluation of Safety and Efficacy of Laser Assisted Insitu keratomileusis for Correction of High Myopia - A Retrospective Study.

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### ABSTRACT

To evaluate safety and efficacy of Laser Assisted Insitu keratomileusis for correction of high myopia. Several factors determine the maximum correction possible for patients with high myopia. A retrospective study was conducted on 118 (171 eyes) patients who had undergone LASIK for myopia of  $>-10D$  and above, with or without astigmatism. A comparison between pre and post-operative visual acuity was done on the first day, first month and sixth month. Among the 118 patients, 39 patients (33.1%) had simple myopia and 79 patients (66.9%) had compound myopic astigmatism. Comparing the preoperative best corrected visual acuity with postoperative best corrected visual acuity at the end of 6 months, revealed that 160 eyes (93.6%) improved to  $\geq 6/12$ , while 11 eyes (6.4%) had a best corrected visual acuity of less than 6/12. Analysis of the best corrected visual acuity revealed a gain of 2 lines in 1 eye (0.6%) and a gain of 1 line in 28 eyes (16.4%), whereas 110 eyes (64.3%) remained the same. Our study shows that LASIK is an effective procedure for correction of high myopia (especially upto  $-15D$ ) with regard to an improvement in the best corrected visual acuity, uncorrected visual acuity and the stability of refraction and is a safe procedure with minimum complication involving no threat to vision.

**Keywords:** LASIK, High myopia, Laser Assisted Insitu keratomileusis

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## INTRODUCTION

Myopia is a refractive error where in parallel rays of light are brought to a focus in front of the retina, with accommodation at rest. Myopia is one of the most common ocular conditions in humans. The prevalence [1] of myopia is as follows:

Myopia above -6D is termed as high myopia. The elongation of the eye which results in pathological myopia is almost entirely confined to the posterior pole. The role of genetics is strongly considered in this myopia with higher prevalence among the Japanese and the Jews.

The greater the degree of myopia, the higher the incidence of abnormalities like Image minification, Anisometropic amblyopia, Visual field defects, Impaired dark adaptation, Abnormal colour discrimination and Suboptimal binocularity

Complications of high myopia includes Premature cataract formation, Retinal detachment, Rubeosis iris, Vitreous haemorrhage and Strabismus fixus convergences-due to lateral rectus underaction.

Treatment of high myopia[2]

- Optical -Spectacles, Contact lens and Orthokeratology
- Surgical - Alterations of cornea, Non corneal interventions.

### Surgical

Refractive surgeries par excellence is the ophthalmic surgery of the 21<sup>st</sup> century. Refractive surgeries encompasses a wide range of surgical modalities, which have the aim of changing the refractive status of the eye.

Keratorefractive surgery can alter the corneal biomechanics in several ways such as Incisional effect, Tissue addition/subtraction, Alloplastic material addition, Laser effect and Collagen shrinkage

Alterations of cornea [3] includes Radial Keratotomy, Lamellar procedure, Epikeratoplasty, Alloplastic intracorneal implants and Lasers (Photorefractive keratectomy, LASIK and LASEK).

Non corneal interventions includes Removal of clear lens and Phakic intraocular lenses [7].

### Lasik

Advantages of LASIK over PRK in high myopia

- Earlier post operative stabilization of visual acuity
- Less post operative patient discomfort
- Faster improvement in visual acuity
- Less stromal haze formation

- Possibly improved predictability, stability and corneal clarity
- Shorter duration of post operative medications use.
- Easier enhancement procedure

### **Customised ablation**

After refractive surgery, the most frequent optical aberration is spherical aberration which causes a reduction in visual acuity and the formation of halos in scotopic conditions. Customized ablation is designed to achieve aberration free ablations that improve quality of vision after refractive surgery.

Current customized ablation systems are based on corneal topography and wavefront measurements[4-6].

Refractive surgeries started in the year 1850 with Von grafe :ab externo incision for cataract surgery and has been developing till date[8]

### **LASERS IN CORNEAL REFRACTIVE SURGERY**

#### **Mechanism of action of corneal laser surgery [9]**

“Excimer” describes a recently developed class of lasers with output in the UV range of electromagnetic spectrum. The possibility that this type of laser could be built was first suggested in 1975, when Xenon atoms were found to react with halogens (X) to produce an unstable noble gas – halide compound XeX.

These compound XeX were found to rapidly dissociate to ground state with the release of an energetic UV photons. This pattern of excitation and dissociation led to the observation that “these emissions have considerable potential as a UV laser system for mixtures of Xenon (or other rare gases) and halogen containing compounds. Shortly after this report, 4 molecules Xenon Fluoride (XeF), Xenon chloride (XeCl), Xenon bromide (XeBr) and Krypton Fluoride (KrF) Were observed to lase when excited in an electron beam of laser action at 193.3nm. The Argon fluoride (ArF) molecule was reported in May 1976.

Different names are being used for these UV lasers. The short lived excited complan molecule at the heart of the laser’s action has come to be known as an “Excimer” short for an “excited dimmer” and has given rise to the most popular name for the series of laser based on this class of compounds.

This word small excimer first used by photo chemists in 1960 was originally coined to describe an energized molecule with two identical components. Because it was first theorized that the rare gas molecule in these new UV lasers formed an excited dimer with two identical components during its excitation. The descriptive name excimer was applied to the active medium

#### **Excimer Laser Type [13]**

some of the laser types are Fluorine, Argon Fluoride, Krypton Chloride, Krypton fluoride, Xenon Chloride,

Nitrogen, Xenon fluoride etc

## **BIOLOGICAL RESPONSE OF EXCIMER**

### **LASER CORNEAL ABLATION**

Excimer induced changes in corneal morphology

#### **Epithelial response to excimer laser photo ablation:**

Clinical studies have shown that reepithelialisation occurs within 3 to 5 days and the initial epithelial thickness consists of 3-5 cells. Over the following 6 to 18 months, the epithelium thickens primarily at the deepest part of the ablation site [14-19].

#### **Bowman's layer response to excimer laser photobleaching**

Destruction of Bowman's layer has previously been associated with permanent corneal scarring in the area of its removal either by injection or following the free hand lamellar dissection<sup>20</sup>. Acute and short-term studies of cornea excised after excimer laser photobleaching have demonstrated a smooth but sharply defined excision of Bowman's layer in the periphery of ablation site [21-24].

#### **Corneal stromal response of excimer laser photobleaching**

Proteoglycans are also produced in response to injury in most studies suggesting keratan sulfate as major compound produced [25-26]. The stromal events leading up to the production of new collagen and proteoglycans may be due in part to the absence of epithelium overlying the freshly ablated corneal collagen. Within first 24 hours after excimer PRK, stromal wound healing begins, as inflammatory cells invade the corneal stroma from tear film [27].

Ingress of (PMNS) polymorpho nuclear leucocytes can be seen after de-epithelisation alone but the number is significantly greater after PRK. Tear film plasmin levels are also markedly elevated during the post op period and signify involvement of the plasminogen activator system, which facilitates degradation, removal and repair of damaged collagen and extracellular matrix [28]. Immediately following PRK keratocytes in the anterior most collagen layers have vacuolated cytoplasm with ruptured cell membrane [29]. Within the first 3 days both PMNs and anterior stromal keratocytes disappear [30].

Since the cornea mounts a wound healing response following excimer PRK in the form of fibroblast activation and since it has previously been demonstrated that corticosteroids inhibit fibroblast proliferation [6-10, 31-33], it was logical to treat cornea with topical steroids following excimer photobleaching.

### **Descemments membrane response to excimer laser photoablation**

Acute and chronic morphological studies demonstrated an unusual fibrillar response in the mid to anterior one third in the rabbit. Only one human specimen has been found to have similar change.

### **Endothelial response to excimer laser photoablation**

Acute morphological studies of endothelium in animals and humans have failed to demonstrate endothelial changes, unless the excimer laser beam approaches Descemments membrane[34,35].

### **LASER EFFECT**

The amount of tissue to remove centrally is estimated by **Munnerlyn's formula** ablation depth in microns (micrometer) equals dioptres (D) of myopia divided by 3 times the square of optical zone (mm)

$$\text{Ablation depth in microns} = D/3 \times (\text{ablation diameter in mm}^2)$$

Clinical experience has confirmed that the effective change is independent of the initial curvature of the cornea although other formula have been proposed that include pre operative curvature

The amount of ablation increase by the square of the optical zone but the complication of glare, halos and regression increase when the optical zone decreases. To reduce these side effects the optical zone ideally should be 6 mm or larger.

### **EFFICACY OF LASIK – Review of literature**

Recently excimer laser keratomileuses to correct high myopia[36-38] has generated high expectation among refractive surgeons. This technique combined the excimer laser's accuracy to remove the corneal tissue and the microtomes ability to access inner stroma and preserve Bowman's membrane, reducing the effect of wound healing and problems associated with PRK

In reviewing the literature, it is difficult to compare studies [39,40] because of variations in the range of preoperative myopia ,follow up period, Laser Nomograms, microkeratomes and techniques , time frame of the study, investigator's experience ,compliance to follow-up.

Because of the rapid evolution of LASIK technology, it is difficult to extrapolate results in the literature that or comparable to current practices that use the most recent generation lasers.

A compelling advantage of LASIK over other refractive surgical procedures is the rate of visual recovery [41,42]

LASIK for high myopia&myopic astigmatism[43] P.I.Condon et al.BJO 1997;81:199-206

The authors describe initial experiences in 51 eyes of myopic patients, ranging from -8 to -37D. Stable refraction, reasonably predictable outcomes, minimal regression, less post operative pain, little subepithelial haze were seen when compared to high myopic PRK.

LASIK to correct high myopia.[44,55] Juan.J.Perez Santonja et al.JCRS1997;23:372-385

This study evaluated the efficacy, predictability & safety of LASIK in 143 eyes with myopia from -8D to -20D. Uncorrected visual acuity improved in 45% of eyes at 3 months & at 6 months, 46.4% had UCVA of 6/9 or better. Best corrected visual acuity improved by one line over pre operative values. Both UCVA & BCVA were stable after 3 months. Also 46% with moderate myopia & 50% with high myopia were within 1D of emmetropia. Results showed regression of effect of 0.50D between 1-3 months. This indicates that when the preoperative myopia is between -8D to -16D. The refractive effect of LASIK tends to remain stable after 3 months after surgery.

Stability after LASIK in moderately & extremely high myopic eyes.<sup>45</sup> Roberto Magallenes et al.JCRS 2001;27:1007-1012

Single centre clinical trial conducted on 52 eyes. The refractive effect of myopic LASIK upto -15D [range -7D to -15D] remained reasonably stable during the second post operative year. Significant regression of refractive effect occurred in eyes with higher levels of myopia [>-15D]. Corneal ectasia was evident in 1 eye in the extreme high myopic group.

Excimer LASIK & PRK for the correction of high myopia <sup>45,61</sup> I.Pallikaris et al. Journal of Refractive Surgery;10:498-510.

Concerning predictability, in a series of 10 myopic eyes with a preoperative myopia between -10D to -26D, found that 66% had a refraction within 1 D of emmetropia, 12 months after surgery. They observed a mean regression greater than 5D after PRK & less than 1.50D after LASIK.

Results of LASIK in different degrees of myopia.<sup>47</sup> Arturo Maldonado Bas et al. Ophthalmology 1998;105:606-611

300 consecutive eyes were divided into 4 groups according to their degree of pre operative myopia. Group III was between -10.25D & -15D, Group IV was between -15.25D & -25.50D. In this study, LASIK corrected 92.12% of the spherical equivalent. Best corrected visual acuity increases in the post operative periods in terms of the percentage of the eyes that have 6/9 or better.

LASIK for high myopia [-9D to -22D] with the VISX Star laser [48] Gary.M.K.Kwaesh et al. Ophthalmology 2000;107:653 to 661

290 eyes of 175 patients were studied. Early results showed that 75% of eyes had 6/9 or better vision. Reoperations for refractive enhancement were performed on 60 eyes.

Late results, including reoperations, showed UCVA results of 6/9 or better in 85% of eyes. This analysis showed that refractive stability was present in most eyes 77.1%.

LASIK for moderate to high myopia & myopic astigmatism [49,58] Michael.C.Knorz et al. Ophthalmology 1998;105:932-940.

This study evaluated the predictability, stability and safety of LASIK in 35 eyes of myopic patients.

|  | <u>Subgroup1</u><br>[-5D to -9D] | <u>Subgroup11</u><br>[-10D to -14.9D] | <u>Subgroup111</u><br>[-15D to -29D] |
|--|----------------------------------|---------------------------------------|--------------------------------------|
| 1] Predictability                      | 100% +/-1D                       | 78.3% +/-1D                           | 38.9% +/-1D                          |
| 2] Regression less than or equal to 1D | 100%                             | 100%                                  | 72.2%                                |
| 3] UCVA > 6/9                          | 87.5%                            | 77.8%                                 | 33.3%                                |
| 4] Lost 2 lines                        | None                             | 10%                                   | 5.6%                                 |
| 5] Highly satisfied                    | 100%                             | 90%                                   | 78%                                  |

Regression & its mechanism after LASIK in moderate & high myopia [50,55] Arturo.S.Chayet et al. Ophthalmology. 1998;105:1194-1199.

Early regression of refractive effect appears to be a consequence of an increase in corneal thickness associated with corneal steepening. No evidence of progressive corneal ectasia was observed during the first year of follow up in this study.

PRK versus LASIK for moderate to high myopia. A randomized prospective study [51] Peter.S.Hersh et al. Ophthalmology 1998;105 :1512-1523

A total of 220 eyes entered the study cohort. 105 were randomised to PRK & 115 to LASIK. Improvement in UCVA was more rapid after LASIK. From months 1 to 6, there was an average regression of 0.89D in the PRK group and 0.55D in the LASIK group. After PRK, 8 eyes had a decrease in spectacle corrected visual acuity, whereas in LASIK it was 2 eyes.

Visual outcome in high myopia after LASIK [52, 54] Noel.Moniz et al. JRS 2000;16 suppl:s247-s250

145 myopic eyes with >-12D were studied. 40% of eyes gained at least 1 line, 56% remained the same, 4% lost 1 line of visual acuity. 35 eyes were under corrected. No eye had any visually disabling gaze

Functional, psychological and satisfaction outcome of LASIK for high myopia. [53] Charles M.J. Mc Ghee et al. JCRS 2000:497-509

An anonymous 34 item questionnaire was forwarded to 50 consecutive patients. 81% to 100% reported functional improvement; 88% experienced difficulty with night time driving, 97.9% were satisfied with the speed of recovery, 97.9% reported improved quality of life, 97.9% were satisfied with the overall outcome of LASIK.

## COMPLICATIONS OF LASIK

### Intraoperative Complications [8,59]

Inadequate exposure, inadequate suction, microkeratome complications, Flap complications.

### Early Post-Operative Complications [8,59] (24 To 48 Hrs)

Keratitis , Sands of Sahara , Interface debris , Flap complications

### Late Post-Operative Complications [8,59]

Epithelial ingrowth, Irregular astigmatism, Regular astigmatism , regression, over correction , under correction , Ectasia, Central Islands , Visual problems

## AIMS OF THE STUDY

- To study the **safety** - measured by intra and postoperative complications following LASIK for high myopia
- To study the **efficacy** - as measured by the stability and improvement in visual acuity

## MATERIALS AND METHODS

A retrospective study, conducted at the Ophthalmology Department of Sri Lakshmi Narayana Institute of Medical Sciences and Indhra Gandhi Medical College And Research Institute , on patients who had undergone LASIK

Duration of study : 13 Months  
Number of patients : 118  
Number of eyes : 171

### Inclusion criteria

Patients aged 18yrs and above of either sex, patient with high myopia of >-10D and above, with or without astigmatism were included

### Exclusion criteria

Patients with glaucoma ,keratoconus, systemic disease like collagen vascular disease ,corneal power <41D or >47D, dry eyes ,previous refractive surgery ,associated cataract ,pregnancy ,pathological myopia ( relative contraindication) were excluded.

### Preoperative evaluation

Patients underwent uncorrected visual acuity ,best corrected visual acuity –dry refraction and cycloplegic refraction ,automated refraction ,keratometry , corneal

topography ,slit lamp examination ,ultrasonic pachymetry, dilated fundus examination by retinal surgeon.

**Post-operative evaluation**

Was done on the first day, first month and sixth month. Uncorrected visual acuity, best corrected visual acuity ,slit lamp evaluation was done on all the above visits

**RESULTS**

**Preoperative Uncorrected Visual Acuity Vs Postoperative Uncorrected Visual Acuity – Day 1**

| Preoperative Uncorrected Visual Acuity | Postoperative Uncorrected Visual Acuity – Day 1 |      |      |      |      |     |     | Total |
|--|---|------|------|------|------|-----|-----|-------|
|  | 6/60  | 6/36 | 6/24 | 6/18 | 6/12 | 6/9 | 6/6 |       |
| 1/60                                   | –   | –    | 2    | 5    | 4    | 7   | 5   | 23    |
| 2/60                                   | 2   | 2    | 2    | 5    | 16   | 29  | 14  | 70    |
| 3/60                                   | –   | –    | 4    | 6    | 9    | 16  | 21  | 56    |
| 4/60                                   | 1   | –    | 1    | 2    | 5    | 9   | 4   | 22    |
| Total                                  | 3   | 2    | 9    | 18   | 34   | 61  | 44  | 171   |

In 139 eyes (81.3%), postoperative uncorrected visual acuity had improved to  $\geq 6/12$  and 32 eyes (18.7%) had an uncorrected visual acuity less than 6/12.

**Preoperative Uncorrected Visual Acuity Vs Postoperative Uncorrected Visual Acuity – Month 1**

| Preoperative Uncorrected Visual Acuity | Postoperative Uncorrected Visual Acuity – Month 1 |      |      |      |      |      |     |     | Total |
|--|---|------|------|------|------|------|-----|-----|-------|
|  | 5/60  | 6/60 | 6/36 | 6/24 | 6/18 | 6/12 | 6/9 | 6/6 |       |
| 1/60                                   | 1   | 1    | 4    | 1    | 6    | 3    | 2   | 5   | 23    |
| 2/60                                   | –   | 3    | 2    | 4    | 6    | 12   | 22  | 21  | 70    |
| 3/60                                   | –   | 1    | 3    | 3    | 2    | 7    | 16  | 24  | 56    |
| 4/60                                   | 1   | 1    | –    | –    | 1    | 5    | 4   | 10  | 22    |
| Total                                  | 2   | 6    | 9    | 8    | 15   | 27   | 44  | 60  | 171   |

In 131 eyes (76.5%), postoperative uncorrected visual acuity improved to  $\geq 6/12$  and 40 eyes (23.5%) had a postoperative uncorrected visual acuity of less than 6/12.

**Preoperative Uncorrected Visual Acuity Vs Postoperative Uncorrected Visual Acuity – Month 6**

| Preoperative Uncorrected Visual Acuity | Postoperative Uncorrected Visual Acuity – Month 6 |      |      |      |      |      |      |     |     | Total |
|--|---|------|------|------|------|------|------|-----|-----|-------|
|  | 4/60  | 5/60 | 6/60 | 6/36 | 6/24 | 6/18 | 6/12 | 6/9 | 6/6 |       |
| 1/60                                   | –   | 2    | 1    | 3    | 1    | 5    | 4    | 1   | 6   | 23    |
| 2/60                                   | 2   | –    | 2    | 1    | 5    | 4    | 11   | 24  | 21  | 70    |
| 3/60                                   | –   | –    | 2    | 2    | 2    | 2    | 5    | 17  | 26  | 56    |
| 4/60                                   | –   | 1    | 1    | –    | 1    | 1    | 4    | 4   | 10  | 22    |
| Total                                  | 2   | 3    | 6    | 6    | 9    | 12   | 24   | 46  | 63  | 171   |

In 133 eyes (78%), postoperative best corrected visual acuity improved to  $\geq 6/12$  and while 38 eyes (22%) had a postoperative uncorrected visual acuity of  $\leq 6/12$ .

**Preoperative Best corrected Visual Acuity Vs  
Postoperative Best corrected Visual Acuity – Month 1**

| Preoperative Best corrected Visual Acuity | Postoperative Best Corrected Visual Acuity – Month 1 |      |      |      |     |     | Total |
|---|--|------|------|------|-----|-----|-------|
|   | 6/36   | 6/24 | 6/18 | 6/12 | 6/9 | 6/6 |       |
| 6/24                                      | 1  | –    | 2    | –    | –   | –   | 3     |
| 6/18                                      | –  | 1    | 1    | 6    | –   | –   | 8     |
| 6/12                                      | –  | –    | 2    | 19   | 4   | 1   | 26    |
| 6/9                                       | –  | –    | 2    | 9    | 33  | 17  | 61    |
| 6/6                                       | –  | –    | 1    | 1    | 19  | 52  | 73    |
| Total                                     | 1  | 1    | 8    | 35   | 56  | 70  | 171   |

In 161 eyes (94.1%), postoperative best corrected visual acuity had improved to  $\geq 6/12$ , where as 10 eyes (5.9%) had postoperatively a best corrected visual acuity of less than 6/12.

**Preoperative Best corrected Visual Acuity Vs  
Postoperative Best corrected Visual Acuity – Month 6**

| Preoperative Best corrected Visual Acuity | Postoperative Best Corrected Visual Acuity – Month 6 |      |      |      |     |     | Total |
|---|--|------|------|------|-----|-----|-------|
|   | 6/36   | 6/24 | 6/18 | 6/12 | 6/9 | 6/6 |       |
| 6/24                                      | 1  | –    | 2    | –    | –   | –   | 3     |
| 6/18                                      | –  | 1    | 2    | 5    | –   | –   | 8     |
| 6/12                                      | –  | –    | 3    | 18   | 4   | 1   | 26    |
| 6/9                                       | –  | 1    | 1    | 8    | 34  | 17  | 61    |
| 6/6                                       | –  | –    | –    | 1    | 16  | 56  | 73    |
| Total                                     | 1  | 2    | 8    | 32   | 54  | 74  | 171   |

In 160 eyes (93.6%), postoperative best corrected visual acuity had improved to  $\geq 6/12$ , where as 11 eyes (6.4%) had a postoperative best corrected visual acuity less than 6/12.

**Gain/ Loss in Snellen Lines - Day 1 Postoperative**

In our study of 171 eyes, on the first postoperative day, 17 eyes (9.9%) gained one line. 113 eyes (66.1%) stayed same. 39 eyes (22.8%) lost one line and 2 eyes (1.2%) lost 2 lines.

**Gain/Loss in Snellen Lines - Month 1 Postoperative**

In our study of 118 patients, follow up on the first post operative month showed that 29 eyes (17.0%) had gained one line, 1 eye (0.6%) had gained 2 lines. 105 eyes (61.4%) remained the same 32 eyes (18.7%) had lost 1 line, 3 eyes (1.8%) lost 2 lines and 1 eye (0.6%) lost 3 lines.

**Gain/Loss in Snellen Lines - Month 6 Postoperative**

In our study of 171 eyes gain of Snellen’s line (best corrected visual acuity) at 6<sup>th</sup> postoperative month showed the following.

28 eyes (16.4%) had gained one line, 1 eye (0.6%) had gained 2 lines, 29 eyes (17%) had lost one line, 2 eyes (1.2%) had lost two lines, 1 eye (0.6%) had lost 3 lines and 110 eyes (64.3%) remained the same.

**Post operative regression in high myopes– Month 6**

| Preoperative Spherical Equivalent | Postoperative Spherical Equivalent<br>– Month 6 |               |                 |                |               |         |
|-----------------------------------|---|---------------|-----------------|----------------|---------------|---------|
|                                   | -5d to –<br>6D                                  | -4D to–5<br>D | -3D to –<br>4 D | -2D to -<br>3D | -1D to-<br>2D | Oto –1D |
| -18.0D to -20.0D                  | 1   | –             | 1               | –              | 1             | –       |
| -15.0D to -18D                    | –   | 1             | 4               | 2              | 1             | 1       |
| -10.0D to -15D                    | –   | –             | –               | 4              | 6             | 5       |
| Total                             | 1   | 1             | 5               | 6              | 8             | 6       |

In our study of 171 eyes, comparison of spherical equivalent preoperatively and postoperatively on sixth month revealed:

In the preoperative range – 18 to –20D, out 5 eyes 1 eye had regression between –5D to –6D, 1 eye had regression of –4D and 1 eye had regression of –1 to –2D.

In the preoperative range of –15 to –18D, out of 28 eyes, 4 eyes were less than –3D, 4 eyes were within –3D to –4D, 1 eye was within –4 to –5D.

In the preoperative range –10 to –15D, out of 138 eyes, 15 eyes had less than –3, 1 eye was less than 1D.

**Postoperative Complications**

Out of 171 eyes, only 1 eye had interface debris, on the first postoperative day which had resolved on subsequent follow up on the 1<sup>st</sup> and 6<sup>th</sup> month.

**Summary of Results**

In a study of 118 patient involving 171 eyes, who had undergone, Laser assisted in situ keratomileusis for myopia (without or with astigmatism) of ≥ -10D, with follow up of 6 months, the following were the observations:

- Out of 118 patients, 76 patients (64.4%) were within 21-30 years age group.
- Out of 118 patients in the study, 63 patients (53.4%) were males and 55 (46.6%) were females.
- Among the 118 patients, 39 patients (33.1%) had simple myopia and 79 patients (66.9%) had compound myopic astigmatism.

- Comparison of the preoperative uncorrected visual acuity and postoperative uncorrected visual acuity at the end of 6 months showed that 133 eyes (78%) had improved to  $\geq 6/12$  postoperatively, while 38 eyes (22%) had uncorrected visual acuity of less than 6/12
- Comparing the preoperative best corrected visual acuity with postoperative best corrected visual acuity at the end of 6 months, revealed that 160 eyes (93.6%) improved to  $\geq 6/12$ , while 11 eyes (6.4%) had a best corrected visual acuity of less than 6/12.
- Analysis of the best corrected visual acuity revealed a gain of 2 lines in 1 eye (0.6%) and a gain of 1 line in 28 eyes (16.4%), where as 110 eyes (64.3%) remained the same.
- Myopic regression calculated on the basis of spherical equivalent revealed that in the myopes with preoperative power of  $-18D$  to  $-20D$ , 3 eyes had myopic regression at the end of 6 months. In myopes of between  $-15D$  to  $-18D$ , out of 28 eyes, 9 eyes had a myopic regression in the range of 0 to  $-5D$ . In myopes of  $-10$  to  $-15D$ , out of 130 eyes, 15 eyes had myopic regression in the range of 0 to  $-3D$ .
- Out of 171 eyes, 1 eye had interface debris on the first postoperative day.
- There were no intraoperative complications. There was no complication at the end of first and 6th month postoperatively.

## DISCUSSION

Laser in situ keratomileusis is a keratorefractive surgical technique that combines the precision of excimer laser photoablation with the advantages of an intrastromal procedure that maintains the integrity of Bowman's layer and the overlying corneal epithelium. Parameters analysed were uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BCVA), residual refractive error, regression of correction and presence of any complications.

- The age group of our study population ranged from 19-42 years. The average age of our study population was 26.5 years. In a study by Juan. J. Perez Santonja, the age ranged between 20 to 60 years. In a study by Arturo Maldonado et al, the average age was 31.5 with a range of 11 to 57 years.
- In our study, gender distribution was 53.4% male and 46.6% females. In a study by P.I. Condon et al, 70% of the cases were females. In a study by Arturo Maldonado et al, gender distribution was 58.2% female & 41.8% males.
- At the end of 6<sup>th</sup> postoperative month, 133 eyes (78%) improved to a postoperative uncorrected visual acuity of  $\geq 6/12$ .
- In a study by Gary M. Kawesch et al., a postoperative uncorrected visual acuity of  $\geq 6/12$  occurred in 166 of 195 eyes (85.1%).
- In a study by Michael C. Knorz et al., showed postoperative uncorrected visual acuity of  $\geq 6/12$  in 45% to 78% of the study population.
- In a study by Arturo Maldonado et al., 62 eyes (68.13%) had postoperative uncorrected visual acuity  $\geq 6/12$  and 3 eyes (3.30%) had postoperative uncorrected visual acuity of 6/6 in myopia of  $-10.25$  to  $-15D$  and 14 eyes (32.5%) had a postoperative uncorrected visual acuity  $\geq 6/12$  (in myopia of  $> -15D$ ).

- In our study, analysis of best corrected visual acuity at the end of 6<sup>th</sup> operative month revealed that 160 eyes (93.6%) improved to  $\geq 6/12$ .
- In a study by Arturo Maldonado et al, 68 eyes (80.95%) obtained a best corrected visual acuity of  $\geq 6/12$ .
- In a study by P.I. Condon et al., 58% of cases, improved to a postoperative best-corrected visual acuity of  $\geq 6/12$ .
- In a study by Peter. S. Hersh et al, 16 eyes (26.2%) and 34 eyes (55.7%) eyes saw 20/20 and 20/40 or better respectively.
- In our study, among the 171 eyes, 1 eye (0.6%) revealed a gain of 2 lines, 28 eyes (16.4%) revealed a gain of 1 line, 110 eyes (64.3%) remained the same, 29 eyes (17%) had lost 1 line, 2 eyes (1.2%) lost 2 lines and 1 eye (0.6%) lost 3 lines.
- In a study by Noel Moniz et al., 40% gained atleast one line, 56% remained the same, 4% lost one line of visual acuity (145 eyes with myopia  $> -12D$  were studied)
- Gary et al., approximately 3.6% eyes lost 2 lines more of best corrected visual acuity.
- In a study by Arturo Maldonado et al, 12 eyes (14.11% had lost Snellen line, where as 6 eyes (7.05%) had lost 2 lines, 20 eyes (23.52%) had gained 1 line and 13 eyes (15.29%) gained 2 lines.
- Loss of Snellen's line may be due to interface abnormalities ,flap abnormalities ,central island,errors in marking / ablation ,decentration, optical aberrations due to reshaping cornea.
- In our study, the loss in Snellen's lines could have been due to one of the above factor, wrong documentation of preoperative best corrected visual acuity or an fundus pathology.
- In our study, analysis of the spherical equivalent of the study population revealed that majority of eyes that is 143 eyes (83.6%) had no refractive error, 7 eyes (4.1%) were within  $\pm 1D$  of myopia, 8 eyes (4.7%) had a final spherical equivalent ranging from  $-1$  to  $-2D$ , 6 eyes had a final spherical equivalent ranging from  $-2$  to  $-3D$ , 5 eyes (2.9%) had a final spherical equivalent ranging from  $-3$  to  $-4D$  and 2 eyes (1.2%) had a final spherical equivalent ranging from  $-4$  to  $-6D$ , at the end of 6 months.
- Myopic regression calculated on the basis of spherical equivalent, showed that in myopes with preoperative power of  $-18$  to  $-20D$ , 40% had myopic regression at the end of 6 months. In myopes between  $-15$  to  $-18D$ , 9 eyes had myopic regression in the range of 0 to  $-5D$ . In myopes of  $-10D$  to  $-15D$ , 15 eyes (10.8%) had myopic regression in the range of 0 to  $-3D$ .
- In a study by Arturo S. Chayet, the mean refractive regression was  $-1.07$  (7.6%) from the first week to the third month.
- In a study by Arturo Maldonado et al., 86 eyes showed the following results; 44 eyes (51.16%) were within  $\pm 1D$ , 30 eyes (34.88%) within  $\pm 2D$ , and 12 eyes (13.95%) within  $\pm 3D$  (in myopia of  $-10$  to  $-15D$ ).
- Potential mechanisms for regression of refractive effect include:corneal ectasia,corneal hydration, stromal synthesis, compensatory epithelial hyperplasia,nuclear sclerosis of the crystalline lens.However, none of the above causes were found in our study.
- There were no intra operative complications. This may be due to fairly strict selection of cases.

- On the first postoperative visit, interface debris was seen in 1 patient, which resolved in subsequent visits. No complications were encountered in the first and six postoperative months.
- In a study by Juan. J. Perez Santonja et al., corneal flap melt or necrosis was observed postoperatively in 3.5% of eyes.
- In a study by Gary et al., flap wrinkling and epithelial in growth were reported in approximately 2 % of eyes.
- In a study by P.I. Condon et al., corneal complications occurred in 17 cases.

### CONCLUSION

Several factors determine the maximum correction possible for patients with high myopia:

- The total corneal thickness
- A flap of atleast 120 micrometer thickness must be created.
- The residual corneal thickness beneath the ablation must not be less than 250 micrometer.
- The diameter of the optical ablation zone.

Our study shows that LASIK is an effective procedure for correction of high myopia (especially upto -15D) with regard to an improvement in the best corrected visual acuity, uncorrected visual acuity and the stability of refraction and is a safe procedure with minimum complication involving no threat to vision.

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