

## STUDY THE VISUAL OUTCOME AND COMPLICATION OF FEMTOSECOND LASIK.

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### BACKGROUND

In the past decade the introduction of femtosecond lasers (FSL) has made a drastic change in the way refractive surgery is being done. The Intralase Femtosecond Laser was released for use in the year 2001 by the American owned Abbott Medical Optics. This technique has the advantage that the laser is used to cut the tissues of the lenticule a part of the corneal stroma instead of ablating it with the excimer laser. With this in mind we tried to assess the visual outcome and complication of femtosecond Lasik at the tertiary eye care centre. **Methods:** A case

series study was conducted at tertiary eye care institute. The patients were within age group of 18 to 40 years of age attending the outpatient department suffering from difficulty in vision due to refractive error like myopia, hyperopia, and astigmatism. This study included 101 patients with the refractive error undergoing femtosecond lasik surgery. Follow up was performed after a period of 2 days, 5 days, 2 weeks, 1 month of surgery. **Results:** In this study, we found majority of patients undergoing femtosecond lasik were in the age group of 20-24 years. In 200 eyes examined preoperatively LogMAR visual acuity has a mean variation of 0.19 with SD 0.08. Unaided postoperative day 2 vision revealed excellent outcome when compared to preop vision with  $p(0.001)$  stating it to be statistically significant. Consistent results sprang up during the study period in subsequent post op day follow up on 5th day, 2 weeks and 1 month. **Conclusions:** Femtosecond Lasik had Excellent Visual Outcomes and Lesser Complications.

**KEYWORDS:** Visual Complication, Femtosecond Lasik.

## BACKGROUND

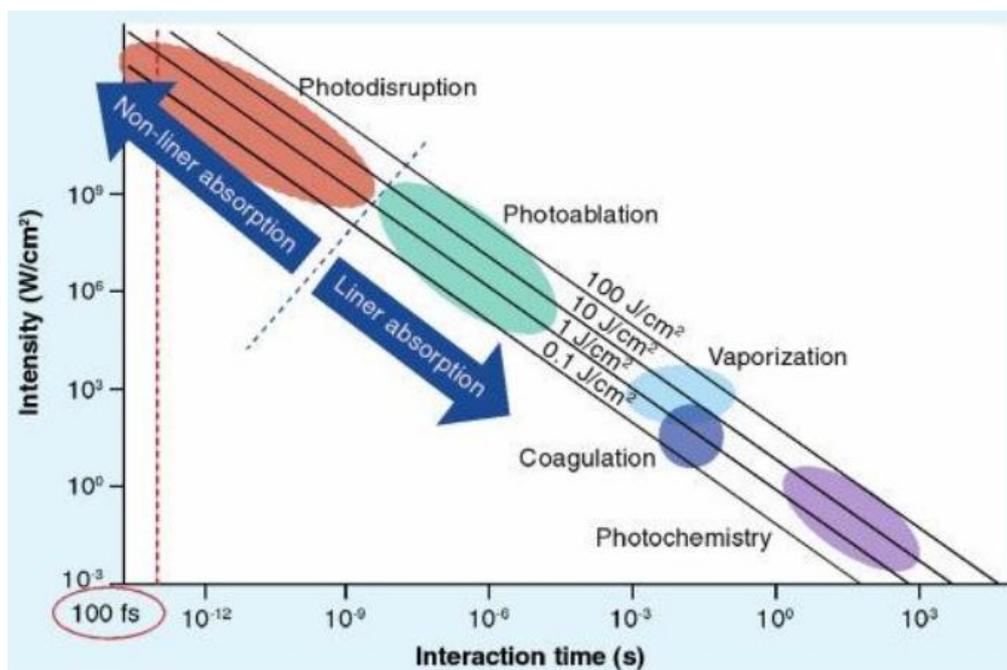
In the past decade the introduction of femtosecond lasers has made a drastic change in the way refractive surgery is being done. the Intralase Femtosecond Laser was released for use in the year 2001 by the American owned Abbott Medical Optics.

This technique has the advantage that the laser is used to cut the tissues of the lenticule a part of the corneal stroma instead of ablating it with the excimer laser. The method of bladeless flap construction gained recognition at a very fast pace since of its promised improved protection and safety,<sup>[1]</sup> along with a rapid improvement and exceptional results.

As this method is easy and fast many centres that have a high turnover of patients who come of treatment of refractive errors and require surgery uses this new modality, This new modality femtosecond laser to make the flap.

All the devices that are available in the market for commercial use, make use of the near infrared femtosecond laser that has an approximate wavelength 1053 nm.

Even though the neodymium-doped yttrium-aluminium garnet laser and the femtosecond laser have a very similar wavelength, the shorter pulses in in the femtosecond laser has a very great advantage that it causes much less damage to the collateral tissues.<sup>[2]</sup>



**Figure 1: Varying the Duration of the Laser Pulses and Energy applied can Generate different Effects on the Tissue.**

Laser pulse repetition rate the spot size energy of the pulse generated and the pattern of the pulse are the chief procedural specifications that has an important part to play in the femtosecond laser. There is an opposite association linking the laser pulse period and the energy necessary in,<sup>[3]</sup> each pulse to produce the optical breakdown. That means a short (200–500 fs) will require lesser energy to attain the threshold of photodisruption than a longer pulse (500–1300 fs). The numerical opening of the lens has an important influence on the the laser spot with respect to both the diameter and volume.

A higher numerical aperture causes less dispersion when it focuses the beam. This is the behind why higher numerical aperture devices make use of a lower energy. Higher numerical aperture leads to an increase in the accuracy of the depth and the overall precision of the lamellar cut.

The initial devices operated with a low KHz repetition rate (15 KHz – first Intralase model) and required a higher energy to photodissection. The latter devices (even the newer high-energy devices such as IntraLase 150 KHz) aim to augment the repetition rate, which helps to reduce the duration, use a lower energy hence reducing the inflammation

The spot size and separation can also be lowered in higher repetition rates. that will help to make the cut surface smoother without altering the duration of the procedure.

Hence an the ideal device would comprise a high repetition rate, small spot size and low energy per pulse. The commonly used are the pulse patterns are corneal cutting devices: raster and spiral. The first involves pulses that are applied in a linear pattern, starting at the hinge area, passing through the center of the cornea and finally extending to the opposite edge.

The spiral pattern is applied when the laser pulses begin centrally and expand centrifugally out to the periphery (centripetally can also be used). Most devices use the raster pattern, which was found to produce a smoother stromal bed in the Intralase machine. Visumax (Carl Zeiss Meditec AG, Jena, Germany) uses the spiral pattern. Rainbow glare is an optical effect due to light scattering from the perfect array of laser spots remaining on the back surface of the flap. It can create a spectral pattern whose visual impact is clinically inconsequential in the majority of patients. Both of these situations are predominately related to earlier, femtosecond laser devices with higher raster energy and lower numerical aperture

optics. The IntraLase was the first device and set the standards regarding energy delivered and geometry of cuts. The IntraLase had the strategic advantage of being the first, and achieved a significant market penetration, so that it is number one in the marketshare.

In the past decade the introduction of femtosecond lasers (FSL) has made a drastic change in the way refractive surgery is being done. The Intralase Femtosecond Laser was released for use in the year 2001 by the American owned Abbott Medical Optics.

This technique has the advantage that the laser is used to cut the tissues of the lenticule a part of the corneal stroma instead of ablating it with the excimer laser. though the overall outcomes are not as good as the excimer laser, it has many other advantages that i.e ablates the need for two lasers and is much less time consuming with acceptable results. The reduction the efficacy of the laser at the edge of the cornea that is seen with the excimer laser ablation that causes varying results is much less likely to happen with the femtosecond lasers, with the first results showing a large prelate treatment zone, and with less induction of high-order aberrations.<sup>[5]</sup>

With this in mind we tried to assess the visual outcome and complication of femtosecond Lasik at the tertiary eye care centre.

## METHODOLOGY

A case series study was conceived and planned at the National Institute Of Ophthalmology Hospital, Pune, Maharashtra, a comprehensive eye care centre which acts as a tertiary unit for eye care in western Maharashtra. Following clearance from the institutional scientific committee and ethical committee to carry out the study the study was initiated. The patients attending the outpatient department of National Institute Of Ophthalmology Hospital, Pune, Maharashtra, between June 2018 to May 2019 were chosen based on a pre defined criteria mentioned below.

### Inclusion Criteria

- Patients with refractive error.
- Patients with stable refraction for 1 year.
- Patients from either sex were included in the study.
- Patient within age group of 18 to 40 yrs.
- Patients with no media opacity or retinal pathology or gross ocular disease, Central

corneal thickness minimum of 500 micrometers.

- Patients having refractive error falling within the range mentioned in the below table were included in the study.

### **Refractive Error Type Range**

- The range to define Myopia in the study was -1.00 Ds to -12.00 Ds.
- The range to define Hypermetropia in the study was +1.00 Ds to + 6.00 Ds.
- The range to define Astigmatism in the study was +1.00 Ds to + 5.00 Ds.

### **Exclusion Criteria**

- Patients with retinal pathology other than MRD and low vision due to other cause other than refractive error, Patient who has preoperative inflammatory ocular disease or glaucoma, Patient who has media opacification and cataract, Patient with pre-existing corneal disease(keratoconus, opacity),
- Patients with moderate to severe dry eyes, Previous intraocular surgery/ trauma to same eye.
- Patient who doesn't follow up, Patient who doesn't understand implication of protocol.

### **Data Collection**

The patients who met the criteria were chosen for the study and were given detailed information of the study. 200 eyes of 101 patients who gave informed written consent were chosen by universal sampling method to be included in the study All patients underwent a detailed slit lamp examination using Appaswamy machine to rule out dry eye, any conjunctival pathology, corneal diseases like keratoconus or another degenerative, The intraocular pressure is measured using NCT (Keeler Plusair). The pupil morphology and reaction and corneal topography and pachymetry was done using Pentacam (Sirius) A detailed fundus examination was done by retina consultant using IDO by volks 20 D to note any pathology like MRD, WWOP, Lattice degeneration so that if any patient found with the lattice degeneration or so is pre operatively treated with Barrage laser. Once the patient was fit for the surgery they were given an appointment. All the cases underwent femtosecond lasik surgery for difficulty in vision as a result of all types of error in the refraction. The patients were evaluated by Autorefractometre (Tomey) to take reading. Follow up was performed following femtosecond lasik surgery on post-operative day 2 days 5 day, 14 day (2 weeks) and day 20 (1 month). The follow up visits included-Visual acuity testing using log mar

vision chart, IOP measurement, the condition of cornea assessment and documented on each post-operative visit with the slit lamp examination. The results of the studies was analysed based on the demographic details pre and post-operative visual outcome, intraocular pressure, and were presented in appropriate charts, tables, graphs and figures and statistically interpreted.

### **Analysis of the data and the statistics**

The data was tabulated in the MS Excel. this was then statistically analyzed in SPSS version 16. The data of the study was categorised into quantitative variables and the qualitative variables. The quantitative variables were evaluated with mean, standard deviation, frequency and percentage. the qualitative variables were analyzed by the Paired 't' test. A p value less than 0.05 was taken to be statistically significant.

### **The observations and results in the study**

Majority of the sample population i.e. 75% belonged to age group between 20-29 years. Males formed 44% of sample and 56/5 of them were females (Table 1). 86% of eyes had pre operatively normal anterior segment findings. Exophoria existed in the 11% of the eyes studied. For 74.5% of eyes with the refractive error were corrected with the spectacles. In Table 2 we can see that 25.5 % of eyes had previously contact lens application to rectify the refractive error. Pre op fundus evaluation of 32.5.% of eyes revealed normal findings, Myopic retinal degeneration existed in 61.0% eyes pre operatively. Pre operatively barrage laser treatment was given in 2.5% of eyes.

In table 3a we can see that the average LogMar Visual acuity significantly improved at day 2, day5, week 2 and 1-month follow-up compared to pre-op LogMar Visual acuity ( $P < 0.001$ ). Table 3b shows Significantly higher proportion of eyes achieved 6/6 vision at Day 2, day 5, week 2 and 1month post-op follow-up compared to Pre-op vision ( $P < 0.001$ ). Initial post op follow up period(Day 2 – 2 weeks) 76.5% eyes following post femtosecond lasik surgery had no complication. Diffuse lamellar keratitis was noted in 13.5%. Of eyes out of 200 eyes studied. At the end of 1 month 98% of eyes had no complication.(Table4a and 4b)

**Table 1: Showing the Demographic distribution among the Operated Cases.**

Characteristics	No. of Cases (n=101)	Percentage of Cases
<b>Age (years)</b>		
<20	6	5.9
20 – 24	45	44.6
25 – 29	31	30.7
>=30	19	18.8
<b>Sex</b>		
Male	44	43.6
Female	57	56.4

**Table 2: The Distribution of Baseline Characteristics.**

Characteristics	No. of Eyes (n=200)	Percentage of Eyes	
<b>Laterality</b>	Right Eye	101	50.5
	Left Eye	99	49.5
<b>Retina</b>	Normal	65	32.5
	MRD	122	61
	PVD	2	1
	WWOP	5	2.5
	Pre-op Barrage Laser	5	2.5
	Lasered Retina	1	0.5
<b>ContactLens</b>	Yes	51	25.5
	No	149	74.5
<b>Ant. Segment</b>	Normal	172	86
	Exophoria	22	11
	ADS	6	3

**Table 3a: The Pre-Op and Post-Op Comparison of Visual Acuity.**

Visual Acuity (Log. Mar.)	No. of Eyes Examined	Mean	SD	Min.	Max.
Pre op	200	0.19	0.08	0	0.5
Post op Day 2	200	0.097	0.18	0	2
Post op Day 5	200	0.031	0.08	0	0.5
Post op Week 2	200	0.012	0.06	0	0.5
Post op Month 1	200	0.014	0.07	0	0.5
<b>Comparisons</b>	<b>P value by Paired analysis</b>				
Pre op versus Post op Day 2	Less than 0.001 (statistically significant.)				
Pre op versus Post op Day 5	Less than 0.001 (statistically significant.)				
Pre op versus Post op Week 2	Less than 0.001 (statistically significant.)				
Pre op versus Post op Month 1	Less than 0.001 (statistically significant.)				
SD: Standard Deviation. P values are obtained using paired 't' test (Paired analysis). p value <0.05 is considered to be statistically significant. S: Statistically Significant.					

**Table 3b: The Pre-Op and Post-Op distribution of Eyes having 6/6 Vision.(Log Mar = 0).**

Visual Acuity	No. of Eyes Examined	6/6 Vision (Log Mar = 0)	
		No. of Eyes	% of Eyes
Pre-op	200	16	8
Post op Day 2	200	112	56
Post op Day 5	200	156	78
Post op Week 2	200	184	92
Post op Month 1	200	189	94.5
<b>Comparisons</b>	<b>P value by Paired analysis</b>		
Pre-op v/s Post-op Day 2	0.001 (S)		
Pre-op v/s Post-op Day 5	0.001 (S)		
Pre-op v/s Post-op Week 2	0.001 (S)		
Pre-op v/s Post-op Month 1	0.001 (S)		

**Table 4b: Showing Complication at the End of Post Op FUP (1 Month).**

Complications	No. Eyes(n= 200)	Percentage of Eyes (%)
Nil	153	76.5
DLK(Diffuse Lamellar Keratitis)	27	13.5
Dry eyes	20	10
<b>Total</b>	<b>200</b>	<b>100</b>

**Table 4a. List of Post Complication in Early Post Operative Period (Day 2 – 2 Weeks)**

Complications	No. Eyes(n=200)	Percentage of Eyes(%)
Nil	196	98
Dry eyes	4	2
<b>Total</b>	<b>200</b>	<b>100</b>

## DISCUSSION

Femtosecond lasik surgery is very popular surgery commonly known as bladeless lasik surgery among common people. It gives better quality of unaided vision by giving them freedom from spectacle or contact lens in near future. It also emerged as most efficient surgery in recent decades. With more safety, precision, accuracy, and finally better visual outcome. It can be recommended as a good surgical option for patient undergoing refractive surgeries.

A baseline data from our study showed Females outnumbered males in undergoing femtosecond lasik surgery. This demographic data correlate with the other studies.<sup>[6,7]</sup> In present study, patients undergoing femtosecond lasik were in the age group of 18-40 years. Which was chosen as a criteria In reference to study Zhang J etal<sup>[7]</sup> where age group from 18 to 48years was taken. In our majority of patients undergoing femtosecond lasik were in the age group of 20-24 years.(44.6).

Un aided post operatively day 2 examination revealed visual outcome was excellent when compared to pre op vision with p (0.001) stating it to be statistically significant. Note: As it was difficult to find study exclusively done on intralase lasik and compare to our study, so intralase lasik outcome from various studies have been compared.

**Table 5a: Our Study Vs Daniel et al.<sup>[8]</sup>**

Our study Post Op Vision (%) {200} Eyes UCVA		Daniel et al Post Op Vision (%) {102} Eyes UCVA
Day2	56	45 (day 1)
Day 5	78	43(1 week)
2nd week	92	---
1 month	94	67(1 month)

In comparison to other studies the visual outcome of our studies was good. When post op day1 vision of Daniel et al is 45%. But our study vision post op day 2 is 56%. Finally 1 month post op UCVA is 94 %. As compared to UCVA of Daniel et al which is 67%.

**Table 5b: Our Study Vs Steven C et al.<sup>[9]</sup>**

Our Study Post Op Vision (%) {200} Eyes UCVA		Steven C et al Post Op Vision (%) {300} Eyes UCVA
Day2	56	68(DAY1)
Day 5	78	---
2 <sup>nd</sup> week	92	---
1 month	94	85(1 month)

Findings of Steven C et al are good (68%) as compared to our study group (56%). But final outcome at the end of 1 month UCVA of our study excelled far with 94%. As compared to Steven C et al.(85%).

**Table 5c: Our Study Vs Edward et al.<sup>[10]</sup>**

Our study Post Op Vision (%) {200} Eyes UCVA		Edward E et al Post Op Vision (%) {94} eyes UCVA
Day2	56	54 (day1)
Day 5	78	79 (1 week)
2nd week	92	----
1 month	94	94 (1 month)

As compared to Edward et al the results of our study are almost same. i.e (1 month post op UCVA of both studies are 94%).

**Table 5d: Our Study Vs Charls C et al.<sup>[11]</sup>**

Our Study Post Op Vision (%) {200} Eyes	Charls C et al Post Op Vision (%) {1020} Eyes
Day 256	60 (day1)

Finally comparing with Charls C e tal. post op day1 UCVA which is (60%) which is good as compared to our study day 2 (56%).

Complications Initial post op follow up period (Day 2 – 2 weeks), 76.5 % eyes following post femtosecond lasik surgery had no complication. Diffuse lamellar keratitis was noted in 13.5%. Of eyes out of 200 eyes studied which closely matches with the Choe CH, Guss C e tal.<sup>[12]</sup> 20% of eyes had dry eyes in initial post operative period but they were treated with the lubricating eye drops. Finally the reducing the dry eyes in subsequent post op follow ups. In Late post op follow up period (1 month) 98% of eyes had no complication at the end of 1 month post op visit. The result of our studies is similar to that.<sup>[12]</sup> Dry eyes were noted in only of 2 % of eyes at the end of post op 1 month follow up.

## CONCLUSIONS

Refractive error 2<sup>nd</sup> major cause of impaired vision. Patients with refractive error can be corrected by many methods. But femtosecond lasik has arrived as an safe, accurate and most feasible and more precise in current days. Making the femtosecond lasik surgery to be recommended as the procedure of choice in refractive surgery. Post femtosecond lasik complication are very less as noted in the above study. Making it safer procedure. In giving freedom from glasses to the patients and helping them to achieve better quality of vision.