Study of the Visual Outcome and Complication of Femtosecond Lasik

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ABSTRACT

BACKGROUND

Femtosecond lasers have changed refractive surgery in the last 9 years since the market release of the IntraLase Femtosecond Laser (Abbott Medical Optics, IL, USA) in 2001. In refractive surgery, a promising treatment modality using only the femtosecond laser (no excimer laser involved) is called FLEEx. In this procedure, the femtosecond laser is used to cut a lenticule of corneal stroma, instead of an excimer laser ablating this same tissue. 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. Study participants were in the 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 that the 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. Un aided post-operative day 2 vision revealed excellent outcome when compared to preop vision with p (0.001). It was statistically significant. Consistent results sprang up during the study period in the subsequent post op follow up on 5th day, 2 weeks and 1 month.

CONCLUSIONS

Femtosecond Lasik had excellent visual outcomes and lesser complications.

KEY WORDS

Visual Complication, Femtosecond Lasik

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BACKGROUND

Femtosecond lasers have changed refractive surgery in the last 9 years since the market release of the IntraLase Femtosecond Laser (Abbott Medical Optics, IL, USA) in 2001. The bladeless flap creation rapidly gained popularity because of its promised increased safety¹, fast recovery and excellent results. Nowadays, the majority of high-volume refractive surgery centres in the world uses a femtosecond laser to create the flap. All commercially available devices use a near infrared femtosecond laser with a wavelength of approximately 1053 nm. Despite the fact that the neodymium-doped yttrium aluminium garnet and femtosecond lasers have very similar wavelengths. The ultra-short duration of the pulses (10–9 vs. 10–15) in the latter causes significantly less damage in the collateral tissue.² The main technical specifications that play a role in the femtosecond laser are Laser pulse repetition rate; Spot size; Pulse energy; Pulse pattern. There is an inverse relationship between the laser pulse duration and the energy required in³ each pulse to generate the optical breakdown. A shorter pulse (200–500 fs) needs lower energy to achieve the threshold of photo disruption than a longer pulse (500–1300 fs). The numerical aperture (NA) of the lens influences the laser spot in terms of diameter and volume. A higher NA focuses the beam with less dispersion and is the reason why higher NA devices use lower energy. It is also suggested that a higher NA increases the depth accuracy and overall precision of the lamellar cut.

The first devices operated with a low KHz repetition rate (15 KHz – first IntraLase model) and needed a higher energy to photo dissection. Newer devices (even the newer high-energy devices such as IntraLase 150 KHz) intend to increase the repetition rate, which makes the procedure duration shorter and uses lower energy with an intention of diminishing the inflammation. In addition, the spot size and separation can be lowered in higher repetition rates to produce smoother surface cuts without increasing the time of the procedure. In summary, the ideal device would include a high repetition rate, small spot size and low energy per pulse two main pulse patterns are used in commercially available 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 centre 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 significant market penetration, so that it is number one in the market share.

In refractive surgery, a promising treatment modality using only the femtosecond laser (no excimer laser involved)⁴

is called FLEx. In this procedure, the femtosecond laser is used to cut a lenticule of corneal stroma, instead of an excimer laser ablating this same tissue. The refractive outcomes are still not as good as the excimer laser treatments, but there is room for improvement. The theoretical advantage over the standard procedure is that it is faster, has no need of two different lasers and less energy is applied. In addition, in excimer laser ablation we observe a reduction in laser efficiency in the periphery of the cornea, yielding results that differ from that expected with wave front-guided and optimized treatments. This would not be a problem with the femtosecond laser-cut lenticules, with the first results showing a large prelate treatment zone, and with less induction of high-order aberrations.⁵

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

Refractive Error Type Range

- Myopia - 1.00 Ds to - 12.00 Ds.
- Hypermetropia + 1.00 Ds to + 6.00 Ds.
- Astigmatism + 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 IDOby volks 20 D to note any pathology like MRD, WWOP (White With-Out Pressure), Lattice degeneration so that if any patient found with the lattice degeneration or so is preoperatively 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 refractive error like myopia, hyperopia, and astigmatism. The patients were evaluated by Autorefractometer (Tomey) to take reading. Follow up was performed following femtosecond Lasik surgery on post-operative day-2, day-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 (Intra-Ocular Pressure) measurement, the condition of cornea assessment and documented on each post-operative visit with the slit lamp examination. The results of the studies were 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.

Statistical Analysis

The data on categorical variables is shown as n (% of cases) and the data on quantitative variables (LogMAR Vision, IOP etc.) is presented as Mean $\pm$ Standard Deviation (SD) along with range (min – max). The pre-op and post-op comparisons of quantitative variables is done using paired 't' test, after confirming the underlying normality assumption of difference of variables measured. The post-op day 2 and post-op day 5, 2-week and 1-month comparisons of cornea status are done using paired "t" test. The entire data was entered and cleaned in MS Excel before it was statistically analysed in SPSS. All the results are shown in tabular as well as graphical format to visualise the statistically significant difference more clearly. The p-values less than 0.05 are considered to be statistically significant. All the hypotheses data was analysed statistically using Statistical Package for Social Sciences (SPSS Ver. 16.0, Inc. Chicago, USA) for MS Windows.

RESULTS

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 preoperatively 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.

Characteristics	No. of Cases (n=101)	Percentage of Cases
Age (years)		
<20	6	5.9
20 – 24	45	44.6
25 – 29	31	30.7
>=30	19	18.8
Sex		
Male	44	43.6
Female	57	56.4
Demographic Distribution among the Operated Cases		
Characteristics	No. of Eyes (n=200)	Percentage of Eyes
Laterality	Right Eye	101
	Left Eye	99
Retina	Normal	65
	MRD	122
	PVD	2
	WWOP	5
	Pre-op Barrage Laser	5
Contact Lens	Lasered Retina	1
	Yes	51
	No	149
Ant. Segment	Normal	172
	Exophoria	22
	ADS	6

Table 1. Distribution of Baseline Characteristics

Visual Acuity (LogMAR.)	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
Comparisons	P value by Paired analysis				
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)				
Pre-Op and Post-Op Comparison of Visual Acuity					
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.					
Visual Acuity	No. of Eyes Examined	6/6 Vision (LogMAR = 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		
Comparisons	P value by Paired analysis				
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 2. Pre-Op and Post-Op Distribution of Eyes Having 6/6 Vision. (LogMAR = 0)					

Table 2. Pre-Op and Post-Op Distribution of Eyes Having 6/6 Vision. (LogMAR = 0)

Complications	No. Eyes (n= 200)	Percentage of Eyes (%)
Nil	153	76.5
DLK (Diffuse Lamellar Keratitis)	27	13.5
Dry eyes	20	10
Total	200	100
List of Post-Op 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
Total	200	100

Table 3. Complication at the End of Post Op FUP (1 Month)

Pre op fundus evaluation of 32.5 % of eyes revealed normal findings, Myopic retinal degeneration existed in 61.0 % eyes preoperatively. Preoperatively 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, day 5, 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 1-month 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. (Table 4a and 4b).

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 correlates with the other studies.^{6,7} In present study, patients undergoing femtosecond Lasik were in the age group of 18 - 40 years, which was chosen as a criterion. In reference to study Zhang J et al⁷ where age group from 18 to 48 years was taken. In our study 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.

In comparison to other studies the visual outcome of our studies was good. When post op day 1 vision of Daniel et al is 45 %. But our study vision post op day 2 is 56 %. Finally, 1-month post op UCVA (UN-Corrected Visual Acuity) is 94 %. As compared to UCVA of Daniel et al which is 67 %. 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 %). 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 %). Finally comparing with Charls C et al. post op day 1 UCVA which is (60 %) is good as compared to our study day 2 (56 %).

Complications of 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.¹² 20 % of eyes had dry eyes in initial post-operative period but they were treated with the lubricating eye drops. Finally, 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 results of our studies are similar to that.¹² Dry eyes were noted in only 2 % of eyes at the end of post op 1 month follow up.

Our study Post Op Vision (%) {200} Eyes UCVA		Daniel et al Post Op Vision (%) {102} Eyes UCVA	
Day 2	56	45 (day 1)	
Day 5	78	43(1 week)	
2nd week	92	---	
1-month	94	67(1 month)	
Our Study Vs Daniel et al ⁸			
Our Study Post Op Vision (%) {200} UCVA		Steven C et al Post Op Vision (%) {300} Eyes UCVA	
Day 2	56	68 (Day 1)	
Day 5	78	---	
2nd week	92	---	
1-month	94	85(1 month)	
Our Study Vs Steven C et al ⁹			
Our study Post Op Vision (%) {200} Eyes UCVA		Edward E et al Post Op Vision (%) {94} eyes UCVA	
Day 2	56	54 (day 1)	
Day 5	78	79 (1 week)	
2nd week	92	---	
1 month	94	94 (1 month)	
Our Study Vs Edward et al ¹⁰			
Our Study Post Op Vision (%) {200} Eyes		Charls C et al Post Op Vision (%) {1020} Eyes	
Day 2	56	60 (day1)	
Our Study Vs Charls C et al ¹¹			

Table 4

CONCLUSIONS

Refractive error is the 2nd major cause of impaired vision. Patients with refractive error can be corrected by many methods. But femtosecond Lasik is safe, accurate, is 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.

Data sharing statement provided by the authors is available with the full text of this article at jemds.com.

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