



Original Research Article

Comparative study on incidence of posterior vitreous detachment (PVD) between conventional and femtosecond laser-assisted laser in situ keratomileusis (LASIK)

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ABSTRACT

Aim: To compare incidence of posterior vitreous detachment (PVD) in patients after microkeratome and femtosecond laser-assisted laser in situ keratomileusis (LASIK) using ultrasound B-scan.

Design: Prospective, non-randomised, comparative and interventional hospital based study.

Materials and Methods: This study was performed on 138 eyes of 69 patients, 64 eyes in microkeratome group and 74 eyes in femtosecond laser group for a period of 10 months from December 2017 to October 2018. The mean age of patients in microkeratome group was 23.34 years and in femtosecond laser group was 23.19 years. All patients in both the groups underwent one of the two procedure. Patients were assessed for subjective and objective refraction, presence of PVD, subjective complaints of floaters and axial length changes at each visit.

Results: At 1 week and 1 month postoperative period there was no PVD in either of the groups and none of the patients complained about disturbing floaters. At one week postoperative period, 17 eyes (26.5%) in microkeratome group and 22 eyes (29.6%) in femtosecond laser group had residual refraction ranging from -0.25D to -0.75D. The changes in axial length following surgery was 0.08 ± 0.08 mm in microkeratome group and 0.1 ± 0.07 mm in femtosecond laser group at one month.

Conclusion: Our study did not demonstrate any difference between both the procedures with respect to posterior segment complications. Patients in our study are relatively younger compared to other studies and hence, age of the patient undergoing LASIK may affect the incidence of PVD.

Key message: Both microkeratome assisted LASIK and femtosecond assisted LASIK were comparable with respect to posterior segment complications. The mean age of patients in this study is assumed to have an effect on outcome. Whereas axial length, power of the eye, procedure opted did not significantly have any impact on outcome. A larger population with longer follow up is needed in Indian population to conclude our results.

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1. Introduction

Refractive error is the most common cause for visual morbidity, of which myopia constitutes 3/4th portion. Prevalence of myopia is 30% of total population at present.¹ Main modality of treatment for myopia are spectacles, contact lenses and refractive surgeries. Laser in situ keratomileusis (LASIK) is a lamellar procedure in which

flap is created using either microkeratome or femtosecond laser with ease. Following which excimer laser is used to ablate the stroma to achieve emmetropia. The suction pressure for microkeratome is 65mmHg and femtosecond laser is 40mmHg.²

LASIK being a refractive surgery many surgeons talk about refractive outcomes, quality of vision, quality of life after LASIK and anterior segment complications. The importance given to posterior segment complications is less as the incidence reported is as low as 0.06% to 0.36%, and

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most of them occur late and are managed by vitreoretinal surgeons.^{3–5} It is believed that the initial event which leads to most of these complications is posterior vitreous detachment (PVD).⁶

Some authors theorize that these adverse effects occur as the result of excimer laser shock waves during corneal ablation, whereas others hypothesize that the suction exerted during the keratome cut causes anteroposterior traction that results in pathologic alterations.⁷

Femtosecond laser in refractive surgery uses less vacuum compared with conventional microkeratomers, which should result in less vitreoretinal traction and possibly fewer posterior segment complications.⁷ However the incidence of PVD between both the procedures have varied greatly among different studies.^{8–10}

We have done this study to know the incidence of PVD following microkeratome-assisted LASIK and femtosecond laser-assisted LASIK, as it is precursor of many posterior segment complications like vitreo-macular traction, retinal holes, macular oedema, retinal detachment, macular holes, retinal haemorrhages, vitreous haemorrhages.^{4,11–13}

2. Materials and Methods

This is a prospective, non-randomized, comparative, hospital based study done on patients attending the department of cornea and refractive surgery at a tertiary eye care centre in Tamil Nadu, India. One hundred thirty-eight eyes of 69 patients were studied for a period of 10 months from 01/12/2017 to 01/10/2018. Out of 69 subjects, 38 (55.1%) were males and 31 (44.9%) were females.

2.1. Inclusion criteria

Subjects included in this study were myopes from -0.5 dioptre (D) to -10D with mean age of 23.26 ± 3.1 years (range 19-30 years), having stable refraction for at least one year and willing to undergo LASIK.

2.2. Exclusion criteria

Patients excluded were those with pre-existing posterior vitreous detachment before LASIK, ophthalmic abnormalities, systemic disorders and pregnant women.

Two different surgical treatment modalities namely microkeratome-assisted LASIK and femtosecond laser-assisted LASIK was done by two experienced surgeons in both the groups of patients. The study adhered to the principles of the Declaration of Helsinki. Informed consent was obtained from all patients before surgery. The clinical outcomes of these two different procedures were compared by analysing the presence or absence of the posterior vitreous detachment postoperatively at first week and first month. The relevant investigation, ultrasound B-Scan and IOL Master was done preoperatively and postoperatively to compare the presence and absence of posterior vitreous

detachment and to measure axial length.

2.3. Surgical procedure

All patients underwent one of the two procedures. Femtosecond laser was reserved for patients with thinner corneas, flatter corneas, deep sockets, patients with prominent brow, patients who are not having residual bed thickness of minimum 300 microns. After topical anesthesia with 0.5% proparacaine hydrochloride, proper draping was done.

In the microkeratome group, Zyoptix XP microkeratome (Bausch & Lomb Surgical) was used to create the flap. The parameters chosen were superior hinge and an intended flap thickness of $120\mu\text{m}$ or $140\mu\text{m}$. The dimensions of the suction ring determines the diameter of flap and size of the hinge. The suction ring is connected to a vacuum pedal which increases the intraocular pressure to 60 mmHg.

In the femtosecond group, Intralase system 60-KHz (IntraLase Corp, Irvine, California, USA) was used. The flap parameters were superior hinge, intended thickness ranging from 90 to $110\mu\text{m}$. The raster line and spot separation were $6\mu\text{m}$, hinge angle of 55° , side cut angle of 70° . After application of the suction ring, the cornea is applanated against the appplanation plate and the IOP is raised to 45 mmHg.

In both groups, created flap was raised with a spatula, and the ablation was performed using the Technolas z100 excimer laser (Bausch and Lomb Surgical) using a wavefront guided treatment algorithm. Corneal irrigation and flap repositioning was performed.

All patients were treated postoperatively with topical 0.1% dexamethasone 4 times daily for 1 week, gatifloxacin 0.3% 4 times daily for 1 week and artificial tears for at least a month following the procedure.

2.4. Statistical analysis plan

Mean (standard deviation) and frequency (percentage) was used to describe the summary data. Two sample t test / Mann Whitney test was used to compare the mean difference of the ocular parameters between the groups. Categorical variables was compared by Fisher's exact test / Chi squared test. P-value less than 0.05 is considered as statistically significant. All the statistical analysis was performed by STATA 11.1 (Texas).

3. Results

Out of 138 eyes, 64 (46%) eyes of 32 patients were enrolled in microkeratome-assisted LASIK group and 74 (54%) eyes of 37 patients were enrolled in femtosecond laser-assisted LASIK group who fit in the inclusion criteria and are willing for follow-up (Table 1). An informed consent was taken before recruitment.

Primary outcomes of our study are objective and subjective assessment of PVD. Secondary outcomes of our study are epidemiological characteristics, axial length measurements and visual acuity.

Out of 32 patients in microkeratome group, 11(34.4%) were females and 21 (65.5%) were males, whereas out of 37 patients in femtosecond laser group, 17 (46%) were males and 20 (54%) were females. There were equal number of left and right eyes in both the groups.

The mean age of patients in microkeratome group was 23.34 ± 2.9 years and in femtosecond laser group was 23.19 ± 3.2 years. The median age of microkeratome group was 23 years and femtosecond laser group was 22 years. There was no statistically significant difference between age distribution among the 2 groups with p-value of 0.768 (Table 2).

The overall Mean spherical equivalent in our study was $-4.20D \pm 1.98D$, while in microkeratome group was $-3.35D$ and in femtosecond group was $-4.99D$ which was significantly different between the 2 groups (Table 3).

Out of 138 eyes, 39 (28.2%) eyes showed residual refraction ranging from $-0.25D$ to $-0.75D$. No lines were lost in any of the patients except 2 to 3 letters in one line in one patient whose residual power was $-0.75D$.

In microkeratome group and femtosecond group there were no cases of posterior vitreous detachment at 1 week and 1 month postoperative period. Few cases were followed up between 3 to 6 months postoperatively and they showed no evidence of PVD (Table 4). None of our patients complained of significant increase in number and size of floaters. In our follow-up period of one week and one month, patients were not asked leading questions.

The axial length measurements between microkeratome and femtosecond laser group were not statistically significant so the samples were comparable. The change in postoperative axial length in microkeratome group at one week was $0.07 \pm 0.07mm$ and at one month was $0.08 \pm 0.08mm$. In femtosecond group, the change in axial length at one week was $0.1 \pm 0.13mm$ and at one month was $0.1 \pm 0.07mm$ (Table 5).

Table 1: Number of eyes in each group

Group	n	%
Microkeratome	64	46%
Femtosecond laser	74	54%
Total	138	100

4. Discussion

According to WHO, uncorrected refractive error is leading cause of visual impairment in world. Myopia constitutes major portion of refractive errors. LASIK corrects refractive errors permanently in a safe, precise, predictable and reliable way with less postoperative pain and fewer

complications.¹⁴ Most of the studies concentrate on refractive outcome, quality of vision, anterior segment complications. Few articles speak about posterior segment complications which are very rare and dealt by vitreoretinal surgeons. Posterior vitreous detachment will not affect vision directly, but it acts as an inciting event for many vitreoretinal pathologies. Studies have shown 24% of symptomatic PVDs result in retinal complications.^{15,16}

The prevalence of PVD increases with the axial length of the eye and age.¹⁷ It can also occur in trauma, myopes, inflammatory disease and following any intraocular surgery. For PVD to occur two processes has to occur simultaneously, liquefaction of vitreous and weakening of vitreoretinal adhesions.

PVD in myopia occurs 0.91 years for each dioptre of myopia earlier than emmetropic individuals according to Yonemoto et al.¹⁸ In myopia, vitreous is liquified earlier compared to controls. It is attributed to reduced concentration of protein, collagen contents and hyaluronan.¹⁹ Premature liquefaction of vitreous with strong vitreoretinal adhesions may lead to anomalous PVD causing pathological vitreoretinal interactions.²⁰ Anomalous PVD can give rise to persistent traction and lead to retinal tears.

The exact mechanism of PVD following LASIK is still unclear. Vitreous body modification after LASIK has been topic of discussion in many studies. Mirshahi et al.² studied the effect of microkeratome on ocular structures and proposed that microkeratome application induces biomechanical changes due to suction pressure which increases up to 60mmHg, which increases even more while creating flap.

The effect of microkeratome on globe is compared to that of blunt trauma where there is sudden compression and release of globe.⁷ It is described as "coup-countercoup" injury which creates concussive forces leading to rhegmatogenous sequelae.²¹

Krueger et al.²² have studied the effect of excimer laser (193nm) which produces shock waves at cornea during stromal bed ablation in animal models and enucleated human eyes. Stress wave amplitudes up to 100 atm were measured with pressure focus located in the posterior lens and anterior vitreous. At the retina level, the stress wave amplitudes decreased to approximately 10 atm, which appears harmless but may play a role in the development of posterior PVD especially in large spot diameter ablation and higher fluence.

Gavrilov et al.¹⁰ explained that the longer suction time needed to create the corneal flap with a femtosecond laser has resulted in incidence of PVD similar to that reported after microkeratome assisted LASIK, inspite of low rise in IOP compared to microkeratome.

Though serious complications after LASIK are infrequent, myopic eyes carry the potential for retinal

Table 2: Age-wise distribution

Group	n	Age (years) (mean±SD)	Median	Range	P-value ^t
Microkeratome	64	23.34 ± 2.9	23.0	19 – 30	0.768
Femtosecond laser	74	23.19 ± 3.2	22.0	19 – 30	
Overall	138	23.26 ± 3.1	23.0	19 – 30	

^tindependent-t-test**Table 3:** Preoperative spherical equivalent of both groups

Group	n	Mean SE ± SD	Range	P-value ^t
Microkeratome	64	-3.35 ± 1.80	-7.50 to -0.25	<0.001
Femtosecond laser	74	-4.99 ± 1.67	-10.00 to -1.50	
Overall	138	-4.20 ± 1.98	-10.00 to -0.25	

SE=Spherical equivalent ^t independent t-test**Table 4:** Posterior vitreous detachment

Group	Preoperative	1 week	1 month
Microkeratome	0	0	0
Femtosecond laser	0	0	0
Total	0	0	0

Table 5: Average difference of axial length after surgery

AL difference	Microkeratome	Femtosecond laser
1week Mean±SD Min – Max (range)	0.07 ± 0.07mm 0.05 to 0.40mm	0.10 ± 0.13mm 0.08 to 1.11mm
1month Mean±SD Min – Max (range)	0.08 ± 0.08mm 0.05 to 0.41mm	0.10 ± 0.07mm 0.09 to 0.48mm

AL=Axial length

tears, vitreous haemorrhage and retinal detachment which are the worst complications that we could encounter in patients undergoing LASIK. They are sight threatening, unless managed promptly. Long axial length, vitreous changes and peripheral abnormalities are major risk factors.

We have done this study to compare the incidence of PVD between the two procedures, because PVD is the most important predisposing event to development of posterior segment complications. In this study we have also assessed the quality of vision, by analysing number of patients who subjectively complained of disturbing floaters. To the best of our knowledge this study was not published among Indian population.

We studied 138 eyes of 69 patients, 64 eyes of 32 patients in microkeratome group and 74 eyes of 37 patients in femtosecond group. Both groups were comparable in terms of age, sex, demographics.

In our study we used IntraLase advanced laser system and Zyoptix Xp type microkeratome to create flap. Several studies conducted with different IntraLase laser system have shown that with INTRALASE FS 60 the incidence of PVD was 16% and with INTRALASE FS150 it was 85%.^{10,23} With mechanical microkeratome incidence of PVD was 9.5% to 21%.^{8,9,23,24} With Moria M2 microkeratome PVD was seen in 20%, with Hansatome microkeratome 9.5% and with AMADEUS II microkeratome 20%.

Some studies have shown that femtosecond laser was superior to microkeratome in terms of flap thickness predictability, contrast sensitivity, astigmatic neutrality and minimal complications.^{25,26} With respect to posterior vitreous detachment, studies like Wang et al.⁹ and Gavrilov et al.¹⁰ have shown comparable incidence of PVD following both the procedures.

However, a study conducted by Osman et al.²³ showed significant difference in incidence of PVD between both the procedures. In this study femtosecond laser-assisted LASIK showed 85% of PVD after one month compared to microkeratome-assisted LASIK which showed 20%.

The mean age of our patients in microkeratome group was 23.3 ± 2.9 years and femtosecond group was 23.29 ± 3.2 years, whereas the mean age in similar study conducted by Osman et al. was 24 ± 4 years in M-group and 25.7 ± 3.3 years in F- group. In Luna et al.²⁷ study mean age was 28±5.4 years, in Mirshahi et al. study 36.3 years, in Hosny et al.²⁸ study 25.47 years, in Gavrilov et al. study 28±5 years. The mean age in our study was significantly less. It signifies stronger vitreous attachment and less vitreous liquefaction as patients are younger in our study.

Mean spherical equivalent in our study was -3.35D in microkeratome group and -4.99D in femtosecond group. In Osman et al. mean spherical equivalent was -4.2±2.2D in M-group and -4.25±1.65D in F-group. In microkeratome studies done by Mirshahi et al., one study had mean

spherical equivalent of $-5.03D$ and other study had $-4.85D$.^{8,24} In Luna et al. study patients with marked anisometropia of range $-3.2D$ to $-7.7D$ were included. In femtosecond group of studies, spherical equivalent in Honsy et al. study was $3.92 \pm 2.16D$ and Gavrilov et al. study was $-4.38D \pm 1.37D$.

In our microkeratome group, mean spherical equivalent was less compared to other studies whereas mean spherical equivalent in femtosecond laser group was similar to other studies. Akiba et al.¹⁷ found that in eyes with power $>-6.0D$, PVD was seen 10 years earlier than emmetropes and in eyes with axial length >26 mm PVD occurs 20 years earlier.

The mean preoperative axial length in our study was 25.1 ± 0.5 mm and 25.01 ± 0.8 mm in microkeratome and femtosecond laser group respectively. There was no significant difference between axial lengths of both groups. In Osman et al. study the mean axial length in M-group was 24.2 ± 1.2 mm and in F-group was 23.8 ± 1.2 mm which was comparable to our study. In microkeratome studies the mean axial length was 25.08 mm, 25.13 mm.^{8,24}

The mean suction time in our study was 22 ± 4 seconds in microkeratome group and 63 ± 3 seconds in femtosecond group. In Osman et al. study suction time in M-group was 18 ± 2 s and in F-group was 63 ± 4 seconds. The suction time in our study was similar.

In our study there was no PVD in 64 eyes of 32 patients who underwent microkeratome-assisted LASIK and 74 eyes of 37 patients who underwent femtosecond laser-assisted LASIK, at one week and one month post-operative period. Few cases were evaluated at 3 to 6 months of postoperative period and they showed no evidence of PVD.

In Osman et al. study PVD was seen in 4 eyes (20%) in M-group and 17 eyes (85%) in F- group at one month postoperative period. In Wang et al. study, PVD was seen in 8 eyes (20%) in microkeratome group and 11eyes (27.5%) in femtosecond group. In microkeratome LASIK group the incidence of PVD was 9.5%, 21% after 1 week in Mirshahi et al.^{8,24} study and 28% in Luna et al.²⁷ study. Gavrilov et al. study done for femtosecond laser showed 16% incidence of PVD after 48 hours of procedure. In Honsy et al. study, incidence of PVD was 10% following femtosecond laser after 3 weeks.

The only variable parameter we noticed in our study was age, which was slightly less compared to other studies. Hence, we could attribute the absence of PVD in our cases to strong vitreous attachment to retina and less liquefaction of vitreous. There are no similar studies done in Indian population especially South Indian population.

In our study we wanted to assess the correlation between incidence of increase in floaters to PVD. None of our patients complained of disturbing floaters during follow-up. No leading questions were asked. In US-FDA website,²⁹ a link was provided for patients and doctors to complain about side effect and complications of LASIK as there are very few papers published on this topic. Few patients had

complained of disturbing increase in number of floaters which affected their quality of life. As there were no patients who complained of significant increase in floaters in our study, we may assume it was probably due to lack of PVD following the procedure.

The change in axial length in microkeratome group at one week postoperative period was 0.07 ± 0.07 mm and at one month was 0.08 ± 0.08 mm. In femtosecond laser group, the change in axial length at one week postoperative period was 0.1 ± 0.13 mm and at one month was 0.1 ± 0.07 mm. This was statistically not significant in both groups. Tay et al.³⁰ has shown that an increase in preoperative spherical equivalent of 1D led to decrease in axial length of 0.023 ± 0.001 mm. An increase in ablation depth of 1micron led to a decrease in axial length of 0.00118 ± 0.00005 mm. A study by Chalkiadakis et al.³¹ stated that the axial length changes between theoretical and practical measurements were not correlating. They could not conclude any correlation between ablation depth and change in axial length.

Major limitations in our study are that the cases were non randomized, limited number of cases were recruited, intraocular pressure was not measured intra-operatively. We recommend that future studies with same objective should be done in larger population, longer follow up to assess late posterior segment complications, intraoperative IOP measurement and A-scan to detect any anatomical and biophysical changes in eye. We may use a standard questionnaire to assess the number and size of floaters and effect of floaters on quality of vision.

5. Conclusion

In summary, both microkeratome-assisted LASIK and femtosecond-assisted LASIK were comparable with respect to posterior segment complications, axial length changes, and uncorrected visual acuity postoperatively. Our observation in our study regarding cause for nil incidence of PVD was that we have comparatively younger age group which is associated with stronger attachment of vitreous to retina. The suction pressure was not the factor involved in causing PVD. Hence, we conclude that the posterior segment complications are due to pathological myopia.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare that there is no conflict of interest.

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