

Incidence and risk factors for retinal detachment following laser-assisted *in-situ* keratomileusis

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Purpose: The aim of this work was to study the incidence and potential risk factors for development of retinal detachment (RD) after laser-assisted *in situ* keratomileusis (LASIK) surgery over a long-term follow-up. **Methods:** This was a retrospective interventional case series. A total of 694 eyes of 352 patients were included who had undergone LASIK surgery at a tertiary eye care institute between January 2005 and September 2015 who had a minimum follow-up of 5 years after the surgery were included. Kaplan–Meier analysis and Cox proportion regression model was used to estimate the potential risk factors and cumulative risk for the development of RD. **Results:** Out of the total patients, 5 eyes developed RD after a mean follow-up of 7 years. The cumulative risk of RD after 1 year was 0.4%, after 2 years was 0.5% and after 7 years was 0.7%. Increased risk of RD was not associated with age at LASIK surgery, gender, laterality, and spherical equivalent ($P > 0.05$). A significantly increased risk for the development of RD was observed in eyes that were given prior prophylactic laser photocoagulation for peripheral lesions in multivariate cox proportional regression analysis with a hazard ratio (HR) of 9.33 (CI- 1.554-56.094; $P = 0.015$). **Conclusion:** We emphasize the need for a regular follow-up after the LASIK procedure to ensure timely treatment of any new retinal lesions.

Key words: Incidence, LASIK, prophylactic laser photocoagulation, retinal detachment, risk factors

Myopia is the commonest refractive error with varying prevalence across different ethnic populations.^[1-4] Last decade has witnessed a great improvement in the outcome of refractive procedures. Although the vitreoretinal pathologies after refractive surgery are infrequent, however complications like retinal tears, retinal detachment (RD), macular hole and choroidal neovascularisation have been reported by various authors.^[5-9] Retinal detachment is one of the most devastating sight-threatening complications after Laser-assisted *in situ* Keratomileusis (LASIK) surgery which requires immediate management. The incidence of retinal detachment has been reported between 0.04% and 0.36% by previous studies.^[10-15] The patients have presented with the detachment as early as 2 months and even up to 10 years after the surgery.

The development of retinal detachment has been reported to occur even in patients who received prophylactic treatment or who did not have the presence of peripheral lesion prior to the surgery.^[9,13,14] Thus, the protective role of prophylactic laser is debatable. Most of the previous studies and case series have described the incidence and characteristics of the detachment and the outcomes following reattachment surgeries.

The aim of our study was to report the incidence and potential risk factors for the development of retinal detachment in patients undergoing LASIK surgery for myopia who had at least 5-year follow-up after LASIK.

Methods

We retrospectively reviewed the electronic medical records of all the patients who underwent LASIK surgery for myopia and had a follow-up of at least 5 years or more at a tertiary care institute between January 2005 and September 2015. The study adhered to the tenets of the declaration of Helsinki and was approved by the Institutional review board of the Medical Research Foundation. The data collected included age at LASIK surgery, gender, previous ocular diseases including myopia, pre-operative spherical equivalent, presence of peripheral retinal degenerations, history of RD in the fellow eye, positive family history of RD, and details of prophylactic treatment of these lesions were obtained. We also recorded the data about development of any new peripheral lesions and details of its treatment until the final follow-up. For patients who had developed a retinal detachment, we additionally obtained data on the time between LASIK and development of RD, best-corrected visual acuity (BCVA), the characteristics of detachment in terms of extent, location of break, type, number of retinal breaks, macular involvement, presence of posterior vitreous detachment, presence of proliferative vitreoretinopathy, vitreous hemorrhage, presence of other peripheral retinal degenerations, cataract, hypotony and choroidal detachment. Intra-operative details of type of surgery performed and

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postoperative details about the status of attachment of retina and macula and BCVA at final follow-up were also acquired.

The preoperative examination of all the patients included a thorough dilated fundus examination with scleral depression by an experienced retina specialist to look for any peripheral degenerative lesions which may predispose to development of retinal detachment such as presence of lattices, holes, and tears. In our tertiary eye care center, it is a policy that all patients were treated for retinal peripheral identifiable degenerations/breaks before undergoing LASIK. The treatable lesions (flap tears, lattice degeneration, and operculated holes) were treated with barrage laser photocoagulation. Adequacy of laser was assessed prior to LASIK surgery by retina specialist with scleral indentation. The patients were then planned for LASIK surgery after a period of 3-4 weeks once the adequacy of the laser was assured on follow-up visits.

All LASIK procedures were performed by experienced refractive surgeons with an automated microkeratome (CB; Moria SA, Antony, France) the scanning-spot Allegretto laser with a 0.95 mm spot size and a Gaussian-like spot profile. The eye-tracking system was tested before each clinical procedure, as per the manufacturer's specifications. The procedure was performed under topical anesthesia with 0.5% proparacaine hydrochloride (Alcaine; Alcon Co, Puurs, Belgium). After placement of the suction ring, the intraocular pressure was verified to 65 mm Hg or more with a Barraquer tonometer. The Hansatome (Bausch & Lomb) was used with a 160 mm head to create a 9.5 mm diameter corneal lamellar flap with a superior hinge. The optic zone was 6.5 mm with a concentric transition zone extending to 8.5 mm. The excimer laser ablation was performed on the stromal bed. After ablation, the flap was replaced without any suture. Patients were scheduled to be seen after LASIK surgery on the first postoperative day, at one and three months, and yearly thereafter.

For analysis, the continuous variables of age at LASIK and pre-operative spherical equivalent were categorized into two groups each. Age was classified as ≤ 30 years and > 30 years and Spherical equivalent were grouped into ≤ 6 Diopters and > 6 Diopters. Hazard ratios (HRs) with 95% confidence interval (95% CIs) for development of RD after LASIK were calculated for potential predictors using a cox proportional hazard regression model with time since surgery as the underlying time scale and both univariate and multivariate analysis were performed. A Kaplan–Meier survival estimate was plotted to calculate the cumulative risk of RD with each year after the surgery.

Statistical analysis was performed using SPSS statistical software version 21. A value of $P < 0.05$ was considered to be statistically significant.

Results

A total of 8021 patients underwent LASIK at the tertiary eye care center between 2005 and 2017. Among these patients, 352 patients (182 males (51.7%) and 170 females (48.3%)) had a follow-up of 5 or more years after LASIK surgery. The mean age of patients at LASIK was 24.79 ± 5.02 years (range 18-46 years). The mean spherical equivalent of eyes that underwent LASIK was -5.89 ± 3.12 D (range -0.25 D to -16.00 D). The mean follow-up of patients was 7 years (Range: 5-12 years).

Of the 694 eyes of 352 patients that had undergone LASIK, 5 eyes developed RD. The incidence of RD after LASIK surgery in patients with more than 5 years of follow-up was 0.7%, 95% CI (0.09%, 1.35%). Table 1 shows the Cox proportional hazard ratios (HR) of developing RD after LASIK surgery for possible risk factors. Increased risk of RD was not associated with age at LASIK surgery, gender, laterality, spherical equivalent and lattice degeneration- number of quadrants involved ($P > 0.05$). Risk of RD was significantly greater in the eyes which were given prior prophylactic laser photocoagulation for preoperative peripheral lesions (HR, 10.42; CI- 1.741-62.427; $P = 0.010$) as compared to the eyes which were not given prior peripheral ablation. Multivariate analysis for Cox regression HR model was done. A significantly increased risk of development of RD was observed in the eyes which were given prior prophylactic laser photocoagulation for peripheral lesions (HR, 9.33; CI- 1.554-56.094; $P = 0.015$). Only one patient who had peripheral lesion but was not lasered before surgery, while 3 out of 86 patients had peripheral lesion were lasered before surgery developed RD. There was no statistically significant difference between lasered peripheral degeneration vs not lasered peripheral degeneration ($P = 0.919$). Of the 694 eyes, lattice degeneration was present in 87 eyes with location anterior to equator in all the subjects.

Table 2 shows the characteristics of patients who developed RD. The mean age of patients was 24 ± 7.35 years (range 18-33 years). Out of the 5 patients, 4 were females (80%) and 1 was male (20%). The median spherical equivalent in the eyes that developed RD was -9.00 D (25th quartile, -10.00 D; 75th quartile -8.38 D; Range: -1.00 D to -12.50 D). Lattice degeneration was present on examination before LASIK surgery in 3 eyes (60%). Lattices were prophylactically given barrage laser in all the 3 eyes. The time interval between LASIK surgery and occurrence of RD was within 1 year in three eyes, 1.5 years in one eye and 7 years in one eye. The median time between LASIK and development of RD was 12 months (25th quartile, 10 months; 75th quartile 30 months; Range: 4 months to 84 months). Mean BCVA after development of RD was 20/50 (20/20-20/120). The new retinal breaks involved areas were previously not treated by laser retinoplexy.

One eye had a total RD at presentation and other four eyes had a partial RD. Macula was involved in 3 out of 5 eyes. Lattices were present in all 5 eyes, with accompanying holes in 4 eyes and horseshoe tear in 1 eye. In 2 out of 5 eyes, lattice degeneration developed after LASIK surgery and were identified only after the occurrence of RD. Three eyes underwent scleral buckling with cryotherapy to the break, 1 eye underwent barrage laser around the area of subretinal fluid and 1 eye underwent vitrectomy with fluid gas exchange, endolaser, and perfluoropropane injection. Amongst 5 patients, postoperatively 1 patient was lost to follow-up after surgery. The mean BCVA in remaining 4 eyes was 20/32 postoperatively. Retina was attached in all 4 eyes with macula on. The median follow-up in these patients was 8 years (25th quartile, 7 years; 75th quartile, 8.75 years; Range: 7-11 years). The cause of RD was the same treated lattice in 3 eyes, new lattice in 1 eye and the edge of the previously lasered scar in 1 eye.

Fig. 1 shows the Kaplan–Meier estimates of the risk of RD since LASIK surgery by years in the overall group. The

Table 1: Cox proportional hazard ratios (HR) of developing RD after LASIK surgery

Variables	Total	Developed RD*	Didn't Develop RD*	Cox Hazard Ratio Univariate			Cox Hazard Ratio Multivariate		
				Hazard Ratio	CI ¹	P	Hazard Ratio	CI ¹	P
Each Patient considered as a case									
Age at LASIK									
≤30 years	303	3	300	1	-	0.444	1	-	0.459
>30 years	49	2	47	2.575	[0.299-28.954]		2.491	[0.233-27.868]	
Gender									
Male	182	1	181	1	-	0.520	1	-	0.535
Female	170	4	166	2.2	[0.199-24.366]		2.144	[0.193-23.861]	
Each Eye considered as a case									
LASIK performed									
†OS	348	1	347	1	-	0.211	1	-	0.208
‡OD	346	4	342	4.053	[0.453-36.264]		4.090	[0.457-36.618]	
Refractive error									
Spherical equivalent	694	5	689	0.850	[0.666-1.084]	0.189	0.887	[0.697-1.128]	0.329
Lattice degeneration-No of quadrants									
1 and 2	68	2	66	1	-	0.144	1	-	0.192
3 and 4	19	1	18	0.646	[0.359-1.161]		0.663	[0.358-1.229]	
Lasered peripheral degeneration Vs. Others (overall)									
No	608	2	606	1	-	0.010	1	-	0.015
Yes	86	3	83	10.424	[1.741-62.427]		9.335	[1.554-56.094]	
Lasered peripheral degeneration vs not lasered peripheral degeneration									
LASER not performed	1	0	1	1	-	0.919	-	-	-
LASER performed	86	3	83	25.440	-		-	-	-

*RD: Retinal Detachment, †OS: Left eye, ‡OD: Right eye, §D: Diopters, ¹CI: Confidence interval

cumulative risk of RD after 1 year was 0.4%, after 2 years was 0.5% and after 7 years was 0.7%. Fig. 2 shows the Kaplan–Meier estimates of the risk of RD since LASIK surgery in the group who were administered prophylactic laser photocoagulation for peripheral lesions. The cumulative risk of developing RD in eyes who were had laser was 3.5% as compared to 0.3% in those eyes who were not given laser treatment and this difference was statistically significant ($P = 0.0012$; CI- 0.71 to 9.45).

Discussion

In this study, we evaluated the incidence and potential risk factors for the development of retinal detachment in myopic patients who underwent LASIK surgery. Among the 352 patients, 5 eyes developed RD who had more than 5 years of follow-up post LASIK, the incidence was found to be 0.7%. Previous studies have reported an incidence between 0.03% and 0.36%. Bo Qin *et al.* found that the incidence of RD at a mean of 20 months after LASIK was 0.033%.^[16] Faghihi *et al.* found the cumulative incidence of rhegmatogenous retinal detachment was 0.082%, and the yearly incidence was 0.032% after LASIK.^[14] Their result is lower than the incidence of RD in myopic eyes (0.7% to 6.0%),^[17] because of the shorter duration of follow-up. Retinal detachment is one of the dreaded complications in spite of its low reported incidence. In general, the risk of developing rhegmatogenous RD in myopic patients has been considered to be 3 to 5 times higher for low

to moderate myopes which increases more than 15 times in high myopes. This risk appears to increase almost 10 times higher when accompanied with lattice degeneration for each refractive class and in high myopes with lattice degeneration the risk is nearly 200 times as compared to a non-myopic person without lattice degeneration.^[18] In our study the time interval between laser photocoagulation and LASIK surgery was between 3-4 weeks as the strength of chorioretinal adhesion forms in 3 weeks. Yoon Y H *et al.* reported the strength of retinal adhesion after laser photocoagulation, the maximum strength of adhesion reached at 2 weeks that was three times normal.^[19]

Arevalo *et al.* postulated the role of increase in intraocular pressure to up to 60 mm of Hg during the application of suction ring in the development of RRD. They proposed that the sudden fluctuation of the IOP may cause a series of compression and decompression similar to a closed globe injury leading to traction at the vitreous base and posterior pole predisposing the eye to retinal breaks. They also suggested a role of excimer laser shock-waves in inducing posterior vitreous detachment.^[15] These mechanisms may play a role in development of RD immediately following the procedure. However, over a long term, it appears to be a part of the natural history of myopic eyes with vitreous modifications over time. In our study, the median time to development of RD was 12 months which makes it unlikely to be a direct result of intraoperative rise in intraocular pressure.

Table 2: Characteristics of patients with retinal detachment post LASIK

Parameters	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Before LASIK* surgery					
Age at LASIK*	18	19	19	31	33
Gender	M	F	F	F	F
Eye	OD [¶]	OD [¶]	OS ^{**}	OD [¶]	OD [¶]
SE [‡] (D) [§]	-1.00	-12.50	-6.50	-10.00	-9.00
Previous lesions	No	Lattice	Lattice	No	Lattice
Lattice-No of Quadrant involved	-	1	1	-	2
Lattice-Location	-	Anterior to equator	Anterior to equator	-	Anterior to equator
Had laser barrage	No	Yes	Yes	No	Yes
RD[†] Characteristics					
Time to develop RD [†] after LASIK ^a (months)	18	12	84	10	4
BCVA [†]	20/60	20/120	20/120	20/30	20/20
Partial/Total	Partial	Total	Partial	Partial	Partial
Macula On/Off	Off	Off	Off	On	On
Causative break	Lattice with hole	Lattice with multiple holes	Inferior break with lattice	Lattice with holes	Lattice with HST
Treatment	SB ^{††} + Cryo ^{‡‡}	SB ^{††} + Cryo ^{‡‡}	SB ^{††} + Cryo ^{‡‡}	Barrage Laser	§§V + ¶¶FGE + ¶¶EL + ***C3F8
At Final Follow-up					
BCVA [†]	20/40	20/60	No FU ^{†††}	20/30	20/20
Retina status	Attached	Attached	No FU ^{†††}	Attached	Attached
Macula status	On	On	No FU ^{†††}	On	On
Total follow-up (years)	8	7	7	8	11

*LASIK - Laser *In Situ* Keratomileusis, [†]RD - Retinal Detachment, [‡]SE - Spherical Equivalent, [§]D - Diopters, [¶]BCVA - Best Corrected Visual Acuity, [¶]OD - Right eye, ^{**}OS - Left eye, ^{††}SB - Scleral Buckle, ^{‡‡}Cryo - Cryotherapy, ^{§§}V - Vitrectomy, ^{¶¶}FGE - Fluid Gas Exchange, ^{¶¶}EL - Endolaser, ^{***}C3F8 - Perfluoropropane, ^{†††}FU - Follow-up

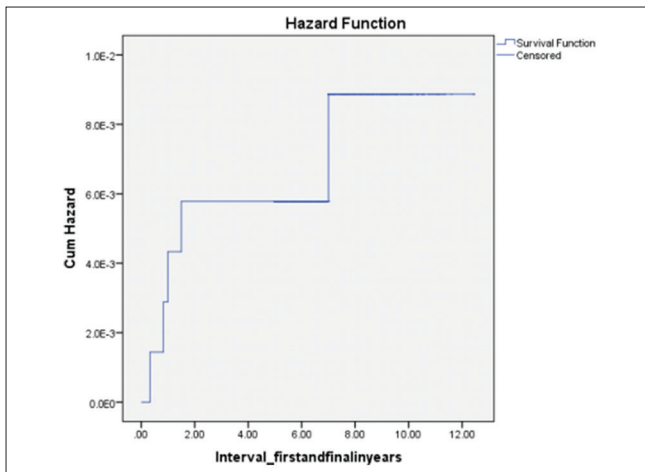


Figure 1: Risk of RD after LASIK surgery after each year

We estimated the risk of developing RD in presence of potential factors using the cox proportional hazard ratios. There was no significant association found with the age at LASIK surgery, gender, laterality and the pre-operative spherical equivalent with the development of RD. However, the hazard was almost twice in female patients and in patients in older age group and almost five times in patients with higher spherical equivalent. Similar associations were reported by Faghihi *et al.*

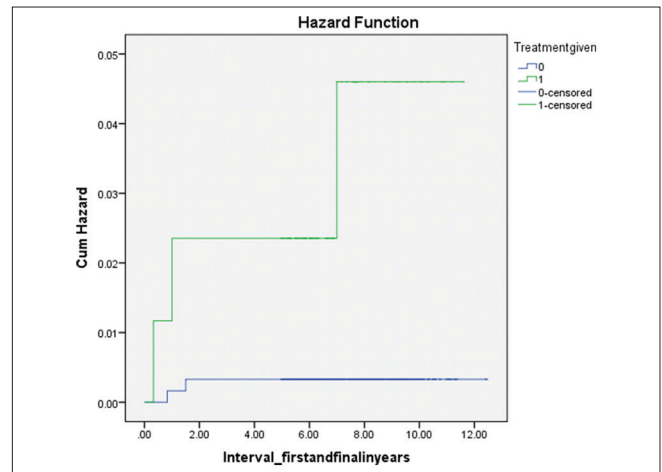


Figure 2: Risk of RD with and without preoperative prophylactic treatment

in their case series who found increased odds of RD in older age group, with increased severity of myopia and males were reported to have a higher risk.^[14]

When we compared the risk between patients who were administered prophylactic laser photocoagulation for peripheral treatable lesions and those who were not given any prior treatment, the former had a significantly higher risk of developing

RD which was 10 times more than the latter. The incidence of RD was significantly more in the treated group (3.5%) as compared to the non-treated group (0.3%). Among the five patients who developed RD, three patients had lattices that had prophylactic treatment before the surgery. The prophylactic laser treatment did not reduce the risk of RD. The reasons can be due to that the patients could have developed fresh lattices at other locations, the lesions were missed during initial examination and attrition of non lasered cases, which probably predisposed them for the detachment. The other two patients did not have any peripheral lesions prior to surgery. However at the time of development of RD, they presented with lattices with holes. It may be due to acute posterior vitreous detachment (PVD) with the formation of breaks and holes which can later cause RD occurring months after LASIK surgery. However, the occurrence of PVD can theoretically induce retinal tears at edge of treated area and can still produce RD. This would be the limitation of the prophylactic treatment to lattice degeneration and not a complication. Our results are comparable with Ruiz Moreno *et al.* who studied the incidence and characteristics of RD in patients who underwent LASIK surgery. Among the four patients who had developed RD, two did not undergo any previous treatment. They compared the incidence of retinal detachment in patients treated with laser photocoagulation with the non treated patients and found it to be statistically significant.^[9] Previous study by Byer NE reviewed on lattice degeneration of retina, demonstrates a lack of efficacy of directed prophylactic laser to the areas of lattice degeneration.^[20] Further studies have also described the development of RD in patients who had received prior treatment for peripheral lesions.^[11-13] But these RDs occurred at sites not related to the previous lesions. Thus, it is important to inform the patients that the prophylactic treatment is necessary prior to the surgery, but following the natural history of their refractive error, they are still prone to develop fresh lesions and predisposed to RD thus, emphasizing the need for regular screening even after the refractive surgery. All patients in our series were promptly managed with either scleral buckling with cryotherapy, pars plans vitrectomy, or barrage laser and had a favorable anatomical and visual outcome with retinal attachment in all four patients who followed up after the surgery.

An important limitation of our study is its inherent retrospective design and a limited number of patients with a long term follow-up. It is possible that some patients who developed RD would have been seen by ophthalmologists outside the institute, which were missed.

Conclusion

Although there have been previous studies reporting the incidence of RD after LASIK, most of them are case series describing the incidence and characteristics of the detachment. None of the studies have been done in Indian settings with a long-term follow-up. Our study also assessed the potential risk factors in the development of RD and identified that in spite of laser photocoagulation, there is a significant risk of developing RD.

Thus, patients should be made aware of the need for long term follow-up and thorough fundus evaluation even after the refractive procedure to identify the new lesions timely. Owing to the progressive changes in myopic eyes, patients should be well counseled to seek medical care in case they observe symptoms of sudden onset decreased vision, flashes, or floaters.

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Conflicts of interest

There are no conflicts of interest.

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