Assessment of Intra-operative and early Post-operative Complications of Laser In-situ Keratomileusis

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Abstract

Background: Several Laser in-situ keratomileusis (LASIK) complications were identified over the years. Reporting complications of LASIK surgery will help refine the approach to their management.

Objectives: Purpose of this study is to assess incidences, possible etiology of the intra-operative and early post-operative complications of LASIK

Patients and methods: a cross-sectional study for the correction of refractive errors was performed on 378 eyes of 189 individuals who underwent LASIK refractive surgery in private LASIK centers (AlForsan and El-Nour) between January, 2021 and January, 2022.

Results: intra-operatively, the majority of cases (81.5%) had no intra-operative complications. Flap-related complications were found in 7 cases (1.85%), interface complications were found in 11 cases (3%). The most common complication found in 41 cases (10.8%) was bleeding.

Post-operatively, the majority of cases had no complications at 1st day, 1st month and 3rd month (94.2%, 98.7% and 99.5% respectively). At 1st day, there were debris and flap complications (3.6% and 1.7%, respectively). At 1st month, dry eyes and under-correction complications were present (0.5% and 0.8%, respectively). At 3rd month, only two cases showed dry eyes (0.5%).

Conclusion: The goal of this study was to showcase the rates of complications over a period of time. We found that there was statistically significant decrease in rates of complications over time **(P< 0.001)**. The majority of cases had no intra-operative complications. The majority of cases had no complications at 1st day, 1st month and 3rd month. Overall rates of complications of LASIK are still relatively rare.

Keywords: Laser in–situ keratomileusis; Intra-operative complications; early post-operative complications; Refractive surgery; LASIK.

DOI: 10.21608/SVUIJM.2023.189463.1507

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Received: 20 January,2023.

Revised: 26 January,2023.

Accepted: 29 January,2023.

Published: 10 January, 2025

Cite this article as: Abdelrahman Mohamed Saad, Tarek Ahmed Mohamed, Khaled Abdelazeem, Dalia Mohammed El-Sebaity.(2024). Assessment of Intra-operative and early Post-operative Complications of Laser In-situ Keratomileusis. *SVU-International Journal of Medical Sciences*. Vol.7, Issue 2, pp: 1059-1067.

Introduction

Laser refractive surgery was introduced in the late 1980s with the development and improvement of the ophthalmic excimer laser **(Trokel et al.,1983)**.In response to the perceived shortcomings of PRK, LASIK was introduced **(Pallikaris et al.,1990)**.LASIK quickly increased in popularity and surpassed PRK as the predominant form of refractive surgery in the late 1990s, a trend that continues to this day **(Duffy and Leaming,2004)**.The correction of different refractive errors, including myopia, hyperopia, and astigmatism is the goal of all laser refractive procedures **(Munnerlyn et al.,1988)**.

The technique of laser in situ keratomileusis (LASIK) has been used with very encouraging results in the treatment of all degrees of myopia and also shows considerable promise in the treatment of hyperopia. Compared with photorefractive keratectomy, LASIK is advantageous in causing minimal postoperative discomfort, in its rapid recovery of clear vision and stabilization of refractive change, in the infrequent occurrence of haze, and in its greater facility in correcting high degrees of myopia **(Gimbel and Levy, 1998)**.

Intra-operative Complications include Microkeratome-related flap complications (flap buttonhole, free cap, and incomplete, short, or irregular flaps), corneal perforation, corneal epithelial defect, limbal Bleeding, subconjunctival hemorrhage, and interface debris. **(Azar and Koch, 2002)**

Postoperative Complications include undercorrection, overcorrection, visual aberrations, flap fold or striae (macrostriae - microstriae) **(Abdelazeem et al., 2019)**, flap dislocation, dry eye, diffuse lamellar keratitis (DLK), pressure-induced stromal keratitis (PISK), infectious keratitis **(Gimbel et al., 1998)**, and epithelial ingrowth **(Mohammed et al.2019)**.

The aiim of the study was to assess incidences, possible etiology of the intra-operative and early post-operative complications of LASIK

Patients and methods

A cross-sectional study was performed on 378 eyes of 189 individuals who underwent LASIK refractive surgery in private LASIK centers (AlForsan and El-Nour) for the correction of refractive errors between January, 2021 and January, 2022.This study included individuals above 18 years old and all individuals were suitable candidates for LASIK. Patients who lost follow up were excluded from this study. The proposal was reviewed by the ethical committee of the faculty of medicine Assuit University.

All study conducted adhered to the tenets of the Declaration of Helsinki. Preoperative evaluation consisted of complete ophthalmic examination was performed for all cases, and evaluation of corneal topography, thickness, and elevations using pentacam HR (WaveLight Allegretto Oculyzer II, Erlangen, Germany). Pre-operatively the patient's skin is prepared with povidone-iodine, 5%–10%, and povidone-iodine solution, 5%, is applied as drops to the ocular surface. The microkeratome and vacuum unit were assembled, carefully inspected, and tested to ensure proper functioning before each surgery.

LASIK procedure was done using EYE-Q system (WaveLight Allegretto Wave EYE-Q 400 Hz, Alcon Laboratories, Inc. 2004) and The WaveLight EX500 excimer laser (Alcon Laboratories, Inc. 2010).A sterile drape was placed over the skin and eyelashes, topical anesthetic drops were placed in the eye, and an eyelid speculum was placed in the eye to be treated. Asymmetric sterile ink marks were made in the corneal periphery. Using a single-use Moria M2 microkeratome (Moria, Antony, France), the lamellar flap creation can was

performed. After the ablation was completed, the flap was replaced onto the stromal bed. The surface of the flap was gently stroked using a smooth moistened microsurgical sponge, from the center, to the periphery to ensure that wrinkles were eliminated and that the flap settled back into its original position, as indicated by realignment of the corneal marks made earlier.

Immediate intra-operative evaluation of any encountered intra-operative complications. Post-operative evaluation of early post-operative complications during complete ophthalmic evaluation, refraction, and UCVA at 1 day, a 1 month, and 3 months after LASIK. Antibiotic, lubricants, and corticosteroid drops were used post-operatively.

Statistical analysis

Data were verified, coded by the researcher, and analyzed using International Business Machine-Statistical Package for the Social Sciences 24.0 (IBM-SPSS 24.0 for short) (IBM-SPSS Inc., Armonk, NY, USA) **(IBM corp,2016)**. Descriptive statistics: Means, standard deviations (SD), Median/ interquartile range (IQR), frequency and percentages were calculated. Test of significances: chi-square test was used to compare the difference in distribution of frequencies among different groups and McNemar test was used for repeated analysis. Normality was explored using Shapiro-Wilk test for continuous data. Independent t-test/Mann Whitney U test was calculated to test the mean/median differences of the data as appropriate. A significant p value was considered when it is <0.05.

Results

The mean patients' age was 25.9 ± 6.4 years with a median of 24. Male /female ratio was 41/148.Intra-operatively, the majority of cases (81.5%) had no intra-operative complications. The most common complication found in 41 cases (10.8%) was bleeding**. (Fig. 1, Fig. 2, and Fig. 3)**.Flap-related complications found in 7 cases (1.85%) of the total sample **(Fig. 4, Fig. 5, and Fig. 6)**, and interface complications were found in 11 cases (3%) of the total sample **(Fig. 7)**. **(Table. 1).**

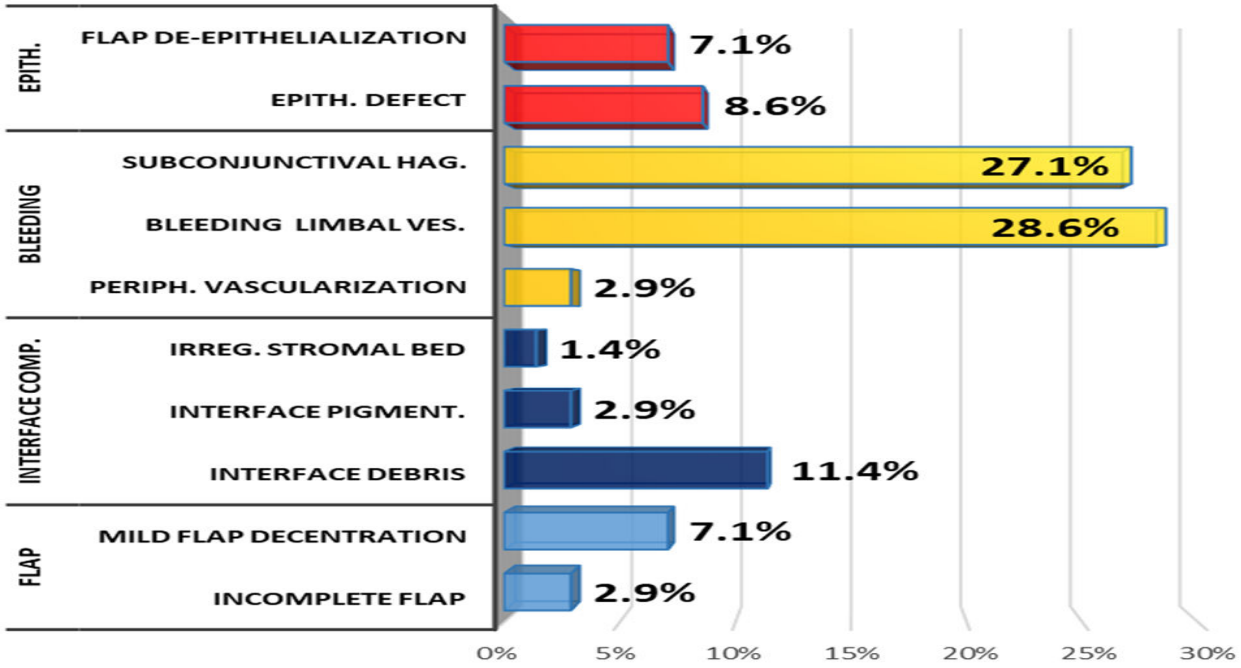

Fig. 1.Intra-operative Complications among Cases

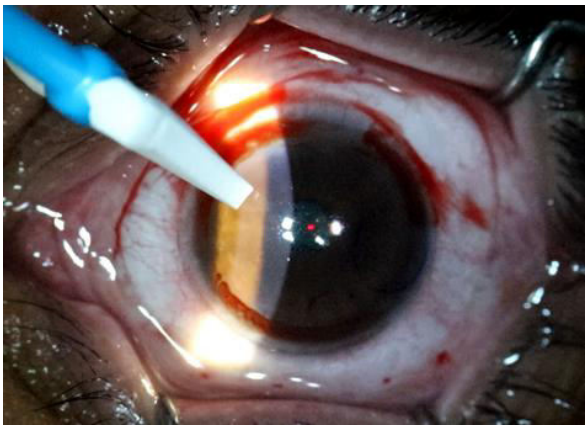

Fig. 2. Limbal bleeding

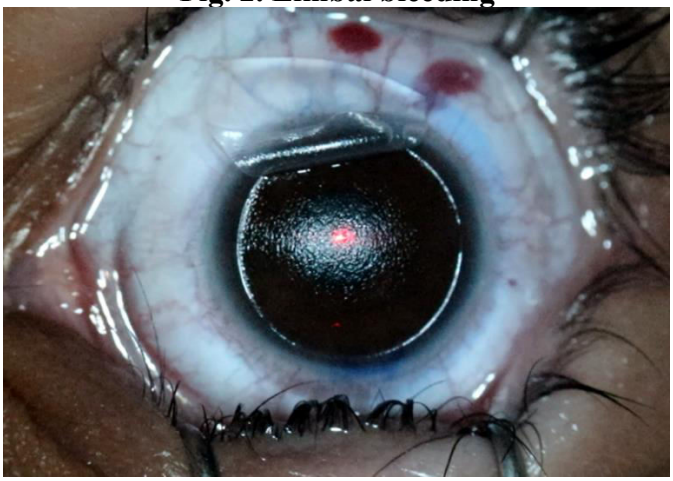

Fig. 3. Subconjunctival haemorrhage

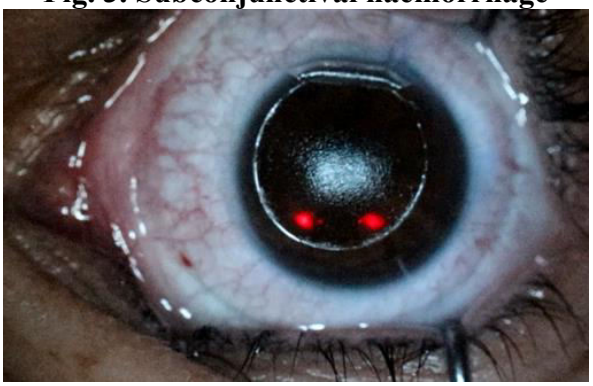

Fig. 4. Decentred flap

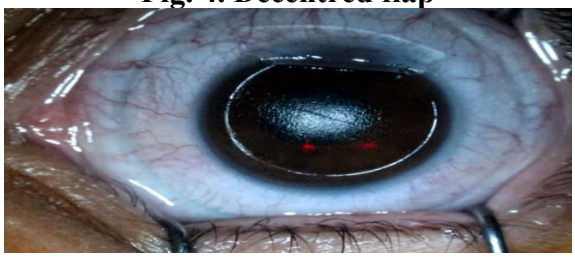

Fig. 5. Irregular stromal bed

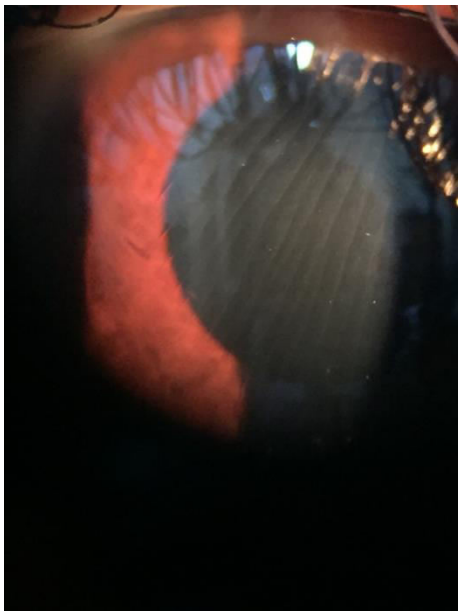

Fig. 6. Flap striae

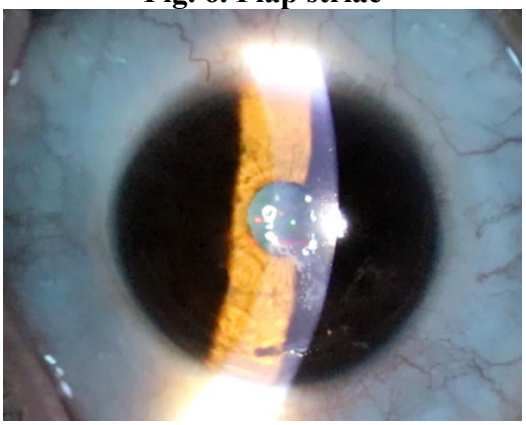

Fig. 7. Epithelial ingrowth

Table 1. Intra-operative Complications of the studied sample

Variable	Category	Intra-operative complications (n = 70)
Flap-related	• **Incomplete Flap**	2 (2.9%)
	• **Mild Flap Decentration**	5 (7.1%)
Interface complications	• **Interface Debris**	8 (11.4%)
	• **Interface Pigmentation**	2 (2.9%)
	• **Irregular Stromal Bed**	1 (1.4%)
Bleeding	• **Peripheral Vascularization**	2 (2.9%)
	• **Bleeding from limbal vessels**	20 (28.6%)
	• **Subconjunctival haemorrhage**	19 (27.1%)
Epithelium	• **Epithelial Defect**	6 (8.6%)
	• **De-epithelialization of flap Epithelium**	5 (7.1%)

The majority of cases had no complications at 1st day, 1st month and 3rd month (94.2%, 98.7% and 99.5% respectively). At 1st day, there were debris and flap complications (3.6% and 1.7%, respectively). At 1st month, dry eyes and under-correction complications were present (0.5% and 0.8%, respectively). After three months, only two cases showed dry eyes (0.5%). **(Table .2).**

Table 2.Postoperative Complications of the studied sample

Variable	Category	
1st Day		
Flap-related	• **Horizontal Striae**	**1 (0.3%)**
	• **Micro-striae**	**4 (1.1%)**
Interface	• **Interface Debris**	**11 (3%)**
Inflammation	• **Diffuse Lamellar Keratitis (DLK)**	**3 (0.8%)**
1st Month		
Under-correction		**2 (0.5%)**
Interface	• **Epithelial Ingrowth**	**2 (0.5%)**
Dry eyes	• **Dry eyes**	**3 (0.8%)**
Clear Cornea		**371 (98.1%)**
3rd Month		
Dry eyes	• **Dry eyes**	**2 (0.5%)**

The difference between complicated and uncomplicated cases regarding baseline, preoperative and operative among the studied sample. All determinants showed non-significant differences **(p>0.05)**. **(Table. 3)**.The difference in the rates of complications over the follow up period. There was statistically significant **(P< 0.001)** decrease in rates of complications over time i.e., complicated cases showed improvement when comparing intra-operative results with those at 1st day, 1st month and 3rd month. **(Table. 4).**

Table 3. Comparative analysis of Complicated vs. Uncomplicated Cases

Parameter	Uncomplicated (n = 308)	Complicated (n = 70)	P-value
Baseline Data			
Age/years (Mean ± SD)	**25.47 ± 5.5**	**26.04 ± 6.6**	**= 0.453***
Sex			
• **Female**	**118 (76.6%)**	**30 (85.7%)**	**= 0.096****
• **Male**	**36 (23.4%)**	**5 (14.3%)**	
Eye			
• **OD**	**151 (49%)**	**38 (54.3%)**	**= 0.327****
• **OS**	**158 (51%)**	**32 (45.7%)**	
Preoperative Data (Median (IQR))			
• **UCVA (Decimal)**	**0.05 (0.2)**	**0.05 (0.2)**	**= 0.713*****
• **UCVA Log MAR**	**1.3 (0.6)**	**1.3 (0.6)**	**= 0.713*****
• **MR-S (D)**	**-3.3 (2.8)**	**-3.5 (2.8)**	**= 0.555*****
• **MR-C (D)**	**-0.8 (1)**	**-0.8 (1)**	**= 0.737*****
• **MR-Axis**	**83 (54)**	**81.5 (57)**	**= 0.808*****

• SE (D)	-3.6 (2.8)	-4 (2.6)	= 0.343***
• CR-S (D)	-2.8 (2.5)	-3.3 (2.5)	= 0.592***
• CR-C (D)	-0.8 (0.2)	-0.8 (1)	= 0.123***
• CR-Axis	82 (56)	88 (50)	= 0.221***
• BCVA (Decimal)	1 (0.2)	1 (0.2)	= 0.793***
• BCVA Log MAR	0 (0.1)	0 (0.1)	= 0.793***
• K1 (D)	43 (2.3)	42.5 (2.2)	= 0.213***
• K1 Axis	77 (58)	51.5 (38)	= 0.366***
• K2 (D)	44.5 (2.2)	44 (2.2)	= 0.250***
• K2 Axis	90 (21)	93.5 (21.5)	= 0.308***
• K-Mean (D)	44 (2.2)	43 (2.4)	= 0.205***
• K-Max (D)	45 (2.2)	44.5 (2.1)	= 0.297***
• CCT (µm)	547 (42)	555.5 (41)	= 0.119***
• T at TL (µm)	542 (44)	551.5 (43)	= 0.124***
Operative Data (Median (IQR))			
• Flap Thickness	110 (40)	110 (1)	= 0.481***
• Stromal bed	372 (60)	365.5 (50)	= 0.631***
• Percentage of stromal bed to corneal thickness (%)	68 (8.5)	68.5 (6)	= 0.271***

*Independent t-test was used for comparison of means among groups.;**Chi-square test was used to compare proportions between groups.; ***Mann Whitney U test was used for comparison of medians among groups.

Table 4.Rate of Complication over Time

Parameter	Intraoperative		P-value*
	Uncomplicated (n = 308)	Complicated (n = 70)	
1st Day			
• Uncomplicated	297 (78.6%)	59 (15.6%)	< 0.001*
• Complicated	11 (2.9%)	11 (2.9%)	
1st Month			< 0.001*
• Uncomplicated	303 (80.2%)	70 (18.5%)	
• Complicated	5 (1.3%)	0 (0%)	
3rd Month			
• Uncomplicated	306 (81%)	70 (18.5%)	< 0.001*
• Complicated	2 (0.5%)	0 (0%)	

*McNemar test was used to compare the repeated frequency analysis

Discussion

LASIK for the treatment of myopia, hyperopia and astigmatism is one of the most widely performed ophthalmic surgical procedures in the world. The quest for a safer, more precise and effective refractive procedure has led to many strides in the technology and the procedure itself. With significant advancements in technology, the complications associated with this procedure have declined significantly. The study included 378 eyes of 189 individuals, who underwent LASIK refractive surgery in private LASIK centers (AlForsan- El-Nour) for the correction of refractive errors between January, 2021 and January, 2022.

In our work, the majority of cases (81.5%) had no complications. Flap-related

complications are the most common intraoperative complications during LASIK surgery as noted by Azar DT et al; **(Azar and Koch, 2002)** an incomplete flap, which is reported in 3% of cases, can occur when the smooth passage of the microkeratome is obstructed within the surgical field. Other significant causes of flap-related complications include the intraoperative loss of suction, electrical failure, accidental release of the vacuum, and damage to the microkeratome. Also in the work of Howard Gimbel et al, **(Gimbel et al., 1998)** intraoperative complications and surgical events recorded, including 19 (1.9%) microkeratome-related flap complications.

In current study we detected intraoperative flap decentration (1.5%) interface debris (2.2%) interface pigmentation (0.6%) epithelial defect (1.8%) de-epithelialization of the flap epithelium (1.5%). We detected incomplete flaps 3 (0.8%), and irregular stromal bed (0.3%) this was comparable with the work of Haft P et al, there was 3 (0.06%) eyes had incomplete flaps due to suction loss, and 1 (0.02%) eye had irregular flap due to previous corneal scar **(Haft et al., 2009)**.

The incidence of flap striae ranges from 0.03% up to 3.5% of patients and is, therefore, more common than full flap dislocations. **(Wallerstein et al., 2017)** This complication is a result of the misalignment of the flap and can be classified into macro-striae and microstriae. Here we had better results with Macro-striae (0.3%) and Micro-striae (1.1%) without full flap dislocation probably due to meticulous washing and careful replacement of the flap after ablation. In the work by Harmanjit Singh et al, **(Harmanjit et al., 2012)** 335 eyes with post-LASIK striae underwent flap relift, incidence of 0.54%.

Epithelial trauma at the time of surgery can lead to the proliferation of epithelial cells into the space between the stromal bed and the flap, which, in turn, may result in epithelial in-growth. Important risk factors for this condition are peripheral epithelial defects, poor flap adhesion or its perforation, and free cap. Epithelial In-growth in our study represented (0.5%) this was comparable to the work of Mohamed TA et al 2011, **(Mohamed et al., 2011)** where the total incidence of epithelial ingrowth was 4.7%, the incidence after primary treatment was 3.9%, the incidence after enhancement was 12.8%, and the total incidence of epithelial ingrowth was 3% in the myopic group compared with 23% in the hyperopic group. After primary myopic treatment, there was a 3% incidence of epithelial ingrowth compared with 17% after primary hyperopic treatment. The incidence after enhancement was 7% in the myopic group and 43% in the hyperopic group **(Mohamed et al., 2011)**.

Intraoperative epithelial defects (IED) occurred in (9.7%) of cases done by Navin Tekwani et al **(Tekwani et al., 2002)** Intraoperative epithelial defects significantly increased with older age, maintenance of suction ring vacuum during the reverse pass of the microkeratome. The preoperative and intraoperative eye-drop regimen had a significant effect on IED In patients undergoing bilateral LASIK, the incidence of IED is much higher in the second eye if the first eye developed an IED (57% vs 1%). Again we got much less epithelial defect than this study as we had younger age group in addition to minimization of eye drops preoperatively.

Conclusions

The goal of this study was to showcase the rates of complications over a period of time. We found that there was statistically significant decrease in rates of complications over time. The majority of cases had no intra-operative complications. The majority of cases had no complications at 1st day, 1st month and after three months.

Overall rates of complications of LASIK are still relatively rare due to new advances in technology and refinement of surgical techniques.

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