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# Intraoperative Complications of Laser in Situ Keratomileusis in Yazd

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# Authors' contributions

This work was carried out in collaboration between all authors. Authors MRS and SK designed the study, wrote the protocol, collected the data and did the literature searches. Author MRB did expert consultation. Author NO collaborated in English draft of manuscript and revising. Author EAS wrote the first draft of the manuscript, managed the literature searches and revised the manuscript. All authors read and approved the final manuscript.

**Original Research Article** 

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# ABSTRACT

**Purpose:** Laser in situ keratomileusis (LASIK) is a popular method for correcting refractive errors. We survived the incidence and types of LASIK intraoperative flap complications in Yazd refractive surgery center.

**Methods:** Medical records of all patients who underwent Laser in situ keratomileusis were reviewed retrospectively. Flap related complications including buttonhole, incomplete, irregular, free and thin flaps were studied. Finally data was analyzed by SPSS-16 based on aims.

**Results:** In 1000 eyes (from 395 males and 605 females), 16 cases (1.6%) were affected by flap related complications. the most frequent complications were incomplete flap (56.3%), irregular flap (31.3%) and buttonhole (12.5%), respectively. The age group of 40-45 years old and patients with 580-590 $\mu$  corneal thickness affected from the complications frequently. Also, statistically significant difference was seen between anterior and posterior corneal radius of curvature and incidence of complications (P. Value=0.0001).

Conclusions: Incomplete flap is the most frequent flap related complication in Yazd; we

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conclude that with higher corneal radius of curvature incidence of this complication is higher.

Keywords: Laser in situ keratomileusis; intraoperative; flap complication.

# 1. INTRODUCTION

Laser in situ keratomileusis (LASIK) is one of the most common and effective surgical approaches. That's popular among patients for correcting refractive errors (myopia, hyperopia and astigmatism), a safe method with rare complications as well. LASIK was established by Pallikaris in 1990 in Greece. He cut a thin layer of the cornea using a microkeratome, then reshaped corneal tissue using an excimer laser [1-4]. Flap creation is the first step in the surgery. It allows for rapid visual and medical rehabilitation. However, flap creation can be associated with specific complications, resulting from an abnormal cut. Different models of microkeratome are used to create the corneal flap of which the most common are mechanical and femtosecond [5].

LASIK because of its possible as an outpatient surgery, short lasting, rapid and painless correction of vision, no sub epithelial opacity [4-6], least postoperative care and correcting a wide range of myopia (about 8D) is preferred. These benefits are basically related to creating a corneal flap, thus unsuccessful flap making could be the most concerning complication during surgery, leading to free, irregular, buttonhole, thin and incomplete flaps<sup>6</sup>. [7]. However the experience and skill of surgeon play an important role in flap related complications [2-8] and sometimes applying modern microkeratomes was superior in order to lower the complications than surgeon skills. Understanding different flap complications and also preventive and curative strategies are of much importance [9-10].

Considering that intraoperative complications of LASIK are mostly preventable, and awareness of results and complications and causes of the complications could be a guide to next steps and crisis management, we decided to evaluate LASIK complications during surgery in Yazd LASIK center in order to achieve less complication rate.

# 2. MATERIAL AND METHODS

This is a retrospective cross-sectional study. We studied Medical records of all patients undergone LASIK at Yazd refractive surgery center located in Seyyed Al Shohada Hospital from Jun 2003 to Jun 2007. One file among 3 was selected randomly and systematically. The information of patient's file including demographic data, central corneal thickness, corneal radius of curvature and the refractive error type was enrolled. In complicated cases a special checklist was arranged which included additional information about the use of contact lens and degree of refractive error.

Ten experienced surgeons performed the surgeries using hansatome microkeratome (Bausch& Lomb), a mechanical type. In this study we divided cases into 6 age groups with 5 year intervals; however the last group (sixth one) consisted of 6<sup>th</sup> and 7<sup>th</sup> groups because the number of cases was inconsiderable in these two groups. The degree of refractive error was divided into 3 groups: 0-3, 3-6 and 6-9 u. Anterior and posterior corneal radius of curvature (ACRC and PCRC) were measured by orbscan (Bausch& Lomb). ACRC was divided into 5 groups and PCRC into 4 groups with 50µ intervals. Totally 1000 operated eyes were

selected and five flap related complications including buttonhole, incomplete, irregular, free and thin flaps were studied. Finally data was analyzed by SPSS-16 based on aims, using descriptive statistics and chi square test with significance set at 0.05.

## 3. RESULTS

In our article 1000 eyes (from 395 males and 605 females) were studied. 23 eyes (2.3%) were hyperopic and 977 (97.7%) myopic. Among these 1000 eyes, 16 cases (1.6%) were affected by flap related complications. Ten eyes (62.5%) were right and 6 (37.5%) left.

The most frequent flap related complication in this study was incomplete flap, in 16 eyes (56.3%). Other complications were irregular flap (31.3%), buttonhole (12.5%) and free flap and thin flap (0.0%) respectively.

The frequency of LASIK complications based on the age groups is shown in Table 1. As shown the most frequent complications were seen in the age group of 40-45 years old (9.5%) and the least in the age group of 30-35 (0.7%), and this difference was statistically significant (P value=0. 027).

There was no statistically significant between males and females in our study, 9 (2.3%) males and 7(1.2%) females.

All complicated eyes were myopic. There was no statistically significant difference based on spherical equivalent (SE) groups. The most frequent complicated groups based on SE were 3-6D (37.5%), 0-3D (31.3%) and 6-9D (31.3%) respectively.

Different approaches to intraoperative complications include stopping the procedure or resuming it. In our study, about 7 eyes procedure continued (43.8%) and for others procedure was stopped.

According to Table 2, patients who had a corneal thickness of 580-590µ had the most intraopertative complications, using Chi-square test (P-value=0. 004).

Also in our study, a statistically significant difference was seen between ACRC and incidence of complications (Table 3). The most frequent of complications was seen in group with ACRC of 8-8.5 $\mu$  (8.1%) (P-value=0. 0001). Intraoperative complications in the group with PCRC of 6-6.49 $\mu$  were the highest amongst, 3.1% (P-value=0. 002) (Table 4).

Just one patient complicated had used soft contact lens (6.3%) and others had not used any lens before. None of complicated patients ever used hard contact lens.

According to the results of this study, postoperative uncorrected visual acuity (UCVA) in complicated eyes was as follows: in 6(37.5%) eyes was 1/10-2/10; in 4(25%), 2/10-3/10; in 4(25%), 7/10-8-/10; in 2(12.5%), 9/10-10/10. While best corrected visual acuity (BCVA) in these eyes was as follows: in 8(50%) eyes, 9/10-10/10; in 6(37.5%), 7/10-8/10 and in 2(12.5%), 5/10-6/10.

#### Table 1. Frequency of intraoperative LASIK complications based on age

A.G*	15-19 yrs	20-24 yrs	25-29 yrs	30-34 yrs	35-39 yrs	>40 yrs	Total
Comp**	No (%)	No (%)	No (%)	No (%)	No (%)	No (%)	No (%)
With	2 (2.9%)	5 (1.3%)	4 (1.2%)	1 (0.7%)	2 (4.3%)	2 (9.5%)	16 (1.6%)
Without	66(97.1%)	377(98.7%)	335(98.8%)	143(99.3%)	44(95.7%)	19(95.5%)	840(98.4%)
Total	68(100%)	382(100%)	339(100%)	144(100%)	46(100%)	21(100%)	1000(100%)
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\*Age Group \*Complication P. Value= 0.027 Chi-Square test

#### Table 2. Frequency of intraoperative LASIK complications based on central corneal thickness

CCT*	500-519 μ	520-539 μ	540-559 μ	560-579 μ	>580 µ	Total
Comp**	No (%)	No (%)	No (%)	No (%)	No (%)	No (%)
With	1 (1.9%)	1 (0.3%)	7 (1.7%)	3 (1.9%)	4 (7.4%)	16 (1.6%)
Without	52(98.1%)	325(99.7%)	404(98.3%)	153(98.1%)	50(92.6%)	984(98.4%)
Total	53(100%)	326(100%)	411(100%)	156(100%)	54(100%)	1000(100%)
	* Central Corne	eal Thickness	**Complication	P. Value= 0.004 C	Chi-Square test	

Central Corneal Thickness

P. Value= 0.004 Chi-Square test

#### Table 3. Frequency of intraoperative LASIK complications based on anterior corneal radius of curvature

	ACRC*	6-6.49	6.5-6.99 μ	7-7.49 μ	7.5-7.99 μ	8-8.5 μ	Total
Comp**		No (%)	No (%)	No (%)	No (%)	No (%)	No (%)
With		0 (0%)	1 (0.3%)	1 (0.3%)	7 (4%)	7 (8.1%)	16 (1.6%)
Without		39(100%)	334(99.7%)	366(99.7%)	166(96%)	79(91.9%)	984(98.4%)
Total		39(100%)	335(100%)	367(100%)	173(100%)	86(100%)	1000(100%)
		* Antorior Cor	and Radius of Curvatura	** Complication D	Value 0.000 Chi	Causers tost	

Complication P. Value= 0.000 Chi-Square test Anterior Corneal Radius of Curvature

#### Table 4. Frequency of intraoperative LASIK complications based on the posterior corneal radius of curvature

PCRC*	6-6.49	6.5-6.99 μ	7-7.49 μ	7.5-8.5 μ	Total
Comp**	No (%)	No (%)	No (%)	No (%)	No (%)
With	2 (3.1%)	13 (2.8%)	0 (0%)	1 (1.2%)	16 (1.6%)
Without	63(96.9%)	459(97.2%)	380(100%)	82(98.8%)	984(98.4%)
Total	65(100%)	472(100%)	380(100%)	83(100%)	1000(100%)
	* Postorior Corport Padius	fourvoturo **C	amplication D Value	0 0022 Chi Square	a toot

Posterior Corneal Radius of curvature

\*Complication P. Value= 0.0023 Chi-Square test

## 4. DISCUSSION

We studied intraoperative LASIK complications in 1000 eyes in Yazd, of which 16 eyes (1.6%) were complicated. Studying the interpretive LASIK complications has been widely done worldwide, and different prevalence of complication rates of 0.3% [11] to 20% [12] has been reported. The most frequent flap related complications in our study were: incomplete, irregular and buttonhole flap respectively. Flap complication rates are different in every study.

In a retrospective study in Colorado 84711 patients were studied [13], using mechanical microkeratome, 256 patients (0.3%) were complicated, lower compared to our study but the most frequent flap was Incomplete, compatible with our study.

In a study in Yemen flap complication was reported 0.8%, lower than our reported, and the most frequent flap complication was buttonhole [14].

In Nakano et al. study from 0.63% complications, 0.23% was incomplete flap, 0.13% buttonhole flap, and thin flap and free flap were 0.08% [15].

In a study by Valles et al. intraoperative complications reported to be 3.92% and the most frequent complication was free flap (1.6%), which is not compatible with our results [16].

Ito et al in Japan reported complication of 0.67% in LASIK and the most frequent complication was incomplete flap (0.48%) which is compatible with our results [9].

In a study in Saudi Arabia in 2011 the complication rate was reported to be 1% of which the most frequent was incomplete, and it's compatible with our results [17].

The incidence rate of complications in Carrillo et al study [18] was completely different from ours. According to their findings 0.24% of cases were complicated which the most frequent one was free flap (0.08%) and incomplete flap was the second most frequent (0.049%) that is much lower than ours (in our study no free flap was reported).

Also in Brazil the rate of complications was 2.1%. The most frequent complications were thin flap (0.73%) and free flap (0.58%) [19].

In a study by Pallikaris et al. [20], the incidence rate of complications was 14% which is much more than ours. These complications were as follows: incomplete (5.6%), buttonhole (3.5%), irregular (2.6%), thin (1.1%) and free flap (1.1%). In 77% of complicated procedures the surgery continued and management was arranged during surgery, and in 23% the surgery was stopped. However in our study just in 43.8% of cases the surgery continued. Also using hard and soft contact lens increased the complication rate, while in our study most of complicated patients (93.8%) never used contact lens.

An important and necessary step in LASIK surgery is to create the flap, which is possible using different models of microkeratomes. Two most common used microkeratomes are mechanical and femtosecond. Many surgeons still use a mechanical microkeratome [5,15,17,18]. In this study we used a mechanical microkeratome too and in our study like some other studies [15,17] the most frequent complication with mechanical microkeratome reported to be incomplete flap. However in Jacobs study buttonhole flap was the most common [13].

In many studies incidence of complications in right eye was more than left [13,16,20].

According to our results, increase in anterior corneal radius of curvature increases flap related complications, which was statistically significant. In Valles study [16] considering preoperative keratometry, corneas with less than 41D of power (flatter corneas) are more susceptible to free flap and incomplete flap, while corneas with more than 46 D of power (steeper corneas) are more susceptible to corneal scratch, irregular flap and thin flap, (P-value<0.05). In Ito study [9] there was no significant difference between flap complications based on preoperative keratometry and vertical and horizontal diameters.

In our study 50% of complicated patients, achieved BCVA 9/10 or more, and visual acuity less than 4/10 was not seen at all. In Pallikaris study [20], totally 35 complicated eyes (95%) achieved BCVA 20/40 or more after one year, and 25 eyes (68%) achieved visual acuity of 20/20.

In Ito study [9] in 2003 for all complicated patients the procedure was stopped and in 60% of them another surgery was performed. 6 months after the first LASIK surgery 97.6% of the complicated eyes UCVA was 20/40 or more and in 66.7% of patients UCVA was 20/20.

In a study by Stulting et al just 3 complicated patients lost 2 lines of Snellen chart or more for BCVA of which were all buttonhole flaps<sup>7</sup> and in a study by Tham et al. 44% of patients lost one Snellen line and just one patient lost 2 lines of the Snellen chart [21].

## 5. CONCLUSION

The incidence of intraoperative flap complications during LASIK in our study was acceptably small, compared to other studies. Incomplete flap is the most frequent flap related complication in Yazd; we conclude that with higher corneal radius of curvature incidence of this complication is higher.

# CONSENT

Not applicable.

# ETHICAL APPROVAL

Local Ethics Committee approval was obtained for this retrospective study and consent forms were not required.

#### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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