

1 Research Paper

2 Title page

3 Original article

4 Title: Intraoperative complications of laser in situ keratomileusis in Yazd

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6 ABSTRACT

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

10 **Methods:** we retrospectively reviewed the profile of all patients whom presented in a LASIK
11 center in Yazd from Jun 2003 to Jun 2007 and undergone LASIK. Flap related complications
12 including buttonhole, incomplete, irregular, free and thin flaps were studied. Finally data was
13 analyzed by SPSS-16 based on aims.

14 **Results:** In 1000 patients (395 males, and 605females), 16 cases (1.6%) were affected by flap
15 related complications. the most frequent complications was incomplete flap (56.3%), irregular
16 flap (31.3%) and buttonhole (12.5%) respectively which were seen in the age group of 40-45
17 years old (9.5%) and patients who had a corneal thickness of 580-590 μ frequently. Also,
18 statistically significant difference was seen between anterior and posterior corneal radius of
19 curvature and incidence of complications (P. Value=0.0001).

Conclusions: 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.

Keywords: Laser in situ keratomileusis, intraoperative, flap complication

Introduction:

Laser in situ keratomileusis (LASIK) is one of the most common and effective surgical approaches and 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. Different models of microkeratome are used to create the corneal flap of which the most common are mechanical and femtosecond ⁵.

Benefits of LASIK are being short lasting and possible as an outpatient surgery, rapid and painless correction of vision, leaving no sub epithelial opacity ⁴⁻⁶, least postoperative care needed and correcting a wide range of myopia (about 8D). 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 ^{6, 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.

Material and Methods:

This is a retrospective cross-sectional study. We studied data recorded in all patient file whom presented in a LASIK center from Jun 2003 to Jun 2007 and undergone LASIK. One file among 3, was selected randomly and systematically. Then patient information including age, gender, 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.

Microkeratome applied in the Yazd LASIK center was mechanical type. In this study we divided cases into 6 age groups with 5 year intervals; however the last group (sixth one) consisted of 6th and 7th groups because the number of cases was inconsiderable in these two groups. The degree of refractive error was divided into 3 groups: 0-3 D (diopter), 3-6 D and 6-9 D. Anterior corneal radius of curvature was divided into 5 groups and posterior corneal radius of curvature into 4 groups with 50 μ intervals. Totally 1000 operated patients 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.

62 **Results:**

63 In our article 1000 patients (395 males and 605 females) were studied. 23 patients (2.3%) were
64 hyperopic and 977 patients (97.7%) were myopic. Among these 1000 patients, 16 patients
65 (1.6%) were affected by flap related complications.

66 According to our study the most frequent flap related complication in Yazd was incomplete flap
67 found in 16 complicated patients (56.3%). Other complications in order of frequency were
68 irregular flap, 5 patients (31.3%) buttonhole, 2patients (12.5%) and free flap and thin flap in
69 none of the patients (0.0%).

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

74 9 males and 7 females in our study were complicated, which means 2.3% of males and 1.2% of
75 females that this was statistically no significant.

76 All complicated patients were myopic. Based on the degree of refractive error, from 16
77 complicated cases, 6 patients (37.5%) belonged to the group of 3-6D which was the most
78 complicated group. 5 patients (31.3%) belonged to the group of 0-3D and 5 other ones (31.3%)
79 to the group of 6-9D, which there was no statistically significant difference seen amongst.

80 In our study just one of the eyes was complicated in all patients, 10 patients in right eye (62.5%)
81 and 6 patients in left eye (37.5%).

Different approaches to intraoperative complications include stopping the procedure or resuming it. In our study, for 7 patients procedure continued (43.8%) and for 9 other cases procedure was stopped.

According to table 2, patients who had a corneal thickness of 580-590 μ had the most intraoperative complications, using Chi-square test (P-value=0.004).

Also in our study, statistically significant difference was seen between anterior corneal radius of curvature and incidence of complications (table 3). Increase in anterior corneal radius of curvature leads to increase in incidence of complications. The highest rate of incidence of complications (8.1%) belonged to the group with anterior corneal radius of curvature of 8-8.5 μ (P-value=0.0001).

According to our results intraoperative complications in the group with posterior corneal radius of curvature of 6-6.49 μ were the highest amongst, 3.1% (P-value=0.002) (table4).

Considering the use of contact lens (soft lens, hard lens, no lens used) before surgery, just one patient complicated had used soft contact lens (6.3%) and other 15 patients had not used any lens before (93.8%). None of complicated patients ever used hard contact lens.

According to the results of this study, postoperative uncorrected visual acuity (UCVA) in complicated patients was as follows: UCVA in 6 patients (37.5%) was 1/10-2/10, in 4 patients (25%) 2/10-3/10, in 4 patients (25%) 7/10-8-/10, in 2 patients (12.5%) 9/10-10/10, and none was 3/10-4/10.

101 While best corrected visual acuity (BCVA) in these patients was as follows: in 8 patients (50%)
 102 9/10-10/10, in 6patients (37.5%) 7/10-8/10, in 2 patients (12.5%) 5/10-6/10, but in no one BCVA
 103 was lower than 4/10.

104 Table 1: Frequency distribution of intraoperative LASIK complications based on age in Yazd

Age Complication	15-19		20-24		25-29		30-34		35-39		>40		Total	
	NO	(%)	NO	(%)	NO	(%)	NO	(%)	NO	(%)	NO	(%)	NO	(%)
Without complication	66	97.1	377	98.7	335	98.8	143	99.3	44	95.7	19	95.5	98.4	98.4
Complicated	2	2.9	5	1.30	4	1.2	1	0.7	2	4.3	2	9.5	16	1.6
Total	68	100	382	100	339	100	144	100	46	100	21	100	1000	100

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106 **P. Value= 0.027** **Chi-Square test**

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112 Table 2: Frequency distribution of intraoperative LASIK complications based on central corneal
113 thickness (μ) in Yazd

CCT Complication	500-519		520-539		540-559		560-579		>580		Total	
	NO	(%)	NO	(%)	NO	(%)	NO	(%)	NO	(%)	NO	(%)
Without complication	52	98.1	325	99.7	404	98.3	153	98.1	50	92.6	984	98.4
Complicated	1	1.9	1	0.3	7	1.7	3	1.9	4	7.4	16	1.6
Total	53	100	326	100	411	100	156	100	54	100	1000	100

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115 **P. Value= 0.004**

Chi-Square test

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122 Table 3: Frequency distribution of intraoperative LASIK complications based on anterior corneal
123 radius of curvature in Yazd

Corneal radius of curvature (Anterior) Complication	6-6.49		6.5-6.99		7-7.49		7.5-7.99		8-8.5		Total	
	NO	(%)	NO	(%)	NO	(%)	NO	(%)	NO	(%)	NO	(%)
Without complication	39	100	334	99.7	366	99.7	166	96	79	91.9	984	98.4
Complicated	0	0	1	0.3	1	0.3	7	4	7	8.1	16	1.6
Total	39	100	335	100	367	100	173	100	86	100	1000	100

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125 **P. Value= 0.0001**

Chi-Square test

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132 Table 4: Frequency distribution of intraoperative LASIK complications based on the posterior
133 corneal radius of curvature in Yazd

Corneal radius of curvature (Posterior) Complication	6-6.49		6.5-6.99		7-7.49		7.5-5.8		Total	
	NO	(%)	NO	(%)	NO	(%)	NO	(%)	NO	(%)
Without complication	63	96.9	459	97.2	380	100	82	98.8	984	98.4
Complicated	2	3.1	13	2.8	0	0	1	1.2	16	1.6
Total	65	100	472	100	380	100	83	100	1000	100

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135 **P. Value= 0.0023**

Chi-Square test

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142 Discussion

143 We studied intraoperative LASIK complications in 1000 patients in Yazd, of which 16 patients
144 (1.6%) were complicated. Studying the interpretive LASIK complications has been widely done
145 worldwide, and different prevalence of complication rates of 0.3% ¹¹ to 20% ²¹ has been
146 reported. The most frequent flap related complications in our study respectively were as follows:
147 incomplete flap 56.3% (9 patients), irregular flap 31.3% (5 patients), buttonhole flap 12.5% (2
148 patients), and thin and free flap which were not seen (0.0%). Flap complication rates are
149 different in every study.

150 In a retrospective study in Colorado 84711 patients were studied ¹³, using mechanical
151 microkeratome, 256 patients (0.3%) were complicated, which was lower compared to our study.
152 However the most frequent flap complications were respectively as follows: 84 incomplete flaps
153 (0.09%), 74 thin flaps (0.87%), 59 buttonhole flaps (0.07%) and 10 free flaps (0.012%), hence
154 incomplete flap was the most frequent flap which is compatible with our study in the mentioned
155 study, from 256 complicated patients. In 134 cases the right eye was complicated and in 122
156 cases the left eye was complicated, which was not statistically significant (P-value=0.45). This
157 difference is compatible with our study too.

158 In a study 2000 myopic patients undergone LASIK surgery were analyzed in Yemen in 2010,
159 flap complication incidence was reported to be 0.8% (15 cases) which was lower than our
160 reported incidence rate and the most frequent flap complication was buttonhole ¹⁴.

161 In a study by Nakano et al in 2004 from 0.63% complications, 0.23% contributed to incomplete
162 flap, 0.13% to buttonhole flap, and 0.08% to thin flap and free flap each ¹⁵.

163 In a study by Valles et al in Spain ¹⁶ on 34099 LASIK surgeries, intraoperative complications
164 reported to be 3.92% and the most frequent complication was free flap (1.6%), which is not
165 compatible with our results, Irregular and thin flaps 0.8% each, incomplete flap 0.36% and
166 buttonhole flap 0.11%. There was no significant difference between right and left eye
167 involvement.

168 Ito et al in Japan analyzed myopic and astigmatic patients whom undergone LASIK surgery from
169 1997 to 2000. Of these patients 0.67% was complicated, and the most frequent complication was
170 incomplete flap (0.48%) which is compatible with our results ⁹.

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

173 In a study in Mexique 26600 patients were analyzed ¹⁸. Only 65 cases were complicated (0.24%)
174 of which the most frequent one was free flap (0.08%), incomplete flap was the second most
175 frequent (0.049%). The incidence rate for buttonhole flap and irregular flap was 0.041% and
176 0.019% respectively. The incidence rate of complications in this study is much lower than ours;
177 however the order of the frequency of complications was completely different from ours. While
178 in our study no free flap was reported and irregular flap was the second most frequent
179 complication, in mentioned study free flap was the most frequent complication and irregular flap
180 was rare.

181 In Brazil the rate of complications was reported to be 2.1%. The most frequent complications
182 were thin flap (0.73%) and free flap (0.58%). Though the rate is almost similar to our achieved
183 rate the order of the frequency is different from ours ¹⁹.

184 In a study by Pallikaris et al which was done on 334 patients ²⁰, the incidence rate of
185 complications was 14% which is much more than our achieved rate. These complications were
186 as follows: incomplete flap 19 cases (5.6%), buttonhole flap 12 cases (3.5%), irregular flap 9
187 cases (2.6%), thin flap 4 cases (1.1%) and free flap 4 cases (1.1%).

188 Free flap which is the most frequent complication in our study (0.563%) is the most frequent
189 complication in this study too. In Pallikaris study thin flap and free flap were the least frequent
190 complications. In the mentioned study in 77% of complicated procedures (37 cases) the surgery
191 has been continued and management was arranged during surgery, and in 23% of cases (11
192 cases) the surgery has been stopped by the surgeon. However in our study just in 43.8% of cases
193 the surgery has been continued. Also from 48 complicated patients 29 patients (64.5%) were
194 affected in the right eye and 19 patients (39.5%) were affected in the left eye. In Pallikaris study
195 using hard and soft contact lens increased the complication rate, while in our study most of
196 complicated patients (93.8%) never used contact lens.

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

203 According to our results, increase in anterior corneal radius of curvature increases flap related
204 complications, which was statistically significant. In Valles study ¹⁶ considering preoperative
205 keratometry, corneas with less than 41D of power (flatter corneas) are more susceptible to free

206 flap and incomplete flap, while corneas with more than 46 D of power (steeper corneas) are more
 207 susceptible to corneal scratch, irregular flap and thin flap, (P-value<0.05). In Ito study ⁹ there
 208 was no significant difference between flap complications based on preoperative keratometry and
 209 vertical and horizontal diameters.

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

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

216 In a study by Stulting et al just 3 complicated patients lost 2 lines of snellen chart or more for
 217 BCVA of which were all buttonhole flaps ⁷ and in a study by Tham et al 44% of patients lost one
 218 Snellen line and just one patient lost 2 lines of the Snellen chart ²¹.

219 **Conclusion**

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

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