

When case report became case series: 45 cases of late traumatic flap complications after laser-assisted in situ keratomileusis and review of Chinese literature

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ABSTRACT

Objective To report 45 cases of late traumatic flap complications after laser-assisted in situ keratomileusis (LASIK) and discuss the continually increasing number of cases in China.

Methods A multicentre retrospective survey of eye injuries was carried in 31 military hospitals from January 2006 to December 2011. Detailed information from the medical records of all 92 cases with a history of prior LASIK treatment were collected and summarised, with respect to visual acuity (VA), flap condition, treatment and final outcome. All Chinese publications relevant to late traumatic flap complications in Chinese patients were retrieved and summarised.

Results 92 inpatients (92 eyes) underwent LASIK surgery; 45 of these had traumatic LASIK flap complications. Flap dislocation was the commonest and most needed surgical repair. VA after treatment was good and no statistically significant difference was observed when compared with the 47 cases without flap complications. 109 articles related to late traumatic flap complications after LASIK were retrieved from four Chinese document databases. There were 550 cases of late traumatic flap complications. From 2004, case reports became more common; 10 or more cases were reported in some case series. VA of most cases was good and there was no remarkable vision loss after treatment.

Conclusions Late traumatic flap complications after LASIK have become more frequent in China, although the prognosis of most cases is good.

INTRODUCTION

A picture of corneal flap after screwdriver trauma was published in the *New England Journal of Medicine* in January 2013.¹ It became another weapon for those who had criticised laser-assisted in situ keratomileusis (LASIK) for many years, even though the author stated that late flap dehiscence due to trauma is a rare complication. LASIK is the most popular refractive surgery in China as in developed countries and many patients with refractive errors have undergone LASIK. Various reports about late traumatic flap complications after LASIK have been published in international journals, but there have been hardly any reports from mainland China. From 2010, a retrospective eye injuries survey of hospitalised military personnel has been carried out in 31 military hospitals of the Chinese People's Liberation Army; 45 cases of traumatic flap complications after LASIK have been collected. To obtain more details, we reviewed all

retrieved literature about late traumatic LASIK flap complications in the Chinese population and summarise all the cases reported.

METHODS

All medical records of military inpatients with eye injuries admitted to 31 military hospitals from January 2006 to December 2011 were reviewed. Data collected included: mechanism of injury, past history of eye surgery and diseases, type of eye injury, visual acuity (VA) at presentation, details of eye examinations, treatments, VA at discharge, outcome and sequelae. VA was categorised into five grades (no light perception, light perception to hand movement, 1/200 to 19/200, 20/200 to 20/50 and $\geq 20/40$) according to the Ocular Trauma Score (OTS).² Case details of patients who underwent LASIK were collected and summarised. More details were obtained from the doctors in charge of the patients. Ophthalmic equipment and staff at each hospital were also recorded.

The study conformed to the tenets of the Declaration of Helsinki.

A Chinese literature review was conducted through the Chinese Biomedical Literature database (SinoMed), Chongqing VIP Chinese Science and Technology Periodical database (CQVIP), Wanfang database and China National Knowledge Infrastructure (CNKI), updated to 1 July 2013 (no start date limit was applied). English language articles were not included. The term 'late' was defined as post-operative week 1 or later as defined by Kim.³ All literature relevant to late traumatic flap complications after LASIK in Chinese patients was retrieved. The following key words were used: 'laser in situ keratomileusis', 'LASIK', 'refractive surgery', 'flap', 'complication', 'injury' and 'trauma'. Alternative spellings and synonyms were also considered. Only one article was selected if the case or case series was repeatedly reported. All reported cases were summarised, including published year of the article, journal type, occupation of the patient, mechanism of injury, injury time after LASIK, VA at presentation, flap condition, other associated eye injuries, treatment, VA at discharge, outcome and sequelae.

Statistical analysis was performed using Stata V10.0.

RESULTS

Case series

This was a retrospective multicentre study of 1426 cases of eye injuries during the 6-year period in 31 military hospitals. Ninety-two of the eye injuries



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had a history of prior LASIK treatment. In 45 of the 92 previously LASIK treated patients, the eye injury involved the LASIK flap (dislocation/folds/oedema/loss of flap/infection/foreign body/flap loss or tear). Eleven of these flap traumas were associated with other eye injuries. Time between LASIK treatment and the trauma was known in 31 of 45 (between 2 months and 6 years). VA at the time of trauma presentation and after treatment is presented along with the method of treatment.

Mechanism of injury

In the 45 cases of traumatic flap complications after LASIK, the commonest cause of eye injuries was being knocked by a relatively blunt object, such as a fist, table, foot or ball (34 cases, 75.6%). Only a few injuries were caused by a relatively sharp object such as a fingernail, screwdriver or tree branch (11 cases, 24.4%).

VA at presentation

VA of several cases was too poor to be tested by the Snellen chart and LogMAR chart, so VA at presentation was only grouped as described by the OTS. The presenting VA of 15 cases was grade 1 ($\geq 20/40$, 33.3%); 10 cases were grade 2 (20/200 to 20/50, 22.2%), 8 were grade 3 (1/200 to 19/200, 17.8%), and 8 were grade 4 (light perception to hand movement, 17.8%). There were no presenting VA records for four patients.

Time after LASIK

Time after LASIK was recorded in 31 cases. The longest interval between initial surgery and onset of traumatic flap complications after LASIK was 6 years and the shortest was 2 months.

Flap condition

Flap condition was categorised according to published definitions and descriptions.^{3–6} Traumatic flap complications after LASIK are shown in table 1. Flap dislocation was the commonest condition after injury (32 cases, 71.1%). Corneal foreign body was often concomitant with flap dislocation (7 cases, 15.6%). Epithelial growth on exposed corneal bed was also concomitant with flap dislocation in the late treated cases (9 cases, 20.0%). Flap tear and part loss were seen in 2 cases (4.4%) of flap dislocation. Flap fold or striae without flap dislocation was not common. Isolated severe flap oedema, epithelial ingrowth, loss of flap, flap infection and ulcer were also not commonly seen. No diffuse lamellar keratitis was recorded.

Table 1 Flap condition of 45 cases with traumatic flap complications after LASIK

Flap condition	No. of cases	%
Flap dislocation	32	71.1
Flap folds or striae without flap dislocation	4	8.9
Isolated severe flap oedema	3	6.7
Isolated epithelial ingrowth	3	6.7
Loss of flap	2	4.4
Flap infection and ulcer	1	2.2
Corneal foreign body	7	15.6
Flap tear and part loss	2	4.4

LASIK, laser-assisted in situ keratomileusis.

Other associated eye injuries

In addition to flap problems, other associated eye injuries were seen in 11 cases (24.4%). There were four cases (8.9%) with hyphema, two cases (4.4%) with iridodialysis, one case (2.2%) with traumatic cataract, one case (2.2%) with lens subluxation, one case (2.2%) with vitreous haemorrhage, one case (2.2%) with macular oedema, two cases (4.4%) with conjunctiva laceration, two cases (4.4%) with eyelid laceration and one case (2.2%) with orbital fractures. Three cases (6.7%) had more than one associated eye injury.

Time between injury and treatment

The shortest time between injury and treatment was 1 h and the longest was 10 months. Twenty-six cases (57.8%) were treated within 1 day after injury, 9 cases (20.0%) were treated between 2 days and 1 week, and 10 cases (22.2%) were treated after 1 week.

Treatment

Treatments of 45 cases with traumatic flap complications after LASIK are shown in table 2. Of 32 flap dislocated cases, 25 cases underwent flap replacement surgery under the operating microscope, and the epithelium on the exposed corneal bed was scraped. Seven cases were treated with eye drops (antibiotics and steroids) because the flap was attached to the corneal bed spontaneously. Corneal foreign bodies were removed in seven cases under the operating microscope or a slim lamp. The flap was lifted and the epithelium was scraped in three cases of isolated epithelial ingrowth. Four cases of flap fold or striae, three cases of isolated severe flap oedema and two cases of flap loss were treated only with eye drops (antibiotics and steroids). The flap infection and ulcer case was intractable. Eye drops (antibiotics and steroids) were first applied but there was no progress. The flap was then lifted and the necrotic tissue removed; there was no remarkable progress and the edge of the flap began to melt. Finally, the flap was removed and corneal epithelium steadily covered the bed. Other associated eye injuries were also treated with surgery or eye drops. Some patients underwent surgery more than once; the maximum number was four times.

VA at discharge

VA at discharge of all 92 cases with a history of LASIK surgery is shown in table 3. At discharge, VA of 41 cases was grade 1 ($\geq 20/40$, 91.1%); 2 cases were grade 2 (20/200–20/50, 4.4%), and 2 cases were grade 3 (1/200–19/200, 4.4%). VA of 16 cases (35.56%) was $\geq 20/20$ at discharge. As the VA of several cases was too poor to be tested by the Snellen chart and LogMAR

Table 2 Treatment of 45 cases with traumatic flap complications after LASIK

Treatment	No. of cases	%
Flap replacement	25	55.6
Epithelial scrape	13	28.9
Corneal foreign bodies removal	7	15.6
Flap removal	1	2.2
Isolated eye drops	17	37.8
Cataract extraction and iris suture	1	2.2
Eyelid laceration suture	2	4.4
Conjunctival laceration suture	2	4.4

LASIK, laser-assisted in situ keratomileusis.

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Table 3 VA at discharge of all 92 cases with LASIK surgery history

Group	Grade 1	Grade 2	Grade 3	Grade 4
With traumatic flap complications (n=45)	41	2	2	0
Without traumatic flap complications (n=47)	38	3	1	5

LASIK, laser-assisted in situ keratomileusis; VA, visual acuity.

chart, the Wilcoxon rank sum test was used for statistical analysis. There was a statistically significant difference ($p=0.00$, $Z=4.72$) when compared with VA at presentation; when compared with VA at discharge of the other 47 eye injury cases with a history of LASIK surgery but without flap complications, there was no statistically significant difference ($p=0.85$, $Z=0.19$).

Outcome and sequelae

Most cases had good recovery after treatment. Haze was seen in one case of flap loss, and particle superficial corneal opacity was seen in the case of flap infection and ulcer. Flap melting occurred in one case of part flap tear; this was mild, with no severe sequelae. Macular oedema and lens subluxation were responsible for two cases of low vision.

Ophthalmic equipment and staff of each hospital

Of 31 research hospitals, 24 had refractive surgery equipment and 21 had skilled refractive surgical doctors and technicians. Seven hospitals had no refractive surgery equipment and doctors did not receive refractive surgery training.

Review of Chinese literature

A total of 109 articles related to late traumatic flap complications after LASIK were retrieved from four Chinese document databases. Sixty-nine articles (63.3%) were published in ophthalmic journals and 40 (36.7%) in comprehensive medical journals. Case series of 10 or more were reported in 24 articles (22.0%). There were a total of 550 cases of late traumatic flap complications after LASIK after subtraction of 61 repeatedly reported cases.

Published year of the article

The first article describing late traumatic flap complications after LASIK was published in 1998,⁴ although the first LASIK surgery was introduced to China in 1994, then quickly and widely developed. From 1998 to 2003, there were a few case reports. However, from 2004, more cases were reported; there were 10 or more cases in some case series. Fifteen articles were published in 2008 and the number of articles reached a peak; the number of reported cases peaked in 2010. Subsequently the number of articles published and cases reported decreased slightly (table 4).

The amount of medical information provided by each author was inconsistent and some case reports or case series did not provide detailed medical information. It was therefore difficult to summarise the data as has been done by other authors in the English literature^{3,5}; only cases with exact information were summarised (table 5).

Table 4 Literature published and cases reported from 1998 to 2013

Year	1998	1999	2000	2001	2002	2003	2004	2005
Literature published	1	1	0	3	0	4	8	10
Cases reported	2	1	0	6	0	4	29	13
Year	2006	2007	2008	2009	2010	2011	2012	2013
Literature published	13	13	15	8	11	9	10	3
Cases reported	79	79	72	18	122	94	70	22

DISCUSSION

Although LASIK was approved by the US Food and Drug Administration in 1998, it had been rapidly and widely developed since 1994 when it was first introduced to China. For nearly 20 years, LASIK was the most popular type of refractive surgery in China. There were more than 1000 refractive surgery centres, and more than 1 000 000 cases underwent LASIK every year.⁶

However, LASIK was criticised due to complications such as dry eyes, night vision problems and flap complications. Some criticisms even came from medical staff. Late traumatic flap complications were a potential risk and were very uncommon.^{7,8} However, with the total number of patients undergoing LASIK increasing every year in China, the uncommon complications were sometimes seen; case reports became case series in the published literature. The literature relevant to this complication published in Chinese can not be shared by colleagues in other countries due to the language barrier, though there have been many valuable cases and experience.

Mechanisms of late traumatic flap complications were different; the commonest one was being knocked by blunt objects, which was the same in our series and reported cases. Several articles verified the stability of the flap using the rabbit model.^{9,10} However, in Kato's study,¹¹ Periodic acid Schiff (PAS) positive material and disorganised collagen fibre were seen along the interface of the corneal flap of rabbits 9 months after LASIK, which indicated that a much longer time than expected was required for corneal wound healing following LASIK. In Schmack's study, the strength of healed wound margin was 28.1% of the normal cornea on average, and the healed corneal stroma was only 2.4% of its normal strength.¹² Priglinger's in vitro model showed a lack of pronounced morphological changes in the central area of the LASIK interface and that scar

Table 5 Summary of 550 cases of late traumatic flap complications after LASIK

Items	No. of cases with detailed information	The commonest or maximum
Occupation of the patient	204	Military personnel (134, 65.7%)
Mechanism of injury	379	Knocked by blunt object (346, 91.3%)
Injury time after LASIK	524	12 years
Flap condition	276	Flap dislocation (258, 93.5%)
Other associated eye injuries	47	Hyphema (13, 27.7%)
Time between trauma and repair	463	10 months
Treatment	550	Flap replacement (497, 90.4%)
VA of last visit	548	≥20/30 (523, 95.4%)

LASIK, laser-assisted in situ keratomileusis; VA, visual acuity.

tissue formation can appear only at the rim zone of the incision, which might form an incomplete fixation zone for the corneal flap.¹³ Absence of scar formation in the lamellar interface explains the rapid restoration and persistence of VA after LASIK, but at the same time it could be a potential risk when injured. So even several years after the LASIK procedure, a corneal flap displacement can occur. The longest period from operation to onset of traumatic flap complications was 6 years in our cases, and the longest one reported in the Chinese literature we reviewed was 12 years.¹⁴ In the English literature, the longest period was 14 years (published in 2012).¹⁵

VA often remarkably decreased after injury; it was the commonest reason to see a doctor. In some cases, however, the flap was not dislocated and just had folds or striae; post-injury VA was slightly decreased, which was often neglected. Cases summarised by Kim often received timely treatment; the longest time from trauma to treatment was 9 days,³ while it was 10 months in our series and cases reported in the Chinese literature.¹⁶ In the army, the reason could be that a military mission delayed visiting time, or the initial visited doctor, possibly a general practitioner, had no refractive surgery experience. Cases associated with other eye injuries had very poor sight; the commonest one was hyphema both in our series and in cases reported in the literature.

Flap dislocation was the commonest finding and usually need surgical repair. In our case series, 32 cases (71.1%) had flap dislocation and 25 cases (55.6%) underwent flap replacement. Among 550 cases reported, 497 cases (90.4%) underwent flap replacement. The possible reason could be that the ophthalmic doctors had no refractive surgery experience in the seven military hospitals we surveyed. As a result they preferred conservative treatment to surgery. In contrast, most authors in the literature relevant to late traumatic flap complications had refractive surgery experience and some of them were refractive surgery experts in China. So they preferred to operate for timely repair of flap complication as other refractive surgery experts did.^{3,5} With regard to severely damaged flap, flap removal seemed to be more effective than keeping it. Cases of lost flaps often had good VA after treatment with eye drops; severe haze was not common either in our series or in cases reported in the literature.

Final VA was often good after treatment in our series, and in cases reported in the Chinese and other languages.^{3,5} To some extent, late traumatic flap complications were more scared than hurt. There was almost no loss of VA in most patients after timely treatment. Poor results were often associated with severe injury, other eye injuries and delayed treatment. Unlike radial keratotomy (RK), where traumatic rupture of RK incisions can still occur after 20 years and there may be serious complications,¹⁷ ocular integrity after LASIK did not decrease as Peacock's study showed.¹⁸ Exaggeration of late traumatic flap complications after LASIK equal to those of RK is therefore unwise.

However, the need for refractive surgery is massive. LASIK has been popular for nearly 20 years and the number of patients who have undergone LASIK is huge. In addition, refractive surgery is performed on nearly normal eyes, so patients undergoing the procedure are more critical than those undergoing other surgical procedures. Attention should be paid to any post-operative complications. Compared with millions of patients who have undergone LASIK, late traumatic flap complications occurred in a very small number which did not reach significance. However, data from the 550 cases reported revealed that the proportion of late traumatic flap complications in military personnel is large. So for those who are vulnerable to eye

injuries such as military personnel, the type of surgery should be carefully selected. Surface ablation would be a better option.

Just as laser refractive surgery is taking the place of RK, and with developing technology, LASIK might in the future be replaced by a more advanced type of surgery. Some studies showed that flap adhesion created with the femtosecond laser were stronger, and more uniform, regular and accurate than with the mechanical microkeratome.^{19,20} But there have also been reports of late traumatic flap complications, in the literature published in both English and Chinese.^{21,22} Small incision lenticule extraction (SMILE) is a promising new and nearly 'flapless' corneal refractive surgery. Only one femtosecond laser was used to complete the surgery, so it potentially eliminated traumatic flap complications and could potentially replace LASIK^{23,24}; however it is a developing type of surgery and needs more clinical practice to verify its superiority to LASIK.

On the other hand, just as there is lifelong potential risk of eyeball rupture after RK when injured, there could be lifelong potential risk of traumatic flap complications after LASIK. However, considerably more patients have undergone LASIK than RK. Standardised treatment for late traumatic flap complications should be mastered by every ophthalmic doctor, not just by those specialised in refractive surgery.

The shortcoming of the study was that there was no more detailed medical information following review of the medical records, even though we talked with the doctors who managed the patients. With regard to the Chinese literature review, all cases in mainland China were included and those in Taiwan and Hong Kong Chinese were excluded, because local journals in these two areas can not be obtained.

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