Intraoperative and early postoperative complications of laser in situ keratomileusis in Yemen

Mahfouth A. Bamashmus, FRCS (Ed), FRCOphth, *Mohamed A. Awadalla,* MBBS, FRCS (Ed), *Mahmoud F. Saleh,* MSc, MD, *Mohamed A. Al-Shekeil,* MBBS, ICO.

ABSTRACT

الأهداف: تحديد مضاعفات ما بعد الجراحة في وقت مبكر و نتيجة الإبصار بعد عمليات تصحيح النظر بالليزك (LASIK) للمصابين بقصر النظر.

الطريقة: ضمت مجموعة الدراسة أول 2000 عملية ليزك متتالية خلال الفترة من يونيو 2005م إلى أكتوبر 2006م، والتي تم إجراؤها في مستشفى مغربي للعيون – صنعاء – اليمن. تعتبر هذه الدراسة الإستعادية دراسة ملاحظه غير مقارنة. تحتوي البيانات التي تم مراجعتها على المقاسات ما قبل وبعد العملية، و أفضل قوة الأبصار، و وضع القرنية. تم تسجيل المضاعفات خلال وبعد عملية الليزك.

النتائج: كانت هناك 15 حالة (0.8%) مضاعفات بسبب المشرط المستخدم ميكروكيراتوم في قطع القرنية وهي ثقب في القرنية في 5 حالة، و قطع غير كامل في 3 حالة، و قطع رقيق في 3 حالة، و خلل ظاهري في القرنية 3 حالة، وقطع غير متوسط للقرنية في حالة واحدة. كانت هناك أيضا 4 حالة (0.2%) حدثت بسبب عجز تكون مصد كاف لضغط العين. كانت هناك 46 حالة (2.3%) حدثت فيها مضاعفات خلال اليوم الأول للعملية. احتاجت 9 حالات إرجاع سديلة الليزك بسبب رجوع رؤية السطور إلى ما كانت عليه من قبل في 5 حالة، أو خروج السديلة من مكانها 4 حالة. احتاجت 4 حالة إلى غسل أسفل السديلة بسبب التهاب القرنية شديد في 2 حالة، أو تجمع ألياف خيطية تحت السديلة في 2 حالة. تم زيادة الليزر أي إعادة العملية في 28 عين (1.4%). كان النظر بدون نظارة 20/40، أو أفضل في 96.9% من الحالات التي أجريت لها عملية الليزك. فقدت 24 عين (1.3%) أكثر من سطرين من الرؤية الأفضل لما قبل العملية.

خاتمة: عملية الليزك آمنة وفعالة في تصحيح قصر النظر. قد يحدث مضاعفات في عدد قليل من المرضى، وهي غير خطيرة ونادرا ما تؤدي إلى فقدان أكثر من سطرين على مقياس سنيلين.

Objectives: To determine the intraoperative and early postoperative complications and visual outcome of laser in situ keratomileusis (LASIK) surgery for the correction of myopia.

Methods: The first 2000 consecutive myopic LASIK eyes operated at the Department of Refractive Surgery, Yemen Magrabi Hospital, Sana'a, Yemen from June 2005 to October 2006 were the study group. This is a retrospective observational noncomparative clinical study. The preoperative and postoperative spherical equivalent, best-corrected visual acuity, and corneal status was recorded. The intraoperative and early postoperative complications were reviewed.

Results: There were 15 (0.8%) intraoperative microkeratome-related flap complications recorded namely, buttonhole (5), incomplete cut (3), thin flap (3), epithelial defect (3) and eccentric flap (1). There were 4 (0.2%) non-keratome related surgical events of inability to obtain sufficient suction. There were 46 (2.3%) first-day postoperative complications. Nine eyes required repositioning of the flap for macro-striae (5), or displaced flap (4). Four needed washing under the flap for severe deep lamellar keratitis (2), and gauze debris under the flap (2). Laser enhancement was carried out in 28 eyes (1.4%), and uncorrected visual acuity of 20/40 or better was attained in 96.9% of treated eyes. Twenty-four eyes (1.3%) lost more than 2 lines of best-corrected vision.

Conclusion: The LASIK is a safe and effective procedure for the correction of myopia. A small number of patients may suffer complications, most of which are not serious, and rarely lead to visual loss of more than 2 Snellen lines.

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From the Eye Department (Bamashmus), Faculty of Medicine and Health Sciences, Sana'a University, and Department of Refractive Surgery, (Bamashmus, Awadalla, Saleh, El-Shekeil), Magrabi Eye Hospital, Sana'a, Republic of Yemen, and the Eye Department (Saleh), Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

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Address correspondence and reprint request to: Dr. Mahfouth A. Bamashmus, Associate Professor of Ophthalmology, Eye Department, Faculty of Medicine and Health Sciences, PO Box 19576, Sana'a University, Sana'a, Republic of Yemen. Tel. +967 (73) 3270277. Fax. +967 1210021. E-mail: bamashmus@hotmail.com

Laser in situ keratomileusis (LASIK) has gained popularity worldwide as the surgical procedure of choice for the correction of myopic refractive errors.[1] Refractive surgery techniques have continued to evolve over the last 3 decades, and now offer potential freedom from correction by spectacle and contact lenses for almost all refractive errors. The LASIK is now accepted as a safe and effective method of correcting refractive errors,[2,3] and has many advantages over photorefractive keratectomy (PRK), namely, quicker visual recovery, less postoperative pain, and no corneal haze.[4] The rapid recovery of vision and high patient satisfaction allows most patients who have LASIK to recommend the procedure to their relatives and friends.[4,5] The LASIK surgery is performed as an elective procedure, often on young adults so their vision can be corrected to 20/20, so the index of safety of this procedure should be as high as possible. This procedure is now being performed by an increasing number of ophthalmologists.[6] Refractive surgery is gaining popularity in Yemen, and it started in 2005, and since then the number of eye centers introducing excimer laser surgery is on the rise. The learning curve of initial LASIK procedures, even by experienced surgeons is well documented.[7-9] Our standard technique for LASIK is using Moria M2 microkeratome (Moria Co., Antony, France) and using Nidek EC-5000 excimer laser (Nidek Co., Gamagori, Japan). This article aims to determine the intraoperative, early postoperative complications, and visual outcome of our first 2000 LASIK cases performed by 2 surgeons.

Methods. The medical records of the first 2000 consecutive myopic LASIK cases between June 2005 and October 2006, operated in Yemen Magrabi Hospital, Sana'a, Yemen were reviewed. This retrospective observational noncomparative study was facilitated by an electronic database record system for recording preoperative, intraoperative, and postoperative patient data since the establishment of the hospital in 2005. Written consent after detailed discussion with the patient was obtained. Preoperative information recorded included uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), refractive error (subjective and cycloplegic), mesopic pupil size, slit-lamp biomicroscopy, and dilated retinal evaluation. From the printout of the laser machine, the attempted correction, and dates of surgery was recorded. Flap complications were noted, and visual acuity (VA) during the last recorded visit was recorded. The preoperative spherical equivalent, microkeratome-related intraoperative flap complications (incomplete flap, buttonhole, thin flap, free cup, and eccentric flap), early postoperative flap complications (macrostriae, flap displacement, diffuse lamellar keratitis, epithelial ingrowth, microbial keratitis) were recorded. Last documented postoperative spherical equivalent, UCVA, and retreatments were also analyzed. Criteria for selecting myopic patients for LASIK are shown in **Table 1**. The LASIK is not performed in patients who do not meet these criteria. Keratoconus, pellucid marginal degeneration, and keratoconus suspect must be detected to avoid unpredictable results. We used TMS-2 computerized videokeratography (Tomey Corporation, Nagoya, Japan), and the Klyce-Maeda keratoconus index (KCI [Tomey Corporation, Nagoya, Japan]) to detect early keratoconus.[7,10] The Nidek US 1000 pachymeter (Nidek Technologies, Gamagori, Japan) was used to measure central corneal thickness (CCT). If the preoperative CCT was less than 480 μm, or the residual stromal bed thickness was less than 250 μm, LASIK was not performed. The Nidek EC-5000 excimer laser (Nidek Co. Ltd., Gamagori, Japan) was used for laser ablation. The diameter of the ablation zone used was usually 6.0 mm (range from 5.5-6.5 mm) with a 1.0 mm transitional zone. The minimal ablation zone used was 5.5 mm, and if the corneal thickness is insufficient for the target correction, LASIK was

Table 1 - Criteria for selecting myopic patients for laser in situ keratomileusis (LASIK) in Yemen.

Criteria
Age 18 years or older
Patients approaching presbyopic age are informed of the requirement of wearing spectacles for near correction
Stable refractive of at least one year's duration (if the sphere and cylinder had not changed >0.50 diopters [D] per year)
Myopia ≤-11.00 D
Astigmatism ≤4.00 D
Flattest corneal curvature ≥40.0 D, and steepest corneal curvature of <48.0 D.
Central corneal thickness of >480 μm
Presumed residual stromal bed thickness of ≥250 μm
Best spectacle corrected visual acuity in both eyes of 20/50 or better
Absence of any corneal pathology (we used Klyce-Maeda Keratoconus Index of the TMS2 topography system for keratoconus screening)
Keratoconus
Forme fruste keratoconus
Pellucid marginal degeneration
Absence of any other ocular pathology
Herpes keratitis
Corneal dystrophy or degeneration
Lens opacities
Retinal pathology
Glaucoma suspect
Dry eyes
Absence of medical contraindications
Diabetes mellitus
Autoimmune disease
Immunocompromised status
Pregnancy or lactation
Written consent after detailed discussion with the patient

not performed. The amount of ablation used depends on corneal thickness, residual stromal bed thickness, required correction, and mesopic pupil size. The Moria M2 microkeratome (Moria Co., Antony, France) was used to create a superiorly hinged flap with a 130 µm depth plate producing flap thickness of 130-160 µm. An A-1 ring was used for mean keratometry (MK) of <41 diopters (D), 0 ring was used for MK of 41-43 D, +1 ring was used for MK of 43-46 D, and +2 ring was used if MK was >46 D. Surgical technique included wearing a gown and mask by the surgeon and nurse, and no gloves were used. Inspection of the suction ring and microkeratome was performed by the nurse. All patient data and laser treatment parameter input were double checked. Gentian violet marking was at 5 and 7 o'clock, and then the suction ring was placed. After the cut is finished, the suction was then turned off. The corneal flap was then turned up using an iris sweep, and the bed dried before laser ablation. After the ablation, the flap was repositioned, then floated with gentle irrigation. The procedure was aborted in any patient who had a buttonhole or incomplete cut. Usually, the surgeon started with the right eye, and if the right eye developed buttonhole or incomplete flap, the procedure to the left eye was abandoned. The patient was then examined by a trained resident after 30 minutes with slitlamp biomicroscopy to check for the presence of micro- and macro-striae, or interface debris, and to ensure good flap position. After surgery, the patient was given written and oral instructions on not touching or rubbing the eye, instructed not to read, or use a computer the night of the surgery. Sunglasses were given to the patients, but no eye patches or eye shield to wear at home. Preservative free artificial tears were given hourly, and all patients received topical ciprofloxacin (Ciloxan, Alcon Lab., Fort Worth, Texas, USA) and topical prednisolone acetate 1.0% (Predforte, Allergan, USA), 4 times daily for one week after surgery. Patients were examined at day one, where VA testing and anterior segment examination was performed. Any folds or displacement of the flap were treated by lifting and refloating the flap. Any patients with diffuse lamellar keratitis (DLK) were given hourly topical prednisolone acetate 1.0%, and according to the grade of DLK, a systemic steroid was prescribed. In severe cases, washing under the flap was performed. Patients were examined again after one week, one month, 3 months, and 6 months. In patients with undercorrection or regression, refraction was performed at one, 3, and 6 months. At the 3- and 6-month follow up visit, topography, and pachymetry were performed. Patients who were dissatisfied with the visual outcome, and had residual refractive errors or regression underwent enhancement if no contraindication were present. Enhancement was performed 6 months after the initial LASIK surgery. Although every attempt was made to contact all patients for follow-up, 158 eyes (7.9%) lost follow-up prior to their one-month examination as most patients were living outside Yemen, and were therefore excluded from VA analysis. The study was approved by the Research and Ethics Committee of Yemen Magrabi Hospital, and the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional), and with the Helsinki Declaration of 1975, as revised in 2000.

We calculate the percentages for the data by utilizing the Excel 2003 program.

Results. Two thousand primary myopic LASIK cases performed were retrospectively reviewed. **Table 2** shows the demographic data and preoperative refraction profile of the LASIK cases. The number of females outnumbered the number of males, and the mean age at the time of surgery was 26 years (**Table 2**).

Microkeratome-related complications. Fifteen (0.8%) microkeratome-related intraoperative flap complications were recorded in the first 2000 myopic LASIK cases such as, button hole, incomplete cut, thin flap, eccentric flap, and epithelial defect. All these cases were covered with a bandage contact lens at the end of the procedure. No free cap occurred in this series. Seven eyes were ablated during the same treatment session, and those with button hole or incomplete flap were aborted, and were completed 3 months later. Two of our 15 cases resulted in a loss of more than 2 lines of BSCVA, 4 eyes lost 2 lines of BSCVA and 4 eyes lost one line while 5 eyes retained same vision as BSCVA. The most common intraoperative adverse events were corneal bleeding (3.6%) from limbal vessels or from

Table 2 - Demographic and preoperative data of laser in situ keratomileusis (LASIK) patients in Yemen.

Variable	n	(%)
Total number of patients	1061	
Gender		
Male	478	(45.1)
Female	583	(54.9)
Age at surgery, years		
Mean	26.0	
Range	18-45	
Total primary myopic LASIK cases	2000	
Total eyes that lost follow-up after one month	158	(7.9)
Spherical equivalent		
Low: -0.25 to -4.75	1343	(67.2)
Moderate: -5.00 to -8.50	641	(32.0)
High: >-8.50	16	(0.8)

corneal pannus that occurred due to the pass of the microkeratome.

Surgical events. There were 4 (0.2%) non-keratome related surgical events of inability to obtain sufficient suction, and these cases were postponed to the following week (**Table 3**). Bleeding pannus occurred in 72 eyes (3.6%) due to the cutting of limbal blood vessels by the microkeratome. The bleeding was stopped by gentle pressure on the bleeding vessel, and application of topical Naphcon-A (Alcon Lab, Texas, USA).

Early transient sequelae. Foreign body sensation and discomfort occurred in all patients, but rarely lasted more than 24 hours. Severe dry eyes were noted in 4 eyes.

Early postoperative complications. There were 5 macro-striae and 4 displaced flaps seen among this series of eyes. One was diagnosed 30 minutes after the procedure, and the remaining 8 were diagnosed during the first postoperative visit. All nine cases were returned to the operating theater, and under the operating microscope, the displaced flap and macro-striae were stretched back with a Merocel sponge, then refloated to get it back into position. Thirteen eyes needed intervention during the first postoperative day. Two eyes needed flap lifting and interface irrigation for severe DLK, and 2 for removal of significant interface deposits mainly remnants of gauze.

Refractive problems. Decentered ablation occurred in 7 eyes due to unsteady fixation of the eye. Small central island occurred in 2 eyes, and both eyes had no major complaints.

Table 3 - Intraoperative and early postoperative complications after laser in situ keratomileusis (LASIK) in Yemen study.

Type of complication	n	(%)
Microkeratome-related complications	15	(0.8)
Button hole	5	
Thin flap	3	
Incomplete cut or pass	3	
Epithelial defect	3	
Eccentric flap	1	
Free cup	0	
Surgical events		
Insufficient suction	4	(0.2)
First day postoperative complications	46	(2.3)
Non-specific interface flap deposits (no intervention)	25	
Significant interface deposits (needed wash under flap)	2	
Mild to moderate DLK (no intervention)	7	
Severe DLK (needed wash under flap)	2	
Macro-striae (needed repositioning)	5	
Displaced flap (needed repositioning)	4	
Mild microbial keratitis (fortified topical antibiotics)	1	
Postoperative complications	15	(0.8)
Severe dry eye	4	
Epithelial ingrowth	2	
Decentered ablation	7	
Central island	2	
Enhancement rate	28	(1.4)
Low myopia	9	(0.7)
Moderate myopia	17	(2.7)
High myopia	2	(12.5)
Total complications	**108**	**(5.4)**

DLK - diffuse lamellar keratitis

Table 4 - Comparison of preoperative best spectacle corrected visual acuity (BSCVA) with postoperative uncorrected visual acuity (UCVA) after laser in situ keratomileusis (LASIK).*

Variable	n	(%)
Preoperative BSCVA	2000	
20/20	1604	(80.2)
20/25	1826	(91.3)
20/30	1894	(94.7)
20/40	1950	(97.5)
Postoperative UCVA	1842	
20/20	1392	(75.6)
20/25	1549	(84.1)
20/30	1731	(94.0)
20/40	1784	(96.9)
Preoperative BSCVA-postoperative UCVA	1842	
Within one line	1534	(83.3)
Within 2 lines	1819	(98.8)
Loss of >2 lines	24	(1.3)

*158 eyes lost to follow up before the first month's visit

Table 5 - Comparison of microkeratome-related flap complications between recently published articles.

Authors	Year	n	Microkeratome used	Microkeratome-related flap complications	
				n	(%)
Jacobs[9]	2002	84711	Chiron automated corneal shaper or Hansatome (Bausch & Lomb, New York, USA)	256	(0.3)
Hakiem[10]	2002	1000	Hansatome (Bausch & Lomb, New York, USA)	13	(1.3)
Bowers[8]	2004	755	Chiron automated corneal shaper or Hansatome (Bausch & Lomb, New York, USA)	7	(0.9)
Al-Swailem[11]	2006	700	Moria LSK2 CB manual microkeratome (Moria, Antony, France)	19	(2.7)
Al-Tobaigy[12]	2007	200	Moria LSK2 CB manual microkeratome (Moria, Antony, France)	5	(2.5)
This study		2000	Moria M2 microkeratome (Moria, Antony, France)	15	(0.8)

A comparison of preoperative BSCVA and postoperative UCVA is provided in **Table** 4. After primary LASIK and 28 enhancement procedures, 83.3% of eyes had UCVA, which was within one line of preoperative BSCVA, 98.8% was within 2 lines, and 1.3% lost more than 2 lines of BSCVA. The UVA of 20/40, or better was attained in 96.9% of the treated eyes, and 94.5% were within 1 D of emmetropia.

Eighteen of those who lost more than 2 lines were due to undercorrection or regression, and patients refused to have laser enhancement. Two eyes were due to the intraoperative buttonhole with epithelial ingrowth, 2 eyes after enhancement, and 2 eyes with displaced flap were among the group of eyes, who lost more than 2 lines of BSCVA. Uncorrected visual acuity of 20/40 or better was attained in 96.9% of the treated eyes.

Discussion. The LASIK complications have been discussed in the literature in detail, and if LASIK is performed, taking care of all pre- and postoperative precautions (namely, preoperative evaluation, surgical technique, postoperative care, and management complications), the rate of complications can be reduced.[4] The 0.8% incidence of microkeratome-related flap complications found in this study was similar to that of Bowers et al[8] (0.9%), presumably because of improvements in microkeratome design that have occurred since these earlier reports. Other recent reports of microkeratome-related flap complications range between 0.3-2.7%[8,9-12] (**Table 5**).

The actual incidence of microkeratome-related flap complications is not as important as how these events can contribute to permanent visual loss. Intraoperative flap complications may be attributed to the microkeratome, the surgeon, or the patient. Usually, we start routinely with the right eye, and if a flap complication arises in the right eye, the procedure to the left is usually abandoned. This most likely reduced the number of flap complications. In a study by Lichter et al,[13] they found that buttonholes are significantly more likely to occur in the second of 2 consecutively treated eyes. A new blade for the second eye when the flap in the first eye appears to be thin, should be considered.[13] It has been shown that carrying out laser ablation in eyes with buttonholes or irregular flap leads to loss of BSCVA, while abandoning the ablation helps the eye to return to the preoperative state, and these eyes do well with a later procedure.[13,14] With proper management of these complications, VA in most cases is better.[15] Care was taken following photoablation to irrigate the interface to remove coagulated blood.

The first day postoperative complication rate was 2.3%, which compared favorably with that reported in other studies.[8,9-12] Toxic chemicals produced during instrument autoclaving sterilization, meibomian secretions, and marker pens are possible causes of DLK. Immediate diagnosis and treatment with intensive corticosteroid drops is critical, and can resolve DLK.[16] Early recognition of flap displacement needs prompt management, which is crucial to achieve a successful surgical and visual outcome.[17] Early flap repositioning usually prevents visual loss, however, irregular astigmatism due to permanent residual folds remains the main factor affecting the visual and refractive outcomes.[18] Among the postoperative flap complications in our series, 39 eyes maintained the same BSCVA, 2 lost one line, 3 lost 2 lines, and 2 lost more than 2 lines, comparable to other published series.[8,9-12]

Decentered ablation is another potential problem in LASIK surgery in the treatment of myopia.[19] Seven eyes with decentered ablation were one mm or less decentered, and the patients did not notice it except from glare and slight blurring of vision at night. Keyhole or central island topographical patterns occurred in 2 eyes, and both cases lost more than 2 lines. This can be attributed to variation in stromal hydration producing a heterogeneous pattern.[20] Enhancement was carried out 6 months after the primary LASIK. Some patients are satisfied with the vision outcome after the procedure, and even if they have lost one or 2 lines of BSCVA, they were happy to move around spectacle-free, and were not ready to undergo further surgery to improve their vision. Eighteen eyes losing more than 2 lines refused to have laser enhancement, as they were not willing to undergo further surgery, but agreed to decide on it in the future. Laser enhancement was carried out in 1.4% of cases, and this is comparable to other studies.[8,9-12]

For the purposes of this study, we used functional visual outcome as the standard of success in achieving the goal of the procedure, which was defined as the difference between preoperative BSCVA and postoperative UCVA. This difference, referred to as the "net loss," represented the amount of functional acuity that the patient "sacrificed" to get rid of his/her glasses.[12] Serious postoperative complications are much more likely to result in permanent visual impairment than intraoperative complications.[21,22] In the present series, there were no sight-threatening complications, such as severe microbial keratitis, sterile flap ulceration or persistent epithelial defects. Only one case had mild infiltrates due to epithelial defect, and was treated vigorously, and responded well to fortified antibiotic regimen within 3 days.

Keratectasia usually arises late,[23] and this study only concentrated on the postoperative complications arising within the first 6 months post LASIK. Physician experience with the microkeratome, and with the

handling of the corneal flap can decrease the incidence of flap complications. The proper management of microkeratome-related flap complications and postoperative flap-related complications is very important in minimizing the adverse impact of such events on final visual outcome. The safety and results in our series was excellent even in cases in which intraoperative complications and events occurred.

This study has limitations. First, the short postoperative follow-up period of 6 months. We recommend conducting a study with follow-up for 2 or more years for these cases to assess the final visual outcome and the occurrence of late postoperative complications of LASIK, namely, keratectasia and its adverse effects on VA and vitreoretinal complications.[23] Second, the unrealistic comparison of this study with other published studies in the literature, where some report the complications by experienced surgeons, and other by supervised non-experienced fellows. Third, the different types of microkeratome used in each study, where the new microkeratomes reduced the rate of intraoperative flap complications. Finally, the nature of retrospective review of medical records.

Confocal microscopy and anterior segment optical coherence tomography imaging are now being applied for post-LASIK corneas.[24] These objective evaluations must be correlated with subjective patient evaluation of quality of vision. With the new technology of wavefront-guided and topography-guided excimer laser surgery, refractive surgery is expected to get better results, more acceptance among patients and excellent quality of vision is anticipated.

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