

The Outcome of the First 1000 Cases of LASIK Performed at the King Hussein Medical Center

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Abstract

Aims: The current study evaluates the refractive and visual outcome of patients who had laser in situ keratomileusis (LASIK) performed at the Refractive Center at the King Hussein Medical Centre in Jordan.

Methods: This is a descriptive study of 500 patients (1000 eyes) which was conducted to assess the visual and refractive outcome of patients who underwent laser in situ keratomileusis (LASIK) surgery between 2006 and 2007. Various levels of myopia encountered were included in the study. The mean preoperative spherical equivalent was -4.15 Diopter. The main outcomes measured were safety, predictability, efficacy, and stability. Postoperative complications were also recorded. Simple descriptive statistical methods (mean, frequency and percentage) were used.

Results: At one month postoperatively, 78% of the eyes were within plus or minus 0.5D of the intended correction while 92% were within plus or minus 1.0 D. At one year postoperatively, 85% of the eyes were within plus or minus 0.5D of intended correction while 96% were within plus or minus 1.0D. At three years, 80% were within plus or minus 0.5D of the intended correction whereas 89% were within plus or minus 1 D. Ninety-four percent of eyes had a vision of 6/12 or better at one month compared to 89% at one year.

Best spectacle-corrected visual acuity (BSCVA) was unchanged or improved in 73%. No eye lost more than one line of best spectacle-corrected visual acuity. Overall, there was regression towards myopia with a mean change in refraction of -0.5 D over the first year.

Severely myopic patients regressed more with a mean change of -1.00D. However, there was a very good patient satisfaction with this surgery.

Conclusion: The predictability of LASIK surgery in terms of refractive and visual outcome results is very good with mild regression in refraction over time.

Keywords: Complications, King Hussein Medical Centre (KHMC), LASIK, Refractive outcome.

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Introduction

Although laser in situ keratomileusis (LASIK) surgery is now one of the most common

operations performed worldwide, few studies have been published on the long term outcome and safety.¹⁻⁶

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LASIK is a more invasive procedure than surface refractive surgeries since it involves the formation of a flap at a level of 130 μ m and 90 μ m from the corneal surface. This, theoretically, could disturb the organisation of collagen fibres that make up the corneal stroma at these levels which could lead to a compromise in corneal strength. Thus, there has been concern expressed over the long term refractive and biomechanical stability associated with LASIK surgery.⁷⁻¹⁰

In this study, we assessed the refractive stability for all levels of myopic correction and we reviewed patient satisfaction.

Methods

This is a descriptive study that involved 500 patients (1000 eyes) which was conducted to assess the visual and refractive outcome of patients who underwent laser in situ keratomileusis (LASIK) surgery between 2006 and 2007. The main outcomes measured were safety, efficacy, predictability and stability of refraction and vision over 3 years.

All levels of myopia were included in the study. Out of 500 patients, 54% were males and 46% were females. The mean age was 33 years. Classification of patients in terms of myopic level is shown in Table (1).

Patients were grouped into mild (0 to -3.0D), moderate (-3.0 to -6.0 D), and severe (more than -6.0 D) myopia. The preoperative and postoperative spherical equivalent for each group is also demonstrated in Table (1).

All patients had a detailed preoperative examination including unaided visual acuity (UAVA), best spectacle-corrected visual acuity (BSCVA), refraction, topography, slit lamp examination, pachymetry, and fundal examination.

The eyes undergoing surgery were prepared as follows: One or two drops of topical anesthetic were instilled and a sterile drape was used to isolate the surgical field. A lid speculum was inserted to allow maximum exposure of the

globe, and additional topical anesthetic was applied.

Automated mechanical microkeratomes were used to create superior lamellar corneal hinged flaps. The flaps were cut with a microkeratome (Nidek). Laser ablation was done with a 193 nm argon fluoride excimer laser (Nidek). The flap was lifted, the tracker activated, and the excimer laser ablation was delivered to the stroma.

Patients fixated on a red fixation light, coaxial with the surgeons' line of sight, and the excimer laser beam, throughout the ablation, allowing the tracker to remain centered on the pupil. The flap was repositioned and the interface was irrigated with a balanced salt solution, removing any debris, and then the flap was smoothed into position.

Patients were seen at 1 day, 1 week, 1 month, 6 months, 1 year, and 3 years postoperatively. The mean length of follow up was 30 months with a range of 24-36 months.

In order to assess their satisfaction with the procedure, patients received a simple medical questionnaire form at their annual follow up visit consisting of four questions (i.e. Would you have this surgery again? Are you happy with the quality of your vision nowadays? Would you recommend this surgery to a friend? And Are you satisfied with the standard of care after treatment?).

Results

The main outcomes measured were safety, efficacy, predictability and stability of refraction and vision over the 3 years.

Predictability

Predictability is defined as the difference in percentage of eyes within plus or minus 0.5D and plus or minus 1.0D of the intended correction at 1 month, 12 months and 36 months. The achieved results are shown in Table (2).

Stability

Stability is the percentage of eyes with a change in mean refractive spherical equivalent to one diopter at a three month interval as well as a mean rate of change in mean refractive spherical equivalent to 0.5 diopter or less per year.

In all cases, there was myopic regression of at least -0.5 D. Severely myopic patients regressed more with a mean change of -1.0 D which continued up to the third year follow up. The mild myopes regressed in the first year and stabilized thereafter.

Efficacy

In terms of refractive outcome and visual acuity, 77% of all patients had an unaided visual acuity of 6/6 or better at 3 years and 94% had an uncorrected visual acuity (UCVA) of 6/12 or better. Ninety three per cent of mild myopes, 95% of moderate myopes, and 75% of severe myopes achieved a UCVA of 6/12 or better.

Safety

Safety which is defined as the loss of best spectacle-corrected visual acuity (BSCVA) was

unchanged in 70% of the eyes while 17% gained one line, 3% gained two lines, 10% lost one line and no eye lost more than one line of best corrected vision as illustrated in Table (3).

Complication rate

Table (4) shows the complications rate as follows: Thirty two per cent of patients reported glare and night vision problems postoperatively, 3% of eyes had debris under the flap requiring a re-lift and 1% had striae of the flap, and 3% of patients reported haloes. At 3 years, 11 eyes had been retreated for regression (1.1%). Eight of these eyes were severe myopes, 3 eyes were retreated within the moderate myopic group and no eye was retreated in the mild myopic group.

There was a 98% response rate to the medical form record. Ninety six per cent of patients screened would have LASIK surgery again and 97% of patients thought that the surgery changed their life significantly. Ninety six per cent of patients are currently happy with the quality of their vision and would recommend the surgery to a friend. Ninety eight per cent of patients reported that they were satisfied with the standard of care after treatment.

Table (1): Classification of all eyes into mild, moderate, and severe myopia.

	<u>No of eyes</u>	<u>Pre-op SE</u>	<u>Post-op SE at 1 year</u>	<u>Post-op SE at 3 years</u>
<i>Mild (0 to -3.0D)</i>	524			
<i>Mean</i>		-2.15	-0.18	-0.36
<i>Moderate (-3.0 to -6.0)</i>	340			
<i>Mean</i>		-4.18	-0.21	-0.41
<i>Severe (>-6.0)</i>	136			
<i>Mean</i>		-8.21	-1.12	-1.32
<i>All levels</i>	1000			
<i>Mean</i>		-4.15	-0.33	-0.51

SE= Spherical Equivalent

Table (2): Percentage of patients within plus or minus 0.5D and plus or minus 1.0 D of Intended correction.

	<u>1 month</u>		<u>1 year</u>		<u>3 years</u>	
	<u>within +or-0.5 %</u>	<u>within+or-1.0%</u>	<u>within+or-.5%</u>	<u>within+or- 1.0%</u>	<u>Within+or-.5%</u>	<u>within+or-1.0%</u>
<i>Mild</i>	92	99	94	98	96	98
<i>Moderate</i>	82	97	76	93	70	91
<i>Severe</i>	54	68	52	66	48	62
<i>All levels</i>	78	92	85	96	80	89

Table (3): Percentage of patients who achieved their best spectacles corrected visual acuity (BSCVA), .i.e., safety.

<u>BSCVA</u>	<u>Percentage</u>
Unchanged	70
Gained one line	17
Gained two lines	3
Lost one line	10
Lost two lines	0

Table (4): Complications and their rate after Lasik surgery.

<u>Complications</u>	<u>Percentage</u>
glare and night vision	32
debris	3
halos	3
striae	1
retreatment	1.1

Discussion

Refractive surgery was introduced at the King Hussein Medical Centre in 2006. Unfortunately, there are no local long term results available to compare our study with. Although the international and local experience of LASIK is almost 15 years, only few studies have addressed the long term outcomes.^{1-3, 11-14}

One of the first long term studies was by Sekundo et al. in a study of 33 eyes with 6 years of follow up, which reported a cumulative unaided visual acuity of more than 0.4 logMAR in 66% of patients and only 46% of patients were within plus or minus 1.0 D of attempted correction at the end of the study. Furthermore, they reported that 75% of their patients experienced night-time glare. However, 81% of patients were quite happy with overall result.¹

Rajan MS et al. found out in their long term study of photorefractive keratectomy that the long term results for PRK showed that postoperative refraction remained stable over 12 years. In 68 patients studied, it was found that 75% of those who underwent a -0.2D correction and 65% of the patients who received a -3.0D correction were within 1D of intended correction at 12 years. This fell to 25% and 22% for patients having a -6.0D and -7.0D correction, respectively.²

Jaycock et al. with his 5 year results for hyperopic LASIK reported that at a 5 year post treatment, 71% of the eyes treated for +1.0 to +3.0 D of hyperopia were within plus or minus 1.0 D of intended correction, whereas only 37.5% of those between +3.5 D and +6.0 D were within plus or minus 1.0 D of the intended correction.³

To compare our study with Sekundo's study where the mean preoperative SE was -11.4 D, the patients in our study had a broader range of preoperative refraction (mean SE = -4.15, range = -1.5 to -10 D).

Eighty per cent of the eyes were within plus or minus 0.5 D and 89% within plus or minus 1.0 D of the attempted correction at 3 years. Furthermore, 94% of the eyes had a cumulative unaided vision of 6/12 or better with 77% having a visual acuity of 6/6 or better. The superior results are no doubt because of the inclusion of mild myopes in the study population. Our findings showed that LASIK surgery is predictable for mild to moderate myopia; however, beyond -6.0 D its efficacy decreases with a trend towards myopia over 3 years. However, though we saw a myopic trend over 3 years, it is notable that 96% of patients would have the surgery again and 96% are currently happy with their level of vision.

Considering side effects, we found out that the most common one is glare. We were unable to assess changes in glare sensitivity as these measurements were not performed preoperatively. In contrast with Sekundo's study, which reported glare in 75% of patients, only 32% of our patients reported haloes/glare.

We had 11 patients who needed re-treatment (1.1%). Eight of them had severe myopia and three had moderate myopia. Overall, there was a 5% re-treatment rate during the 3 years. These re-treatments were performed in the first 6 months after surgery. Following re-treatment at 3 years, 9 eyes had achieved their best corrected visual acuity, 1 eye is within one line of best corrected acuity, and 1 eye is within two lines of best corrected acuity.

Serious complications like ectasia were not reported in our study. However, dryness was reported in 16% of patients with only 7% requiring tear substitutes at 3 years.

The safety profile of LASIK in this study was excellent. No eye lost more than one line of best spectacle corrected vision and 35 % of the eyes gained one line of vision.

The overall patient satisfaction with the procedure was as high as 98% reporting that they would have the surgery again. We can conclude that this finding is really significant and the predictability of LASIK surgery in terms of refractive and visual outcome results is very good with a mild regression in refraction over time. With a total number of 1000 eyes, this study could be considered the largest study done, at least locally, about the long term effects of LASIK, to the best of our knowledge.

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نتائج أول ألف حالة تصحيح البصر بالليزك عملت في مدينة الحسين الطبية

وجيه العبدالات

قسم العيون، الخدمات الطبية الملكية، عمان، الأردن

الملخص:

- الهدف:** تهدف هذه الدراسة الى تقييم نتائج عمليات تصحيح البصر بطريقة الليزك والتي عملت في مدينة الحسين الطبية في الأردن.
- الطرق:** هذه دراسة وصفية لأول 500 مريض (1000 عين) اجروا عملية تصحيح قصر النظر بالليزك، وكانت عملياتهم ما بين عامي 2006-2007، حيث تم ملاحظة ما يلي:
- مختلف درجات قصر النظر تم إدراجها في هذه الدراسة.
 - أهم مقاييس النتائج كانت الأمان، الفرق بين نتيجة العملية المتوقعة والنتيجة الواقعية، فعالية العملية ونسبة النتائج التي استمرت بدون تغيير لفترة 3 سنوات.
 - تم ايضاً تسجيل مضاعفات العملية.
 - تم استخدام طريقة وصفية احصائية بسيطة في هذه الدراسة مثل (المتوسط، تردد، النسبة المئوية).
 - متوسط قوة الضعف قبل العملية كان -4,15 درجة.

النتائج:

- الشهر الأول بعد العملية:** 78% من العيون كانت بين $\pm 0,5$ درجة من النتيجة المتوقعة. 92% من العيون كانت بين $\pm 1,0$ درجة من النتيجة المتوقعة.
- السنة الأولى بعد العملية:** 85% من العيون كانت بين $\pm 0,5$ درجة من النتيجة المتوقعة. 96% من العيون كانت بين $\pm 1,0$ درجة من النتيجة المتوقعة.
- السنة الثالثة بعد العملية:** 80% من العيون كانت بين $\pm 0,5$ درجة من النتيجة المتوقعة. 89% من العيون كانت بين $\pm 1,0$ درجة من النتيجة المتوقعة. 94% حصلوا على قوة نظر 6/12 أو أحسن بعد شهر واحد من العملية مقارنةً مع 89% حصلوا على نفس النتيجة بعد سنة من العملية.
- أفضل قوة نظر باستخدام النظارات لم يحصل عليها تغيير أو حتى تحسنت عند 73% من المرضى.
 - لم تفقد أي عين من سطر واحد من أصل أفضل قوة نظر باستخدام النظارات.
 - بشكل عام كان هناك تراجع نحو قصر النظر بمعدل -0,5 خلال السنة الأولى من العملية.
 - كما هو متوقع المرضى اللذين يعانون من قصر نظر شديد كان تراجعهم أكثر و بمعدل -0,1 درجة.
 - كان هناك درجة جيدة جداً من الرضى من هذه العملية من قبل المرضى.
- الخلاصة:** الفرق بين العملية المتوقعة والنتيجة الواقعية من حيث التصحيح وقوة النظر كانت نتيجة جيدة جداً مع وجود تراجع بسيط في النتائج على المدى البعيد.
- الكلمات الدالة:** مضاعفات، مدينة الحسين الطبية، ليزك، نتائج عملية تصحيح البصر.