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Original Article

Visual and Refractive Outcomes of Laser *In Situ* Keratomileusis in Low to High Myopia: Two Years' Follow-up

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Abstract

Objectives: The purpose of this study was to determine the refractive and visual acuity changes in myopic eyes after laser *in situ* keratomileusis (LASIK) surgery and to evaluate the stability, predictability, efficacy, and safety of the procedure.

Methods: A total of 199 eyes of 113 patients were evaluated retrospectively at the Beyoğlu Eye Training and Research Hospital in terms of myopia and/or myopic astigmatism correction with LASIK surgery. The cases were classified as low to moderate myopia/myopic astigmatism (-0.50 to -6.00 diopters [D]) (Group 1) and high myopia (-6.25 to -16.00 D) (Group 2). Uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), the rate of achieving the planned diopter value, and insufficient and excessive correction were investigated. In all cases, the laser procedure was performed with an LSX (LaserSight, Inc., FL, USA) device, and keratome incisions with a Carrazio-Barraquer or a Moria M2 microkeratome.

Results: The patients were followed up for a median of 18.82±6.06 months. In the group, 52 were male (46.0%), 61 were female (53.9%), and the mean age was 30.5±8.76 years. At the last visit, the mean spherical and cylindrical refractive error in Group 1 regressed from the preoperative values of -3.31±1.54 D and -1.00±1.08 D to -0.17±0.56 D and -0.71±0.57 D, respectively. In Group 2, the mean spherical and cylindrical refractive error regressed from the preoperative values of -8.55±2.26 D and -1.64±3.36 D to -1.53±1.06 D and -0.66±0.71 D, respectively. Preoperative UCVA increased from 0.07±0.46 D to 0.83±0.75 D in Group 1 ($p<0.001$), and 0.03±0.58 D to 0.43±0.54 D in Group 2 ($p<0.001$). There was no statistically significant change in the BCVA in either group at the final visit ($p>0.05$ for each group). Five eyes (10%) in Group 1 and 6 eyes (18%) in Group 2 had a loss of ≥1 line on the Snellen chart with best correction. Four eyes (8%) in Group 1 and 7 eyes (21%) in Group 2 gained ≥1 line on the Snellen chart with best correction.

Conclusion: LASIK surgery yielded better results in cases of low to moderate myopia, and had acceptable results in high myopia. Although refractive improvement may be achieved in high myopia, considering the low visual quality obtained and the possibility of regression, the results of high dioptric correction can be variable.

Keywords: Laser *in situ* keratomileusis, myopia, visual acuity.

Introduction

With the advent of corneal ablation with an excimer laser, photorefractive keratectomy began to be widely used. However, complications, such as stromal haze, refractive regression, and a decrease in visual acuity especially seen in high diopters (D), led to the quick adoption of the laser *in situ* keratomileusis (LASIK) procedure (1, 2). This method demonstrated earlier refractive stability as a result of the combination of the early healing property of automated lamellar keratoplasty and the sensitivity of photorefractive keratectomy. Nonetheless, because LASIK requires the creation of flap in the cornea, the ability to use a microkeratome is important for the success of surgery (3).

Numerous studies have demonstrated good efficacy, safety, stability, and predictability in the use of LASIK for the treatment of myopia (4-6). However, one-third of the studies did not provide information on a gain or loss of best corrected visual acuity (BCVA), an important safety measure

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for refractive surgery (7). The aim of this study was to evaluate the visual outcomes of LASIK surgery performed on all levels of myopic patients and to improve understanding of the impact of the surgery in terms of safety, stability, predictability, and efficacy.

Methods

The charts of 186 consecutive patients who underwent LASIK surgery at the Beyoglu Eye Research and Training Hospital (ZKO) were systematically evaluated. Of these patients, 78 had low to moderate myopia and myopic astigmatism, and 35 had high myopia and myopic astigmatism. Patients were followed for at least 6 months after the surgery (mean: 18.82±6.06 months).

Patients who met the following criteria were eligible for the study: preoperative corneal thickness of ≥400 μm and estimated residual thickness of the stromal bed ≥250 μm after laser ablation, severe dry eye, progressive corneal degeneration, forme fruste keratoconus, cataract, glaucoma, uveitis, and no history of ocular surgery. Eyes that had a progressive refractive error for 1 year or that had previous LASIK surgery were excluded. The retrospective review of the data was approved by the Institutional Review Board of Beyoglu Eye Research and Training Hospital and followed the tenets of the Declaration of Helsinki.

Prior to the operation, the patients underwent a complete ophthalmological examination. Rigid contact lens users were asked not to use the lenses for 4 weeks before their examination, and soft lens users for 2 weeks. The following data were collected for each patient: age, gender, uncorrected visual acuity (UCVA) and BCVA with Snellen chart, cycloplegic refraction, biomicroscopic examination, intraocular pressure of both eyes with Goldmann applanation tonometer, detailed evaluation of the fundus with 3-mirror Goldmann lens under full dilation, corneal topography with EyeSys, keratometric measurement with Javal keratometer, measurement of corneal thickness with a DGH 4000 ultrasonic pachymeter, and axial length measurement with an Axis II A-scan ultrasound device.

A total of 138 eyes of 78 patients with low to moderate myopia and/or myopic astigmatism (-0.50 D to -6.00 D), and 61 eyes of 35 patients with high myopia and/or myopic astigmatism (-6.25 D to -16.00 D) were included in the study.

Visual acuity was determined using the Snellen chart, and scores were converted to logMAR units for statistical analysis. Eyes with a peripheral retinal hole or lattice degeneration were treated with argon laser photocoagulation. If the eyes were considered safe enough to proceed after 1 month, LASIK was then applied. Corneal topography performed with EyeSys was evaluated using the Holladay Diagnostic Summary 2000 program. In all eyes, flap formation was performed with a Carrazio-Barraquer and a Moria M2 microkeratome and the laser application was performed with an LSX (LaserSight Inc., FL, USA) excimer laser using the spot scan technique.

Operation Technique

All of the patients were fully informed about the procedure in order to facilitate cooperation, including advisement that there would be a sensation of pressure and a loss of vision for a short time. Prior to the operation, anesthesia was provided with a 0.5% proparacaine drop 3 times at 5-minute intervals.

After topical anesthesia was achieved, a corneal flap of 130 μm thickness was lifted toward the nasal hinge. The laser was applied with a broad beam profile in a 6-mm optical zone. In all eyes, the preoperative manifest refraction was selected as the target for myopic correction. A daily dose of 5x1 tobramycin sulfate, 5x1 prednisolone acetate, and 6x1 artificial tear drops were prescribed for 1 week. Tobramycin sulfate was discontinued at the end of the first week and prednisolone acetate was discontinued gradually within 1 month.

Follow-up of the patients was performed on the postoperative first day, first week, first month, third month, and sixth month, and continued every 6 months afterward. In each examination, the UCVA and the BCVA, biomicroscopic examination, and intraocular pressure measurement were evaluated. Corneal topography with Orbscan II and corneal pachymetry measurements were also included in the follow-up of new patients who were not included in the present study since the length of the follow-up was shorter.

The final refractive errors and UCVA and BCVA measurements were compared with preoperative values. The rate of success in achieving the planned diopter and insufficient and excessive correction were also investigated. SPSS for Windows, Version 11.5 (SPSS Inc., Chicago, IL, USA) was used for the statistical analysis. A t-test was used to compare means and a chi-square test was used to compare ratios. A p value of <0.05 was considered statistically significant.

Results

A total of 199 eyes of 113 patients (52 men, 61 women) were evaluated in the study. The mean patient age was 30.5±8.7 years (range: 17-57 years). The preoperative refractive error and UCVA and BCVA values are shown in Table 1.

Group 1

Improvement in preoperative refractive error and changes in visual acuity can be seen in Table 2. In 138 eyes with low to moderate myopia, the mean spherical and cylindrical refractive error decreased from -3.31±1.54 D to -0.17±0.56 D (correction rate: 94.8%) ($p<0.001$) and from -1.00±1.08

D to ±0.71±0.57 D (correction rate: 29.0%) (p<0.05), respectively, at the final examination (Fig. 1). Among 41 eyes examined at the postoperative second year, 40 eyes (97.6%) had a spherical refractive error within ±1.00 D and all eyes were within ±2.00 D. Thirty-eight eyes (92.7%) had a cylindrical refractive error within ±1.00 D and 1 eye (2.4%) was within ±2.00 D.

Table 1. The clinical characteristics of myopic patients undergoing LASIK surgery

Characteristics	Low to moderate myopia (Group 1)	High myopia (Group 2)
Mean spherical RE (diopter)	-3.31±1.54	-8.55±2.26
Mean cylindrical RE (diopter)	-1.00±1.08	-1.64±3.36
UCVA	0.07±0.46	0.03±0.58
BCVA	0.92±0.13	0.61±0.67

BCVA: best corrected visual acuity; LASIK: laser *in situ* keratomileusis; RE: refractive error; UCVA: uncorrected visual acuity.

The mean UCVA increased from 0.07±0.46 D to 0.83±0.75 D (p<0.001), and there was no statistically significant increase in the BCVA (p>0.05) at the final visit (Fig. 2).

The UCVA was 20/20 or better in 24 (48%) of 50 eyes and 20/40 or better in all eyes. Three eyes (6%) had a loss of 1 line, 1 eye (2%) had a loss of 3 lines, and 1 eye (2%) had a loss of 4 lines on the Snellen chart with best correction. One eye (2%) had a gain of 2 lines, and 3 eyes (6%) had a gain of 1 line (Fig. 3).

There was undercorrection in 19 eyes (13.7%), overcorrection in 7 eyes (5%) and regression in 6 eyes (4.3%). Of the undercorrected eyes, 17 had a second LASIK procedure at an average of 3.3±3.3 months, and 13 of these eyes had a mean spherical and cylindrical refractive error within ±1.00 D at the last visit. No further operation was applied in eyes with overcorrection or regression in the 2-year period.

Group 2

Data of the improvement in preoperative refractive error and changes in visual acuity are provided in Table 3. In 61 eyes with high myopia, the mean spherical and cylindrical refractive error decreased from -8.55±2.26 D to -1.53±1.06 D (correction rate: 82.1%) (p<0.001) and from -1.64±3.36 D to ±-0.66±0.71 D (correction rate: 59.7%) (p<0.05), respec-

Table 2. The preopeartive and postoperative spherical and cylindrical refractive error and uncorrected and best corrected visual acuity in patients with low to moderate myopia in 2 years of follow-up after LASIK

Parameters	Preoperative	Postoperative					p
	(n=138)	1 month (n=125)	3 months (n=115)	6 months (n=108)	1 year (n=109)	2 years (n=50)	
Mean spherical RE (diopter)	-3.31±1.54	-0.41± 1.09	-0.12±0.95	-0.14±0.90	-0.17±0.80	-0.17±0.56	<0.001
Mean cylindrical RE (diopter)	-1.00±1.08	-0.62± 0.69	-0.75±0.65	-0.73±0.57	-0.78±0.70	-0.71±0.57	<0.05
UCVA	0.07±0.46	0.69±0.66	0.72±0.65	0.77±0.67	0.76±0.63	0.83±0.75	<0.001
BCVA	0.92±0.13	0.81±0.77	0.79±0.78	0.81±0.80	0.82±0.79	0.87±0.80	>0.05

BCVA: best corrected visual acuity; LASIK: laser *in situ* keratomileusis; RE: refractive error; UCVA: uncorrected visual acuity.

Table 3. The preopeartive and postoperative spherical and cylindrical refractive error and uncorrected and best corrected visual acuity in patients with high myopia in 2 years of follow-up after LASIK

Parameters	Preoperative	Postoperative					p
	(n=61)	1 month (n=61)	3 months (n=59)	6 months (n=60)	1 year (n=57)	2 years (n=57)	
Mean spherical RE (diopter)	-8.55±2.26	-2.98±2.32	-2.50±1.47	-2.27±1.67	-1.46±1.55	-1.53±1.06	<0.001
Mean cylindrical RE (diopter)	-1.64±3.36	-0.63±0.61	-0.66±0.73	-0.57±0.70	-0.67±0.76	-0.66±0.71	<0.05
UCVA	0.03±0.58	0.30±0.40	0.34±0.43	0.40±0.47	0.50±0.52	0.43±0.54	<0.001
BCVA	0.61±0.67	0.60±0.64	0.65±0.68	0.63±0.68	0.61±0.62	0.65±0.58	>0.05

BCVA: best corrected visual acuity; LASIK: laser *in situ* keratomileusis; RE: refractive error; UCVA: uncorrected visual acuity.

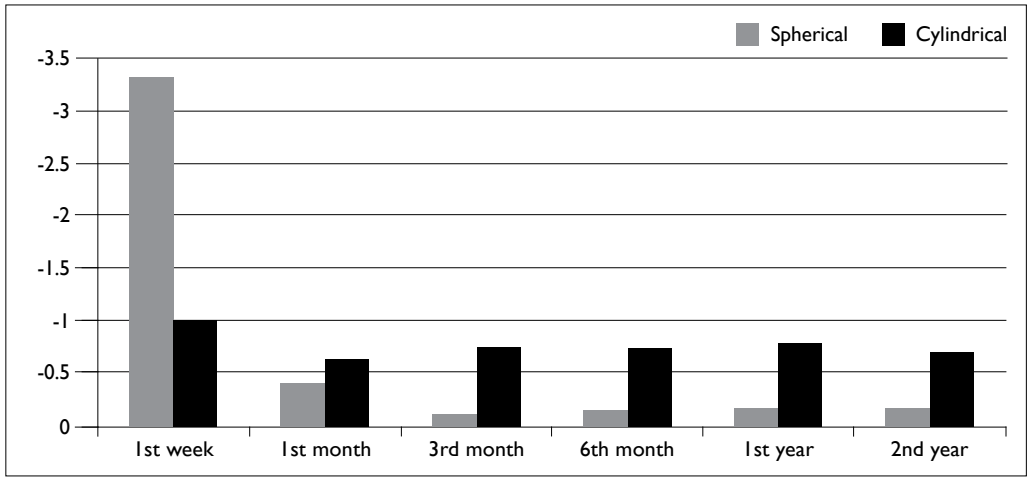

Figure 1. The preoperative and postoperative spherical and cylindrical refractive error of patients with low to moderate myopia in 2 years of follow-up after LASIK. The rate of spherical and cylindrical refractive correction was 94.8% and 29.0%, respectively.

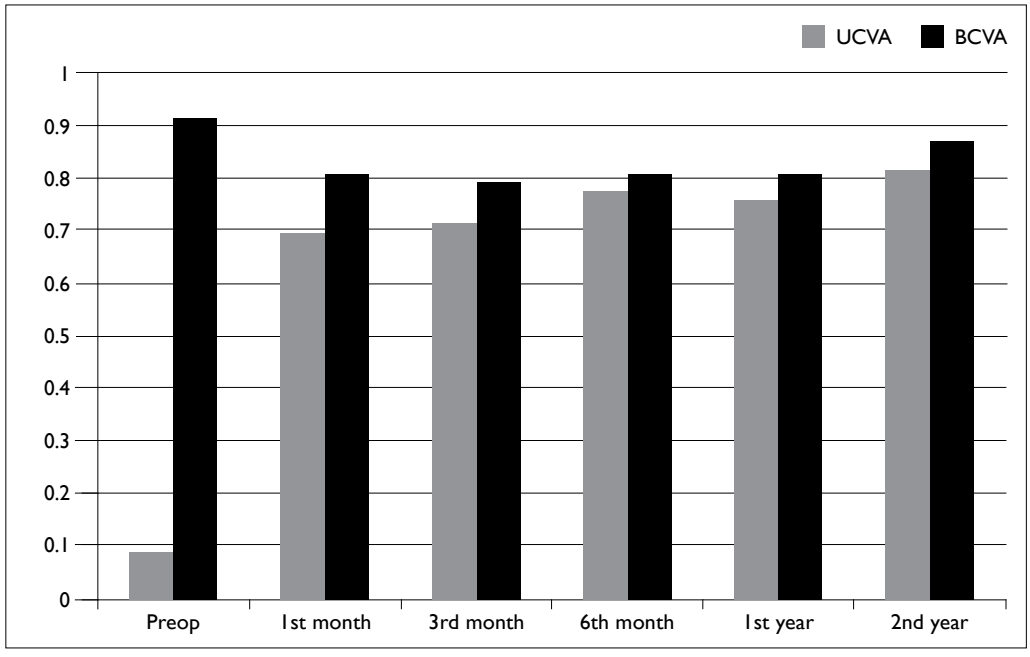

Figure 2. The preoperative and postoperative uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) in patients with low to moderate myopia in 2 years of follow-up after LASIK. The UCVA improved from 0.07±0.46 D to 0.83±0.75 D with no change in BCVA.

tively, at the final examination (Fig. 4). Among 44 eyes examined at the postoperative second year, 24 eyes (54.4%) had a spherical refractive error within ±1.00 D, 31 eyes (70.5%) were within ±2.00 D, and in 12 eyes (27.3%) it was greater than ±2.00 D. Thirty-four eyes (77.3%) had a cylindrical refractive error within ±1.00 D, 39 eyes (88.6%) were within ±2.00 D and it was greater than ±2.00 D in 5 eyes (11.4%). The mean UCVA increased from 0.03±0.58 D to 0.43±0.54 D ($p<0.001$), and there was no statistically significant increase in the BCVA ($p>0.05$) at the final visit (Fig. 5).

The UCVA was 20/20 or better in 3 (9.0%) of 33 eyes and 20/40 or better in 19 eyes (57.5%). Two eyes (6%) had a loss of 1 line, 3 eyes (9%) had a loss of 2 lines, and 1 eye (3%) had a loss of 4 lines on the Snellen chart with best correction. Two eyes (6%) had a gain of 1 line, three eyes (9%) had a gain of 2 lines, and 2 eyes (6%) had a gain of 4 lines (Fig. 6).

There was undercorrection in 25 eyes (40.9%), overcorrection in 1 eye (1.6%), and regression in 15 eyes (24.5%). Of those that were undercorrected, 15 eyes had a second LASIK procedure at an average 2.7±2.3 months and 9 had a mean spherical and cylindrical refractive error within ±1.00 D at the last visit. Seven eyes with regression had secondary

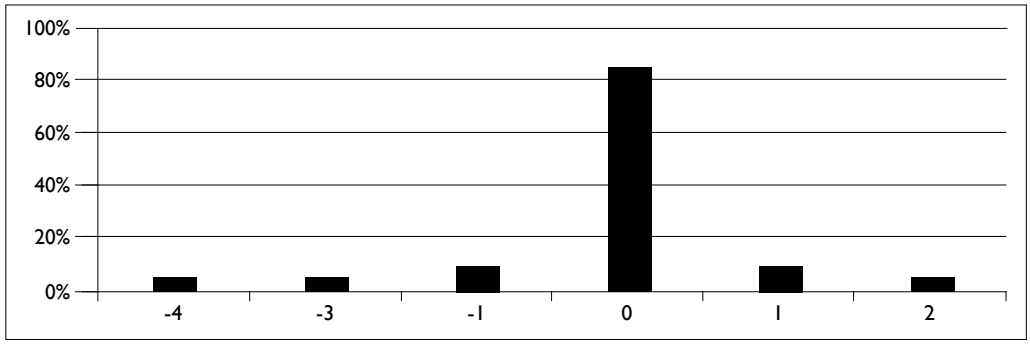

Figure 3. The percentage of eyes with a loss or gain of best corrected visual acuity Snellen lines postoperatively in patients with low to moderate myopia.

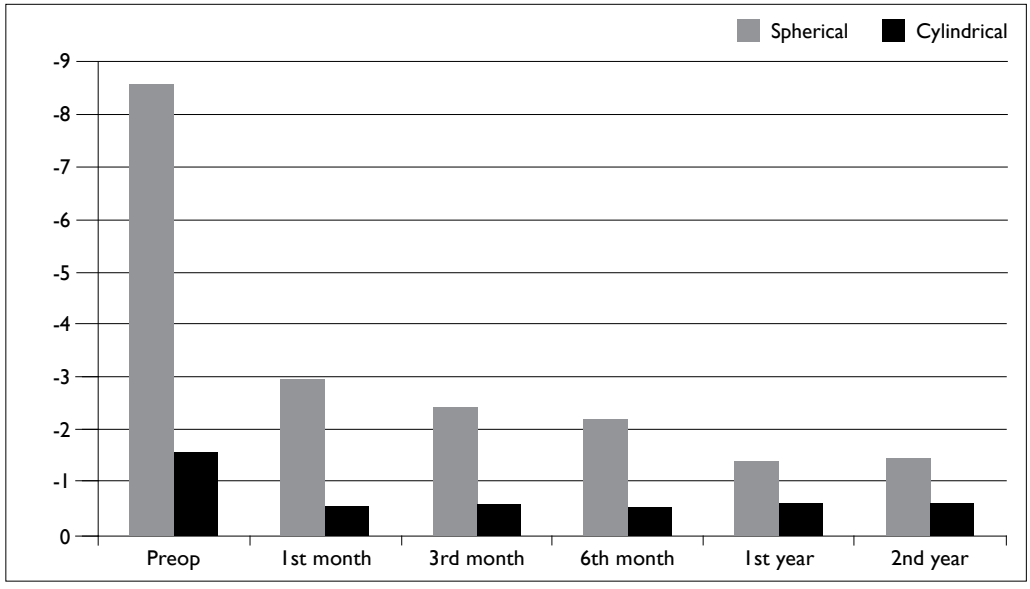

Figure 4. The preoperative and postoperative spherical and cylindrical refractive error of patients with high myopia in 2 years of follow-up after LASIK. The rate of spherical and cylindrical refractive correction was 82.1% and 59.7%, respectively.

LASIK and 5 had a mean spherical and cylindrical refractive error within ±1.00 D at the last visit. No operation was applied in the eyes with overcorrection.

Discussion

In this study, we retrospectively reviewed myopic patients who were followed up regularly for 2 years after LASIK surgery and evaluated the visual and refractive results. We found that 97.6% of eyes with low to moderate myopia and 54.5% of eyes with high myopia were within ±1.00 D 2 years after undergoing LASIK surgery. It has been reported that low to moderate myopic patients show a manifest spheric equivalent refraction within ±1.00 D in 94% to 100% of eyes in the early postoperative period (8). In longer follow-up studies with similar groups of patients, 96% of eyes after 2 years5, 94% after 5 years, (9) and 95% after 10 years (5) had a spherical equivalent refractive error within ±1.00 D at the final examination. In one study, the authors reported only minimal regression between the third postoperative month to 10 years postoperatively, suggesting that the visual outcome at the third month gives an estimate of the last visual results at 10 years (10).

In our study, the higher myopic treatment group had lower refractive stability. Sekundo et al. (11) demonstrated that 46% of eyes with high myopia that underwent LASIK surgery had a mean spherical refractive error within ±1.00 D at the end of 6 years of follow-up. In a recent study, a similar result was found at 15 years (12). These findings were attributed to myopic regression, as described previously (13).

A final UCVA of 20/20 or 20/40 is a measure of the effectiveness of LASIK surgery. Of eyes with low to moderate myopia in our study, 48% achieved an UCVA of 20/20 or better and all eyes achieved 20/40 or better. However, 20/20 vision was detected in only 9% of eyes in the high myopic

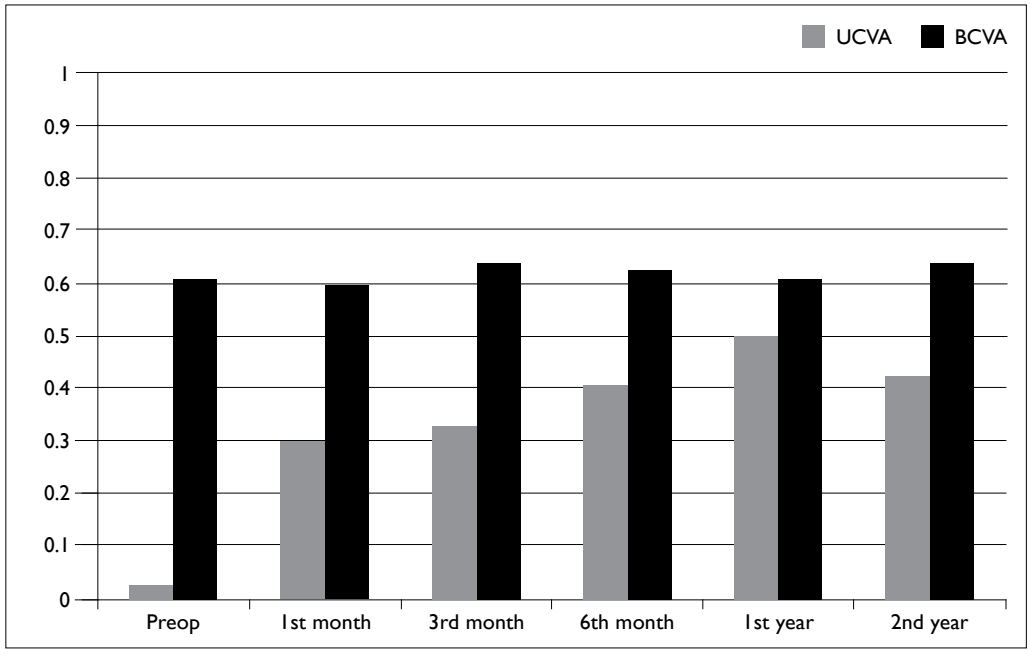

Figure 5. The preoperative and postoperative uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) in patients with high myopia in 2 years of follow-up after LASIK. The UCVA improved from 0.03±0.58 D to 0.43±0.54 D with no change in BCVA.

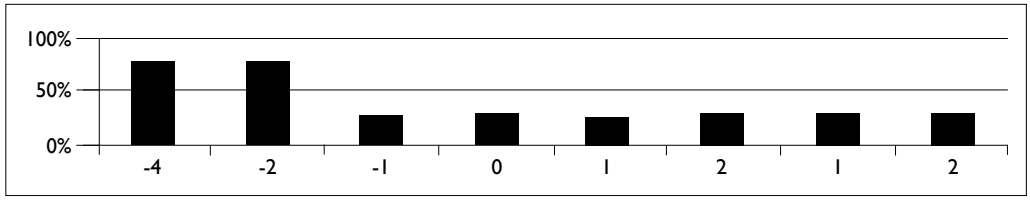

Figure 6. The percentage of eyes with a loss or gain of best corrected visual acuity Snellen lines postoperatively in patients with high myopia.

group, while 57% achieved 20/40 vision. Clinical trials have shown that in cases of low myopia of ≥-6.00 D, 66% to 86% of eyes achieved a UCVA of 20/20 and 93% to 100% achieved 20/40 (5, 9). In moderate myopia, results from large series indicate that 26% to 71% of eyes achieved a UCVA of 20/20 (14, 15). In the highest myopia group, the results were unfavorable in terms of efficacy, safety, and refractive predictability compared with other myopic levels. Over the 10-year period, the mean was 30% for 20/20, and 79% for 20/40 vision (5, 10). This may be due to slower wound healing associated with a greater cutting depth, and myopic regression due to excessive central ablation (8).

Regarding lost or gained Snellen lines in our patients, 8% of the low to moderate myopic eyes gained lines and 10% lost lines with best correction. In the high myopic group, 21% of eyes gained lines, and 18% lost lines with best correction. In a similar study of patients with different degrees of myopia, it was concluded that although visual results were better in patients with lower myopia, high myopic eyes showed better improvement in visual acuity (16). Our study found that the rate of gain of Snellen lines in high myopic eyes was more than twice that of the low to moderate myopic eyes. This may confirm reports that high myopic patients treated with LASIK have satisfaction rates as high as 96.3% (11, 17).

The clinical results of low to moderate myopic correction seem to be slightly better than high myopic correction. The disadvantage of keratorefractive surgery is the inability to maintain long-term refractive stability in high myopic patients. Several studies have shown the occurrence of myopic regression after LASIK, especially when there is a large myopic correction. Regression was found in the early post-LASIK period (3 and 6 months) in high myopia and was attributed to epithelial hyperplasia (18-20). In one study, myopic eyes over -15.00 D showed regression without evidence of stromal ectasia (12). Magallanes et al. (21) reported regression at the postoperative second year, although the refraction was stable at the postoperative first year. High myopic eyes may respond to LASIK surgery differently than low myopic eyes because of the greater corneal elasticity and relatively thinner sclera. In addition, different mediators may play role in

wound healing in these eyes.

Residual myopia after LASIK has also been detected more frequently in eyes with high myopia, and it was found to be -1.00 D higher in high myopic eyes after LASIK (22, 23). This may be due to insufficient correction, which involves incorrect data entry and calibration, and differences between manifest and cycloplegic refraction values.

We chose a follow-up period of 2 years after the operation to analyze the results. Long-term studies indicate that the effectiveness of laser refractive surgery is usually stable at 6 months, and this finding provides an estimation of the final visual outcome (10, 24-26). Studies with longer follow-up may involve the development of other age-related ocular disease and additional ocular surgery, such as cataract procedures, which may affect visual outcomes. For this reason, 2 years is an appropriate time frame for evaluating the results in our study. Other studies of postoperative safety, efficacy, and stability may have better outcomes. However, differences in the study population, dioptric correction, and the model of the laser device and the microkeratome may influence the results.

Although a range of visual results have been evaluated in this study, other results, such as ocular surface-related symptoms or patient satisfaction were not included. It is not uncommon for patients who have undergone refractive surgery to have visual complaints, even if their visual acuity is 20/20. This indicates the need for future research.

In conclusion, our findings show that LASIK surgery is predictable for mild to moderate myopia. However, its efficacy decreases with a trend toward myopia over 2 years, particularly in higher myopic eyes. Treatment protocols and technologies in challenging cases are developing, and future studies may provide additional evidence in this evolving field.

Disclosures

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Involved in design and conduct of the study (ZKO VK); preparation and review of the study (ZKO, VK); data collection (ZKO); and statistical analysis (ZKO).

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