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Original Article

Comparison of LASEK, mechanical microkeratome LASIK and Femtosecond LASIK in low and moderate myopia

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Abstract

Purpose: We conducted a prospective study to determine the best treatment option for patients with low-to-moderate spherical myopia or myopic astigmatism who are considered equally eligible for LASEK with mitomycin-C (MMC) and LASIK with either mechanical microkeratome or femtosecond laser flap creation.
Methods: Forty-six adult patients (86 eyes) who underwent LASEK with MMC (16 patients, 31 eyes), and mechanical microkeratome LASIK (13 patients, 23 eyes) or Femtosecond LASIK (17 patients, 32 eyes) were assessed for clinical outcomes 1, 3 and 6 months post-operatively.
Results: Six months after surgery, all eyes in all three groups were within 1 D of the intended refractive change. UCVA 20/20 or better was achieved in 96% of eyes undergoing LASEK with MMC 88% of eyes in the mechanical microkeratome LASIK and 72% of eyes in the Femtosecond LASIK group at 6 months. Mean spherical equivalent was −0.12 ± 0.22 D, −0.09 ± 0.28 D and −0.25 ± 0.28 D in the three groups, respectively ($p = 0.077$). Patients in the LASEK with MMC group had less high order aberrations at 3 and 6 months compared to the two LASIK groups. None of the three procedures were associated with early- or late-onset complications or loss of 2 or more lines after surgery.
Conclusions: After an initially slower visual improvement, LASEK with MMC, and to lesser extent, LASIK with mechanical microkeratome, produced better visual acuity and less corneal aberrations compared to Femtosecond LASIK at 3 and 6 months after surgery. These observations deserve further investigation in a randomized controlled trial.

Keywords: Myopia, LASIK, LASEK, Mechanical microkeratome, Femtosecond laser

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Introduction

Laser in situ keratomileusis (LASIK) is the most popular surgical procedure for the correction of myopia.[1] However, reports of post-LASIK ectasia have increased the interest in surface-ablation techniques, such as photorefractive keratectomy (PRK), laser-assisted subepithelial keratomileusis (LASEK) and Epi-LASIK, which eliminate the need for a corneal flap and aim to preserve a thicker stromal bed less prone to mechanical destabilization.[2] LASEK is a relatively new surgical procedure, in which certain elements of both LASIK and PRK are combined, providing an improved benefit/risk ratio. It is particularly valuable in patients with thin corneas who would not qualify for LASIK surgery. The LASEK procedure is known for long-term stable results and the lack of serious complications, including infections, scars, recurrent erosions, or late-onset corneal haze formation. Its major disadvantages compared to LASIK surgery are considered

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to be postoperative discomfort and prolonged visual recovery until the epithelium heals.[3] A more recent improvement in LASIK flap creation has been the femtosecond laser photodisruption.[4,5] Several randomized comparative studies showed that femtosecond laser photodisruption produces comparable or better visual outcome within 6 months after the procedure and fewer complications compared to mechanical microkeratomes,[6–8] although no differences in clinical outcomes at 12 months after keratomileusis were also reported.[9]

The aim of this study was to determine the best treatment option for patients with low-to-moderate spherical myopia or myopic astigmatism by comparing the efficacy and safety of three surgical procedures routinely performed at our center: LASEK with mitomycin-C (MMC) 0.02%, mechanical microkeratome LASIK (MM LASIK), and LASIK with femtosecond laser (Femtosecond LASIK). To the author's best knowledge, this is the first report of a formal comparison of these three laser treatment modalities.

Patients and methods

In this prospective, non-randomized study, 86 eyes of 46 patients (29 men, 17 women, mean age 27.8 ± 5.6 years) with low-to-moderate myopia were treated with one of three laser refractive procedures (LASEK with MMC, MM LASIK, or Femtosecond LASIK), at the Magrabi Centre Dammam, Kingdom of Saudi Arabia, between March and December 2009. The study was conducted according to the principles of the Declaration of Helsinki and approved by the local institutional review board. All participants were informed about the risks and benefits of the procedures and provided written informed consent.

Patients were included if they were above 18 years of age, had a confirmed low (−0.50 to −3.00 D) or moderate myopia (−3.10 to −8.00 D), stable refraction for at least 12 months, and had no known ocular or medical contraindications for laser refractive surgery. Baseline characteristics of study patients are provided in Table 1.

Pre-operative assessments

Pre-operative assessments included a complete medical and ophthalmological history and a thorough ocular examination, including uncorrected visual acuity (UCVA), manifest refraction, best spectacle-corrected visual acuity (BSCVA), using a Snellen's chart, central corneal thickness by ultrasonic pachymetry (DGH Technology Inc., USA), and slitlamp biomicroscopic examination of both anterior and posterior segments. In addition, corneal topography, ocular wavefront aberrations (HOA), autorefraction and pupil diameter measurements were measured by Optical Path Difference scan (OPD Scan II, Nidek Co., Ltd., Japan). Additional measurements, including surface regularity index (SRI), area compensated surface regularity index (SRC) and Strehl ratio were obtained from the OPD station (Nidek Co. Ltd., Japan). SRI is correlated to potential visual acuity and is a measure of local fluctuations in central corneal power, whereas SRC is a weighted form of the surface regularity index.

All treated eyes were considered suitable for vision correction using any of the three laser treatment modalities. After they received a detailed explanation regarding the known risks and benefits of the three treatment options, patients were asked to decide about the method that they considered most suitable. The selection was not guided or otherwise influenced by the treating surgeon.

Surgical procedures

All surgical procedures were performed by a single surgeon (M.M.H.). For patients in all three groups, who required refractive surgery in both eyes, the selected procedure was performed simultaneously, starting with the right eye and followed by the left eye. Conventional excimer laser ablation was performed using the Nidek platform (EC-5000 CXIII, Nidek Co. Ltd.), with a mean optic zone (OZ) of 5.51 ± 0.61 mm and mean transitional zone (TZ) of 8.14 ± 0.71 mm. The target in each case was full correction and pupil tracking was used in all eyes. Astigmatism between 0.25 and 1.00 D was treated with an attempted astigmatic correction.

The ocular surface pre-treated with moxifloxacin eye drops (Vigamox®, Alcon Laboratories Inc., USA) and anesthetized with five drops of oxybuprocaine hydrochloride eyedrops (Novesin®, Novartis, Switzerland) administered at five-minute intervals.

LASEK with MMC 0.02% application

Thirty-one myopic eyes (15 right, 16 left) of 16 patients underwent LASEK with the use of Nidek EC 5000 CXIII

Table 1. Baseline patient characteristics.

	LASEK + MMC group	MM LASIK group	Femtosecond LASIK group
Age, mean (SD), years	29.5 (5.3)	25.7 (3.9)	27.9 (6.6)
Gender, M/F	9 M/7 F	10 M/3 F	10 M/7 F
Number of eyes	31	23	32
UCVA 20/400 or worse, *n* (%) of eyes	12 (39%)	11 (48%)	18 (56%)
BSCVA 20/20, *n* (%) of eyes	28 (90%)	22 (96%)	26 (77%)
Manifest refraction, mean (SD), D			
SEQ	−2.60 (1.05)	−3.26 (1.25)	−4.67 (2.34)
Sphere	−2.36 (1.12)	−3.01 (1.24)	−4.42 (2.27)
Cylinder	−0.47 (0.61)	−0.50 (0.43)	−0.50 (0.38)
HOA, mean (SD), μm			
Coma	0.15 (0.09)	0.10 (0.06)	0.15 (0.14)
Trefoil	0.26 (0.13)	0.25 (0.15)	0.23 (0.20)
Tetrafoil	0.09 (0.06)	0.09 (0.24)	0.06 (0.05)
Spherical	0.07 (0.05)	0.07 (0.05)	0.07 (0.05)

Abbreviations: D, diopter; F, female; HOA, high-order aberration; LASEK, laser epithelial keratomileusis; LASIK, laser in situ keratomileusis; M, male; MM, mechanical microkeratome; MMC, mitomycin-C; SD, standard deviation; SEQ, spherical equivalent.

excimer laser. A 9.0 mm epithelial trephine (Katena Products Inc., USA) was used to create epithelial dehiscence from the underlying Bowman's membrane. After 15 s of exposure of the corneal epithelium to 20% ethanol (in distilled water), ethanol was absorbed with a Merocel® sponge (Medtronic Solan, USA), and the cornea was thoroughly rinsed with 40 cc chilled balanced salt solution. The epithelial layer was avulsed totally by a sharp Beaver blade (#69, Katena Products Inc., USA). The laser was then applied to the stromal bed. Mitomycin-C 0.02% was applied on the ablated stroma for a duration depending on ablation depth (12 s if ablation depth $\leqslant$ 75 μ, 20 s if ablation depth 76–100 μ), programming an undercorrection of 10% of the intended spherical correction. Mean maximum ablation depth was 48.1 ± 19.1 μm (range from 20.4 to 86.7 μm).

Mechanical microkeratome LASIK

In the second group of 13 patients, 23 eyes (12 right, 11 left) were treated with MM LASIK. Suction rings of Moria M_2 110 (Moria Inc., France) were used according to the manufacturer's nomogram to cut superiorly hinged 120 ± 19 μm corneal flaps. The flap was lifted and ultrasonic pachymetry of the central stromal bed was performed. Following laser treatment, the flap was carefully repositioned. Mean maximum ablation depth was 61.8 ± 21.4 μm (range from 18.0 to 103. μm). For patients with both eyes undergoing the procedure, the same cut parameters and the same blade were used for the fellow eye.

Femtosecond LASIK

In the third group, 32 myopic eyes (18 right, 14 left) of 17 patients underwent LASIK with flap created using a 60 kHz femtosecond laser keratome (IntraLase™ FS60, Abbott Medical Optics Inc., USA) with the following settings: attempted flap depth of 100 μm, a 90° side cut, raster energy level of 1.70 mJ, and a side-cut energy of 1.90 mJ, (following the manufacturer's instructions). The laser was programmed to achieve a superior hinge of 45° (corresponding to a hinge length of 3.5 mm) and a flap diameter of 9.0 mm. Maximum ablation depth averaged at 69.7 ± 26.9 μm (range from 19.8 to 112.0 μm) and the actual flap thickness was 114 ± 12 μm.

Post-operative care and follow-up

At the conclusion of the procedure, tobramycin 0.3% and dexamethazone 0.1% (TobraDex®, Alcon Laboratories Inc., USA) eye drops were administered 4 times a day. All LASEK patients were fitted with soft bandage contact lens (Acuvue® Oasys®, Johnson & Johnson Vision Care Inc., USA) at the end of the procedure and removed after complete epithelization, usually at 4th day postoperatively. Patients were instructed to immediately start using preservative-free lubricating eye drops (Tears Naturale Free, Alcon Laboratories Inc., USA) every hour for three months postoperatively. Post-operative pain was managed with oral diclofenac 100 mg (Voltaren®-XR, Novartis, Switzerland).

Post-operative assessments were completed 1, 3 and 6 months after the refractive surgery. Clinical outcomes of interest were distant UVCA to 6 months, changes in HOAs, predictability, stability, and Strehl ratio between the three groups.

Data collection and statistical analysis

Clinical outcome data were collected pre- and 1, 3 and 6 months after refractive surgery and entered in an Excel-based database. The following variables were assessed at 1, 3 and 6 months post-surgery and compared to pre-operative values: UCVA, manifest refraction, BSCVA, HOA, Strehl ratio, SRI and SRC. For the purposes of statistical comparisons, visual acuity measurements (UCVA, BSCVA) were converted to logarithm of the minimum angle of resolution (LogMAR) units, using a Snellen-LogMAR Visual Acuity Calculator. Ocular aberrations were evaluated by analyzing the root mean square (RMS) of high order aberrations for 6 mm pupil diameters at 1, 3 and 6 months post-surgery. One-way analysis of variance (ANOVA) was used to compare the groups in terms of the achieved spherical equivalent (SEQ) correction at each postoperative assessment as well as the 6-month UCVA, BSCVA and HOA. Stability of the achieved spherical equivalent (SEQ) correction was monitored over the 6-month follow-up period and presented graphically, using Datagraph Software 4.0. Predictability of SEQ was evaluated by comparing the attempt to achieved SEQ at the end of the 6-month follow-up period. Unless otherwise indicated, data are expressed as mean (SD). Differences were considered to be statistically significant when $P < .05$.

Results

All 46 patients who underwent refractive surgery had a minimum of 3 months follow-up. Three patients (6 eyes) in the LASEK with MMC group and four patients (7 eyes) in the MM LASIK group did not return for their 6-month follow-up due to relocation from the Eastern Province of Saudi Arabia.

Efficacy

Three months after surgery, UCVA was 20/20 or better in 28 eyes (90%) of the LASEK with MMC group, 20 eyes (87%) of the MM LASIK group and 16 eyes (50%) of the Femtosecond LASIK group. Based on patients with a complete 6-month follow-up, UCVA was 20/20 or better in 96%, 88% and 72% of the treated eyes in the three groups, respectively at 6 months. Importantly, an UVCA of 20/15 or better was achieved in 56% of the eyes undergoing LASEK with MMC, 25% undergoing MM LASIK and none of the Femtosecond LASIK group 6 months after surgery (see Table 2). The between-group differences in UCVA and BSCVA were statistically and clinically significant in favor of the LASEK with MMC group (see Table 3).

One month after surgery, SEQ averaged −0.14 ± 0.63 D in the LASEK plus MMC group, −0.07 D ± 0.38 D in the MM LASIK group and −0.43 D ± 0.37 D in the Femtosecond LASIK group; $p = 0.012$. Importantly, the achieved corrections were maintained throughout the follow-up, with the between-group differences remaining statistically significant at 3 months post-procedure (−0.19 ± 0.34 D, −0.04 D ± 0.52 D and −0.43 D ± 0.47 D, respectively; $p = 0.012$), but not at the end of the 6-month follow-up period (−0.12 ± 0.22 D,

Table 2. Postoperative uncorrected visual acuity in the three treatment groups.

UCVA[a]	LASEK + MMC group			MM LASIK group			Femtosecond LASIK group		
	1 mo *n* = 31	3 mo *n* = 31	6 mo *n* = 25	1 mo *n* = 23	3 mo *n* = 23	6 mo *n* = 16	1 mo *n* = 32	3 mo *n* = 32	6 mo *n* = 32
20/15 or better	0	0	14 (56)	2 (9)	4 (17)	4 (25)	0	0	0
20/20 or better	13 (42)	28 (90)	24 (96)	16 (70)	20 (87)	14 (88)	27 (84)	16 (50)	23 (72)
20/25 or better	25 (81)	25 (81)	25 (100)	18 (78)	22 (96)	16 (100)	30 (94)	25 (78)	29 (91)

Abbreviations: LASEK, laser epithelial keratomileusis; LASIK, laser in situ keratomileusis; MM, mechanical microkeratome; MMC, mitomycin-C; *n*, number of eyes; UCVA, uncorrected visual acuity.

[a] Results are presented as number (%) of eyes examined at the specified follow-up visits.

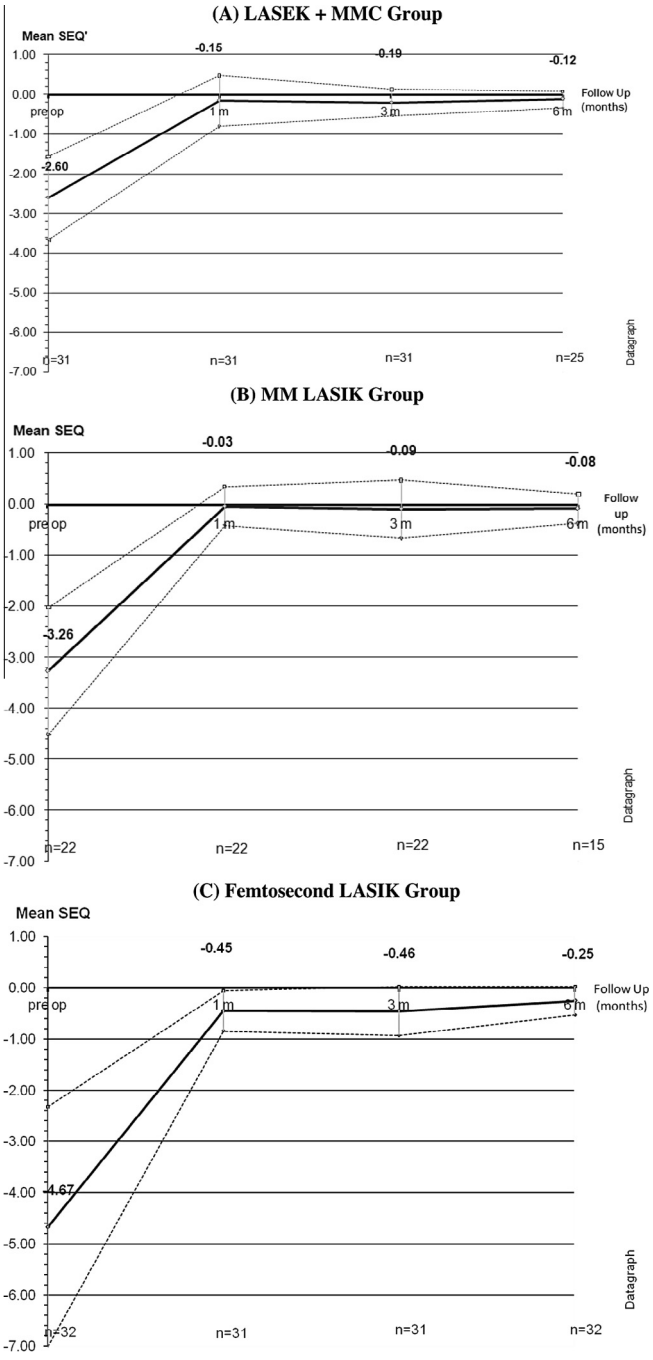

Figure 1. Stability of the achieved correction (spherical equivalent) over 6 months of follow-up.

−0.09 D ± 0.28 D and −0.25 D ± 0.28 D, respectively; $p = 0.077$); see Fig 1. All eyes in all three groups were within 1 D of the intended refractive change at 6 months. In addition, 22 out of 25 eyes (88%) in the LASEK, 15 out of 16 eyes (94%) in the MM LASIK and 30 out of 32 eyes (94%) in the Femtosecond LASIK group were within 0.5 D of the target refractive correction (see Fig 2). The LASEK with MMC group had fewer high order aberrations compared to two other groups, including a significantly lower occurrence of coma aberrations at the end of the 6-month follow-up (see Table 3).

Conversely, six months after refractive surgery, quality of vision, assessed by the Strehl ratio was comparable to pre-operative values in the two LASIK groups, whereas it increased from 0.07 to 0.20 in the LASEK with MMC group (see Fig 4).

Safety

None of the procedures were associated with early- or late-onset complications, including diffuse lamellar keratitis, infections or interface haze or fibrosis at 1, 3 or 6 months post surgery (see fig 3).

The safety of the three procedures was also evaluated by the number of lines lost or gained after surgery. Six months after refractive surgery, all eyes (100%) treated with LASEK with MMC, 93% of the eyes undergoing MM LASIK and 77% of the eyes undergoing Femtosecond LASIK surgery had an unchanged BSCVA. There was a gain of 1 line in 19% of eyes treated with Femtosecond LASIK, whereas the remaining 7% of eyes in the MM LASIK group and 3% of the eyes in the Femtosecond LASIK group showed a loss of 1 line after surgery.

Discussion

The objective of this prospective study was to determine the best treatment option for patients with low-to-moderate spherical myopia or myopic astigmatism who were considered equally eligible for LASEK with MMC, MM LASIK, and Femtosecond LASIK procedures. Our data indicate that both LASEK with MMC and MM LASIK may produce comparable or better as well as more stable visual acuity and comparable or less high order aberrations compared to the Femtosecond LASIK group at 6 months after surgery. Patients in the Femtosecond group achieved a relatively faster visual rehabilitation (UCVA was 20/20 or better in 84% of patients) compared to MM LASIK or LASEK with MMC (70% and 42%, respectively) during the first post-operative month. However, this initial

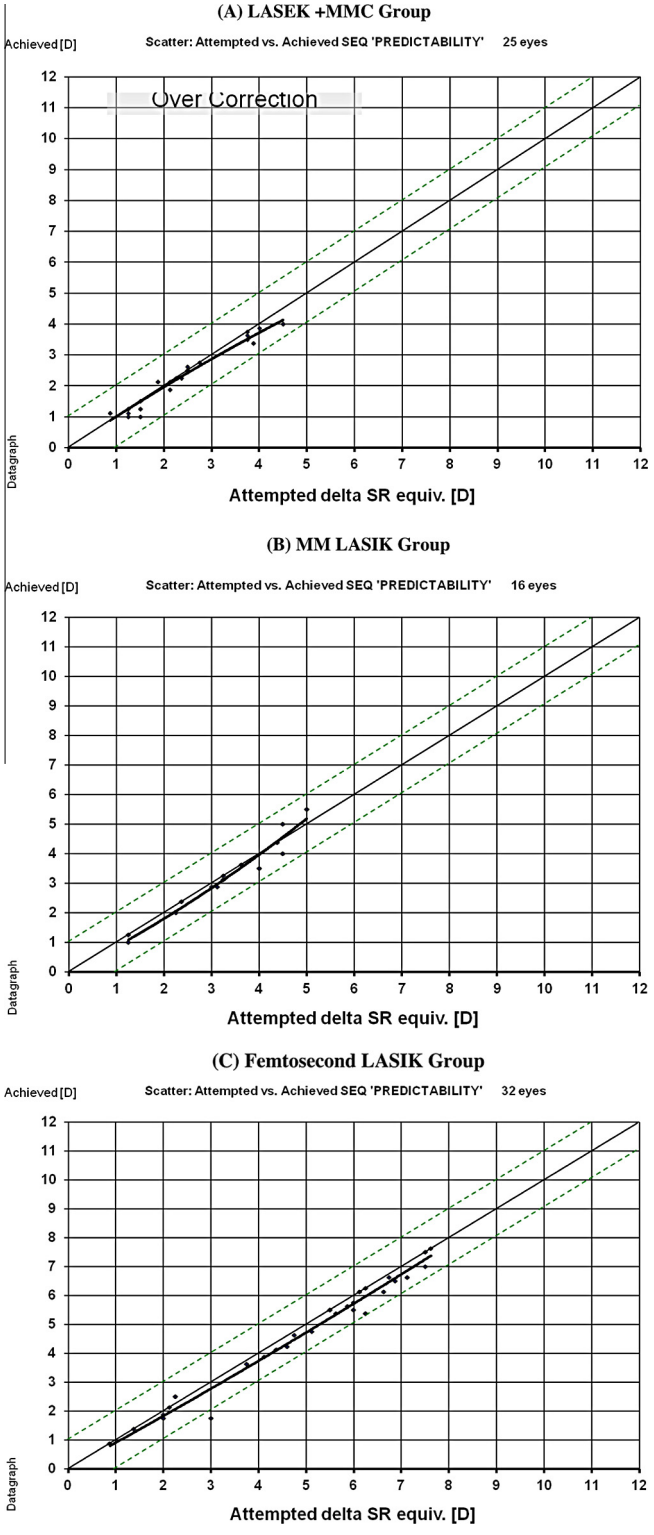

Figure 2. Attempted vs. achieved correction of spherical equivalent (SEQ; predictability) at 6 months after refractive surgery.

advantage was reversed by 3 months (UCVA was 20/20 in half of the Femtosecond LASIK group compared to approximately 90% in the LASEK with MMC and MM LASIK groups), and 6 months after the procedure (UCVA was 20/20 in 78%, 96%, and 88% of the patients in the three groups, respectively). In terms of the stability of spherical equivalent over time, best correction was achieved in patients undergoing MM LASIK, followed by the LASEK with MMC and Femtosecond LASIK groups. At the end of the 6-month follow-up period, all three procedures have achieved what was intended in more than 95% of cases, indicating comparable predictability.

For a 6-mm pupil, there was a temporary increase in the HOA RMSs in all three groups during the first 3 months after

Table 3. Summary of 6 month post-operative data.

	LASEK + MMC Group	MM LASIK group	Femto LASIK group	*P*-value[a]
Number of eyes	25/31	16/23	32/32	–
UCVA[b], mean (SD)	−0.07 (0.06)	−0.02 (0.07)	0.04 (0.07)	<0.0001
BSCVA[b], mean (SD)	−0.02 (0.05)	0.01 (0.03)	0.00 (0.02)	0.012
Manifest refraction, D				
SEQ, mean (SD)	−0.12 (0.22)	−0.09 D (0.28)	−0.25 (0.28)	0.012
Range	[−0.50, 0.25]	[-0.50, 0.50]	[−1.25, 0.00]	
HOA, mean (SD), μm				
Coma	0.08 (0.05)	0.15 (0.06)	0.16 (0.09)	0.001
Trefoil	0.14 (0.07)	0.15 (0.06)	0.17 (0.12)	0.423
Tetrafoil	0.04 (0.03)	0.06 (0.04)	0.06 (0.04)	0.097
Spherical	0.04 (0.03)	0.05 (0.04)	0.05 (0.04)	0.193

Abbreviations: D, diopter; HOA, high-order aberration; LASEK, laser epithelial keratomileusis; LASIK, laser in situ keratomileusis; MM, mechanical microkeratome; SD, standard deviation; SEQ, spherical equivalent.

[a] *P*-value: between-group comparison based on single-factor ANOVA.

[b] LogMAR units.

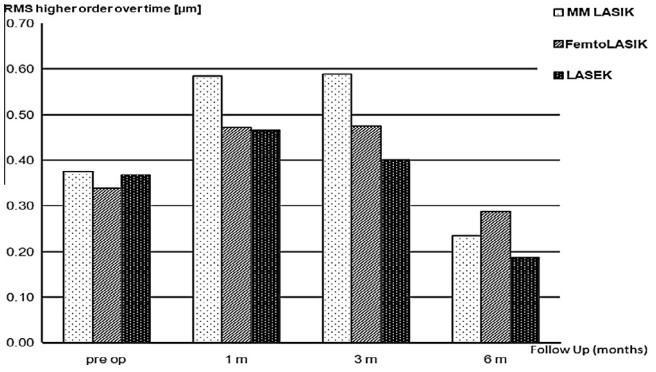

Figure 3. Mean root mean square of high order aberrations over 6-months of follow-up.

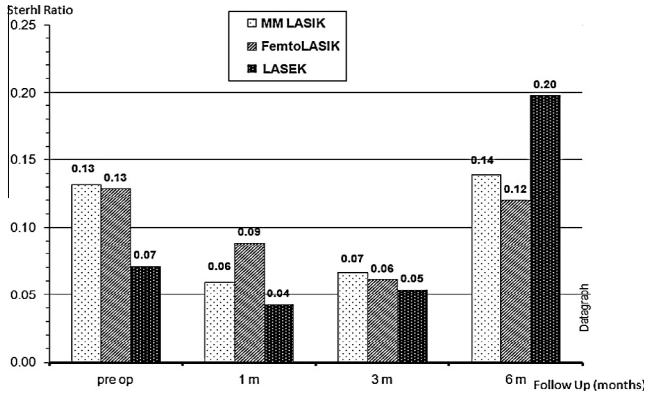

Figure 4. Strehl ratio over 6-months of follow-up.

surgery, followed by a reduction to below pre-operative values by 6 months with a non wavefront guided ablation profile. In our study the amount of high order aberrations was higher in patients undergoing Femtosecond LASIK compared to MM LASIK or LASEK with MMC (HOA RMS 0.29, 0.23 and 0.19, respectively) at 6 months. These results challenge the findings of earlier reports[8–10] showing less high order aberrations with flap creation using Femtosecond LASIK compared to mechanical microkeratome LASIK, whereas they are consistent with several recently published studies that failed to demonstrate better visual outcomes[11–15] and less high order aberrations[11–15] with Femtosecond compared to MM LASIK.

Changes in the optics of the eye induced by corneal refractive surgery are well reflected by the Strehl intensity ratio. The Strehl ratio is considered useful for the qualitative assessment of the retinal image and for quantifying optical degradation imposed by different optical conditions.[16] In the current study, the Strehl ratio was higher for the LASEK-treated eyes compared to eyes undergoing either of the LASIK procedures 6 months post-surgery.

Several previous clinical trials found that LASEK and LASIK produce similar visual outcomes when used for the correction of low and/or moderate myopia.[17–19] However, to our knowledge, the current study is the first to compare clinical outcomes between patients undergoing LASIK with either mechanical microkeratome or femtosecond laser and patients treated with LASEK.

The observations from our study have several weaknesses. The non-randomized method of treatment allocation resulted in a small imbalance in the number of patients and in some baseline patient characteristics between the three groups. Notably, the degree of pre-operative myopia was slightly higher in the Femtosecond LASIK group compared to the other two groups. Selection bias was at least partially offset by having each patient select one of the three laser refractory procedures, however it could not be completely ruled out. Due to a disproportion in the number of patients lost to follow up, the withdrawal rate varied between 0% in the Femtosecond LASIK and 31% in the MM LASIK group. Lastly, despite the good visual and refractive results observed in our patients, the study follow-up was limited to six months, which does not rule out the possibility of subsequent regression.

In summary, consistent with previous reports, all three procedures can be considered adequate for the correction of myopia. However the results of the current study indicate that, after an initially slower visual improvement, LASEK with MMC, and to a lesser extent, LASIK with mechanical microkeratome, may produce comparable or better visual acuity and comparable or less high order aberrations compared to Femtosecond LASIK at 3 and 6 months after surgery. These observations deserve further investigation in an adequately controlled, randomized trial.

Conflict of interest

The authors declared that there is no conflict of interest.

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