Femtosecond-Assisted LASIK Versus PRK: Comparison of 6-Month Visual Acuity and Quality Outcome for High Myopia

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Objective: To compare the results of femtosecond-assisted laser in situ keratomileusis (femto-LASIK) and photorefractive keratectomy with mitomycin C (PRK-MMC) for the correction of myopia more than 7.0 diopters (D).

Methods: In this comparative nonrandomized trial, 60 eyes (30 eyes in each group) were enrolled. Patients were tested for uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction spherical equivalent, ocular and corneal aberrations, and contrast sensitivity (CS) before surgery and at 3 and 6 months postoperatively.

Results: Mean preoperative myopia was -8.65 ± 1.51 and -8.04 ± 1.70 D in the femto-LASIK and PRK-MMC groups, respectively ($P=0.149$). Intergroup differences in baseline indices were not statistically significant. At 6 months after surgery, UDVA showed an improving trend, but it was better in the femto-LASIK group ($P=0.026$). CDVA in the two groups remained similarly unchanged ($P=0.170$). For the femto-LASIK and PRK-MMC groups, the safety indices were 1.01 ± 0.05 and 1.01 ± 0.14 ($P=0.949$), respectively, and the efficacy indices were 0.99 ± 0.07 and 0.93 ± 0.22 ($P=0.192$), respectively. Comparing CS, only CS18 showed a significantly greater decrease in the femto-LASIK group compared with the PRK-MMC group ($P=0.016$). Intergroup differences were not statistically significant in other spatial frequencies. Changes in the ocular and corneal higher order aberrations were not statistically different between the two groups except ocular coma, which increased in the femto-LASIK group ($P=0.041$).

Conclusion: Femto-LASIK improves UDVA better than PRK-MMC in high myopia. However, because of increased coma, the quality of vision is reduced. In other words, visual acuity outcome is better with femto-LASIK and visual quality outcome is better with PRK-MMC.

Key Words: High myopia—Femtosecond-assisted LASIK—PRK-MMC—Contrast sensitivity—Corneal aberration—Ocular aberration—OPD scan III.

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Correction of high myopia using different refractive surgical procedures has been studied in long term[1–3] and comparative[4–6] studies. Apart from intraocular lenses, which are associated with risks of an intraocular surgery, short-term[7] and long-term[6,8] results of refractive surgeries, including photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK), have also been compared. These studies have shown that outcomes with LASIK are superior to PRK. On the other hand, LASIK is associated with the risk of post-LASIK ectasia, and some find PRK a better choice than LASIK,[9] especially that the application of mitomycin C (MMC) in the correction of high myopia reduces the risk of corneal haze.[10] Today, femtosecond laser technology makes it possible to create a thinner more uniform and reproducible corneal flap in LASIK.[11,12] In the correction of high myopia, because the amount of removed tissue has a greater effect on corneal biomechanics, the use of this technology can help prevent complications. In this study, we compare the outcomes with femtosecond-assisted LASIK (femto-LASIK) versus PRK-MMC in visual acuity (VA) and quality for the correction of myopia greater than 7.00 diopters (D).

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MATERIALS AND METHODS

This study is a comparative nonrandomized clinical trial conducted on high myopic patients. Patients were treated with either femto-LASIK or PRK-MMC provided that the corneal thickness and amount of correction allowed for a minimum residual bed thickness of 300 μm. Inclusion criteria were a minimum age of 20 years, more than 7.00 D of myopia, and refraction stability during the past 12 months. Patients with a history of ocular surgery and ocular pathology and those with any sign of keratoconus or keratoconus suspect were excluded. Patients who used contact lenses were instructed to stop wearing them 4 weeks before surgery. For each group, 30 eyes were enrolled in the study.

After explaining the aims and methods of the study, written informed consents were obtained from patients. The study was approved by the institutional review board, and all study procedures adhered to the tenets of the Declaration of Helsinki.

Preoperative and Postoperative Examinations

Patients were examined before surgery and at 3 and 6 months after surgery. Recorded VA, tested using a Snellen chart, included uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA). Manifest refraction spherical equivalent (MRSE) was measured using the retinoscope (ParaStop HEINE BETA 200; HEINE Optotechnik, Herrsching, Germany). Aberrometry was performed using the OPD scan III (Nidek, Tokyo, Japan) without dilation. Ocular and corneal higher order aberrations (HOAs), such as coma, trefoil, spherical aberration (SA), and the sum of HOAs, were measured under photopic conditions. Mean pupil diameter was 4.19 ± 0.56 mm. Contrast sensitivity (CS) was assessed in spatial frequencies of 3 (CS3), 6 (CS6), 12 (CS12), and 18 (CS18) cycles per degree without glare using the CVS-1000 grating charts (VectorVision, Greenville, OH).

Surgical Techniques

Photorefractive Keratectomy With Mitomycin C

Under topical anesthesia with 0.5% proparacaine hydrochloride, the corneal epithelium was mechanically scraped without the use of alcohol. Ablation was applied using the WaveLight Allegretto EX500 (Alcon, Fort Worth, TX) excimer laser set for an ablation zone of 6 mm and a blend zone of 1.25 mm. After laser ablation, a sponge soaked in 0.02% MMC was applied to the ablated stroma for 10 sec/D correction. After rinsing with 30 mL sterile balanced salt solution, a bandage contact lens (Air Optix; CIBA Vision, Duluth, GA) was placed. Postoperative medications included 0.1% betamethasone and 5 mg/mL levofloxacin eye drops four times daily and artificial tears (hypromellose, preservative free) as required. Follow-up examinations were performed daily until complete epithelial healing was observed. On complete reepithelialization, the contact lens was removed and levofloxacin was discontinued. Betamethasone and artificial tears were continued for another 2 weeks, and then 0.1% fluorometholone drops were prescribed with a tapering dosage over a course of 3 months.

Femtosecond-Assisted Laser In Situ Keratomileusis

After topical anesthesia with 0.5% proparacaine hydrochloride, a flap was created using the femto LDV (Ziemer Ophthalmic Systems AG, Port, Switzerland). After lifting the flap, ablation was performed using the WaveLight Allegretto EX500 (Alcon) set for a 6.00-mm optical zone and a blend zone of 1.25 mm. The postoperative treatment regimen included 0.5% chloramphenicol every 6 hr for 3 days and 0.1% betamethasone every 6 hr for 7 days.

Statistical Analyses

The analysis of this study was conducted in two parts. In the first part, changes in indices were compared between the two groups as the main objective of the study. In the second part, the changes in indices were assessed in each group. We used repeated measures analysis of covariance and the post hoc test. A significance level of 0.05 was considered.

RESULTS

Mean preoperative MRSEs were −8.19±2.05 D (−13.25 to −7.00) and −8.54 ±1.42 D (−14.50 to −7.00) in femto-LASIK and PRK-MMC groups, respectively (P=0.149) and mean ablation depths were 109.37±9.07 and 105.09±12.59 μm, respectively (P=0.138). In the same order, the proportion of male participants was 53.3% and 51.7% (P=0.902) and the mean age was 28.60±7.85 and 27.14±5.63 years, respectively (P=0.416). Comparing all baseline characteristics of the two groups showed no statistically significant difference between the two groups, and the two groups were similar (all P values >0.05). No complications were observed in either group up to 6 months after surgery.

At 3 months, changes in CDVA (P=0.112), spherical error (P=0.336), cylinder error (P=0.977), and MRSE (P=0.369) were not statistically different between the two groups, and they only differed significantly in UDVA change (P=0.041) (Table 1).

TABLE 1. *Comparison of Changes in Visual Acuity and Refraction Indices 6 Months After Femto-LASIK and PRK-MMC*

		After Surgery		
	Before Surgery	3 mo	6 mo	P^a
UDVA, logMAR				
Femto-LASIK	1.80±0.15	0.03±0.07	0.04±0.06	0.026
PRK+MMC	1.75±0.16	0.09±0.12	0.09±0.15	
CDVA, logMAR				
Femto-LASIK	0.02±0.06	0.02±0.06	0.02±0.06	0.170
PRK+MMC	0.04±0.05	0.07±0.10	0.04±0.08	
Spherical error, D				
Femto-LASIK	−7.61±1.61	0.01±0.06	0.09±0.25	0.362
PRK+MMC	−7.93±1.52	0.17±0.45	−0.17±0.64	
Cylindrical error, D				
Femto-LASIK	−1.16±1.52	−0.25±0.37	−0.35±0.39	0.988
PRK+MMC	−1.22±1.18	−0.32±0.45	−0.42±0.30	
MRSE, D				
Femto-LASIK	−8.19±2.05	−0.11±0.19	−0.09±0.24	0.390
PRK+MMC	−8.54±1.42	0.01±0.40	−0.38±0.64	

[a]Intergroup differences in 6-month changes.

CDVA, corrected distance visual acuity; Femto-LASIK, femtosecond-assisted laser in situ keratomileusis; MRSE, manifest refraction of spherical equivalent; PRK-MMC, photorefractive keratectomy with mitomycin C; UDVA, uncorrected distance visual acuity.

At this time, intergroup differences showed borderline significance in changes in CS6 (P=0.093), CS12 (P=0.056), and CS18 (P=0.055), and the two groups significantly differed in CS3 change (P=0.046) (Table 2). Intergroup differences were not statistically significant in changes in corneal HOA (P=0.81), corneal coma (P=0.945), corneal trefoil (P=0.491), corneal SA (P=0.690), ocular HOA (P=0.468), ocular coma (P=0.263), ocular trefoil (P=0.807), or ocular SA (P=0.824) (Table 3).

Six-month changes in vision and refraction indices between the two groups are compared in Table 1. In both groups, UDVA had an improving trend over 6 months after surgery, but it was better in the femto-LASIK group than the PRK-MMC group (P=0.026). Corrected distance visual acuity remained similarly unchanged in both groups (P=0.170). For femto-LASIK and PRK-MMC groups, the safety indices were 1.01±0.05 and 1.01±0.14, respectively (P=0.949), and the efficacy indices were 0.99±0.07 and

TABLE 2. *Comparison of Changes in Contrast Sensitivity Without Glare 6 Months After Femto-LASIK and PRK-MMC*

		After Surgery		
	Before Surgery	3 mo	6 mo	P^a
C3 (CPD)				
Femto-LASIK	1.73±0.07	1.68±0.11	1.71±0.11	0.172
PRK+MMC	1.59±0.23	1.67±0.10	1.66±0.14	
C6 (CPD)				
Femto-LASIK	1.90±0.09	1.84±0.16	1.86±0.12	0.393
PRK+MMC	1.80±0.20	1.73±0.19	1.78±0.17	
C12 (CPD)				
Femto-LASIK	1.58±0.12	1.59±0.19	1.51±0.17	0.408
PRK+MMC	1.40±0.28	1.46±0.12	1.44±0.21	
C18 (CPD)				
Femto-LASIK	1.11±0.13	1.13±0.18	0.98±0.21	0.016
PRK+MMC	0.90±0.29	1.02±0.14	0.98±0.13	

[a]Intergroup differences in 6-month changes.

CPD, cycles per degree; Femto-LASIK, femtosecond-assisted laser in situ keratomileusis; PRK-MMC, photorefractive keratectomy with mitomycin C.

TABLE 3. *Comparison of Changes in HOAs Measured by the OPD Scan III 6 Months After Femto-LASIK and PRK-MMC*

	Before Surgery	After Surgery 3 mo	After Surgery 6 mo	P^a
Corneal HOA				
RMS HOA, μm				
Femto-LASIK	0.66±0.66	1.15±0.89	1.09±0.87	0.671
PRK+MMC	0.88±1.54	1.59±0.89	1.32±0.64	
Coma, μm				
Femto-LASIK	0.35±0.39	0.76±0.53	0.64±0.47	0.717
PRK+MMC	0.39±0.68	0.79±0.51	0.66±0.39	
Trefoil, μm				
Femto-LASIK	0.20±0.12	0.28±0.23	0.31±0.31	0.546
PRK+MMC	0.39±0.71	0.31±0.28	0.27±0.22	
SA, μm				
Femto-LASIK	0.28±0.16	0.74±0.68	0.76±0.73	0.708
PRK+MMC	0.59±1.21	1.22±0.73	1.02±0.48	
Ocular HOA				
RMS HOA, μm				
Femto-LASIK	0.38±0.24	1.11±0.92	1.39±1.49	0.109
PRK+MMC	0.47±0.22	1.03±0.64	0.87±0.45	
Coma, μm				
Femto-LASIK	0.16±0.14	0.75±0.71	0.83±0.74	0.041
PRK+MMC	0.22±0.12	0.58±0.47	0.46±0.27	
Trefoil, μm				
Femto-LASIK	0.24±0.17	0.31±0.22	0.49±0.80	0.958
PRK+MMC	0.31±0.20	0.36±0.23	0.56±0.91	
SA, μm				
Femto-LASIK	0.13±0.17	0.51±0.52	0.58±0.63	0.240
PRK+MMC	0.16±0.14	0.58±0.48	0.42±0.32	

[a]Intergroup differences in 6-month changes.

Femto-LASIK, femtosecond-assisted laser in situ keratomileusis; HOA, higher order aberration; PRK-MMC, photorefractive keratectomy with mitomycin C; RMS, root mean square; SA, spherical aberration.

0.93±0.22, respectively (P=0.192) (Fig. 1). Spherical error (P=0.362), cylinder error (P=0.988), and MRSE (P=0.390) reduced similarly in both groups.

Six-month changes in CS and intergroup comparisons of these variations are shown in Table 2. Reduced CS was statistically significant only for CS18 in the femto-LASIK group, but there was no significant change in the PRK-MMC group; the two groups were different in this regard (P=0.016). In other spatial frequencies, the intergroup difference was not statistically significant.

According to Table 3, variations in ocular and corneal HOAs had no significant difference between the two studied groups, except for ocular coma which was significantly higher in the femto-LASIK group (P=0.041).

DISCUSSION

This study compares 6-month results after surgery with femto-LASIK and PRK-MMC for patients with myopia more than 7.00 D. Because refraction and corneal thickness are decision-making factors for choosing the surgical method, the study could not be designed as a randomized one. To compare postoperative changes with minimal bias, the two groups of patients were matched based on preoperative indices.

Uncorrected distance visual acuity improvement in the femto-LASIK group was 0.1 logMAR or 1 Snellen line better than the PRK-MMC group. By the end of the sixth month, 86.7% of femto-LASIK cases had 20/20 CDVA. In the PRK-MMC group, CDVA was 20/20 and 25/20 for 58.6% and 27.6%, respectively. This intergroup difference was also observed in the third month after surgery. But after 3 months, no significant changes were found between the two groups. In other words, vision improvement in the femto-LASIK group was faster and reached its maximum in less than 3 months, but in the PRK-MMC group, the process continued up to the sixth month and the outcome was still better in the femto-LASIK group. Efficacy was less than 1 in both groups. Although efficacy was slightly better in the femto-LASIK group than the PRK-MMC group (0.99 vs. 0.93), CDVA was almost constant in the two groups during the 6 months. Significant UDVA improvement and no significant change in CDVA have also been reported in the study by Vega-Estrada et al.[13] Safety was within acceptable levels for both surgical approaches. None of them had any case with more than 1 Snellen line loss of CDVA. In the study by Montes-Mico et al.,[14] the safety of femto-LASIK was similar to our study. Faster UDVA improvement with femto-LASIK compared with PRK-MMC can be expected in light of the type of surgery. Comparison of long-term follow-ups, for example, at 1 year, could give different results.

In 6-month predictability, there was no difference between the two groups. The significant reduction in refraction and refractive astigmatism by the third month after surgery was similar in both

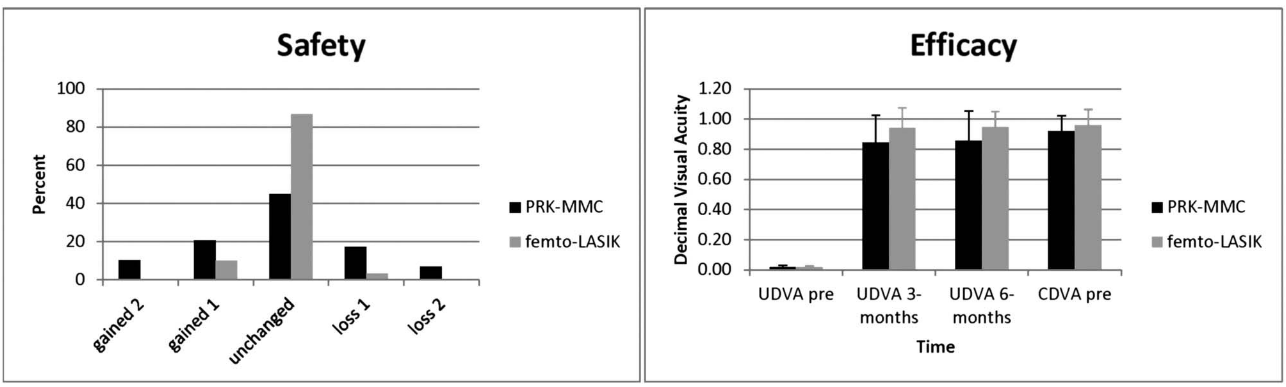

FIG. 1. Comparison of safety and efficacy indices between femtosecond-assisted laser in situ keratomileusis (femto-LASIK) and photorefractive keratectomy with mitomycin C (PRK-MMC) for high myopia.

groups and remained unchanged until the sixth month. Refractive outcome in both our study groups was similar to or slightly better than the Vega-Estrada et al.[13] study. According to Table 1, astigmatism reduced by 0.1 D between the third and sixth months in both groups, and in other words, it was stable after the third month. Refraction in the femto-LASIK group decreased by 0.02 D, but in the PRK-MMC group, it changed from 0.01 to -0.38 D. This is why we believe long-term results are needed to determine any refractive regression.

Contrast sensitivity remained unchanged in low and middle spatial frequencies in both groups. Unlike the PRK-MMC group, CS reduced slightly for CS18 in the femto-LASIK group. On the other hand, corneal and ocular HOAs similarly increased in both groups. The two surgical techniques differed only in their impact on ocular coma, and the increase was higher in the group treated with femto-LASIK. It is suggested that after femto-LASIK, increased HOAs reduce CS at high spatial frequencies.[15] Therefore, the significant CS18 reduction in the femto-LASIK group could be because of the increase in ocular coma because we found no other intergroup difference for other HOAs. Studies also indicate that after femto-LASIK, coma increases more than other HOAs under photopic conditions.[13,14] This could be because of an off-centered treatment, and there is need for a more precise technique to examine the visual axis. It should be noted that in addition to optical factors, CS is also affected by neural processes, whereas aberrations simply show optical factors. Thus, it could be said that both surgical procedures have a similar effect on visual quality in low and middle spatial frequencies. But in high spatial frequencies, PRK-MMC results were better than femto-LASIK.

In conclusion, based on a 6-month follow-up of correcting more than 7.0 D of myopia, femto-LASIK improves UDVA better than PRK-MMC. However, because of increased coma, visual quality is reduced in high spatial frequencies. In other words, results were better with femto-LASIK in VA and with PRK-MMC in visual quality. Predictability was similar in both types of surgery. To judge stability, this study will continue to report long-term results. Two limitations of the study were the inability to perform contralateral comparisons as a consequence of the inclusion criteria and limited sample sizes. We minimized these limitations by matching preoperative data in the two groups.

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