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Wavefront – guided laser – assisted subepithelial keratectomy in low myopia, myopic astigmatism and high myopia

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Received: 2012-11-17 Accepted: 2014-11-04

应用波前像差引导的 LASEK 治疗近视散光和低、高度近视

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摘要

目的:对比在矫正低度近视,近视散光和高度近视时应用波前像差引导的激光上皮瓣下角膜磨镶术(LASEK)的安全性,有效性,可预测性,稳定性和并发症。

方法:该回顾性分析共纳入 416 眼,分为 3 组,低度近视组 159 眼,等值球镜-3.68±1.33D; 近视散光组 161 眼,等值球镜-5.99±2.24D,柱镜度 2.41±1.07D;高度近视组 96 眼,等值球镜-7.41±0.80D. 制瓣后,进行波前像差为基础的准分子激光削切术。在术后 10d,2,6 和 12mo 后评估其安全性,有效性,可预测性和稳定性。

结果:术后 12mo,低度近视组等值球镜-0.36±0.31D,近视散光组 0.15±0.41D,高度近视组 0.58±0.68D。低度近视组中,裸眼视力为 20/20 的患者占 90.60%,近视散光组 78.90%,高度近视组 67%。疗效指标在三组中分别为 0.98, 1.04 和 0.92. 安全性指标分别为 1.00, 1.07 和 1.05。低度近视组有 5 眼(3.1%)最佳矫正视力提升 1 行,近视散光组有 44 眼 (27.3%)提升 1~3 行,高度近视组 18 眼 (19.2%)提升 1~2 行。低度近视组只有 2 例产生角膜雾状混浊。在疗效和安全性方面三组比较均无统计学差异。

结论:波前像差引导的激光上皮瓣下角膜磨镶术是治疗低度近视,近视散光和高度近视的一种有效安全的方法,而在治疗近视散光时其可预测性、有效性和安全性更佳。

关键词:波前像差引导;激光上皮瓣下角膜磨镶术;近视;散光;激光视力矫正

引用:Hashemian SJ, Sheikh-Hassai A, Foroutan A, Ghempanah MJ, Jafari ME, Hashemian MS, Nabili S. 应用波前像差引导的 LSAEK 治疗近视散光和低、高度近视. 国际眼科杂志 2015;15(2):192-197

Abstract

• AIM: To compare the safety, efficacy, predictability, stability and complications of wavefront-guided laser-assisted subepithelial keratectomy (LASEK) in low myopia, myopic astigmatism and high myopia correction.

• METHODS: A retrospective analysis of 416 eyes were assigned to 3 groups: 159 eyes with low myopia (LM) and mean refractive spherical equivalent (MRSE) of -3.68±1.33 dioptre (D); 161 eyes with myopic astigmatism (MA) and MRSE of -5.99±2.24D and mean cylinder of 2.41±1.07D; and 96 eyes with high myopia (HM) and MRSE of -7.41±0.80D. After an epithelial flap creation, a wavefront-based excimer laser ablation was performed. Safety, efficacy, predictability and stability were evaluated at day 10, 2, 6 and 12mo postoperatively.

• RESULTS: At 12mo, the MRSE was -0.36±0.31D in LM group, 0.15±0.41D in MA group and 0.58±0.68D in HM group. The uncorrected visual acuity (UCVA) was 20/20 in 90.60% of patients in LM group, 78.90% in MA group and 67% in HM group. Efficacy indices were 0.98, 1.04 and 0.92 in LM, MA and HM groups, respectively. Safety indices were 1.00, 1.07 and 1.05 in LM, MA and HM respectively. Five eyes (3.1%) in the LM group gained 1 line. Forty-four eyes (27.3%) in MA gained 1-3 lines and eighteen eyes (19.2%) of HM group gained 1-2 lines of BSCVA. Only 2 eyes in LM group developed corneal haze. There were not statistically significant differences in efficacy and safety indices amongst three groups.

• CONCLUSION: Wavefront-guided LASEK is an effective and safe procedure for the treatment of LM, MA, and HM. although in myopic astigmatism the predictability, efficacy and safety indices had been better.

• KEYWORDS: wavefront - guided; laser - assisted subepithelial keratectomy; myopia; astigmatism; laser vision correction
DOI:10.3980/j. issn. 1672-5123. 2015. 2. 02

Citation: Hashemian SJ, Sheikh - Hassai A, Foroutan A, Ghempanah MJ, Jafari ME, Hashemian MS, Nabili S. Wavefront-guided laser - assisted subepithelial keratectomy in low myopia, myopic astigmatism and high myopia. *Guoji Yanke Zazhi* (*Int Eye Sci*) 2015;15(2):192-197

INTRODUCTION

Surface ablation has been established as a safe method for correcting refractive errors. Surface ablation procedures including photorefractive keratectomy (PRK) and laser - assisted subepithelial keratectomy (LASEK) have gained popularity due to the elimination of flap complications and the reduction of postoperative corneal ectasia[1]. Corneal haze is a major complication associated with surface ablation; however, the use of mitomycin C (MMC) 0. 02% solution (12s to 2min) has reduced the chance of corneal haze in eyes with higher risk of this complication[1-8]. It is well known that conventional surface ablation procedures and laser-assisted *in suit* keratomileusis (LASIK) increases higher order aberrations (HOAs), which explains visual symptoms such as glare and halos, despite the apparent success of surgery[9-11]. Preoperative wavefront analysis has been used to create individualized ablation patterns to compensate for pre-existing aberration[12-14]. Although the true clinical significance of HOAs is not fully understood, HOAs may have a role in degradation of retinal image especially in mesopic vision[15-18]. Wavefront - guided LASEK may improve the quality of vision and reduce the amount of aberration after corneal refractive surgery[19-23]. The effectiveness, predictability, stability and safety of wavefront - guided PRK for low and moderate myopia have been widely reported. The present study evaluates the safety, efficacy, predictability, stability and complications of wavefront - guided LASEK for low myopia (LM), myopic astigmatism (MA) and high myopia (HM).

SUBJECTS ANDMETHODS

A retrospective chart review was developed containing data of patients underwent customized surface ablation from December 2005 to December 2007. All surgeries were performed by the same surgeon (SJH). The Review Board of Eye Research Centre in Iran University of Medical Sciences approved this study.

The datacontaining age, sex, date of surgery, spherical equivalent refraction, uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were collected.

The inclusion criteria for each group were stable refraction for at least 6mo prior to the surgery, the post-ablation of residual corneal thickness of more than 350 μm without epithelium and the discontinuation of contact lenses for at least 1mo prior to ocular examination to eliminate the warping effect on the cornea.

The exclusion criteria included history of previous refractive procedures, keratoconus, cataract surgery, diabetes mellitus, glaucoma, connective tissue disorders, retinal disease, dry eye, amblyopia, pregnancy and breast-feeding periods.

Patients that did not complete whole follow up periods were excluded from the study.

Preoperatively all patients had a complete ophthalmic examination including UDVA and CDVA using Snellen chart with the same light condition, manifest, subjective and cycloplegic refractions, Goldmann applanation tonometry, slit lamp assessment, pachymetry, topography, aberrometry and dilated indirect ophthalmoscopy.

At this study all eyes aberration was assessed with Zywave aberrometer (Bausch & Lomb, Rochester, New York, USA) based on the Hartmann - Shack principle. The same experienced examiner performed all wavefront measurements. Optical aberrations were measured with a dilated pupil (>6mm) 20min after instillation of topical 0. 5% Tropicamide drop (Sina Darou, Tehran, Iran). Each eye was tested 3 times by Zywave aberrometer. The best image was included in the study based on the image quality. If refraction of the patient was in the range (spherical dioptre: ±0. 75D, cylindrical dioptre: ±0. 5D and astigmatic axis: ±15°) of subjective refraction, it was included in the study and HOAs and root mean square (RMS) values were documented.

The corneal data sets including pachymetry, anterior and posterior elevation maps were analysed with Orbscan IIz (Bausch & Lomb, Rochester, USA).

Surgical Technique LASEK was performed under topical anesthesia with Anestocaine (Tetracaine HCL 0. 5%, Sina Darou, Tehran, Iran). An alcohol solution cone (J2905, Janach, UK) with an 8. 5mm diameter was placed on the cornea. An ethyl alcohol 20% solution was instilled inside the cone and left for about 20s. All alcohol was carefully absorbed using a dry sponge and thoroughly washed off with balanced salt solution. The epithelial flap was gently lifted with an epithelial micro hook and peeled back as a single sheet toward the 12 o'clock position. Excimer laser ablation was performed by Technolas 217z excimer laser (Technolas Perfect Vision, St Louis, USA) using a wavefront-guided ablation algorithm with iris registration. Following laser ablation, MMC 0. 02% solution was applied for 12s in eyes with more than 60. 0 micron tissue ablation. In patients with more than 6. 0D spherical equivalent, spherical refractive errors was under corrected by 10%. The flap was washed with balanced salt solution and then carefully repositioned. All eyes were fitted with an AirOptix® Night & Day® AQUA contact lens (CIBA VISION, Novartis AG Company, USA). A drop of Ciplex (Ciprofloxacin 0. 3%, Sina Darou, Tehran, Iran) and a drop of Betasonathe (Betamethasone disodium Phosphate 0. 1%, Sina Darou, Tehran, Iran) were applied at the conclusion of

Table 1 Patients demographics and preoperative data $\bar{x}\pm s$

Parameters	Low myopia	Myopic astigmatism	High myopia	*P*
Age (a, range)	27.39±6.96 (18-52)	27.24±7.30 (18-49)	26.03±7.81(18-49)	NS
F/M (*n*, %)	117 (73.6)/42 (26.4)	125 (77.6)/36 (22.4)	75 (78.1)/21 (21.9)	NS
Follow-up (mo)	>12	>12	>12	NS
Preoperativekeratometry (Dioptre)	43.98±1.26 (40.75-48.25)	44.20±1.43 (39.75-47.50)	43.94±1.31 (40.50-47.00)	NS
Preoperative pachymetry (Micron)	541.8±33.8 (480-640)	542.5±35.5 (480-660)	547.2±31.8 (480-630)	NS

NS: Non-significant.

procedure. Postoperative medications include Ciplex drops (Ciprofloxacin 0.3%, Sina Darou, Tehran, Iran) 4 times a day for 1wk and Flurometholon 0.1% drops (Sina Darou, Tehran, Iran 4 times per day for 1mo, 3 times for 1mo, 2 times for 1mo, once per day for 1mo. In addition, all patients were prescribed hypromellose 0.32% minims (Dr Gerhard Mann Chem-pharm Fabrik GmbH, 13581 Berlin, Germany) 4 times per day for 2mo. Postoperatively, the eyes were checked daily. Following complete closure of epithelial defect, bandage contact lens was removed usually after 3d.

Statistical Analysis This study presented the result by utilising mean, standard deviation, median and range in addition to one - way ANOVA in order to analyse the differences between the sets and the probability value. *P* value of less than 0.05 was considered to be statistically significant. All statistical analysis was performed by SPSS (version 20) software and Chi- square test was used for the qualitative data comparison.

RESULTS

The mean ages of low myopic group, myopic astigmatism group and high myopic group were 27.39 (range 18-52y), 27.24 (range 18-49y) and 26.03 (range 18-49y), respectively (P = 0.306). A total of 416 eyes were categorised to low myopia with spherical equivalent (SE) of <-6.00D (range -1.00D to -600D) and astigmatism under 1D, myopic astigmatism with mean SE and astigmatism of -5.99±2.24D (range -1D to -9.25D) and -2.41±1.07D (range -1.25D to -5.00D) respectively and high myopic group with SE of >-6.00D and mean SE of -7.41±0.80D (range -6.25D to -9.5D) with astigmatism under -1.00D. Demographics and preoperative data of patients were shown in Table 1.

Predictability In the LM group, 95.2%, 99.4%, 99.5% and 99.4% of eyes were within 1D of target SE, at day 10 and 2, 6 and 12mo respectively. In the MA group, 90.1%, 98.2%, 98.8% and 97.9% of eyes were within 1D at the above-mentioned periods respectively and these figures were 90.7%, 97.9%, 92.7% and 83.9% at these intervals respectively in the HM group (Figure 1).

Postoperative spherical equivalent refraction was within ±0.5D of 94.3%, 86.3% and 62.4% of eyes in the LM, MA, and HM groups at month 12, respectively (Figures 1, 2).

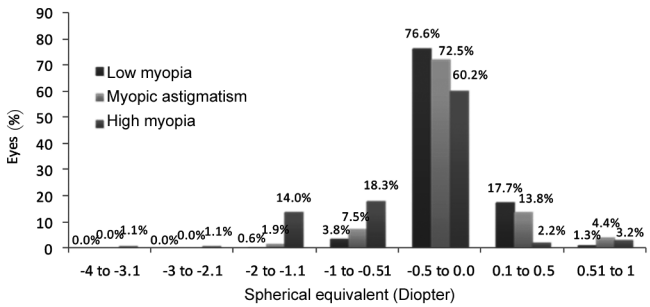

Figure 1 Post-operative spherical equivalent refractive errors at the 12th month in low myopia, myopic astigmatism and high myopia groups.

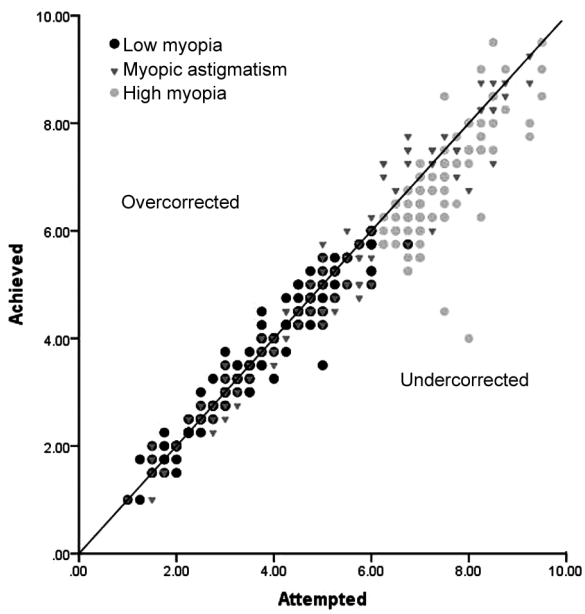

Figure 2 One-year post-operative attempted and achieved spherical equivalent in low myopia, myopic astigmatism and high myopia All figures are in dioptre.

Safety The safety indices (postoperative CDVA/preoperative CDVA) were 1.00, 1.05 and 1.02 at 2mo in LM, MA and HM groups respectively. At 6mo, these figures were 1.003, 1.066 and 1.037 and at 12mo, we calculated them as 1.00, 1.07 and 1.05, respectively. In the LM group, 1 eye (0.6%) lost 2 lines of CDVA and 5 eyes (3.10%) gained 1 line of CDVA. In the MA group, no loss of CDVA was seen and 29 eyes (18.0%) gained 1 line, 13 eyes (8.1%) gained 2 lines and 2 eyes (1.2%) gained 3 lines of CDVA. In the HM group, 2 eyes (2.1%) lost 1 line of CDVA and 15 eyes

Table 2 Visual acuity outcomes at 10d, 2, 6 and 12mo

UDVA/snellen	10d postop.			2mo postop.			6mo postop.			12mo postop.		
	LM	MA	HM	LM	MA	HM	LM	MA	HM	LM	MA	HM
>20/20	62[a](48.4)	39 (32.5)	22 (33.3)	147 (92.5)	111 (68.9)	66 (68.8)	148 (93.1)	121 (75.2)	72 (75)	144 (90.6)	127 (78.9)	63 (67)
>20/25	112 (87.5)	94 (78.3)	45 (68.1)	157 (98.8)	149 (92.5)	86 (89.6)	156 (98.1)	151 (93.8)	87 (90.6)	155 (97.5)	152 (94.4)	73 (77.6)
>20/30	122 (95.3)	113 (94.1)	59(89.3)	157 (98.8)	161 (100)	90 (93.6)	156 (98.1)	161 (100)	92 (95.8)	155 (97.5)	161 (100)	81 (85.6)

[a]Number of patients (%).

(16%) gained 1 line and 3 eyes (3.2%) gained 2 lines of CDVA (Figure 3). In the LM group, we had 2 eyes (1.2%) with haze formation grade 1-2 based on Fantes grading. Both eyes improved 4mo following surgery.

High intraocular pressure (IOP) (more than 25mmHg) was found in 3 eyes (1.9%) in LM group. In the MA group, we had only one case with high IOP but no case of haze formation. Amongst HM group patients, neither corneal haze nor high IOP was noted during 12mo follow up.

Efficacy The efficacy indices (postoperative UCVA/preoperative CDVA) in the LM, MA and HM groups were 0.98, 1.02 and 0.96 at 2mo and 0.98, 1.03 and 0.98 at 6mo. These figures were noted as 0.98, 1.04 and 0.92 at 12mo, respectively. This study found 90.6% of eyes in LM group, 78.9% of eyes in MA and 67.0% of eyes in HM groups achieved UCVA of 20/20 or better at the 12th month (Table 2).

Stability The UCVA of LM and MA groups showed no change at 2-12mo postoperatively. The SE in LM and MA groups also revealed no significant change during the above period; however, in HM group, UCVA and SE decreased from the second month to the twelfth month ($P<0.05$) (Figure 4).

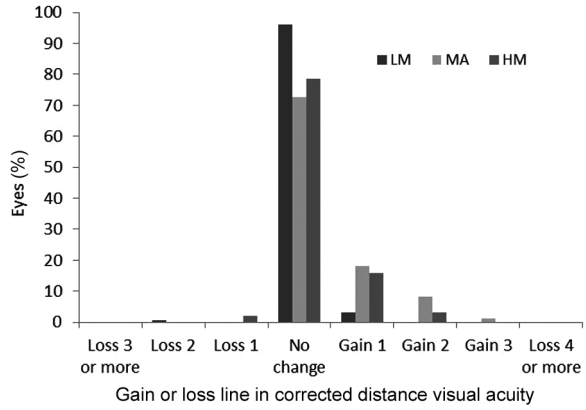

Figure 3 Changes in corrected distance visual acuity The X axis denotes the changes in reading Snellen charts lines and the Y axis shows the percentage of patients. No patients lost 3 or more lines on Snellen chart.

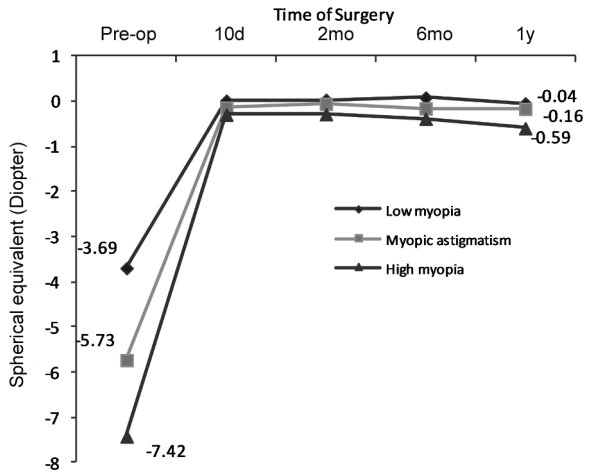

Figure 4 Stability of wavefront-guided LASEK in 416 eyes with low myopia, myopic astigmatism and high myopia groups. All figures denote spherical equivalents in dioptre.

DISCUSSION

The aim of this study wasto compare the safety, efficacy, predictability, stability and complications of wavefront-guided LASEK in the treatment of low myopia, myopic astigmatism and high myopia.

It is believed that not only wavefront-guided LASEK may decrease the amount of induced aberrations and improve the quality of vision but also epithelial flap may decrease pain and improve epithelial healing following procedure[5,10].

Safety data were excellent in three groups with safety indices of 1.00, 1.07 and 1.05 at 12mo in LM, MA and HM groups, respectively. The efficacy indices were 0.98, 1.04 and 0.92 at 12mo, respectively. The UCVA and SE of LM and MA groups show no change during 12mo of postoperative examination ($P<0.05$). We also noted a considerable number of treated eyes *i.e.* 90.6% of LM eyes, 78.9% of MA eyes and 67.0% of HM eyes groups achieved UCVA of 20/20 or better after 12mo follow up.

In the LM group, only 1 eye (0.6%) lost 2 lines of CDVA and 5 eyes (3.1%) gained 1 line of CDVA after 1y. Postoperative SE was within ±1.0D in 99.4% of eyes at 1y. Corneal haze formation was found in 1.2% (2 eyes) of patients. In the MA group, no eye lost any line of CDVA and 18.00% (29 eyes) gained 1 line of DCVA. In this cohort, 97.9% of eyes were within ±1D SE at the end of the study. In the HM group, 2.1% (2 eyes) lost 1 line of DCVA and 16.0% (15 eyes) gained 1 line of DCVA and post-operative SE were within ±1D in 83.9% of eyes at 12mo. There was no case of haze formation in both MA and HM groups.

The interesting point was that there was 1.6% haze formation in LM group but no case of haze formation in MAand HM groups. This may be due to the usage of MMC 0.02% in patients with tissue ablation ≥ 60.0μm according to our treatment protocol.

Our co-authors (Hashemian SJ, Foroutan A, Ghempanah MJ, Jafari ME) at the other study[24] assessed the visual and refractive outcomes of LASEK in low myopic eyes. They found UCVA was 20/20 or better in 96.1% eyes and 20/40 or better

in 99.52% respectively after 12mo.

Kohnen *et al*[25] performed wavefront-guided LASIK in 97 eyes with a mean subjective manifest spherical equivalent of -5.25±2.07D (range -0.24 to -9.00). UCVA was 20/20 or better in 83% of the eyes and 20/40 or better in 98% at 1-year postoperatively. During this period, no eyes lost 2 lines of corrected distance visual acuity (CDVA) and 40 eyes (40.81%) gained 1 line of CDVA and 5 eyes (5%) gained 2 lines. In comparison, our study signified the visual acuity was 20/20 or better in 78.8% in three groups, 11.77% gained 1 line, 3.8% gained 2 lines and 0.48% gained 3 lines of corrected distance visual acuity at 1y postoperatively.

In 2009 de Benito-Llopis *et al*[26] compared femtosecond assisted LASIK (FS-LASIK) in 1072 eyes with LASEK in 1036 eyes. Preoperative mean sphere and BSCVA were -3.93D *vs* -3.87D and 1.12 *vs* 1.12 in FS-LASIK and LASEK, respectively. UCVA was 0.92 *vs* 0.62, 0.98 *vs* 0.78, 0.96 *vs* 0.91, and 1.06 *vs* 1.03 in FS-LASIK and LASEK, respectively, at 1d, 1wk, and 1 and 3mo after surgery ($P<0.01$ for all comparisons). Three months postoperatively, BSCVA was 1.13 and 1.10, respectively ($P=0.001$). At that stage, 20 eyes (1.93%) in the LASEK group *vs* 9 eyes (0.84%) in the FS-LASIK group had lost 2 or more lines of CDVA. Ten eyes (0.96%) in the LASEK group gained 2 or more lines of CDVA, whereas 3 eyes (0.28%) in the FS-LASIK group gained 2 lines. Six months postoperatively, only 2 LASEK eyes (0.19%) showed loss of 2 or more lines of CDVA, compared to 3 FS-LASIK treated eyes (0.28%). In our study, preoperative CDVA were 0.99 and 0.91 in LM and MA groups respectively. UCDVA were 0.97 and 0.95 and CDVA were 0.99 and 0.97 at 1 year postoperatively, respectively. Only 0.6% of eyes lost 2 lines in LM and no eye lost visual acuity in MA and 3.1% gained 1 line and 27.3% gained 1-3 lines of visual acuity in LM and MA groups at 1y postoperatively.

Sia *et al*[27] reported the visual outcomes after Epi-LASIK and PRK for low and moderate myopia in 2012. Safety indices were 1.33 *vs* 1.29, efficacy indices were 0.85 *vs* 0.67, predictability were 86.2% *vs* 92.5%. And 75.9% *vs* 61.9% of eyes achieved UCDVA 20/20 or better at 12mo in epi-LAKSIK and PRK respectively after surgery. No eyes lost ≥2 lines of DCVA in either group at 12mo; whereas, at our study the safety indices in LM and MA groups were 1.00 and 1.07, efficacy indices were 0.98 and 1.04 and predictability indices were 99.4 and 97.9 within ±1.0D. UCDVA was 20/20 or better in 90.6% of LM eyes and in 78.9% of MA eyes at 1y follow up.

Teus *et al*[28] reported the visual result of LASEK and epi-LASIK in 94 eyes (47 LASEK and 47epi-LASIK) in myopic patients (range -0.5 to -9.00) in 2008. The UCVA, 3mo postoperatively, was 1.06±0.1 and 1.03±0.18 in LASEK and epi-LASIK group respectively. UCVA was ≥1.0 in 78.7% of LASEK eyes and 65.9% of Epi-LASIK eyes three months after surgery. The safety indices were (0.99±0.1) after LASEK and (0.93±0.1) after Epi-LASIK ($P=0.04$). The efficacy indices were (0.97±0.1) and (0.89±0.1) respectively ($P=0.01$).

This study evaluates the visual outcomes in different types of myopic patients treated with wavefront-guided LASEK. Our results showed that wavefront-guided LASEK was a safe, effective and predictable procedure for treatment of low, moderate and high myopia. Visual and refractive outcomes of this technique were better in low myopia and myopic astigmatism groups compared to high myopic group.

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