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Comparison of FS-LASIK and WFG FS-LASIK Procedures in Terms of Predictability, Efficacy and Safety

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Abstract

***Purpose:** To compare the results of femtosecond-assisted laser in situ keratomileusis (FS-LASIK) and wavefront-guided femtosecond-assisted laser in situ keratomileusis (WFG FS-LASIK) procedures in terms of predictability, efficacy and safety.*

***Material and Methods:** One hundred and ten eyes of 55 patients with myopia and/or myopic astigmatism who had undergone FS-LASIK procedure were compared with 110 eyes of 55 patients with myopia and/or myopic astigmatism who had undergone WFG FS-LASIK procedure.*

***Results:** In respect to age and sex, there was no significant difference between FS-LASIK and WFG FS-LASIK groups. Regarding preoperative and postoperative spherical, cylinderical and spherical equivalent values, uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), there was no significant difference between two groups. Predictability, efficacy and safety index values were high and similar in both groups.*

***Conclusion:** Both FS-LASIK and WFG FS-LASIK are efficient, safe and predictable procedures for correction of myopia and myopic astigmatism.*

Keywords: FS-LASIK, WFG FS-LASIK, efficacy, safety, predictability

Introduction

The aim of refractive surgery is to reduce dependence on contact lens or spectacles for use in routine daily activities. A wide variety of surgical techniques and technologies are available. LASIK is currently the most frequently performed keratorefractive procedure because of its safety, efficacy, quick recovery of vision and minimal patient discomfort. LASIK combines two refractive technologies, one is the Excimer laser stromal ablation and the other is the creation of a stromal flap[1]. In FS-LASIK procedure, femtosecond laser is used to create corneal flaps. Its main advantage over mechanical microkeratomes is that femtosecond laser allows surgeonsto customize the parameters of corneal flap, such as diameter, thickness and hinge position, which may reduce the incidence of intraoperative complications, including irregular or buttonholed flaps and epithelial defects[2-6]. The femtosecond laser-created flaps also show stronger adhesions at the interface and flap edge than microkeratome flaps[7]. However, LASIK can not correct preexisting high-order aberrations (HOAs) and may induce HOAs postoperatively. HOAs are responsible for postoperative symptoms like halos, glare, monocular diplopia and contrast sensitivity after succesful refractive surgery[8]. Wavefront-guided LASIK has been shown to correct preexisting aberrations and to result in less postoperative HOAs[9,10].

In this study, retrospectively FS-LASIK procedure is compared with WFG FS-LASIK in terms of predictability, efficacy and safety.

Material And Methods

The study protocol was approved by the local ethics commitee (Selcuk University, Faculty of Medicine Ethics Commitee, Konya, Turkey). An informed written consent was obtained from the patients before the surgery. The study was carried out according to the tenets of the Declaration of Helsinki.

One hundred and ten eyes of 55 patients with myopia and/or myopic astigmatism who had undergone FS-LASIK procedure between June 2017 and August 2017 comprised Group I. Their mean age was 26.31 ± 5.53 (SD) (19-42) years. Twenty-seven of them were males (49%) and 28 (51%) were females. One hundred and ten eyes of 55 patients with myopia and/or myopic astigmatism who had undergone WFG FS-LASIK procedure between June 2017 and August 2017 comprised Group II. Their mean age was 26.98 ± 5.75 (SD) (19 - 42) years. Twenty-eight of them were males (51%) and 27 (49%) were females. All of the surgeries were performed by a single surgeon (SC). Patients included in the study did not have Diabetes Mellitus, Connective tissue diseasesor any ocular diseases that might affect the vision. Patients wearing soft contact lenses were instructed to stop wearing them at least 1 week prior to the surgery. This duration was four weeks for hard contact lens wearers.

FS-LASIK procedures were performed by the Visumax femtosecond laser system (Carl Zeiss, Meditec AG, Jena, Germany) with a repetition rate of 500 Khz and a pulse energy of 150 nj, for flap creation. The ablation was performed with Wavelight EX500 (Alcon) Laser system.

WFG FS-LASIK procedures were performed by the Visumax femtosecond laser system (Carl Zeiss, Meditec AG, Jena, Germany) with a repetition rate of 500 Khz and a pulse energy of 150 nj, for flap creation. Refraction and wavefront information gathered by Wavelight Oculyzer II (Alcon, GmbH-Am, Wolsfmatel S-91058 Ertagen, Germany) and Wavelight Allegro Topolyzer-VARIO (Alcon, GmbH-Am, Wolsfmatel S-91058 Ertagen, Germany) was transferred to Wavelight EX500 (Alcon) Laser system. The ablation was performed, an eye tracker was used to perform accurate ablation on the centre of pupil. After irrigation, the flap was repositioned.

After the surgical procedures, patients used topical antibiotic (Moxifloxacin 0.5 %, Vigamox, Alcon, USA) 4 times a day for a week, topical steroid (Dexametasone Na Phosphate 0.1 %, Dexa-sine, Liba, USA) 4 times a day for 2 weeks and a preservative-free topical lubricating drop (Na Hyaluronate 0.15%, Eyestil, SIFI, Italy) 4 times a day for 3 months.

Full opthalmological examinations including uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), intraocular pressure measurement, fundus examination and topographic measurements were performed preoperatively and 1st day, 1st week, 1st month, 3rd month and 6th month after the operation. Efficacy index was calculated by postoperative UDVA/preoperative CDVA.Safety index was calculated bypostoperative CDVA/preoperative CDVA. Predictability was presented as percentage of eyes within ±0.50 D, postoperatively.

For statistical analysis, SPSS version 22 programme was used. For comparison of data Chi- square test and t test were used. A $p<0.05$ value was accepted as statistically significant.

Results

In respect to age, sex, preoperative spherical, cylendrical and spherical equivalent (SE) values, UDVA, CDVA, K values, CCT values, flap diameter and thickness, optic zone diameter,ablation depth and residual stromal bed thickness, there was no significant difference between the first (FS-LASIK) and second (WFG FS-LASIK) group. The preoperative and intraoperative patient charactheristics areshown in Table 1.

Table 1. *The preoperative and intraoperative patient charactheristics*

Parameters	FS-LASIK	WFG FS-LASIK	P value
	n=110	n=110	
Age (Years)	26.31 ± 5.53 (SD)	26.98 ± 5.75 (SD)	0.875
	(19-42)	(19 - 42)	
Sex (Male/Female)	27/28	28 / 27	0.801
	(49% / 51%)	(51% / 49%)	
Sphere (D)	-5.45 ± 2.56	-5.67 ± 2.43	0.278
	(-10.00 to 0.00)	(-10.00 to 0.00)	
Cylinder (D)	-1.49 ± 1.21	-1.53 ± 1.27	0.655
	(-5.00 to 0.00)	(-5.00 to 0.00)	

SE (D)	-6.01 ± 2.12	-6.14 ± 2.23	0.223
	(-10.00 to -2.00)	(-10.00 to -2.00)	
UDVA (logMAR)	1.61 ± 0.24	1.55 ± 0.27	0.402
	(1.00 - 2.00)	(1.00 - 2.00)	
CDVA (logMAR)	0.02 ± 0.02	0.02 ± 0.01	0.997
	(0.00 to 0.10)	(0.00 to 0.10)	
K (D)	44.76 ± 1.33	44.32 ± 1.64	0.689
	(40.9 – 46.7)	(40.6 - 46.9)	
CCT (µm)	534.71 ± 27.77	526.32 ± 28.01	0.211
	(500 - 604)	(503 - 608)	
Flap Diameter (mm)	8.90 ± 0.24	8.80 ± 0.29	0.915
	(8 - 9)	(8 - 9)	
Flap Thickness (µm)	109.18 ± 3.34	109.53 ± 3.45	0.973
	(100-110)	(100 - 110)	
Optic Zone Diameter (mm)	6.52 ± 0.20	6.56 ± 0.30	0.926
	(6 - 7)	(6 - 7)	
Ablation Depth (µm)	79.57 ± 27.05	79.83 ± 28.09	0.903
	(31 -160)	(29 - 162)	
Residual Stromal Bed Thickness (µm)	324.49 ± 22.48	327.66 ± 22.37	0.399
	(300- 407)	(301 - 412)	

Abbrevations:FS-LASIK; femtosecond-assisted laser in situ keratomileusis, WFG FS-LASIK; wavefront guided femtosecond-assisted laser in situ keratomileusis, D; diopter, SE; spherical equivalent, UDVA; uncorrected distance visual acuity, CDVA; corrected distance visual acuity, K; keratometry, CCT; central corneal thickness, SD; standard deviation.

In respect to postoperative spherical, cylendrical and SE values, UDVA and CDVA, there was no significant difference between the first (FS-LASIK) and second (WFG FS-LASIK) group. Postoperative findings of the patients are shown in Table 2.

Table 2. *Postoperative findings of the patients*

Parameters	FS-LASIK n=110	WFG FS-LASIK n=110	p value
1 month postoperative Spherical Value (D)	-0.04 ± 0.24 (SD) (-1.00 to 0.75)	-0.07 ± 0.23 (SD) (-1.00 to 0.75)	0.285
6 month postoperative Spherical Value (D)	-0.05 ± 0.17 (-1.00 to 0.50)	-0.03 ± 0.17 (-1.00 to 0.50)	0.344
1 month postoperative Cylinderical Value (D)	-0.12 ± 0.21 (-1.00 to 0.00)	-0.11 ± 0.22 (-0.75 to 0.00)	0.505
6 month postoperative Cylinderical Value (D)	-0.06 ± 0.15 (-1.00 to 0.00)	-0.04 ± 0.12 (-0.50 to 0.00)	0.578
1 month postoperative SE Value (D)	-0.07 ± 0.24 (-1.00 to 0.75)	-0.009 ± 0.31 (-1.25 to 0.75)	0.403
6 month postoperative SE Value (D)	-0.06 ± 0.18 (-1.00 to 0.00)	-0.05 ± 0.19 (-1.00 to 0.50)	0.771

1 month postoperative UDVA (logMAR)	0.03 ± 0.05 (0.00 to 0.30)	0.04 ± 0.05 (0.00 to 0.20)	0.889
6 month postoperative UDVA (logMAR)	-0.04 ± 0.06 (-0.10 to 0.20)	-0.04 ± 0.07 (-0.10 to 0.20)	0.921
1 month postoperative CDVA (logMAR)	0.005 ± 0.02 (0.00 to 0.10)	0.006 ± 0.02 (0.00 to 0.10)	0.810
6 month postoperative CDVA (logMAR)	-0.06 ± 0.05 (-0.10 to 0.10)	-0.06 ± 0.06 (-0.10 to 0.10)	0.956

Abbrevations: FS-LASIK; femtosecond-assisted laser in situ keratomileusis, WFG FS-LASIK; wavefront guided femtosecond-assisted laser in situ keratomileusis, D; diopter, SE; spherical equivalent, UDVA; uncorrected distance visual acuity, CDVA; corrected distance visual acuity SD; standard deviation.

The predictability values, efficacy and safety indexes of both groups were high and there was no significant differences between two groups. Predictability, efficacy and safety index of the patients are shown in Table 3.

Table 3. *Predictability, efficacy and safety index of the patients*

Parameters	FS-LASIK n=110	WFG FS-LASIK n=110	p values
1 day postoperative Predictability Value	76.3	76.1	0.640
1 week postoperative Predictability Value	86.4	87.1	0.227
1 month postoperative Predictability Value	91.2	90.8	0.335
3 month postoperative Predictability Value	95.3	95.0	0.771
6 month postoperative Predictability Value	97.2	97.4	0.544
1 day postoperative Efficacy Index	0.86±0.07 (SD) (0.60-1.00)	0.87±0.07 (SD) (0.60-1.00	0.772
1 week postoperative Efficacy Index	0.89±0.07 (SD) (0.60-1.00)	0.89±0.07 (SD) (0.60-1.00)	0.654
1 month postoperative Efficacy Index	0.95±0.08 (SD) (0.70-1.00)	0.96±0.08 (SD) (0.70-1.00)	0.422
3 month postoperative Efficacy Index	1.09±0.10 (SD) (0.60-1.20)	1.1±0.10 (SD) (0.60-1.00)	0.444
6 month postoperative Efficacy Index	1.18±0.09 (SD) (0.60-1.00)	1.17±0.09 (SD) (0.60-1.00)	0.503
1 day postoperative Safety Index	0.96±0.05 (SD) (0.80-1.00)	0.96±0.05 (SD) (0.80-1.00)	0.912
1 week postoperative Safety Index	0.98±0.04 (SD) (0.90-1.00)	0.98±0.04 (SD) (0.90-1.00)	0.924
1 month postoperative Safety Index	1.02±0.06 (SD) (1.00-1.20)	1.02±0.06 (SD) (1.00-1.20)	0.945
3 month postoperative Safety Index	1.10±0.07 (SD) (1.00-1.20)	1.10±0.07 (SD) (1.00-1.20)	0.933
6 month postoperative Safety Index	1.20±0.05 (SD) (1.10-1.30)	1.20±0.05 (SD) (1.10-1.30)	0.889

Abbrevations: FS-LASIK;femtosecond-assisted laser in situ keratomileusis, WFG FS-LASIK; wavefront guided femtosecond-assisted laser in situ keratomileusis, SD; standard deviation

Discussion

Laser refractive surgery represents one of the most remarkable inventions in eye surgery. Since 1990, when the first LASIKprocedure was described, people worldwide have turned to refractive surgery and gave up glasses or contact lenses[11]. Then, LASIK has become a widespread and effective surgical treatment to correct myopia and myopic astigmatism. Like other corneal refractive surgeries such as radial keratotomy and photorefractive keratectomy, it is designed to modify central corneal curvature, making it flatter to correct myopia and steeper to correct hyperopia[12].

Conventional LASIK involved the stromal flap creation with the help of a mechanical microkeratome.It treats lower order or spherocylindrical aberrations like myopia, hyperopia and astigmatism, but it can not correct high-order aberrations which are responsible for poor quality of vision[13,14]. FS-LASIK creates flaps with good predictability of thickness and eliminates flap-related complications[15]. WFG FS-LASIK corrects high-order aberrations such as spherical aberrations, coma and trefoil to increase retinal image resolution, offering a more accurate refractive correction with fewer optical side effects[16].

In this study FS-LASIK procedure is compared with WFG FS-LASIK in respect to predictability, efficacy and safety. The predictability values, efficacy and safety indexes of both groups were high and there was no significant differences between two groups.

Fares[17] et al. reported that metaanalysis showed no clear evidence of a benefit of wavefront-guided over non-wavefront-guided ablations. However, there was a lack of standardized reporting of UDVA better than 20/20, which might mark an advantage in wavefront-guided treatment. With high preexisting HOAs, wavefront-guided has advantages over non-wavefront-guided treatment. Keir[18] et al. observed that despite an increase in higher-order aberrations, wavefront-guided LASIK yields excellent visual acuity and contrast sensitivity. Spherical aberration, which increases the most following non-wavefront-guided LASIK, showed no significant change. Liu[19] et al. stated that four-year follow-up outcomes indicated that the myopic patients after LASIK had the long-term stable corneal aberration and satisfaction of daily visual functions. Vongthongsri[20] found that LASIK with both conventional ablation and wavefront-guided customized ablation resulted in the same BSCVA 1 month after LASIK. Preoperative and 1-month postoperative high-order aberrations were not statistically different following LASIK between ablation types. Caster[21] et al. reported that CustomCornea wavefront-guided LASIK surgery appears safe and effective and provides clinical benefits that appear to exceed those of conventional surgery.

In conclusion, both FS-LASIK and WFG FS-LASIK are efficient, safe and predictable procedures for correction of myopia and myopic astigmatism.

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