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Femtosecond Lasik Versus SMILE for Management of High Myopic Astigmatism: Six Months Outcome

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Abstract

Background: To compare the outcome of femtosecond lasik ablation and small incision lenticule extraction for the management of high myopic astigmatism regarding visual acuity, residual ser and astigmatism pre and postoperative HOAs and TBUT.

Patients and Methods: The visumax surgical platform was used for surgery. The femtosecond laser was used for flap creation in FS - LASIK group and for lenticule creation for the SMILE group. The MEL 90 excimer laser used for ablation in FS - LASIK while manual dissection and extraction of the lenticule in SMILE group patient is examines regularly one, three and six month post surgery.

Visual acuity improved earler in FS-Lasik earler than SMILE group. TBUT worsen in FS-Lasik group more than SMILE group. The postoperative HOAs were higher in smile than LASIK group. There is slight myopic regression in LASIK group also there is hyperopic shift in some patients of l ASIK as an overcorrection.

Results: Postoperative SER improved in both groups. The residual SER in LASIK is –0.05±0.57 and –0.25±0.43D. Both groups got 57.5% 20/20, and for 20/16 30% and 25% respectively. TBUT affected markedly post surgery in LASIK group but improved later while smile did not affected so much. HOAs was above one in smile group while near one in FS-Lasik group.

Conclusion: Both procedures are same effective in management of high myopic astigmatism.

Key Words: *Small incision lenticule extraction – Femtosecond – TBUT – HOAs.*

Introduction

LASIK surgery is the commonest refractive surgery worldwide. Mechanical flap based lasik surgery is good and effective surgery, however the risk of flap complication using the microkeratome is high like incomplete cut, button hole, free cap, and irregular flap. FS-Lasik based flap is bladeless surgery which is infrared wave light followed by reshaping of the cornea using excimer laser which is ultraviolet wave light. FS-LASIK surgery is a safe, effective surgery with a high predictability. However the flap manipulation problems still existing like flap epithelial down growth. Moreover other side effects like dry eye and the range of refractive correction in high myopia is not solved yet **[1-8]**. Smile is a different technique of refractive surgery which is based on the creation of small lenticule in the corneal stroma followed by manual excision of the lenticule through a small corneal incision. The first surgery of smile was in 2011. The smile works successfully on dry eye, moreover it has an extended range in high myopia but with more extended recovery time **[9-11]**. Both (FS-LASIK) and (SMILE) are a preferred choice for the refractive surgeons especially in high myopia **[12]**. This study will evaluate the effect of both FS-Lasik and smile on high myopia astigmatism patients.

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Patients and Methods

This is a prospective comparative controlled study contain two groups. FS-Lasik group has forty eyes of twenty three patients and forty eyes of twenty five patients in smile group. All surgeries were on 2017. The surgeries were at the cornea and refractive unit of the specialized eye hospital between 2018-2019. The follow-up period was six months. The study adhered to the tenets of the Declaration of Helsinki. An informed consent obtained from each patient after explaining the refractive errors of his or her eye or eyes, the surgical steps, the postoperative recovery time, and the postoperative medications. after preoperative investigations and eligibility for surgery.

Inclusion criteria: Include myopia with SER range –6.00 to –9.00 D and astigmatism below

–3.00 D. Age 18-29 years with stable refraction for at least one year. All patients should have the cornea with a residual stromal bed 280µm. All patient should complete the six months follow-up period. All patients should have preoperative CDVA of 20/20. Emmetropia was the target of the study.

Exclusion criteria: Include anisometropia, amblyopia, one eye patients, corneal dystrophy, formefrustekeratoconus, pellucid marginal degeneration, severe dry eye syndrome and previous corneal or intraocular surgery. Patients with cataract, diabetic retinopathy, maculopathy and retinopathy, eye lid disorders, glaucoma, tissue collagen diseases and any systemic disease affect the ocular tissue all are excluded from the study. Full detailed examinations performed for all patients preoperatively and at postoperatively, one day, one week, one months, three months, and six months. Examinations included the uncorrected and corrected distance visual acuity (UDVA) and (CDVA), manifest and cycloplegic refraction, slit-lamp examination (Haag-Streit, Köniz, Switzerland), slit-lamp biomicroscopy, fundus examination, corneal epithelium assessment by fluorescein staining, tear breakup time, Schirmer I test, intraocular pressure measurement (noncontact tonometer; NT-530, NCT Nidek Co., Ltd., Japan), central corneal thickness (CCT) using ultrasound pachymetry (UP-1000; Nidek), Corneal wave front,and Scheimpflug-based corneal topography (Pentacam HR, Oculus, Wetzlar, Germany). All patients instructed to discontinue contact lens wearing three weeks before assessment and before the surgical procedure. Visual acuity was measured at 6 meters using Snellen chart and converted to the log MAR scale for statistical analysis.

Procedures:

Visu Maxplatform which contain femtosecond laser system and excimer laser Mel 90 system (Carl Zeiss Meditec, Jena, Germany) was used for all procedures. All surgeries performed using topical anesthesia (oxybuprocaine hydrochloride) installed twice three minutes prior to surgery. In FS-Lasik group FS used to create the flaps with the following parameters, flap diameter is 8.5mm,flap thickness is 100 micron, hinge at 90 degree with 4mm length, side cut angle is 90 degree and optical zone is 6.5mm. Followed by flap elevation and applying excimer laser with Triple A algorithm using the eye tracker and iris registration. Followed by stromal bed wash by BSS, reposition of the flap and applying the therapeutic contact lens. In the smile group FS laser used to create the lenticule with the following parameter, the lenticule diameter is about 6.5mm, the cap diameter is 7.5mm at a 120µm depth. A 90° single-sidecut, with a length of 2mm. the was requested to fixate light target before suction initiation, the posterior surface of the lenticule was cut from periphery to center followed by cutting the anterior surface from center to periphery. A special spatula is used to separate the lenticule from the surrounding followed by removal of the lenticule using a smile forceps. After surgery, all patients given topical fluorometholone 0.1% four times daily for 1 week, followed by a reduced dosage of once daily per week, and levofloxacin 0.3% four times daily for 1 week. Preservative free artificial tears were given four times a day for six months.

Statistical analysis:

Data were coded and entered using the statistical package for the Social Sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA). Data was summarized using mean,standard deviation, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between quantitative variables were done using the non-parametric Mann-Whitney test.,For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. p-values less than 0.05 were considered statistically significant.

Results

The mean SER for LASIK is –7.74±0.91D and for smile group –8.11±0.68 D and after surgery it was –0.05±0.57 AND FOR SMILE –0.25±0.43 D for LASIK the preoperative astigmatism was 2.22±0.57 D and for smile it was 2.5±0.41 D. AND and postoperative astigmatism 0.47±0.25D and for smile it was 0.49±0.20D. preoperative HOAs drop in FS-Lasik group from 0.41±0.04 to 0.93±0.07 while in smile group 0.38±0.02 to 1.00±0.1. The preoperative CDVA WAS 20/20 both groups while the postoperative CDVA by the six month were -0.03±0.05 for FS-Lasik and –0.03±0.04 for smile surgery. UDVA improved in LASIK more than smile for FS-LASIK it was –0.02±0.04, –0.03±0.05, –0.02±0.06 and for smile were 0.12±0.06, 0.00±0.06, –0.01±0.07 Log Mar for the first, third and six months postoperative for the tear break up time it was 12.05±1.66 for FS-LASIK and 12.10±1.52 for smile while it was as follow after surgery 2.97±1.07, 5.43±1.22, 9.48±1.13 for LASIK and 8.05±0.85, 8.73±0.55, 10.57±0.96 for smile one, three and six months after surgery.

Table (1): Comparison between groups.

	FS-LASIK F&S					SMILE F&S					*p*-value
	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	
Age	23.63	3.48	24.00	18.00	29.00	23.40	3.60	23.00	18.00	29.00	0.776
PRE SER	-7.74	0.91	-7.75	-6.00	-9.00	-8.11	0.68	-8.00	-7.00	-9.00	0.064
POST SER	-0.05	0.57	-0.25	-0.75	0.75	-0.25	0.43	-0.50	-0.75	0.50	0.155
PRE ASTIG	2.22	0.57	2.25	1.00	3.00	2.50	0.41	2.50	1.50	3.00	0.029
POST ASTIG	0.47	0.25	0.50	0.25	1.00	0.49	0.20	0.50	0.25	1.00	0.560
PRE AXIS	117.17	52.32	130.00	10.00	180.00	119.00	52.88	115.00	5.00	180.00	0.881
PRE HOAs	0.41	0.04	0.40	0.33	0.50	0.38	0.02	0.38	0.33	0.40	0.003
POST HOAs	0.93	0.07	0.92	0.80	1.12	1.00	0.10	0.98	0.82	1.33	0.002
PRE CDVA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.000
POST CDVA	-0.03	0.05	0.00	-0.10	0.00	-0.03	0.04	0.00	-0.10	0.00	0.332
UDVA1	-0.02	0.04	0.00	0.00	-0.10	0.12	0.06	0.10	0.20	0.00	<0.001
UDVA3	-0.03	0.05	0.00	0.00	-0.10	0.00	0.06	0.00	0.10	-0.10	0.010
UDVA6	-0.02	0.06	0.00	0.10	-0.10	-0.01	0.07	0.00	0.10	-0.10	0.494
TBUT Pre	12.05	1.66	12.00	10.00	14.00	12.10	1.52	12.00	10.00	15.00	0.832
TBUT1	2.97	1.07	3.00	1.00	5.00	8.05	0.85	8.00	7.00	9.00	<0.001
TBUT3	5.43	1.22	5.00	3.00	8.00	8.73	0.55	9.00	8.00	10.00	<0.001
TBUT6	9.48	1.13	9.00	8.00	12.00	10.57	0.96	11.00	9.00	14.00	<0.001

Table (2): Changes of astigmatic axis by degree.

	FS-LASIK F&S		SMILE F&S		*p*-value
	Count	%	Count	%	
Gender:					
M	18	45.0	18	45.0	1
F	22	55.0	22	55.0	
GAIN 1:					
Yes	12	30.0	10	25.0	0.617
No	28	70.0	30	75.0	
LOST 1:					
Yes	5	12.5	8	20.0	0.363
No	35	87.5	32	80.0	
POST AXIS CHANGES:					
-25	2	5.0	6	15.0	0.005
-20	3	7.5	4	10.0	
-15	1	2.5	3	7.5	
-10	7	17.5	3	7.5	
-5	4	10.0	0	0.0	
0	1	2.5	0	0.0	
5	8	20.0	0	0.0	
10	6	15.0	4	10.0	
15	3	7.5	7	17.5	
20	2	5.0	6	15.0	
25	3	7.5	7	17.5	

Table (3): Visual outcome two groups.

	FS-LASIK F&S		SMILE F&S		*p*-value
	Count	%	Count	%	
PRE CDVA:					
20/20	40	100.0	40	100.0	–
POST CDVA:					
20/16	14	35.0	10	25.0	0.329
20/20	26	65.0	30	75.0	
UDVA1:					
20/16	10	25.0	0	0.0	< 0.001
20/20	30	75.0	5	12.5	
20/25	0	0.0	23	57.5	
20/32	0	0.0	12	30.0	
UDVA3:					
20/16	12	30.0	6	15.0	0.009
20/20	28	70.0	27	67.5	
20/25	0	0.0	7	17.5	
UDVA6:					
20/16	12	30.0	10	25.0	0.773
20/20	23	57.5	23	57.5	
20/25	5	12.5	7	17.5	
POST ASTIG:					
0.25	18	45.0	12	30.0	0.247
0.50	11	27.5	19	47.5	
0.75	8	20.0	8	20.0	
1.00	3	7.5	1	2.5	
RESIDUAL ERORR:					
-1.00 TO -0.50	7	17.5	6	15.0	0.028
-0.50 TO -O.14	16	40.0	24	60.0	
-0.13 TO +0.13	0	0.0	0	0.0	
+0.14 TO +0.50	10	25.0	10	25.0	
+0.50 TO +1	7	17.5	0	0.0	
RESIDUAL ERORR details:					
-0.75	7	17.5	6	15.0	0.089
-0.50	10	25.0	15	37.5	
-0.25	6	15.0	9	22.5	
0.25	2	5.0	3	7.5	
0.50	8	20.0	7	17.5	
0.75	7	17.5	0	0.0	

Discussion

In this study the UDVA improved so much in both groups **[13,14]**. We noticed fast improvement of UDVA in lasik group compared to smile group starting from the second postoperative day. Most of patients of lasik group reach stability of visual acuity by the first postoperative month 75% 20/20 and 25% 20/16 while in smile group they reach the same results by the third month 17.5% 20/25, 67.5% 20/20 and15% 20/16. The two groups did not show loss of one or two lines of CDVA. By the sixth month the UDVA was 12.5% and 17.5% of lasik and smile group respectively got 20/25, 57.5% of both groups got 20/20 and 30% and 25% of both got 20/16.

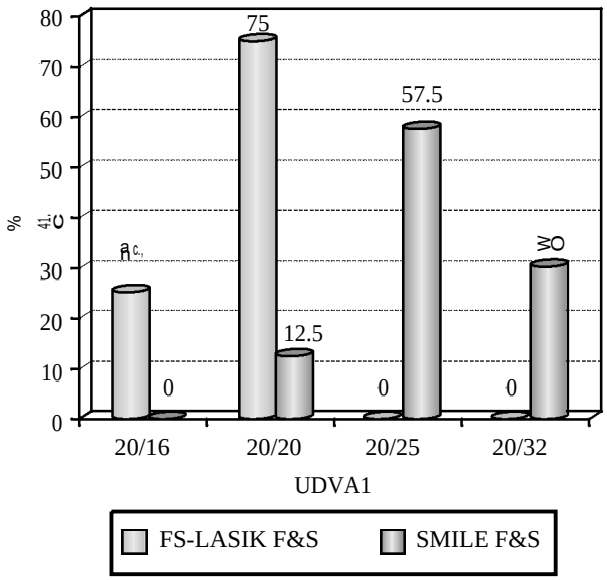

Fig. (1): UDVA one month.

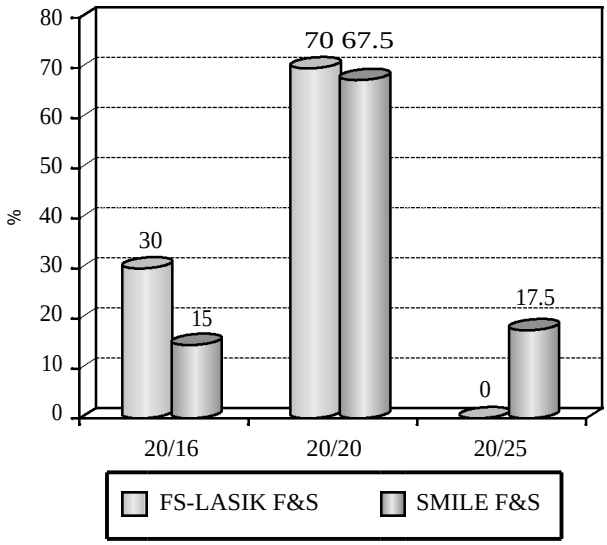

Fig. (2): UDVA three months.

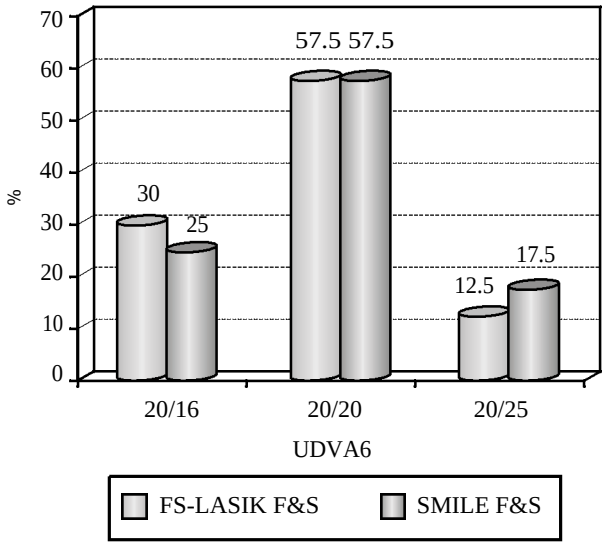

Fig. (3): UDVA six months.

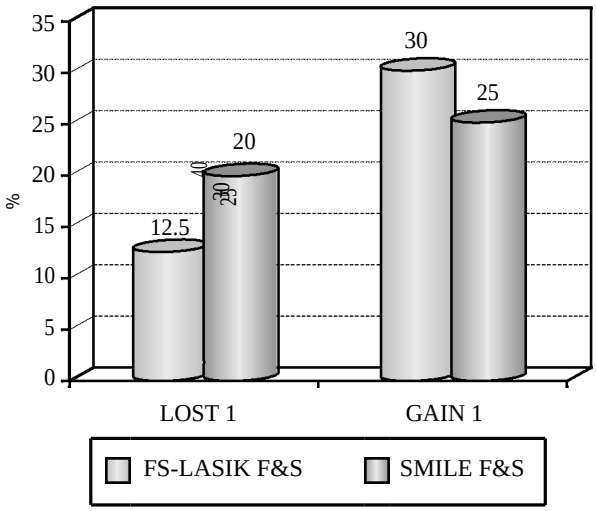

Fig. (4): Gain and lost lines of UDVA.

Moreover the efficacy, safety, and predictability of both groups were high and close to each other **[15-19]**. Regarding the residual SE in both groups it is noticed that almost there is a significant difference by the six month, however slight tendency toward regression noticed in the femtosecond laser group of lasik group 65% were ±0.50 while 17% were up –1.00 while in smile group 85% were ±0.50 and 15% up to –0.75. Previous studies have revealed that myopic shifting and regression may occur following LASIK, especially in patients who have undergone a high degree of myopia correction **[20-22]**. It is noticed also that the postoperative residual astigmatism was better in smile group. Residual astigmatism was 72.5% 0.50 and 100% up to one diopter while in smile 77.5% was 0.50 and 100% up to one diopter. However certain studies reported that smile has a higher ability to correct higher degrees of astigmatism **[23-25]**.

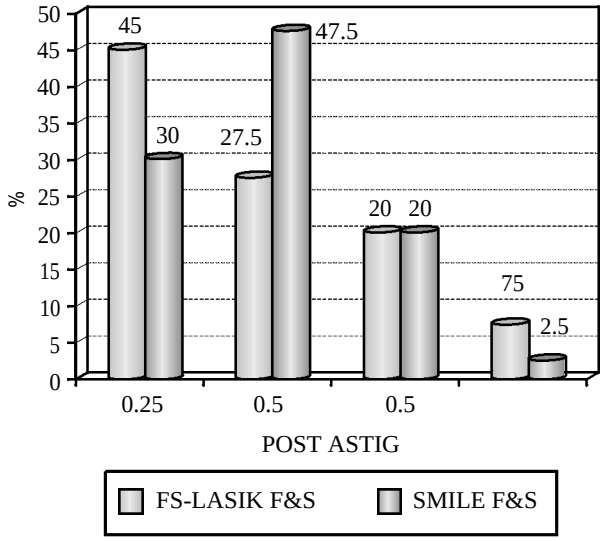

Fig. (5): Residual astigmatism.

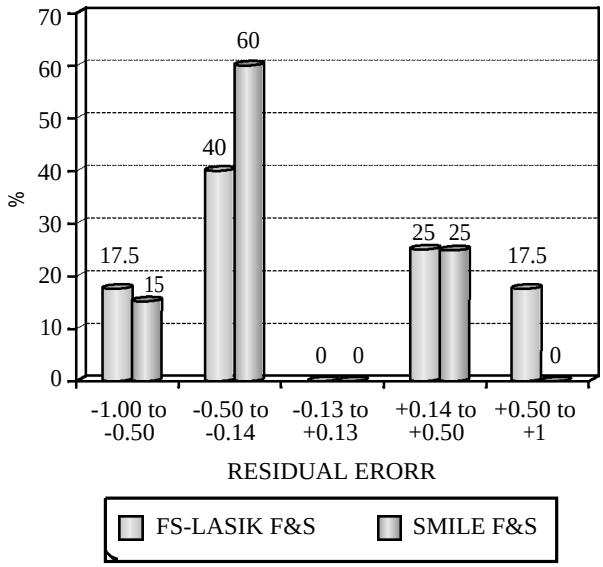

Fig. (6): Residual erorr

The achieved SER was so close to the attempted SER but a tendency to overcorrection noticed in FS-LASIK group and could be attributed to long procedure time with corresponding dryness of the corneal stroma and changes in the ablation depth which end by more ablation of the stroma than the planned one and corresponding overcorrection 37.5% of FS-Lasik group were 0.50 or more. However a major difference in tear break up time and dryness noticed between the two groups. TBUT was markedly affected in the first month improved by the the third month and reach close to normal by the six month in FS-Lasik while it is affected in the first month of smile and near normal in the following. The FS-Lasik group develop more dryness and last near six month compared to smile group. Regarding HOAs it was challenging due to many factors. However, most of HOAs in smile group were related to incomplete dissection and removal of the lenticule also decantation of the lenticule creation and that could be related to many factors regarding the fixation of the patients and the surgical procedure. However due to eye tracker and iris registration the possibility of decantation is null in FS-Lasik, but other factors related to the flap, hinge, and ablation zone affect the HOAs directly.

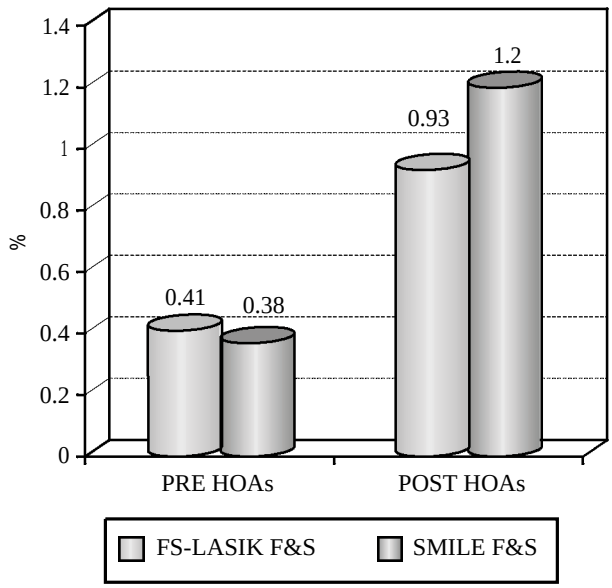

Fig. (7): Pre and post HOAs.

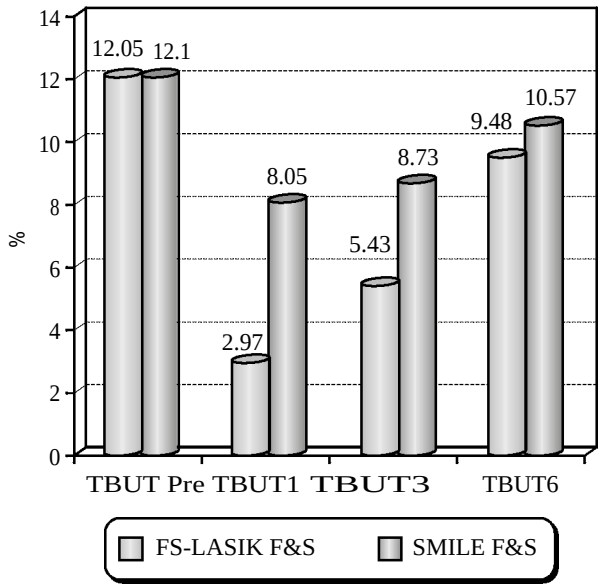

Fig. (8): Tear break up time.

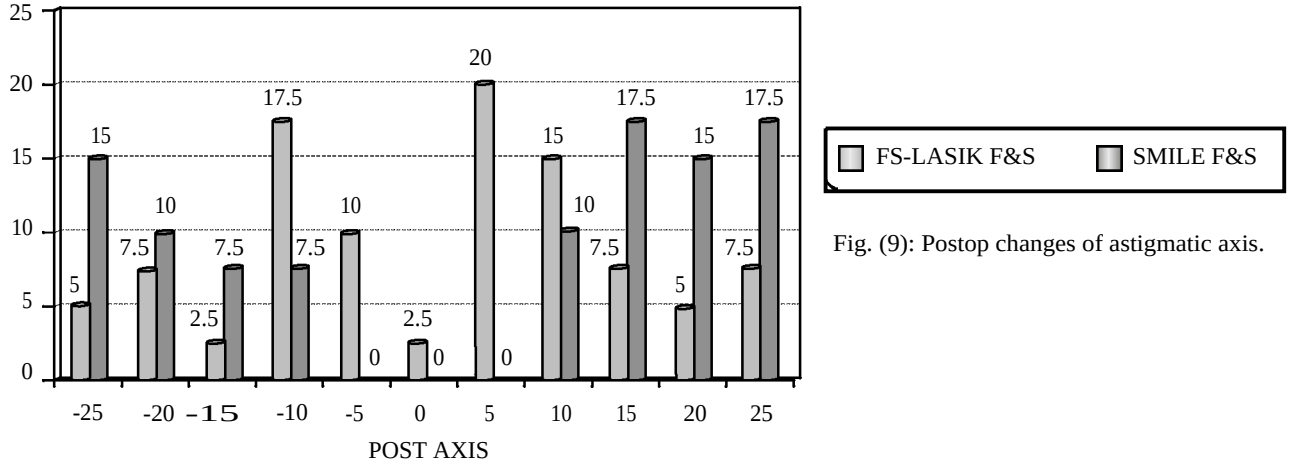

Fig. (9): Postop changes of astigmatic axis.

One study compared higher-order aberrations (HOAs) between SMILE and LASIK groups and found that spherical, coma, and total HOAs were significantly lower in the SMILE group than in the LASIK group **[13]**. Another study also compared HOAs and contrast sensitivity between the two groups and found that postoperative HOAs were significantly lower and contrast sensitivity was significantly better in the SMILE group compared with the LASIK group **[18]**. However increased HOA is a known cause of night vision disturbances such as glare, halos, and decreased contrast sensitivity **[26-28]**. Corneal refractive power changes at the peripheral cornea may have affected these differences between the LASIK and SMILE groups. Previous studies have reported that LASIK surgery changed the prolate shape of the cornea to an oblate shape and therefore increased the spherical aberrations after surgery. These changes are considered to be due to decreased ablation efficiency on the peripheral cornea in LASIK surgery. Generally the excimer laser is applied perpendicularly at the central cornea, but not at the peripheral cornea therefore, ablation efficiency is reduced at the peripheral part of the cornea **[29-31]**. Moreover excimer laser ablation is performed after the corneal flap is lifted so water content of the corneal stroma and humidity of the surgical suite could affect ablation efficiency. However SMILE surgery is performed using a femtosecond laser. One of the advantages of FS-Laser is that it can disrupt the corneal tissue accurately at the peripheral cornea **[32-34]**. The technology of Smile is totally different of all used in refractive surgery. As all laser based refractive surgery depend on photoablations, with improvement of the technique efficiency through using wave front guided ablation which is not available in Smile and the introduction of different ablation algorithm that improve the refractive outcome and reduce the aberrations. However with all advancement of laser technique even with femtosecond Lasik still some points not solved. Like the large corneal cut to create the flap and the stromal tissue response to excimer laser and femtosecond laser. Moreover the corneal tissue is exposed to two different laser beam one for flap creation (infrared) and the second for photoablation (ultraviolet). However the situation is different in smile procedure it is only infrared for stromal lenticule creation. The corneal wound is only 2mm, only femtosecond laser is used for creation of the lenticule, and short procedure time relative to FS-Lasik. However the precise centration is notachieved in Smile compared to lasik due to the absence of wave front guided surgery and iris registration technology. To summarize both smile and FS-Lasik are safe, effective and highly predictable in treating myopia. Both procedures are used effectively in treatment of myopic astigmatism especially high myopia. The incidence of complication is very low.

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مقارنة تقنية فمتو سكند ليزك وتقنية سميل لتصحيح الابصار لمرضى قصر النظر العالى

فى هذه الدراسة الإكلينيكية تم تقسيم المرضى إلى مجموعتين وتم علاج كل مجموعة بأحدى التقنيات مع متابعة المرضى لمدة ستة أشهر وتم تقييم نتائج الدراسة بناء على قوة الابصار وسرعة تحسن الرؤية ونسبة جفاف العين ومعدل التشويس البصرى بعد الجراحة ولوحظ أن كلتا التقنيتين آمنتين وفعالتين فى علاج قصر النظر العالى كما تبين سرعة استجابة مرضى فمتو سكند ليزك مقارنة بمرضى سميل كما أن معدلات الجفاف كانت أعلى فى مرضى فمتو سكند ليزك.