

Visumax Femtosecond and MEL90 Excimer Laser Outcome in Mild, Moderate and High Myopic Astigmatism: Six Months Follow-up

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Abstract

Background: Myopia is the most common refractive disorders worldwide. There is progressive demand for myopia correction. The popularity of techniques and the machines is based on the outcome of surgery regarding visual acuity, recovery time and stability of refraction.

Aim of Study: To evaluate the efficacy, safety, predictability, and visual outcome of visumax femtosecond laser and Mel 90 excimer laser for correction of mild, moderate and high myopic astigmatism through six months follow-up.

Patients and Methods: Patients divided into three groups each group has 50 eyes based on refractive errors into mild myopia with SER up to -3.00 D, moderate myopia with SER -3.00 up to -6.00 D and high myopia with SER more than -6.00 up to -9.00 D. All patients selected based on specific criteria and evaluated properly. Preoperative UDVA & CDVA, central corneal thickness, pentacam, wave front, flap thickness and postoperative residual stromal bed thickness, postoperative UDVA one month, three months and six months and the residual SER were recorded. All patients operated using same machines, the visumax femtosecond laser for flap creation and Mel 90 excimer laser for ablation.

Results: Preoperative mean SER were -2.19 ± 0.60 , -4.54 ± 0.87 , -7.94 ± 0.84 D for mild, moderate and high myopia consecutively. The mean UDVA six months post surgery were -0.09 ± 0.05 , -0.05 ± 0.06 , -0.01 ± 0.03 Log MAR for mild, moderate and high myopia groups. The mean preoperative central corneal thicknesses were 547.38 ± 20.59 , 541.30 ± 18.22 and 555.92 ± 9.78 micron for the three groups consequently. The mean postoperative residual stromal bed thicknesses were 407.52 ± 19.85 , 359.12 ± 15.41 and 313.60 ± 15.81 micron for the three groups consecutively.

Conclusion: Visumax femtosecond laser and MEL90 lasik ablation has a high safety and predictability in the three groups. The refraction was stable till the six month follow-up. The visual outcome and refraction were better in mild to moderate myopia than in high myopia. HOAs were higher in high myopia group compared to the other two groups. The triple A algorithm has a minimal ablation depth and low aberrations.

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Introduction

FEMTOSECOND laser-assisted in situ keratomileusis (FS-LASIK) Refractive surgery is becoming increasingly popular for myopic astigmatism correction, among all types of refractive surgeries. Femtosecond laser create flaps were found to be more accurate, reproducible with a uniform thickness and reduced incidence of flap complications like button hole, incomplete flap, decentered flap and other postoperative flap complications. The refraction outcome, safety and visual outcomes of FS-LASIK are highly predictable, with low incidence of visual complications [1-5]. When using femtosecond laser for flap creation, each pulse of the laser causes the generation of a small amount of micro plasma at its focal point in the corneal tissue leading to formation of microscopic gas bubbles and cavitations, which then dissipate into the surrounding tissue [6,7]. FS-LASIK requires two kinds of lasers, a femtosecond laser (wave length in infrared light at 1043nm) for flap creation and an excimer laser (wave length in ultraviolet light at 193nm) for refractive ablation. One unique advantage of femtosecond flap is the fastest recovery period, accurate and uniform thickness with relatively small flap thickness which is considered as a major advantage in highly myopic patients which save the rest of corneal tissue for ablation [8,9]. This prospective clinical study evaluates the Visumax FSL and the Mel 90 excimer laser in treating myopic astigmatism. The study evaluates the outcomes like efficacy, safety, predictability, corneal aberration, flap thickness and refraction. The Triple-A (Advanced Ablation Algorithm) ablation profile (Carl Zeiss Meditec Jena, Germany)

combining minimal ablation depth and less spherical aberration, for patients with high, moderate and low myopic astigmatism. The surgical procedure of combining femtosecond thin flap and the Triple-A profile should be able to correct a wide range of high myopia and thin cornea myopic patients. This prospective study is to investigate the efficacy and safety of thin-flap FS-LASIK with the Triple-A profile for mild, moderate and high myopia correction [10-12].

Patients and Methods

In this prospective case controlled clinical study 150 eyes of 75 patient divided into three groups based on SER. each group has 50 eyes of 25 patients of mild, moderate and high myopic astigmatism. The patients had operated in the specialized eye hospital between 2018 to 2019. The study adhered to the tenets of the Declaration of Helsinki. A detailed informed consent obtained from each patient after explaining the refractive errors of his or her eyes, the surgical steps, the postoperative recovery period, the postoperative medications, and the six months follow-up period. The inclusion criteria were mild myopia up to -3.00 D SER, moderate myopia -3.00 to -6.00 D SER and high myopia > -6.00 D SER [13]. The astigmatism was not more than 2.00 D in all groups. Ages of the patients were more than 18 and less than 30 years with stable refraction for at least one year. All patients should have postoperative cornea with residual stromal bed thickness ≥ 290 μ m [14]. All patients should complete 6 months follow up after surgery. All patients had preoperative CDVA of 20/20. Emmetropia was the target of the study. Exclusion criteria included anisometropia, amblyopia, one eye patients, corneal dystrophy, forme fruste keratoconus, pellucid marginal degeneration, severe dry eye syndrome and previous corneal or intraocular surgery. Patients with cataract, diabetic retinopathy, maculopathy, retinopathy, eye lid disorders, glaucoma, and any systemic diseases affecting the ocular tissue all were 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 and investigations included the uncorrected and corrected distance visual acuity (UDVA) and (CDVA), manifest and cycloplegic refraction, slit-lamp examination (Haag-Streit, K oniz, Switzerland), slit-lamp biomicroscopy, fundus examination, corneal epithelium assessment by fluorescein staining, tear breakup time, Schirmer test, intraocular pressure measurement (noncontact tonometer, NT-530, NCT Nidek

Co, Ltd, Japan), central corneal thickness (CCT) using ultrasound pachymetry (UP1000; Nidek), Corneal aberrations were measured using the Keratron Scout wavefront (Optikon 2000, Italy), and Scheimpflug-based corneal topography using (Pentacam HR, Oculus, Germany). All patients instructed to discontinue contact lens wearing three weeks before assessment and before the procedure. Visual acuity was measured at 6 meters with a Snellen chart and converted to the log MAR scale for statistical analysis. The Carl Zeiss Refractive platform which includes the Visumax femtosecond laser and MEL 90 excimer laser (Carl Zeiss Meditec, Jena, Germany), were used for all FS-LASIK procedures for all patients. All patients had bilateral FS-LASIK on the same day using the Visumax femtosecond laser for flap creation and Mel 90 excimer laser for ablation. The Mel 90 excimer laser has 1024 Hz pupil and limbal tracker that compensates for cyclotorsion and a shot frequency of 500 Hz. All surgeries were wave front guided. The ablation treatment was centered on the visual axis and Emmetropia was aimed for all eyes. Superior-hinged flap parameters were programmed the same for all eyes. Treatment parameters were selected using CRS-Master software (Carl Zeiss Meditec AG), which combines refractive, wave front, topography, and flap parameters through an interactive user interface. The ablation optical zone (OZ) diameter was selected based on the same mesopic pupil diameter obtained from the wavefront analyzer and the software automatically calculates the transition zone up to 2.2mm. The Visumax FSL system was used to create the LASIK flap. The femtosecond laser uses a wavelength of 1043nm, repetition rate of 500kHz, and pulse duration of 220 to 580 femtosecond. One of 3 curved contact glass sizes for the FSL was selected depending on corneal diameter measured with topography system. The recommended minimum corneal diameter was 11.2mm for the small contact glass, 11.7mm for the medium contact glass, and 12.4mm for the large contact glass. One drop of topical anesthesia proparacaine hydrochloride 0.50% (Alcaine) was applied to the eye twice with two minutes interval before starting surgery. Diluted povidone iodine was applied on the lashes and eye lids. A closed loop lid speculum was placed. one drop of diluted povidone iodine is applied to conjunctival sac then wash of conjunctival sac with BSS followed by drying the sac using a micro sponge. All patients had planned a flap with the visumax femtosecond laser (500-kHz). The flap parameters were as follows: 8.5mm flap diameter, 100 μ m flap thickness, 90 $^\circ$ side-cut angles, and 4.0mm hinge length set in a superior orientation.

After the flap was lifted, ablations were performed using the MEL-90 excimer laser with a tissue-saving function (triple-A profile). After surgery, the post-operative topical antibiotic moxifloxacin (vigamox) was applied 4 times a day for 7 days, the topical steroid prednisolone acetate (predforte) 4 times a day for one week and twice a day for the second week, and a preservative free lubricant Propylene glycol (systane ultra) was used four times a day for 6 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 Kruskal-Wallis and Mann-Whitney tests. For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. Correlations between quantitative variables were done using Spearman correlation coefficient. *p*-values less than 0.05 were considered as statistically significant.

Results

The mean ages were 22.16 ± 3.16 , 21.30 ± 1.67 and 24.72 ± 2.47 years for the mild, moderate and high myopia consecutively. Preoperative mean SER were -2.19 ± 0.60 , -4.54 ± 0.87 , -7.94 ± 0.84 D for mild, moderate and high myopia consecutively. The mean UDVA six months post surgery were -0.09 ± 0.05 , -0.05 ± 0.06 , -0.01 ± 0.03 Log MAR for mild, moderate and high myopia groups. The mean preoperative central corneal thicknesses were 547.38 ± 20.59 , 541.30 ± 18.22 and 555.92 ± 9.78

micron. The mean postoperative residual stromal bed thicknesses were 407.52 ± 19.85 , 359.12 ± 15.41 and 313.60 ± 15.81 micron. The mean femtosecond flap thicknesses were 100.40 ± 2.87 , 99.78 ± 2.08 and 100.98 ± 2.11 micron for the three groups consecutively. Preoperative HOAs were 0.36 ± 0.05 , 0.37 ± 0.02 and 0.38 ± 0.02 microns. While the post-operative HOAs were considerably different 0.59 ± 0.05 , 0.70 ± 0.04 and 0.95 ± 0.10 microns for mild, moderate and high myopia consecutively. Regarding the mean ablation depth it was 39.38 ± 11.30 , 81.58 ± 15.70 and 142.20 ± 15.07 micron for the three groups consecutively. By the six month postoperative follow-up the residual errors were as follow in each group: From 0.13 to -0.13 D it was 34% in mild myopia, 32% in moderate myopia and 6% in high myopia. From -0.14 to -0.50 D it was 22%, 24%, and 6% consecutively. From -0.50 to -1.00 D it was 4%, 14% and 26% consecutively. From 0.14 to 0.50 D it was 34%, 10% and 14%. And from 0.50 to 1.00 D it was 6% in mild myopia, 20% in moderate myopia and 24% in high myopia group.

Regarding the postoperative UDVA, for the first month, 54% got 20/20 and 46% got 20/16 in mild myopia group while 66% got 20/20 while 34% got 20/16 in moderate myopia group and in high myopia group 90% got 20/20 and 10% 20/25. For the third month the UDVA were as follow 20% got 20/20, 66% got 20/16 and 14% got 20/12.5 in mild myopia group. The UDVA in moderate myopia were 48% got 20/20, 44% got 20/16 and 8% got 20/12.5. While the UDVA in high myopia 94% were 20/20 and 6% were 20/16. The UDVA at the six month post surgery were as follow, 18% 20/20, 72% 20/16 and 10% 20/12.5 in mild myopia group. The UDVA in moderate myopia group were 52% 20/20, 42% 20/16 and 6% 20/12.5. The High myopia group UDVA were 92% got 20/20 and 8% got 20/16.

Table (1): The Mean values of the three groups.

	Mild myopia										Moderate myopia										High myopia										P - value																																																																																																																																																																																																																		
	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum																																																																																																																																																																																																																								
	Preop SER	-2.19	0.60	-2.25	1.25	-2.75	4.54	0.87	4.50	3.00	5.75	7.94	0.84	8.25	6.00	9.00	<0.001	Preop UCDVA	0.40	0.08	0.40	0.50	0.30	0.73	0.10	0.70	0.90	0.60	0.90	0.08		0.90	1.00	0.80	<0.001	Preop CDVA	0.04	0.05	0.00	0.00	0.1	0.02	0.04	0.00	0.00	0.10	0.00	0.00	0.00	0.00	0.00	0.00	<0.001	One month UCDVA	0.01	0.08	0.00	0.10	0.10	0.03	0.05	0.00	0.00	0.01	0.05	0.05	0.05	0.10	0.00	0.00	<0.001	Three months UCDVA	0.11	0.06	0.10	0.00	0.20	0.06	0.06	0.10	0.00	0.20	0.01	0.02	0.00	0.00	0.10	0.10	<0.001	Six months UCDVA	0.09	0.05	0.10	0.00	0.20	0.05	0.06	0.00	0.00	0.20	0.01	0.03	0.00	0.00	0.10	0.10	<0.001	Preop CCT	547.38	20.59	544.50	516.00	600.00	541.30	18.22	541.00	516.00	575.00	555.92	9.78	559.00	533.00	569.00	<0.001	Postop CCT	407.52	19.85	404.50	371.00	453.00	359.12	15.41	357.50	334.00	403.00	313.66	15.81	312.50	296.00	391.00	<0.001	Flap thickness	100.40	2.87	101.00	94.00	108.00	99.78	2.08	99.00	97.00	105.00	100.98	2.11	101.00	96.00	105.00	0.023	Residual error	0.04	0.24	0.00	0.50	0.50	0.01	0.33	0.00	0.50	0.50	0.04	0.41	0.25	0.50	0.75	0.278	Age	22.16	3.16	21.00	18.00	29.00	21.30	1.87	21.00	18.00	25.00	24.72	2.47	25.00	20.00	29.00	<0.001	Preop HOAs	0.36	0.05	0.37	0.23	0.47	0.37	0.02	0.37	0.32	0.39	0.38	0.02	0.38	0.33	0.40	0.002	Post op HOAs	0.59	0.05	0.60	0.48	0.70	0.70	0.04	0.70	0.57	0.79	0.95	0.10	0.97	0.69	1.23	<0.001	Ablation depth	39.38	11.30	40.50	21.00	57.00	81.58	15.70	81.00	52.00	103.00	142.20	15.07	147.00	109.00

Table (2): The relation between ablation depths and HOAs.

	Mild myopia	Moderate myopia	High myopia
	Post op HOAs	Post op HOAs	Post op HOAs
Correlation	-0.134	0.792	0.602
Coefficient	0.352	<0.001	<0.001
N	50	50	50

Table (3): Residual errors in each group.

	Mild myopia	Moderate myopia	High myopia	P - value			
	Count	%	Count	%	Count	%	
Sex:							
M	22	44.0	20	40.0	22	44.0	0.897
F	28	56.0	30	60.0	28	56.0	
Residual error:							
-0.50	2	4.0	7	14.0	13	26.0	<0.001
-0.50 TO -0.14	11	22.0	12	24.0	15	30.0	
-0.13 TO +0.13	17	34.0	16	32.0	3	6.0	
+0.14 TO +0.50	17	34.0	5	10.0	7	14.0	
+0.50 TO +1	3	6.0	10	20.0	12	24.0	

Discussion

FS-lasik has a high popularity among refractive surgeons due to several advantages like greater options in flap thickness, flap diameter, hinge position and hinge length, stronger flap adherence to stromal bed, lower incidence of complications like epithelial abrasion, button-hole, free cap, irregular cut, flap decentration, better contrast sensitivity and finally fewer induced higher order aberrations [15-17]. The thin flap created by FS-LASIK increases the range of refractive correction and preserves the stromal bed thickness. FS-LASIK is used to correct all grades of myopia, low, moderate and high myopia. MEL 90 excimer laser provides the triple A profile which combines the Tissue Saving Ablation (TSA) profile with the Aberration Smart Ablation (ASA) profile, with corresponding improvement of all myopia outcome especially high myopia, the improvement include less ablation depth, less HOAs, higher safety and higher efficacy of the visual outcome. Moreover, the triple A ablation profile (MEL90) combined with Femtosecond Laser (visumax) are used for correction of high myopic astigmatism successfully [18,19]. Although most of studies concentrate on either low and moderate myopia or high myopia only. This study evaluate the effect of FS-LASIK on the three groups. In this study most patients of mild, moderate and high myopia groups achieved UDVA of 20/20 or more by the end of the first month postoperatively. 100% of patients in group one and two got UDVA of 20/20 or more by the end of first month while 90% of the third group got 20/20 five patients of the third group developed corneal haze, two patient were in grade three and three were in grade two, both grades treated with frequent steroid therapy and the five patients resolved completely by the third month. In other studies on small lenticule extraction SMILE on the same three groups of myopia, patients achieved the same results of UDVA but after more than three months follow-up [20,21]. There is a significant difference in the postoperative UDVA in the three groups. The difference in favor of low myopia more than moderate myopia and in moderate myopia more than high myopia. However no loss of preoperative CDVA in all groups.

Moreover there is a gain of lines of postoperative UDVA compared to preoperative CDVA in all groups which is as follow, in low myopia there is gain of UDVA by one or two lines 82% and in moderate and high myopia 48% and 8% respectively. Regarding the postoperative residual SER by the 6th month follow-up it was noticed that up to $\pm 0.50D$ residual error were 100% in mild and

moderate myopia and 96% in high myopia. While most of refractive results are accepted it is noticed that there a significant difference between achieved and attempted refraction in the three groups more obvious at the high myopia group with tendency near the overcorrection. One study reported that 88.2% patients of high myopia got SER refraction of $\pm 0.50D$ by the six month postoperative follow-up while other study reported that 87% of high myopia patients operated using smile technique got $\pm 0.50D$ by the 6th month follow-up (20,22). Regarding the safety, all the three groups got safety index (postop CDVA/preop CDVA) more than one no lost lines of CDVA. The efficacy index (postop UDVA/preop CDVA) was high in the three groups more than one. There was variability in actual flap thickness in the three groups but it was insignificant. Many studies had reported that HOAs were related to the shadows, halos and night vision glare [23]. In order for HOAs to be significant and to affect the retinal image it should be more than one. Many studies reported that HOAs caused by corneal flap and stromal ablation. The increase of spherical aberration is mainly related to excimer laser ablation, while the increase of coma aberration is related to the decentration of ablation also the increase of coma aberrations after surgery is due to the effect of the flap hinge on the aberrations. Many studies reported that femtosecond flap have less HOAs [24-27]. In the three groups the HOAs were variable, it was low and insignificant in mild myopia and average in moderate myopia group and significantly higher in high myopia group but still below one. Moreover it was noticed that the higher the ablation depth the higher the HOAs values.

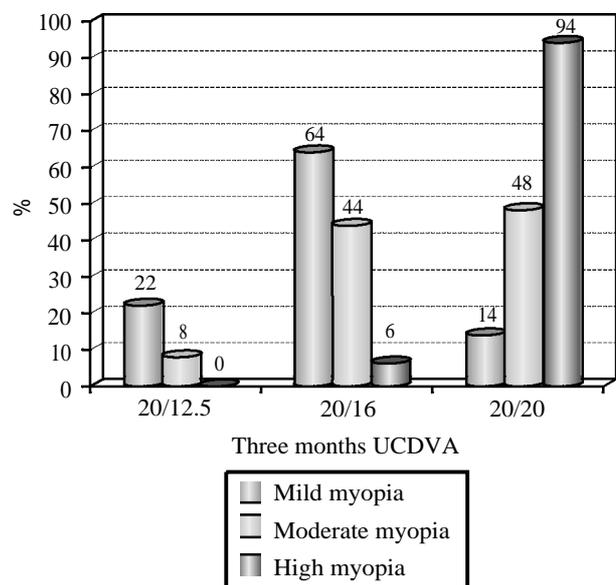


Fig. (1): Three months postop. UDVA.

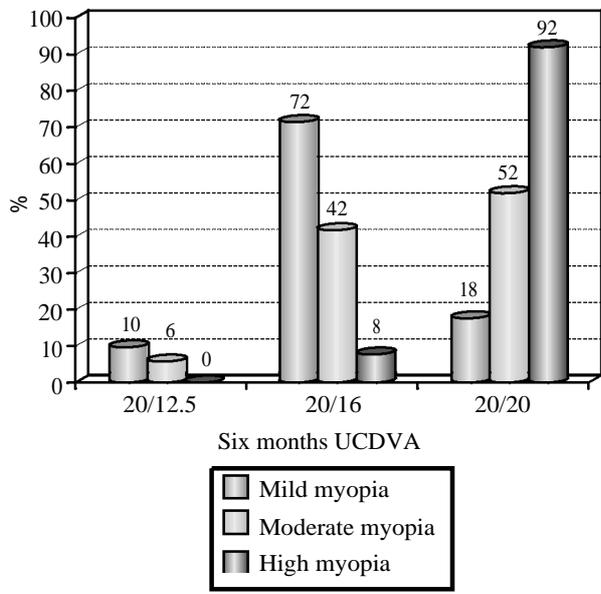


Fig. (2): Six months postop. UDVA.

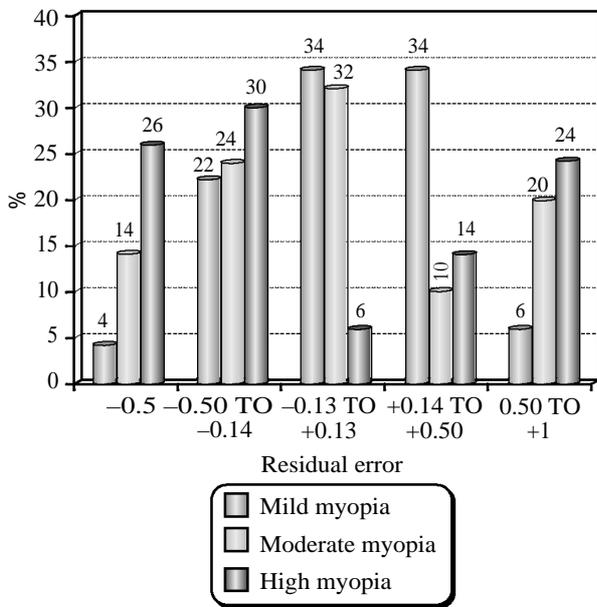


Fig. (3): Residual errors.

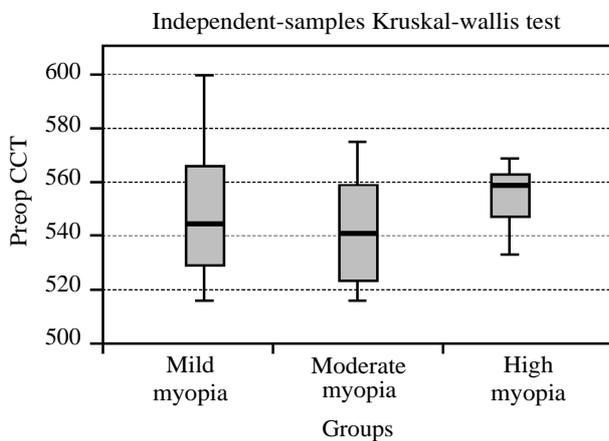


Fig. (4): Preoperative central corneal thickness three groups.

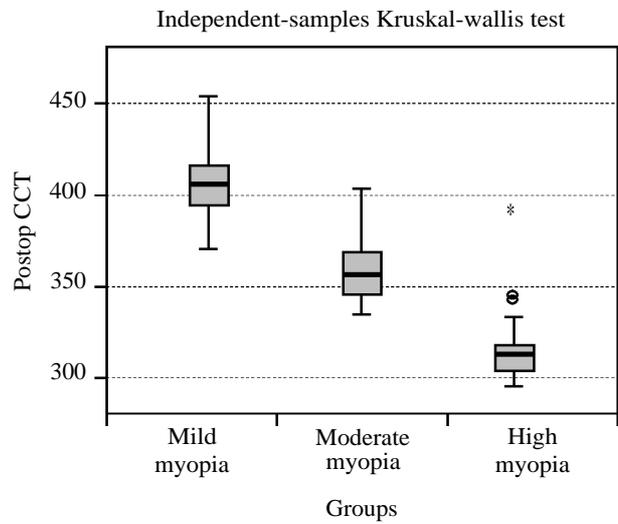


Fig. (5): Residual stromal bed three groups.

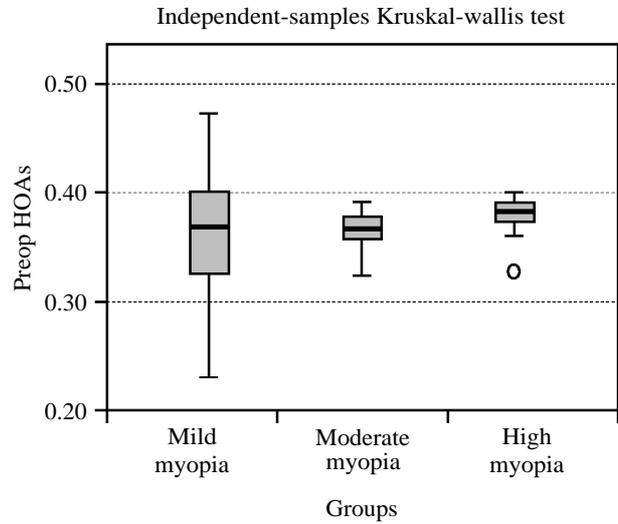


Fig. (6): Preoperative HOAs.

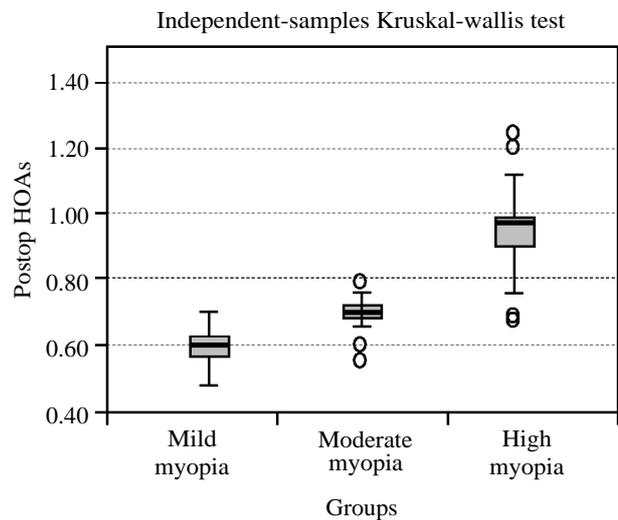


Fig. (7): Postoperative HOAs.

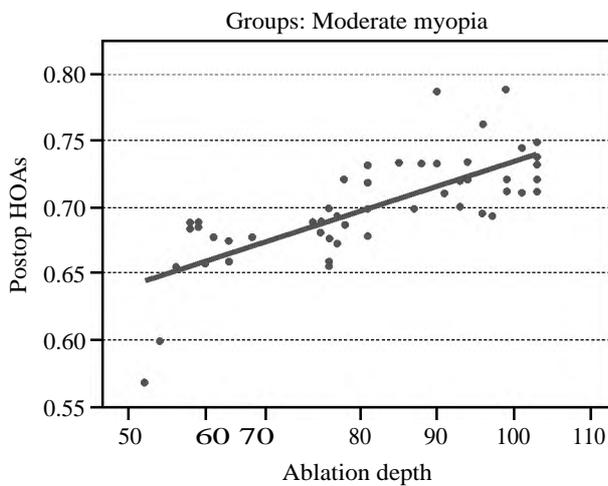


Fig. (8): Relation between ablation depth and HOAs moderate myopia.

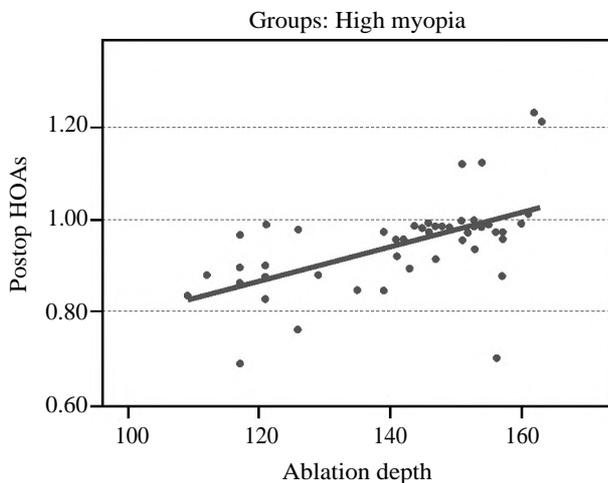


Fig. (9): Relation between ablation depth and HOAs high myopia.

The benefits of triple A algorithm are clear in preserving corneal thickness and minimizing HOAs specially in high myopia. Visumax femtosecond laser has a uniform flap thickness with accurate central flap thickness with minimal deviation [28,29]. No reported major flap complication with visumax femtosecond like button hole, epithelial defect, flap striae and epithelial ingrowth. In addition, corneal optical coherence tomography (OCT) shows that FSLs create more planar flaps with precise flap architecture and uniform thickness.

Conclusion: This study showed the safety and efficacy when using the visumax platform (FS laser and MEL 90 excimer laser) for the correction of mild, moderate and high myopic astigmatism. The triple A with the tissue saving property reduced the ablation depth and corresponding HOAs especially in high myopia. There is still need to increase the group size especially high myopia.

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استخدام تقنية فزيوماكس فمتو سكند ليزك لتصحيح قصر النظر

لقد تم تقسيم المرضى إلى ثلاث مجموعات بناء على درجة قصر النظر وتم إجراء فحوصات ما قبل العملية لجميع المرضى وتم إجراء الجراحة لجميع بنفس الجهاز وتم تقييم النتائج خلال الفترة شهر واحد، ثلاثة أشهر، وستة أشهر بعد الجراحة وتم تقييم قوة الابصار، نسب ضعف الابصار بعد الجراحة نسب تحسن قوة الابصار وكذلك تمت مقارنة النتائج بين المجموعات الثلاثة وخلصت الدراسة إلى أن تقنية فزيوماكس فمتو سكند ليزك آمنة لمرضى قصر النظر بدرجاته الثلاث.