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Comparative Study between Conventional and Custom Lasik Ablation in The Treatment of Myopic Astigmatism

Mohamed El Moddather Ahmed Dardyr*, Ibrahim Mohammed Ahmed, Mohamed Abd Elaal Mohamed
Ophthalmology Department, Faculty of Medicine, Al-Azhar University (Assuit), Egypt
***Corresponding author:** Mohamed El Moddather Ahmed Dardyr, **E-Mail:** almoddather2016@gmail.com

ABSTRACT

Background: The popularity of laser-assisted in situ keratomileusis (LASIK) stems from its ability to treat a wide range of refractive errors with rapid visual recovery and minimal patient discomfort. The conventional treatment is a Munnerlyn based spherocylindrical ablation, Customized Ablation is a topography and wavefront guided ablation treating corneal high-order aberrations

Objective: to evaluate the visual and refractive outcomes of customized ablation and conventional ablation in the treatment of myopic astigmatism**.**

Patients and Methods: This randomized prospective comparative study was carried out on 60 eyes of 34 patients with compound myopic astigmatism (myopic sphere ≤ -10.0 D and myopic cylinder ≤ - 4.0D) with age range between 18 and 50 years at Al-Azhar University Hospital, Assuit and Al-Nahar Eye Centre, Assuit, between April 2018 and October 2018. These patients were divided into two groups: Group (1) included 30 eyes of 18 patients who had Standard LASIK ablation. Group (2) included 30 eyes of 16 patients who had WFG (Custom) LASIK ablation.

Results: Regarding the refractive safety, both procedures were highly safe (all the patients maintained the preoperative BSCVA in the 6th month). It was obvious that the WFG LASIK was superior to the conventional LASIK in the visual outcome and this can be approved by applying the efficacy index for the procedures (mean postoperative UCVA/mean preoperative BSCVA), and it was 1.14 in the custom group and 0.97 in the conventional group in the 1st month. Improving the visual acuity after custom LASIK, in spite of similar refractive results (predictability) indicates that not only the defocus, but also the high order aberrations affect the final visual acuity level.

Conclusion: the two procedures have high degree of safety, refractive stability and predictability but the custom LASIK is superior to the conventional LASIK.

Keywords: Myopic astigmatism, Custom LASIK, Conventional LASIK, Visual quality, High order aberrations.

INTRODUCTION

Corneal refractive surgery is based on the change in corneal curvature to compensate for refractive errors of the eye. After many mechanical approaches, such as radial keratotomy, keratomileusis, and astigmatic keratotomies, ablative procedures using the excimer laser have become the most successful technique. It was mainly the submicron precision and the high repeatability of the ablation of the cornea accompanied by minimal side effects that guaranteed this success [(1)].

More than 20 years have passed since the first excimer laser treatment for the correction of a refractive error was performed. The procedure was done in a myopic patient. Today, although demographic data show there are more hyperopes than myopes, most treatments are myopic or myopic-astigmatic corrections. The classic laser algorithms are based on Munnerlyn's formula for calculating a laser profile and removing a convex–concave tissue lenticules with spherocylindrical surfaces [(2)]. Although these algorithms proved to be effective to compensate for refractive error, the quality of vision deteriorated, especially under mesopic and low-contrast conditions secondary to induced high-order aberrations [(3,4,5,6,7)].

PATIENTS AND METHODS

This study is randomized prospective comparative study.

Ethical considerations: The study protocol and all procedures performed involving human participants were in accordance with the ethical standards of the Faculty of Medicine, Al-Azhar University, Assuit, Egypt. Informed consent was obtained from each patient before the enrollment in the study and Al-Azhar University, Assiut Institutional Ethics Committee approval was obtained.

The current study was randomized prospective comparative study carried on 60 eyes of 34 patients with compound myopic astigmatism (myopic sphere ≤ -10.0 D and myopic cylinder ≤ -4.0D) of 34 patients with age range between 18 and 50 years presented to Al-Azhar University Hospital, Assiut and Al-Nahar Eye Centre, Assuit, between April 2018 and October 2018. The patients were divided into two groups: Group (1) patients in this group had Standard LASIK ablation and Group

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(2) patients in this group had WFG (Custom) LASIK ablation.

Exclusion criteria: Any patient had best corrected visual acuity less than 6/12, patients below 18 or above 50 years old, high myopic astigmatism (in myopic sphere more than -10.00 D and in myopic cylinder more than -4.00 D), mixed astigmatism, previous ocular surgery, intraocular pressure more than 21mmHg, presence of any ocular diseases (adnexa, anterior segment and posterior segment) and any medical contraindications as diabetes mellitus, pregnancy or lactation. We also excluded all patients had intraoperative or postoperative complications like:

- Flap related complications (1 patient, with incomplete cut).
- Interface related complications: DLK (1 eye).
- Missed follow up (2 patients).

Our main target was the evaluation of high order aberrations before and after LASIK treatment in the two groups using ZY WAVE[(3)] aberromter and their reflection on the visual acuity and quality.

Figure (1): ZY WAVE 3 Aberrometer

The **ZY WAVE 3** is a diagnostic device which measures the corneal aberrations from the deviation in light beams reflected off the eye's retina to define the wave front deformation as a function of the position on the pupil. Laser light which scattered on the retina generates the signal data for the calculation of the wave front deformation.

RESULTS

In this study we evaluated 60 eyes; group 1 standard LASIK ablation included 30 eyes of 18 patients and group 2 custom LASIK ablation included 30 eyes of 16 patients.

The age of the patients ranged from 18 – 41years for the 1st group and from 20-43 for the 2nd group. In the 1stgroup the mean age was 26.39 ± 7.23 years. In the 2nd group the mean age was 32.31 ± 7.94 (Table 1).

Table (1): Comparison between conventional and custom groups regarding the age

	Range	Mean± SD
Conventional LASIK	18-41	26.39 ±7.23
Custom LASIK	20-43	32.31 ±7.94

Regarding the sex distribution, in the first group, 38.9 % were males and 61.1% were females. In the second group, 43.8 %were males and 56.3 % were females (Table 2 & chart 1).

Table (2): Sex distribution in conventional and custom groups

	Conventional LASIK		Custom LASIK	
	No.	%	No.	%
Male	7	38.9	7	43.8
Female	11	61.1	9	56.3

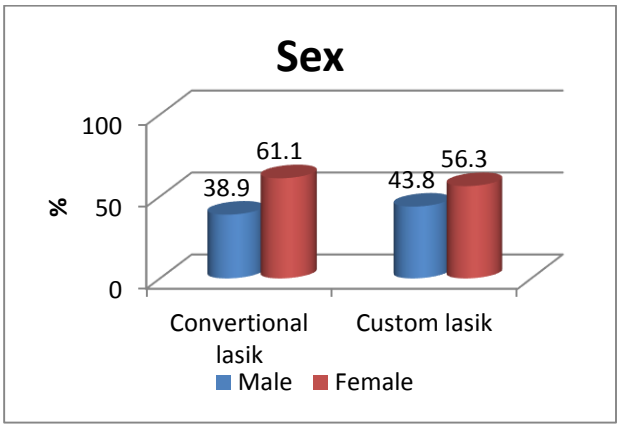

Chart 1: Sex distribution in conventional and custom groups.

Preoperative refraction and visual acuity:

1st group preoperative refraction and visual acuity

The preoperative sphere mean for the conventional ablation group was (-5.83± 2.41D), cylinder mean (-2.05± 0.86D), UCVA mean (0.13± 0.05) and BSCVA mean (0.77± 0.15). (Table 3).

Table 3: 1st group preoperative refraction and visual acuity

Conventional LASIK (n=30)	Range	Mean ±SD
Pre_UCVA	0.05-0.2	0.13±0.05
Pre_BCVA	0.5-1	0.77±0.15
Pre_sphere	-9.25--1.25	-5.83±2.41
Pre_Cylinder	-3.5--0.75	-2.05±0.86

2nd group preoperative refraction and visual acuity:

The preoperative sphere mean for the custom ablation group was (-4.85± 2.48 D), cylinder mean (-2.4± 1.18 D), UCVA mean (0.2± 0.06) and BSCVA mean (0.91± 0.19) (Table 4& chart 2, 3).

Table 4: 2nd group preoperative refraction and visual acuity

Custom LASIK (n=30)	Range	Mean±SD
Pre_UCVA	0.1-0.3	0.2±0.06
Pre_BCVA	0.6-1.2	0.91±0.19
Pre_sphere	-8.75—1	-4.85±2.48
Pre_Cylinder	-4--0.5	-2.4±1.18

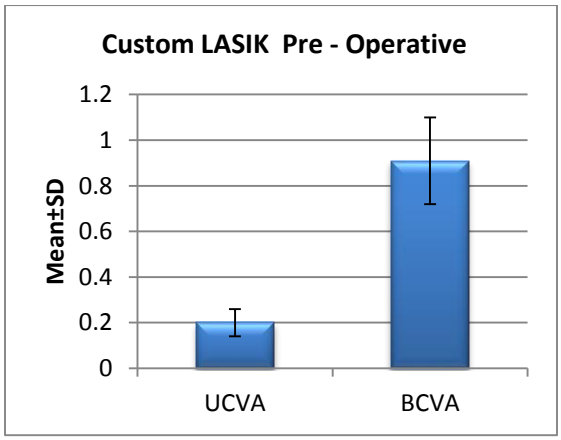

Chart 2: the 2nd group preoperative visual acuity.

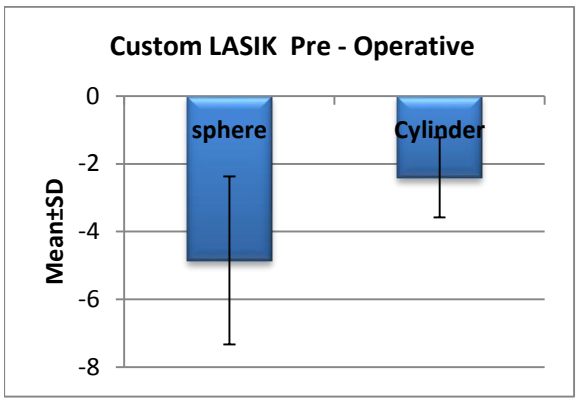

Chart 3 : the 2nd group preoperative refraction

Refractive and visual acuity outcomes:

1st group postoperative refraction and visual acuity:

The 6th month, postoperative sphere mean for the conventional ablation group is (-1.1 ± 0.24 D), cylinder mean (-0.54 ± 0.19 D) and UCVA mean (0.76 ± 0.2) (Table 5). Regarding refractive safety (determined by percentage of the patients who maintain their best corrected visual acuity (BCVA)), all the patients maintained the preoperative BSCVA (safe).

Table 5: 1st group postoperative refraction and visual acuity

Conventional LASIK (n=30)	Range	Mean ±SD
Post_sphere	-0.75--1.50	-1.1±0.24
Post_Cylinder	-0.85--0.25	-0.54±0.19
Post_UCVA1d	0.5-1	0.74±0.16
1w	0.5-1	0.73±0.16
1m	0.5-1	0.75±0.17
3m	0.5-1	0.72±0.16
6m	0.5-1.2	0.76±0.2

The course of the UCVA up to 6 months postoperative is shown in table 6 and chart 7, indicating a little decrease in the early postoperative UCVA from the preoperative BSCVA, then increasing later on to the same level or a little higher than it.

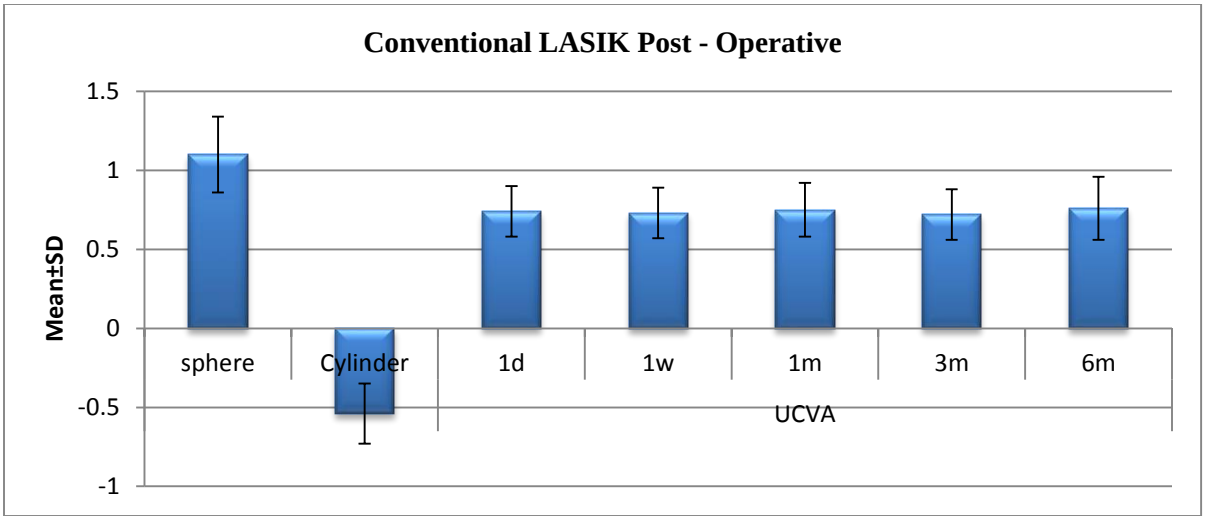

Chart 4 : 1st group postoperative refraction and visual acuity.

2nd group postoperative refraction and visual acuity:

The 6th month, postoperative sphere mean for the custom ablation group is (-0.23 ± 0.3 D), cylinder mean (-0.03 ± 0.37 D) and UCVA mean (1.04 ± 0.11) (Table 6). Regarding safety, all the patients got the preoperative BSCVA or more (safe).

Table 6: 2ndgroup postoperative refraction and visual acuity

Custom LASIK (n=30)	Range	Mean±SD
Post_ sphere	-0.75-0.25	-0.23±0.3
Post_ Cylinder	-0.65-0.5	-0.03±0.37
Post_UCVA1d	0.8-1.2	1.02±0.13
1w	0.8-1.2	1.02±0.12
1m	0.9-1.2	1.04±0.1
	0.9-1.2	1.04±0.11
	0.9-1.2	1.04±0.11

The course of the UCVA up to 6 months postoperative is shown in table 6 and chart 5, indicating a considerable increase in the early postoperative UCVA which remains increasing to get its highest level by the 6 month postoperatively.

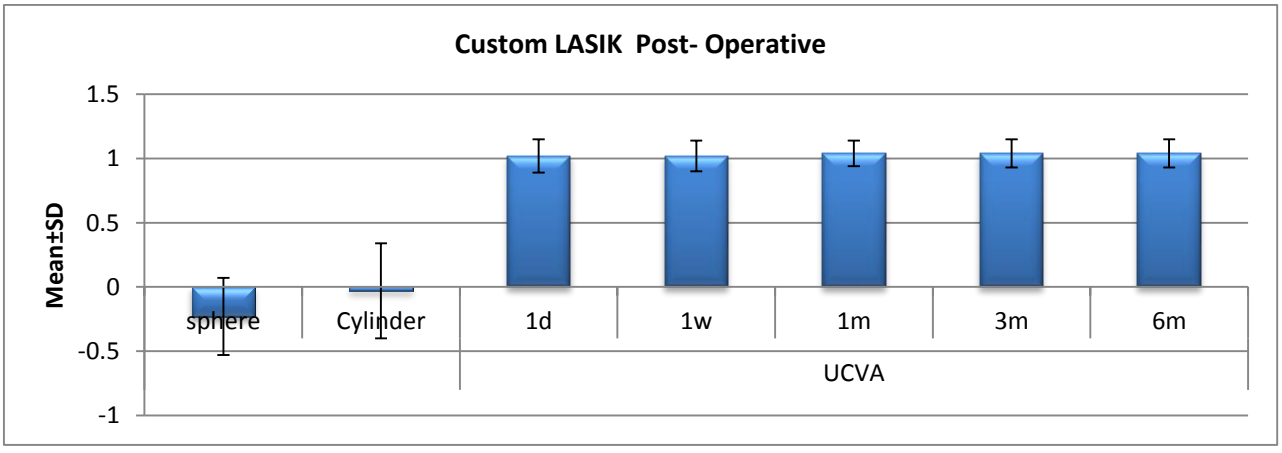

Chart 5 : 2ndgroup postoperative refraction and visual acuity.

High order aberrations:

1st group HOAs:

The preoperative HOAs RMS mean is (0.51 ± 0.18 µm) and the postoperative (6th month) is (0.702 ± 0.199 µm). Preoperative and postoperative individual HOA means are shown in table 7 and chart 6.

Table (7): First group pre- and postoperative HOAs analysis

Conventional LASIK	Pre – Operative		Post – Operative	
	Range	Mean± SD	Range	Mean± SD
RMS	0.19-0.77	0.51±0.18	0.31-1.08	0.7±0.24
COMA	0.01-0.55	0.27±0.17	0.15-0.89	0.54±0.23
SPHAb	-0.15-0.55	0.27±0.2	-0.1-0.88	0.47±0.3
TreFoil	-0.02-0.66	0.33±0.2	-0.12-0.78	0.35±0.31

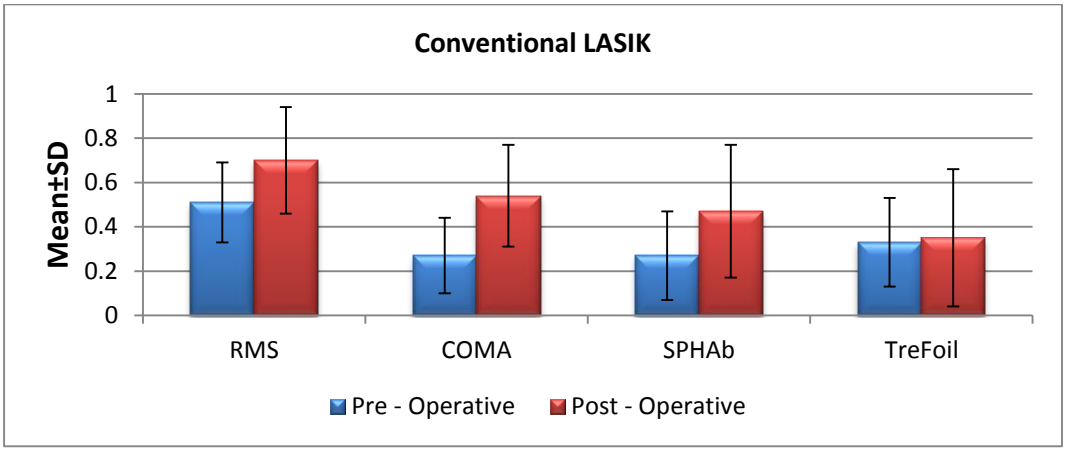

Chart 6: 1st group pre.& postoperative "6th month" HOAs analysis.

The paired "t" test mean analysis (Table 7) between the preoperative and postoperative RMS and individual HOA reveals highly significant increase in the postoperative RMS, COMA and Spherical Aberration, with non-significant increase in the postoperative trefoil.

2nd group HOAs:

The preoperative HOAs RMS mean is (0.53 ± 0.2 µm) and the postoperative (6th month) is (0.59 ± 0.22 µm). Preoperative and postoperative individual HOA means are shown in table 8 and chart 7.

Table 8: 2nd group pre. & postoperative HOAs analysis

Custom LASIK	Pre – Operative		Post – Operative	
	Range	Mean±SD	Range	Mean±SD
RMS	0.19-0.88	0.53±0.2	0.22-0.92	0.59±0.22
COMA	-0.14-0.44	0.15±0.19	-0.21-0.36	0.12±0.15
SPHAb	-0.06-0.29	0.13±0.11	-0.12-0.34	0.11±0.15
TreFoil	-0.55-0.59	0.12±0.32	-0.08-0.12	0.02±0.06

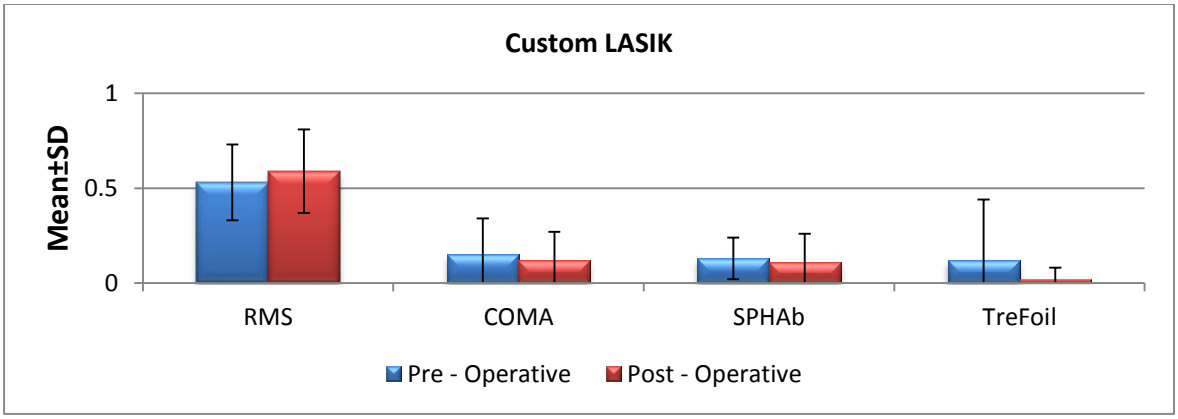

Chart 7: 2nd group pre- & postoperative "6th month" HOAs analysis.

The paired "t" test mean analysis (Table 8) between the preoperative and postoperative RMS and individual HOA reveals non significant increase in the postoperative RMS, while COMA and Spherical Aberration means show low significant decrease. the postoperative trefoil mean reveals significant decrease.

Comparison of pos operative UCVA and HOAs between the two groups

Table 9 and chart 8; show the course of the **UCVA** up to 6 months of the two groups. The 1st group UCVA course is stationary while the 2nd group postoperative UCVA is increasing up to the 6th month. Also show the postoperative **HOAs** mean analysis between the 1st group and 2nd group, which reveals, highly significant differences between the postoperative RMS and individual HOAs although, there are no significant differences between the preoperative ones.

Table 9 : Postoperative visual acuity and HOAs in 1st and2nd group

Post – Operative	Conventional LASIK Mean±SD	Custom LASIK Mean±SD	P .value
UCVA1d	0.74±0.16	1.02±0.13	<0.001**
UCVA1w	0.73±0.16	1.02±0.12	<0.001**
UCVA1m	0.75±0.17	1.04±0.1	<0.001**
UCVA3m	0.72±0.16	1.04±0.11	<0.001**
UCVA6m	0.76±0.2	1.04±0.11	<0.001**
RMS	0.7±0.24	0.59±0.22	0.060
COMA	0.54±0.23	0.12±0.15	<0.001**
SPHAb	0.47±0.3	0.11±0.15	<0.001**
TreFoil	0.35±0.31	0.02±0.06	<0.001**

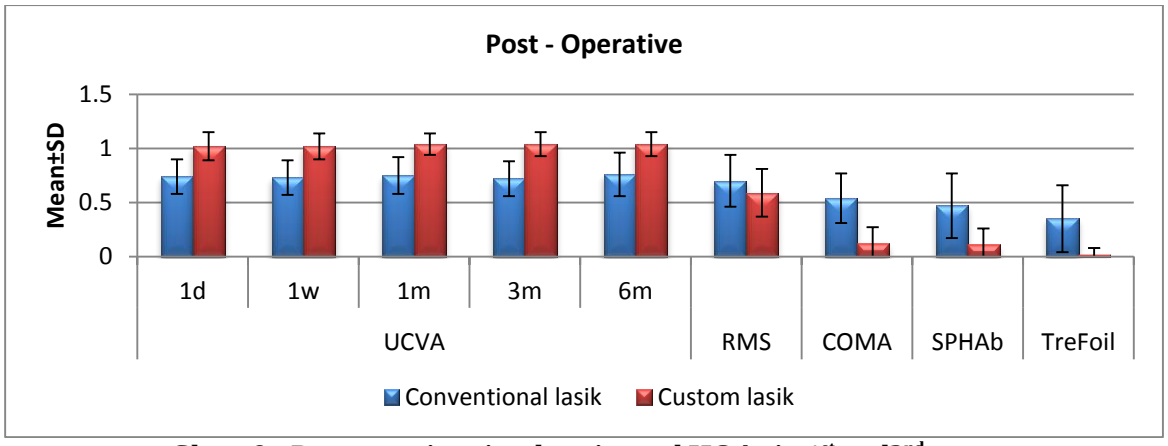

Chart 8 : Postoperative visual acuity and HOAs in 1st and2nd group

Visual Quality:

For night vision problems analysis (questionnaire) between the two groups (Table 10 and chart 9), about 70% of the 1st group complained from night vision problems like haloes, glare and starbursts for 6 months while only 16.7% of the 2nd group had similar complain. This is a highly significant difference using the Pearson Chi-Square test.

Table 10: Night vision problems in the 2 groups.

NVP	Group				P .value
	Conventional lasik		Custom lasik		
	No.	%	No.	%	
	9	30.0	25	83.3	<0.001**
	21	70.0	5	16.7	

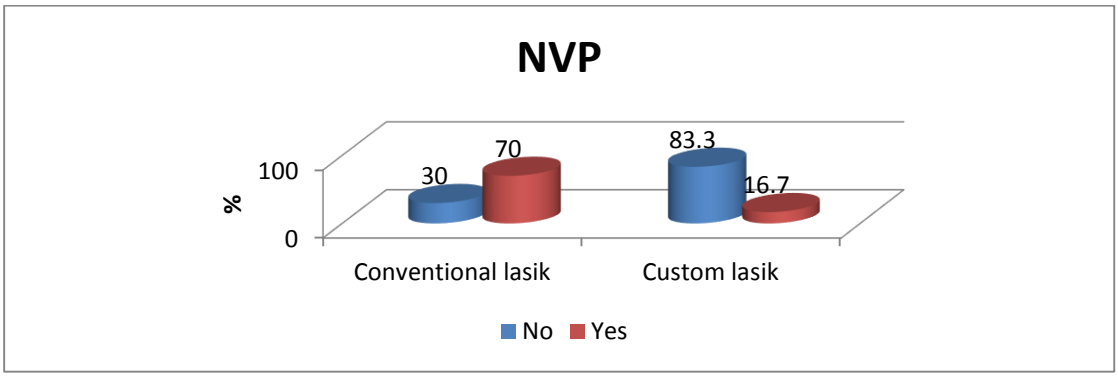

Chart 9 : Night vision problems in the 2 groups.

Regarding patient satisfaction after 1 month of surgery,(questionnaire) like Sharpness &clarity, consistency of vision, overall visual comfort & contrast sensitivity (Table 11 and chart 10) only 13.3% of patients were highly satisfied in the 1st group while about 73.3% were highly satisfied in the 2nd group, and this also is a highly significant difference using the Pearson Chi-Square test.

Table 11: Patient satisfaction in the 2 groups

Satisfaction	Group				P .value
	Conventional LASIK		Custom LASIK		
	No.	%	No.	%	
Low	12	40.0	2	6.7	
Medium	14	46.7	6	20.0	<0.001**
High	4	13.3	22	73.3	

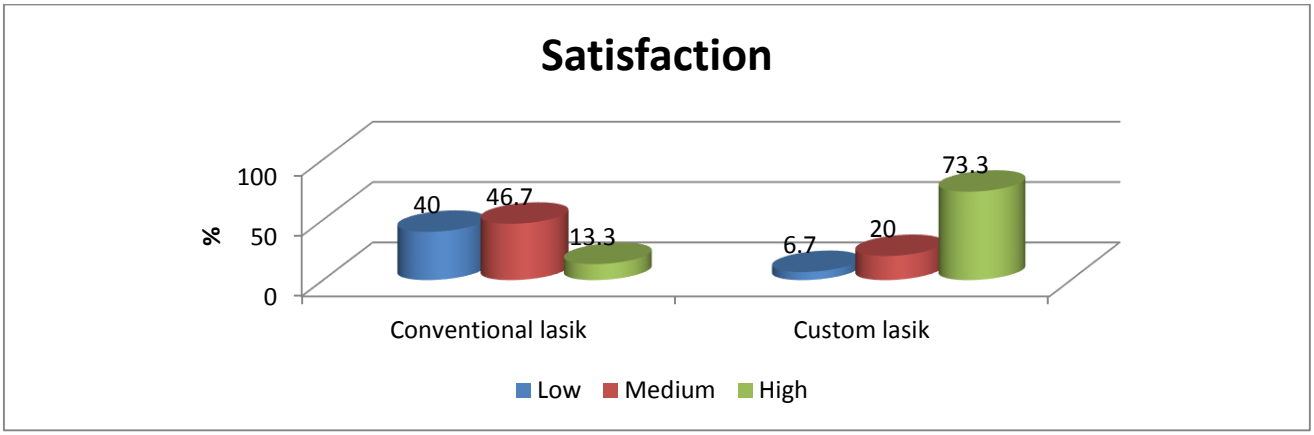

Chart 10: Patient satisfaction in the 2 groups.

DISCUSSION

The aim of our study was comparing the results of Standard versus Custom LASIK ablation in patients with compound myopic astigmatism (sphere≤ -10.0 D& cylinder ≤ -4.0D) range from 18 to 50 years of age.

Although the main purpose of this study was to compare the results of the high order aberrations and their influence on the visual quality, visual acuity and patient satisfaction, we also evaluated both procedures in the scope of basic LASIK parameters (efficacy, safety, predictability and stability).

The efficacy, for the standard group in the 6th month the UCVA ≥ 1.0 was obtained in about (30%) and this is similar to what was obtained by **Zalentein *et al.*** **(2)** (29 %) after long term follow up and for the custom group was (92.9%) and this is similar to what were obtained by **Schallhorn and Venter** **(3)** (92%). Regarding the refractive safety, both procedures were highly safe (all the patients maintained the preoperative BSCVA in the 6th month) and this agrees with the safety of studies by ***Caster et al***[8]for the **two groups**, ***Zalenteinet al*** **(2)** for the conventional group, ***Schallhorn and Venter*** **(3)** for the **custom group**.

Concerning the myopic astigmatism, the6th month postoperative sphere and cylinder means of the **two groups** were < 0.54, similar to what were obtained by ***Zalenteinet al***[2], ***Dougherty and*** **Bains** **(1)**, **Schallhorn and Venter** **(3)** .It was obvious that the **WFG LASIK** is superior to the **conventional LASIK** in the visual outcome and this can be approved by applying the efficacy index for the procedures (mean postoperative UCVA/mean preoperative BSCVA), and it is 1.14 in the **custom group** (higher than what obtained by ***Schallhorn and Venter*** **(3)**"0.96") and 0.97 in the **conventional group** in the 1st month.

Improving the visual acuity after **CUSTOM LASIK**, in spite of similar refractive results (predictability) indicates that not only the defocus, but also the high order aberrations affect the final visual acuity level. Although the **HOAs** major effect is on the visual quality, but we found that they influence greatly the visual acuity as well. We agreed with many studies concerning significant increase in **HOAs** total **RMS** postoperatively in the **conventional group** like ***Caster et al***[1]and ***Kim et al*** **(9)** similar high mean values for postoperative coma (0.54±0.23μm) and postoperative spherical aberration (0.47±0.3μm) of ***Zalenteinet al*** **(2)**. For the **custom group**, ***Kim et al*** **(9)** agreed with us for a non-statistically significant increase in the postoperative total **RMS**. Both ***Slade*** **(10)**and ***Awwad et al*** **(11)** agreed with us in the part that the highest change affects the spherical aberration. We also obtained similar results with ***Awwad et al*** **(11)** concerning that there were decrease in the postoperative trefoil and disagree with it in the point of minimal increase in the postoperative coma as in our result there are no significant changes.

CONCLUSIONS

The two procedures have high degree of safety, refractive stability and predictability but the **custom LASIK**is superior to the **conventional LASIK**. This superiority is mainly due to the significant reduction of the high postoperative high orders aberration in the **custom group**in comparison to **the standard group**which reflected on the visual acuity and quality outcomes being better in the customized patients than the others

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