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RESEARCH ARTICLE

Evaluation of Hinge Position on the Clinical Outcome of Laser in Situ Keratomileusis in Thi-Qar Governorate

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Abstract

Purpose: To compare the difference in the clinical results of LASIK with a nasal and superior corneal flap locations. **Design:** prospective, randomized comparative clinical study is to evaluate the different outcome parameters of Laser In Situ Keratomileusis (LASIK) with nasal and superior hinge locations was carried out from January 2018 to January 2020 .The follow up duration were preoperatively assessed as well as 1 week and 1,3,6 months postoperatively. **Patients and methods:** This study included 1200 eyes of patients(400 female and 200 male), the eyes were randomly assigned to have a nasal or superior hinge flap with 600 eyes in each group. All patients underwent LASIK surgery for correction of myopia and myopic astigmatism using MEL 90 Excimer laser for stromal ablation, Moria M2, SBK microkeratomes were used to create superior and nasal hinged flap. Uncorrected visual acuity (UCVA), Best corrected visual acuity(BCVA) and spherical equivalent (SE) were compared before surgery and 1 week ,1,3 and 6 months after surgery. **Results:** The two groups had been compared regarding the achieved improvement in the UCVA, BCVA, spherical equivalent. There was significant statistical association where P values of paired t test for all of the compared pairs below 0.001, but there is no correlated difference for pre and post-operative in different occasions regarding the best corrected visual acuity, under corrected visual acuity and spherical equivalent, so there is no statistically significant results were found in the most of the compared groups. **Conclusion:** This study compared efficacy, predictability and safety between both groups. The mean UCVA and BSCVA were significantly improved and the mean spherical equivalent was significantly reduced. There were no differences in efficacy, predictability and safety between nasal and superior hinge Flap.

Key words: laser in situ keratomileusis, superior flap, Moria microkeratome, best corrected visual acuity.

1 | INTRODUCTION

Laser in situ keratomileusis (LASIK) is a common ophthalmologic surgical procedure used to correct refractive error. LASIK was patented in 1989 by Dr. Gholam Peyman.(1) This procedure quickly became popular due to decreased time of recovery and post-surgical complications, with no decrease in efficacy.(2) The refractive power of the eye is attributed, in part, to the cornea. It is responsible for about two-thirds of the eye's power of refraction.(3) LASIK alters the cornea's refractive power in myopic, hyperopic, and astigmatic patients. LASIK surgery changes the refractive power of the cornea first by creating a hinged corneal flap from the epithelium, Bowman's membrane, and the superficial part of the corneal stroma. The more posterior layers of the stroma are exposed for ablation treatment. Thus, for a myopic treatment, central corneal curvature is decreased with the ablation, and the total refractive power of the eye decreases to attain emmetropia, or normal vision. Thereby, LASIK corrects for myopia by removing tissue in the center of the cornea, flattening the cornea and decreasing the refractive power of the eye. (4) It is generally indicated in patients with low to moderate myopia, from -0.5 D up to -9.00 D, as these patients have a higher probability of reaching emmetropia.(5) Currently, LASIK is the most common laser treatment for refractive error. In addition to its applications for a wide variety of refractive errors, patients suffer relatively little pain compared with techniques that do not create a flap, with recovery time to baseline being only a few days.(2)(6)(7).

Microkeratome is the basic instrument required to create a uniform and a homogeneous corneal flap by cutting across the stromal corneal lamellae. The cutting action of microkeratome is derived from a blade, which is powered by an electromechanical system (or turbine system). The microkeratome motor is powered through a cable and activated by a foot pedal control. An ideal microkeratome should be simple to assemble and operate, easy to clean and reassemble or readily disposable, allow visibility of the cornea during creation of the flap.(8)

There are several commercially available microkeratome systems with variable flap orientation possible such as:Moria Microkeratome(9), Carriazo -Pendular Microkeratome and Chiron Hansatome. Other microkeratomes with only superior flap orientation such as: Hansatome Microkeratome, or only nasal flap like MK2000 Keratome System.

The location of the hinge determines the orientation of the LASIK flap–which typically is either superior (vertical) or nasal (horizontal). Conflicting reports have been published regarding the exact location of the point of entry, distribution, and orientation of sensory (long ciliary) corneal nerves at the limbus. Based on the greater corneal sensitivity of the nasal and temporal corneal limbus compared with the inferior limbus, corneal innervation has been thought to be the highest in these two areas. (10)

However, creation of the corneal flap is the single most important step in LASIK (11). and flap related complications occur in as many as 5% of cases. (12)

Aim of the Work

The purpose of this study is to prospectively evaluate the different clinical outcome in patients undergoing myopic LASIK who were randomly allocated to nasal hinge or superior-hinge flaps.

2 | PATIENTS AND METHODS

A Prospective randomized comparative clinical study was performed to evaluate the different outcome parameters of Laser in Situ Keratomileusis (LASIK) with superior and nasal hinge locations. The LASIK procedure was performed in Nasiriya

Supplementary information The online version of this article (https://doi.org/10.15520/arjmcs.v8i06.441) contains supplementary material, which is available to authorized users.

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specialized Eye center, Department of ophthalmology , in Thi-qar governorate, Iraq.
The study was performed from January 2018 to February 2020.The Study was carried out on 1200 eyes of 600 patients who underwent LASIK for myopia and myopic astigmatism using MEL 90 Excimer laser for stromal ablation, Moria M2, SBK microkeratomes were used to create superior and nasal hinged flap. All our tests were done preoperatively, 1 week, 1month, 3 months and 6 months after surgery for each eye.

Inclusion criteria:

Patients included were:
1. Age more than 21 years old.
2. Myopia less than -6.5D and astigmatic up to -1.5.
3. Normal corneal topography.
4. Central corneal thickness > 500 microns.
5. A stable refraction for at least 12 months before surgery, according to patients' ophthalmic history.
6. At least one week without using soft contact lenses and three weeks without using hard contact lenses respectively

The patients were classified randomly into two groups:

Group 1 (nasal hinges):
It included 600 eyes of 300 patients for whom a nasal hinged flap LASIK was performed

Group 2 (superior hinges):
It included 600 eyes of 300 patients for whom a superior hinged flap LASIK was performed

Preoperative evaluation:

• Measurement of the BCVA, expressed in the terms of Snellen charts in the form of decimal acuity.
• Slit lamp examination.
• IOP measurement using Goldmann applanation tonometry.
• Fundus examination
• Corneal topography was performed using Sirius tomograph and corneal topographer.

3 | RESULTS

The patients were classified randomly into two groups according to hinge flap position (Nasal and Superior).

Result of group 1 (Nasal Hinge):

This group included 600 eyes of 300 patients (120 males and 180 females). The mean age for these patients at the time of surgery was 23. 13± 3.55 years old (range 21-35 years old). There was significant statistical association where P values of paired t test for most of the compared pairs below 0.05, but the only significant week positive correlation was proved by as significant week correlation for pre-operative and after 1 week of nasal approach in best corrected visual acuity and pre and post-operative after 6 months in spherical equivalent as shown in table (1).

Table(1): *Preoperative ,1 week and 1,3 and 6 months patient data of nasal group. UCVA: Uncorrected Visual Acuity. BCVA: Best Corrected Visual Acuity. S Eq: Spherical Equivalent*

		Mean	S. D	Correlation	Sig.	Paired t	P
UCVA	preoprative-nasal	.1317	.07699	.030	.461	-97.928-	.0001
	After 1 week-nasal	.813	.1545				
	preoprative-nasal	.1317	.07699	.015	.718	-113.780-	.0001
	After 1 month-nasal	.853	.1361				
	preoprative-nasal	.1317	.07699	-.002-	.959	-167.356-	.0001
	After 3 month-nasal	1.120	.1223				
	preoprative-nasal	.1317	.07699	.001	.975	-170.282-	.0001
	After 6 month-nasal	.9467	.08852				
BCVA	preoprative-nasal	.987	.1361	.114	.005	-7.645-	.0001
	After 1 week-nasal	1.040	.1201				
	preoprative-nasal	.987	.1361	-.033-	.417	-13.905-	.0001
	After 1 month-nasal	1.093	.1243				
	preoprative-nasal	.987	.1361	.060	.141	-18.409-	.0001
	After 3 month-nasal	1.120	.1223				
	preoprative-nasal	.987	.1361	-.052-	.203	-10.557-	.0001
	After 6 month-nasal	1.067	.1194				
S.Eq	preoprative-nasal	-4.58333-	1.11958	.037	.366	-85.055-	.0001
	After 1 week-nasal	-.46250-	.437150				
	preoprative-nasal	-4.58333-	1.11958	-.029-	.472	-83.269-	.0001
	After 1 month-nasal	-.40833-	.473013				
	preoprative-nasal	-4.58333-	1.11958	.062	.127	-90.394-	.0001
	After 3 month-nasal	-.42083-	.223755				
	preoprative-nasal	-4.58333-	1.11958	.092	.024	-93.406-	.0001
	After 6 month-nasal	-.31250-	.211200				

Uncorrected Visual Acuity (UCVA):

The mean preoperative UCVA in this group was 0.12 ±0.07 Improvement of the UCVA occurred at the postoperative period to be 0.81 ± 0.15 at the end of the first week, 0.85 ± 0.13 at the end of the first month, 0.90 ± 0.12 at the end of the 3rd month, and finally 0.94 ± 0.08 at 6th month follow-up. The changes in the mean UCVA during the follow-up period were statistically significant (p=0.001 at the whole follow-up period). The maximum improvement was observed at the end of the 6th month postoperatively (Fig.1).

Best Corrected Visual Acuity (BCVA):

The mean preoperative BCVA was 0.98 ± 0.13. Improvement of the BCVA occurred to be 1.04 ± 0.13 at the end of the 1st postoperative week. At the end of the 1st month postoperative the mean BCVA was 1.09 ± 0.12. At the 3rd month the mean BCVA was 1.12 ± 0.12. At the 6 month the mean BCVA was 1.06 ± 0.11. The changes in the BCVA at the postoperative period were statistically significant (p=0.001) (Fig. 1).

Spherical Equivalent (S Eq):

The mean preoperative S EQ was -4.85 ± 1.11. Improvement of the S EQ occurred at the end of the 1st postoperative week to be -0.46 ± 0.43. At the end of the 1st postoperative month the mean S EQ was -0.40 ± 0.47. At the 3rd month the mean S EQ was -0.42 ± 0.22. At the 6 month the mean S EQ was -0.31 ± 0.21. All the changes in the mean Spherical Equivalent were statistically significant (p <0.001 at 1 week, 1, 3 and 6 months) (Fig. 1).

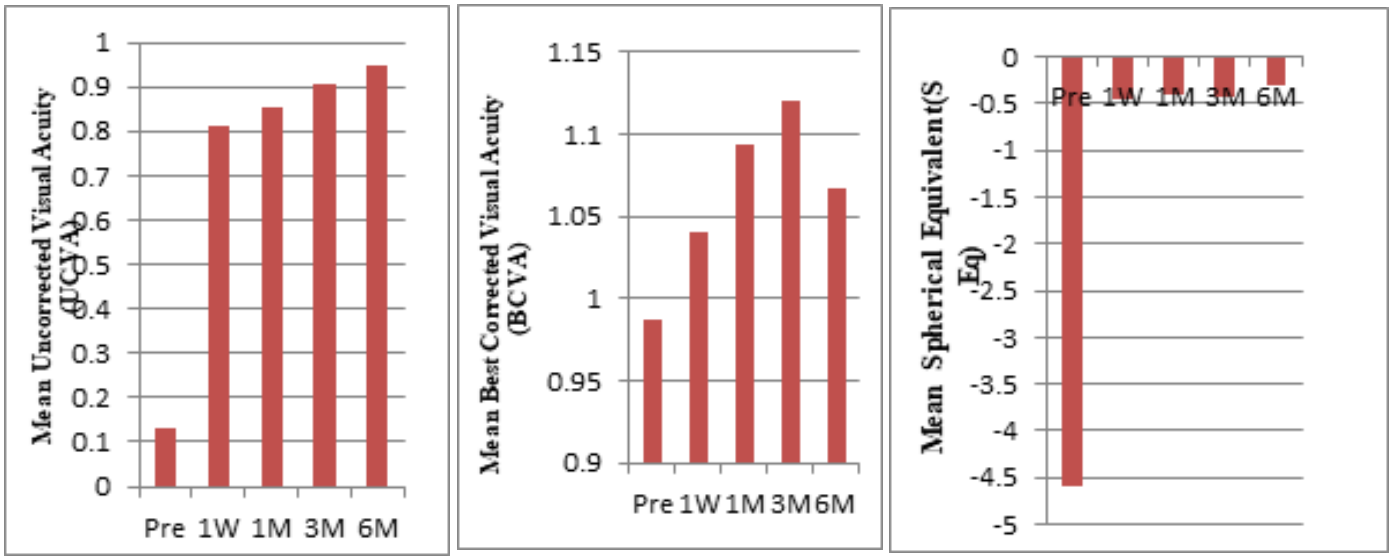

Fig.1: *The Changes in the mean of UCVA, BCVA and spherical equivalent of nasal Group*

SAFETY (Safety Index=1.05):

The safety index is the relation between the mean postoperative BCVA and the mean preoperative BCVA (Mean postoperative BCVA / Mean preoperative BCVA). The higher the index the better the safety. The safety index for nasal group was 1.05 After a period of 6 months follow up on 600 eyes we reported that 100/600 eyes (16.7%) gained 2 lines of BCVA, 140 eyes (23.3%) gained 1 line of BCVA. We reported that 220 eyes (36.7%) did not gain any line of BCVA and 140 eyes (23.3%) lost 1 line of BCVA as shown in table (2).

Table 2: *The lines of BCVA gained or lost by each eye at the end of Postoperative period*

No. of lines Gained or Lost	No. of Eyes	%
2 Lines Gained	100	17%
1 Line Gained	140	23%
No Lines Gained	220	37%
1 Line lost	140	23%

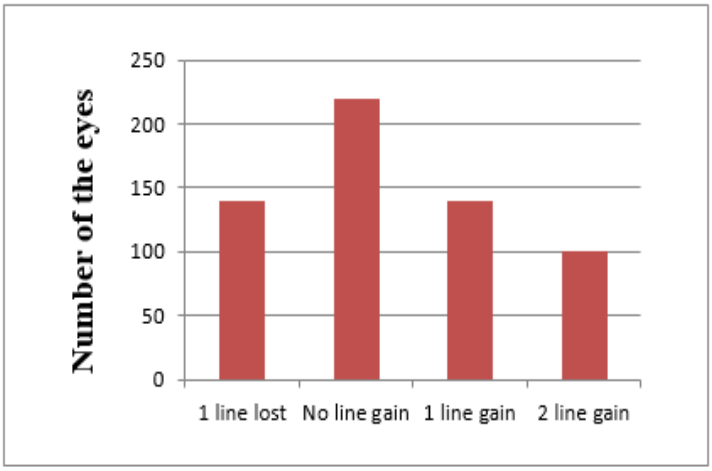

Fig. 2: *The lines of BCVA gained or lost by each eye at the end of the postoperative period.*

EFFICACY (Efficacy Index=0.82):

The efficacy index is a relationship between the mean postoperative UCVA and the mean preoperative BCVA (Mean postoperative UCVA / Mean preoperative BCVA). Efficacy index for the nasal group was 0.82, as the safety index, higher values indicate that the procedure is more efficient as shown in figure 3.

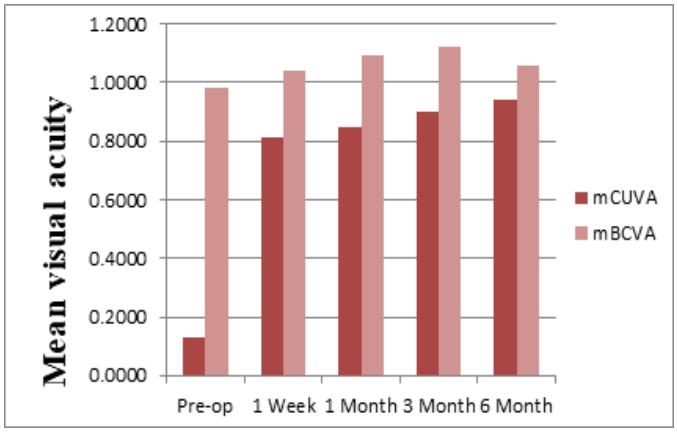

Fig.3: Bar showing the efficacy of the relation between the mean postoperative UCVA and the mean preoperative BCVA at different follow up periods.

4 | PREDICTABILITY:

The predictability of any refractive procedure is determined by the number or percentage of eyes having a desired correction (postoperative spherical equivalent) within ± 0.5-1.0D of the desired preoperative correction (preoperative spherical equivalent).In this group, we reported an improvement of the mean spherical equivalent in the follow up period. This improvement was statistically significant ($p<0.001$) at 1 week, 1, 3 and 6 months, as we obtained a reduction of the mean spherical equivalent from – 4.58D ± 1.11 preoperatively, to –0.031D ± 0.21 at the end of the 6th month

Result of group 2 (Superior Hinge):

This group included 600 eyes of 300 patients (80 males and 220 females). The mean age for these patients at the time of surgery was 27.11± 2.83 years old (range: 23-34 years old). There was significant statistical association where P values of paired t test for all of the compared pairs below 0.001, and there was significant week positive correlation was proved by as significant week correlation for pre-operative and after 1 week, 1 month and 6 month of superior approach in best corrected visual acuity and no correlated difference for pre and post-operative in different occasions regarding the under corrected visual acuity and spherical equivalent.

Table 3: Preoperative, 1 week, 1 month, 3 month and 6 month patient data of superior group UCVA: Uncorrected Visual Acuity. BCVA: Best Corrected Visual Acuity. S Eq: Spherical Equivalent.

		Mean	Std. Deviation	Correlation	Siq.	Paired t	P
UCVA	preoperative-superior	.11300	.052159	.023	.573	-174.027-	.0001
	After 1 week-superior	.960	.1084				
	preoperative-superior	.11300	.052159	.000	.996	-137.821-	.0001
	After 1 month-superior	.973	.1437				
	preoprative-superior	.11300	.052159	-.029-	.480	-145.942-	.0001
	After 3 month-superior	.960	.1307				
	preoprative-superior	.11300	.052159	-.076-	.064	-147.631-	.0001
	After 6 month-superior	1.013	.1361				.
BCVA	preoperative-superior	1.047	.1148	.126	.002	-3.164-	.0001
	After 1 week-superior	1.067	.1194				
	preoperative-superior	1.047	.1148	.161	.000	-9.505-	.0001
	After 1 month-superior	1.107	.1238				.
	preoperative-superior	1.047	.1148	-.005-	.906	-7.495-	.0001
	After 3 month-superior	1.093	.0999				-
	preoprative-superior	1.047	.1148	-.180-	.000	3.040-	.0001
	After 6 month-superior	1.067	.0944				
S.Eq	preoprative-superior	-3.87500-	.837981	-.033-	.425	-82.388-	.0001
	After 1 week-superior	-.48958-	.530916				
	preoprative-superior	-3.87500-	.837981	.043	.288	-94.461-	.0001
	After 1 month-superior	-.49583-	.295139				
	preoprative-superior	-3.87500-	.837981	.036	.384	-101.942-	.0001
	After 3 month-superior	-.25625-	.263834				
	preoprative-superior	-3.87500-	.837981	-.047-	.251	-102.222-	.0001
	After 6 month-superior	-.21458-	.222732				

Uncorrected Visual Acuity (UCVA):

The mean preoperative UCVA in this group was 0.11 ±0.05. Improvement of the UCVA occurred at the postoperative period to be 0.96 ± 0.10 at the end of the 1st week, 0.97 ± 0.14 at the end of the 1st month, 0.96 ± 0.13 at the end of the 3rd month, and finally 1.01 ± 0.13 at 6th month follow-up. The changes in the mean UCVA during the follow-up period were statistically significant ($p<0.001$ at the whole follow-up period). The maximum improvement was observed at the end of 6th month postoperatively.as shown in Fig.4.

Best Corrected Visual Acuity (BCVA):

The mean preoperative BCVA was 1.04 ± 0.11. Improvement of the BCVA occurred to be 1.06 ± 0.11 at the end of the first postoperative week. At the end of the first postoperative month the mean BCVA was 1.10 ± 0.12. At the 3rd month the mean BCVA was 1.09 ± 0. 09. At the end of 6th month postoperatively the mean BCVA was 1.06 ± 0.09 as shown in Fig.4.

Spherical Equivalent (S Eq):

The mean preoperative S EQ was -3.87 ± 0.83. Improvement of the S EQ occurred at the end of the 1st postoperative week to be -0.49 ± 0.53. At the end of the 1st postoperative month the mean S EQ was -0.49 ± 0.29. At the 3rd month the mean S EQ was -0.25 ± 0.26. At the 6 month the mean S EQ was -0.21 ± 0.22. All the changes in the mean Spherical Equivalent were statistically significant (p= <0.001 at 1 week, 1month 3months and 6 months) (Fig. 4).

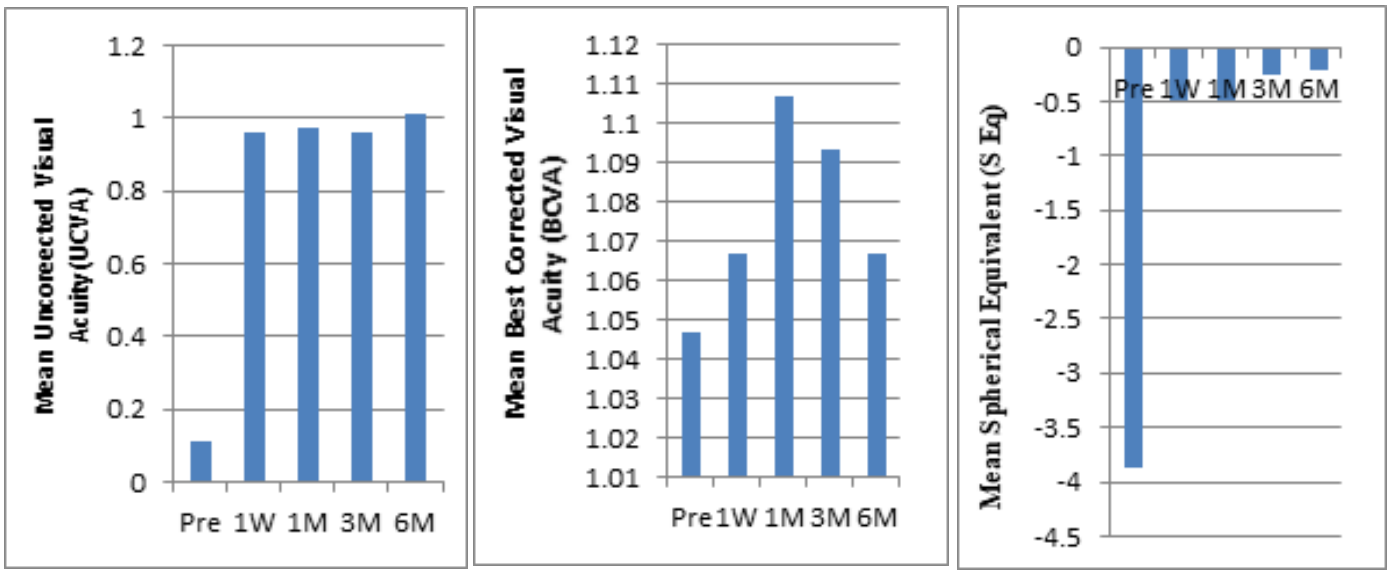

Fig. 4: The Changes in the mean of UCVA, BCVA and spherical equivalent of nasal superior Group

SAFETY (Safety Index=1.01):

After a period of 6 months follow up on 600 eyes we reported that 200/600 eyes (33%) gained 1 line of BCVA. We reported that 200/600 eyes (33%) did not gain any line of BCVA, 100/600 eyes (17%) gained 2 lines of BCVA and 100 eyes (17%) lost 1 line of BCVA. The safety index for superior group was 1.01 (Table 4).

Table 4: *The lines of BCVA gained or lost by each eye at the end of postoperative period*

No. of lines Gained or Lost	No. of Eyes	%
2 Lines Gained	100	17%
1 Line Gained	200	33%
No Lines Gained	200	33%
1 Line lost	100	17%

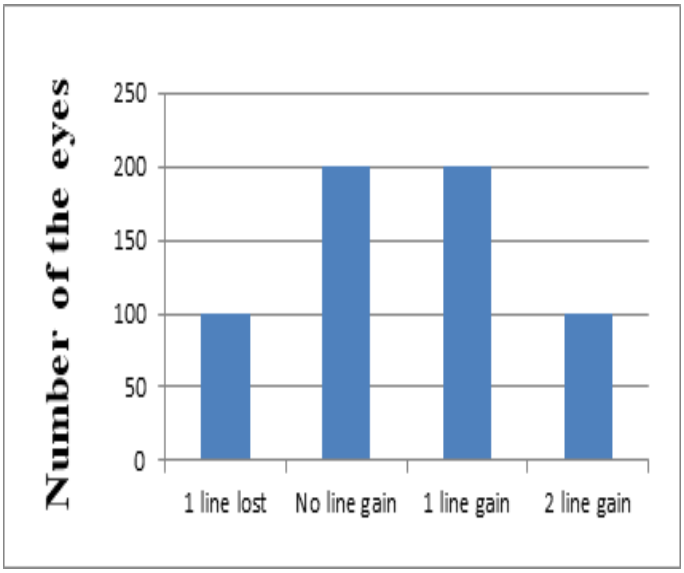

Fig.5: *The Lines of BCVA Gained or lost by Each Eye at the End of Post-operative period*

EFFICACY (Efficacy Index=0.97):

Efficacy index for the superior group was 0.97

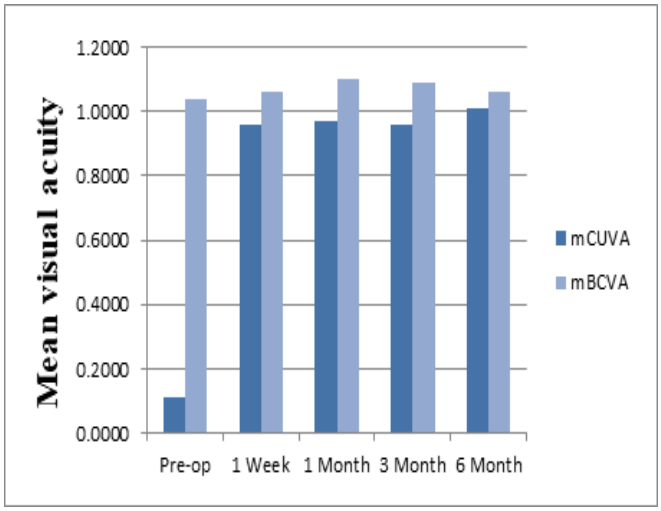

Fig.6: Bar showing the efficacy of the relation between the mean postoperative UCVA and the mean preoperative BCVA at different follow up periods.

5 | PREDICTABILITY

There is reduction of the mean spherical equivalent from -3.87D ± 0.83 preoperatively to -0.215D ± 0.22 at the end of the 6th month postoperatively. This improvement was statistically significant ($p<0.001$).

6 | COMPARISON BETWEEN THE RESULTS OF THE 2 GROUPS:

The two groups had been compared regarding the achieved improvement in the UCVA, BCVA, and spherical equivalent. There was significant statistical association where P values of paired t test for all of the compared pairs below 0.001, but there is no correlated difference for pre and post-operative in different occasions regarding the best corrected visual acuity, under corrected visual acuity and spherical equivalent as in table 5.

Table 5: *Preoperative, 1 week, 1 month, 3 month and 6 month patient data of nasal and superior groups. UCVA: Uncorrected Visual Acuity. BCVA: Best Corrected Visual Acuity. S EQ: Spherical Equivalent.*

		Mean	S. D	Correlation	Sig.	Paired t	P
	preoperative-nasal	.1317	.07699	-.045-	.267	4.817	0.001
	preoperative-superior	.11300	.052159				
UCVA	After 1 week-nasal	.813	.1545	.056	.172	-19.557-	0.001
	After 1 week-superior	.960	.1084				
	After 1 month-nasal	.853	.1361	-.040-	.330	-14.564-	0.001
	After 1 month-superior	.973	.1437				
	After 3 month-nasal	.907	.1238	-.008-	.840	-7.227-	0.001
	After 3 month-superior	.960	.1307				
	After 6 month-nasal	.9467	.08852	.037	.366	-10.233-	0.001
	After 6 month-superior	1.013	.1361				
	preoperative-nasal	.1317	.07699	.067	.100	-167.436-	0.001
	preoperative-superior	1.047	.1148				
	After 1 week-nasal	1.040	.1201	.009	.820	-3.876-	
	After 1 week-superior	1.067	.1194				0.001
BCVA	After 1 month-nasal	1.093	.1243	.053	.195	-1.961-	
	After 1 month-superior	1.107	.1238				0.001
	After 3 month-nasal	1.120	.1223	.022	.593	4.182	
	After 3 month-superior	1.093	.0999				
	After 6 month-nasal	-.31250-	.211200	-.059-	.151	-142.953-	0.001
	After 6 month-superior	1.067	.0944				
	preoperative-nasal	-4.58333-	1.119588	.012	.763	-12.481-	0.001
	preoperative-superior	-3.87500-	.837981				
	After 1 week-nasal	-.46250-	.437150	.001	.974	.965	
	After 1 week-superior	-.48958-	.530916				0.001
S.Eq	After 1 month-nasal	-.40833-	.473013	-.038-	.350	3.780	
	After 1 month-superior	-.49583-	.295139				0.001
	After 3 month-nasal	-.42083-	.223755	.001	.983	-11.659-	
	After 3 month-superior	-.25625-	.263834				
	After 6 month-nasal	-.31250-	.211200	.012	.776	-7.860-	0.001
	After 6 month-superior	-.21458-	.222732				

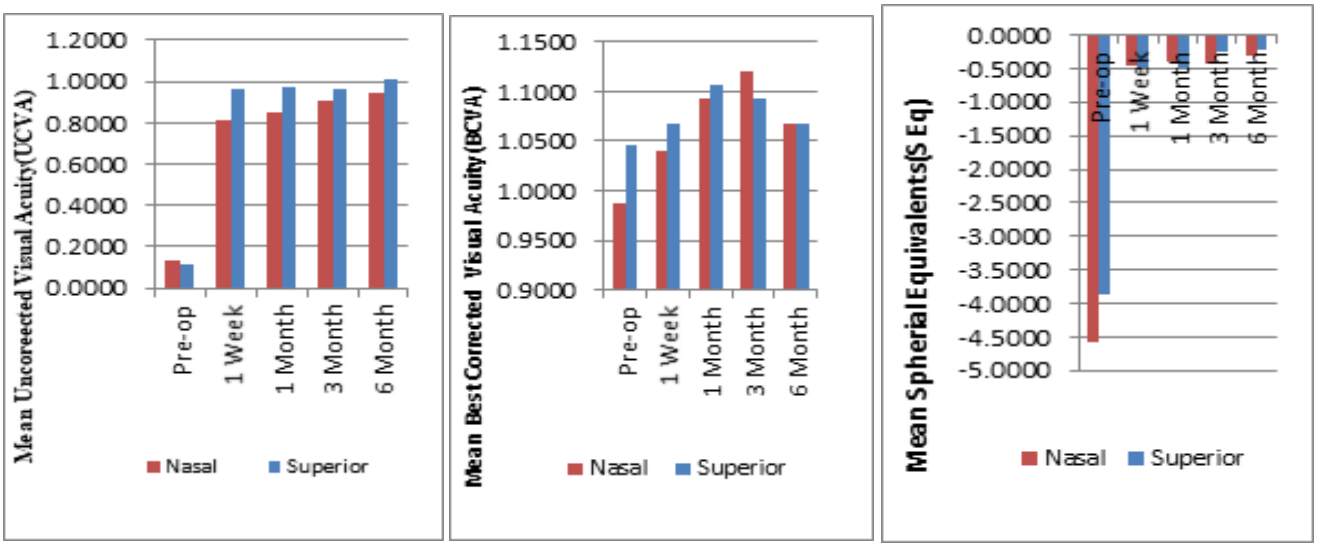

Fig.7: *Means of UCVA, BCVA and Spherical Equivalent in Both Nasal and Superior Groups*

7 | DISCUSSION AND CONCLUSION

LASIK has rapidly become the most frequently performed refractive surgical procedure. It involves the use of a microkeratome to create a thin corneal flap followed by excimer laser ablation of the corneal stroma. LASIK is not a complication-free procedure; that is why all efforts are directed to minimize the complications reaching the highest safety profile with best improvement of visual outcome of the procedure. With improvement in the techniques and instruments used in LASIK, the incidence of complications has decreased. Clinical outcome, safety, and patient satisfaction from modern LASIK with advanced technology have been found to be significantly better than when LASIK was first introduced about 30 years ago.(13) The purpose of this prospective, randomized comparative clinical study is to evaluate the different outcome parameters of Laser in Situ Keratomileusis (LASIK) with superior and nasal hinge locations.

We compared the efficacy with nasal and superior hinge positions. The number of eyes having a postoperative UCVA of 0.5 (6/12) or more at the end of the follow up period estimates the efficacy. No significant differences were present between the nasal and superior hinge groups until 6 months as all patients (100%) have postoperative UCVA better than 0.5. Same results (100% efficacy) were found with el Danasoury and coworkers and with Montes and colleagues (14, 15). Efficacy was 93% with Pirzada and Kalaawry (16) and 91% with Davidorf and coworkers. (17) Predictability which is defined as the number or percentage of eyes having a desired correction (postoperative spherical equivalent) within ± 0.5-1.0D of the desired preoperative correction (preoperative spherical equivalent) was also compared. We found that 540/600 (90.0%) patients in the nasal group and 580/600 (96.0%) patients in superior group are within ±0.5. Many published articles showed the predictability percentages within ±0.5% of emmetropia, and they were ranging between 87.5 – 100%(,18,14,15,19), and within ±1 D of emmetropia were ranging between 91 - 100% (21,20,18,14,15). Safety of the nasal group, which is estimated by the number and percentage of lines of BCVA gained by every eye at the end of the follow up period, was compared with that of superior group. We reported that 140/600(23%) eyes gained 1 or more lines, 220/600 (37%) eyes gained no lines and 140/600 (23%) eyes lost 1 line in the nasal group when compared with preoperative BCVA. In the Superior group 200/600 (33%) eyes gained 1 line, 200/600 (33%) gained no lines and 100/600(17%) lost 1 line. We found that the visual acuity became satisfactory within the 1st month postoperative with minimal further improvement thought out the follow-up period in both groups. Lee and joo believed that the preoperative refractive error is the factor that most significantly affects visual acuity and myopic regression after LASIK rather than the microkeratome, excimer laser, and skill of the surgeon (22). Pallikaris and Siganos report that visual acuity remains stable 3 months after LASIK (23). In a 1-year follow-up study of LASIK , Pallikaris and coauthors report that visual acuity is satisfactory by 2 months, improves until 6 months, and stabilizes thereafter(23,24). In conclusion, LASIK is a safe and effective procedure in correcting low and moderate degrees of myopia. The mean UCVA and BSCVA were significantly improved and the mean spherical equivalent was significantly reduced. There were no differences in efficacy, predictability and safety between nasal and superior hinge flap.

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