Australian Journal of Basic and Applied Sciences, 6(10): 689-695, 2012
ISSN 1991-8178

Comparative Study Between Lasik Procedure Using Ultrathin Moria Sub-Bowman Keratomileusis (Sbk) 90 And That Using Classic Thin Moria M2 90 Microkeratomes Regarding Visual,Refractive Results and Flap Complications

Dr.Tamer Adel Refai, MD, FRCS, Dr.Olfat A. Hassanin, MD, Dr. Mohamed S. Elbalkeeny, MD.

Ophthalmology Department, Research Institute of ophthalmology Giza Egypt

Abstract: Objective*:* to compare the visual ,refractive results and flap complications in patients performing lasik procedure using ultrathin Moria sub-bowman keratomileusis (SBK) 90 with that using the classic thin Moria M2 90 microkeratomes. **Design:** Retrospective, consecutive case series**. Participants***:* The study was performed on a total of 80 consecutive eyes of 47 patients undergoing the lasik procedure for myopia, and hypermetropia with or without astigmatism in the Research Institute of ophthalmology between January and November 2012. Patients were divided into two groups:Group A(40 eyes of 25 patients) :including patients in which SBK 90 moria microkeratome,Antony, France was used and Group B(40 eyes of 22 patients) :including patients in which M2 90 moria microkeratome, Antony, France was used.The female to male ratio was 29:11 for Group A and 23:17 for Group B.The age ranged from 19-46 years with a mean value of 29.49±7.36 years for the Group A,and from 18-41 years with a mean value of 28.5±8.15 years for the Group B. **Methods***:* Preoperatively,patients were subjected to complete ophthalmic examination with accurate determination of spherical equivalent (Sph.Eq.) and pentacam(topography and pachymetry) has been performed for all cases.After flap creation with either keratome, excimer laser ablation was performed by Allegretto Wave Light Eye-Q 1010 (400 Hertz) with active eyetracker (frequency 400 Hertz).Patients were then divided into two groups:Group A(40 eyes) :including patients in which ultrathin Moria SBK 90 microkeratome was used and Group B(40 eyes) :including patients in which classic thin Moria M2 90 microkeratome was used.Postoperative ophthalmic evaluation was done at first day, first week and first month after Lasik procedure for uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), spherical equivalent (Sph.Eq.), flap related complications The collected data were tabulated and analysed with the suitable statistical methods.The mean values and standard deviation were calculated for quantitive data. Comparison tests (t-test) and correlation tests (Pearson) were also performed. **Main outcome measures***:* sub-bowman keratomileusis (SBK) 90, classic Moria M2 90 microkeratomes, uncorrected visual acuity (UCVA), best spectacle corrected visual acuity(BSCVA), spherical equivalent (Sph.Eq.), flap related complications. **Results:** The Postoperative spherical equivalent (Sph.Eq.) had a mean value of -0.76±0.67D for Group A and 0.27±1.26D for Group B denoting a non significant difference (P>0.05). The postoperative uncorrected visual acuity(UCVA) in Snellen lines had a mean value of 0.63±0.23 for Group A and 0.77±0.23 for Group B denting a non significant difference (P>0.05). The postoperative best visual acuity(BSCVA) in Snellen lines had a mean value of 0.77±0.22 for Group A and 0.87±0.22 for Group B denting a non significant difference (P>0.05). Regarding flap complications;striae (partial thickness bends in the flap) occurred in 12 eyes (30%) in Group A and in 8(20%) in Group B .Folds (full thickness bends in the flap) occurred in 2 eyes (5%) in Group A and in 3(7.5%) in Group B .Interface debris occurred in 13 eyes (32.5%) in Group A and in 5(12.5%)in Group B.Free cap occurred in 1 eye (2.5%) in Group A and in 0(0%) in Group B.There was no cases of flap buttonhole formation in either Group. Collectively,flap related complications occurred in 28/40(70%) in Group A and in 16/40(40%) in Group B. A non significant correlation exists between the occurrence of flap striae and preoperative spherical equivalent in Group A r=0.02(P>0.05)and in Group B r=-0.03(p>0.05). A statistically significant correlation exists between the occurrence of Interface debris and preoperative spherical equivalent in Group A r= 0.25(P<0.05)while a non significant correlation exists between the occurrence of Interface debris and preoperative spherical equivalent r=-0.06(P>0.05)in Group B. **Conclusions***:* There were no statistically significant differences(p>0.05) in postoperative refractive and visual outcomes between Lasik performed with ultrathin sub-bowman keratomileusis (SBK 90 moria) and thin flap M2 90 moria mickrokeratome groups. Flap related complications mainly striae and interface debris were lower in eyes that underwent thin -flap LASIK as compared to SBK. A statistically significant correlation (p<0.05) exists between the occurrence of interface debris and the preoperative spherical equivalent in the SBK but not in the classic thin moria M2 90 microkeratome groups.Therefore , thin flap M2 90 moria mickrokeratome is generally preferable to ultrathin Sub-bowman keratomileusis (SBK 90 moria) because of less flap related complcations except in cases with insufficient residual stromal bed. *Financial disclosure(s):* The authors have no proprietary or commercial interest in any of the materials discussed in this article.

Corresponding Author: Dr.Tamer Adel Refai, Ophthalmology Department, Research Institute of ophthalmology Giza Egypt
E-mail: tamerrefaey@hotmail.com

Key words: Lasik Procedure, Ultrathin Moria Sub-Bowman Keratomileusis, Classic Thin Moria, Flap Complications

INTRODUCTION

LASIK, a variation of keratomileusis, is currently the technique of choice to correct moderate and high degrees of myopia achieving a success rate of up to 94% in one study(McDonald *et al.,* 2001). This technique appears to have a number of advantages over other refractive surgical procedures(e.g:PRK), among which almost pain free healing, faster visual recovery, and no postoperative subepithelial haze formation. Also the procedure can be performed in an outpatient setting under topical anaesthesia without postoperative patching (McDonald *et al.,* 2001). Unfortunately, patients with -8 diopter (D) myopia or more and corneal thickness less than 500 μ are not suitable candidates for LASIK due to the inadequate corneal thickness with the risk of structural instability, tissue ectasia and associated complications such as irregular astigmatism,loss of best spectacle-corrected visual acuity (BSCVA) and sometimes iatrogenic Keratoconus(Walker and Wilson 2000). Leaving a sufficient residual stromal bed is very important factor to decrease the incidence of postoperative ectasia (Randleman, 2006; Pallikaris *et al.,* 2001,Binder, 2003 ; Randleman *et al.,* 2003). The residual stromal bed thickness depends on the preoperative corneal thickness, the thickness of the corneal flap, and the amount of tissue ablation by the excimer laser (Durrie *et al.,* 2008).The use of very thin flaps thin (≤ 100 μm) flap i:e sub-Bowman's keratomileusis may be, a hybrid of PRK and LASIK offering the biomechanical stability of surface ablation with the quicker visual recovery and relatively pain-free experience of LASIK (Stephen and Slade, 2008).

Objective:

The aim of this study is to compare the visual ,refractive results and flap complications if any in patients performing lasik procedure with the ultrathin Moria SBK 90 microkeratome (expected to provide actual flap thickness of about 90μ) and that using the classic thin Moria M2 90 microkeratome (expected to provide actual flap thickness of about 110μ) aiming to preserve additional residual bed for the same refractive correction aiming to decrease the incidence of ectasia.

Design:

Retrospective, consecutive case series.

Participants:

The study was performed on a total of 80 consecutive eyes of 47 patients undergoing the lasik procedure for myopia, and hypermetropia with or without astigmatism in the Research Institute of ophthalmology between January and November 2012. Patients were divided into two groups:Group A(40 eyes of 25 patients) :including patients in which SBK 90 moria microkeratome,Antony, France was used and Group B(40 eyes of 22 patients) :including patients in which M2 90 moria microkeratome, Antony, France was used.The female to male ratio was 29:11 for Group A and 23:17 for Group B.The age ranged from 19-46 years with a mean value of 29.49±7.36 years for the Group A,and from 18-41 years with a mean value of 28.5±8.15 years for the Group B .

Methods:

preoperatively patients were subjected to complete ophthalmological examination,including; UCVA,BSCVA,Spherical equivalent , and pentacam (topography and pachymetry).

Exclusion criteria:

- ***i.*** Thin cornea(less than 500 microns by Pentacam).
- ***ii.*** Ectatic cornea e.g:keratconus ,and related disorders
- ***iii.*** Glaucoma.
- ***iv.*** pregnancy.
- ***v.*** Autoimmune and systemic collagen disease e.g. rheumatoid arthritis, SLE.
- ***vi.*** Signs of previous viral keratitis or iridocyclitis.
- ***vii.*** Post.segment gross pathology.

The preoperative uncorrected visual acuity(UCVA) in Snellen lines had a mean value of 0.07±0.1 for Group A and 0.11±0.09 for Group B. The preoperative best visual acuity(BSCVA) in Snellen lines had a mean value of 0.72±0.22 for Group A and 0.83±0.23 for Group B. The preoperative spherical equivalent(Sph.Eq.) has a mean value of -7.54±3.36D for Group A and -4.79±3.92D for Group B. The preoperative central pachymetry(Cent.pach.) had a mean value of 538.48±21.43μ for Group A and 548.44±19.64μ for Group B . The preoperative average keratometric readings (Km) had a mean value of 43.71±1.56D for Group A and 44.04±1.71D for Group B (table 1).

Table 1: showing the mean value and standard deviations for various preoperative parameters for the SBK(A) Group and M2(B) Group.

Item	GroupA Mean±SD	GroupB Mean±SD
Age	29.49±7.36	28.5±8.15
Preop. UCVA	0.07±0.1	0.11±0.09
Preop. BCVA	0.72±0.22	0.83±0.23
Preop. Sph.Eq.(D)	-7.54±3.36	-4.79±3.92

SD=Standard deviation.
D=Diopters.

The LASIK Procedure:

1) Topical anesthesia with proparacaine hydrochloride 0.4 % (Benox eye drops) 5 minutes just before the operation.

2) Sterilizing the eyelids with Povidone-Iodine10% (Betadine) .

3) Speculum application.

4) Corneal marking using surgical marker with marks created at (temporal quadrants for SBK) and at (lower quadrants for M2).

5)Suction ring application.

6) The microkeratome handle was applied over the cornea creating a nasal hinged corneal flap for Moria SBK 90 and a superior hinged corneal flap for Moria M2 90 microkratomes.

7) Ablation was performed by the Allegretto Wave Light Eye-Q 1010 (400 Hertz) with active eyetracker (frequency 400 Hertz).

8) The stromal bed was irrigated with balanced salt solution (BSS).

9) The flap was reposed in position painted by jet of air.

10) The flap alignment was checked by preoperative corneal marks alignment.

11) Patient received antibiotics, corticosteroid eye drops and preservatives free artificial tears eye drops.

Postoperative follow up and evaluation was done on first day,first week and first month after Lasik for UCVA,BSCVA,Spherical equivalent ,flap related complications and the patients were divided into two groups:Group A(40 eyes) :including patients in which ultrathin Moria SBK 90 was used and Group B(40 eyes) :including patients in which classic thin Moria M2 90 microkeratome was used .

The collected data were tabulated and analysed with the suitable statistical methods.The mean values and standard deviation were calculated for quantitive data. Comparison tests (t-test) and correlation tests (Pearson) were also performed.

Results:

The postoperative uncorrected visual acuity(UCVA) at 1 month in Snellen lines had a mean value of 0.63±0.23 for Group A and 0.77±0.23 for Group B compared with "t"test showing a value of 0.01 denting a non significant difference (P>0.05) (Table 2 & Chart 1).

Table 2: showing the mean value and standard deviations for various 1 month postop.parameters for the SBK(A) Group and M2(B) Group and their comparison by t-test and significance.

Item	GroupA Mean±SD	GroupB Mean±SD	"t"test value	"P"value	Significance
Postop. UCVA	0.63±0.23	0.77±0.23	0.01	>0.05	Non significant
Postop. BSCVA	0.77±0.22	0.87±0.22	0.05	>0.05	Non significant
Postop. Sph.Eq.(D)	-0.76±0.67	0.27±1.26	0.01	>0.05	Non significant

SD=Standard deviation
D=Diopters
t=t student test
P=probability

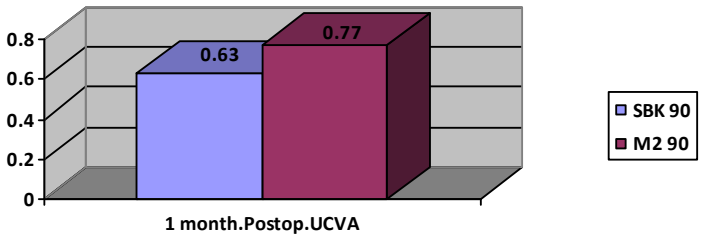

Chart 1: showing the mean value for the UCVA in Snellen lines 1 month postoperatively for both SBK (A) Group and M2(B) Group.

The postoperative best visual acuity(BSCVA) at 1 month in Snellen lines had a mean value of 0.77±0.22 for Group A and 0.87±0.22 for Group B compared with "t"test showing a value of 0.05 denting a non significant difference (P>0.05)denting a non significant difference (P>0.05) .(Table 2 & Chart 2).

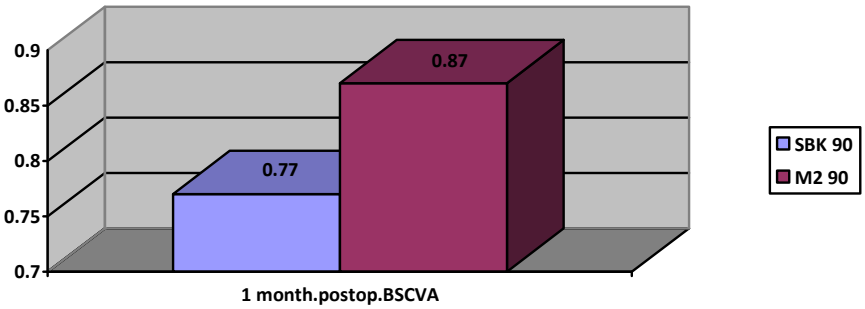

Chart 2: showing the mean value for the BSCVA in Snellen lines 1 month postoperatively for both SBK (A) Group and M2(B) Group.

The Postoperative spherical equivalent(Sph.Eq.) in diopters (D) at 1 month had a mean value of -0.76±0.67D for Group A and 0.27±1.26D for Group B compared with "t"test showing a value of 0.01 denting a non significant difference (P>0.05). (Table 2 & Chart 3).

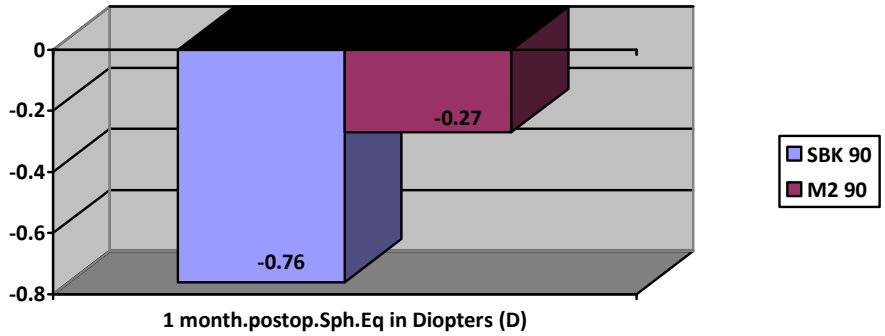

Chart 3: showing the mean value for the Spherical equivalent in diopters (D)1 month postoperatively for both SBK (A) Group and M2(B) Group.

Regarding flap related complications at 1 month postoperatively:

Striae (partial thickness bends in the flap) occurred in 12 eyes (30%) in Group A and in 8(20%) in Group B (Table 3 & Chart 4).

Table 3: showing the incidence of flap related complications per 40 cases and their percentage for the SBK(A) Group and M2(B) at 1 month postoperatively.

Flap Complication	Group A number/40 eyes & percentage	Group B number/40 eyes & percentage
Striae	12(30%)	8(20%)
Folds	2(5%)	3(7.5%)
Interface Debris	13(32.5%)	5(12.5%)
Free cap	1(2.5%)	0(0%)
Button hole	0(0%)	0(0%)
Total flap complications	28 (70%)	16 (40%)

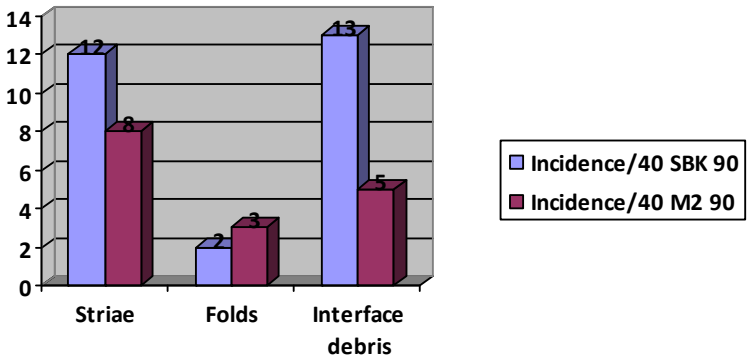

Chart 4: showing the incidence of striae,folds and interface debris per 40 cases for both SBK (A) Group and M2(B) Group.

Folds (full thickness bends in the flap) occurred in 2 eyes (5%) in Group A and in 3(7.5%)in Group B (Table 3 & Chart 4).

Folds in the cap are generally more frequently seen in higher myopic ablations, where the flap has to coapt itself to the greater ablated stromal bed (Buratto and Brint, 2000).

Interface Debris occurred in 13 eyes (32.5%) in Group A and in 5(12.5%)in Group B (Table 3 & Chart 4).

Free cap occurred in 1 eye (2.5%) in Group A and in 0(0%) in Group B (Table 3).

There was no cases of flap buttonhole formation in either Group(Table 3).

Flap related complications occurs in 28/40(70%) in Group A and in 16/40(40%) in Group B (Table 3 & Chart 5).

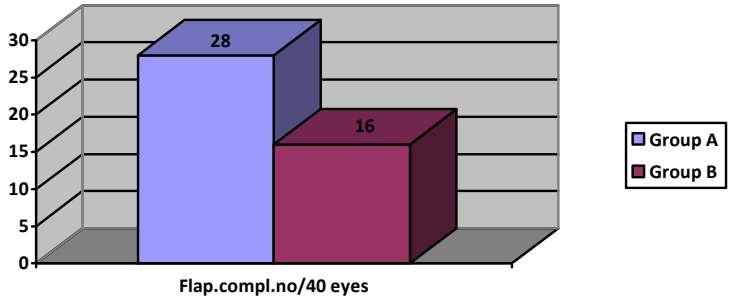

Chart 5: showing the incidence of flap related complications per 40 cases for both SBK (A) Group and M2(B) Group.

Pearson Correlation was done between occurrence of flap striae and interface debris (being the two most commonly repored complications in this study in either Group) and the preoperative spherical equivalent (reflecting the extent of laser ablation).

Pearson Correlation between the occurrence of flap striae and preoperative spherical equivalent revealed a value of r=0.02 (P>0.05) in Group A and r=-0.03(P>0.05) in Group B denoting a non significant correlation in either group (Table 4).

Table 4: showing the correlation between occurrence of flap striae and the preoperative spherical equivalent (D) for the SBK(A) Group and M2(B) Group by pearson correlation "r" test and significance.

flap striae Vs preoperative spherical equivalent(D)	Correlation coeifficient"r|"	"P"value	Significance
Group A	0.02	>0.05	Non significant
Group B	-0.03	>0.05	Non significant

VS=versus
D=Diopters
P=probability value

Pearson Correlation between the occurrence of Interface debris and preoperative spherical equivalent revealed a value of 0.25(P<0.05)in Group A denoting a statistically significant correlation and -0.06(P>0.05)in Group B denoting a non significant correlation(Table 5) .

Table 5: showing the correlation between occurrence of interface debris and the preoperative spherical equivalent (D) for the SBK(A) Group and M2(B) Group by pearson correlation "r" test and significance.

Interface debris Vs preoperative spherical equivalent(D)	Correlation coeifficient"r|"	"P"value	Significance
Group A	0.25	<0.05	significant
Group B	-0.06	>0.05	Non significant

VS=versus
D=Diopters
P=probability value

Discussion:

LASIK, a variation of keratomileusis, had become the technique of choice to correct moderate and high amounts of myopia having a number of advantages over other refractive surgical procedures(e.g:PRK), including almost pain free healing, faster visual recovery, and no subepithelial haze formation (McDonald *et al*., 2001). Refractive surgery is routinely planned according to preoperative measurement of central corneal thickness to avoid complications such as corneal ectasia (Price and Koller 1999). Central corneal thickness (CCT) below 500 µ is considered an important risk factor for post-Lasik corneal ectasia rendering Lasik procedure unsafe (Binder, 2007). Alternatively, PRK for correcting intermediate to high levels of myopia may result in a strong wound-healing reaction, leading to haze formation and suboptimal refractive outcomes.The use of very thin flaps thin (≤ 100 µm) flap i:e sub-Bowman's keratomileusis can leave the patient with more residual stromal bed for the same refractive correction,an important factor that decreases the risk of ectasia (Condon *et al.,* 2007).Dimitri *et al.,* 2008.Retrospectively analyzed the refractive and visual outcomes of 33 eyes that underwent SBK (flap thickness 82–120 µm) and 62 eyes that underwent thick-flap LASIK (flap thickness ≥ 160) with spherical equivalent (Sph.Eq.) -4 to -10 diopters (D), and follow-up of ≥ 3 months. The postoperative UCVA (-LogMAR, mean ± SD) was 0.16 (20/29) ± 0.22 for SBK, and 0.14 (20/28) ± 0.15 for thick-flap LASIK respectively .The postoperative BSCVA was 0.002 (20/20) ± 0.06 for SBK and 0.003 (20/20) ± 0.04 for thick-flap LASIK. No significant differences in the postoperative UCVA, BSCVA were found between groups. The postoperative SE (spherical equivalent) was −0.55 ± 0.70 in SBK and −0.51 ± 0.64 in thick-flap LASIK with no statistically significant differences in the two groups. No flap complications were reported.

In our study, comparing and analysing the results of 40 Lasik eyes(Group A) performed with ultrathin SBK 90 moria microkeratome,Antony, France (expected to provide actual flap thickness of about 90µ) with 40 Lasik eyes(Group B) performed with the classic thin M2 90 moria microkeratome, Antony, France expected to provide actual flap thickness of about 110µ),we found that;

The Postoperative spherical equivalent(Sph.Eq.) had a higher mean value for Group A (-0.76±0.67D) than for Group B (0.27±1.26D) that could be explained by the higher mean value of preoperative spherical equivalent for Group A (-7.54±3.36D) than for Group B (-4.79±3.92D) with more incidence of undercorrection in myopic eyes . The postoperative uncorrected visual acuity(UCVA) in Snellen lines had a lower mean value for Group A(0.63±0.23) than for Group B (0.77±0.23) which could be explained by the higher mean value for the postoperative spherical equivalent in Group A. The postoperative best visual acuity(BSCVA) in Snellen lines had a lower mean value for Group A (0.77±0.22) than for Group B (0.87±0.22) which could be explained by the higher degrees of amblyopia that is usually associated with higher degrees of preoperative myopic errors that was found in Group A. Regarding flap complications;striae (partial thickness bends in the flap) occurred more in Group A i:e;12 eyes (30%) than in Group B in 8(20%) that could be attributed to the more difficult handling of the thinner flap .Folds (full thickness bends in the flap) occurred in 2 eyes (5%) in Group A and in 3(7.5%)in Group B with no marked difference in the incidence in either Groups.Interface debris occurred more in Group A i:e;13 eyes (32.5%) than in in Group B i:e; 5(12.5%) which could be attributed to more amounts of tissue ablated in Group A (due to higher preoperative spherical equivalent) generating more amounts of debris particularly that there was a statistically significant correlation between the occurrence of Interface debris and preoperative spherical equivalent in Group A r= 0.25(P<0.05) but not in Group B.Free cap occurred in 1 eye (2.5%) in Group A and in 0(0%) in Group B without evident difference in either Group.There was no cases of flap buttonhole formation in either Group. Collectively,flap related complications occurred more in Group A i:e; 28/40(70%) eyes than in in Group B i:e 16/40(40%) and this incidence was higher than that repored by Dimitri *et al,* 2008 probably because they did more cases with thicker flaps i:e; 62 eyes had underwent thick-flap LASIK (flap thickness ≥ 160) which we concluded results in much lower incidence of flap related complications.We recommend that when performing Lasik procedure using sub-bowman keratomileusis (SBK) ,it is better to apply a contact lens (or to attempt to dehydrate the flap more thoroughly to achieve rapid

attachment) to decrease the incidence of flap striae and to carefully irrigate and clean the interface to decrease the incidence of interface debris.

Conclusions:

There were no statistically significant differences($p>0.05$) in postoperative refractive and visual outcomes between Lasik performed with ultrathin sub-bowman keratomileusis (SBK 90 moria) and thin flap M2 90 moria mickrokeratome groups. Flap related complications mainly striae and interface debris were lower in eyes that underwent thin -flap LASIK as compared to SBK. However, no statistical significant differences($p>0.05$) were evident. A statistically significant correlation ($p<0.05$) exists between the occurrence of interface debris and the preoperative spherical equivalent in the SBK but not in the classic thin moria M2 90 microkeratome groups. Therefore, thin flap M2 90 moria mickrokeratome is generally preferable to ultrathin Sub-bowman keratomileusis (SBK 90 moria) except in cases with insufficient residual stromal bed.

REFERENCES

Binder, P.S., 2003. Ectasia after laser in situ keratomileusis. J Cataract Refract Surg., 29: 2419-2429.

Binder, P.S., 2007. Analysis of ectasia after laser in situ keratomileusis: risk factors. J Cataract Refract Surg., 33: 1530-1538.

Buratto, L. and S. Brint, 2000. Complications of Lasik: In LASIK;surgical techniques and complications, Buratto L,Brint S(eds.)., Slack incorporated, Thorofare NJ: 8: 177-264.

Condon, P.I., M. O'Keefe, P.S. Binder, 2007. Long-term results of laser in situ keratomileusis for high myopia: risk for ectasia. J Cataract Refract Surg., 33(4): 583-590.

Dimitri, T. Azar, C. Ramon, Ghanem, Jose de la Cruz, 2008. Thin-flap (sub-Bowman keratomileusis) versus thick-flap laser in situ keratomileusis for moderate to high myopia: Case-control analysis;J cataract Refract Surg., 34(12): 2073-2078.

Durrie, D.S, S.G. Slade, J. Marshall, 2008. Wavefront-guided excimer laser ablation using photorefractive keratectomy and sub-Bowman's keratomileusis: a contralateral eye study. J Refract Surg., 24(1): S77-S84.

McDonald, M.B., J.D. Cars, J.M. Frantz, 2001. Laser in situ keratomileusis for myopia up to -11diopters with up to -5diopters of astigmatism with the summit autonomous LADAR vision excimer laser system. Ophthalmology, 108(2): 309-16.

Pallikaris, I.G., G.D. Kymionis, N.I. Astyrakakis, 2001. Corneal ectasia induced by laser in situ keratomileusis. J Cataract Refract Surg., 27: 1796-1802.

Price, F.W. Jr., D.L. Koller, 1999. Central corneal pachymetry in patients undergoing laser in situkeratomileusis. Ophthalmology,106: 2216-2220.

Randleman, J.B., 2006. Post-laser in-situ keratomileusis ectasia: current understanding and future directions. Curr Opin Ophthalmol., 17(4): 406-412.

Randleman, J.B., B. Russell, M.A. Ward, 2003. Risk factors and prognosis for corneal ectasia after LASIK. Ophthalmology, 110: 267-275.

Stephen, G., M.D. Slade, 2008. Sub-Bowman's Keratomileusis,A case for a new "K" in refractive surgery.J Cataract Refract Surg., 34(12): 2073-8.

Walker, M.B., S.E. Wilson, 2000. Incidence and prevention of epithelial growth within the interface after laser in situ keratomileusis. Cornea., 19: 170-173.