Original Article

Efficiency of Moria One-Use Plus Sub-Bowman's Keratomileusis Head in Achieving Predicted Corneal Flap Thickness in Sub Bowmans Keratomileusis

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ABSTRACT

Purpose: To evaluate the difference between predicted and resultant corneal flap thickness in Sub-Bowmans Keratomileusis using Moria One-Use Plus sub-Bowman's keratomileusis head.

Study Design: Interventional case series.

Place and Duration of Study: Liaquat National Hospital, Karachi, from April 2019 to September 2019.

Methods: Total 55 patients of either gender with age 20 to 45 years undergoing Sub-bowmans Keratomileusis (SBK) were included. Frequencies and percentages were computed for qualitative variables. Quantitative variables were presented as mean ± standard deviation. Student t-test, pair t test and ANOVA were used to compare the mean of resultant and predicted corneal flap thickness. Effect modifiers were controlled through stratification. Post stratification student t-test was again used to compare the mean of resultant and predicted corneal flap thickness. P-value ≤ 0.05 was considered significant.

Results: The mean age was 26.83 ± 4.38. There was an insignificant differences in preoperative, intraoperative and corneal flap thickness of both eye with respect to gender (P > 0.05). There was insignificant mean difference in preoperative and intraoperative corneal thickness (P > 0.05) of both eye with respect to age group but significant mean difference in resultant flap corneal thickness seen with both age group (P < 0.05). Significant difference was found in the flap thickness between the right and left eyes. The difference in the predicted and resultant flap thickness was statistically significant for right eye and insignificant for the left eye.

Conclusion: With Moria microkeratome, accuracy of the flap can be predicted in SBK. It is a safe and effective method to achieve the desired results.

Key Words: Corneal Flap, Moria one use plus, Microkeratome, refractive surgery, LASIK.

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INTRODUCTION

Freedom from spectacle and contact lenses by correction of refractive error has been accomplished by corneal refractive surgeries.[1] Among the refractive surgeries, Laser-assisted in situ keratomileusis (LASIK) is the most widely used procedure for the correction of refractive errors including myopia, hyperopia, and astigmatism.[2,3] This refractive technique provides good safety and efficacy and yields predictable and stable results without significant complications.[4] During LASIK anterior flap is created and corneal stroma is photoablated. First critical step during LASIK surgery is creation of successful flap of adequate thickness.[5] Excellent LASIK outcomes require safe, predictable, and reproducible flap

parameters.[6,7] Great attention must be given to improve the predictability and to minimize the degree of variation in corneal flap thickness, which is directly related to LASIK predictability and safety.[8] The procedure is fast, with painless recovery of vision and lack of sub epithelial haze, which are mainly due to the creation of a corneal flap with a microkeratome. Proper preoperative screening of candidates should be done for stable refraction and normal cornea that are free of diseases that predispose to complications.Sub-Bowman's keratomileusis (SBK) is a LASIK procedure in which a special mechanical blade (SBK One-Use Plus blade) is used to create a thinner flap.

Although much work is being done in Pakistan on refractive surgery but data related with accuracy of corneal flap thickness and SBK is scarce.[9,10] The rationale of our study is to evaluate the mean thickness of corneal flap created using One use plus SBK head microkeratome and to compare it from the intended flap thickness in our population. This will help in planning SBK to achieve best results of refractive surgery.

METHODS

We conducted this study at department of Ophthalmology, Liaquat National Hospital, Karachi, from April 2019 to May 2020, after approval from hospital ethical review committee. By taking mean flap thickness of right eyes as 97.50 ± 11 µm[11] and margin of error (d) = 5%, the total calculated sample size was 19 (WHO software for sample size calculation taking 95% confidence level). We included 55 patients of either gender with age 20 to 45 years. Data included; name, gender, age, pre-operative refraction, unaided visual acuity and visual acuity after spectacle correction with spherical equivalent and slit lamp examination. Surgical procedure was performed after informed consent from the patient. Data was analyzed using SPSS version 21. All the information was collected on especially designed proforma. Patients with preoperative refractive error of -2.00 to -12.00D myopia up to +4.00 hyperopia, cylinder of <-3.00D, and central corneal thickness greater than or equal to 490 µm were included. Exclusion criteria was patients with ocular pathologies such as dystrophy, degeneration, scarring, viral herpetic disease, glaucoma, collagen vascular diseases, uveitis, use of systemic corticosteroids or antimetabolites, topographically diagnosed corneal ectasia and dry eye. Corneal topography was done pre-operatively (wave Light Allegro Oculyzer) for the measurement of central corneal thickness (CCT), and residual corneal stromal bed. Before creating the flap with pupil centration and focusing on corneal apex CCT was obtained intraoperatively (wave front optimized via Wave Light). Corneal flap with nasal hinge was created using Moria one use plus microkeratome with mechanical stop safety design to create flap thickness of 100 µm. First right then left flap was made with the use of same blade. Suction ring was chosen on the reading of keratometric (K1) value. Hinged flap was raised to ablate the stromal bed using Wave Light® EX500 Excimer Laser and the residual stromal bed (RSB) was immediately measured. Subtracting RSB thickness from the preoperative total central corneal thickness gave flap thickness. Moxifloxacin and lubricant eye drops were started 2 days before the procedure and continued for 2 weeks and 2 months respectively. Dexamethasone 1% was used and tapered from five times a day to twice a day.

RESULTS

The mean age was 26.83 ± 4.38 with range from 20 to 45 years. There were 22 (40%) patients with age ≤ 25 years and 33 (60%) with > 25 years. Females were 42.9% and males were 57.1%. The spherical equivalent refraction was distributed as 46% patients had myopia, 9.5% had hyperopia and 44.4% had myopic with astigmatism. We compared the mean preoperative, intraoperative and resultant flap corneal thickness of both eyes with respect to gender, age group and spherical equivalent refraction. There was an insignificant difference in preoperative, intraoperative and flap corneal thickness of both eye sides with respect to gender ($P > 0.05$). There was insignificant mean difference in preoperative and intraoperative corneal thickness ($P > 0.05$) of both eye with respect to age group but significant mean difference in resultant flap corneal thickness seen with both age groups ($P < 0.05$). The details are presented in Table 1.

There was statistically insignificant difference in the pre-operative and intra-operative corneal flap thickness between the right and left eyes. However, significant difference was found in the flap thickness between the right and left eyes (Table 2). The difference in the predicted and resultant flap thickness was statistically significant for right eye and insignificant for the left eye (Table 3).

Table1: *Association of gender, age group and spherical equivalent refraction with corneal and flap thickness.*

	Pre-operative Corneal Thickness RE	Pre-operative Corneal Thickness LE	Intra-operative Corneal Thickness RE	Intra-operative Corneal Thickness LE	Corneal Flap Thickness-RE	Corneal Flap Thickness-LE
Gender						
Male	534.18 ± 23.48	534.36 ± 24.64	532.63 ± 23.54	532.22 ± 529.72	101.45 ± 3.92	100.9 ± 3.72
Female	534.81 ± 20.81	532.21 ± 21.08	530.48 ± 20.92	529.72 ± 21.68	101 ± 3.25	100.42 ± 3.37
P-value	0.916	0.730	0.724	0.686	0.643	0.619
Age group						
≤25 years	535.72 ± 20.15	533.95 ± 21.58	531.22 ± 20.84	530.86 ± 20.92	102.54 ± 3.56	101.90 ± 3.63
>25 years	533.78 ± 22.96	532.48 ± 23.20	530.86 ± 20.92	530.63 ± 23.27	100.27 ± 3.21	99.75 ± 3.16
P-value	0.749	0.814	0.974	0.971	0.017*	0.024*
Spherical Equivalent Refraction						
Myopic	528.45 ± 27.11	526.62 ± 28.15	525.08 ± 27.50	524.66 ± 27.97	102.37 ± 3.39	101.79 ± 3.33
Hyperopia	549.40 ± 5.54	548.60±2.50	548.40 ± 6.10	545.60 ± 3.91	99.60 ± 4.39	99.22 ± 4.43
Myopia with astigmatism	537.34 ± 15.78	536.03 ± 15.93	533.84 ± 14.97	533.46 ± 15.85	100.38 ± 3.22	99.80 ± 3.24
P-value	0.096	0.086	0.066	0.107	0.075	0.083

Student t-test, Pair t test, anova is applied.
*Significant at $p \leq 0.05$ or $p \leq 0.01$
**Highly significant at $p \leq 0.001$

Table 2: *Mean comparison of right versus left eye corneal thickness.*

	Mean ± SD	p-value
Pre operative corneal thickness RE	534.56 ± 21.71	0.115
Pre operative corneal thickness LE	533.07 ± 22.37	
Intra operative corneal thickness RE	531.34 ± 21.82	0.417
Intra operative corneal thickness LE	530.72 ± 22.16	
Corneal flap thickness RE	101.18 ± 3.51	< 0.0001**
Corneal flap thickness LE	100.61 ± 3.49	

Paired t-test is applied.
*Significant at $p \leq 0.05$ or $p \leq 0.01$
**Highly significant at $p \leq 0.001$

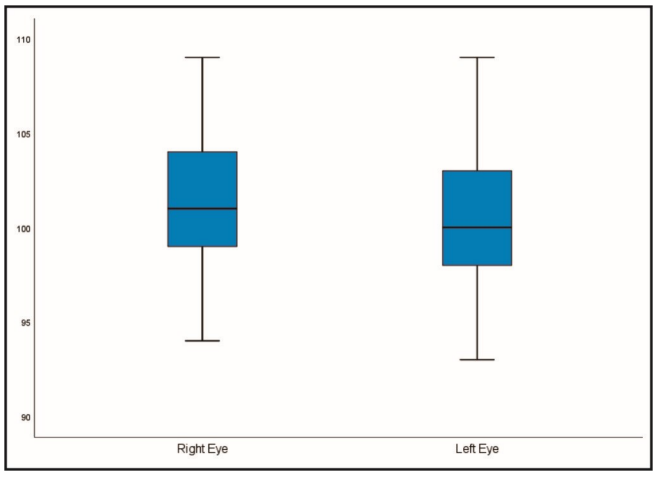

Figure 1: Corneal flap thickness of right eye & left eye.

Table 3: *Mean comparison of Resultant versus Predicted corneal flap thickness.*

	Mean ± SD	p-value
Resultant corneal flap thickness RE	101.18 ± 3.51	0.016*
Predicted corneal flap thickness	100 ± 0.00	
Resultant corneal flap thickness LE	100.61 ± 3.49	0.195
Predicted corneal flap thickness	100 ± 0.00	

DISCUSSION

Corneal topography is considered a standard of care for all refractive surgical procedures. There is a relationship between preoperative corneal thickness, ablation depth, and flap thickness in determining the relative amount of biomechanical change that has occurred after a LASIK procedure.[11] Intraoperative measurements can help surgeons determine the accuracy of programmed versus achieved flap thickness (FT). Mechanical microkeratomes may have a wide variance from the intended to actual flap thickness. Thinner flaps usually occur in thinner corneas and when the same blade is used for the second eye.[12] A wide variety of microkeratomes are in clinical use nowadays. Different microkeratomes have shown that the achieved flap thickness varies from the intended value. Research shows that there is difference in the flap thickness when same blade is used between the first and the second eye.[13]

Special mechanical blade (SBK One-Use Plus blade) is used in Sub-Bowman's keratomileusis to create a thinner flap providing greatest advantage by leaving sufficient stromal tissue to allow safer excimer laser ablation, especially in patients with moderate or high myopia.[14] It has been suggested, that a minimal stromal depth of 250 μm should remain after LASIK and the amount of residual stroma left behind after its formation influence the correction of refractive error and the visual outcome of the patient.[15,16]

Thin flaps may lead to striae and tearing, flap irregularities, buttonholes and epithelial defects. However, thicker flaps result in decreased stromal-bed thickness leading to instable integrity of eye and cloudiness and iatrogenic corneal ectasia. If the flap is uniformly made it results in more residual corneal stoma and nerve preservation. This helps in reduction of post-operative dry eye.[17]

Moreover, careful evaluation for precise estimation of flap thickness results in minimizing the post-operative complications and avoids the need for additional surgery. With the advent of single one use head microkeratome as compare to previous metallic head microkeratomes, there is a decreased in the rate of complications related to flap.[18,19] This corresponds to our results in which the flap thick was close to the predicted values and lesser complications. Practitioners have considered that the ideal flap thickness should be 130 um or slightly greater than this, because thinner flaps are more prone to develop corneal folds, in growth of corneal epithelium and astigmatism. This was very successfully achieved by Moria keratome in our study. Contrary to that Kanclerz P et al have shown that the evidence of the superiority of one technique in terms of complications over another cannot be stated.[20]

In our study the resultant corneal flap thickness was found as 101.18 ± 3.51 in right eye ($p < 0.05$) and 100.61 ± 3.49 in left eye ($p > 0.05$) which was statistically significant in right but insignificant in left eye respectively from the predicted value. There is a highly significant mean difference in resultant corneal flap thickness ($P < 0.0001$) of right and left eye. Similar result were reported by Du S et al, who showed that the intended corneal flap thickness was 100 um and the difference in flap thickness between the two eye was not statistically significant.[18] Zhai CB found that the flap thickness created by the Moria One Use-Plus SBK was more uniform, more regular and more accurate than those created by the Moria M2.[19]

Limitations of our study was limited follow up and single center research. More work needs to be done using different variables and different centers so that the results can be generalized.

CONCLUSION

With the use of one use plus SBK, accuracy of the flap can be predicted, it is a safe and effective method to achieve the desired results. With creation of thinner flap, higher error of refraction can be treated while leaving more residual stromal bed tissue.

Ethical Approval

The study was approved by the Institutional review board/Ethical review board **(0474-2019-LNH-ERC).**

Conflict of Interest: Authors declared no conflict of interest.

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Authors' Designation and Contribution

Munira Shakir; Professor: *Concepts, Design, Literature search, Manuscript preparation, Manuscript review.*

Sahira Wasim; Consultant Ophthalmologist: *Design, Literature search, Data acquisition, Data analysis, Statistical analysis, Manuscript preparation, Manuscript editing, Manuscript review.*

Ronak Afza Memon; Consultant Ophthalmologist: *Statistical analysis, Manuscript preparation, Manuscript editing, Manuscript review.*

Shakir Zafar; Professor: *Literature search, Statistical analysis, Manuscript review.*