

Research Article**IMPACT OF CAP THICKNESS IN SMALL INCISION LENTICULE EXTRACTION (SMILE) SURGERY ON OCULAR SURFACE AND VISUAL ACUITY****Rakesha Anjenappa¹, Soumya Patil^{2*}, KH Srinivas³, Sampoorna H Rao⁴**¹Consultant, Sairam Nethralaya, Karatagi, Koppal district.² Assistant Professor, Koppal Institute of Medical Sciences, Koppal, India³Associate Professor, BMCRI⁴Consultant, Sathyasree clinic. Bangalore*Corresponding author: Dr. SoumyaPatil, Assistant Professor, Koppal Institute Of Medical Sciences, Koppal, India. gpatilsoumya@gmail.com

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Abstract:

Objective: to assess the tear film by schirmer test, TBUT, OSDI score in patients undergoing SMILE refractive surgery with cap thickness of 120µm and 140µm and to study the visual acuity in patients undergoing SMILE refractive surgery with cap thickness of 120µm and 140µm.

Methods: This hospital based Prospective, Comparative Study was conducted among patients with myopia an myopic astigmatism (spherical equivalent -1 to -6D) undergoing SMILE procedure at Midnto Ophthalmic Hospital, Regional Institute of Ophthalmology attached to Bangalore Medical College and Research Institute.

Results and Conclusion: The study showed comparable outcome of visual outcome and dry eye in both groups. SMILE at deeper depth might provide chance of secondary SMILE within the cap to correct residual refraction. Further clinical studies with larger sample size and longer duration are required to confirm studies.

Keywords: Cap Thickness,

Small Incision Lenticule Extraction (Smile), Ocular Surface, Visual Acuity.

INTRODUCTION

Corneal refractive surgeries are one of the commonly performed procedures for correction of refractive errors.¹ Small incision lenticule extraction (SMILE) is a relatively newer corneal refractive procedure designed to treat refractive errors.²

SMILE is a novel form of refractive surgery for the treatment of myopia and myopic astigmatism. During the SMILE procedure, an intrastromallenticule is created using the femtosecond lenticule extraction (FLEx) technique; the lenticular interfaces are separated by a dissector through a small 2-3 mm incision so that the lenticule can be removed in a flapless fashion.³

Tear film abnormality is the most common postoperative complication of corneal refractive surgeries.

Consequently, these procedures represent a clinically significant cause of dry eye disease. The mechanisms which lead to dry eye disease include corneal sensory nerve dysfunction, ocular surface desiccation, and ocular surface inflammation.¹

SMILE procedure does not create a flap, thereby preserving more of the corneal nerve fibers, which has been shown to minimize dry eye and maintain higher corneal sensitivity. In 2016, expert consensus from the Chinese Ophthalmology Association recommended that the standard cap thickness would be maintained between 110 and 120 μm . Theoretically, it would be expected that deeper cap thickness would maintain more anterior peripheral stroma and corneal nerve fibers with stronger corneal rigidity and faster recovery of ocular surface function. However, the effect of cap thickness on visual function outcomes of cornea after SMILE has not been fully assessed.⁴

With the advantages of better ocular surface stability and biomechanical strength, SMILE is gaining worldwide acceptance and increasing popularity in recent years. Therefore, its effects on eyes, particularly on pre corneal tear film layer based on different cap thickness should be fully understood.

Present study aims to assess the age and sex distribution, refractive power, visual acuity, tear film assessment by schirmer test, TBUT, OSDI, contrast sensitivity in patients undergoing SMILE refractive surgery.

Hence this study was conducted to assess the tear film by schirmer test, TBUT, OSDI score in patients undergoing SMILE refractive surgery with cap thickness of 120 μm and 140 μm and To study the visual acuity in patients undergoing SMILE refractive surgery with cap thickness of 120 μm and 140 μm .

MATERIAL AND METHODS

This hospital based Prospective, Comparative Study was conducted among patients with myopia and myopic astigmatism (spherical equivalent -1 to -6D) undergoing SMILE procedure at Midnto Ophthalmic Hospital, Regional Institute of Ophthalmology attached to Bangalore Medical College and Research Institute.

Study period: August 2022 to March 2023.

Sample size: 28 eyes (14 eyes with 120 μ and 14 eyes with 140 μ cap thickness)

INCLUSION CRITERIA:

1. Patients with simple myopia and myopic astigmatism
2. Patients with adequate corneal thickness (RST of >300)
3. Patients consenting for the procedure.

EXCLUSION CRITERIA:

1. Patients with complicated systemic diseases such as diabetes, hypertension, heart disease, or connective tissue disorder or ocular diagnoses including amblyopia, anisometropia, keratoconus, central corneal residual stromal bed thickness less than 300 μ or history of other ocular pathology were excluded from the study.
2. Inability to complete the follow schedule.

3. Patients not giving consent for the procedure

Methodology:

After obtaining approval and clearance from the institutional ethical committee, the patients fulfilling the inclusion criteria will be enrolled for the study after obtaining informed consent. The present comparative study was carried out on 40 eyes undergoing SMILE surgery of which cap thickness was 120 μ in 20 eyes and 140 μ in 20 eyes, during the period from January 2023 to December 2023.

The demographic details such as age, sex, address and occupation are noted. Detailed histories of symptoms, duration of spectacle use, contact lens use, any ocular surgery, topical medication use, allergic eye disease, systemic illness etc. are noted.

Patients were required to suspend soft contact lens wear prior to their SMILE procedure. Basic soft contact lenses were forbidden for a week or more, more than 3 weeks for astigmatic correcting contacts lenses.

All patients received routine preoperative topical antibiotic eye drops (0.5% Moxifloxacin eye drops). Preoperative surface anesthesia was administered, (0.5% proparacaine hydrochloride eye drops) prior to the start of the procedure. Surgery in both eyes of the patients was performed by experienced surgeon using the VisuMax femtosecond laser system (Zeiss, Germany). Thickness of the cap was intended to be 120 μ m in one group and 140 μ m in the other group,

and the rest of the surgical parameters remained the same in the two groups. Refractive lenticule's diameter of the two groups was 6.3–6.5 mm, and the side cut for accessing the lenticule was 90° at a circumferential width of 2 mm.

Visual acuity at presentation and post surgery is recorded by snellens chart. Detailed ocular examination with slit lamp was carried out. Tear film was assessed by schirmer test, tear film break up time, tear meniscus height and OSDI score chart. Contrast sensitivity was assessed by Pelli Robson chart. Cases were followed up at post operative day 1, day 7 and day 30 to know for visual acuity and tear film changes.

Assessment tools:

1. Slit lamp examination
2. Visual acuity by Snellen chart
3. Schirmer test strips
4. Tear film break up time (TBUT) using fluorescein strips
5. Ocular surface disease index (OSDI) score chart
6. Pelli Robson chart

OSDI SCORE ⁵

The OSDI, was created in order to quickly assess the symptoms of ocular irritation in dry eye disease and how they affect functioning related to vision.

This 12-item questionnaire assesses dry eye symptoms and the effects it has on vision-related function.

The questionnaire has 3 subscales: ocular symptoms, vision-related function, and environmental triggers.

Patients rate their responses on a 0 to 4 scale with 0 corresponding to “none of the

time” and 4 corresponding to “all of the time.”

A final score is calculated which ranges from 0 to 100 with scores 0 to 12

representing normal, 13 to 22 representing mild dry eye disease, 23 to 32 representing moderate dry eye disease, and greater than 33 representing severe dry eye disease

Ocular Surface Disease Index[®] (OSDI[®])²

Ask your patients the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

Have you experienced any of the following <i>during the last week</i> ?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light? ..	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 (A)

Have problems with your eyes limited you in performing any of the following <i>during the last week</i> ?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9 (B)

Have your eyes felt uncomfortable in any of the following situations <i>during the last week</i> ?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned? ...	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12 (C)

Add subtotals A, B, and C to obtain D (D = sum of scores for all questions answered) (D)

Total number of questions answered (do not include questions answered N/A) (E)

Please turn over the questionnaire to calculate the patient's final OSDI[®] score.

Statistical Analysis:

The data collected will be analyzed statistically using suitable descriptive statistics namely mean, median, standard deviation, percentage, tables and graphs whenever applicable.

RESULTS

PRE OPERATIVE PARAMETERS

	GROUP A (120μ CAP)	GROUP B (140μ CAP)	P value
AGE DISTRIBUTION (Years)	25.28 ± 2.18	26.42 ± 2.30	0.721
GENDER DISTRIBUTION(M:F)	1.2:1	1.1:1	0.400
BCVA (LogMAR)	-0.078 ± -0.0081	-0.062 ± -0.0028	0.642
SPHERICAL EQUIVALENT (D)	-3.93 ± 1.20	4.12 ± 1.37	0.910
MEAN K (D)	43.07 ± 1.99	44.23 ± 1.52	0.471
CCT (μ)	521.23 ± 38.10	543.74 ± 30.43	0.080

Preoperative parameter

	GROUP A (120μ CAP)	GROUP B (140μ CAP)	P value
OSDI SCORE	8.55 ± 0.99	8.89 ± 1.40	0.061
SCHIRMER 1 (mm)	31.25 ± 2.1	30.15 ± 1.89	0.125
TBUT (sec)	13.10 ± 1.12	12.80 ± 1.68	0.070

Visual Acuity

VISUAL ACUITY (Log MAR)	GROUP A (120μ CAP)	GROUP B (140μ CAP)	P value
POST OP DAY 1	-0.18 ± 0.05	-0.16 ± 0.07	0.450
POST OP DAY 7	-0.18 ± 0.04	-0.17 ± 0.03	0.710
POST OP 3 MONTHS	-0.20 ± 0.06	-0.19 ± 0.06	0.533

Tear Film Report 3 months

TEAR FILM PARAMETERS	GROUP A (120 μ CAP)	GROUP B (140 μ CAP)	P value
OSDI SCORE	8.00 $\pm$ 1.1	7.08 $\pm$ 1.26	0.522
SCHIRMER I (mm)	30.27 $\pm$ 1.1	28.15 $\pm$ 2.39	0.201
TBUT (sec)	12.19 $\pm$ 1.18	12.22 $\pm$ 1.02	0.065

DISCUSSION

In this study we tried to evaluate visual acuity and dry eye status post SMILE surgery with different cap thickness. , In current study comparable results were observed in terms of visual outcomes with both group and no eye losing lines of CDVA in either group demonstrating good safety. No remarkable difference in dry eye status was found at the end of three months in both groups. As it is said that SMILE performed at deeper depth of 140 μ m may lead to sparing of nerve plexus resulting in lesser post operative dry eye. This may be preferred for better outcomes in patients with pre existing dry eye.

CONCLUSION

The study showed comparable outcome of visual outcome and dry eye in both groups. SMILE at deeper depth might provide chance of secondary SMILE within the cap to correct residual refraction. Further clinical studies with larger sample size and longer duration are required to confirm studies.

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