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# Correlation Between the Visual Quality and the Morphology of Corneal Cap after Femto SMILE

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Purpose: This study aims to investigate the morphology of corneal caps in femtosecond laser small incision lenticule extraction (Femto SMILE) and its relation to the visual outcomes. Methods: An observational nonrandomized study of fifty corneal caps created with VisuMax femtosecond laser were examined using a Fourier-domain optical coherence tomography at 3 months after SMILE. The cap thickness at nine points on each of the four meridians (0°, 45°, 90°, and 135°), cap morphology and its correlation with visual outcomes were assessed. Results: The mean achieved central cap thickness was 114.5 µm ±4.37. Cap morphology showed good regularity. The uniformity of cap was maintained at the different areas as the mean cap thickness in the center was significantly thinner than in the paracentral area and peripheral area. Also, the paracentral cap thickness was significantly thinner than peripheral area (p value <0.001 with positive correlation coefficient). Uncorrected visual acuity (UCVA) showed low significant correlation to the central cap thickness (p value < 0.05) with negative correlation coefficient (r =-0.419). Otherwise, the correlations of central cap thickness with BCVA, SE or contrast sensitivity were statistically insignificant. Conclusions: Corneal caps of Femto SMILE are predictable with good reproducibility, regularity, and uniformity. Cap morphology had a mild effect on UCVA although it was significantly low correlated.

**Keywords:** Femto SMILE, corneal cap, anterior segment OCT, cap morphology.

## 1. Introduction

Femtosecond Small incision lenticule extraction (femto SMILE) is a recent form of ‘flapless’ corneal refractive surgery, whereby a flap is not made and lifted but the lenticule is separated and removed through a small incision, leaving an interface in the cornea and the upper arcade of the corneal tissue (equivalent to a flap) called ‘‘cap’’. SMILE uses only one femtosecond laser to complete the refractive surgery, potentially reducing surgical time, side effects, and cost [1]. If successful, SMILE could potentially replace the current, widely practiced laser in-situ keratomileusis (LASIK) [2].

LASIK, which is the current gold standard for corneal refractive surgery, already produces good visual outcomes with refractive predictability. As we do not expect to see a great improvement to the results from the already established LASIK, we aim to demonstrate that if

SMILE is just as good as LASIK.

Fourier-domain optical coherence tomography (OCT) is useful in analyzing cap morphology due to its advantageous non-contact technique, relative ease of use, the ability to visualize wide areas of the cornea including multiple cap interfaces, and to directly measure cap thickness in different meridians [3].

Contrast sensitivity (CS) shows higher correlation than visual acuity with performance of visual functions [4],[5]. The luminance level in the environment in which we live promotes physiological changes in the visual system that affects vision.

Thus, the present study will utilize anterior segment Fourier-domain OCT to perform non-contact comprehensive examination for corneal caps after Femto SMILE. The predictability, regularity and uniformity of the caps created will be assessed and will be correlated with visual outcomes and contrast sensitivity, measured by F.A.C.T. tests (Functional Acuity Contrast Test),

## 2. Material and methods

This observational, non-randomized study included 50 eyes of 25 myopic patients. Criteria for inclusions were age from 18 years or older, best corrected distant visual acuity (BCVA) of 1 Decimal, manifest refraction spherical equivalence (MRSE) not more than 9 Diopters (D), cylinder not more than 3D, no topographic evidence of forme fruste Keratoconus (FFKC), stable refraction for two years prior to surgery and no uses of any kind of contact lenses within the last two weeks before surgery. Exclusion criteria were previous history of ocular trauma or surgery, concomitant active or previous ocular disease such as uveitis and glaucoma, systemic diseases affecting wound healing such as diabetes or collagen vascular diseases, severe dry eye, residual refractive error, or severe allergic eye. Routine pre-operative examinations were conducted in each patient to rule out contraindications for the SMILE procedure.

The study was performed in accordance with the Declaration of Helsinki and was reviewed and approved by the Ethics Committee of Ophthalmology department in our university. Written informed consent was obtained from each patient after the nature and possible consequences of the study were explained.

In this study, all SMILE procedures had been performed using a VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany). A series of bubbles had been created in a spiral fashion with a spot distance of 262 mm resulting in cleavage of the following four tissue planes: the posterior surface of the refractive lenticule, the lenticule border, the anterior surface of the refractive lenticule, and a single small 90-degree angled side-cut incision with a circumferential length of 3 to 4.5 mm in the superior position. In all cases, the intended anterior surface of the lenticule was 100 mm deep, a depth equivalent to the thickness of the cap and its intended diameter was 7.5 mm, 1 mm larger than the diameter of the refractive lenticule. After the FS cutting procedure was done, the refractive lenticule of intrastromal corneal tissue was dissected and separated through the side-cut opening incision and finally manually removed. All corneal caps were created uneventfully.

Evaluations were performed at 3rd month after surgery including manifest refraction, uncorrected distance visual acuity (UCVA), best corrected distant visual acuity (BCVA), anterior segment OCT and contrast sensitivity.

All the operated eyes underwent assessment with a Fourier-domain OCT system (Optovue, Inc., Fremont, CA, USA). A wide-angle (long lens) adapter lens was used in this study. The cornea had been imaged with an 8.0 mm long line scan pattern along the 0, 45, 90, and 135 meridians at the reflective line along each meridian will be assessed. Thus, each cap across the central 8 mm of the cornea was measured at 8 points of each eccentricity (at ±1.5 mm, ±2.5 mm, ±3.25 mm and ±3.75 mm from the center) (figure 1) with a total of 33 points including the vertex.

Visual acuity and visual quality with contrast sensitivity were measured. Contrast sensitivity measurements were made by F.A.C.T. tests (Functional Acuity Contrast Test). The 5 slides had been used at different spatial frequencies and denoted A to E:

•A= 1.5cycles/º

•B = 3 cycles/º

•C = 6 cycles/º

•D = 12 cycles/º

•E = 18 cycles/º

The test consists of sinusoidal gratings aligned at 0º, 15º or –15º. In each step, contrast decreases by 0.15 log units. The test conditions are:

•Luminance 3 cd/m2.

•Peripheral glare 1 lux.

•Test chart at long distance (6m).

•Sinusoidal wave test.

The last corrected grating seen for each spatial frequency was plotted on CS curve figure (2).

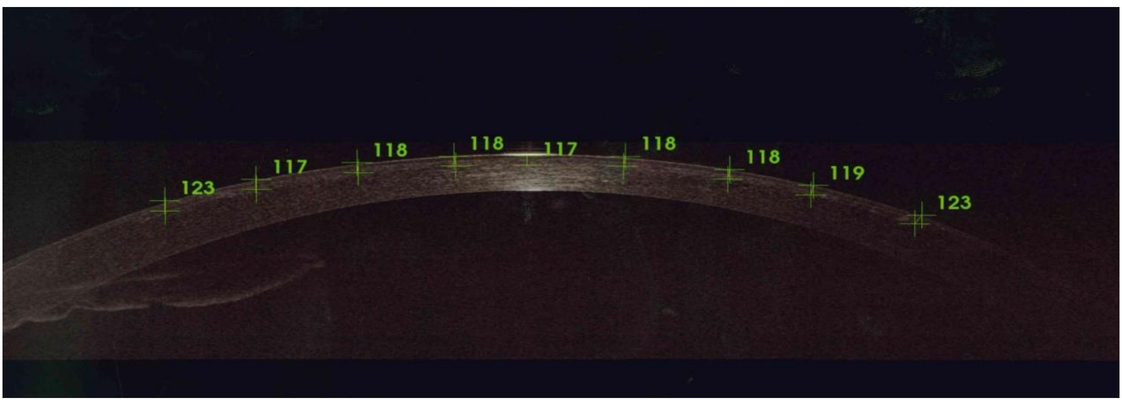


Figure (1): AS OCT showing cap thickness in 8 points across 45° meridian

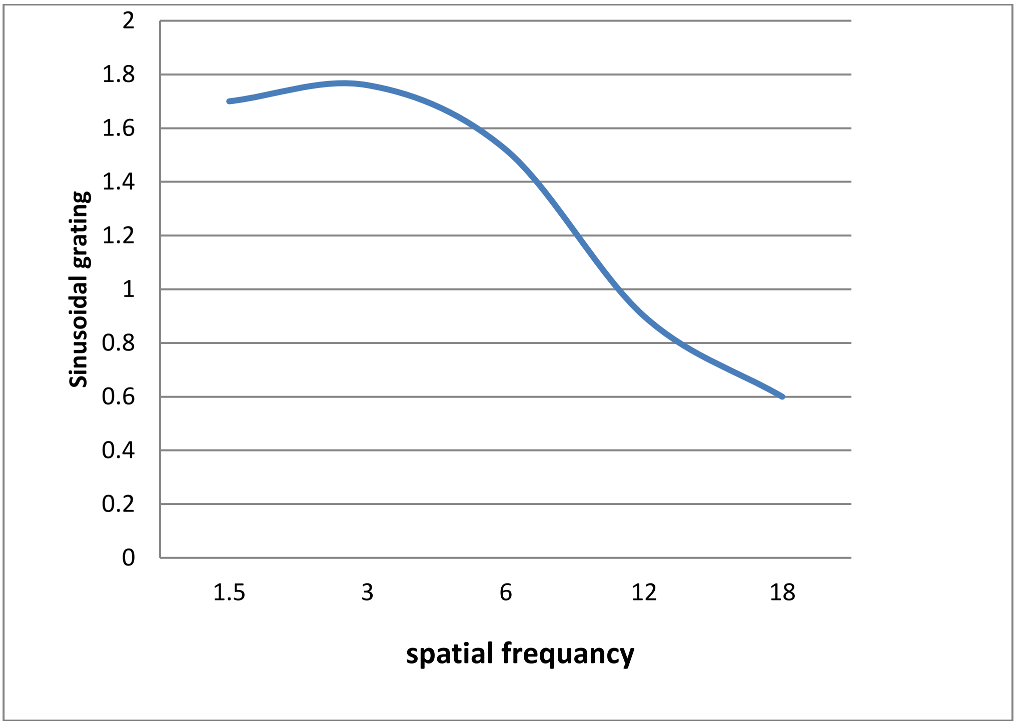


Figure 2: contrast sensitivity curve

Statistical Analyses

The accuracy of central corneal cap thickness was calculated as the difference between the achieved and intended values. Reproducibility was evaluated as the inter-individual standard deviation (SD) of the central cap thickness between eyes. To evaluate the regularity of the caps, the mean cap thickness of each eight points at the same eccentricity were compared, respectively. Moreover, the cap measurements at the center position along four medians were averaged to calculate the mean central cap thickness. Similarly, the cap measurements at the 1.5 mm and 2.5 mm positions were averaged to calculate the mean paracentral cap thickness while the 3.25 mm and 3.75 mm positions were averaged to calculate the mean peripheral thickness. To show the uniformity of the caps, a generalized linear mixed-model for repeated measures was applied to compare peripheral to central measurements.

Furthermore, the Spearman correlation analysis was used to assess the relation between postoperative visual outcomes and cap morphology. The parameters of visual outcomes were Decimal, UCVA and BCVA, SE, and contrast sensitivity. The parameters of cap morphology comprised of central cap thickness and the gross index of uniformity, U, defined as the standard deviation of the cap thickness of the total 33 points. The normality of the data distributions was tested using the Kolmogorov-Smirnov test. A P value of less than 0.05 was statistically significant. All data were collected using Excel software, version 2003 (Microsoft Corporation, Redmond, WA, USA). Statistical analyses were performed using SAS system software, version 8.2 (SAS Institute Inc., Cary, NC, USA).

## 3. Results

In this study, 50 eyes of 25 patients were included and completed the 3-month follow-up. The mean age was 30.08 years (range 22 to 39 years). Thirteen patients were males (52%). The mean preoperative UCVA was 0.16 decimal 0.102 ranging from 0.05 to 0.3. The mean preoperative SE was -4.16 D ± 1.86 ranging from -3.5 to -8.5. The mean preoperative BCVA 1.03 decimal ± 0.096 ranging from 0.9 to 1.2

The mean post-operative UCVA was 1 decimal ± 0.1 ranging from 0.7 to 1.2. The mean post-operative SE was -0.08 D ±0.33 ranging from -0.5 to 0.5. The mean post-operative BCVA was 1.1 decimal ± 0.1 ranging from 1 to 1.2. The mean contrast sensitivity measurements were 1.427 cd/m2 ± 0.134 ranging from 1.236 to 1.744.

Anterior segment OCT and cap morphology results

The mean achieved central cap thickness was 114.5 µm ±4.37 (range from 109.80 to 124.40) µm. As regard the cap predictability the mean achieved central cap thickness was 14.5 µm ±4.37 thicker than intended thickness (ranging between 9.8 to 24.4). The mean para central cap thickness was 114.68 µm ±4.34 (ranging from 110.19 to 124.56). The mean peripheral cap thickness was 116.15 µm ±4.16 (ranging from 112 to 125.69). The mean value of gross index uniformity (index U) was 1.1 ±0.30 ranging from 0.7 to 1.7. When we examined cap thickness in each eccentricity, we found that the mean thickness in 1.5 mm eccentricity was 114.33 µm ±4.4 (ranging from 109.75 to 124.5), the mean thickness in 2.5mm eccentricity was 115.02µm ±4.2 (ranging from 110.62 to 125.5), the mean thickness in 3.25 eccentricity was 115.77µm ±4.19 (ranging from 111.62 to 125.5) and the mean thickness in 3.75 eccentricity was 116.53µm ±4.14 (ranging from 112.37 to 125.87) table (1). When cap thickness between each eccentricity was compared. It showed statistically significant different (P value <0.001) with good positive correlation coefficients (> 0.9). This reveals a good regularity. table (2).

The uniformity of cap was maintained at the different area as the mean cap thickness in the center was significantly thinner than in the paracentral area and peripheral area (figure 3 and figure 4). Also, the paracentral cap thickness was significantly thinner than peripheral area (p value <0.001 with positive correlation coefficient) (figure 5).

Spearman correlation analysis revealed a low significant correlation between central cap thickness and UCVA (p value < 0.05) with negative correlation coefficient (r =-0.419) (figure 6). Otherwise, the correlations of central cap thickness with BCVA, SE or contrast sensitivity were statistically insignificant. Also, the correlations of index U with UCVA, BCVA and SE were statistically insignificant table (3).

Contrast sensitivity data was averaged and was correlated to mean central cap thickness and gross uniformity index. There was no statistically significant correlation between contrast sensitivity and either central cap thickness (P value was 0.06) (figure 7) or uniformity index (p value was 0.225) (figure 8).

Table (1): show average thickness of each 33 point of corneal cap

| location | 0 | 45 | 90 | 135 |
|---|---|---|---|---|
| 0mm | 113.76 | 113.76 | 113.76 | 113.76 |
| 1.5mm | 114.18 | 114.52 | 114.14 | 114.48 |

| | | | | |
|---|---|---|---|---|
| -1.5 | 113.884 | 114.432 | 114.556 | 114.52 |
| 2.5 | 114.8 | 115.02 | 114.9 | 115.2 |
| -2.5 | 114.848 | 115.12 | 115.192 | 115.144 |
| 3.25 | 115.44 | 115.86 | 115.46 | 115.88 |
| -3.25 | 115.62 | 115.816 | 116.14 | 115.976 |
| 3.75 | 116.22 | 116.32 | 116.76 | 116.64 |
| -3.75 | 116.34 | 116.568 | 116.72 | 116.712 |

Table (2): correlation between cap thicknesses through different eccentricities

| | 2.5 mm eccentricity | | 3.25 mm eccentricity | | 3.75 mm eccentricity | |
|---|---|---|---|---|---|---|
| | p | R | p | R | p | R |
| 1.5mm eccentricity | 0.001 | 0.974 | 0.001 | 0.973 | 0.001 | 0.931 |
| 2.5mm eccentricity | | | 0.001 | 0.98 | 0.001 | 0.43 |
| 3.25mm eccentricity | | | | | 0.001 | 0.963 |

Table (3): show the p value and correlation coefficient between cap morphology and visual outcomes.

| Cap morphology | | Post Op UCVA | Post OP SE | Post Op BCVA | Contrast sensetivity |
|---|---|---|---|---|---|
| Gross index uniformity | Correlation Coefficient | .078 | -.263 | -.056 | -.252 |
| | p-value | .710 | .203 | .792 | .225 |
| | N | 50 | 50 | 50 | 50 |
| Mean central cap thickness | Correlation Coefficient | -.416* | .131 | -.111 | .383 |
| | p-value | .039 | .533 | .596 | .059 |
| | N | 50 | 50 | 50 | 50 |

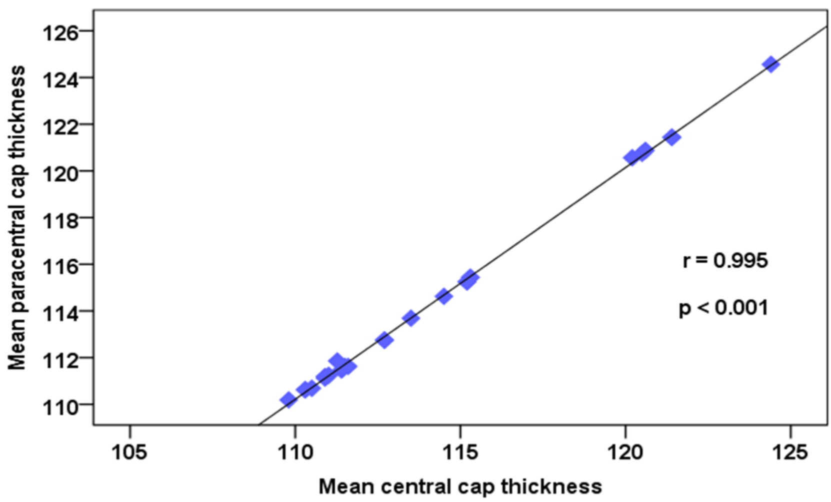


Figure (3): correlation between mean central cap thickness and paracentral thickness

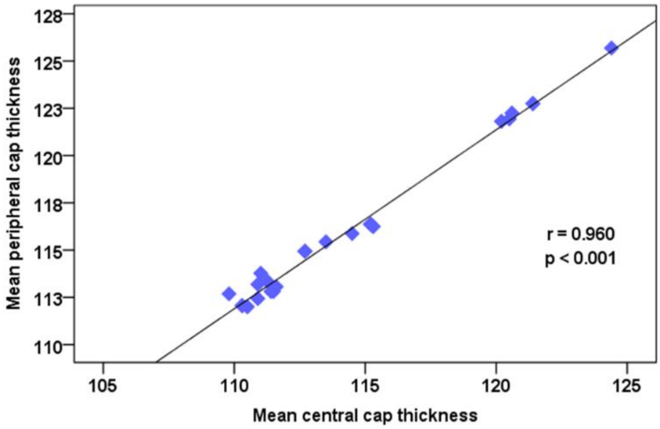


Figure (4): correlation between mean central cap thickness to mean paracentral thickness

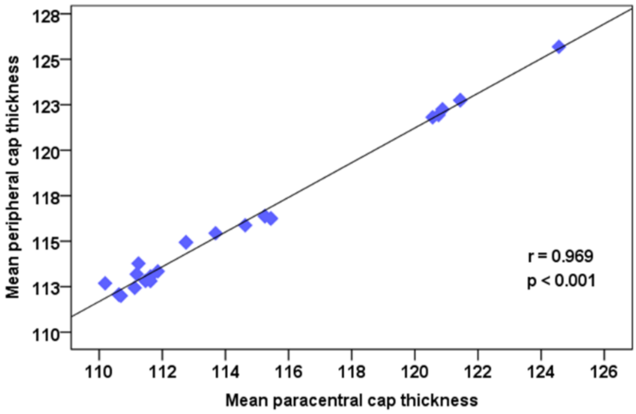


Figure (5): Correlation of mean paracentral cap thickness and peripheral cap thickness

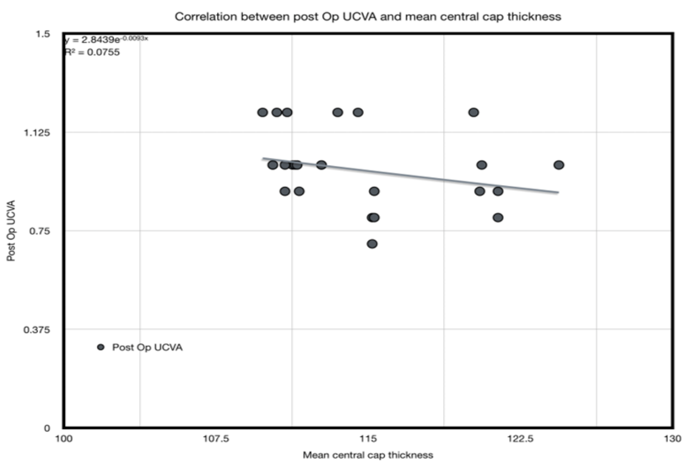


Figure (6): Correlation of post-operative UCVA and mean central cap thickness

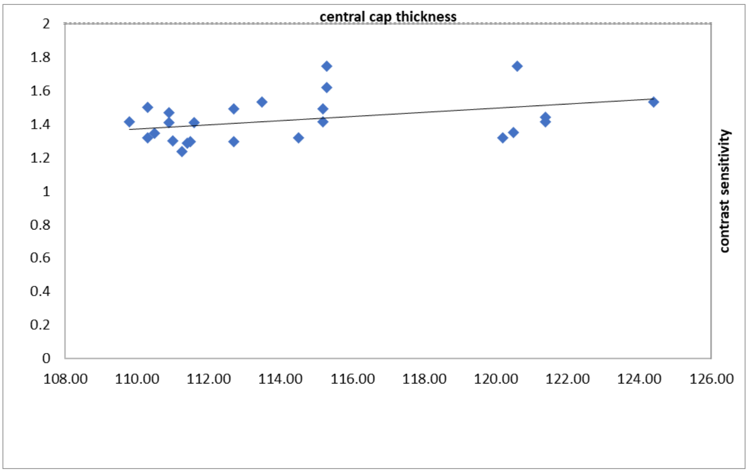


Figure (7): correlation between central cap thickness and contrast sensitivity

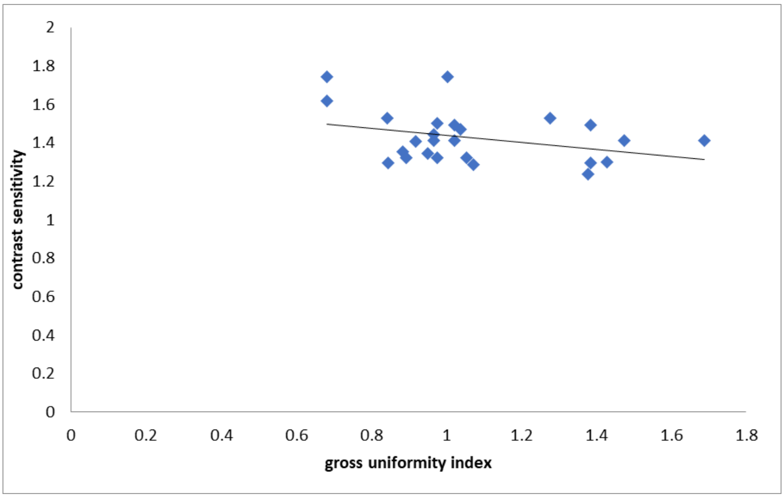


Figure (8): correlation between contrast sensitivity and gross uniformity index

## 4. Discussion

The present study demonstrated a good predictability for SMILE central cap thickness. The caps were 14.5 µm ±4.37 thicker than intended thickness (ranging between 9.8 to 24.4). Similar to a study published by Zhao et al, they found that VisuMax FS yielded SMILE caps 10.81 µm, 9.58 µm, 7.32 µm, and 8.74 µm thicker than the intended thickness at 1 day, 1 week, 1 month and 6 months respectively after surgery [1]. Binder suggested that the speed of the FS was important and correlated with flap thickness predictability, and he also reported that the FS photodisrupted more deeply when set between 110 µm and 120 µm with a SD of 12 µm but dissected less deeply when set between 130 µm and 140 µm with a SD of 18.5 µm [6]. However, the mechanism of the impact of cap creation and corneal wound healing on cap thickness after SMILE remains unclear. Furthermore, our results showed good regularity of cap thickness with no difference among the different measurement points at each eccentricity. Regularity in cap thickness has a role in providing adequate biomechanical support and strength as well as in producing successful refractive and wavefront outcomes [7]. This finding went hand by hand to results detected by Zhao et al. Although, they found two pairs of points at 1.5 mm and 2.5 mm eccentricities, which had significant difference in the first day post-operative, the difference improved over the time with clearance of opaque bubble layer and tissue healing. They suggested that this may had an impact on UCVA in the first day post-operative day [1].

When we look to cap uniformity, we found the cap is thinner centrally compared to paracentral and peripheral area, as well as paracentral is thinner to peripheral cap area. This finding was matched to those result by Zhao et al as regard to central cap compared to peripheral cap thickness but they found no difference in the thickness between paracentral to peripheral cap thickness [1]. Also, similar results were yielded by Kim et al , who detected factors influencing the corneal flap thickness in FS Lasik. They found that the mean achieved flap thickness in central 1.5 mm radius was thinner than that in the peripheral 3 to 4 mm radius [8]. Von Jagow et al, who compared corneal architecture after FS LASIK & microkeratome assisted LASIK, also reported that the mean FS flap thickness increases toward the periphery [9]. This outcome was explained by Dawson et al, who examined the biomechanical and wound healing characters of cornea after LASIK. They demonstrated an increasing tensile strength from the center to the periphery of cornea [10].

When we compared the cap thickness to the visual outcome, the cap thickness was found to have a low significant impact on post-operative UCVA. Similarly, Zhao et al found that the decrease in postoperative UCVA was associated with increase central corneal thickness at day 1 and week 1 follow up [1]. They attributed this finding to the post-operative corneal edema, which leads to an increase in the cap thickness affecting visual acuity. Otherwise, we did not detect any impacts of cap thickness or index uniformity on other visual outcomes. This finding contrasts Zhoa et al, who found that index uniformity had an impact on both UCVA and BCVA only at one week follow up but faded away at 6month post-operative follow up [1].

Decreased contrast sensitivity can negatively affect the quality of vision and patient satisfaction [11]. So, the assessment of CS along with UCVA and BCVA provides an evaluation of post-operative visual quality. In our study we used Functional Acuity Contrast Test (F.A.C.T.) to assess CS. We found that CS was not affected either by central cap thickness or uniformity index. This finding was matched to a study by Andreas et al. They used the Freiburg acuity and contrast test method to compare and evaluate CS in patient with high myopia who received FLEx in one eye and Femto SMILE on the other eye. They found that CS was not affected objectively or subjectively 6 months after surgery.

In conclusion, our study demonstrated that corneal cap created in FS SMILE using VisuMax was predictable with good regularity and uniform morphology. The cap morphology showed minimal effect on only UCVA although it was of low statistical significance, but not on other visual outcomes.

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