

Effect of Residual Stromal Bed and Postoperative Dry Eye on Quality of Life after FS-LASIK and SMILE

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Aim: Several studies have highlighted the importance of residual stromal beds (RSB) in the quality of patient vision. Patients with RSB <350 μ m experienced a significant decrease in vision quality over time. A thinner RSB after refractive surgery increased corneal ectasia risk. Dry eye complaints are the leading cause of decreased quality of life post-surgery. These complaints can manifest immediately after surgery and typically improve within 6 months. This study aimed to compare the improvement in patient quality of life pre- and post-refractive surgery procedures in relation to RBS and postoperative dry eye status.

Methods: This was a prospective, analytical, observational study. A total of 57 patients met the inclusion criteria: 33 underwent a femtosecond laser-assisted in situ keratomileusis (FS-LASIK) procedure, and 24 underwent small incision lenticule extraction (SMILE). Samples were taken using a purposive method at the LASIK Center. Patients were asked to fill out the National Eye Institute Refractive Error Quality of Life (NEI-RQL) 42 questionnaire, and an integrated dry eye assessment (IDRA) ocular surface analyzer examination was conducted at the Aesthetic and Dry Eye clinic.

Results: Significant differences in characteristics were found, with greater refractive error in the thinner RSB group. A comparison of questionnaire score improvements showed higher scores in the thinner RSB group, especially for distance vision and dependence on corrections. No differences in quality-of-life improvement were observed among the different noninvasive break-up time (NIBUT) postoperative groups.

Conclusion: Patients with thinner RSB experienced a better quality of life improvement one-month post-surgery.

Keywords: SMILE, FS-LASIK, patients' quality of life

Introduction

Refractive errors are the leading cause of reversible visual impairment. Surveys conducted by the World Health Organization (WHO) and the International Agency for Prevention of Blindness (IAPB) show that the blindness rate in Indonesia is 3%, with refractive errors being the second most common cause of moderate visual impairment. Aldiana et al showed that the prevalence of refractive errors in children in Bandung was 15.9%, with 12.1% remaining uncorrected. Uncorrected refractive errors can significantly reduce the patients' quality of life, education, and work.¹⁻⁸

Treatments for refractive errors include glasses, contact lenses, or refractive surgical procedures. The most common refractive surgeries are laser-assisted in situ keratomileusis (LASIK) and small-incision lenticule extraction (SMILE). Traditional LASIK procedures use a microkeratome to create a corneal flap. However, femtosecond laser use is currently more common because it can produce a more accurate flap and reduce complication rates. SMILE uses a femtosecond laser to create a lenticular layer that is extracted through a small incision in the cornea. This procedure involves minimal modifications to the structure of the cornea and its innervation.⁹⁻¹⁴

LASIK surgery requires the stroma thickness after the procedure to be thicker than 280 μ m with normal corneal curvature. Several studies have reported the importance of the residual stromal bed (RSB) in determining patients'

quality of vision. Kosuke et al showed that patients with RSB < 350 µm will have a significant decrease in vision over time when compared to patients with RSB > 350 µm. Navid et al also demonstrated a correlation between RSB thickness and visual outcomes. A thinner RSB after refractive surgery increases the risk of corneal ectasia. Postoperative ectasia rates are lowest in the SMILE procedure, which usually has a higher postoperative RSB. Some studies have shown that visual acuity and stability are maintained in RSB >300 µm. To date, the relationship between RSB thickness and subjective visual quality outcomes has not been extensively explored, particularly in the early postoperative period.^{15–19}

Dry eye complaints are the leading cause of a decreased quality of life post-surgery. The femtosecond laser-assisted in situ keratomileusis (FS-LASIK) procedure involves creating a flap which causes more severe corneal nerve damage and increases postoperative dry eye symptoms. Yingjie et al showed that post-SMILE surgery patients had higher TBUT and minimal dry eye symptoms than post-FS-LASIK surgery patients. Postoperative dry eye symptoms can manifest immediately after surgery and typically improve within six months. Non-invasive modalities such as the integrated dry eye assessment (IDRA) ocular surface analyzer can be used to objectively measure break-up time and obtain results in the form of non-invasive break-up time (NIBUT). Dry eye disease is caused by several risk factors. The surgical techniques chosen have different levels of reduction in corneal nerve thickness. This decrease in nerve thickness often occurs particularly in the temporal region.^{20–24}

Considering these factors, this study aimed to compare the improvement in patients' quality of life before and after refractive surgery procedures in relation to RSB and postoperative dry eye status.

Subjects and Methods

This analytical, observational study employed a prospective cohort design. The sampling was done using purposive sampling. The study population was recruited from the LASIK Center, Cicendo National Eye Hospital, Indonesia. The study acquired ethical approval from the local ethics committees of Cicendo National Eye Hospital, Indonesia. All procedures conducted in studies were in accordance with the ethical standards of institutional and/or research committee, and with the 1975 Declaration of Helsinki, as revised in 2013. Written informed consent was obtained from all participants, with legal guardians providing consent for minor participants prior to their inclusion in the study. Patients undergoing screening for refractive surgery and NIBUT were examined using IDRA at the Aesthetic Eye Center. Patients were asked to complete the National Eye Institute Refractive Error Quality of Life (NEI-RQL) 42 questionnaire before surgery and one-month post-surgery. The research was conducted from February to May 2024 after obtaining approval from the Cicendo National Eye Hospital Ethics Committee.

The inclusion criteria were as follows: patients undergoing the SMILE or FS-LASIK procedure in both eyes, willing to participate in the study and fill out a questionnaire before and 1 month after the SMILE or FS-LASIK procedure, and had never undergone a surgical procedure. Exclusion criteria were patients who experienced complications during and after the SMILE or FS-LASIK procedure and those who could not visit 1 month after the SMILE or FS-LASIK procedure.

The required sample size for this study is 20 subjects in each group of SMILE and FS-LASIK. The sample size calculation was based on the following formula:

$$n_1 = n_2 = 2 \left(\frac{(z_\alpha + z_\beta)s}{x_1 - x_2} \right)^2$$

$$n_1 = n_2 = 2 \left(\frac{(1.64 + 0.84) * 4.61}{3.61} \right)^2$$

$$= 2(10) = 20$$

where n represents the sample size, z denotes the chosen alpha and beta values for significance and power tests, s represents the standard deviation, and $x_1 - x_2$ represents minimum clinically significant difference in means between the two groups. After accounting a non-response rate of 10%, the final sample size consisted of 44 eyes.

Each patient undergoing SMILE or FS-LASIK surgery was examined for uncorrected and best corrected distance and near visual acuity, followed by comprehensive refractive surgery screening. All patients then underwent ocular surface analysis using IDRA ocular surface analyzer conducted by a single examiner to minimize inter-examiner variability. The results were interpreted by ophthalmologist. Patients were asked to complete a validated local-language version of NEI-RQL 42 questionnaire. At one-month follow-up, patients were re-evaluated for uncorrected and best corrected distance and near visual acuity and were asked to complete the same questionnaire.

Analysis of research data was performed using SPSS version 24.0 for Windows. Data are presented as percentages (%) for categorical variables and mean $\pm$ standard deviation (std) and median for numerical variables. Statistical tests were used to compare the means of numerical variables between the two groups using the unpaired *t*-test and Mann-Whitney *U*-test. Meanwhile, statistical analysis for categorical data was performed using the chi-square test if the chi-square requirements were met; if not met, Fisher's exact test was used for 2 $\times$ 2 tables and the Kolmogorov Smirnov test for tables other than 2 $\times$ 2. The chi-square test requirement is that no expected values <5 are in 20% of the table. Statistical significance was set at $p < 0.05$.

Results

In this study, 59 patients met the inclusion criteria during the study period: 35 patients who underwent the FS-LASIK procedure and 24 patients who underwent the SMILE procedure. There are two patients who underwent FS-LASIK were lost to follow-up and did not return for the one-month postoperative evaluation.

Table 1 summarizes the demographics and clinical characteristics of patients in the RSB <350 and NIBUT group. The mean age in RSB <350 μm group is significantly higher compared to that of the RSB ≥ 350 group. This study showed

Table 1 Baseline and Clinical Characteristics of Patients Stratified by Residual Stromal Bed Thickness and Postoperative Tear Film Stability (NIBUT)

Variable	RSB		P value	NIBUT		P value
	<350 N=32	≥ 350 N=25		≤ 10 seconds N=25	>10 seconds N=32	
Age			0.013*			0.464
Mean $\pm$ Std	21.31 $\pm$ 5.152	19.08 $\pm$ 3.662		19.40 $\pm$ 2.432	21.06 $\pm$ 5.775	
Median	20.00	18.00		19.00	19.00	
Range (min-max)	17.00–40.00	17.00–36.00		17.00–26.00	17.00–40.00	
Sex			0.396			0.368
Male	21(65.6%)	19(76.0%)		16(64.0%)	24(75.0%)	
Female	11(34.4%)	6(24.0%)		9(36.0%)	8(25.0%)	
Education			0.067			1.000
Middle	25(78.1%)	24(96.0%)		22(88.0%)	27(84.4%)	
Advance	7(21.9%)	1(4.0%)		3(12.0%)	5(15.6%)	
Occupation			0.761			0.997
Students	25(78.1%)	24(96.0%)		23(92.0%)	26(81.3%)	
Work	6(18.8%)	1(4.0%)		2(8.0%)	5(15.6%)	
Does not work	1(3.1%)	0(0.0%)		0(0.0%)	1(3.1%)	
SE			0.0001*			0.590
Mean $\pm$ Std	−5.22 $\pm$ 2.820	−2.21 $\pm$ 1.951		−3.76 $\pm$ 2.747	−4.01 $\pm$ 3.022	
Median	−4.57	−1.75		−2.50	−3.13	
Range (min-max)	−10.63(−1.50)	−10.75(−0.63)		−9.25(−0.75)	−10.75(−0.63)	
SE Category			0.0001*			0.295
< -3.00 D	8(25.0%)	20(80.0%)		14(56.0%)	14(43.8%)	
-3.00 to 6.00 D	11(34.4%)	4(16.0%)		4(16.0%)	11(34.4%)	
> -6.00 D	13(40.6%)	1(4.0%)		7(28.0%)	7(21.9%)	

(Continued)

Table 1 (Continued).

Variable	RSB		P value	NIBUT		P value
	<350 N=32	≥350 N=25		≤10 seconds N=25	>10 seconds N=32	
NIBUT			0.931			
Mean±Std	10.50±2.584	10.43±3.056				
Median	10.60	10.20				
Range (min-max)	5.10–14.50	4.90–15.40				
NIBUT Category			0.578			
≤10 seconds	13(40.6%)	12(48.0%)				
>10 seconds	19(59.4%)	13(52.0%)				
RSB Category						0.578
<350				13(52.0%)	19(59.4%)	
≥350				12(48.0%)	13(40.6%)	
Operation			0.057			0.172
SMILE	17(53.1%)	7(28.0%)		8(32.0%)	16(50.0%)	
FS-LASIK	15(46.9%)	18(72.0%)		17(68.0%)	16(50.0%)	

Notes: *indicates a statistically significance difference.

a greater proportion of patients in <350 µm group with higher myopic corrections compared to the RSB ≥350 µm group with mean SE -5.22 ± 2.820 D and -2.21 ± 1.951 , respectively. The highest percentage in RSB <350 µm group is >−6.00 D category. No significant differences in RSB group regarding sex, education, occupation or NIBUT values. Similarly, in NIBUT group, there are no statistically significant differences in age, sex, education, occupation or spherical equivalent. Continuous variables (age and SE) were analyzed using Mann–Whitney test, while categorical variables were assessed using chi-square, Fisher's exact, or Kolmogorov–Smirnov tests.

Table 2 presents postoperative quality of life using NEI-RQL 42 questionnaire scores stratified by RSB thickness and postoperative NIBUT. Patients with RSB < 350 µm group demonstrated significantly greater improvements in several

Table 2 Comparison of Quality of Life Outcomes by Residual Stromal Bed Thickness and NIBUT Categories

Variable	RSB		P value	NIBUT		P value
	<350 N=32	≥350 N=25		≤10 seconds N=25	>10 seconds N=32	
Clarity of vision			0.146			0.889
Mean±Std	38.02±26.160	27.17±29.257		32.67±27.335	33.73±28.660	
Median	38.54	33.33		39.58	32.29	
Range (min-max)	−12.50–83.33	−29.17–91.67		−20.83–91.67	−29.17–83.33	
Expectations			0.694			0.451
Mean±Std	21.09±33.062	25.00±34.611		20.00±32.275	25.00±34.780	
Median	12.50	25.00		0.00	25.00	
Range (min-max)	−50.00–100.00	−50.00–100.00		−50.00–100.00	−50.00–100.00	
Near vision			0.239			0.401
Mean±Std	26.55±26.851	15.58±19.636		18.67±23.490	24.15±25.164	
Median	14.58	14.58		14.58	14.58	
Range (min-max)	−8.33–81.25	−27.08–62.50		−8.33–81.25	−27.08–68.75	
Distance vision			0.005*			0.784
Mean±Std	30.72±26.734	9.87±16.124		22.73±27.027	20.67±23.356	
Median	24.17	8.33		15.00	19.17	
Range (min-max)	−6.67–89.00	−41.67–46.67		−6.67–89.00	−41.67–76.67	

(Continued)

Table 2 (Continued).

Variable	RSB		P value	NIBUT		P value
	<350 N=32	≥350 N=25		≤10 seconds N=25	>10 seconds N=32	
Diurnal fluctuations			0.061			0.619
Mean±Std	35.55±31.466	20.50±26.786		26.67±29.117	30.73±31.372	
Median	29.17	16.67		29.17	20.84	
Range (min-max)	-20.83–100.00	-29.17–58.33		-29.17–83.33	-29.17–100.00	
Activity limitations			0.367			0.212
Mean±Std	12.61±24.532	6.25±28.183		6.64±25.883	12.30±26.492	
Median	9.38	0.00		0.00	12.50	
Range (min-max)	-37.50–62.50	-37.50–68.75		-25.00–68.75	-37.50–62.50	
Glare			0.016*			0.949
Mean±Std	8.20±28.506	-10.00±26.021		0.50±31.350	0.00±26.941	
Median	12.50	-12.50		0.00	6.25	
Range (min-max)	-50.00–75.00	-50.00–50.00		-50.00–62.50	-50.00–75.00	
Symptoms			0.267			0.300
Mean±Std	3.35±21.542	-2.57±17.238		3.86±20.823	-1.68±18.985	
Median	3.57	-3.57		0.00	-3.57	
Range (min-max)	-42.86–46.43	-42.86–28.57		-42.86–46.43	-42.86–35.71	
Dependence on correction			0.004*			0.853
Mean±Std	46.40±35.740	19.00±25.347		33.23±36.428	35.29±32.946	
Median	45.14	12.50		29.17	31.25	
Range (min-max)	-29.17–100.00	-20.83–83.33		-29.17–100.00	-16.67–83.33	
Worry			0.315			0.641
Mean±Std	21.48±35.389	11.50±38.683		14.50±39.967	19.14±34.778	
Median	18.75	0.00		12.50	12.50	
Range (min-max)	-62.50–100.00	-87.50–100.00		-87.50–100.00	-62.50–100.00	
Suboptimal correction			0.435			1.000
Mean±Std	9.38±36.201	14.50±32.612		11.50±36.961	11.72±32.986	
Median	0.00	0.00		0.00	0.00	
Range (min-max)	-37.50–100.00	-50.00–100.00		-50.00–100.00	-37.50–100.00	
Appearance			0.939			0.152
Mean±Std	12.92±32.348	13.60±34.237		6.13±33.218	18.75±32.059	
Median	6.67	6.67		0.00	13.33	
Range (min-max)	-66.67–73.33	-73.33–80.00		-66.67–80.00	-73.33–73.33	
Satisfaction with correction			0.827			0.225
Mean±Std	10.63±25.895	8.80±16.411		12.80±18.148	7.50±24.757	
Median	10.00	0.00		20.00	0.00	
Range (min-max)	-40.00–60.00	-20.00–40.00		-20.00–40.00	-40.00–60.00	
Average			0.023*			0.605
Mean±Std	19.78±14.793	11.37±11.554		14.99±14.367	16.95±13.880	
Median	20.97	12.99		12.99	15.56	
Range (min-max)	-5.25–53.11	-15.87–32.85		-10.23–53.11	-15.87–50.23	

Notes: *indicates a statistically significance difference.

quality of life (QoL) categories. In comparison to the RSB ≥ 350 μm group, this group reported superior distance vision ($p=0.005$), significant reduction in glare symptoms ($p=0.016$), reduced dependence on corrective lenses ($p=0.004$) and higher overall average QoL scores ($p=0.023$). Clarity of vision, near vision, diurnal fluctuations, symptoms and satisfaction with correction were not significantly different between the RSB group in the first month following surgery. In contrast, the comparison of postoperative NIBUT revealed no statistically significant differences in any QoL

categories ($p>0.05$). Clarity of vision, dry eye symptoms, glare, dependence on correction, and overall satisfaction were comparable in both NIBUT group. This suggests that subjective visual quality did not significantly affected by early postoperative tear film stability as evaluated by NIBUT during the first month follow-up period. For NIBUT comparison, unpaired *t*-test and Mann–Whitney tests were used based on data distribution.

Discussion

Stromal thickness measurement is a mandatory examination that must be carried out before refractive surgery. In a study conducted by Hashmani et al, no differences were found in the stromal thickness between men and women. They also found that age was negatively correlated with stromal thickness. This aligns with the demographic data in this study, in which the group of patients with an RSB $<350\text{ }\mu\text{m}$ was significantly older. The SMILE and FS-LASIK procedures involve stromal modification using an excimer or femtosecond laser. The thickness of the modified stroma is in accordance with the degree of refractive error, which must be corrected. In accordance with this theory, it can be seen in this study that the lower postoperative stromal bed residual group had a higher preoperative refractive error.^{14,17,24–26}

When comparing the improvement in quality of life in patients with RSB $<350\text{ }\mu\text{m}$ and $>350\text{ }\mu\text{m}$, it was found that there was a significant difference in the RSB group of $<350\text{ }\mu\text{m}$, especially in the variables of distance vision and dependence on correction. This is because the two groups differed in the severity of refractive errors. The lower RSB group had a more severe degree of refractive error; therefore, after surgery, they felt their distance vision was clearer. In addition, patients with severe degree of refractive errors often use assistive devices for their daily activities; thus, after surgery, there is an increase in delta dependence on correction.^{27–32}

The lower RSB group also has a higher score in clarity of vision, near vision, and activity limitation but not statistically significant. However, the mean scores in clarity of vision, near vision and activity limitations suggest a trend toward better subjective visual outcomes. The difference in refractive error status may also contribute to the difference in quality of life overtime. Several studies showed that the efficacy index of post-operative high myopia was worse at 5 years post-operatively when compared to mild and moderate myopia. This might have been due to lower RSB that affect the corneal biomechanic, and long-term growth of axial length in high myopia. A long term study to assess the difference in quality of life score after long-term surgery may be helpful to address this problem.^{33–35}

In this study, there are significant difference in glare variable, where people with higher RSB have more significant glare complaint post-operatively. Glare, halos, and starburst can happen after refractive surgery and is caused by induction of Higher Order Aberration (HOA). HOA may be caused by intraoperative issues such as eye movement or poor fixation that cause decentered ablation, central island, and small ablation zone. In this study, there are no noticeable complication intra-operatively. Study by Elsa et al also shows that HOA post-refractive surgery is higher in high myopia group that caused by ablation-induced change in corneal asphericity and may be positively correlated with the amount of refraction correction. This is different from the results of our study where people with higher myopia complain less glare than patient with lower myopia. This may be caused by the fact that patient with higher myopia usually already have more severe glare than lower myopia, so they did not feel any significant difference post-operatively. Future study need to address this variable quantitatively using wavefront analysis to determine the difference in HOA induction in both groups.^{27–32}

In this study, no significant differences existed in the population with postoperative NIBUT $<10\text{ s}$ or $>10\text{ s}$. Previous studies stated that SMILE resulted in a lower degree of dry eye than FS-LASIK; however, no difference was found in this study. This can be attributed to providing artificial tears to all patients after refractive surgery, which disguises dry eyes. In addition, there was no statistically significant difference in the increase in quality of life scores in the two groups.^{11,14,20,21,24,30}

A limitation of this study is that no matching was performed in the study population. This study also only compared the quality of life one-month post-surgery, when the influence of corneal ectasia caused by a thinner stromal bed is usually more significant in the longer term. All postoperative patients were administered artificial tear drops so that dry eye symptoms could be disguised and affect the patient's quality of life. Another limitation in this study is that potential confounders such as age, refractive error, and preoperative dry eye were not fully controlled, which may have influenced

the outcomes. A future study is needed to understand the long-term effect on patient's quality of life and also use the objective HOA measurement such as wavefront aberrometry and contrast sensitivity.

Conclusion

In this study, there was a greater improvement in quality-of-life scores average in patients with RSB <350 one month postoperatively. This suggest that patients with higher refractive error usually have better subjective benefit postoperatively. Glare was more pronounced in the lower refractive error group subjectively and still needed further study to confirm these findings quantitatively. No differences were observed in quality-of-life improvement among the different NIBUT postoperative groups, however this may be caused by surgeon providing artificial tears to all patients after refractive surgery, which disguises dry eye symptoms. These findings provide insight for clinician when counseling patients, particularly in early postoperative follow-up and with high myopia. Further long-term studies are needed to assess quality of life, dry eye progression and visual quality beyond the first postoperative month.

Disclosure

The authors report no conflicts of interest in this work.

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