ORIGINAL ARTICLE

VISUAL AND REFRACTIVE OUTCOME OF NEW GENERATION SMALL INCISION LENTICULE EXTRACTION (SMILE) IN MYOPIA AND MYOPIC ASTIGMATISM

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ABSTRACT

Introduction: *Two main options for the surgical correction of high myopia and myopic astigmatism are corneal refractive surgery and implantation of phakic intraocular lens (IOL). Small Incision Lenticule Extraction (SMILE) is becoming more popular technique which includes a minimally invasive flap-free procedure. The aim of this study is to evaluate the visual and refractive outcome of New Generation SMILE in myopia and myopic astigmatism.*

Methods: *This is an observational retrospective study in patients who underwent SMILE using Visumax 800 Femtosecond laser procedure at Undaan Eye Hospital in period December 2022 to February 2023. Pre and post operative uncorrected visual acuity (UCVA), spherical equivalent (SE), astigmatism value, keratometry and intra ocular pressure (IOP) were evaluated at 1 day, 1 week and 1 month follow-up.*

Results: *The study comprised 30 eyes of 15 patients age from 18 to 32 years old. The mean post operative UCVA was significantly improved to 0.03 ± 0.06 logMAR at 1-day, 0.02 ± 0.04 logMAR at 1-week and -0.01 ± 0.02 logMAR at 1-month follow-up compared to preoperative UCVA 1.35 ± 0.23 logMAR ($p<0.001$). The mean refractive spherical equivalent was significantly changed from -4.60 ± 1.47 D preoperatively to -0.57 ± 0.38 D at 1-month follow up ($p < 0.001$). The mean refractive astigmatism decreased from -1.02 ± 0.66 D preoperatively to -0.34 ± 0.25 D at 1- month follow up ($p<0.001$).*

Conclusion: *New Generation of SMILE has shown good visual and refractive outcome for the correction of myopia and myopic astigmatic eyes since the early phase after surgery.*

Keywords: *small incision lenticule extraction, New Generation SMILE, myopia astigmatism*

INTRODUCTION

Myopia is one of the cause of visual impairment in the world. According to Holden et al. in 2050 the global prevalence increase 49,8% (4758 million people) suffer from myopia. The surgical correction of high myopia and myopic astigmatism is challenging for refractive surgeon. Two main option for the surgical correction are corneal refractive surgery and implantation of phakic intraocular lens (IOL). [2] In refractive corneal surgery, Small Incision Lenticule Extraction (SMILE) is gaining more popularity nowadays. [2,3] It is a minimally invasive flap-free procedure for myopia and myopic astigmatism correction using only one type of laser (femtosecond laser) for the whole surgery. [4,5,6] Compared to Femto-LASIK, SMILE

offers better ocular surface stability and biomechanical strength, higher visual quality and patients satisfaction. [6,7,8,9]

One of latest advancement in Laser Vision Correction is New Generation of SMILE using Visumax 800 femtosecond laser procedure. To the best of our knowledge, no study about outcome of New Generation of SMILE especially in Indonesian population has been published. Therefore, the aim of this study is to evaluate the visual and refractive outcome of New Generation Small Incision Lenticule Extraction (SMILE) in myopic and myopic astigmatism.

METHODS

This is observational retrospective study at Undaan Eye Hospital, Surabaya, Indonesia. This study followed the principles of the Declaration of Helsinki and was approved by the Health Research Ethics Committee of Medical Faculty of Airlangga University Surabaya, Indonesia No 107/EC/KEPK/ FKUA/2023. Data were collected from patient medical records.

The inclusion criteria were: 1) Patients with myopic and myopic astigmatism eyes who underwent New Generation SMILE using Visumax 800 femtosecond laser procedure presented to Undaan Eye Hospital between December 2022 and February 2023; 2)minimum age of 18 years old; 3)Pre-operative best corrected visual acuity (BCVA) was 20/20 (Snellen chart); 4)Follow up time at 1-day, 1-week and 1-month post-surgery. Patients who did not fulfil the inclusion criteria and had uncomplete medical records were excluded from the study.

The demographic data collected were patients' age, gender, classification of sphere and cylinder value and Central Corneal Thickness (CCT). Pre-operative examination was uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), Spherical Equivalent (SE), astigmatism value, keratometry, intra ocular pressure (IOP), anterior and posterior segment of the eyes. Post operative assessment included UCVA, Spherical Equivalent (SE), astigmatism value, keratometry and IOP. The patients were followed-up postoperatively at routine 1-day, 1-week, and 1-month visits.

Visual acuity was measure using Snellen chart and converted to logMAR visual acuity. Spherical Equivalent, astigmatism value and keratometry were measured using Auto Kerato-Refractometer. Intra Ocular Pressure was measured using Non-Contact Tonometry (NCT). Slit lamp examination for anterior segment evaluation and 90 D lens with slit lamp examination for posterior segment evaluation.

All statistical analyses were performed using SPSS software. Continuous data are presented as mean and standard deviation, frequency and prevalence data are presented as n (%). For analytic statistical analyses, the distribution of the data was measured using Shapiro Wilk test, then Wilcoxon test were used to evaluate pre and post operative comparation. All statistical test were performed with a 95% confidence level ($p < 0.05$). A p value < 0.05 was considered as statistically significant.

RESULTS

The study evaluated 30 eyes of 15 patients comprising 11 male (73.3%) and 4 female (26.7%). Patients ages ranged from 18 to 32 years old ; the median age was 18 years old (IQR= 18 to 27).

Table 1. Clinical Characteristics and Pre Operative Data

Clinical Characteristics	Number of patients
• Gender	
- Male	11 (73.3%)
- Female	4 (26.7%)
• Sphere	
- 0 - < 3 D	11 (36.7%)
- 3 - 6 D	12 (40%)
- > 6 D	7 (23.3%)
• Astigmatism	
- Without astigmat	3 (10%)
- < 2 D	22 (73.3%)
- ≥ 2 D	5 (16.7%)
Pre Operative Data	**Mean ± SD**
• Pre – operative UCVA (logMAR)	1.35 ± 0.23
• Pre-operative BCVA (logMAR)	0.00 ± 0.00
• Pre – operative Spherical Equivalent (SE)	-4.60 ± 1.47 D
• Pre–operative astigmatism value	-1.02 ± 0.66 D
• Pre–operative keratometry	
- K1	42.38 ± 1.53 D
- K2	43.76 ± 1.82 D
• Pre-operative IOP	14.9 ± 3.37mmHg
• Central Corneal Thickness (CCT)	527.47 ± 17.05 µm

Visual Acuity

The mean pre operative UCVA was 1.35 ± 0.23 logMAR and the mean post operative UCVA was significantly improved to 0.03 ± 0.06 logMAR at 1-day, 0.02 ± 0.04 logMAR at 1-week and -0.01±0.02 logMAR at 1-month post operation (Wilcoxon test, $p < 0.001$), without any significant differences between follow-up time (Wilcoxon test, p value > 0.05). Cumulative uncorrected visual acuities using Snellen chart are shown in Figure 1A and the change of BCVA lines is shown in Figure 1B.

Table 2. Pre- and post-operative Visual Acuity

Uncorrected Visual Acuity (UCVA)	**Mean ± SD (LogMAR)**
Pre–op	1.35 ± 0.23
Post–Op 1D	0.03 ± 0.06
Post–Op 7 D	0.02 ± 0.04
Post–Op 30 D	-0.01 ± 0.02
Best Corrected Visual Acuity (BCVA)	**Mean ± SD (LogMAR)**
Pre–op	0.00 ± 0.00
Post–Op 30 D	-0.01 ± 0.02

Spherical Equivalent (SE)

The mean refractive spherical equivalent was significantly changed from -4.60 ± 1.47 D preoperatively to -0.81 ± 0.54 D at 1-day, -0.63 ± 0.54 D at 1-week, and -0.57 ± 0.38 D at 1-month postoperative evaluation (Wilcoxon test, $p < 0.001$). No significant differences were observed when 1 week follow up was compared to 1 month follow up (Wilcoxon test, $p = 0.957$). The stability of spherical equivalent in 1 month follow-up is shown in Figure 1C.

Table 3. Pre- and post-operative spherical equivalent.

Spherical Equivalent (SE)	**Mean ± SD (Diopter)**
Pre–op	-4.60 ± 1.47
Post–Op 1D	-0.81 ± 0.54
Post–Op 7 D	-0.63 ± 0.54
Post–Op 30 D	-0.57 ± 0.38

Astigmatism Value

The mean refractive astigmatism value decreased significantly from -1.02 ± 0.66 D preoperatively to -0.38 ± 0.28 D, -0.35 ± 0.25, and -0.34 ± 0.25 D at 1-day, 1-week, and 1-month postoperative evaluation respectively (Wilcoxon test, $p<0.001$), without any significant differences between follow ups (Wilcoxon test ; 1 day vs 1 week ($p = 0.371$); 1 week vs 1 month ($p=0.864$)).

Table 4. Pre- and post-operative astigmatism value.

Astigmatism Value	**Mean ± SD (Diopter)**
Pre–op	-1.02 ± 0.66
Post–Op 1D	-0.38 ± 0.28
Post–Op 7 D	-0.35 ± 0.25
Post–Op 30 D	-0.34 ± 0.25

Intra Ocular Pressure (IOP)

No significant value were identified when comparing the intra ocular pressure pre and post operative examination (Wilcoxon test, p<0.001), also when paired follow-ups were compared (Wilcoxon test, p=0.984).

Table 5. Pre- and post-operative IOP

IOP	Mean ± SD (mmHg)	Range (mmHg)
Pre – op	14.9 ± 3.4	10 – 21.0
Post–Op 7 D	14.2 ± 3.6	9.5 – 24.4
Post–Op 30 D	14.4 ± 3.3	9.5 – 20.7

Keratometry

The value of keratometry showed statistically significant compared to pre operative and post operative examination (Wilcoxon test, p<0.001).

Table 6. Pre- and post-operative keratometry

Keratometry	Mean K1 (Diopter)	Mean K2 (Diopter)
Pre – op	42.37 ± 1.53	43.76 ± 1.82
Post–Op 1D	39.04 ± 1.36	39.73 ± 1.49
Post–Op 7 D	39.10 ± 1.46	39.70 ± 1.60
Post–Op 30 D	39.15 ± 1.58	39.98 ± 1.64

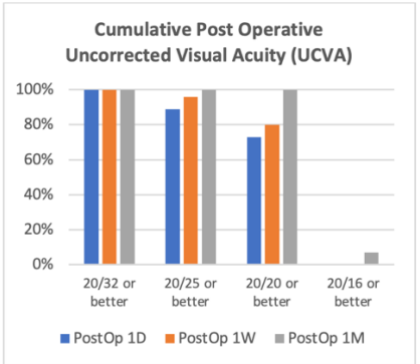

Figure 1.A. Uncorrected Visual Acuity

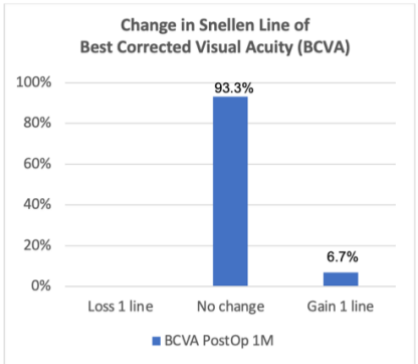

Figure 1B. Change in Best Corrected Visual Acuity

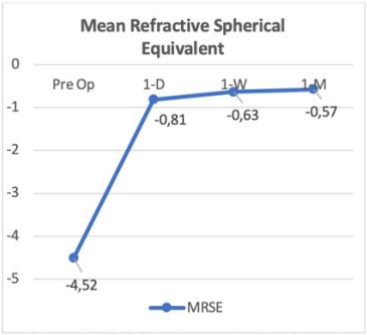

Figure 1C. Stability of Spherical Equivalent

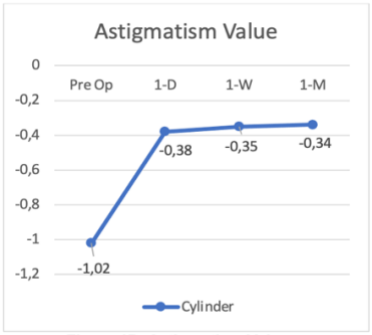

Figure 1D. Astigmatism Value

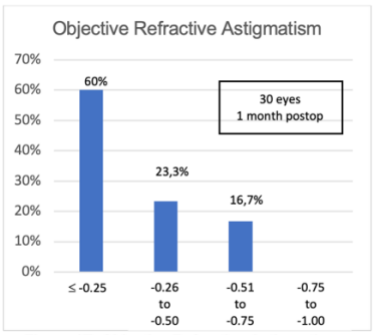

Figure 1E. Objective Refractive Astigmatism

DISCUSSION

There is increasing interest in SMILE as one of treatments in correcting myopia and myopic astigmatism. Several studies have investigated the surgical outcome of SMILE, most of them use previous generation of SMILE procedure. In this study, we analyse data from patients who underwent New Generation SMILE procedure using Visumax 800 femtosecond laser. This is pre and post study that presented visual and refractive outcome at 1 month after New Generation SMILE procedure in myopic and astigmatism myopia.

Regarding efficacy, the result of post operative uncorrected visual acuity (UCVA) was better than pre-operative best corrected visual acuity (BCVA). The efficacy index (post operative UCVA/ pre operative BCVA) in this study was 1.01 ± 0.05. This result represents an UCVA post-surgery at least as good as a correction with patients' glasses or contact lens before surgery. According to other studies, Kamiya et al. showed that the efficacy index of high myopia was 0.83 ± 0.24 and Ağca et al. reported that the efficacy index of mild to moderate myopia was 0.98 ± 0.21.[10,11] In the present study, 73.3% and 100% of patients had 20/20 or better UCVA at 1-day and 1-month follow up respectively (Figure 1A). Compare to Kim study with previous generation of SMILE procedure, 65.5% and 86.8% of cases had 20/20 or better UCVA at 1-day and 1 month follow up.[12] Sekundo et al. reported that 94% of patients had 20/20 or better at 6 months post operation.[13] Our current finding were comparable with the result of previous studies. It showed better result because the patients underwent new generation SMILE procedure and most of the patients were moderate myopia. Based on the Jin et al. study, efficacy of SMILE in mild to moderate myopia is higher than high myopia. [14]

All eyes had BCVA of 0.00 logMAR at baseline (pre-operation). At 1-month follow up, 93.3% of eye had unchanged BCVA and chart) and 6.7% of eyes had gained 1 line (Figure 1B). Previous study conducted by Reinstein et al. stated that 91% of eyes had unchanged BCVA or had gained lines. Hou et al. also reported that 87.28% of eyes had unchanged BCVA or had gained lines. [5,15] We found no significant difference between preoperative BCVA and 1 month

post operative BCVA (p >0.05, Wilcoxon test). Similarly, Kamiya et al. reported the same result (p=0.48, Wilcoxon test). [10] The reason is that the corneal biomechanical changes are small after surgery. SMILE does not create corneal flap and involve small incision, thus preserving the integrity of corneal tissue to the greatest extent possible. [7,8,16] Regarding safety, there were no eyes with BCVA loss of one or more line. Due to the result, New Generation SMILE consider to be safe as the patient has not lost any potential vision. There were no cases of suction loss, black spots, epithelial ingrowth, severe diffuse lamellar keratitis or kerato-ectasia were found in this study. According to Kim et al. study, no incidence of visual threatening complications also indicates that the procedure is safe.[17]

In our study, The mean refractive spherical equivalent (MRSE) decreased significantly from baseline -4.60 ± 1.47 D to -0.81 ± 0.54 D, -0.63 ± 0.54, -0.57 ± 0.38 at 1-day, 1-week, and 1-month respectively (p value=0.000, Wilcoxon test) as seen in Figure 1C. No significant differences were seen comparing 1 week follow up and 1 month follow up (p = 0.957, Wilcoxon test). In line with our study, Nicula et al. reported that the mean refractive spherical equivalent (MRSE) reduced from -4.25 D to -0.5 D at 1 month follow up with no significant changes of MRSE during post operative follow-ups up to 12 months (p=0.593, Wilcoxon test). [18] No significant changes of MRSE during post operative follow-up indicates that new generation SMILE provides stable correction. Additionally, there was no significant myopic regression from 1 day to 1 month follow up. According to Ağca et al., the refractive result of previous generation SMILE were stable over long term (5 years) follow up in mild to moderate myopia. [11] The results is in line with our study because 76.7% of our patients were mild to moderate myopia. In contrast, due to the increased keratocyte activation present in high myopic correction, high myopia may be more prone to refractive regression after laser surgery than mild to moderate myopia. [5,16,19] A careful long term observation is still required to confirm whether refractive regression occurs in the late operative period.

The mean refractive astigmatism value improved significantly from -1.02 ± 0.66 D preoperatively to -0.38 ± 0.28 D, -0.35 ± 0.25 D and -0.34 ± 0.25 D at 1-day, 1-week and 1-month after surgery respectively (p<0.001, Wilcoxon test) as seen in Figure 1D, without any significant differences between follow-ups (1 day vs 1 week (p = 0.371) ; 1 week vs 1 month (p=0.864); Wilcoxon test). Study conducted by Nicula et al. stated that the value of astigmatism decreased to -0.50 D at 1 month follow up. However, it showed significant differences among follow-up to 1 year after surgery (p < 0.000, friedman test).[18] The significant difference of astigmatism value in her study can occur because study from Nicula et al had longer follow-up time (one year follow up) compare to our 1 month follow-up study. At one month post-

surgery, objective refraction of astigmatism value were measured by auto keratometry. 60% of eyes had ≤ -0.25D as shown in Figure 1E. Similarly, Kamiya et al. reported that 65% of eyes had ≤ -0.25D at 1 year follow up and Lang et al. showed 62% of eyes had ≤ -0.25D at 5 year follow up. [10,16] In our study, no under-correction of astigmatism were found. Based on Ivarsen et al. study, under-correction of astigmatism could possibly be influenced by attempted astigmatism correction preoperatively, the axis rotation during the surgery or wound healing postoperatively.[19] Several studies suggested that nomograms should be adjusted in correcting astigmatism with previous generation of SMILE surgery but our study shows that satisfaction outcome can be achieve without manual compensation and normogram adjustment. [20,21]

There were several limitations in this study. First, this study was a single-centre study conducted in a big city in Indonesia; thus, generalization of this study's findings should be done cautiously. Second, the current study was a small sample with retrospective study design, but it can encourage further study with the larger sample and prospective study. Third, the follow-up duration was only 1-month, so we don't have any complication data beyond 1 month follow up time. Fourth, all patients underwent one technique treatment in this study; therefore, whether New Generation SMILE gives better outcomes compared to other techniques could not be seen. Patients' variability was not controlled as all eligible subjects were included in the study. However, inter-physician variability was withdrawn in this study because only one surgeon treated all patients.

CONCLUSION

In conclusion, our result demonstrate that New Generation SMILE proved as an effective and safe refractive procedure also provide stable correction of myopia and myopic astigmatism. In short-term results, New Generation of SMILE has shown good visual outcome for the correction of myopia and myopic astigmatic eyes since the early phase after surgery. The long term follow up will provide clinically relevant information on the efficacy of the New Generation SMILE procedure.

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