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ORIGINAL RESEARCH

Three-Month Outcomes of SMILE Pro with the VISUMAX 800 for Myopic Astigmatism in a Large Population

Hong Son Cung[1,2], Lan Huong Thi Tran[1,2], Thanh Ngoc Tran[1,2]

[1]Vietnam National Eye Hospital, Ha Noi, Vietnam; [2]Hong Son Eye Hospital, Ha Noi, Vietnam

Correspondence: Lan Huong Thi Tran, Vietnam National Eye Hospital, Ha Noi, Vietnam, Email huonglanmat1991@gmail.com

Purpose: To report the visual and refractive outcomes of small-incision lenticule extraction (SMILE) Pro using a 2 MHz femtosecond laser for myopic astigmatism in a large population of Vietnamese patients.

Methods: This was a retrospective clinical study of subjects that underwent keratorefractive lenticule extraction (KLEx) with the VISUMAX 800 at Hong Son Eye Hospital (Ha Noi, Vietnam) between June 2023 and October 2023. Primary outcome measures of monocular uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and refraction, including vector analysis, were evaluated at 3-months postoperatively. Secondary outcome measures of intraoperative and postoperative complications were also recorded.

Results: A total of 765 eyes from 389 patients (60.66% women, mean age of 23.54±5.20 years) were analyzed 3 months after surgery. The mean preoperative spherical equivalent refraction was −5.98±2.26 D. The postoperative spherical equivalent refraction was within ±0.50 D of the intended target in 81% and within ±1.00 D in 97% of eyes. The mean spherical equivalent refraction was −0.11±0.45 D. UDVA was 20/25 or better in 92% and 20/32 or better in 97% of eyes. The mean postoperative UDVA and CDVA values were 0.05 ±0.09 and 0.00±0.02 logMAR, respectively. There was no change in CDVA in 99% of eyes. Efficacy index was 0.92, and safety index was 1.00. One eye (0.13%) had a suction loss, which resulted in a lenticule remnant. No other complications were reported during surgery or the postoperative follow-up period.

Conclusion: The current study, carried out on a large cohort of Asian patients, showed SMILE Pro with the VISUMAX 800 was safe and effective for treating myopic astigmatism.

Keywords: SMILE, femtosecond laser, myopia, astigmatism

Introduction

Keratorefractive lenticule extraction (KLEx) is a type of corneal refractive surgery used to treat a range of refractive errors including myopia, hyperopia, and astigmatism. KLEx, which is considered a minimally invasive procedure compared to other techniques based on flap creation (ie, *laser* in situ *keratomileusis*, LASIK), uses a femtosecond laser to create a "lenticule" of stromal tissue that is removed through a small incision.

Small-incision lenticule extraction (SMILE), a type of lenticule extraction, using the VisuMax femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany), has been shown to be a safe and predictable option for treating ametropia.[1–5] A more recent version of the laser introduced to the market, the VISUMAX 800 (Carl Zeiss Meditec AG, Jena, Germany), uses a 2 MHz femtosecond. The reduced treatment time compared to the VisuMax may improve patient comfort as well as possibly reduce the overall risk of suction loss compared to VisuMax.[6]

A centration aid and cyclotorsion assistance were also lacking on the VisuMax and have been seen as a limitation of treatment.[7,8] These were addressed on the VISUMAX 800. CentraLign is an aid that uses visual representations during docking to help guide the surgeon towards correct treatment centration. Once docking is complete and suction is activated, OcuLign allows for rotation of the cylinder axis to align with the manually pre-marked axis of astigmatism.

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To the best of our knowledge, only a few recent studies[6,9–11] have evaluated SMILE surgery using the new platform; all of which reported excellent outcomes in terms of refractive accuracy, visual acuity, and complication rates. However, the majority of these studies have small sample sizes. The purpose of this study was to analyze visual acuity and refractive outcomes in a large population undergoing SMILE Pro with the VISUMAX 800 for myopic astigmatism to provide clinical evidence on the safety, efficacy, and predictability of treatment in Asian patients, which is particularly important given the high incidence of myopia and myopic astigmatism in the geographic region.

Methods

Study Design and Patients

This was a retrospective study approved by the Institutional Review Board of Vietnam National Eye Hospital (IRB ID: IRB-VN01.037, 289/HDDD/BVMTW), following the principles of the Declaration of Helsinki. Patients were given a detailed explanation of the procedure, and all patients provided written informed consent for treatment and inclusion of their data for research purposes.

Inclusion criteria were eyes with spherical myopia up to −10.00 D and astigmatism up to 5.00 D, age between 18 and 40 years old, corrected distance visual acuity (CDVA) of 20/25 or better, residual stromal thickness (RST) estimated to be at least 260 μm, and stable refraction for at least six months. Exclusion criteria were irregular corneal topography, previous corneal ocular surgery, a history of ocular trauma, ocular disease including keratitis, corneal dystrophies and dry eye, general systemic diseases that may affect the eyes or healing such as diabetes and autoimmune disorders, as well as pregnant or currently taking medications that may affect the eyes such as hormone replacement therapies or immunosuppressants.

Surgical Procedure

Target refraction was emmetropia for all cases. No adjustment or nomogram was used for the current population. However, if there was a slight discrepancy between two refractions that provided the same CDVA, the higher amount of myopia was used for planning treatment (eg refraction one = −5.50 and refraction two = −5.75, then −5.75 was used). All treatments were performed by two experienced surgeons (CHS and LTHT) using the VISUMAX 800 following a standard surgical technique.[6] The lenticule was dissected and removed using a Chansue ReLEx dissector and lifter (Angel Medical Systems) and SMILE lenticule removal forceps (Duckworth & Kent). Surgical parameters include a cap thickness of 100 μm, optical zone between 6.0 and 6.8 mm, and a single 2.0 mm small incision located at 60°. For bilateral treatments, both eyes were treated consecutively in the same session. A slit-lamp examination was performed immediately after treatment.

Preoperative and Postoperative Assessment

Before surgery, all patients received a complete eye examination including slit-lamp examination, ophthalmoscopy, intraocular pressure (IOP), central corneal thickness (CCT) measurement (Sirius + topographer, CSO, Italia), refraction (sphere, cylinder, and axis), photopic and mesopic pupil size measurement (Sirius + topographer, CSO, Italia), and LogMAR monocular uncorrected distance visual acuity (UDVA) and CDVA.

After treatment, all patients were prescribed a topical antibiotic (levofloxacin hydrate 0.5%, Cravit 0.5%, Santen) four times per day for one week, an anti-inflammatory (fluorometholone 0.1%, Santen) four times per day for one week, and artificial tears (sodium hyaluronate 0.3%, Sanein 0.3%, Santen) four times per day for three months. A total of three follow-visits were carried out at 1-week, 1-month, and 3-months postoperatively. UDVA, CDVA, and refraction were assessed at each visit. All preoperative and postoperative examinations were performed by experienced examiners. Efficacy (ratio between postoperative UDVA and preoperative CDVA converted to decimal notation) and safety (ratio between postoperative and preoperative CDVA converted to decimal notation) indices were calculated. Any surgical complications or postoperative adverse events were also recorded. The outcomes were analyzed 3-months after treatment.

Statistical Analysis

The preoperative and postoperative data from all the patients were obtained from the medical records. The data was imported into an Excel spreadsheet (Excel Version 2406, Microsoft Corporation, Redmond, USA) for analysis. Quantitative variables were reported as mean, standard deviation, and ranges (where available). Qualitative variables were expressed as percentages. The clinical results were presented in accordance with the standard reporting for refractive surgery outcomes.[12] Additionally, double-angle plots were generated in order to assess preoperative and postoperative cylinders.

Results

A total of 756 eyes from 389 patients were included that underwent treatment at Hong Son Eye Hospital in Ha Noi (Vietnam), between June 2023 and October 2023 and had 3-month postoperative data available for analysis. Patient demographics and preoperative ocular measurements are summarized in Table 1.

Accuracy and Predictability

Figure 1 shows the standard graphs for reporting refractive surgery outcomes. The postoperative UDVA was 20/25 (0.1 LogMAR) or better in 93% of eyes and 20/32 (0.2 LogMAR) or better in 97% (Figure 1A). The UDVA was the same or better than the preoperative CDVA in 69% of eyes and within 1 line of CDVA in 93% of eyes (Figure 1B). The mean postoperative monocular UDVA was 0.05±0.09 LogMAR, and the mean monocular CDVA was 0.00±0.02 LogMAR. The efficacy index was 0.92. Predictability of attempted versus achieved spherical equivalent (SEQ) showed that 34% (n=254) of eyes were within ±0.13 D, 81% (n=610) of eyes were within ±0.50 D, and 97% (n=734) were within ±1.00 D (Figure 1E).

Stability

The SEQ results were stable from the 1-week to 3-month postoperative visit. The mean postoperative SEQ refraction was −0.10±0.46 D at 1 month and −0.11±0.45 D at 3 months, a mean change of −0.01 D (Figure 1F).

Table 1 Patient Demographics

Characteristic	Value, Mean± SD (range)
Eyes (n)	756
Patients (n)	389
Sex (n, male/female)	153/236
Age (years)	23.54±5.20 (18 to 40)
Sphere (D)	−5.30±2.16 (0.00 to −10.50)
Cylinder (D)	−1.36±0.92 (0.00 to −5.00)
Spherical Equivalent (D)	−5.98±2.26 (−1.13 to −12.50)
UDVA (logMAR)	1.30±0.21 (0.10 to 1.70)
CDVA (logMAR)	0.00±0.00
CCT (μm)	539.59±32.14 (451 to 648)
Photopic pupil size (mm)	3.75±0.59 (2.50 to 5.60)
Mesopic pupil size (mm)	6.41±0.73 (3.61 to 8.61)
Optical zone (mm)	6.72±0.20 (6.00 to 6.80)
RST (μm)	314.40±40.08 (260 to 445)
IOP (mmHg)	16.11±2.45 (9 to 23)

Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; CCT, central corneal thickness; RST, residual stromal thickness; IOP, intraocular pressure.

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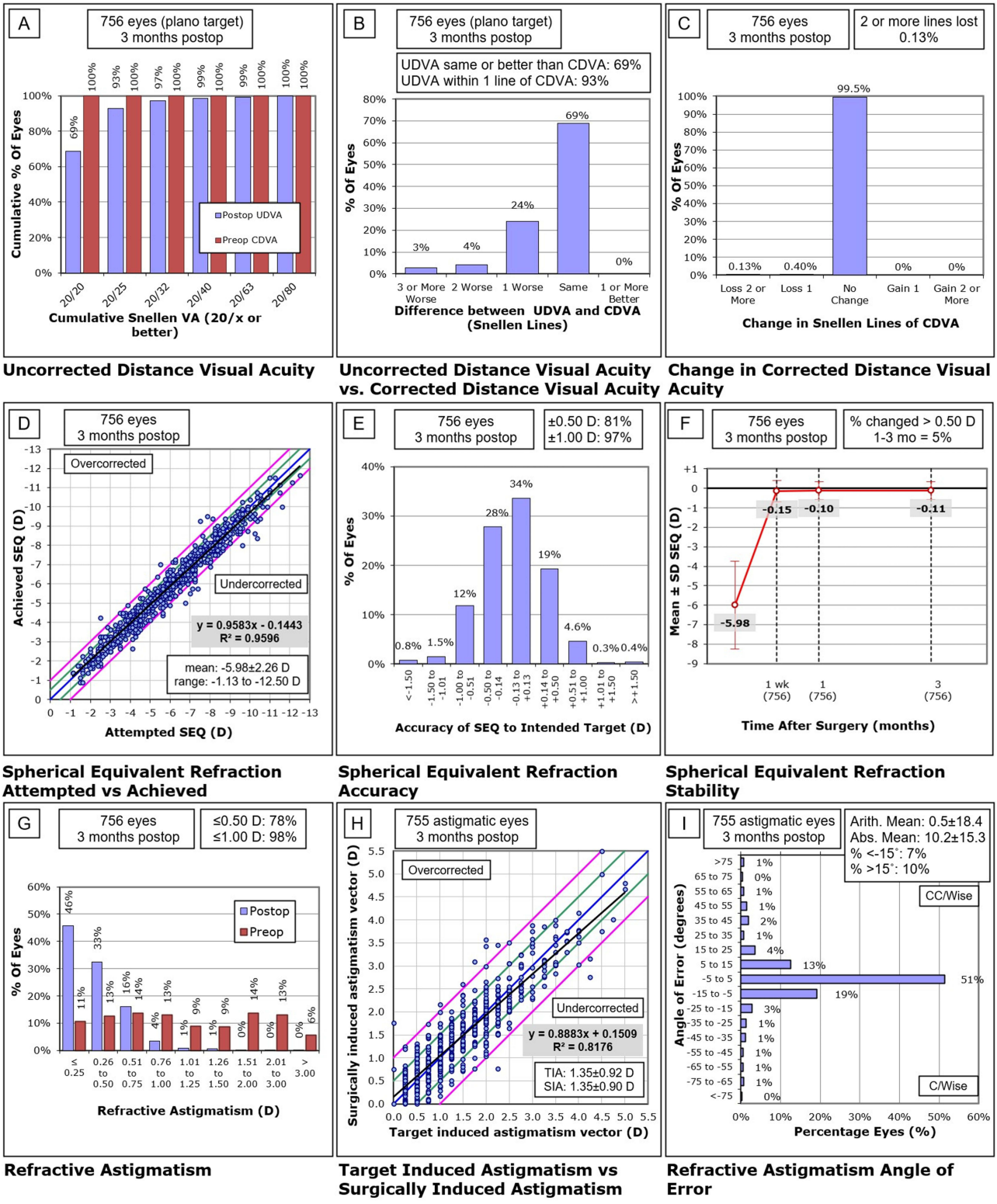

Figure 1 Refractive outcomes three months after SMILE Pro using the VISUMAX 800: (**A**) uncorrected distance visual acuity; (**B**) uncorrected distance visual acuity versus corrected distance visual acuity; (**C**) change in corrected distance visual acuity; (**D**) spherical equivalent refraction attempted versus achieved; (**E**) spherical equivalent refraction accuracy; (**F**) spherical equivalent refraction stability; (**G**) refractive astigmatism; (**H**) target induced astigmatism versus surgical induced astigmatism; (**I**) refractive astigmatism angle of error.

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Astigmatism Analysis

The mean postoperative refractive cylinder was −0.44±0.31 D. A total of 78% (n=592) of eyes had ≤0.50 D, and 98% (n=741) had ≤1.00 D of residual refractive cylinder (Figure 1G). There was a target-induced astigmatism (TIA) of 1.35 ±0.92 D and a similar surgically induced astigmatism (SIA) of 1.35±0.90 D. The angle of error plot (Figure 1I) showed that 83% of eyes were within ±15°. The double-angle plots for preoperative and postoperative refractive cylinder showed a concentration of results after the surgery (black dots) at the origin (0,0), corresponding to eyes with no astigmatism. The preoperative centroid was 1.153 D at 88°, and the postoperative centroid was 0.083 D at 105° (Figure 2).

Safety

Comparing preoperative CDVA to postoperative CDVA, there was no change in 99.47% of eyes. Three eyes (0.4%) lost one line of CDVA, and one eye (0.13%) lost two or more lines of CDVA (Figure 1C). The safety index was 1.00. Further analysis of the intraoperative and postoperative visits showed that one eye (0.13%) experienced a suction loss. No eyes experienced any postoperative complications during the first three months after treatment.

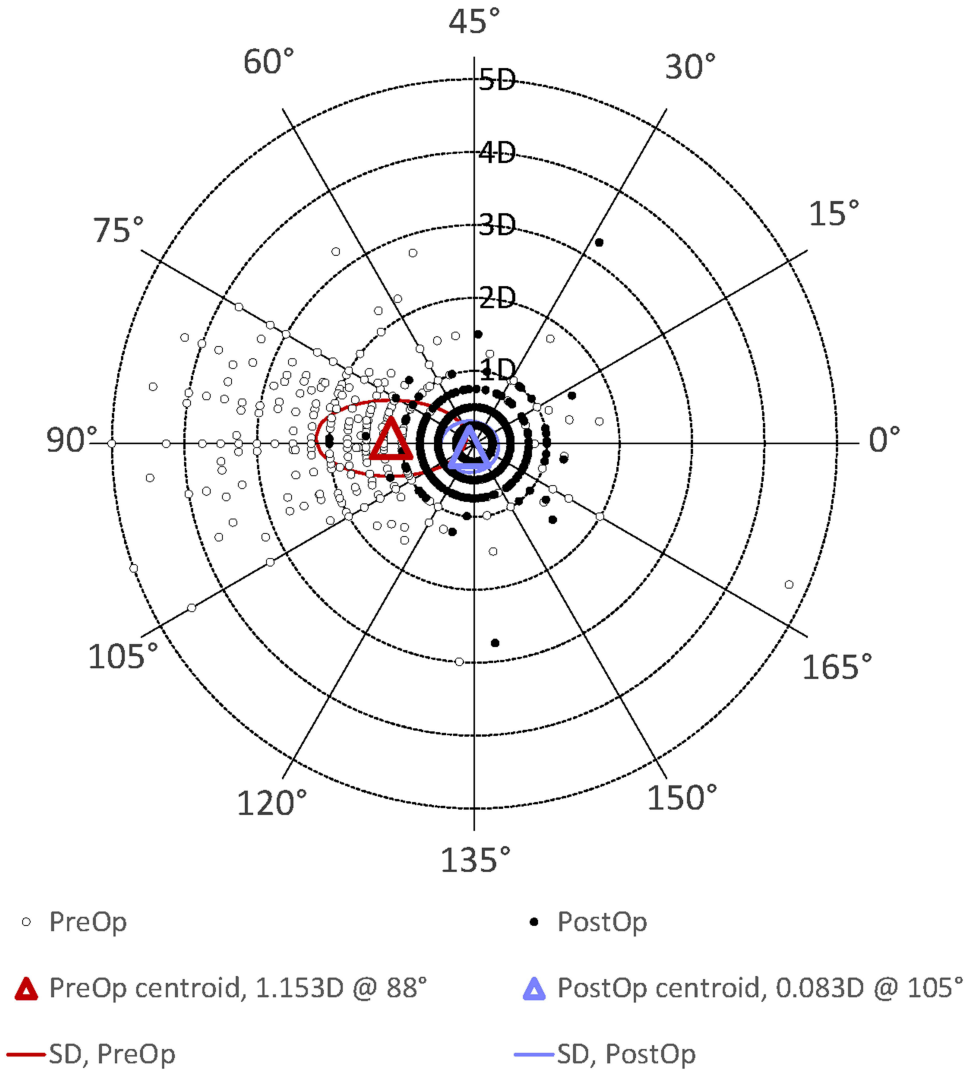

Figure 2 Double-angle plot for the cylinder before and three months after SMILE Pro using the VISUMAX 800.

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Discussion

The current study describes the refractive and visual acuity outcomes after SMILE Pro with the VISUMAX 800. The current large cohort of eyes confirms the early results reported by other authors.[6,9–11] Table 2 shows the main characteristics of previous literature reporting outcomes with the VISUMAX 800. One strength of the current study is the significantly larger sample size when compared to the other studies in the literature evaluating the VISUMAX 800.

At the 3-month postoperative visit, 97% of eyes showed a spherical equivalent refraction within ±1.00 D with a mean value of less than a quarter of a diopter (−0.11±0.45 D). This is correlated with good outcomes in terms of predictability as shown in Figure 1D. The percentage of eyes within ±1.00 D was close to that found by Reinstein et al[6] (100%) and Saad et al[9] (99%) at the same follow-up time period, and Yoo et al[10] (100%) 1-month after surgery. Table 3 shows the refractive and visual acuity outcomes for these studies using the same platform. The mean spherical equivalent refraction for these studies was also close to emmetropia, varying from +0.05 D[6] to −0.04 D.[9]

In addition to being significantly larger in sample size than the other published studies, it should be noted that the mean preoperative sphere (−5.30±2.16 D) and cylinder (−1.36±0.92 D) values in the current population were higher than in the previous published studies (Table 2) which might have an effect on the accuracy of the procedure. Saad et al[9] performed a sub-analysis as a function of the preoperative spherical equivalent of their eyes for low (−1.00 to −3.00 D,

Table 2 Review of Clinical Studies Reporting Outcomes After Small-Incision Lenticule Extraction with the VISUMAX 800 Femtosecond Laser

Authors	Year	Type	Eyes (n)	Follow-up (months)	Mean Preoperative Sphere (D)	Mean Preoperative Cylinder (D)	Measurements
Reinstein et al[6]	2023	Retrospective	118	3	–4.16±1.89	–0.98±0.78	Refraction, UDVA, CDVA, Mesopic CS
Saad et al[9]	2024	Retrospective	152	3	–4.44±1.86*	NR	Refraction, UDVA, CDVA
Yoo et al[10]	2024	Retrospective	50	1	–3.63±1.42	–0.78±0.53	Refraction, UDVA, Corneal HOAs
Current study	2024	Retrospective	756	3	–5.30±2.16	–1.36±0.92	Refraction, UDVA, CDVA

Note: *spherical equivalent.
Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, corrected-distance visual acuity; CS, contrast sensitivity; HOAs, higher-order aberrations; NR, not reported.

Table 3 Review of Refractive and Visual Outcomes After Small-Incision Lenticule Extraction with the VISUMAX 800 Femtosecond Laser

Authors	Eyes (%) with SE ±0.50 D	Eyes (%) with SE ±1.00 D	Mean SE (D)	Eyes (%) with Cylinder ≤0.50 D	Eyes (%) with Cylinder ≤1.00 D	Eyes (%) with UDVA ≥20/25	Eyes (%) without Change in CDVA	Eyes (%) without Change or Gaining 1 line in CDVA
Reinstein et al[6]	86	100	+0.05±0.35	85	98	98	76	91
Saad et al[9]	91	99	–0.04±0.02	95	100	100	81	90
Yoo et al[10]	98	100	–0.02±NR	94	100	100	48	94
Current study	80.69	97.09	–0.11±0.45	78.31	98.02	92.86	99.47	99.47

Abbreviations: SE, spherical equivalent; UDVA, uncorrected distance visual acuity; CDVA, corrected-distance visual acuity; NR, not reported.

n=46 eyes), moderate (−3.25 to −6.00 D, n=84 eyes), and high (−6.25 to −10.00 D, n=18 eyes) myopia. The analysis showed a slight under-correction in the moderate myopia group (55% of the cohort), which was reflected in a lower regression compared to the other two groups. While no sub-analysis was performed on the current data set, a similar under-correction can be seen for moderate-to-high myopes when looking at the predictability graph (Figure 1D). The stability in the current population was good, with a mean spherical equivalent value of −0.10 D at 1 month and −0.11 D at 3 months after the surgery (Figure 1F). This agrees with the stability reported by Reinstein et al[6] over the same period (from +0.11 D to +0.05 D with a mean change of 0.06 D from 1 month).

In relation to astigmatism, there was a concentration of the data points at (0,0), which represents no residual astigmatism as plotted in the vector analysis graph (Figure 2). In the current population, 98% of eyes had a value ≤1.00 D of refractive cylinder with a mean value of −0.44±0.31 D. The percentages in the other studies were similar, ranging from 98% to 100%.[6,9,10] Similar to the predictability of the SEQ, there was an under-correction for cylinder above 2.50 D. Varman et al[11] recently showed excellent results after SMILE, both with and without accounting for any cyclotorsion. However, the sub-analysis showed more predictable outcomes for eyes with moderate-to-high astigmatism when using OcuLign. Because OcuLign was used for alignment in the current study, the under-correction was likely due to not using a nomogram for cylinder.

In the current population, 93% of eyes achieved a postoperative UDVA of 20/25 or better (Figure 1A). Reinstein et al[6] found 98%, while Saad et al[9] and Yoo et al[10] both reported 100% of eyes with a UDVA of 20/25 or better (Table 3). Our outcomes were similar to those found by Saad et al,[9] who found a mean postoperative UDVA of −0.06±0.08 logMAR and an efficacy index of 0.93, where our efficacy index was 0.92. Saad et al[9] reported a safety index of 1.00 with a mean CDVA of −0.09±0.07 logMAR with 81% of eyes showing no change in CDVA. Reinstein et al[6] found a similar percentage of eyes with no change in CDVA (76%), while, in contrast, Yoo et al[10] reported a lower percentage (48%) with a similar percentage (46%) gaining one line. Considering the percentages that showed no change or which gained one line in CDVA, the values reported in the previous literature were similar, ranging from 90% to 94% (Table 3). These results are comparable to the current population, with an approximate mean UDVA and CDVA of about 20/20, with 99% of eyes showing no change after the surgery.

There are a number of complications associated with lenticule extraction including suction loss, difficult lenticule dissection, incision tear, epithelial defects, and cap perforation.[13] As noted in previous publications, the main benefit of increased speed of lenticule creation may be less suction loss. This may be of particular importance for less experienced surgeons. In the current population, the only complication noted during the intraoperative and postoperative periods was one reported case of suction loss (0.13%) which resulted in a small peripheral lenticule remnant. The suction loss occurred early in the lenticule creation process; therefore, it was decided to recut a new lenticule using the same settings. During dissection, a small peripheral area of tissue (near the original aborted cut) was unable to be fully separated and removed. At the 3-month visit, the UDVA was 20/63, and the CDVA was 20/25 with residual cylinder. The subject was lost to follow-up after the 3-month visit, without any additional corrective action. Reinstein et al[14] evaluated 4000 eyes and found that suction loss occurred in 0.5% of eyes, with 65% of the cases occurring after 10 seconds. When using the new platform, which involves a shorter treatment time, they anticipated a possible 65% reduction in the incidence of suction loss. While a comparison in suction loss between the VisuMax and VISUMAX 800 was not the aim of this study, the results of this large sample (n=756) help to further add to the body of literature around the incidence of suction loss with the new device.

There are several limitations with the current study. The first limitation is the short follow-up period. However, the follow-up period is similar to other early VM800 populations that have been reported in the literature that allowed for a comparison between studies. While the comparison between studies was a benefit of reporting outcomes at 3-months postoperatively, long-term outcomes are necessary. The current cohort will continue to be followed, as per standard of care, with the goal of providing long-term results for accuracy and predictability. A second limitation of the current study was that visual acuity was not pushed beyond 20/20 Snellen equivalent. Standard procedure at the site is to perform refraction pushing as much “plus (+)” and cylinder as possible to see 20/20 (rather than showing the 20/16 line) to limit the risk of over-correction. This limitation of not pushing subjects to achieve their best possible visual acuity after treatment is most noticeable for the histogram comparing

postoperative UDVA to preop CDVA as well as change in Snellen lines of CDVA. For future prospective studies, a refraction protocol including pushing subjects beyond 20/20 will be implemented. In addition to the limitations of the current study, the results show that a formal nomogram should be applied for future treatments and studies. Based on the current outcomes, this will likely be of most benefit for treatments above −6.00 D of myopia and cylinder above 2.50 D. Finally, results of the current study have not been compared with those found using the VisuMax since other studies have done this and found similar early outcomes.[6,9,10]

The current study, evaluating three-month results on a large cohort of Vietnamese patients after SMILE Pro with the VISUMAX 800, found the treatment to be safe and effective for myopic astigmatism. The treatment was predictable across a large range of prescriptions, with the majority of eyes within 1.00 D of the intended correction. While the long-term safety and efficacy of lenticule extraction has been reported on with previous devices, continued follow-up of the cohort will be useful in determining if there are additional clinical findings that may be of interest. Future studies using a fine-tuned nomogram and the forthcoming iris recognition cyclotorsion control software will help to evaluate the utility of SMILE Pro with the VISUMAX 800 for moderate and high astigmatism.

Disclosure

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