• Clinical Research •

Enhanced predictability and axis precision of SMILE Pro, a retrospective analysis of myopic astigmatism correction

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Abstract

● **AIM:** To evaluate three-month visual and refractive outcomes after small incision lenticule extraction (SMILE) Pro with the VISUMAX 800 femtosecond laser for myopic astigmatism correction and to compare results with previously reported VISUMAX 800 and VisuMax 500 outcomes.

● **METHODS:** Retrospective, observational clinical study. Records of 64 patients (128 eyes) who underwent SMILE Pro using the VISUMAX 800 laser (Carl Zeiss Meditec AG, Jena, Germany) between June and November 2024 were reviewed. Preoperative and 3-month postoperative data were analyzed in eyes with corrected distance visual acuity (CDVA) of 1.0 or better, including spherical equivalent (SE), refractive astigmatism, and vector analysis. Patients were classified into low (≤1.50 D) and high (>1.50 D) astigmatism subgroups.

● **RESULTS:** The mean age of 64 patients (128 eyes) was 26.10±4.25y (19–36y). Attempted and achieved SE were strongly correlated (r=0.97, P<0.001). At 3mo, 36.7% and 87.5% of eyes were within ±0.50 and ±1.00 D of target refraction, respectively. Mean residual astigmatism was -0.56±0.27 D, lower in the low-astigmatism group (-0.39±0.23 D) than in the high group (-0.72±0.21 D; P<0.001). The mean absolute astigmatic angle of error was 4.47°±4.68°, with 97.6% ≤15°. No intraoperative or postoperative complications occurred.

● **CONCLUSION:** SMILE Pro using the VISUMAX 800 femtosecond laser provides safe and predictable correction of myopic astigmatism with good axis alignment. However, the observed undercorrection in higher cylinders suggests that further optimization of astigmatic nomograms may improve refractive accuracy.

● **KEYWORDS:** SMILE Pro; VISUMAX 800; myopic astigmatism

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INTRODUCTION

The VisuMax femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany) was first used for the introduction of small incision lenticule extraction (SMILE) in 2011[1-2]. Since its development, SMILE has become a major advancement in corneal refractive surgery, offering a minimally invasive, flap-free approach for the correction of myopia and myopic astigmatism.

SMILE represents the latest generation in corneal refractive techniques. The procedure employs a femtosecond laser to create an intrastromal lenticule that is extracted through a small incision, preserving corneal biomechanics and promoting rapid recovery. This design minimizes flap-related complications, maintains corneal stability, and enhances postoperative comfort. In their pioneering work, Sekundo *et al*[1] (2011) demonstrated that SMILE yields predictable, stable outcomes for myopic astigmatism and is particularly advantageous for patients with higher myopia or thinner corneas who may not be suitable candidates for laser-assisted *in situ* keratomileusis (LASIK) or photorefractive keratectomy (PRK)[1,3].

A more recent innovation, the VISUMAX 800 femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany), operates at a 2 MHz repetition rate, significantly reducing treatment time compared with the original VisuMax platform. This improvement is associated with greater patient comfort and a lower risk of suction loss[4]. Furthermore, limitations in the earlier VisuMax—such as the absence of centration guidance and cyclotorsion compensation—have been addressed in

the VISUMAX 800 through the CentraLign and OcuLign systems[5]. The former assists the surgeon in achieving precise centration during docking, while the latter allows intraoperative alignment of the astigmatic axis, thus enhancing the accuracy of astigmatism correction.

In summary, SMILE technology continues to redefine the landscape of corneal refractive surgery. Ongoing innovations, including the VISUMAX 800 platform, hold the promise of further improving safety, precision, and efficiency.

The purpose of this study was to evaluate the surgical and refractive outcomes of SMILE Pro performed with the VISUMAX 800 femtosecond laser in eyes with moderate to high myopic astigmatism.

PARTICIPANTS AND METHODS

Study Design This retrospective clinical study was conducted at Medipol University, and patient records from June 2024 to November 2024 were reviewed. The study received ethical approval from the Ethics Committee of Medipol University Faculty of Medicine (Approval No.20241212/1257). All procedures adhered to the Declaration of Helsinki, and written informed consent had been obtained from all patients prior to surgery.

Patient Selection Electronic medical records were analyzed to obtain preoperative and postoperative data.

Inclusion criteria were: myopia ranging from 0 to –8.0 D with astigmatism ≥0.75 D; corrected distance visual acuity (CDVA) of 1.0 or better.

Exclusion criteria included irregular corneal topography, a history of corneal surgery or trauma, ocular diseases such as keratitis, corneal dystrophies, or dry eye, and systemic conditions affecting corneal health or wound healing (*e.g.*, diabetes mellitus or autoimmune disorders). Pregnant patients and those using medications that could alter ocular physiology, such as hormone replacement therapy or immunosuppressive agents, were excluded.

Preoperative Assessment According to patient files, all subjects had undergone a comprehensive ophthalmologic evaluation prior to surgery. The examination included slit-lamp biomicroscopy, fundus examination, intraocular pressure (IOP) measurement, and central corneal thickness (CCT) assessment using Scheimpflug corneal topography.

Additional measurements included manifest refraction (sphere, cylinder, and axis), photopic and mesopic pupil diameter, and logMAR monocular, uncorrected distance visual acuity (UCDVA), CDVA.

Data Collection A total of 128 eyes were evaluated preoperatively and 3mo postoperatively. The following parameters were extracted from patient charts: age, sex, UCDVA, CDVA, spherical equivalent (SE), and preoperative and postoperative refractive astigmatism.

Patients were stratified into two subgroups based on preoperative cylinder values: low cylinder: ≤1.50 D; high cylinder: >1.50 D.

Vector analysis of astigmatic correction was performed according to the Alpins method. In addition to target-induced astigmatism (TIA), surgically induced astigmatism (SIA), and angle of error, the following parameters were calculated: correction index (CI=SIA/TIA); difference vector (DV), representing the residual astigmatic vector required to achieve the intended correction; index of success (IOS=DV/TIA); flattening index (FI), representing the proportion of astigmatic flattening achieved along the intended meridian; coefficient of adjustment (CA), indicating the magnitude of correction required to achieve ideal astigmatic treatment.

Surgical Technique According to surgical records, all SMILE procedures were performed by the same experienced surgeon using the SMILE Pro VISUMAX 800 (Carl Zeiss Meditec AG, Jena, Germany), which operates with a 2 MHz femtosecond laser. Particular attention was paid to accurate patient alignment with the laser bed and avoidance of head tilt during docking. Topical anesthesia was achieved with one drop of unpreserved oxybuprocaine hydrochloride (Conjucain EDO), and a small contact glass was used for all procedures. Based on operative documentation, the surgical parameters included a cap thickness of 100 μm, an optical zone diameter between 6.0 and 6.8 mm, and a single 2.0 mm incision positioned at approximately 60°.

Postoperative Care Postoperative treatment regimens noted in the records indicated that all patients were prescribed unpreserved moxifloxacin combined with unpreserved dexamethasone eye drops, administered four times daily for 5d. Additionally, patients were instructed to instill unpreserved artificial tears hourly for 1 to 2wk after surgery.

Statistical Analysis All enrolled eyes were included in the analyses of intraoperative and postoperative complications. Statistical analyses were conducted using SPSS for Windows (Version 23, IBM Corp.), with data expressed as mean±standard deviation (SD). The treatments were divided into 2 subgroups based on preoperative astigmatism as follows: low astigmatism and high astigmatism. Differences in SE refraction attempted and achieved, SE refraction accuracy, refractive astigmatism, TIA and SIA and refractive astigmatism angle of errors efficacy, and safety between the low and high-astigmatism groups, as well as between pre and postoperative time points, were assessed. The Wilcoxon signed-rank test was used to compare pre-operative and post-operative measurements within each group. The Mann-Whitney *U* test were used to assess pre-operative and post-operative patient characteristics between two groups. A $P<0.05$ was considered statistically significant.

Table 1 Preoperative patient characteristics median (mean±SD)

Characteristics	Total (*n*=64)	Low astigmatism ≤1.50 D (*n*=32)	High astigmatism >1.50 D (*n*=32)	*P*
Age, y	25 (26.10±4.25)	25 (25.86±3.99)	26 (26.34±4.52)	0.631
Range	19–36	20–36	19–36	
Myopia, D	-4.00 (-4.11±1.54)	-4.13 (-4.21±1.56)	-4.00 (-4.00±1.53)	0.440
Range	-7.00 to -1.50	-7.00 to -1.50	-7.00 to -1.50	
Cylinder, D	-1.50 (-1.64±0.67)	-0.75 (-0.75±0.44)	-1.75 (-1.46±0.82)	<0.001
Range	-3.50 to -0.75	-1.50 to -0.75	-3.50 to -1.75	
Axis, degree	180 (152.11±40.29)	175 (152.03±40.40)	180 (152.19±40.49)	0.983
Range	80–180	80–180	80–180	
Spherical equivalent, D	-4.75 (-4.71±2.14)	-4.69 (-4.76±1.55)	-4.87 (-4.66±2.60)	0.782
Range	-8.12 to -1.50	-7.75 to -1.87	-8.12 to -1.75	

SD: Standard deviation.

Table 2 Preoperative and postoperative refractive outcomes median (mean±SD)

Characteristic	Total (*n*=128)	Low astigmatism (*n*=64)	High astigmatism (*n*=64)	*P*
Spherical equivalent, D				
Preop	-4.75 (-4.71±2.14)	-4.69 (-4.76±1.55)	-4.87 (-4.66±2.60)	0.535
Postop	-0.62 (-0.66±0.39)	-0.50 (-0.56±0.34)	-0.75 (-0.76±0.41)	0.001
Intra-group difference				<0.001
Sphere, D				
Preop	-4.00 (-4.11±1.54)	-4.13 (-4.21±1.56)	-4.00 (-4.00±1.53)	0.142
Postop	-0.25 (-0.39±0.27)	-0.38 (-0.40±0.27)	-0.25 (-0.39±0.28)	0.458
Intra-group difference				<0.001
Cylinder, D				
Preop	-1.63 (-1.65±0.67)	-1.00 (-1.10±0.28)	-2.00 (-2.20±0.47)	<0.001
Postop	-0.50 (-0.56±0.27)	-0.38 (-0.39±0.23)	-0.75 (-0.72±0.21)	<0.001
Intra-group difference				<0.001
Axis, degree				
Preop	180 (152.11±40.29)	175 (152.03±40.40)	180 (152.19±40.49)	0.905
Postop	170 (148.55±38.61)	170 (149.53±39.60)	165 (147.56±37.88)	0.185
Intra-group difference				<0.001

Mann-Whitney *U* test between groups; Wilcoxon signed-rank test for intra-group comparisons. SD: Standard deviation.

RESULTS

Three-month postoperative data were available for all 64 patients (128 eyes) included in the analysis. Baseline characteristics are presented in Table 1. There were no statistically significant differences in preoperative parameters between the low-astigmatism (≤1.50 D) and high-astigmatism (>1.50 D) subgroups, except for the cylinder magnitude (P<0.001). Table 2 summarizes the preoperative and postoperative refractive outcomes for the entire cohort and subgroups. Table 3 summarizes the vector analysis parameters for the overall cohort and stratified according to preoperative astigmatism magnitude.

At 3mo, UCDVA of 20/20 or better was achieved in 89.1% of eyes, and 20/25 or better in 96.9%. The efficacy index was 0.98, and the safety index was 1.01. No eyes lost two or more lines of CDVA, while 4.7% gained one line of CDVA.

A strong and consistent correlation was observed between the attempted and achieved SE refractions across all eyes (r=0.97, P<0.001), demonstrating excellent refractive predictability (Figure 1). This correlation remained stable in both the low- and high-astigmatism subgroups (Figures 2 and 3).

Overall, 36.7% of eyes were within ±0.50 D, and 87.5% were within ±1.00 D of the intended SE correction (Figure 4); in subgroup analysis: low-astigmatism eyes: 51.5% (n=33) were within ±0.50 D and 96.9% (n=62) within ±1.00 D of target (Figure 5); high-astigmatism eyes: 21.8% (n=14) were within ±0.50 D and 78.1% (n=50) within ±1.00 D of target (Figure 6).

The mean residual refractive astigmatism for the total cohort was -0.56±0.27 D (range: 0 to -1.00 D; Figure 7). Residual cylinder was significantly lower in the low-astigmatism group (-0.39±0.23 D) than in the high-astigmatism group (-0.72±0.21 D; P<0.001). Astigmatic predictability was superior in the low-astigmatism subgroup: 85.9% of eyes had ≤0.50 D residual

Table 3 Vector analysis of astigmatic correction outcomes

Parameter	Total (*n*=128)	Low astigmatism ≤1.50 D (*n*=64)	High astigmatism >1.50 D (*n*=64)
TIA (D, mean±SD)	1.65±0.67	1.10±0.28	2.20±0.47
SIA (D, mean±SD)	1.09±0.52	0.71±0.28	1.47±0.41
DV (D, mean±SD)	0.56±0.27	0.39±0.23	0.73±0.21
CI=SIA/TIA	0.66	0.65	0.67
IOS=DV/TIA	0.34	0.35	0.33
FI	0.72	0.74	0.70
CA=1/CI	1.52	1.54	1.49
Mean absolute angle of error (°, mean±SD)	4.47±4.68	2.94±3.08	6.00±5.47

Vector analysis parameters for the overall cohort and stratified according to preoperative astigmatism magnitude. TIA: Target-induced astigmatism; SIA: Surgically induced astigmatism; DV: Difference vector; CI: Correction index; IOS: Index of success; FI: Flattening index; CA: Coefficient of adjustment; SD: Standard deviation.

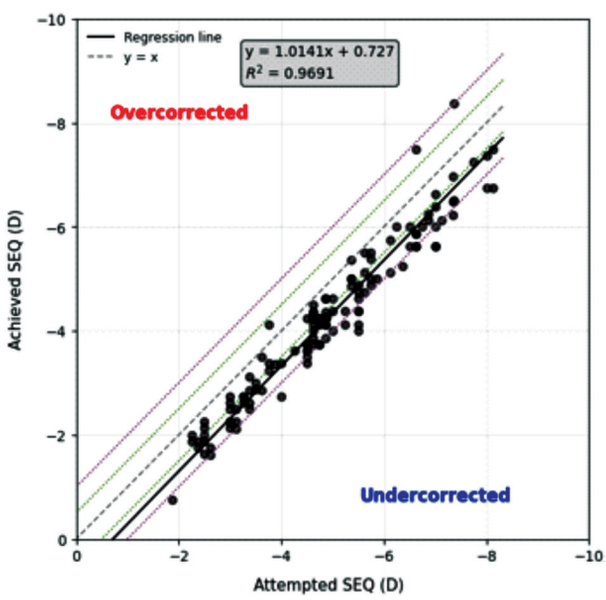

Figure 1 Spherical equivalent refraction attempted *vs* achieved in overall cohort SEQ: Spherical equivalent.

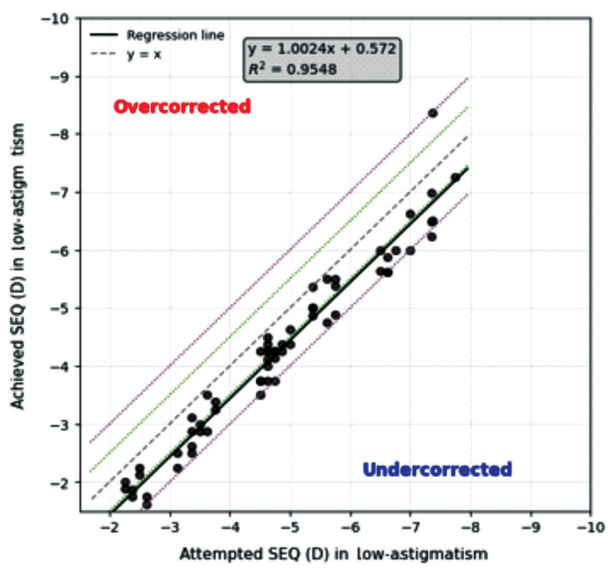

Figure 2 Spherical equivalent refraction attempted *vs* achieved in low astigmatism SEQ: Spherical equivalent.

cylinder, compared with 31.3% in the high-astigmatism subgroup (Figures 8 and 9).

The mean SIA was slightly less than the TIA across all eyes (Figure 10); in the low-astigmatism subgroup, this difference averaged 0.39 D (35.4%; Figure 11), while in the high-astigmatism subgroup it averaged 0.73 D (33.2%; Figure 12).

The mean absolute astigmatic angle of error was 4.47°±4.68°, with 97.6% of eyes ≤15° (Figure 13); by subgroup: low-astigmatism: mean 2.94°±3.08°, with 100% (64/64) ≤15° (Figure 14); high-astigmatism: mean 6.00°±5.47°, with 95.3% (61/64) ≤15° (Figure 15).

Comparative analysis between preoperative and postoperative data demonstrated statistically significant improvements in all key refractive parameters (Table 2). The procedure achieved substantial reductions in SE, myopia, cylinder, and astigmatic axis, with all intra-group changes reaching statistical significance (P<0.001).

The mean TIA for the overall cohort was 1.65±0.67 D, while the mean SIA was 1.09±0.52 D, corresponding to a CI of 0.66, indicating a tendency toward undercorrection. The mean DV was 0.56±0.27 D, and the IOS was 0.34, reflecting the proportion of residual astigmatism relative to the intended correction. The FI was 0.72, indicating effective flattening along the intended meridian. The calculated CA suggested that an increase in astigmatic treatment magnitude may improve refractive accuracy in higher-cylinder eyes (Table 3).

Preoperatively, there were no significant differences in SE between groups (P=0.535). Postoperatively, a minor yet statistically significant difference emerged (P=0.001), with the high-astigmatism group showing slightly higher residual SE. Despite this small inter-group variation, both groups experienced marked and clinically meaningful improvement from baseline.

The spherical error (myopia) showed consistent, significant reduction in both subgroups, with no inter-group differences pre- or postoperatively.

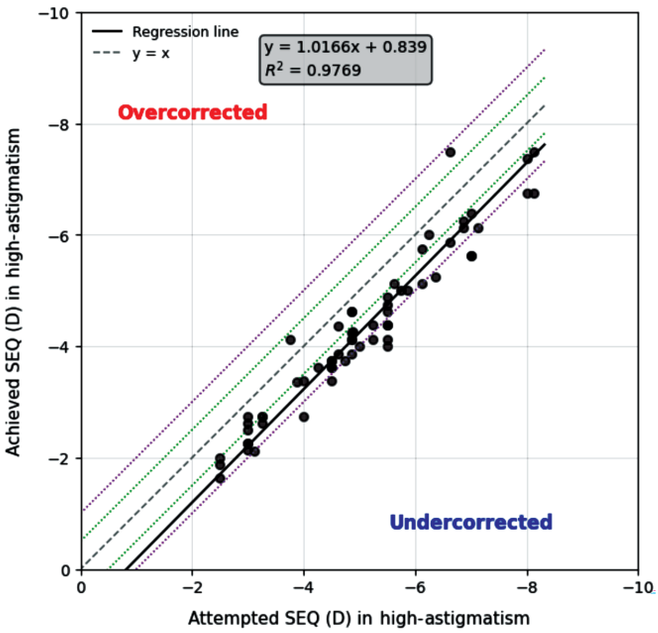

Figure 3 Spherical equivalent refraction attempted *vs* achieved in high astigmatism SEQ: Spherical equivalent.

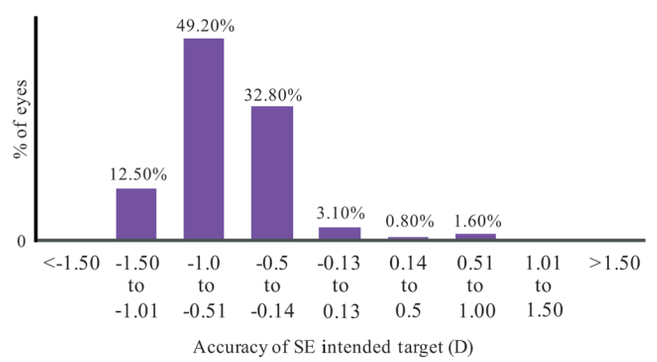

Figure 4 SE refraction accuracy in overall cohort SE: Spherical equivalent.

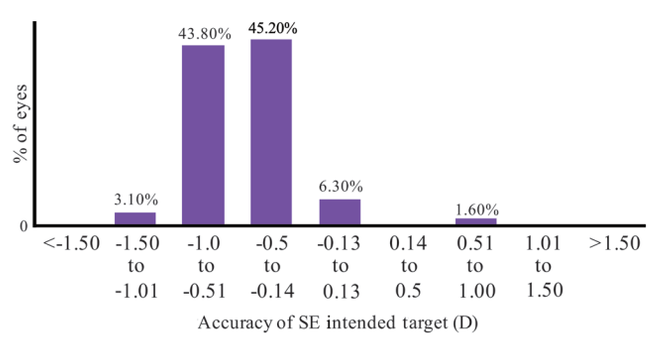

Figure 5 SE refraction accuracy in low astigmatism SE: Spherical equivalent.

As expected, cylinder values differed significantly between groups at baseline (P<0.001). Both groups exhibited substantial postoperative reduction (P<0.001), although a residual difference persisted (P<0.001), indicating effective but incomplete elimination of the initial disparity in astigmatism severity.

The axis of astigmatism demonstrated statistically significant intra-group changes but without meaningful clinical relevance,

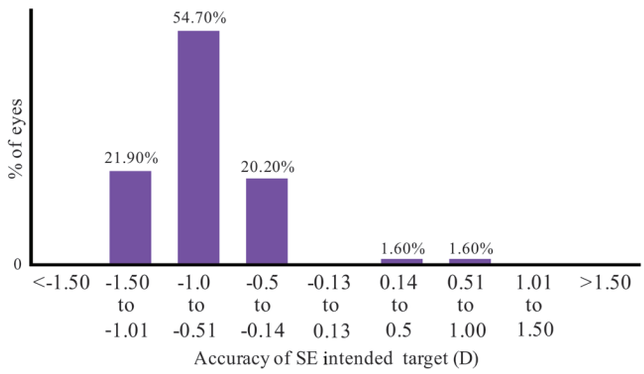

Figure 6 SE refraction accuracy in high astigmatism SE: Spherical equivalent.

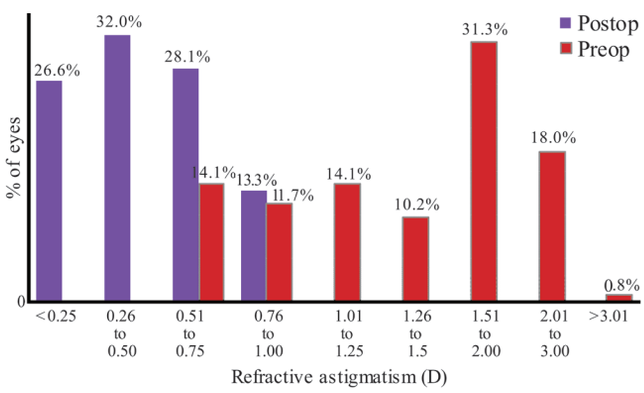

Figure 7 Refractive astigmatism in overall cohort.

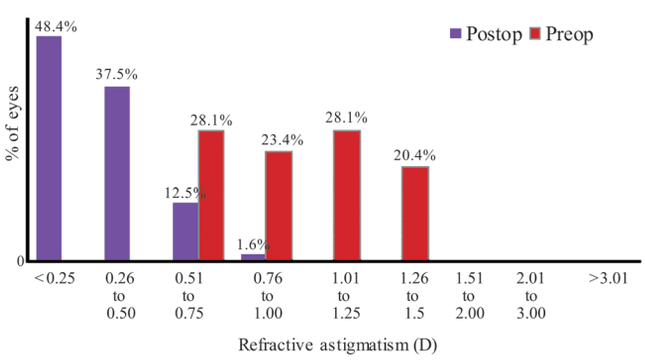

Figure 8 Refractive astigmatism in low astigmatism.

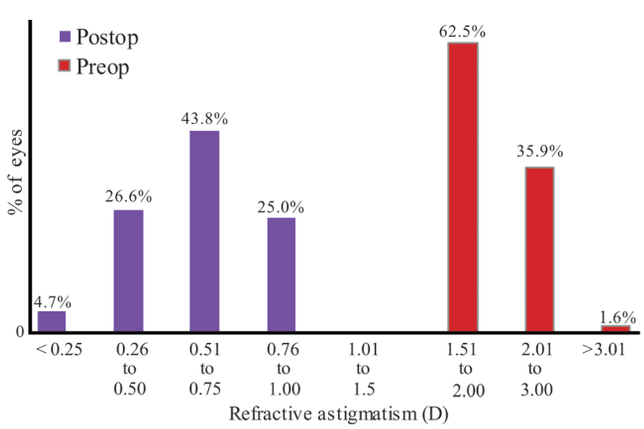

Figure 9 Refractive astigmatism in high astigmatism.

as inter-group differences remained nonsignificant at all time points. No intraoperative or postoperative complications were reported in patient records.

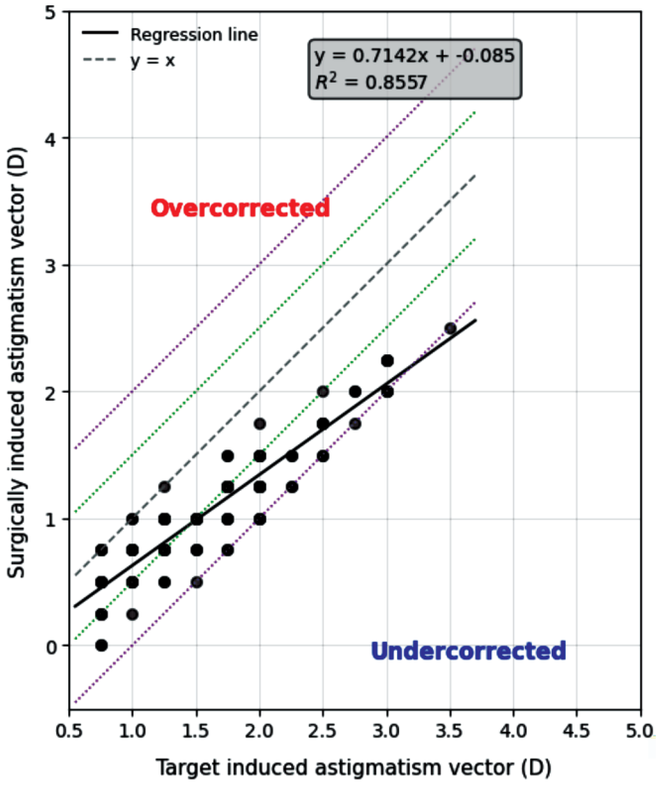

Figure 10 Target induced astigmatism vector *vs* surgically induced astigmatism vector in overall cohort.

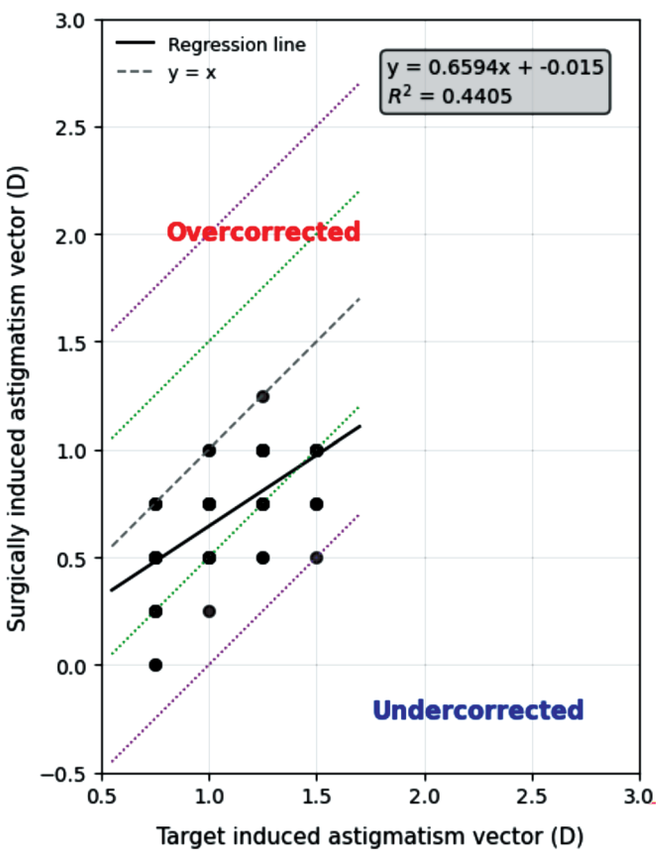

Figure 11 Target induced astigmatism vector *vs* surgically induced astigmatism vector in low astigmatism.

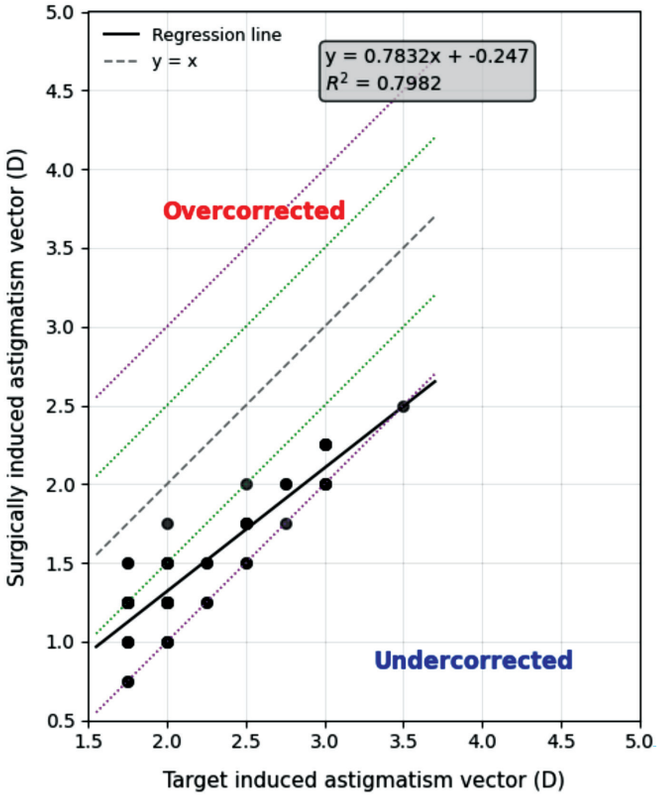

Figure 12 Target induced astigmatism vector *vs* surgically induced astigmatism vectors in high astigmatism.

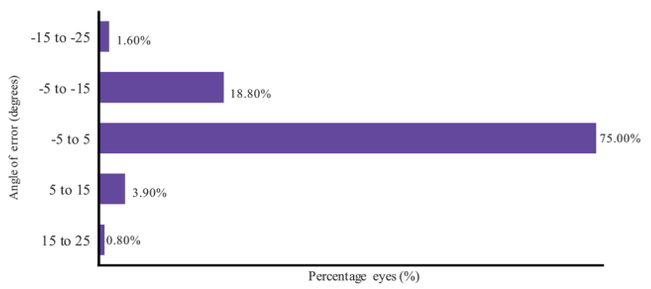

Figure 13 Refractive astigmatism angle of error in overall cohort.

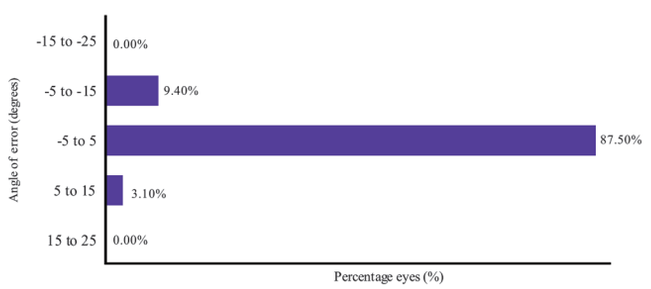

Figure 14 Refractive astigmatism angle of error in low astigmatism.

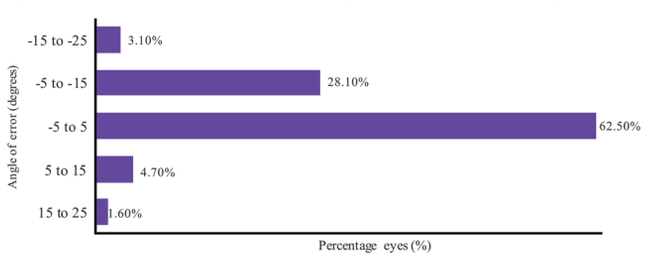

Figure 15 Refractive astigmatism angle of error in high astigmatism.

DISCUSSION

This retrospective study evaluated the three-month refractive and visual outcomes of SMILE Pro using the VISUMAX 800 femtosecond laser in myopic astigmatism. The findings

demonstrate that the procedure provides safe, accurate, and predictable correction, comparable to or exceeding results reported with both previous-generation SMILE systems and early VISUMAX 800 series studies.

Our data showed that 36.7% of eyes were within ±0.50 D and 87.5% within ±1.00 D of the intended SE, confirming high refractive predictability. These results align closely with the large-cohort study by Cung *et al*[5] who reported 81% and 97% within the same ranges, and are consistent with Reinstein *et al*[4], who observed 86% and 100% predictability, respectively. Similarly, Saad *et al*[6] found 91% within ±0.50 D and 99% within ±1.00 D, reinforcing the reproducibility of VISUMAX 800 outcomes. Although a high proportion of eyes were within ±1.00 D of target refraction, only 36.7% were within ±0.50 D, indicating that refractive accuracy may be influenced by astigmatism magnitude and nomogram calibration.

Our mean residual cylinder of -0.56±0.27 D corresponds well with the outcomes of Taneri *et al*[7] using the older VisuMax 500, who reported -0.32±0.29 D after 3mo. Subgroup analysis revealed that the low-astigmatism group (≤1.50 D) exhibited lower residual cylinder (-0.39 D) and greater predictability (86% ≤0.50 D) than the high-astigmatism group (>1.50 D; -0.72 D). This under-correction pattern, also noted by Reinstein *et al*[4] and Taneri *et al*[7], suggests that minor residual astigmatism may stem from nomogram calibration differences, particularly in higher cylinders. Refinement of astigmatic nomograms and improved axis tracking may further enhance accuracy.

In the high-astigmatism subgroup, the difference between TIA (2.20 D) and SIA (1.47 D) corresponds to approximately 33% undercorrection. Similar trends have been reported in previous SMILE studies, particularly in higher cylinders. Possible explanations include incomplete compensation of cyclotorsion, biomechanical remodeling of the cornea after lenticule extraction, and the absence of individualized nomogram optimization. Future studies should explore customized astigmatic nomograms to further improve correction accuracy in higher cylinders.

Vector analysis showed a mean angle of error of 4.47°, with 97.6% of eyes ≤15°, similar to the 94%–96% reported by Taneri *et al*[7] and Saad *et al*[6] The VISUMAX 800's CentraLign and OcuLign technologies likely contribute to this precision by providing centration and rotational guidance, addressing cyclotorsion limitations of earlier systems.

Our vector analysis findings (CI=0.66) confirm that SIA remained lower than intended correction, consistent with prior SMILE literature, suggesting the need for further refinement of astigmatic nomograms in higher cylinders.

From a biomechanical perspective, SMILE preserves corneal stromal integrity, which may explain the strong predictability of SE correction while also contributing to postoperative astigmatic remodeling[8].

Additionally, preoperative corneal characteristics appear to play a critical role. Previous studies have shown that anterior corneal astigmatism and keratometry significantly influence postoperative optical outcomes, including effective optical zone morphology[9].

This aligns with our findings of reduced accuracy in higher astigmatism, suggesting that baseline corneal topography may limit correction efficiency.

Safety and efficacy outcomes were excellent. Cung *et al*[5] and Saad *et al*[6] reported no major complications, and Reinstein *et al*[4] described only minor transient interface reactions. In our study, no intraoperative or postoperative complications were recorded, confirming the VISUMAX 800's reliability and safety profile. Collectively, these findings reinforce that SMILE Pro achieves outcomes equivalent to or better than femtosecond LASIK, with shorter treatment time and reduced biomechanical impact.

While our results demonstrate short-term stability, future studies with longer follow-up are warranted to evaluate long-term refractive stability, nomogram optimization, and higher-order aberration outcomes.

This study has several limitations. Its retrospective design and single-center scope may limit generalizability. The follow-up period of 3mo provides only short-term outcomes and does not allow evaluation of long-term refractive stability or regression. Objective optical quality measures such as wavefront aberrations were not included. Additionally, no nomogram customization was applied, so optimization strategies for high-cylinder correction could not be analyzed.

Because both eyes of many patients were included, inter-eye correlation may have influenced statistical independence. Future studies using generalized estimating equations (GEE) or mixed-effects modeling would provide more robust statistical adjustment for paired-eye data. Future prospective, multicenter studies with extended follow-up are necessary to address these limitations.

SMILE Pro using the VISUMAX 800 femtosecond laser provides safe and predictable correction of myopic astigmatism with good axis alignment. However, the observed undercorrection in higher cylinders suggests that further optimization of astigmatic nomograms may improve refractive accuracy. Further prospective research with longer follow-up is recommended to optimize nomogram adjustments and confirm long-term performance.

SMILE is a minimally invasive, flap-free refractive procedure providing stable correction for myopia and low-to-moderate astigmatism; The VISUMAX 800 is a new-generation 2 MHz femtosecond laser with faster scanning, shorter suction

time, and enhanced centration and cyclotorsion aids; Early VISUMAX 800 studies[4-6] confirmed high efficacy and safety but with limited cohort diversity and short follow-up.

This study presents real-world retrospective data confirming the VISUMAX 800's safety, accuracy, and reproducibility in both low and high astigmatism; It demonstrates excellent axis precision and consistency with international VISUMAX 800 outcomes, supporting global clinical applicability; It emphasizes the need for refined nomogram adjustments in higher-cylinder corrections to further improve predictability.

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