NOK- WM-FF

Comparison of Visual and Refractive Outcomes for SMILE Performed with Two Different Femtosecond Lasers



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INTRODUCTION

- Following its introduction in 2011, SMILE using the VisuMax 500 has proven to be an effective treatment for myopia and myopic astigmatism, and it has been widely used worldwide.
- · However, there are some limitations of SMILE
 - Risk of suction loss
 - Decentration
 - Cyclotorsion
- VisuMax 800 (SMILE pro), a second-generation femtosecond laser, was introduced in 2021 with several improvements
 - Faster speed (about 3 times faster than VisuMax 500)
 - CentraLign®: guides the surgeon for centration by visual overlays on the monitor to align the eye



OcuLign®: control for cyclotorsion by rotation of the axis of the treatment



Purpose: To compare the clinical outcomes of SMILE performed with VisuMax 800 (SMILE pro) versus VisuMax 500 (SMILE)

METHODS

- 2023/Aug/1 ~ 2023/Oct/30
- Onnuri Smile Eye Clinic, Seoul, South Korea
- 50 patients, 100 eyes for each group
- By one experienced SMILE surgeon (KBK)
- SMILE group: VisuMax 500, manual centration
- SMILE pro group: VisuMax 800, using CentraLign®
- Laser settings for both groups
 - Spot distance 3.0 ~ 4.0 μm
 - Lenticule diameter 5.9 ~6.7 mm
 - Cap thickness 110 ~ 120 μm
 - Side cut thickness 15 μm
 - Incision 1.0 mm
- Same nomogram was applied to both groups
- Follow up: POD 1 day, 1 week, 1 month, 3 months

Table 1. Main equipment parameters of two machines

	Visumax 500	Visumax 800	
Manufacturer	Carl Zeiss, Jena, Germany	Carl Zeiss, Jena, Germany	
Wavelength (nm)	1043	1043	
Pulse duration (fs)	220-580	220-580	
Laser pulse repetition rate (kHz)	500	2,000	
Weight (kg)	870	520	
Dimensions (see)	380 x 440	171 x 93	
Dimensions (cm)	(fixed installation with patient bed)	(laser only)	
Energy (nJ)	100-260 (personal setting possible)	75-260 (personal setting possible)	
Spot distance (µm)	3-5	1-5	
Docking method	Joystick (patient to system docking)	Joystick (system to patient docking)	
Contact glass on suction system	Curved	Curved	
Automatic detection of pupil	No	Yes	
Pupil central offsetting	No	Yes	

RESULTS

Table 2. Patient demographics

	SMILE	SMILE pro	<i>p</i> -value
Age (years)	26.14 ± 4.27	26.24 ± 5.56	0.920*
Gender (M/F)	54/46	60/40	0.294 [†]
Refractive errors (D)			
Spherical	-4.06 ± 1.68	-3.87 ± 1.54	0.383*
Cylindrical	-1.18 ± 0.85	-1.4 ± 0.95	0.079*
SE	-4.65 ± 1.86	-4.57 ± 1.6	0.724*
CCT (µm)	564.6 ± 31.27	562.9 ± 25.88	0.676*
Optic zone (mm)	6.42 ± 0.3	6.43 ± 0.23	0.749*
Preoperative pupillary offset (mm)		27.7	
X-axis	0.13 ± 0.1	0.13 ± 0.09	0.594*
Y-axis	0.15 ± 0.12	0.14 ± 0.11	0.445*
Pupil diameter (mm)	6.92 ± 0.52	6.75 ± 0.66	0.087*
HOAs (µm)			
Oblique trefoil	0.12 ± 0.08	0.11 ± 0.09	0.474*
Vertical coma	0.16 ± 0.1	0.17 ± 0.13	0.425*
Horizontal coma	0.15 ± 0.11	0.14 ± 0.11	0.745*
Horizontal trefoil	0.09 ± 0.07	0.11 ± 0.08	0.164*
Spherical aberration	0.2 ± 0.07	0.22 ± 0.06	0.160*
Total HOAs	0.45 ± 0.1	0.48 ± 0.14	0.082*

SMILE = small incision lenticule extraction; M/F = male/female; D = diopters; SE = spherical equivalent; CCT = central corneal thickness; HOAs = higher order aberrations.

Table 3. Comparison of intraoperative findings between two surgeries

	SMILE	SMILE pro	p-value*
Intraoperative complication	0	0	N/A
Time for lenticule creation (seconds)	28.27 ± 2.34	10.33 ± 0.82	<0.001
Time for lenticule removal (seconds)	35.33 ±13.5	30.73 ± 9.55	0.101
Decentration (mm)			
X-axis	0.21 ± 0.19	0.16 ± 0.15	0.021
Y-axis	0.32 ± 0.21	0.13 ± 0.1	<0.001
Total	0.39 ± 0.26	0.22 ± 0.15	<0.001

SMILE = small incision lenticule extraction; N/A = non-applicable.

^{*}Independent sample *t*-test; †chi-square test.

^{*}Independent sample *t*-test.

RESULTS

Table 4. Comparison of postoperative findings between two surgeries at 3 months

	SMILE	SMILE pro	<i>p</i> -value*
UDVA (logMAR)	-0.08 ± 0.04	-0.07 ± 0.05	0.539
CDVA (logMAR)	-0.1 ± 0.06	-0.09 ± 0.05	0.957
Refractive errors (D)			
Spherical	-0.09 ± 0.38	-0.05 ± 0.39	0.552
Cylindrical	-0.36 ± 0.23	-0.32 ± 0.23	0.250
SE	-0.27 ± 0.36	-0.21 ± 0.39	0.337
CCT (µm)	473.6 ± 35.4	469.8 ± 29.6	0.408
Efficacy index	1.06 ±1.07	1.04 ± 0.15	0.292
Safety index	1.12 ± 0.21	1.09 ± 0.19	0.417
HOAs (µm)			
Oblique trefoil	0.16 ± 0.12	0.14 ± 0.11	0.235
Vertical coma	0.24 ± 0.18	0.2 ± 0.14	0.383
Horizontal coma	0.18 ± 0.13	0.18 ± 0.13	0.983
Horizontal trefoil	0.11 ± 0.09	0.12 ± 0.1	0.266
Spherical aberration	0.3 ± 0.16	0.29 ± 0.12	0.853
Total HOAs	0.64 ± 0.21	0.63 ± 0.17	0.766

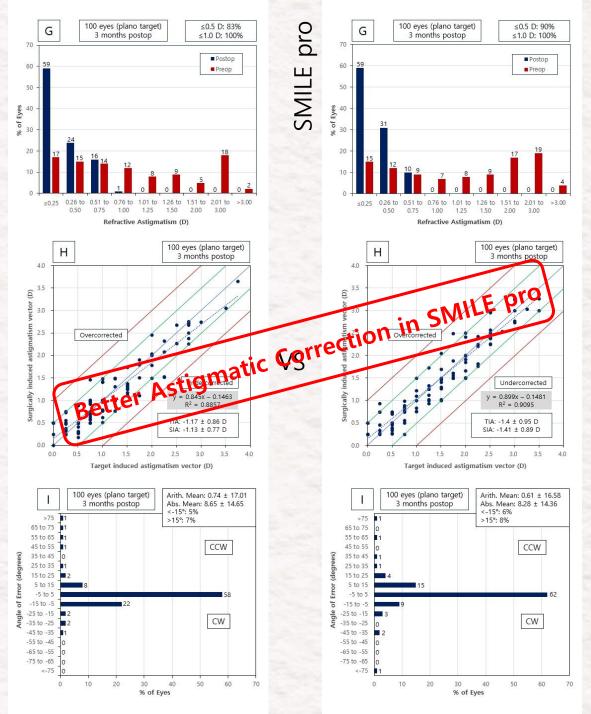
SMILE = small incision lenticule extraction; UDVA = uncorrected distance visual acuity; logMAR = logarithm of the minimum angle of resolution; CDVA = corrected distance visual acuity; D = diopters; SE = spherical equivalent; CCT = central corneal thickness; HOAs = higher order aberrations.

No vision-threatening complications were detected in either group during the 3-month follow-up period.

There were no cases of epithelial ingrowth, severe diffuse lamellar keratitis, or keratectasia.

^{*}Independent sample t-test.





Residual astigmatism ≤0.5 D: 83% vs 90%

SIA-TIA

Slope of trend line: 0.845 vs 0.899

R2: 0.8857 vs 0.9095

Angle of error

Arith. mean: 0.75 vs 0.61

≤5°: 58% vs 62%

Figure 3. RMS of total HOAs and individual Zernike coefficients in the SMILE and SMILE pro groups 3 months postoperatively. Error bars indicate standard errors and * indicates *P* < .05. HOAs = higher order aberrations; HC = horizontal coma; HT = horizontal trefoil; OT = oblique trefoil; SA = spherical aberration; VC = vertical coma.

Changes after the surgery by paired t-test.

Inter-group difference of change by independent sample t-test.

CONCLUSIONS

- Both SMILE procedures performed with VisuMax 500 and VisuMax 800 are comparable in efficacy, safety, and predictability for correcting myopia.
- There were no significant differences in postoperative visual acuity, residual refractive errors, central corneal thickness, and corneal higher-order aberrations.
- Decentration was significantly lower in SMILE with VisuMax 800 than in SMILE with VisuMax 500.
- Astigmatic correction tended to be better in SMILE with VisuMax 800 than in SMILE with VisuMax 500.
- SMILE with VisuMax 800 induced significantly less vertical coma than SMILE with VisuMax 500.