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Three-month refractive results, high-order aberrations, and complications after myopic Small Incision Lenticule Extraction (SMILE® pro) with the latest generation of Femtosecond Lasers, VISUMAX® 800 from ZEISS

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Background

To report three-month outcomes of the Small Incision Lenticule Extraction (SMILE® pro) for correction of myopia and myopic astigmatism with the latest generation of ZEISS Femtosecond Lasers, VISUMAX® 800.

Method

- Prospective observational study
- Between June 15 2022 and December 31 2022
- 104 eyes of 53 patients
- The mean spherical equivalent (SE) of -3,9±2,6 underwent SMILE pro procedure with VISUMAX femtosecond laser system (Carl Zeiss Meditec AG, Germany) with a 800 kHz repetition rate
- Patients were followed up at 1 day, 1 week, 1 month and 3 months after surgery
- Uncorrected (UDVA) and corrected distance visual acuity (CDVA), refraction , corneal high-order aberrations (HOAs) were obtained in each visit.
- Perioperative complications were also recorded.

Method: Outcome Measures

- **Efficacy of Procedure:** Percentage of **UCVA** of 20/25 or better and percentage of **UCVA** of 20/20 or better @ day 1 , week 1 , month 1 and month 3
  (efficacy index: mean post op UCDVA / mean pre op CDVA)

- **Safety of Procedure : BCVA** after surgery (no change – loose line - gain line)
  Safety Index: mean postop CDVA / mean preop CDVA) @ day 1 , week 1 , month 1 and month 3

- **Predictability of the Procedure :** Percentage of patients within 0.5 D of intended refraction
  @ day 1, week 1 , month 1, month 3 ,
  Correlation with the target of "0" refraction

- **Stability of Procedure**: Change in SE @ day 1 , week 1, month 1, month 3

- **Postop astigmatism correction**: percentage of residual astigmatism < 0.5 D
  percentage of residual astigmatism < 0.25 D
  @ day 1 , week 1 , month 1, month 3 ,

Results: Demographics

- 104 eyes of 53 patients with the mean age of 30,5±5,8 years
- 28 patients (52,8%) were female
- Nationalities; 35,8 % (n=19) UAE, 26,4 % (n=14) China, 37,7% (n=20) other nationalities

Results:Changes in Spherical Equivalent (SE)

The mean preoperative SE of -3,9±2,6 decreased to -0,2±0,4 at 1 month and -0,09±0,4 at 3 months after SMILE.

Spherical Equivalent (SE)	Mean ±sd	Median
[1]Preoperative	-3,92±2,6	-3,9 (-8-7,6)
[2]Postoperative Day 1	-0,20±0,5	-0,25 (-2,6-0,9)
[3]Postoperative Week 1	-0,20±0,6	-0,13 (-3,9-1,3)
[4]Postoperative Month 1	-0,24±0,4	-0,25 (-1,9-0,88)
[5]Postoperative Month 3	-0,09±0,4	-0,12 (-1,8-1,0)
	p	**0,001****
	Post Hoc	**1<2,3,4,5**

Results: Efficacy of Procedure

The percentage of UDVA equal or better than 20/20 was 90.4 % (94/104 eyes) at 1 month and 97.1% (101/104 eyes) at 3 months.

Efficacy Index (EI) : mean post op UDVA / mean pre op CDVA

	[1]EI Day 1	[2]EI Week 1	[3]EI Month 1	[4]EI Month 3	p	Post hoc
Mean	0,073	0,035	0,019	0,008	0,001**	1>3 1>4
SD	0,121	0,094	0,064	0,039		
Median	0,00	0,00	0,00	0,00		
Minimum	0,00	0,00	-0,11	-0,11		
Max.	0,71	0,50	0,33	0,27		

Results: Safety of Procedure

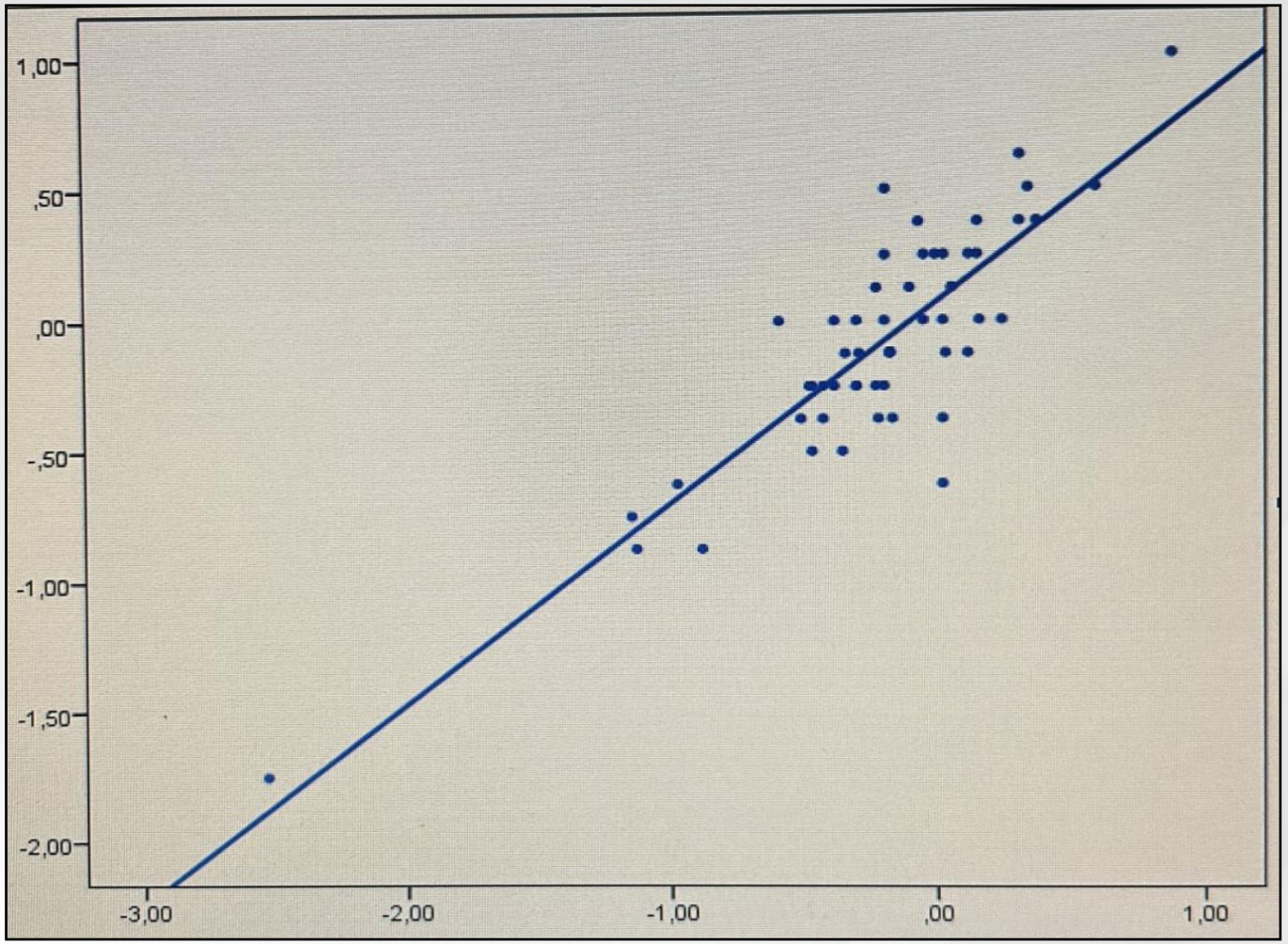
- ✓ A loss of 1 line of CDVA was observed in 5 eyes (4,8%) and 2 or more lines in 3 eyes (2,9%) at 1 month
- ✓ A loss of 1 line of CDVA was observed in 1 eye (0.96%) at 3 months. No patient lost 2 or more lines of CDVA at 3 months.
- ✓ Four eyes (3.8%) gained 1 line

Safety Index (SI): mean postop CDVA / mean preop CDVA)

	[1]SI Day 1	[2]SI Week 1	[3]SI Mo 1	[4] SI Mo 3	p	Post Hoc
Mean	0,0731	0,026	0,007	0,009	0,001**	1>2,3,4
SD	0,122	0,068	0,037	0,039		
Median	0	0	0	0		

Results: Predictibility of Procedure

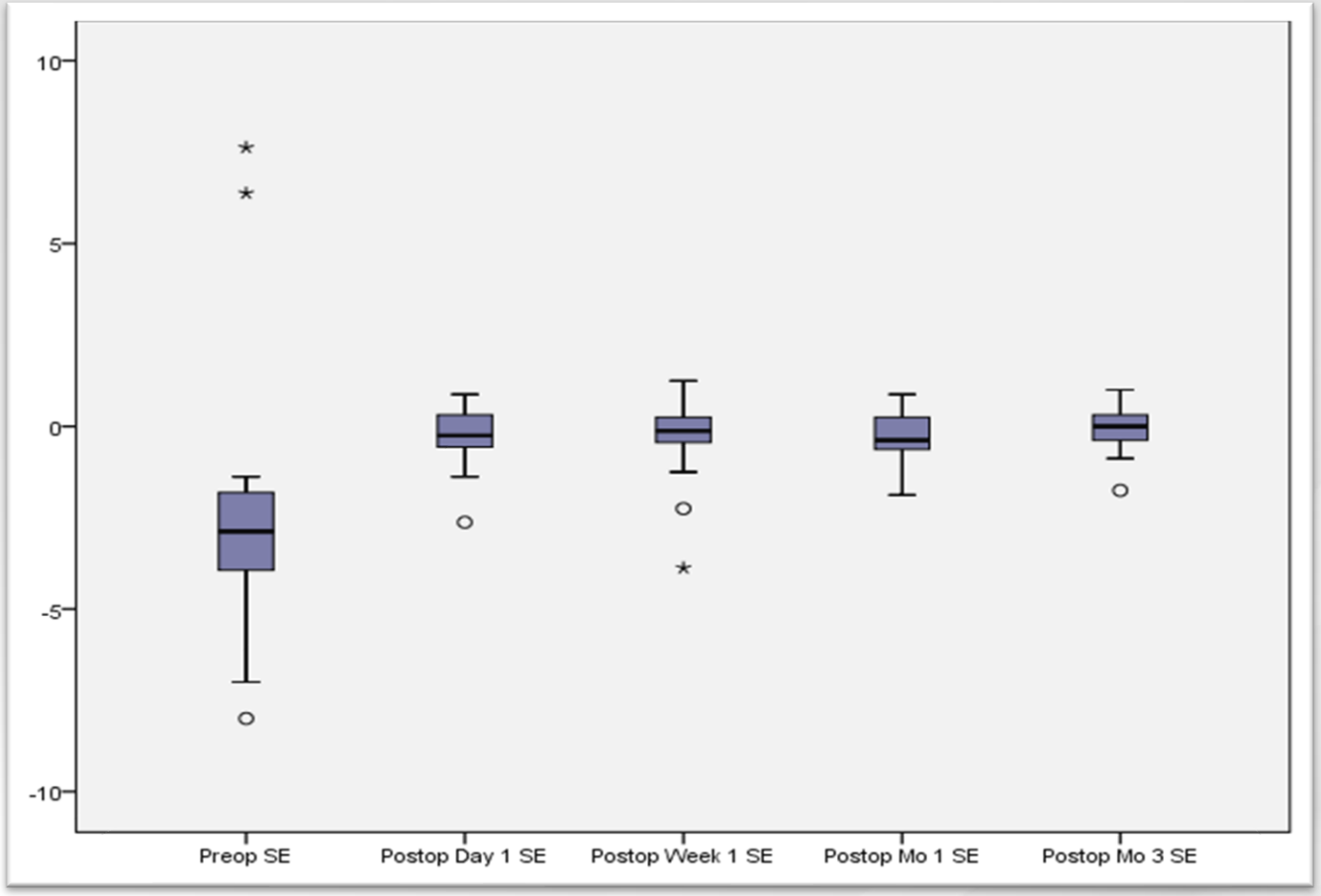
Proximity to targeted "0" refraction



The achieved and attempted SE were highly corelated (R=0.86; P < 0.001)
with a mean postoperative refraction of 0,2 ±0,4
with a mean error in treatment of 0,014 ± 0,07

Results: Stability of Procedure

Change in SE @ day 1 , week 1, month 1, month 3



Refraction was stable during follow-up visits

Results: Postoperative Astigmatic Correction

Percentage of residual astigmatism less than 0.5 D at 1 month : **80%**

Percentage of residual astigmatism less than 0.25 D at 1month: **70%**

Percentage of residual astigmatism less than 0.5 D at 3 months: 89%

Percentage of residual astigmatism less than 0.25 D at 3 months: 83%

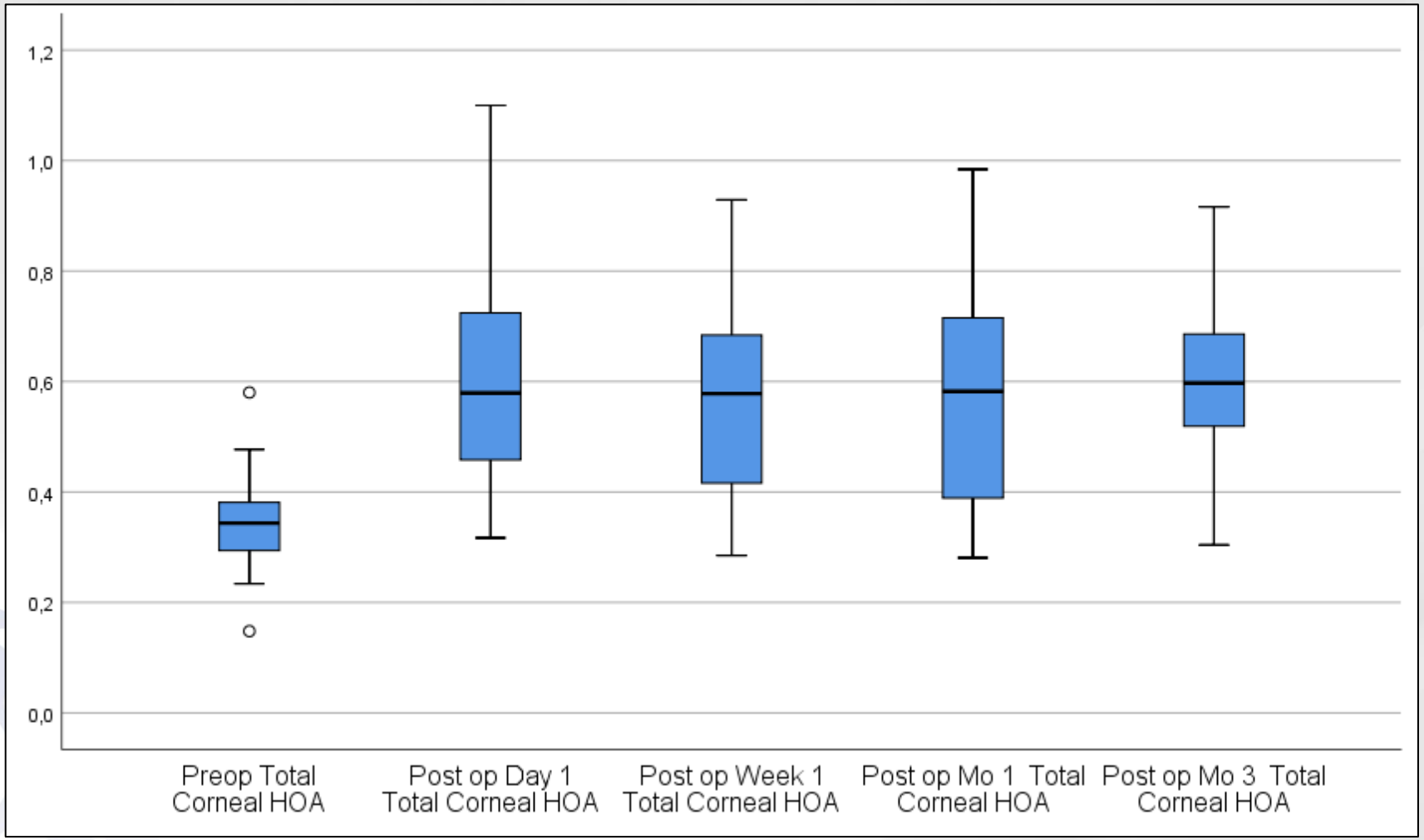
Results: Changes in Corneal HOAs

	Mean ± SD	Median
[1]Preop	0,37±0,13	0,36 (0,30-0,42)
[2]Post op Day 1	0,63±0,22	0,59 (0,46-0,73)
[3]Post op Week 1	0,61±0,21	0,59 (0,45-0,76)
[4]Post op Month 1	0,62±0,21	0,59 (0,46-0,75)
[5]Post op Month 3	0,64±0,23	0,62 (0,49-0,69)
p	0,001**	
Post Hoc	1<2,3,4,5	

Corneal HOA significantly increased after SMILE compared to preop values

Results: Changes in Corneal HOAs

The mean change in corneal HOAs from baseline was 0.25±0.13 at 1 month and 0.27±0.11 at 3 months



Results: Intraoperative Complications

	N :104	%
None	16	15,4%
Difficult lenticule dissection (Anterior plan)	7	6,7%
OBL	5	4,8%
Incisional abrasion	5	4,8%
Black spot	4	3,8%
Lenticule tear	3	2,9%
Incisional bleeding	2	1,9%
Difficult lenticule dissection (Posterior plan)	2	1,9%
Suction loss	1	1,0%
Epithelial defect	1	1,0%
Difficult lenticule extraction	1	1,0%
Incisional tear	1	1,0%
Anterior cap tear	-	-
Partially retained lenticule	-	-
Completely retained lenticule	-	-

- ✓ **The most frequent perioperative complication reported was difficulty in anterior plan lenticule dissection (7/104 , 6.7%) , followed by opaque bubble layer (OBL) (5/104 , 4.8%) and incisional abrasion (5/104 , 4.8%).**
- ✓ **Loss of suction was reported only in 1 eye (0.96%).**
- ✓ **No visually threatening complications were observed.**

Summary

- ✓**SMILE® pro for correction of myopia and myopic astigmatism with VISUMAX® 800 is effective, safe, predictable and stable.**
- ✓**Mild induction of HAOs as previously reported**
- ✓**Less suction loos rate than previously reported.**