المؤتمر السنوي الدولي للجمعية المصرية
INTERNATIONAL CONGRESS OF THE
EGYPTIAN OPHTHALMOLOGICAL SOCIETY
EOS 2023

First Experience Visumax 800 SMILE Pro®

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Financial Disclosure

- Consultant Carl Zeiss
- Consultant Alcon

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Lenticular intrastromal surgery:

- First experience with the latest generation of Visumax 800 Femtosecond Laser;
- Three month refractive outcome,
- High-order aberrations,
- Complications after myopic Small Incision Lenticular Extraction (SMILE Pro) surgery

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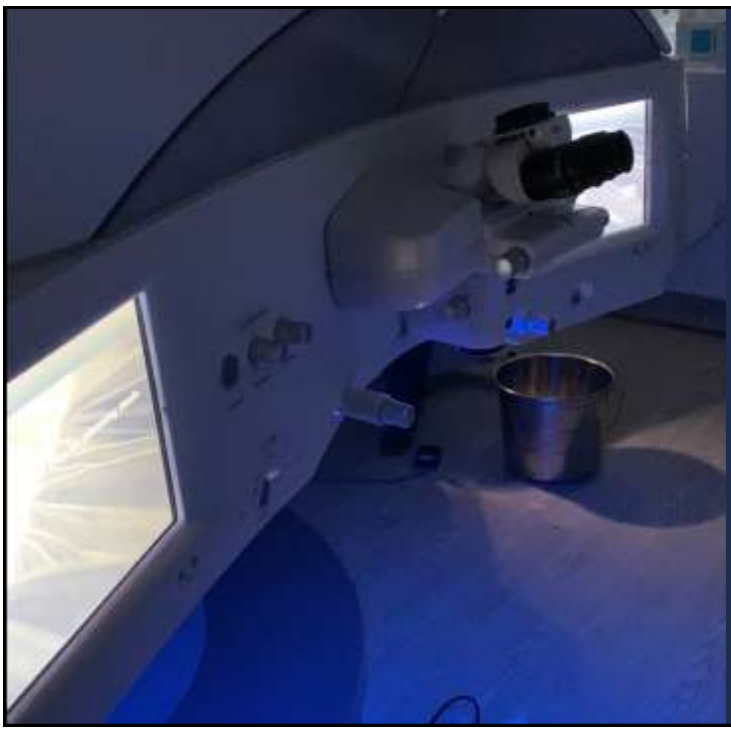

Started
ReLex SMILE
March 2021

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Challenges with VM500 (ReLex SMILE)

- Long duration; 24 seconds = Suction Loss
- Unpredictable PO Day#1 Auto Refraction = less 20/20 (vs FS-LASIK)
- Low Waw effect Rate

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ESCRS 39th Congress of the ESCRS AMSTERDAM 8 - 11 October 2021

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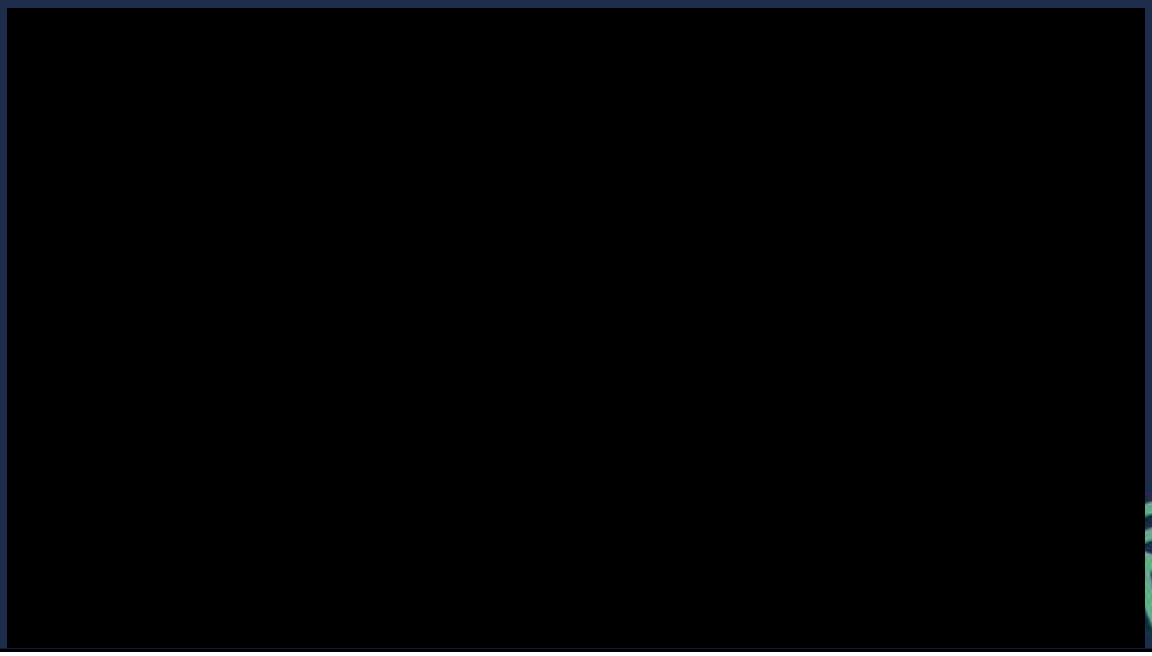
March2022 Arrival of 1st VM800 in Middle East



Features: Visumax 800

- **Increased laser frequency and faster cut speeds.**
- Creates the Lenticule 10 sec
- Flap cutting 6 seconds
- This performance is driven by a faster laser pulse repetition rate of **2 MHz** and an innovative **scanner system**.
- All this ensures a very short **overall suction time.**

Features: Spead

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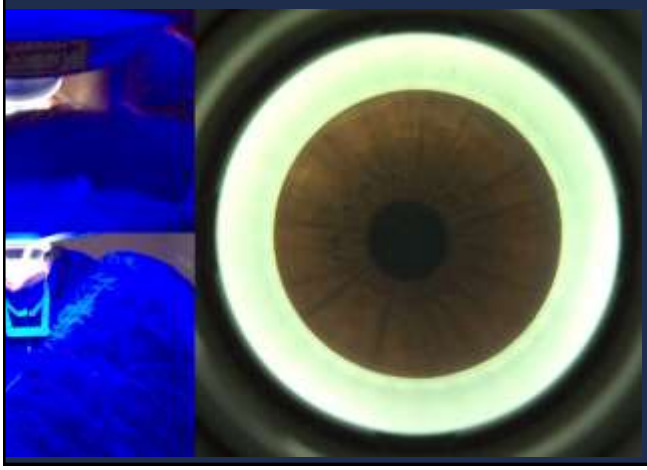
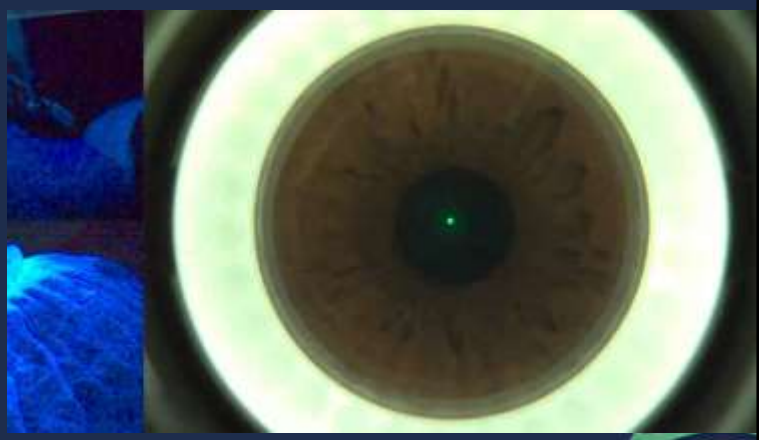
Visumax 800



Visumax 500

Features: Shorter suction time

- The faster cutting speed leads to a shorter suction time, which reduces the probability of a potential suction loss.
- This can increase peace of mind and reduce stress for surgeon and patients patients during the laser treatment.



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Features: Tracking distances positioning made easy

- Ultrasound sensors assist in actuating the robotic arms.
- Integrated top-view, side-view and therapy cameras allow you to intelligently observe the surgical environment between device and patient.
- You are able to observe the patient with ease and ergonomic comfort while docking the cornea correctly.

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Features: CentraLign System®

- The CentraLign® assistant system is a computer-controlled function for easy centration.
- It uses pupil center and vertex position, giving control of centration already during the docking phase.
- There is no need to shift the cutting pattern after docking.

Features: OcuLign system for easy cyclotorsion alignment

- ZEISS VISUMAX 800 features the intuitive OcuLign® pattern rotation.
- Automatically re-calculates the treatment pattern and helps to counter cyclotorsion that may occur.
- This feature Expected to be unlocked by Early 2024

Features: Interactive touchscreens and networking

- **Touch screen**
- **Direct data import from Zeiss forum**
- **Reduced errors of data entry**
- **Auto upload of surgical report and videos to patient electronic file**
- **Intraoperative data access and update of plan**
- **Nurses/techs love it.**

Technical Data

- **Laser type**：Femtosecond laser
- **Available treatment options**：
  - Flap,
  - SMILE® pro,
  - CIRCLE,
  - ICR,
  - Keratoplasty1

Optical data

- **Maximum laser repetition frequency**
  - **2 MHz** previous visumax had **500 KHz**
- **Wavelength**
  - 1043 nm
- **Pulse duration**
  - 220 – 580 fs

Why do I prefere SMILE Pro

1. Corneal Suction is Shorter
2. No Flap Complications
3. Larger Aspheric zone of treatment
4. Biomechanically Stronger cornea
5. Less dry eyes
6. Better surgical alignemnt
7. Solid state laser , not affected by invironmental factors
8. Better surgical experience for the patient

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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

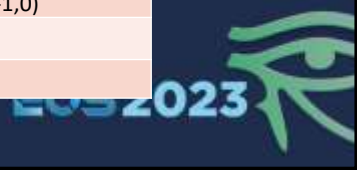
- Prospective observational study,
- Between June 15 2022 and December 31 2022
- 104 eyes of 53 patients
- The mean spherical equivalent (SE) of -3.9 ±2.6 underwent SMILE pro procedure with VISUMAX femtosecond laser system (Carl Zeiss Meditec AG, Germany) with a 800 kHz repetition rate
- Patients were 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.

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

Friedman test&post hoc Dunn test **p<0,01



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 Month 1	[4] SI Month 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		

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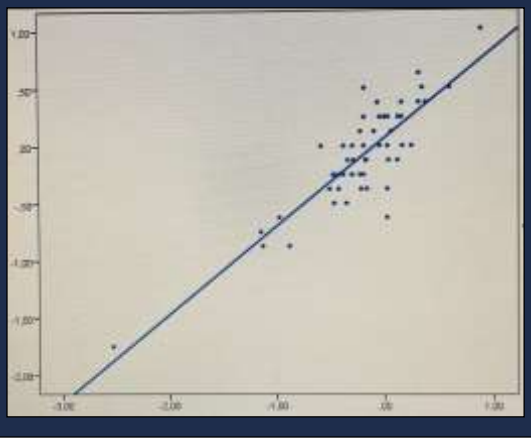
Results: Predictability of Procedure

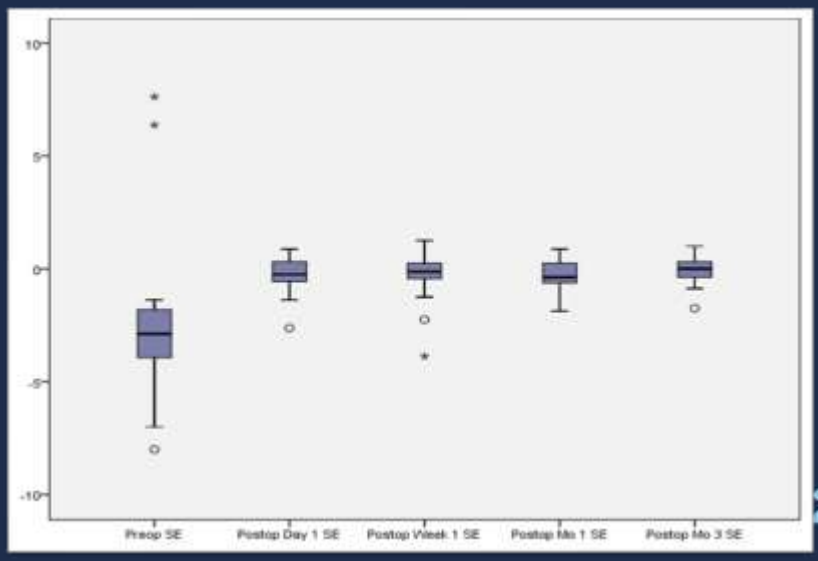
Proximity to targeted "0" refraction



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



2023

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%**

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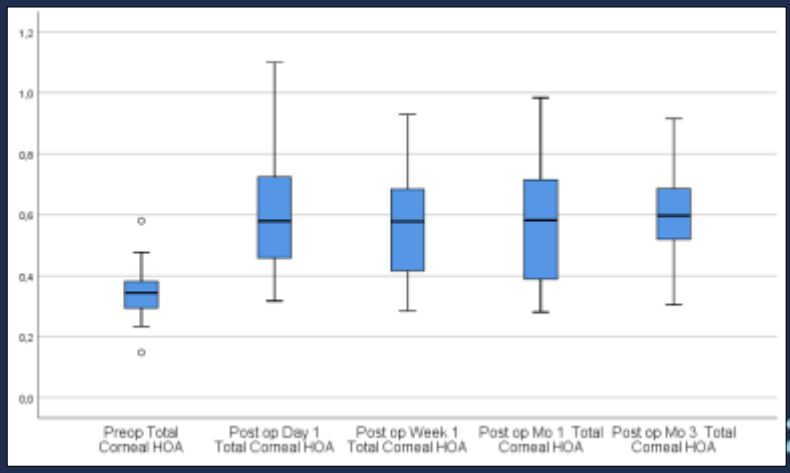
Results: Changes in Corneal HOAs

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



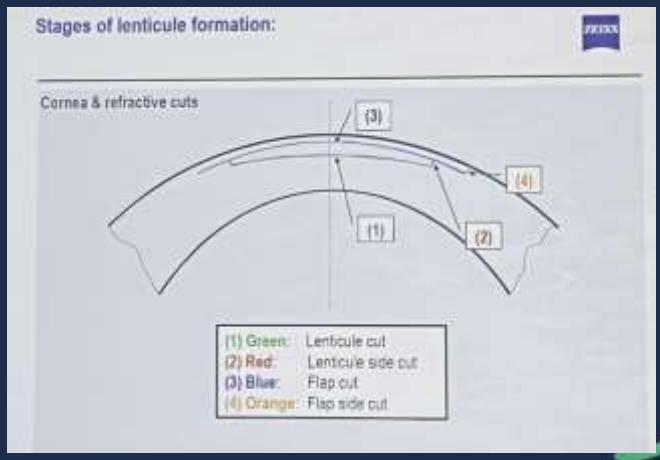
Results: Intraoperative Complications

	N :104	%
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	-	-

SUCTION LOSS

CAUSES:

- sudden movement or squeezing of the eye
- Excess fluid around the eye
- Improper cone selection
- Loose conjunctiva



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Management

- Covert to FS-LASIK
  - Lenticule cut progress >10%
- Proceed to SMILE
  - Lenticule cut progress <10%
  - Side cut
  - Cap cut
  - Cap side cut

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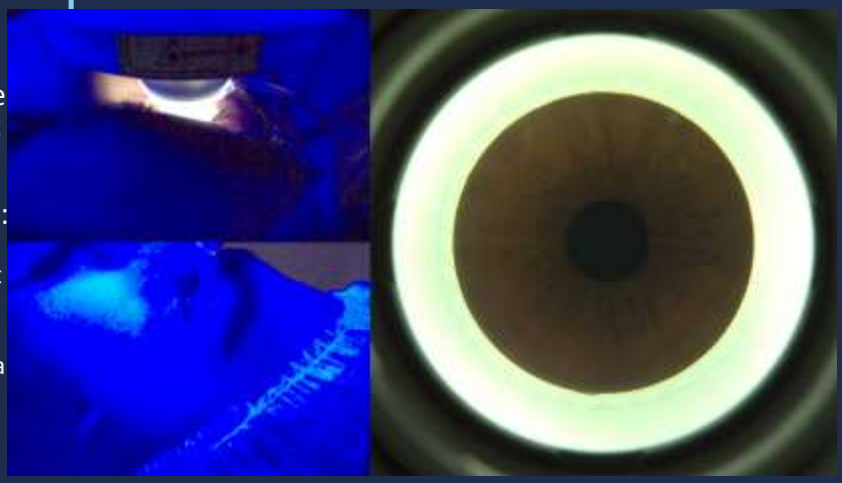
Incision/cap tear

- Small incision
- Excessive side to movement

- Management:
  - Small = leave it as it is
  - Large= BCL
  - Heals with a faint line
  - Risk of epithelial ingrowth



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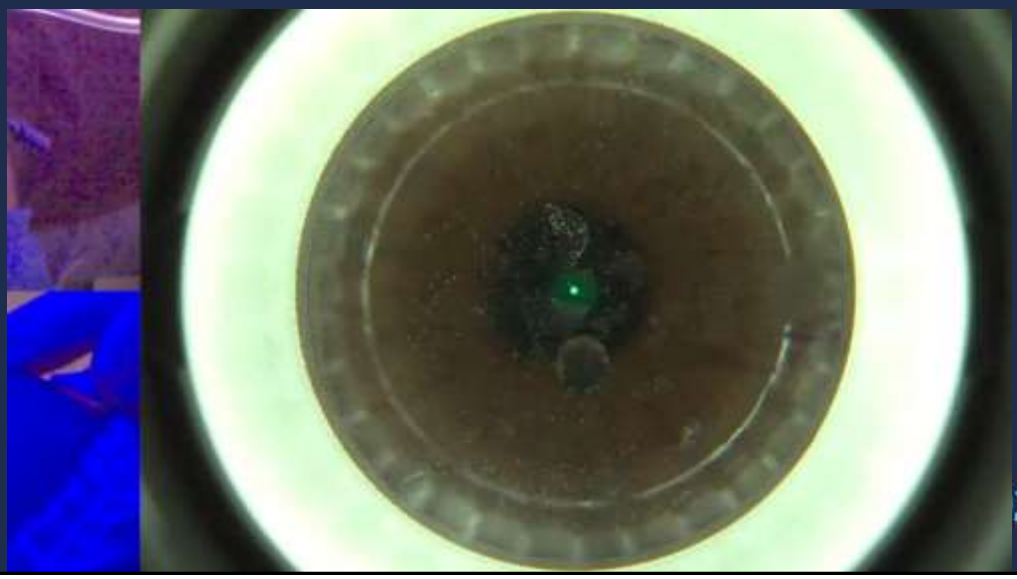
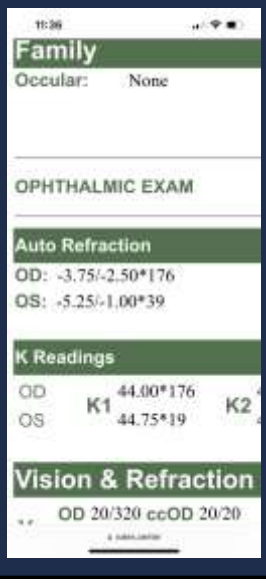
Black spot



23

Vision

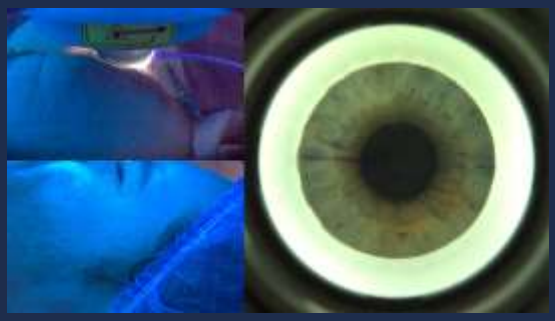
Pre SMILE Pro



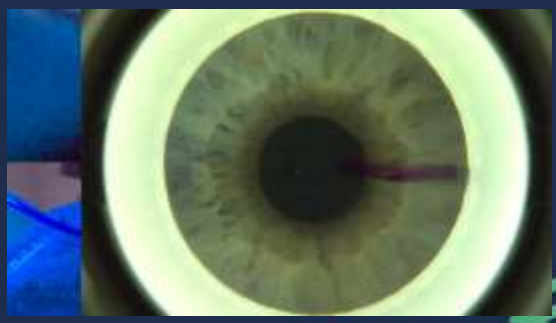
Post SMILE Pro

LASER head energy variation

Right Eye normal



Left eye Subthreshold laser



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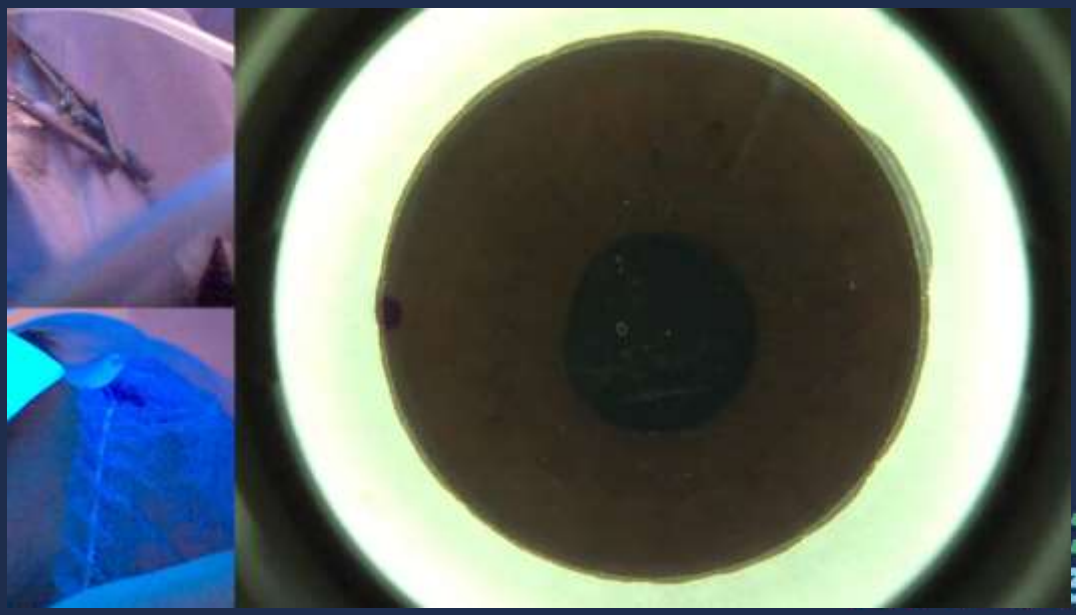

Summary

- ✓Small Incision Lenticule Extraction (SMILE® pro) for correction of myopia and myopic astigmatism with the latest generation of ZEISS Femtosecond Lasers, VISUMAX® 800 is **effective, safe, predictable and stable.**
- ✓Mild induction of HAOs as previously reported
- ✓Less suction loos rate than previously reported.

Thank you