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Keynote Lecture

Klex – My new toy

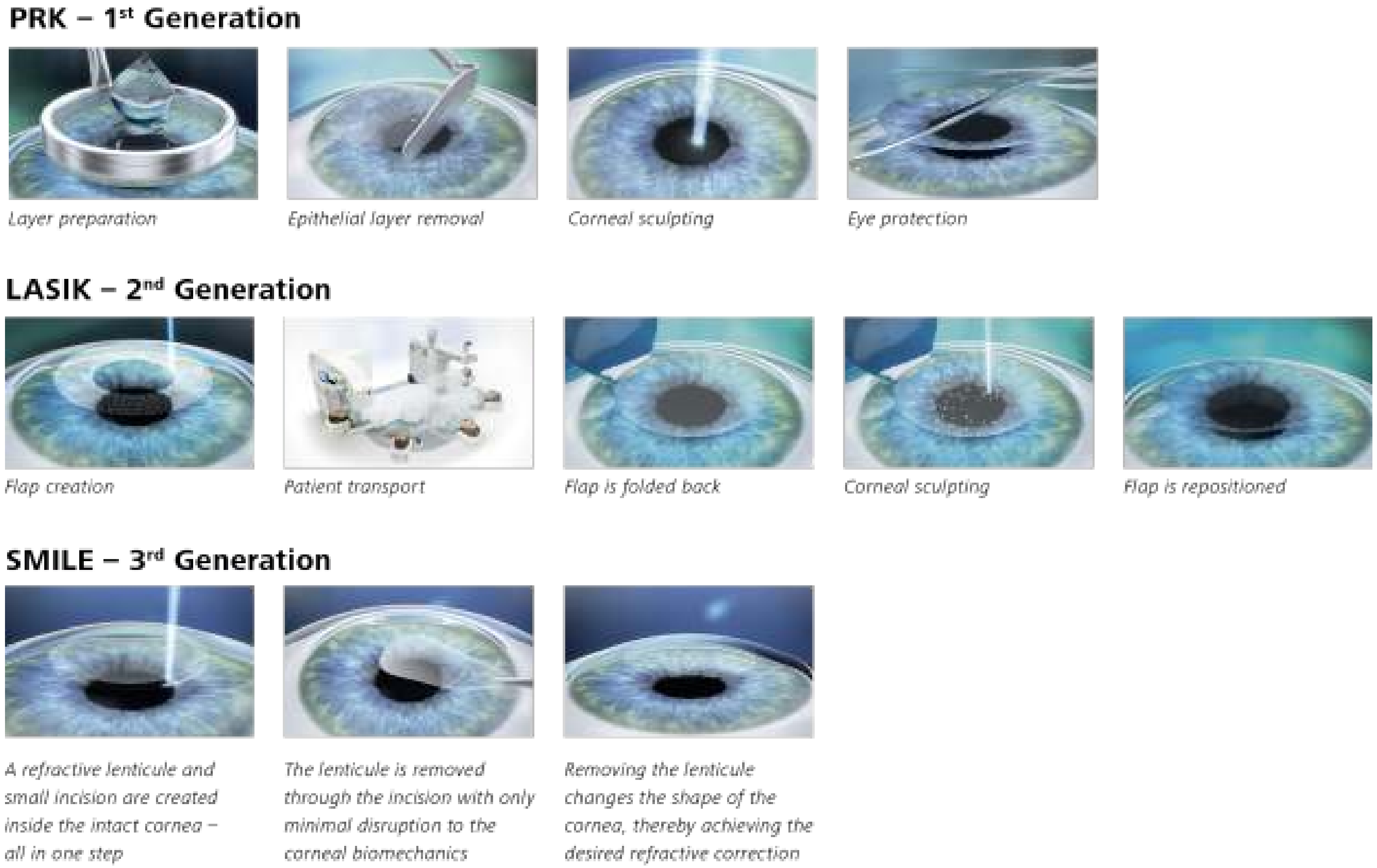
Thomas Kohnen

Financial disclosure:
T. Kohnen: *Consultant and Research* for Alcon, J&J, Lensgen, Oculentis, Oculus, Presbia, Schwind, Zeiss. *Consultant for* Allergan, Bausch & Lomb, Geuder, Med Update, Santen, Staar, Thieme, Ziemer.

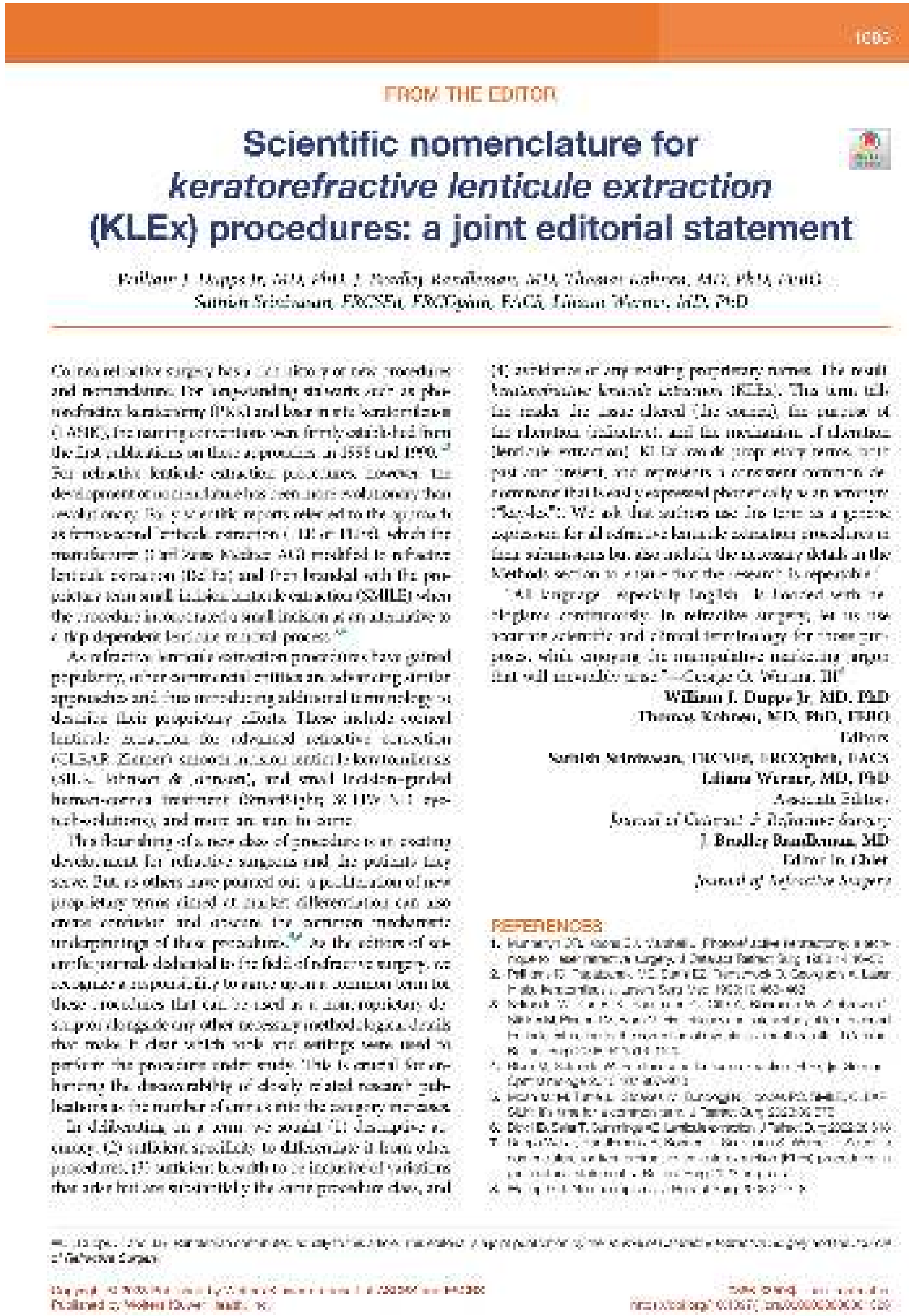
Department of Ophthalmology
Goethe University Frankfurt, Germany
Chair: Univ.-Prof. Dr. med. Thomas Kohnen, FEBO

Corneal refractive procedures

- PRK
- LASEK
- Epi-LASIK
- LASIK
- SMILE



https://insighteye.com.au/wp-content/uploads/2017/09/PRK-LASIK-SMILE-3generations-px-education.png


FROM THE EDITOR
Scientific nomenclature for keratorefractive lenticule extraction (KLEx) procedures: a joint editorial statement
William J. Dupps Jr, MD, PhD, J. Bradley Randleman, MD, Thomas Kohnen, MD, PhD, FEBO, Sathish Srinivasan, FRCSEd, FRCOphth, FACS, Liliana Werner, MD, PhD
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Journal of Cataract & Refractive Surgery
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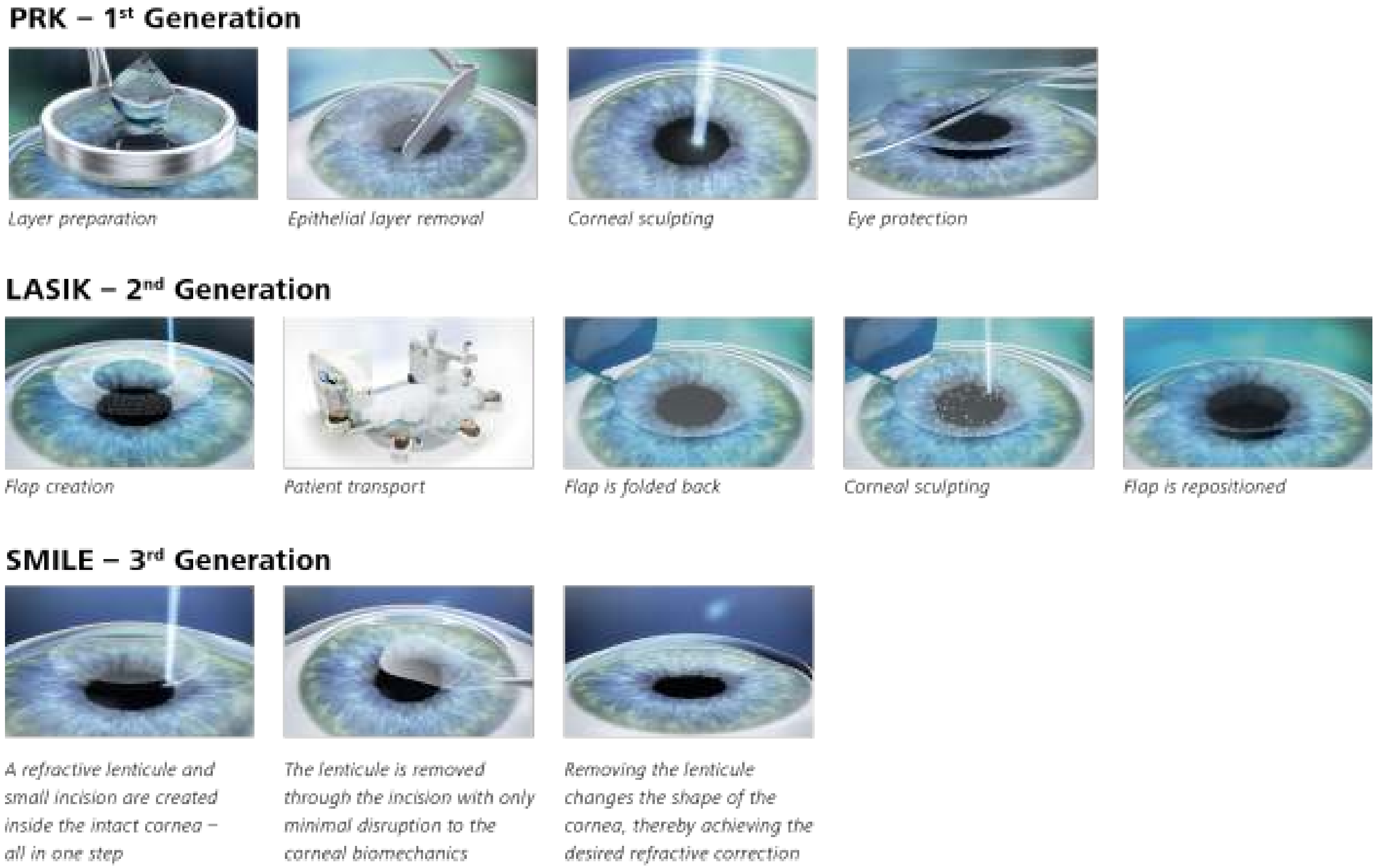
Editor in Chief
Journal of Refractive Surgery
REFERENCES

Corneal refractive procedures

- PRK
- LASEK
- Epi-LASIK
- LASIK
- KLEx



https://insighteye.com.au/wp-content/uploads/2017/09/PRK-LASIK-SMILE-3generations-px-education.png

- **1896** – Leendert Jan Lans publishes the first experimental study on refractive surgery
- **1930** – Tsutomu Sato performs PRK for the first time
- **1963** – José Ignacio Barraquer develops keratomileusis
- **1985** – First PTK is performed by Theo Seiler
- **1986** – Development of the BKS technique
- **1987** – Marguerite McDonald performs the first successful **PRK** treatment
- **1988** – ALK is introduced by Luis Ruiz
- **1990** – Ioannis Pallikaris performs the first **LASIK** procedure and coins the term
- **1999** – LASEK as further development of PRK
- **2000** – First Femto-LASIK treatment is performed by Imola Ratkay-Traub
- **2006** – Walter Sekundo performs the first **SMILE** procedure
- **2011** – SMILE is launched internationally*
- **2015** – 200,000* patient is treated with SMILE

The development

- 2011 → Smile CE (Carl Zeiss)
- 2016 → Smile FDA (Carl Zeiss)
- 2020 → Clear CE (Zimmer)
- 2020 → SmartSight (Schwind)
- 2022 → Smile Pro/Visumax 800 (Carl Zeiss)
- 2023 → SILK (J&J)




German KRC recommendations for laser treatments

		Laser in situ Keratomileusis (LASIK) and Femto-LASIK	Surface treatments (e.g. photorefractive keratectomy (PRK), trans-PRK and LASEK)	Keratorefractive lenticule extraction (KLEx)
Application	**Myopia**	Up to -8 D	Up to -6 D	from -1 D to -8 D
	Hyperopia	Up to + 3 D		
	Astigmatism	Up to 5 D	Up to 5 D	Up to 5 D
Limit range	**Myopia**	Up to -10 D	Up to -8 D	-8 to -10 D
	Hyperopia	Up to +4 D	Up to +3 D	
	Presbyopia	Also possible as monovision		
	Astigmatism	Up to 6 D	Up to 6 D	Up to 6 D

KRC recommendations as of June 2022

ESCRS guidelines for refractive surgery (in progress)

ESCRS

5.3 Keratorefractive Lenticule Extraction (KLEx)

5.3.1 Indications and contra-indications

What are the indications and contraindications for Keratorefractive Lenticule Extraction? (Question [include number from big document])

Limits of application KLEx:

- Myopia ≤-10.0D (GRADE +)
- Myopia >-8.00D only in case of a regular cornea, without any risk factors, and a sufficient corneal thickness (>500 microns) according to cap and lenticule thickness and residual estimated thickness (Level of evidence)
- Astigmatism ≤5.0D, however laser platforms that do not provide cyclotorsion compensation, are able to correct only ≤2.0D. (GRADE +)
- Hyperopia-correcting procedures are off-label. The CE-mark for hyperopic KLEx has recently been approved, resulting in only limited evidence on long-term safety and efficacy outcomes. (GRADE +)

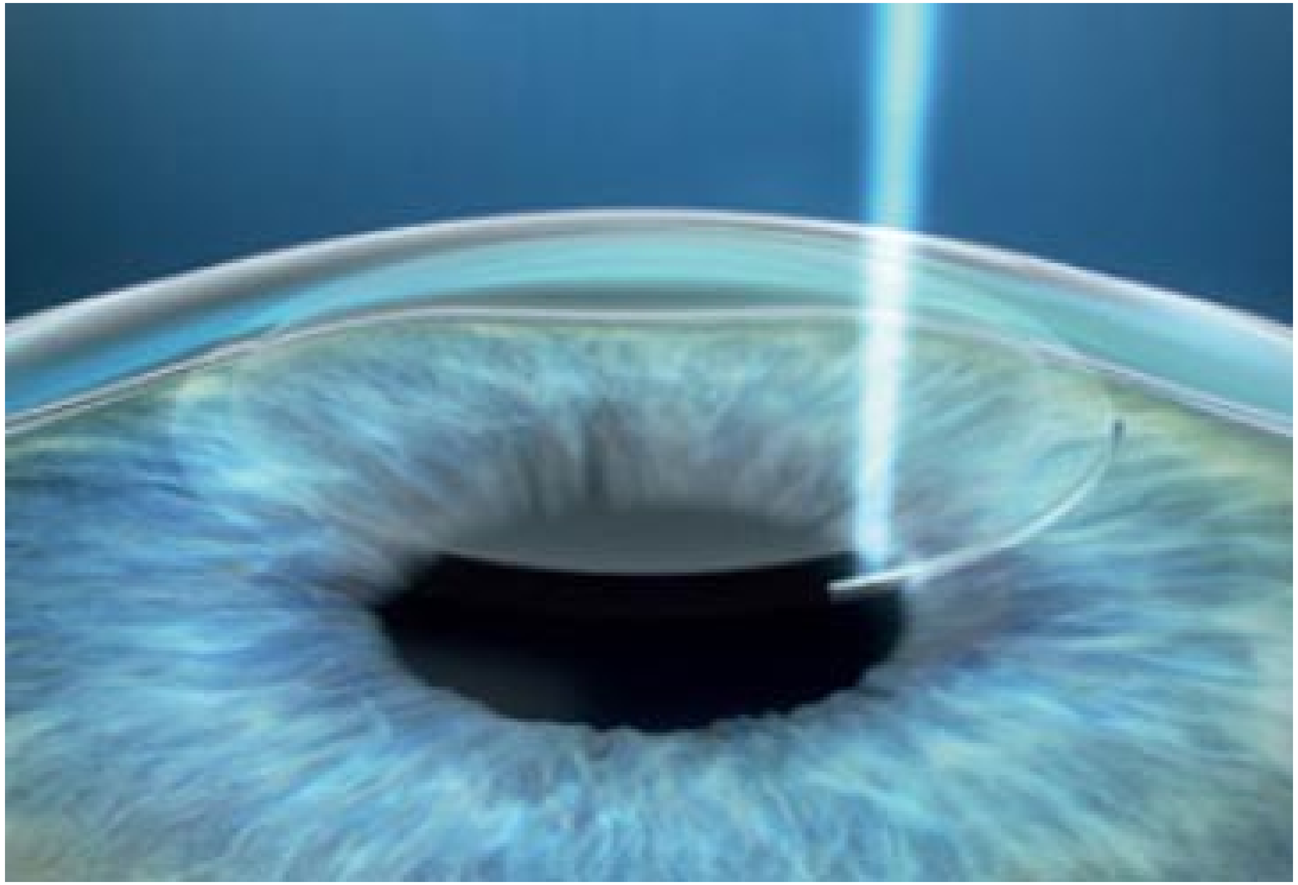
These limits of application must take into account a minimal preoperative cornea thickness of 480 microns, and a minimal residual stromal bed thickness of 250nm. (Level of evidence)

Who is it for?

- Ideal for:
  - Patients with thin corneas
  - Athletes avoiding laser surgery
  - Patients with dry eyes

- Why:
  - Minimal impact on corneal biomechanics
  - Tiny incision spares most superficial layers
  - Few nerves affected → less dry eye post-op

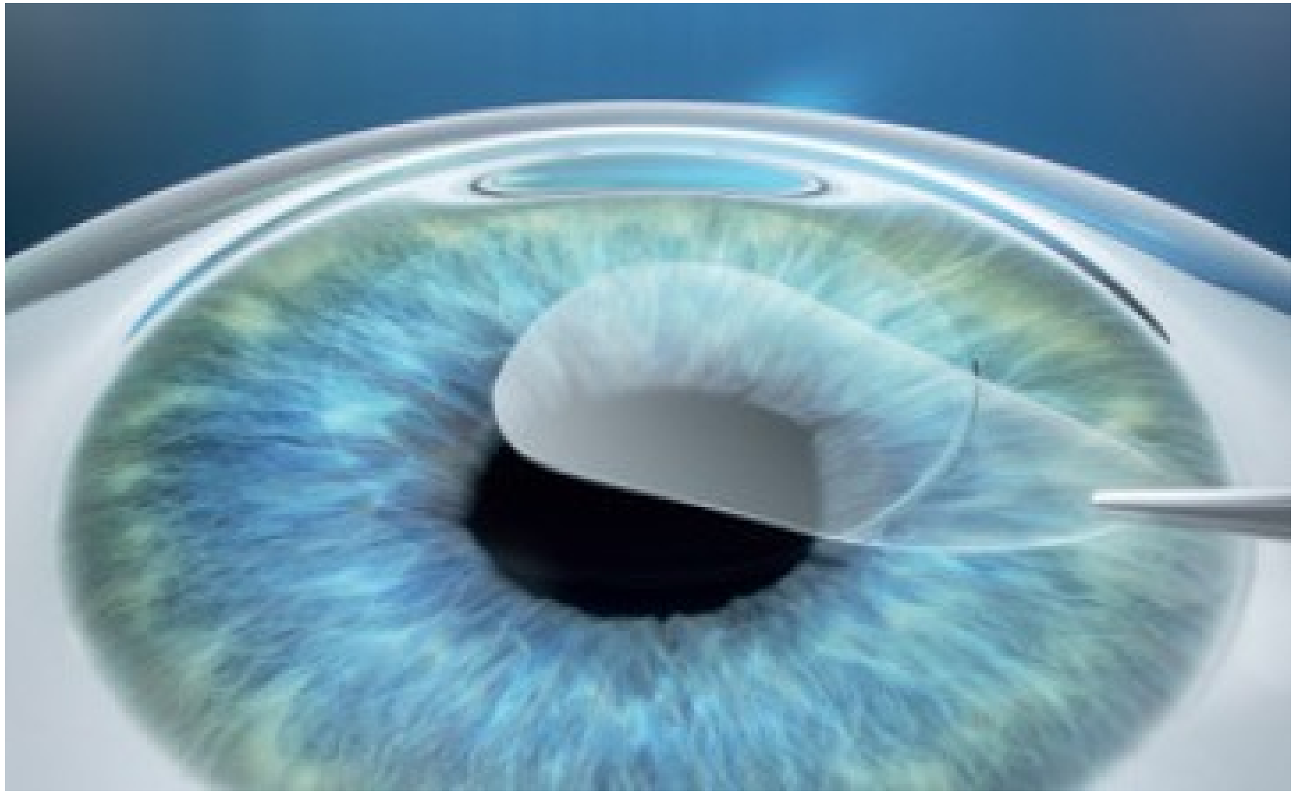
KLEx surgical workflow



http://bva.dog/krc/index.php?seite=lle

a. The laser creates a refractive corneal lenticule and a corneal incision less than 4 mm wide in a single step.

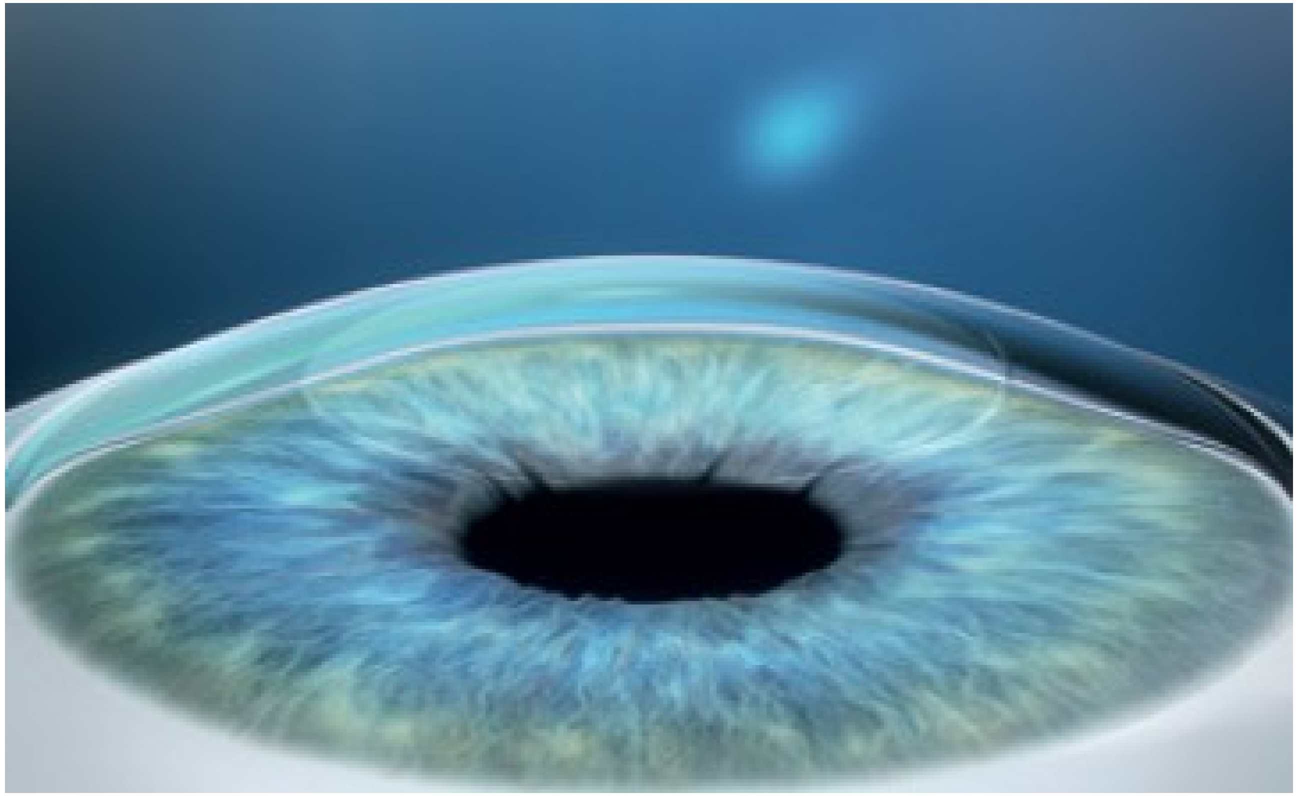
KLEx surgical workflow



b. The lenticule is removed through the small incision. Since no corneal flap is created, the impact on corneal biomechanical stability is minimal.

http://bva.dog/krc/index.php?seite=lle

KLEx surgical workflow



http://bva.dog/krc/index.php?seite=lle

c. Lenticule extraction replaces the point-by-point tissue ablation of the excimer laser.

Removing the lenticule reshapes the cornea to correct existing myopia.

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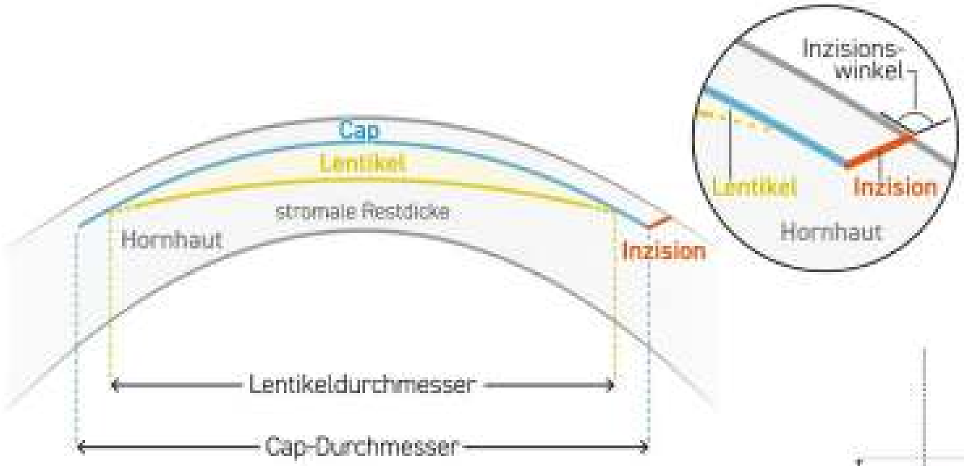
Comparison of Klex and Femto-LASIK

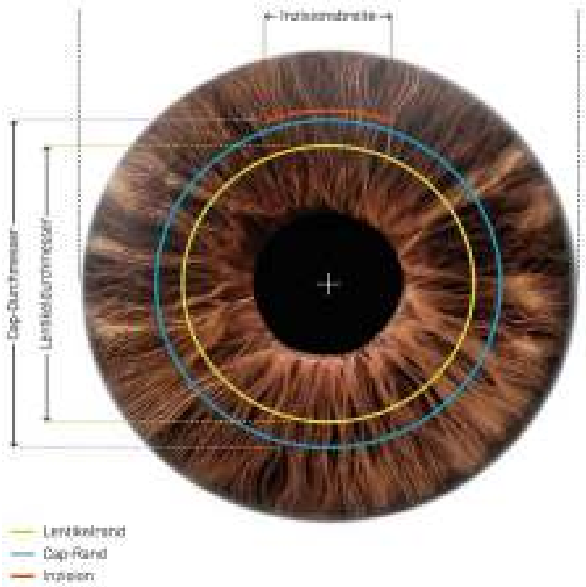
- No corneal flap is created with KLEx
- The inner cornea is not exposed
- A tiny tunnel incision is sufficient to remove the corneal tissue
- A 3–4 mm incision replaces the approx. 20 mm circular flap cut

http://bva.dog/krc/index.php?seite=lle

The principle of a keratorefractive lenticule extraction



https://www.eye-tech-solutions.com/
schwind-smartsight



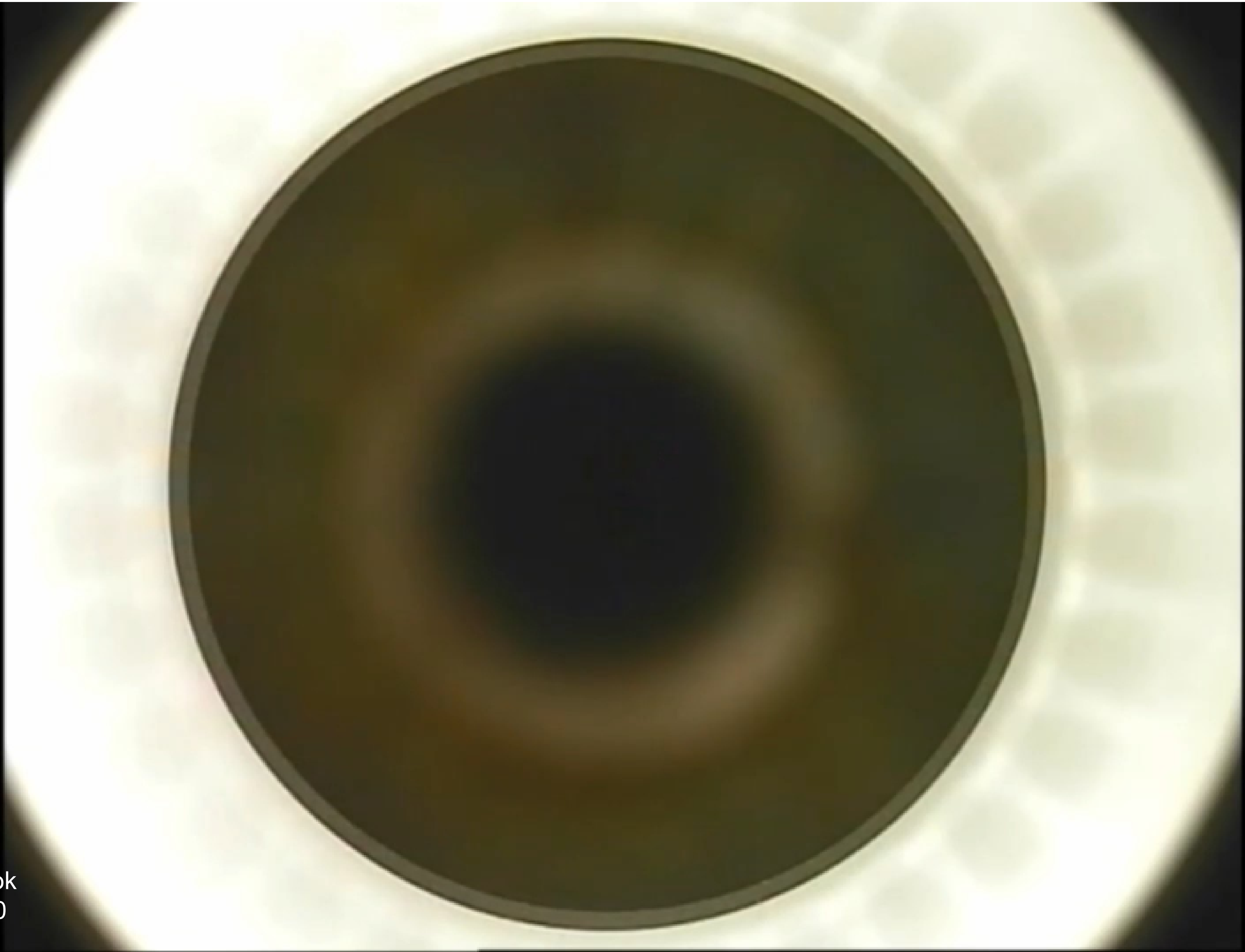
With SmartSight, the SCHWIND ATOS femtosecond laser creates a pre-calculated lenticule within the intrastromal tissue and prepares small peripheral incisions in the uppermost corneal layer for lenticule access.

After the laser process, the lenticule is removed through these small entry points.

SmartSight uses no corneal flap and involves no tissue ablation as with the excimer laser.

Lenticule Extraction with Femtosecond Laser: The Advantages

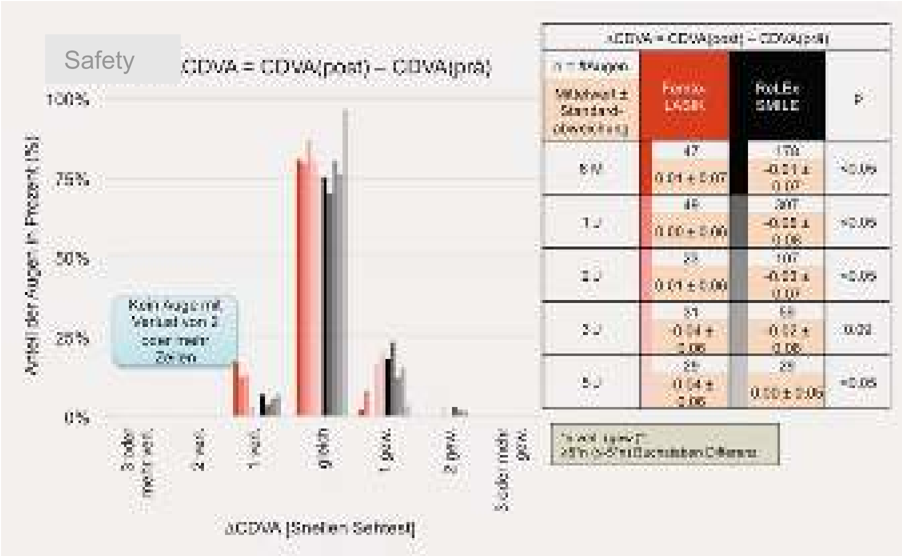
- Less dryness
- Fewer optical side effects: halos, spherical aberrations
- No flap (no flap-related trauma or epithelial ingrowth)

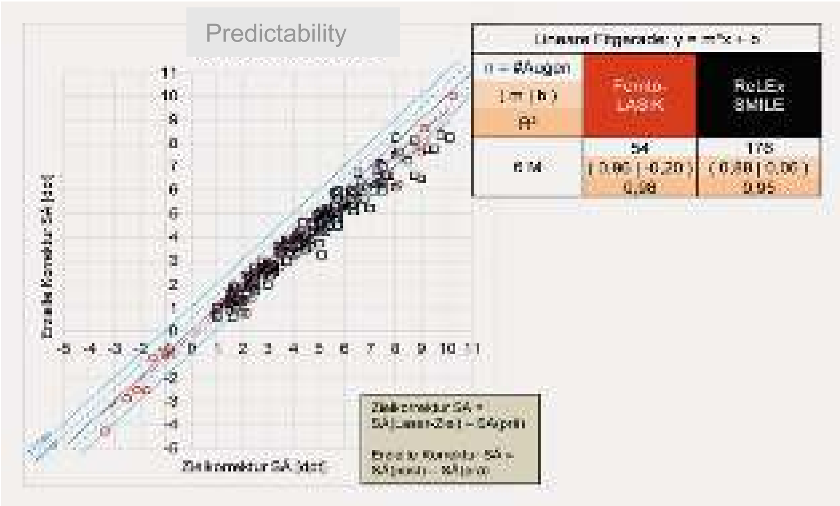


Video & surgery
Prof. Dr. Daniel Kook
Zeiss Visusmax 500

ReLEX SMILE vs. Femto-LASIK

- Comparison of long-term results with ReLEX SMILE vs. femto-LASIK
- Retrospective analysis, 5 years postoperatively
    - 404 eyes after FsLASIK
    - 1192 eyes after ReLEx SMILE
- Outcome was equally good
- Good predictability





Breyer DRH, Beckers L, Hagen P, Kaymak H, Klabe K, Auffarth GU, Kretz FTA. Klin Mon Augenheilkd 2019

Corneal lenticular extraction

ZEISS VisuMax

https://www.zeiss.de/meditec/produkte/ophthalmologie/augenlaserkorrektur/laserbehandlung/femtosekundenlaser-loesungen/visumax.html

ZIEMER FEMTO LDV

https://www.ziemergroup.com/en/products/femto-ldv/

SCHWIND ATOS

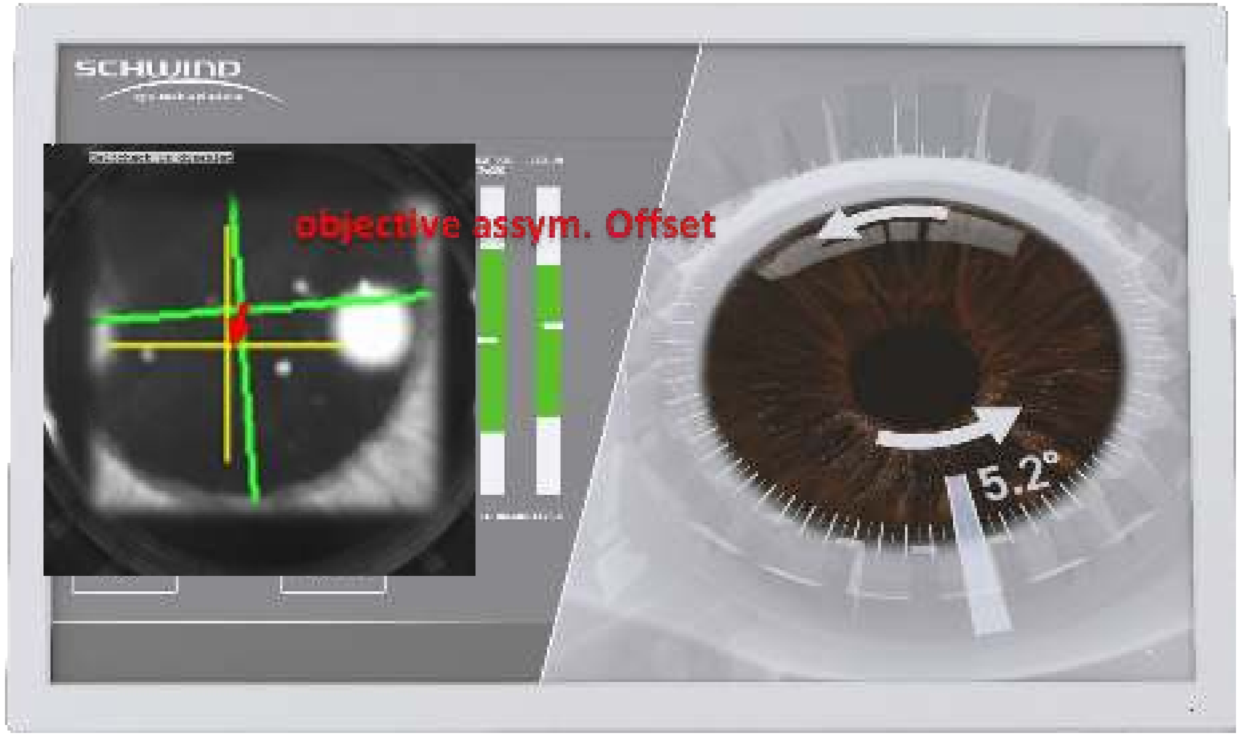
https://www.eye-tech-solutions.com/schwind-atos


SCHWIND
eye-tech-solutions
Intelligent femtosecond laser technology for lenticule extraction (SmartSight) and flap creation (Femto-LASIK)
Maximum safety with intelligent eye tracking and cyclotorsion compensation
High-precision treatment with perfect centering, even in higher astigmatism
Tissue saving through optimized lenticular geometry
Large flap diameters made possible by innovative contact glass design
Comfortable for the eye through curved patient interface
Compact and flexible in use
User-friendly with clear, intuitive planning and efficient workflow
SCHWIND ATOS®
SCHWIND ATOS 01/2020 – V1.0

Key data of the laser

- Femtosecond laser with a wavelength of 1030±50nm
- Repetition rate of up to 4MHz
  with average energy treatment energy of <100nJ

- Features
  - eye tracking
  - cyclotorsion correction
  - pupil detection
  - astigmatism correction



June 2022

Corneal Lenticule Creation Using a New Solid-State Femtosecond Laser Measured by Spectral Domain OCT in a Porcine Eye Model

Christoph Lwowski; Anna Voigt; Karel Van Keer; Thomas Kohnen

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Image from Rossi et al.

tvst

Article

Corneal Lenticule Creation Using a New Solid-State Femtosecond Laser Measured by Spectral Domain OCT in a Porcine Eye Model

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Keywords: lenticule extraction; femtosecond laser; SmartSight; corneal refractive surgery

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Purpose: To determine the accuracy and precision of corneal lenticule creation with a new solid-state femtosecond laser in a porcine eye model.

Methods: Corneal lenticule creation was performed using a new solid state femtosecond laser on 60 porcine eyes with 10 subgroups. Optical coherence tomography images were acquired immediately after laser treatment. Cap thickness (CT), cap diameter (CD), and lenticule thickness (LT) were measured manually by three independent readers. Additionally, CT and LT were measured by an automated algorithm (aLT, aCT).

Results: Measured LT was significantly greater than the intended LT (average difference 14.3 ± 5.6 µm, $P < 0.001$). aLT was closer but still significantly different from the intended LT (−2.9 ± 5.8 µm, $P < 0.001$). Measured CT showed no significant difference from the intended CT (2.6 ± 13.3, $P = 0.145$). aCT was significantly smaller compared to the intended CT (−9.6 ± 13.6, $P < 0.001$). Measured CD was significantly smaller compared to the intended CD (−0.21 ± 0.20 mm, $P < 0.001$). All lenticules were cut as planned with no laser-related complications.

Conclusions: This new solid-state femtosecond laser used in our trial provides corneal lenticule creation in a porcine eye model comparable to other established systems. However, measuring those lenticules in the provided setting seems too challenging even when using automated algorithms, which seems to be due to the experimental setting of the trial.

Translational Relevance: This trial shows the precision and repeatability of corneal cuts performed by a new femtosecond laser that could translate to refractive corneal lenticule surgery.

Introduction

With an increasing demand of being spectacle independent due to modern aesthetics and active lifestyle, and myopia becoming more common in the Western world,[1] refractive surgery is becoming one of the most popular fields in recent ophthalmology. Since most of the patients who present themselves in our practice have a rather low to medium refractive error, laser treatment of the cornea is still the most common procedure worldwide.[2,3] In particular, laser in situ keratomileusis, with its fast visual rehabilitation combined with high postoperative comfort and a low rate of complications, is currently the most used technique.[2–6] Nevertheless, in the past 25 years, a new procedure called lenticule extraction, has been introduced in which a lenticule is cut with a femtosecond laser and either taken out through a flap (femtosecond lenticule extraction [FLEX])[7] or a cut (small incision lenticule extraction [SMILE][8] [Carl Zeiss Meditec, Jena, Germany] or corneal lenticule extraction for advanced refractive correction [CLEAR][9] [Ziemer, Biel, Switzerland]). Those procedures have become more popular because, especially in SMILE procedures, no flap-associated complications and prolonged dry eye symptoms occur.[10,11] Simultaneously, the short- and

long-term results seem to be comparable with the well-established femtosecond laser assisted laser in situ keratomileusis (fs-LASIK) treatment.[10,12] Another factor in favor of lenticule extraction is that the surgeon does not need an excimer since all cuts are made by the femtosecond (fs) laser.

Now with SMILE being commercially used worldwide, other laser manufactures such as Ziemer (CLEAR) and SCHWIND eye-tech-solutions (SmartSight) have started to introduce fs lasers and femtosecond profiles to offer surgeons a broad range of different machines and treatment patterns.

The SCHWIND ATOS laser system and the SmartSight treatment (both SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany) have had the Conformité Européenne (CE) mark since July 2020. First clinical results seem to indicate that the laser and the treatment are able to reach similar results compared to the established systems.[13]

Features of this solid-state femtosecond laser would be cyclotorsion correction before, during, and after docking; a low-dose treatment, with typically less than 100 nJ per pulse; no minimum lenticule thickness, a progressive, refractive transition zone and therefore less undercorrection; less regression; and a better centration of the optical zone. The laser source is a sophisticated solid-state laser, and it works with a 1030 ± 50-nm wavelength to produce femtosecond pulses with a pulse duration of 225 ± 70 fs.

To reach good clinical results, the corneal cuts need to be accurate, precise, and reproducible for different optical zones, refractive errors, and cap/lenticule thicknesses and diameters. Prior studies have shown that not only in LASIK but also in SMILE eyes, there can be a deviation of thickness and diameter of flap or lenticule respectively, depending on laser type and intended depth.[14–16] Therefore, this study was conducted to examine the accuracy and precision of the cap and lenticule thickness and diameter for the currently introduced SmartSight protocol using a new all solid-state femtosecond laser.

Methods

Femtosecond Laser

The ATOS Laser System (version 1.5.0.1; SCHWIND eye-tech-solutions) is a recently introduced solid-state femtosecond laser working at 1030 ± 50 nm. It offers eye tracking, cyclotorsion correction, and pupil recognition, which lead to efficient astigmatic corrections. The repetition rate is up to 4 MHz with typical treatment energy of less than 100 nJ

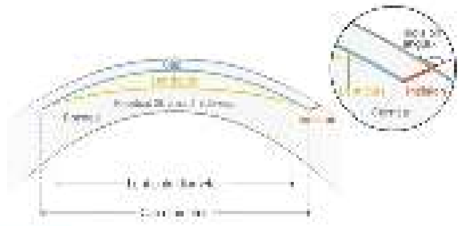


Figure 1. Schematic image of the SmartSight protocol.

Figure 2. Porcine eye underneath the laser interface prior to docking.

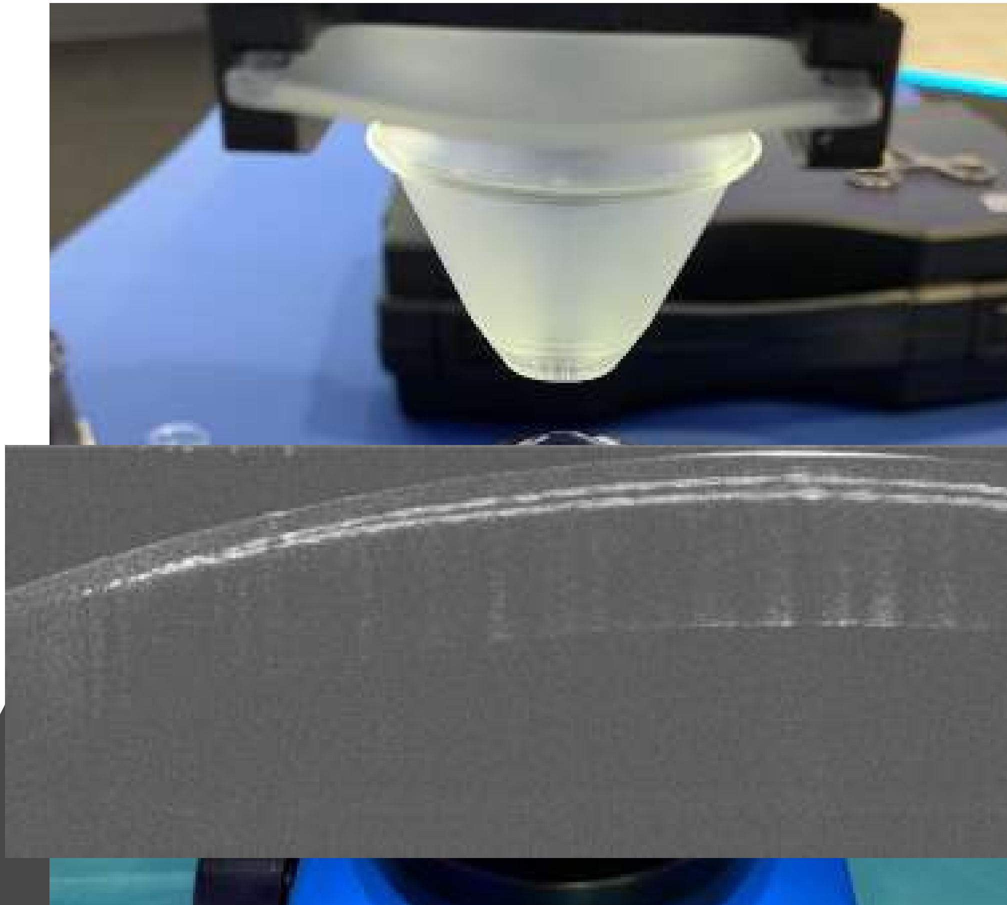
(maximum laser output <500 mW) and pulse duration 225 ± 70 fs.

SmartSight Protocol

The SmartSight protocol for the femtosecond laser is a lenticule-based protocol for corneal myopic correction. It first produces the refractive cut with a possible diameter of the optical zone from 5.5 to 7.5 mm extended by the required progressive, refractive transition zone, granting a standardized transition zone that automatically adjusts to the intended correction. Afterward, it produces the anterior cut with a diameter of 6.5 to 9.0 mm at a cap thickness selectable from 100 to 160 µm. The last step is the edge cut or incision with an angulation from 45° to 135° and an arc length from 2.0 to 5.0 mm (Figs. 1, 2).

Study protocol

- 60 fresh pig eyes (max 8 h post enucleation)
  - 10 groups (6 eyes per group)
- Before the operation
  - Manual removal of the epithelium
  - Placement in special stabilizing holder
  - Setting an adequate intraocular pressure
- Set parameters
  - Spot and track distance: 3 µm for lamellar cuts
  - Edge distance: 1.5 µm
  - Edge cut angle: 120°
  - 100 nJ per pulse
- Measurement with OCT (TELESTO SP5 Spectral Domain OCT) after treatment
- Measurement of the parameters by 3 independent doctors & automatic measurements



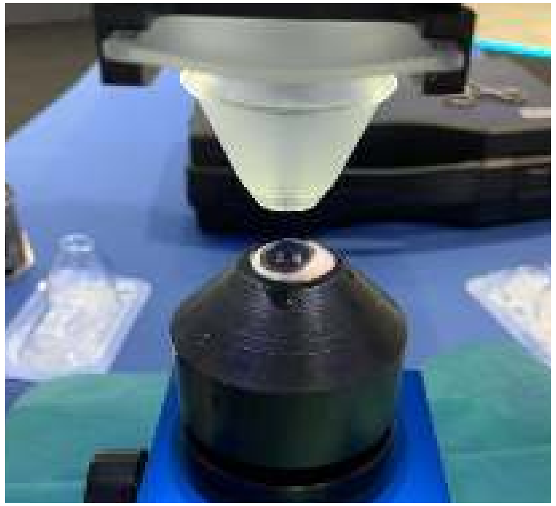
Conclusion

solid-state femtosecond laser (SmartSight protocol)

- Accurate and predictable Cap thickness (CT)
- Slight deviations in the cap diameter (CD) and the lenticule thickness (LT)

- Comparable with already established systems and protocols

- Provided settings seems to be challenging (even with semi-automated algorithms)
  → could be due to experimental setting of trial



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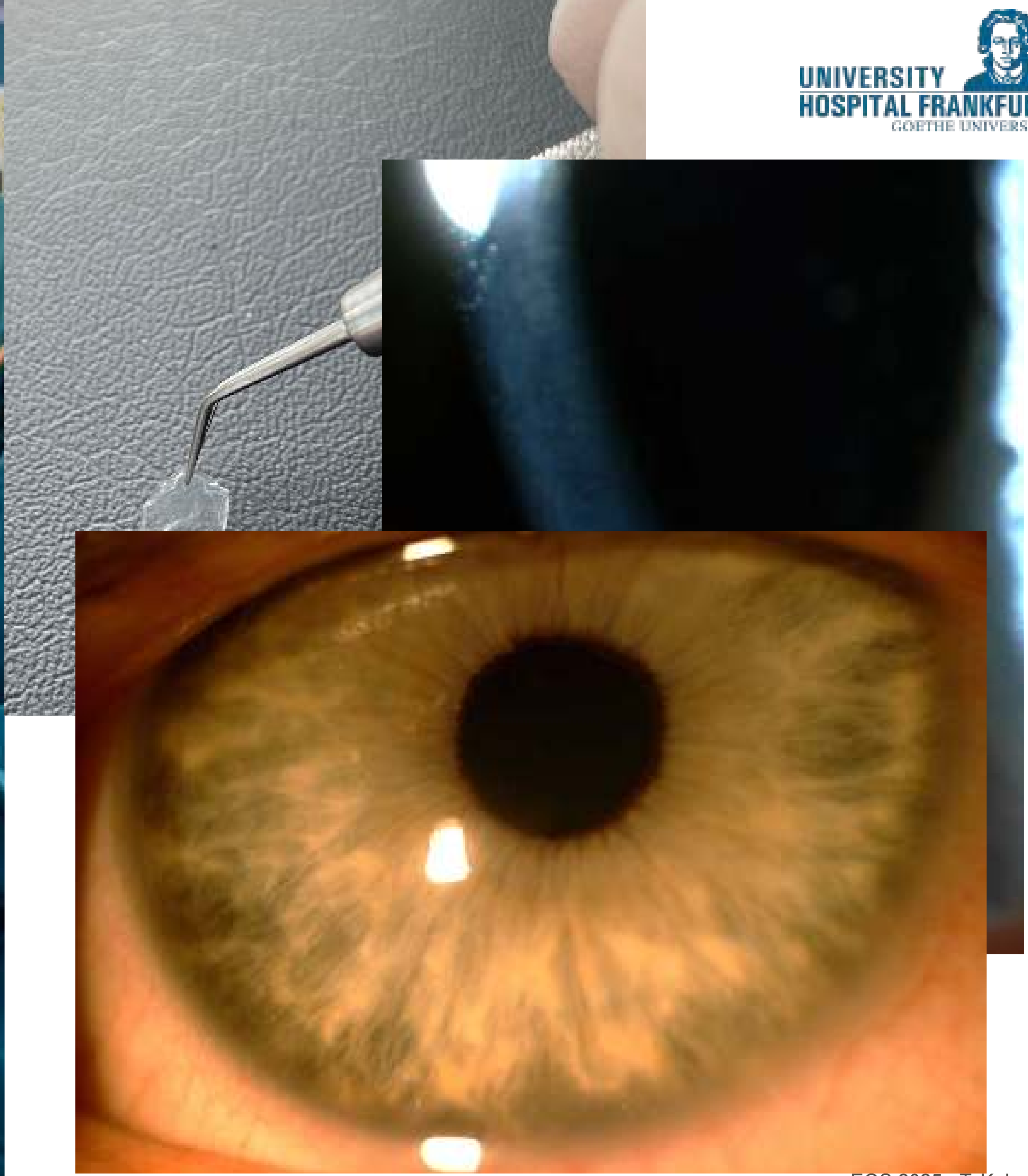
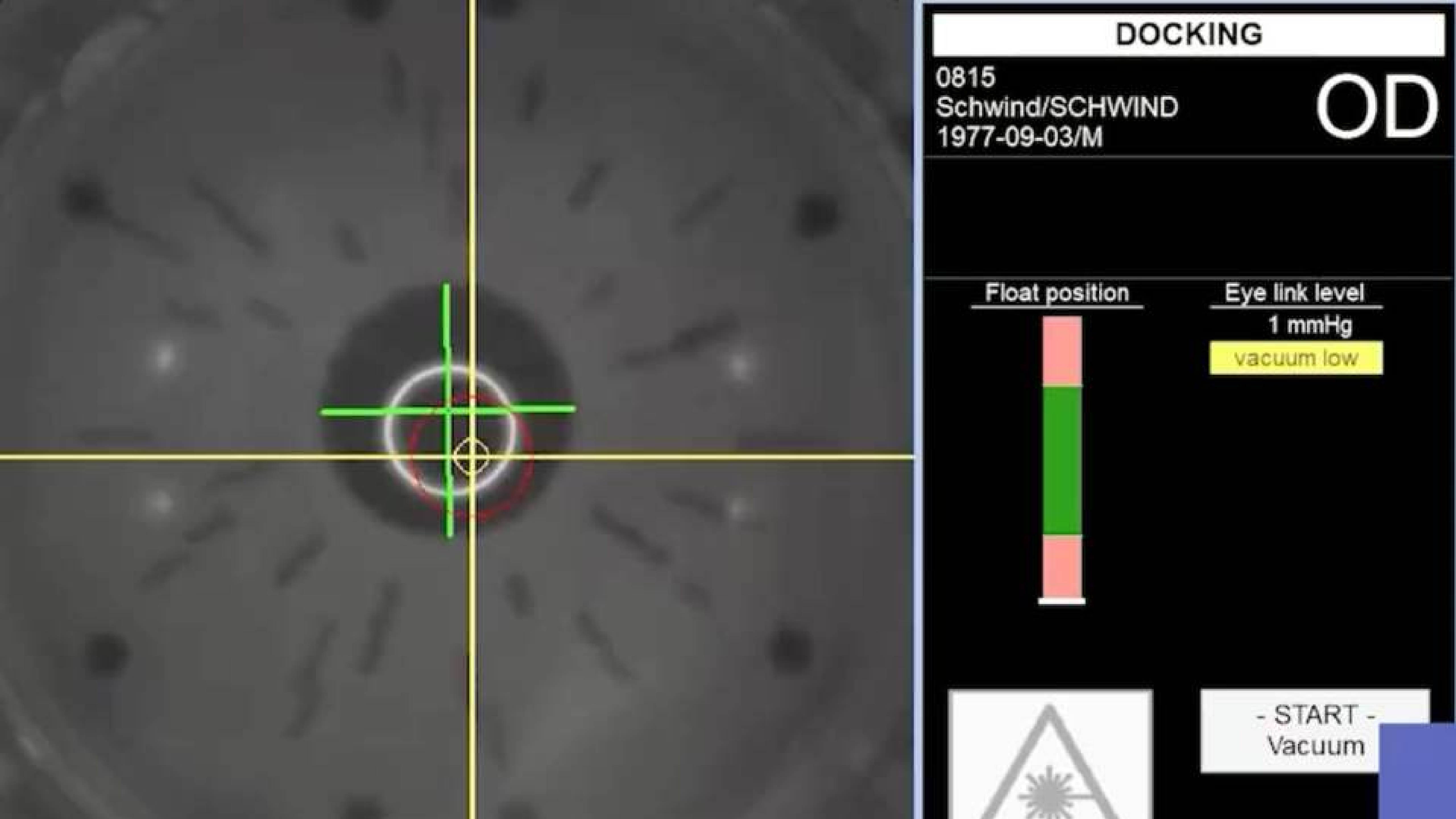


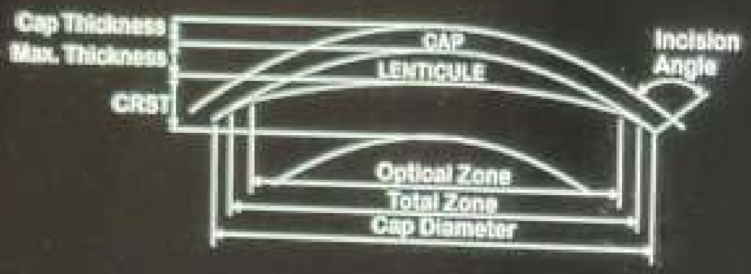

DOCKING
0815
Schwind/SCHWIND
1977-09-03/M
OD
Float position
Eye link level
1 mmHg
vacuum low
- START -
Vacuum

PLAN | REVIEW | EYE SELECT | DOCKING | LINKED | TREATMENT | RELEASE

Machine Sta
Operation

No Patient ID | No Last Name | No First Name | No Date Of Birth | No Gender | Edit

OD < **Lenticule** > **OS** < **None**



Lenticule Parameters

Optical Zone	6,3	mm
Total Zone	0,0	mm
Max. Thickness	0	µm
Cap Thickness	120	µm

Edit

Incision Parameters

Incision Width	3,0	mm
Inc. Orientation	90	deg
Incision Angle	120	deg
Cap Diameter	7,5	mm

Edit

Refraction

VD 12,0 mm

	Sphere		Cylinder		Axis	
Manifest	0,00	D	0,00	D	0	deg
Target	0,00	D	0,00	D	0	deg
Laser	0,00	D	0,00	D	0	deg

Edit

Pupil Data

Diameter	0,0	mm		
Offset	0,00	mm	0	deg

Edit

Cornea Pre-OP

Pachymetry	0	µm		
K1	0,00	D	0	deg

Cornea Post-OP

Pachy / CRST


PLAN
REVIEW
EYE SELECT
DOCKING
LINKED
TREATMENT
RELEASE
Machine Status
Operational
Battery Status
OK
SCHWIND
0815
Schwind
1982-11-20
M
Lenticule Parameters
Optical Zone 6,3 mm
Total Zone 7,1 mm
Max. Thickness 122 µm
Cap Thickness 120 µm
Lenticule
OD
Refraction
VD 12,0 mm
Manifest S C A -0,25 D -1,75 D 178 deg
Target S C A 0,00 D 0,00 D 178 deg
Laser S C A -0,25 D -1,75 D 178 deg
Eye link level
2 mmHg
Eyetracker Status: Enabled
Change Eyetracking
Float position
Laser Energy
P(single) - nJ
P(single) -
Incision Parameters
Incision Width 3,0 mm
Inc. Orientation 90 deg
Incision Angle 90 deg
Cap Diameter 7,5 mm
Laser Parameters
Spot/Track Dist. 3,0 µm 6,0 µm
Edgecut distance 1,5 µm
En. Level B/E 100 nJ 100 nJ
Vacuum Level 290 mmHg
0%
Back

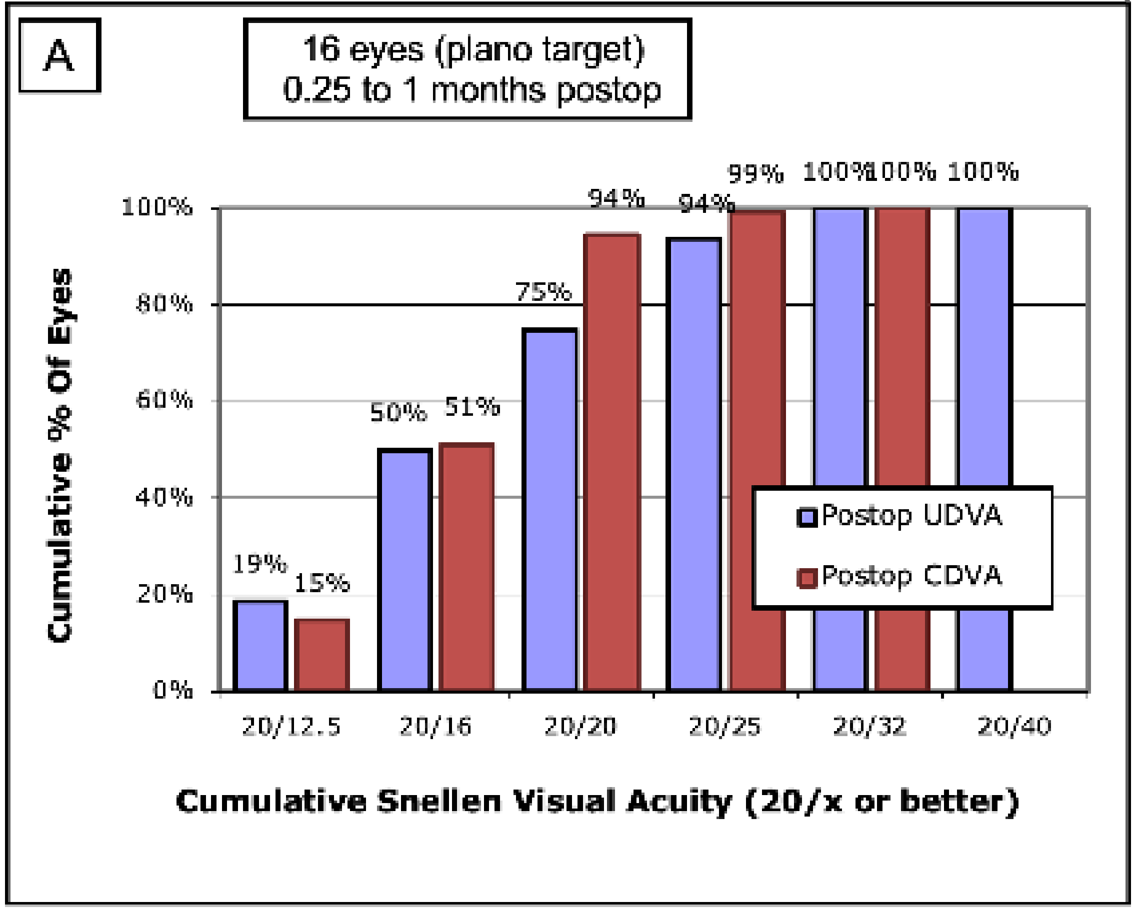

DOCKING
0815
Schwind/SCHWIND
1977-09-03/M
OD
Float position
Eye link level
1 mmHg
vacuum low
- START -
Vacuum

Video and surgery
Dr. Victor Derhartunian
Schwind ATOS

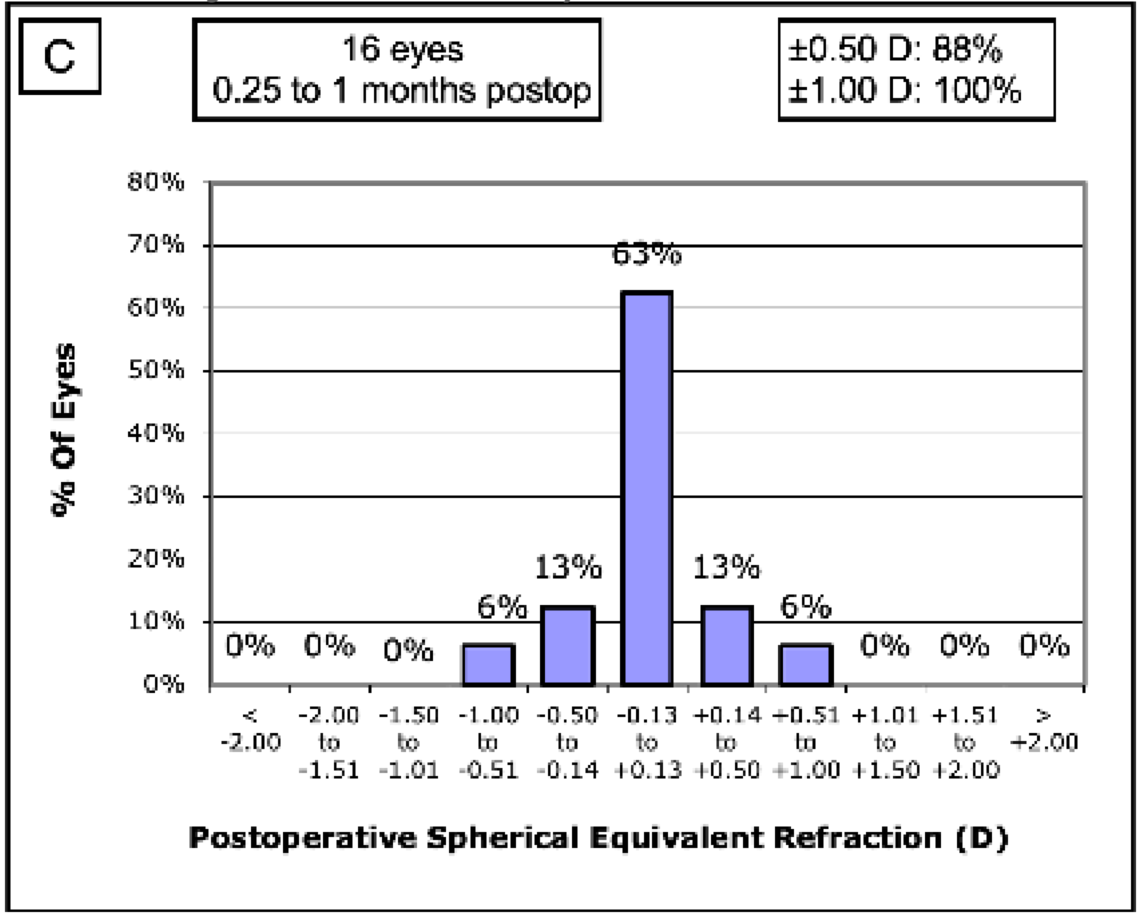
KLEx

Video and surgery
Prof. Dr. Thomas Kohnen
Schwind ATOS

Recent (early) outcomes KLEx for myopia and astigmatism Schwind Atos (University Frankfurt)

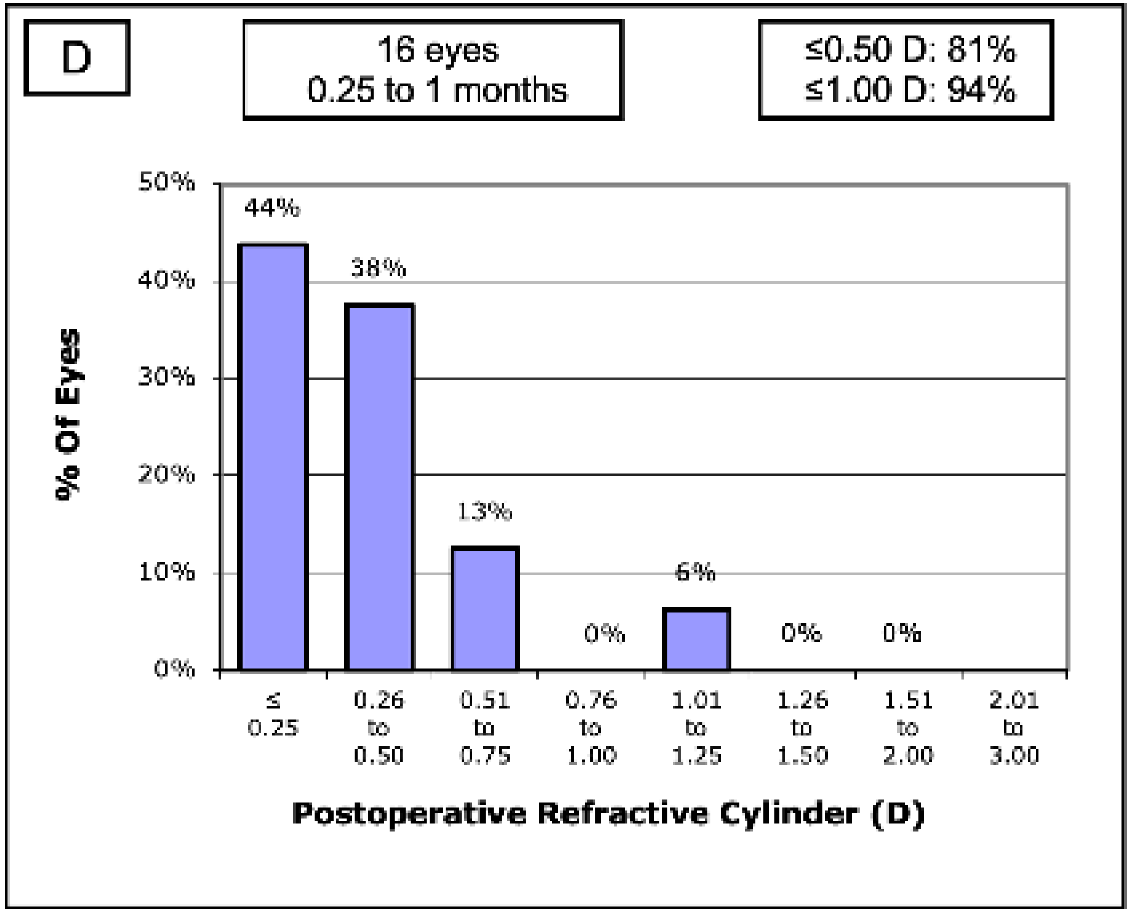


Uncorrected Distance Visual Acuity



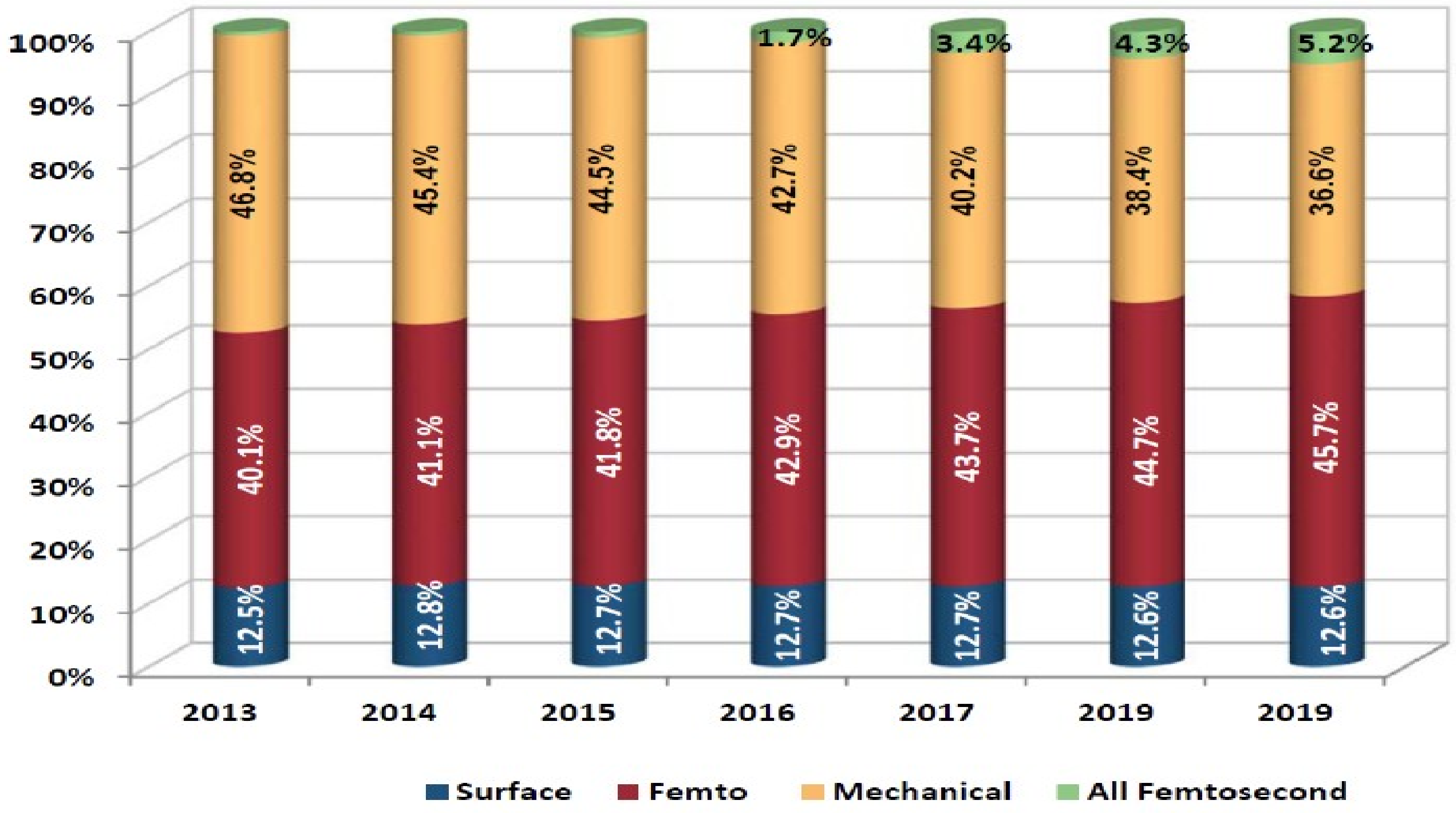
Spherical Equivalent Refractive Accuracy

Recent (early) outcomes KLEx for myopia and astigmatism Schwind Atos (University Frankfurt)



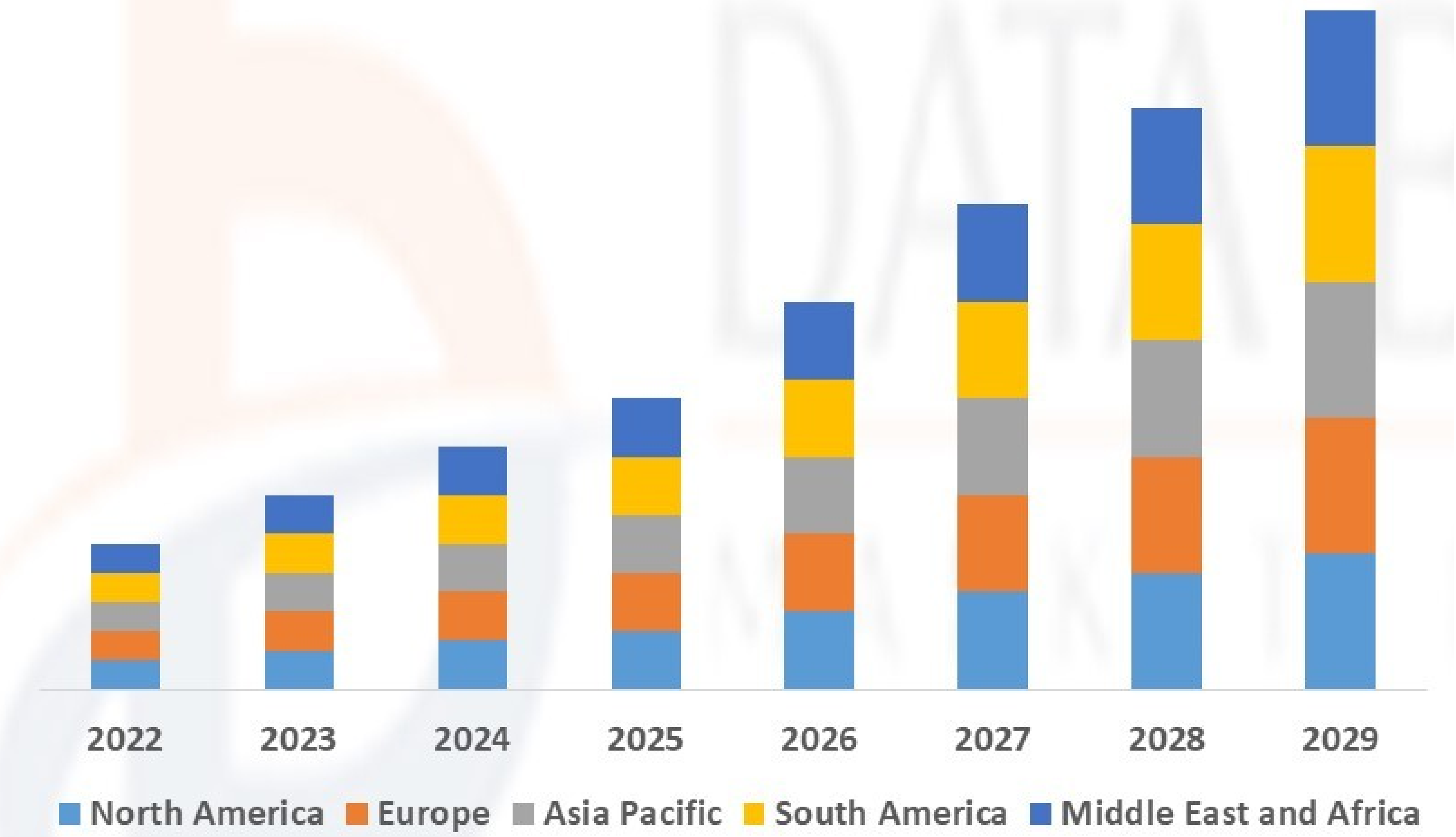
Refractive Cylinder

Figure 48: Surface and Microkeratome Procedure Market Shares



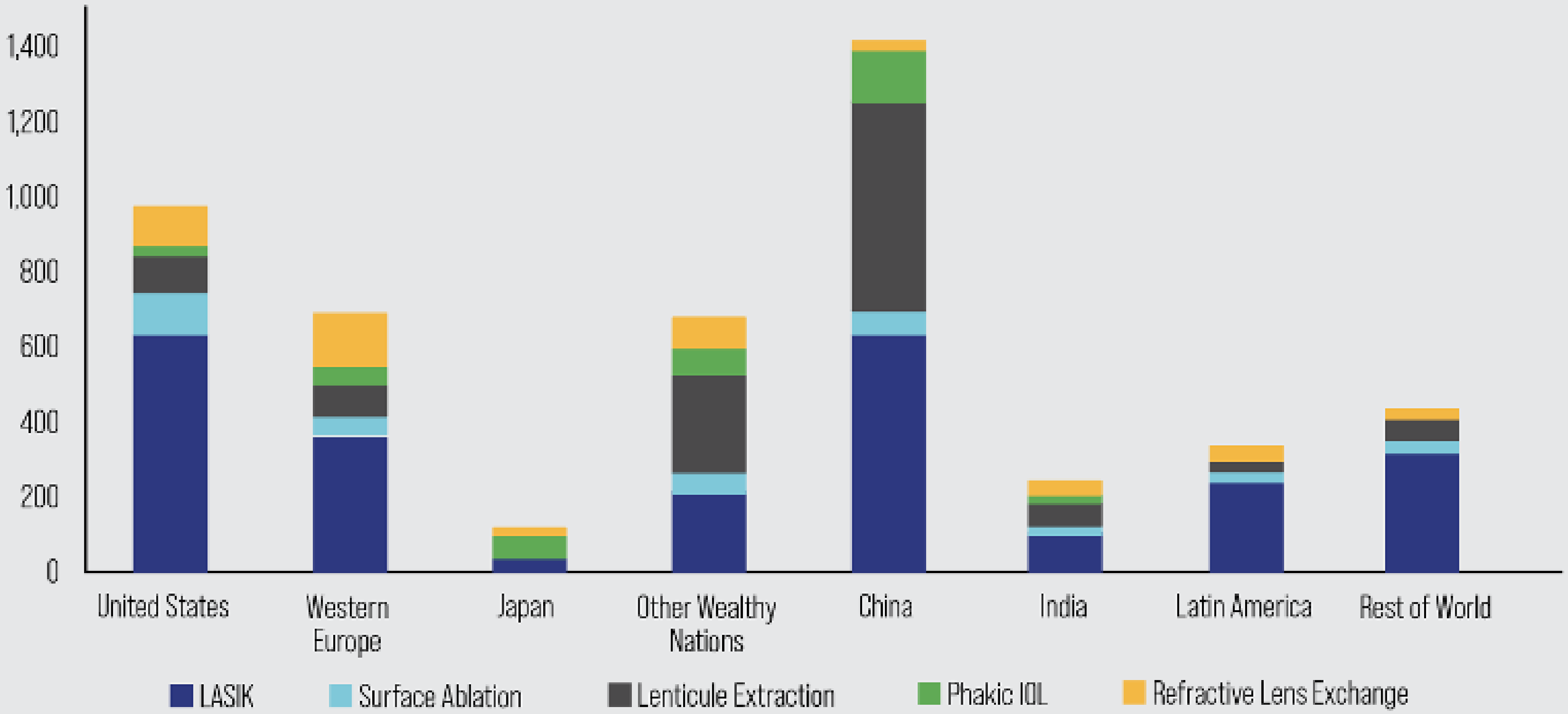
Source: Market Scope estimates

Global LASIK Eye Surgery Market is Expected to Account for USD 4.56 Billion by 2029



Source: Data Bridge Market Research Market Analysis Study 2022

Global Refractive Procedures by Region and Type



Source: Market Scope 2022 Refractive Surgery Market Report

Stand: 2022

What else can be expected in the future with KLEx?

Hyperopia correction?

Sphere up to +6.00 D and astigmatism up to 5.00 D

Presbyopia correction?

Keratoplasty in keratoconus

Glaucoma drainage devices?


43RD CONGRESS OF THE ESCRS
COPENHAGEN
12-16 SEPTEMBER 2025
Bella Center, Copenhagen - Denmark

Thank you for your attention and the invitation to Egypt

Thomas Kohnen



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