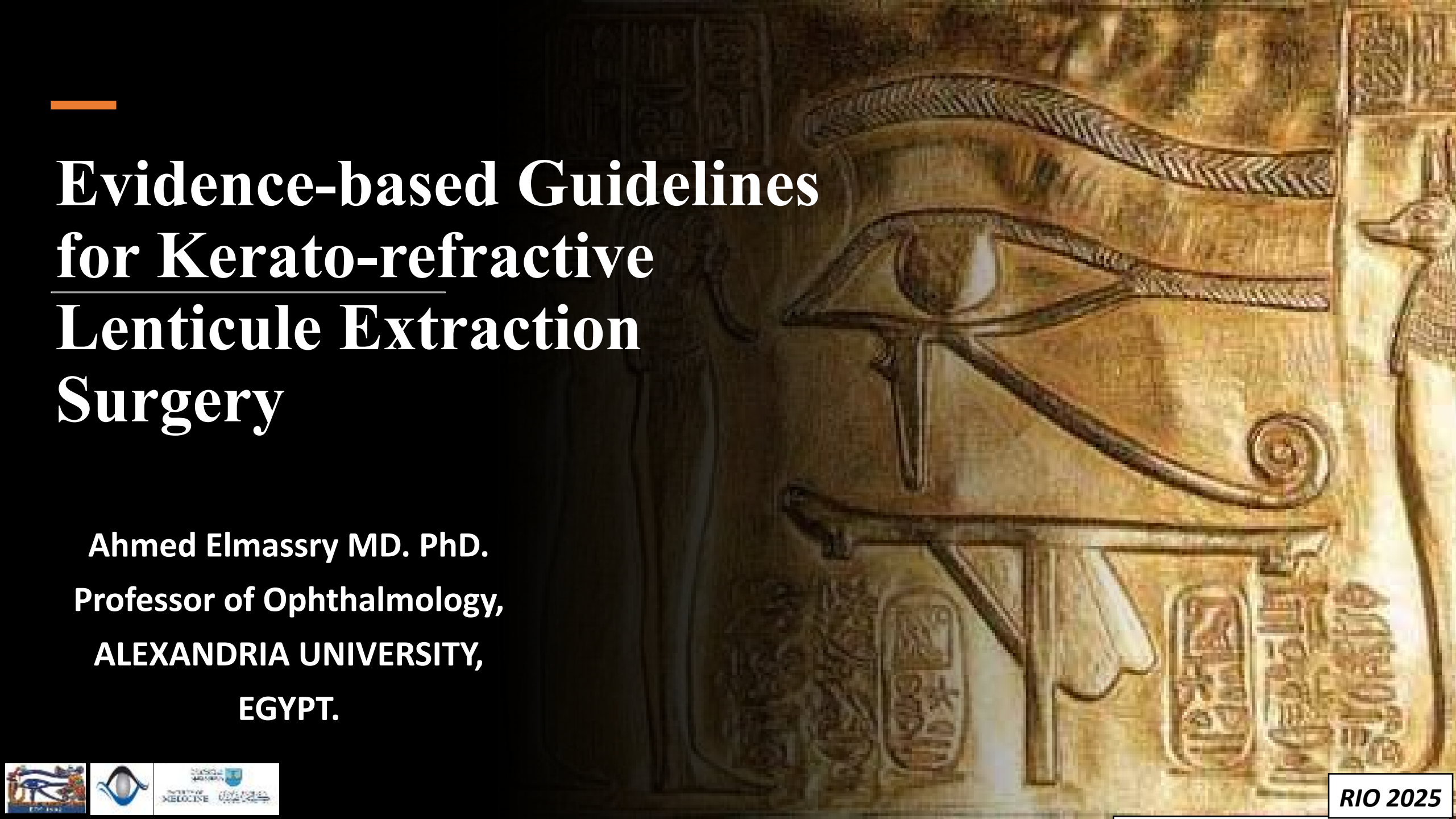




Evidence-based Guidelines for Kerato-refractive Lenticule Extraction Surgery

Ahmed Elmassry MD. PhD.
Professor of Ophthalmology,
ALEXANDRIA UNIVERSITY,
EGYPT.



Acknowledgement

Shaimaa Elbassiouny MD
Consultant Ministry of Health



Aim of the study

Develop an evidence-based guidelines for kerato-refractive lenticule extraction (KLEx).

Methods (Scope of the Guidelines)

These evidence-based guidelines were **developed** following the **WHO guidebook**, utilizing the AGREE II tool and adhering to the RIGHT statement.

The body of evidence was drawn from **eight literature databases, five clinical guideline databases, and two academic organizations.**

Recommendations were developed via a Delphi consensus of **44 global experts in refractive surgery, corneal diseases, retinal diseases, glaucoma, and optometry.**



Evidence-Based Guidelines for Keratorefractive Lenticule Extraction Surgery

Yan Wang, MD, PhD,^{1,2,3} Lixin Xie, MD, PhD,⁴ Ke Yao, MD, PhD,^{5,6} Walter Sekundo, MD, PhD,⁷ Jorge L. Alió, MD, PhD,⁸ Jod S. Mehta, MD, PhD,⁹ Sanjay Goel, MD,¹⁰ Ahmed Elmassry, MD, PhD,¹¹ Julie Schallhorn, MD,¹² Tatiana Shilova, MD,¹³ Huazheng Cao, MD,¹⁴ Lulu Xu, MD,¹⁵ Xuan Chen, PhD,¹⁴ Fengju Zhang, MD, PhD,¹⁵ Ji Bai, MD,¹⁶ Wenfang Zhang, MD, PhD,¹⁷ Qin Liu, MD,¹⁸ Xingtao Zhou, MD, PhD,¹⁹ Yueguo Chen, MD, PhD,²⁰ Zheng Wang, MD, PhD,²¹ Vishal Jhanji, MD,²² Kehu Yang, PhD,^{23,24,25} Writing Committee for the Guideline Working Group

Topic: Development of evidence-based guidelines for keratorefractive lenticule extraction (KLEx).

Clinical Relevance: Keratorefractive lenticule extraction refers to various corneal refractive procedures involving removal of refractive lenticules of intrastromal corneal tissue, typically through a small incision, thereby eliminating creation of a corneal flap. This technique has gained popularity rapidly as a possible alternative to flap-based procedures; however, no clinical practice guidelines exist for KLEx.

Methods: These evidence-based guidelines were developed following the World Health Organization guidebook using the Appraisal of Guidelines for Research and Evaluation II tool and adhering to the Reporting Items for Practice Guideline in Healthcare statement. The body of evidence was drawn from 8 literature databases, 5 clinical guideline databases, and 2 academic organizations. Recommendations were developed via a Delphi consensus of 44 global experts in refractive surgery, corneal diseases, retinal diseases, glaucoma, and optometry. The certainty of evidence, balance of benefits and harms, patient preferences and values, and economic evaluations were considered fully. The Grading of Recommendations Assessment, Development, and Evaluation approach was used to assess evidence quality and recommendation strengths.

Results: From 385 initial clinical questions, 15 were identified, prompting a review of 250 717 studies, with 609 included for conducting and updating 26 and 2 systematic reviews, respectively. Subsequently, consensus was reached on 38 recommendations for preoperative screening, candidate selection, intraoperative quality control, operating principles, postoperative monitoring, and complication management. For KLEx, an effective and accurate refractive correction is attributed to various factors such as corneal thickness, degree of myopia, treatment nomogram, and optical zone. For KLEx-related complications that could affect vision, comprehensive and effective management strategies were proposed, particularly for wrong-plane dissection and difficult lenticule removal, suction loss, and perioperative infection. Customized surgical planning protocols and operative techniques were analyzed. Among all recommendations, 29 (76%) were labelled as strong, each externally reviewed. The assessment of corneal biomechanical properties may help to improve safety and predictability, although they need further validation. The development process also revealed several research gaps for enhancing KLEx safety.

Discussion: These guidelines provide evidence-based recommendations for KLEx in clinical practice, such as for preoperative screening for keratoconus, surgical planning, and management and prevention of complications and infection. The guidelines are expected to improve the safe and effective application of KLEx procedures and achieve more satisfactory visual correction.

Financial Disclosure(s): Proprietary or commercial disclosure may be found in the Footnotes and Disclosures at the end of this article. *Ophthalmology* 2024;■:1–23 © 2024 Published by Elsevier Inc. on behalf of the American Academy of Ophthalmology



Supplemental material available at www.aaojournal.org.

Keratorefractive lenticule extraction (KLEx) is a novel laser corneal refractive procedure that has gained popularity in recent years.^{1,2} The initial technique of femtosecond lenticule extraction (FLEx; also known as refractive corneal lenticule extraction) was developed into the now

commonly used small-incision lenticule extraction (SMILE) surgery. Further developments of the technique included cornea lenticule extraction for advanced refractive correction, smooth incision lenticule keratomileusis, small incision-guided human-cornea treatment (SmartSight), and

Methods (Scope of the Guidelines)

These guidelines are covering **three domains:**

- Preoperative screening and indications.
- Intraoperative quality control , surgical planning and technique .
- Prevention and treatment of KLEx-related complications.

Results



Elmassry



Domain 1 Indications



Domain 1: Indications

preoperative screening of keratoconus, selection of surgical options, and surgical plans

Recommendation 1 :

Keratoconus is contraindicated for corneal refractive surgery; preoperative screening of keratoconus and risk assessment are required.

Recommendation 2 :

This surgery **can preserve biomechanical properties** postoperatively.

Domain 1: Indications

preoperative screening of keratoconus, selection of surgical options, and surgical plans

Recommendation 3:

- **The thickness of the removed corneal tissue** directly affects the corneal biomechanical strength.
- lower thickness of removed corneal tissue is recommended.

Recommendation 4:

Corneal biomechanical properties **influence the surgical predictability** of refractive outcomes.

Domain 2:
Surgical Planning
and Technique

Domain 2: Surgical Planning and Technique

Safe ranges of corneal thicknesses in surgical planning

Recommendation 5:

- The calculation of the **percentage of tissue alteration (PTA)** for such procedures is mainly based on the removed corneal tissue (lenticular thickness).
- A PTA value $\geq 40\%$ was significantly associated with the development of **corneal ectasia**.

Domain 2: Surgical Planning and Technique

Safe ranges of corneal thicknesses in surgical planning

Recommendation 6:

The exact **cause** leading to postoperative corneal ectasia remains **unclear**; however, when considering :

- Corneal thickness settings, **and RST $\geq 280 \mu\text{m}$** .
- Lenticule thickness index (**LT index**; ratio of maximum lenticule thickness to CCT) **$\geq 28\%$ could** be used as **reference values**.

Recommendation 7:

Surgeons could reduce the **cap thickness** to ensure a sufficient RST in surgical planning; however, an extremely thin corneal cap **$< 100 \mu\text{m}$ is not recommended**.

Domain 2: Surgical Planning and Technique

Setting ranges of the optical zone

Recommendation 8:

- **Large optical zones** may result in **less under-correction**
- Small optical zones may increase the risk of refractive regression after surgery.

Recommendation 9:

- **Larger optical zones** are associated with **fewer** surgery-induced **higher order aberrations**.
- **large optical zone is recommended** if the corneal thickness is sufficient.

Domain 2: Surgical Planning and Technique

Setting ranges of the optical zone

Recommendation 10:

Smaller optical zones have a **smaller effect** on postoperative corneal **biomechanical** strength.

Recommendation 11:

For patients with **thinner corneas** or **higher degrees of myopia**, if the pupil size is small, an appropriate **reduction in optical zone size**.

Domain 2: Surgical Planning and Technique

Astigmatism correction ranges and auxiliary positioning technique

Recommendation 12:

Correction of **astigmatism ranges** from **-0.25 D to -5.00 D**; the higher the target astigmatism, the weaker the effects of correction postoperatively.

Recommendation 13:

Correcting astigmatism with **axis alignment and cyclotorsion** compensation achieves better results postoperatively.

Domain 2: Surgical Planning and Technique

The relationship between decentration and postoperative visual quality

Recommendation 14 (Centration):

- The centration locations are the coaxially sighted corneal light reflex (CSCLR) and entrance pupil centre.
- However, CSCLR- centered procedures might be associated with better postoperative visual acuity, lower residual refractive error, and fewer induced higher-order aberrations, particularly coma.

Recommendation 15 (Decentration):

- 0.2 mm decentration will not cause a significant decrease in postoperative visual acuity and quality.

Domain 2: Surgical Planning and Technique

The relationship between decentration and postoperative visual quality

- **Recommendation 16 : Angle kappa**
large angle kappa may lead to **impaired postoperative visual acuity** or visual quality.

Domain 2: Surgical Planning and Technique

Factors influencing the accuracy of **preoperative refraction** measurement

Recommendation 17: Organic diseases:

- **Functional abnormalities** (accommodation or binocular vision anomalies, visual fatigue, and inappropriate prescriptions for spectacles).
- **Organic diseases** (nystagmus, strabismus, and corneal clarity).

Recommendation 18 Cycloplegic Refraction

- **Accommodation** is one of the most important factors affecting the precision of refraction measurement.
- **Cycloplegic refraction is recommended.**

Domain 2: Surgical Planning and Technique

Factors related to **nomograms** and adjusting strategies

Recommendation 19 (Nomogram):

- **Preoperative SE** (or simple spherical values).
- Age.
- eye laterality.
- corneal curvature.
- **Diameter.**
- Biomechanical properties.
- Cap and lenticule thickness, CCT, RST, optical zone diameter, accommodation, and laser energy.

Domain 2: Surgical Planning and Technique

Recommendation 20 (Nomogram adjustment):

Simple spherical and cylindrical modification:

For spherical correction:

- **10%-overcorrected** nomogram for low to moderate myopia. **(-3.00D to -7.00 D)**
- **7%** overcorrected nomograms showed better refractive outcomes for myopia between **(-1.00 and -3.00 D.)**
- **12%-overcorrected** nomograms were better for myopia **over -7.00 D.**

For astigmatism correction:

Surgeons should **increase** nomogram values by **10%** for the target cylinder treatment.



Domain 3 Complications

Domain 3: complications

Prevention and management of intraoperative adverse events

(difficult lenticule dissection, wrong plane dissection and difficult lenticule removal, incision tearing, and cap perforation)

Recommendation 21 (preventive measures):

- **Difficult** lenticule dissection.
- **Improper** laser energy.
- Severe OBL and **black spots** should be prevented and avoided.

Domain 3: complications

Recommendation 22 (Lenticular management) :

- The lenticule should be carefully **identified and dissected**.
- If the lenticule cannot be found, a relatively **sharp dissector** should be used to search for the edge of the lenticule.
- The **magnification of the microscope** should be increased, & the built-in **slit lamp** should be used to identify the lenticule.
- In **cap perforations or tearing**, the cornea must be **tightly aligned**, and a bandage contact lens is recommended

Domain 3: complications

Prevention and management of suction loss

Recommendation 23 :

- Patient **education** and **fixation training** should be reinforced.
- During the procedure, the patient's **head and eye positions** should be appropriately adjusted.
- Patients should be instructed to **remain relaxed and to maintain fixation**; during suction.
- **Conjunctival tissue trapping** and excess water on the ocular surface and conjunctival sac should be avoided.

Domain 3: complications

Prevention and management of suction loss

Recommendation 24 (management principles)

- If **suction loss** occurs during laser scanning at the **periphery of the lower lenticule plane (< 10%)**,
 - ✓ The original parameters should be retained.
 - ✓ **Redocking** and reinitiating the procedure should be performed.
- If **suction loss at the near-central (>10%)** or central region of the lower plane,
 - ✓ KLEx should be **rescheduled**.



Domain 3: complications



Black spots refer to points where the femtosecond laser fails to produce effective cutting action on the corneal tissue during KLEx.



Insufficient energy is a risk factor for black spots.

Domain 3: complications

Prevention and management of black spots

Recommendation 25:

- Strict patient selection,
- **Clean and properly humidified ocular surface.**
- **Suction ring/patient interface**, avoidance of repeated suction.

Recommendation 26:

- **Small peripheral Black spots**-----→ **continue**
- **Large central black spots** -----→ **suspend and rescheduled.**

Domain 3: complications

Prevention and management of retained lenticule fragments

Recommendation 27:

Preoperatively, **laser energy, temperature and humidity** Should be properly set.

Recommendation 28:

Retained lenticular tissue should be thoroughly removed, especially when in the optical zone.

Domain 3: complications

Prevention and management of perioperative infections Recommendation 29

- Preoperatively, **antimicrobial drugs**.
- Treat and control **ocular surface diseases**.

Recommendation 30

- Pathogens should be suspected as early as possible and adopt anti-infection measures.
- If the infection is uncontrollable,
 - ✓ The **incision should be enlarged**.
 - ✓ The **lesion should be removed** in the intrastromal pocket followed by **rinsing the pocket** with antibiotics.

Domain 3: complications

Prevention and management of postoperative DLK

Recommendation 31 (preventive measures)

Preoperatively:

- The **external eye** should be carefully examined.
- The **operative eye** should be strictly **cleaned** and disinfected.
- **Disinfection methods** for medical apparatus and instruments should be improved.

Recommendation 32(treatment principals)

- **Infection** should be differentiated from inflammation.
- Combined medications or interlamellar **steroid rinsing**.

Domain 3: complications

Causes, prevention, and treatment principles of **delayed visual recovery** and **poor visual acuity** after surgery

Recommendation 33 (Causes of Delayed Visual recovery)

- **Individual** differences among patients.
- The occurrence of various **intraoperative** conditions.

Recommendation 34 (preventive measures)

- **Excessive manipulation** can induce early post-operative corneal oedema and healing reactions.

Domain 3: complications

Causes, prevention, and treatment principles of **delayed visual recovery** and poor visual acuity after surgery

Recommendation 35: (treatment principles)

- **Vision often improves gradually** over time and with the subsiding of tissue edema.
- For residual postoperative refractive error, **enhancement surgery** can be performed **after six months** of stable refraction.

Domain 3: complications

Early diagnosis, prevention, and management of postoperative corneal Ectasia

Recommendation 36 (early diagnosis):

- Visual **decline** and newly detected refractive errors.

Recommendation 37 (preventive measures):

- **Avoid** corneas with abnormal morphology and eye rubbing.
- **Pay attention** to changes in posterior corneal elevation.

Recommendation 38 (treatment principles) :

- **Cross-linking** are recommended to halt disease progression.
- followed by **Rigid contact lens** to improve vision.



Conclusions:

**These evidence-based recommendations for
KLEx in clinical practice
are expected to improve the safety and
effective application of KLEx procedures
and achieve more satisfactory visual
correction**

THANK YOU



In collaboration with:



MEACO
MIDDLE EAST AFRICA
COUNCIL OF OPHTHALMOLOGY

INTERNATIONAL CONGRESS OF THE
EGYPTIAN
OPHTHALMOLOGICAL SOCIETY

EOS
2025

Save the Date
7-9 MAY
INTERCONTINENTAL
CITYSTARS, CAIRO, EGYPT

eos-egypt.org



YouTube channel: @Dr.AhmedElmassry