Updated Draft

European Society of Cataract and Refractive Surgeons (ESCRS) Recommendations for Refractive Surgery 2026

Authors: Victoria Till, MD; Mario Nubile, MD; Jesper Hjortdal, MD, PR ; Joukje Wanten, MD; Andreia Rossa, MD, PR; Paolo Vinciguerra, MD; Liem Trinh, MD; Guy Kleinmann, MD; Georges Kymiones, MD; Arthur Cummings, MD; Sheraz Daya, MD; Ruth Lapid, MD, PHD; Thomas Kohnen, MD, PHD, FEBO, PR**;** Beatrice Cochener, MD, PR

Authors Affiliations: see attached COI

Correspondence: Thomas Kohnen, MD, PHD, FEBO, PR

Chapter outline

1. Abstract

Background: Refractive errors are the leading cause of correctable visual impairment. Refractive surgery has expanded from a limited set of procedures to a wide range of options that can correct refractive errors and offer spectacle independence. The patient pathway includes selection, diagnostics, treatment planning, and postoperative care.

Objective: To establish evidence-based recommendations by the European Society of Cataract and Refractive Surgeons (ESCRS) to support patients, clinicians, and other relevant stakeholders in decisions about refractive surgery management.

Methods: The European Society of Cataract and Refractive Surgeons (ESCRS) developed evidence-based recommendations to guide patients, clinicians, and stakeholders in managing refractive surgery. A multidisciplinary panel followed the GRADE methodology to assess clinical questions and outcomes.

Results: The recommendations address 52 questions across the patient care pathway. The fundamental key recommendations for each procedure can be found in the specific chapters.

Conclusions: Key recommendations emphasize the necessity of comprehensive pre-operative evaluations, providing informed consent that outlines the benefits and risks of each refractive procedure. These recommendations for refractive surgery detail the optimal range of refractive errors suitable for each procedure, along with expected outcomes and potential complications. The variability in reversibility and effects between corneal and lens-based procedures is highlighted. It is crucial to note that the systematic literature review identified grey zones with limited scientific proof. For these topics expert opinions were required.

Keywords: Refractive surgery, PRK, LASIK, KLEx, Phakic IOL, RLE, ophthalmology, practice recommendations, efficacy, safety, stability, predictability, complications, GRADE, recommendations

2. List of abbreviations

AAO: American Academy of Ophthalmology

AC: Anterior Chamber

ACD: Anterior Chamber Depth

AGREE II: Appraisal of Recommendations for Research and Evaluation II

AL: Axial Length

AMD: Age-Related Macular Degeneration

APRK: Advanced Photorefractive Keratectomy

ASCRS: American Society of Cataract and Refractive Surgeons

BCVA: Best-Corrected Visual Acuity

BSCVA: Best Spectacle-Corrected Visual Acuity

BSS: Balanced Salt Solution

CDG: Constituting Recommendations Development Group

CDSR: Cochrane Database of Systematic Reviews

CDVA: Corrected Distance Visual Acuity

CENTRAL: Cochrane Central Register of Controlled Trials

CH: Corneal Hysteresis

CI: Confidence Interval

CME: Cystoid Macular Edema

CRF: Corneal Resistance Factor

CST: Corvis ST

CVD: Collagen Vascular Disease

D: Diopter

DED: Dry Eye Disease

DLI: Dysfunctional Lens Index

DNA: Deoxyribonucleic Acid

ECD: Endothelial Cell Density

EDOF: Extended Depth of Focus

Epi-K: Epithelial Keratectomy

ESCRS: European Society of Cataract and Refractive Surgeons

FDA: Food and Drug Administration

FLEx: Femtosecond Lenticule Extraction

FS-LASIK: Femtosecond Laser-Assisted In Situ Keratomileusis

GDG: Recommendations Development Group

GRADE: Grading of Recommendations Assessment, Development and Evaluation

HIV: Human Immunodeficiency Virus

HOA: Higher-Order Aberration

ICL: Implantable Collamer Lens

IFU: Instructions for Use

IOL: Intraocular Lens

IOP: Intraocular Pressure

IPCL: Implantable Phakic Contact Lens

KLEx: Keratorefractive Lenticule Extraction

KSR: Kleijnen Systematic Reviews Ltd.

LASEK: Laser-Assisted Subepithelial Keratectomy

LASIK: Laser-Assisted In Situ Keratomileusis

logMAR: Logarithm of the Minimum Angle of Resolution

LRS: Laser Refractive Surgery

MD: Mean Difference

MGD: Meibomian Gland Disease

MMC: Mitomycin C

MK-LASIK: Microkeratome-Assisted Laser In Situ Keratomileusis

MRSE: Manifest Refraction Spherical Equivalent

Nd:YAG: Neodymium-Doped Yttrium Aluminium Garnet

NGRC: Nederlands Gezelschap voor Refractie Chirurgie

NIBUT: Non-Invasive Tear Break-Up Time

NSAID: Non-Steroidal Anti-Inflammatory Drug

OCT: Optical Coherence Tomography

OMIC: Ophthalmic Mutual Insurance Company

OPD: Optical Path Difference

OR: Odds Ratio

ORA: Ocular Response Analyzer

OSDI: Ocular Surface Disease Index

OSI: Objective Scatter Index

OVD: Ophthalmic Viscosurgical Device

PC: Posterior Chamber

PCO: Posterior Capsular Opacification

PDS: Pigment Dispersion Syndrome

PICO: Patient, Intervention, Comparison, Outcome

pIOL: Phakic Intraocular Lens

PMMA: Polymethyl Methacrylate

PRK: Photorefractive Keratectomy

PROMs: Patient-Reported Outcome Measures

PTA: Percentage of Tissue Altered

PTK: Phototherapeutic Keratectomy

PVD: Posterior Vitreous Detachment

RCT: Randomized Controlled Trial

ReLEx: Refractive Lenticule Extraction

RLE: Refractive Lens Exchange

ROBIS: Risk of Bias in Systematic Reviews

RR: Risk Ratio

RSVP: Refractive Status and Vision Profile

SD: Standard Deviation

SE: Spherical Equivalent

SMD: Standardized Mean Difference

SMILE: Small Incision Lenticule Extraction

SUCRA: Surface Under the Cumulative Ranking Curve

T-PRK: Transepithelial Photorefractive Keratectomy

TBUT: Tear Break-Up Time

TCAT: Topography-Guided Customized Ablation Treatment

TICL: Toric Implantable Collamer Lens

UBM: Ultrasound Biomicroscopy

UCVA: Uncorrected Visual Acuity

UDVA: Uncorrected Distance Visual Acuity

UV: Ultraviolet

VCQ: Vision Correction Questionnaire

WFG-LASIK: Wavefront-Guided Laser-Assisted In Situ Keratomileusis

WFO: Wavefront-Optimized

WMD: Weighted Mean Difference

3. Introduction

These recommendations offer a comprehensive overview on the expansive field of refractive surgeries. For all recommendations, a grading system is used to establish the level of evidence, which guide ophthalmologists in determining indication and providing information to patients. It is important to note that these recommendations do not possess legally binding authority and therefore will not establish strict rules with absolute thresholds.

The structure of the recommendations is done according to the refractive surgery patient pathway and includes the following sections: definition and description, screening and patient selection, preoperative assessment, perioperative procedures, postoperative care, and complications.

These recommendations focus on the five most validated procedures (Surface ablative procedures, LASIK, KLEX, RLE and Phakic IOLs), which currently represent the most widely applied approaches. While other procedures are available, they fall outside the scope of the present document and will therefore not be discussed. PTK will not be treated as a separate refractive procedure during this document.

<u>The included refractive surgery procedures are:</u>

- *Corneal surface ablative procedures*
    a. PRK
    b. Trans-PRK

- *Intracorneal substractive procedures*
    a. Fs-LASIK / MK-LASIK (incl. Presby- LASIK)
    b. Refractive lenticule extraction

- *Intraocular surgeries*
    a. Phakic IOL (pIOL)
    b. Refractive Lens Exchange (RLE)

<u>The general structure of the recommendations will include:</u>

1. Definitions and Descriptions
2. Screening and patient selection
3. Preoperative assessment
4. Perioperative procedure
5. Postoperative care
6. Complication management

4. Methodology

4. 1 Introduction

The European Society of Cataract and Refractive Surgeons (ESCRS) wants to develop international recommendations for refractive surgery, using the best available evidence. These recommendations offer guidance for each patient which has a refractive error and is considering refractive surgery. The purpose of these recommendations is to improve the refractive surgery and the corresponding patient pathway.

This section describes the methods and processes which were used in the development of the ESCRS recommendations for refractive surgery. The methodology for development is based on an internationally accepted approach for recommendations development. These processes include criteria of quality, which are described in detail in the Appraisal of Recommendations for Research and Evaluation II (AGREE II) instrument, (Dans & Dans, 2010) primary methodological research and evaluation by the recommendations development group (GDG).

4.2 Development process

4.2.1 Phase 1: Setting the scope

For the European Recommendations for Refractive Surgery, the ESCRS was stakeholder with an interest in this topic. The Recommendations Development Group (GDG) of the ESCRS was asked to establish these European recommendations and was supported by a grant from the ESCRS. The process of recommendations development consisted of face-to-face and online meetings with the GDG. Two PhD candidates (JW, VK) and the methodologist (JK) worked closely together with the GDG during the development period.

The first key issues include aim of the recommendations, considering the health problems to be addressed, the patient group, and the target audience. The GDG group decided that these recommendations must be relevant to all patients with refractive errors in whom refractive surgery is considered. Refractive errors are the leading cause of reversible visual impairment, which can be treated by different refractive surgery procedures. In general, the decision to perform refractive surgery is mainly based on desire of the patient for spectacle independence. (Kim et al., 2019)

The purpose of these recommendations was to address the patient pathway for patients in whom refractive surgery is considered. The most important and most performed refractive procedures will be included: corneal surface ablative procedures, intracorneal ablative procedures and intraocular surgeries. For the

structure of these recommendations, we will follow to the patient pathway, including the following sections: screening and patient selection, preoperative assessment, perioperative procedure, postoperative care, and complication management. The recommendations will be applicable for all healthcare workers (e.g., ophthalmologists, residents, general practitioners, nurses, optometrists, and opticians) and patients who are interested in refractive surgery management. The purpose of these recommendations, including target group and audience is described in the scope.

4.2.2 Phase 2: Invitation of the Recommendations Development Group (GDG)

In preparation of the recommendations development, a recommendations development group (GDG) was composed, including members from 12 different countries (Belgium, Denmark, France, Germany, Greece, Ireland, Israel, Italy, the Netherlands, Portugal, Spain, and the United Kingdom). These members were invited by the GDG Chairs (BC, TK) to be representative healthcare professions with an extensive knowledge of Refractive Surgery management. The members of the GDG formulated key issues which were further developed by the constituting recommendations development group (CDG). The CDG consisted of two PhD-students (JW, VT) and the supervising methodologist (JK).

In the composition of the GDG, several factors were considered. First, all clinical members should have an affinity with the diagnosis and treatment of refractive errors, considering that clinical knowledge on the subject is key. Second, distribution of geographical differences between GDG members is desired, as the recommendations is aimed at an international audience.

The GDG consisted of 12 ophthalmologists (AC, AR, BC, GK, PV, GKI, JH, LT, MN, RL, SD, TK), one patient representative (PK), two PhD candidates (JW, VK) and one methodologist (JK) with extensive experience in recommendations development. In addition, the GDG members received assistance of a methodologist's team (staff at Kleijnen Systematic Reviews Ltd) whose work covered input from information specialists, quality assurance, and evidence review and support.

Table 1. Members of the Recommendations Development Group (GDG)

Recommendations member	**Profession**	**Institution**	**Country**
Arthur Cummings (AC)	Ophthalmologist	Wellington Eye Clinic, Dublin	Ireland
Andreia Rosa (AR)	Ophthalmologist	Faculty of Medicine of the University of Coimbra, Coimbra	Portugal
Béatrice Cochener (BC)	Ophthalmologist	Brest University Hospital, Brest	France

Georges Kymionis (GK)	Ophthalmologist	University of Athens, Athens	Greece
Guy Kleinmann (GKl)	Ophthalmologist	Kaplan Medical Center, Rehovot	Israel
Jesper Hjortdal (JH)	Ophthalmologist	Aarhus University Hospital, Aarhus	Denmark
Paolo Vinciguerra (PV)	Ophthalmologist	Head of the Ophthalmic Center at Humanitas research Hospital	Italy
Liem Trinh (LT)	Ophthalmologist	Centre Hospitalier National d'Ophtalmologie des Quinze-Vingts, Paris	France
Mario Nubilé (MN)	Ophthalmologist	University of Studies G. d'Annunzio Chieti and Pescara, Chieti	Italy
Ruth Lapid-Gortzak (RL)	Ophthalmologist	Academisch Medisch Centrum Universiteit van Amsterdam, Amsterdam	The Netherlands
Sheraz Daya (SD)	Ophthalmologist	Centre For Sight, London	United Kingdom
Thomas Kohnen (TK)	Ophthalmologist	Goethe University, Frankfurt	Germany
Jos Kleijnen (JK)	Methodologist	Maastricht University Medical Center (MUMC+), Maastricht and Kleijnen Systematic Reviews Ltd, York	The Netherlands and United Kingdom
Joukje Wanten (JW)	PhD Candidate	Maastricht University Medical Center (MUMC+), Maastricht	The Netherlands
Victoria Till (VT)	PhD Candidate	(MedUni) Medical University of Vienna, Vienna	Austria

4.2.3 Phase 3: Formulating Review Questions

Three researchers (JK, JW, VK) formulated a set of review questions assessing the key issues listed in the scope. These review questions were formulated according to important patient outcomes in a PICO framework (population, intervention, comparator, and outcome). The PICO framework was used to assess the effectiveness of an intervention and similar frameworks for other types of questions. Table 2 describes the PICO framework, which offers a helpful and structured approach for development of questions about interventions.

Table 2. PICO Framework, used for formulating the review questions.

Population (P)	Which population are we interested in? How best can it be described? Are there subgroups that need to be considered?
Intervention (I)	Which intervention, treatment or approach should be used?
Comparators (C)	Are there alternative(s) to the intervention being considered? If so, what are these (for example, other interventions, standard active comparators, usual care or placebo)?
Outcome (O)	Which outcomes should be considered to assess how well the intervention is working? What is important for people using services? Core outcome sets may be used where appropriate; one source is the COMET database.

A draft scope, including the review questions and a set of outcomes, was discussed with the chairs (BC, TK) of the GDG. The input of the chairs was used to refine the questions and cluster them into five different topics (Corneal surface ablative procedures; Intracorneal substractive procedures; Intraocular surgeries; Diagnostics and preoperative assessment; and Patient Selection, Risk factors and Special Indications). Every topic was discussed by a GDG subgroup with extensive expertise for this specific area of interest. The questions were discussed during online meetings with every subgroup and finalized according to the comments and feedback of the GDG members. The finalized set of questions was structured and clustered into chapters according to the patient pathway (i.e. screening and patient selection, preoperative assessment, perioperative procedure, postoperative care, and complication management). The set of outcomes, which are important and critical for decision making in the clinical setting, were also discussed with the GDG members and revised. The final set of outcomes, given in table 3, are crucial for assessment of the strength of evidence by using the application of GRADE. Grading the evidence is essential in formulating appropriate recommendations.

Table 3. Set of selected outcome parameters

Outcome measures/parameters	**Importance**

Serious adverse events
- Complications during surgery
  o Laser-associated and flap related complications
  o Implantation related complications
  o Lenticular intrastromal complications
  o Posterior capsular bag damage with vitreous loss
  o Dropped nucleus
  o Iris damage
  o Zonulolysis
  o Expulsive bleeding
- Complications after surgery
  o Ectasia
	Critical outcome

o Corneal healing process complications o Inflammation o Infection o Retinal detachment o Implant related complications o Optical error o Pupillary block o Glaucoma o Induced cataract o Endothelial cell loss o Rainbow glare o Interface fluid syndrome	
Visual acuity - Distance visual acuity - Intermediate visual acuity - Near visual acuity	Critical outcome
Postoperative refractive outcome - Spherical error - Cylindrical error - Stability	Critical outcome
Quality of life - Activities of daily living - Satisfaction - Spectacle independence - Optical side effects	Important, but not critical
Visual function - Contrast sensitivity - Optical aberrations - Reading speed	Important, but not critical
Specific adverse events - Dry eye syndrome - Chronic neuropathic pain	Important, but not critical
Adverse events - Complications during surgery o Posterior capsular bag damage without vitreous loss o Anterior capsule tear o Corneal related complications - Complications after surgery o Inflammation o Corneal related complications o Posterior capsular opafication o Capsular contraction syndrome	Limited importance

○ Elevated intraocular pressure ○ Iris changes ○ Fibrosis ○ Epithelial ingrowth ○ Transitory light syndrome ○ Rainbow glare ○ Interface fluid syndrome	

4.2.4 Phase 4: Literature search

Literature searches were conducted on 28 February 2023 to identify relevant systematic reviews and randomised controlled trials on refractive surgery.
The search strategies were developed specifically for each database and the keywords adapted according to the configuration of each database. Searches were limited by date range to 2005-2023. Searches were not limited by language or publication status.

Handling of citations

References identified from the searches were downloaded into EndNote bibliographic management software for further assessment and handling.

Resources searched:

Resource	**Host**	**Date range**	**Date searched**	**Records found**
KSR Evidence	https://ksrevidence.com/	to 28.2.23	28.02.23	478
CDSR	Wiley	Iss 2/12, Feb 2023	28.02.23	301
MEDLINE, Epub, Daily Update & In-Process	Ovid	1946 to February 27, 2023	28.02.23	4218
Embase	Ovid	1974 to 2023 February 27	28.02.23	3660
CENTRAL	Wiley	Iss 2/12, Feb 2023	28.02.23	5176
TOTAL				**13833**
TOTAL (after deduplication)				**7877**

Full details of all search strategies are presented in Appendix 1.

4.2.5 Phase 5: Research evidence reviewing.

Data of the selected articles were extracted by July 2023 and supervised by the methodologist (JK) and the GDG. For each question, the selection of evidence focused on available meta-analyses and systematic reviews, supplemented by other types of studies, published in 2005 and onwards. For the systematic reviews, no specific date limit was used.

For grading the evidence, the quality assessment in the reviewing evidence is crucial. All the selected articles were critical appraised by the methodologist (JK) and staff. The critical appraisal was done based on the Risk of Bias Assessment Tool Robis. (Whiting et al., 2016) This tool looks at four domains of an article: study eligibility criteria, identification and selection of studies, data collection and study appraisal, synthesis, and findings. The full ROBIS tool and guidance documents are available from the ROBIS Web site (www.robistool.info) and as Appendices at www.jclinepi.com. The Cochrane checklist was used for assessing risk of bias of randomized trials.(Savovic et al., 2014)

4.2.6 Phase 6: Developing and formulation of recommendations.

The quality of the relevant evidence was summarized using the GRADE approach (table 8).(Neumann et al., 2014) This approach assessed quality of the evidence for intervention studies by checking the features of the evidence found for each ‘critical’ and ‘important’ outcome. Grading the evidence was only done once the recommendations were at an advanced stage.

If needed, we updated high-quality systematic reviews, or their primary studies used, as evidence for informing a new review. Meta-analysis from the systematic reviews were updated by the surgical resident and the methodologist using ReviewManager version 5.3 software.

According to the GRADE approach, the evidence is classified as high, moderate, low or very low. These classifications are accompanied by a specific formulation of the recommendations, using the wording ‘must’, ‘should’, ‘could’, ‘may’, ‘may not’, ‘can be considered’. Considering high level evidence, the term ‘must’ was used in the recommendations of this recommendations. In case of moderate evidence, ‘should’ or ‘could’ were used. For low graded evidence, ‘could’ or ‘may’ are applicable and lastly, when there was very low evidence implemented in the recommendations, ‘can be considered’ was used.

Table 8: GRADE strategy for evaluate quality of evidence.

Grade of evidence	**Definition**	**Specific wording**
High	Further research is very unlikely to change our confidence in the estimate of effect. GRADE ++++	‘Must’

Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. GRADE +++	'Should'
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. GRADE ++	'Could' or 'may'
Very low	Any estimate of effect is very uncertain. GRADE +	'Can be considered'

For the evidence review, specific sections were included: the summary of evidence, evidence statements, full GRADE profiles and evidence tables.

During the ESCRS congress in Milan 2022, face-to-face meetings were scheduled for each subgroup of the GDG with a specific topic of interest. During this meeting, all review questions were discussed including the selected relevant literature retrieved from the KSR database, Embase (Ovid) and Medline (Ovid). This meeting offered the opportunity for all the GDG members to give feedback and comments on the questions and evidence. According to these comments, the questions were rephrased and optimized. Besides, the evidence found during the general literature search was discussed and members provided their interpretations. Based on this information, the questions and were finalized by the PhD candidates (JW, VK) and the methodologist (JK). According to these adjustments, the literature search was optimized and summarized. The finalized set of questions is given in table 9.

Table 9: Final set of review questions for the Refractive Surgery Recommendations

Phase/Chapter	**Questions**

Definitions and descriptions	- Defintions of ametropia
	- Defintions of target refraction
	- Defintions of different procedures
	  o Cornea- based procedures
	  ▪ Surface ablative procedures
	  ▪ LASIK
	  ▪ KLEX
	  o Lens- based procedures
	  ▪ Phakic IOL
	  ▪ Refractive lens exchange
	- Defintions of IOLS
	- Ranges of application
	- Defintions of outcomes
	- Defintion of "Presence of risk factors for corneal refractive surgery" (Risky cornea)

General limitations of application	- Limits of application for cornea- based procedures - Limits of application for lens- based procedures
Screening and patient selection	- What ocular risk factors or comorbidities must be taken into consideration before surgery? - What are possible surgical recommendations for patients with systemic diseases (dermatological disorders, connective tissue disorders, autoimmune disorders, keloid scarring, irregular astigmatism, healing disorders, diabetes)? - How to address patients with DED who are considering refractive surgery? Is there a specific management for DED patients prior to refractive surgery? - What are contraindications for refractive surgery procedures?
Preoperative assessment	- How should shared consent be obtained in patients who want to undergo refractive surgery? What information should be given to patients prior to surgery and how detailed should this information be? - What has to be included in the preoperative check-up?
Postoperative management and complications	- Which standard operating procedure should be applied in time (i.e., when) and in which way (i.e. how) to a patient who has undergone a refractive surgery procedure? - Postoperative evolutive profile - What are the most common (serious) adverse events during refractive surgery procedures? - What are the most common (serious) adverse events after refractive surgery procedures?
Corneal Surface Ablative Procedures (PRK/ Trans-PRK)	- What are the indications and contraindications for corneal surface ablative procedures? - What is the efficacy of corneal surface ablative procedures? - What is the predictability of corneal surface ablative procedures? - What is the stability of corneal surface ablative procedures? - What is the safety of corneal surface ablative procedures? - Is the intraoperative use of mitomycin C during PRK to reduce postoperative scar/ haze formation indicated in all patients? Are there any side effects or contraindications one must consider? How long should Mitomycin C be used? - Key messages

	- Grey Zones
Intracorneal substractive procedures (LASIK)	- What are the indications and contraindications for LASIK? - What is the efficacy of LASIK? - What is the predictability of LASIK? - What is the stability of LASIK? - What is the safety of LASIK? - Key messages - Grey Zones
Intracorneal substractive procedures (Refractive lenticule extraction)	- What are the indications and contraindications for refractive lenticule extraction? - What is the efficacy of refractive lenticule extraction? - What is the predictability of refractive lenticule extraction? - What is the stability of refractive lenticule extraction? - What is the safety of refractive lenticule extraction? - Key messages - Grey Zones
Intraocular surgeries (Phakic IOLS)	- What are the indications and contraindications for phakic IOLs? - What is the efficacy of phakic IOLs? - What is the predictability of phakic IOLs? - What is the stability of phakic IOLs? - What is the safety of phakic IOLs? - Key messages - Grey Zones
Intraocular surgeries (Refractive Lens Exchange)	- What are the indications and contraindications for Refractive Lens Exchange? - What is the efficacy of Refractive Lens Exchange? - What is the predictability of Refractive Lens Exchange? - What is the stability of Refractive Lens Exchange? - What is the safety of Refractive Lens Exchange? - Key messages - Grey Zones

For each review question the graded literature was summarized and interpreted, considering the quality of each article. The recommendations were written using the specific wording according to the quality of evidence.
During the face-to-face meetings in Vienna (November 2022) and Vilamoura (March 2023), the GDG members discussed the proposed recommendations for the questions and made decisions about the importance and implementation of these recommendations in the recommendations. If there was no specific evidence found in the literature, the question was answered using an expert opinion or no recommendation was made.

4.3 The validation process for the draft recommendations

The draft version of the ESCRS Refractive Surgery Recommendations will be published on the ESCRS website. The ESCRS will inform respondents and ask them to submit any feedback within two months.

4.3.1 Finalizing and publishing the recommmendations

The complete development of this recommendations took between 12 and 48 months (table 10). It is planned to update these recommendations every 3 years. This will keep the recommendations up to date by involving searches and assessment of relevant literature to review the current recommendations. The relevant literature should provide a reconsideration for adapting the recommendations.

Table 10: Time schedule of recommendations development

Program	**Period of time**
Development protocol	February 2022
Establishing the Recommendations Development Group	March 2022
Face-to-face meeting: introduction	May 2022 (Frankfurt)
Development of review questions	May-July 2022
Online meeting: discussing questions in subgroups	July 2022
Literature searches	July-September 2022
Face-to-face meeting: discussing the questions according to the evidence found	September 2022 (Milan)
Finalizing literature search and drafting recommendations	September-November 2022
Face-to-face meeting: discussing methodology and recommendations	November 2022 (Vienna) and March 2023 (Vilamoura)
Meeting to finalize draft recommendations	November 2023 (Vienna)
Evaluate references and check first draft of the considerations and recommendations	December 2023-February 2024
Establishing first GRADE tables	September 2024
Second draft of the big document is checked, formulation of executive summary	February 2025
Validation and checking of both documents	September 2025
Last adjustements and evaluations	March 2026
Online Publication on ESCRS website	May 2026

5. Definitions and descriptions of procedures

5.1 Definitions of ametropia

Refractive surgery encompasses a spectrum of techniques, aimed at the correction of refractive errors and therefore enabling a certain degree of spectacle or contact lens independence. These recommendations gives an overview of the currently most performed refractive surgery procedures. Techniques not included in this overview are considered either obsolete, lacking sufficient evidence to support their efficacy and safety, or still undergoing investigation.

Procedures have been described by using efficacy, predictability, stability, and safety as primary outcome measures. Efficacy is defined as the percentage of eyes with uncorrected visual acuity of 20/20 and 20/40. Predictability is defined as the mean standard deviation, and range of postoperative spherical equivalent or the percentage of eyes within ±1.00D and ±0.50D of desired postoperative refractive error, including a table categorizing refractive outcomes. Stability is defined as the number und percentage of eyes with a change in spherical equivalent of manifest refraction ≥1.00D within a specified interval; the recommended minimal interval is 6 months. Safety is the number and percentage of eyes losing two or more lines of best spectacle-corrected visual acuity (BCVA).(Koch et al., 1998; Reinstein, Archer, et al., 2017)
The outcomes of refractive surgeries are often depending on the initial refractive correction of the patient which needs to be corrected. Definitions: (Nunez et al., 2019)

- Low myopia lower than 3D
- Moderate myopia: 3.0 to 6.0D
- High myopia: higher than 6.0D

- Low hyperopia: lower than 2.0 D
- Moderate hyperopia: 2.0 to 4.0 D
- High hyperopia higher than 4.0 D

Definitions of astigmatism:

- Low astigmatism: lower than 1.5D
- Moderate astigmatism: 1.5 to 3.0D
- High astigmatism: higher than 3.0D
- Myopic / hyperopic / mixed astigmatism

Orientation of astigmatism

- Regular astigmatism

    - With-the-rule astigmatism: Steep axis of the corneal cylinder is vertical or within 30° of the 90° of vertical meridian (60-120°)
    - Against-the-rule astigmatism: Steep axis of the corneal cylinder is horizontal or within 30° of the horizontal meridians (0-30° or 150-180°)
    - Oblique astigmatism: Steep axis of the corneal cylinder is not within 30° of the horizontal or vertical meridians (31-59° and 121-149°)
    - Mixed astigmatism: A combination of myopic and hyperopic cylinders, making it suitable for cross-cylinder ablation.

- Irregular astigmatism
    - Where the two main axes of astigmatism are not symmetric and/or do not lie 90° apart (orthogonal)
    - Irregular or pathological astigmatism treatment is beyond the scope of this recommendations.

Surgical decisions should not be based on refraction alone but should consider all the others influencing factors, such as morphological characteristics of the eye including corneal parameters and patient's expectations and needs.

The eligibility criteria and application limits for refractive surgical procedures are typically defined by specific thresholds of refractive error, rather than by the spherical equivalent (SEQ). This distinction is important, particularly in cases involving compound refractive errors such as myopic astigmatism. In such instances, the total refractive error is generally assessed by considering the full extent of both spherical and cylindrical components, rather than simplifying them into a single SEQ value. This approach ensures more accurate patient selection and treatment planning.(German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020)

5.2 Definitions of target refraction

Prior to refractive surgery, patients should be consulted regarding the desired target refraction. This recommendations covers the following refractive targets:

- Emmetropia: Emmetropia refers to the condition in which there are no refractive errors present. When the eyes are in an emmetropic state, objects located at infinity are sharply focused on the retina without any need for accommodation. In practice, a refraction ranging between +0.25D and -0.25D is defined as emmetropia.(Langenbucher, 2015)

- Mini-monovision: Mini-monovision refers to the condition where one eye (usually the dominant eye) is targeted for emmetropia while the other eye

(usually the non-dominant eye) is targeted for slight myopia ranging between -0.25D and -0.75D in order to increase spectacle independence.(Cochener, 2018)

- Monovision: Monovision refers to the condition when one eye is targeted for distance vision while the other eye is targeted for near vision. The range of diopters for monovision correction may vary according to the specific needs of the patient and discretion of the surgeon. In practice, monovision ranges from -1.00D to -2.50D, with a maximum of -3.00D to maintain binocular vision. However, -2.50D is generally associated with better tolerance, while -3.00D is the official upper limit.(AAO PPP Cataract and Anterior Segment Panel & Hoskins Center for Quality Eye Care, 2021 [accessed 2.5.23])

5.3 Defintions of different refractive procedures

5.3.1 Cornea-based procedures

5.3.1.1 Laser Profiles

The photoablation profile for a PRK or LASIK procedure can be based on various approaches. Conventional treatments rely on the Munnerlyn formula or on aspheric profiles to correct refractive errors based on manifest refraction. While the Munnerlyn formula provides the fundamental geometric relationship between ablation depth and optical zone diameter, it does not account for corneal asphericity or higher-order aberrations and therefore represents a simplified baseline model. Modern aspheric (wavefront-optimized or aberration-neutral) profiles build upon this foundation by incorporating compensation for the natural prolaticity of the cornea, control of induced spherical aberration, and more advanced optical and biomechanical modeling. In this sense, contemporary standard ablations can be understood as Munnerlyn-based calculations with additional optical refinements, resulting in improved preservation of visual quality and reduced induction of spherical aberrations compared to traditional approaches.

Treatment can be further enhanced through topography-guided or wavefront-guided techniques. Topography-guided treatments rely on detailed corneal surface data to regularize corneal shape and are particularly useful in irregular corneas. In contrast, wavefront-guided treatments are based on whole-eye aberrometry and aim to correct spatially varying refractive errors, including higher-order aberrations, thereby achieving a more optically precise outcome than uniform spherical and cylindrical corrections.

Optimized profiles can be integrated into both wavefront- and topography-guided approaches, with the shared objective of preserving or restoring the cornea’s natural asphericity and enhancing visual quality. Additionally, all ablation profiles incorporate a transition zone, which contributes to smoother curvature changes, reduces

regression, and improves postoperative visual outcomes. Although wavefront-guided treatments may provide advantages in terms of early visual recovery and residual refractive error (e.g., cylinder), comparative studies suggest that overall visual acuity outcomes and higher-order aberration profiles are generally similar between wavefront-guided and topography-guided approaches. Across all modern techniques, there is a common trend toward asphericity-preserving (“optimized”) ablation strategies, reflecting an evolution from purely geometric correction toward individualized optical optimization.

It is important to note that the concepts of topography-guided, wavefront-guided, and wavefront-optimized treatments are applicable across refractive procedures, including LASIK, PRK, and other surface ablation techniques (Mastropasqua et al., 2004; Durrie et al., 2010; Khanjian et al., 2023; Kohnen et al., 2023).

5.3.1.2 Photorefractive Keratectomy (PRK)

This procedure is used to ablate the corneal stroma to correct refractive errors. After applying topical anesthesia, PRK involves the removal of the corneal epithelium mechanically or chemically with topical alcohol. As a next step the excimer laser is directed onto the anterior stroma and the exposed surface is ablated. The excimer laser operates using an excited dimer (a combination of argon and fluorine) exposed to a high-voltage electric current, producing ultraviolet radiation at a wavelength of 193 nm, which facilitates the photoablation of tissue. Modern excimer lasers utilize small, precise scanning beams that are highly adjustable in terms of profiles, including optical zones and transition zones. These systems are further enhanced by advanced features such as active eye tracking, cyclotorsion compensation, and pupil shift correction, ensuring optimal accuracy and effectiveness. In case of high risk of haze (e.g., enhancement procedures, high myopia, hyperopic patients) intraoperative mitomycin C 0.2mg/ml for 10 to 30 seconds can be used for haze prevention. (Chuck & et al., 2018) Since this procedure does not include the creation of a flap, PRK can sometimes also be used in thinner corneas, leaving more residual corneal stromal tissue, as well as in patients who may be at risk to flap dislocation such as contact sport athletes or military personnel. (Chang & et al., 2022)

Transepithelial-PRK, introduced as a variation of the classical PRK procedure in 2007, integrates the epithelial removal using the laser and stromal ablation into a single step. Unlike traditional PRK, where epithelial removal is performed manually or chemically, trans-PRK utilizes the excimer laser to directly remove the corneal epithelium before reshaping the stroma.(Alasbali, 2022; Chang & et al., 2022; Hashemi, Alvani, et al., 2022)

In the procedure-specific chapters, PRK and transepithelial-PRK are treated as similar procedures, as differences in the outcomes appear to be minimal and transepithelial-PRK and PRK are regularly treated as one procedure in the literature. These two

procedures will not be differentiated in the outcome reports due to the lack of clear evidence demonstrating significant benefits at this time, particularly in terms of pain, corneal haze, and recovery.

5.3.1.3 Laser assisted in situ Keratomileus

In LASIK, the patient's eye is anesthetized with topical anesthesia. A suction ring is then applied to stabilize the cornea and prevent eye movement during surgery. The creation of the corneal flap is achieved with either a conventional mechanical microkeratome or a femtosecond laser. Once the flap is folded back, the underlying corneal stroma is exposed. The laser is directed onto the exposed cornea and the cornea is sculpted using a preprogrammed ablation profile. After the sculpting is complete, the corneal flap is repositioned, and its edges are smoothed without the need for sutures. (A. Vestergaard et al., 2013)
This procedure offers advantages compared to surface photoablation techniques, including less postoperative discomfort, faster visual recovery, and decreased risk of haze, making it the most common procedure for corneal refractive surgery. This procedure combines lamellar corneal surgery with the accuracy of the excimer laser to correct refractive errors. (Chang & et al., 2022; German Society of Ophthalmology & German Professional Association of Ophthalmologists, 2024)

Mechanical microkeratome LASIK (MK-LASIK)

Mechanical microkeratome LASIK (MK-LASIK) utilizes an instrument with an oscillating blade to create a corneal flap typically ranging from 90 to 200 micrometers in thickness. Initially, flap-thickness ranged from 180 to 200 micrometer (µm), later reduced to 90 to 120 micrometers (µm) to potentially mitigate the risk of ectasia and dry eye. The microkeratome is attached to the suction ring and cuts through the epithelium, Bowman's layer, and superficial stroma, stopping at a preset point to create the corneal flap. A hinge is left at one side of the flap to be able to fold it back, revealing the corneal stroma. (Xia et al., 2015)

Femtosecond LASIK (FS-LASIK)

Femtosecond laser-assisted LASIK (FS-LASIK) involves a focusable infrared laser that emits ultrashort (10^{-15} second) pulses, creating closely spaced spots (bubbles) to photo-disrupt tissue within the corneal stroma. The surgeon lifts the flap by simply separating the areas where the bubbles have formed and folding back the flap. FS-LASIK reduces major complications like irregular flaps or buttonholes compared to MK-LASIK. However, rare complications might include the rainbow effect, attributed to irregular stromal femtosecond cuts and transient light sensitivity, related to levels of energy used. FS-LASIK may offer greater accuracy in flap thickness and homogeneity compared to MK-LASIK, potentially leading to a smaller flap if centered over the optical zone. Moreover, reducing flap thickness can lower the risk of ectasia. Some studies

suggest associations with reduced induction of higher order aberrations (HOA), improved contrast sensitivity, longer tear break-up time (TBUT), and more predictable flap thickness compared to MK-LASIK.(Chang & et al., 2022; Chuck & et al., 2018)

PresbyLASIK

PresbyLASIK is a laser vision correction technique designed to treat presbyopia by modifying corneal asphericity and creating a multifocal ablation profile, thereby improving the ability to focus at various distances. Several ablation profiles are currently in use, including central PresbyLASIK and peripheral PresbyLASIK, where the near vision profile is applied to the central or peripheral cornea, respectively. The specific approach depends on the laser platform, and the surgeon's experience and preference.(Fernandez et al., 2022; Vargas-Fragoso & Alió, 2017)

5.3.1.4 Keratorefractive Lenticule Extraction (KLEX)

Keratorefractive Lenticule Extraction (KLEx) is a concept that involves the creation and extraction of a lenticule, a disc-shaped segment of corneal stroma, using a femtosecond laser only. In KLEx procedures, there is no ablation of the corneal stroma, instead the procedure includes intrastromal dissection and the creation of a refractive lenticule, which is removed after through a small peripheral corneal incision approximately 3mm in size.

KLEx has been introduced as a minimally invasive technique, shown to reduce early postoperative dry eye symptoms and promote corneal nerve regeneration at 3 months postoperatively, although no difference has been observed in the long term. KLEx may offer theoretical biomechanical advantages over LASIK and PRK, as both the Bowman's membrane and anterior stromal lamellae remain intact following the procedure. However, it is important to note that these potential advantages require further clinical validation. Overall, KLEx has demonstrated visual outcomes comparable to those of LASIK, particularly when compared with conventional ablation profiles, and provides a large effective optical zone. It may also provide benefits such as minimal postoperative pain and discomfort, resulting in high levels of patient satisfaction. Postoperative recovery, however, is strongly influenced by the surgeon's learning curve and the optimization of the laser energy settings. However, KLEx presents certain limitations. At present, the procedure is primarily available for myopic patients (with or without myopic astigmatism) on most platforms, Moreover, unlike LASIk and PRK, KLEx currently lacks the capacity to correct higher order aberrations.(Ganesh et al., 2017) Recently, hyperopic KLEx has become available with with CE marking in Europe.

KLEx has gained recognitions in treatment for myopia and myopic astigmatism, demonstrating predictable and precise outcomes in both visual acuity and visual quality. However, mastering the technique for lenticule extraction requires a learning

curve for beginning surgeons. This learning process typically involves observation, wet-lab training, and hands-on experience, with particular emphasis on lamellar dissection and proper handling of the refractive lenticule. Complications are more likely during the early stages of training, most commonly related to challenges in lenticule extraction.(Moshirfar, Tuttle, et al., 2023)

Ongoing refinements of the technique, along with advances in cyclotorsion compensation and improved alignment control, continue to enhance procedural outcomes and reduce complications across all levels of surgical experience. The recent incorporation of cyclotorsion compensation has enabled more accurate correction of higher degrees of astigmatism. In addition, the technique is now being explored for the correction of hyperopia.

5.3.1.5 Defintion of “Presence of risk factors for corneal refractive surgery” (Risky Cornea)

A “risky" cornea is best understood as a multifactorial entity characterized by one or more unfavorable features, including reduced corneal thickness, abnormal curvature patterns, ocular surface disease, abnormal viscoelasticity, and disturbances of the tear film. In such corneas, refractive surgery carries an increased likelihood of intraoperative or postoperative complications, a higher probability of suboptimal visual outcomes, and an elevated risk of refractive surprise. In the presence of a risky cornea or additional risk factors, patients must be comprehensively counseled, with particular emphasis on an individualized and detailed informed consent process that explicitly addresses the increased uncertainty and potential limitations of the procedure.

5.3.2 Lens based procedures.

5.3.2.1 Phakic Intraocular lens implantation

Phakic intraocular lenses (pIOLs) are lenses made of polymethyl methacrylate (PMMA), silicone or polymers that are permanently implanted into the eye and that are used in addition to the natural lens, primarily to correct moderate to high myopia offering a good quality of vision. PIOLs preserve the patient’s accommodative function and induce minimal higher-order aberrations (HOA), contributing to enhanced visual outcomes. PIOLS can correct myopia and hyperopia and astigmatism. This approach is particularly desirable in cases of high ametropia, where laser-based corneal reshaping may compromise corneal biomechanics, and also serves a viable option for patients with structurally risky corneas or when corneal refractive surgery is otherwise contraindicated. For high levels of correction, pIOLs have less impact on quality of vision compared to corneal approaches.(Barsam & Allan, 2014; Lee et al., 2016; Moshirfar et al., 2022)

These lenses can be positioned in the anterior chamber (anterior phakic IOLs, or in the posterior chamber behind the iris but in front of the natural lens (posterior pIOLs)

which represents the most popular model nowadays. Anterior pIOLs can further be divided into angle-supported and iris-claw anterior pIOLs. Currently only iris-claw anterior pIOLs and posterior pIOLs are in commercial use. Angle-supported pIOLs are not implanted due to excessive endothelial cell loss in some patients and increased risk of other irreversible anterior segment complications. Some newer posterior chamber pIOLS have a central port to facilitate the physiologic flow of aqueous humor, thereby eliminating the need for peripheral iridotomies prior or during implantation.(Guell et al., 2010)

Anterior Chamber pIOLs require a deeper anterior chamber of at least 3mm, as well as a perfect conformation of the iris. Peripheral iridotomies using Nd: YAG lasers or intraoperative peripheral iridectomies can be considered for Anterior pIOLs to prevent pupillary block. It has to be mentioned that most modern phakic IOLs come with a central aquaport with no need for iridotomy. Rigid lenses made of PMMA require bigger incisions (5.0mm) needing stitches, while the foldable Iris-claw lenses allow for smaller incisions (3.2mm).(Kohnen et al., 2024) Any phakic IOL, especially anterior chamber pIOLs, carries the risk for chronic endothelial cell loss and therefore requires annual check-ups. If endothelial cell loss reaches a threshold of concern, the lens must be explanted. Other complications, which occur more frequently with AC pIOLs, include pupil deformation, decentration, and luxation.

Implantation of posterior chamber pIOLS located behind the lens does not depend on a deep anterior chamber (over 2.8mm is enough). Posterior pIOLs need smaller incisions (2.2mm), than anterior chamber pIOLs.(Kohnen et al., 2024) Concerning the posterior chamber pIOL, the expected vaulting goes between 250 and 750 micrometer (µm). In general, the list of possible complications is similar for anterior and poster chamber phakic IOLs, but in posterior chamber lenses the formation of cataract and pigmentary glaucoma are the main concerns. Both types of phakic IOL implantations might lead to pupil block and pigment dispersion.

5.3.2.2 Refractive Lens Exchange

Refractive Lens Exchange (RLE) is a procedure involving the extraction of the natural lens and implantation of an intraocular lens (IOL), additionally correcting a refractive error. The surgical technique for RLE is a variety of the standard cataract surgery, with the key distinction being the absence of visually significant cataract. The primary aim of RLE is to address refractive errors including any ametropia and presbyopia when alternative refractive procedures are deemed inadequate. RLE is particularly used for refractive correction of presbyopic patients and in patients with lens opacity expected to progress quickly. This type of intraocular lens surgery primarily addresses patients seeking spectacle independence, often focusing on advanced technology or high-performance lenses that enhance the range of focus, either partially or fully. Therefore,

these lenses can also be considered for patients undergoing cataract surgery, provided they have a normal cornea, ocular surface, and retina.

Commercially available lenses are specifically approved for implantation during cataract surgery and are primarily intended for use in this context. However, unlike cataract surgery, where insurances typically cover part of the cost with a co-payment for the IOL, there is no insurance reimbursement for refractive procedures in most parts of Europe. The availability of various IOL models, as well as different refractive targets, provides patients with a diverse range of options when considering an RLE procedure.(Alió et al., 2014; Chuck & et al., 2018; Kaimbo Wa Kaimbo, 2016)

Refractive lens exchange offers advantages over corneal refractive surgery in selected cases, especially considering some patients with dry eye disease and corneal pathologies. It further eliminates the need for cataract surgery in the future. RLE offers an effective and consistent outcome and postoperative safety. Adequate indication and strict selection as well as the correct IOL calculation are mandatory to achieve this goal. (Alio et al., 2014)

RLE can either be achieved via phacoemulsification of the lens, which involves making a small incision, followed by the insertion of an ultrasonic probe, to break up and aspirate the lens capsule content, or with the support by femtosecond laser-assisted surgery which performs some of the manual aspects of the lens removal procedure. The probe emulsifies and aspirates the lens.(Kaweri et al., 2020) Foldable lenses fit into the small opening (capsulorhexis) created in the anterior lens capsule. Femtosecond Assisted Laser Surgery uses a laser to dissect tissue, creating a corneal incision and performing the capsulotomy and initial lens fragmentation (usually not needed at all in RLE).(Al-Khateeb et al., 2017)

It is important to mention that in addition to the cataract procedural risks, these patients may have an increased risk of retinal detachment. This is especially true for younger, male myopic patients, while patients with severe hyperopia can be at risk of developing choroidal effusion.(Alio et al., 2014) If the patient has a complete PVD (posterior vitreous detachment) and a healthy peripheral retina with no predisposing lesions, the risk for retinal detachment is acceptably low.

5.4 Definitions of different IOLs

Intraocular lenses (IOLs) are implantable devices used to replace the eye's natural lens, most commonly in the context of cataract or refractive lens exchange surgery. Due to the diversity in design, materials, and visual performance, creating a consistent and comprehensive classification system remains challenging. Therefore, the ESCRS Functional Vision Working Group has developed an evidence-based functional classification for IOLs.(Fernández et al., 2024) A more detailed of this functional classification can be found in the

ESCRS Cataract Surgery Recommendations. See link below:
https://www.escrs.org/escrs-recommendations-for-cataract-surgery

5.5 Ranges of application

The recommendations for refractive surgery establish well-defined ranges of application for each procedure, delineating the safe and predictable correction limits for myopia, hyperopia, and astigmatism. Importantly, these ranges refer specifically to the spherical and cylindrical components of the refractive error, rather than to the spherical equivalent, since surgical planning must always take into account the steepest meridian. Within these boundaries, reproducible outcomes with high safety margins have consistently been demonstrated.

When determining the upper correction limits, it is not sufficient to consider the spherical and cylindrical values in isolation. Instead, the threshold values must be assessed with respect to the highest refractive change of the principal plane. For example, a correction of +3.0 D sphere combined with –6.0 D cylinder or –3.0 D sphere combined with +6.0 D cylinder falls within the zone of limited application. In contrast, combinations such as 0.0 D sphere with +6.0 D cylinder or +6.0 D sphere with –6.0 D cylinder exceed these limits and therefore lie outside the recommended application range. Other clinically relevant examples include –2.0 D sphere with –5.5 D cylinder (borderline but permissible) versus +5.0 D sphere with +5.0 D cylinder (exceeding the defined range). When evaluating the applicable ranges, it is essential not to rely on the spherical equivalent as a composite measure. Instead, the spherical and cylindrical components must be analysed independently, with each parameter assessed against its respective tolerance limits to ensure an accurate and clinically meaningful determination of applicability.

The recommendations for refractive surgery also recognize that borderline cases inevitably occur. In such scenarios, candidacy cannot be determined solely by the magnitude of the refractive error. Instead, it requires a more nuanced assessment that integrates additional anatomical and technological parameters, including corneal thickness, the anticipated ablation depth, and the performance characteristics of the laser platform employed.

From a biomechanical standpoint, the critical determinant of postoperative safety is not simply the residual stromal bed thickness, but the overall ablation volume in relation to the corneal architecture. Particular caution is warranted in the presence of risk factors such as high astigmatic components, irregular corneal geometry, or a history of chronic eye rubbing, all of which are strongly associated with an increased risk of postoperative ectasia.

In summary, the defined ranges represent the core safety zone for refractive surgery. However, cases at or beyond these margins require individualized decision-making, balancing corneal anatomy, tissue preservation, and laser technology to ensure both efficacy and long-term biomechanical stability.

The zone of application refers to the range within which a given procedure is considered appropriate according to these recommendations. In this zone, the intervention can be expected to achieve reliable and predictable outcomes, and the incidence of adverse events is low. Application within this range is regarded as consistent with current standards of care, provided that the customary requirements for informed consent are fulfilled. This includes comprehensive disclosure of the procedure's nature, benefits, risks, alternatives, and realistic outcome expectations in accordance with established medical and ethical principles.

The zone of limited application designates the range in which the respective procedure may still be performed; however, outcomes are typically less predictable and are associated with a higher frequency or severity of side effects and complications. Although treatment in this zone is not categorically contraindicated, it requires careful case selection and a particularly stringent risk–benefit assessment. In this context, enhanced informed consent standards apply. Patients must be explicitly informed about the comparatively reduced efficacy, the increased likelihood of adverse effects, and any specific uncertainties related to the intervention in this extended range.

Outside both the zone of application and the zone of limited application, the use of the respective procedure is not recommended. Should a procedure nevertheless be performed beyond the recommended zone of limited application, the informed consent process must explicitly state that the intervention is being undertaken outside the recommended range. (German Society of Ophthalmology and German Professional Association of Ophthalmology, 2024) (German Society of Ophthalmology & German Professional Association of Ophthalmologists, 2024)

5.6 Definitions of outcomes

Procedures in refractive surgery are commonly evaluated using efficacy, predictability, stability, and safety as the primary outcome measures.(Koch, 1995) These parameters provide a standardized framework for comparing surgical techniques and assessing clinical performance.

Efficacy

Efficacy is defined as the proportion of treated eyes achieving an uncorrected distance visual acuity (UDVA) of 20/20 or better, and in some reports also 20/40 or better.(Koch, 1995)

Predictability

Predictability describes the accuracy of the refractive outcome in relation to the intended correction. It is traditionally expressed as the mean, standard deviation, and range of postoperative spherical equivalent, as well as the percentage of eyes within ±1.00 D and ±0.50 D of the intended postoperative refraction.(Koch, 1995)

Stability

Stability refers to the maintenance of refractive outcomes over time. It is generally measured as the change in manifest refraction spherical equivalent (MRSE) of ≥1.00 D within a given follow-up interval, with a minimum recommended interval of 6 months.(Koch, 1995) Stability is often further categorized into short-term stability (≤1 year) and long-term stability (>1 year).

Safety

Safety is primarily defined as the proportion of eyes losing two or more lines of CDVA on the Snellen chart.(Koch, 1995)

6 General recommendations for refractive surgery procedures

This chapter serves as a foundational and introduction guide, offering overreaching recommendations applicable to cornea and lens-based procedures in general. Within this chapter, essential principles for decision-making in the refractive surgery care pathway are provided. For more detailed and procedure-specific insights, readers are directed to corresponding chapters where recommendations specific to each refractive surgery technique are presented.

6.1 General limitations of application

General indications for refractive surgery procedures include a stable refraction (lower than 0.5 diopter (D) change over one year), which lies within the specific limits of application for the procedures of interest.(German Society of Ophthalmology & German Professional Association of Ophthalmologists, 2024) The specific limits of application for each procedure can be found in the procedure-specific chapters.

Please be aware that while it is up to the certified clinician's judgement considering all risk factors and patient characteristics whether to apply a certain refractive surgery technique in a patient, the absolute limit of each laser platform is defined by the laser's IFU (Instructions ForUse). In certain patients, general limits can be discussed and adjusted if recorded in the patients' files after considering all relevant factors. Deviations from recommendations need to be motivated and recorded in the patient chart.

<u>Limits of application for cornea-based procedures:</u>

- Low to moderate myopia. High myopia (higher than -6 D) can be corrected but specific precautions must be taken into account, such as characteristics of the cornea and other (ocular) comorbidities, to ensure safety and effectiveness in correcting high myopia through cornea-based procedures.
- PRK, LASIK and KLEx are indicated to correct low to moderate hyperopia.
- Low to high astigmatism can be corrected. Cyclotorsion compensation and perfect alignment is required in case of a cylindrical component of higher than 1.5D.

The laser-platform specific conditions are described in the instructions for use for each device. The surgeon is recommended to follow these instructions. (GRADE +)

Limits of application for lens-based procedures:

- Low to high myopia
- Low to high hyperopia
- Low to high astigmatism

Company product specific conditions are summarized in the instructions for use for each product. The surgeon needs to follow these instructions. Special care is needed in case of high ametropia regarding accuracy of IOL calculation and the impact on quality of vision. (GRADE +)

6.2 Risk factors and contraindications

6.2.1 Systemic Risk Factors

Output question

What are possible surgical recommendations for patients with systemic diseases?

P: Patients who are suitable for refractive surgery and undergo preoperative assessment.
I: Risk Factor A is taken into consideration
C: Risk Factor A is not taken into consideration
O: Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Risk factors:

- Metabolic diseases
- Dermatological disorders (e.g., Keloid scarring)
- Autoimmune disorders (e.g., Rheumatic disorders, Connective tissue disorders)
- Healing disorders
- Diabetes mellitus

Recommendation

In cases with uncontrolled systemic diseases, performing refractive surgery is contraindicated. In stable cases, refractive surgery may be considered after evaluating the contraindications for the specific procedure. (GRADE +)

In case of cornea-based surgery, special attention has to be given to diabetes and collagen vascular diseases, such as rheumatoid arthritis or dermatological conditions such as psoriasis, eczema, lichen planus, Ehlers Danlos syndrome or fibromyalgia, which may influence recovery or lead to neuropathic pain. (GRADE +)

Refractive surgery should be avoided during pregnancy and breast feeding. (GRADE +)

Considerations

When evaluating candidates for refractive surgery, the identification of systemic and ocular comorbidities that may compromise surgical safety or outcomes is of paramount importance. Careful preoperative screening allows the clinician to determine whether a patient’s systemic condition constitutes an absolute or relative

contraindication to surgery, thereby guiding clinical decision-making and minimizing the risk of complications.(Kim et al., 2019)

Dermatological disorders.
Patients with dermatological conditions such as keloid formation, which are characterized by excessive fibrous scarring, have been the subject of concern due to their predisposition for abnormal wound healing. However, clinical evidence suggests that laser refractive procedures, including photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK), do not lead to significant corneal scarring in these individuals. Thus, the presence of dermatological keloids is not considered a contraindication for refractive surgery. (Bower & Woreta, 2014)

Uncontrolled systemic disease.
The presence of an uncontrolled systemic disease is regarded as an absolute contraindication to refractive surgery, as active systemic pathology can adversely affect both intraoperative stability and postoperative wound healing. Conversely, in patients with stable systemic disease, surgical intervention may be contemplated provided that the risks are thoroughly discussed with the patient. Representative conditions include collagen vascular diseases (e.g., Sjögren's syndrome, rheumatoid arthritis, systemic lupus erythematosus, vasculitis, relapsing polychondritis, and seronegative spondyloarthropathies), in which impaired healing and ocular surface involvement may complicate surgical outcomes.(AlKharashi et al., 2014)

Autoimmune and immunodeficiency disorders.
Autoimmune diseases constitute a relative contraindication to refractive surgery because of the potential for impaired epithelial recovery, persistent ocular surface inflammation, and delayed wound healing. Similarly, patients with immunodeficiency disorders such as HIV infection require individualized assessment. In the absence of immunosuppression, refractive surgery may be cautiously considered, but in the presence of immunosuppression the procedure is absolutely contraindicated owing to the heightened risk of infection and impaired tissue repair. (Bower & Woreta, 2014; Kim et al., 2019)

Metabolic diseases.
Metabolic disorders may adversely influence wound healing and ocular tissue homeostasis, thereby increasing the risk of suboptimal visual outcomes. The degree of risk depends on the specific metabolic condition and its degree of control. In particular, endocrine disorders affecting hormonal balance and metabolic regulation may contribute to corneal instability or abnormal healing responses. These conditions should therefore be carefully evaluated, and surgical intervention should be deferred in cases of metabolic instability.(Bower & Woreta, 2014)

Healing disorders.
Any systemic condition associated with impaired wound healing represents a

potential contraindication to corneal refractive surgery. Disorders that interfere with collagen synthesis, angiogenesis, or epithelial regeneration may result in delayed epithelial closure, persistent corneal haze, or stromal irregularities. Such patients should be considered high-risk, and surgical candidacy must be weighed against the likelihood of poor healing responses.

Diabetes mellitus.
Diabetes mellitus warrants particular attention due to its well-documented effects on corneal sensitivity, epithelial repair, and susceptibility to infection. While refractive surgery may be undertaken in patients with stable glycaemic control, poorly controlled diabetes constitutes a contraindication due to the increased likelihood of delayed epithelial healing, recurrent erosions, and postoperative infections. Preoperative evaluation should include an assessment of systemic glycaemic control, and patient counseling must emphasize the potential for slower recovery and increased complication rates. (AlKharashi et al., 2014; Bower & Woreta, 2014)

Pregnancy and lactation.
Refractive surgery is contraindicated during pregnancy and lactation, as hormonal fluctuations may lead to corneal biomechanical instability, refractive unpredictability, and altered wound healing responses. Additionally, concerns regarding the safety of perioperative medications during pregnancy and breastfeeding further reinforce this restriction. (Bower & Woreta, 2014; Ortega-Usobiaga et al., 2023)

Conclusion

Implications for practice
In summary, systemic conditions must be carefully assessed prior to refractive surgery, as certain diseases constitute absolute contraindications, while others may be regarded as relative contraindications depending on disease activity and stability. Relative contraindications include collagen vascular disorders, autoimmune and immunodeficiency conditions, metabolic and healing disorders, and diabetes mellitus under stable control. Absolute contraindications comprise uncontrolled systemic disease, immunosuppression in the context of HIV, uncontrolled diabetes, and refractive surgery during pregnancy or lactation

Knowledge gaps
Current evidence regarding refractive surgery in patients with systemic disease remains limited, and further clinical research is required to establish more precise risk stratification recommendations.

Identified research evidence

Findings from Systematic Reviews

There were no systematic reviews included.

Findings from additional studies

There was one additional study included.

A literature review evaluated the contraindications for laser refractive surgery (including LASIK and PRK). Ocular contraindications to LRS include unstable refractive error, corneal ectatic disorders, a history of herpetic keratitis, Avellino corneal dystrophy, significant cataract, and uncontrolled glaucoma. LRS should also be avoided in uncontrolled diabetes, collagen vascular disease (CVD), pregnancy, and in patients taking amiodarone and isotretinoin.(Bower & Woreta, 2014)

6.2.2 Ocular Risk Factors

Output question

What ocular risk factors or comorbidities must be taken into consideration before surgery?

P: Patients who are suitable for refractive surgery and undergo preoperative assessment.
I: Risk Factor A is taken into consideration
C: Risk Factor A is not taken into consideration
O: Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Risk factors:

- Ocular surface disease (active herpetic disease, DED)
- Corneal comorbidities
- Irregular astigmatism
- Retinal comorbidities (diabetic retinopathy, AMD)
- Other ocular comorbidities (amblyopia, strabismus, monocular eye, active inflammation, anatomical limitation)

Recommendation

In cases with uncontrolled ocular pathologies, performing refractive surgery is contraindicated. In stable cases, refractive surgery may be considered after taking into account the contraindications for the specific procedure. (GRADE +)

Corneal comorbidities, particularly dry eye disease (DED), Meibomian gland disease (MGD), herpes simplex or herpes zoster infection, and Fuchs corneal dystrophy are to be considered as risk factors for cornea-based surgeries requiring specific management. (GRADE +)

Considerations

The preoperative evaluation of candidates for refractive surgery must include a systematic assessment of ocular comorbidities that may negatively influence surgical safety, refractive predictability, and long-term outcomes. A number of ocular disorders are regarded as relative contraindications, while others are considered absolute depending on their severity, progression, and interaction with the corneal healing response.

Relative ophthalmological contraindications.
Ocular conditions such as amblyopia, monocularity, preoperative visual acuity below 0.25 Snellen, pre-existing glaucoma, a history of uveitis, irregular astigmatism, and various retinal abnormalities represent relative contraindications. These conditions do not invariably preclude surgery but significantly increase the risk of poor visual outcomes. Progressive retinal diseases—including diabetic retinopathy and age-related macular degeneration—substantially compromise refractive predictability. Likewise, a history of retinal detachment or the presence of central retinal atrophy is associated with a heightened risk of postoperative complications and reduced visual potential. (Nederlands Gezelschap Voor Refractie Chirurgie (NGRC), 2018)

Keratoconus and corneal ectatic disorders.
Keratoconus and other ectatic corneal disorders pose a major risk in keratorefractive surgery due to the risk of biomechanical destabilization and progression of ectasia. As such, these patients are generally excluded from corneal laser procedures. In carefully selected cases, alternative intraocular solutions such as phakic intraocular lenses (IOLs) or refractive lens exchange (RLE) may be considered. Nevertheless, these procedures require thorough preoperative counseling, as patients must be informed about the inherent limitations and the potential for disease progression irrespective of surgical intervention. (Bower & Woreta, 2014)

Corneal surface disease and ocular inflammation.
Patients with pre-existing ocular surface disease, including severe keratitis sicca, chronic blepharitis, or other eyelid inflammations, are at elevated risk for impaired postoperative recovery. In addition, conditions such as neurotrophic keratopathy, corneal scars, and corneal vascularization are relevant contraindications for corneal refractive surgery. Special attention must also be paid to patients with a history of herpetic keratitis, as keratorefractive procedures may trigger viral reactivation. Such risks necessitate careful screening and detailed patient education prior to surgery. (German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020)

Corneal biomechanics and morphology.
Abnormal corneal geometry is an independent risk factor in refractive surgery. Corneas that are excessively steep or flat, exhibit abnormal topographic patterns, or demonstrate significant irregular astigmatism are prone to biomechanical instability and poor optical outcomes. In such cases, keratorefractive procedures are not recommended, as the likelihood of inducing secondary ectasia or compromising visual quality outweighs potential benefits. (American Academy of Ophthalmology, 2017)

Dry eye disease.
Dry eye disease (DED) represents one of the most prevalent comorbidities encountered in refractive surgery candidates and is associated with both worsened

preoperative symptoms and increased postoperative morbidity. The disruption of corneal innervation following laser procedures frequently exacerbates pre-existing dryness, leading to visual fluctuations and patient dissatisfaction. (Zhao et al., 2021) Preoperative optimization with artificial tear supplementation, anti-inflammatory therapy, and management of meibomian gland dysfunction has been shown to reduce postoperative complications. Regular re-evaluation and long-term follow-up are crucial, as untreated DED can impair both healing and refractive predictability. In selected cases, intraocular approaches such as phakic IOL implantation or RLE may provide safer alternatives by preserving ocular surface integrity.

Conclusion

Implications for practice

A broad range of ocular comorbidities must be accounted for when selecting candidates for refractive surgery. Relative contraindications include amblyopia, monocularity, glaucoma, uveitis, irregular astigmatism, and retinal abnormalities, while progressive retinal disease and corneal ectatic disorders generally represent exclusion criteria. Ocular surface diseases, corneal scars, vascularization, and prior herpetic keratitis require particular caution due to their impact on healing and long-term outcomes.

Knowledge gaps

Despite the clinical significance of ocular risk factors, the current evidence base remains incomplete. Further studies are required to clarify the long-term outcomes of refractive surgery in patients with specific comorbidities, particularly progressive retinal diseases, ectatic corneal disorders, and ocular surface disease. Given the high prevalence of dry eye disease among refractive candidates, additional research is particularly warranted to develop standardized protocols for risk stratification, preoperative optimization, and postoperative management.

Identified research evidence

Findings from Systematic Reviews

There were no systematic reviews included.

Findings from additional studies

There were multiple additional studies included.

6.2.3 Patients with Dry Eye Disease

Output question

How to address patients with DED who are considering refractive surgery? Is there a specific management for DED patients prior to refractive surgery?

P: Patients with DED who are considering refractive surgery and undergo preoperative assessment
I: Performing specific preoperative diagnostics
C: Not performing specific preoperative diagnostics
O: Visual acuity, visual function, (serious) adverse events, postoperative refractive outcome

Recommendation

The tear film, tear production and ocular surface should be evaluated in patients who are considering refractive surgery, since this is one of the relative contra-indications. (GRADE +)

All patients should undergo a thorough slitlamp examination, including dye-tests (?), to assess for ocular surface diseases prior to refractive surgery, with particular attention to those presenting with dry eye symptoms. Both functional symptoms and objective findings should be evaluated. As many asymptomatic patients may reveal ocular surface dysfunction postoperatively, special caution is needed in cases of poorly controlled dry eye syndrome. (GRADE +)

Tear film can be assessed by measuring the tear film break up time (TBUT), performing Schirmer's test with topical anesthesia, evaluating the lid margins and the Meibomian glands (including gland expression), conducting meibography, and, if available assessing tear osmolarity to quantify the severity of ocular surface disease. (GRADE +)

Considerations

Dry eye disease (DED) is a highly prevalent ocular surface disorder, with reported prevalence rates ranging from 5% to 50% depending on study design, diagnostic criteria, and geographic or ethnic population. It is a multifactorial condition characterized by disturbances of the tear film and ocular surface, leading to ocular discomfort, fluctuating vision, and—in severe cases—corneal damage. Ethnic variations in presentation have been described: for example, Asian populations demonstrate a higher incidence of incomplete blinking and lid wiper epitheliopathy compared to Caucasians, even in pediatric cohorts. (Wang & Craig, 2019)

Assessment methods.

DED symptoms and signs can be objectively assessed with a range of clinical tests. Commonly employed diagnostic modalities include measurement of tear film breakup time, Schirmer testing for tear production, corneal sensitivity testing, and ocular surface staining to detect epithelial compromise. These tools provide valuable information for risk stratification prior to refractive surgery and should form part of the routine preoperative evaluation. (Wang & Craig, 2019)

DED in refractive surgery.

Following refractive procedures, symptoms of ocular dryness are common and are reported by the majority of patients in the early postoperative phase. Although these complaints are typically transient and improve with time, they may persist in a subset of individuals and contribute to dissatisfaction with surgical outcomes. Careful identification of ocular surface abnormalities and tear film dysfunction prior to surgery has been shown to improve both safety and predictability. (Bower et al., 2015)

Comparisons across surgical techniques.

The literature demonstrates discrepancies regarding the relative impact of different refractive procedures on the development and persistence of dry eye symptoms. No clear long-term superiority of one surgical method has been established with respect to either subjective symptom burden or objective clinical parameters. Some early postoperative studies suggest that procedures such as small incision lenticule extraction (SMILE), laser epithelial keratomileusis (LASEK), lenticule extraction (KLEx), and photorefractive keratectomy (PRK) may be associated with a lower incidence of DED symptoms compared to LASIK. However, long-term follow-up studies indicate that differences between techniques diminish over time and are not clinically significant. (Cai et al., 2017; Sambhi et al., 2020; Shen, Zhu, et al., 2016)

Conclusion

Implications for practice

In summary, dry eye disease (DED) represents one of the most critical ocular surface disorders to identify in candidates for refractive surgery, given its high prevalence and significant impact on both surgical predictability and patient satisfaction. Preoperative diagnosis through standardized assessments, including tear film stability testing, Schirmer testing, and ocular surface staining, is essential to ensure accurate baseline measurements and to minimize postoperative complications. Equally important, appropriate management of pre-existing DED or other ocular surface abnormalities must be undertaken prior to surgery, as optimization of the ocular environment has been shown to improve both visual outcomes and patient-reported satisfaction. A structured approach that integrates early detection with targeted preoperative treatment therefore constitutes best clinical practice for enhancing the safety, predictability, and long-term success of refractive surgery.

Knowledge gaps

Despite its high prevalence, important knowledge gaps remain regarding the long-term impact of pre-existing DED on refractive surgery outcomes. Additional research is warranted to optimize preoperative screening strategies, develop standardized treatment protocols, and further evaluate the comparative effects of different refractive techniques on ocular surface health.

Identified research evidence

Findings from Systematic Reviews

There were four relevant systematic reviews identified.

A pooled analysis of three methodologically comparable studies examined ethnic differences in the natural history of dry eye disease (DED). Incomplete blinking was the earliest detectable difference between Asian and Caucasian populations, while lid wiper epitheliopathy appeared first in Asian children, potentially reflecting greater eyelid tension. In young Asian adults, meibomian gland dropout preceded broader abnormalities, whereas differences in gland function, tear osmolarity, tear-film stability, symptoms, and DED diagnosis became apparent by middle age. Corneal and conjunctival staining differed mainly in older adults, and DED in Asian populations appeared predominantly evaporative and associated with refractive surgery and contact lens use (Wang & Craig, 2019). Risk of bias assessment: high risk of bias.

Compared with femtosecond laser-assisted in situ keratomileusis (FS-LASIK), small-incision lenticule extraction (SMILE) was associated with lower Ocular Surface Disease Index scores and longer tear-film break-up time at one and three months. Schirmer test results did not differ significantly between procedures. Corneal sensitivity was higher after SMILE during the first three postoperative months but was comparable by six months. Overall, SMILE appeared to permit faster ocular surface recovery than FS-LASIK (Cai et al., 2017). Risk of bias assessment: high risk of bias.

SMILE and FS-LASIK showed comparable safety, visual acuity, postoperative spherical equivalent, and refractive predictability. Sensitivity analysis suggested a possible advantage of FS-LASIK in achieving 20/20 uncorrected visual acuity. Early reductions in tear production and tear-film stability occurred after both procedures but were greater after FS-LASIK, while corneal sensitivity remained higher after SMILE. The reported six-month OSDI findings were internally inconsistent regarding the direction of symptom severity (Shen, Zhu, et al., 2016). Risk of bias assessment: low risk of bias.

A meta-analysis compared long-term tear-film outcomes after SMILE, LASIK, photorefractive keratectomy, and femtosecond lenticule extraction. Tear-film break-up time decreased significantly after LASIK and FLEX but not after SMILE or PRK. Schirmer test values changed significantly after LASIK but not after SMILE or FLEX. Because several effect estimates were interpreted inconsistently across the

manuscript, the findings should be considered cautiously (Sambhi et al., 2020). Risk of bias assessment: high risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

SMILE compared to FS-LASIK in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FS-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FS-LASIK	Risk difference with SMILE
Ocular Surface Disease Index (OSDI) follow-up: 3 months	199 (2 observational studies)	⊕◯◯◯ Very low[a,b]	-	The mean ocular Surface Disease Index was **20.6**	MD **5.67 lower** (6.77 lower to 4.57 lower)
Tear film break-up time (TBUT) follow-up: 3 months	523 (5 observational studies)	⊕◯◯◯ Very low[a,b]	-	The mean tear film break-up time was **5.67**	MD **0.66 higher** (0.36 higher to 0.96 higher)
Schirmer Test follow-up: 3 months	433 (4 observational studies)	⊕◯◯◯ Very low[a,b]	-	The mean 45chirmer Test was **18.2**	MD **0.83 higher** (0.4 lower to 2.06 higher)

SMILE compared to FS-LASIK in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FS-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FS-LASIK	Risk difference with SMILE
Corneal sensitivity follow-up: 3 months	444 (5 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean corneal sensitivity was **36.1**	MD **15.39 higher** (9.43 higher to 21.35 higher)
Corneal Hysteresis/Corneal Resistance Factor	(10 observational studies)	⊕◯◯◯ Very low[a,c,d,e]	-	Inestimable	Hedges' g **0.407 SE higher** (0.003 higher to 0.812 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **SE:** standard error

GRADE Working Group grades of evidence
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. High or very high risk of bias of the included studies.
b. Small sample size
c. Significant statistical heterogeneity detected.
d. Wide confidence intervals around the effect estimate
e. Observational evidence pooled together with experimental studies
References:

Cai WT, Liu QY, Ren CD, Wei QQ, Liu JL, Wang QY, Du YR, He MM, Yu J. Dry eye and corneal sensitivity after small incision lenticule extraction and femtosecond laser-assisted in situ keratomileusis: a Meta-analysis. Int J Ophthalmol. 2017 Apr 18;10(4):632-638
Guo H, Hosseini-Moghaddam SM, Hodge W. Corneal biomechanical properties after SMILE versus FLEX, LASIK, LASEK, or PRK: a systematic review and meta-analysis. BMC Ophthalmol. 2019 Aug 1;19(1):167.

SMILE compared to LASEK/PRK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASEK/PRK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASEK/PRK	Risk difference with SMILE
Corneal Hysteresis/Corneal Resistance Factor	370 (4 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	Hedges' g **0.256 lower** (0.67 lower to 0.16 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval

GRADE Working Group grades of evidence
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. All studies were observational at a high risk of bias
b. Significant statistical heterogeneity detected
c. Results from observational studies pooled together with RCTs
d. Small sample size

Reference: Guo H, Hosseini-Moghaddam SM, Hodge W. Corneal biomechanical properties after SMILE versus FLEX, LASIK, LASEK, or PRK: a systematic review and meta-analysis. BMC Ophthalmol. 2019 Aug 1;19(1):167

SMILE compared to FLEX for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FLEX

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FLEX	Risk difference with SMILE
Corneal Hysteresis/Corneal Resistance Factor	176 (3 RCTs)	⊕◯◯◯ Very low[a,b,c,d]	-	Inestimable	Hedges' g **0.005 lower** (0.309 lower to 0.298 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval

GRADE Working Group grades of evidence
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. One of the pooled studies was of cross-sectional design (high risk of bias)
b. Significant statistical heterogeneity detected.
c. Results from observational studies pooled together with RCTs
d. Small sample size
Reference: Guo H, Hosseini-Moghaddam SM, Hodge W. Corneal biomechanical properties after SMILE versus FLEX, LASIK, LASEK, or PRK: a systematic review and meta-analysis. BMC Ophthalmol. 2019 Aug 1;19(1):167

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Corneal Hysteresis/Corneal Resistance Factor	115 (2 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	Inestimable	Hedges' g **1.306 higher** (0.53 higher to 2.07 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Observational studies at a high risk of bias
b. Significant statistical heterogeneity detected.
c. Small sample size
Reference: Guo H, Hosseini-Moghaddam SM, Hodge W. Corneal biomechanical properties after SMILE versus FLEX, LASIK, LASEK, or PRK: a systematic review and meta-analysis. BMC Ophthalmol. 2019 Aug 1;19(1):167.

LASIK compared to LASEK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: LASIK
Comparison: LASEK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASEK	Risk difference with LASIK
Schirmer test (mm/5 min) follow-up: 12 months	80 (1 observational study)	⊕◯◯◯ Very low[a,b]	-	The mean 50chirmer test (mm/5 min) was **22.5**	MD **1.2 lower** (4.63 lower to 2.23 higher)
Dry Eye Workshop Severity Scale follow-up: 12 months	80 (1 observational study)	⊕◯◯◯ Very low[a,b]	-	The mean dry Eye Workshop Severity Scale was **0.50**	MD **0.26 lower** (0.56 lower to 0.04 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference

GRADE Working Group grades of evidence
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Very high risk of bias in this observational study
b. Very small sample size
Reference: Dooley I, D'Arcy F, O'Keefe M. Comparison of dry-eye disease severity after laser in situ keratomileusis and laser-assisted subepithelial keratectomy. J Cataract Refract Surg. 2012 Jun;38(6):1058-64.

6.2.4 Contraindications for refractive surgery procedures

What are the contraindications for refractive surgery procedures?

General contraindications for cornea-based procedures

Absolute contraindications:

- Uncontrolled systemic diseases: auto-immune disorders, connective tissue diseases, diabetes
- Unstable, uncontrolled or advanced stage of certain ocular diseases (such as glaucoma, inflammatory ocular diseases, and retinal progressive pathologies)
- Presence of progressive cataract
- Presence of progressive corneal diseases and thinning disorders or abnormal corneal topography (forme fruste keratoconus)
- Pregnant or nursing women

Relative contraindications:

- Age lower than 18 years old
- Functional monocularity
- Unstable refraction (higher than 0.5D change over one year) (exceptions might include unstable refraction for certain professional groups (e.g., policemen, military personnel, in certain countries)
- Specific corneal characteristics:
    - Corneal thickness lower than 500 micrometers (µm)
    - Excessively steep corneas (higher than 46D) for moderate to high hyperopic treatments or excessively flat corneas (lower than 38D) for moderate to high myopic treatments
    - Abnormal corneal topography
    - Corneal dystrophies
- History of herpes simplex or herpes zoster keratitis
- History of uveitis
- Pregnant or nursing women
- Uncontrolled ocular surface disease
- Unrealistic patient expectation

Concerning the relative contraindications for corneal procedures it must be mentioned that the risk for ectasia does not exclusively rely on the residual stromal thickness but is among others highly dependent on the patients' age, preoperative pachymetry, corneal topography, the percentage of tissue and viscoelasticity altered, the

percentage of stromal subtraction as well as the amount of refractive error to be corrected. (GRADE +)

The clinical refractive range of indications depends on features of the individual patient: morphology of the cornea, pupil size that will influence the limits and therefore the specific refractive indications. (GRADE +)

General contraindications for lens-based procedures

Absolute contraindications:

- Uncontrolled systemic diseases: auto-immune disorders, connective tissue diseases, diabetes
- Unstable or advanced stage of certain ocular diseases: glaucoma, retinal detachment or macular degeneration
- Active ocular inflammation

Relative contraindications:

- Unstable or untreated external eye diseases
- Unstable refraction (higher than 0.5D change over one year) (only true for phakic IOLS, not for RLE)
- Severe and uncontrolled dry eye disease (DED)
- Unrealistic patient expectations
- Presence of progressive cataract (when considering phakic IOL implantation, not true for RLE)

The procedure-specific indications and contraindications can be found in the procedure-specific chapters.

6.3 Preoperative assessment

6.3.1 Shared informed consent

Output question
How should shared consent be obtained in patients who want to undergo refractive surgery? What information should be given to patients prior to surgery and how detailed should this information be?

P: Patients who are suitable for refractive surgery and undergo preoperative patient education
I: Patients receive detailed information about the procedure and possible complications.
C: Patients receive a limited amount of patient information
O: Quality of life

Recommendation

Proper screening of the patients as well as setting realistic expectations is mandatory prior to refractive surgery. (GRADE +)

Patients should be informed about the course of the procedure, possible complications, alternatives to the procedure, occurrence of aging of the lens leading to presbyopia in the fourties, postoperative treatment as well as postoperative desired behavior. (GRADE +)

Informed consent might be achieved in multiple formats (verbal discussion, videos, written form), but depending on the country's legal requirements a written consent may be mandatory. The patient should receive a reflection period after receiving all information before signing informed consent. (GRADE +)

The patient and ophthalmologist should take the shared decision for surgery and be well-documented in the patient's medical records. (GRADE +)

Preoperative informed consent must be achieved by an ophthalmologist and should be documented. (GRADE +)

The informed consent should minimally include:
- Indication and limits of the procedure
- Detailed description of the process of the procedure
- Potential risk factors

- Preoperative assessment
- Potential adverse events and serious adverse events
- Mid- and long-term expected outcomes
- Postoperative desired behavior
- Postoperative medications
- In specific cases: possibility of intraoperative change of surgical method
- Alternative surgical and non-surgical methods to achieve the desired goal

In cases where elevated risk factors are present, the informed consent process must be conducted with particular rigor. Patients should be provided with a more extensive discussion of the specific risks relevant to their individual condition, ensuring that both common and less frequent complications are clearly addressed. In addition to the verbal explanation, these risk factors must also be explicitly documented and presented in written form within the informed consent document, thereby reinforcing patient understanding and supporting ethical and legal standards of care.

Considerations

In elective procedures such as keratorefractive surgery, the provision of detailed and comprehensible information is essential. Most patients seek these interventions to reduce dependence on spectacles or contact lenses, making it necessary to explore their personal motivations and expectations in depth. The discussion must include the theoretical possibilities and limitations of the available surgical techniques as well as nonsurgical alternatives. The final indication for surgery must be established by an ophthalmologist.

Educational tools, such as instructional videos or web-based modules, may provide a general overview of the procedure and potential complications. However, they cannot replace direct, face-to-face counseling by the operating surgeon, which remains mandatory. Written informed consent must always follow a personal consultation with the ophthalmologist. (Schallhorn et al., 2018) Delegation of this process to other healthcare professionals is not permissible. Patients must never sign a consent form before their questions have been addressed in person. Sufficient time should be allowed between the provision of information, the signing of consent, and the day of surgery to enable reflection and informed decision-making. (German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020)

When elevated risk factors are present, the informed consent process requires particular rigor. In such cases, patients must be provided with a more extensive explanation tailored to their specific risk profile, including both common and less frequent complications. These individualized risks must be explicitly documented and

clearly outlined in the written consent form, reinforcing patient understanding and supporting the ethical and legal standards of care.

The decision to undergo keratorefractive surgery and the choice of technique should be based on shared decision-making between patient and surgeon. Patient-specific factors, desired outcomes, and potential risks of each procedure must be clearly discussed. Possible complications must be explained before consent is obtained. In addition to a signed form, documentation of the discussion in the medical record, including patient-specific information, is required. The surgeon must explicitly verify that the patient has understood the planned procedure and provide a signed and dated copy of the consent form. (Ophthalmic Mutual Insurance Company (OMIC), [accessed 25.3.23])

Finally, the potential negative influence of advertising must be considered. Marketing elective refractive procedures as risk-free or guaranteed in outcome creates unrealistic expectations and exposes providers to medicolegal risk in the event of complications. Ethical advertising should therefore emphasize realistic outcomes and acknowledge the possibility of complications to preserve transparency and patient trust.

Conclusion

Implications for practice

Informed consent is a fundamental component of keratorefractive surgery and must be regarded as a structured process rather than a mere formality. It ensures that patients receive accurate, comprehensive, and individualized information about indications, limitations, alternatives, and potential complications of the procedure. In clinical practice, the process should always include discussion of the surgical indication, available alternatives, preoperative assessments, postoperative care, and possible complications. Adequate time must be provided between the delivery of information, the signing of consent, and the intervention itself, to allow for reflection and informed decision-making.

In patients with elevated risk factors, informed consent must be conducted with particular rigor. Such patients require individualized counseling with explicit discussion of both common and less frequent complications. These risks must be carefully documented and clearly stated in the written consent form to ensure patient comprehension and to provide medicolegal protection.

The process must remain the sole responsibility of the operating surgeon, cannot be delegated, and must be documented in detail, including patient-specific notes in the medical record. A signed and dated copy of the consent form should always be given to the patient. Telecommunication tools may be employed as supportive elements but cannot replace direct surgeon–patient interaction. Taken together, this approach

safeguards ethical and legal standards, enhances patient autonomy, and reinforces trust in the surgical process.

Knowledge gaps

Evidence on the integration of telecommunication and digital education into the informed consent process remains limited. Further studies are required to assess their safety, validity, and patient acceptance as adjuncts to conventional face-to-face discussions. Particular attention should be given to patients with elevated risk factors, in whom more extensive counseling and documentation are essential. Future research should also explore whether digital tools can improve patient understanding, support shared decision-making, and reduce medicolegal disputes while preserving the interpersonal surgeon–patient relationship.

Identified research evidence

Findings from Systematic Reviews

There was one systematic review identified.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

Video consultation compared to conventional consultation for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: video consultation
Comparison: conventional consultation

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with conventional consultation	Risk difference with video consultation
Knowledge Scale from: 0 to 25	113 (1 RCT)	⊕◯◯◯ Very low[a,b,c]	-	not pooled	not pooled
Satisfaction	113 (1 RCT)	⊕◯◯◯ Very low[a,b,c]	**RR 0.99** (0.83 to 1.18)	818 per 1,000	**8 fewer per 1,000** (139 fewer to 147 more)
Time with surgeon	113 (1 RCT)	⊕◯◯◯ Very low[a,b,c]	-	The mean time with surgeon was **30**	MD **5 lower** (5.59 lower to 4.41 lower)
Anxiety	113 (1 RCT)	⊕◯◯◯ Very low[a,b,c]	-	The median anxiety was **8**	median **9 higher** (0 to 0)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Video consultation compared to conventional consultation for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: video consultation
Comparison: conventional consultation

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with conventional consultation	Risk difference with video consultation

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. High risk of bias of the included study
b. Clinical and methodological heterogeneity in terms of population, intervention, comparator and outcome measures.
c. Small sample size, results from a single study
Reference: Baenninger PB, Faes L, Kaufmann C, Reichmuth V, Bachmann LM, Thiel MA. Efficiency of video-presented information about excimer laser treatment on ametropic patients' knowledge and satisfaction with the informed consent process. J Cataract Refract Surg. 2018 Dec;44(12):1426-1430

6.3.2 Preoperative assessment in patients receiving refractive surgery

Output question

What has to be included in the preoperative check-up?

P: Patients who are suitable for refractive surgery and undergo preoperative assessment
I: Patients receive assessment A
C: Patients receive assessment B
O: Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Recommendation

Patient selection via a preoperative assessment of the patients' expectations, risk factors and medical history must be performed during a preoperative check-up. (GRADE +)

A patient's stable refraction must be ensured prior to surgery. (GRADE +)

The following preoperative assessments should be considered:

Mandatory assessment	Optional assessment

- Testing of uncorrected and corrected visual acuity - Refraction: autorefraction, manifest (if necessary following elimination of accommodation (in the case of hyperopia, elimination of accommodation is mandatory when determining subjective refraction in patients aged under 45 years)) - Cycloplegic refraction (mandatory for all pre-presbyopic patients) - Intraocular pressure - Slit lamp assessment - Pupil diameter measurement (most importantly mesopic pupil diameter) - Examination of the anterior and posterior eye segments after drug-induced mydriasis - Biometry (in case of intraocular procedure) - Corneal topography and/or tomography (Placido, Scheimpflug, OCT, etc.) - Pachymetry - Tear film assessment - Medical history assessment, medications, allergy to medication, ophthalmic family history - Gonioscopy (in case of specific iris configurations, pIOL implantation in high hyperopia) - In the case of pIOLs (additionally mandatory assessments): o Anterior OCT/ UBM o Specular microscopy - In the case of anisometropia: measurement of aniseikonia and determination of the patient's tolerance of the planned correction by means of contact lens-wearing test.	- Anterior and posterior OCT - Ultrasound Biomicroscopy - Biomechanical assessment - Epithelial thickness mapping - Specular microscopy (mandatory in phakic IOLs,, optional in cornea-based procedures) - Aberrometry - Quality of vision (halos, glare, blurred vision, fluctuations in vision, dysphotopsia) - Contrast sensitivity - Orthoptic status - Contact lens trial - Monovision testing - Defocus curves - Reading speed - Halometry - Questionnaires and PROMS - Ocular surface assessment: - Questionnaire - Schirmers test Ia/Ib/II - OCT (epithelial mapping) / topography - OSI index / DLI index - Meibography

On indication of suspicious cases, additional glaucoma or retinal assessment must be performed. (GRADE +)

Considerations

Preoperative assessment is a critical component of patient selection for keratorefractive surgery. Its primary role is to identify patient-specific risk factors, determine suitability for a particular surgical technique, and ensure that the chosen procedure aligns with the patient's expectations and visual needs. A thorough preoperative evaluation also allows clinicians to exclude patients who are not appropriate candidates for refractive surgery, thereby preventing poor outcomes and reducing the likelihood of postoperative dissatisfaction.

Beyond eligibility screening, preoperative assessment enables the evaluation of whether a patient's desired visual outcomes can realistically be achieved through surgery. It also identifies the precautions or adjunctive measures that may be necessary to minimize the risk of adverse events. Patient selection must therefore be conducted with caution and attention to detail. Unrealistic expectations must be identified and addressed, and the degree of refractive correction should be carefully discussed. Importantly, patients must be counseled that complete spectacle independence is not always possible, and that certain ocular conditions may limit the predictability of postoperative visual acuity.

Preoperative evaluation must also encompass both clinical and psychological aspects of the patient. Clinically, a history of refractive stability should be documented, as unstable refraction is a contraindication to surgery. Age is another key determinant: most refractive procedures are approved for individuals over 18 years of age, but younger patients with unstable refractive errors remain at increased risk for regression or complications. Conversely, older patients who also present with presbyopia may be better suited to alternative surgical strategies, such as monovision correction. From a psychological perspective, assessing the patient's motivations, expectations, and understanding of surgical limitations is essential in order to avoid postoperative dissatisfaction.

Additional factors, including a patient's profession and daily activities, must also be considered during the selection process. Occupational visual demands, tolerance for potential side effects such as glare or halos, and lifestyle requirements should guide the choice of procedure. Once a patient has been appropriately selected and matched to a specific technique, the preoperative assessment provides the necessary baseline information to optimize surgical planning and maximize the likelihood of achieving favorable postoperative outcomes. This preoperative assessment can be split up into mandatarory and optional preopartive assessments.

<u>Mandatory preoperative assessment</u>

- **Visual acuity** (distance, intermediate, near)

Both uncorrected and corrected visual acuities must be systematically evaluated during the preoperative assessment. Depending on the patient's age and clinical profile, testing should include near, intermediate, and distance vision to establish realistic postoperative expectations for spectacle independence. Particular caution is required in presbyopic patients, as correction across multiple focal ranges must be carefully considered when planning the surgical approach (German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020).

- **Refraction**
  A manifest refraction must always be performed and should be verified against a cycloplegic refraction to exclude accommodative influence. Cycloplegic refraction is mandatory in myopic patients and in hyperopic patients with presbyopia, and it is also recommended when determining subjective refraction in individuals younger than 45 years. Comparing manifest and cycloplegic results is essential to avoid overcorrection in myopia and to detect latent hyperopia. Surgical correction should only be undertaken in cases of stable refraction, generally defined as no more than a ±0.5 diopter (D) change within the preceding 1–2 years. Reliance solely on autorefraction (AR) is contraindicated in preoperative evaluation (German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020).

- **IOP**
  Intraocular pressure (IOP) measurement is an essential part of the preoperative assessment to exclude ocular hypertension and detect undiagnosed glaucoma. Elevated IOP not only represents a risk factor for glaucomatous optic neuropathy but may also influence postoperative outcomes, particularly in procedures that alter corneal biomechanics and complicate future tonometric measurements. In patients with glaucoma suspicion—such as those with elevated IOP, optic disc cupping, or a positive family history—further evaluation is mandatory. This includes a detailed funduscopic assessment of the optic nerve head and retinal nerve fiber layer, as well as posterior segment OCT to detect early structural damage. Establishing baseline IOP values and optic nerve status prior to refractive surgery is crucial, as surgical corneal alterations may mask or delay the detection of glaucoma progression (German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020).

- **Corneal topography/ Corneal tomography/ Pachymetry**
  Anterior corneal surface imaging is a mandatory element of the preoperative assessment, as it enables detection of both regular and irregular astigmatism, as well as corneal comorbidities such as scarring. Corneal tomography provides a more comprehensive evaluation by assessing both the anterior and posterior corneal surfaces, in addition to generating corneal thickness maps (pachymetry).

Available technologies include Scheimpflug-based devices and anterior segment OCT, both of which offer high-resolution analysis of corneal shape and thickness. Beyond astigmatism assessment, corneal tomography plays a pivotal role in screening for ectatic disorders. It allows for early identification of keratoconus, pellucid marginal degeneration, and other subclinical abnormalities that may predispose to postoperative corneal ectasia. Detecting these conditions prior to surgery is critical, as they represent absolute or relative contraindications for keratorefractive procedures.("[Evaluation and quality assurance of refractive surgical interventions by the DOG and the BVA - recommendations of the Committee of Refractive Surgery - Status June 2022]," 2023)

- **Biometry**
  Biometric measurements represent a critical component of the preoperative assessment for intraocular refractive procedures. Parameters such as anterior chamber depth, axial length, and keratometric values must be obtained prior to implantation of phakic intraocular lenses (pIOLs) or refractive lens exchange (RLE). Accurate determination of these values is essential not only for precise intraocular lens power calculation but also for ensuring adequate anterior chamber dimensions to prevent postoperative complications such as angle crowding or endothelial cell loss. Keratometry further contributes to the evaluation of corneal curvature, which is fundamental for the selection and customization of intraocular lens design. In corneal refractive surgery, however, biometry is not routinely required, as correction is achieved through direct modification of corneal curvature rather than implantation of an intraocular device. Nevertheless, biometry may provide valuable additional information in complex cases, particularly in patients with atypical ocular anatomy or when long-term refractive stability must be carefully anticipated ("[Evaluation and quality assurance of refractive surgical interventions by the DOG and the BVA - recommendations of the Committee of Refractive Surgery - Status June 2022]," 2023).

- **Medical history**
  A thorough medical history is indispensable in the preoperative assessment, as systemic diseases may significantly influence both surgical outcomes and postoperative recovery. Patients with systemic conditions that compromise visual acuity or wound healing must be counseled regarding the potential for a reduced visual prognosis after surgery. Particular attention should be given to diabetes mellitus, autoimmune diseases, and collagen vascular disorders, as these are associated with impaired epithelial repair, chronic inflammation, and increased risk of postoperative complications. A history of keloid formation should also be considered, as it may indicate a predisposition to abnormal fibrotic responses. Pregnancy and nursing are of special concern, as hormonal changes during these periods can lead to unstable refractive error, altered tear film quality, and impaired healing capacity. Uncontrolled diabetes, in particular, may result in fluctuating refraction, delayed epithelial closure, and neurotrophic alterations that

further compromise surgical success. In addition, a history of allergies should be systematically evaluated, as ocular or systemic hypersensitivity reactions may exacerbate postoperative inflammation or dry eye symptoms. Comprehensive identification of these conditions allows for appropriate risk stratification, patient counseling, and, when necessary, deferral of surgery until systemic factors are stabilized (Expert opinion).

- **Ocular history**
  Both chronic and acute ocular diseases must be carefully evaluated during the preoperative assessment, as they can directly influence surgical safety and visual outcomes. Conditions such as ocular herpes or keratitis are of particular concern, as surgical trauma or postoperative inflammation may reactivate latent infections, leading to corneal scarring or visual loss. Retinal disorders, including diabetic retinopathy and age-related macular degeneration, as well as glaucomatous optic neuropathy, may limit postoperative visual acuity regardless of successful refractive correction. Patients with a history of strabismus may exhibit altered binocular vision or postoperative diplopia, necessitating detailed orthoptic evaluation. Furthermore, the presence of anisometropia or aniseikonia should be identified, as these conditions may affect binocular balance and visual comfort after surgery. It is equally important to address unrealistic expectations in patients with preexisting ocular pathology, as their risk of suboptimal results and complications is significantly higher. A complete history of prior ocular surgeries, including refractive, corneal, or retinal interventions, must be obtained to assess corneal integrity, residual tissue thickness, and the potential for adverse outcomes. Careful identification of these risk factors, combined with thorough patient counseling, is essential to ensure realistic prognostication and to minimize adverse events during and after surgery (Expert opinion).

- **Medication**
  A comprehensive list of all medications taken regularly must be obtained during the preoperative evaluation, as several systemic and topical agents can significantly influence surgical outcomes. Drugs that impair wound healing, such as systemic corticosteroids or immunosuppressants, increase the risk of delayed epithelial recovery and postoperative complications. Anticoagulant or antiplatelet therapy may elevate the risk of intraoperative or postoperative bleeding, requiring careful perioperative management. Additionally, medications known to exacerbate ocular surface disease, such as antihistamines, antidepressants, or isotretinoin, can aggravate dry eye symptoms and negatively affect both patient comfort and visual quality after refractive surgery. The identification and discussion of these risk factors with the patient are essential to optimize ocular surface health, minimize postoperative complications, and tailor the perioperative management plan to the individual’s medical profile.(Patasova et al., 2021)

- **Social history**

Excessive alcohol consumption and cigarette smoking are important risk factors that can negatively influence wound healing and postoperative outcomes after refractive surgery. Smoking, in particular, has been linked to delayed epithelial recovery, reduced tear film stability, and increased infection risk. In addition, a patient's occupation and daily activities must be carefully considered to ensure that surgical outcomes align with functional visual needs. Individuals engaged in high-risk activities such as contact sports, military service, or security work may not be suitable candidates for LASIK due to the elevated risk of flap dislocation, making alternative procedures such as surface ablation or KLEX more appropriate.(Upaphong et al., 2022)

- **Slit lamp assessment (Anterior segment assessment)**
  A comprehensive slit lamp examination is essential before refractive surgery. Evaluation of the eyelids and meibomian gland function is critical, as meibomian gland dysfunction is a major contributor to ocular surface disease. In patients with symptoms of dry eye, pretreatment with lubricants or other therapies is mandatory to optimize ocular surface health. Careful inspection of the anterior segment, particularly the cornea, is required to exclude preexisting pathologies such as scars, dystrophies, or degenerations, which may compromise surgical outcomes.(Chuck et al., 2018)

- **Funduscopic assessment**
  A dilated fundus examination must be performed to assess the posterior segment prior to surgery. This is particularly important in highly myopic patients, in whom the risk of peripheral retinal tears, holes, or lattice degeneration is increased. Retinal pathologies, macular disorders, and optic nerve abnormalities must be excluded to ensure accurate prognostication of postoperative visual outcomes.(Chuck et al., 2018)

- **Tear film assessment**
  Pre-existing dry eye disease (DED) is a significant risk factor for worsening symptoms following refractive surgery. Patients identified with DED during the preoperative assessment must receive immediate treatment, which may include tear substitutes, punctal plugs, or topical immunomodulators such as cyclosporine, alongside detailed counseling regarding prognosis. Severe DED represents a contraindication for corneal refractive procedures, and in such cases, ongoing follow-up and reassessment are mandatory.

  Tear film evaluation should address both quality and quantity. Tear film stability is commonly assessed with tear breakup time (TBUT) or non-invasive TBUT (NIBUT), while tear production is measured with Schirmer testing. Additional diagnostic methods include ocular surface staining, lipid layer analysis using slit-lamp specular reflection, optical quality analysis (OQAS II), osmolarity testing,

epithelial mapping with anterior OCT, and meibography to visualize meibomian gland structure.

Available Diagnostic Tools:

- Symptom questionnaires
- Dye tests / TBUT / Slit-lamp evaluation
- Schirmer tests Ia/Ib/II
- OCT epithelial mapping / corneal topography
- OSI index
- Tear film osmolarity
- Meibography

- **Pupil diameter measurement**
  Assessment of mesopic pupil diameter is an essential component of the preoperative evaluation for keratorefractive surgery. This measurement, typically performed with an infrared pupillometer, provides reliable and reproducible data on pupil size under low-light conditions, which closely approximate the patient's everyday visual environment. Pupil size plays a decisive role in visual quality after surgery, as larger mesopic pupils increase the likelihood of postoperative photic phenomena, including glare, halos, starbursts, and reduced contrast sensitivity. These disturbances are particularly pronounced when the pupil diameter exceeds the optical zone created by the ablation profile. Accurate preoperative measurement of mesopic pupil size therefore enables surgeons to anticipate potential complications, optimize the ablation zone, and tailor surgical planning to minimize unwanted visual side effects. (Mathôt, 2018)

- **Gonioscopy**
  Gonioscopy should be performed prior to refractive surgery in hyperopic patients, patients with a family history of glaucoma, those with pigment dispersion syndrome (PDS), or when considering phakic intraocular lenses (p-IOLs) to assess the anterior chamber drainage angle and identify risks of angle-closure glaucoma or pigmentary glaucoma. While ideally recommended for all patients, it is most crucial for these high-risk groups to prevent serious complications after surgery.(Kodali et al., 2024)

Mandatory in the cases of pIOLs

- **Specular microscopy (Endothelial cell count)**
  Specular microscopy is a non-invasive imaging modality that enables high-resolution visualization and quantitative assessment of the corneal endothelium, playing a critical role in the diagnosis and monitoring of endothelial pathologies. Its use is particularly important in keratorefractive procedures, phakic intraocular lens (IOL) implantation, and multifocal IOL surgery, where endothelial integrity is

essential for long-term corneal clarity and surgical safety (Kaur & Gurnani, 2023). The corneal endothelium possesses minimal regenerative capacity, meaning that cellular injury or loss is largely irreversible. Consequently, endothelial damage may lead to progressive cell loss, compensatory cell enlargement, polymegathism, and pleomorphism, which together compromise endothelial function and can result in corneal decompensation. Physiologically, endothelial cell density (ECD) ranges between 4000 and 5000 cells/mm² at birth and undergoes a steady decline with age, emphasizing the importance of establishing baseline values in surgical candidates (Islam et al., 2017).

- **Anterior and posterior OCT**
  Optical coherence tomography (OCT) is an indispensable imaging modality in the preoperative evaluation of refractive surgery candidates, providing high-resolution cross-sectional images of both the anterior and posterior ocular structures. Anterior OCT enables detailed analysis of the corneal architecture, including epithelial and stromal thickness profiles, and is essential for accurate keratometric measurements and the detection of early corneal pathologies. In the context of phakic intraocular lens (IOL) implantation, anterior OCT is mandatory to assess anterior chamber depth and angle configuration, thereby ensuring appropriate lens sizing and minimizing postoperative complications. Posterior OCT, although optional in corneal refractive procedures, is strongly recommended in intraocular surgery because it facilitates comprehensive evaluation of the retina and optic nerve (Asam et al., 2019). This includes the detection of macular dystrophies, age-related macular degeneration, sequelae of retinal detachment, retinal atrophy or scarring, and diabetic retinopathy, all of which may compromise postoperative visual outcomes if left unidentified. Furthermore, posterior OCT is a critical tool in glaucoma assessment, allowing precise analysis of the optic nerve head and retinal nerve fiber layer. Thus, anterior and posterior OCT collectively play a pivotal role in ruling out contraindications, tailoring surgical planning, and safeguarding long-term visual prognosis in refractive and intraocular surgery.

- **Ultrasound biomicroscopy**
  Ultrasound biomicroscopy (UBM) provides high-resolution, non-invasive in vivo imaging of the anterior ocular segment, enabling detailed visualization of structures such as the cornea, anterior chamber, iris, ciliary body, and lens zonules (He et al., 2012). This modality is particularly valuable for assessing anterior chamber anatomy in patients considered for phakic intraocular lens (IOL) implantation, where it is mandatory to ensure adequate chamber depth, angle configuration, and lens–endothelium distance. UBM also facilitates the detection of subtle anatomical abnormalities that may contraindicate phakic IOL placement or increase the risk of postoperative complications. While indispensable for phakic IOL planning, UBM remains optional in other refractive surgery procedures, where its utility is more limited. Nonetheless, in selected cases, UBM

can provide important supplementary information for surgical decision-making, particularly in patients with atypical anterior segment morphology.

Mandatory in the case of anisometropia

- **Measurement of aniseikonia**
  Aniseikonia is a binocular visual disorder defined by a discrepancy in the perceived size or shape of images between the two eyes, most often caused by anisometropia (*optical aniseikonia*) or macular changes such as edema or distortion (*retinal aniseikonia*). In children, untreated cases may lead to amblyopia, while in adults it can produce asthenopia, headaches, diplopia, dizziness, imbalance, nausea, spectacle intolerance, suppression of binocular vision, and disturbed spatial perception. Although the eikonometer is the most accurate diagnostic tool, it is rarely available in clinical practice; practical alternatives include dissociation tests that estimate interocular differences in size and shape. Because of its varied causes and significant impact on visual function, the evaluation and management of aniseikonia require an interprofessional approach, with ophthalmologists, optometrists, and orthoptists collaborating to tailor treatment strategies such as optical correction or surgical intervention to the individual patient.(Stokkermans & Day, 2025)

- **Determination of the patient´s tolerance of the planned correction/ Contact lens-wearing trial (monovision testing)**
  In patients with presbyopia and underlying anisometropia, contact lens trials represent a valuable tool for preoperative evaluation. By simulating monovision correction—assigning one eye for distance and the other for near vision—these trials allow patients to experience the functional implications of this strategy before committing to permanent refractive surgery. This approach facilitates shared decision-making, ensures realistic expectation management, and reduces the risk of postoperative dissatisfaction, making it an essential adjunct in the assessment of surgical candidacy (Expert opinion).

Preoperative assessments on indication

- **Quality of vision**
  The evaluation of quality of vision is an important adjunct to preoperative assessment, as it helps align surgical outcomes with patient expectations. This assessment may include the analysis of higher-order aberrations (HOAs) that contribute to visual disturbances such as glare, halos, and difficulties with night vision or night driving. Additional parameters, including contrast sensitivity, stereopsis, and color and light sensitivity, provide a more comprehensive

understanding of the patient's subjective visual experience. Incorporating these measures ensures a patient-centered approach and facilitates realistic counseling regarding postoperative outcomes (German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020).

- **Biomechanical assessment**
  A thorough understanding of corneal biomechanical properties is critical for excimer laser refractive surgery, corneal collagen crosslinking, and the early detection of ectatic corneal diseases (De Stefano & Dupps, 2017). Assessments of corneal viscoelasticity, although considered optional, may provide valuable adjunctive information in preoperative planning for corneal refractive procedures (Ambrósio et al., 2016; De Stefano & Dupps, 2017).

- **Aberrometry (corneal/ internal)**
  Aberrometry provides a detailed evaluation of the optical properties of the eye by quantifying monochromatic aberrations across the entire dioptric system, including both the anterior and posterior corneal surfaces as well as the crystalline lens. This technique, particularly when performed with wavefront analysis, is critical for identifying higher-order aberrations (HOAs) that are not correctable with standard spectacles or contact lenses. HOAs such as glare, halos, and reduced contrast sensitivity can profoundly affect visual quality, especially under mesopic conditions, and are therefore highly relevant in the context of refractive surgery. Incorporating aberrometry into the preoperative assessment enables the detection of subtle optical imperfections, facilitates individualized surgical planning, and supports realistic counseling regarding postoperative outcomes (Marcos, 2006).

- **Contrast sensitivity**
  Assessment of contrast sensitivity provides valuable insight into visual quality beyond conventional visual acuity measurements. This test evaluates the eye's ability to discern objects against varying levels of contrast, which is particularly relevant for daily activities such as night driving or reading in dim light. Various methods are available, including the Hamilton-Veale Contrast Sensitivity Test and the Mars Letter Contrast Sensitivity Test, both of which allow subjective evaluation. In addition, objective testing can be performed with devices such as the Optical Path Difference (OPD) analyzer, which measures contrast sensitivity under standardized conditions. Incorporating contrast sensitivity testing into the preoperative workup can help identify subtle visual impairments that may influence surgical planning and postoperative expectations.(Jindra & Zemon, 1989)

- **Orthoptic status**
  Evaluation of orthoptic status is essential for detecting binocular vision anomalies

and ocular motility disorders. Patients with strabismus or significant anisometropia, particularly greater than 4 diopters, require careful assessment to avoid unexpected postoperative visual disturbances, such as diplopia or suppression. Preoperative orthoptic evaluation ensures that binocular function is stable and helps to identify patients at risk for compromised visual outcomes. This assessment is therefore a critical component of the preoperative examination in selected cases (Expert opinion).(Sabetti et al., 2020)

- **Contact lens trial (monovision testing)**
  Contact lens trials are frequently employed in patients with presbyopia or anisometropia to evaluate the suitability of monovision correction before refractive surgery. By temporarily wearing lenses that simulate the expected surgical outcome, patients can experience the visual effect and determine whether it aligns with their needs, a practice particularly useful in refractive lens exchange where intraocular lenses replace the natural crystalline lens. To ensure reliable preoperative measurements, contact lenses must be discontinued for an appropriate period prior to evaluation, as prolonged wear can induce corneal warpage, distort corneal topography, and compromise surgical planning. Such corneal instability may lead to inaccurate assessments and, consequently, suboptimal surgical outcomes.(Lloyd-McKernan et al., 2017)

- **Epithelial thickness mapping**
  The corneal epithelial thickness profile is intrinsically asymmetric, being thinner superiorly than inferiorly and temporally than nasally. This nonuniformity reflects a predictable compensatory response to stromal curvature gradients, modulated by the eyelid as an external template. Such remodeling provides valuable diagnostic markers for early keratoconus, postoperative ectasia monitoring, and risk assessment before additional hyperopic correction. In irregular astigmatism, epithelial changes may mask stromal irregularities, making epithelial mapping essential for diagnosis and for planning trans-epithelial PRK. The profile can also be altered by conditions such as dry eye, anterior basement membrane dystrophy, and eyelid ptosis, all of which should be considered in clinical evaluation.(Reinstein, Archer, et al., 2022)

- **Defocus curve**
  A defocus curve, obtained during preoperative assessment, quantifies visual acuity under controlled levels of induced blur by introducing trial lenses of varying dioptric power at a fixed testing distance. This method provides a detailed profile of a patient’s functional vision across distance, intermediate, and near ranges, thereby characterizing both the degree and distribution of presbyopia. By simulating different focal conditions, the defocus curve not only reveals the patient’s unaided visual performance but also serves as a predictive tool for postoperative outcomes with refractive procedures and presbyopia-correcting

intraocular lenses (IOLs), including multifocal and extended depth-of-focus designs.(Kohnen et al., 2022)

- **Reading speed**
  Preoperative reading speed is a functional parameter that reflects the impact of visual disorders such as cataracts, strabismus, or uncorrected refractive errors. Depending on the severity of these conditions, patients may demonstrate normal performance or significantly reduced rates, particularly when confronted with small print or suboptimal lighting. Reading speed is objectively quantified in words per minute (wpm) using standardized charts, with lower values indicating functional visual compromise. Its assessment prior to refractive surgery establishes a baseline of visual efficiency and identifies limitations that surgical correction is intended to improve.(Brar et al., 2021)

- **Halometry**
  Although not part of the standard preoperative assessment, halometry or glare testing can be applied to evaluate visual performance under simulated glare conditions, providing valuable information on a patient's risk of experiencing postoperative halos or glare. These assessments are particularly relevant in individuals with large scotopic pupils or a history of prior ocular surgery. Equally essential is detailed corneal imaging with topography and pachymetry, which permits characterization of previous ablation patterns, quantification of corneal higher-order aberrations, and detection of pathological changes such as keratoconus. Together, these evaluations play a critical role in optimizing patient selection, guiding surgical planning, and predicting visual outcomes following refractive surgery.(Buckhurst et al., 2015)

- **Questionaires and PROMS**
  Validated questionnaires and patient-reported outcome measures (PROMs) are used before refractive surgery to capture the subjective impact of vision on daily life, complementing objective measures such as visual acuity. They provide insights into visual quality, spectacle dependence, ocular comfort, emotional wellbeing, and overall satisfaction, thereby supporting informed consent, aligning expectations, and guiding surgical planning. Postoperatively, PROMs serve as standardized tools to evaluate patient satisfaction and quality-of-life improvements. Common instruments include the Vision Correction Questionnaire (VCQ), which assesses dependence on spectacles, visual quality, and emotional wellbeing, and the Refractive Status and Vision Profile (RSVP), which evaluates symptoms such as glare, functional limitations, and driving performance.(Braithwaite et al., 2019)

- **Ocular surface assessment**
  Ocular surface assessment is an essential component of the preoperative evaluation for refractive surgery, combining subjective and objective measures to

identify tear film and surface abnormalities. Symptom questionnaires such as the Ocular Surface Disease Index (OSDI) provide standardized patient-reported data, while diagnostic tests—including Schirmer's test for tear production, tear breakup time (TBUT) for tear film stability, ocular surface staining for epithelial integrity, and meibography for meibomian gland morphology—offer complementary objective findings. Advanced imaging modalities, such as high-definition anterior segment imaging, further enhance the ability to detect structural changes. Together, these tools enable comprehensive characterization of ocular surface health, ensuring accurate risk stratification and optimization of outcomes following refractive surgery.(Karaca et al., 2019)

Conclusion

Implications for practice

A comprehensive preoperative assessment, encompassing the full range of diagnostic examinations described above, is essential for selecting appropriate surgical options and minimizing the risk of unexpected postoperative outcomes. Ensuring stable refraction and systematically excluding ocular comorbidities are fundamental prerequisites for achieving reliable results. Moreover, preoperative evaluation provides the foundation for tailoring the surgical procedure to the individual patient's anatomical, functional, and psychological characteristics, thereby enhancing both safety and patient satisfaction.

Knowledge gaps

Despite significant advances, important gaps remain in the evidence base. The impact of systemic and ocular comorbidities—such as autoimmune disease, diabetes, pregnancy, and a history of keloid formation—on keratorefractive outcomes is insufficiently studied, limiting the accuracy of preoperative counseling in such cases. Similarly, the role of higher-order aberration (HOA) assessment in optimizing surgical planning requires further investigation, particularly regarding its predictive value for visual quality after surgery. In addition, dry eye disease (DED) continues to pose a major challenge; more research is needed to elucidate its effect on refractive outcomes and to establish effective preventive strategies for mitigating postoperative DED symptoms.

Identified research evidence

Findings from Systematic Reviews

There were no relevant systematic reviews identified.

Findings from additional studies

There were multiple additional studies included.

6.4 Postoperative management

6.4.1 Postoperative care

Which standard operating procedure should be applied in time (i.e., when) and in which way (i.e., how) to a patient who has undergone a refractive surgery procedure?

Check-up appointments should be continued until the operated eye has reached a stable situation. (GRADE +)

Patients should seek help if they experience a decrease in vision following an initial improvement, increased pain, sensitivity to light, foreign body sensation or redness, and/or the sudden onset of black dots or flashing lights. (GRADE +)

After surgery, patients should adhere to medical guidance to prevent infection, including avoiding exposure to dust, trauma, tap water, and swimming pools. To promote proper healing, they should also refrain from rubbing the eye, engaging in contact sports, heavy lifting, and using eye make-up until recovery is complete—typically within 1 to 2 weeks, depending on the procedure. Patients must also wait for legal clearance before resuming driving. (GRADE +)

<u>Cornea-based procedures</u>
Patients are instructed to follow a strict eye drop regimen after corneal laser procedures, including antibiotics, corticosteroids and for specific indications NSAIDs. The specific regimen may differ depending on the procedure (Surface ablation, LASIK, or KLEx). In general, the following drops are used: antibiotics, corticosteroids, lubricants. Antibiotic drops are used during the early postoperative period. NSAIDs can be applied in the early postoperative period for pain management, but prolonged use should be avoided as it may impair wound healing, especially in epithelium off procedures. Additionally, low-grade topical corticosteroids are recommended after epithelial regrowth for wound healing modulation. Furthermore, artificial tears are often prescribed to lubricate the eye after surgery. (GRADE+)

A check-up during the first week after surgery is recommended to confirm epithelial healing assess stability and evaluate interface transparency in cases of lamellar surgery. (GRADE +)

Oral NSAIDs or analgesics can reduce postoperative pain as well as a bandage contact lens which is commonly used during the first days. However, patients should be monitored for an increased risk of infection with the bandage contact lens. (GRADE +).

Postoperative follow-up visits should include assessment of the corrected and uncorrected visual acuity, including refraction assessment, keratometry, corneal topography or tomography, and slit lamp examination. Optional assessments include tonometry, funduscopic exam, specular microscopy, meibography, epithelial mapping, and optical coherence tomography (posterior segment). (GRADE +)

Patients should inform their surgeon of any prior corneal refractive surgery when developing cataracts, as this requires special attention during IOL power calculation. Additionally, younger patients who have undergone refractive surgery will eventually develop age-related presbyopia and require near-vision glasses. (GRADE +)

Lens-based procedures

Following pIOL implantation, a check-up on the day of surgery or during the first postoperative day is recommended to assess the intraocular pressure (IOP) and the inflammation status of the eye. (GRADE +)

Following RLE a follow-up visit should be considered between 1 week and 2 weeks after surgery. (GRADE +)

Postoperative follow-up should include assessment of uncorrected and corrected visual acuity, refraction, intraocular pressure, slit-lamp examination (with attention to anterior chamber depth, IOL centration, and pupil reactivity), and a funduscopic examination. In patients with pIOLs, additional evaluations should include gonioscopy, measurement of the pIOL vault, and specular microscopy. An annual check-up is mandatory after pIOL implantation. Corneal topography or tomography may be performed as optional assessment. (GRADE +)

During the early postoperative period following lens-based procedures, antibiotic eye drops, corticosteroid drops, and lubricants should be applied after RLE and pIOL implantation. NSAID drops can be considered after pIOL implantation. Antibiotics can also be applied intraoperatively and can be omitted postoperatively. (GRADE +)

6.4.2 Postoperative evolution profile

Cornea-based procedures

The complaints during the early postoperative period differ for each procedure:

- Surface ablative procedures (PRK): patients typically may experience pain and discomfort during the first days postoperatively, along with blurry vision. These symptoms diminish gradually as the corneal epithelium heals and visual acuity improves over time. Mild dry eye symptoms can be present during the first weeks to months after surgery.
- Intrastromal refractive procedures (LASIK, KLEx): patients may commonly experience slight discomfort, blurry or fluctuating vision during the first hours or few days; mild dry eyes symptoms can be present for longer period after surgery (weeks to months, especially after LASIK).
- All cornea-based procedures: halos and glare, especially at night, are commonly reported in the first 1 to 3 months following surgery.

Lens-based procedures

After intraocular surgeries patients may experience mild discomfort in the eye (foreign body sensation or grittiness) and blurred vision, which will improve as the eye heals and especially with the recovery of the normal ocular surface.

6.4.3 Complications

What are the most common (serious) adverse events during and after refractive surgery procedures? (Questions [include numbers from big document])

In general, both corneal- and lens-based procedures demonstrate a high safety profile, with a correspondingly low incidence of complications. These complications can be categorized into two main groups: intraoperative and postoperative, based on their time of onset.

It is essential to distinguish objective complications from subjective symptoms. Subjective symptoms may be associated with specific complications or occur independently, even in cases of uncomplicated surgery, and may persist for variable durations. Objective complications refer to measurable clinical findings resulting from deviations from an uneventful intraoperative or postoperative course. In contrast, 'subjective symptoms' are patient-reported and not necessarily indicative of complications.

Patients should be aware that the typical postoperative course may include transient symptoms such as pain, corneal and lid edema, dryness of the eye, and fluctuations in visual acuity. These symptoms are not classified as complications unless they persist beyond three months. True complications, on the other hand, include persistent dry eye, loss in best corrected visual acuity, dysphotopsia, pronounced halos and glare, impaired night vision, and diplopia. It is crucial to counsel patients on the possibility of these complications and their potential impact on postoperative outcomes for each procedure.

Objective complications of cornea-based procedures

Intraoperative complications

Complications that occur during laser-based procedures can be general or technique-specific. The most common include:(Asif et al., 2020; Krueger & Meister, 2018; Sahay et al., 2021; Tse et al., 2016)

- Decentered corrections (Surface ablation procedures, LASIK or KLEx). Decentered corrections may result in suboptimal optical zones, leading to postoperative reduced uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), and overall visual quality. Patients may experience symptoms such as halos and glare or diplopia.

Suction loss (LASIK and KLEx). Loss of suction from the vacuum system that stabilizes the globe-device contact can result in incomplete flap creation or incomplete lenticule, cap, or side-cut formation. This may prevent the procedure from being completed in the same session. Depending on the case, refractive correction can either be completed during the same session or postponed. Subsequent correction may involve the same or an alternative technique.

- Sub-optimal femtosecond laser dissection, as seen in procedures like FS-LASIK and KLEx, can result in issues such as dark spots of non-dissection, opaque bubble layers, or vertical gas breakthrough. These complications may cause difficulties in flap opening or lenticule extraction and, in some cases, prevent the procedure from being completed in the same session. Flap-related complications (LASIK), include inadequate flap cutting, free caps, flap ruptures, or buttonholes, and can occur during the flap creation phase or become evident during manipulation. Such issues may result in suboptimal outcomes and could necessitate additional corrective procedures. In KLEx, abnormal lenticule dissection and extraction may arise due to cap or incision laceration, stromal dissection in the wrong plane, or incomplete lenticule extraction, leaving a remnant portion of the lenticule. These complications can lead to suboptimal visual outcomes and may require further interventions or corrective procedures.

Postoperative complications

Postoperative complications generally manifest at varying intervals after surgery. These complications may be directly linked to intraoperative events, influenced by patient-specific factors or behaviors, or occur independently. While some are common, transient, and cause minimal disruption to quality of life, rarer complications can have a more profound effect, impairing visual function, causing significant symptoms, and negatively impacting overall quality of life. Among the relevant postoperative complications, the following are included:

- Under- or over-Correction: This may occur due to discrepancies between predicted and actual healing after surgery, loss of best corrected distance visual acuity due to intraoperative complications, or from suboptimal stromal tissue ablation during the procedure, unrelated to complications or laser malfunction. It should not be considered a complication unless the residual refractive error is significant in relation to the original refractive state. Evaluation should take place at the end of the wound healing phase before considering refractive enhancement procedures.(Naderi et al., 2018; Taneri et al., 2021)
- Dry Eye Symptoms (Surface Ablation, LASIK, KLEx): These symptoms can vary in severity and duration and are typically caused by transient changes in corneal innervation due to the surgical procedure. Pre-existing ocular conditions may predispose patients to more severe symptoms. (Cohen &

Spierer, 2018) (Asif et al., 2020; Kobashi et al., 2017) (Y. Wang et al., 2017) (Cai et al., 2017; Shen, Zhu, et al., 2016)

- Alterations in Stromal Transparency and Regularity (Surface Ablation, LASIK, KLEx): Excessive wound healing responses, such as persistent stromal haze after PRK, or acute inflammatory factors and infections, can lead to changes in stromal transparency and regularity. (Tomás-Juan et al., 2015) (Chan et al., 2016)
- Infectious keratitis (Surface Ablation, LASIK, KLEx): Most infections occur within a week of the procedure, but sometimes infections might occur even after a month. Infections after LASIK and KLEx occur most frequently, but not exclusively, in the stromal interface. Keratitis after Laser refractive surgery can delay visual recovery. Keratitis might be non-infectious as in diffuse lamellar keratitis or central toxic keratopathy, occurring frequently during the first few days after LASIK and KLEx. Both infectious and non-infectious keratitis occasionally can be induced years after the surgery by an infective or traumatic insult.(Soltani Shahgoli et al., 2023)
- Flap folds: Flap striae or flap folds can be best described as small wrinkles in cornea after LASIK surgery. Flap folds mostly occur due to uneven alignment of the flap edge with the epithelial ring. Microstriae are mostly asymptomatic, while full thickness folds might lead to visual impairment. Bowman's and cap folds or distortions can occur, similarly, after KLEx surgery. In KLEx, microstriae might appear secondary to epitheliopathy, interface debris, and fibrosis at the KLEx incision.(Moshirfar, Santos, et al., 2023) Flap striae can be treated via lifting the flap, removing the remnant epithelium on the surface followed by irrigation. Persistent stria may lead to astigmatism.(Moshirfar, Santos, et al., 2023)
- Epithelial Ingrowth (LASIK, KLEx): In the stromal interface, epithelial ingrowth can lead to irregular astigmatism and a loss of interface transparency, negatively affecting visual quality. If significant symptoms develop, surgical removal of the abnormal epithelial sheet may be required. (Ting et al., 2018) (Asif et al., 2020) (Sahay et al., 2021) (Kamiya et al., 2020)
- Corneal Ectasia (Surface Ablation, LASIK, KLEx): Any corneal subtractive procedure carries the risk of progressive corneal ectasia. This may result from misdiagnosed preoperative corneal abnormalities (e.g., form fruste keratoconus) or excessive weakening of the corneal stroma, which depends on preoperative corneal characteristics (thickness, profile, curvature) and the amount of tissue removed to treat the refractive error. (Giri & Azar, 2017) (Moshirfar et al., 2021) (Krueger & Meister, 2018; Moshirfar et al., 2017)
- Flap dislocation (LASIK) : flap dislocation may occur due to inproper replacing of flap during operative procedure or in the early post-operative period due to mechanical forces. Late traumatic flap dislocations have been described. Dislocated flaps should be rinsed and replaced or sutured.

Objective complications of lens-based procedures

Intraoperative complications

Complications that occur during intraocular procedures can be general or technique-specific. The most common include:(Apple & Werner, 2001; Foster et al., 2021; Lundström et al., 2020; Schallhorn et al., 2019; Stark et al., 1983; Zare et al., 2009)

- Iris damage (pIOL, RLE). Damage to the iris can result in haemorrhages, pupillary irregularities and permanent mydriasis, which influences the visual function and appearance of the patient.
- Posterior capsule rupture with/without vitreous loss (RLE). Posterior capsule rupture can lead to suboptimal visual acuity outcomes, with the presence or absence of vitreous loss playing a significant role in determining the severity and management of the complication. The impact on visual outcomes may vary depending on whether vitreous prolapse occurs and how the rupture is addressed during surgery.
- Dropped nucleus (RLE). Dropped nucleus is a rare complication and might be caused by zonular weakness or by the intraoperative procedure itself and necessitates a posterior vitrectomy. When capsular bag stability is compromised, presbyopic IOLs are no longer suitable and must be replaced with an appropriate monofocal IOL. Patients should be informed of this possibility prior to surgery.

Postoperative complications

Postoperative complications generally manifest at varying intervals after surgery and are different between procedure.

Complications after pIOL implantation

Complications following pIOL implantation can differ depending on the type of IOL used, with iris-fixated, angle-fixated, and posterior chamber IOLs presenting distinct complication profiles. Angle-supported pIOLs have been withdrawn from the market due to concerns regarding accelerated endothelial cell loss, and patients with these implants should be monitored closely. The most important postoperative complications can be subdivided based on the time period they occur: (Kohnen et al., 2010)

- Elevated intraocular pressure. This condition may arise due to several factors, such as pupillary block, inflammation, or the use of viscoelastic materials (OVD) during surgery. Elevated IOP needs to be closely monitored, as it can lead to optic nerve damage and vision loss if left untreated. Early detection and

management are crucial to prevent long-term complications. (Galvis et al., 2017)

- Endothelial cell loss. Damage to the corneal endothelial cells can lead to corneal edema. Anterior chamber IOLs generally but not exclusively induce corneal endothelial cell loss. Symptoms of corneal endothelial cell loss are a cloudy cornea, resulting in decreased visual acuity. (Jonker et al., 2018)
- Cataract formation. The location of the phakic IOL as well as the alteration of the aqueous humor and vault predispose the crystalline lens and the pIOL to come into contact, which might lead to the formation of anterior subcapsular cataract. This is more common but not e(Deshpande et al., 2020)

After pIOL implantation it is mandatory to conduct annual follow-ups for these patients, including specular microscopy for AC pIOLS (not for PC pIOLS). IOP measurement, and intraocular imaging such as anterior segment OCT. Patients must be informed that a pIOL will remain in place only until cataracts develop, or other intraocular changes induced by the pIOL occur.

Complications after RLE

Postoperative complications after RLE are similar to those seen in regular cataract surgery but occur in patients without cataracts. RLE is typically an elective procedure performed in patients with higher refractive errors or presbyopia who seek spectacle independence. These patients may have higher expectations compared to the general cataract population. Important postoperative complications include:

- Retinal detachment. Retinal detachment is a serious complication that can occur after RLE, particularly in patients with risk factors such as high myopia, high axial length, young age (under 50 years) - especially when natural posterior vitreous detachment (PVD) is incomplete - Caucasian ethnicity, and peripheral retinal degeneration. Additionally, Nd:YAG capsulotomy can increase the risk of retinal detachment. Patients with hyperopia generally have a lower risk of retinal detachment, and younger hyperopic patients undergoing RLE tend to face fewer concerns about this complication.(Kook et al., 2008; Nanavaty & Daya, 2012)
- Cystoid Macular Edema (CME). CME involves macular thickening due to a breakdown of the blood-retinal barrier, leading to increased permeability in the perifoveal capillaries and subsequent capillary leakage. This can result in visual impairment, including reduced central vision and visual distortion. Management typically involves topical anti-inflammatory medications, and in some cases, intravitreal injections may be required for severe cases.(Scholl et al., 2010)
- Endophthalmitis. Endophthalmitis is a severe intraocular infection most commonly caused by Staphylococcus epidermidis. This rare but serious condition is associated with factors such as posterior capsule rupture, the need for an anterior vitrectomy, and the use of topical anesthesia. Additional

risk factors include older age and male gender. Prompt treatment with antibiotics and, in some cases, surgical intervention is critical to preventing vision loss.(American Academy of Ophthalmology Preferred Practice Pattern Cataract and Anterior Segment Committee, 2021; Lemley & Han, 2007)

- Posterior capsular opacification. PCO is a common complication after RLE, caused by the migration and proliferation of residual epithelial cells onto the posterior capsule. This leads to opacification, impairing visual clarity and contrast sensitivity. PCO can significantly reduce visual acuity and may require a Nd:YAG capsulotomy to restore vision.(Schallhorn et al., 2019) (Nanavaty & Daya, 2012) PCO tends to occur earlier in younger patients and in those implanted with presbyopic IOLs, where the impact on visual quality is perceived sooner due to capsular fibrosis. However, Nd:YAG capsulotomy should not be performed too early, as this increases the risk of cystoid macular oedema (CME), and should only be considered once PCO is confirmed as the cause of reduced visual outcomes.

7. Corneal Surface Ablative Procedures (PRK/ Trans-PRK)

7.1 Indications and contraindications for corneal surface ablative procedures

Output question
What are the indications and contraindications for corneal surface ablative procedures?

Recommendations

Limits of application PRK and Transepithelial-PRK:

- Myopia lower than 6.0D with or without astigmatism lower than 4.0D. (GRADE +)
- Myopia higher than 6.00D only after further evaluation of risk factors as well as different morphological aspects, corneal tissue, and the optical zone
- Hyperopia lower than 3.00D with or without astigmatism lower than 4.0D. In this group of patients an increased complication risk, including haze development have to be considered. (GRADE +)

These limits of application must consider a minimal preoperative corneal thickness of 480 micrometer (µm) and an adequate residual stromal thickness after ablation. Surgical planning in surface ablation procedures (PRK and transepithelial PRK) should primarily rely on preoperative corneal tomography, epithelial profile assessment when available, and careful estimation of the residual stromal thickness. (GRADE +)

It is mandatory to regard the different laser system approvals (CE-markings) which include the ranges of indication for specific devices.

In cases of higher ametropia, special attention should be given to sufficient corneal thickness according to ablation depth and residual estimated corneal thickness. Additionally, other critical factors such as corneal symmetry, regularity, stability of ametropia, associated cylindrical components, and history of eye rubbing should also be evaluated. (GRADE +)

Considerations

Photorefractive keratectomy (PRK) and transepithelial PRK are generally considered safe and effective procedures within clearly defined refractive limits. Current evidence supports their application in patients with myopia up to approximately –6.00 D and hyperopia up to +3.00 D, typically in combination with astigmatic correction not exceeding 4.00 D. In higher myopic corrections beyond –6.00 D, surgical

planning requires more careful evaluation, taking into account morphological factors such as corneal thickness, symmetry, and the size of the intended optical zone. Similarly, hyperopic treatments are associated with a comparatively increased risk of postoperative complications, particularly corneal haze, which necessitates thorough preoperative counseling.

Across all refractive ranges, corneal safety parameters remain critical determinants of eligibility. A minimal preoperative corneal thickness of 480 µm and a percentage of tissue ablation not exceeding 40% are widely regarded as necessary thresholds to preserve biomechanical integrity. Beyond these metrics, attention must also be directed to the long-term stability of refractive error, the presence of associated cylindrical components, and behavioral factors such as frequent eye rubbing, which may predispose to ectatic complications. Finally, surgeons must adhere to the specific regulatory approvals of the excimer laser platforms employed, since device-dependent variations in indications exist. Taken together, these considerations underscore the importance of individualized patient assessment to balance efficacy with safety in PRK and transepithelial PRK.

Conclusion

Implications for practice

Based on the current available evidence, the decision for a corneal surface ablative procedure should be made in shared consent by patient and surgeon. To guarantee safety and effectiveness, selection criteria must strictly be followed.

Knowledge gaps

Additional research into dissatisfied patients after a corneal surface ablative procedure is necessary to further optimize the selection criteria for these procedures.

Identified research evidence

Findings from Systematic Reviews

There were no relevant systematic reviews identified.

Findings from additional studies

There were multiple additional studies included.

7.2 Efficacy of corneal surface ablative procedures

Output question
What is the efficacy of PRK/Trans-PRK?

P Patients with a refractive error (myopia, hyperopia, and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery.
I Performing corneal surface ablative procedures
C Other procedures:
- Use of spectacles
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O Visual acuity, Visual function, Quality of life, Postoperative refractive outcome, complications, adverse events

Recommendation

Surface ablation is effective for correcting low to moderate myopia (lower than -6.0D) with or without astigmatism (lower than -4.0D). The evidence for surface ablation correcting for high myopia (higher than 6.0D) and astigmatism (higher than -3.0D) is limited. (GRADE +/++)

The evidence considering the efficacy of surface ablation for hyperopia (lower than 3.0D) is limited. (GRADE +)

Surface ablation is comparable to other refractive surgery procedures. Although the evidence is highly heterogenic, no statistically significant differences were found in terms of efficacy between surface ablation and other corneal laser refractive surgery procedures. (GRADE +)

No statistical differences concerning efficacy outcomes could be found between PRK and Trans- PRK. (GRADE +)(Serfözö et al., 2025)

Considerations

Clinical evidence supports the efficacy of photorefractive keratectomy (PRK) and transepithelial PRK (Trans-PRK) for the correction of myopia and myopic astigmatism across a broad dioptric spectrum. In myopic eyes up to –7.00 D, Trans-PRK achieved uncorrected distance visual acuity (UDVA) of 20/20 or better in 94% of cases (95% CI, 0.86–0.97) (Sabau et al., 2021). Long-term outcomes further demonstrate the durability of surface ablation, with a 16-year follow-up study reporting UDVA ≥20/20 in 45% of eyes ranging from –1.25 D to –20.25 D (A. H. Vestergaard et al., 2013). In contrast, the evidence for hyperopic correction using

surface ablation remains sparse, and current data do not permit robust or reliable conclusions (Settas et al., 2012).

Comparative studies indicate that PRK and Trans-PRK provide efficacy equivalent to other surface ablative techniques, including LASEK and epi-LASIK, particularly in moderate myopia (–2.00 D to –6.00 D). Odds ratios for achieving equivalent efficacy include 0.86 (95% CI, 0.58–1.26) for PRK versus LASEK and 1.23 (95% CI, 0.45–3.34) for PRK versus epi-LASIK, with no statistically significant differences observed (Wen et al., 2018). SUCRA rankings for short-term efficacy place LASEK and PRK ahead of epi-LASIK and Trans-PRK (Wen et al., 2018). Broader comparisons that include LASIK, femtosecond LASIK (FS-LASIK), SMILE, and KLEx similarly show no significant differences among procedures, although PRK and related surface techniques generally rank lower in relative efficacy (Wen et al., 2017).

Meta-analysis revealed no significant difference in efficacy between transPRK and PRK, with a pooled estimate of 0.00 (95% CI: −0.32 to 0.33) and reported efficacy values ranging from 25% to 100%. Similarly, no significant difference was observed in the efficacy index (pooled estimate −0.08; 95% CI: −0.32 to 0.17), with values ranging from 0.72 to 1.09.(Serfözö et al., 2025)

Long-term analyses confirm the stability and safety of PRK. A meta-analysis of patients with moderate to high myopia (–2.75 D to –8.00 D) demonstrated a relative risk (RR) of 0.98 (95% CI, 0.92–1.05) for PRK compared with LASEK, again without significant differences (Li et al., 2016). Furthermore, a low-quality but extended follow-up study reported a safety index of 0.97 for PRK, with statistically significant improvements in corrected distance visual acuity (CDVA) between 1 and 20 years postoperatively and no sight-threatening complications. (O'Brart et al., 2014)

Taken together, these findings establish PRK and Trans-PRK as reliable and effective procedures for myopia correction, characterized by long-term stability and a favorable safety profile. However, the heterogeneity of available studies, particularly in terms of follow-up duration and outcome measures, continues to limit the strength of direct comparisons across different refractive techniques. Further high-quality, long-term studies are required to clarify their role relative to alternative procedures and to better define their efficacy in hyperopia.

Conclusion

Implications for practice

Based on the currently available evidence, PRK and Trans-PRK demonstrate efficacy comparable to other established refractive surgery techniques. Nevertheless, these conclusions must be interpreted with caution, as the overall body of evidence remains limited in both quantity and methodological quality.

Moreover, variability in laser platforms, particularly between first- and newer-generation systems, may significantly influence postoperative outcomes and must be taken into account when evaluating efficacy across studies.

Knowledge gaps

Despite encouraging findings, substantial knowledge gaps remain. The existing literature is characterized by considerable heterogeneity, with inconsistencies in study design, outcome measures, and follow-up duration limiting the strength of comparative analyses. Most available data are confined to myopic and astigmatic populations, leaving the efficacy and safety of PRK and Trans-PRK in hyperopic patients largely unexplored. Future high-quality, standardized trials are therefore essential to establish definitive evidence, reduce heterogeneity, and broaden the applicability of these procedures across diverse refractive error profiles.

Identified research evidence

Findings from Systematic Reviews

There were five relevant systematic reviews identified.

A network meta-analysis found no significant differences among PRK, LASEK, epi-LASIK, and transepithelial PRK in achieving 20/20 uncorrected distance visual acuity, refractive accuracy within ±0.50 D, or loss of corrected distance visual acuity. LASEK was associated with slightly less postoperative haze than PRK, while most other haze comparisons were inconclusive. Pain and epithelial healing outcomes varied across isolated comparisons, with PRK associated with greater day-one pain and slower epithelial healing than transepithelial PRK. Based on SUCRA rankings, LASEK performed best overall for efficacy, predictability, safety, and early postoperative pain (Wen et al., 2018). Risk of bias assessment: low risk of bias.

A network meta-analysis comparing corneal refractive procedures found a significant efficacy advantage only for LASIK over LASEK in direct comparisons. Femtosecond LASIK showed superior predictability compared with LASIK, PRK, LASEK, and epi-LASIK, and ranked highest overall for predictability. Combined direct and indirect comparisons showed no significant differences in efficacy or safety between procedures. The principal between-procedure distinction was therefore the greater refractive predictability of femtosecond LASIK (Wen et al., 2017). Risk of bias assessment: low risk of bias.

Low- to very-low-quality evidence showed no meaningful differences between PRK and LASEK in refractive accuracy, uncorrected visual acuity, or loss of best spectacle-corrected visual acuity at 12 months. Adverse-event reporting was limited and inconsistent across studies. Corneal haze outcomes were generally similar, although one trial reported slightly lower haze scores after LASEK at 24 months.

Overall, the evidence did not establish a clinically relevant advantage of either procedure (Li et al., 2016). Risk of bias assessment: low risk of bias.

A systematic review of 16 prospective and retrospective studies evaluated refractive correction of myopic astigmatism across heterogeneous populations and follow-up periods. Pooled efficacy, safety, and predictability rates were 94%, 100%, and 89%, respectively. Vector analysis showed a mean correction index of 1.01, a difference vector of 0.20, and an index of success of 0.12. These findings suggest favourable overall refractive outcomes, although interpretation is limited by methodological heterogeneity and predominantly non-randomised evidence (Sabau et al., 2021). Risk of bias assessment: high risk of bias.

A systematic review comparing PRK with LASIK for hyperopic refractive correction identified no eligible studies. Consequently, no conclusions could be drawn regarding the relative efficacy, stability, or safety of the two procedures. The absence of comparative evidence highlights an important gap in the literature (Settas et al., 2012). Risk of bias assessment: low risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

Laser epithelial keratomileusis (LASEK) compared to photorefractive keratectomy (PRK) for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: Laser epithelial keratomileusis (LASEK)
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with Laser epithelial keratomileusis (LASEK)
UCVA of 20/20 or better at 1 week	244 (4 RCTs)	⊕⊕◯◯ Low[a,b]	**RR 1.26** (0.90 to 1.78)	311 per 1,000	**81 more per 1,000** (31 fewer to 243 more)
UCVA of 20/20 or better at 12 months post treatment	102 (1 RCT)	⊕⊕◯◯ Low[c,d]	**RR 0.98** (0.92 to 1.05)	980 per 1,000	**19 fewer per 1,000**
Proportion of eyes within ± 0.50 D of target refraction at 1 month post treatment	140 (2 RCTs)	⊕⊕◯◯ Low[a,b]	**RR 0.96** (0.77 to 1.19)	714 per 1,000	**29 fewer per 1,000** (164 fewer to 136 more)
Proportion of eyes within ± 0.50 D of target refraction at 12 months post treatment	152 (1 RCT)	⊕⊕◯◯ Low[c,d]	**RR 0.93** (0.84 to 1.03)	934 per 1,000	**65 fewer per 1,000** (149 fewer to 28 more)

Laser epithelial keratomileusis (LASEK) compared to photorefractive keratectomy (PRK) for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: Laser epithelial keratomileusis (LASEK)
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with Laser epithelial keratomileusis (LASEK)
Loss of 1 or more lines of BSCVA at 12 months post treatment	102 (1 RCT)	⊕◯◯◯ Very low[c,e]	**RR 3.00** (0.13 to 71.96)	Inestimable	Inestimable
Mean spherical equivalent at 12 months post treatment	386 (3 RCTs)	⊕⊕◯◯ Low[a,b]	-	The mean spherical equivalent at 12 months post treatment ranged from **-0.2 to 0.1**	MD **0.06 higher** (0.02 lower to 0.14 higher)
Postoperative healing time (days) at 1 week	528 (6 RCTs)	⊕◯◯◯ Very low[a,b,f]	-	The mean postoperative healing time (days) at 1 week ranged from **2.5 to 4.0**	MD **0.34 lower** (0.45 lower to 0.23 lower)
Postoperative pain scores at 1 day	458 (5 RCTs)	⊕◯◯◯ Very low[a,b,f]	-	The mean postoperative pain scores at 1 day ranged from **0.7 to 4.0**	MD **0.08 lower** (0.63 lower to 0.47 higher)

Laser epithelial keratomileusis (LASEK) compared to photorefractive keratectomy (PRK) for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: Laser epithelial keratomileusis (LASEK)
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with Laser epithelial keratomileusis (LASEK)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the pooled studies.
b. Small sample size
c. Clinical and methodological heterogeneity in terms of population, intervention, comparator and outcome measures.
d. Small sample size, results from a single study
e. Small sample size, results from a single study; very wide confidence intervals around the effect estimate.
f. Significant statistical heterogeneity detected.
Reference: Li SM, Zhan S, Li SY, Peng XX, Hu J, Law HA, et al. Laser-assisted subepithelial keratectomy (LASEK) versus photorefractive keratectomy (PRK) for correction of myopia. Cochrane Database Syst Rev. 2016;2(2):CD009799.

LASIK compared to photorefractive keratectomy (PRK) for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: LASIK
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with LASIK
UCVA of 20/20 or better	(9 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 1.35** (0.82 to 2.21)	Inestimable	Inestimable
refractive error within ±0.50 D of the target refraction	(7 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 0.81** (0.57 to 1.15)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(5 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 0.57** (0.17 to 1.83)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I,

Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.

PRK compared to Epi-LASIK for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: PRK
Comparison: Epi-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Epi-LASIK	Risk difference with PRK
UDVA of 20/20 or better	(2 RCTs)	⊕⊕◯◯ Low[a,b]	**OR 1.23** (0.45 to 3.34)	Inestimable	Inestimable
Refractive error within ± 0.50 D of target refraction	(2 RCTs)	⊕⊕◯◯ Low[a,b]	**OR 0.87** (0.30 to 2.47)	Inestimable	Inestimable
Loosing 2 or more lines of CDVA	(1 RCT)	⊕⊕◯◯ Low[c]	**OR 1.00** (0.05 to 17.90)	Inestimable	Inestimable
Postoperative haze grade 0.5 or more	(1 RCT)	⊕⊕◯◯ Low[c]	**OR 2.80** (0.53 to 14.74)	Inestimable	Inestimable
Postoperative haze grade 1.0 or more	(1 RCT)	⊕⊕◯◯ Low[c]	**OR 7.50** (0.73 to 76.77)	Inestimable	Inestimable
Postoperative pain on day 1	(1 RCT)	⊕⊕◯◯ Low[c]	**OR -0.01** (-1.76 to 1.66)	Inestimable	Inestimable
Epithelial healing time	(2 RCTs)	⊕◯◯◯ Very low[a,d]	**OR 0.13** (-1.63 to 1.90)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

PRK compared to Epi-LASIK for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: PRK
Comparison: Epi-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Epi-LASIK	Risk difference with PRK

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Small sample size; wide confidence intervals around the effect estimate.
c. Small sample size, results from a single study; very wide confidence intervals around the effect estimate.
d. Significant statistical heterogeneity detected.

Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, et al. Corneal surface ablation laser refractive surgery for the correction of myopia: a network meta-analysis. J Refract Surg. 2018;34(11):726-35

Excimer Laser compared to Phakic Intraocular Lenses for Myopia and Astigmatism

Patient or population: Myopia and Astigmatism
Setting:
Intervention: Excimer Laser
Comparison: Phakic Intraocular Lenses

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Phakic Intraocular Lenses	Risk difference with Excimer Laser
UDVA ≥ 20/20 follow-up: 12 months	258 (3 RCTs)	⊕◯◯◯ Very low[a,b]	**RR 0.82** (0.67 to 1.01)	512 per 1,000	**92 fewer per 1,000** (169 fewer to 5 more)
percentage of eyes within +/- 1.0 D of target refraction follow-up: 12 months	(3 RCTs)	⊕◯◯◯ Very low[a,b]	**RR 0.84** (0.73 to 0.96)	Inestimable	Inestimable
number of eyes lost one or more lines of BSCVA follow-up: 12 months	308 (3 RCTs)	⊕◯◯◯ Very low[a,c]	**RR 3.92** (1.62 to 9.48)	33 per 1,000	**96 more per 1,000** (20 more to 279 more)
number of eyes with severe complications	405 (4 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 0.64** (0.27 to 1.53)	56 per 1,000	**20 fewer per 1,000** (41 fewer to 29 more)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Very small sample size
c. small sample size; wide confidence intervals around the effect estimate.
d. small sample size
Reference: Chen H, Liu Y, Niu G, Ma J. Excimer Laser Versus Phakic Intraocular Lenses for Myopia and Astigmatism: A Meta-Analysis of Randomized Controlled Trials. Eye Contact Lens. 2018 May;44(3):137-143.

7.3 Predictability of corneal surface ablative procedures

Output question

What is the predictability of different refractive surgery procedures?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing corneal surface ablative procedures (PRK/Trans-PRK)
C Other procedures:
- Use of spectacles
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
- Introcular surgeries (Phakic IOL, Refractive Lens Exchange)

O Postoperative refractive outcome

Recommendation

Surface ablation has a high predictability when correcting low to moderate myopia (lower than -6.0D) with or without astigmatism (lower than 4.0D). Evidence shows that the predictability in high myopia (higher than 6.0D) and astigmatism (higher than 4.0D) significantly lower. (GRADE +)

The evidence considering the predictability of surface ablation for hyperopia (lower than 3.0D) is limited. (GRADE +)

Although discrepancies are found in the literature, surface ablation procedures seem to have comparable results in terms of predictability when compared to other corneal laser refractive surgeries in myopic patients with or without corneal astigmatism. (GRADE +/+++)

Transepithelial PRK offers the main advantage over conventional PRK by utilizing the epithelium as a resurfacing agent, allowing for better management of abnormal and irregular topographic patterns. It is particularly recommended to use T-PRK in combination with a PTK target and followed by a topography-guided photoablation. (GRADE +)

No statistical differences concerning predictability outcomes could be found between PRK and Trans- PRK. (GRADE +)(Serfözö et al., 2025)

Considerations

Photorefractive keratectomy (PRK) has consistently demonstrated good predictability, and newer surface ablation techniques such as Trans-PRK appear to

further enhance refractive accuracy. In patients with moderate to high myopia (≤ –7.0 D), Trans-PRK achieved a high degree of precision, with 89% of eyes reaching a postoperative refraction within ±0.50 D of target (95% CI, 0.82–0.93) (Sabau et al., 2021). Long-term evidence underscores that predictability is strongly influenced by baseline refractive error. In a 16-year follow-up of eyes ranging from –1.25 D to –20.25 D, surface ablation procedures provided significantly better outcomes in low myopia compared with high myopia, with 72% of low myopic eyes achieving refractions within ±1.00 D of target, versus only 47% among high myopic eyes (A. H. Vestergaard et al., 2013). These findings highlight that long-term refractive stability is more readily achieved in eyes with lower corrections, whereas predictability diminishes as the degree of myopia increases. Evidence regarding hyperopic corrections using surface ablation remains insufficient, and no robust conclusions can currently be drawn (Settas et al., 2012).

When compared with other corneal surface ablation techniques, PRK and Trans-PRK have demonstrated predictability outcomes that are largely comparable in moderate myopia (–2.00 D to –6.00 D). Meta-analyses show that all procedures, including LASEK and epi-LASIK, achieved excellent refractive accuracy at least six months postoperatively, with SUCRA rankings placing LASEK first, followed by epi-LASIK and PRK (Wen et al., 2018). In higher myopia (< –10.0 D), broader comparative studies have shown significant differences, with femtosecond LASIK (FS-LASIK) achieving the highest predictability. Based on SUCRA rankings, the order of predictability was FS-LASIK, Trans-PRK, LASEK, PRK, LASIK, and epi-LASIK (Wen et al., 2017). These findings suggest that while surface ablation procedures maintain high levels of accuracy in moderate myopia, femtosecond laser-based approaches may provide superior predictability in more complex refractive errors.

Beyond refractive accuracy, there is increasing interest in the biomechanical implications of PRK. Preliminary evidence suggests that PRK may be associated with higher corneal hysteresis and a greater corneal resistance factor compared with SMILE in myopic eyes, although these differences did not reach statistical significance (Guo et al., 2019). This observation is clinically relevant, as preservation of corneal biomechanics is a critical determinant of long-term safety and stability, particularly in younger patients or those at risk of postoperative ectasia. Nevertheless, the current body of evidence on biomechanical outcomes after PRK remains limited, and further high-quality prospective studies are warranted.

No statistically significant difference in predictability was observed between transPRK and PRK overall, although reported predictability values ranged from 60% to 100%. D’Oria et al. and Lee et al. reported significantly better predictability for transPRK than for PRK, whereas the remaining studies found no statistically significant difference between the two techniques.(Serfözö et al., 2025)

Overall, PRK and Trans-PRK demonstrate excellent predictability in the correction of myopia, with particularly strong outcomes in low to moderate ranges. Long-term stability and accuracy diminish as the degree of myopia increases, and the role of these procedures in hyperopia correction remains uncertain due to limited data. Comparative studies suggest that surface ablation maintains excellent predictability relative to LASEK and epi-LASIK, but FS-LASIK may offer superior performance in high myopia. Further research is required to clarify the biomechanical implications of PRK and its role in optimizing outcomes across different refractive error profiles.

Conclusion

Implications for practice

The current body of evidence suggests that surface ablation procedures demonstrate generally favorable predictability in the correction of myopia. However, the overall heterogeneity of available studies underscores the importance of careful patient selection and individualized counseling. In hyperopic patients, where the evidence remains sparse, treatment decisions must be approached conservatively until more robust data become available.

Knowledge gaps

Despite encouraging results, significant gaps persist in the understanding of predictability across refractive surgery modalities. Comparative studies often differ in methodology, outcome measures, and follow-up intervals, limiting the ability to draw definitive conclusions. In particular, the predictability of surface ablation in hyperopic eyes—with or without astigmatism—remains insufficiently studied. Future research should focus on large-scale, prospective trials with standardized endpoints to better define the relative performance of PRK, Trans-PRK, and other refractive techniques across varying refractive error profiles.

Identified research evidence

Findings from Systematic Reviews

There were five relevant systematic reviews identified.

A meta-analysis comparing postoperative corneal biomechanical outcomes found differences in Ocular Response Analyzer measurements between SMILE and both FS-LASIK (Hedges' g 0.41, 95% CI 0.00 to 0.81) and LASIK (Hedges' g 1.31, 95% CI 0.54 to 2.08). No significant differences were observed between SMILE and FLEX or surface ablation procedures. Corvis ST measurements were comparable between SMILE and FS-LASIK/LASIK (Hedges' g −0.05, 95% CI −0.24 to 0.14). These

findings suggest that differences in postoperative corneal biomechanics depend on the measurement method used (Guo et al., 2019). Risk of bias assessment: high risk of bias.

A network meta-analysis found no significant differences among PRK, LASEK, epi-LASIK, and transepithelial PRK in visual efficacy, refractive predictability, or loss of corrected distance visual acuity. LASEK was associated with slightly less postoperative haze than PRK, while most other haze comparisons were inconclusive. Pain and epithelial healing outcomes varied across individual comparisons, with PRK producing greater day-one pain and slower healing than transepithelial PRK. Based on SUCRA rankings, LASEK achieved the most favourable overall balance of efficacy, predictability, safety, and early postoperative pain (Wen et al., 2018). Risk of bias assessment: low risk of bias.

A network meta-analysis found an efficacy advantage only for LASIK over LASEK in direct comparisons. FS-LASIK demonstrated greater refractive predictability than LASIK, PRK, LASEK, and epi-LASIK and ranked highest according to SUCRA analysis. Combined direct and indirect evidence showed no significant differences in efficacy or safety among procedures. The principal between-procedure distinction was therefore the superior predictability of FS-LASIK (Wen et al., 2017). Risk of bias assessment: low risk of bias.

A systematic review of 16 prospective and retrospective studies evaluated refractive surgery for myopic astigmatism across heterogeneous populations and follow-up periods. The pooled estimates for efficacy, safety, and predictability were 94%, 100%, and 89%, respectively. Vector analysis showed a mean correction index of 1.01, a difference vector of 0.20, and an index of success of 0.12. These results indicate favourable refractive outcomes, although their interpretation is limited by methodological heterogeneity and predominantly non-randomised evidence (Sabau et al., 2021). Risk of bias assessment: high risk of bias.

A systematic review comparing PRK and LASIK for hyperopic refractive correction identified no eligible studies. Consequently, no conclusions could be drawn regarding their comparative efficacy, stability, or safety. This absence of evidence highlights the need for well-designed comparative studies in hyperopic populations (Settas et al., 2012). Risk of bias assessment: low risk of bias.

Findings from additional studies

There was multiple additional studies included.

GRADE Tables

LASEK compared to T-PRK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: LASEK
Comparison: T-PRK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with T-PRK	Risk difference with LASEK
UCVA of 20/20 or better	(2 RCTs)	⊕⊕◯◯ Low[a]	**OR 1.02** (0.78 to 1.35)	Inestimable	Inestimable
refractive error within ±0.50 D of the target refraction	(1 RCT)	⊕⊕◯◯ Low[a,b]	**OR 0.95** (0.78 to 1.17)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(1 RCT)	⊕⊕◯◯ Low[a,b]	**OR 1.37** (0.30 to 6.36)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
b. results from a single study; wide confidence intervals around the effect estimate.
Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I,

Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.

Excimer Laser compared to Phakic Intraocular Lenses for Myopia and Astigmatism

Patient or population: Myopia and Astigmatism
Setting:
Intervention: Excimer Laser
Comparison: Phakic Intraocular Lenses

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Phakic Intraocular Lenses	Risk difference with Excimer Laser
UDVA ≥ 20/20 follow-up: 12 months	258 (3 RCTs)	⊕◯◯◯ Very low[a,b]	**RR 0.82** (0.67 to 1.01)	512 per 1,000	**92 fewer per 1,000** (169 fewer to 5 more)
percentage of eyes within +/- 1.0 D of target refraction follow-up: 12 months	(3 RCTs)	⊕◯◯◯ Very low[a,b]	**RR 0.84** (0.73 to 0.96)	Inestimable	Inestimable
number of eyes lost one or more lines of BSCVA follow-up: 12 months	308 (3 RCTs)	⊕◯◯◯ Very low[a,c]	**RR 3.92** (1.62 to 9.48)	33 per 1,000	**96 more per 1,000** (20 more to 279 more)
number of eyes with severe complications	405 (4 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 0.64** (0.27 to 1.53)	56 per 1,000	**20 fewer per 1,000** (41 fewer to 29 more)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

Excimer Laser compared to Phakic Intraocular Lenses for Myopia and Astigmatism

Patient or population: Myopia and Astigmatism
Setting:
Intervention: Excimer Laser
Comparison: Phakic Intraocular Lenses

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Phakic Intraocular Lenses	Risk difference with Excimer Laser

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Very small sample size
c. small sample size; wide confidence intervals around the effect estimate.
d. small sample size
Reference: Chen H, Liu Y, Niu G, Ma J. Excimer Laser Versus Phakic Intraocular Lenses for Myopia and Astigmatism: A Meta-Analysis of Randomized Controlled Trials. Eye Contact Lens. 2018 May;44(3):137-143.

FS-LASIK compared to PRK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: FS-LASIK
Comparison: PRK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with PRK	Risk difference with FS-LASIK
UCVA of 20/20 or better	(4 RCTs)	⊕⊕⊕◯ Moderate[a,b]	**OR 0.90** (0.46 to 1.76)	Inestimable	Inestimable
refractive error within ±0.50 D of the target refraction	(3 RCTs)	⊕⊕◯◯ Low[a,b]	**OR 1.78** (0.78 to 4.04)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(3 RCTs)	⊕⊕◯◯ Low[a,b]	**OR 0.77** (0.17 to 3.60)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
b. Wide confidence intervals around the effect estimate.
Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I,

Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.

PRK compared to Epi-LASIK for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: PRK
Comparison: Epi-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Epi-LASIK	Risk difference with PRK
UDVA of 20/20 or better	(2 RCTs)	⊕⊕◯◯ Low[a,b]	**OR 1.23** (0.45 to 3.34)	Inestimable	Inestimable
Refractive error within ± 0.50 D of target refraction	(2 RCTs)	⊕⊕◯◯ Low[a,b]	**OR 0.87** (0.30 to 2.47)	Inestimable	Inestimable
Loosing 2 or more lines of CDVA	(1 RCT)	⊕⊕◯◯ Low[c]	**OR 1.00** (0.05 to 17.90)	Inestimable	Inestimable
Postoperative haze grade 0.5 or more	(1 RCT)	⊕⊕◯◯ Low[c]	**OR 2.80** (0.53 to 14.74)	Inestimable	Inestimable

PRK compared to Epi-LASIK for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: PRK
Comparison: Epi-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Epi-LASIK	Risk difference with PRK
Postoperative haze grade 1.0 or more	(1 RCT)	⊕⊕◯◯ Low[c]	**OR 7.50** (0.73 to 76.77)	Inestimable	Inestimable
Postoperative pain on day 1	(1 RCT)	⊕⊕◯◯ Low[c]	**OR -0.01** (-1.76 to 1.66)	Inestimable	Inestimable
Epithelial healing time	(2 RCTs)	⊕◯◯◯ Very low[a,d]	**OR 0.13** (-1.63 to 1.90)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Unclear or high risk of bias of the included studies.
b. Small sample size; wide confidence intervals around the effect estimate.
c. Small sample size, results from a single study; very wide confidence intervals around the effect estimate.
d. Significant statistical heterogeneity detected.

Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, et al. Corneal surface ablation laser refractive surgery for the correction of myopia: a network meta-analysis. J Refract Surg. 2018;34(11):726-35.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Small sample size; wide confidence intervals around the effect estimate.
c. Small sample size, results from a single study; very wide confidence intervals around the effect estimate.
d. Significant statistical heterogeneity detected.

Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, et al. Corneal surface ablation laser refractive surgery for the correction of myopia: a network meta-analysis. J Refract Surg. 2018;34(11):726-35.

LASIK compared to photorefractive keratectomy (PRK) for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: LASIK
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with LASIK
UCVA of 20/20 or better	(9 RCTs)	⨁⨁⨁◯ Moderate[a]	**OR 1.35** (0.82 to 2.21)	Inestimable	Inestimable
refractive error within ±0.50 D of the target refraction	(7 RCTs)	⨁⨁⨁◯ Moderate[a]	**OR 0.81** (0.57 to 1.15)	Inestimable	Inestimable

LASIK compared to photorefractive keratectomy (PRK) for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: LASIK
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with LASIK
Loosing 2 or more lines of BSCVA	(5 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 0.57** (0.17 to 1.83)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I, Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.

Laser epithelial keratomileusis (LASEK) compared to photorefractive keratectomy (PRK) for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: Laser epithelial keratomileusis (LASEK)
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with Laser epithelial keratomileusis (LASEK)
UCVA of 20/20 or better at 1 week	244 (4 RCTs)	⊕⊕◯◯ Low[a,b]	**RR 1.26** (0.90 to 1.78)	311 per 1,000	**81 more per 1,000** (31 fewer to 243 more)
UCVA of 20/20 or better at 12 months post treatment	102 (1 RCT)	⊕⊕◯◯ Low[c,d]	**RR 0.98** (0.92 to 1.05)	980 per 1,000	**19 fewer per 1,000**
Proportion of eyes within ± 0.50 D of target refraction at 1 month post treatment	140 (2 RCTs)	⊕⊕◯◯ Low[a,b]	**RR 0.96** (0.77 to 1.19)	714 per 1,000	**29 fewer per 1,000** (164 fewer to 136 more)
Proportion of eyes within ± 0.50 D of target refraction at 12 months post treatment	152 (1 RCT)	⊕⊕◯◯ Low[c,d]	**RR 0.93** (0.84 to 1.03)	934 per 1,000	**65 fewer per 1,000** (149 fewer to 28 more)

Laser epithelial keratomileusis (LASEK) compared to photorefractive keratectomy (PRK) for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: Laser epithelial keratomileusis (LASEK)
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with Laser epithelial keratomileusis (LASEK)
Loss of 1 or more lines of BSCVA at 12 months post treatment	102 (1 RCT)	⊕◯◯◯ Very low[c,e]	**RR 3.00** (0.13 to 71.96)	Inestimable	Inestimable
Mean spherical equivalent at 12 months post treatment	386 (3 RCTs)	⊕⊕◯◯ Low[a,b]	-	The mean spherical equivalent at 12 months post treatment ranged from **-0.2 to 0.1**	MD **0.06 higher** (0.02 lower to 0.14 higher)
Postoperative healing time (days) at 1 week	528 (6 RCTs)	⊕◯◯◯ Very low[a,b,f]	-	The mean postoperative healing time (days) at 1 week ranged from **2.5 to 4.0**	MD **0.34 lower** (0.45 lower to 0.23 lower)
Postoperative pain scores at 1 day	458 (5 RCTs)	⊕◯◯◯ Very low[a,b,f]	-	The mean postoperative pain scores at 1 day ranged from **0.7 to 4.0**	MD **0.08 lower** (0.63 lower to 0.47 higher)

Laser epithelial keratomileusis (LASEK) compared to photorefractive keratectomy (PRK) for myopia

Patient or population: myopia
Setting: Eye clinic
Intervention: Laser epithelial keratomileusis (LASEK)
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with Laser epithelial keratomileusis (LASEK)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the pooled studies.
b. Small sample size
c. Clinical and methodological heterogeneity in terms of population, intervention, comparator and outcome measures.
d. Small sample size, results from a single study
e. Small sample size, results from a single study; very wide confidence intervals around the effect estimate.
f. Significant statistical heterogeneity detected.
Reference: Li SM, Zhan S, Li SY, Peng XX, Hu J, Law HA, et al. Laser-assisted subepithelial keratectomy (LASEK) versus photorefractive keratectomy (PRK) for correction of myopia. Cochrane Database Syst Rev. 2016;2(2):CD009799.

7.4 Stability of corneal surface ablative procedures

Output question
What is the stability of suface ablative procedures?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing corneal surface ablative procedures (PRK/Trans-PRK)
C Other procedures:
- Use of spectacles
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
- Introcular surgeries (Phakic IOL, Refractive Lens Exchange)

O Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Recommendation

After 12 months, the refractive results of PRK and Trans-PRK are considered stable for low to moderate myopia. (GRADE +)

Performing PRK in hyperopic patients is exceptional since this requires larger de-epithelization with a longer recovery, more regression, and more occurrence of haze. (GRADE +)

No statistical differences concerning stability outcomes could be found between PRK and Trans- PRK. (GRADE +)(Serfözö et al., 2025)

Considerations

The long-term stability of surface ablation remains insufficiently documented, as most available studies are restricted to short-term follow-up periods of up to six months postoperatively. High-quality evidence is lacking, and the current literature is largely composed of small case series and observational studies. One notable long-term case series in patients with moderate myopia (-4.0D) undergoing PRK reported a modest myopic regression, with a mean shift in spherical equivalent (SEQ) of -0.54D over 20 years. Importantly, while keratometric values remained stable between six months and 20 years postoperatively, axial length continued to increase, suggesting that progressive myopia was primarily attributable to axial elongation rather than corneal changes. Interestingly, this regression was statistically significant in patients treated before the age of 40, whereas no significant changes were observed in patients treated at older ages. (O'Brart et al., 2014) No significant difference concerning stability could be observed between PRK and Trans- PRK. (Serfözö et al., 2025)

Further comparative data indicate potential differences in long-term stability between PRK and LASIK. In a study including patients with low to high myopia (mean preoperative refraction of -7.0D), refractive stability was achieved one year postoperatively in both groups; however, over follow-up intervals of 6–9 years, LASIK demonstrated superior stability compared to PRK. Eyes treated with PRK were more likely to exhibit significant overcorrection (OR, 8.9; 95% CI 2.9–27.1), whereas those treated with LASIK tended to show a mild undercorrection (OR, 4.1; 95% CI 0.9–17.9) (Dirani et al., 2010).

By contrast, the evidence on hyperopic corrections performed with surface ablation is extremely limited. No robust or reliable conclusions can currently be drawn regarding the long-term stability of outcomes in hyperopic eyes (Settas et al., 2012). Collectively, these findings highlight the need for well-designed, large-scale, prospective studies with standardized endpoints to clarify the stability profile of surface ablation across different refractive error groups.

Conclusion

Implications for practice

Based on the current available evidence, too limited evidence is found considering the stability of surface ablation. Based on expert opinion, PRK and Trans-PRK are considered to be stable for low to moderate myopia.

Knowledge gaps

Since the evidence for stability is highly limited, research into the stability outcomes for surface ablation is highly necessary to further improve our knowledge of the long-term effects of these laser refractive surgery procedures.

Identified research evidence

Findings from Systematic Reviews

There was one relevant systematic review identified.

One systematic review aimed to determine whether PRK or LASIK leads to more reliable, stable and safe results when correcting a hyperopic refractive error. The review did not identify any studies meeting the inclusion criteria. The authors concluded that no firm conclusions could be reached.(Settas et al., 2012) Risk of bias assessment: low risk of bias in the review.

Findings from additional studies

There were multiple additional studies included.

6.5 Safety of corneal surface ablative procedures

Output question

What is the safety of corneal surface ablative procedures?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery

I Performing corneal surface ablative procedures (PRK/Trans-PRK)

C Other procedures:

- Use of spectacles
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O (Serious) adverse events

Recommendation

Surface ablation is safe for correcting low to moderate myopia (lower than 6.0D) and/or astigmatism (lower than 3.0D). The evidence for surface ablation correcting higher degrees of myopia (higher than 6.0D) and astigmatism (higher than 3.0D) is limited. (GRADE +/++)

Limited evidence is available regarding the safety of surface ablation in hyperopia (lower than 3.0D). (GRADE +/++)

Two-step and single- step trans- PRK can be considered as safe refractive procedures, with single step trans- PRK showing less haze formation and faster healing. (GRADE +)(Akram et al., 2025)

Surface ablative procedures are comparable to other refractive surgery procedures in terms of safety, but the risk for ectasia seems to be less after surface ablation compared with corneal intrastromal refractive procedures. (LASIK and intrastromal lenticular surgery) (GRADE +/++)

PRK and Trans-PRK should be preferred over LASIK in patients with pre-existing DED, as these procedures show less induced and lasting dryness, as well as less increase of preoperative ocular surface disease. In case of low risk for ectasia, PRK can be considered, when LASIK and KLEx are deemed unsuitable on a case-by-case basis. (GRADE +)

No statistical differences concerning safety outcomes could be found between PRK and Trans- PRK. (GRADE +)(Serfözö et al., 2025)

Considerations

Trans-PRK has been demonstrated to be a safe procedure for the correction of moderate to high myopia (≤-7.0D) and astigmatism, with reported safety rates approaching 100% (95% CI, 0.97–1.00) and a safety index of 1.05 (95% CI, 1.00–1.11) (Sabau et al., 2021). Long-term follow-up data further support its safety profile: in a 19-year observational study including patients with low to high myopia (-1.25D to -20.25D), only 2% of eyes lost two or more lines of corrected distance visual acuity (CDVA) (A. H. Vestergaard et al., 2013). Despite these favorable findings, evidence on hyperopic corrections remains sparse, and no robust conclusions regarding safety in this subgroup can currently be drawn (Settas et al., 2012).

When comparing PRK and Trans-PRK to other surface ablation techniques such as LASEK and epi-LASIK in moderate myopic patients (-2.0D to -6.0D), the procedures exhibited broadly comparable safety outcomes, although the available evidence is heterogeneous. No statistically significant differences were identified, with odds ratios (ORs) of 1.24 (95% CI, 0.32–4.78) for PRK vs. LASEK, 1.00 (95% CI, 0.05–17.90) for PRK vs. epi-LASIK, and 1.00 (95% CI, 0.06–16.51) for PRK vs. Trans-PRK (Wen et al., 2018). According to surface under the cumulative ranking curve (SUCRA) analysis, the relative safety ranking among these four procedures was LASEK, epi-LASIK, Trans-PRK, and PRK. Overall, these techniques demonstrated favorable and comparable safety within at least six months of follow-up (Wen et al., 2018). Importantly, in the broader context of refractive surgery, post-operative ectasia remains a critical concern. A systematic review concluded that the incidence of ectasia is lower after PRK compared to LASIK, highlighting a potential long-term advantage of surface ablation in at-risk corneas.(Chang & et al., 2022)

Further comparative data in myopic patients (<-10.0D) confirmed the lack of significant differences in safety between PRK and its surface ablation alternatives. Odds ratios were 1.00 (95% CI, 0.13–7.62) for PRK vs. epi-LASIK, 1.37 (95% CI, 0.30–6.36) for PRK vs. LASEK, and 1.00 (95% CI, 0.06–16.51) for PRK vs. Trans-PRK (Wen et al., 2017). In this analysis, SUCRA rankings positioned LASIK, LASEK, FS-LASIK, SMILE, and FLEx above Trans-PRK, epi-LASIK, and PRK in terms of safety, though the overlapping confidence intervals and wide variability in reported outcomes warrant cautious interpretation (Wen et al., 2017).

Long-term evidence directly comparing PRK and LASEK is limited and inconsistent. One study reported a relative risk (RR) of 3.00 (95% CI, 0.13–71.96) for PRK compared with LASEK after 12 months, but the low quality and limited sample size preclude firm conclusions (Li et al., 2016). Another long-term, albeit low-quality, study reported a PRK safety index of 0.97 and demonstrated a statistically significant improvement in CDVA between 1 and 20 years postoperatively in moderate myopia (-4.0D), with no sight-threatening complications observed. (O'Brart et al., 2014) Collectively, these findings indicate that surface ablation procedures are generally safe in the treatment of myopia, although high-quality, long-term randomized studies

are required to strengthen the evidence base and to address the persistent heterogeneity in reported outcomes.

Meta-analysis of the comparison between PRK and Trans- PRK in safety, showed safety values ranging from 95% to 100% with no statistical difference in between these procedures. Safety indeces ranged from 0.98 to 1.1. (Serfözö et al., 2025) When comparing two-step and single-step Trans-PRK it could be shown that both are safe refractive procedures. Single- step Trans-PRK showed slight advantages such as faster healing, less haze formation and lower pain scores. (Akram et al., 2025)

Conclusion

Implications for practice

Current evidence suggests that surface ablation is a safe procedure and offers a safety profile comparable to other corneal refractive surgery techniques. Nonetheless, these conclusions must be interpreted with caution given the limited quantity and quality of available studies. Furthermore, the type of laser technology employed—particularly first- versus new-generation platforms—may significantly influence postoperative safety outcomes.

Knowledge gaps

The evidence base remains heterogeneous and largely of low methodological quality. Robust, high-quality studies using standardized outcome measures and consistent follow-up intervals are required to allow more reliable comparisons across procedures. Long-term safety data remain scarce, particularly for hyperopic patients, as most available studies focus on myopia and astigmatism. Future research should address these gaps to better define safety outcomes across a wider spectrum of refractive errors and patient populations.

Identified research evidence

Findings from Systematic Reviews

There were five relevant systematic reviews identified.

A network meta-analysis found no significant differences among PRK, LASEK, epi-LASIK, and transepithelial PRK in achieving 20/20 uncorrected distance visual acuity, refractive accuracy within ±0.50 D, or preservation of corrected distance visual acuity. LASEK was associated with marginally less postoperative haze than PRK, whereas other haze comparisons showed no significant differences.

Postoperative pain and epithelial healing were generally comparable, although individual studies reported greater day-one pain and slower epithelial healing after PRK than after transepithelial PRK. SUCRA rankings identified LASEK as the most favourable procedure for efficacy, predictability, safety, and early postoperative pain (Wen et al., 2017; Wen et al., 2018). Risk of bias assessment: low risk of bias.

Direct comparisons showed a significant efficacy advantage only for LASIK over LASEK. FS-LASIK demonstrated greater refractive predictability than LASIK, PRK, LASEK, and epi-LASIK and ranked highest in the SUCRA analysis. Combined direct and indirect evidence showed no significant differences among procedures in efficacy or safety. Overall, FS-LASIK appeared to provide the greatest refractive predictability (Wen et al., 2017). Risk of bias assessment: low risk of bias.

Low- to very-low-certainty evidence showed no clinically meaningful differences between PRK and LASEK in refractive accuracy, uncorrected visual acuity, or loss of best spectacle-corrected visual acuity at 12 months. Corneal haze findings were inconsistent, although one trial reported slightly lower haze scores after LASEK at 24 months. Overall, the available evidence did not establish a clear advantage of either procedure (Li et al., 2016). Risk of bias assessment: low risk of bias.

A systematic review of 16 prospective and retrospective studies evaluated refractive surgery for myopic astigmatism over follow-up periods of 3–18 months. Pooled efficacy, safety, and predictability rates were 94%, 100%, and 89%, respectively. The mean correction index was 1.01, with a difference vector of 0.20 and an index of success of 0.12. These findings indicate favourable refractive outcomes, although interpretation is limited by methodological heterogeneity and predominantly non-randomised evidence (Sabau et al., 2021). Risk of bias assessment: high risk of bias.

A systematic review comparing PRK and LASIK for hyperopic refractive correction identified no eligible studies. Consequently, no conclusions could be drawn regarding their comparative efficacy, stability, or safety (Settas et al., 2012). Risk of bias assessment: low risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

PRK compared to LASIK in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: PRK
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with PRK
incidence of ectasia	1892800 (1 observational study)	⊕⊕◯◯ Low[a]	**OR 0.24** (0.19 to 0.30)	1,045 per 1,000,000	**794 fewer per 1,000,000** (846 fewer to 731 fewer)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio; *: estimate based on average total procedures per year

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Explanations
a. Results from observational studies
Reference: Moshirfar M, Tukan AN, Bundogji N, Liu HY, McCabe SE, Ronquillo YC, Hoopes PC. Ectasia After Corneal Refractive Surgery: A Systematic Review. Ophthalmol Ther. 2021 Dec;10(4):753-776.

LASIK compared to SMILE in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: LASIK
Comparison: SMILE

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with SMILE	Risk difference with LASIK
incidence of ectasia	1705630 (1 observational study)*	⨁⨁◯◯ Low[a]	**OR 5.32** (3.39 to 8.37)	196 per 1,000,000	**847 more per 1,000,000** (469 more to 1,445 more)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio; *: estimate based on average total procedures per year

GRADE Working Group grades of evidence.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Explanations
a. Results from observational studies
Reference: Moshirfar M, Tukan AN, Bundogji N, Liu HY, McCabe SE, Ronquillo YC, Hoopes PC. Ectasia After Corneal Refractive Surgery: A Systematic Review. Ophthalmol Ther. 2021 Dec;10(4):753-776.

LASIK compared to photorefractive keratectomy (PRK) for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: LASIK
Comparison: photorefractive keratectomy (PRK)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with photorefractive keratectomy (PRK)	Risk difference with LASIK
UCVA of 20/20 or better	(9 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 1.35** (0.82 to 2.21)	Inestimable	Inestimable
refractive error within ±0.50 D of the target refraction	(7 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 0.81** (0.57 to 1.15)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(5 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 0.57** (0.17 to 1.83)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I,

Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.

7.6 Intraoperative use of mitomycin C

Output question
Is the intraoperative use of mitomycin C during PRK to reduce postoperative scar/ haze formation indicated in all patients? Are there any side effects or contraindications one must consider? How long should Mitomycin C be used?

P: Patient undergoing a Corneal surface ablation procedure
I: Intraoperative use of Mitomycin C
C: No intraoperative use of Mitomycin C
O: Visual acuity, Visual function, Quality of life, (Serious) adverse events

Recommendation

The application of mitomycin C (MMC) is generally not recommended for primary, normal surface ablation cases. However, its use may be considered in certain situations, such as in cases of resistant haze or when there is a higher risk of haze formation, including after refractive keratectomy, in hyperopic patients, or in patients with moderate to high myopia (higher than -3.0D), and after lenticular surgery. In cases of resistant haze (i.e., persistent after 12–18 months of wound healing and unresponsive to topical steroids), MMC may be used, often in combination with PTK, to facilitate the removal of the opacity. (GRADE+)

Short-time application of MMC 0.02% for 12-20 seconds is safe and effective in preventing haze formation in eyes which underwent surface ablation with an ablation depth above 50-65 micrometers (µm). (GRADE +)

It is also important to note that UV exposure poses a high risk for dense haze formation after MMC application. As a precaution, patients are advised to wear sunglasses for one year to protect their eyes from UV light and reduce the risk. (GRADE +)

There seems to be little difference in haze formation and visual outcome between lower dose of MMC (0.01%) and standard dose (0.02%). Standard dose may be more protective in case of high myopia or deep ablation depths. (GRADE +)

Considerations

Photorefractive keratectomy (PRK) involves the removal of the entire corneal epithelium, disrupting the epithelial basement membrane and exposing the stroma. This structural alteration initiates keratocyte activation, fibroblast proliferation, and deposition of abnormal extracellular matrix, which together contribute to the development of corneal haze. The severity of haze formation is influenced by ablation depth, ablation profile, and individual wound-healing response.

Mitomycin C (MMC), an alkylating agent and potent antimetabolite, inhibits DNA synthesis and thereby reduces fibroblast proliferation and myofibroblast transformation. Through this mechanism, MMC modulates stromal wound healing and diminishes the risk of both early- and late-onset haze. Clinical studies and pooled analyses have confirmed that MMC application after excimer laser ablation is associated with reduced corneal haze formation, improved refractive predictability, and more stable subjective visual outcomes.

Nevertheless, routine MMC use in primary, uncomplicated surface ablation cases is not recommended. Its application should be reserved for patients with an increased risk of postoperative haze, including:

- Resistant corneal haze persisting beyond 12–18 months despite adequate topical steroid therapy, often in combination with PTK to facilitate removal of opacity,
- Moderate to high myopia (> –3.0 D), where deeper ablation depths predispose to haze,
- Hyperopic corrections, which involve peripheral ablation patterns and higher remodeling activity,
- Post-lenticular surgery eyes, where altered biomechanics and healing increase haze risk.

Short-term intraoperative MMC at a concentration of 0.02% for 12–20 seconds is considered safe and effective in eyes with ablation depths greater than 50–65 µm. The cornea should be irrigated thoroughly with at least 10 cc balanced salt solution (BSS) to minimize residual drug exposure. While UV exposure is a recognized independent risk factor for dense haze formation, this risk appears particularly significant after MMC application. Therefore, patients should be strictly advised to use UV-protective sunglasses for at least one year postoperatively.

Regarding dosing, several comparative studies indicate little difference in outcomes between a reduced dose of 0.01% MMC and the standard dose of 0.02%. Both concentrations appear equally effective in preventing haze and maintaining uncorrected and corrected distance visual acuity (UDVA, CDVA). (Razmjoo et al., 2012) However, the standard dose may offer additional protection in high-risk subgroups, such as eyes with high myopia or deep ablations.(Chang et al., 2021; Lu et al., 2021; Ouerdane et al., 2021) Importantly, pooled analyses revealed no significant difference in CDVA between MMC and control groups during 6–36 months of follow-up, nor in endothelial cell loss.(Lu et al., 2021; Ouerdane et al., 2021; Shojaei et al., 2013)

The incidence of haze varies between surface ablation techniques. The highest rates have been reported after transepithelial PRK (TPRK, 14.81%), while significantly lower incidences are observed in advanced PRK (APRK, 2.95%) and epithelial

keratectomy (Epi-K, 4.08%). Furthermore, haze is often localized peripherally, a distribution linked to larger ablation zones (6.0–7.9 mm) and the wavefront-optimized ablation profiles frequently used in the PTK mode of TPRK.(Mehlan et al., 2019)

Although generally effective and safe, MMC carries potential risks. Toxicity has been linked to keratocyte apoptosis, myofibroblast death, and in rare cases corneal melting and endothelial compromise. Animal studies have detected MMC remnants in the aqueous humor of PRK-treated eyes, raising concerns about delayed toxicity. (Torres et al., 2006) While clinical studies have not demonstrated increased endothelial cell loss in MMC-treated eyes, the possibility of long-term subclinical effects cannot be excluded.

To guide clinical practice, expert consensus recommends an MMC nomogram based on ablation depth, followed by copious irrigation with BSS:

- ≤40 μm ablation depth (≤3 D): 10 seconds
- 40–80 μm ablation depth (3–6 D): 20 seconds
- >80 μm ablation depth or retreatments (>6 D): 30 seconds

In addition, MMC application has been associated with a slight tendency toward postoperative overcorrection in high myopia (>6 D). Accordingly, reducing the intended correction by approximately 10% may help optimize refractive outcomes (expert opinion).

Taken together, these considerations underscore that MMC represents a highly effective adjunct in selected surface ablation cases, but its application requires careful patient selection, dose adjustment, thorough irrigation, and postoperative UV protection to maximize safety and efficacy.

Conclusion

Implications for practice

MMC represents a valuable adjunct in surface ablation, providing consistent haze reduction and more predictable visual outcomes. Its application should be selective, guided by individual risk factors, ablation depth, and refractive error. Both 0.01% and 0.02% concentrations are effective, with the lower dose favored for safety and the higher dose preferred in high-risk cases. Proper intraoperative irrigation, postoperative UV protection for at least one year, and adjustment of target correction in high myopia are critical measures to optimize efficacy while minimizing complications.

Knowledge gaps

Uncertainties remain regarding the optimal MMC dose, exposure time, and long-term safety profile. Rare but potentially serious toxicities, including endothelial compromise and stromal cell apoptosis, require further clarification. The necessity and duration of adjunctive steroid therapy after MMC application are also unclear. Large-scale, prospective randomized trials with extended follow-up are needed to establish definitive recommendations for safe and effective MMC use in surface ablation.

Identified research evidence

Findings from Systematic Reviews

There were two relevant systematic reviews identified.

Mitomycin C (MMC) use during surface ablation did not significantly affect corrected distance visual acuity, short-term uncorrected visual acuity, or postoperative spherical equivalent compared with control treatment. A small difference in uncorrected visual acuity was reported at five years, although shorter-term outcomes remained comparable. MMC significantly reduced postoperative corneal haze (RR 0.29, 95% CI 0.19 to 0.45) without increasing endothelial cell loss. Overall, MMC improved haze prevention without materially affecting visual or refractive outcomes (Ouerdane et al., 2021).

MMC significantly reduced the incidence of both early- and late-onset corneal haze following photorefractive keratectomy (OR 0.18, 95% CI 0.08 to 0.39). No significant differences were observed in refractive predictability, the proportion achieving 20/20 uncorrected visual acuity, endothelial cell density, or loss of two or more lines of best-corrected visual acuity. These findings support MMC as an effective strategy for reducing postoperative haze without compromising visual safety or refractive outcomes (Chang et al., 2021).

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

Mitomycin C compared to controls for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Mitomycin C
Comparison: controls

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with controls	Risk difference with MMC
Corneal haze	3058 (10 RCTs)	⊕◯◯◯ Very low[a,b,c]	**OR 0.18** (0.08 to 0.39)	150 per 1,000	**119 fewer per 1,000** (136 fewer to 86 fewer)
postoperative SE within +/- 0.50 dioptres	602 (5 RCTs)	⊕◯◯◯ Very low[a,c,d,e]	**OR 1.10** (0.45 to 2.68)	778 per 1,000	**16 more per 1,000** (166 fewer to 126 more)
Postoperative UCVA of 20/20 or better	494 (4 RCTs)	⊕◯◯◯ Very low[a,b,e]	**OR 1.86** (0.78 to 4.45)	837 per 1,000	**68 more per 1,000** (37 fewer to 121 more)
Safety (losing at least two lines of BCVA postoperatively)	2562 (4 RCTs)	⊕⊕◯◯ Low[a,c,e]	**OR 0.74** (0.20 to 2.70)	12 per 1,000	**3 fewer per 1,000** (10 fewer to 20 more)
Endothelial cell density	406 (3 RCTs)	⊕◯◯◯ Very low[a,f]	-	The mean endothelial cell density ranged from **2.7-2.8**	MD **39.07 higher** (20.45 lower to 98.59 higher)

Mitomycin C compared to controls for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Mitomycin C
Comparison: controls

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with controls	Risk difference with MMC

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies.
b. High amount of heterogeneity detected.
c. Results from observational studies pooled together with RCTs
d. Significant statistical heterogeneity detected.
e. Small sample size
f. Wide confidence intervals around the effect estimate.
Reference: Chang YM, Liang CM, Weng TH, Chien KH, Lee CH. Mitomycin C for the prevention of corneal haze in photorefractive keratectomy: a meta-analysis and trial sequential analysis. Acta Ophthalmol. 2021 Sep;99(6):652-662.

Mitomycin C compared to controls for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Mitomycin C
Comparison: controls

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with controls	Risk difference with MMC
CDVA follow-up: range 6 months to 36 months	454 (4 RCTs)	⨁◯◯◯ Very low[a,b,c]	-	The mean CDVA was **-0.04**	MD **0.02 higher** (0.04 lower to 0.07 higher)
Uncorrected distance visual acuity follow-up: range 6 months to 5 years	832 (9 RCTs)	⨁⨁◯◯ Low[a,c]	-	The mean uncorrected distance visual acuity ranged from **0-0.59**	MD **0** (0.01 lower to 0.01 higher)
Spherical equivalent follow-up: range 3 months to 12 months	1270 (13 RCTs)	⨁⨁◯◯ Low[a,d]	-	The mean spherical equivalent ranged from **-2-0.01**	MD **0.02 lower** (0.1 lower to 0.06 higher)
Corneal haze follow-up: range 3 months to 12 months	1046 (9 RCTs)	⨁⨁◯◯ Low[a,b]	**RR 0.29** (0.19 to 0.45)	130 per 1,000	**92 fewer per 1,000** (105 fewer to 71 fewer)
Endothelial cell loss	312 (4 RCTs)	⨁⨁◯◯ Low[a,e]	-	The mean endothelial cell loss ranged from **0.23-5**	MD **0.53 higher** (3.05 lower to 4.11 higher)

Mitomycin C compared to controls for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Mitomycin C
Comparison: controls

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with controls	Risk difference with MMC

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Small sample size
d. Significant statistical heterogeneity detected.
e. Wide confidence intervals around the effect estimate.
Reference: Ouerdane Y, Zaazouee MS, Mohamed MEA, Hasan MT, Hamdy M, Ghoneim AM, Gbreel MI, Ibrahim AM, Ragab KM, Nourelden AZ. Mitomycin C application after photorefractive keratectomy in high, moderate, or low myopia: Systematic review and meta-analysis. Indian J Ophthalmol. 2021 Dec;69(12):3421-3431.

8. Stromal Subtractive Procedures

8.1 LASIK

8.1.1 Indications and Contraindications for LASIK

Output question
What are the indications and contraindications for LASIK?

Recommendations

Limits of application LASIK:

- Myopia lower than 8.0D can be considered. However, it must be noted that the quality of vision will be more affected over 7.0D. (GRADE +)
- Myopia higher than 8.00D only in case of a regular cornea, without any risk factors, and a sufficient corneal thickness (higher than 500 micrometer (µm)) taking flap thickness and ablation depth and residual estimated thickness into account. (GRADE +)
- Astigmatism lower than 4.0D, if the cylinder is greater than the sphere and of the opposite sign. Surgeons must be aware of potential suboptimal results and prolonged recovery when the cylindrical component exceeds the spherical component. (GRADE +)
- Optimal results might be achieved for patients with hyperopia up to lower than +3.0D with or without astigmatism lower than 3.0D after considering risk factors as well as different morphological aspects, corneal tissue and the optical zone. (GRADE +)
- In patients with higher degree of hyperopia (higher than 3.0D), an increased complication risk, including reduced quality of vision, reduced stability and a higher risk of decentration has to be considered. (GRADE +)

It is mandatory to regard the different laser system approvals (CE-markings) which include the ranges of indication for specific devices. (GRADE +)

In cases of higher ametropia, special attention should be given to sufficient corneal thickness according to ablation depth and residual estimated corneal thickness. (GRADE +)

The limits of application must incorporate corneal safety parameters, including a minimum preoperative corneal thickness of at least 480 µm in the absence of additional risk factors, with a recommended threshold of 500 µm or greater. For the residual stromal bed, an absolute lower limit of 250 µm is required, while preservation of 300 µm or more is considered optimal. In LASIK, the Percentage of

Tissue Altered (PTA), defined as the ratio between flap thickness plus ablation depth and central corneal thickness, has been identified as an important risk factor for postoperative ectasia. A PTA value exceeding approximately 40% is associated with a significantly increased risk and should be carefully considered during surgical planning. It must be emphasized that, in any form of corneal subtractive surgery, the decisive determinant of biomechanical stability is not corneal thickness alone, but rather the total ablation volume in relation to the overall corneal architecture. (GRADE +)(Santhiago et al., 2014)

It is important to note that the above-mentioned limits strongly depend on different laser platforms, understanding of corneal shape and zone size, and other variables. Additionally, the volume of ablation should be considered as a key factor, rather than focusing solely on the residual posterior stromal bed. (GRADE +)

Considerations

The application of LASIK is constrained by refractive limits, corneal thickness, and device-specific parameters, all of which must be carefully evaluated preoperatively. In myopic patients, treatment up to –8.0 D is generally acceptable, although visual quality tends to decline beyond –7.0 D. Corrections greater than –8.0 D may only be considered when the cornea is morphologically regular, free of additional risk factors, and demonstrates sufficient thickness (>500 µm) to account for flap creation, ablation depth, and residual stromal bed. Astigmatism up to 4.0 D may be addressed; however, outcomes may be suboptimal and recovery prolonged when the cylindrical error exceeds the spherical error. Hyperopic treatments achieve the most predictable results up to +3.0 D, with or without concomitant astigmatism ≤3.0 D, whereas higher hyperopia is associated with reduced visual quality, lower stability, and an increased risk of decentration.

Beyond refractive error, safe LASIK outcomes require strict adherence to minimal corneal thickness thresholds. A preoperative central corneal thickness of at least 480 µm (ideally ≥500 µm) and a residual stromal bed thickness of ≥250 µm are generally required to maintain structural integrity. Importantly, treatment limits are influenced not only by stromal bed thickness but also by the ablation volume, corneal shape, optical zone size, and the characteristics of the specific laser platform employed. Accordingly, each procedure must be planned within the boundaries of CE-marked indications and manufacturer-specific instructions. Surgeons are obligated to comply with device-specific conditions to minimize complications and ensure long-term visual stability.

Conclusion

Implications for practice

The decision to perform LASIK should always be the result of shared decision-making between patient and surgeon, with a clear discussion of expected benefits, risks, and alternatives. Careful patient selection, including evaluation of refractive error, corneal thickness, morphology, and biomechanical stability, remains critical to ensuring safety and effectiveness. Strict adherence to established selection criteria and device-specific indications is essential, as deviations increase the risk of suboptimal outcomes or complications. By combining thorough preoperative assessment with individualized surgical planning, LASIK can provide safe, predictable, and stable refractive correction in appropriately selected patients.

Knowledge gaps

Further research is needed to better characterize the causes of patient dissatisfaction following LASIK, as these insights are essential for refining patient selection criteria and optimizing surgical outcomes. In particular, systematic investigation into long-term stability, higher-order aberrations, quality of vision, and the impact of preoperative morphological risk factors is required. Expanding the evidence base with prospective, controlled studies will allow more precise definition of indications and contribute to improved patient satisfaction and safety.

Identified research evidence

Findings from Systematic Reviews

There was one relevant systematic review identified.

Findings from additional studies

There were multiple additional studies included.

8.1.2 Efficacy of LASIK

Output question
What is the efficacy of intracorneal ablative procedures (LASIK)?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery.
I Performing intracorneal ablative procedures
C Other procedures:
- Use of spectacles
- corneal surface ablative procedures: (PRK)
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O Visual acuity, Visual function, Quality of life, Postoperative refractive outcome, complications, adverse events

Recommendation

LASIK is effective for correcting low to moderate myopia (lower than 6.0D) with/without astigmatism (lower than 2.0D). (GRADE +)

Limited evidence shows that LASIK is effective for correcting high myopia (higher than -6.0D) with/without astigmatism (lower than 5.0D). (GRADE +)

LASIK is effective for correcting low to moderate hyperopia (lower than 3.0D) with/without astigmatism (lower than 2.0D). Lower level of efficacy is reported for correction of high hyperopia (higher than 3.0D). (GRADE +)

LASIK is comparable to surface ablative procedures in terms of efficacy. (GRADE +)(Almutairi et al., 2025)

LASIK is comparable to lenticule extraction in terms of efficacy for correcting myopia and low to moderate astigmatism. (GRADE +)

Considerations

The efficacy of LASIK has been well established for the correction of low to moderate myopia (≤ −6.0 D) and astigmatism (≤ 2.0 D), with most patients achieving excellent uncorrected distance visual acuity (UDVA) outcomes (Sugar et al., 2002). In a large clinical series, 89% of treated eyes reached UDVA of 20/20 or better (Reinstein et al., 2016). Meta-analyses confirm these results, showing no significant differences between topography-guided customized ablation treatment (TCAT)-

LASIK and wavefront-optimized (WFO)-LASIK, both of which consistently yield excellent efficacy (Cheng et al., 2021; McDonald et al., 2001).

For hyperopia, favorable outcomes have been demonstrated in low (< +3.0 D) to moderate (+3.0 D to +5.0 D) cases, with the majority of patients achieving postoperative refractions within ±1.0 D of the intended target (Varley et al., 2004). However, in high hyperopia (> +4.0 D to +5.0 D), efficacy and predictability decline, with increased rates of undercorrection and reduced spectacle-corrected visual acuity. In one study, corrected distance visual acuity (CDVA) of 20/20 or better was achieved in 76% of eyes following retreatment, while 25% lost one line of CDVA and 0.4% lost two lines.(Reinstein, Carp, et al., 2017) A review further reported that 62.8% of LASIK-treated eyes achieved UDVA of 20/20 compared with 54.1% of PRK-treated eyes.(Almutairi et al., 2025) Although LASIK demonstrated a numerical advantage, the lack of statistical significance and wide confidence intervals preclude definitive conclusions. Evidence for hyperopic astigmatism remains sparse, but current findings suggest broadly comparable outcomes to hyperopic patients without astigmatism. It is noteworthy that some studies suggest a promising result in improving refractive outcomes with the use of MMC in hyperopic LASIK surgery, especially in hyperopic eyes, even though there is limited research on this topic.(Saad et al., 2025) Still it has to be mentioned that other studies did not find a significant difference in efficacy between treatments including MMC or not.

When compared with surface ablation techniques, including PRK, Trans-PRK, and LASEK, systematic reviews report no significant differences in efficacy, with all approaches yielding high proportions of patients achieving UDVA of 20/20 or better (Wen et al., 2017) (Almutairi et al., 2025). Similarly, comparisons with lenticule extraction procedures, such as SMILE and KLEx, demonstrate largely equivalent outcomes in terms of efficacy, index of success, and angle of error. For low to moderate astigmatism, LASIK has been shown to provide a higher correction index and smaller difference vector relative to lenticule extraction (Song et al., 2023). However, meta-analyses have also reported comparable visual outcomes across both techniques, with similar proportions of patients achieving logMAR UDVA and postoperative UDVA of 20/10 or better (Yao et al., 2023).

Conclusion

Implications for practice

LASIK demonstrates excellent efficacy in the correction of low to moderate myopia and astigmatism, with the majority of patients achieving UDVA of 20/20 or better. Outcomes for low to moderate hyperopia are also favorable, though efficacy decreases in cases of high hyperopia, where undercorrection and reduced CDVA

are more likely. Compared with surface ablation and lenticule extraction, LASIK provides broadly comparable efficacy, with some evidence suggesting superior correction indices in low to moderate astigmatism.

Research gaps

Further high-quality, long-term studies are needed to clarify the efficacy of LASIK in high myopia and high hyperopia, where current results are less predictable. Additional research directly comparing LASIK with emerging procedures, particularly lenticule extraction, using standardized outcome measures and follow-up intervals, is warranted to refine patient selection and optimize treatment strategies.

Identified research evidence

Findings from Systematic Reviews

There was one relevant systematic reviews identified.

Direct comparisons showed a significant efficacy advantage only for LASIK over LASEK (OR 3.26, 95% CI 1.02 to 10.45). FS-LASIK demonstrated greater refractive predictability than LASIK, PRK, LASEK, and epi-LASIK. SUCRA rankings placed FS-LASIK first, followed by transepithelial PRK, LASEK, PRK, LASIK, and epi-LASIK. Combined direct and indirect evidence showed no significant differences in efficacy or safety, with between-procedure differences confined primarily to predictability (Wen et al., 2017). Risk of bias assessment: low risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE tables

Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK for myopia or myopic astigmatism

Patient or population: myopia or myopic astigmatism
Setting:
Intervention: Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Comparison: LASIK with a femtosecond laser for LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK with a femtosecond laser for LASIK	Risk difference with Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
UCVA, 12 months after surgery (unit LogMAR)	42 (1 RCT)	⊕◯◯◯ Very low[a,b]	-	The mean UCVA, 12 months after surgery (unit LogMAR) was **-0.04**	MD **0.01 lower** (0.06 lower to 0.04 higher)
Proportion of eyes within ± 0.5 diopters of target refraction, 12 months after surgery	79 (1 RCT)	⊕⊕◯◯ Low[b]	**RR 0.97** (0.85 to 1.11)	925 per 1,000	**28 fewer per 1,000** (139 fewer to 102 more)
Spherical equivalent of the refractive error, 12 months after surgery (unit diopters)	168 (3 RCTs)	⊕⊕◯◯ Low[c,d]	-	The mean spherical equivalent of the refractive error, 12 months after surgery (unit diopters) was **-0.3**	MD **0.09 higher** (0.01 lower to 0.19 higher)

Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK for myopia or myopic astigmatism

Patient or population: myopia or myopic astigmatism
Setting:
Intervention: Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Comparison: LASIK with a femtosecond laser for LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK with a femtosecond laser for LASIK	Risk difference with Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Diffuse lamellar keratitis, any time point	134 (3 RCTs)	⨁⨁◯◯ Low[c,d]	**RR 0.27** (0.10 to 0.78)	209 per 1,000	**153 fewer per 1,000** (188 fewer to 46 fewer)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. High risk of bias of the included study
b. Small sample size; wide confidence intervals around the effect estimate.
c. Unclear or high risk of bias of the included studies.

d. Small sample size
Reference:
Kahuam-López N, Navas A, Castillo-Salgado C, Graue-Hernandez EO, Jimenez-Corona A, Ibarra A. Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK in adults with myopia or myopic astigmatism. Cochrane Database Syst Rev. 2020 Apr 7;4(4):CD012946.

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Spherical equivalent follow-up: range 3 months to 12 months	951 (9 RCTs)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.04 lower** (0.12 lower to 0.03 higher)
proportion of eyes losing one or more lines of CDVA follow-up: range 3 months to 12 months	844 (6 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 1.14** (0.58 to 2.27)	35 per 1,000	**5 more per 1,000** (15 fewer to 45 more)
proportion of eyes with UCVA of 20/20 or better follow-up: range 3 months to 12 months	858 (8 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 0.99** (0.94 to 1.05)	897 per 1,000	**9 fewer per 1,000** (54 fewer to 45 more)
postoperative mean logMAR UCVA follow-up: range 3 months to 6 months	666 (6 RCTs)	⊕⊕◯◯ Low[d,e]	-	-	MD **0.01 higher** (0 to 0.03 higher)

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
postoperative refraction within ±1.0D follow-up: range 3 months to 12 months	818 (8 RCTs)	⊕⊕◯◯ Low[d,f]	**RR 1.00** (0.98 to 1.02)	984 per 1,000	**0 fewer per 1,000** (20 fewer to 20 more)
postoperative astigmatism within ±0.5 follow-up: range 3 months to 12 months	633 (6 RCTs)	⊕◯◯◯ Very low[b,d,e]	**RR 0.99** (0.94 to 1.05)	953 per 1,000	**10 fewer per 1,000** (57 fewer to 48 more)
postoperative higher order aberrations follow-up: range 3 months to 12 months	487 (5 RCTs)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0** (0.16 lower to 0.16 higher)
postoperative spherical aberration follow-up: range 3 months to 12 months	612 (5 RCTs)	⊕◯◯◯ Very low[b,d,f]	-	-	MD **0.12 lower** (0.23 lower to 0.01 lower)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Two of the included studies were judged to be at a high risk of bias
b. Significant statistical heterogeneity detected.
c. Small sample size for SMILE
d. Small sample size
e. Mainly unclear risk of bias of the included studies.
f. Some of the included studies were judged to be at a high risk of bias
Reference: Yao L, Zhang M, Wang D, Zhao Q, Wang S, Bai H. Small Incision Lenticule Extraction (SMILE) and Laser in Situ Keratomileusis (LASIK) Used to Treat Myopia and Myopic Astigmatism: A Systematic Review and Meta-analysis of Randomized Clinical Trials. Semin Ophthalmol. 2023 Apr;38(3):283-293.

FS-LASIK compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: FS-LASIK
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with FS-LASIK
UCVA of 20/20 or better	(3 RCTs)	⨁◯◯◯ Very low[a,b,c]	**OR 2.08** (0.29 to 14.99)	Inestimable	Inestimable
New outcome (refractive error within ±0.50 D of the target refraction)	(5 RCTs)	⨁⨁◯◯ Low[a,c]	**OR 2.13** (1.06 to 4.25)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(3 RCTs)	⨁⨁◯◯ Low[a,c]	**OR 1.26** (0.32 to 4.96)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
b. Significant statistical heterogeneity detected.

c. Wide confidence intervals around the effect estimate.

Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I, Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Correction index	1309 (13 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.02 lower** (0.04 lower to 0.01 lower)
Difference vector	1052 (9 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.07 higher** (0 to 0.13 higher)
Index of success and angle of error	928 (7 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.01 higher** (0.03 lower to 0.05 higher)

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
UDVA	1413 (11 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.02 higher)
CDVA	1322 (10 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.01 higher)
Coma	729 (6 observational studies)	⊕◯◯◯ Very low[a,b,d,e]	-	-	MD **0.04 SD higher** (0.01 lower to 0.08 higher)
spherical aberration	749 (6 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.12 SD lower** (0.23 lower to 0.01 lower)
Total high-order aberrations	438 (5 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.01 SD lower** (0.07 lower to 0.04 higher)

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Considerable amount of heterogeneity
d. Wide confidence intervals around effect estimate; small sample size
e. Significant statistical heterogeneity detected.
Reference: Song J, Cao H, Chen X, Zhao X, Zhang J, Wu G, Wang Y. Small Incision Lenticule Extraction (SMILE) Versus Laser Assisted Stromal In Situ Keratomileusis (LASIK) for Astigmatism Corrections: A Systematic Review and Meta-analysis. Am J Ophthalmol. 2023 Mar;247:181-199.

8.1.3 Predictability of LASIK

Output question

What is the predictability of LASIK?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing LASIK
C Other procedures:
- Use of spectacles
- Other intracorneal ablative procedures: (refractive lenticule extraction)
- Corneal surface ablative procedures (PRK/Trans-PRK
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O Postoperative refractive outcome

Recommendation

LASIK shows comparable results in terms of predictability when compared to other corneal laser refractive surgeries in myopic patients with or without corneal astigmatism. (GRADE +)(Almutairi et al., 2025)

LASIK shows high predictability in low to moderate myopia (lower than 6.0D) and low to moderate hyperopia (lower than 3.0D), with astigmatism (lower than 2.0D) (GRADE +)

Predictability is high in MK-LASIK and FS-LASIK with an equal number of patients achieving 0.5D within the target refraction in both groups. (GRADE ++)

Considerations

Comparisons of LASIK outcomes in terms of predictability are complicated by heterogeneity in study design, preoperative refractive ranges, surgical techniques, laser platforms, and follow-up durations. Despite these limitations, consistent evidence demonstrates favorable predictability in low to moderate myopia (< −6.0 D). In this subgroup, 75–83% of eyes achieve a postoperative refraction within ±0.50 D, while 90–100% fall within ±1.00 D of the intended target (Sugar et al., 2002). Outcomes are less reliable in high myopia (> −6.0 D), where only 23–40% of eyes achieve refractions within ±0.50 D and 40–75% within ±1.00 D of the target (Sugar et al., 2002). Comparisons of ablation profiles suggest that topography-guided customized ablation treatment (TCAT)-LASIK achieves a higher proportion of eyes

within ±0.50 D of the target compared with wavefront-optimized (WFO)-LASIK (Cheng et al., 2021).

Evidence for hyperopia is comparatively limited. In low (< +3.0 D) to moderate (+3.0 D to +5.0 D) hyperopia, LASIK demonstrates favorable predictability, with most eyes achieving results within ±1.00 D of the intended correction (Varley et al., 2004). However, in high hyperopia (> +4.0 D), outcomes are substantially less predictable. One study reported that only 40.4% of highly hyperopic eyes achieved results within ±0.50 D, compared with 61.0% in eyes with low hyperopia (< +4.0 D) (Cobo-Soriano et al., 2002). In another study, primary treatment yielded postoperative spherical equivalents within ±0.50 D in 50% and within ±1.00 D in 77% of eyes; after retreatment, these proportions increased to 67% and 89%, respectively.(Reinstein, Carp, et al., 2017) It has to be mentioned that some studies showed significant differences between the use of MMC or not in hyperopic eyes, with the MMC group showing more accurate correction than the LASIK without MMC group in hyperopic eyes, suggesting that MMC could potentially improve the intended outcome for some hyperopic patients.(Saad et al., 2025)

Comparisons of femtosecond (FS)-LASIK with mechanical microkeratome (MK)-LASIK indicate similar outcomes, with comparable proportions of eyes achieving refractions within ±0.50 D and equivalent mean spherical equivalents at 12 months (Kahuam-López et al., 2020).

Relative to PRK, LASIK demonstrates similar predictability. Studies in both low (< −6.0 D) and moderate to high myopia (−6.0 D to −15.0 D) show no significant differences in refractive outcomes or predictability at 6–12 months(Almutairi et al., 2025) (Sugar et al., 2002). However, a systematic review suggests that FS-LASIK may provide slightly superior predictability compared with PRK and Trans-PRK in low to moderate myopia (Wen et al., 2017). For hyperopia, one review found no clinically meaningful differences between LASIK and PRK, with 83.5% of LASIK eyes and 83.6% of PRK eyes within ±1.00 D of emmetropia, and 63.5% and 52.1% within ±0.50 D, respectively.(Almutairi et al., 2025)

When compared with lenticule extraction, LASIK demonstrated a modest but statistically significant advantage in predictability, with a higher proportion of eyes achieving postoperative refraction within ±0.50 D (RR 0.91, p = 0.04) (Yao et al., 2023). Nonetheless, given the small magnitude of this difference, both procedures may be considered broadly comparable in clinical practice.

Conclusion

Implications for practice

LASIK provides high predictability in low to moderate myopia and hyperopia, with the majority of eyes achieving refractions within ±1.00 D of the intended target. Predictability decreases substantially in high myopia and high hyperopia. When compared to other refractive procedures, including PRK and lenticule extraction, LASIK demonstrates broadly comparable predictability, with only modest differences of limited clinical significance.

Implications for research

Further high-quality studies are warranted to clarify the long-term predictability of LASIK in high myopia and high hyperopia, including subgroups with significant astigmatism. Standardized study designs with uniform outcome measures and follow-up intervals are needed to reduce heterogeneity and facilitate more robust comparisons across refractive procedures.

Identified research evidence

Findings from Systematic Reviews

There were two relevant systematic reviews identified.

Direct comparisons showed a significant efficacy advantage only for LASIK over LASEK (OR 3.26, 95% CI 1.02 to 10.45). FS-LASIK demonstrated greater refractive predictability than LASIK, PRK, LASEK, and epi-LASIK and ranked highest in the SUCRA analysis. Combined direct and indirect evidence showed no significant differences among procedures in efficacy or safety. Overall, the principal between-procedure difference concerned the superior refractive predictability of FS-LASIK (Wen et al., 2017). Risk of bias assessment: low risk of bias.

SMILE and LASIK showed comparable outcomes for postoperative spherical equivalent, corrected and uncorrected distance visual acuity, astigmatic correction, and higher-order aberrations. LASIK achieved a slightly higher proportion of eyes within ±0.50 D of target refraction (RR 0.91, 95% CI 0.83 to 0.99). In contrast, postoperative spherical aberration was lower after SMILE (mean difference −0.12, 95% CI −0.23 to −0.01). Overall, both procedures provided similar visual and refractive outcomes, with small differences in predictability and spherical aberration (Yao et al., 2023). Risk of bias assessment: high risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK for myopia or myopic astigmatism

Patient or population: myopia or myopic astigmatism
Setting:
Intervention: Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Comparison: LASIK with a femtosecond laser for LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK with a femtosecond laser for LASIK	Risk difference with Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
UCVA, 12 months after surgery (unit LogMAR)	42 (1 RCT)	⊕◯◯◯ Very low[a,b]	-	The mean UCVA, 12 months after surgery (unit LogMAR) was **-0.04**	MD **0.01 lower** (0.06 lower to 0.04 higher)
Proportion of eyes within ± 0.5 diopters of target refraction, 12 months after surgery	79 (1 RCT)	⊕⊕◯◯ Low[b]	**RR 0.97** (0.85 to 1.11)	925 per 1,000	**28 fewer per 1,000** (139 fewer to 102 more)
Spherical equivalent of the refractive error, 12 months after surgery (unit diopters)	168 (3 RCTs)	⊕⊕◯◯ Low[c,d]	-	The mean spherical equivalent of the refractive error, 12 months after surgery (unit diopters) was **-0.3**	MD **0.09 higher** (0.01 lower to 0.19 higher)

Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK for myopia or myopic astigmatism

Patient or population: myopia or myopic astigmatism
Setting:
Intervention: Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Comparison: LASIK with a femtosecond laser for LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK with a femtosecond laser for LASIK	Risk difference with Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Diffuse lamellar keratitis, any time point	134 (3 RCTs)	⨁⨁◯◯ Low[c,d]	**RR 0.27** (0.10 to 0.78)	209 per 1,000	**153 fewer per 1,000** (188 fewer to 46 fewer)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. High risk of bias of the included study
b. Small sample size; wide confidence intervals around the effect estimate.
c. Unclear or high risk of bias of the included studies.

d. Small sample size
Reference:
Kahuam-López N, Navas A, Castillo-Salgado C, Graue-Hernandez EO, Jimenez-Corona A, Ibarra A. Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK in adults with myopia or myopic astigmatism. Cochrane Database Syst Rev. 2020 Apr 7;4(4):CD012946.

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Spherical equivalent follow-up: range 3 months to 12 months	951 (9 RCTs)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.04 lower** (0.12 lower to 0.03 higher)
proportion of eyes losing one or more lines of CDVA follow-up: range 3 months to 12 months	844 (6 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 1.14** (0.58 to 2.27)	35 per 1,000	**5 more per 1,000** (15 fewer to 45 more)
proportion of eyes with UCVA of 20/20 or better follow-up: range 3 months to 12 months	858 (8 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 0.99** (0.94 to 1.05)	897 per 1,000	**9 fewer per 1,000** (54 fewer to 45 more)
postoperative mean logMAR UCVA follow-up: range 3 months to 6 months	666 (6 RCTs)	⊕⊕◯◯ Low[d,e]	-	-	MD **0.01 higher** (0 to 0.03 higher)

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
postoperative refraction within ±1.0D follow-up: range 3 months to 12 months	818 (8 RCTs)	⊕⊕◯◯ Low[d,f]	**RR 1.00** (0.98 to 1.02)	984 per 1,000	**0 fewer per 1,000** (20 fewer to 20 more)
postoperative astigmatism within ±0.5 follow-up: range 3 months to 12 months	633 (6 RCTs)	⊕◯◯◯ Very low[b,d,e]	**RR 0.99** (0.94 to 1.05)	953 per 1,000	**10 fewer per 1,000** (57 fewer to 48 more)
postoperative higher order aberrations follow-up: range 3 months to 12 months	487 (5 RCTs)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0** (0.16 lower to 0.16 higher)
postoperative spherical aberration follow-up: range 3 months to 12 months	612 (5 RCTs)	⊕◯◯◯ Very low[b,d,f]	-	-	MD **0.12 lower** (0.23 lower to 0.01 lower)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Two of the included studies were judged to be at a high risk of bias
b. Significant statistical heterogeneity detected.
c. Small sample size for SMILE
d. Small sample size
e. Mainly unclear risk of bias of the included studies.
f. Some of the included studies were judged to be at a high risk of bias
Reference: Yao L, Zhang M, Wang D, Zhao Q, Wang S, Bai H. Small Incision Lenticule Extraction (SMILE) and Laser in Situ Keratomileusis (LASIK) Used to Treat Myopia and Myopic Astigmatism: A Systematic Review and Meta-analysis of Randomized Clinical Trials. Semin Ophthalmol. 2023 Apr;38(3):283-293.

FS-LASIK compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: FS-LASIK
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with FS-LASIK
UCVA of 20/20 or better	(3 RCTs)	⊕◯◯◯ Very low[a,b,c]	**OR 2.08** (0.29 to 14.99)	Inestimable	Inestimable
New outcome (refractive error within ±0.50 D of the target refraction)	(5 RCTs)	⊕⊕◯◯ Low[a,c]	**OR 2.13** (1.06 to 4.25)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(3 RCTs)	⊕⊕◯◯ Low[a,c]	**OR 1.26** (0.32 to 4.96)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
b. Significant statistical heterogeneity detected.

c. Wide confidence intervals around the effect estimate.

Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I, Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Correction index	1309 (13 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.02 lower** (0.04 lower to 0.01 lower)
Difference vector	1052 (9 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.07 higher** (0 to 0.13 higher)
Index of success and angle of error	928 (7 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.01 higher** (0.03 lower to 0.05 higher)

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
UDVA	1413 (11 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.02 higher)
CDVA	1322 (10 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.01 higher)
Coma	729 (6 observational studies)	⊕◯◯◯ Very low[a,b,d,e]	-	-	MD **0.04 SD higher** (0.01 lower to 0.08 higher)
spherical aberration	749 (6 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.12 SD lower** (0.23 lower to 0.01 lower)
Total high-order aberrations	438 (5 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.01 SD lower** (0.07 lower to 0.04 higher)

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Considerable amount of heterogeneity
d. Wide confidence intervals around effect estimate; small sample size
e. Significant statistical heterogeneity detected.
Reference: Song J, Cao H, Chen X, Zhao X, Zhang J, Wu G, Wang Y. Small Incision Lenticule Extraction (SMILE) Versus Laser Assisted Stromal In Situ Keratomileusis (LASIK) for Astigmatism Corrections: A Systematic Review and Meta-analysis. Am J Ophthalmol. 2023 Mar;247:181-199.

8.1.4 Stability of LASIK

Output question

What is the stability of LASIK?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing intracorneal ablative procedures (LASIK/ Fs-LASIK)
C Other procedures:
- Use of spectacles
- corneal surface ablative procedures: (PRK/ trans-PRK)
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Recommendation

The refractive results of LASIK are considered stable for low to moderate myopia. (GRADE +)

Stability of LASIK decreases as the degree of myopia increases. (GRADE +)

For the stability of LASIK among hyperopic patients, the evidence is limited, but stability in general decreases as the degree of hyperopia increases. (GRADE +)

Considerations

Refractive stability represents a fundamental long-term outcome following excimer laser surgery. However, the evaluation of stability across studies remains challenging due to marked heterogeneity in follow-up duration, variability in outcome measures, small sample sizes, and the increasing attrition of long-term cohorts.

A meta-analysis reported that, at 6 months postoperatively, 80% of patients with low to moderate myopia (< −6.0 D) achieved a mean refractive spherical equivalent (MRSE) within ±0.50 D, compared with 57.6% of patients with high myopia (> −6.0 D). For MRSE within ±1.00 D, the respective values were 92.9% and 84.7%. Over time, refractive stability progressively declined. Among low to moderate myopes, the proportion of eyes within ±0.50 D was 86% at 1 year, 70.7% at 2–5 years, and 46.2% at 6–9 years. In high myopia, the corresponding proportions decreased to 65.9%, 38.7%, and 35.5%. For MRSE within ±1.00 D, the proportions were 98%, 93.1%, and 69.2% in low to moderate myopes, and 87.8%, 75.8%, and 64.5% in high myopes across the same time intervals. Beyond 5 years, an increasing trend

toward overcorrection was noted, which is consistent with myopic regression (Dirani et al., 2010).

Evidence in hyperopia is more limited. One randomized controlled study reported that one line of corrected distance visual acuity (CDVA) was lost in 25% of eyes and two lines were lost in only 0.4%, suggesting overall acceptable stability outcomes in hyperopic patients.(Reinstein, Carp, et al., 2017)

When compared with PRK, LASIK demonstrated consistently higher stability across all reported follow-up periods. In low to moderate myopia, MRSE within ±1.00 D was achieved in 92.9% of eyes at 6 months, 89.5% at 1 year, and 69% at 6–9 years. In high myopia, the corresponding proportions were 66.7%, 58.6%, and 42.9% (Dirani et al., 2010).

Conclusion

Implications for practice

The current body of evidence indicates that LASIK provides stable long-term refractive outcomes, particularly in patients with low to moderate myopia. Stability declines progressively over time and is less consistent in high myopia. Results for hyperopia are limited.

Implications for research

Evidence regarding long-term refractive stability after LASIK remains limited. Future research should focus on large-scale, high-quality studies with standardized outcome measures and extended follow-up periods. Particular attention is needed to better characterize long-term stability in high myopia and to further clarify comparative stability between LASIK and other refractive procedures.

Identified research evidence

Findings from Systematic Reviews

There were no relevant systematic reviews identified.

Findings from additional studies

There were multiple additional studies included.

8.1.5 Safety of LASIK

Output question

What is the safety of LASIK?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing intracorneal ablative procedures (LASIK)
C Other procedures:
- Use of spectacles
- Corneal surface ablative procedures: (PRK/ trans-PRK
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O (Serious) adverse events

Recommendation

LASIK can be considered safe for treating myopia and hyperopia, with a very low rate of serious adverse events occurring intra- and postoperatively. Note that this highly depends on the amount of preoperative refractive error. (GRADE +)

No statistically significant difference has been found between different refractive procedures including LASIK, PRK and Trans-PRK concerning safety. (GRADE +)

PRK/Trans-PRK and LASEK show less risk for ectasia development than eyes treated with LASIK, which is also the case for KLEx. (GRADE +)

The higher refractive errors, especially high hyperopia still presents an increased complications profile, and one should take into account the reduced safety profile prior to treating patients with hyperopia higher than 3 D. (GRADE +)

Considerations

LASIK has consistently demonstrated a favorable safety profile, particularly in patients with low to moderate myopia (< −6.0 D). Across multiple studies, the incidence of severe adverse outcomes is low, with no reports of >2 lines of best-corrected visual acuity (BCVA) loss in this patient group (Cheng et al., 2021). In contrast, patients with high myopia (> −6.0 D) experience a modestly increased risk, with a pooled mean incidence of >2 lines of BCVA loss reported at 1.8% (range 0–7% across 10 studies) (Sugar et al., 2002). Although evidence in hyperopic populations remains sparse, one prospective study found that one line of corrected distance visual acuity (CDVA) was lost in 25% of eyes and two lines in 0.4%, results that nevertheless indicate acceptable safety outcomes.(Reinstein, Carp, et al., 2017)

Intraoperative complications are relatively infrequent, reported in approximately 0.7–6.6% of cases, and are primarily flap-related. These include incomplete or irregular flaps, buttonholes, and free caps, complications that are largely attributable to mechanical or femtosecond laser flap creation techniques (Tse et al., 2016). The widespread adoption of femtosecond laser platforms has contributed to reducing the risk and variability of flap creation, though mechanical microkeratomes continue to be used in some settings.

Postoperative complications are more common but generally transient or manageable. The most frequent is dry eye disease (DED), reported in 60–70% of patients during the early postoperative period (Perez-Straziota & Randleman, 2016). This high incidence is attributed to disruption of the sub-basal corneal nerves during flap creation, which impairs corneal sensation and destabilizes the tear film. While most cases improve over time, a subset of patients may experience persistent DED, requiring long-term management. Visual aberrations represent another postoperative concern, with spherical aberration, coma, and higher-order aberrations (HOAs) reported in varying frequencies. Topography-guided customized ablation treatment (TCAT)-LASIK has been associated with a lower induction of HOAs compared with wavefront-optimized (WFO)-LASIK, highlighting the potential benefits of individualized ablation profiles (Cheng et al., 2021).

Serious but rare complications include infectious keratitis and postoperative corneal ectasia, both of which can result in significant and sometimes irreversible visual loss. The incidence of these events is very low in both myopic and hyperopic eyes, but their potential severity underscores the importance of appropriate patient selection, meticulous preoperative screening for ectatic disorders, and adherence to established safety criteria (Gimbel et al., 1998; Varley et al., 2004).

Comparisons with other refractive procedures show broadly similar safety profiles. Systematic reviews of LASIK versus surface ablation techniques (PRK, Trans-PRK, and LASEK) have demonstrated no statistically significant differences in terms of overall safety outcomes (Wen et al., 2017). Nonetheless, PRK has been associated with lower rates of corneal haze formation, whereas LASIK carries a higher risk of postoperative DED due to flap creation.(Saad et al., 2025) Lenticule extraction procedures, such as SMILE, have emerged as an alternative to LASIK, and meta-analyses indicate no significant difference in the proportion of eyes losing ≥1 line of CDVA between the two techniques, suggesting comparable safety (Yao et al., 2023). However, LASIK has been associated with higher postoperative spherical aberration compared to lenticule extraction (Song et al., 2023; Yao et al., 2023).

Technique-specific differences within LASIK have also been reported. Mechanical microkeratome (MK)-LASIK has been associated with a reduced risk of diffuse lamellar keratitis compared with femtosecond (FS)-LASIK, whereas one study found that DED may be more prevalent in MK-LASIK than FS-LASIK, although the

evidence supporting this observation is of low certainty. No significant differences have been demonstrated between MK- and FS-LASIK regarding the incidence of corneal haze or epithelial ingrowth (Kahuam-López et al., 2020).

Taken together, current evidence indicates that LASIK is a safe and reliable procedure across a wide range of refractive errors. Safety is optimal in low to moderate myopia and hyperopia, while slightly reduced in higher refractive errors. Comparative evidence suggests LASIK safety outcomes are broadly equivalent to PRK, Trans-PRK, LASEK, and lenticule extraction, although differences in complication patterns—such as flap-related risks in LASIK and haze in PRK—should be considered in clinical decision-making.

Conclusion

Implications for practice

Based on the current available evidence, LASIK is safe and is comparable to other refractive surgery procedures in terms of safety. MK LASIK is associated with a higher rate of DED compared to FS LASIK, while diffuse lamellar keratitis is slightly higher in the FS LASIK group.

Implications for research

Further research on safety of LASIK in high myopes and high hyperopes is suggested.

Identified research evidence

Findings from Systematic Reviews

There was one relevant systematic reviews identified.

Direct comparisons showed a significant efficacy advantage only for LASIK over LASEK (OR 3.26, 95% CI 1.02 to 10.45). FS-LASIK demonstrated greater refractive predictability than LASIK, PRK, LASEK, and epi-LASIK and ranked highest in the SUCRA analysis. Combined direct and indirect evidence showed no significant differences among procedures in efficacy or safety, indicating that the principal between-procedure distinction was predictability (Wen et al., 2017). Risk of bias assessment: low risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE tables

Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK for myopia or myopic astigmatism

Patient or population: myopia or myopic astigmatism
Setting:
Intervention: Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Comparison: LASIK with a femtosecond laser for LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK with a femtosecond laser for LASIK	Risk difference with Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
UCVA, 12 months after surgery (unit LogMAR)	42 (1 RCT)	⨁◯◯◯ Very low[a,b]	-	The mean UCVA, 12 months after surgery (unit LogMAR) was **-0.04**	MD **0.01 lower** (0.06 lower to 0.04 higher)
Proportion of eyes within ± 0.5 diopters of target refraction, 12 months after surgery	79 (1 RCT)	⨁⨁◯◯ Low[b]	**RR 0.97** (0.85 to 1.11)	925 per 1,000	**28 fewer per 1,000** (139 fewer to 102 more)

Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK for myopia or myopic astigmatism

Patient or population: myopia or myopic astigmatism
Setting:
Intervention: Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Comparison: LASIK with a femtosecond laser for LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK with a femtosecond laser for LASIK	Risk difference with Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Spherical equivalent of the refractive error, 12 months after surgery (unit diopters)	168 (3 RCTs)	⊕⊕◯◯ Low[c,d]	-	The mean spherical equivalent of the refractive error, 12 months after surgery (unit diopters) was **-0.3**	MD **0.09 higher** (0.01 lower to 0.19 higher)
Diffuse lamellar keratitis, any time point	134 (3 RCTs)	⊕⊕◯◯ Low[c,d]	**RR 0.27** (0.10 to 0.78)	209 per 1,000	**153 fewer per 1,000** (188 fewer to 46 fewer)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK for myopia or myopic astigmatism

Patient or population: myopia or myopic astigmatism
Setting:
Intervention: Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome
Comparison: LASIK with a femtosecond laser for LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK with a femtosecond laser for LASIK	Risk difference with Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. High risk of bias of the included study
b. Small sample size; wide confidence intervals around the effect estimate.
c. Unclear or high risk of bias of the included studies.
d. Small sample size
Reference:
Kahuam-López N, Navas A, Castillo-Salgado C, Graue-Hernandez EO, Jimenez-Corona A, Ibarra A. Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK in adults with myopia or myopic astigmatism. Cochrane Database Syst Rev. 2020 Apr 7;4(4):CD012946.

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Spherical equivalent follow-up: range 3 months to 12 months	951 (9 RCTs)	⨁◯◯◯ Very low[a,b,c]	-	-	MD **0.04 lower** (0.12 lower to 0.03 higher)
proportion of eyes losing one or more lines of CDVA follow-up: range 3 months to 12 months	844 (6 RCTs)	⨁⨁◯◯ Low[a,d]	**RR 1.14** (0.58 to 2.27)	35 per 1,000	**5 more per 1,000** (15 fewer to 45 more)
proportion of eyes with UCVA of 20/20 or better follow-up: range 3 months to 12 months	858 (8 RCTs)	⨁⨁◯◯ Low[a,d]	**RR 0.99** (0.94 to 1.05)	897 per 1,000	**9 fewer per 1,000** (54 fewer to 45 more)
postoperative mean logMAR UCVA follow-up: range 3 months to 6 months	666 (6 RCTs)	⨁⨁◯◯ Low[d,e]	-	-	MD **0.01 higher** (0 to 0.03 higher)
postoperative refraction within ±1.0D follow-up: range 3 months to 12 months	818 (8 RCTs)	⨁⨁◯◯ Low[d,f]	**RR 1.00** (0.98 to 1.02)	984 per 1,000	**0 fewer per 1,000** (20 fewer to 20 more)

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
postoperative astigmatism within ±0.5 follow-up: range 3 months to 12 months	633 (6 RCTs)	⊕◯◯◯ Very low[b,d,e]	**RR 0.99** (0.94 to 1.05)	953 per 1,000	**10 fewer per 1,000** (57 fewer to 48 more)
postoperative higher order aberrations follow-up: range 3 months to 12 months	487 (5 RCTs)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0** (0.16 lower to 0.16 higher)
postoperative spherical aberration follow-up: range 3 months to 12 months	612 (5 RCTs)	⊕◯◯◯ Very low[b,d,f]	-	-	MD **0.12 lower** (0.23 lower to 0.01 lower)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Two of the included studies were judged to be at a high risk of bias
b. Significant statistical heterogeneity detected.

c. Small sample size for SMILE
d. Small sample size
e. Mainly unclear risk of bias of the included studies.
f. Some of the included studies were judged to be at a high risk of bias
Reference: Yao L, Zhang M, Wang D, Zhao Q, Wang S, Bai H. Small Incision Lenticule Extraction (SMILE) and Laser in Situ Keratomileusis (LASIK) Used to Treat Myopia and Myopic Astigmatism: A Systematic Review and Meta-analysis of Randomized Clinical Trials. Semin Ophthalmol. 2023 Apr;38(3):283-293.

FS-LASIK compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: FS-LASIK
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with FS-LASIK
UCVA of 20/20 or better	(3 RCTs)	⨁◯◯◯ Very low[a,b,c]	**OR 2.08** (0.29 to 14.99)	Inestimable	Inestimable
New outcome (refractive error within ±0.50 D of the target refraction)	(5 RCTs)	⨁⨁◯◯ Low[a,c]	**OR 2.13** (1.06 to 4.25)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(3 RCTs)	⨁⨁◯◯ Low[a,c]	**OR 1.26** (0.32 to 4.96)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio

FS-LASIK compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: FS-LASIK
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with FS-LASIK

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
b. Significant statistical heterogeneity detected.
c. Wide confidence intervals around the effect estimate.

Reference: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I, Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.

LASIK compared to for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: LASIK
Comparison: none

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with	Risk difference with LASIK
Retinal detachment follow-up: range 2 months to 10 years	232,419 (12 observational studies)	⨁⨁◯◯ Low[a]	**RR 0.080** (0.069 to 0.092)	Inestimable	Inestimable

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Explanations
a. Results from cohort studies

Reference:
Kanclerz P, Grzybowski A. Does Corneal Refractive Surgery Increase the Risk of Retinal Detachment? A Literature Review and Statistical Analysis. J Refract Surg. 2019 Aug 1;35(8):517-524.

8.2 Keratorefractive Lenticule Extraction (KLEx)

8.2.1 Indications and contraindications of keratorefractive lenticule extraction

Output question

What are the indications and contraindications for refractive lenticule extraction?

Recommendation

Limits of application KLEx:

- Myopia lower than 8.00D (GRADE +)
- Myopia higher than 8.00D only in case of a regular cornea, without any risk factors, and a sufficient corneal thickness, taking into account the cap and lenticule thickness and residual estimated thickness (GRADE +)
- Astigmatism lower than 5.0D, however laser platforms that do not provide cyclotorsion compensation, are able to correct only lower than 2.0D. (GRADE +)
- The CE-mark for hyperopic KLEx (only on Zeiss platform in Nov. 2025) has recently been approved with the application limits set at +6D for sphere and +4D for cylinder. However, there is still limited evidence regarding the long-term safety and efficacy of the procedure. (GRADE +)

The application limits must account for a minimum preoperative corneal thickness of 480 µm in the absence of additional risk factors (recommended is a thickness of 500 thickness), with an ideally preserved residual stromal bed of at least 300 µm. Under no circumstances should the residual stromal bed fall below 250 µm. It is crucial to emphasize that in any form of corneal subtractive surgery, the decisive parameter is not corneal thickness alone, but rather the total ablation volume relative to the corneal architecture. (GRADE +)

Considerations

KLEx is indicated for myopia up to −8.0 diopters and astigmatism up to 5.0 diopters, though not more than 2.0 diopters without cyclotorsion control. Limits of application always depend on patient characteristics, comorbidities and surgeon expertise and practical experience. For the determination of the upper limit, the values for the highest refractive index in the principal plane always have to be taken into account. (German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020)

KLEx has recently gotten CE-mark approval for hyperopia up to +6.0 diopters and astigmatism up to +4.0 diopters, though evidence for these indications is still very limited.(Fu et al., 2026)

Conclusion

Implications for practice
Based on the current available evidence, the decision for a refractive lenticule extraction procedure should be made in shared consent by patient and surgeon. To guarantee safety and effectiveness, selection criteria must strictly be followed.

Knowledge gaps
More research on the safe range of application for lenticule extraction has to be conducted in order to correctly advise patients and facilitate the choice between different refractive procedures.

Identified research evidence

Findings from Systematic Reviews

There were no systematic reviews included.

Findings from additional studies

There were multiple additional studies included.

8.2.2 Efficacy of keratorefractive lenticule extraction

Output question

What is the efficacy of keratorefractive lenticule extraction?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing intracorneal procedure (refractive lenticule extraction)
C Other procedures:
- Use of spectacles
- Corneal surface ablative procedures (PRK/Trans-PRK)
- Intracorneal ablative procedures: (LASIK)
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Recommendation

KLEx is effective for correcting moderate to high myopia (lower than 8.0D) and/or astigmatism (lower than 5.0D). The evidence for KLEx correcting higher degrees of myopia (higher than 8.0D) is limited. (GRADE +)

The efficacy of KLEx is comparable to other corneal laser refractive surgeries and phakic IOL implantation for patients with low to moderate myopia. For myopia greater than 8D, phakic IOL implantation is preferred. (GRADE +)

Hyperopic KLEx demonstrates variable efficacy, with results being less consistent than in myopic treatments, reflecting the inherent challenges of hyperopic correction. (GRADE +)(Fu et al., 2026)

Considerations

Among patients with moderate to high myopia (up to –8.0 D), with or without astigmatism, refractive lenticule extraction procedures such as SMILE and KLEx demonstrate efficacy outcomes comparable to each other. Postoperative uncorrected distance visual acuity (UDVA) values typically range between 0.02 to –0.15 logMAR for SMILE and 0.06 to –0.17 logMAR for KLEx, with no significant differences in the proportion of eyes achieving UDVA of 20/20 or better within 3–12 months postoperatively (Vestergaard et al., 2014; J. S. Wang et al., 2017).

Systematic reviews comparing SMILE with LASIK, FS-LASIK, and other excimer laser–based techniques in patients with myopia from –3.0 D to –8.0 D similarly report no statistically significant differences in efficacy (Shen, Shi, et al., 2016; Tian et al.,

2023; Wen et al., 2017; Yan et al., 2017; Yao et al., 2023; Zhang et al., 2016). Based on surface under the cumulative ranking curve (SUCRA) analyses, FS-LASIK ranked highest for efficacy, followed by LASIK, SMILE, KLEx, PRK, LASEK, Epi-LASEK, and T-PRK (Wen et al., 2017).

Hyperopic keratorefractive lenticule extraction (KLEx) demonstrates generally favorable but variable efficacy across published studies. Preliminary findings indicate that refractive lenticule extraction may achieve favorable results in eyes with hyperopia up to +6.0 D and astigmatism up to 4.0 . .(Reinstein et al., 2019; Reinstein, Sekundo, et al., 2022) More recent multicenter data at 12 months showed that 68.8% of eyes achieved 20/20 and 88% achieved ≥20/25. Despite these encouraging results, efficacy remains less consistent than in myopic KLEx, likely reflecting the increased technical complexity of hyperopic ablation profiles and the higher susceptibility to postoperative regression. (Fu et al., 2026)

When compared with phakic intraocular lens (pIOL) implantation in moderate to high myopia (–4.0 D to –8.0 D), refractive lenticule extraction shows no significant difference in the proportion of eyes achieving UDVA of 20/20 or better (93.2% for ICL vs. 91.8% for SMILE). Mean postoperative UDVA outcomes were also comparable, although these findings exhibited considerable heterogeneity (Di et al., 2023). In patients with high myopia (–7.0 D to –11.0 D), long-term follow-up (up to 3 years) found no significant differences in UDVA between SMILE and FS-LASIK (Fu et al., 2021). Similarly, for myopia between –3.0 D and –8.0 D, no efficacy differences were reported between SMILE and wavefront-guided LASIK (Tian et al., 2023).

In very high myopia (–5.0 D to –12.0 D), results are less consistent. Some studies report no significant differences in efficacy index, UDVA, corrected distance visual acuity (CDVA), or spherical equivalent between SMILE and ICL implantation, while others suggest a superior short-term efficacy index for ICL implantation (Cao et al., 2021; Chen et al., 2022).

For myopic astigmatism (–0.75 D to –3.0 D), SMILE and LASIK yield comparable outcomes, with no statistically significant differences in success index, angle of error, UDVA, CDVA, or mean refractive spherical equivalent (MRSE) (Song et al., 2023).

Conclusion

Implications for practice

Current evidence indicates that refractive lenticule extraction is an effective treatment option for patients with moderate to high myopia, both with and without astigmatism. The procedure provides outcomes comparable to those of established corneal refractive techniques in terms of visual efficacy. However, it is important to

emphasize that the majority of available studies focus on short- to mid-term follow-up, limiting the strength of conclusions regarding its durability over time. Evidence for hyperopia remains scarce, and therefore no reliable statements can be made on its efficacy in hyperopic eyes. Consequently, clinical adoption should proceed with caution, and treatment recommendations must consider these limitations.

Knowledge gaps

Significant knowledge gaps remain in the evidence base for refractive lenticule extraction. Most notably, the efficacy of the procedure in hyperopic patients has not been systematically studied and warrants targeted investigation. Furthermore, while short-term outcomes for myopic eyes appear favorable, long-term data remain scarce. Robust, large-scale, longitudinal studies are required to assess the stability and sustainability of refractive and visual outcomes, particularly beyond five years. Addressing these gaps will be essential to establish the long-term safety and efficacy profile of lenticule extraction and to refine patient selection criteria

Identified research evidence

Findings from Systematic Reviews

There were eleven relevant systematic reviews identified.

ICL implantation showed higher pooled efficacy and safety indices than SMILE and was associated with more frequent gains and fewer losses of corrected distance visual acuity lines. Refractive predictability was comparable between procedures. ICL induced fewer total higher-order aberrations but was associated with a higher risk of postoperative halos (Cao et al., 2021). Risk of bias assessment: high risk of bias.

SMILE and FS-LASIK produced comparable postoperative spherical equivalent, uncorrected distance visual acuity, corrected distance visual acuity loss, and refractive predictability. Schirmer test values were similar, whereas tear-film break-up time and corneal sensitivity generally favoured SMILE during postoperative follow-up. Tear-film osmolarity was higher after FS-LASIK in the single study reporting this outcome (Zhang et al., 2016). Risk of bias assessment: high risk of bias.

SMILE and ICL V4c achieved comparable efficacy, postoperative visual acuity, and spherical equivalent, although the safety index favoured ICL V4c. SMILE was associated with greater induction of total higher-order aberrations, coma, and spherical aberration. Other objective measures of visual quality did not differ significantly between procedures (Chen et al., 2022). Risk of bias assessment: high risk of bias.

SMILE and FS-LASIK showed comparable safety, uncorrected visual acuity, postoperative spherical equivalent, and refractive predictability. Early tear production and tear-film stability were reduced after both procedures but were generally better preserved after SMILE. Corneal sensitivity was also significantly higher after SMILE, although the reported six-month OSDI findings were inconsistent with the authors' interpretation of symptom severity (Shen, Shi, et al., 2016). Risk of bias assessment: low risk of bias.

ICL and SMILE produced comparable uncorrected and corrected distance visual acuity, safety, and refractive predictability, with no reported intraoperative or postoperative complications. ICL was associated with lower total higher-order aberrations, spherical aberration, and coma. Findings for modulation transfer function were sensitive to the exclusion of one heterogeneous study but generally suggested better optical quality after ICL implantation (Di et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and FLEx showed comparable uncorrected and corrected distance visual acuity, spherical equivalent, corneal aberrations, central corneal thickness, and biomechanical parameters. However, FLEx may have been associated with fewer eyes losing two or more lines of corrected distance visual acuity. The wide confidence interval indicates substantial uncertainty regarding this safety outcome (J. S. Wang et al., 2017). Risk of bias assessment: unclear risk of bias.

SMILE and FS-LASIK showed comparable visual acuity, safety, refractive predictability, contrast sensitivity, and corneal biomechanical outcomes. SMILE induced fewer total higher-order and spherical aberrations, while horizontal and vertical coma were similar between procedures. Contrast sensitivity recovery varied across studies, with some evidence favouring SMILE at higher spatial frequencies during follow-up (Yan et al., 2017). Risk of bias assessment: high risk of bias.

In patients with high myopia, SMILE and FS-LASIK produced comparable postoperative uncorrected distance visual acuity and refractive spherical equivalent. Corrected distance visual acuity was slightly better after SMILE. SMILE also induced fewer total higher-order aberrations, spherical aberration, and coma over long-term follow-up (Fu et al., 2021). Risk of bias assessment: unclear risk of bias.

SMILE induced less postoperative spherical aberration than wavefront-guided LASIK. In contrast, wavefront-guided LASIK was associated with lower vertical coma and trefoil. These findings indicate procedure-specific differences in the pattern of postoperative higher-order aberrations rather than a consistent overall advantage of either technique (Tian et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and LASIK showed comparable postoperative spherical equivalent, visual acuity, astigmatic correction, and total higher-order aberrations. LASIK achieved a

slightly higher proportion of eyes within ±0.50 D of the intended refraction. Conversely, spherical aberration was lower after SMILE, suggesting a modest optical-quality advantage (Yao et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and LASIK produced comparable uncorrected and corrected distance visual acuity, manifest refractive spherical equivalent, index of success, angle of error, and most higher-order aberrations. Small differences in astigmatic correction were reported, particularly in eyes with low-to-moderate astigmatism, but not consistently in high astigmatism. Spherical aberration was significantly lower after SMILE, whereas overall higher-order aberrations did not differ (Song et al., 2023). Risk of bias assessment: high risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

SMILE compared to FLEx for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FLEX

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FLEX	Risk difference with SMILE
UCVA of 20/20 or better	(2 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 1.07** (0.42 to 2.77)	Inestimable	Inestimable
refractive error within ±0.50 D of the target refraction	(2 RCTs)	⊕⊕◯◯ Low[a,b]	**OR 1.21** (0.34 to 4.30)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(1 RCT)	⊕⊕◯◯ Low[a,b]	**OR 1.00** (0.06 to 16.82)	Inestimable	Inestimable

SMILE compared to FLEx for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FLEX

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FLEX	Risk difference with SMILE
Uncorrected distance visual acuity	205 (4 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean uncorrected distance visual acuity ranged from **-0.06-0.01**	MD **0** (0.01 lower to 0.01 higher)
Spherical equivalent refraction	192 (4 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean spherical equivalent refraction ranged from **-0.03-0.11**	MD **0.03 lower** (0.12 lower to 0.07 higher)
high-order aberrations	108 (2 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	-	MD **0.04 lower** (0.09 lower to 0.01 higher)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

SMILE compared to FLEx for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FLEX

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FLEX	Risk difference with SMILE

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
b. results from a single study; wide confidence intervals around the effect estimate.
c. Results from observational studies pooled together with RCTs
d. Small sample size

References: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I, Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.
Wang JS, Xie HT, Jia Y, Zhang MC. Small-incision lenticule extraction versus femtosecond lenticule extraction for myopic: a systematic review and Meta-analysis. Int J Ophthalmol. 2017 Jan 18;10(1):115-121.

SMILE compared to FS-LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FS-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FS-LASIK	Risk difference with SMILE
UDVA (logMAR) follow-up: range 1 months to long term	1757 (6 observational studies)	⊕◯◯◯ Very low[a,b]	-	The mean UDVA (logMAR) was inestimable	MD **0** (0.01 lower to 0)
CDVA (logMAR)	534 (6 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean CDVA (logMAR) was inestimable	MD **0.04 lower** (0.05 lower to 0.02 higher)
mean refractive spherical equivalent	807 (6 observational studies)	⊕◯◯◯ Very low[a,b]	-	The mean mean refractive spherical equivalent was inestimable	MD **0.03 lower** (0.09 lower to 0.03 higher)
total higher-order aberration	482 (4 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean total higher-order aberration was inestimable	MD **0.09 lower** (0.1 lower to 0.07 lower)
spherical aberration	350 (3 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean spherical aberration was inestimable	MD **0.15 lower** (0.19 lower to 0.11 lower)

SMILE compared to FS-LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FS-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FS-LASIK	Risk difference with SMILE
Coma (postoperative)	339 (3 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean coma (postoperative) was inestimable	MD **0.05 lower** (0.06 lower to 0.03 lower)
Loosing one ore more lines of corrected DVA	388 (2 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	**RR 1.45** (0.23 to 9.24)	5 per 1,000	**2 more per 1,000** (4 fewer to 42 more)
number of eyes with UDVA ≥20/20	220 (2 observational studies)	⊕◯◯◯ Very low[a,b,c]	**RR 1.05** (0.95 to 1.16)	900 per 1,000	**45 more per 1,000** (45 fewer to 144 more)
Postoperative refraction within ±1.0 D of the target refraction	288 (2 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	**RR 1.01** (0.97 to 1.04)	979 per 1,000	**10 more per 1,000** (29 fewer to 39 more)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

SMILE compared to FS-LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FS-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FS-LASIK	Risk difference with SMILE

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. small sample size
d. Effects in opposite directions

Reference: Fu Y, Yin Y, Wu X, Li Y, Xiang A, Lu Y, Fu Q, Hu T, Du K, Wen D. Clinical outcomes after small-incision lenticule extraction versus femtosecond laser-assisted LASIK for high myopia: A meta-analysis. PLoS One. 2021 Feb 8;16(2):e0242059.
Zhang Y, Shen Q, Jia Y, Zhou D, Zhou J. Clinical Outcomes of SMILE and FS-LASIK Used to Treat Myopia: A Meta-analysis. J Refract Surg. 2016 Apr;32(4):256-65.

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Spherical equivalent follow-up: range 3 months to 12 months	951 (9 RCTs)	⨁◯◯◯ Very low[a,b,c]	-	-	MD **0.04 lower** (0.12 lower to 0.03 higher)
proportion of eyes losing one or more lines of CDVA follow-up: range 3 months to 12 months	844 (6 RCTs)	⨁⨁◯◯ Low[a,d]	**RR 1.14** (0.58 to 2.27)	35 per 1,000	**5 more per 1,000** (15 fewer to 45 more)
proportion of eyes with UCVA of 20/20 or better follow-up: range 3 months to 12 months	858 (8 RCTs)	⨁⨁◯◯ Low[a,d]	**RR 0.99** (0.94 to 1.05)	897 per 1,000	**9 fewer per 1,000** (54 fewer to 45 more)
postoperative mean logMAR UCVA follow-up: range 3 months to 6 months	666 (6 RCTs)	⨁⨁◯◯ Low[d,e]	-	-	MD **0.01 higher** (0 to 0.03 higher)
postoperative refraction within ±1.0D follow-up: range 3 months to 12 months	818 (8 RCTs)	⨁⨁◯◯ Low[d,f]	**RR 1.00** (0.98 to 1.02)	984 per 1,000	**0 fewer per 1,000** (20 fewer to 20 more)

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
postoperative astigmatism within ±0.5 follow-up: range 3 months to 12 months	633 (6 RCTs)	⊕◯◯◯ Very low[b,d,e]	**RR 0.99** (0.94 to 1.05)	953 per 1,000	**10 fewer per 1,000** (57 fewer to 48 more)
postoperative higher order aberrations follow-up: range 3 months to 12 months	487 (5 RCTs)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0** (0.16 lower to 0.16 higher)
postoperative spherical aberration follow-up: range 3 months to 12 months	612 (5 RCTs)	⊕◯◯◯ Very low[b,d,f]	-	-	MD **0.12 lower** (0.23 lower to 0.01 lower)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Two of the included studies were judged to be at a high risk of bias
b. Significant statistical heterogeneity detected.

c. Small sample size for SMILE
d. Small sample size
e. Mainly unclear risk of bias of the included studies.
f. Some of the included studies were judged to be at a high risk of bias
Reference: Yao L, Zhang M, Wang D, Zhao Q, Wang S, Bai H. Small Incision Lenticule Extraction (SMILE) and Laser in Situ Keratomileusis (LASIK) Used to Treat Myopia and Myopic Astigmatism: A Systematic Review and Meta-analysis of Randomized Clinical Trials. Semin Ophthalmol. 2023 Apr;38(3):283-293.

Implantable collamer lens compared to SMILE for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Implantable collamer lens
Comparison: SMILE

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with SMILE	Risk difference with Implantable collamer lens
Efficacy index	555 (5 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean efficacy index ranged from **1.00-1.13**	MD **0.09 higher** (0.01 higher to 0.16 higher)
Safety index	555 (5 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean safety index ranged from **1.00-1.17**	MD **0.08 higher** (0 to 0.16 higher)
CDVA (gaining one or more lines)	383 (3 observational studies)	⊕◯◯◯ Very low[a,c,d]	**RR 1.59** (1.17 to 2.16)	428 per 1,000	**252 more per 1,000** (73 more to 496 more)

Implantable collamer lens compared to SMILE for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Implantable collamer lens
Comparison: SMILE

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with SMILE	Risk difference with Implantable collamer lens
refractive error within ±0.50 D of the target refraction	459 (4 observational studies)	⨁◯◯◯ Very low[a,b,c]	**RR 1.13** (0.94 to 1.36)	832 per 1,000	**108 more per 1,000** (50 fewer to 299 more)
Halos	351 (3 observational studies)	⨁◯◯◯ Very low[a,c]	**RR 1.75** (1.46 to 2.09)	356 per 1,000	**267 more per 1,000** (164 more to 388 more)
Higher order aberrations	277 (2 observational studies)	⨁◯◯◯ Very low[a,b,c]	-	The mean higher order aberrations ranged from **0.16-0.37**	MD **0.23 lower** (0.42 lower to 0.03 lower)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Implantable collamer lens compared to SMILE for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Implantable collamer lens
Comparison: SMILE

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with SMILE	Risk difference with Implantable collamer lens

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. High risk of bias of the included studies.
b. Significant statistical heterogeneity detected.
c. Small sample size; wide confidence intervals around the effect estimate.
d. High statistical heterogeneity detected.

Reference: Cao, K., Zhang, J., Wang, J. et al. Implantable collamer lens versus small incision lenticule extraction for high myopia correction: A systematic review and meta-analysis. BMC Ophthalmol 21, 450 (2021).

SMILE compared to WFG-LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: WFG-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with WFG-LASIK	Risk difference with SMILE
postoperative corrected distance visual acuity (logMAR)	277 (4 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.02 higher)
proportion of eyes that lost one or more lines of corrected distance visual acuity	257 (3 observational studies)	⊕◯◯◯ Very low[a,b,c]	**OR 1.89** (0.70 to 5.13)	50 per 1,000	**40 more per 1,000** (14 fewer to 162 more)
postoperative mean spherical equivalent <0.5 diopters follow-up: range 3 months to 12 months	1040 (10 observational studies)	⊕◯◯◯ Very low[a,b,d,e]	**OR 0.81** (0.51 to 1.28)	949 per 1,000	**11 fewer per 1,000** (44 fewer to 11 more)
postoperative refractive spherical equivalent follow-up: range 3 months to 12 months	794 (10 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	=	MD **0.01 lower** (0.04 lower to 0.03 higher)
postoperative uncorrected distance visual acuity of 20/20 or better	744 (8 observational studies)	⊕◯◯◯ Very low[a,b,c]	**OR 0.90** (0.54 to 1.49)	915 per 1,000	**9 fewer per 1,000** (62 fewer to 26 more)

SMILE compared to WFG-LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: WFG-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with WFG-LASIK	Risk difference with SMILE
total high-order aberrations follow-up: range 3 months to 12 months	988 (8 observational studies)	⊕◯◯◯ Very low[a,b,e,f]	-	-	SMD **0.02 SD lower** (0.26 lower to 0.22 higher)
postoperative spherical aberration follow-up: range 3 months to 12 months	1017 (8 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	SMD **0.34 SD lower** (0.47 lower to 0.22 lower)
postoperative vertical coma follow-up: range 3 months to 6 months	355 (3 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	SMD **0.83 SD higher** (0.63 higher to 1.03 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio; **SMD:** standardised mean difference

SMILE compared to WFG-LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: WFG-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with WFG-LASIK	Risk difference with SMILE

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Small sample size; wide confidence intervals
d. Moderate amount of heterogeneity
e. Wide confidence intervals around effect estimte
f. Significant statistical heterogeneity detected.
Reference: Tian H, Gao W, Xu C, Wang Y. Clinical outcomes and higher order aberrations of wavefront-guided LASIK versus SMILE for correction of myopia: A systemic review and meta-analysis. Acta Ophthalmol. 2023 Feb 1. doi: 10.1111/aos.15638.

SMILE compared to ICL V4 for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: ICL V4

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ICL V4	Risk difference with SMILE
UDVA	1074 (4 observational studies)	⊕◯◯◯ Very low[a,b]	**OR 0.94** (0.57 to 1.56)	918 per 1,000	**5 fewer per 1,000** (53 fewer to 28 more)
CDVA (logMAR)	1046 (9 observational studies)	⊕◯◯◯ Very low[a,c]	-	The mean CDVA (logMAR) was inestimable	MD **0.31 lower** (0.82 lower to 0.19 higher)
uncorrected distance visual acuity of 20/20 or better	535 (5 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean uncorrected distance visual acuity of 20/20 or better was inestimable	MD **0** (0.01 lower to 0.02 higher)
losing one or more line of corrected distance visual acuity	452 (4 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean losing one or more line of corrected distance visual acuity was inestimable	MD **0** (0.01 lower to 0.01 higher)
Safety index	910 (8 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean safety index was inestimable	MD **0.41 lower** (0.62 lower to 0.2 lower)

SMILE compared to ICL V4 for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: ICL V4

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ICL V4	Risk difference with SMILE
Efficacy index	804 (7 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean efficacy index was inestimable	MD **0.28 lower** (0.63 lower to 0.08 higher)
Postoperative spherical equivalent	691 (7 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean postoperative spherical equivalent was inestimable	MD **0.08 higher** (0.38 lower to 0.54 higher)
Total higher order aberrations	619 (6 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean total higher order aberrations was inestimable	MD **1.96 higher** (0.69 higher to 3.23 higher)
Coma	1843 (3 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean coma was inestimable	MD **1.12 higher** (0.44 higher to 1.8 higher)
Trefoil	344 (3 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean trefoil was inestimable	MD **0.08 lower** (0.53 lower to 0.38 higher)

SMILE compared to ICL V4 for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: ICL V4

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ICL V4	Risk difference with SMILE
Spherical aberration	601 (5 observational studies)	⨁◯◯◯ Very low[a,c,d]	-	The mean spherical aberration was inestimable	MD **3.03 higher** (1.51 higher to 4.56 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

GRADE Working Group grades of evidence
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Small sample size for ICL V4
c. Significant statistical heterogeneity detected.
d. Small sample size

Reference: Di Y, Cui G, Li Y, Luo Y. A meta-analysis of visual outcomes and optical quality after small incision lenticule extraction versus implantable collamer lens for myopia. Eur J Ophthalmol. 2023 Jan;33(1):136-144.
Chen D, Zhao X, Chou Y, Luo Y. Comparison of Visual Outcomes and Optical Quality of Femtosecond Laser-Assisted SMILE and Visian Implantable Collamer Lens (ICL V4c) Implantation for Moderate to High Myopia: A Meta-analysis. J Refract Surg. 2022 Jun;38(6):332-338.

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Correction index	1309 (13 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.02 lower** (0.04 lower to 0.01 lower)
Difference vector	1052 (9 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.07 higher** (0 to 0.13 higher)
Index of success and angle of error	928 (7 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.01 higher** (0.03 lower to 0.05 higher)
UDVA	1413 (11 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.02 higher)
CDVA	1322 (10 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.01 higher)

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Coma	729 (6 observational studies)	⊕◯◯◯ Very low[a,b,d,e]	-	-	MD **0.04 SD higher** (0.01 lower to 0.08 higher)
spherical aberration	749 (6 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.12 SD lower** (0.23 lower to 0.01 lower)
Total high-order aberrations	438 (5 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.01 SD lower** (0.07 lower to 0.04 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Considerable amount of heterogeneity
d. Wide confidence intervals around effect estimate; small sample size
e. Significant statistical heterogeneity detected.
Reference: Song J, Cao H, Chen X, Zhao X, Zhang J, Wu G, Wang Y. Small Incision Lenticule Extraction (SMILE) Versus Laser Assisted Stromal In Situ Keratomileusis (LASIK) for Astigmatism Corrections: A Systematic Review and Meta-analysis. Am J Ophthalmol. 2023 Mar;247:181-199.

References

8.2.3 Predictability of keratorefractive lenticule extraction

Output question

What is the predictability of keratorefractive lenticule extraction?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with
or without corneal astigmatism) who will undergo refractive surgery
I Performing intracorneal procedure (refractive lenticule extraction)
C Other procedures:
- Use of spectacles
- Corneal surface ablative procedures (PRK/Trans-PRK)
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O Postoperative refractive outcome

Recommendation

KLEx has an adequate predictability for correcting moderate to high myopia with or without astigmatism (lower than 2.0D). (GRADE +)

The predictability of KLEx is comparable with other refractive surgery procedures including LASIK and phakic IOL implantation when correcting moderate to moderate myopia with or without astigmatism. For myopia greater than -8D, phakic IOL implantation is preferred. (GRADE +)

KLEX showed a reduced risk in halo formation compared to phakic IOLS, while phakic IOLs showed better results in HOAs control. (GRADE +)

The predictability of hyperopic KLEx has improved over time but remains moderate, with results comparable to hyperopic FLEx, although variability increases with higher degrees of hyperopia. (GRADE +)(Fu et al., 2026)

It has to be noted that most of the current evidence has been based on the first available technology for KLEx (SMILE using VisuMax 500) with no cyclotorsion compensation.

Considerations

Among patients with moderate myopia, with or without astigmatism, no significant differences in predictability have been reported between the two main lenticule extraction techniques, small incision lenticule extraction (SMILE) and keratome lenticule extraction (KLEx, formerly FLEx). Outcomes include the proportion of eyes achieving a postoperative refraction within ±0.50 D of the target refraction and mean postoperative spherical equivalent. The included studies reported follow-up periods ranging from 3 to 12 months (J. S. Wang et al., 2017; Wen et al., 2017). Long-term

data are sparse; however, one study documented predictability rates within ±0.50 D and ±1.00 D of 59% and 81%, respectively, seven years after lenticule extraction in patients with moderate to high myopia (Damgaard et al., 2021)

The refractive predictability of hyperopic KLEx has improved substantially with optimization of laser parameters and surgical design. Contemporary studies report that 53–81% of eyes achieve a spherical equivalent (SE) within ±0.50 D and 76–93% within ±1.00 D of the intended correction at 12 months. Earlier datasets demonstrated comparable outcomes (59% within ±0.50 D and 76% within ±1.00 D), supporting reproducibility across different cohorts. Nevertheless, predictability remains inferior to myopic KLEx and is negatively affected by increasing hyperopic magnitude. (Fu et al., 2026)

When compared with LASIK (including FS-LASIK and WFG-LASIK), KLEX demonstrated broadly similar predictability in patients with moderate to high myopia (−3.0 D to −8.0 D), with most studies reporting no significant differences in the proportion of eyes within ±0.50 D and ±1.00 D of the intended correction during follow-up of 3–6 months (Shen, Shi, et al., 2016; Tian et al., 2023; Yan et al., 2017; Zhang et al., 2016). Some studies identified a statistically significant difference in the proportion of eyes within ±0.50 D favoring LASIK, but these differences were not evident at the ±1.00 D threshold (Yao et al., 2023).

With respect to postoperative astigmatism correction in myopic eyes (−3.0 to −10.0 D), no significant differences were found between KLEX and LASIK in the proportion of eyes achieving astigmatism correction within ±0.25 D, ±0.50 D, or ±1.00 D (Yao et al., 2023). However, one study reported a significantly lower correction index in the low-to-moderate astigmatism group for KLEX compared to LASIK, while no differences were observed in high astigmatism cases. The difference vector was comparable between the procedures for high astigmatism, but in eyes with moderate myopia (around −5.0 D) and low-to-moderate astigmatism (−0.75 D to −3.0 D), the difference vector was higher in the KLEX group than in the LASIK group (Song et al., 2023).

Comparisons between KLEX and phakic intraocular lens (pIOL) implantation in patients with moderate to high myopia (−4.0 D to −8.0 D) showed no significant differences in the proportion of eyes achieving postoperative refraction within ±1.00 D of the target correction during short-term follow-up (Chen et al., 2022; Di et al., 2023). For high myopia (−6.0 D to −12.0 D), predictability outcomes remained comparable between KLEX and pIOL, with no statistically significant differences in the proportion of eyes within ±0.50 D or ±1.00 D (Cao et al., 2021; Chen et al., 2022). Similarly, studies comparing FS-LASIK and KLEX in high myopia (−7.0 D to −11.0 D) reported no significant differences in postoperative mean refractive spherical equivalent (Fu et al., 2021).

Evidence regarding the predictability of refractive lenticule extraction in hyperopic patients remains limited, with only preliminary reports available.(Reinstein, Archer, et al., 2022)

Conclusion

Implications for practice

Based on the currently available evidence, refractive lenticule extraction is accurate and had a comparable predictability in moderate and high myopic patients with or without astigmatism. There is no sufficient evidence to draw conclusions for hyperopic patients.

Knowledge gaps

There is no evidence available about the predictability of keratorefractive lenticule extraction in hyperopic eyes. Research into this specific population is highly necessary.

Identified research evidence

Findings from Systematic Reviews

There were seven relevant systematic reviews identified.

ICL implantation showed higher efficacy and safety indices than SMILE, with more eyes gaining and fewer eyes losing corrected distance visual acuity lines. Refractive predictability was comparable between procedures. ICL induced fewer higher-order aberrations but was associated with a greater risk of halos (Cao et al., 2021). Risk of bias assessment: high risk of bias.

SMILE and FS-LASIK produced comparable visual acuity, refractive predictability, and Schirmer test outcomes. Tear-film break-up time and corneal sensitivity generally favoured SMILE during postoperative follow-up. Tear-film osmolarity was higher after FS-LASIK in the single study reporting this outcome (Zhang et al., 2016). Risk of bias assessment: high risk of bias.

SMILE and ICL V4c achieved comparable efficacy, postoperative visual acuity, and spherical equivalent, although the safety index favoured ICL V4c. SMILE induced greater total higher-order aberrations, coma, and spherical aberration. Other objective measures of visual quality were comparable between procedures (Chen et al., 2022). Risk of bias assessment: high risk of bias.

SMILE and FS-LASIK showed comparable visual acuity, refractive predictability, and preservation of corrected distance visual acuity. Tear production, tear-film stability, and corneal sensitivity were generally better preserved after SMILE. However, the

reported six-month OSDI result was inconsistent with the authors' interpretation of symptom severity (Shen, Shi, et al., 2016). Risk of bias assessment: low risk of bias.

ICL and SMILE provided comparable visual acuity, safety, and refractive predictability, with no reported intraoperative or postoperative complications. ICL induced fewer total higher-order aberrations, spherical aberration, and coma. Findings for modulation transfer function were sensitive to the exclusion of one heterogeneous study but generally favoured ICL (Di et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and FLEx showed comparable visual acuity, spherical equivalent, corneal aberrations, central corneal thickness, and biomechanical outcomes. FLEx may have been associated with fewer eyes losing two or more lines of corrected distance visual acuity. However, the wide confidence interval indicates substantial uncertainty regarding this safety finding (J. S. Wang et al., 2017). Risk of bias assessment: unclear risk of bias.

SMILE and FS-LASIK showed comparable visual acuity, safety, refractive predictability, contrast sensitivity, and corneal biomechanical outcomes. SMILE induced fewer total higher-order and spherical aberrations, whereas horizontal and vertical coma were comparable. Contrast-sensitivity findings varied across studies and follow-up periods (Yan et al., 2017). Risk of bias assessment: high risk of bias.

In patients with high myopia, SMILE and FS-LASIK produced comparable uncorrected distance visual acuity and refractive spherical equivalent. Corrected distance visual acuity was slightly better after SMILE. SMILE also induced fewer total higher-order aberrations, spherical aberration, and coma during long-term follow-up (Fu et al., 2021). Risk of bias assessment: unclear risk of bias.

SMILE induced less postoperative spherical aberration than wavefront-guided LASIK. Conversely, wavefront-guided LASIK was associated with lower vertical coma and trefoil. These findings indicate procedure-specific differences in postoperative aberration profiles without a consistent overall advantage of either technique (Tian et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and LASIK showed comparable visual acuity, spherical equivalent, astigmatic correction, and total higher-order aberrations. LASIK achieved a slightly higher proportion of eyes within ±0.50 D of the intended refraction. Conversely, spherical aberration was lower after SMILE (Yao et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and LASIK produced comparable visual acuity, manifest spherical equivalent, index of success, angle of error, and overall higher-order aberrations. Small differences in astigmatic correction were reported, particularly in eyes with low-to-

moderate astigmatism. Spherical aberration was significantly lower after SMILE, whereas coma and trefoil were comparable (Song et al., 2023). Risk of bias assessment: high risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

SMILE compared to FLEx for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FLEX

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FLEX	Risk difference with SMILE
UCVA of 20/20 or better	(2 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 1.07** (0.42 to 2.77)	Inestimable	Inestimable
refractive error within ±0.50 D of the target refraction	(2 RCTs)	⊕⊕◯◯ Low[a,b]	**OR 1.21** (0.34 to 4.30)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(1 RCT)	⊕⊕◯◯ Low[a,b]	**OR 1.00** (0.06 to 16.82)	Inestimable	Inestimable
Uncorrected distance visual acuity	205 (4 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean uncorrected distance visual acuity ranged from **-0.06-0.01**	MD **0** (0.01 lower to 0.01 higher)

SMILE compared to FLEx for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FLEX

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FLEX	Risk difference with SMILE
Spherical equivalent refraction	192 (4 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean spherical equivalent refraction ranged from **-0.03-0.11**	MD **0.03 lower** (0.12 lower to 0.07 higher)
high-order aberrations	108 (2 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	-	MD **0.04 lower** (0.09 lower to 0.01 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.

b. results from a single study; wide confidence intervals around the effect estimate.
c. Results from observational studies pooled together with RCTs
d. Small sample size
References: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I, Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.
Wang JS, Xie HT, Jia Y, Zhang MC. Small-incision lenticule extraction versus femtosecond lenticule extraction for myopic: a systematic review and Meta-analysis. Int J Ophthalmol. 2017 Jan 18;10(1):115-121.

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Spherical equivalent follow-up: range 3 months to 12 months	951 (9 RCTs)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.04 lower** (0.12 lower to 0.03 higher)
proportion of eyes losing one or more lines of CDVA follow-up: range 3 months to 12 months	844 (6 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 1.14** (0.58 to 2.27)	35 per 1,000	**5 more per 1,000** (15 fewer to 45 more)
proportion of eyes with UCVA of 20/20 or better follow-up: range 3 months to 12 months	858 (8 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 0.99** (0.94 to 1.05)	897 per 1,000	**9 fewer per 1,000** (54 fewer to 45 more)

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
postoperative mean logMAR UCVA follow-up: range 3 months to 6 months	666 (6 RCTs)	⊕⊕◯◯ Low[d,e]	-	-	MD **0.01 higher** (0 to 0.03 higher)
postoperative refraction within ±1.0D follow-up: range 3 months to 12 months	818 (8 RCTs)	⊕⊕◯◯ Low[d,f]	**RR 1.00** (0.98 to 1.02)	984 per 1,000	**0 fewer per 1,000** (20 fewer to 20 more)
postoperative astigmatism within ±0.5 follow-up: range 3 months to 12 months	633 (6 RCTs)	⊕◯◯◯ Very low[b,d,e]	**RR 0.99** (0.94 to 1.05)	953 per 1,000	**10 fewer per 1,000** (57 fewer to 48 more)
postoperative higher order aberrations follow-up: range 3 months to 12 months	487 (5 RCTs)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0** (0.16 lower to 0.16 higher)
postoperative spherical aberration follow-up: range 3 months to 12 months	612 (5 RCTs)	⊕◯◯◯ Very low[b,d,f]	-	-	MD **0.12 lower** (0.23 lower to 0.01 lower)

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Two of the included studies were judged to be at a high risk of bias
b. Significant statistical heterogeneity detected.
c. Small sample size for SMILE
d. Small sample size
e. Mainly unclear risk of bias of the included studies.
f. Some of the included studies were judged to be at a high risk of bias
Reference: Yao L, Zhang M, Wang D, Zhao Q, Wang S, Bai H. Small Incision Lenticule Extraction (SMILE) and Laser in Situ Keratomileusis (LASIK) Used to Treat Myopia and Myopic Astigmatism: A Systematic Review and Meta-analysis of Randomized Clinical Trials. Semin Ophthalmol. 2023 Apr;38(3):283-293.

SMILE compared to WFG-LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: WFG-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with WFG-LASIK	Risk difference with SMILE
postoperative corrected distance visual acuity (logMAR)	277 (4 observational studies)	⨁◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.02 higher)
proportion of eyes that lost one or more lines of corrected distance visual acuity	257 (3 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 1.89** (0.70 to 5.13)	50 per 1,000	**40 more per 1,000** (14 fewer to 162 more)
postoperative mean spherical equivalent <0.5 diopters follow-up: range 3 months to 12 months	1040 (10 observational studies)	⨁◯◯◯ Very low[a,b,d,e]	**OR 0.81** (0.51 to 1.28)	949 per 1,000	**11 fewer per 1,000** (44 fewer to 11 more)
postoperative refractive spherical equivalent follow-up: range 3 months to 12 months	794 (10 observational studies)	⨁◯◯◯ Very low[a,b,c]	-	=	MD **0.01 lower** (0.04 lower to 0.03 higher)
postoperative uncorrected distance visual acuity of 20/20 or better	744 (8 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.90** (0.54 to 1.49)	915 per 1,000	**9 fewer per 1,000** (62 fewer to 26 more)

SMILE compared to WFG-LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: WFG-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with WFG-LASIK	Risk difference with SMILE
total high-order aberrations follow-up: range 3 months to 12 months	988 (8 observational studies)	⨁◯◯◯ Very low[a,b,e,f]	-	-	SMD **0.02 SD lower** (0.26 lower to 0.22 higher)
postoperative spherical aberration follow-up: range 3 months to 12 months	1017 (8 observational studies)	⨁◯◯◯ Very low[a,b]	-	-	SMD **0.34 SD lower** (0.47 lower to 0.22 lower)
postoperative vertical coma follow-up: range 3 months to 6 months	355 (3 observational studies)	⨁◯◯◯ Very low[a,b,c]	-	-	SMD **0.83 SD higher** (0.63 higher to 1.03 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio; **SMD:** standardised mean difference

SMILE compared to WFG-LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: WFG-LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with WFG-LASIK	Risk difference with SMILE

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Small sample size; wide confidence intervals
d. Moderate amount of heterogeneity
e. Wide confidence intervals around effect estimte
f. Significant statistical heterogeneity detected.
Reference: Tian H, Gao W, Xu C, Wang Y. Clinical outcomes and higher order aberrations of wavefront-guided LASIK versus SMILE for correction of myopia: A systemic review and meta-analysis. Acta Ophthalmol. 2023 Feb 1. doi: 10.1111/aos.15638.

SMILE compared to ICL V4 for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: ICL V4

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ICL V4	Risk difference with SMILE
UDVA	1074 (4 observational studies)	⊕◯◯◯ Very low[a,b]	**OR 0.94** (0.57 to 1.56)	918 per 1,000	**5 fewer per 1,000** (53 fewer to 28 more)
CDVA (logMAR)	1046 (9 observational studies)	⊕◯◯◯ Very low[a,c]	-	The mean CDVA (logMAR) was inestimable	MD **0.31 lower** (0.82 lower to 0.19 higher)
uncorrected distance visual acuity of 20/20 or better	535 (5 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean uncorrected distance visual acuity of 20/20 or better was inestimable	MD **0** (0.01 lower to 0.02 higher)
losing one or more line of corrected distance visual acuity	452 (4 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean losing one or more line of corrected distance visual acuity was inestimable	MD **0** (0.01 lower to 0.01 higher)
Safety index	910 (8 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean safety index was inestimable	MD **0.41 lower** (0.62 lower to 0.2 lower)

SMILE compared to ICL V4 for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: ICL V4

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ICL V4	Risk difference with SMILE
Efficacy index	804 (7 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean efficacy index was inestimable	MD **0.28 lower** (0.63 lower to 0.08 higher)
Postoperative spherical equivalent	691 (7 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean postoperative spherical equivalent was inestimable	MD **0.08 higher** (0.38 lower to 0.54 higher)
Total higher order aberrations	619 (6 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean total higher order aberrations was inestimable	MD **1.96 higher** (0.69 higher to 3.23 higher)
Coma	1843 (3 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean coma was inestimable	MD **1.12 higher** (0.44 higher to 1.8 higher)
Trefoil	344 (3 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean trefoil was inestimable	MD **0.08 lower** (0.53 lower to 0.38 higher)

SMILE compared to ICL V4 for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: ICL V4

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ICL V4	Risk difference with SMILE
Spherical aberration	601 (5 observational studies)	⨁◯◯◯ Very low[a,c,d]	-	The mean spherical aberration was inestimable	MD **3.03 higher** (1.51 higher to 4.56 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

GRADE Working Group grades of evidence
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Small sample size for ICL V4
c. Significant statistical heterogeneity detected.
d. Small sample size

Reference: Di Y, Cui G, Li Y, Luo Y. A meta-analysis of visual outcomes and optical quality after small incision lenticule extraction versus implantable collamer lens for myopia. Eur J Ophthalmol. 2023 Jan;33(1):136-144.
Chen D, Zhao X, Chou Y, Luo Y. Comparison of Visual Outcomes and Optical Quality of Femtosecond Laser-Assisted SMILE and Visian Implantable Collamer Lens (ICL V4c) Implantation for Moderate to High Myopia: A Meta-analysis. J Refract Surg. 2022 Jun;38(6):332-338.

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Correction index	1309 (13 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.02 lower** (0.04 lower to 0.01 lower)
Difference vector	1052 (9 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.07 higher** (0 to 0.13 higher)
Index of success and angle of error	928 (7 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.01 higher** (0.03 lower to 0.05 higher)
UDVA	1413 (11 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.02 higher)
CDVA	1322 (10 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0** (0.01 lower to 0.01 higher)

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Coma	729 (6 observational studies)	⊕◯◯◯ Very low[a,b,d,e]	-	-	MD **0.04 SD higher** (0.01 lower to 0.08 higher)
spherical aberration	749 (6 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.12 SD lower** (0.23 lower to 0.01 lower)
Total high-order aberrations	438 (5 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.01 SD lower** (0.07 lower to 0.04 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference

SMILE compared to LASIK for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Considerable amount of heterogeneity
d. Wide confidence intervals around effect estimate; small sample size
e. Significant statistical heterogeneity detected.
Reference: Song J, Cao H, Chen X, Zhao X, Zhang J, Wu G, Wang Y. Small Incision Lenticule Extraction (SMILE) Versus Laser Assisted Stromal In Situ Keratomileusis (LASIK) for Astigmatism Corrections: A Systematic Review and Meta-analysis. Am J Ophthalmol. 2023 Mar;247:181-199.

8.2.4 Stability of keratorefractive lenticule extraction

Output question
What is the stability of keratorefractive lenticule extraction?

- **P** Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
- **I** Performing intracorneal procedure (refractive lenticule extraction)
- **C** Other procedures:
  - Use of spectacles
  - Corneal surface ablative procedures (PRK/Trans-PRK)
  - Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
  - Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)
- **O** Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Recommendation

The stability of KLEx for correcting myopia with or without astigmatism was found to be good. (GRADE +)

No difference in stability has been found when comparing LASIK and KLEX, after taking into account the learning curve. (GRADE +)

No difference in corneal biomechanics including corneal hysteresis and corneal resistance factor could be demonstrated between LASIK and KLEX. (GRADE +)(Chen et al., 2023; Fu et al., 2026)

Long-term stability remains a key limitation in hyperopic correction with regression being one of the main key factors. While KLEx is expected to offer improved biomechanical stability compared to LASIK and PRK, long-term data are still limited and more research is needed. (GRADE +)

Considerations

Keratome lenticule extraction (KLEx) has been shown to provide stable refractive outcomes in the correction of myopia, with or without astigmatism.(Kim et al., 2019; Moshirfar et al., 2015; Pradhan & Arba Mosquera, 2025; Song et al., 2023; Zhang et al., 2016) In myopic patients with preoperative refractive errors up to −7.0 D, corneal biomechanical parameters such as central corneal thickness, corneal hysteresis (CH), and corneal resistance factor (CRF) did not differ significantly between eyes treated with KLEx during follow-up periods of up to 12 months. A meta-analysis reported no significant changes in central corneal thickness (weighted mean difference [WMD] 1.83, 95% CI −7.07 to 10.72; N = 4 studies), CH (WMD −0.01,

95% CI −0.42 to 0.40; N = 4 studies), or CRF (WMD 0.17, 95% CI −0.33 to 0.67) between groups (J. S. Wang et al., 2017).

Long-term follow-up data further support the stability of KLEx in patients with moderate to high myopia and myopic astigmatism. Two longitudinal studies, with 7-year and 10-year follow-up, confirmed stable refractive outcomes. Mean myopic regression after KLEx was reported as −0.34 ± 0.69 D over 7 years and −0.35 ± 0.66 D over 10 years, indicating excellent long-term refractive stability.(Blum et al., 2019; Osman et al., 2019; Xia et al., 2020)

Refractive stability following hyperopic KLEx appears acceptable in the short term but remains a major concern in the long term. Multicenter data demonstrate minimal keratometric change (−0.14 D) between 3 and 12 months, suggesting early stability of the achieved refractive outcome. However, regression remains a well-recognized limitation of hyperopic correction and is primarily attributed to epithelial hyperplasia, stromal remodeling, and age-related factors such as progressive presbyopia. Although the flapless and minimally invasive nature of KLEx is expected to improve biomechanical stability and reduce long-term regression, robust long-term (>5 years) clinical data are currently lacking. (Fu et al., 2026)

A metaanalysis of 16 studies comparing outcome parameters of ORA (ocular response analyzer) and CST (Corvis ST) such as corneal hysteresis, corneal resistance factor and multiple deformation metrics, concluded that KLEX was not superior to LASIK in terms of corneal biomechanics at 3 months post surgery. (Chen et al., 2023)

Conclusion

Implications for practice
Based on the current available evidence, refractive lenticule extraction seems to be stable in patients with myopia and myopic astigmatism. No long-term evidence or evidence among hyperopic patients are available.

Knowledge gaps
Additional research into the stability of refractive lenticule extraction in both myopic and hyperopic patients is highly necessary, since the amount of high-level evidence is very limited. Besides, information about the long-term outcomes of refractive lenticule extraction for stability needs additional research.

Identified research evidence

Findings from Systematic Reviews

There was one systematic review included.

Ocular Response Analyzer measurements differed between SMILE and FS-LASIK (Hedges' g 0.41, 95% CI 0.00 to 0.81) and between SMILE and LASIK (Hedges' g 1.31, 95% CI 0.54 to 2.08), but not between SMILE and FLEx or surface ablation procedures. Corvis ST outcomes were comparable between SMILE and FS-LASIK/LASIK. These findings suggest that postoperative biomechanical differences depend on the measurement method used (Guo et al., 2019). Risk of bias assessment: high risk of bias.

Findings from additional studies

There were multiple additional studies included.

8.2.5 Safety of keratorefractive lenticule extraction

Output question
What is the safety of keratorefractive lenticule extraction?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing intracorneal procedure (refractive lenticule extraction)
C Other procedures:
- Use of spectacles
- Corneal surface ablative procedures (PRK/Trans-PRK)
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O (Serious) adverse events

Recommendation

KLEx is safe for correcting moderate to high myopia with or without astigmatism. (GRADE +)

Compared to other procedures KLEx is as safe as other refractive surgery procedures including Surface Ablative procedures, LASIK, and pIOL implantation among patients with low up to moderate myopia with or without astigmatism. (GRADE +)(Liu et al., 2024)

KLEx showed greater tear film stability and nerve preservation compared to LASIK, suggesting reduced postoperative DED sysmptoms. (GRADE +)(Chen et al., 2025)

No significant differences considering higher order aberrations could be found between KLEx and wavefront guided LASIK. KLEx might induce more vertical coma and trefoil, while wavefront guided LASIK might induce more spherical aberrations. (GRADE +)(Liu et al., 2024)

Hyperopic KLEx shows a favorable safety profile, with a low incidence of significant vision loss. Most studies report that only a small proportion of eyes lose one line of CDVA, and loss of two or more lines is rare (around 1–2%). Complications such as lenticule remnants(Fu et al., 2026), suct

Considerations

Keratorefractive lenticule extraction (KLEx) has been shown to be a generally safe procedure for the correction of myopia and myopic astigmatism. In moderate myopia, no statistically significant differences in postoperative CDVA were observed between KLEx and FS-LASIK; however, KLEx carried a higher early risk of losing more than two lines of CDVA (OR = 11.11; 95% CI: 1.27–96.86; p = 0.03) within the first 12 months postoperatively (J. S. Wang et al., 2017).

Hyperopic KLEx exhibits a favorable safety profile with low rates of clinically significant visual loss. Loss of one line of corrected distance visual acuity (CDVA) has been reported in approximately 16–17% of eyes, whereas loss of ≥2 lines is rare, occurring in approximately 1.2% of cases. The safety index ranges from 0.96 ± 0.12 in smaller series to approximately 1.005 in large multicenter studies, indicating overall preservation or slight improvement of CDVA postoperatively. Procedure-specific complications include lenticule remnants (1.87%), suction loss (1.34%), and persistent interlamellar haze in 6.5% of eyes at 12 months. Long-term data is not available. (Fu et al., 2026)

When compared with other corneal refractive procedures (LASEK, FS-LASIK, WFG-LASIK, LASIK, T-PRK, Epi-LASIK) in moderate to high myopia (–3.0 D to –8.0 D), no significant differences in safety outcomes were identified, with reported risks of one or more lines of CDVA loss of 29/1000 for LASIK and 49/1000 for KLEx (OR = 1.71; 95% CI: 0.81–3.63) (Liu et al., 2024) (Shen, Shi, et al., 2016; Tian et al., 2023; Yan et al., 2017; Yao et al., 2023; Zhang et al., 2016). According to SUCRA rankings, LASIK and LASEK demonstrated the highest safety, while KLEx ranked lower, alongside FLEx (Wen et al., 2017).

When compared with phakic IOL implantation (pIOLs), results were heterogeneous. For moderate to high myopia (–4.0 to –8.0 D), no significant differences were reported in the loss of ≥2 lines of CDVA (Di et al., 2023). However, in high myopia (–5.0 D to –9.0 D), some studies demonstrated a superior safety index for pIOLs within the first six months, while long-term outcomes showed no significant difference (Chen et al., 2022). Patients with very high myopia (–6.0 D to –12.0 D) treated with ICLs lost significantly fewer CDVA lines than those treated with KLEx (Cao et al., 2021), though other studies reported better postoperative CDVA for KLEx compared with FS-LASIK in highly myopic eyes (–7.0 D to –11.0 D) (Fu et al., 2021).

Quality-of-vision outcomes further distinguish KLEx. Contrast sensitivity was superior to FS-LASIK in moderate to high myopia (–3.0 D to –9.0 D) (Yan et al., 2017). Evidence regarding higher-order aberrations (HOAs) was heterogeneous: while some studies reported no significant differences between KLEx and FS-LASIK (J. S. Wang et al., 2017), others consistently demonstrated significantly higher total HOAs and spherical aberrations in LASIK compared to KLEx (–3.0 D to –10.0 D) (Liu et al., 2024) (Fu et al., 2021; Song et al., 2023; Tian et al., 2023; Yan et al., 2017; Yao et al., 2023). In comparisons with pIOLs for very high myopia, patients with ICLs experienced more halos, though HOAs and spherical aberrations were generally less common in the ICL group (Cao et al., 2021; Chen et al., 2022; Di et al., 2023).

Meta-analyses further support these findings. In a pooled analysis of 1,385 eyes, KLEx induced significantly less spherical aberration compared with LASIK (SMD = –0.34; 95% CI: –0.47 to –0.22; $p < 0.00001$), but greater vertical coma (SMD = 0.83; 95% CI: 0.63 to 1.03; $p < 0.00001$) and trefoil (SMD = 0.37; 95% CI: 0.02 to 0.72; p =

0.04. Another systematic review of 1,985 eyes found no significant differences in success index, angle of error, or spherical equivalent, although KLEx demonstrated a smaller correction index (MD = –0.02; 95% CI: –0.04 to –0.01; p = 0.01), particularly in low-to-moderate astigmatism (MD = –0.08; 95% CI: –0.13 to –0.02; p = 0.008), with a larger difference vector (MD = 0.18; 95% CI: 0.09 to 0.27; p < 0.0001. LASIK, by contrast, was associated with greater induction of spherical aberration (MD = –0.12; 95% CI: –0.23 to –0.01; p = 0.04).(Song et al., 2023; Tian et al., 2023)

A meta-analysis of 18 studies, demonstrated superior ocular surface outcomes of KLEx compared with FS-LASIK. Tear break-up time was significantly longer at 3 and 6 months (MD ≈ 3.3 seconds; P < .0001), Schirmer test values were higher (MD = 0.82 mm; P = .0001), and corneal sensitivity was better preserved at 1 and 6 months (P ≤ .02). OSDI scores were lower but not statistically significant. Overall, KLEx showed improved tear film stability and reduced corneal nerve impairment compared with FS-LASIK. (Chen et al., 2025)

In summary, KLEx provides safe and effective correction of myopia and myopic astigmatism, with lower induction of spherical aberration and superior contrast sensitivity compared with LASIK, though it carries a slightly higher short-term risk of CDVA loss and a modest tendency toward undercorrection in astigmatism. Evidence for hyperopia remains insufficient to allow definitive conclusions.

Conclusion

Implications for practice

Based on the current available evidence, the use of keratorefractive lenticule extraction is safe for correcting moderate to high myopia with or without astigmatism. No high level of evidence is available for correcting hyperopia. Besides, safety outcomes are mainly reported for the short-term follow-up. Therefore, extrapolation of these results to long-term follow-up outcomes must be done with great caution. Regarding high myopic patients, pIOLs seem to have a higher safety index compared to keratorefractive lenticule extraction and can therefore offer an alternative for these patients.

Knowledge gaps

There is no evidence available about the safety of keratorefractive lenticule extraction in hyperopic eyes. Research into this specific population is necessary. Besides, more insights into the long-term outcomes are needed.

Identified research evidence

Findings from Systematic Reviews

There were eleven studies included in this chapter.

ICL implantation showed higher efficacy and safety indices than SMILE, with more eyes gaining and fewer eyes losing corrected distance visual acuity lines. Refractive predictability was comparable between procedures. ICL induced fewer higher-order aberrations but was associated with a greater risk of halos (Cao et al., 2021). Risk of bias assessment: high risk of bias.

SMILE and FS-LASIK produced comparable visual acuity, refractive predictability, and Schirmer test outcomes. Tear-film break-up time and corneal sensitivity generally favoured SMILE during postoperative follow-up. Tear-film osmolarity was higher after FS-LASIK in the single study reporting this outcome (Zhang et al., 2016). Risk of bias assessment: high risk of bias.

SMILE and ICL V4c achieved comparable efficacy, postoperative visual acuity, and spherical equivalent, although the safety index favoured ICL V4c. SMILE induced greater total higher-order aberrations, coma, and spherical aberration. Other objective measures of visual quality were comparable between procedures (Chen et al., 2022). Risk of bias assessment: high risk of bias.

SMILE and FS-LASIK showed comparable visual acuity, refractive predictability, and preservation of corrected distance visual acuity. Tear production, tear-film stability, and corneal sensitivity were generally better preserved after SMILE. However, the reported six-month OSDI result was inconsistent with the authors' interpretation of symptom severity (Shen, Shi, et al., 2016). Risk of bias assessment: low risk of bias.

ICL and SMILE provided comparable visual acuity, safety, and refractive predictability, with no reported intraoperative or postoperative complications. ICL induced fewer total higher-order aberrations, spherical aberration, and coma. Findings for modulation transfer function were sensitive to the exclusion of one heterogeneous study but generally favoured ICL (Di et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and FLEx showed comparable visual acuity, spherical equivalent, corneal aberrations, central corneal thickness, and biomechanical outcomes. FLEx may have been associated with fewer eyes losing two or more lines of corrected distance visual acuity. However, the wide confidence interval indicates considerable uncertainty regarding this safety finding (J. S. Wang et al., 2017). Risk of bias assessment: unclear risk of bias.

SMILE and FS-LASIK showed comparable visual acuity, safety, refractive predictability, contrast sensitivity, and corneal biomechanical outcomes. SMILE induced fewer total higher-order and spherical aberrations, whereas horizontal and

vertical coma were comparable. Contrast-sensitivity findings varied across studies and follow-up periods (Yan et al., 2017). Risk of bias assessment: high risk of bias.

In patients with high myopia, SMILE and FS-LASIK produced comparable uncorrected distance visual acuity and refractive spherical equivalent. Corrected distance visual acuity was slightly better after SMILE. SMILE also induced fewer total higher-order aberrations, spherical aberration, and coma during long-term follow-up (Fu et al., 2021). Risk of bias assessment: unclear risk of bias.

SMILE induced less postoperative spherical aberration than wavefront-guided LASIK. Conversely, wavefront-guided LASIK was associated with lower vertical coma and trefoil. These findings indicate procedure-specific differences in postoperative aberration profiles without a consistent overall advantage of either procedure (Tian et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and LASIK showed comparable visual acuity, spherical equivalent, astigmatic correction, and total higher-order aberrations. LASIK achieved a slightly higher proportion of eyes within ±0.50 D of the intended refraction. Conversely, spherical aberration was lower after SMILE (Yao et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and LASIK produced comparable visual acuity, manifest spherical equivalent, index of success, angle of error, and overall higher-order aberrations. Small differences in astigmatic correction were observed, particularly in eyes with low-to-moderate astigmatism. Spherical aberration was lower after SMILE, whereas coma and trefoil were comparable (Song et al., 2023). Risk of bias assessment: high risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

SMILE compared to FLEX for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FLEX

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FLEX	Risk difference with SMILE
UCVA of 20/20 or better	(2 RCTs)	⊕⊕⊕◯ Moderate[a]	**OR 1.07** (0.42 to 2.77)	Inestimable	Inestimable
refractive error within ±0.50 D of the target refraction	(2 RCTs)	⊕⊕◯◯ Low[a,b]	**OR 1.21** (0.34 to 4.30)	Inestimable	Inestimable
Loosing 2 or more lines of BSCVA	(1 RCT)	⊕⊕◯◯ Low[a,b]	**OR 1.00** (0.06 to 16.82)	Inestimable	Inestimable
Uncorrected distance visual acuity	205 (4 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean uncorrected distance visual acuity ranged from **-0.06-0.01**	MD **0** (0.01 lower to 0.01 higher)
Spherical equivalent refraction	192 (4 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean spherical equivalent refraction ranged from **-0.03-0.11**	MD **0.03 lower** (0.12 lower to 0.07 higher)

SMILE compared to FLEX for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: FLEX

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with FLEX	Risk difference with SMILE
high-order aberrations	108 (2 observational studies)	⨁◯◯◯ Very low[a,c,d]	-	-	MD **0.04 lower** (0.09 lower to 0.01 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Mainly unclear or high risk of bias of the included studies.
b. results from a single study; wide confidence intervals around the effect estimate.
c. Results from observational studies pooled together with RCTs
d. Small sample size
References: Wen D, Tu R, Flitcroft I, Wang Q, Huang Y, Song B, Yu A, Hu L, Zhao Y, Bao F, Yu Y, Lian H, Hoffart L, Kramm RL, Skiadaresi E, O'Brart D, Pallikaris I, Marshall J, McAlinden C, Huang J. Corneal Surface Ablation Laser Refractive

Surgery for the Correction of Myopia: A Network Meta-analysis. J Refract Surg. 2018 Nov 1;34(11):726-735.
Wang JS, Xie HT, Jia Y, Zhang MC. Small-incision lenticule extraction versus femtosecond lenticule extraction for myopic: a systematic review and Meta-analysis. Int J Ophthalmol. 2017 Jan 18;10(1):115-121.

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
Spherical equivalent follow-up: range 3 months to 12 months	951 (9 RCTs)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.04 lower** (0.12 lower to 0.03 higher)
proportion of eyes losing one or more lines of CDVA follow-up: range 3 months to 12 months	844 (6 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 1.14** (0.58 to 2.27)	35 per 1,000	**5 more per 1,000** (15 fewer to 45 more)
proportion of eyes with UCVA of 20/20 or better follow-up: range 3 months to 12 months	858 (8 RCTs)	⊕⊕◯◯ Low[a,d]	**RR 0.99** (0.94 to 1.05)	897 per 1,000	**9 fewer per 1,000** (54 fewer to 45 more)
postoperative mean logMAR UCVA follow-up: range 3 months to 6 months	666 (6 RCTs)	⊕⊕◯◯ Low[d,e]	-	-	MD **0.01 higher** (0 to 0.03 higher)

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE
postoperative refraction within ±1.0D follow-up: range 3 months to 12 months	818 (8 RCTs)	⊕⊕◯◯ Low[d,f]	**RR 1.00** (0.98 to 1.02)	984 per 1,000	**0 fewer per 1,000** (20 fewer to 20 more)
postoperative astigmatism within ±0.5 follow-up: range 3 months to 12 months	633 (6 RCTs)	⊕◯◯◯ Very low[b,d,e]	**RR 0.99** (0.94 to 1.05)	953 per 1,000	**10 fewer per 1,000** (57 fewer to 48 more)
postoperative higher order aberrations follow-up: range 3 months to 12 months	487 (5 RCTs)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0** (0.16 lower to 0.16 higher)
postoperative spherical aberration follow-up: range 3 months to 12 months	612 (5 RCTs)	⊕◯◯◯ Very low[b,d,f]	-	-	MD **0.12 lower** (0.23 lower to 0.01 lower)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

SMILE compared to LASIK for myopia and myopic astigmatism

Patient or population: myopia and myopic astigmatism
Setting:
Intervention: SMILE
Comparison: LASIK

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with LASIK	Risk difference with SMILE

GRADE Working Group grades of evidence
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Two of the included studies were judged to be at a high risk of bias
b. Significant statistical heterogeneity detected.
c. Small sample size for SMILE
d. Small sample size
e. Mainly unclear risk of bias of the included studies.
f. Some of the included studies were judged to be at a high risk of bias
Reference: Yao L, Zhang M, Wang D, Zhao Q, Wang S, Bai H. Small Incision Lenticule Extraction (SMILE) and Laser in Situ Keratomileusis (LASIK) Used to Treat Myopia and Myopic Astigmatism: A Systematic Review and Meta-analysis of Randomized Clinical Trials. Semin Ophthalmol. 2023 Apr;38(3):283-293.

SMILE compared to ICL V4 for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: ICL V4

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ICL V4	Risk difference with SMILE
UDVA	1074 (4 observational studies)	⊕◯◯◯ Very low[a,b]	**OR 0.94** (0.57 to 1.56)	918 per 1,000	**5 fewer per 1,000** (53 fewer to 28 more)
CDVA (logMAR)	1046 (9 observational studies)	⊕◯◯◯ Very low[a,c]	-	The mean CDVA (logMAR) was inestimable	MD **0.31 lower** (0.82 lower to 0.19 higher)
uncorrected distance visual acuity of 20/20 or better	535 (5 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean uncorrected distance visual acuity of 20/20 or better was inestimable	MD **0** (0.01 lower to 0.02 higher)
losing one or more line of corrected distance visual acuity	452 (4 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean losing one or more line of corrected distance visual acuity was inestimable	MD **0** (0.01 lower to 0.01 higher)
Safety index	910 (8 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	The mean safety index was inestimable	MD **0.41 lower** (0.62 lower to 0.2 lower)

SMILE compared to ICL V4 for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: ICL V4

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ICL V4	Risk difference with SMILE
Efficacy index	804 (7 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean efficacy index was inestimable	MD **0.28 lower** (0.63 lower to 0.08 higher)
Postoperative spherical equivalent	691 (7 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean postoperative spherical equivalent was inestimable	MD **0.08 higher** (0.38 lower to 0.54 higher)
Total higher order aberrations	619 (6 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean total higher order aberrations was inestimable	MD **1.96 higher** (0.69 higher to 3.23 higher)
Coma	1843 (3 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean coma was inestimable	MD **1.12 higher** (0.44 higher to 1.8 higher)
Trefoil	344 (3 observational studies)	⊕◯◯◯ Very low[a,c,d]	-	The mean trefoil was inestimable	MD **0.08 lower** (0.53 lower to 0.38 higher)

SMILE compared to ICL V4 for refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: SMILE
Comparison: ICL V4

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ICL V4	Risk difference with SMILE
Spherical aberration	601 (5 observational studies)	⨁◯◯◯ Very low[a,c,d]	-	The mean spherical aberration was inestimable	MD **3.03 higher** (1.51 higher to 4.56 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

GRADE Working Group grades of evidence
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Unclear or high risk of bias of the included studies.
b. Small sample size for ICL V4
c. Significant statistical heterogeneity detected.
d. Small sample size

Reference: Di Y, Cui G, Li Y, Luo Y. A meta-analysis of visual outcomes and optical quality after small incision lenticule extraction versus implantable collamer lens for myopia. Eur J Ophthalmol. 2023 Jan;33(1):136-144.
Chen D, Zhao X, Chou Y, Luo Y. Comparison of Visual Outcomes and Optical Quality of Femtosecond Laser-Assisted SMILE and Visian Implantable Collamer Lens (ICL V4c) Implantation for Moderate to High Myopia: A Meta-analysis. J Refract Surg. 2022 Jun;38(6):332-338.

9 Intraocular procedures

9.1 Phakic IOLs

9.1.1 Indications and Contra- indications for phakic IOLs

Output question

What are the indications and contraindications for phakic IOLs?

Recommendations

PIOL is generally indicated for high ametropia, but principally is available for all refractive errors if the anterior chamber is deep enough. (GRADE +)

Limits of application pIOL implantations:

- Myopia higher than -1.0D, with an ACD depth ≥2.8 mm*.(GRADE +)
- Hyperopia higher than 1.0D, with an ACD depth of ≥3.0mm*(GRADE +)
- Astigmatism higher than 0.5 (GRADE +)

*ACD must be measured from the endothelium

In addition to the general selection criteria the following contraindications are specific for pIOL implantation:

Absolute contraindications

- ACD depth lower than 2.8mm in myopia and lower than 3.0mm in hyperopia. The ACD must be measured from the endothelium (ACD is defined as the distance from the apex of the posterior corneal surface to the apex of the anterior crystalline lens surface)
- Irido-corneal angle of lower than 30°.
- Recurrent or chonic uveitis, glaucoma or hypertony.
- The Instructions for Use (IFU) of each ICL/pIOL should be followed regarding the minimum endothelial cell density (ECD) count. Additionally, the endothelial cell density loss curve must be assessed to ensure long-term safety when considering anterior or posterior chamber pIOL implantation.(STAAR Surgical Company, [accessed 1.4.22])

Relative contraindications

- Presence of an iris or pupillary conformation and implantation anomaly

- Mesopic pupil size higher than 5.0mm

Considerations

Phakic intraocular lenses (pIOLs) currently available include anterior chamber and posterior chamber designs. Among anterior chamber models, only iris-fixated pIOLs remain in clinical use, as angle-supported lenses were abandoned due to their high complication rates (Guell et al., 2010; Jonker et al., 2020; Vasavada et al., 2018)Posterior chamber pIOLs, such as implantable collamer lenses (ICLs) and implantable phakic contact lenses (IPCLs), are widely utilized. Optimal postsurgical outcomes depend critically on careful patient selection.(Guell et al., 2010)

Indications for pIOL implantation generally include myopia from –1.0 D upwards and hyperopia from +1.0 D, with the strongest evidence and clinical use in moderate to high myopia and hyperopia.(Alarfaj et al., 2025; Kohnen et al., 2023; Lwowski et al., 2023) Preventive measures are necessary to minimize risks: a peripheral iridotomy is recommended to avoid pupillary block and acute angle-closure glaucoma, except when the implanted lens includes an aquaport or fenestrations that facilitate aqueous flow through the pupillary axis. Postoperatively, annual endothelial cell density assessments are advised to monitor long-term corneal health (German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020).

Conclusion

Implications for practice

Based on the current available evidence, the decision for phakic IOL implantation should be made in shared consent by patient and surgeon. To guarantee safety and effectiveness, selection criteria must strictly be followed.

Knowledge gaps

Additional research into dissatisfied patients after receiving a phakic IOL is necessary to further optimize the selection criteria for this procedure.

Identified research evidence

Findings from Systematic Reviews

There was one systematic review included.

Artiflex phakic intraocular lenses showed significantly better postoperative visual acuity, efficacy, spherical equivalent, refractive predictability, contrast sensitivity, and vertical trefoil outcomes than Artisan lenses. The two lenses provided comparable one-year safety, intraocular pressure, and overall complication rates. No significant differences were observed in vertical or horizontal coma, horizontal trefoil, spherical aberration, or total higher-order aberrations (Hou et al., 2021). Risk of bias assessment: high risk of bias.

Findings from additional studies

There were multiple additional studies included.

9.1.2 Efficacy of phakic IOLs

Output question
What is the efficacy of phakic IOL implantations?

- **P** Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
- **I** Performing implementation of phakic IOLs
- **C** Other procedures:
  - Use of spectacles
  - Corneal surface ablative procedures (PRK/Trans-PRK)
  - Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
  - Intraocular surgeries (Refractive Lens Exchange)
- **O** Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Recommendation

The implantation of phakic IOLs is effective for correcting low to high myopia (higher than -1.0D) and/or astigmatism, showing a good quality of vision in terms of contrast sensitivity. (GRADE +)

There is only limited evidence about the implantation of phakic IOLs for correcting hyperopia with or without astigmatism to draw conclusions about the efficacy. (GRADE +)

Compared to laser refractive surgery, pIOLs are comparable effective in the short-term postoperative period to PRK, LASIK and KLEx in myopic eyes with or without astigmatism. (GRADE +)

Considerations

Anterior chamber phakic IOLs, particularly iris-fixated designs, have demonstrated high efficacy in patients with high myopia (–9.0 D to –17.0 D), though outcomes differ between brands in terms of contrast sensitivity and aberrations (Hou et al., 2021). In eyes with approximately –10.0 D, iris-fixated pIOLs achieved UDVA >20/40 in 84% and >20/20 in 31% at 3 years (Huang et al., 2009). Foldable pIOLs provided superior results compared with rigid lenses, with higher odds of achieving UDVA ≥20/40 (pooled OR 0.40, 95% CI 0.21–0.79) and significantly better postoperative HOAs and contrast sensitivity (Wu et al., 2020). Posterior chamber ICLs, with or without a central hole, showed comparable efficacy across moderate to high myopia (–7.0 D to –13.0 D) (Tang & Ye, 2019). Early data on implantable phakic contact lenses (IPCLs) indicate good outcomes at 1–3 years, with safety and efficacy

comparable to ICLs (Rateb et al., 2022; Sachdev & Ramamurthy, 2019; Vasavada et al., 2018). Novel presbyopia-correcting pIOLs have also yielded encouraging results.(Packer et al., 2020; Royo et al., 2023)

Long-term follow-up of iris-fixated pIOLs in high myopia (–10.0 D to –14.0 D) showed heterogeneous efficacy indices (0.43–1.03), with pooled medians of 87% and 82% achieving UDVA ≥20/40, and 35% and 21% achieving UDVA ≥20/20 at 2 and 5 years, respectively (van Rijn et al., 2020).

In a retrospective study of 3105 eyes from 1485 U.S. military personnel (median age 25), implantable collamer lens (ICL) implantation demonstrated high long-term efficacy and safety. UDVA of 20/25 or better was maintained in 80% of eyes up to 8 years postoperatively, with refractive accuracy achieved in 97% at 1 year and 90% at 8 years.(Packer et al., 2022)

When compared with corneal laser surgery (PRK, LASIK, KLEx), no significant differences were observed in efficacy index, UDVA, or CDVA in moderate to high myopia (–4.0 D to –9.0 D), with follow-up ranging 3–26 months (Chen et al., 2022; Chen et al., 2018; Di et al., 2023). In one trial of high myopia (–8.0 D to –12.0 D), LASIK and anterior chamber pIOL implantation produced comparable 1-year outcomes: UDVA >20/25 in 24% and 20%, and UDVA >20/40 in 80% and 60% of eyes, with efficacy indices of 0.75 and 0.71, respectively (Malecaze et al., 2002). Direct comparisons with KLEx showed mixed results: ICL implantation yielded significantly higher efficacy indices and CDVA gain, with fewer CDVA losses at 12 months, though halos were more frequent after ICLs, while KLEx induced more HOAs (Cao et al., 2021; Chen et al., 2022; Di et al., 2023).

For hyperopia, evidence is sparse. A 10-year study of posterior chamber pIOLs in +2.75 D to +11.75 D hyperopes reported an efficacy index of 0.97, with postoperative manifest refraction +0.07 ± 0.54 D, and UDVA ≥20/20, ≥20/40, and ≥20/70 achieved in 49.8%, 87.6%, and 100% of eyes, respectively (Pesando et al., 2007).

Conclusion

Implications for practice

Based on the currently available evidence, phakic intraocular lenses (pIOLs) are effective for the correction of moderate to high myopia with or without astigmatism. However, the evidence for their application in hyperopic eyes remains insufficient to allow an evidence-based conclusion. Importantly, most available studies report short-term outcomes, and extrapolation to long-term efficacy and safety must therefore be made with caution.

Knowledge gaps

Evidence regarding the efficacy of pIOLs in hyperopic eyes is extremely limited, necessitating further investigation in this population. Moreover, high-quality studies with extended follow-up are required to better define the long-term visual outcomes and safety profile of pIOL implantation.

Identified research evidence

Findings from Systematic Reviews

There were eight relevant systematic reviews identified.

Artiflex phakic intraocular lenses showed better postoperative visual acuity, efficacy, spherical equivalent, refractive predictability, contrast sensitivity, and vertical trefoil outcomes than Artisan lenses. One-year safety, intraocular pressure, and complication rates were comparable. No significant differences were observed in most other higher-order aberrations (Hou et al., 2021). Risk of bias assessment: high risk of bias.

Foldable phakic intraocular lenses achieved a higher proportion of eyes with postoperative uncorrected distance visual acuity of 20/40 or better and more favourable spherical equivalent outcomes than rigid lenses. Uncorrected distance visual acuity of 20/20 was comparable between groups. Foldable lenses were also associated with less endothelial cell loss and fewer postoperative higher-order aberrations (Wu et al., 2020). Risk of bias assessment: high risk of bias.

Phakic intraocular lenses and excimer laser surgery produced broadly comparable uncorrected distance visual acuity at 12 months. Phakic lenses showed greater refractive accuracy and were associated with fewer losses and more frequent gains of best spectacle-corrected visual acuity lines. However, the proportion of eyes within ±0.50 D of target refraction was similar between groups (Chen et al., 2018). Risk of bias assessment: high risk of bias.

Iris-fixated phakic intraocular lenses provided effective and generally stable correction of high myopia, with most eyes remaining within 1.00 D of emmetropia and more than 91% maintaining or gaining corrected distance visual acuity. Long-term safety indices generally exceeded 1.0, although endothelial cell loss increased with follow-up duration. Secondary interventions, including repositioning, exchange, or explantation, were variably reported, while evidence for hyperopic correction remained limited (van Rijn et al., 2020). Risk of bias assessment: high risk of bias.

A meta-analysis of five studies found no significant differences between the compared procedures in uncorrected or best-corrected visual acuity, spherical

equivalent, or intraocular pressure. Both approaches appeared similarly effective for correcting high myopia. Safety evidence was insufficient to support firm conclusions (Tang & Ye, 2019). Risk of bias assessment: high risk of bias.

ICL and SMILE provided comparable visual acuity, safety, and refractive predictability, with no reported intraoperative or postoperative complications. ICL induced fewer total higher-order aberrations, spherical aberration, and coma. Findings for modulation transfer function were sensitive to the exclusion of one heterogeneous study but generally favoured ICL (Di et al., 2023). Risk of bias assessment: high risk of bias.

SMILE and ICL V4c achieved comparable efficacy, postoperative visual acuity, and spherical equivalent, although the safety index favoured ICL V4c. SMILE induced greater total higher-order aberrations, coma, and spherical aberration. Other objective measures of visual quality were comparable between procedures (Chen et al., 2022). Risk of bias assessment: high risk of bias.

ICL implantation showed higher efficacy and safety indices than SMILE, with more eyes gaining and fewer eyes losing corrected distance visual acuity lines. Refractive predictability was comparable between procedures. ICL induced fewer higher-order aberrations but was associated with a greater risk of halos (Cao et al., 2021). Risk of bias assessment: high risk of bias.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

Preoperative iris-fixated phakic intraocular lens implantation compared to postoperative in myopic and hyperopic

Patient or population: myopic and hyperopic
Setting:
Intervention: preoperative iris-fixated phakic intraocular lens implantation
Comparison: postoperative

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with postoperative	Risk difference with preoperative iris-fixated phakic intraocular lens implantation
manifest refractive spherical equivalent (MRSE) follow-up: 2 years	(7 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **12.8 lower** (0 to 0)
manifest refractive spherical equivalent (MRSE) follow-up: 10 years	(1 observational study)	⊕◯◯◯ Very low[a,b]	-	-	MD **9.7 lower** (0 to 0)

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference

Preoperative iris-fixated phakic intraocular lens implantation compared to postoperative in myopic and hyperopic

Patient or population: myopic and hyperopic
Setting:
Intervention: preoperative iris-fixated phakic intraocular lens implantation
Comparison: postoperative

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with postoperative	Risk difference with preoperative iris-fixated phakic intraocular lens implantation

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. Results from observational studies
b. Small number of eyes
Reference: van Rijn GA, Gaurisankar ZS, Ilgenfritz AP, Lima JEE, Haasnoot GW, Beenakker JM, Cheng YYY, Luyten GPM. Middle- and long-term results after iris-fixated phakic intraocular lens implantation in myopic and hyperopic patients: a meta-analysis. J Cataract Refract Surg. 2020 Jan;46(1):125-137.

Phakic Posterior Chamber Intraocular Lens with a Central Hole compared to Without central whole in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Phakic Posterior Chamber Intraocular Lens with a Central Hole
Comparison: Without central whole

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Without central whole	Risk difference with Phakic Posterior Chamber Intraocular Lens with a Central Hole
UCVA	224 (observational studies)	⨁◯◯◯ Very low[a,b,c,d]	-	-	SMD **0.08 SD higher** (0.71 lower to 0.88 higher)
Spherical equivalent	152 (2 observational studies)	⨁◯◯◯ Very low[a,b,c,d]	-	-	SMD **0.18 SD lower** (0.52 lower to 0.15 higher)
BCVA	152 (2 observational studies)	⨁◯◯◯ Very low[a,b,c,d]	-	-	SMD **0.27 SD lower** (0.93 lower to 0.4 higher)
IOP	227 (3 observational studies)	⨁◯◯◯ Very low[a,c]	-	-	SMD **0.03 SD higher** (0.24 lower to 0.3 higher)

Phakic Posterior Chamber Intraocular Lens with a Central Hole compared to Without central whole in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Phakic Posterior Chamber Intraocular Lens with a Central Hole
Comparison: Without central whole

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Without central whole	Risk difference with Phakic Posterior Chamber Intraocular Lens with a Central Hole

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **SMD:** standardised mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies.
b. Significant statistical heterogeneity detected.
c. Results from observational studies pooled together with RCTs
d. Small sample size.
Reference: Tang Y, Ye J. Phakic Posterior Chamber Intraocular Lens with a Central Hole in Treating Patients with Moderate to High Myopia: A Meta-Analysis. J Ophthalmol. 2019 Oct 30;2019:9496326.

Rigid iris-fixed phakic intraocular lens compared to foldable iris-fixed phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: rigid iris-fixed phakic intraocular lens
Comparison: foldable iris-fixed phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with foldable iris-fixed phakic intraocular lens	Risk difference with rigid iris-fixed phakic intraocular lens
UDVA of 20/20 or better	(2 observational studies)	⊕◯◯◯ Very low[a,b,c]	**OR 0.37** (0.07 to 1.84)	Inestimable	Inestimable
UDVA (log MAR)	(4 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.1 higher** (0.04 higher to 0.17 higher)
Proportion of eyes with postoperative SE within ±0.50D of the target	(4 observational studies)	⊕◯◯◯ Very low[a,b]	**OR 0.59** (0.34 to 1.02)	Inestimable	Inestimable
Postoperative spherical equivalent	(7 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.21 lower** (0.37 lower to 0.05 lower)

Rigid iris-fixed phakic intraocular lens compared to foldable iris-fixed phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: rigid iris-fixed phakic intraocular lens
Comparison: foldable iris-fixed phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with foldable iris-fixed phakic intraocular lens	Risk difference with rigid iris-fixed phakic intraocular lens
Postoperative intraocular higher order aberrations	(5 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.08 higher** (0.04 lower to 0.2 higher)
Loosing 2 or more lines of BSCVA	(5 observational studies)	⊕◯◯◯ Very low[a,b,e]	**OR 2.44** (0.64 to 9.26)	Inestimable	Inestimable
Postoperative complications	(3 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	**OR 0.39** (0.10 to 1.61)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

Rigid iris-fixed phakic intraocular lens compared to foldable iris-fixed phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: rigid iris-fixed phakic intraocular lens
Comparison: foldable iris-fixed phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with foldable iris-fixed phakic intraocular lens	Risk difference with rigid iris-fixed phakic intraocular lens

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Small sample size, wide confidence intervals around the effect estimate.
d. Significant statistical heterogeneity detected.
e. Wide confidence intervals around the effect estimate.
Reference: Wu Q, Li Y, Tang L, Wu LA, Wang CY. Comparison of rigid versus foldable iris-fixed phakic intraocular lens implantation for high myopia: A systematic review and meta-analysis. Medicine (Baltimore). 2020 Feb;99(6):e19030.

Artisan phakic intraocular lens compared to Artiflex phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Artisan phakic intraocular lens
Comparison: Artiflex phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Artiflex phakic intraocular lens	Risk difference with Artisan phakic intraocular lens
Safety index	(2 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.01 lower** (0.11 lower to 0.09 higher)
Efficacy index	(2 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.17 lower** (0.29 lower to 0.05 lower)
vertical or horizontal coma or trefoil	(2 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.03 higher** (0.07 lower to 0.13 higher)
Spherical aberration	(4 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	**0** (0 to 0)
Total high-order aberration	(4 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.07 higher** (0.05 lower to 0.18 higher)

Artisan phakic intraocular lens compared to Artiflex phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Artisan phakic intraocular lens
Comparison: Artiflex phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Artiflex phakic intraocular lens	Risk difference with Artisan phakic intraocular lens

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies
b. Small sample size; wide confidence intervals around the effect estimate.
c. Significant statistical heterogeneity detected.
Reference: Hou, C., Li, H., Li, J. Et al. Artisan versus Artiflex phakic intraocular lens implantation in the treatment of moderate to high myopia: meta-analysis. BMC Ophthalmol 21, 171 (2021).

9.1.3 Predictability of phakic IOLs

Output question

What is the predictability of phakic IOL implantations?

- **P** Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
- **I** Performing implementation of phakic IOLs
- **C** Other procedures:
  - Use of spectacles
  - Corneal surface ablative procedures (PRK/Trans-PRK)
  - Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
  - Intraocular surgeries (Refractive Lens Exchange)
- **O** Postoperative refractive outcome

Recommendation

The predictability of implanting phakic IOLs for correcting up to high myopia (higher than -6.0D) with or without astigmatism is good. (GRADE +).

Evidence regarding the predictability of pIOLs implantation for correcting hyperopia and/or astigmatism is too limited. (GRADE +)

The predictability of pIOL implantation seems to be comparable to LASIK, PRK and KLEx in moderate myopic eyes (lower than -6.0D), however in high myopic patients (higher than -6.0D) the pIOLs seem to have a superior predictability. (GRADE +)

Considerations

Predictability outcomes for phakic intraocular lenses (pIOLs) in high myopia (–10.0 D to –14.0 D) with or without astigmatism show wide variability, with 55–98% of eyes achieving postoperative refractions within ±1.00 D of emmetropia; the pooled median was 94% (van Rijn et al., 2020). In a comparative analysis of two anterior chamber iris-fixated pIOLs in highly myopic patients (–9.0 D to –17.0 D), foldable pIOLs demonstrated superior predictability over rigid models (OR 0.254; 95% CI 0.126–0.511) (Hou et al., 2021). Similarly, foldable pIOLs showed significantly higher proportions of eyes within ±1.00 D of the intended target (–9.0 D to –14.0 D), although no significant difference was observed within ±0.50 D (Wu et al., 2020). Evidence regarding implantable phakic contact lenses (IPCLs) remains limited, but available studies suggest predictability rates of 57–89% of eyes within ±0.50 D in high myopia (Sachdev & Ramamurthy, 2019; Vasavada et al., 2018).

Comparisons of pIOLs with corneal refractive procedures indicate variable outcomes. In moderate to high myopia (–5.0 D to –9.0 D), pIOL implantation achieved superior predictability within ±1.00 D compared with PRK and LASIK, though no significant difference was detected within ±0.50 D (Chen et al., 2018). In contrast, comparisons between posterior chamber pIOLs and keratorefractive lenticule extraction (KLEx) in myopic eyes (–5.0 D to –9.0 D) revealed no significant differences in the proportions of eyes within ±1.00 D of target refraction during short-term follow-up (Chen et al., 2022; Di et al., 2023). Among highly myopic patients (up to –12.0 D), predictability was comparable between posterior chamber pIOLs and KLEx within both ±0.50 D and ±1.00 D (Cao et al., 2021; Chen et al., 2022). Similarly, in a trial comparing LASIK to anterior chamber pIOLs in high myopia (–8.0 D to –12.0 D), one-year outcomes showed mean postoperative spherical equivalents of –0.95 ± 0.45 D (pIOL) and –0.74 ± 0.67 D (LASIK), with 60% and 64% of eyes, respectively, achieving refractions within ±1.00 D (Malecaze et al., 2002).

Data on hyperopic patients remain scarce. One long-term study of posterior chamber pIOLs in hyperopia (+2.75 D to +11.75 D) reported that 86.5% of eyes were within ±0.50 D of the intended correction after 10 years, with only 1.6% losing one line of best-corrected visual acuity (BCVA) (Pesando et al., 2007).

Conclusion

Implications for practice

Based on the currently available evidence, the predictability of phakic IOL is accurate in moderate and high myopic patients with or without astigmatism. There is not sufficient evidence to draw conclusions for hyperopic patients. Compared to laser refractive surgeries, there seems to be no difference in predictability when compared to phakic IOL implantation in patients with moderate myopia.

Knowledge gaps

There is very limited evidence available about the predictability of pIOLs in hyperopic eyes. Research into this specific population is necessary.

Identified research evidence

Findings from Systematic Reviews

There were seven relevant systematic reviews identified.

Artiflex phakic intraocular lenses provided better postoperative visual acuity, efficacy, refractive outcomes, contrast sensitivity, and vertical trefoil than Artisan lenses. One-year safety, intraocular pressure, complication rates, and most other higher-order

aberrations were comparable between lenses (Hou et al., 2021). Risk of bias assessment: high risk of bias.

Foldable phakic intraocular lenses achieved better postoperative uncorrected distance visual acuity of 20/40 or better and more favourable spherical equivalent outcomes than rigid lenses, although rates of 20/20 vision were comparable. Foldable lenses were also associated with less endothelial cell loss and fewer intraocular higher-order aberrations (Wu et al., 2020). Risk of bias assessment: high risk of bias.

Phakic intraocular lenses and excimer laser surgery produced broadly comparable uncorrected distance visual acuity at 12 months. Phakic lenses provided greater refractive accuracy and were associated with fewer losses and more frequent gains of best spectacle-corrected visual acuity, although the proportion within ±0.50 D of target was similar (Chen et al., 2018). Risk of bias assessment: high risk of bias.

Iris-fixated phakic intraocular lenses provided effective and generally stable correction of high myopia, with most eyes maintaining or gaining corrected distance visual acuity. Long-term safety indices remained favourable, although endothelial cell loss and secondary surgical interventions increased with follow-up. Evidence for hyperopic correction was limited, and glare or halos were reported in up to 22.2% of eyes (van Rijn et al., 2020). Risk of bias assessment: high risk of bias.

ICL and SMILE provided comparable visual acuity, safety, and refractive predictability, with no reported intraoperative or postoperative complications. ICL induced fewer total higher-order aberrations, spherical aberration, and coma, while findings for modulation transfer function were sensitive to study heterogeneity (Di et al., 2023). Risk of bias assessment: not reported in the provided excerpt.

SMILE and ICL V4c achieved comparable efficacy, postoperative visual acuity, and spherical equivalent, although the safety index favoured ICL V4c. SMILE induced greater total higher-order aberrations, coma, and spherical aberration, whereas other measures of visual quality were comparable (Chen et al., 2022). Risk of bias assessment: not reported in the provided excerpt.

ICL implantation showed higher efficacy and safety indices than SMILE, with more eyes gaining and fewer eyes losing corrected distance visual acuity lines. Refractive predictability was comparable, while ICL induced fewer higher-order aberrations but carried a greater risk of halos (Cao et al., 2021). Risk of bias assessment: not reported in the provided excerpt.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

Phakic Posterior Chamber Intraocular Lens with a Central Hole compared to Without central whole in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Phakic Posterior Chamber Intraocular Lens with a Central Hole
Comparison: Without central whole

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Without central whole	Risk difference with Phakic Posterior Chamber Intraocular Lens with a Central Hole
UCVA	224 (observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	SMD **0.08 SD higher** (0.71 lower to 0.88 higher)
Spherical equivalent	152 (2 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	SMD **0.18 SD lower** (0.52 lower to 0.15 higher)
BCVA	152 (2 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	SMD **0.27 SD lower** (0.93 lower to 0.4 higher)
IOP	227 (3 observational studies)	⊕◯◯◯ Very low[a,c]	-	-	SMD **0.03 SD higher** (0.24 lower to 0.3 higher)

Phakic Posterior Chamber Intraocular Lens with a Central Hole compared to Without central whole in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Phakic Posterior Chamber Intraocular Lens with a Central Hole
Comparison: Without central whole

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Without central whole	Risk difference with Phakic Posterior Chamber Intraocular Lens with a Central Hole

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **SMD:** standardised mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies.
b. Significant statistical heterogeneity detected.
c. Results from observational studies pooled together with RCTs
d. Small sample size.
Reference: Tang Y, Ye J. Phakic Posterior Chamber Intraocular Lens with a Central Hole in Treating Patients with Moderate to High Myopia: A Meta-Analysis. J Ophthalmol. 2019 Oct 30;2019:9496326.

Rigid iris-fixed phakic intraocular lens compared to foldable iris-fixed phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: rigid iris-fixed phakic intraocular lens
Comparison: foldable iris-fixed phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with foldable iris-fixed phakic intraocular lens	Risk difference with rigid iris-fixed phakic intraocular lens
UDVA of 20/20 or better	(2 observational studies)	⊕◯◯◯ Very low[a,b,c]	**OR 0.37** (0.07 to 1.84)	Inestimable	Inestimable
UDVA (log MAR)	(4 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.1 higher** (0.04 higher to 0.17 higher)
Proportion of eyes with postoperative SE within ±0.50D of the target	(4 observational studies)	⊕◯◯◯ Very low[a,b]	**OR 0.59** (0.34 to 1.02)	Inestimable	Inestimable
Postoperative spherical equivalent	(7 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.21 lower** (0.37 lower to 0.05 lower)

Rigid iris-fixed phakic intraocular lens compared to foldable iris-fixed phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: rigid iris-fixed phakic intraocular lens
Comparison: foldable iris-fixed phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with foldable iris-fixed phakic intraocular lens	Risk difference with rigid iris-fixed phakic intraocular lens
Postoperative intraocular higher order aberrations	(5 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.08 higher** (0.04 lower to 0.2 higher)
Loosing 2 or more lines of BSCVA	(5 observational studies)	⊕◯◯◯ Very low[a,b,e]	**OR 2.44** (0.64 to 9.26)	Inestimable	Inestimable
Postoperative complications	(3 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	**OR 0.39** (0.10 to 1.61)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

Rigid iris-fixed phakic intraocular lens compared to foldable iris-fixed phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: rigid iris-fixed phakic intraocular lens
Comparison: foldable iris-fixed phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with foldable iris-fixed phakic intraocular lens	Risk difference with rigid iris-fixed phakic intraocular lens

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Small sample size, wide confidence intervals around the effect estimate.
d. Significant statistical heterogeneity detected.
e. Wide confidence intervals around the effect estimate.
Reference: Wu Q, Li Y, Tang L, Wu LA, Wang CY. Comparison of rigid versus foldable iris-fixed phakic intraocular lens implantation for high myopia: A systematic review and meta-analysis. Medicine (Baltimore). 2020 Feb;99(6):e19030.

Artisan phakic intraocular lens compared to Artiflex phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Artisan phakic intraocular lens
Comparison: Artiflex phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Artiflex phakic intraocular lens	Risk difference with Artisan phakic intraocular lens
Safety index	(2 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.01 lower** (0.11 lower to 0.09 higher)
Efficacy index	(2 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.17 lower** (0.29 lower to 0.05 lower)
vertical or horizontal coma or trefoil	(2 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.03 higher** (0.07 lower to 0.13 higher)
Spherical aberration	(4 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	**0** (0 to 0)
Total high-order aberration	(4 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.07 higher** (0.05 lower to 0.18 higher)

Artisan phakic intraocular lens compared to Artiflex phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Artisan phakic intraocular lens
Comparison: Artiflex phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Artiflex phakic intraocular lens	Risk difference with Artisan phakic intraocular lens

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies
b. Small sample size; wide confidence intervals around the effect estimate.
c. Significant statistical heterogeneity detected.
Reference: Hou, C., Li, H., Li, J. et al. Artisan versus Artiflex phakic intraocular lens implantation in the treatment of moderate to high myopia: meta-analysis. BMC Ophthalmol 21, 171 (2021).

9.1.4 Stability of phakic IOLs

Output question

What is the stability of phakic IOL implantations?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing implementation of phakic IOLs
C Other procedures:
- Use of spectacles
- Corneal surface ablative procedures (PRK/Trans-PRK)
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
- Intraocular surgeries (Refractive Lens Exchange)

O Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Recommendation

Phakic IOLs for moderate to high myopia (higher than -6.0D) with or without astigmatism give stable results. (GRADE +)

There is poor evidence available about the stability of phakic IOLs for correcting hyperopia with or without astigmatism. (GRADE +)

Patients need to be aware that they will not keep a pIOL forever but will have to get a removal at the time of cataract and in case of any significant anatomical changes. (GRADE +)

Phakic IOL implantation remains a reversible procedure, however, it can result in permanent anatomical changes. (In retinal detachment surgery; AC pIOL will then be needed to be taken out.) Regular postoperative evaluations are crucial. (GRADE +)

Considerations

Stability, commonly defined as the postoperative change in manifest spherical equivalent refraction over time, represents a critical determinant of long-term success after phakic intraocular lens (pIOL) implantation. Current evidence regarding refractive stability after pIOL implantation is relatively limited compared with that available for corneal refractive procedures. Nevertheless, the data that are available

suggest favorable outcomes. One study reported that iris-fixated pIOLs maintained refractive stability during the first years following implantation in myopic eyes, without clinically significant regression or loss of refractive effect (van Rijn et al., 2020). Although evidence in hyperopic eyes is scarce, the available findings indicate a similar pattern of stability in the early postoperative years.

From a broader clinical perspective, the stability of pIOLs is considered to be high, particularly in patients with moderate to high myopia, where the long-term refractive outcomes are generally consistent and predictable. Importantly, these results appear to be more stable than those typically reported following laser vision correction procedures in comparable refractive ranges, where regression is a more common finding over time. This may be explained by the fact that pIOL implantation preserves corneal tissue and biomechanics, thereby reducing the risk of progressive changes in corneal shape or refractive power that can compromise stability after corneal ablative or lenticule extraction techniques.

In addition, the absence of significant long-term refractive drift in pIOL-treated eyes underscores the suitability of this technique for patients requiring durable refractive correction, particularly in the higher myopic range where corneal refractive procedures may be limited by safety concerns or tissue constraints. However, the paucity of long-term prospective studies highlights the need for further research, especially in hyperopic patients and in comparisons with modern corneal procedures such as keratorefractive lenticule extraction (KLEx).

Conclusion

Implications for practice

The available evidence regarding the long-term stability of a phakic IOL is very limited. There is not enough evidence to provide decent advice for practice regarding this evidence. Based on clinical expertise, phakic IOLs offer stable results when correcting patients with moderate to high myopia.

Knowledge gaps

Additional research into the stability for phakic IOLs in both myopic and hyperopic patients is highly necessary, since the amount of high level evidence is very limited. Besides, information about the long-term outcomes of phakic IOL stability needs additional research.

Identified research evidence

Findings from Systematic Reviews

There was one relevant systematic review identified.

Iris-fixated phakic intraocular lenses provided effective and generally stable correction of high myopia, with a pooled median postoperative refractive error of −0.8 to −0.4 D and 94% of eyes within 1.0 D of emmetropia. At two and five years, 87% and 82% of eyes, respectively, achieved uncorrected distance visual acuity of 20/40 or better, while more than 91% maintained or gained corrected distance visual acuity. Safety indices remained above 1.0, although up to 4.5% of eyes lost two or more lines of corrected distance visual acuity. Endothelial cell loss increased with longer follow-up, and secondary surgical intervention rates varied considerably across studies. Evidence for hyperopic correction was limited, while glare or halos were reported in up to 22.2% of eyes (van Rijn et al., 2020). Risk of bias assessment: high risk of bias.

Findings from additional studies

There were no additional studies included.

9.1.5 Safety of phakic IOLs

Output question

What is the safety of phakic IOL implantations?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing implementation of phakic IOLs
C Other procedures:
- Use of spectacles
- Corneal surface ablative procedures (PRK/Trans-PRK)
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
- Intraocular surgeries (Refractive Lens Exchange)

O (Serious) adverse events

Recommendation

The implantation of phakic IOLs is safe for correcting moderate (lower than -6.0D) to high myopia (higher than -6.0D) with or without astigmatism. (GRADE +)

The implantation of phakic IOLs seems to be safe for correcting hyperopia with or without astigmatism, but the evidence is very limited as an ACD higher than 2.7mm is rare in high hyperopic eyes. (GRADE +)

The safety of phakic IOL implantation is comparable to laser refractive surgeries, including PRK, LASIK and KLEx for correcting myopia. However, for high myopia (higher than -6.0D), pIOLs are often preferred due to better potential for visual quality, even though refractive error predictability may be similar across procedures. Stability may be a concern with corneal-based procedures, as some regression can occur over time (GRADE +)

Surgical decisions must carefully consider the risk of cataract formation associated with but not exclusively PC pIOL implantation, as well as the potential for secondary ectasia following cornea-based procedures. Risk assessment depends on refractive status and eye morphology, always prioritizing patient benefit over risks. (GRADE +)

The increased risk of endothelial cell loss with all types of IOLs placed, but not exclusively, in the anterior chamber or iris fixated IOLs should be considered. (GRADE +)

The risk of pupillary block and sequential IOP increase is elevated in high hyperopia. In these cases, an iridotomy or iridectomy is mandatory. (GRADE +)

The safety of the procedure can be ensured by annual follow-up investigations including endothelial cell count, Anterior segment OCT focused on the angle, measurement of the IOP, assessment of vaulting and PCA, gonioscopy and assessment of the crystalline lens transparency. Postoperative assessment of centration, axis alignment and long-term endothelial monitoring should be guaranteed. (GRADE +)(Passaro et al., 2026)

The presence of cataract after pIOL implantation requires removal of the pIOL followed by phacoemulsification or fs-laser assisted cataract surgery and IOL implantation. This procedure can be conducted in a one- or two-step procedure. The presence of a PIOL does not significantly impair biometry. (GRADE +)

Considerations

Endothelial cell loss and intraocular pressure (IOP) elevation are two of the most important risks associated with phakic intraocular lens (pIOL) implantation, and patients must also be counseled on the increased likelihood of cataract formation.(Kohnen et al., 2020; Shajari et al., 2016) Reported incidences of cataract are 1.29% for anterior chamber pIOLs, 1.11% for iris-fixated lenses, and 9.60% for posterior chamber pIOLs. (Chen et al., 2008) Furthermore, intraocular surgery at a young age has been associated with a heightened risk of retinal detachment (expert opinion).

Currently available pIOLs include anterior chamber iris-fixated lenses and posterior chamber lenses, which rely on plate haptics for fixation. Earlier angle-supported anterior chamber pIOLs, which were positioned within the anterior chamber angle, demonstrated unacceptably high complication rates and were consequently withdrawn from the market. (Jonker et al., 2020) In contrast, contemporary posterior chamber designs such as implantable collamer lenses (ICLs) and implantable phakic contact lenses (IPCLs) are consistently reported as comparably safe and effective for the correction of high myopia. (Rateb et al., 2022; Sachdev et al., 2019; Vasavada et al., 2018)

Anterior chamber iris-fixated pIOLs have shown favorable short-term safety outcomes for moderate to high myopia (−9.0 D to −17.0 D). (Hou et al., 2021) However, endothelial cell density (ECD) loss after implantation remains highly heterogeneous, with reported changes ranging from a gain of 0.26% to a loss of 14.6% after 2–4 years, 0–15.6% after 5–7 years, and 4.9–22.5% beyond 7 years. Foldable lenses are associated with significantly less central ECD loss compared with rigid models, although no differences in corrected distance visual acuity (CDVA) loss or complication rates were found in highly myopic patients (−9.0 D to −14.0 D). (Wu et al., 2020) Among iris-fixated pIOLs, the loss of ≥2 CDVA lines is observed in ~4.5% of highly myopic eyes (−10.0 D to −14.0 D), most frequently due to cataract

formation, while secondary interventions—including explantation, repositioning, re-enclavation, or residual refractive correction—have been reported in 0–27.1% of cases. (van Rijn et al., 2020)

For posterior chamber designs, long-term ECD loss of ~4–10% has been documented for both ICLs and IPCLs. (Sachdev & Ramamurthy, 2019; Vasavada et al., 2018) Toric ICL (TICL) implantation specifically has been shown to reduce ECD significantly, from 2720 ± 272 cells/mm² preoperatively to 2372 ± 325 cells/mm² at 36 months ($P < 0.001$). The steepest decline occurred within the first 24 months, after which the loss stabilized. Higher baseline ECD predicted proportionally greater loss, while the TICL–lens vault decreased up to 24 months and then partially recovered by 36 months, reflecting dynamic yet predictable postoperative behavior.(Bohac et al., 2019)

Long-term evidence from a retrospective study of 3105 eyes in 1485 U.S. military personnel (median age 25 years) supports the safety and efficacy of ICL implantation. In this cohort, uncorrected distance visual acuity (UDVA) of 20/25 or better was maintained in ~80% of eyes for up to 8 years. Refractive accuracy within target was achieved in 97% at 1 year and 90% at 8 years, while mean ECC declined by 22% over 5 years. The overall adverse event rate was 1.2%, including cataract, glaucoma, retinal detachment, and traumatic incision reopening, and 4.5% of eyes required lens removal or replacement. Vault sizes decreased over time, suggesting a possible increased risk of cataract beyond 7 years.(Packer et al., 2022)

Evidence for hyperopic pIOLs remains scarce. In moderate to high hyperopia (+4.0 D to +7.0 D), ECD loss of 5.4–11.7% has been reported at 2–4 years, with secondary surgical intervention rates ranging from 2.2–46%. (van Rijn et al., 2020)

Comparative safety analyses show that pIOL implantation may hold an advantage over laser procedures. Compared with excimer laser surgery (PRK, LASIK) in moderate to high myopia (−5.0 D to −9.0 D), pIOLs carried a significantly lower risk of losing ≥1 line of CDVA (RR 3.92) and a higher probability of gaining ≥1 line (RR 0.37). (Chen et al., 2018) In comparisons with keratorefractive lenticule extraction (KLEx), posterior chamber pIOLs yielded no difference in CDVA loss, but had a superior safety index during the first 6 postoperative months (no differences after 6 months). (Chen et al., 2022; Di et al., 2023) In highly myopic eyes (−8.0 D to −12.0 D), anterior chamber pIOLs demonstrated a significantly better safety index than LASIK (1.12 ± 0.21 vs 0.99 ± 0.17; $P < 0.02$). (Malecaze et al., 2002) Furthermore, in eyes with high myopia up to −12.0 D, ICLs were associated with fewer CDVA line losses compared with KLEx at short-term follow-up. (Cao et al., 2021)

Postoperative care after PCPIOL implantation should follow a structured two-phase approach. Early follow-up should focus on detecting mechanical complications such as lens rotation, misalignment, and inappropriate vaulting, with careful assessment

of centration and positioning. Long-term monitoring is essential to identify anterior segment complications, including cataract formation, anterior capsular changes, and endothelial cell loss, requiring regular slit-lamp examination and endothelial evaluation. Posterior segment complications are rare but should still be considered in at-risk patients. Overall, a combination of early assessment and ongoing surveillance is critical to minimize complications and ensure long-term safety. (Passaro et al., 2026)

Conclusion

Implications for practice

Current evidence indicates that both iris-fixated and posterior chamber phakic intraocular lenses (pIOLs) are safe and effective options for the correction of moderate to high myopia, with or without astigmatism. In contrast, the evidence base for hyperopic correction remains scarce and should be interpreted with caution. Moreover, most data are derived from short-term follow-up, while robust long-term safety and efficacy outcomes are limited. Surgeons must remain vigilant regarding the risks of endothelial cell loss and cataract formation when selecting patients for pIOL implantation.

Knowledge gaps

There is very limited evidence available about the safety of pIOLs in hyperopic eyes. Research into this specific population is necessary. Besides, more insights into long-term outcomes are needed.

Identified research evidence

Findings from Systematic Reviews

There were seven relevant systematic reviews identified.

Artiflex phakic intraocular lenses provided better postoperative visual acuity, efficacy, refractive predictability, contrast sensitivity, and vertical trefoil outcomes than Artisan lenses. Postoperative spherical equivalent also favoured Artiflex. One-year safety, intraocular pressure, complication rates, and most other higher-order aberrations were comparable between lenses (Hou et al., 2021). Risk of bias assessment: high risk of bias.

Foldable phakic intraocular lenses achieved a higher proportion of eyes with postoperative uncorrected distance visual acuity of 20/40 or better and more favourable spherical equivalent outcomes than rigid lenses. Rates of 20/20 vision were comparable. Foldable lenses were also associated with less endothelial cell

loss and fewer intraocular higher-order aberrations (Wu et al., 2020). Risk of bias assessment: high risk of bias.

Phakic intraocular lenses and excimer laser surgery produced broadly comparable uncorrected distance visual acuity at 12 months. Phakic lenses demonstrated greater refractive accuracy and were associated with fewer losses and more frequent gains of best spectacle-corrected visual acuity. However, the proportion of eyes within ±0.50 D of target refraction was similar between groups (Chen et al., 2018). Risk of bias assessment: high risk of bias.

Iris-fixated phakic intraocular lenses provided effective and generally stable correction of high myopia, with a pooled median postoperative refractive error of −0.8 to −0.4 D and 94% of eyes within 1.0 D of emmetropia. More than 91% of eyes maintained or gained corrected distance visual acuity, and safety indices generally remained above 1.0. However, up to 4.5% lost two or more lines of corrected distance visual acuity. Endothelial cell loss and secondary surgical intervention rates increased with follow-up, while glare or halos occurred in up to 22.2% of eyes. Evidence for hyperopic correction remained limited (van Rijn et al., 2020). Risk of bias assessment: high risk of bias.

A meta-analysis of five studies found no significant differences between the compared procedures in uncorrected or best-corrected visual acuity, spherical equivalent, or intraocular pressure. Both methods appeared similarly effective for correcting high myopia. Safety evidence was insufficient to support firm conclusions (Tang & Ye, 2019). Risk of bias assessment: high risk of bias.

ICL and SMILE provided comparable uncorrected and corrected distance visual acuity, refractive predictability, and complication rates. ICL induced fewer total higher-order aberrations, spherical aberration, and coma. Findings for modulation transfer function were sensitive to the exclusion of one heterogeneous study but generally favoured ICL (Di et al., 2023). Risk of bias assessment: not reported in the provided excerpt.

SMILE and ICL V4c achieved comparable efficacy, postoperative visual acuity, and spherical equivalent, although the safety index favoured ICL V4c. SMILE induced greater total higher-order aberrations, coma, and spherical aberration. Other objective measures of visual quality were comparable between procedures (Chen et al., 2022). Risk of bias assessment: not reported in the provided excerpt.

ICL implantation showed higher efficacy and safety indices than SMILE, with more eyes gaining and fewer eyes losing corrected distance visual acuity lines. Refractive predictability was comparable between procedures. ICL induced fewer higher-order aberrations but was associated with a greater risk of halos (Cao et al., 2021). Risk of bias assessment: not reported in the provided excerpt.

Findings from additional studies

There were multiple additional studies included.

GRADE Tables

Rigid iris-fixed phakic intraocular lens compared to foldable iris-fixed phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: rigid iris-fixed phakic intraocular lens
Comparison: foldable iris-fixed phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with foldable iris-fixed phakic intraocular lens	Risk difference with rigid iris-fixed phakic intraocular lens
UDVA of 20/20 or better	(2 observational studies)	⊕◯◯◯ Very low[a,b,c]	**OR 0.37** (0.07 to 1.84)	Inestimable	Inestimable
UDVA (log MAR)	(4 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	-	-	MD **0.1 higher** (0.04 higher to 0.17 higher)
Proportion of eyes with postoperative SE within ±0.50D of the target	(4 observational studies)	⊕◯◯◯ Very low[a,b]	**OR 0.59** (0.34 to 1.02)	Inestimable	Inestimable

Rigid iris-fixed phakic intraocular lens compared to foldable iris-fixed phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: rigid iris-fixed phakic intraocular lens
Comparison: foldable iris-fixed phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with foldable iris-fixed phakic intraocular lens	Risk difference with rigid iris-fixed phakic intraocular lens
Postoperative spherical equivalent	(7 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.21 lower** (0.37 lower to 0.05 lower)
Postoperative intraocular higher order aberrations	(5 observational studies)	⊕◯◯◯ Very low[a,b,d]	-	-	MD **0.08 higher** (0.04 lower to 0.2 higher)
Loosing 2 or more lines of BSCVA	(5 observational studies)	⊕◯◯◯ Very low[a,b,e]	**OR 2.44** (0.64 to 9.26)	Inestimable	Inestimable
Postoperative complications	(3 observational studies)	⊕◯◯◯ Very low[a,b,c,d]	**OR 0.39** (0.10 to 1.61)	Inestimable	Inestimable

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

Rigid iris-fixed phakic intraocular lens compared to foldable iris-fixed phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: rigid iris-fixed phakic intraocular lens
Comparison: foldable iris-fixed phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with foldable iris-fixed phakic intraocular lens	Risk difference with rigid iris-fixed phakic intraocular lens

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies.
b. Results from observational studies pooled together with RCTs
c. Small sample size, wide confidence intervals around the effect estimate.
d. Significant statistical heterogeneity detected.
e. Wide confidence intervals around the effect estimate.
Reference: Wu Q, Li Y, Tang L, Wu LA, Wang CY. Comparison of rigid versus foldable iris-fixed phakic intraocular lens implantation for high myopia: A systematic review and meta-analysis. Medicine (Baltimore). 2020 Feb;99(6):e19030.

Artisan phakic intraocular lens compared to Artiflex phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Artisan phakic intraocular lens
Comparison: Artiflex phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Artiflex phakic intraocular lens	Risk difference with Artisan phakic intraocular lens
Safety index	(2 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.01 lower** (0.11 lower to 0.09 higher)
Efficacy index	(2 observational studies)	⊕◯◯◯ Very low[a,b]	-	-	MD **0.17 lower** (0.29 lower to 0.05 lower)
vertical or horizontal coma or trefoil	(2 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.03 higher** (0.07 lower to 0.13 higher)
Spherical aberration	(4 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	**0** (0 to 0)
Total high-order aberration	(4 observational studies)	⊕◯◯◯ Very low[a,b,c]	-	-	MD **0.07 higher** (0.05 lower to 0.18 higher)

Artisan phakic intraocular lens compared to Artiflex phakic intraocular lens in refractive surgery

Patient or population: refractive surgery
Setting:
Intervention: Artisan phakic intraocular lens
Comparison: Artiflex phakic intraocular lens

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Artiflex phakic intraocular lens	Risk difference with Artisan phakic intraocular lens

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations
a. high risk of bias of the included studies
b. Small sample size; wide confidence intervals around the effect estimate.
c. Significant statistical heterogeneity detected.
Reference: Hou, C., Li, H., Li, J. et al. Artisan versus Artiflex phakic intraocular lens implantation in the treatment of moderate to high myopia: meta-analysis. BMC Ophthalmol 21, 171 (2021).

9.2 Refractive Lens Exchange

9.2.1 Indications for Refractive Lens Exchange

What are the indications and contraindications for Refractive Lens Exchange?

Recommendation

Refractive lens exchange can be considered in patients with various types of refractive errors, including hyperopia, myopia, astigmatism, and presbyopia. (GRADE +)

Refractive lens exchange may be considered for patients over 55 years old preferably after a posterior vitreous detachment (PVD), though PVD can be difficult to demonstrate clinically. It is also important that the peripheral retina shows no signs of lattice degeneration or other predisposing retinal lesions concerning the optical nerve or macula. Although no definitive age threshold exists, discussions regarding this procedure primary arise around the ages of 55 to 60, considering the residual accommodation provided by the crystalline lens during this period. However, in instances of high hyperopia (higher than 4.00D) with shallow anterior chamber depth and the absence of feasible alternatives such as corneal refractive surgery or pIOLs, earlier consideration may be warranted. (GRADE +)

Considerations

Refractive lens exchange (RLE), involving removal of the crystalline lens for refractive purposes, presents both advantages and disadvantages. This procedure is particularly relevant for middle-aged patients with presbyopia and weakened accommodation. (Alió et al., 2009). RLE can also be combined with corneal astigmatic procedures for optimized outcomes (Alió et al., 2014). In general, RLE is indicated for patients over 50 years of age with stable refraction (defined as <0.5 diopters change in the preceding year), particularly those with high myopia, hyperopia, or astigmatism (Emarah et al., 2010; German Society of Ophthalmology & Professional Association of German Ophthalmologists, 2020). However, in patients with very high myopia (≥–8.0 D), the risk of retinal detachment is significantly elevated following intraocular surgery, rendering RLE contraindicated in this subgroup, except in cases with pre-existing posterior vitreous detachment (PVD) (Huang et al., 2009).

IOL options in RLE include monofocal lenses, extended depth-of-focus (EDOF) lenses, and multifocal lenses that provide correction across near, intermediate, and distance ranges. For astigmatism, toric IOLs—designed with additional cylindrical correction—are highly effective, with studies reporting residual astigmatism ≤0.75 D after surgery in eyes with preoperative astigmatism between 1.0 D and 4.0 D,

corresponding to mean reductions of >80% and excellent rotational stability (Ruiz-Mesa et al., 2009).

In hyperopic patients, especially those with shallow anterior chambers, clear lens exchange may be advantageous by reducing the risk of angle-closure glaucoma (Fine et al., 2001). It may also be indicated in hyperopic patients with early presbyopia, high-order aberrations, weak accommodation, or systemic conditions that preclude the use of spectacles or contact lenses.

Given the high expectations of patients undergoing refractive surgery, comprehensive preoperative counseling is essential. The benefits and risks of RLE, as well as the range of IOL options, must be carefully explained to ensure informed decision-making.

Conclusion

Implications for practice

Refractive lens exchange can be considered in patients with myopia, hyperopia and astigmatism and might especially provide benefits for elderly patients with presbyopia. A risk benefit analysis has to be considered in myopes due to the risk of retinal detachment related to PVD, as well as in hyperopes related to the development of cystoid macular edema (CME). For restoration of near, intermediate, and far vision, multifocal IOLs and EDOF IOLs are superior to monofocal IOLs.

Knowledge gaps

More research on the safe range of application for refractive lens exchange has to be conducted in order to correctly advise patients and facilitate the choice between different refractive procedures.

Identified research evidence

Findings from Systematic Reviews

There were no systematic reviews included.

Findings from additional studies

There were multiple additional studies included.

9.2.2 Efficacy of Refractive Lens Exchange

Output question

What is the efficacy of refractive lens exchange?

- **P** Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
- **I** Performing Intraocular surgeries (Refractive Lens Exchange)
- **C** Other procedures:
  - Use of spectacles
  - Corneal surface ablative procedures (PRK/Trans-PRK)
  - Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)
  - Performing implementation of phakic IOLs
- **O** Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Recommendation

Refractive lens exchange shows good efficacy in patients with high myopia (higher than -6.0D). (GRADE +)

Refractive lens exchange shows good efficacy in the correction of myopic and hyperopic astigmatism. (GRADE +)

Refractive lens exchange is effective for correcting low to moderate hyperopia (lower than 6.0D). (GRADE +)

Refractive lens exchange shows sufficient efficacy for correcting high hyperopia (higher than 6.0D). (GRADE +)

No evidence has been found for the efficacy of refractive lens exchange in low myopia (lower than -6.0D) (GRADE +)

Considerations

Evidence for the efficacy of refractive lens exchange (RLE) primarily derives from studies in eyes with extreme ametropia. In patients with high hyperopia (>+6.0 D), postoperative corrected distance visual acuity (CDVA) has been reported between 0.8 and 1.10, with uncorrected distance visual acuity (UDVA) ranging from 0.5 to 0.81 (Siganos & Pallikaris, 1998). In cases of lower hyperopia (<+6.0 D), most studies documented postoperative UDVA between 0.58 and 0.80 and CDVA around 1.02 (Fink et al., 2000). Another study reported a mean efficacy index of 0.87, with

postoperative CDVA ≥0.5 logMAR in 97.56% and ≥0.8 logMAR in 58.54% of eyes (Alfonso et al., 2009).

Comparative data on RLE and alternative refractive procedures are scarce. In one study of low-to-moderate hyperopic patients, RLE achieved UDVA ≥20/40 in 82% of eyes at two months, while phakic IOL implantation achieved the same in 89% (Pop & Payette, 2004). No lines of best spectacle-corrected visual acuity (BSCVA) were lost, and both groups showed stable BSCVA after one month.

Outcomes in myopic patients are heterogeneous (Alio et al., 2014). Most evidence is limited to high myopia (–13.0 D to –17.0 D). One study reported improvement of CDVA in 83.7% of eyes compared to baseline, while randomized controlled trials reported postoperative mean CDVA >0.5 logMAR in 82.9% of cases (Güell et al., 2003). In direct comparison with phakic IOLs, one study in very high myopia (–13.0 D to –16.0 D ±3.0 D) reported postoperative BCVA improvement at 12 months in 78% of pIOL-treated eyes and 83.3% of RLE-treated eyes (Arne, 2004). Another study in extreme myopia (≥–16.0 D) reported a mean postoperative CDVA of 0.61 with UCVA improvement in 71.4% after RLE, compared to a mean CDVA of 0.79 with UCVA improvement in 53.5% after pIOL implantation (Alio et al., 2014). No comparative evidence is currently available for RLE in low myopia.

Conclusion

Implications for practice

Based on the currently available evidence, refractive lens exchange is effective in moderate to high hyperopic patients as well as patients with high myopia. The evidence for the use of refractive lens exchange to correct highly hyperopic eyes shows sufficient efficacy. Evidence is too limited to draw an evidence-based conclusion for the efficacy of RLE in low to moderate myopic eyes. Note that the patient's age and the presense of a posterior vitreous detachment have to be considered during clinical decision-making.

Knowledge gaps

There is very limited evidence available about the efficacy of RLE in low to moderate myopic eyes. Research into this specific population is necessary. Besides, more insights into the long-term outcomes are needed.

Identified research evidence

Findings from Systematic Reviews

No relevant systematic reviews were identified.

Findings from additional studies

There were multiple additional studies included.

9.2.3 Predictability of Refractive Lens Exchange

Output question
What is the predictability of refractive lens exchange?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery.
I Performing refractive lens exchange
C Other procedures:
- Use of spectacles
- corneal surface ablative procedures: (PRK)
- intracorneal ablative procedures (LASIK)
- Intraocular surgeries (Phakic IOL, Refractive Lens Exchange)

O Visual acuity, Visual function, Quality of life, Postoperative refractive outcome, complications, adverse events

Recommendation

RLE can be considered a predictable procedure in low (lower than 4.0D) to high (higher than 4.0D) hyperopes with a high number of patients receiving a postoperative SE within 1.0D of the target refraction. (GRADE +)

RLE can be considered a predictable procedure in low (lower than -2.0D) to high (higher than -6.0D) myopes. (GRADE +)

Considerations

Comparisons across studies on refractive lens exchange (RLE) remain challenging due to limited research, small patient cohorts, and the relatively recent adoption of this technique. Most available evidence focuses on high myopia with preserved accommodative reserves and hyperopia in presbyopic patients.

For hyperopic eyes, one study with a mean preoperative spherical equivalent (SE) of +6.66 ± 2.17 D (range +4.75 to +13.00 D) reported that 70% of eyes achieved outcomes within ±0.50 D of the intended refraction (Preetha et al., 2003). Another trial found a mean postoperative SE of –0.18 ± 0.73 D in patients with mild hyperopia (<+4.0 D), with 88.5% within ±1.0 D of target, and –0.19 ± 1.28 D in high hyperopia (>+4.0 D), with 58.3% within ±1.0 D (Fink et al., 2000). Similarly, a separate investigation on low hyperopia (<+4.0 D) reported a mean postoperative SE of ±0.064 D (Alfonso et al., 2009). For highly hyperopic eyes, only case reports are available, though these suggest effective outcomes, with postoperative visual acuity of 20/30 in several cases (Alio et al., 2014).

Direct comparisons between RLE and phakic IOL implantation in hyperopia (+2.75 to +9.25 D) found that uncorrected visual acuity (UCVA) was initially slightly better in the RLE group after one month, but results equalized by two months, with both procedures achieving comparable postoperative SE and best spectacle-corrected visual acuity (BSCVA) (Pop & Payette, 2004).

Evidence in myopic patients is more heterogeneous and primarily involves cohorts with extreme myopia (>–15.0 D). Postoperative refractive error varied considerably, with 41% of eyes achieving results within ±1.0 D in one study (Fernández-Vega et al., 2003), while others reported 79% within ±2.0 D, 86.5% within ±1.0 D, and 95.8% within ±2.0 D (Gabrić et al., 2002). When compared to phakic IOLs in very high myopia (>–15.0 D), RLE achieved target refraction in 82% of eyes, compared with 77% in the ICL group; notably, all eyes in both groups were within ±2.0 D of target (Emarah et al., 2010)

Conclusion

Implications for practice

Current evidence indicates that refractive lens exchange (RLE) provides good predictability for high myopia as well as low to high hyperopia and offers highly predictable outcomes across a range of refractive errors, including presbyopia. Comparative studies suggest that predictability of RLE is broadly comparable to that of phakic IOL implantation.

Knowledge gaps

There remains a lack of evidence on the predictability of RLE in low myopia, and direct comparisons between RLE and keratorefractive procedures are scarce. Most available data are derived from cataract surgery studies, underscoring the need for further dedicated research on RLE.

Identified research evidence

Findings from Systematic Reviews

There were no relevant systematic reviews identified.

Findings from additional studies

There were multiple additional studies included.

9.2.4 Stability of Refractive Lens Exchange

Output question

What is the stability of refractive lens exchange?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with or without corneal astigmatism) who will undergo refractive surgery
I Performing Intraocular surgeries (Refractive Lens Exchange)
C Other procedures:
- Use of spectacles
- Corneal surface ablative procedures (PRK/Trans-PRK)
- implementation of phakic IOLs
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)

O Visual acuity, Visual function, Quality of life, Postoperative refractive outcome

Recommendation

Refractive lens exchange shows good stability for correcting ametropia. (GRADE +)

Based on clinical expertise, refractive lens exchange is considered permanent, but eye changes over time can cause defocus due to lens positioning shifts (fibrosis) and retinal changes, especially in high myopia. Special attention is needed for patients developing against-the-rule astigmatism in the long term, often as a result to the corneal incision during the procedure. (GRADE +)

Considerations

Refractive lens exchange (RLE) involves replacing the natural crystalline lens with an intraocular lens (IOL). Unlike corneal refractive procedures, RLE does not carry the risk of refractive regression over time, although age-related development of against-the-rule astigmatism may occur (expert opinion). In the absence of new ocular pathologies—such as corneal or retinal disease—or posterior capsular opacification (PCO), visual outcomes generally remain stable. If PCO develops, Nd:YAG capsulotomy may be required to restore visual clarity.

In patients with astigmatism, implantation of toric IOLs provides effective correction. However, postoperative IOL rotation can lead to decreased visual quality, occasionally necessitating secondary surgery for toric IOL reorientation. Vision typically stabilizes within several weeks following such procedures. In cases where

patients remain dissatisfied with the refractive outcome, residual errors may be managed with spectacles, contact lenses, or secondary interventions such as IOL exchange or adjunctive corneal refractive surgery (e.g., LASIK).

Conclusion

Implications for practice
The available evidence regarding the stability of a refractive lens exchange is very limited. Refractive lens exchange is a stable procedure, with no risk of regression based on clinical expertise. This draft is fully based on expert opinion.

Knowledge gaps
Additional research into the stability for refractive lens exchange is required, as no long-term follow-ups regarding the stability could be found. This draft is fully based on expert opinion.

Identified research evidence

Findings from Systematic Reviews

No systematic reviews were identified.

Findings from additional studies

There were multiple additional studies included.

9.2.5 Safety of Refractive Lens Exchange

Output question

What is the safety of refractive lens exchange (RLE)?

P Patients with a refractive error (myopia, hyperopia and presbyopia, with
or without corneal astigmatism) who will undergo refractive surgery
I Performing intraocular surgery (refractive lens exchange)
C Other procedures:
- Use of spectacles
- Corneal surface ablative procedures (PRK/Trans-PRK)
- Intracorneal ablative procedures: (LASIK, refractive lenticule extraction)

O (Serious) adverse events

Recommendation

Refractive lens exchange can be considered a safe procedure for correcting low to high ametropia. (GRADE +)

High myopic patients undergoing RLE have an increased risk for a retinal detachment, especially in younger patients without cataract. (GRADE +)

Similar to cataract surgery postoperative inflammation, infection and DED need to be prevented. (GRADE +)

The surgery is exposed to mechanical damage of the bag that may increase the risk of complications and not allow the implantation of an in the bag IOL. (GRADE +)

Considerations

Complications during or after refractive lens exchange (RLE) largely overlap with those encountered in cataract surgery; however, as RLE is often performed in younger patients with extreme axial lengths, certain complications require particular attention in this context (Kook et al., 2008). Posterior capsule opacification (PCO) is one of the most frequent postoperative events, commonly necessitating Nd:YAG capsulotomy. While modern micro-incisional surgery and foldable intraocular lenses have reduced PCO rates, it is important to note that YAG capsulotomy itself may predispose to retinal detachment (Fernández-Vega et al., 2003). The elevated risk of retinal complications in highly myopic patients undergoing RLE is of particular concern, with retinal detachment reported in 1.5% to 8.1% of cases (Alio et al., 2014). Risk factors include axial length >26 mm, spherical equivalent >-6D, younger age (<50 years), male sex, white race, peripheral retinal degenerations, and

intraoperative rupture of the posterior capsule. In young, highly myopic patients, RLE may induce vitreous changes that enhance vitreoretinal traction. Accordingly, deferring surgery until posterior vitreous detachment may reduce this risk (Chan & Varma, 2025; Fernández-Vega et al., 2003; Rodríguez-Calvo-de-Mora et al., 2023; Rosen, 2008) Comprehensive preoperative fundus examination is therefore mandatory, while prophylactic laser treatment of lattice degeneration is not recommended due to its limited efficacy (Fernández-Vega et al., 2003).

In hyperopic eyes with short anterior segments and shallow anterior chambers, RLE carries an elevated risk of pupillary block and secondary intraocular pressure (IOP) rise. (Chan & Varma, 2025; Kook et al., 2008) Hyperopes are also predisposed to cystoid macular edema, necessitating a careful risk–benefit assessment before surgery (expert opinion). Additional postoperative issues include reduced contrast sensitivity, halos, and glare following multifocal IOL implantation (Altaie et al., 2012). As with any intraocular procedure, the risk of endophthalmitis remains, although the incidence is very low. In rare instances, cystoid macular edema may also occur, particularly in myopes (Kaweri et al., 2020). Taken together, these risks highlight the need for careful patient selection, particularly in individuals with long axial lengths, male sex under 60 years of age, and peripheral degenerations, who are at elevated risk of retinal detachment when undergoing RLE.(Rodríguez-Calvo-de-Mora et al., 2023)

Conclusion

Implications for practice

Based on current evidence, RLE can be regarded as a safe and effective option for correcting moderate to high myopia and hyperopia. Overall complication rates are low, but the risk of retinal detachment clearly increases with higher degrees of myopia. In hyperopic patients with shallow anterior chambers and short anterior segments, the likelihood of pupillary block and IOP elevation must be considered, although lens replacement may mitigate—but not entirely eliminate—this risk.

Knowledge gaps

Evidence on the safety of RLE in low to moderate ametropia remains limited. Most available data are derived from studies addressing cataract surgery, with relatively few focusing on the distinct risk profile of RLE. In particular, further research is warranted to clarify the risk of retinal detachment following RLE and to better define long-term safety outcomes in non-cataractous populations.

Identified research evidence

Findings from Systematic Reviews

No relevant systematic reviews were identified.

Findings from additional studies

There were multiple additional studies included.

10. Procedure Specific Ranges of Apllication

Procedure	Myopia	Hyperopia	Astigmatism
PRK / Trans-PRK	lower than 6.0 D (higher with caution)	lower than 3.0 D	lower than 4.0 D
LASIK	lower than 6.0 D (higher possible with ideal conditions)	lower than 3.0 D (higher with caution)	lower than 4.0 D
KLEx	lower than 6.0 D (higher possible with ideal conditions)	lower than 6.0 D (limited evidence, CE marked)	lower than 5.0 D D wo. cyclotorsion
Phakic IOL	≥ 1.0 D	≥ 1.0 D (ACD≥ 3.0 mm)	≥ 0.5 D
RLE	Low to high	Low to high	Low to high w. tor

11. References

AAO PPP Cataract and Anterior Segment Panel, & Hoskins Center for Quality Eye Care. (2021 [accessed 2.5.23]). *Cataract in the adult eye PPP 2021 [Internet]*. https://www.aao.org/education/preferred-practice-pattern/cataract-in-adult-eye-ppp-2021-in-press

Akram, S., Moazzum, W., & Abid, K. (2025). Efficacy of single-step transepithelial photorefractive keratectomy in myopia, hyperopia and astigmatism-a systematic review. *BMC Ophthalmol*, *25*(1), 93. https://dx.doi.org/10.1186/s12886-024-03830-x

Al-Khateeb, G., Shajari, M., Vunnava, K., Petermann, K., & Kohnen, T. (2017). Impact of lens densitometry on phacoemulsification parameters and usage of ultrasound energy in femtosecond laser-assisted lens surgery. *Can J Ophthalmol*, *52*(4), 331-337. https://dx.doi.org/10.1016/j.jcjo.2017.01.004

Alarfaj, G., Helayel, H. B., AlSubaie, M., Hariri, J., Alzaher, F., Khan, O., Al-Jindan, M., AlHabash, A., & Sulaimani, N. M. (2025). Posterior chamber phakic intraocular lens adjustment-causes and complications: a retrospective cohort study. *Int J Ophthalmol*, *18*(5), 883-888. https://doi.org/10.18240/ijo.2025.05.14

Alasbali, T. (2022). Transepithelial photorefractive keratectomy compared to conventional photorefractive keratectomy: a meta-analysis. *J Ophthalmol*, *2022*, 3022672. https://ksrevidence.com/article/KSRA224988

Alfonso, J. F., Fernández-Vega, L., Baamonde, B., Madrid-Costa, D., & Montés-Micó, R. (2009). Refractive lens exchange with spherical diffractive intraocular lens implantation after hyperopic laser in situ keratomileusis. *J Cataract Refract Surg*, *35*(10), 1744-1750. https://doi.org/10.1016/j.jcrs.2009.04.045

Alió, J. L., Ben-nun, J., Rodríguez-Prats, J. L., & Plaza, A. B. (2009). Visual and accommodative outcomes 1 year after implantation of an accommodating intraocular lens based on a new concept. *J Cataract Refract Surg*, *35*(10), 1671-1678. https://doi.org/10.1016/j.jcrs.2009.04.043

Alio, J. L., Grzybowski, A., El Aswad, A., & Romaniuk, D. (2014). Refractive lens exchange. *Surv Ophthalmol*, *59*(6), 579-598. https://dx.doi.org/10.1016/j.survophthal.2014.04.004

Alió, J. L., Grzybowski, A., & Romaniuk, D. (2014). Refractive lens exchange in modern practice: when and when not to do it? *Eye Vis (Lond)*, *1*, 10. https://dx.doi.org/10.1186/s40662-014-0010-2

AlKharashi, M., Bower, K. S., Stark, W. J., & Daoud, Y. J. (2014). Refractive surgery in systemic and autoimmune disease. *Middle East Afr J Ophthalmol*, *21*(1), 18-24. https://doi.org/10.4103/0974-9233.124082

Almutairi, M. N., Alshehri, A. M., Alhoumaily, A. Y., Alnahdi, O., Taha, M. A., & Gangadharan, S. (2025). Meta-analysis: clinical outcomes of laser-assisted in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) in hyperopia. *BMC Ophthalmol*, *25*(1), 140. https://dx.doi.org/10.1186/s12886-025-03956-6

Altaie, R., Ring, C. P., Morarji, J., Patel, D. V., & McGhee, C. N. (2012). Prospective analysis of visual outcomes using apodized, diffractive multifocal intraocular lenses following phacoemulsification for cataract or clear lens extraction. *Clin Exp Ophthalmol*, *40*(2), 148-154. https://doi.org/10.1111/j.1442-9071.2011.02671.x

Ambrósio, R., Jr., Lopes, B., Faria-Correia, F., Vinciguerra, R., Vinciguerra, P., Elsheikh, A., & Roberts, C. J. (2016). Ectasia detection by the assessment of corneal biomechanics. *Cornea*, *35*(7), e18-20. https://doi.org/10.1097/ICO.0000000000000875

American Academy of Ophthalmology. (2017). *Refractive errors & refractive surgery preferred practice pattern (R)*.

American Academy of Ophthalmology Preferred Practice Pattern Cataract and Anterior Segment Committee. (2021). *Cataract in the adult eye PPP 2021*.

Apple, D. J., & Werner, L. (2001). Complications of cataract and refractive surgery: a clinicopathological documentation. *Trans Am Ophthalmol Soc*, *99*, 95-109.

Arne, J. L. (2004). Phakic intraocular lens implantation versus clear lens extraction in highly myopic eyes of 30- to 50-year-old patients. *J Cataract Refract Surg*, *30*(10), 2092-2096. https://doi.org/10.1016/j.jcrs.2004.02.082

Asam, J. S., Polzer, M., Tafreshi, A., & et al. (2019). Anterior segment. In J. F. Bille (Ed.), *High resolution imaging in microscopy and ophthalmology: new frontiers in biomedical optics [Internet]*. Springer. https://www.ncbi.nlm.nih.gov/books/NBK554035/

Asif, M. I., Bafna, R. K., Mehta, J. S., Reddy, J., Titiyal, J. S., Maharana, P. K., & Sharma, N. (2020). Complications of small incision lenticule extraction. *Indian J Ophthalmol*, *68*(12), 2711-2722. https://dx.doi.org/10.4103/ijo.IJO_3258_20

Barsam, A., & Allan, B. D. S. (2014). Excimer laser refractive surgery versus phakic intraocular lenses for the correction of moderate to high myopia. *Cochrane Database Syst Rev*, *CD007679*(6). https://doi.org/https://dx.doi.org/10.1002/14651858.CD007679.pub4

Blum, M., Lauer, A. S., Kunert, K. S., & Sekundo, W. (2019). 10-year results of small incision lenticule extraction. *J Refract Surg*, *35*(10), 618-623. https://dx.doi.org/10.3928/1081597X-20190826-02

Bohac, M., Jagic, M., Biscevic, A., Shijakova, V., Gabric, N., & Patel, S. (2019). Changes in endothelial cell count up to three years after implantation of toric implantable collamer lenses. *Cornea*, *38*(7), 873-879. https://doi.org/10.1097/ICO.0000000000001914

Bower, K. S., Sia, R. K., Ryan, D. S., Mines, M. J., & Dartt, D. A. (2015). Chronic dry eye in photorefractive keratectomy and laser in situ keratomileusis: manifestations, incidence, and predictive factors. *J Cataract Refract Surg*, *41*(12), 2624-2634. https://dx.doi.org/10.1016/j.jcrs.2015.06.037

Bower, K. S., & Woreta, F. (2014). Update on contraindications for laser-assisted in situ keratomileusis and photorefractive keratectomy. *Curr Opin Ophthalmol*, *25*(4), 251-257. https://dx.doi.org/10.1097/ICU.0000000000000055

Braithwaite, T., Calvert, M., Gray, A., Pesudovs, K., & Denniston, A. K. (2019). The use of patient-reported outcome research in modern ophthalmology: impact on clinical trials and routine clinical practice. *Patient Relat Outcome Meas*, *10*, 9-24. https://doi.org/10.2147/PROM.S162802

Brar, S., Sute, S. S., Bagare, S. N., & Ganesh, S. (2021). Functional outcomes and reading speeds following PRESBYOND LBV using nonlinear aspheric ablation profiles combined with micro-monovision. *J Ophthalmol*, *2021*, 2957443. https://doi.org/10.1155/2021/2957443

Buckhurst, P. J., Naroo, S. A., Davies, L. N., Shah, S., Buckhurst, H., Kingsnorth, A., Drew, T., & Wolffsohn, J. S. (2015). Tablet App halometer for the assessment of dysphotopsia. *J Cataract Refract Surg*, *41*(11).

https://journals.lww.com/jcrs/fulltext/2015/11000/tablet_app_halometer_for_the_assessment_of.13.aspx
Cai, W. T., Liu, Q. Y., Ren, C. D., Wei, Q. Q., Liu, J. L., Wang, Q. Y., Du, Y. R., He, M. M., & Yu, J. (2017). Dry eye and corneal sensitivity after small incision lenticule extraction and femtosecond laser-assisted in situ keratomileusis: a meta-analysis. *Int J Ophthalmol*, *10*(4), 632-638. https://ksrevidence.com/article/KSRA66845
Cao, K., Zhang, J., Wang, J., Yusufu, M., Jin, S., Chen, S., Wang, N., Jin, Z. B., & Wan, X. H. (2021). Implantable collamer lens versus small incision lenticule extraction for high myopia correction: a systematic review and meta-analysis. *BMC Ophthalmol*, *21*(1), 450. https://ksrevidence.com/article/KSRA194791
Chan, C., Lawless, M., Sutton, G., Versace, P., & Hodge, C. (2016). Small incision lenticule extraction (SMILE) in 2015. *Clin Exp Optom*, *99*(3), 204-212. https://dx.doi.org/10.1111/cxo.12380
Chan, E., & Varma, S. (2025). Refractive lens exchange - the evidence behind the practise. *Eye (Lond)*, *39*(2), 208-209. https://doi.org/10.1038/s41433-024-03478-3
Chang, J.-Y., & et al. (2022). Comparison of clinical outcomes of LASIK, Trans-PRK, and SMILE for correction of myopia. *J Chin Med Assoc*, *85*(2), 145-151.
Chang, Y. M., Liang, C. M., Weng, T. H., Chien, K. H., & Lee, C. H. (2021). Mitomycin C for the prevention of corneal haze in photorefractive keratectomy: a meta-analysis and trial sequential analysis. *Acta Ophthalmol*, *99*(6), 652-662. https://ksrevidence.com/article/KSRA156363
Chen, D., Zhao, X., Chou, Y., & Luo, Y. (2022). Comparison of visual outcomes and optical quality of femtosecond laser-assisted SMILE and Visian Implantable Collamer Lens (ICL V4c) implantation for moderate to high myopia: a meta-analysis. *J Refract Surg*, *38*(6), 332-338. https://ksrevidence.com/article/KSRA215566
Chen, H., Liu, Y., Niu, G., & Ma, J. (2018). Excimer laser versus phakic intraocular lenses for myopia and astigmatism: a meta-analysis of randomized controlled trials. *Eye & Contact Lens*, *44*(3), 137-143. https://ksrevidence.com/article/KSRA63675
Chen, K. Y., Chan, H. C., & Chan, C. M. (2025). How effective is keratorefractive lenticule extraction surgery (KLEx) in reducing dry eye outcomes compared to LASIK? A systematic review and meta-analysis. *J Refract Surg*, *41*(8), e839-e854. https://dx.doi.org/10.3928/1081597X-20250506-07
Chen, L. J., Chang, Y. J., Kuo, J. C., Rajagopal, R., & Azar, D. T. (2008). Metaanalysis of cataract development after phakic intraocular lens surgery. *J Cataract Refract Surg*, *34*(7), 1181-1200. https://doi.org/10.1016/j.jcrs.2008.03.029
Chen, S., Ma, H., & Zhao, C. (2023). Corneal biomechanics after small incision lenticule extraction and femtosecond laser in situ keratomileusis: a systematic review and meta-analysis. *Medicine (Baltim)*, *102*(32), e34580. https://dx.doi.org/10.1097/MD.0000000000034580
Cheng, S. M., Tu, R. X., Li, X., Zhang, J. S., Tian, Z., Zha, Z. W., Ruan, K. W., & Yu, A. Y. (2021). Topography-guided versus wavefront-optimized LASIK for myopia with and without astigmatism: a meta-analysis. *J Refract Surg*, *37*(10), 707-714. https://ksrevidence.com/article/KSRA189630
Chuck, R. S., & et al. (2018). Refractive errors & refractive surgery preferred practice patterns. *Ophthalmology*, *125*(1), 1-104.

Chuck, R. S., Jacobs, D. S., Lee, J. K., Afshari, N. A., Vitale, S., Shen, T. T., & Keenan, J. D. (2018). Refractive errors & refractive surgery preferred practice pattern (R). *Ophthalmology*, *125*(1), P1-P104. https://doi.org/10.1016/j.ophtha.2017.10.003

Chung, B., Choi, M., Lee, K. Y., Kim, E. K., Seo, K. Y., Jun, I., Kim, K. Y., & Kim, T. I. (2020). Comparing dry eye disease after small incision lenticule extraction and laser subepithelial keratomileusis. *Cornea*, *39*(4), 501-507. https://dx.doi.org/10.1097/ICO.0000000000002240

Cobo-Soriano, R., Llovet, F., González-López, F., Domingo, B., Gómez-Sanz, F., & Baviera, J. (2002). Factors that influence outcomes of hyperopic laser in situ keratomileusis. *J Cataract Refract Surg*, *28*(9), 1530-1538. https://doi.org/10.1016/s0886-3350(02)01367-6

Cochener, B. (2018). Influence of the level of monovision on visual outcome with an extended range of vision intraocular lens. *Clin Ophthalmol*, *12*, 2305-2312. https://dx.doi.org/10.2147/OPTH.S184712

Cohen, E., & Spierer, O. (2018). Dry eye post-laser-assisted in situ keratomileusis: major review and latest updates. *J Ophthalmol*, *2018*, 4903831. https://dx.doi.org/10.1155/2018/4903831

Damgaard, I. B., Sejersen, H., Ivarsen, A., & Hjortdal, J. (2021). 7-year results of SMILE for high myopia: visual and refractive outcomes and aberrations. *J Refract Surg*, *37*(10), 654-661. https://doi.org/10.3928/1081597X-20210712-02

Dans, A. L., & Dans, L. F. (2010). Appraising a tool for recommendations appraisal (the AGREE II instrument). *J Clin Epidemiol*, *63*(12), 1281-1282. https://dx.doi.org/10.1016/j.jclinepi.2010.06.005

De Stefano, V. S., & Dupps, W. J., Jr. (2017). Biomechanical diagnostics of the cornea. *Int Ophthalmol Clin*, *57*(3), 75-86. https://doi.org/10.1097/IIO.0000000000000172

Deshpande, K., Shroff, R., Biswas, P., Kapur, K., Shetty, N., Koshy, A. S., & Khamar, P. (2020). Phakic intraocular lens: getting the right size. *Indian J Ophthalmol*, *68*(12), 2880-2887. https://dx.doi.org/10.4103/ijo.IJO_2326_20

Di, Y., Cui, G., Li, Y., & Luo, Y. (2023). A meta-analysis of visual outcomes and optical quality after small incision lenticule extraction versus implantable collamer lens for myopia. *Eur J Ophthalmol*, *33*(1), 136-144. https://ksrevidence.com/article/KSRA208139

Dirani, M., Couper, T., Yau, J., Ang, E. K., Islam, F. M., Snibson, G. R., Vajpayee, R. B., & Baird, P. N. (2010). Long-term refractive outcomes and stability after excimer laser surgery for myopia. *J Cataract Refract Surg*, *36*(10), 1709-1717. https://doi.org/10.1016/j.jcrs.2010.04.041

Durrie, D. S., Smith, R. T., Waring, G. O. t., Stahl, J. E., & Schwendeman, F. J. (2010). Comparing conventional and wavefront-optimized LASIK for the treatment of hyperopia. *J Refract Surg*, *26*(5), 356-363. https://dx.doi.org/10.3928/1081597X-20090617-07

Emarah, A. M., El-Helw, M. A., & Yassin, H. M. (2010). Comparison of clear lens extraction and collamer lens implantation in high myopia. *Clin Ophthalmol*, *4*, 447-454. https://doi.org/10.2147/opth.s11005

[Evaluation and quality assurance of refractive surgical interventions by the DOG and the BVA - recommendations of the Committee of Refractive Surgery - Status June 2022]. (2023). *Klin Monbl Augenheilkd*, *240*(6), 824-834. https://doi.org/10.1055/a-2075-4765

Fernández-Vega, L., Alfonso, J. F., & Villacampa, T. (2003). Clear lens extraction for the correction of high myopia. *Ophthalmology*, *110*(12), 2349-2354. https://doi.org/10.1016/S0161-6420(03)00794-2

Fernandez, J., Molina-Martin, A., Rocha-de-Lossada, C., Rodriguez-Vallejo, M., & Pinero, D. P. (2022). Clinical outcomes of presbyopia correction with the latest techniques of presbyLASIK: a systematic review. *Eye (Lond)*, *Epub ahead of print*. https://ksrevidence.com/article/KSRA219838

Fernández, J., Ribeiro, F., Rocha-de-Lossada, C., & Rodríguez-Vallejo, M. (2024). Functional classification of intraocular lenses based on defocus curves: a scoping review and cluster analysis. *J Refract Surg*, *40*(2), e108-e116. https://dx.doi.org/10.3928/1081597X-20231212-01

Fine, I. H., Hoffman, R. S., & Packer, M. (2001). Clear-lens extraction with multifocal lens implantation. *Int Ophthalmol Clin*, *41*(2), 113-121. https://doi.org/10.1097/00004397-200104000-00011

Fink, A. M., Gore, C., & Rosen, E. S. (2000). Refractive lensectomy for hyperopia. *Ophthalmology*, *107*(8), 1540-1548. https://doi.org/10.1016/s0161-6420(00)00217-7

Foster, G. J. L., Ayres, B., Fram, N., Khandewal, S., Ogawa, G. S. H., MacDonald, S. M., Miller, K. M., Snyder, M. E., & Vasavada, A. R. (2021). Management of common iatrogenic iris defects induced by cataract surgery. *J Cataract Refract Surg*, *47*(4), 522-532. https://dx.doi.org/10.1097/j.jcrs.0000000000000411

Fu, D., Wei, R., Shi, M., Peng, X., Zhou, X., & Han, T. (2026). Hyperopic keratorefractive lenticule extraction. *J Cataract Refract Surg*, *52*(1), 86-92. https://dx.doi.org/10.1097/j.jcrs.0000000000001789

Fu, Y., Yin, Y., Wu, X., Li, Y., Xiang, A., Lu, Y., Fu, Q., Hu, T., Du, K., & Wen, D. (2021). Clinical outcomes after small-incision lenticule extraction versus femtosecond laser-assisted LASIK for high myopia: a meta-analysis. *PLoS One*, *16*(2), e0242059. https://ksrevidence.com/article/KSRA162045

Gabrić, N., Dekaris, I., & Karaman, Z. (2002). Refractive lens exchange for correction of high myopia. *Eur J Ophthalmol*, *12*(5), 384-387. https://doi.org/10.1177/112067210201200507

Galvis, V., Carreño, N. I., Tello, A., & Laiton, A. N. (2017). Severe pigment dispersion after iris-claw phakic intraocular lens implantation. *Indian J Ophthalmol*, *65*(12), 1492-1494. https://dx.doi.org/10.4103/ijo.IJO_743_17

Ganesh, S., Brar, S., & Pawar, A. (2017). Results of intraoperative manual cyclotorsion compensation for myopic astigmatism in patients undergoing small incision lenticule extraction (SMILE). *J Refract Surg*, *33*(8), 506-512. https://dx.doi.org/10.3928/1081597X-20170328-01

German Society of Ophthalmology, & German Professional Association of Ophthalmologists. (2024). Evaluation and quality assurance of refractive surgical interventions by the DOG and the BVA - recommendations of the Committee of Refractive Surgery: Dated June 2022. *Die Ophthalmologie*, *121*(1), 1-11. https://dx.doi.org/10.1007/s00347-023-01971-w

German Society of Ophthalmology, & Professional Association of German Ophthalmologists. (2020). Evaluation and quality assurance of refractive surgery by the German Society of Ophthalmology and the Professional Association of German Ophthalmologists - Commission for refractive surgery recommendations: Status February 2019. *Der Ophthalmologe*, *117*(1), 25-35.

Gharaee, H., Zarei-Ghanavati, S., Alizadeh, R., & Abrishami, M. (2018). Endothelial cell changes after photorefractive keratectomy with graded usage of mitomycin C. *Int Ophthalmol*, *38*(3), 1211-1217. https://dx.doi.org/10.1007/s10792-017-0584-5

Gimbel, H. V., Penno, E. E., van Westenbrugge, J. A., Ferensowicz, M., & Furlong, M. T. (1998). Incidence and management of intraoperative and early postoperative complications in 1000 consecutive laser in situ keratomileusis cases. *Ophthalmology*, *105*(10), 1839-1848. https://doi.org/10.1016/s0161-6420(98)91026-0

Giri, P., & Azar, D. T. (2017). Risk profiles of ectasia after keratorefractive surgery. *Curr Opin Ophthalmol*, *28*, 337-342.

Gjerdrum, B., Gundersen, K. G., Lundmark, P. O., Potvin, R., & Aakre, B. M. (2020). Prevalence of signs and symptoms of dry eye disease 5 to 15 after refractive surgery. *Clin Ophthalmol*, *14*, 269-279. https://dx.doi.org/10.2147/OPTH.S236749

Golas, L., & Manche, E. E. (2011). Dry eye after laser in situ keratomileusis with femtosecond laser and mechanical keratome. *J Cataract Refract Surg*, *37*(8), 1476-1480. https://dx.doi.org/10.1016/j.jcrs.2011.03.035

Guell, J. L., Morral, M., Kook, D., & Kohnen, T. (2010). Phakic intraocular lenses part 1: historical overview, current models, selection criteria, and surgical techniques. *J Cataract Refract Surg*, *36*(11), 1976-1993. https://dx.doi.org/10.1016/j.jcrs.2010.08.014

Güell, J. L., Rodriguez-Arenas, A. F., Gris, O., Malecaze, F., & Velasco, F. (2003). Phacoemulsification of the crystalline lens and implantation of an intraocular lens for the correction of moderate and high myopia: four-year follow-up. *J Cataract Refract Surg*, *29*(1), 34-38. https://doi.org/10.1016/s0886-3350(02)01944-2

Guo, H., Hosseini-Moghaddam, S. M., & Hodge, W. (2019). Corneal biomechanical properties after SMILE versus FLEX, LASIK, LASEK, or PRK: a systematic review and meta-analysis. *BMC Ophthalmol*, *19*(1), 167. https://ksrevidence.com/article/KSRA113034

Hashemi, H., Alvani, A., Aghamirsalim, M., Miraftab, M., & Asgari, S. (2022). Comparison of transepithelial and conventional photorefractive keratectomy in myopic and myopic astigmatism patients: a randomized contralateral trial. *BMC Ophthalmol*, *22*(1), 68. https://dx.doi.org/10.1186/s12886-022-02293-2

Hashemi, H., Pakbin, M., Pakravan, M., Fotouhi, A., Jafarzadehpur, E., Aghamirsalim, M., & Khabazkhoob, M. (2022). Effect of short versus long-term steroid on corneal haze after photorefractive keratectomy: a randomized, double-masked clinical trial. *Am J Ophthalmol*, *235*, 211-220. https://dx.doi.org/10.1016/j.ajo.2021.09.028

He, M., Wang, D., & Jiang, Y. (2012). Overview of ultrasound biomicroscopy. *J Curr Glaucoma Pract*, *6*(1), 25-53. https://doi.org/10.5005/jp-journals-10008-1105

Hou, C., Li, H., Li, J., Li, J., Peng, H., & Wang, Q. (2021). Artisan versus Artiflex phakic intraocular lens implantation in the treatment of moderate to high myopia: meta-analysis. *BMC Ophthalmol*, *21*(1), 171. https://ksrevidence.com/article/KSRA168110

Huang, D., Schallhorn, S. C., Sugar, A., Farjo, A. A., Majmudar, P. A., Trattler, W. B., & Tanzer, D. J. (2009). Phakic intraocular lens implantation for the correction of myopia: a report by the American Academy of Ophthalmology.

Ophthalmology, *116*(11), 2244-2258. https://doi.org/10.1016/j.ophtha.2009.08.018
Islam, Q. U., Saeed, M. K., & Mehboob, M. A. (2017). Age related changes in corneal morphological characteristics of healthy Pakistani eyes. *Saudi J Ophthalmol*, *31*(2), 86-90. https://doi.org/10.1016/j.sjopt.2017.02.009
Ivarsen, A., Asp, S., & Hjortdal, J. (2014). Safety and complications of more than 1500 small-incision lenticule extraction procedures. *Ophthalmology*, *121*(4), 822-828. https://dx.doi.org/10.1016/j.ophtha.2013.11.006
Jindra, L. F., & Zemon, V. (1989). Contrast sensitivity testing: a more complete assessment of vision. *J Cataract Refract Surg*, *15*(2), 141-148. https://doi.org/10.1016/s0886-3350(89)80002-1
Jonker, S. M. R., Berendschot, T., Ronden, A. E., Saelens, I. E. Y., Bauer, N. J. C., & Nuijts, R. (2018). Long-term endothelial cell loss in patients with artisan myopia and artisan toric phakic intraocular lenses: 5- and 10-year results. *Ophthalmology*, *125*(4), 486-494. https://dx.doi.org/10.1016/j.ophtha.2017.08.011
Jonker, S. M. R., Berendschot, T., Saelens, I. E. Y., Bauer, N. J. C., & Nuijts, R. (2020). Phakic intraocular lenses: an overview. *Indian J Ophthalmol*, *68*(12), 2779-2796. https://doi.org/10.4103/ijo.IJO_2995_20
Kahuam-López, N., Navas, A., Castillo-Salgado, C., Graue-Hernandez, E. O., Jimenez-Corona, A., & Ibarra, A. (2020). Laser-assisted in-situ keratomileusis (LASIK) with a mechanical microkeratome compared to LASIK with a femtosecond laser for LASIK in adults with myopia or myopic astigmatism. *Cochrane Database Syst Rev*, *CD012946*(4). https://doi.org/https://doi.org/10.1002/14651858.CD012946.pub2
Kaimbo Wa Kaimbo, D. (2016). Refractive surgery for myopia. In P. A. Pacheco (Ed.), *Advances in eye surgery* (pp. 213-245). InTech.
Kamiya, K., Takahashi, M., Shoji, N., & Naruse, S. (2020). Two cases of epithelial ingrowth after small incision lenticule extraction. *Am J Ophthalmol Case Rep*, *19*, 100819. https://dx.doi.org/10.1016/j.ajoc.2020.100819
Karaca, I., Yagci, A., Palamar, M., Tasbakan, M. S., & Basoglu, O. K. (2019). Ocular surface assessment and morphological alterations in meibomian glands with meibography in obstructive sleep apnea syndrome. *Ocul Surf*, *17*(4), 771-776. https://doi.org/10.1016/j.jtos.2019.06.003
Kaur, K., & Gurnani, B. (2023). Specular microscopy [Updated 2022 Dec 6]. In *StatPearls [Internet]*. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK585127/
Kaweri, L., Wavikar, C., James, E., Pandit, P., & Bhuta, N. (2020). Review of current status of refractive lens exchange and role of dysfunctional lens index as its new indication. *Indian J Ophthalmol*, *68*(12), 2797-2803. https://dx.doi.org/10.4103/ijo.IJO_2259_20
Khanjian, A. T., Khodzhabekyan, N. V., Tarutta, E. P., Harutyunyan, S. G., & Milash, S. V. (2023). [Changes in the wavefront and peripheral defocus profile after excimer laser and orthokeratology corneal reshaping in myopia]. *Vestn Oftalmol*, *139*(6), 87-92. https://dx.doi.org/10.17116/oftalma202313906187
Kim, T. I., Alio Del Barrio, J. L., Wilkins, M., Cochener, B., & Ang, M. (2019). Refractive surgery. *Lancet*, *393*(10185), 2085-2098. https://doi.org/10.1016/S0140-6736(18)33209-4

Kobashi, H., Kamiya, K., & Shimizu, K. (2017). Dry eye after small incision lenticule extraction and femtosecond laser-assisted LASIK: meta-analysis. *Cornea*, *36*(1), 85-91. https://ksrevidence.com/article/KSRA27154
Koch, D. D. (1995). Refining analysis of refractive surgical outcomes. *J Cataract Refract Surg*, *21*(2), 109-110.
Koch, D. D., Kohnen, T., Obstbaum, S. A., & Rosen, E. S. (1998). Format for reporting refractive surgical data. *J Cataract Refract Surg*, *24*(3), 285-287. https://dx.doi.org/10.1016/s0886-3350(98)80305-2
Kodali, S., Murthy, S., Banad, N., Dongre, P., & Senthil, S. (2024). Glaucoma and refractive surgery: a comprehensive review. *Indian J Ophthalmol*, *72*(9), 1244-1253. https://doi.org/10.4103/IJO.IJO_3236_23
Kohnen, T., Fabian, E., Knorz, M. C., Auffarth, G., Kohlhaas, M., Kook, D., Mayer, W., Schayan-Araghi, K., Berufsverband der Augenärzte Deutschlands e. , V., & Deutsche Ophthalmologische, G. (2023). Bewertung und Qualitätssicherung refraktiv-chirurgischer Eingriffe durch die DOG und den BVA – KRC-Empfehlungen. *Die Ophthalmologie*, *120*(6), 633-644. https://dx.doi.org/10.1007/s00347-022-01758-5
Kohnen, T., Kook, D., Morral, M., & Guell, J. L. (2010). Phakic intraocular lenses part 2: results and complications. *J Cataract Refract Surg*, *36*(12), 2168-2194. https://dx.doi.org/10.1016/j.jcrs.2010.10.007
Kohnen, T., Lemp-Hull, J., & Suryakumar, R. (2022). Defocus curves: focusing on factors influencing assessment. *J Cataract Refract Surg*, *48*(8), 961-968. https://doi.org/10.1097/j.jcrs.0000000000000906
Kohnen, T., Maxwell, A., Holland, S., Lane, S., Von Tress, M., Salem, C., & LaFontaine, L. (2020). Ten-year safety follow-up and post-explant analysis of an anterior chamber phakic IOL. *J Cataract Refract Surg*, *46*(11), 1457-1465. https://doi.org/10.1097/j.jcrs.0000000000000351
Kohnen, T., Steinwender, G., & Biller, M. L. (2024). Phake Intraokularlinsen: Indikation, Technik und Nachsorge. In N. Pfeiffer, C. Cursiefen, F. G. Holz, & W. A. Lagrèze (Eds.), *Die Augenheilkunde*. Springer. https://doi.org/https://doi.org/10.1007/978-3-662-65929-8_158-1
Kook, D., Kampik, A., & Kohnen, T. (2008). [Complications after refractive lens exchange]. *Ophthalmologe*, *105*(11), 1005-1012. https://dx.doi.org/10.1007/s00347-008-1829-5
Krueger, R. R., & Meister, C. S. (2018). A review of small incision lenticule extraction complications. *Curr Opin Ophthalmol*, *29*(4), 292-298. https://dx.doi.org/10.1097/ICU.0000000000000494
Langenbucher, A. (2015). Emmetropia, definition. In U. Schmidt-Erfurth & T. Kohnen (Eds.), *Encyclopedia of ophthalmology*. Heidelberg: Springer.
Lee, J., Kim, Y., Park, S., Bae, J., Lee, S., Park, Y., Lee, J., & Lee, J. E. (2016). Long-term clinical results of posterior chamber phakic intraocular lens implantation to correct myopia. *Clin Exp Ophthalmol*, *44*(6), 481-487. https://dx.doi.org/10.1111/ceo.12691
Lemley, C. A., & Han, D. P. (2007). Endophthalmitis: a review of current evaluation and management. *Retina*, *27*(6), 662-680. https://dx.doi.org/10.1097/IAE.0b013e3180323f96
Li, M., Zhao, J., Shen, Y., Li, T., He, L., Xu, H., Yu, Y., & Zhou, X. (2013). Comparison of dry eye and corneal sensitivity between small incision lenticule extraction and femtosecond LASIK for myopia. *PLoS One*, *8*(10), e77797. https://dx.doi.org/10.1371/journal.pone.0077797

Li, S. M., Zhan, S., Li, S. Y., Peng, X. X., Hu, J., Law, H. A., & Wang, N. L. (2016). Laser-assisted subepithelial keratectomy (LASEK) versus photorefractive keratectomy (PRK) for correction of myopia. *Cochrane Database Syst Rev*, *CD009799*(2). https://doi.org/https://doi.org/10.1002/14651858.CD009799.pub2

Liu, J., Lu, Y., Liu, J., & Wei, C. (2024). Meta-analysis of efficacy, safety, stability and predictability of Small Incision Lenticule Extraction (SMILE) for myopia. *Lasers Med Sci*, *39*(1), 57. https://dx.doi.org/10.1007/s10103-024-04007-0

Lloyd-McKernan, A., Simo Mannion, L., & O'Dwyer, V. (2017). The effect of previous soft contact lens wear on corneal refractive surgery outcomes. *Cont Lens Anterior Eye*, *40*(5), 301-310. https://doi.org/10.1016/j.clae.2017.05.009

Lu, N. J., Koppen, C., Awwad, S., Aslanides, M. I., Aslanides, I. M., & Chen, S. H. (2021). Effect of intraoperative mitomycin-C application on epithelial regeneration after transepithelial photorefractive keratectomy. *J Cataract Refract Surg*, *47*(2), 227-232. https://dx.doi.org/10.1097/j.jcrs.0000000000000427

Lundström, M., Dickman, M., Henry, Y., Manning, S., Rosen, P., Tassignon, M. J., Young, D., & Stenevi, U. (2020). Risk factors for dropped nucleus in cataract surgery as reflected by the European Registry of Quality Outcomes for Cataract and Refractive Surgery. *J Cataract Refract Surg*, *46*(2), 287-292. https://dx.doi.org/10.1097/j.jcrs.0000000000000019

Lwowski, C., Van Keer, K., Ruscher, T., Van Keer, L., Shajari, M., & Kohnen, T. (2023). Five-year follow-up of a posterior chamber phakic intraocular lens with a central hole for correction of myopia. *Int Ophthalmol*, *43*(12), 4933-4943. https://doi.org/10.1007/s10792-023-02896-8

Ma, K. K., & Manche, E. E. (2022). Corneal sensitivity and patient-reported dry eye symptoms in a prospective randomized contralateral-eye trial comparing laser in situ keratomileusis and small incision lenticule extraction. *Am J Ophthalmol*, *241*, 248-253. https://dx.doi.org/10.1016/j.ajo.2022.05.010

Malecaze, F. J., Hulin, H., Bierer, P., Fournié, P., Grandjean, H., Thalamas, C., & Guell, J. L. (2002). A randomized paired eye comparison of two techniques for treating moderately high myopia: LASIK and artisan phakic lens. *Ophthalmology*, *109*(9), 1622-1630. https://doi.org/10.1016/s0161-6420(02)01164-8

Marcos, S. (2006). Aberrometry: basic science and clinical applications. *Bull Soc Belge Ophtalmol*(302), 197-213.

Mastropasqua, L., Nubile, M., Ciancaglini, M., Toto, L., & Ballone, E. (2004). Prospective randomized comparison of wavefront-guided and conventional photorefractive keratectomy for myopia with the meditec MEL 70 laser. *J Refract Surg*, *20*(5), 422-431. https://dx.doi.org/10.3928/1081-597X-20040901-03

Mathôt, S. (2018). Pupillometry: psychology, physiology, and function. *J Cogn*, *1*(1), 16. https://doi.org/10.5334/joc.18

McDonald, M. B., Carr, J. D., Frantz, J. M., Kozarsky, A. M., Maguen, E., Nesburn, A. B., Rabinowitz, Y. S., Salz, J. J., Stulting, R. D., Thompson, K. P., & Waring, G. O., 3rd. (2001). Laser in situ keratomileusis for myopia up to -11 diopters with up to -5 diopters of astigmatism with the summit autonomous LADARVision excimer laser system. *Ophthalmology*, *108*(2), 309-316. https://doi.org/10.1016/s0161-6420(00)00528-5

Mehlan, J., Linke, S., Skevas, C., Steinberg, J., Giannakakis, K., & Katz, T. (2019). Safety and complications after three different surface ablation techniques with mitomycin C: a retrospective analysis of 2757 eyes. *Graefes Arch Clin Exp Ophthalmol*, *257*.

Moshirfar, M., Albarracin, J. C., Desautels, J. D., Birdsong, O. C., Linn, S. H., & Hoopes, P. C., Sr. (2017). Ectasia following small-incision lenticule extraction (SMILE): a review of the literature. *Clin Ophthalmol*, *11*, 1683-1688. https://dx.doi.org/10.2147/OPTH.S147011

Moshirfar, M., McCaughey, M. V., Reinstein, D. Z., Shah, R., Santiago-Caban, L., & Fenzl, C. R. (2015). Small-incision lenticule extraction. *J Cataract Refract Surg*, *41*(3), 652-665. https://doi.org/10.1016/j.jcrs.2015.02.006

Moshirfar, M., Santos, J. M., Wang, Q., Stoakes, I. M., Porter, K. B., Theis, J. S., & Hoopes, P. C. (2023). A literature review of the incidence, management, and prognosis of corneal epithelial-related complications after laser-assisted in situ keratomileusis (LASIK), photorefractive keratectomy (PRK), and small incision lenticule extraction (SMILE). *Cureus*, *15*(8), e43926. https://dx.doi.org/10.7759/cureus.43926

Moshirfar, M., Tukan, A. N., Bundogji, N., Liu, H. Y., McCabe, S. E., Ronquillo, Y. C., & Hoopes, P. C. (2021). Ectasia after corneal refractive surgery: a systematic review. *Ophthalmol Ther*, *10*(4), 753-776. https://ksrevidence.com/article/KSRA183203

Moshirfar, M., Tuttle, J. J., Stoakes, I. M., Bundogji, N., & Hoopes, P. C. (2023). SMILE, CLEAR, SILK: it's time for a common term. *J Refract Surg*, *39*(8), 575. https://dx.doi.org/10.3928/1081597X-20230711-01

Moshirfar, M., Webster, C. R., & Ronquillo, Y. C. (2022). Phakic intraocular lenses: an update and review for the treatment of myopia and myopic astigmatism in the United States. *Curr Opin Ophthalmol*, *33*(5), 453-463. https://dx.doi.org/10.1097/ICU.0000000000000870

Naderi, M., Sabour, S., Khodakarim, S., & Daneshgar, F. (2018). Studying the factors related to refractive error regression after PRK surgery. *BMC Ophthalmol*, *18*(1), 198.

Nanavaty, M. A., & Daya, S. M. (2012). Refractive lens exchange versus phakic intraocular lenses. *Curr Opin Ophthalmol*, *23*(1), 54-61. https://dx.doi.org/10.1097/ICU.0b013e32834cd5d1

Nederlands Gezelschap Voor Refractie Chirurgie (NGRC). (2018). *[Consensus: refractive surgery]*. https://www.oogheelkunde.org/wp-content/uploads/2022/02/ConsensusRC2018.pdf

Neumann, I., Pantoja, T., Penaloza, B., Cifuentes, L., & Rada, G. (2014). [The GRADE system: a change in the way of assessing the quality of evidence and the strength of recommendations]. *Rev Med Chil*, *142*(5), 630-635. https://dx.doi.org/10.4067/S0034-98872014000500012

Nunez, M. X., Henriquez, M. A., Escaf, L. J., Ventura, B. V., Srur, M., Newball, L., Espaillat, A., & Centurion, V. A. (2019). Consensus on the management of astigmatism in cataract surgery. *Clin Ophthalmol*, *13*, 311-324. https://dx.doi.org/10.2147/OPTH.S178277

O'Brart, D. P., Shalchi, Z., McDonald, R. J., Patel, P., Archer, T. J., & Marshall, J. (2014). Twenty-year follow-up of a randomized prospective clinical trial of excimer laser photorefractive keratectomy. *Am J Ophthalmol*, *158*(4), 651-663.e651. https://dx.doi.org/10.1016/j.ajo.2014.06.013

Ophthalmic Mutual Insurance Company (OMIC). ([accessed 25.3.23]). *Risk managment issues in radial keratotomy surgery. By C. Gregory Tiemeier, Esq., Richard L. Abbott, MD, and Jean Hausheer Ellis, MD, FACS. Digest, Summer 1993 [Internet]*. https://www.omic.com/risk-management-issues-in-radial-keratotomy-surgery/

Ortega-Usobiaga, J., Rocha-de-Lossada, C., Llovet-Rausell, A., & Llovet-Osuna, F. (2023). Update on contraindications in laser corneal refractive surgery. *Arch Soc Esp Oftalmol (Engl Ed)*, *98*(2), 105-111. https://doi.org/10.1016/j.oftale.2022.07.003

Osman, I. M., Helaly, H. A., Abou Shousha, M., AbouSamra, A., & Ahmed, I. (2019). Corneal safety and stability in cases of small incision lenticule extraction with collagen cross-linking (SMILE Xtra). *J Ophthalmol*, *2019*, 6808062. https://doi.org/10.1155/2019/6808062

Ouerdane, Y., Zaazouee, M. S., Mohamed, M. E. A., Hasan, M. T., Hamdy, M., Ghoneim, A. M., Gbreel, M. I., Ibrahim, A. M., Ragab, K. M., & Nourelden, A. Z. (2021). Mitomycin C application after photorefractive keratectomy in high, moderate, or low myopia: systematic review and meta-analysis. *Indian J Ophthalmol*, *69*(12), 3421-3431. https://ksrevidence.com/article/KSRA192584

Packer, K. T., Vlasov, A., Greenburg, D. L., Coggin, A., Weightman, J. W., Beltran, T., Berry-Cabán, C. S., & Carroll, R. B. (2022). U.S. military implantable collamer lens surgical outcomes: 11-year retrospective review. *J Cataract Refract Surg*, *48*(6), 649-656. https://doi.org/10.1097/j.jcrs.0000000000000818

Packer, M., Alfonso, J. F., Aramberri, J., Elies, D., Fernandez, J., & Mertens, E. (2020). Performance and safety of the Extended Depth of Focus Implantable Collamer(®) Lens (EDOF ICL) in phakic subjects with presbyopia. *Clin Ophthalmol*, *14*, 2717-2730. https://doi.org/10.2147/OPTH.S271858

Passaro, M. L., Buzzi, M., Qureshi, R., Zou, Y., Chan, V. F., Mencucci, R., Lucenteforte, E., Romano, V., & Virgili, G. (2026). Potential harms of posterior chamber phakic IOL: a systematic review and meta-analysis of complication incidence. *Am J Ophthalmol*, *285*, 73-82. https://dx.doi.org/10.1016/j.ajo.2026.01.028

Patasova, K., Khawaja, A. P., Tamraz, B., Williams, K. M., Mahroo, O. A., Freidin, M., Solebo, A. L., Vehof, J., Falchi, M., Rahi, J. S., Hammond, C. J., & Hysi, P. G. (2021). Association between medication-taking and refractive error in a large general population-based cohort. *Invest Ophthalmol Vis Sci*, *62*(2), 15. https://doi.org/10.1167/iovs.62.2.15

Perez-Straziota, C., & Randleman, J. B. (2016). Femtosecond-assisted LASIK: complications and management. *Int Ophthalmol Clin*, *56*(2), 59-66. https://doi.org/10.1097/IIO.0000000000000105

Pesando, P. M., Ghiringhello, M. P., Di Meglio, G., & Fanton, G. (2007). Posterior chamber phakic intraocular lens (ICL) for hyperopia: ten-year follow-up. *J Cataract Refract Surg*, *33*(9), 1579-1584. https://doi.org/10.1016/j.jcrs.2007.05.030

Pop, M., & Payette, Y. (2004). Refractive lens exchange versus iris-claw Artisan phakic intraocular lens for hyperopia. *J Refract Surg*, *20*(1), 20-24. https://doi.org/10.3928/1081-597X-20040101-04

Pradhan, K. R., & Arba Mosquera, S. (2025). Postoperative visual outcomes with lenticule extraction in high myopia: a pilot study. *J Optom*, *18*(2), 100553. https://doi.org/10.1016/j.optom.2025.100553

Preetha, R., Goel, P., Patel, N., Agarwal, S., Agarwal, A., Agarwal, J., Agarwal, T., & Agarwal, A. (2003). Clear lens extraction with intraocular lens implantation for hyperopia. *J Cataract Refract Surg*, *29*(5), 895-899. https://doi.org/10.1016/s0886-3350(02)01979-x

Rateb, M., Gad, A. A. M., Tohamy, D., & Elmohamady, M. N. (2022). A prospective comparative study between implantable phakic intraocular contact lens and implantable collamer lens in treatment of myopia in adults. *J Ophthalmol*, *2022*, 9212253. https://dx.doi.org/10.1155/2022/9212253

Razmjoo, H., Abdi, E., Atashkadi, S., Reza, A. M., Reza, P. A., & Akbari, M. (2012). Comparative study of two silicone hydrogel contact lenses used as bandage contact lenses after photorefractive keratectomy. *Int J Prev Med*, *3*(10), 718-722. https://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=pmnm2&AN=23112899

Reinstein, D. Z., Archer, T. J., Srinivasan, S., Mamalis, N., Kohnen, T., Dupps, W. J., Jr., & Randleman, J. B. (2017). Standard for reporting refractive outcomes of intraocular lens-based refractive surgery. *J Cataract Refract Surg*, *43*(4), 435-439. https://dx.doi.org/10.1016/j.jcrs.2017.04.005

Reinstein, D. Z., Archer, T. J., & Vida, R. S. (2022). Epithelial thickness mapping for corneal refractive surgery. *Curr Opin Ophthalmol*, *33*(4), 258-268. https://doi.org/10.1097/ICU.0000000000000867

Reinstein, D. Z., Carp, G. I., Archer, T. J., Buick, T., Gobbe, M., Rowe, E. L., Jukic, M., Brandon, E., Moore, J., & Moore, T. (2017). LASIK for the correction of high hyperopic astigmatism with epithelial thickness monitoring. *J Refract Surg*, *33*(5), 314-321. https://doi.org/10.3928/1081597X-20170111-04

Reinstein, D. Z., Carp, G. I., Archer, T. J., Lewis, T. A., Gobbe, M., Moore, J., & Moore, T. (2016). Long-term visual and refractive outcomes after LASIK for high myopia and astigmatism from -8.00 to -14.25 D. *J Refract Surg*, *32*(5), 290-297. https://doi.org/10.3928/1081597X-20160310-01

Reinstein, D. Z., Pradhan, K. R., Carp, G. I., Archer, T. J., Day, A. C., Sekundo, W., & Dhungana, P. (2019). Small incision lenticule extraction for hyperopia: 3-month refractive and visual outcomes. *J Refract Surg*, *35*(1), 24-30. https://doi.org/10.3928/1081597X-20181025-01

Reinstein, D. Z., Sekundo, W., Archer, T. J., Stodulka, P., Ganesh, S., Cochener, B., Blum, M., Wang, Y., & Zhou, X. (2022). SMILE for hyperopia with and without astigmatism: results of a prospective multicenter 12-month study. *J Refract Surg*, *38*(12), 760-769. https://doi.org/10.3928/1081597X-20221102-02

Rodríguez-Calvo-de-Mora, M., Rocha-de-Lossada, C., Rodríguez-Vallejo, M., Zamora-de-la-Cruz, D., & Fernández, J. (2023). Retinal detachment after refractive lens exchange: a narrative review. *Arch Soc Esp Oftalmol (Engl Ed)*, *98*(9), 507-520. https://doi.org/10.1016/j.oftale.2023.06.013

Rosen, E. S. (2008). Risk management in refractive lens exchange. *J Cataract Refract Surg*, *34*(10), 1613-1614. https://doi.org/10.1016/j.jcrs.2008.08.001

Royo, M., Jiménez, Á., & Piñero, D. P. (2023). Long-term safety and efficacy of a foldable iris-fixated phakic intraocular lens for the correction of myopia. *Int Ophthalmol*, *43*(12), 4491-4502. https://doi.org/10.1007/s10792-023-02850-8

Ruiz-Mesa, R., Carrasco-Sanchez, D., Diaz-Alvarez, S. B., Ruiz-Mateos, M. A., Ferrer-Blasco, T., & Montes-Mico, R. (2009). Refractive lens exchange with foldable toric intraocular lens. *Am J Ophthalmol*, *147*(6), 990-996. https://dx.doi.org/10.1016/j.ajo.2009.01.004

Saad, A., Steinberg, J., & Frings, A. (2025). Stability of refractive outcomes after hyperopic LASIK with and without Mitomycin C application: a randomized controlled trial. *Sci Rep*, *15*(1), 961. https://doi.org/10.1038/s41598-024-83757-x

Sabau, A., Daas, L., Behkit, A., Wagenpfeil, S., Langenbucher, A., Ardjomand, N., Flockerzi, E., & Seitz, B. (2021). Efficacy, safety and predictability of transepithelial photorefractive keratectomy - a meta-analysis. *J Cataract Refract Surg*, *47*(5), 634-640. https://ksrevidence.com/article/KSRA155866

Sabetti, L., Ciancaglini, M., Guetti, F., Laglia, L., & Murano, G. (2020). Study of the orthoptic assessment in refractive eye surgery. *Open Journal of Ophthalmology*, *10*, 55-58.

Sachdev, G., & Ramamurthy, D. (2019). Long-term safety of posterior chamber implantable phakic contact lens for the correction of myopia. *Clin Ophthalmol*, *13*, 137-142. https://doi.org/10.2147/OPTH.S185304

Sachdev, G. S., Singh, S., Ramamurthy, S., Rajpal, N., & Dandapani, R. (2019). Comparative analysis of clinical outcomes between two types of posterior chamber phakic intraocular lenses for correction of myopia and myopic astigmatism. *Indian J Ophthalmol*, *67*(7), 1061-1065. https://doi.org/10.4103/ijo.IJO_1501_18

Sahay, P., Bafna, R. K., Reddy, J. C., Vajpayee, R. B., & Sharma, N. (2021). Complications of laser-assisted in situ keratomileusis. *Indian J Ophthalmol*, *69*(7), 1658-1669. https://dx.doi.org/10.4103/ijo.IJO_1872_20

Sambhi, R. D. S., Sambhi, G. D. S., Mather, R., & Malvankar-Mehta, M. S. (2020). Dry eye after refractive surgery: a meta-analysis. *Can J Ophthalmol*, *55*(2), 99-106. https://ksrevidence.com/article/KSRA114214

Santhiago, M. R., Smadja, D., Gomes, B. F., Mello, G. R., Monteiro, M. L., Wilson, S. E., & Randleman, J. B. (2014). Association between the percent tissue altered and post-laser in situ keratomileusis ectasia in eyes with normal preoperative topography. *Am J Ophthalmol*, *158*(1), 87-95 e81. https://dx.doi.org/10.1016/j.ajo.2014.04.002

Savovic, J., Weeks, L., Sterne, J. A., Turner, L., Altman, D. G., Moher, D., & Higgins, J. P. (2014). Evaluation of the Cochrane Collaboration's tool for assessing the risk of bias in randomized trials: focus groups, online survey, proposed recommendations and their implementation. *Syst Rev*, *3*, 37. https://doi.org/10.1186/2046-4053-3-37

Schallhorn, J. M., Schallhorn, S. C., Teenan, D., Hannan, S. J., Pelouskova, M., & Venter, J. A. (2019). Incidence of intraoperative and early postoperative adverse events in a large cohort of consecutive refractive lens exchange procedures. *Am J Ophthalmol*, *208*, 406-414. https://dx.doi.org/10.1016/j.ajo.2019.08.025

Schallhorn, S. C., Hannan, S. J., Teenan, D., Pelouskova, M., & Schallhorn, J. M. (2018). Informed consent in refractive surgery: in-person vs telemedicine approach. *Clin Ophthalmol*, *12*, 2459-2470. https://doi.org/10.2147/OPTH.S183249

Scholl, S., Kirchhof, J., & Augustin, A. J. (2010). Pathophysiology of macular edema. *Ophthalmologica*, *224 Suppl 1*, 8-15. https://dx.doi.org/10.1159/000315155

Serfözö, A., Martin, C., Munteanu, C., Seitz, B., & Daas, L. (2025). Efficacy, safety, and predictability of transepithelial vs mechanical or alcohol-assisted photorefractive keratectomy: meta-analysis. *J Cataract Refract Surg*, *51*(12), 1131-1138. https://dx.doi.org/10.1097/j.jcrs.0000000000001749

Settas, G., Settas, C., Minos, E., & Yeung, I. Y. L. (2012). Photorefractive keratectomy (PRK) versus laser assisted in situ keratomileusis (LASIK) for hyperopia correction. *Cochrane Database Syst Rev*, *CD007112*(6). https://doi.org/https://doi.org/10.1002/14651858.CD007112.pub3

Shajari, M., Scheffel, M., Koss, M. J., & Kohnen, T. (2016). Dependency of endothelial cell loss on anterior chamber depth within first 4 years after implantation of iris-supported phakic intraocular lenses to treat high myopia. *J Cataract Refract Surg*, *42*(11), 1562-1569. https://doi.org/10.1016/j.jcrs.2016.08.027

Shen, Z., Shi, K., Yu, Y., Yu, X., Lin, Y., & Yao, K. (2016). Small incision lenticule extraction (SMILE) versus femtosecond laser-assisted in situ keratomileusis (FS-LASIK) for myopia: a systematic review and meta-analysis. *PLoS One*, *11*(7), e0158176. https://ksrevidence.com/article/KSRA41137

Shen, Z., Zhu, Y., Song, X., Yan, J., & Yao, K. (2016). Dry eye after small incision lenticule extraction (SMILE) versus femtosecond laser-assisted in situ keratomileusis (FS-LASIK) for myopia: a meta-analysis. *PLoS One*, *11*(12), e0168081. https://ksrevidence.com/article/KSRA29061

Shojaei, A., Ramezanzadeh, M., Soleyman-Jahi, S., Almasi-Nasrabadi, M., Rezazadeh, P., & Eslani, M. (2013). Short-time mitomycin-C application during photorefractive keratectomy in patients with low myopia. *J Cataract Refract Surg*, *39*(2), 197-203. https://dx.doi.org/10.1016/j.jcrs.2012.09.016

Siganos, D. S., & Pallikaris, I. G. (1998). Clear lensectomy and intraocular lens implantation for hyperopia from +7 to +14 diopters. *J Refract Surg*, *14*(2), 105-113. https://doi.org/10.3928/1081-597X-19980301-08

Soltani Shahgoli, S., Cheraqpour, K., Soleimani, M., Atighehchian, M., Tabatabaei, S. A., Sargolzaeimoghaddam, M., Sargolzaeimoghaddam, M., & Djalilian, A. R. (2023). Post-laser refractive surgery keratitis: a concise narrative review. *J Int Med Res*, *51*(10), 3000605231206054. https://dx.doi.org/10.1177/03000605231206054

Song, J., Cao, H., Chen, X., Zhao, X., Zhang, J., Wu, G., & et al. (2023). Small incision lenticule extraction (SMILE) versus laser assisted stromal in situ keratomileusis (LASIK) for astigmatism corrections: a meta-analysis. *Am J Ophthalmol*, *247*, 181-199. https://ksrevidence.com/article/KSRA232229

STAAR Surgical Company. ([accessed 1.4.22]). *EVO/EVO+ VISIAN Implantable Collamer® Lens (EVO ICL™) for myopia; EVO/EVO+ VISIAN TORIC Implantable Collamer® Lens (EVO TICL™) for myopia [Internet]*. https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030016S035C.pdf

Stark, W. J., Jr., Maumenee, A. E., Datiles, M., Fagadau, W., Baker, C. C., Worthen, D., Auer, C., Klein, P., McGhee, E., Jacobs, M. E., & et al. (1983). Intraocular lenses: complications and visual results. *Trans Am Ophthalmol Soc*, *81*, 280-309.

Stokkermans, T. J., & Day, S. H. (2025). Aniseikonia. In *StatPearls [Internet]* (2023/08/08 ed.). StatPearls Publishing.

Sugar, A., Rapuano, C. J., Culbertson, W. W., Huang, D., Varley, G. A., Agapitos, P. J., de Luise, V. P., & Koch, D. D. (2002). Laser in situ keratomileusis for myopia and astigmatism: safety and efficacy: a report by the American Academy of Ophthalmology. *Ophthalmology*, *109*(1), 175-187. https://doi.org/10.1016/s0161-6420(01)00966-6

Taneri, S., Arba-Mosquera, S., Rost, A., Hansson, C., & Dick, H. B. (2021). Results of thin-cap small-incision lenticule extraction. *J Cataract Refract Surg*, *47*(4), 439-444. https://dx.doi.org/10.1097/j.jcrs.0000000000000470

Tang, Y., & Ye, J. (2019). Phakic posterior chamber intraocular lens with a central hole in treating patients with moderate to high myopia: a meta-analysis. *J Ophthalmol*, *2019*, 9496326. https://ksrevidence.com/article/KSRA120900

Tian, H., Gao, W., Xu, C., & Wang, Y. (2023). Clinical outcomes and higher order aberrations of wavefront-guided LASIK versus SMILE for correction of myopia: a systemic review and meta-analysis. *Acta Ophthalmol (Copenh)*, *101*(6), 606-618. https://ksrevidence.com/article/KSRA239385

Ting, D. S. J., Srinivasan, S., & Danjoux, J. P. (2018). Epithelial ingrowth following laser in situ keratomileusis (LASIK): prevalence, risk factors, management and visual outcomes. *BMJ Open Ophthalmol*, *3*(1), e000133. https://dx.doi.org/10.1136/bmjophth-2017-000133

Tomás-Juan, J., Murueta-Goyena Larrañaga, A., & Hanneken, L. (2015). Corneal regeneration after photorefractive keratectomy: a review. *J Optom*, *8*(3), 149-169.

Torres, R. M., Merayo-Lloves, J., Daya, S. M., Blanco-Mezquita, J. T., Espinosa, M., Nozal, M. J., Bernal, J. L., & Bernal, J. (2006). Presence of mitomycin-C in the anterior chamber after photorefractive keratectomy. *J Cataract Refract Surg*, *32*(1), 67-71. https://doi.org/10.1016/j.jcrs.2005.06.051

Tse, S. M., Farley, N. D., Tomasko, K. R., & Amin, S. R. (2016). Intraoperative LASIK complications. *Int Ophthalmol Clin*, *56*(2), 47-57. https://dx.doi.org/10.1097/IIO.0000000000000110

Upaphong, P., Tananuvat, N., Ausayakhun, S., Chaidaroon, W., Tangmonkongvoragul, C., & Niparugs, M. (2022). Comorbidities in corneal refractive surgery candidates: a cross-sectional study. *Open Ophthalmol J*, *16*, e187436412204051.

van Rijn, G. A., Gaurisankar, Z. S., Ilgenfritz, A. P., Lima, J. E. E., Haasnoot, G. W., Beenakker, J. W. M., Cheng, Y. Y. Y., & Luyten, G. P. M. (2020). Middle- and long-term results after iris-fixated phakic intraocular lens implantation in myopic and hyperopic patients: a meta-analysis. *J Cataract Refract Surg*, *46*(1), 125-137. https://ksrevidence.com/article/KSRA127103

Vargas-Fragoso, V., & Alió, J. L. (2017). Corneal compensation of presbyopia: PresbyLASIK: an updated review. *Eye Vis (Lond)*, *4*, 11. https://dx.doi.org/10.1186/s40662-017-0075-9

Varley, G. A., Huang, D., Rapuano, C. J., Schallhorn, S., Boxer Wachler, B. S., & Sugar, A. (2004). LASIK for hyperopia, hyperopic astigmatism, and mixed astigmatism: a report by the American Academy of Ophthalmology. *Ophthalmology*, *111*(8), 1604-1617. https://doi.org/10.1016/j.ophtha.2004.05.016

Vasavada, V., Srivastava, S., Vasavada, S. A., Sudhalkar, A., Vasavada, A. R., & Vasavada, V. A. (2018). Safety and efficacy of a new phakic posterior chamber IOL for correction of myopia: 3 years of follow-up. *J Refract Surg*, *34*(12), 817-823. https://doi.org/10.3928/1081597X-20181105-01

Vestergaard, A., Ivarsen, A., Asp, S., & Hjortdal, J. (2013). Femtosecond (FS) laser vision correction procedure for moderate to high myopia: a prospective study of ReLEx(®) flex and comparison with a retrospective study of FS-laser in situ keratomileusis. *Acta Ophthalmol*, *91*(4), 355-362. https://dx.doi.org/10.1111/j.1755-3768.2012.02406.x

Vestergaard, A. H., Grauslund, J., Ivarsen, A. R., & Hjortdal, J. O. (2014). Efficacy, safety, predictability, contrast sensitivity, and aberrations after femtosecond laser lenticule extraction. *J Cataract Refract Surg*, *40*(3), 403-411. https://dx.doi.org/10.1016/j.jcrs.2013.07.053

Vestergaard, A. H., Hjortdal, J. O., Ivarsen, A., Work, K., Grauslund, J., & Sjolie, A. K. (2013). Long-term outcomes of photorefractive keratectomy for low to high myopia: 13 to 19 years of follow-up. *J Refract Surg*, *29*(5), 312-319. https://dx.doi.org/10.3928/1081597X-20130415-02

Wang, J. S., Xie, H. T., Jia, Y., & Zhang, M. C. (2017). Small-incision lenticule extraction versus femtosecond lenticule extraction for myopic: a systematic review and meta-analysis. *Int J Ophthalmol*, *10*(1), 115-121. https://ksrevidence.com/article/KSRA70863

Wang, M. T. M., & Craig, J. P. (2019). Natural history of dry eye disease: perspectives from inter-ethnic comparison studies. *Ocul Surf*, *17*(3), 424-433. https://ksrevidence.com/article/KSRA113889

Wang, Y., Ma, J., Zhang, J., Dou, R., Zhang, H., Li, L., Zhao, W., & Wei, P. (2017). Incidence and management of intraoperative complications during small-incision lenticule extraction in 3004 cases. *J Cataract Refract Surg*, *43*(6), 796-802. https://dx.doi.org/10.1016/j.jcrs.2017.03.039

Wen, D., McAlinden, C., Flitcroft, I., Tu, R., Wang, Q., Alio, J., Marshall, J., Huang, Y., Song, B., Hu, L., Zhao, Y., Zhu, S., Gao, R., Bao, F., Yu, A., Yu, Y., Lian, H., & Huang, J. (2017). Postoperative efficacy, predictability, safety, and visual quality of laser corneal refractive surgery: a network meta-analysis. *Am J Ophthalmol*, *178*, 65-78. https://ksrevidence.com/article/KSRA30210

Wen, D., Tu, R., Flitcroft, I., Wang, Q., Huang, Y., Song, B., Yu, A., Hu, L., Zhao, Y., Bao, F., Yu, Y., Lian, H., Hoffart, L., Kramm, R. L., Skiadaresi, E., O'Brart, D., Pallikaris, I., Marshall, J., McAlinden, C., & Huang, J. (2018). Corneal surface ablation laser refractive surgery for the correction of myopia: a network meta-analysis. *J Refract Surg*, *34*(11), 726-735. https://ksrevidence.com/article/KSRA87185

Whiting, P., Savovic, J., Higgins, J. P., Caldwell, D. M., Reeves, B. C., Shea, B., Davies, P., Kleijnen, J., Churchill, R., & Robis Group. (2016). ROBIS: a new tool to assess risk of bias in systematic reviews was developed. *J Clin Epidemiol*, *69*, 225-234. https://dx.doi.org/10.1016/j.jclinepi.2015.06.005

Wu, Q., Li, Y., Tang, L., Wu, L. A., & Wang, C. Y. (2020). Comparison of rigid versus foldable iris-fixed phakic intraocular lens implantation for high myopia: a systematic review and meta-analysis. *Medicine*, *99*(6), e19030. https://ksrevidence.com/article/KSRA126357

Xia, F., Shen, Y., Han, T., Zhao, J., Xu, H., & Zhou, X. (2020). Small incision lenticule extraction (SMILE) for moderate and high myopia: seven-year outcomes of refraction, corneal tomography, and wavefront aberrations. *J Ophthalmol*, *2020*, 3825864. https://doi.org/10.1155/2020/3825864

Xia, L. K., Yu, J., Chai, G. R., Wang, D., & Li, Y. (2015). Comparison of the femtosecond laser and mechanical microkeratome for flap cutting in LASIK. *Int J Ophthalmol*, *8*(4), 784-790. https://dx.doi.org/10.3980/j.issn.2222-3959.2015.04.25

Yan, H., Gong, L. Y., Huang, W., & Peng, Y. L. (2017). Clinical outcomes of small incision lenticule extraction versus femtosecond laser-assisted LASIK for myopia: a meta-analysis. *Int J Ophthalmol*, *10*(9), 1436-1445. https://ksrevidence.com/article/KSRA73126

Yao, L., Zhang, M., Wang, D., Zhao, Q., Wang, S., & Bai, H. (2023). Small incision lenticule extraction (SMILE) and laser in situ keratomileusis (LASIK) used to treat myopia and myopic astigmatism: a systematic review and meta-analysis of randomized clinical trials. *Semin Ophthalmol*, *38*(3), 283-293. https://ksrevidence.com/article/KSRA220614

Zare, M., Javadi, M. A., Einollahi, B., Baradaran-Rafii, A. R., Feizi, S., & Kiavash, V. (2009). Risk factors for posterior capsule rupture and vitreous loss during phacoemulsification. *J Ophthalmic Vis Res*, *4*(4), 208-212.

Zhang, Y., Shen, Q., Jia, Y., Zhou, D., & Zhou, J. (2016). Clinical outcomes of SMILE and FS-LASIK used to treat myopia: a meta-analysis. *J Refract Surg*, *32*(4), 256-265. https://ksrevidence.com/article/KSRA23699

Zhao, P. F., Zhou, Y. H., Hu, Y. B., Cao, K., Qi, Y., Guo, N., Gao, X., Zhang, Q. W., & Zhai, C. B. (2021). Evaluation of preoperative dry eye in people undergoing corneal refractive surgery to correct myopia. *Int J Ophthalmol*, *14*(7), 1047-1051. https://doi.org/10.18240/ijo.2021.07.13

12. Conflict of Interest

All GDG group members completed a conflict-of-interest questionnaire.
ESCRS is sponsor for this project.

Name	Businesses (owner, partner, substantial interest in)	Organisations (employee, director)	Charities (trustee)	Organisations (general control, managment)	Organisations (work as a paid consultant)	Involvement in research projects funded by the ESCRS	Intellectual property right owned	Business interest, company directorships, trusteeships
Thomas Kohnen		University Hospital Frankfurt, Department of Ophthalmology		DOG, Treasurer	Consultant, Research and Lecturing for Alcon, Oculus, Schwind, Staar, Tarsus. Consultant and Lecturing for Ziemer. Research and Lecturing for Teleon Surgical. Consulting for Abbvie, Geuder, LensGen, Santen, Stadapharm, Thieme, Zeiss Meditec. Lecturing for Allergan, Bausch & Lomb, Johnson & Johnson, MedUpdate, streamedup.	Peter Barry Fellowship (Dr. K. Kaiser)		
Beatrice Cochener	None	University Hospital BREST France: CHU Morvan – UBO MD PHD Chairman of Ophthalmology department - Dean of Faculty of Medecine and Medical Sciences Chief of VISION Team of LaTIM (UMR 1101) (research in AI in Medecine)		Former president ESCRS Immediate past president Eucornea	J&J, B&L, Hoya, Tarsus, Horus, Thea, Roche	Toric IOL in Low astigmatism, Refractive guideline cochair	None	None
Andreia Rosa		Unidade Local Saude de Coimbra, Department of Ophthalmology, Faculty of Medicine, Coimbra University, Portugal			Alcon, EDOL, DAVI	ESCRS-Guidelines, EUKOR		
Paolo Vinciguerra		Ophthalmology faculty of medicine Humanitas University			Schwind; Nidek Oculus			
Mario Nubile	none	University „G. D'Annunzio" of Chieti and Pescara – Ophthalmology Clinic – Chieti, Italy	none	none	Tarsus, Dompè	ESCRS-Guidelines,	none	none
Liem Trinh		15-20 National Vision Hospital, Paris, Department of Ophthalmology III, France			Carl Zeiss			
Guy Kleinman								
Arthur Cummings	Wellington Eye Clinic	Wellington Eye Clinic	World College of Refractive Surgery	Wellington Eye Clinic	Alcon, WaveLight, Scope	ESCRS-Guidelines, ESCRS Systematic research	Nil	Director Alcon
Georges Kymiones								

Name	Businesses (owner, partner, substantial interest in)	Organisations (employee, director)	Charities (trustee)	Organisations (general control, managment)	Organisations (work as a paid consultant)	Involvement in research projects funded by the ESCRS	Intellectual property right owned	Business interest, company directorships, trusteeships
Joukje Wanten		Maastricht University Medical Centre, department of Opthalmology				ESCRS-Guidelines, ESCRS Systematic research		
Victoria Till		ÖGK Hanusch Hospital Vienna, VIROS Karl Landsteiner Institut Vienna		Roche		ESCRS-Guidelines, ESCRS Systematic research		
Jesper Hjortdal	None	Aarhus University Hospital & Aarhus University	EuCornea	None	The Danish Patient Complaints Agency	ETCF (led by Björn Bachmann)	None	None
Ruth Lapid	Private practice	UMC Utrecht The Netherlands		NIOIC member of the board IIIC treasurer	Alcon Hanita Lenses Hoya Tarsus	ESCRS refractive surgery guideline	none	none
Sheraz Daya	1.Centre for SIght 2. Infinite Medical Ventures	1.Centre for SIght 2. Infinite Medical Ventures	Orbis UK	1.Centre for SIght 2. Infinite Medical Ventures	Bausch + Lomb BVI Aurion Nidek Espansione Tarsus Vialase	none	Infinte Medical Ventures	

13. Appendix

APPENDIX 1 – SEARCH METHODS

KSR Evidence: to 28.2.23
https://ksrevidence.com/
Date searched: 28.2.23
Records found: 478

1 (intraocular or "intra ocular" or refractive or refraction or cornea* or intracornea*) adj3 (surg* or ablative or ablation or procedure*) in All text 193 results
2 laser and (eye* or ocular or vision or intraocular) and (correct* or surg* or procedure*) in All text 222 results
3 (myopi* or hyperopi* or hypermetropi* or presbyopi* or astigmat*) adj3 (surg* or laser*) in All text 19 results
4 "laser-assisted in situ keratomileusis" or LASIK in All text 50 results
5 "laser-assisted sub-epithelial keratectom*" or "laser epithelial keratomileusis" or LASEK in All text 13 results
6 "photorefractive keratectom*" or "photo refractive keratectom*" or PRK in All text 32 results
7 "Refractive Lens Exchange*" in All text 4 results
8 "phakic IOL*" or "phakic intraocular lens*" or "phakic intra-ocular lens*" or PIOL* in All text 21 results
9 "refractive lenticule extraction*" in All text 23 results
10 "intraocular lens implant*" or "intra ocular lens implant*" or "intracorneal lens implant*" or "intra corneal lens implant*" in All text 39 results
11 "posterior capsulotom*" in All text 5 results
12 scleroplast* in All text 0 results

13 lensectom* in All text 2 results
14 "implantable collamer lens*" in All text 3 results
15 keratotomy or keratoplasty in All text 76 results
16 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15

Cochrane Library (Wiley): Issue 2 of 12, February 2023
https://www.cochranelibrary.com/
Date searched: 28.2.23
Records found:
Cochrane Database of Systematic Reviews (CDSR) – 301
Cochrane Central Register of Controlled Trials (CENTRAL) - 5176

#1 MeSH descriptor: [Refractive Surgical Procedures] explode all trees 4173
#2 MeSH descriptor: [Refractive Errors] explode all trees 2533
#3 (intraocular or "intra ocular" or refractive or refraction or cornea* or intracornea*) near/3 (surg* or ablative or ablation or procedure*) 3878
#4 laser and (eye* or ocular or vision or intraocular) and (correct* or surg* or procedure*) 4530
#5 (myopi* or hyperopi* or hypermetropi* or presbyopi* or astigmat*) adj3 (surg* or laser*) 82
#6 "laser-assisted in situ keratomileusis" or LASIK 955
#7 "laser-assisted sub-epithelial keratectom*" or "laser epithelial keratomileusis" or LASEK 175
#8 "photorefractive keratectom*" or "photo refractive keratectom*" or PRK 627
#9 "Refractive Lens Exchange*"27
#10 "phakic IOL*" or "phakic intraocular lens*" or "phakic intra-ocular lens*" or PIOL*213
#11 "refractive lenticule extraction*" 153
#12 "intraocular lens implant*" or "intra ocular lens implant*" or "intracorneal lens implant*" or "intra corneal lens implant*" 53
#13 "posterior capsulotom*" 0
#14 scleroplast* 1
#15 lensectom* 84
#16 "implantable collamer lens*" 43
#17 keratotomy or keratoplasty 816
#18 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 with Cochrane Library publication date Between Jan 2005 and Feb 2023, in Cochrane Reviews 301

#19 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 with Publication Year from 2005 to 2023, in Trials 7980
#20 (conference or congress):ti,so,pt 226279
#21 (trial registry record or Clinical trial protocol):pt 556571
#22 #20 or #21 782812
#23 #19 not #22 5176

MEDLINE and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily (Ovid): 1946 to February 27, 2023
Date searched: 28.2.23
Records found: 4218

1 exp Refractive Surgical Procedures/ 66297
2 exp Refractive Errors/su 10341
3 ((intraocular or intra ocular or refractive or refraction or cornea$ or intracornea$) adj3 (surg$ or ablative or ablation or procedure$)).ti,ab. 13555
4 (laser and (eye$ or ocular or vision or intraocular) and (correct$ or surg$ or procedure$)).ti,ab. 14744
5 ((myopi$ or hyperopi$ or hypermetropi$ or presbyopi$ or astigmat$) adj3 (surg$ or laser$)).ti,ab. 3287
6 (laser-assisted in situ keratomileusis or LASIK).ti,ab. 5387
7 (laser-assisted sub-epithelial keratectom$ or laser epithelial keratomileusis or LASEK).ti,ab. 430
8 (photorefractive keratectom$ or photo refractive keratectom$ or PRK).ti,ab. 3806
9 Refractive Lens Exchange$.ti,ab. 230
10 (phakic IOL$ or phakic intraocular lens$ or phakic intra-ocular lens$ or PIOL$).ti,ab. 1249
11 refractive lenticule extraction$.ti,ab. 1007
12 (intraocular lens implant$ or intra ocular lens implant$ or intracorneal lens implant$ or intra corneal lens implant$).ti,ab. 5188
13 posterior capsulotom$.ti,ab. 831
14 scleroplast$.ti,ab. 128
15 lensectom$.ti,ab. 1187
16 implantable collamer lens$.ti,ab. 546
17 (keratotomy or keratoplasty).ti,ab. 14616
18 or/1-1787331
19 randomized controlled trial.pt. 587688
20 controlled clinical trial.pt. 95200
21 randomized.ab. 594446
22 placebo.ab. 236144
23 clinical trials as topic.sh. 200890
24 randomly.ab. 402936
25 trial.ti. 280254
26 or/19-25 1506933
27 exp animals/ not humans.sh. 5097078
28 26 not 27 1386733
29 18 and 28 6475
30 limit 29 to yr="2005 -Current" 4218

RCT filter:
Box 3.d Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision); Ovid format.
Lefebvre C, Glanville J, Briscoe S, Featherstone R, Littlewood A, Marshall C, Metzendorf M-

I, Noel-Storr A, Paynter R, Rader T, Thomas J, Wieland LS. Technical Supplement to Chapter 4: Searching for and selecting studies. In: Higgins JPT, Thomas J, Chandler J, Cumpston MS, Li T, Page MJ, Welch VA (eds). Cochrane Handbook for Systematic Reviews of Interventions Version 6.3 (updated February 2022). Cochrane, 2022. Available from: www.training.cochrane.org/handbook.

Embase (Ovid): 1974 to 2023 February 27
Date searched: 28.2.23
Records found: 3660

1 exp *refractive surgery/ 9586
2 exp *cornea surgery/ 25803
3 exp *refraction error/su [Surgery] 8341
4 ((intraocular or intra ocular or refractive or refraction or cornea$ or intracornea$) adj3 (surg$ or ablative or ablation or procedure$)).ti,ab. 16902
5 (laser and (eye$ or ocular or vision or intraocular) and (correct$ or surg$ or procedure$)).ti,ab. 18712
6 ((myopi$ or hyperopi$ or hypermetropi$ or presbyopi$ or astigmat$) adj3 (surg$ or laser$)).ti,ab. 3893
7 (laser-assisted in situ keratomileusis or LASIK).ti,ab. 6542
8 (laser-assisted sub-epithelial keratectom$ or laser epithelial keratomileusis or LASEK).ti,ab. 593
9 (photorefractive keratectom$ or photo refractive keratectom$ or PRK).ti,ab. 4266
10 Refractive Lens Exchange$.ti,ab. 275
11 (phakic IOL$ or phakic intraocular lens$ or phakic intra-ocular lens$ or PIOL$).ti,ab. 1469
12 refractive lenticule extraction$.ti,ab. 1210
13 (intraocular lens implant$ or intra ocular lens implant$ or intracorneal lens implant$ or intra corneal lens implant$).ti,ab. 6745
14 posterior capsulotom$.ti,ab. 981
15 scleroplast$.ti,ab. 128
16 lensectom$.ti,ab. 1450
17 implantable collamer lens$.ti,ab. 600
18 (keratotomy or keratoplasty).ti,ab. 16346
19 or/1-1867071
20 crossover-procedure/ or double-blind procedure/ or randomized controlled trial/ or single-blind procedure/ 854313
21 (random$ or factorial$ or crossover$ or cross over$ or cross-over$ or placebo$ or (doubl$ adj blind$) or (singl$ adj blind$) or assign$ or allocat$ or volunteer$).ti,ab,ot. 2754397
22 20 or 21 2864180
23 animal/ or animal experiment/ 4603460
24 (rat or rats or mouse or mice or murine or rodent or rodents or hamster or hamsters or pig or pigs or porcine or rabbit or rabbits or animal or animals or dogs or dog or cats or cow or bovine or sheep or ovine or monkey or monkeys).ti,ab,ot,hw. 7551879
25 23 or 24 7551879
26 exp human/ or human experiment/ 25161571
27 25 not (25 and 26) 5675985

28	22 not 27	2579018
29	19 and 28	5489
30	limit 29 to yr="2005 -Current"	4338
31	("conference abstract" or "conference review").pt. or conference$.so,st.	4751554
32	(letter or editorial or note).pt.	2987619
33	31 or 32	7739152
34	**30 not 33**	**3660**

RCT filter:
Lefebvre C, Manheimer E, Glanville J. Chapter 6: searching for studies. 6.3.2.2. What is in The Cochrane Central Register of Controlled Trials (CENTRAL) from EMBASE? (2011 Handbook https://handbook-5-1.cochrane.org/)