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Gesellschaft für Augenheilkunde

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Evaluation and quality assurance of refractive surgical interventions by the DOG and the BVA—recommendations of the Committee of Refractive Surgery

Dated June 2022

German Society of Ophthalmology (Deutsche Ophthalmologische Gesellschaft, DOG)[1] · German Professional Association of Ophthalmologists (Berufsverband der Augenärzte Deutschlands e. V., BVA)[2]

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Introduction

Refractive surgery encompasses surgical techniques that cannot be described as generally recognized treatment methods as yet. Therefore, both the German Society of Ophthalmology (*Deutsche Ophthalmologische Gesellschaft*, DOG) and the Professional Association of German Ophthalmologists (*Berufsverband der Augenärzte Deutschlands*, BVA) consider an updated assessment of refractive surgical procedures as essential. Furthermore, the measures prescribed by law to ensure the quality of medical practice (volume 5 of the German Social Insurance Code [*Sozialgesetzbuch V*, SGB V]) should be set out in the form of verifiable structural, process, and outcome quality. These recommendations (formerly guidelines) were first published in June 1995 [1].

Refractive surgery commission

The German Commission for Refractive Surgery (*Kommission Refraktive Chirurgie*, KRC) was first set up in 1995 as a joint commission of the German Society of Ophthalmology (DOG) and the Professional Association of German Ophthalmologists (BVA).

Members of the KRC currently include: Prof. Dr. Thomas Kohnen, Frankfurt, Germany (Chairman); Prof. Dr. Ekkehard Fabian, Rosenheim, Germany (Vice Chairman); Prof. Dr. Michael C. Knorz, Mannheim, Germany (Secretary); Prof. Dr. Gerd Auffarth, Heidelberg, Germany; Prof. Dr. Markus Kohlhaas, Dortmund, Germany; Prof. Dr. Daniel Kook, Gräfelfing, Germany; Prof. Dr. Wolfgang J. Mayer, Munich, Germany; Dr. Kaweh Schayan-Araghi, Dillenburg, Germany.

In consultation with the boards of the DOG and the BVA, the KRC has the following tasks:

1. to carry out an up-to-date evaluation of the known refractive surgical procedures on the basis of current scientific knowledge;
2. to formulate appropriate recommendations for the quality assurance of new procedures in anticipation of the structural, process, and outcome quality required by the German Medical Association (*Bundesärztekammer*);
3. to hold theoretical and practical courses that comply with KRC recommendations on quality assurance.

Assessing refractive surgical procedures

In order to assess refractive surgery procedures, the following criteria based on articles published in the scientific literature are provided for each procedure:

- description,
- range of application and range of limited application,
- secondary effects.

For the purposes of these recommendations, the *range of application* is the range in which the respective procedure is considered suitable and rarely produces side effects. The usual requirements in terms of patient information apply.

For the purposes of these recommendations, the *range of limited application* is the range in which the respective procedure can still be used, but with increasingly poor results and more frequent side effects. Greater requirements in terms of patient information apply for the range of limited application.

Use of the respective procedure is not recommended outside the range of application and the range of limited application. The same applies to all refractive surgical procedures that have not been explicitly evaluated in these recommendations. If a procedure is used nevertheless, the patient needs to be explicitly informed that the procedure is being performed outside the recommended range of limited application and/or approval obtained from the ethics committee in the context of a study.

1. Excimer laser correction of refractive errors

Using excimer lasers, it is possible to ablate extremely thin layers of tissue per laser pulse. By aligning numerous pulses of this kind on the surface of and deep within the corneal tissue, a certain area of the corneal surface can be shaped in such a way as to alter its refractive power. This enables correction of refractive errors in the entire eye.

There are two main variants of excimer laser surgery:

1.1. Surface treatments (photorefractive keratectomy [PRK], trans-PRK, and LASEK)

Description

In a first step, the surface layer of the cornea, the epithelium, is removed either mechanically or by laser. Using the excimer laser, the center of the cornea is then abraded to correct the refractive error. The epithelium regenerates beneath a contact lens within a few days and closes the superficial wound. PRK, LASEK, and trans-PRK are essentially equivalent.

Range of application

Myopia correction up to −6 dpt and astigmatism correction to 5 dpt. To assess myopic astigmatism, the total is calculated by adding myopia and astigmatism and not the spherical equivalent. Monovision is also possible in the case of concomitant presbyopia.

Range of limited application

Myopia correction up to −8 dpt, astigmatism correction up to 6 dpt, and hyperopia correction up to +3 dpt. In order to determine the upper limits, the threshold values for the highest refractive index of the principal plane also need to be taken into account (e.g.,: +3 sph and −6 cyl or −3 sph and +6 cyl are within the range of limited application, 0 sph and +6 cyl or +6 sph and −6 cyl are outside the range of limited application).

Prophylactic intraoperative use of mitomycin C to reduce postoperative scar formation: the scientific evidence does not permit any clear statement to be made on establishing the indication. At present, the KRC sees no scientific basis for the primary use of mitomycin C in the previously unoperated cornea and does not recommend its use. The KRC deems the intraoperative use of mitomycin C in previously operated corneas acceptable.

Secondary effects

Vision is reduced in the first few days following PRK, LASEK, and trans-PRK, and there is usually moderate discomfort; more severe pain is seen in exceptional cases. As a general rule, the complication rate increases with the extent of correction required. Possible secondary effects include superficial corneal scarring (haze), a partial decline in surgical success within the first weeks and months, and worsened twilight and night vision, with patients perceiving halos and shadow images, particularly patients with wide pupils. Transient eye dryness is also often seen. Other extremely rare secondary effects include infection and marked scarring accompanied by a significant deterioration in vision.

Contraindications

Chronic progressive corneal disorders, patient age under 18 years, symptomatic cataract, glaucoma with severe visual field defects, and exudative macular degeneration.

1.2. Laser in situ keratomileusis (LASIK) and femto-LASIK

Description

LASIK involves partially separating a 0.1- to 0.15-mm thick corneal flap using a microkeratome and folding this flap back like a lid. The modern form of LASIK, femto-LASIK, as well as laser-LASIK replaces the microkeratome with the femtosecond laser. The interior of the cornea is then ablated with the excimer laser in order to correct the refractive error. The flap is then folded back and adapts independently.

Range of application

Myopia correction up to −8 dpt, astigmatism correction up to 5 dpt, and hyperopia correction up to +3 dpt. Also as monovision in the case of concomitant presbyopia. To determine the upper limits, the threshold values for the highest refractive index of the principal plane must also be taken into account (e.g.,: +3 sph and −5 cyl or −3 sph and +5 cyl are within the range of application, while 0 sph and +5 cyl or +5 sph and −5 cyl are outside the range of application).

Range of limited application

Myopia correction up to −10 dpt, astigmatism correction up to 6 dpt, and hyperopia correction up to +4 dpt. In order to determine the upper limits, the threshold values for the highest refractive index of the principal plane also needs to be taken into account (e.g.,: +4 sph and −6 cyl or

–4 sph and +6 cyl are within the range of limited application, 0 sph and +6 cyl or +6 sph and –6 cyl are outside the range of limited application).

Secondary effects

The patient experiences reduced vision and moderate discomfort in the first hours following LASIK or femto-LASIK. As a general rule, the complication rate increases with the extent of correction required. Possible secondary effects include superficial corneal scarring (haze), a partial decline in surgical success within the first weeks and months, and worsened twilight and night vision, with patients perceiving halos and shadow images, particularly patients with large pupils. Transient eye dryness is also often seen. In rare cases, circumscribed epithelial detachment and incision errors can occur when cutting the corneal flap. Subtle folds in the anterior corneal flap are extremely rare side effects of early wound healing. In some cases, irregular incision surfaces form, which can lead to irregularities in the corneal surface and impaired vision. Extremely rare side effects include sterile inflammatory reactions during wound healing, infection with severe scarring, as well as a weakening and bulging of the cornea (keratectasia) and significantly impaired vision.

Contraindications

Preoperative corneal thickness of less than 480 µm (when using a femtosecond laser) or less than 500 µm (when using a mechanical microkeratome), corneal stromal thickness under the flap after ablation of less than 250 µm even after revision surgery, chronic progressive corneal disease and forme fruste keratoconus, patient age under 18 years, glaucoma with pronounced visual field defects, and exudative macular degeneration.

2. Keratorefractive lenticular extraction (KLEx)

Description

KLEx uses only a femtosecond laser. This makes two incisions in the cornea, creating a slice of tissue that is extracted through one or two small lateral openings.

Range of application

Myopia correction from –1 to –8 dpt and astigmatism correction up to –5 dpt, also as monovision in the case of concomitant presbyopia. In order to determine the upper limits, the threshold values for the highest refractive index of the principal plane also need to be taken into account.

Range of limited application

Myopia correction from –8 to –10 dpt.

Secondary effects

Revision surgery using the same procedure is not possible; the patient needs to be explicitly informed of this. Patients often experience impaired vision and moderate discomfort in the first days following laser-assisted lenticule extraction. As a general rule, the complication rate increases with the extent of correction required. Possible secondary effects include superficial corneal scarring (haze), a partial decline in surgical success within the first weeks and months, and worsened twilight and night vision, with patients perceiving halos and shadow images, particularly patients with large pupils. Transient eye dryness is also often seen. In rare cases, circumscribed epithelial detachment and incision errors can occur when cutting the corneal flap. In some cases, irregular incision surfaces form, which can lead to irregularities in the corneal surface and impaired vision. Likewise, complete removal of the flap of tissue is not possible in some cases, which can also lead to irregularities in the corneal surface and impaired vision. Extremely rare side effects include sterile inflammatory reactions during wound healing, infection with severe scarring, as well as a weakening and bulging of the cornea (keratectasia) and significantly impaired vision.

Contraindications

Preoperative corneal thickness of less than 480 µm, corneal stromal thickness under the cap following removal of the tissue disc of less than 250 µm even after revision surgery, chronic progressive corneal disease and forme fruste keratoconus, treatment under the age of 18 years, symptomatic cataract, glaucoma with pronounced visual field defects, and exudative macular degeneration.

3. Astigmatic keratotomy (AK), laser keratotomy (laser AK), and limbal relaxing incisions (LRI)

Description

AK, laser AK, and LRI involve making one or two deep arc-shaped cuts in the cornea with a diamond knife/disposable knife or a laser. These incisions relax the cornea in the axis of astigmatism, thereby reducing astigmatism.

Range of application

Astigmatism reduction especially before or after lens surgery or following keratoplasty.

Secondary effects

Irregular astigmatism or marked under- or over-correction sometimes occur, particularly following keratoplasty. Epithelial ingrowth into the incision is also possible. Perforation of the eye is possible in extremely rare cases.

Contraindications

Chronic progressive corneal disease and patient age under 18 years.

4. Intracorneal ring segments

Description

In order to implant the ring segments, narrow tunnels are cut into the outer cornea—either mechanically or using a femtosecond laser—into which differently shaped ring segments made of acrylic glass (PMMA) are inserted.

Range of application

Improvement of corneal refractive properties, stabilization of the cornea to improve visual acuity in keratoconus or keratectasia, and following decentered laser ablation if contact lenses no longer provide sufficient correction.

Range of limited application

Not applicable.

Secondary effects

Visually disturbing secondary effects such as the perception of halos and increased sensitivity to glare, as well as a decline in the effect of correction, are common. In rare cases, infection, scar formation, or corneal melting with rejection of the ring segments occur.

Contraindications

Corneal thickness in the area of the ring segment of less than 300 µm.

5. Corneal crosslinking

Description

Following mechanical ablation of the corneal epithelium, riboflavin drops are applied to the cornea, and the cornea is irradiated with UV-A light for approximately 10–30 min (depending on irradiation intensity). This is intended to stiffen the cornea in order to halt chronic progressive corneal disease. It is possible that a shorter corneal irradiation time is also sufficient with higher radiation energy.

Range of application

Surgical correction of keratoconus or pellucid marginal degeneration (PMD) in order to stabilize the cornea and reduce astigmatism, as well as treatment of keratectasia following refractive corneal laser surgery. When used therapeutically, the age limit for refractive surgery (18 years) does not apply.

Range of limited application

Simultaneous PRK and corneal crosslinking for the refractive correction of keratoconus or to treat keratectasia following refractive corneal laser surgery.

Secondary effects

Sterile inflammation as well as infection and scar formation are rare. Endothelial damage and corneal opacification may also occur if the cornea is too thin. Increased sensitivity to light or glare may be present for a number of weeks, in rare cases also longer. Patients are often unable to work for 1–2 weeks due to the temporary corneal opacification. Moreover, a change in refraction, in particular astigmatic change, is possible even after years.

Contraindications

The minimum corneal thickness with or without epithelium depends on the method used (e.g., hydration using Hafezi's protocol, etc.) to minimize the risk of endothelial cell damage.

In addition to the therapeutic use of corneal crosslinking, a significantly shortened form of this method in combination with LASIK is also advocated for the correction of refractive errors. The efficacy of this treatment form has not been demonstrated as yet in scientific investigations. Sufficient data are lacking on possible damage to the cornea compared to LASIK without corneal crosslinking, meaning that, in the opinion of the KRC, the use of this procedure is currently not justified other than in scientific studies with ethics committee approval.

6. Implantation of phakic intraocular lenses (phakic IOLs)

Description

The use of phakic IOLs involves opening the eye at the corneal margin and inserting an additional lens (= phakic IOL) into the eye, much like a contact lens. This additional lens is either anchored to the iris or sits behind the iris in the ciliary sulcus. Following insertion of the IOL, the incision either closes spontaneously or is closed using a suture.

At present, sufficient data are available only on the Visian ICL (Staar Surgical) and the Artisan/Verisyse (Ophtec or Johnson & Johnson Vision AMO Germany GmbH, Emmerich / Rhein or Ettlingen), or Artiflex/Veriflex IOL (Ophtec or AMO).

Range of application

Myopia from −1 dpt and hyperopia from +1 dpt, as well as astigmatism. In the case of concomitant astigmatism or residual ametropia following implantation of a phakic IOL, a laser procedure according to Sect. 1.1 or 1.2 can be additionally performed, or a toric phakic IOL can be used.

Range of limited application

Use of phakic IOLs for presbyopia correction. In the case of presbyopia correction, patients must be informed about the temporary efficacy of this approach and the increased risk of lens opacification (cataract).

Secondary effects

Rare cases have been described of paroxysmal increase in intraocular pressure (acute angle-closure glaucoma attack), iris damage consistent with Urrets–Zavalia syndrome, pupil distortion (corectopia), damage to the posterior surface of the cornea (endothelium) with corneal opacification, natural lens opacification (cataract), dislocation or loosening of the artificial lens, as well as chronic eye inflammation. Retinal detachment, particularly following myopia correction and bacterial infection, has also been described, among other phenomena. Since the eye is opened during surgery, infection can cause blindness in extremely rare cases.

Contraindications

Patient age under 18 years, glaucoma and severe visual field defects, pre-existing retinal defects and a significantly reduced number of endothelial cells as well as endothelial cell density of less than 2000/mm^2, and insufficient anterior chamber depth (less than 2.8 mm in myopia and 3.0 mm in hyperopia, measured from the endothelium; when measuring from the endothelium, corneal thickness needs to be subtracted from the measured value).

Other information

Follow-up examinations of corneal endothelial cell density are required at least annually for all phakic IOLs. These examinations are currently not reimbursed by German statutory health insurance.

The KRC advises against bilateral implantation of phakic IOLs during one surgical session.

7. Exchange of the ocular lens for an artificial lens to correct refractive errors (refractive lens exchange, RLE)

7.1. Monofocal IOL (aspheric and/or toric)

Description

Refractive lens exchange involves opening the eye at the edge of the cornea and, much like modern cataract surgery, removing the natural lens and replacing it with an artificial lens. Lens exchange can be performed using ultrasound or as a laser lens exchange using a femtosecond laser. The artificial lens has one focal point (monofocal IOL) and, where necessary, can also correct a cylinder (toric IOL).

Range of application

Myopia and hyperopia in the setting of concomitant presbyopia and presbyopia in emmetropia. In the case of concomitant astigmatism, either a toric IOL or a laser method as described in Sects. 1.1 and 1.2 or AK as described in Sect. 3 can be used.

Range of limited application

High myopia (> –6 dpt) and high hyperopia (> +4 dpt) without presbyopia.

Secondary effects

Reading glasses are needed with monofocal IOLs. Secondary opacification (secondary cataract) behind the new artificial lens can occur months to years following RLE, but can be easily treated without reopening the eye. Since the eye is opened during surgery, infection can cause blindness in extremely rare cases. In the case of pre-existing myopia, the risk of retinal detachment is higher, particularly when the procedure is used in patients under the age of 50 years or in the presence of incomplete posterior vitreous detachment.

Contraindications

Patient age under 18 years.

The KRC advises against bilateral surgical lens exchange during one surgical session.

7.2. Multifocal (bifocal/trifocal/quadrifocal, A+, IOL combination system, etc.) IOL or extended depth of focus (EDOF) IOL (aspheric and/or toric)

Description

Refractive lens exchange involves opening the eye at the edge of the cornea and, much like modern cataract surgery, removing the natural lens and replacing it with an artificial lens. Lens exchange can be performed using ultrasound or as a laser lens exchange using a femtosecond laser. The artificial lens has two or more focuses (multifocal IOL). In addition, the lens can be aspheric and, if necessary, also correct a cylinder (toric multifocal IOL).

Range of application

Hyperopia and high myopia (> –6 dpt) with concomitant presbyopia. In the case of concomitant astigmatism, either a toric IOL or a laser method as described in Sects. 1.1 and 1.2 or AK as described in Sect. 3 can be used.

Range of limited application

Myopia and hyperopia without presbyopia, as well as presbyopia and emmetropia.

Secondary effects

As a general rule, neither distance glasses nor reading glasses are required with multifocal IOLs, but there may be a deterioration in twilight vision with halo perception and glare sensitivity. Secondary opacification (secondary cataract) behind the new artificial lens can occur months to years following RLE, but can be easily treated without reopening the eye. Since the eye is opened during surgery, infection can cause blindness in extremely rare cases. In the case of pre-existing myopia, the risk of retinal detachment is higher, particularly when used under the age of 50 years or in the presence of incomplete posterior vitreous detachment.

Contraindications

Patient age under 18 years.

The KRC advises against bilateral surgical lens exchange during one surgical session.

8. Eye drops for presbyopia correction

Range of application: presbyopia and prepresbyopia.

Secondary effects: worsened twilight and night vision, myopic shift with worsened distance vision, spasm of accommodation, increased risk of retinal detachment.

Contraindications: hypersensitivity to constituents.

Treatment fees

As a general rule, refractive surgical treatment as well as possible additional and related pre- or postoperative medical services are not covered by statutory health insurance. Patients cannot be provided with a certificate of incapacity for work, since, according to current legal opinion, any incapacity to work is self-inflected (unless there are complications), and thus the patient has no claim to continued pay.

Refractive surgery has been included by the German National Association of Statutory Health Insurance Physicians (*Kassenärztliche Bundesvereinigung*) in the catalog of individual healthcare services to be paid for by the patient (*individuelle Gesundheitsleistungen*, IGEL). In line with German guidelines on the assessment of medical examination and treatment methods in accordance with § 135 para. 1 of the German Social Code (*SGB V*; BUB Guidelines) issued by the German Federal Committee of Physicians and Health Insurances (*Bundesausschuss der Ärzte und Krankenkassen*) on 10.12.1999, it is also one of the "methods that may not be provided as a contracted medical service reimbursable by a health insurance" according to Annex B (published in [2]).

Detailed consultation prior to refractive surgery, possibly including additional

examinations and referral to a suitable surgeon, is to be billed by the physician providing the service in strict accordance with the German Physician Fee Schedule (*Gebührenordnung für Ärzte*, GOÄ). The surgical fees themselves should also be set according to the GOÄ and should include fee codes. The German Medical Association has issued recommendations in this regard (e.g., fee code A 5855 for PRK and PTK, and fee code 1345 combined with fee code A 5855 for LASIK).

Since refractive surgery is not cosmetic surgery, the treatment of potential postoperative complications can be covered by the statutory health insurance. In the case of no complications, one can assume that refractive surgical treatment is completed after 3 months, meaning that, according to current legal opinion, any further treatment can be covered by the statutory health insurance. This excludes repeat refractive surgical procedures.

Annual follow-up of the corneal endothelium required following the implantation of phakic IOLs cannot be charged to the statutory health insurance, but must be billed for by the examining physician according to the GOÄ (see BVA fee codes). The same applies to the follow-up of intraocular pressure.

Quality assurance recommendations: refractive corneal surgery (PRK, LASEK, Trans-PRK, LASIK, femto-LASIK, laser-assisted lenticule extraction, AK, laser AK, LRI, intracorneal implants, corneal crosslinking)

1. Structural quality

1.1. Personal qualification

Refractive surgical procedures are invasive ophthalmological surgical interventions that require specialist expertise. When performing these procedures, the general guidelines issued by the German Medical Association on quality assurance in outpatient surgery must be adhered to. The following conditions must also be fulfilled:

- participation in a theoretical course (basic course and advanced course) accredited by and organized in collaboration with the KRC;
- sitting-in on a KRC-accredited trainer;
- the first surgical procedure must be performed in the presence of a KRC-accredited trainer.

Training in line with Sect. 1.1 will be certified by the KRC. The training guidelines under Sect. 1.1 apply to all applicants wising to be included on the register of refractive surgeons. A prerequisite of this is that the applicant is a certified ophthalmologist.

1.2. Technical requirements

- In accordance with § 6 of the German Accident Prevention Regulations for Laser Radiation (*Unfallverhütungsvorschrift Laserstrahlung*), a laser safety officer must be appointed (if lasers are to be used).
- Prior to all surgical procedures, the refractive surgeon must ensure that the excimer laser and the keratome or femtosecond laser to be used are able to perform the required functions (if lasers or keratomes are to be used).

1.3. Facility requirements

- The treatment room must comply with the German Accident Prevention Regulations for Laser Radiation (if lasers are to be used).
- The minimum requirements in terms of structural features, surgical instrumentation, and hygiene facilities must be fulfilled in accordance with Annex 1 of the Guidelines of the German Medical Association for Quality Assurance in Outpatient Surgery (*Richtlinien der Bundesärztekammer zur Qualitätssicherung ambulanter Operationen*) of 13.04.1994.

2. Process quality

2.1. Patient information

It is mandatory for all refractive surgeons to preoperatively provide their patients with detailed information on the planned procedure. The indication must be made by an ophthalmologist included on the KRC register of ophthalmologists. Patient information must be provided by a physician. Since these procedures are highly elective, it is often necessary for both the indication to be made and the patient information to be provided in advance of the day of surgery in order to ensure that the patient has sufficient time for reflection. On the actual day of surgery, only the method on which the patient was informed and for which they have given signed consent should be performed. In individual cases, the patient must be informed preoperatively of the possibility of an intraoperative change of method.

2.2. Preoperative diagnostic work-up

The preoperative diagnostic work-up must be performed by an ophthalmologist included on the KRC register of ophthalmologists. The following preoperative examinations represent the minimum requirements and should be documented:

- examination of corneal topography and refractive power using computer-assisted methods (Placido, Scheimpflug, OCT, etc.);
- testing of uncorrected and corrected visual acuity, 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);
- intraocular pressure measurement;
- measurement of mesopic pupil diameter (0.05–50 lx);
- measurement of aniseikonia in anisometropia and determination of the patient's tolerance of the planned correction by means of contact lens-wearing test;
- examination of the anterior and posterior eye segments after drug-induced mydriasis;
- measurement of the cornea (corneal tomography) using optical methods over a central area of at least 6 mm;
- exclusion of medical contraindications.

2.3. Postoperative diagnosis (see also Sect. 3.1.)

Regular postoperative ophthalmological check-ups are required and should be documented. The minimum requirements here include:

- examination of corneal topography and refractive power using computer-assisted methods (Placido, Scheimpflug, OCT, etc.; at least once

within the first 12 postoperative months);
- measurement of uncorrected and corrected visual acuity;
- intraocular pressure measurement;
- examination of the anterior and posterior eye segments.

If the surgeon and follow-up physician are not the same person, their collaboration during follow-up must be ensured.

2.4. Surgical procedure

As a basic principle, the following minimum requirements must be met:
- local anesthesia (eye drop anesthesia);
- keratotomy or epithelial removal using an aseptic technique with sterile instruments (exception: purely intrastromal AK with a femtosecond laser);
- the diameter of the full-correction zone should not be under 6 mm;
- residual stromal bed thickness should not fall below 250 µm after secondary treatment;
- secondary treatment with antibiotics and steroid eye drops (exception: purely intrastromal AK with a femtosecond laser).

3. Outcome quality

3.1. Documentation

For the documentation of treatment outcome, findings and surgical data from the examinations specified in Sects. 2.2–2.4 constitute the minimum requirements.

3.2. Continuing medical education

Regular continuing medical education is mandatory. Proof of participation in one KRC advanced training course per calendar year, for instance, is suitable to this end.

4. List of refractive surgeons

Upon request, all refractive surgeons meeting the requirements set out in Sect. 4.1. will be listed by name in an official register of refractive surgeons. Refractive surgeons will remain on the register for a period of 1 year. Surgeons wishing to extend their inclusion on the register must prove—on their own initiative and by 15.12. of the year—that they meet the requirements set out in Sect. 4.2. However, re-inclusion is possible within 3 years for those refractive surgeons who have already met the requirements set out in Sect. 4.1. and been included on the register.

In this case, only the requirements set out in Sect. 4.2 need to be demonstrated.

Refractive surgeons who have not been on the list for longer than 3 years must once again provide proof that they meet all requirements set out in Sect. 4.1.

At the request of hospital directors, university eye hospitals will be included on a separate register of university eye hospitals as institutions responsible for research and teaching, without their relevant specialists being named.

The register of refractive surgeons is updated every 3 months (31.03., 30.06., 30.09., 31.12.). The register is available from the office of the BVA as well as online via the BVA homepage.

4.1. Requirements for inclusion on the register of refractive surgeons

- Proof of training as set out in Sect. 1.1 of these recommendations.
- Submission of a written declaration in which the refractive surgeon undertakes to comply with these quality assurance recommendations (forms available from the KRC).

4.2. Requirements to remain on the register of refractive surgeons

- Participation in one KRC advanced training course per calendar year.
- The performance of treatments as set out in Sects. 2.1–2.4 of these guidelines. This also applies to lower-level personnel and internet presence.

If this is evidently not the case, the KRC will ask for a written statement from the refractive surgeon. Failure to react within 4 weeks, or if the statement does not satisfy the KRC, a warning notice will be issued; this needs to be signed by the refractive surgeon. Failure to do so, or violation of the warning, will result in the surgeon's removal from the register without further consultation. The KRC will inform the refractive surgeon of this step. Re-inclusion can take place after 3 years at the earliest and only *upon request* and with proof that all requirements set out in Sect. 4.1 are met.

4.3. Certificate

A certificate will be issued upon application once the requirements set out in Sects. 4.1. and/or 4.2. have been fulfilled.

Quality assurance recommendations: intraocular refractive surgery (phakic IOLs, refractive lens exchange, laser-assisted lens exchange)

1. Structural quality

1.1. Personal qualification

Phakic IOL implantation and refractive lens exchange (RLE) are invasive ophthalmological surgical interventions requiring specialist expertise. When performing these procedures, the general guidelines issued by the German Medical Association on quality assurance in outpatient surgery must be complied with. The following conditions must also be fulfilled:
- participation in a theoretical course (basic course and advanced course) accredited by and organized in collaboration with the KRC;
- sitting-in on a KRC-accredited trainer;
- the first surgical procedure must be performed in the presence of a KRC-accredited trainer.

Training in line with Sect. 1.1 will be certified by the KRC. The training guidelines under Sect. 1.1 apply to all applicants wishing to be included on the register of refractive surgeons. A prerequisite of this is that the applicant is a certified ophthalmologist.

1.2. Technical requirements

- In accordance with § 6 of the German Accident Prevention Regulations for Laser Radiation (*Unfallverhütungsvorschrift Laserstrahlung*), a laser safety officer must be appointed (if lasers are to be used).
- Prior to all surgical procedures, the refractive surgeon must ensure that the equipment to be used is able to perform the required functions.

1.3. Facility requirements

- The treatment room must comply with the German Accident Prevention Regulations for Laser Radiation (*Unfallverhütungsvorschrift Laserstrahlung*, if lasers are to be used).
- The minimum requirements in terms of structural features, surgical instrumentation, and hygiene facilities must be fulfilled in accordance with Annex 1 of the Guidelines of the German Medical Association for Quality Assurance in Outpatient Surgery (*Richtlinien der Bundesärztekammer zur Qualitätssicherung ambulanter Operationen*) of 13.04.1994.

2. Process quality

2.1. Patient information

It is mandatory for all refractive surgeons to preoperatively provide their patients with detailed information on the planned procedure. The indication must be made by an ophthalmologist included on the KRC register of ophthalmologists. Patient information must be provided by a physician. Since these procedures are highly elective, it is often necessary for both the indication to be made and the patient information to be provided in advance of the day of surgery in order to ensure that the patient has sufficient time for reflection.

2.2. Preoperative diagnostic work-up

The preoperative diagnostic work-up must be performed by an ophthalmologist included on the KRC register of ophthalmologists. The following preoperative examinations represent the minimum requirements and should be documented:

- examination of corneal topography and refractive power using computer-assisted methods (Placido, Scheimpflug, OCT, etc.);
- testing of uncorrected and corrected visual acuity, 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);
- intraocular pressure measurement;
- measurement of mesopic pupil diameter (0.05–50 lx);
- measurement of aniseikonia in anisometropia and determination of the patient's tolerance of the planned correction by means of contact lens-wearing test;
- examination of the anterior and posterior eye segments after drug-induced mydriasis;
- measurement of anterior chamber depth;
- measurement of axial eye length;
- in phakic IOL implantation: quantitative analysis of the corneal endothelium and visualization of the anterior eye segment using imaging methods (OCT, Scheimpflug camera, ultrasound);
- exclusion of medical contraindications.

2.3. Postoperative diagnosis (see also Sect. 3.1.)

Regular postoperative ophthalmological check-ups are required and should be documented. The minimum requirements here include:

- examination of corneal topography and refractive power using computer-assisted methods (Placido, Scheimpflug, OCT, etc.; at least once within the first –12 postoperative months);
- testing of uncorrected and corrected visual acuity;
- intraocular pressure measurement;
- examination of the anterior and posterior eye segments;
- phakic IOLs: quantitative analysis of the corneal endothelium at least 1 ×/year.

If the surgeon and follow-up physician are not the same person, their collaboration during follow-up must be ensured.

2.4. Surgical procedure

As a basic principle, the following minimum requirements must be met:

- local anesthesia;
- surgery using an aseptic technique with sterile instruments;
- secondary treatment with antibiotics (including intraocular antibiotic therapy) and steroid eye drops.

3. Outcome quality

3.1. Documentation

For the documentation of treatment outcome, findings and surgical data from the examinations specified in Sects. 2.2–2.4 constitute the minimum requirements.

3.2. Continuing medical education

Regular continuing medical education is mandatory. Proof of participation in one KRC advanced training course per calendar year, for instance, is suitable to this end.

4. List of refractive surgeons

Upon request, all refractive surgeons meeting the requirements set out in Sect. 4.1. will be listed by name on an official register of refractive surgeons. Refractive surgeons will remain on the register for a period of 1 year. Surgeons wishing to extend their inclusion on the register must prove—on their own initiative and by 15.12. of the year—that they meet the requirements set out in Sect. 4.2. However, re-inclusion is possible within 3 years for those refractive surgeons who have already met the requirements set out in Sect. 4.1. and been included on the register.

In this case, only the requirements set out in Sect. 4.2 need to be demonstrated. Refractive surgeons who have not been on the list for longer than 3 years need to provide proof that they meet all requirements set out in Sect. 4.1.

At the request of hospital directors, university eye hospitals will be included on a separate register of university eye hospitals as institutions responsible for research and teaching, without their relevant specialists being named.

The register of refractive surgeons is updated every 3 months (31.03., 30.06., 30.09., 31.12.). The register is available from the office of the BVA as well as online via the BVA homepage.

4.1. Requirements for inclusion on the register of refractive surgeons

- Proof of training as set out in Sect. 1.1 of these recommendations.
- Submission of a written declaration in which the refractive surgeon undertakes to comply with these quality

assurance recommendations (forms available from the KRC).

4.2. Requirements to remain on the register of refractive surgeons

- Participation in one KRC advanced training course per calendar year.
- The performance of treatments as set out in Sects. 2.1–2.4 of these guidelines. This also applies to lower-level personnel and internet presence.

If this is evidently not the case, the KRC will ask for a written statement from the refractive surgeon. Failure to react within 4 weeks, or if the statement does not satisfy the KRC, a warning notice will be issued; this needs to be signed by the refractive surgeon. Failure to do so, or violation of the warning, will result in the surgeon's removal from the register without further consultation. The KRC will inform the refractive surgeon of this step. Re-inclusion can take place after 3 years at the earliest and only *upon request* and with proof that all requirements set out in Sect. 4.1 are met.

4.3. Certificate

A certificate will be issued upon application once the requirements set out in Sect. 4.1. have been fulfilled.

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- Markus Kohlhaas, Dortmund (DOG)
- Daniel Kook, Gräfelfing (BVA)
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Appendix

Table 1 Declaration of interests and handling of conflicts of interest: KRC 2022 recommendations

	Advisor or consultant	Member of a scientific advisory board	Paid lectures or trainings	Paid authorship/co-authorship	Research projects/ clinical trials	Proprietary interests (patent, copyright, shares)	Indirect interests
Prof. Auffarth, Gerd U.	Johnson & Johnson, EyeYon, Presbia, Santen, SIFI, Alcon, Medvise, VSY, Carl Zeiss	AMO, J, Carl Zeiss, Alcon	Alcon, Alimera, J, Hoya, AMO, OSD Medical, SIFI, Carl Zeiss, Biotech, Bayer, Ursapharm, Teleon, Glaukos, Rayner, Santen, Oculus, Allergan, Eyefox, Esasso Foundation, Aier Global Vision Care Management, VSY	No	Novartis, Alcon, J Vision, Anew IOL Technologies, Glaukos, Ursapharm, Physiol, Hoya, Alimera, SIFI, Rheacell, Advanced Vision Science, Inc., Biotech Healthcare Holding GmbH, Kowa Pharmaceutical Europe, Roche, Chengdu Kanghong Biotechnology, Bayer, Oculus, Contamac, Klaus Tschira Stiftung, Medizinische Fakultät HD, Universität Karlsruhe, Lions Club, Dietmar Hopp Stiftung, Vivior, EyeYon, Okuvision	No	Member: *Deutschsprachige Gesellschaft für Intraokularlinsen-Implantation, interventionelle und refraktive Chirurgie* (DGII)—president/secretary general; member: European Society of Cataract and Refractive Surgeons (ESCRS)—member of the board; scientific activity: intraocular lenses, cataract, glaucoma, retina, cornea; scientific activity: general ophthalmology, anterior segment surgery, glaucoma, cornea, retina; involvement in training and continuing medical education: Helmholtztage (IVOM, KRC courses); involvement in training and continuing medical education for ophthalmologists in private practice: cataract, refractive surgery, retina, strabology, cornea; *Katarakt Forum* (Hoya)
Prof. Fabian, Ekkehard	No	Johnson Vision	DOC	No	Zeiss Meditec	No	Member: AAO, ASCRS, Augen Allianz, BDOC, BVA, DOG, ESCRS, ESCRS Video Judging Commission, scientific activity: cataract surgery, IOL with and without additional functions, biometry, patient questionnaires; author is an ophthalmologist in private practice performing outpatient surgical procedures; no involvement in training or continued medical training, no personal interests
Prof. Dr. med. Knorz, Michael	No	No	No	No	No	No	No
Prof. Dr. med. Kohlhaas, Markus	No	No	Pharm Allergan	No	No	No	No
Prof. Kohnen, Thomas	Alcon/ Novartis, J&J, Lensgen, Oculentis, Oculus, Presbia, Schwind, Zeiss, Allergan, Bausch & Lomb, Geuder, Med Update, Santen, Staar, Thieme, Ziemer	Alcon/ Novartis, Nevakar, Santen	Allergan, Oculus, med update GmbH	JCRS, Thieme	No	No	Member: ESCRS, treasurer; member: DOG, treasurer; member VOL, treasurer; scientific activity: JCRS Editor; scientific activity: *Klinische Monatsblätter*, editor, special topic; scientific activity: *Der Ophthalmologe*, section editor; scientific activity: cataract and refractive surgery

Table 1 (Continued)

	Advisor or consultant	Member of a scientific advisory board	Paid lectures or trainings	Paid authorship/co-authorship	Research projects/ clinical trials	Proprietary interests (patent, copyright, shares)	Indirect interests
Prof. Kook, Daniel	No	No	Alcon, Heidelberg Engineering	No	No	No	No
Prof. Dr. med. Mayer, Wolfgang	*Klinische Monatsblätter für Augenheilkunde*	Zeiss	Zeiss	No	Alcon	No	Member: ESCRS, scientific activity: university research with publications peer reviewed for ophthalmologic journals; scientific board of the *Klinische Monatsblätter für Augenheilkunde*; coeditor book: *Katarakt- und Linsenchirurgie*, Springer Verlag; scientific activity: refractive surgery, lens surgery, cornea surgery; involvement in training and continued medica education: phaco course at the University Eye Hospital of the Ludwig Maximilian University of Munich
Dr. med. Schayan-Araghi, Kaweh	Court expert	Nein	BBMV—*Bundesverband der Betreiber med. Versorgungszentren*	Nein	Nein	Nein	Member: board of the Professional Association of German Ophthalmologists (BVA), second/first chair of the *Bundesverband dt. Ophthalmochirurgen* (BDOC); scientific activity: cataract and refractive surgery, oculoplasty; involvement in training and continuing medical education: Director of the Program Commission of the *augenchirurgischer Nachmittag* of the ARTEMIS eye clinics

Declarations of interest are summarized in tabular form below, as are the results of the conflict of interests assessment and the measures that were decided upon and implemented following discussion of the issues during the consensus conference.

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Declarations

Conflict of interest. See **Table 1** in the Appendix.

For this article no studies with human participants or animals were performed by any of the authors. All studies mentioned were in accordance with the ethical standards indicated in each case.

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