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Die wissenschaftliche Gesellschaft
der Augenärzte

Evaluation and Quality Assurance of Refractive Surgery

by

the Deutsche Ophthalmologische Gesellschaft (German Society of Ophthalmology) and the Berufsverband der Augenärzte Deutschland (Professional Organisation of German Ophthalmologists)

issued by the joint Committee of Refractive Surgery (KRC)

May 2007



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Introduction

Refractive surgery comprises operative techniques which cannot yet be described as generally recognised medical therapies. Thus both the Deutsche Ophthalmologische Gesellschaft –DOG- (German Society of Ophthalmology) and the Berufsverband der Augenärzte Deutschland –BVA- (Professional Organisation of German Ophthalmologists) deem it necessary to issue an updated evaluation of refractive surgical interventions. In addition, the statutory measures for the quality assurance of medical treatment (SGB V) should be codified in a revisable structural as well as process and result quality. These guidelines were first published in June 1995 (Der Augenarzt, 3/95, 77-80).

Committee for Refractive Surgery

The Committee for Refractive Surgery (KRC) was established in 1995 as a joint committee of the Deutsche Ophthalmologische Gesellschaft –DOG- (German Society of Ophthalmology) and the Berufsverband der Augenärzte Deutschland –BVA- (Professional Organisation of German Ophthalmologists). Members of the Committee are: Prof. Dr. Thomas Neuhann, Munich (Chairman); Prof. Dr. Thomas Kohnen, Frankfurt (Deputy Chairman); Prof. Dr. Michael C. Knorz, Mannheim (Recording Secretary); Prof. Dr. Gernot Duncker, Halle; Prof. Dr. Ekkehard Fabian, Rosenheim; Prof. Dr. Rudolf Guthoff, Rostock; Prof. Dr. Markus Kohlhaas, Dortmund; Dr. Kaweh Schayan-Araghi, Dillenburg.

In consultation with board of DOG and BVA the Committee has the following tasks:

1. to evaluate the known refractive surgical interventions according to the current state of scientific knowledge
2. to elaborate guidelines for the quality assurance of new procedures in anticipation to the structural, process and result quality as stipulated by the Bundesärztekammer (German Medical Association)
3. to hold theoretical and practical courses according to the guidelines of quality assurance.

Evaluation of refractive surgical interventions

For the evaluation of refractive surgical interventions the following criteria are presented on the basis of published works in scientific literature:

- Description
- Field of Application and Limit of Application
- Secondary Effects

The field of application in the sense of these guidelines describes the area in which the respective intervention is considered applicable and where secondary effects are rare. The general requirements concerning patient information apply.

The limit of application in the sense of these guideline describes the area in which the respective intervention may still be applied but with decreasing results and increasing secondary effects. For the limit of application extended requirements concerning patient information apply.

Beyond the field and limit of application the respective surgery cannot be recommended.



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1. Excimer-Laser Korrektur von Brechkraftfehlern

Mit sog. Excimer-Laser lassen sich extrem dünne Gewebsschichten je Laserpuls abtragen. Durch die geeignete Aneinanderreihung vieler solcher Pulse in der Fläche und der Tiefe des Hornhautgewebes lässt sich die Hornhautoberfläche über einen bestimmten Bereich so formen, dass sich ihre Brechkraft verändert. Dies ermöglicht die Korrektur von Brechungsfehlern des gesamten Auges. Die Excimer-Laserchirurgie wird in zwei wesentlichen Varianten angewandt:

1.1. Surface Treatment (Photorefractive Keratectomy (PRK) respectively LASEK or Epi-LASIK

Description

As a first step, the surface of the cornea, the epithelium, is mechanically removed. In a next step the excimer laser will ablate the corneal centre to correct the eye's refractive error. Within a few days, the epithelium will regenerate under a contact lens and the superficial wound will close up. PRK, LASEK and EpiLASIK are generally comparable.

Field of Application

Treatment of myopia up to -6 dpt and of astigmatism up to 5 dpt. For the assessment of myopic astigmatism it is necessary to add the up the values of myopia and astigmatism.

Limit of Application

Treatment of myopia up to -8 dpt, astigmatism up to 6 dpt, hyperopia up + 4 dpt. To determine the upper limits, the limit values of the corresponding principal meridian with the highest refractive index must be observed. (e.g. +4 sph with -6 cyl respectively -4 sph with +6 cyl falls within the field of application, 0 sph with +6 cyl respectively with -6 cyl falls outside the field of application.)

Secondary Effects

in the first days after PRK, LASEK or Epi-LASIK vision is reduced and normally a moderate discomfort and in the exceptional case also stronger pain is prevailing. Generally it can be said, that the complication rate is increasing according to the extent of the required correction. As possible secondary effects patients may experience superficial scarring of the cornea (haze), a partial regression of the surgical effects during the first weeks and months and a decreased visual acuity at dawn or at night, with halos and ghosting, especially in patients with wide pupils. Furthermore, a frequent although transient effect is an increasing dryness of the eyes. Further, extremely rare side effects are infection and an extensive scarring with considerable visual impairment.

Contraindications

Chronic progressive corneal diseases, treatments of patients under the age of 18, symptomatic cataract, glaucoma with pronounced visual field defects and exsudative macular degeneration.

1. 2. Laser in situ Keratomileusis (LASIK) and Femto-LASIK

Description

In LASIK, the surgeon cuts a thin corneal flap of app. 0,15 mm with a microkeratome. The flap remains attached to the cornea by a thin hinge of tissue and is folded back like a lid. In Femto-LASIK the microkeratome is replaced by the femtosecond laser. In the subsequent step, the interior of the cornea is ablated with the excimer laser in order to correct the ametropia. Once this is done, the corneal flap is repositioned over the treated area. It remains in position by natural adhesion and no suture is necessary.

Field of Application

Treatment of myopia up to -8 dpt, astigmatism up to 5 dpt and hyperopia up to +3 dpt. For the determination of the upper limits, the limit values of the corresponding principal meridian with the highest refractive index must be observed (e.g. 3 sph with -5 cyl respectively -3 sph with +5 cyl falls within the field of application, 0 sph with +5 cyl respectively +5 sph with -5 cyl falls outside the field of application).

Limit of application

Treatment of myopia up to -10 dpt, astigmatism up to 6 dpt, hyperopia up + 4 dpt. To determine the upper limits, the limit values of the corresponding principal meridian with the highest refractive index must be observed. (e.g. +4 sph with -6 cyl respectively -4 sph with +6 cyl falls within the field of application, 0 sph with +6 cyl respectively with -6 cyl falls outside the field of application.)



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Secondary Effects

During the first hours after LASIK respectively Femto-LASIK vision is reduced and normally a moderate discomfort is prevailing. Generally it can be said, that that the complication rate is increasing according to the extent of the required correction. As possible secondary effects patients may experience a partial regression of the surgical effects during the first weeks and a decreased visual acuity at night, with halos and ghosting, especially in patients with wide pupils. Furthermore, a frequent although transient effect is an increasing dryness of the eyes. Rarely when cutting the corneal lap, an epithelium detachment and cutting errors may occur. A light wrinkling of the lap is a very rare side effect of wound healing. Extremely rare side effects are sterile inflammatory reactions of wound healing, an infection with extensive corneal scarring as well as an impairing and bulging cornea (keratectasia) with an explicit visual impairment.

Contraindications

Pre-operative corneal thickness under 500 μm , size of the corneal stroma under the flap after ablation under 250 μm , chronic progressive corneal diseases and forme fruste of keratoconus, treatment of patients under the age of 18, symptomatic cataract, glaucoma with pronounced visual field defects and exsudative macular degeneration.

2. Conductive Keratoplasty (CK)

Description

In CK a thin probe applies 8 - 16 spots of heat of about 0,3 mm in the medium periphery of the cornea. This causes the cornea to shrink in these spots and as a result, the cornea is reshaped to have more curvature. Thus hyperopia can be corrected.

Field of Application

Treatment of hyperopia up to +1,5 dpt respectively unilateral treatment of presbyopia up to + 1,5 dpt.

Limit of application

Treatment of hyperopia up to +2,5 dpt respectively unilateral treatment of presbyopia up to + 2,5 dpt.

Secondary Effects

During the first hours a moderate discomfort may be prevailing. Typically an overcorrection is caused, the former hyperopic initially will become myopic. Furthermore, in some cases astigmatism with a decreased visual acuity and a partial regression of the surgical effects may prevail during the first months and years.

Contraindications

Chronic progressive corneal diseases, treatments of patients under the age of 18 and symptomatic cataract.

3. Astigmatic Keratotomy (AK) and Limbal relaxing incisions (LRI)

Description

In AK or LRI one or two deep arcuate incisions are applied to the cornea with a diamond knife thus relaxing the cornea in the axis of astigmatism and reducing the astigmatism.

Field of Application

Reduction of astigmatism especially after cataract surgery or after keratoplasty. However, in most cases the exactitude is insufficient for a complete correction.

Secondary Effects

In some cases an irregular astigmatism may result. Furthermore, epithelial growth in the cuts is possible. In extremely rare cases the eye may be perforated.

Contraindications

Chronic progressive corneal diseases and treatments of patients under the age of 18.



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4. Intracorneal Ring Segments

Description

After small tunnel incisions are made on the outer edge of the cornea mechanically or with a femtosecond laser, the crescent-shaped plastic rings of acrylic glass (PMMA) are placed in the eye.

Field of Application

Stabilisation of the cornea for patients with keratoconus or keratectasia and after decentered laser ablations, if contact lenses cannot provide a satisfactory correction

Limit of Application

In exceptional cases correction of low myopia.

Secondary Effects

Possible secondary effects are optical side effects such as the perception of halos and an increased sensitivity to light, a regression of the surgical effects, infection with scarring as well as corneal melting with ring rejection.

Contraindications

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

5. Cornea Cross Linking

Description

After mechanical ablation of the corneal epithelium Riboflavin drops are applied to the cornea, which is then activated for about 30 minutes by ultraviolet light to irrigate the cornea in order to stop chronic progressive corneal diseases.

Field of Application

Keratoconus which may not be corrected with spectacles or contact lenses.

Limit of Application

At the moment, the treatment of keratectasy after LASIK in patients which may not be treated with contact lenses, is examined in prospective studies. Outside these studies cornea cross linking can not be recommended for the treatment of keratectasy after LASIK.

Secondary Effects

Sterile inflammations as well as infections with scarring are possible. If the thickness of the cornea is insufficient, a possible damaging of the endothelium with opacification of the cornea is possible.

Contraindications

Corneal thickness under 400 µm, as the endothelium may be damaged.

6. Implantation of intraocular lenses in phaco eyes (phaco IOLs)

Description

In phaco IOLs, the surgeon makes a small incision at the edge of the cornea and an additional lens (phaco IOL) is implanted, comparable to a contact lens. This additional lens is fixated to the iris or to the peripheral portion of the anterior chamber (iridocorneal angle). Other models are behind the iris on the lens like contact lenses. After implantation of the IOL, the cut will seal up by itself or it will be sutured.

Field of Application

Myopia from -8 dpt and hyperopia from +4 dpt. In case of myopic astigmatism or remaining ametropia after implantation of the phaco IOL additional laser treatment according to 1.1. respectively 1.2 may be applied.

Limit of Application

Myopia from -5 dpt and hyperopia from +3 dpt.

Secondary Effects

Rare cases show a paroxysmal increase of intraocular pressure (acute congestive glaucoma), damaging of the corneal endothelium with opacification of the cornea, pupil distortion, lens opacification (cataract), dislocation or loosening of the artificial lens as well as chronic inflammation of the eye. Furthermore, among others, retinal detachment especially after treatment of myopia and bacterial infections has been described. As during the operation the eye is opened, in extremely rare cases infection may cause blindness.

Contraindications

Treatment of patients under the age of 18, glaucoma with pronounced visual field defects, pre-existing corneal damage with significantly reduced number of endothelial cells, insufficient anterior chamber depth and symptomatic cataract.



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7. Refractive Lens Exchange (RLE) for the treatment of ametropia

Description

In RLE the eye is opened at the edge of the cornea and, as in modern cataract surgery, the lens is removed and then replaced with an artificial lens. The artificial lens either has one focus (monofocal IOL) or two or more focuses (multifocal IOL).

Field of Application

Myopia and hyperopia with simultaneous presbyopia. In case of simultaneous astigmatism or remaining ametropia after RLE additional laser treatment according to 1.1. respectively 1.2 may be applied.

Limit of Application

Presbyopia without further ametropia.

Secondary Effects

After treatment with monofocal IOLs reading spectacles are necessary. After treatment with multifocal IOLs patients generally will need neither reading nor long-distance spectacles. However, decreased visual acuity at dawn with halos and glares may be observed. During months up to years after RLE a secondary opacity behind the new artificial lens (secondary cataract) may occur but can be treated by laser without the necessity of re-opening the eye. Furthermore, among others, retinal detachment especially after treatment of myopia and bacterial infections has been described. As during the operation the eye is opened, in extremely rare cases infection may cause blindness.

Contraindications

Treatment of patients under the age of 18.

Medical Fees

The diagnostics of refractive ametropia and its treatment with spectacles or contact lenses are covered by health insurance. As a basic principle, refractive-surgical care and associated possible pre- and postoperative additional medical services are not covered by health insurance. A certificate of disability may not be issued as according to the current interpretation of law disability with an absence of complications is self-inflicted and thus there is no entitlement to continuation of pay.

Refractive surgery has been included in the catalogue of medical services not covered by health plans and paid for by the patient (IGEL) issued by the Kassenärztliche Bundesvereinigung (National Association of Statutory Health Insurance Physicians). Furthermore, according to Annex B of the "Guidelines on the Evolution of Medical Examination and Treatment Methods" as per § 135 para 1 SGB V (BUB Guidelines) of 10 December 1999, issued by the Bundesausschuss der Ärzte und Krankenkassen (Federal Committee of Physicians and Sick Funds), it ranks among "methods which may not be performed at the expense of health funds" (published in Deutsches Ärzteblatt 2000; 97:A-864 – A-868).

According to the GOÄ (Physician Fee Schedule), the extensive consultation with the patient before refractive surgery including eventually necessary additional examinations and, if necessary, the referral to an adequate surgeon shall be invoiced directly by the performing ophthalmologist; it is not admissible that the surgeon reimburses parts of the fee to the remitter. For the payment of the surgery itself, the GOÄ regulations together with analogous numerals shall be applied. The Bundesärztekammer (German Medical Association) has issued recommendations (e.g. for PRK or PTK number A 5855, for LASIK number 1345 in combination with analogous numeral A 5855).

As refractive surgery is no cosmetic surgery, the treatment of eventual postoperative complications may be settled by the statutory health insurance. In absence of complications it may be assumed that the treatment is completed three months after a refractive surgery. According to the current interpretation of law, the treatment may then be continued at the expense of the statutory health insurance.



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Quality Assurance Guidelines

Excimer-Laser Surgery (PRK, LASEK, Epi-LASEK and Femto-LASIK)

1. Structural Quality

1.1 Personal Qualification

Excimer laser surgery is an ophthalmologic invasive surgical intervention requiring special expertise. The general regulations for the quality assurance of outpatient operations of the Bundesärztekammer (German Medical Association) shall apply. Furthermore the following requirements must be met:

- Participation in a theoretical course (basic course and advanced course) accredited by and organised in co-operation with the KRC
- Participation in a wetlab accredited by the KRC
- Sitting in on a trainer accredited by the KRC
- First surgeries in presence of a trainer accredited by the KRC

The training according to 1.1 will be certified by the KRC. The training guidelines according to 1.1. are applicable for all refractive surgeons who want to be specified by name in the register of refractive surgeons accredited by the KRC. It is a precondition that the applicant is officially approved as a specialist in ophthalmology.

1.2 Technical requirements

- According to § 6 of the "Laser Accident Prevention Regulation", the nomination of a laser safety specialist is required.
- Before each surgery, the users must assure themselves that the laser and the used keratome dispose of the required functions.

1.3 Location requirements

- The surgery shall comply with the "Laser Accident Prevention Regulation"
- The minimum requirements of the structural, technical and hygienic equipment according to annexe 1 of the "Guidelines of the German Medical Association for the Quality Assurance of Outpatient Operations" of April 13, 1994 shall be met.

2. Process Quality

2.1 Patient information

Each user shall give his patients extensive preoperative information on the planned surgery.

The following preoperative examinations shall be executed and documented:

- Corneal topography examination with computer-aided videokeratoscopy
- Examination of the uncorrected and corrected visual acuity, if necessary after paralysis of the accommodation
- Ophthalmotometry
- Measurement of pupil diameter (photopic and skotopic)
- Aniseikonia in anisometropia as well as determination of the compatibility of the planned correction by wearing of contact lenses
- Examination of the anterior and posterior eye segments under medicamentous mydriasis
- Corneal thickness measurement (pachymetry)
- Exclusion of medical contraindications

2.2 Postoperative Diagnostics (see also 3.1)

Regular postoperative ophthalmological check-ups shall be executed and documented. As minimum requirements they must include:

- Corneal topography examination with computer-aided videokeratoscopy (per minimum once within the first 12 postoperative months)



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- Examination of the uncorrected and corrected visual acuity
- Ophthalmotometry
- Examination of the anterior and posterior eye segments

If the surgeon is not the treating ophthalmologist, their co-operation shall be assured.

2.3 Surgery

Basically and essentially the following minimum requirements shall be observed:

- Local anaesthesia (drop anaesthesia)
- Keratotomy or epithelium ablation under aseptic conditions with sterile instruments
- Diameter of the corrected zone not under 6 mm
- After post-operative-treatment the residual corneal thickness may not go below 250 μ for the stromal bed
- After-treatment with antibiotic and steroid eye drops for a minimum for 5 days

3. Outcome quality

3.1 Documentation

The documentation of the treatments results must contain at least the diagnostic findings and the surgery data according to the examinations under 2.2. and 2.3.

3.2 Continuing Medical Education

A continuing medical education is required and may be obtained among others by attending a KRC continuation or advanced course per calendar year.

3. Refractive Surgeons Registers

Upon request, all users meeting the requirements as per 4.1 will be specified by name in an official register of refractive surgeons. The users will be on the register for one calendar year at a time. For an extension, the requirements as per 4.2. shall be promptly provided until 15 December of the current year. Nevertheless, the re-admission to the register is possible at any time for users having once met the requirements as per 4.1. and who have already been on the list. In this case only the requirements as per 4.2 must be accounted for.

As institutions of research and education the university eye clinics upon request may be included in a separate register of university eye clinics without naming of their relevant specialists. The register of refractive surgeons will be updated every 3 months (31.3., 30.6., 30.9., 31.12.). It is available via the BVA office and on the BVA homepage.

4.1. Requirements for the Admission into the Refractive Surgeons Register

- Certificate of training according to 1.1. of these guidelines
- Written declaration, that the user will observe the guidelines of quality assurance (forms to be obtained via the KRC)

4.2 Requirements to remain on the Refractive Surgeons Register

- Participation in a KRC continuation or advanced course per calendar year
- Treatment according to 2.1 – 2.4 of the guidelines. If it is obvious that this is not the case, a written reminder will be sent and in case of further non-observance the user will be deleted from the register for the period of one year. Re-admission will be possible upon request if the requirements as per 4.2. are accounted for.

4.3 Certificate

Upon request a certificate may be issued if all requirements as per 4.1. are met.



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Quality Assurance Guidelines
Conductive Keratoplasty (CK)
Astigmatic Keratotomy (AK) and Limbal relaxing incisions (LRI)
Intracorneal Ring segments

1. Structural Quality

1.1 Personal Qualification

CK, AK, LRI and intracorneal ring segments are ophthalmologic invasive surgical interventions requiring special expertise. The general regulations for the quality assurance of outpatient operations of the Bundesärztekammer (German Medical Association) shall apply. Furthermore, the following requirements must be met:

- Participation in a theoretical course (basic course and continuation course) accredited by and organised in co-operation with the KRC
- Participation in a wetlab accredited by the KRC
- Sitting in on a trainer accredited by the KRC
- First surgeries in presence of a trainer accredited by the KRC

The training according to 1.1. will be certified by the KRC. The training guidelines according to 1.1. are applicable for all users who want to be specified by name in the register of refractive surgeons accredited by the KRC. It is a precondition that the applicant is officially approved as a specialist in ophthalmology.

1.2 Technical requirements

- Before each surgery the users must assure themselves that necessary equipment disposes of the required functions.

1.3 Location requirements

- The minimum requirements of the structural, technical and hygienic equipment according to annexe 1 of the "Guidelines of the German Medical Association for the Quality Assurance of Outpatient Operations" of 13 April 1994 shall be met.

2. Process Quality

2.1 Patient information

Each user shall give his patients extensive preoperative information on the planned surgery.

2.2 Preoperative diagnostics

The following preoperative examinations shall be executed and documented:

- Corneal topography examination with computer-aided videokeratoscopy
- Examination of the uncorrected and corrected visual acuity, if necessary after paralysis of the accommodation
- Ophthalmotonometry
- Examination of the anterior and posterior eye segments under medicamentous mydriasis
- Corneal thickness measurement (pachymetry) also peripheral
- Exclusion of medical contraindications

2.3 Postoperative Diagnostics (see also 3.1)

Regular postoperative ophthalmological check-ups shall be executed and documented. As minimum requirements they must include:

- Corneal topography examination with computer-aided videokeratoscopy
- Examination of the uncorrected and corrected visual acuity
- Examination of the anterior and posterior eye segments



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If the surgeon is not the treating ophthalmologist, their co-operation shall be assured.

2.4 Surgery

Basically and essentially the following minimum requirements shall be observed:

- Local anaesthesia (drop anaesthesia)
- Keratotomy or epithelium ablation under aseptic conditions with sterile instruments
- After-treatment with antibiotic eye drops

3. Outcome quality

3.1 Documentation

The documentation of the treatments results must contain at least the diagnostic findings and the surgery data according to the examinations under 2.2. and 2.3.

3.2 Continuing Medical Education

A continuing medical education is required and may be obtained among others by attending a KRC continuation or advanced course per calendar year.

4. Lists of refractive surgeons

Upon request, all users meeting the requirements as per 4.1 will be specified by name in an official register of refractive surgeons. The users will be on the register for one calendar year at a time. For an extension, the requirements as per 4.2. shall be promptly provided until 15 December of the current year. Nevertheless, the re-admission to the register is possible at any time for users having met once the requirements as per 4.1. and who have already been on the list. In this case only the requirements as per 4.2 must be accounted for.

As institutions of research and education the university eye clinics upon request may be included in a separate register of university eye clinics without naming of their relevant specialists. The register of refractive surgeons will be updated every 3 months (31.3., 30.6., 30.9., 31.12.). It is available via the BVA office and on the BVA homepage.

4.1 Requirements for the admission into the register of refractive surgeons

- Certificate of training according to 1.1. of these guidelines
- Written declaration, that the user will observe the guidelines of quality assurance (forms to be obtained via the KRC)

4.2 Requirements to remain on the register of refractive surgeons

- Participation in a KRC continuation or advanced course per calendar year
- Treatment according to 2.1 – 2.4 of the guidelines. If it is obvious that this is not the case, a written reminder will be sent and in case of further non-observance the user will be deleted from the register for the period of one year. Re-admission will be possible upon request if the requirements as per 4.2. are accounted for.

4.3 Certificate

Upon request a certificate may be issued if all requirements as per 4.1. respectively 4.2 are met.



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Quality Assurance Guidelines Phaco IOLs, Refractive Lens Exchange (RLE)

1. Structural Quality

1.1 Personal Qualification

The implantation of phaco IOLs and the refractive lens exchange are ophthalmologic invasive surgical interventions requiring special expertise. The general regulations for the quality assurance of outpatient operations of the Bundesärztekammer (German Medical Association) shall apply. Furthermore, the following requirements must be met:

- Participation in a theoretical course (basic course and continuation course) accredited by and organised in co-operation with the KRC
- Participation in a wetlab accredited by the KRC
- Sitting in on a trainer accredited by the KRC
- First surgeries in presence of a trainer accredited by the KRC

The training according to 1.1. will be certified by the KRC. The training guidelines according to 1.1. are applicable for all users who want to be specified by name in the register of refractive surgeons accredited by the KRC. It is a precondition that the applicant is officially approved as a specialist in ophthalmology.

1.2 Technical requirements

- Before each surgery the users must assure themselves that necessary equipment disposes of the required functions.

1.3 Location requirements

- The minimum requirements of the structural, technical and hygienic equipment according to annexe 1 of the "Guidelines of the German Medical Association for the Quality Assurance of Outpatient Operations" of 13 April 1994 shall be met.

2. Process Quality

2.1 Patient information

Each user shall give his patients extensive preoperative information on the planned surgery.

2.2 Preoperative diagnostics

The following preoperative examinations shall be executed and documented:

- Corneal topography examination with computer-aided videokeratoscopy
- Examination of the uncorrected and corrected visual acuity, if necessary after paralysis of the accommodation
- Ophthalmotometry
- Measurement of pupil diameter (photopic and skotopic)
- Aniseikonia in anisometropia as well as determination of the compatibility of the planned correction by wearing of contact lenses
- Examination of the anterior and posterior eye segments under medicamentous mydriasis
- Anterior chamber depth measurement
- Measurement of axial length
- Exclusion of medical contraindications

2.3 Postoperative Diagnostics (see also 3.1)

Regular postoperative ophthalmological check-ups shall be executed and documented. As minimum requirements they must include:

- Corneal topography examination with computer-aided videokeratoscopy (per minimum once within the first 12 postoperative months)
- Examination of the uncorrected and corrected visual acuity



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- Ophthalmotonometry
- Examination of the anterior and posterior eye segments

If the surgeon is not the treating ophthalmologist, their co-operation shall be assured.

2.4 Surgery

Basically and essentially the following minimum requirements shall be observed:

- Local anaesthesia (drop anaesthesia)
- Surgery under aseptic conditions with sterile instruments
- After-treatment with antibiotic and steroid eye drops

3. Outcome quality

3.1 Documentation

The documentation of the treatments results must contain at least the diagnostic findings and the surgery data according to the examinations under 2.2. and 2.3.

3.2 Continuing Medical Education

A continuing medical education is required and may be obtained among others by attending a KRC continuation or advanced course per calendar year.

4. Lists of refractive surgeons

Upon request, all users meeting the requirements as per 4.1 will be specified by name in an official register of refractive surgeons. The users will be on the register for one calendar year at a time. For an extension, the requirements as per 4.2. shall be promptly provided until December 15 of the current year. Nevertheless, the re-admission to the register is possible at any time for users having met once the requirements as per 4.1., who have already been on the list. In this case only the requirements as per 4.2 must be accounted for. As institutions of research and education the university eye clinics upon request may be included in a separate register of university eye clinics without naming of their relevant specialists. The register of refractive surgeons will be updated every 3 months (31.3., 30.6., 30.9., 31.12.). It is available via the BVA office and on the BVA homepage.

4.1 Requirements for the admission into the register of refractive surgeons

- Certificate of training according to 1.1. of these guidelines
- Written declaration, that the user will observe the guidelines of quality assurance (forms may be obtained via the KRC)

4.2 Requirements to remain on the register of refractive surgeons

- Participation in a KRC continuation or advanced course per calendar year
- Treatment according to 2.1 – 2.4 of the guidelines. If it is obvious that this is not the case, a written reminder will be sent and in case of further non-observance the user will be deleted from the register for a period of one year. Readmission will be possible upon request if the requirements as per 4.2. are accounted for.

4.3 Certificate

Upon request a certificate may be issued if all requirements as per 4.1. respectively 4.2 are met.