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Clinical consensus for refractive surgery Compiled by the Czech Society of Refractive and Cataract Surgery

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METHODOLOGY

Dokument byl vytvořen jako konsensuální doporučený postThe document was compiled as a consensual recommended procedure, without the use of the rigorous analytical methods (Delphi method, formal group technique or method RAND/UCLA/), on which the methodology is nevertheless based. A team of refractive surgeons was chosen by the board of directors of the Czech Society of Refractive and Cataract Surgery (CSRCS) in such a manner as to represent workers from clinics, hospitals and private centres. The team leader processed the first document according to available evidence of variable quality. Attention was paid to the recommended procedures based on the highest quality evidence, i.e. randomised controlled trials. In creating the recommended approach the team leader also worked with the document Refractive Errors & Refractive Surgery PPP (Preferred Practice Pattern 2013) – American Academy of Ophthalmology and Bewertung und Qualitätssicherung refraktiv -chirurgischer Eingriffe durch DOG und BVA 2014, Kommission Refraktive Chirurgie der DOG und des BVA. The chief resolver drafted a proposal for consensus and sent it by e-mail to the members of the commission for assessment. This proposal and the comments thereon were debated within the framework of the panel discussion held on 20 May 2016 during the course of the CSRCS congress. On the basis of the consensus reached, the chief resolver compiled the definitive document, which shall be published in the journal Czech and Slovak Ophthalmology.

Aim of consensus

The aim of the consensus is an agreement between experts on the current procedures relating to refractive surgery. It processes information about indications, preoperative examination, our own surgical procedure and postoperative care in order to create the preconditions for improving patient care, both in the sense of improving objective results and reducing complications, and in the sense of increasing patient satisfaction.

The consensus is not a binding document in the legal sense. The document is not processed in such a manner as to provide the basis for evaluating the quality of care. The consensus does not deal with cost effectiveness. It does not contain information for patients.

Who is the consensus designated for?

The consensus is designated for surgeons who perform refractive procedures and doctors working in facilities in which these procedures are performed.

Patients and surgical procedures to which the consensus relates

The procedures are designated for adult individuals with a refractive error who have not previously undergone any eye operation, and who do not have any other ocular pathology. Only surgical procedures in which effectiveness and safety are demonstrated in practice are listed.

Sponsor and financing

The sponsor for the compilation of the consensus is CSRCS, which is the sole financier of this project.

Resolving team

Leader: Professor Pavel Kucyhnka, Department of Ophthalmology, 3rd Faculty of Medicine, Charles University and Královské Vinhorady University Hospital Prague

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Recommended period of validity of Consensus

To end of 2019.

Definition of refractive surgery and its types

Refractive surgery improves the refractive condition of the ametropic eye and thereby removes or reduces the necessity for correction of refractive error with the aid of glasses or contact lenses. Refractive surgery addresses all types of refractive errors and presbyopia. The principle of refractive surgery is adjustment of refraction caused by a procedure on the cornea, or adjustment of refraction by means of implantation of an intraocular lens.

In this document, a small and medium refractive error is defined in myopia up to -6.0 D, in hypermetropia up to +3.0 D, and in regular astigmatism up to 3.0 D. A high refractive error is considered to cover myopia with more than -6.0 D, hypermetropia with more than + 3.0 D and regular astigmatism with more than 3.0 D.

Presbyopia is an age related progressive loss of accommodation. Although this is not a typical refractive error, it is referred for refractive surgery due to the similar or identical methods of its correction.

Qualification of surgeon

The surgeon must be a doctor with attestation in ophthalmo-

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logy and work experience at a centre where refractive surgery is regularly performed, and where the doctor has performed refractive operations under the supervision of an experienced surgeon.

Informed consent of patient
The patient must be informed of the indication, course and postoperative care in relation to the procedure, and in addition on the doctor is obliged to respond to the patient's questions relating thereto. The patient must be informed about potential complications which may occur during the operation or postoperatively, either permanent or transitional.

We may divide surgical procedures into Corneal Procedures (1) and Intraocular Procedures (2)

1) Corneal Procedures
Surgical procedures on the surface or stroma of the cornea alter the refractive strength of the cornea, either through partial destruction of the surface or deeper part of the stroma by means of laser pulses, extirpation of the lenticule from the corneal stroma with the aid of corneal implants or incisions in the cornea. The corneal stroma is reinforced by the method of CXL (corneal collagen crosslinking).

Procedures on the cornea are performed:
a) by laser on the corneal surface.
b) by laser on the corneal stroma.
c) by intrastromal segments and rings.
d) by corneal incisions.
e) by corneal implants.
f) by the CXL method.

Preoperative examination
Visual acuity uncorrected and corrected (in hypermetropia necessary cycloplegia, in myopia optimal cycloplegia for exclusion of accommodation spasm).
Measurement of intraocular pressure.
Pachymetry.
Corneal topography and keratometry.
Measurement of pupil width.
Examination of posterior segment in mydriasis.
Monitoring of lachrymal film.

a) Superficial laser procedures
- PRK
- LASEK
- Epi-LASIK

Following mechanical or laser removal or folding of the epithelium, the optic robustness of the cornea is adjusted by means of the destruction of part of the stroma.

Indications:
Myopia up to -6.0 D
Astigmatism up to 5.0 D
Hypermetropia up to +3.0 D
Patients aged 18 years and over.

Contraindications:
Chronic progressive corneal pathology (e.g. corneal dystrophy and degeneration, condition after HSV and VZV keratitis).
Wet form ARMD.
Autoimmune disorder.

Complications:
Although complications following superficial procedures are rare, it is necessary to reckon with them because they can sometimes have permanent consequences. These include:
Under-correction or over-correction of refractive error.
Induced regular or irregular astigmatism.
Regression of refractive error.
Turbidity of superficial layers of corneal stroma (haze).
Reduced contrast sensitivity.
Onset or exacerbation of dry eye syndrome.
Recurring erosion.
Complications as a consequence of use of topical medication.
Keratitis (infectious or sterile).
Postoperative ectasia of cornea.

b) Intrastromal laser procedures
- LASIK (laser in situ keratomileusis).
- Femto LASIK.
- ReLExSMILE.

LASIK and FemtoLASIK
Microkeratome (LASIK) or femtosecond laser (FemtoLASIK) is used to create a lamella with a width of approx. 80-180 micrometres, which is then folded, and a part of the corneal stroma is removed by excimer laser in order to adjust the refractive error. The lamella is folded back, where it adheres firmly due to the activity of the corneal endothelium, without the necessity of suturing.

Indications:
Myopia up to -10.0 D.
Astigmatism up to 5.0 D.
Hyperopia up to +4.0 D.
Solution of presbyopia with the aid of monovision.
Patient aged 18 years and over.

Contraindications:
Abnormal corneal topography (mild keratoconus).
Preoperative corneal thickness of less than 500 micrometres (LASIK), less than 480 micrometres (FemtoLASIK).
Postoperative corneal thickness of 400 micrometres and less, stroma beneath lamella less than 250 micrometres.
Chronic progressive corneal pathology (e.g. corneal dystrophy and degeneration, condition after HSV and VZV keratitis).
Glaucoma with changes in the visual field.
Symptomatic cataract.
Wet form ARMD.
Autoimmune disorder.

Complications:
Under-correction or over-correction of refractive error.
Onset or exacerbation of dry eye syndrome.
Infectious or sterile keratitis (DLK).

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Ingrowth of epithelium.
Postoperative ectasia of cornea.
Striae (buckling of lamella).
Cellular detritus and presence of foreign body on interface.

ReLEx SMILE
In the corneal stroma the femtosecond laser creates a lenticular shaped lamella (lenticule), which is subsequently extracted with forceps from an incision in the cornea.

Indications:
Myopia from -3 to -10.0 D.
Astigmatism up to -6 D.
Solution of presbyopia with the aid of monovision.
Patient aged 18 years and over.

Contraindications:
Preoperative corneal thickness of less than 460 micrometres.
Postoperative corneal thickness beneath lamella less than 250 micrometres.
Chronic progressive corneal pathology.
Glaucoma with changes in the visual field.
Symptomatic cataract.
Wet form ARMD.
Autoimmune disorder.

Complications:
Rupture of lenticule.
Micro-distortion of Bowman's membrane.
Decentration of lenticule.
Infectious or sterile keratitis.
Postoperative ectasia of cornea.
Onset or exacerbation of dry eye syndrome.

Problem of re-operation
c) Intrastromal segments and rings
A microkeratome or femtosecond laser is used to create a tunnel in the cornea, into which a segment or ring is implanted. This flattens the central part of the cornea and it is thus possible to correct small to medium myopia. Upon implantation of a segment or ring into a certain segment of the cornea it is possible to correct irregular astigmatism.

Indications:
Keratoconus.
Keratectasia following previous refractive procedure.
Irregular astigmatism.

Contraindications:
Corneal thickness in place of planned insertion of segment or ring less than 300 micrometres.

Complications:
Infectious or sterile keratitis.
Defect of epithelium above implant.
Expulsion of implant.

d) Corneal incisions
- Arcuate keratotomy (AK).
- Limbal relaxation incision (LRI).

The techniques of AK and LRI are used to perform deep, curved incisions with a metal knife, diamond knife or femtosecond laser in the central periphery or corneal limbus. The cornea is flattened by the incision in the axis of astigmatism, and astigmatism is eliminated or reduced.

Indications:
Elimination or reduction of primary and residual astigmatism (frequently in combination with cataract surgery or after keratoplasty).
Patient aged 18 years and over.

Contraindications:
Chronic progressive corneal pathology (e.g. corneal dystrophy and degeneration, condition after HSV and VZV keratitis).

Complications:
Regression of astigmatism.
Perforation of cornea.
Epithelial ingrowths.
Irregular astigmatism.
Re-correction especially in incisions following keratoplasty.
Infectious keratitis.

e) Corneal implants (KAMRA, FlexiVue Microlens and Raindrop).
Implants with a size of 2-4 mm are implanted into a corneal capsule formed by a femtosecond laser, into the anterior part of the stroma, usually in the non-dominant eye, for correction of presbyopia.

Indications:
Presbyopia in emmetropia in non-dominant eye.
Combination with LASIK method is possible.
Patient aged 18 years and over.

Contraindications:
Chronic progressive corneal pathology.
Symptomatic cataract.
Wet form ARMD.

Complications:
Decentration of implant.
Sterile and infectious keratitis.
Expulsion of implant.
Fibrotisation on interface.
Reduction of visual acuity.

f) CXL (corneal collagen crosslinking).
Following mechanical removal of the epithelium Riboflavin drops are applied to the cornea, which is radiated for 30 minutes or less by UV-A light. The effect of CXL reinforces the stroma and halts or retards further buckling of the cornea.

Indications:

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Stabilisation of buckling of the cornea in keratoconus.
Halting of progression of keratectasia following LASIK.

Contraindications:
Corneal thickness less than 400 micrometres (with the exception of epi-on technique and with the use of hypotonic solution).

Complications:
Sterile and infections keratitis.
Damage to endothelium.
Turbidity of superficial layers of corneal stroma (haze).
Edema of corneal stroma.
Corneal epithelium not healing.

2) Intraocular procedures
In these procedures a further lens is implanted into the phakic eye (phakic intraocular lens), or a transparent lens is replaced with an artificial intraocular lens (CLE-clear lens extraction).
Preoperative examination
Examination of objective and subjective refraction (pay attention to the distance between the anterior surface of the cornea and the posterior surface of the lens of the glasses – vertex distance).
Measurement of intraocular pressure.
Corneal topography and keratometry.
Measurement of pupil size.
Examination of depth of anterior chamber.
Calculation of dioptric value of phakic lens using calculator.
Determination of density of endothelial cells and pachymetry.
Determination of angle-angle or sulcus-sulcus distance.
Examination of lachrymal film.
Examination of ocular fundus in mydriasis.

a) Implantation of phakic intraocular lens
In this procedure a phakic lens is implanted, which is placed in the chamber angle, on the iris, or behind the iris into the posterior chamber. The wound is then sealed with the aid of BSS or closed by suturing.

Indications:
Myopia -6 dpt and more
Hyperopia +4.0 D and more.
Patient aged 18 years and over.

Contraindications:
Glaucoma with changes in visual field.
Number of endothelial cells 2000/mm or less.
Depth of anterior chamber 2.8 mm or less.

Complications:
Increase of intraocular pressure.
Decrease of endothelial cells, especially in anterior chamber phakic lenses.
Ovalisation of pupil in lenses fixed in chamber angle.
Generation of cataract, especially in the case of lenses placed behind iris into posterior chamber.
Retinal detachment, primarily in correction of myopia.
Acute or chronic endophthalmitis, in extremely rare cases leading to blindness of eye.
Decentration, dislocation of implant, especially in anterior chamber lenses.

b) Replacement of transparent lens with artificial intraocular lens (CLE)
In this operation a clear lens is removed by a modern technique of cataract surgery and replaced with an artificial intraocular lens.

Used lenses:
ba) Monofocal (monofocal toric) – both may be aspherical.
bb) Multifocal aspherical (multifocal aspherical toric).
bc) Accommodative.
ba) monofocal lens (aspheric/toric) indications:
High myopia -6 D and more and hyperopia accompanied with presbyopia.
High hyperopia +4 D and more and high myopia -6 D and more without presbyopia.

Contraindications:
Patient aged 18 years or less.

Complications:
Similar to in cataract surgery (see Standard for diagnosis and treatment: Adult cataract, Czech and Slovak Ophthalmology, 5, Supplement, 2016).

bb) multifocal lens – indications:
Presbyopia upon emmetropia.
High myopia -6 D and more.
High hyperopia +4 D and more without presbyopia.

Contraindications:
Patient aged 18 years or less.

Complications:
Similar to in cataract surgery (see Standard for diagnosis and treatment: Adult cataract, Czech and Slovak Ophthalmology, 5, Supplement, 2016).