

# Evidence-based guidelines for cataract surgery: Guidelines based on data in the European Registry of Quality Outcomes for Cataract and Refractive Surgery database

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In March 2008, the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) commenced. This 3-year project was cofunded by the European Union (EU) and the European Society of Cataract & Refractive Surgeons (ESCRS). The ESCRS became the lead partner in the project with 11 national societies as associated partners. The aims of the project were to improve treatment and standards of care for cataract and refractive surgery and to develop evidence-based guidelines for cataract and refractive surgery across Europe. Surgeons from all participating societies contributed to the database, which contained data on 820 000 cataract surgeries in November 2011. The present guidelines are based on data entered from January 1, 2009, to August 28, 2011 (523 921 cataract extractions). The guidelines include only those steps in the cataract surgery process that can be analyzed by the database.

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In 2007, the European Society of Cataract & Refractive Surgeons (ESCRS) applied for a European Union (EU) grant with the purpose of improving the quality of cataract and refractive surgery. The society decided to take this action for many reasons. These included

growing health tourism within the field, increasing patient complaints after refractive surgery, and a rapid technical development of the surgical procedures. In addition, the ESCRS, as a society for professionals, felt a responsibility to improving quality of care for patients.

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The philosophy behind the project was to create a database for learning and quality improvement, not for supervision. Following a successful EU grant application, a cofunded EU project between the ESCRS and the EU commenced on March 1, 2008. The 3-year project was named EUREQUO, an acronym for European Registry of Quality Outcomes for Cataract and Refractive Surgery. The EU funding was under the Public Health Program run by the Executive Agency for Health and Consumers.

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The ESCRS became the lead partner in the project and 11 national societies supported the project as associated partners. The EUREQUO system involves collecting data for the purpose of quality control. Because a substantial number of users was required and entering data via web forms for each patient was time consuming, the number of variables were

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kept low; only a few appropriate and important variables were included.

The goal in both cataract and refractive surgery is to obtain optimal visual acuity and optimal refraction and to avoid complications. The EUREQUO system collects data on achieved visual acuity, achieved refraction including difference between target refraction and final refraction, and surgical complications. For benchmarking purposes, it also collects data on important case-mix variables. This means that differences in preoperative patient characteristics can be adjusted in benchmarking. Furthermore, demographic data are needed for this kind of database. Online coding guidelines describe the meaning of variables in the system.

## BASIS OF THE GUIDELINES

One purpose of the EUREQUO project was to create evidence-based guidelines for cataract surgery based on EUREQUO data. Cataract surgery guidelines could include detailed information on every step in the cataract surgery process. Such a document has recently been published by The Royal College of Ophthalmologists in the United Kingdom (September 2010).<sup>A</sup> The aim of the EUREQUO project was to document only those steps in the cataract surgery process that could be analyzed by the database. These steps include the following: first- or second-eye surgery; outpatient or inpatient surgery; demographic data; preoperative examination (visual acuity, refraction); ocular comorbidity; difficult surgery (complex surgery); type of anesthesia; type of surgery; type of intraocular lens (IOL) material; premium IOLs; surgical complications; visual outcome; refractive outcome; and postoperative complications. For each of these steps, the guidelines include (1) a short overview of recent literature data, (2) how the EUREQUO data fit in the overview, and (3) recommendations if any can be given.

In the present version of evidence-based guidelines for cataract surgery (August 2011), the EUREQUO data are based on surgeries reported to the database from January 1, 2009, to August 28, 2011 (study period). The total number of reported surgeries during this period was 523 921. When comparison between countries is made, only countries with more than 1000 reported surgeries are included. The total EUREQUO cataract surgery database contains over 810 000 cataract extractions (November 2011), but for the guidelines to be current, only recent data (surgeries performed after the end of 2008) are used.

## PREOPERATIVE AND INTRAOPERATIVE DATA

### First- or Second-Eye Surgery

1. Patients with cataract in both eyes benefit from surgery in both eyes according to many studies.<sup>1,2</sup>

The benefits are fewer perceived limitations to perform daily life activities<sup>2,3</sup> and better binocular function.<sup>3</sup> However, if the cataract surgery rate is very low due to economic reasons or infrastructure, best utility is achieved by first-eye surgery in as many individuals as possible.<sup>4</sup>

Same-day bilateral cataract surgery is recommended in selected cases according to some publications.<sup>5</sup> The benefits should be less cost and faster rehabilitation of the patient.<sup>6,7</sup> The risk with this approach is bilateral complications that could be avoided if the surgical strategy had been one eye at a time. The most feared complication is bilateral endophthalmitis—not because of a high incidence but because of an unexpected and spectacular course with an extremely poor outcome.

2. From 2009 to August 2011, second-eye surgery in the EUREQUO database was reported in 40.6% of cases. This number is based on 318 338 operations. Data from Holland (205 583 operations) does not include this variable (not reported to the national database). The variation between countries was 16.4% to 42.1%.

3. Cataracts in both eyes should normally lead to a cataract extraction in both eyes. However, there can be many reasons for not doing second-eye surgery. These include a satisfied patient who does not want further surgery, a patient who dies before second-eye surgery takes place, and an ocular comorbidity that makes second-eye surgery hazardous or without chance of improvement. Considering all these factors, a second-eye surgery rate of about 40% of the total cataract surgery volume seems appropriate. No general recommendations can be given concerning same-day bilateral cataract surgery; in the end, it must be a decision between the surgeon and the patient.

### Outpatient or Inpatient Surgery

1. Cataract surgery changed from an inpatient to an outpatient procedure in many countries during the 1980s.<sup>8,9</sup> Slowly, a change toward outpatient surgery occurred throughout Europe. In the 1998 European Cataract Outcome Study, inpatient surgery was reported in a mean of 28.5% of patients but the range was from 0% to 100%.<sup>10</sup> The varying rate over time from inpatient to outpatient surgery in different countries was probably due to different reimbursement rules and infrastructure/geography as well as tradition.

2. Two large contributors of data—the Dutch and Swedish cataract registries—do not contain information on inpatient or outpatient surgery. Because almost 100% of the operations in these countries are on an outpatient basis, this variable is of no interest in their

national databases. However, for other participating countries, inpatient surgery varied from 1% to 100%. Overall for these countries, the inpatient rate in the study period was 5.4%.

3. From a medical point of view, a modern cataract extraction does not imply hospital overnight care. However, in specific cases (eg, after general anesthesia or severe comorbidities including mental disorders), cataract extraction could require inpatient surgery. Tradition, reimbursement arrangements, and other administrative factors may come together to encourage general inpatient treatment of cataract surgery patients. There will be economic gains for countries if they change to outpatient surgery.

### Demographic Data

1. There is an obvious difference in the literature about sex distribution of cataract surgery. In so-called developed countries, the cataract surgery rate is higher for women<sup>11</sup> than for men; in developing countries, the opposite is true.<sup>12</sup> In Malaysia, the sex distribution is almost equal.<sup>13</sup>

2. In the study period, 60.1% of the operations were in women. The variation between participating countries was 57.3% to 63.4%. The sex distribution in cataract surgery is, among other things, related to age. Women have a longer life expectancy than men. If the mean age of the cataract surgery population is high, there will automatically be a dominance of women.

3. Patients seeking help because of cataract should be treated irrespective of sex or age.

### Preoperative Examination (Visual Acuity, Refraction)

1. An ophthalmic examination should always be performed before cataract surgery<sup>14</sup> and should include the test for corrected distance visual acuity (CDVA). Poor CDVA is the traditional reason for doing a cataract extraction. Reduced CDVA combined with cataract symptoms such as glare or symptomatic refractive difference between the eyes is also a common reason for cataract surgery. In cases involving a dense cataract, the exact refraction may be difficult to obtain. Usually, the preoperative medical records include CDVA but not necessarily the exact refraction. When using "premium" IOLs, it may also be important to test corrected near visual acuity (CNVA) and/or the corneal astigmatic refraction.

2. The EUREQUO database contains data on preoperative CDVA in the eye to be operated on. In most cases, preoperative CDVA in the fellow eye is also reported. This means that the preoperative CDVA in both eyes is available in most cases. There are no

reports of preoperative refraction in the database. In 13.0% of surgery eyes, the preoperative CDVA was 0.1 (6/60) or worse and the between-country variation, 4.3% to 38.5%. In 53.2% of surgery eyes, the preoperative CDVA was worse than 0.5 (6/12) and the between-country variation, 34.0% to 88.5%. In 78.1% of surgery eyes, the CDVA in the better eye was 0.5 or better and the between-country variation, 56.4% to 96.0%. In the upper end of good preoperative visual acuity in the eye to be operated on were country data from Denmark, Germany, Holland, and Belgium, and in the upper end of good preoperative visual acuity in the better eye were data from Belgium, Germany, and Sweden.

3. The CDVA in the eye to be operated on should always be measured. It is a good idea to also measure CDVA in the fellow eye because CDVA in the better eye suggests the visual limitations for the patient to perform daily activities. In second-eye surgery, both CDVA and refraction in the previously operated eye should be measured to obtain a desired balance or difference between the eyes.

No specific CDVA limit can be given for cataract surgery. The indication for cataract surgery should always be individually determined by the combined consequence of reduced visual acuity, perceived difficulty to perform daily life activities because of reduced sight, and disturbing cataract symptoms. However, some national guidelines focus on a visual acuity limit alone.

### Ocular Comorbidity

1. Ocular comorbidity in the eye to be operated on for cataract is a common finding. In the European Cataract Outcomes Study,<sup>10</sup> a coexisting eye disease was present in 37.5% of cases. According to the literature,<sup>15,16</sup> ocular comorbidity is a common reason for a poor self-assessed outcome of cataract extraction.

2. Recent data (study period) from the EUREQUO database with 523 921 cataract extractions showed an ocular comorbidity in 29.9% of cases. Within this number were 12.4% of cases with age-related macular degeneration and 7.7% with glaucoma.

3. An ocular comorbidity is not a contraindication for cataract surgery. However, there is much evidence that it is a common reason for a poor subjective and objective outcome. Therefore, the patient should be properly informed to prevent unrealistic expectations.

### Difficult Surgery

1. In the guidelines, difficult (complex) surgery is defined as a number of preoperative conditions making surgery more complex; eg, previous corneal refractive surgery, previous vitreous surgery, small

pupil with need for mechanical stretching, dense cataract with need for capsule staining, and corneal opacities with reduced visibility of the surgical field. Some of these conditions are related to a capsule complication during surgery.<sup>17</sup>

2. In the EUREQUO database, difficult surgery was reported in 12.2% of cases. The most common reasons were other, 6.1%; small pupil, 2.9%; dense cataract, 3.0%; corneal opacities, 1.1%; and previous vitrectomy, 0.7%. Previous corneal refractive surgery was still very rare (<0.1%). Individual surgical expertise may account for some of the responses. The variable "other" may include difficulties such as patient movements, floppy iris, and other problems that also reflect the experience of the surgeon.

3. Preoperative conditions that make surgery more difficult are not reasons for avoiding cataract surgery. Appropriate timing of surgery may prevent difficulties in cases with a progressing comorbidity. The experience of the surgeon must match the difficulties. If the outcome is doubtful, the patient must be properly informed.

### Type of Anesthesia

1. In modern cataract surgery, the purpose of anesthesia should be pain-free surgery, not immobilization of the eye and lids. The overall goal is, of course, safe surgery. There are different techniques for local anesthesia and a great variation among centers.<sup>10,18</sup>

2. The type of anesthesia was reported in 174 940 cataract extractions. The Swedish National Cataract Register (NCR) does not collect data on type of anesthesia because nearly all local anesthesia is topical. The mean percentages of different types of anesthesia in the EUREQUO database are shown in Table 1. Generally, surgeons used a single method, which means that for surgeons or sites, the percentage of different local anesthesia methods might vary between 0 and 100. The database does not contain information on assisted anesthesia.

3. General anesthesia should be used only in specific cases (confused patients, medical conditions making local anesthesia impossible, young age). The type of local anesthesia should be based on the surgeon's confidence using a specific technique. No general recommendations can be given. However, topical anesthesia seems to be easy for the patient, with very few complications, and is an inexpensive procedure.

### Type of Surgery

1. Phacoemulsification is the preferred surgical technique. However, extracapsular cataract extraction (ECCE) may be the preferred technique in specific cases.

**Table 1.** Types of anesthesia reported in the EUREQUO database.

Type of Anesthesia	Frequency (%)
General	2.7
Retrobulbar	18.3
Peribulbar	5.0
Sub-Tenon	26.2
Topical	37.9
Topical + intracameral	7.7
Other	2.2

2. Phacoemulsification was used in 99.5% of surgeries in the EUREQUO database.

3. Phacoemulsification is the surgical technique of choice. Depending on the condition of the anterior chamber, iris, and lens, an ECCE is occasionally the method of choice. These cases should be referred to surgeons familiar with this surgical procedure.

### Type of Intraocular Lens Material

1. Intraocular lenses are available in different shapes, sizes, and materials. Most are foldable and often injectable. The preferred placement of an IOL is in the capsular bag. Available IOLs change over time, depending on ongoing development by manufacturers. Some evidence suggests that hydrophobic acrylic material<sup>19</sup> and/or a square-edged optic profile<sup>20</sup> are related to less posterior capsule opacification (PCO) after surgery.

2. The only IOL-related variable in the EUREQUO database was the type of optic material. Different brands or shapes of IOLs were not reported. In the EUREQUO database, a hydrophobic acrylic IOL was implanted in 80.8% of cataract extractions, a hydrophilic acrylic IOL in 14.0%, and a silicone IOL in 3.5%. There was a certain variation among countries, but acrylic IOLs, usually hydrophobic acrylic, dominated in all countries.

3. Given literature reports and the EUREQUO database, acrylic IOLs can be recommended. Hydrophobic acrylic material may be the best recommendation at the moment, although problems exist with all types of material. Glistening is a problem with hydrophobic acrylic material.<sup>21</sup>

### Premium Intraocular Lenses

1. In the guidelines, premium IOLs are defined as multifocal, accommodating, and/or toric IOLs. An increasing number of reports in the literature concern these IOLs. However, at the moment, no IOL provides both distance vision and near vision for all types of patients. Successful IOL implantation for both distance

and near is related to the patient's visual demands and activities. Toric IOLs to correct corneal astigmatism is a promising solution, but a drawback may be changing corneal astigmatism with increasing age.

2. To date, premium IOLs appeared to be used rarely according to the EUREQUO database. Multifocal IOLs were reported in 0.2% of all cases and toric IOLs in 0.1%.

3. No general recommendations can be given. The use of premium IOLs must be related to the surgeon's experience and the patient's wishes. Informed consent is also important.

### Surgical Complications

1. The most common surgical complication involves the capsule. In the guidelines, a capsule complication is defined as a rupture of the posterior capsule with or without vitreous loss, a zonular dehiscence of at least 3 clock hours, and/or loss of lens material into the vitreous. A capsule complication is associated with a risk for poor outcome, more costs, additional care, and other subsequent complications.<sup>22,23</sup> A capsule complication has been reported in 1.9% to 5.2% of cases,<sup>24</sup> but a recent publication reports a decreasing rate of this complication over time.<sup>24</sup> Other less frequent surgical complications are iris trauma, corneal damage, and optical errors due to wrong IOL power.

2. A capsule complication was reported in 1.2% of all surgeries in the EUREQUO database. The total percentage of surgical complications was 2.3%, which included 0.2% for iris damage. The between-country variation in capsule complications (with more than 1000 reported surgeries) was 0.1% to 1.79%. However, these numbers must be interpreted carefully because in some countries, only a few centers are represented. Furthermore, this complication may be underreported in this kind of database.<sup>24</sup>

3. Capsule complications in cataract surgery cannot be completely prevented because of the variation in preoperative conditions of the eyes to be operated on. There are also surgical considerations depending on the experience of the surgeon.<sup>17</sup> However, it is important to take measures if there is an increased risk for this complication. This includes matching the suspected surgical severity with the experience of the surgeon.<sup>24</sup> A capsule complication frequency of less than 2% should be possible and desirable to achieve.

### FOLLOW-UP DATA

Complete long-term follow-up data are available for 241 136 cataract extractions (study period: January 1, 2009, to August 28, 2011). The EUREQUO database focuses on 3 important outcome measures: visual acuity, refraction, and surgical complications. The goal with cataract surgery is to obtain optimal visual

acuity, optimal refraction, and no complications. Optimal visual acuity means sight as good as the preoperative condition of the eye permits, and optimal refraction means obtaining the target refraction.

### Visual Outcome

1. Reports of visual outcomes in routine cataract surgery are scarce in the literature. For all cataract extractions, a CDVA of 0.5 or better in the operated eye was achieved by 84% of patients in one report<sup>25</sup> and by 84.5% in another.<sup>10</sup> For eyes with no ocular comorbidity, the numbers were 95.0% and 93.5%, respectively. In a recently published cohort study, 98.5% of patients with no ocular comorbidity achieved a visual acuity of 0.5 or better.<sup>26</sup>

2. Long-term follow-up data in EUREQUO mean data collected 7 to 60 days after surgery. In the EUREQUO database, 94.4% of operated eyes achieved a CDVA of 0.5 or better. This result is based on 241 136 cataract extractions reported to the database with complete long-term follow-up data. In eyes with no ocular comorbidity (N = 195 721), the number was 97.2%. These visual results are excellent.

3. An uncomplicated cataract extraction in an eye without known ocular comorbidity should theoretically achieve a CDVA of 0.5 or better in 100% of cases. However, a complication that may compromise the visual outcome occurs in 1% to 2% of cases. It should be possible to achieve a final CDVA of 0.5 or better in at least 97% of all cataract extractions in eyes with no ocular comorbidity.

### Refractive Outcome

1. In the guidelines, a biometry prediction error is defined as the difference between the target refraction and the spherical equivalent of the final refraction. The mean absolute biometry prediction error was 0.67 diopter (D) in 2002 in Sweden<sup>25</sup> and 0.71 D in 1998 in the European Outcome Study.<sup>10</sup> The percentage of cases that achieved a final refraction within  $\pm 1.0$  D of the target refraction was 79.2% and 77.2%, respectively. In a cohort study with experienced high-volume surgeons and patients with no ocular comorbidity, 97.3% of the cases achieved a final refraction within  $\pm 1.0$  D. The median absolute deviation was 0.25 D.<sup>26</sup>

2. The absolute biometry prediction error in the EUREQUO database was 0.55 D. There was significant variation between clinics when data were shown with correct signs. Some clinics have a tendency to make the patients more myopic than intended, whereas other clinics make them more hyperopic: 91.5% of the values were within  $\pm 1.0$  D.

3. A recommended refractive outcome should be an absolute mean biometry prediction error of 0.6 D or less. A biometry error with a correct sign should be centered on 0 D, and 87% or more of the values should be within  $\pm 1.0$  D of error.

### Postoperative Complications

1. The EUREQUO database collects data on postoperative endophthalmitis, PCO that disturbs vision, persistent corneal edema, uncontrolled elevated intraocular pressure (IOP), and uveitis that requires medication.

**Postoperative Endophthalmitis** This has been reported by single clinics or hospitals primarily. In a few reports, data from many clinics have been published. The ESCRS Endophthalmitis Study<sup>27</sup> reported the incidence of postoperative endophthalmitis with or without prophylactic regimens. In this randomized controlled clinical trial, the incidence varied from 0.07% (with intracameral cefuroxime as prophylaxis) to 0.34% (without prophylactic antibiotics). The Swedish NCR has reported a decreasing incidence; from 0.1% in 1998<sup>28</sup> to 0.048% from 2002 to 2004<sup>29</sup> with intracameral cefuroxime as a prophylactic regimen. A whole population study from Western Australia over the years 1980 to 2001 reported an incidence of 0.18%.<sup>30</sup>

**Persistent Corneal Edema** This occurred in 0.16% in a recent publication.<sup>31</sup> The incidence was based on 129 982 cataract extractions; the outcome measure was admission for pseudophakic corneal edema requiring surgery.<sup>30</sup> There is reason to believe that the true number would be higher if all cases are included.

**Posterior Capsule Opacification That Disturbs Vision** In the guidelines, this complication occurred within 2 months of surgery (EUREQUO follow-up time). It is usually caused by complications during surgery. Reports of the incidence of early PCO in the literature are scarce.

**Uveitis Requiring Medication** This is not rare during the first weeks after a cataract extraction.<sup>31</sup> In one report, the peak was 2 weeks after surgery and the incidence 8.4%.<sup>30</sup> With proper treatment, the uveitis normally heals, but in rare cases, life-long treatment is needed.

**Uncontrolled Elevated Intraocular Pressure** This seems to be a very rare complication according to the literature. However, it has been shown that phacoemulsification with implantation of an IOL generally lowers the IOP.<sup>32</sup>

2. The EUREQUO database contains limited data on endophthalmitis, persistent corneal edema, uncontrolled increased IOP, and reduced vision because of

PCO. Data from national registries or electronic medical records systems may contain some of these complications, depending on how these databases collect their data. Postoperative endophthalmitis is included as a mandatory variable in the Dutch national registry; in the Swedish NCR, it is collected in a specific registry (mandatory); and in the United Kingdom electronic medical records system connected to EUREQUO, the variable is missing. The long-term follow-up time in the EUREQUO data is set at 60 days at the most. This means that postoperative complications after this time period will not be reported to the EUREQUO database.

**Postoperative Endophthalmitis** The incidence was calculated on data from the Dutch and Swedish national registries. In these registries, 148 cases with postoperative endophthalmitis have been reported in 406 703 cataract extractions for the period from January 1, 2009, to August 28, 2011; an incidence of 0.036%.

**Persistent Corneal Edema** This complication was reported in 369 cases, an incidence of 0.15%.

**Posterior Capsule Opacification That Disturbs Vision** This complication was not reported in the 2 large contributors of data to EUREQUO (Holland and Sweden). The incidence in the reported data was 0.21% (75 cases in 35 553 cataract extractions). Note that this is a short-term (2 months) follow-up incidence.

**Uveitis Requiring Medication** This complication was not reported in the 2 large contributors of data to EUREQUO (Holland and Sweden). The incidence in the reported data was 0.35% (123 cases in 35 553 cataract extractions).

**Table 2.** Type of postoperative complication, EUREQUO mean incidence, and recommended maximum incidence.

Postoperative Complication	Mean in EUREQUO (%)	Maximum Acceptable Level (%)
Postoperative endophthalmitis	0.036	0.05
Persistent corneal edema	0.15	0.2
PCO that disturbs vision*	0.21	0.25
Uveitis requiring medication <sup>†</sup>	0.35	0.4
Uncontrolled elevated IOP <sup>†</sup>	0.06	0.1

IOP = intraocular pressure; PCO = posterior capsule opacification

\*Within 60 days after surgery

<sup>†</sup>During at least 60 days after surgery

**Uncontrolled Elevated Intraocular Pressure** The incidence of this complication was 0.06% (151 cases in 241 136 cataract extractions).

3. The incidence of postoperative complications after cataract surgery should be as low as possible. Postoperative complications may be related to the preoperative condition and the surgical procedure. It is reasonable to believe that coexisting eye diseases and the experience of the surgeon are important factors. Much debate has focused on avoiding postoperative endophthalmitis. It seems that avoiding surgical complications such as a capsule rupture, giving prophylactic antibiotics intracamerally, and securing a watertight incision are important steps. Table 2 shows the mean and the recommended maximum levels of postoperative complications.

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