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Outcomes of cataract surgery complicated by posterior capsule rupture in the European Registry of Quality Outcomes for Cataract and Refractive Surgery

Maartje HM Segers[1], MD, Anders Behndig[2], MD, PhD, Frank JHM van den Biggelaar[1], PhD, Lucia Brocato[3], MSc, Ype P Henry[4], MD, FEBO, Rudy MMA Nuijts[1], MD, PhD, Paul Rosen[5], MD, FRCS, FRCOphth, MBA, Marie-José Tassignon[6], MD, PhD, FEBO, David Young[7], PhD, Ulf Stenevi[8], MD, PhD, Mats Lundström[9], MD, PhD, Mor M Dickman[1*], MD, PhD

1. University Eye Clinic, Maastricht University Medical Center+, Maastricht, the Netherlands
2. Department of Clinical Sciences, Ophthalmology, Umeå University, Umeå, Sweden
3. European Society of Cataract and Refractive Surgeons (ESCRS), Dublin, Ireland
4. Department of Ophthalmology, Amsterdam UMC, Amsterdam, the Netherlands
5. Department of Ophthalmology, Oxford Eye Hospital, Oxford, United Kingdom
6. Department of Ophthalmology, Antwerp University Hospital, Antwerp, Belgium
7. Department of Mathematics and Statistics, University of Strathclyde, Glasgow, United Kingdom
8. Department of Ophthalmology, Sahgrenska University Hospital, Mölndal, Sweden
9. Department of Clinical Sciences, Ophthalmology, Lund University, Lund, Sweden

*Corresponding author: Mor M. Dickman, University Eye Clinic Maastricht, Maastricht University Medical Center, PO Box 5800, 6202 AZ, Maastricht, the Netherlands. Email: mor.dickman@mumc.nl

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Short title: outcomes after posterior capsule rupture

ABSTRACT

PURPOSE**:** To analyze the outcomes of cataract surgery complicated by posterior capsule rupture (PCR).

SETTING: European clinics affiliated to the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO).

DESIGN: Retrospective cross-sectional register-based study.

METHODS: Data was retrieved from the EUREQUO between January 1, 2008 and December 31, 2018. The database consists of data on demographics, intraoperative complications, including PCR, type of intraocular lens (IOL) material, postoperative refraction, corrected distance visual acuity (CDVA), and postoperative complications.

RESULTS: 1,371,743 cataract extractions with complete postoperative data were reported in the EUREQUO. In 12,196 cases (0.9%), a PCR was reported. Following PCR, patients were more likely to receive a PMMA IOL (5.2% vs. 0.4%, respectively) or no IOL (1.1% vs. 0.02%, respectively) compared to patients without PCR. The refractive and visual outcomes following PCR were significantly worse than in cases with an intact capsule (mean absolute biometry prediction error of 1.15 diopter ±1.60 vs. 0.41 ±0.45, and 87.2% patients with better postoperative than preoperative CDVA vs. 92.4%). Nonetheless, 90.6% of eyes with PCR achieved a postoperative CDVA of 0.3 logMAR (0.5 decimal) or better. Patients with PCR had significantly more postoperative complications (cornea edema 0.88% vs. 0.17%, adjusted odds ratio (aOR) 2.80 95%CI 2.27–3.45, endophthalmitis 0.11% vs. 0.03%, aOR 4.40 95%CI 2.48–7.81, uncontrolled intraocular pressure 0.55% vs. 0.03%, aOR 14.58 95%CI 11.16–19.06, $p<0.001$).

CONCLUSION: Patients with PCR have significantly worse visual outcomes and more postoperative complications than patients without PCR. However, the vast majority of these patients achieved better postoperative visual acuity than before surgery.

INTRODUCTION

With recent advances in cataract surgery techniques, outcomes have improved significantly, and there is an increasing patient demand to achieve excellent visual acuity. Intraoperative complications are relatively rare, but posterior capsule rupture (PCR) remains one of the most feared complications of cataract surgery.[1,2] PCR might be associated with poorer visual and refractive outcomes.[3,4] Furthermore, other complications such as retinal detachment, cystoid macular edema, and high intraocular pressure are more prevalent in patients with PCR.[5-7] In this study, we investigate the visual and refractive outcomes of patients with a PCR, as reflected in the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO), a multinational registry for cataract and refractive surgery under the auspices of the European Society of Cataract and Refractive Surgeons (ESCRS).

METHODS

Data analyzed in this study was based on the EUREQUO from January 1, 2008, to December 31, 2018.[8,9] In total, 2,853,376 cataract surgeries were reported in the EUREQUO. The database consists of data on demographics (gender, age, eye, year of surgery, country), preoperative and postoperative corrected distance visual acuity (CDVA) in decimal (for analyses transferred to logMAR), refraction, co-existing eye diseases (amblyopia, glaucoma, macular degeneration, diabetic retinopathy, other), complicating comorbidities (previous corneal refractive surgery, white cataract, pseudoexfoliation, previous vitrectomy, corneal opacities, small pupil, and other), material of the implanted intraocular lens (IOL) (acrylic hydrophobic, acrylic hydrophilic, polymethylmethacrylate (PMMA), silicon, no IOL, other IOL material), intraoperative complications (posterior capsule rupture (PCR), anterior capsule tear, dropped nucleus, iris damage, femtosecond laser complication, other), and postoperative complications. PCR is defined as an intraoperative tear in the posterior capsule with or without zonular dialysis or vitreous loss. Postoperative complications included in the study are persistent central corneal edema covering the pupil area, an inflammation that makes any medical treatment necessary at follow-up, central cystoid macular edema (CME) that affects visual acuity, clinical signs of suspected endophthalmitis, uncontrolled elevated intraocular pressure above 30 mmHg with a need for chronic treatment, explantation of the IOL, and other complications that may influence the visual outcome of the surgery. Most follow-up examinations were performed between 7 and 60 days, with a mean of 31 days, after cataract surgery. Data was reported by clinics committed to reporting consecutive postoperative data to EUREQUO. All data in the EUREQUO is anonymized. The study was performed according to the tenets of the Declaration of Helsinki.

Statistical analyses

Statistical analyses were performed using SPSS software for Windows (version 25, SPSS, Inc.). Categorical variables were presented by frequency and percentage, and continuous variables were presented by the mean and standard deviation (SD). Categorical variables were evaluated with the Pearson Chi-square test, and continuous variables were evaluated with the Students T-test. The odds ratio (OR) and 95% confidence intervals (CI) were estimated using both univariable and multivariable logistic regression. Univariable logistic regression measures the relationship between one independent variable and a binary outcome variable. Multivariable logistic regression measures the relationship between two or more independent variables and a binary outcome variable. Possible confounders were included in the multivariable model. A p-value of less than 0.05 was considered statistically significant. Only cases with complete postoperative parameters were analyzed.

RESULTS

From January 1, 2008, to December 31, 2018, 1,371,743 cataract extractions with complete postoperative parameters were reported in the EUREQUO. The mean age of patients was 73.5 ± 9.5 years, and 58.1 percent were female. A PCR complicated 12,196 (0.9%) of reported surgeries. Among these patients, 6,602 (54.1%) were female, and the mean age was 73.8 ± 9.9 years. A co-existing eye disease was present in 6,125 (50.2%) of patients with a PCR, whereas in patients without a PCR 318,248 (23.4%) had a co-existing eye disease. Table 1 shows that the frequency of IOL material used in patients with a PCR differed significantly from patients without a PCR ($p < 0.001$). Patients with a PCR were more likely to receive a PMMA IOL and less likely to receive any intraocular lens directly compared to patients with an intact capsule. A PMMA IOL is frequently used for sulcus implantation.

Visual and refractive outcomes

Overall, 10,637 (87.2%) patients with a PCR had better postoperative CDVA than at presentation compared with 1,256,319 (92.4%) patients without a PCR ($p < 0.001$). In contrast, 5.2% (n = 632) of patients with a PCR had worse CDVA postoperative than at presentation compared with 1.5% (n = 19,952) of patients without a PCR ($p < 0.001$).

The mean postoperative CDVA of patients with PCR was 0.13 ± 0.21 versus 0.05 ± 0.16 logMAR of patients without a PCR. Refractive outcomes after a PCR were also significantly worse compared with patients without a PCR (mean absolute biometry prediction error of 1.15 ± 1.60 diopter (D) compared with 0.41 ± 0.45 D [$p < 0.001$]). It was observed that 90.6% of eyes with a PCR achieve a postoperative visual acuity of 0.3 logMAR (0.5 decimal) or better compared with 96.1% of eyes with an intact capsule.

Patients who had a PCR and did not receive an IOL during the primary surgery had a mean postoperative CDVA of 0.32 ± 0.41 logMAR. The mean postoperative CDVA of patients with

a PCR and a PMMA IOL was 0.23 ± 0.32 compared to 0.12 ± 0.20 logMAR in cases where an IOL of another biomaterial than PMMA was implanted ($p < 0.001$).

In Tables 2 and 3, the preoperative and postoperative CDVA is compared. Table 2 shows this comparison for patients with a PCR and Table 3 shows this comparison for patients without a PCR. The groups are classified according to Lundström et al.[10] and represent (1) excellent vision, (2) good vision, (3) impaired vision, but good enough for driving and reading, (4) poor vision, not good enough for driving, but still good enough for reading, and (5) low vision, not good enough for driving or reading.

Postoperative complications

Patients with a PCR had significantly more postoperative complications compared with patients without a PCR (38.8%, n = 4,738 vs. 1.5%, n = 20,495, aOR 26.82 95% CI 25.71 – 27.99, $p < 0.001$). Table 4 shows that especially cornea edema, endophthalmitis, and uncontrolled high intraocular pressure were significantly more prevalent in patients with a PCR. Postoperative complications did not substantially differ by age group or gender.

DISCUSSION

Complications such as PCR are challenging to study because of their rarity. The current literature largely relies on data out of high-volume centers or national registries. Large-scale, multinational registries, like the EUREQUO enable new opportunities to evaluate the outcomes of patients with this complication. In this study, data of the EUREQUO was used to analyze the results of cataract surgery complicated by a PCR.

We found that patients with PCR had significantly worse outcomes than patients without PCR in terms of postoperative best corrected distance visual acuity, biometric prediction error, and complications. Moreover, the type of IOL differed significantly between patients with and without PCR. In this study, 5.2 percent of patients with a PCR received a PMMA IOL, which is frequently used for sulcus implantation. In addition, 1.1 percent of patients with PCR did not directly receive any IOL, compared to 1.4 to 4.8 percent in the literature.[6,11] Patients with a PCR and a PMMA IOL or no IOL had worse postoperative mean visual outcomes (0.23 and 0.32, respectively, vs. 0.12 logMAR). This worse postoperative CDVA may reflect that eyes with a PMMA or no IOL have larger posterior capsule tears. Another explanation could be that patients with a PMMA or no IOL had more postoperative complications or more ocular comorbidity. However, there was no substantial difference in postoperative complications or ocular comorbidity between these groups in our data (Supplemental Table 1).

Knowledge of outcomes after a PCR is important to inform patients about their prognosis and expectations. Visual outcomes of cataract surgery complicated with PCR are worse than those of surgeries without PCR. Tables 2 and 3 demonstrate that 29.8% of patients with PCR and 60.9% of patients without PCR improve from reading vision (group 4) to excellent vision (group 1). In our study, 30.8% fewer patients with PCR improve from reading vision to excellent vision compared to patients without PCR. Moreover, 5.2% of patients with a PCR had

worse CDVA postoperative than at presentation compared with 1.5% of patients without a PCR... Patients with good corrected visual acuity before surgery have a higher risk of achieving worse corrected vision after cataract surgery complicated by PCR due to a 'ceiling effect'. A ceiling effect occurs when subjects have high scores before surgery (for example, best corrected vision of 1.0 decimal). These subjects have a higher risk of losing than gaining vision after surgery, compared to subjects with low scores (for example, 0.6 decimal best corrected visual acuity before surgery). Since patients with low preoperative visual acuity are likely overrepresented in the PCR group, the difference in the improvement of CDVA postoperatively between the groups with and without PCR may be even larger. Nonetheless, the vast majority of eyes with PCR have better postoperative visual acuity than before surgery (87.1%), and 88.7% of eyes with a PCR achieve a postoperative visual acuity of 0.3 logMAR (0.5 decimal) or better (driving vision). In the literature, this frequency varied from 70.4 to 93.8 percent.[6,7,12,13] Moreover, our findings demonstrate that cataract surgeries complicated with PCR have more often postoperative complications compared with surgeries without a PCR, such as endophthalmitis (0.11% vs. 0.02%), cornea edema (0.88% vs. 0.17%), and high intraocular pressure (0.55% vs. 0.03%) than cases with an intact capsule.

A limitation of this study is that postoperative complications in the EUREQUO were reported on average 31 days after cataract surgery. Long-term complications that are more prevalent after PCR, for example, retinal detachment, as previously described by Jakobsson et al., were not reported in the registry.[14] Also, in our data, the frequency of the variable 'other postoperative complications' is high. More complications, for example, IOL dislocation, retinal tears, or dysphotopsia, may be added to the registry to make a better differentiation between different complications. Another limitation is that the data is self-reported by surgeons and clinics, in which there might be a risk of underreporting poor outcomes or complications. However, clinics committed to participating in the EUREQUO report consecutive cases, and

individual data are only visible for the clinics themselves. The main strength of our study is the large number of reported cases from many countries over a long period. The EUREQUO uses a uniform methodology to prospectively collect consecutive cases, making the data more reliable and the statistical analyses more robust.

In conclusion, this multinational registry study shows that PCR decreases the probability of achieving excellent visual and refractive outcomes and increases the risk of postoperative complications. The results of this study can be used for benchmarking and for counseling patients.

WHAT WAS KNOWN

Patients with a posterior capsule rupture (PCR) have an increased risk of postoperative complications and poorer outcomes.

WHAT THIS PAPER ADDS

The refractive and visual outcomes following a PCR are significantly worse and a PCR increases the probability of receiving a PMMA or no intraocular lens. Moreover, the risk of postoperative complications (e.g. cystoid macular edema) is higher after PCR. However, the vast majority of patients with PCR achieved better visual acuity than before surgery.

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Table 1. Frequency of intraocular lens material used for patients with or without a posterior capsule rupture in the EUREQUO.

Type of IOL	**PCR, % (n)**	**No PCR, % (n)**	**P-value**
Acrylic hydrophobic	50.6 (6,168)	78.9 (1,072,969)	<0.001
Acrylic hydrophilic	9.6 (1,172)	17.0 (230,961)	<0.001
PMMA	5.2 (634)	0.4 (5,690)	<0.001
Silicon	1.4 (171)	1.6 (21,243)	0.155
No IOL	1.1 (131)	0.02 (252)	<0.001
Other IOL material[a]	32.1 (3,918)	2.1 (28,406)	<0.001

IOL = intraocular lens, PCR = posterior capsule rupture, PMMA = polymethylmethacrylate

[a] IOLs of combined material

Table 2. Change in corrected distance visual acuity of patients **with** a posterior capsule rupture in visual acuity groups, according to Lundström et al.[10]

Preoperative CDVA	**Postoperative CDVA, %**				
	Group 1	**Group 2**	**Group 3**	**Group 4**	**Group 5**
Group 1	66.0	13.5‡	9.4‡	3.4‡	7.7‡ [a]
Group 2	60.1†	30.5	6.8‡	1.5‡	1.0‡
Group 3	44.0†	36.4†	15.5	2.5‡	1.6‡
Group 4	29.8† [b]	39.4† [b]	22.2† [b]	5.6	2.9‡
Group 5	24.9†	30.3†	24.7†	9.1†	11.1

CDVA = corrected distance visual acuity

Group 1 = -0.2 to 0.0 logMAR or 1.0 to 1.6 decimal; Group 2 = 0.1 logMAR or 0.8 to 0.9 decimal; Group 3 = 0.2 to 0.3 logMAR or 0.5 to 0.7 decimal; Group 4 = 0.4 to 0.5 logMAR or 0.3 to 0.4 decimal; Group 5 = 0.6 or worse logMAR or 0.25 or worse decimal.

† Improvement to a better visual acuity group

‡ Deterioration to a worse visual acuity group

[a] 7.7% of patients with PCR and excellent preoperative vision (group 1) deteriorated to low vision (group 5) postoperatively.

[b] 91.4% of patients with PCR and poor preoperative vision (group 4) achieved a postoperative visual acuity of 0.3 logMAR or lower (0.5 decimal or higher, group 1 to 3).

Table 3. Change in corrected distance visual acuity of patients **without** a posterior capsule rupture in visual acuity groups, according to Lundström et al.[10]

Preoperative CDVA	**Postoperative CDVA, %**				
	Group 1	**Group 2**	**Group 3**	**Group 4**	**Group 5**
Group 1	93.9	4.0‡	1.6‡	0.3‡	0.3‡ [a]
Group 2	88.3†	9.7	1.7‡	0.2‡	0.1‡
Group 3	75.5†	16.9†	6.8	0.6‡	0.2‡
Group 4	60.9† [b]	20.7† [b]	14.6† [b]	3.1	0.6‡
Group 5	47.7†	16.1†	18.5†	7.8†	9.9

CDVA = corrected distance visual acuity

Group 1 = -0.2 to 0.0 logMAR or 1.0 to 1.6 decimal; Group 2 = 0.1 logMAR or 0.8 to 0.9 decimal; Group 3 = 0.2 to 0.3 logMAR or 0.5 to 0.7 decimal; Group 4 = 0.4 to 0.5 logMAR or 0.3 to 0.4 decimal; Group 5 = 0.6 or worse logMAR or 0.25 or worse decimal.

† Improvement to a better visual acuity group

‡ Deterioration to a worse visual acuity group

[a] 0.3% of patients without PCR and excellent preoperative vision (group 1) deteriorated to low vision (group 5) postoperatively.

[b] 96.2% of patients without PCR and poor preoperative vision (group 4) achieved a postoperative visual acuity of 0.3 logMAR or lower (0.5 decimal or higher, group 1 to 3).

Table 4. Frequency of postoperative complications in cataract surgery complicated with a posterior capsule rupture compared to surgery without posterior capsule rupture.

			Univariable		Multivariable[a]	
Postoperative complications	**PCR % (n)**	**No PCR % (n)**	**OR (95% CI)**	**P-value**	**aOR (95% CI)**	**P-value**
Cornea edema	0.88 (107)	0.17 (2,316)	5.19 (4.27 – 6.30)	<0.001	2.80 (2.27 – 3.45)	<0.001
Inflammation	0.07 (9)	0.03 (419)	2.40 (1.24 – 4.64)	0.010	2.97 (1.53 – 5.80)	0.001
Endophthalmitis	0.11 (13)	0.02 (279)	5.20 (2.98 – 9.07)	<0.001	4.40 (2.48 – 7.81)	<0.001
Uncontrolled IOP	0.55 (67)	0.03 (465)	16.15 (12.49 – 20.87)	<0.001	14.58 (11.16 – 19.06)	<0.001
Explantation	0.02 (2)	0.002 (22)	10.14 (2.38 – 43.11)	<0.001	-	
Clinically significant CME	0.02 (2)	0.002 (30)	7.43 (1.78 – 31.11)	<0.001	-	
Other complications[b]	37.50 (4,573)	1.27 (17,271)	46.62 (44.81 – 48.51)	<0.001	30.30 (29.00 – 31.65)	<0.001

PCR = posterior capsule rupture, OR = odds ratio, aOR = adjusted OR, IOP = intraocular pressure, CME = cystoid macular edema

[a] Dependent variable: postoperative complication. Parameters included in the multivariable logistic regression model: PCR, amblyopia, macular degeneration, glaucoma, diabetic retinopathy, other comorbidities, small pupil, white cataract, corneal opacities, other difficult surgery, year of surgery, country.

[b] Other postoperative complications that may influence the visual outcome of surgery.

Supplemental Table 1. Ocular comorbidities and postoperative complications in patients with PCR who received a PMMA IOL, no IOL, or an IOL of other biomaterial.

	PMMA N (%)	**No IOL N (%)**	**Other biomaterial* N (%)**
Ocular comorbidities			
Macular degeneration	65 (10.3)	15 (11.5)	924 (8.1)
Glaucoma	34 (5.4)	13 (9.9)	700 (6.1)
Diabetic retinopathy	21 (3.3)	4 (3.1)	1052 (9.2)
Postoperative complications			
Inflammation	0 (0)	0 (0)	9 (0.1)
Endophthalmitis	0 (0)	1 (0.8)	12 (0.1)
Clinically significant CME	0 (0)	0 (0)	2 (0.01)

*Acrylic hydrophobic, acrylic hydrophilic, silicon, or combined material.