Risk factors for refractive error after cataract surgery – An analysis of 282,811 cataract extractions reported to the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO).

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ABSTRACT

Purpose: To analyse risk factors for refractive error after cataract surgery. To provide benchmark for refractive outcome after standard cataract surgery.

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

Design: Prospective, multicentre, cohort registry study.

Methods: Data on consecutive cataract extractions reported to the EUREQUO by more than 100 clinics between 1 January 2014 and 31 December 2015 (n=548,392 cases) was analysed. Data included demographics, preoperative corrected distance visual acuity (CDVA), target refraction, co-existing eye diseases, and surgical difficulties including previous ophthalmic interventions. Type of surgery, intraocular lens and surgical complications were also reported. For clinics committed to reporting follow-up data within 7-60 days after surgery, postoperative CDVA and refraction were analysed.

Results: Follow up data was available for a total of 282,811 cases. The absolute mean biometry prediction error (BPE) in spherical equivalent was 0.42D. A BPE within ±0.50D was achieved for 205,675 (72.7%) eyes. A BPE within ±1.0D was achieved for 263,015 (93.0%) eyes. Poor preoperative CDVA, target refraction, co-existing eye diseases, surgical difficulties including previous ophthalmic interventions, and surgical complications were in varying degree related to a postoperative refractive error.

Conclusions: Multiple risk factors (poor preoperative CDVA, myopic target refraction, ocular comorbidity, and previous eye surgery) were related to poor refractive outcome after cataract extraction. When these risk factors are present or even combined it is recommended to be careful with the preoperative examination and choice of IOL to avoid a refractive surprise. Average outcomes are given as a refractive outcome benchmark.

INTRODUCTION

Quality outcomes of cataract surgery include an optimal visual outcome and a refractive outcome on target. The growing use of non-monofocal intraocular lenses (IOL) has increased the demand for a refractive outcome on target. Optimal precision in refractive outcome depends on a good preoperative biometry including measurement of axial length, keratometry and anterior chamber depth. Also important is using an IOL with correct power and implanted in a predicted stable position. The importance of good biometry was highlighted in a study where postgraduates improved their refractive outcome considerably after stepwise biometry lectures. [1] Errors in terms of mixing up IOLs and patients or even mislabelling of an IOL may occur. [2] The preoperative characteristics of an eye to be operated on may imply risk factors for a poor refractive outcome. A well-known risk factor for a poor refractive outcome is previous corneal refractive surgery. [3]

The European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) is a multi-national web-based registry with data from over 2 million cataract cases to date, providing a unique opportunity to benchmark and improve the quality of cataract surgery in Europe. In this study we identify and discuss risk factors for a poor refractive outcome using the database of the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO). The purpose is to analyse risk factors for refractive errors after cataract surgery. Knowing risk factors means that the surgeon can advise a patient before surgery about what to expect and maybe use more than one method for IOL calculation. Furthermore, the analysis of such a big data volume will give a good background for benchmark assessment.

METHODS

The database of EUREQUO was studied for the period 1 January 2014-31 December 2015. The web form guidelines for this database include reporting mandatory data on demographics, target refraction, ocular co-morbidity, previous eye surgery and surgical difficulties, type of surgery and surgical complications. Complete reporting also includes refractive outcome, visual outcome, and postoperative complications at follow-up. Reporting complete data on consecutive cases is decided by the clinic before joining the database and receiving access to the report function with login credentials. Optional data on pre- and postoperative K values, and used technique for biometry, K readings and IOL calculation formula may also be reported. Per protocol, consecutive cases were reported to the database by participating units and a follow-up examination was performed within 7-60 days after surgery. The study was carried out according to the tenants of the Declaration of Helsinki.

Data

The EUREQUO database contains data on 548,392 cataract extractions for the period 1 January 2014-31 December 2015. Preoperative and surgical data only exist for 265,581 cases and for 282,811 cases follow up data have also been reported by clinics committed to reporting complete data. The mean follow up time was 30 days. The mean patient age in the total database for the study period is 73.9 years and in the follow up database 73.5 years. The gender distribution shows 58.3% females in the total database and 57.4% in the follow up database. Complete data for the study period was reported by 53 sites from 12 countries. However, data from the Netherlands is reported to the database as coming from one site although over 60 clinics contribute to that site. This means that over 100 clinics contributed to the follow up database.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics version 22 (IBM SPSS, Chicago, IL, USA). Refractive error levels as dichotomous variables were tested with logistic regression analysis. Odds ratios were tested with Chi square. For all analyses, a p-value of 0.05 or less was considered significant.

RESULTS

Biometry prediction error (spherical equivalent)

The absolute mean biometry prediction error (BPE) [spherical equivalent] was 0.42D (SD 0.52). Absolute mean BPE for females was 0.43D (SD 0.52) and for males 0.42D (SD 0.52) [p=0.133, t test]. The absolute mean BPE for 2014 (N=142,575) was 0.43D (SD 0.55) and for 2015 (N=140,201) 0.41D (SD 0.48) [p<0.001, t test].

A BPE within ±0.5D was achieved for 205,675 eyes (72.7%). For 35 eyes data was missing. More myopic than intended was 30.3%, 10.4% achieved exactly 0 and 32.1% became more hyperopic than intended, all within ±0.5D. A BPE within ±1.0D was achieved for 263,015 eyes (93.0%). Tables 1 and 2 show which preoperative parameters were significantly related to a refractive outcome outside a BPE of ±0.5D (N=77,101) and ±1.0D (N=19,761), respectively.

Table 1. Logistic regression analysis based on the EUREQUO database (N= 282,811).. Stepwise logistic regression. Dependent variable: Biometry Prediction Error (BPE) outside ±0.5D. Categorical variables are coded 1 for existence and 0 for absence of the risk factor.

Independent parameters Dependent: BPE outside ±0.5D

Parameter	Number	B	P	Exp(B)	CI Lower	CI Upper
Age	282,811	0.005	<0.001	1.005	1.004	1.006
Sex (Female coded 1)	282,785	0.023	0.006	1.024	1.007	1.041
Preoperative visual acuity (LogMAR)	282,811	0.229	<0.001	1.257	1,231	1,284
Target refraction, spherical	282,810	-0.112	<0.001	0.894	0.884	0.904
Co-existing glaucoma	15,837	0.175	<0.001	1.191	1.150	1.234
Co-existing macular degeneration	24,283	0.115	<0.001	1.122	1.089	1.156
Co-existing diabetic retinopathy	7,399	0.247	<0.001	1.281	1.218	1.346
Co-existing amblyopia	5,209	0.397	<0.001	1.488	1.404	1.577
Co-existing “other” eye disease	24,237	0.327	<0.001	1.387	1.347	1.428
Previous corneal refractive surgery	762	0.857	<0.001	2.356	2.040	2.721
Previous vitrectomy	3,433		ns			
White cataract	5,216	0.143	<0.001	1.153	1.085	1.227
Small pupil/floppy iris	8,201	0.089	<0.001	1.094	1.042	1.148
Corneal opacities	4,316	0.295	<0.001	1.344	1.261	1.432
“Other” surgical difficulty	15,338	0.149	<0.001	1.161	1.120	1.203

B=B coefficient. Exp(B)= exponentiation of B, CI= 95% confidence interval. LogMAR = logarithm of the minimum angel of resolution.

ns=not significant

Table 2. Logistic regression analyses based on the EUREQUO database (N= 282,811). Stepwise logistic regression. Dependent variable: Biometry Prediction Error (BPE) outside ±1.0D. Categorical variables are coded 1 for existence and 0 for absence of the risk factor.

Independent parameters Dependent: BPE outside ±1.0D

Parameter	Number	B	P	Exp(B)	CI Lower	CI Upper
Age	282,811		ns			
Sex (Female coded 1)	282,785	0.45	0.003	1.046	1.016	1.078
Preoperative visual acuity (LogMAR)	282,811	0.448	<0.001	1.566	1.521	1.612
Target refraction, spherical	282,810	-0.109	<0.001	0.897	0.880	0.913
Co-existing glaucoma	15,837	0.298	<0.001	1.347	1.272	1.427
Co-existing macular degeneration	24,283	0.171	<0.001	1.186	1.129	1.246
Co-existing diabetic retinopathy	7,399	0.571	<0.001	1.769	1.644	1.904
Co-existing amblyopia	5,209	0.542	<0.001	1.720	1.581	1.871
Co-existing “other” eye disease	24,237	0.712	<0.001	2.038	1.951	2.129
Previous corneal refractive surgery	762	1.245	<0.001	3.474	2.904	4.156
Previous vitrectomy	3,433	-0.416	<0.001	0.659	0.583	0.746
White cataract	5,216	0.149	0.001	1.161	1.061	1.270
Small pupil/floppy iris	8,201	0.096	0.018	1.101	1.016	1.193
Corneal opacities	4,316	0.562	<0.001	1.754	1.608	1.913
“Other” surgical difficulty	15,338	0.194	<0.001	1.214	1.148	1.285

B=B coefficient. Exp(B)= exponentiation of B, CI= 95% confidence interval. LogMAR = logarithm of the minimum angel of resolution. ns=not significant

Influence of cylinder refraction

The absolute biometry prediction error (spherical equivalent) of 0.5D or less (205,675 eyes, 72.7%) included 43,644 (21.2%) eyes with a postoperative cylinder more than 1.0D. This means that 162,031 (57.3%) achieved a spherical equivalent refraction within ±0.5D of target and with an included cylinder refraction of no more than 1.0D.

The absolute mean prediction error (spherical equivalent) of 1.0D or less (93.0%, 263.015 eyes) included 79,811 (30.3%) cases with a postoperative cylinder more than 1.0D. This means that 183,204 (64.8%) achieved a spherical equivalent refraction within ±1.0D of target and with an included cylinder refraction of no more than 1.0D.

Refractive outcome for risk eyes and best cases

An overview of the refractive outcome for 1/ Best cases (no surgical complication, no ocular co-morbidity) N=207,598, 2/ Eyes with a co-existing eye disease, N=72,022, and 3/ Eyes that had a surgical complication, N=6,997, including the influence of a cylinder refraction over 1.0D for all three groups is outlined in Table 3.

Table 3. Biometry prediction error (BPE) within ±0.5D and ±1.0D and influence of cylinder refraction more than 1.0D for three groups of eyes.

Type of eye N	BPE within ±0.5D N (%)	BPE within ±0.5D and a cylinder refraction ≤1.0D N (%)	BPE within ±1.0D N (%)	BPE within ±1.0D and a cylinder refraction ≤1.0D N (%)
1. Best cases, 207,598	155,097 (74.7) [95% CI 74.5-74.9]	114,099 (55.0) [95% CI 54.8-55.2]	196,071 (94.5) [95% CI 94.4-94.6]	139,911 (67.4) [95% CI 67.2-67.6]
2. Ocular co-morbidity 72,022	48,647 (67.6) [95% CI 67.2-67.9]	32,619 (45.3) [95% CI 44.9-45.7]	64,283 (89.3) [95%CI 89.0-89.5]	41,563 (57.7) [95% CI 57.4-58.1]
3. Surgical complication 6,997	6,997 (49.2) [95% CI 48.1-50.4]	2,547 (36.4) [95% CI 35.3-37.5]	4,787 (68.5) [95% CI 67.4-69.5]	3,406 (48.7) [95% CI 47.5-49.9]

CI=Confidence Interval. D=Dioptre

The variation in refractive outcomes between reporting clinics was considerable. Achieving a refractive error within ±0.5D for best cases showed a clinic variation between 44.2% and 89.4%.

Refractive surprise (BPE greater than 2.0D)

A regression analysis on the whole database with an error of more than ±2.0D ("refractive surprise") is shown in table 4 (N=3,555).

Table 4. Logistic regression, stepwise. N= 282,811. Dependent variable: Biometry prediction error (BPE) outside ±2.0D. Categorical variables are coded 1 for existence and 0 for absence of the risk factor.

Parameter	Number	B	P	Exp(B)	CI Lower	CI Upper
Age	282,811	-0.006	<0.001	0.994	0.990	0.997
Preoperative visual acuity (LogMAR)	282,811	0.598	<0.001	1.818	1.733	1.906
Target refraction (sph.)	282,810	-0.108	<0.001	0.898	0.862	0.935
Co-existing glaucoma	15,837	0.406	<0.001	1.501	1.322	1.705
Co-existing diabetic retinopathy	7,399	1.092	<0.001	2.980	2.612	3.399
Co-existing amblyopia	5,209	0.652	<0.001	1.920	1.621	2.274
Co-existing "other" eye disease	24,237	1.422	<0.001	4.145	3.829	4.487
Previous corneal refractive surgery	762	1.086	<0.001	2.964	2.064	4.256
Previous vitrectomy	3,433	-0.753	<0.001	0.471	0.370	0.599
Corneal opacities	4,316	0.514	<0.001	1.671	1.424	1.961

B=B coefficient. Exp(B)= exponentiation of B, CI= 95% confidence interval. LogMAR = logarithm of the minimum angel of resolution.
Excluded from the analysis: Gender, macular degeneration, white cataract, small pupil, "other" surgical difficulty.

Surgical complications

If a surgical complication is added as an independent variable in all the analyses shown in Tables 1, 2 and 4, the surgical complication will be significantly related to the refractive error outcome. However, the significant relationship of all risk factors in Table 1, 2 and 4 remain unchanged. The risk for a refractive error when a surgical complication occurs gives an odds ratio of 2.55 for outside ±0.5D, 5.57 for outside ±1D, and 13.8 for outside ±2D. With still higher error a surgical complication will play an increasingly important role with higher odds ratio (data not shown). As for type of complication vitreous loss and capsular break give the highest odds ratio for a refractive error.

Table 5 shows that among preoperative risk factors for a poor refractive outcome are younger age than average (for BPE>2.0D), poorer preoperative visual acuity than average, and a higher percentage of glaucoma, amblyopia and "other co-morbidity" than average. As for surgical complications, a posterior capsule rupture with or without vitreous loss and "other surgical complication" are risk factors. For higher levels of BPE (>3.0D - >6.0D) still younger age is related to the error (data not shown).

Table 5. Mean age, mean preoperative visual acuity and frequency of certain variables within different groups of BPE. Variables significantly related to a certain refractive error are marked with light red.

Parameter	All cases	BPE>0.5D	BPE>1.0D	BPE>2.0D
Mean age	73.5	73.7	73.4	72.3
Sex (Female)	57.4%	57.6%	57.8%	57.3%
Mean Preoperative LogMAR VA	0.39	0.43	0.52	0.65
Mean target refraction, D	-0.307	-0.350	-0.373	-0.403
Glaucoma	5.6%	6.4%	7.2%	7.6%
AMD	8.6%	9.5%	10.0%	8.5%
Diabetic retinopathy	2.6%	3.1%	4.4%	7.3%
Amblyopia	1.8%	2.5%	3.5%	4.4%
Other co-morbidity	8.6%	11.1%	16.9%	30.5%
White cataract	1.8%	2.5%	3.6%	4.6%
Prev. Corn. Refr. Surg.	0.3%	0.5%	0.8%	0.9%

Corneal opacities	1.5%	2.1%	3.5%	5.1%
Small pupil	2.9%	3.3%	3.6%	3.9%
Other surg. difficulty	5.4%	6.5%	8.1%	8.6%
Posterior Capsule Rupture only	0.3%	0.6%	1.1%	1.2%
+ Vitreous loss	1.1%	2.7%	8.2%	26.3%
+ Dropped nucleus	0.3%	0.3%	0.5%	0.7%
Iris damage	0.1%	0.1%	0.2%	0.4%
Other surg. complication	0.8%	1.1%	1.5%	2.1%

VA=visual acuity. LogMAR = logarithm of the minimum angel of resolution. D= dioptre.

All levels of BPE in the database were significantly less frequent in 2015 compared with 2014.

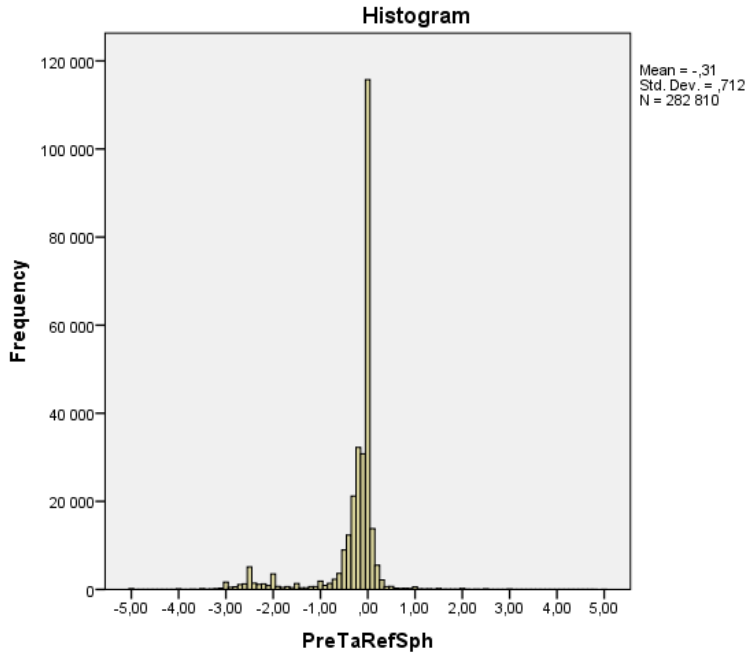
Target refraction

The distribution of target refraction is shown in Figure 1. Mean target refraction was -0.31D (SD ±0.71).

In the logistic regressions outlined in table 1, 2 and 4 the target refraction was significantly related to a refractive error. In more detail the analyses showed that a negative target refraction values was related to the refractive error. This depended on the skewed distribution of target refraction values towards more frequent and more negative values (compare Figure 1 below). If cases with only negative or only positive target refraction values were analysed separately it turned out that for both groups it was a higher absolute value that was related to the error, not the sign (positive or negative) itself (data not shown).

In 103,164 (36.5%) eyes the target was exactly 0.0D. In 24,436 (23.7%) of these eyes the final spherical equivalent became exactly 0.0D. In 54,929 (53.3%) eyes the final spherical equivalent was within -0.25D and +0.25D. In 77,449 (75.1%) eyes the final spherical equivalent ended between -0.50 and +0.50. This is slightly better than the 72.7% for all eyes within BPE ±0.5D, irrespective of the target aim. In 45,787 (44.4%) of eyes targeting at 0.0D the postoperative spherical equivalent was within ±0.5D combined with a cylinder refraction of 1.0D or less.

Figure 1. Distribution of target refraction in the EUREQUO database for 282,810 cataract extractions.



Combined risk factors

Poor preoperative visual acuity and a co-existing eye disease emerged as important risk factors according to our findings. If we combine both risk factors, e.g. preoperative visual acuity of LogMAR 0.6 or worse and a co-existing eye disease 19,551 eyes (6.1% of all) fulfil this condition. In 36% of these eyes a BPE of outside ±0.5D occurred and 14.3% ended outside ±1.0D. The odds ratio of ending outside ±0.5D of target was 1.55 ($p<0.000$, Chi square) when these two risk factors existed compared with no such risk factors. As for ending outside ±1.0D the odds ratio was 2.41 ($p<0.001$, Chi square).

If the preoperative visual acuity was LogMAR 1.0 or worse the odds ratio of ending outside ±1.0D was 2.34 ($p<0.001$, Chi square). Combining this with an age below 60 and co-existing eye disease, the odds ratio for ending outside ±1.0D was 3.1 ($p<0.001$, Chi square) compared with no such combination of risk factors. With the same combination of risk factors, odds ratio for a refractive surprise (outside ±2.0D of target) was 5.73 ($p<0.001$, Chi square). With the same combination of risk factors odds ratio for ending outside ±3.0D of target was 8.51 ($p<0.001$, Chi square).

DISCUSSION

The biometry prediction error (BPE) in our study was lower than reported in some previous studies. [4, 5] However, a more recent study showed comparable results. [6] This is in line with longitudinal studies reporting improvement in BPE over time. [5] This was also true in our study, even though only two years were compared.

We did not find any statistically significant gender difference in refractive outcome in our study. A larger error for female subjects was previously reported [5], and was suggested to be related to the IOL formula that was used. [7]

The influence of rest astigmatism on the spherical equivalent outcome was considerable in our study. To achieve at better outcome in terms of emmetropia the rest astigmatism could be reduced by inserting a toric IOL. [8] At which level of preoperative corneal astigmatism a toric IOL will benefit the outcome is still under discussion. It has been reported that eyes with a preoperative corneal astigmatism between 0.75D and 1.5D could benefit from a toric IOL. [9]

A large number of risk factors was identified in our study. Poor preoperative visual acuity is one such risk factor probably because the patient's inability to fixate properly during biometry measurement. This may lead to keratometry errors. The occurrence of co-existing eye diseases is a risk factor irrespective of the visual acuity. This has also been reported earlier. [5] Surgical difficulties in terms of corneal opacities, previous corneal refractive surgery and pupillary problems are also risk factors according to our study. When all these kind of risk factors exist measurements before surgery need to be careful and preferably repeated with different IOL calculation formulas. For low-grade errors (> ±0.5D or > ±1.0D) previous corneal refractive surgery was the major risk factor in our study. We have previously been able to show that previous corneal refractive surgery has a negative impact on the visual outcome. [10] It has frequently been reported that previous corneal refractive surgery may lead to a refractive surprise after cataract surgery. [11] The large variation in outcomes between clinics in our study points at a considerable room for clinical improvement.

A surgical complication is an obvious risk factor for a poor refractive outcome but a different kind of risk factor as it is not known before surgery and thereby impossible to avoid by measures taken before surgery.

In the evidence-based guidelines based on the EUREQUO database in 2012 an absolute BPE of 0.6D or less was recommended. [12] The average absolute BPE in our study of 0.42D means that the benchmark should be reduced to at least 0.45D or less. As for the percentage of cases ending up within ±1.0D the guidelines recommended at least 87%. [12] The corresponding number in our study was 93% which also can serve as a benchmark. Based on this data we recommend at least 90% of all cases within an absolute error of ±1.0D.

A weakness in our study could be that axial length is not reported to the EUREQUO database. In addition, type of IOL calculation is included in the registry as an optional parameter. Due to a low reporting of this parameter we could not draw any conclusions about the influence of different IOL calculations on the refractive outcome. This is also true for the possible influence of posterior corneal astigmatism on the refractive outcome. If only keratometry of the anterior corneal astigmatism was included and some of the refractive error may be caused by not including posterior corneal astigmatism. According to Koch et al. [13] anterior corneal

measurements underestimate the total corneal astigmatism exceeding 0.5D in about 5% of the eyes. [13]

A strength in our study is the multi-centre multinational approach with a large amount of cases.

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