

# Global multi-site, prospective analysis of cataract surgery outcomes following ICHOM standards: the European CAT-Community

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## Abstract

**Purpose** To evaluate in a large sample of patients from 10 different European centers the results of cataract surgery, characterizing the relationship between patient-reported outcomes (PROMs) and clinician-reported outcome measures (CROMs).

**Methods** Prospective non-interventional multicenter observational descriptive study analyzing the clinical outcomes of a total of 3799 cases undergoing cataract surgery (mean age: 72.7 years). In all cases, the cataract surgery standard developed by the International Consortium for Health Outcomes Measurements (ICHOM) was used to register the clinical data. Three-month postoperative visual acuity and refraction data were considered CROMs, whereas Rasch-calibrated item 2 (RCCQ2) and total Catquest-9SF score (CQ) were considered PROMs.

**Results** Postoperative corrected distance visual acuity (CDVA) was 0.3 logMAR or better in 88.7% (2505/2823) of eyes. Mean differences between preoperative and postoperative RCCQ2 and CQ scores were  $-3.09$  and  $-2.39$ , respectively. Visual function improvement with surgery was reported by 91.5% (2163/2364) of patients. Statistically significant, although weak,

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correlations of postoperative CDVA with postoperative refraction, PROMs, and complications were found ( $0.133 \leq r \leq 0.289$ ,  $p < 0.001$ ). A predictive model ( $R^2$ : 0.254) of postoperative CDVA considering 10 variables was obtained, including preoperative CDVA, different ocular comorbidities, age, gender and intraoperative complications. Likewise, another predictive model ( $R^2$ : 0.148) of postoperative CQ considering a total of 14 variables was obtained, including additionally preoperative CQ, target refraction and previous surgeries.

**Conclusions** Cataract surgery provides an improved functional vision in most of patients although this improvement can be limited by ocular comorbidities and complications. The relationship between PROMs and CROMs is multifactorial and complex.

### Key messages

- Cataract surgery provides an improved functional vision in most of patients undergoing this surgical procedure, which may depend on the presence of ocular comorbidities and complications.
- The relationship between patient-reported outcomes (PROMs) and clinician-reported outcomes (CROMs) is multifactorial and complex, with only a minimal portion of PROMs variability being explained by CROMs and other clinical data
- The outcomes of the current study provide an idea of the trends in global European practice of cataract surgery, but care should be taken when trying to extrapolate and generalize as the selection of the centres involved was not random.
- According to the ICHOM cataract standard, both CROMs and PROMs should be considered when evaluating the outcomes of cataract surgery

**Keywords** Cataract surgery · ICHOM · Patient-reported outcomes (PROMs) · Clinician-reported outcome measures (CROMs) · Catquest-9SF

## Introduction

Traditional clinician-reported outcomes measures (CROMs) are commonly used in clinical research to evaluate changes associated to a specific treatment or the progression of a pathological process [1]. However, CROMs do not fully represent the real change experienced by patients as CROMs do not consider the patients' personal experience and how they perceive the potential improvement or worsening associated with a specific health process [1]. The use of patient-reported outcome measures (PROMs) was developed to implement the clinical evaluation of any surgical intervention, medical treatment, programmed training, and impact of a pathological condition, with the final objective of collecting information for improving quality of care as well as the performance of health care providers [2]. PROMs can be evaluated by means of validated questionnaires developed according to strict and accurate methodology [3]. Despite advances in the evaluation of CROMs and PROMs, more research is still needed to determine the exact relationship between both and how they influence each other [4].

An adequate registry of PROMs and CROMs allows health institutions to extract consistent conclusions about different patient care processes, facilitating the definition of strategies to optimize them and to deliver better value for patients [5]. The International Consortium for Health Outcomes Measurements (ICHOM) is an initiative bringing together patient representatives, clinician leaders, and registry leaders from all over the world to develop standard sets, comprehensive yet parsimonious sets of CROMs and PROMs, and case-mix variables [6]. Each standard set focuses on patient-centered results, providing internationally agreed upon registries of standardized outcomes for different types of pathological conditions and their treatment [6]. This level of standardization offers new possibilities to compare global performance, therefore, enhancing clinician-to-clinician learning, and promoting more rapid improvement of patient care [6].

Within ophthalmology, two global standard outcome sets with the ICHOM framework have been developed, one for cataract surgery and the other one for macular degeneration [7]. The first one was developed for cataract surgery in 2013, the ICHOM Cataract standard [8]. It should be understood

that cataract surgery is the most commonly performed surgical procedure in a great number of countries, although there are very relevant inequalities in cataract service provision between countries according to socioeconomic indicators [9]. This Cataract set proposed to track postoperative visual acuity and target refraction; patient-reported visual function; intraoperative complications, including capsule problems and dropped nucleus; and other postoperative complications [8, 10]. The aim of the current European multi-site study was to evaluate in a large sample of patients the results of cataract surgery registered following the ICHOM Cataract Standard, characterizing the relationship between PROMs and CROMs for this type of surgical intervention.

## Methods

### Patients

This is a prospective non-interventional observational descriptive study involving 10 health institutions that enrolled a total of 3799 cases of cataract surgery. The ICHOM Cataract Standard Set version 2.0.1 was followed to register the clinical data of all these patients undergoing cataract surgery due to the presence of disturbed vision (poor vision or visual disabilities) during the period of recruitment of the study [10]. In order to be eligible for participation in this study, patients needed to meet the following inclusion criteria: patients of 18 years old or older at the time of surgical treatment indication, diagnosis of cataract and undergoing cataract surgery, and ability (e.g., mental and physical condition, language) to participate in all aspects of the study, including completion of PROMs. The following exclusion criteria were considered according to ICHOM Cataract standard [10]: combined surgical procedures (e.g., cataract extraction and corneal transplant surgery, cataract extraction and filtering surgery, cataract extraction and vitrectomy), cataract surgery for other reasons than disturbed vision, and cognitive functions disabling the patient to complete a questionnaire. The study adhered to the tenets of the Declaration of Helsinki and was approved by the ethics committee associated to each participating center.

### Main outcome measures

According to the ICHOM Cataract standard [10], the following outcome measures were collected and evaluated: postoperative corrected distance visual acuity (CDVA) in the operative eye, postoperative absolute refractive error, patient-reported visual function using the validated questionnaire Catquest-9SF, and intraoperative and postoperative complications including re-operation, endophthalmitis, persistent corneal edema, and others. Postoperative data were obtained within the first 3 months after surgery. Visual

acuity and refraction data were considered CROMs, whereas the Rasch-calibrated item 2 and total Catquest-9SF score were considered PROMs. Refraction was performed in all centers by trained optometrists or assistants.

The Catquest-9SF is a Rasch-analyzed, short, and highly responsive patient questionnaire for use in cataract surgery that measures activity limitations in daily life caused by cataract [3]. Specifically, this questionnaire contains seven questions about the perceived difficulty in performing daily-life activities, such as readings texts or watching TV, and two global questions about difficulties in general and satisfaction with vision. There are four possible response options for the perceived level of difficulty: 4, very great difficulty; 3, great difficulty; 2, some difficulty; and 1, no difficulty. For satisfaction with vision, the four response options are as follows: 4, very dissatisfied; 3, rather dissatisfied; 2, fairly satisfied; and 1, very satisfied. Each ordinal numerical score is transformed to adjusted Rasch-calibrated scores as ordinal scoring cannot be assumed to produce an interval scale [3]. The Catquest-9SF was found in a comparative study to be the most responsive to cataract surgery among 16 commonly used Rasch-scaled cataract surgery questionnaires [11].

As case-mix variables in the analysis performed, demographic factors (age, sex), baseline visual status (preoperative visual acuity, target refractive error), ocular comorbidities (glaucoma, macular degeneration, diabetic eye disease, amblyopia, others), prior ophthalmic interventions (previous cataract surgery on fellow eye, corneal refractive surgery, vitrectomy, other), and technical factors (dense brown or white cataract, corneal opacities, pseudoexfoliation, pupil problems) were considered, as established in ICHOM Cataract standard [10]. Likewise, the level of experience of the surgeon was also considered as case-mix variables.

### Data analysis

Given the descriptive nature of the study, the target sample size was not based on any formal tests of hypotheses. This study was aimed at including as many patients as possible for the duration of the data collection phase, with a minimum number of 500 eligible patients to be included per participating site if possible. To avoid the potential bias that can be introduced by considering the two eyes of each participant due to the inherent inter-eye correlation, only an eye per patient was selected randomly and included in the statistical analysis in those cases in which both eyes were eligible for cataract surgery. In patients with previous cataract surgery in one eye, the other eye was directly selected for the analysis.

Statistical analyses were performed with a commercially available software package (SPSS for Mac, Version 20.0; IBM Corporation, Armonk, NY, USA). Continuous variables were summarized using standard descriptive statistics

that included the number of patients ( $n$ ), arithmetic mean, standard deviation (SD), minimum, median, maximum, lower quartile (Q1), upper quartile (Q3), and the interquartile range (IQR). Categorical variables were described using absolute and relative frequencies (counts and percentages). Correlation Spearman's Rho non-parametric correlation coefficient was used in correlation analyses.

Finally, inferential analyses were performed by multiple linear regression for quantitative outcomes. The selection of significant variables was carried out by a step-by-step procedure, considering meanings of  $<0.05$  to enter or  $<0.10$  to remain in the model. Multicollinearity was assessed by the variance inflation factor (VIF) and by the condition index. High values of the condition index associated with an explanatory variable would indicate the presence of multicollinearity or quasi-collinearity associated with that variable. In that case, this variable was eliminated as an explanatory risk factor since its presence would have made the model unstable. The percentage of outcome explained by the variables of the model was quantified by the adjusted  $R$  squared. All the variables included in the final model were statistically significant. The relative importance of the factors included in the final model was established by the semi-partial correlation.

All statistical tests were performed with a level of significance of  $\alpha = 0.05$ .

## Results

### General description of the sample

A total of 3799 cases from 10 different European institutions were analyzed in the study (3799 eyes from 3799 patients). The distribution of the sample as function of gender was as follows: 1661 males (43.7%) and 2138

females (56.3%). A total of 1911 and 1888 right (50.3%) and left eyes (49.7%) were included. The number of cases included per institution ranged from 42 to 1222, with an average value of 400 cases per institution. Table 1 shows the participating centers in the current study and the level of contribution of each one. Mean age of patients enrolled in the study was 72.7 (standard deviation, SD = 9.3) years. The surgical procedure performed in all cases included in the current sample was phacoemulsification, with 95% (3174/3341) of them performed by an independent surgeon and only 5.0% (167/3341) by a trainee. No monovision cases (target refraction of more than  $-0.75$  D) were included in the current sample.

### Main outcome measures and case-mix variables

Table 2 summarizes the main outcome measures, including CROMs and PROMs, obtained in the sample evaluated as well as the case-mix variables defined according to the ICHOM CAT standard. As shown, there was a significant improvement with surgery in uncorrected and corrected distance visual acuity in the operative eye ( $p < 0.001$ ). A total of 88.7% (2505/2823) and 53.5% (1511/2823) of eyes achieved a postoperative CDVA of 0.3 and 0.0 logMAR or better, respectively. Concerning PROMs, mean differences between preoperative and postoperative Rasch-calibrated item 2 and total Catquest-9SF scores were  $-3.09$  and  $-2.39$ , respectively. A total of 91.5% (2163/2364) of patients referred an improvement of the visual function with surgery, whereas 1.6% (37/2364) and 6.9% (164/2364) of patients reported that it remained stable or worsened, respectively.

**Table 1** Summary of the participating centers in the current study and the level of contribution of each one

Center	City, country	Number of cases	% of the global sample
Silmäasema Silmäsairaala NHG	Several cities Finland	1222	32.2
Osakidetza Hospitals	Basque country, Spain	513	13.5
Het Oogziekenhuis Rotterdam	Rotterdam, The Netherlands	475	12.5
Universitätsklinikum Münster - Augenklinik	Münster, Germany	427	11.2
Medisch Centrum Jan van Goyen (OLVG)	Amsterdam, The Netherlands	423	11.1
Barcelona Clinic Hospital	Barcelona, Spain	231	6.1
Trieste University Hospital	Trieste, Italy	218	5.7
Department of Ophthalmology-Qvision, Vithas Virgen del Carmen	Almería, Spain	171	4.5
Optegra Eye Hospital	London, UK	77	2.0
Department of Ophthalmology, Torrecárdenas Hospital	Almería, Spain	42	1.1

**Table 2** Summary of the main outcome measures obtained in the sample evaluated as well as the case-mix variables defined according to the ICHOM CAT standard

	Mean value (SD)	Percentages
<b>Main outcome measures</b>		
Postoperative logMAR UDVA*	0.23 (0.29) surgical eye 0.08 (0.20) fellow eye	
Postoperative logMAR CDVA*	0.16 (0.27) surgical eye 0.40 (0.41) fellow eye	
Postoperative absolute SE (D)*	0.44 (0.58) surgical eye	
Postoperative complications		Return to operative theater within 3 months 0.3% Endophthalmitis 0.0% Persistent corneal edema 0.3% Other postoperative complication 1.5%
Intraoperative complications		Capsule problems 1.0% Dropped nucleus or lens fragment into vitreous 0.1% Zonular dehiscence 0.3% Vitreous prolapse 0.5% Other significant unexpected events during surgery that may influence the visual outcomes 0.6%
<b>Rasch-calibrated data Catquest-9SF</b>		
Preoperative ITEM 2¥	2.08 (1.71)	
Postoperative ITEM 2¥	-0.96 (2.01)	
Preoperative score¥	-0.50 (1.69)	
Postoperative score¥	-2.89 (1.37)	
<b>Case-mix variables</b>		
Preoperative logMAR UDVA	0.76 (0.45) surgical eye 0.47 (0.44) fellow eye	
Preoperative logMAR CDVA	0.43 (0.35) surgical eye 0.26 (0.31) fellow eye	
Ocular comorbidities		Glaucoma 10.1% Macular degeneration 7.1% Diabetic retinopathy and/or diabetic macular edema 2.3% Amblyopia 2.2% Others 15.5%
Prior ophthalmic interventions		Previous cataract surgery on fellow eye 37.5% Previous corneal refractive surgery on operative eye 0.7% Previous vitrectomy on operative eye 1.9% Others 4.1%
Technical factors		White or dense brown cataract 6.7% Corneal opacities 1.3% Pseudoexfoliation 3.4% Pupillary problems 4.2%

*SD*, standard deviation; *UDVA*, uncorrected distance visual acuity; *CDVA*, corrected distance visual acuity; *SE*, spherical equivalent; *D*, diopters

\*CROMs, clinician-reported outcome measures

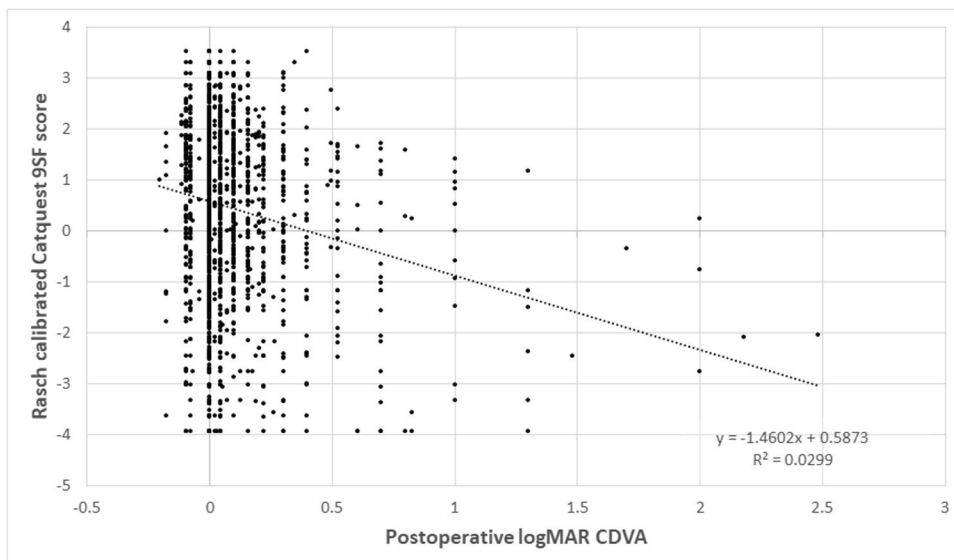
¥PROMs, patient-reported outcome measures

## Correlation between CROMs and PROMs

Statistically significant although weak correlations of postoperative CDVA with the following postoperative variables were found: absolute spherical equivalent ( $r = 0.212$ ,  $p < 0.001$ ), Rasch-calibrated item 2 Catquest-9SF score ( $r = 0.235$ ,  $p < 0.001$ ), Rasch-calibrated Catquest-9SF score ( $r = 0.289$ ,  $p < 0.001$ ) (Fig. 1), and the rate of

complications ( $r = 0.133$ ,  $p < 0.001$ ). Poor although statistically significant correlations of postoperative spherical equivalent with PROMs were found (item 2 Catquest-9SF score:  $r = 0.075$ ,  $p < 0.001$ ; total Catquest-9SF score:  $r = 0.087$ ,  $p < 0.001$ ). A similar finding was obtained when analyzing the correlation of PROMs with the postoperative complication rate (item 2 Catquest-9SF score:  $r = 0.097$ ,  $p < 0.001$ ; total Catquest-9SF score:  $r = 0.089$ ,  $p < 0.001$ ).

**Fig. 1** Scattergram showing the relationship between postoperative corrected distance visual acuity (CDVA) and postoperative Rasch-calibrated Catquest 9SF score. The adjusting line to the data obtained by means of the least-squares fit is shown



## Multiple linear regression analysis

A statistically significant predictive model of postoperative CDVA from a variety of clinical data was obtained, as summarized in Table 3 ( $p < 0.001$ ), including preoperative CDVA, different ocular comorbidities, age, gender, and intraoperative complications. The adjusted  $R^2$  value associated to this predictive model was 0.254. Furthermore, another significant predictive model was found for the postoperative Catquest-9SF score considering a total of 14 variables, with an adjusted  $R^2$  value of 0.148 (Table 3). No multicollinearity was present in these models, with VIF and condition index values within an acceptable range. The level of experience of the surgeon (independent/trainee) and target refraction were not predictive factors for the final visual outcome.

## Discussion

The ICHOM Cataract standard was developed as a minimum standard set of outcome measures for cataract surgery of special relevance for meaningful comparison across contexts [8]. These proposed outcome measures are the result of a compromise between the need for obtaining potentially useful data and the practicalities of data collection [8]. Michelotti et al. [7] reported the first experience of using the ICHOM Cataract standard for a review of ophthalmic outcome measures reported by eye hospitals in diverse populations in various nations, including Australia, India, Singapore, Sweden, the UK, and the USA. This study presented important limitations, being the most relevant that none of the hospitals reported patient-reported visual functioning or vision-related quality of life outcomes measures (PROMs)

[7]. In the current study, this ICHOM Cataract standard was followed in 10 centers across Europe, obtaining relevant data to optimize cataract surgery outcomes and analyzing the real relationship between PROMs and CROMs.

In our sample, as expected, the main technique used for cataract surgery was conventional phacoemulsification, which is currently considered the gold standard [12]. Indeed, clear corneal phacoemulsification has been shown to be the first technique taught to trainees at 91% of ophthalmology training programs [13]. Concerning distance visual outcomes, a significant improvement was found in CDVA, as expected considering the results of previous large series evaluating cataract surgery outcomes with implantation of different types of intraocular lens (IOL) [7, 14, 15]. A database study analyzing 368,256 cataract extractions from 15 European countries revealed that a postoperative CDVA of 0.3 logMAR or better and of 0.0 logMAR or better was achieved in 94.3% and 61.3% of cases, respectively [15]. In our sample, these percentages were somewhat lower, with values of 88.7% and 53.5%, respectively. Several factors may account for these differences between studies, including differences in sample size, the type of IOL implanted, or tests used for evaluating the visual acuity. However, it is important to point out that most of patients undergoing cataract surgery in all studies achieved a satisfactory visual outcome.

Besides the visual outcome, changes in PROMs were evaluated by means of the Catquest-9SF questionnaire, obtaining a significant change with surgery in Rasch-calibrated item 2 score (mean change  $-3.09$ ) as well as in the general score (mean change  $-2.39$ ). It should be considered that the item 2 of the questionnaire asks about satisfaction with the visual outcome. The change in Catquest data was negative, representing a decrease in the score obtained and therefore representing a lower level of difficulty or

**Table 3** Predictive factors of postoperative corrected distance visual acuity after cataract surgery in the analyzed sample obtained by means of multiple linear regression analysis

Variable	Non-standardized <i>B</i> coefficient	Statistical significance	Partial correlation
Postoperative corrected distance visual acuity			
Preoperative corrected distance visual acuity	0.209	<0.001	0.337
Macular degeneration	0.124	<0.001	0.158
Other ocular comorbidities that are likely to significantly impact the outcome of surgery.	0.096	<0.001	0.161
Age over 75 years old	0.049	<0.001	0.116
Glaucoma	0.059	<0.001	0.090
Amblyopia	0.116	<0.001	0.086
Diabetic retinopathy and/or diabetic macular edema	0.099	<0.001	0.082
Sex	0.017	0.014	0.042
White or dense brown cataract	-0.035	0.025	-0.038
Intraoperative complications	0.056	0.026	0.038
Postoperative Catquest-9SF score			
Preoperative Catquest-9SF score	0.192	<0.001	0.240
Macular degeneration	0.560	<0.001	0.110
Other ocular comorbidities that are likely to significantly impact the outcome of surgery.	0.477	<0.001	0.118
Previous cataract surgery on fellow eye	-0.260	<0.001	-0.100
Other previous interventions on surgery eye	0.388	<0.001	0.076
Age over 75 years old	0.184	0.001	0.071
Pupil problems	0.323	0.001	0.070
Preoperative corrected distance visual acuity	0.321	<0.001	0.081
Glaucoma	0.234	0.006	0.060
Amblyopia	0.495	0.005	0.060
Target spherical refraction on surgery eye	0.076	0.023	0.049
Corneal opacities	-0.385	0.036	-0.046
White or dense brown cataract	-0.416	0.001	-0.072
Intraoperative complications	0.449	0.020	0.051

dissatisfaction. This same trend has been reported by other authors using the same questionnaire to evaluate the impact of cataract surgery. [16–23]. Therefore, cataract surgery not only promotes an improvement in visual acuity but also a resolution of activity limitations in daily life caused by visual function. Specifically, an improvement of the Catquest scoring and consequently of the visual function and its impact on daily life actions was found in 91.5% of patients. Chaudhary et al. [16] reported in a prospective study evaluating the cataract surgery outcomes in 343 patients that functional vision improved in 83.7% of the cases.

Several statistically significant correlations were found among PROMs and CROMs, although all of them were weak or poor, confirming the multifactorial nature of the relationship among these two types of variables. As in previous series, [18, 22, 24] the presence of complications was associated with poorer visual outcome and worse self-assessed visual function, although the level of correlation was weak. Other authors have found no significant effect of complications on the visual function outcome [23]. These

apparently contradictory findings between authors may be attributed to the low rates of complications or the lower severity of such complications obtained in some series, having a minimal impact on the global visual outcome. Other factors such as surgeon's experience, the health peculiarities of the population evaluated, technology at the operating theater, or the surgical protocol followed may introduce a significant variability in this relationship among complications and PROMs-CROMs. Furthermore, in our series, the level of correlation of self-assessed visual function with complications was weaker than that corresponding to visual acuity, confirming the limited impact of such complications on the subjective evaluation of the level of vision. Besides complications, other factors correlating with postoperative CDVA were absolute spherical equivalent and Catquest-9SF scores. As in previous studies [16–18, 24, 25], there is a limited but statistically significant correlation of visual acuity and self-assessed level of vision evaluated by the Catquest-9SF questionnaire. Chaudhary and coauthors [16] found in a prospective cohort study that the

mean baseline Catquest-9SF score was the only significant predictor of functional vision improvement. Specifically, these authors confirmed that functional vision improved by 0.74 logits when mean baseline survey score increased by 1 logit after controlling for other variables [16]. All these outcomes confirm that PROMs cannot be derived directly from visual acuity measurements and that visual acuity does not fully reflect patients' visual function. Therefore, the use of patient-reported outcome measure questionnaires must be considered by clinicians to facilitate surgical decision-making and outcome monitoring.

Finally, multiple regression analysis has been conducted to detect predictive factors of postoperative CDVA and Catquest-9SF score. A model predicting postoperative CDVA from ten different clinical variables was found, including preoperative CDVA, different ocular comorbidities, age, gender, and intraoperative complications. Specifically, worse postoperative visual acuity was expected in those females with worse preoperative CDVA, the presence of comorbidities such as macular degeneration, glaucoma, amblyopia, or diabetic retinopathy; and/or diabetic macular edema; no white or dense brown cataract; occurrence of intraoperative complications; and age over 75 years old. As may be expected, the presence of comorbidities with the potential of damaging the ocular structures is a factor related to worse visual outcomes. This finding has been also reported by previous authors in other series and should be considered for defining the visual prognosis of any patient undergoing cataract surgery [18, 22, 25].

In the current study, another predictive model was obtained for postoperative Catquest-9SF score considering a total of 14 predictors. Specifically, a worse postoperative self-assessed visual function after cataract surgery was expected in patients with worse preoperative visual acuity and Catquest-9SF scores; presence of comorbidities such as macular degeneration, glaucoma, amblyopia, or diabetic retinopathy and/or diabetic macular edema; no white or dense brown cataract or corneal opacities; presence of pupil problems; occurrence of intraoperative complications; no previous surgery in the fellow eye; higher target refraction; other previous ocular interventions; and age over 75 years old. This is consistent with some trends reported in previous studies evaluating the relationship between CROMs and PROMs in large sample of cases [4, 16, 18, 22]. Molazadegan and Lundström [22] found that factors such as large anisometropia ( $\geq 3D$ ), capsule complications, biometry prediction error ( $\geq 3D$ ), and ocular comorbidity were related to a poor patient-reported outcome. In another series, good preoperative self-assessed visual functions, poor preoperative visual acuity in the better eye, ocular comorbidity, surgical complications, and large refractive deviation were defined as factors related to poor patient-reported outcomes after surgery [4]. However, despite the different attempts

of obtaining predicting models of PROMs from different clinical data, including CROMs, the variability of PROMs that can be explained by the clinical data considered to date is limited. Measuring over a 2-year period may be able to demonstrate the reduction in variation, based on implementing the standard consistently and have global benchmarking at the 2-year point.

This study provides a real-world evidence of the practice of cataract surgery in different European centers, and due to its nature, some inherent limitations are present. The most relevant limitation is that there was some missing information in some patients mainly due to logistic limitations in the real clinical practice or even drop-out visits. Despite this, a large sample size was obtained to extract relevant conclusions. Furthermore, the selection of the centers involved was not random and for this reason the findings obtained cannot be extrapolated to the global European practice. The inclusion in the sample of independent surgeons and trainees can be also considered a source of bias, but this factor was found to have a non-significant impact on the final visual outcome. Several factors may have accounted for this finding besides the surgeon training program and the competencies acquired. It should be considered that the surgical time which is directly related to the development of some complications has been found to be influenced by factors such as anesthesia type, high case complexity, pupil size, or the use of capsular tension ring [26]. As different optometrists and assistants in each center obtained the manifest refraction of patients, some variability may have been introduced by this factor and should be considered when a data extrapolation to other environments is intended to be done. Finally, a longer follow-up should be considered in future studies to understand the real impact of surgery in the long term.

In conclusion, cataract surgery provides an improved functional vision in most of patients undergoing this surgical procedure. The presence of ocular comorbidities as well as complications is a predictive factor of worse visual acuity and self-assessed visual function after cataract surgery. The relationship between PROMs and CROMs is multifactorial and complex, with the possibility of only explaining a minimal portion of PROMs variability with CROMs and other clinical data. Considering this, as stated by ICHOM cataract standard, both CROMs and PROMs should be considered when evaluating the outcomes of cataract surgery. The results obtained in the current study should be confirmed in future studies evaluating other samples of eyes from different clinical environments.

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## Declarations

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the ethics committees of the centers involved in the study and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

**Conflict of interest** The authors declare no competing interests.

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