

Determinants of patient satisfaction and function related to vision following cataract surgery in eyes with no visually consequential ocular co-morbidity

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Received: 21 April 2015 / Accepted: 23 April 2015
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Abstract

Purpose To investigate subjectively reported outcomes following cataract surgery and the relationships between such outcomes in the context of falling thresholds for cataract surgery.

Setting Large, private, non-refractive cataract practice, Institute of Eye Surgery, Whitfield Clinic, Waterford, Ireland

Methods Pre-operative, intra-operative and post-operative data of 2552 eyes undergoing phacoemulsification and implantation of the Tecnis^R ZCB00 1-piece intraocular lens (IOL) by a single surgeon between July 2009 and October 2013 was analysed. Patients without visually consequential ocular co-morbidity completed two validated questionnaires, designed to assess subjectively perceived visual functioning and identify symptoms of dysphotopsia following cataract surgery.

Results 54.8 % of questionnaire respondents were entirely satisfied (satisfaction 10/10) post-operatively, with 83.7 % reporting satisfaction of $\geq 7/10$. Satisfaction was positively associated with patient age and negatively associated with spectacle dependence, dysphotopsia, and function related to vision (NEI VF-11) score. The mean (\pm standard deviation[SD]) dysphotopsia score was 1.36 (± 1.9 ; scale 0–10), with 40 % of respondents reporting no dysphotopsia symptoms and 9.8 % reporting clinically meaningful dysphotopsia. The mean (\pm SD) National Eye

Institute visual function-11 (NEI VF-11) score was 0.33 (± 0.53 ; scale 0–4) and reduced function related to vision was associated with increasing severity of dysphotopsia symptoms. When linear regression was applied, 17.5 % of the variation in functionality was attributable to symptoms of dysphotopsia.

Conclusion Dysphotopsia is an important determinant of a patient having difficulty with vision-related tasks following cataract surgery, and patient satisfaction is positively associated with patient age and negatively associated with spectacle dependence, dysphotopsia and function related to the vision (NEI VF-11) score.

Keywords Cataract surgery · Dysphotopsia · NEI VF-11 · Satisfaction · Tecnis IOL

Introduction

The falling threshold for cataract surgery over the last number of years has been inextricably and synchronously linked to rising patient expectations [1]. Nevertheless, and in spite of the emerging consensus that visual acuity (VA) is no longer a valid tool (at least in the absence of complementary measures) to inform the surgeon's decision-making process when an offer of cataract surgery is under consideration, measures of VA remain the sole record of visual function in over 90 % of patients scheduled to undergo this procedure, at least in the UK and Republic of Ireland [2].

Accordingly, and especially in an era where the technologies employed in, and goals of, cataract surgery are ever-changing, it is important to intermittently revisit and report the outcomes of cataract surgery, including subjectively perceived changes in visual function following cataract surgery,

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which remains the most commonly performed surgical procedure worldwide [1].

In this study, we report the prevalence of dysphotopsia, and investigate determinants of patient satisfaction and difficulty with vision-related tasks, following cataract surgery in eyes without visually consequential ocular co-morbidity.

Materials and methods

This study adhered to the tenets of the Declaration of Helsinki, and the local ethics committee (Research Ethics Committee, Health Service Executive, South Eastern Area, Ireland) gave approval on the basis that it represents a clinical audit and, therefore, represents best clinical practice.

All patients who underwent phacoemulsification cataract surgery with implantation of the Tecnis^R ZCB00 1-piece intraocular lens (IOL; ZCB00, Advanced Medical Optics Inc, Santa Ana, CA, USA) by a single surgeon (SB) since the introduction of these IOLs to the Institute of Eye Surgery (IoES), Whitfield Clinic, were identified from the electronic medical records (EMR; Medisoft Ophthalmology, Version 5.1.2;) and their data was analysed for this study. No other non-toric IOL type was implanted during this period.

At the IoES, a robust system of informed consent is employed. At the time of listing for a proposed cataract procedure, the patient signs a detailed information leaflet which is then counter-signed by the surgeon; this is then scanned into the patient's EMR and the original is returned to the patient for perusal before the pre-operative assessment, which is typically several weeks later and approximately 2 weeks prior to the proposed surgery date. The pre-operative assessment only commences once the patient acknowledges (in writing) that he/she has read, and understood, the information leaflet. Following a thorough pre-operative assessment, the patient watches an information video (Eyemaginations LUMATM) which explains the risks inherent in cataract surgery, with emphasis on the possibility of losing all vision, or even an eye. Then, once all patient queries are satisfactorily answered, he/she is invited to sign a consent form, which allows the surgeon to undertake the proposed procedure.

Pre-operative assessment at the IoES includes various measures of ocular biometry and visual function, as well as a discussion on the desired post-operative refractive status, and this is standardised according to IoES protocol.

Pre-operative data for this study included: demographic details; best corrected VA (BCVA; Test Chart 2000 Pro; Thomson Software Solutions, Hertfordshire, England; Bailey-Lovie, Snellen notation); autorefractometry (POTEC PRK-500 Autorefractometer, POTEC Co. Ltd, Gaejeon City, Korea); partial coherence interferometry biometry (IOLMaster, Version 5, Carl Zeiss Meditec AG, Jena, Germany); corneal topography (Pentacam Comprehensive Eye Scanner, software

version 1.16; Oculus, Inc, Wetzlar, Germany); assessment for eligibility and suitability for consideration of implantation of a toric IOL (tIOL) at the time of the procedure (Alcon Acrysof [www.acrysoforiccalculator.com] and Abbott Tecnis [www.tecnistoricool.com] websites); and ocular co-morbidity.

Because of the retrospective nature of this study, VA measurements were not consistently recorded in each case; VA was recorded (pre and post-operatively) under at least one of the three following conditions: unaided (UA); best corrected (BC); pinhole (PH). Typically, eyes with sub-optimal UAVA will also have undergone VA testing with current spectacle correction (if available) or PHVA. Where the same VA measurement (UA, PH or BC) was taken both pre- and post-operatively, these paired measurements were analysed for change as a result of the procedure. However, in the wider context, the term optimum VA (OptVA) was adopted to define the best recorded VA (whether UA, PH or BC) in order to compare similar measurements in a pre-operative and post-operative setting.

Research in Sweden [3] has determined that the presence of visually consequential ocular co-morbidity is associated with reduced patient self-assessed visual function post-operatively. Accordingly, and in order to best assess (non-refractive) outcomes of the procedure, we elected to exclude patients with visually consequential ocular co-morbidity for the purpose of analysing patient satisfaction, function related to vision and symptoms of dysphotopsia. In this regard, visually consequential ocular co-morbidity was defined in a way that was in keeping with the questionnaires [4] we used, and included: corneal pathology that affected vision, other than mild guttata; dry eye syndrome, where there is corneal staining; glaucoma; macular pathology, except minimal hard drusen without retinal pigment epithelium pathology; diabetic retinopathy other than minimal non-proliferative background pathology; any cause of central VA loss, including dysfunction of the optic nerve or occipital cortex; amblyopia.

A substantial proportion of the pre-operative discussion centres around the desired post-operative refractive status, and is informed by the Priquest questionnaire [5], completed by the patient, and supported by careful explanation regarding the implications of any decision taken.

Surgical details: One surgeon performed all cataract removal and implantation procedures using a standard technique [6]. All intra-operative details, including IOL model, complications, etc., were immediately inputted, in standardised format, to the EMR by the surgeon following the procedure, thereby facilitating a reliable audit of such data through Medisoft Ophthalmology (Version 5.1.2).

Following an uneventful procedure, the patient was scheduled for first review by the same surgeon two weeks post-operatively [7]. This is a standardised visit for all post-operative patients at the IoES and includes: UA and PH VA; identification of post-operative complications; auto-refraction.

Best corrected subjective refraction is furnished to the IoES by the patient's local optometrist, a minimum of 4 weeks post-operatively.

Refractive results after cataract surgery were reported in terms of the prediction error (PE), which is the result of the actual post-operative spherical equivalent (actual SE) minus the target post-operative spherical equivalent (target SE). Therefore, a patient with a more myopic than intended refractive result would have a negative PE, while a more hyperopic than intended result would be positive. Thus, PE includes both the magnitude and the sign of any post-operative error. When examining deviation from target refractive outcome, we used the absolute PE.

All patients without visually consequential ocular comorbidity were invited to complete two validated questionnaires [4]. The first of these was designed to assess the impact of cataract surgery on subjectively perceived visual function, the second to identify symptoms of dysphotopsia. A global satisfaction question (on a 1–10 scale, with 10 representing total satisfaction) was incorporated. The questionnaires were answered in relation to the operated eye only and, where a patient underwent bilateral surgery, a set of questionnaires was answered in relation to each eye.

Statistical methods

For statistical analysis, Snellen notation was converted to a VA rating (VAR) notation [8]. Snellen acuity of 20/20 was assigned a score of 100 and BCVA was scored relative to this value. Each letter correctly identified was given a nominal value of 1, so that 20/30 would give a score of 90, 20/40 a score of 85. Our EMR does not have a facility to record additional letters on the next line or missed letters on an almost complete line (i.e., 20/20 \pm 1), so the best complete line was recorded.

The principal outcome measure in this study was the subject-reported satisfaction score. Statistical analysis, therefore, focused on the relationship of this satisfaction score to other study variables (individually or jointly). General linear models are often the main statistical tool for this type of analysis, but we also performed linear mixed model analysis to take into account the non-independence of paired eyes (2552 study eyes but only 1628 subjects).

Kinard et al. [4] opted to use Rasch-transformed questionnaire scores in place of the raw questionnaire item scores. We, however, were unable to justify assignment of different weights to individual questionnaire items on the basis of the frequency of high scores for those particular items. We believe that dysphotopsia symptoms are all visually important, and cannot assert that one may be more debilitating than another. Similarly, we feel that the visual functions examined are all equally important and cannot, therefore, give greater weight to

difficulty in one task over another. The questionnaire results reported and analysed in this study, therefore, were obtained by simple summation and averaging of scores on individual questionnaire items.

For statistical purposes, for patients who underwent sequential bilateral cataract surgery, each eye was analysed independently in terms of visual outcome and PE, as it has been shown that the correlation between fellow eyes in relation to refractive outcome is weak [2]. The statistical package SPSS (Version 20) (IBM Corp, Somers, NY) was used for the analysis of visual outcome and PE. For the analysis of post-operative satisfaction, the presence of dysphotopsia symptoms, and visual function, it cannot be assumed that the results of the right and left eyes of the same patient are truly independent. For these datasets, we used a different statistical approach to account for this, the random intercept model from the class of linear mixed models, available in the NLME package in the statistical programming language R [9].

Results

In total, 2552 phacoemulsification cataract procedures with implantation of a ZCB00 were performed during the study period. Of these 2552 eyes (the entire dataset), 1368 eyes (53.6 %) exhibited pre-operative visually consequential ocular co-morbidity; this cohort was termed Group 1. The remainder, 1184 eyes (46.4 %) were free from pre-operative visually consequential ocular co-morbidity; this cohort (Group 2) was invited to complete the questionnaire element of the study. The demographics of these groups are shown in Table 1.

The pre-operative, baseline measures of acuity for the entire dataset are given in Table 2.

Table 3 shows the pre-operative, baseline measures of acuity for Group 1 (those of the entire dataset with pre-operative visually consequential ocular co-morbidity).

Table 4 shows the pre-operative, baseline measures of acuity for Group 2 (those of the entire dataset without pre-operative visually consequential ocular co-morbidity).

Surgical results

Of the entire 2552 procedures, an intra-operative complication occurred in 16 (0.6 %) procedures (Table 5). The most common intra-operative complications were: posterior capsule rupture (PCR) with vitreous loss, all of which required anterior vitrectomy (0.16 %, but representing 25 % of intra-operative complications); zonular dialysis (0.16 %, but representing 25 % of complications); iris trauma (0.12 % of procedures, representing 18.75 % of intra-operative complications).

Post-operative complications were seen in 168 cases (6.6 % of total procedures), the most common being pseudophakic

Table 1 Pre-operative demographics

Group	n (%)	Mean (\pm SD) age	Age Range	R:L ratio (%)
Entire	2558 (100 %)	70.91 (\pm 9.1)	23-99	1269:1283 (49.7 %:50.3 %)
Group 1	1368 (53.6 %)	70.98 (\pm 9.44)	26-97	663:705 (48.8 %:51.5 %)
Group 2	1184 (46.4 %)	69.1 (\pm 8.6)	23-99	605:579 (51.1 %:48.9 %)
Group	M:F ratio (%)	n (%) OptVA \geq 20/30		n (%) OptVA \leq 20/200
Entire	928:1624 (36.4 %:63.6 %)	2313 (90.6 %)		179 (7 %)
Group 1	514:854 (37.6 %:62.4 %)	761 (55.6 %)		124 (9.1 %)
Group 2	390:742 (34.5 %:65.5 %)	926 (78.21)		23 (1.9 %)

Mean (\pm SD) age, mean (\pm standard deviation) age of group; R:L ratio (%), ratio (%) of right to left eyes; M:F (%) ratio, ratio (%) of male:female; n (%) OptVA \geq 20/30, number of patients with OptVA \geq 20/30; n (%) OptVA \leq 20/200, number of patients with OptVA \leq 20/200; Entire, entire dataset; Group 1, those of the entire dataset with pre-operative visually consequential ocular co-morbidity; Group 2, those of the entire dataset without pre-operative visually consequential ocular co-morbidity;

All ratio and OptVA percentages are percentages of the relevant group total

cystoid macular oedema (CMO), which occurred following 87 (3.4 %) procedures (Table 6).

Refractive results

Refractive results were available for 1924 cases (75.3 %) following cataract surgery. PE ranged from -5.18 (one eye) to $+2.95$ D (one eye), mean absolute PE was 0.45 D (± 0.41), with 92.7 % of eyes exhibiting an absolute PE of less than 1D, and 99.1 % of eyes exhibiting an absolute PE of less than 2D. Sixteen eyes (0.8 %) exhibited an absolute PE greater than 2D.

Following exclusion of eyes which underwent cataract surgery combined with planned pars plana vitrectomy (PPV) [n=3], and of those which underwent unplanned anterior vitrectomy and subsequent pars plana vitrectomy for removal of dislocated lens fragments [n=1], the mean absolute PE was 0.44 D (± 0.38 D; range -1.62 D to $+2.6$ D), with 93 % of eyes exhibiting an absolute PE of less than 1D and 99.4 % of eyes exhibiting an absolute PE of less than 2D.

Table 2 Pre-operative measures of visual acuity for 2552 cataractous eyes scheduled to undergo cataract surgery and implantation of a ZCB00

Measure	n	%	Mean	SD	Range
UAVA	1845	72.5	73.33	20.95	2.5-104
PHVA	640	25.1	85.81	14.35	5-104
BCVA	1606	62.9	86.50	20.25	2.5-109
OptVA	2552	100	85.99	20.43	2.5-109

Mean, mean acuity; SD, standard deviation; UAVA, unaided visual acuity; PHVA, pinhole visual acuity; BCVA, best corrected visual acuity; OptVA, best visual acuity measure recorded

Finally, upon exclusion of eyes with pre-operative visually consequential ocular co-morbidity (n=1010), and/or a synchronous and planned PPV (n=3), and/or an intra-operative complication and/or a post-operative complication (n=178), the mean absolute PE was 0.40 (± 0.32), with PE ranging from -1.39 D to 2.6 D, with only 1 eye of 733 (0.001 %) having an absolute PE of greater than 2D.

Post-operative VA results

Post-operative VA is reported for the three groups of operated eyes as follows:

Group 1 operated eyes with pre-operatively observed visually consequential ocular co-morbidity;

Group 2 operated eyes without pre-operatively observed visually consequential ocular co-morbidity;

Table 3 Pre-operative measures of visual acuity for 1368 cataractous eyes with visually consequential ocular co-morbidity (Group 1) scheduled to undergo cataract surgery and implantation of a ZCB00

Measure	n	%	Mean	SD	Range
UAVA	946	69.1	68.6	23.54	2.5-104
PHVA	321	23.5	81.96	16.82	2.5-104
BCVA	898	65.6	81.87	24.08	2.5-104
OptVA	1368	100	81.06	24.41	2.5-104

Mean, mean acuity; SD, standard deviation; UAVA, unaided visual acuity; PHVA, pinhole visual acuity; BCVA, best corrected visual acuity; OptVA, best visual acuity measure recorded

Table 4 Pre-operative measures of visual acuity for 1184 cataractous eyes with no visually consequential ocular co-morbidity (Group 2) scheduled to undergo cataract surgery and implantation of a ZCB00

Measure	n	%	Mean	SD	Range
UAVA	901	76.1	78.22	16.38	5-104
PHVA	318	26.9	89.92	9.72	50-104
BCVA	713	60.2	92.27	11.93	5-109
OptVA	1184	100	91.96	11.71	5-109

Mean, mean acuity; SD, standard deviation; UAVA, unaided visual acuity; PHVA, pinhole visual acuity; BCVA, best corrected visual acuity; OptVA, best visual acuity measure recorded

Group 3 operated eyes which experienced an intra- and/or a post-operative complication;

Visual results for each of these three groups, and statistical significance of observed changes from pre-operative measures of VA, are given in Table 7. The p-values reported in Table 7 are from paired sample t-tests.

In Groups 1 and 2, all measures of VA (UAVA, PHVA, BCVA and OptVA) exhibited a statistically significant improvement following cataract surgery (based on paired t-tests), with the exception of BCVA in Group 1 (eyes which exhibited visually consequential ocular co-morbidity prior to surgery) in which the improvement was not statistically significant.

In Group 3 (operated eyes which experienced an intra- and/or a post-operative complication), a statistically significant improvement in both UAVA and OptVA was observed, despite the occurrence of a complication. A small (but statistically non-significant) reduction in pinhole acuity was observed, but this was from a relatively small sample of eyes where PHVA was recorded pre- and post-operatively (n=64). The observed improvement in BCVA in Group 3 was not statistically significant.

Table 5 Intra-operative complications for 2552 cataractous eyes that underwent cataract surgery and implantation of a ZCB00

Complication	n	%
PC rupture, vitreous loss	4	0.16
Zonular dialysis	4	0.16
Iris trauma	3	0.12
Choroidal/suprachoroidal haemorrhage	2	0.8
Hyphaema	1	0.04
IOL exchange required*	1	0.04
Nuclear fragment dislocated into vitreous cavity	1	0.04

PC, posterior capsule; IOL, intra-ocular lens;

*wrong IOL power implanted, and exchanged immediately;

Table 6 Post-operative complications

Complication	n	%
CMO	87	3.4
Transient corneal oedema	22	0.8
Raised IOP	18	0.7
Decentred IOL	4	0.1
Post-operative uveitis	11	0.43
Unexpected refractive outcome	3	0.12
Post-operative ptosis	1	0.04
Leaking wound	3	0.11
Bleb leakage	1	0.04
Choroidal effusion/haemorrhage	2	0.08
Corneal decompensation	2	0.08
Hyphaema	1	0.04
Diplopia	1	0.04
Retained soft lens matter	9	0.35
Retinal tear	2	0.08
Vitreous in the anterior chamber	1	0.04

CMO, cystoid macular oedema; IOP, intra-ocular pressure; IOL, intra-ocular lens;

Table 7 Measures of post-operative visual acuity, and changes with respect to respective pre-operative measures of visual acuity

Measure	n	%	Mean	SD	AvChange	p
Group 1:						
UAVA	1849	72.5	84.9	20.626	14.77	<0.001
PHVA	644	25.2	82.42	15.57	4.26	0.016
BCVA	1611	63.1	82.11	22.99	0.90	0.264
OptVA	2252	100	84.03	22.86	2.98	<0.001
Group 2						
UAVA	944	79.7	94.37	8.62	15.29	<0.001
PHVA	227	19.2	91.81	9.20	3.59	0.004
BCVA	308	26.0	96.09	8.73	4.66	<0.001
OptVA	1184	100	95.15	12.20	3.19	<0.001
Group 3						
UAVA	124	69.3	88.79	12.71	10.38	<0.001
PHVA	64	35.8	86.81	11.56	-0.18	0.937
BCVA	62	34.6	92.91	13.87	1.64	0.438
OptVA	178*	100	92.00	11.25	3.88	0.010

Mean, mean VA; SD, standard deviation; AvChange, average change in this measure of acuity as a result of cataract surgery; UAVA, unaided visual acuity; PHVA, pinhole visual acuity; BCVA, best corrected visual acuity; OptVA, best measure of visual acuity recorded; p, p value; Group 1, those eyes of the entire dataset with pre-operatively observed visually consequential ocular co-morbidity; Group 2, entire dataset but upon exclusion of eyes with pre-operatively observed visually consequential co-morbidity; Group 3, operated eyes which experienced an intra- or post-operative complication;

*although the total number of complications was 184, some eyes experienced both an intra- and a post-operative complication;

Self-reported post-operative results

658 completed sets of questionnaires were returned, representing 356 right eyes and 302 left eyes, of 429 patients, a 55.6 % response rate, and, once analysed, these provided three self-reported scores for analysis with respect to other variables:

Satisfaction score: Subjects rated their post-operative satisfaction on a scale of 0 to 10, 10 representing complete satisfaction. Of note, 361 respondents (54.9 %) reported complete satisfaction following the procedure (10/10); for 551 eyes (83.7 %), the satisfaction score was ≥ 7 . A satisfaction score of < 5 was assigned to 34 eyes (5.2 %).

Dysphotopsia score: This was obtained by averaging Likert scale scores from the pseudophakic dysphotopsia questionnaire (PDQ) items. The mean (\pm SD) PDQ score was 1.36 (± 1.9), in the context of a maximum score of 10. Of note, 265 patients (40 %) had a dysphotopsia score of 0, reporting no symptoms of dysphotopsia, with only 58 respondents (9.8 %) reporting a clinically meaningful level of dysphotopsia, defined as an average dysphotopsia score of $\geq 4/10$.

Functionality score: This was obtained by averaging Likert scale scores from the functionality questionnaire (NEI VF-11) items. The mean (\pm SD) NEI VF-11 score was 0.33 (± 0.53), where a maximum score is 4, with a higher score indicating a greater level of difficulty in performing tasks.

Relationship of satisfaction score to other study variables

Satisfaction score on preliminary analysis (analysing the relationship of each individual study variable to satisfaction score, and treating all 659 eyes as statistically independent) was found to be statistically related to many study variables, including: age; spectacle dependence; pre-operative BCVA and pre-operative OptVA; change (from pre- to post-op) in BCVA, UAVA and OptVA; dysphotopsia questionnaire (PDQ) score; NEI-VF11 score (functionality related to vision). Of note, the correlation between pre-operative BCVA and satisfaction score is significant but negative ($r = -0.125$, $p = 0.014$), indicating that those with good BCVA pre-operatively reported less satisfaction than others.

However, gender, pre-operative UAVA, post-operative absolute PE, change in PHVA, and intra- or post-operative complications were not associated with patient satisfaction in a statistically meaningful way ($p > 0.05$ for all). Questionnaires were completed by only 15 subjects (19 eyes) who experienced a complication (either intra- or post-operative) and this may account for the non-significant relationship between satisfaction and complications. Of note, all of the eyes which experienced posterior capsular rupture with vitreous loss exhibited visually consequential ocular co-morbidity pre-

operatively, and, therefore, were automatically excluded from the satisfaction survey.

We re-analysed the above significant relationships (between satisfaction score and other study variables) using a linear mixed model, to take account of non-independence of satisfaction scores (many subjects reporting satisfaction scores for both eyes), and to control for statistical confounding (explanatory variables related both to satisfaction score and to other explanatory variables). Just four variables remained related to satisfaction in a statistically meaningful way following this analysis, and these were: patient age; dysphotopsia score; functionality score; and post-operative spectacle dependence.

These four variables were related to patient satisfaction score as follows:

Age Older patients reported greater satisfaction: e.g., in the 34–66 age group, the mean satisfaction score was 8.3 (± 2.26), compared to 8.8 (± 1.99) and 9.0 (± 1.81) in the 67–72 and 73-plus age groups, respectively.

Spectacle dependence As seen in Table 8, the mean satisfaction score steadily declines with increasing dependence on spectacles in the post-operative period.

Satisfaction was positively associated with planned and achieved post-operative mini-monovision (where the dominant eye was targeted for plano and the non-dominant eye was targeted for $\sim -1.25D$), and post-operative independence from even one pair of spectacles impacted patient satisfaction in a positive way.

Dysphotopsia In order to grade severity of pseudophakic dysphotopsia and its incidence, we categorised ranges of scores according to clinical significance (see Table 9). This table shows a steady reduction in satisfaction with an increasing PDQ score.

Table 8 The relationship between spectacle dependence and satisfaction

Dependence	n	%	Satisfaction	SD	Range
0	16	2.6	9.94	.25	9-10
1	234	38.2	9.15	1.56	0-10
2	256	41.8	8.61	2.05	0-10
3	106	17.4	7.69	2.62	0-10
Total	612	100	8.69	2.04	0-10

Dependence, dependence category; satisfaction, corresponding mean satisfaction score; SD, standard deviation; dependence categories: 0, require no spectacles for any viewing distance; 1, require spectacles for one of the following viewing distances: distance, intermediate or near; 2, require spectacles for two of the following viewing distances: distance, intermediate or near; 3, require spectacles for all three viewing distances (distance, intermediate and near)

Table 9 Categories of dysphotopsia scores, and mean satisfaction score within each category

Score range	Category	n	%	Satisfaction	SD	Range
0-3.99	Sub-clinical	568	90.7	8.9	1.7	0-10
4-5.99	Mild	36	5.8	7.33	3.02	0-10
6-7.99	Moderate	14	2.2	6.42	2.13	3-10
8-10	Severe	8	1.3	3.88	1.15	0-8
Total		626	100	8.69	2.05	0-10

Score range, PDQ score range; category, clinical classification of dysphotopsia; %, percentage of respondents with pseudophakic dysphotopsia scores within the stated range; satisfaction, corresponding mean satisfaction score; SD, standard deviation;

Functionality Table 10 shows that satisfaction scores decline steadily with increasing difficulty in function related to vision (NEI VF-11 score).

Dysphotopsia and visual function The NEI VF-11 scores were found to be significantly and positively associated with PDQ scores ($p < 0.001$); reduced function related to vision was associated with increasing severity of dysphotopsia symptoms. When linear regression was applied to this data, 17.5 % of variation in functionality was attributable to symptoms of dysphotopsia.

Because of the highly skewed nature of PDQ and NEI VF-11 scores, we supplemented correlation and regression analyses with analysis based upon categorising both variables, and applied Fisher's exact test to the resulting contingency table – see Table 11. The relationship between these two categorical variables was highly statistically significant ($p < 0.001$). Of note, a total of 96.8 % (85.3 % + 11.5 %) of subjects with sub-clinical dysphotopsia scores had either no, or minimal, difficulty in performing tasks related to vision, and this compared with 93 % of subjects with mild dysphotopsia, 73.9 % of subjects with moderate dysphotopsia, and just 50 % of subjects with severe dysphotopsia.

Table 10 Categories of NEI VF-11 questionnaire score, and satisfaction score within each category

Score range	Category	n	%	Satisfaction	SD	Range
0	No difficulty	246	40.1	9.43	1.13	3-10
0.01-1.75	Minimal	344	56.1	8.36	2.20	0-10
1.76-3	Moderate	21	3.4	5.73	3.08	0-10
3.01-4	Severe	2	0.4	5	7.07	0-10
Total		613	100	8.69	2.04	0-10

Score range, NEI VF-11 score range; category, category of dysfunction related to vision; %, percentage of respondents with NEI VF-11 scores within the stated range; satisfaction, corresponding mean satisfaction score; SD, standard deviation;

Discussion

The pre-, intra- and post-operative data of 2552 eyes undergoing cataract surgery under the care of a single surgeon using the ZCB00 was analysed in relation to visual, refractive and surgical outcomes. We report the incidence of dysphotopsia following cataract surgery, and its relationship with satisfaction and function related to vision, and identify determinants of these subjectively perceived outcomes.

Visually consequential ocular co-morbidity was evident in 55.5 % of eyes scheduled for cataract surgery in this series, reflecting the surgeon's special interest in macular disease [10–12], and this compares with 25.6 % and 37.5 % of eyes in the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) [13] and the European Cataract Outcome Study [14], respectively.

The incidence of intra-operative complication (0.6 %) in this series suggests that this surgeon/phaco/IOL combination is safe. A posterior capsular rupture incidence of 0.16 % is reported herein, and this compares with 1.92 % for all grades of cataract surgeons [15] and 0.68 % in a series of 3339 eyes operated upon by experienced ophthalmic surgeons [16].

Pseudophakic CMO was the most common post-operative complication reported in this series (3.4 %), and this is higher than that reported in the UK National Database of Cataract Surgery (2 %) [15], although the investigators in the latter study did concede that some cases of pseudophakic CMO may have gone undetected, as fundus fluorescein angiography (FFA) was not routinely performed in all suspected cases. Of note, FFA is routinely performed on suspicion of pseudophakic CMO at the IoES, which was the setting for the current study. Prompted by this audit, Yellox™ (bromfenac 0.9 mg/ml eye drops; Bausch and Lomb, Rochester, New York) is now routinely prescribed for the operated eye in the peri-operative period at the IoES, and this measure has resulted in a subsequent fall in the observed incidence of pseudophakic CMO at the IoES (3 of 256 procedures [1.17 %]; data not shown), consistent with the observations of previous investigators [17].

In terms of post-operative refraction, an absolute PE of $\leq 0.5D$, $\leq 1D$ and $\leq 2D$ was observed in 66.5 %, 93 %, and 99.4 %, respectively, of operated eyes in this series, following exclusion of potentially confounding variables, and this compares favourably with the National Health Service (NHS) benchmark standards (55 % and 85 % of operated eyes within 0.5D and 1D of target refraction, respectively [18]).

Satisfaction was found to be positively associated with spectacle independence and, in an era of falling thresholds and rising expectations for cataract surgery, and in an attempt to maximise patient satisfaction following this procedure, the suitability of a patient for mini-monovision should probably be evaluated as a matter of routine in the pre-operative setting. Post-operative UAVA was also found to be positively

Table 11 Categories of pseudophakic dysphotopsia in relation to categories of function relating to vision

Dysph. cat	Funct. cat 1		Funct. cat 2		Funct. cat 3		Funct. cat 4		Total	
	n	%	n	%	n	%	n	%	n	%
1	482	85.3	65	11.5	17	3	1	0.2	565	100
2	20	48.8	17	41.5	3	7.3	1	2.4	41	100
3	13	6.5	4	17.4	6	26.1	0	0	23	100
4	3	25.0	3	25.0	6	50.0	0	0	12	100
TOTAL	518	80.8	89	13.9	32	5	2	0.3	641	100

Dysph. cat, dysphotopsia category: 1, sub-clinical; 2, mild; 3, moderate; 4, severe

Funct. cat, function relating to vision category: 1, no difficulty; 2, minimal; 3, moderate; 4, severe

associated with patient satisfaction, again reflecting the importance of achieving independence from (at least) distance spectacles.

We also observed that an excellent pre-operative BCVA (and, indeed, OptVA) was associated with lower satisfaction when compared with those with poorer respective measures of pre-operative VA. This observation emphasises the importance of managing patient expectations in the pre-operative period, recording measures alternative to VA which are likely to improve following the procedure (such as GD, CS, or questionnaire-based measures of visual function), and of employing all available techniques to maximise satisfaction following the procedure, including consideration of mini-monovision.

Amesbury et al. [19] found a stronger correlation between patient satisfaction and VF-14 scores than between satisfaction and VA, and concluded that the use of VA as a threshold for offering cataract extraction is not always appropriate, and that the VF-14 questionnaire may be of greater value in this regard (it was noted that a patient reporting a score <90 was likely to benefit from cataract surgery).

Patient satisfaction was also, but adversely, influenced by symptoms of dysphotopsia. Tester et al. [20] introduced the term dysphotopsia, defining it as ‘any light-related visual phenomenon encountered by phakic and pseudophakic patients’. Patients report the presence of either dark shadows caused by the absence of light reaching certain portions of the retina (negative dysphotopsia) [21] or bright artifacts such as arcs, streaks, rings or halos (positive dysphotopsia) [22]. Schwiegerling [23] stated that dysphotopic symptoms may only be present in certain lighting conditions or for particular positions of the glare source in the patient’s visual field. Symptoms of dysphotopsia are generally well tolerated [21, 22], however, a small cohort of patients describe them as severe or even debilitating [21].

Recalcitrant, severe negative dysphotopsia was observed in 495 (0.13 %) of 3806 cases reported by Vamosi et al. [24], with one patient (0.02 %) developing a neurosis as a result of the condition, which resolved following IOL explantation and secondary (sulcus) IOL implantation.

Positive dysphotopsia can occur as a result of certain attributes of an IOL [22], thus informing subsequent IOL design, such as the ZCB00. Holladay et al. [22] determined that both square- and round-edged IOLs cause scattering of stray light but that the square-edged lens concentrates this light into a perceptible pattern on the retina, unlike round-edged lenses which disperse this stray light over a larger portion of the retina. The ZCB00 has a proprietary frosted squared posterior optic edge designed to reduce unwanted reflections, i.e., those which can lead to positive dysphotopsia.

In this series of 658 eyes undergoing cataract surgery using the ZCB00 (without visually consequential ocular co-morbidity and who completed the dysphotopsia questionnaire), freedom from any symptom of dysphotopsia (an average dysphotopsia score of 0) was observed in 265 eyes (40.2 %), and this compares favourably with 24 % of eyes where the Acrysof 1 piece aspheric, hydrophobic lens was implanted [4], an IOL which shares many design features with the ZCB00, such as hydrophobicity and asphericity. An incidence of clinically meaningful pseudophakic dysphotopsia (defined as an average dysphotopsia score of $\geq 4/10$, i.e., categories 2 [mild], 3 [moderate] and 4 [severe]) was found in only 5.8 %, 2.2 % and 1.3 % of patients, respectively, with 90.7 % of eyes reporting a sub-clinical score of $< 4/10$. Only 8 eyes (1.3 %) reported a dysphotopsia score of $\geq 8/10$, which again compares favourably with that reported for the implantation of the Acrysof 1-piece lens (11.4 %) [4].

Although symptoms of dysphotopsia are usually transient and improve with the passage of time [25], our findings suggest that patients should, nevertheless, be made aware of the possibility of such symptoms in the early post-operative period. Indeed, the association between symptoms of dysphotopsia and function related to vision has previously been reported by Kinard et al. [4] and is corroborated by the current study, reflected in the inverse relationship between PDQ and the NEI VF-11 score. This finding, taken together with the inverse relationship between PDQ score and patient satisfaction, reflects the clinical importance of pseudophakic dysphotopsia on outcomes of cataract surgery.

Strengths and weaknesses

The retrospective nature of this study represents its principal weakness, although we do believe that the large number of eyes reported goes some way towards addressing this shortcoming.

We believe that a study designed to investigate dysphotopsia, and its impact on patient satisfaction and difficulty with vision-related tasks, should use only a single IOL model and that the procedures should be carried out by a single surgeon, if the influence of potentially important confounders is to be avoided. Accordingly, we believe that these attributes represent important strengths of the current study.

Conclusion

Age is positively associated with post-operative satisfaction following cataract surgery. Symptoms of dysphotopsia are important and adverse determinants of function related to vision (NEI VF-11 score), and of patient satisfaction following the procedure. Patient satisfaction relates strongly with the degree of post-operative spectacle independence.

What was known

Cataract surgery is associated with subjectively perceived improvements in visual function, despite falling thresholds for this procedure.

What this paper adds

Patient age and independence from spectacles following surgery are important determinants of patient satisfaction following cataract surgery, and symptoms of dysphotopsia are important and adverse determinants of patient satisfaction and of function related to vision following the procedure. The ZCB00 is shown to be a safe lens with good refractive outcomes, high satisfaction rates and a low risk of dysphotopsia.

Conflict of interest statement This study was funded by Abbott Medical Optics, Germany. All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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