

Outcomes of cataract surgery in eyes with diabetic macular oedema: Data from the Fight Retinal Blindness! Registry

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Abstract

Importance: There are limited data on real-world outcomes of cataract surgery in eyes receiving intravitreal treatments for diabetic macular oedema (DMO).

Background: Cataract surgery may exacerbate oedema in some eyes with DMO resulting in inferior outcomes.

Design: Matched, case-controlled retrospective study of observational data in routine clinical practice.

Participants: Eyes receiving intravitreal treatments for DMO tracked in the Fight Retinal Blindness! Registry.

Methods: Eyes that underwent cataract surgery were identified and matched 1:1 with phakic controls also receiving intravitreal injections for DMO. We also assessed potential factors that were associated with better visual acuity (VA) outcomes.

Main Outcome Measures: Change in VA 6 months after cataract surgery.

Results: Cataract surgery was identified in 208 eyes of 156 patients of which 147 eyes had 6 months of observations before and after surgery. The mean VA 6 months after surgery improved by 10.6 letters and was similar to their matched phakic controls (68.8 vs 69.2 letters; $P = 0.8$). Mean CST both 6 months before (341 μm) and after (360 μm) surgery were similar ($P = 0.08$). However, these eyes had thicker maculae and they received more injections than their matched phakic controls both before and after surgery. Eyes with worse VA before surgery and those that had received intravitreal treatment in the 4 weeks preceding surgery were more likely to gain vision.

Conclusions and Relevance: Visual outcomes of cataract surgery in eyes receiving intravitreal therapy for DMO were reasonably better. Their maculae were thicker and required more injections in the 6 months before and after surgery than their phakic controls.

KEYWORDS

cataract surgery, diabetic macular oedema, real-world outcome, vascular endothelial growth factor inhibitor

1 | INTRODUCTION

People with diabetes develop cataract, the primary cause of blindness worldwide, at an earlier age and 2 to 5 times more frequently than people without diabetes.^{1,2} Cataract surgery in eyes of patients with diabetes may result in inferior outcomes in some eyes by causing or exacerbating diabetic macular oedema (DMO).³⁻⁵ The UK diabetic retinopathy electronic medical record users group found that the rate of developing treatment-requiring DMO increased after the surgery in a cohort of 4850 eyes of people with diabetes undergoing cataract surgery.⁶

Data on visual acuity (VA) and macular oedema outcomes of cataract surgery in eyes actively receiving intravitreal therapy for DMO in real-world clinical practice are limited. An analysis from the RIDE and RISE clinical trials reported an improvement in vision by 10 letters within 1 month of cataract surgery when they were receiving monthly intravitreal injections of the vascular endothelial growth factor (VEGF) inhibitor, ranibizumab.⁷

This study was undertaken to evaluate outcomes of cataract surgery in eyes receiving intravitreal treatment for DMO in routine clinical practice. These outcomes were compared with a control group of phakic eyes that were also receiving injections for DMO matched for baseline characteristics. We also assessed potential factors at the time of cataract surgery that were predictive for VA outcomes.

2 | METHODS

2.1 | Study design

This was a retrospective, matched, case-control analysis of data from a prospectively designed web-based observational database, the Fight Retinal Blindness (FRB)! Registry. The registry contains a DMO module that tracks outcomes of treatment of eyes with DMO.

2.2 | Setting

The data analysed in this study were from patients receiving intravitreal therapy for DMO in routine clinical practice in Australia, New Zealand, Switzerland and United Kingdom. Institutional approval was obtained from the Royal Australian and New Zealand College of Ophthalmologists Human Research Ethics Committee, the South Eastern Sydney Local Health District Human Research Ethics Committee, the Cantonal Ethics Committee Zurich and the Caldicott Guardian at the Royal Free

London NHS Foundation Trust. The FRB! Registry conformed to the tenets of the Declaration of Helsinki.

2.3 | Data sources/measurements

The details of FRB! Registry for neovascular age-related macular degeneration have been published previously.⁸ The DMO module of the registry collects data from eyes receiving treatment for clinically significant macular oedema (CSMO) as defined by Early Treatment of Diabetic Retinopathy Study investigators.⁹ The number of letters read on a logarithm of the minimum angle of resolution (logMAR) VA chart, central subfield thickness (CST), degree of DMO (centre-involving, non-centre involving or no DMO), additional procedures including cataract surgery, treatment given, and any ocular adverse events were recorded at each visit. Duration and type of diabetes, diabetic retinopathy grading and prior treatment were recorded at the baseline visit. Treatment decisions, including choice of treatment and visit schedules, were at the discretion of the treating physician in consultation with the patient, thereby reflecting real-world practice.

2.4 | Participants and variables

Eyes with DMO tracked by the registry that received cataract surgery between 1 January 2007 and 31 December 2018 and had at least 6 months visit before and after the surgery were included in the analysis.

These eyes were matched to a cohort of phakic eyes (controls) from the registry to assess the effect of cataract surgery on the course of DMO. This cohort comprised one phakic control per case matched on the following characteristics: treatment duration until cataract surgery (including a visit within ± 3 months of cataract surgery of their matched case); prior treatment status (treatment naïve or pre-treated) and year of starting treatment for DMO with intravitreal injections (exact matching); baseline age, baseline VA and baseline CST (propensity score matching). The controls also had at least 6 months of visits before and after cataract surgery of their matched cases to compare visual and anatomic trends before and after the surgery.

2.5 | Outcomes

The main outcome was the mean change in VA 6 months after cataract surgery. The proportions of eyes with VA ≥ 70 letters (20/40 Snellen equivalent) and ≤ 35 letters (20/200) as well as those that gained ≥ 15 or lost ≥ 15 letters 6 months after cataract surgery were also evaluated.

Secondary outcomes included the changes in mean CST and number of injections 6 months after cataract surgery compared with the 6 months before surgery.

VA and CST were assessed at baseline, 6 months before surgery, at the visit immediately preceding surgery and 6 months after surgery. Potential predictive factors were analysed by comparing the characteristics of patients at the time of cataract surgery in the three bands of VA change: gain of ≥ 15 letters, gain of between 1 and 14 letters, and those with no change or loss in VA. Variables considered in the predictive analysis included age, duration of diabetes, VA and degree of macular oedema at the visit before surgery, and whether there was an injection in the 4 weeks before, or during, the operation.

2.6 | Statistical analysis

Descriptive data included the mean (SD), median (first and third quartiles, Q1 and Q3) and percentages where appropriate. Within-group changes in VA and CST after cataract surgery were analysed using paired *t* tests. The comparison of CST between cases and matched controls were also performed using paired *t* tests. The number of injections before and after surgery within the group and between cases and matched controls were compared using Poisson regression. Injection intervals in the 6 months before and 6 months after surgery were compared between cases and matched controls using mixed-effects regression models with the eye as a random effect for repeated visits. Between-group comparisons included an identifier variable to indicate matched eyes as a nested random effect.

Multinomial multivariate regression was used to compare characteristics between groups categorized by change from preoperative VA (gained ≥ 15 letters, gained 1-14 letters and no change or lost letters). Variables analysed in the model included age, duration of diabetes, VA at time of surgery, CSMO degree and whether an injection of a VEGF inhibitor was received in the 4 weeks leading up to surgery.

All analyses were conducted using R version 3.4.4 (<http://www.R-project.org/>) with the *lme4* package (V 1.1-15) for mixed effects regression, *MatchIt* package (V 3.0.2) for propensity score matching and the *nnet* package (V 7.3-12) for multinomial regression.¹⁰⁻¹³

3 | RESULTS

3.1 | Study participants

Two hundred and forty-five eyes from 180 patients with DMO had cataract surgery. Of these, 208 eyes (156 patients) completed 6 months follow up within FRB!

registry of which 147 eyes also had data from the 6 months visits before the surgery. This group of 147 eyes was matched with phakic controls to compare macular thickness, number of treatments and treatment interval before and after surgery. Baseline characteristics of these two groups are summarized in Table 1. Of these 147 eyes, the interval between starting treatment for DMO and cataract surgery was variable with a median duration of 26 months (Q1:Q3, 13:41; Table 2). A few eyes received focal laser (six eyes in cataract surgery group and eight in control group) and none received panretinal photocoagulation prior to surgery. Vitreous haemorrhage was recorded at some point before surgery in 18 eyes in the cataract group and in two eyes in the control group. No eye was recorded to have developed rubeosis.

TABLE 1 Baseline characteristics of eyes with cataract surgery and phakic controls

	Cataract surgery	Phakic controls	P-value
Eyes	147	147	
Patients	112	136	
Female, %	41	41	.90
Baseline age years, mean (SD)	64 (10)	64 (13)	.63
Diabetes duration years, mean (SD)	18 (10)	19 (11)	.52
Diabetes type			
Type I, %	6	12	.14
Type II, %	94	88	
Diabetic retinopathy grading, %			
Mild NPDR	9	9	1
Moderate NPDR	37	37	
Severe NPDR	27	27	
PDR	27	27	
History of DMO treatment, %	46	46	
VA baseline (logMAR letters), mean (SD)	64.4 (14.2)	65.5 (17.1)	.57
Baseline CST μm , mean (SD)	403 (118)	381 (123)	.13
CSMO (degree)			
Centre involving, %	91	86	.02
Non-centre involving, %	8	7	
No CSMO, %	1	7	

Abbreviations: CSMO, clinically significant macular oedema; CST, central subfield thickness; DMO, diabetic macular oedema; logMAR, logarithm of the minimal angle of resolution; NPDR, non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy.

TABLE 2 Visual acuity outcomes 6 months after cataract surgery in matched eyes and their phakic controls

	Cataract surgery, n = 147	Matched phakic controls, n = 147	P-value
Time until surgery, median months (Q1, Q3)	26 (14, 45)	26 (14, 45)	.28
VA prior to surgery, mean letters (SD)	58.2 (18.9)	69.3 (13)	<.001
VA 6 months after surgery, mean letters (SD)	68.8 (14.3)	69.2 (14.1)	.79
VA ≥70 letters (6 months before/6 months after surgery) (%)	36/60	51/57	.002
VA ≤35 letters (6 months before/6 months after surgery) (%)	9/15	4/3	.54
Change VA, mean letters (95% CI)	10.6 (7.9, 13.3)	-0.1 (-1.3, 1.0)	<.001
Gain, %			
≥15 letters	28	4	<.001
1-14 letters	42	38	.63
Loss, %			
≥15 letters	1	2	1
0-14 letters	30	56	.37

Abbreviations: CI, confidence interval; Q1, first quartile; Q3, third quartile; VA, visual acuity.

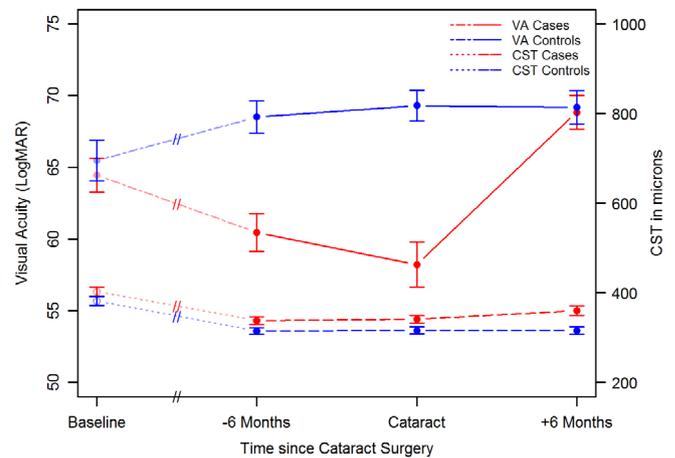
3.2 | Visual acuity

Visual acuity improved after cataract surgery in eyes receiving treatment for DMO. The mean gain in VA was 10.6 letters (95% confidence interval [CI]: 7.9, 13.3; $P < .001$) 6 months after surgery from a mean (SD) VA of 58.2 (18.9) letters at the visit immediately before surgery. A gain of ≥15 letters at 6 months was observed in 28% of eyes while 1% lost ≥15 letters during the same period. The proportion of eyes with a VA ≥70 letters 6 months after surgery was 60% while 5% of eyes had a VA of ≤35 letters.

The mean (SD) VA 6 months after cataract surgery in eyes that had cataract was similar to their matched controls (68.8 [14.3] vs 69.2 [14.1]; $P = .8$; Figure 1).

3.3 | Central subfield thickness

Eyes that underwent cataract surgery had a similar mean (SD) CST at a visit immediately before (341 [106] μm) and 6 months after (360 [124] μm; $P = .08$) surgery.

**FIGURE 1** Mean visual acuity and central subfield thickness for cases (red) and controls (blue) at baseline, 6 months before surgery, the visit immediately prior to surgery and 6 months after surgery. Error bars indicate ± 1 SE. The interval between baseline and 6 months before cataract surgery was variable with a median duration of 26 months (Q1, Q3: 13, 41)

The mean CST reduced from baseline with treatment (Figure 1). However, the mean CST in eyes that had cataract surgery was higher than their matched controls both 6 months before (341 μm vs 316 μm; $P = .01$) and after (360 μm vs 315 μm; $P < .001$) surgery (Table 3).

3.4 | Intravitreal injections

The mean number of intravitreal injections in eyes that underwent cataract surgery was similar during the 6-month periods before and after the surgery (2.4 vs 2.1; $P = .09$; Table 3). Nevertheless, they received more intravitreal injections than their controls both before (mean 2.4 vs 1.6 injections; $P < .001$) and after the surgery (mean 2.1 vs 1.5 injections; $P < .001$; Table 3).

VEGF inhibitors were the preferred treatment during the 6-month period before and after the surgery. Ninety-two percent of the injections prior to surgery and 91% after the surgery was VEGF inhibitors—the remaining injections were intraocular steroids. The proportion of VEGF inhibitors in the phakic controls was 97% before and 98% after surgery.

3.5 | Analysis of predictive factors for visual acuity change after cataract surgery

Predictive factors were assessed in the 208 eyes where data for the 6-month visit after cataract surgery was available. Eyes that gained ≥15 letters had lower mean (SD) VA before surgery than eyes that gained fewer than

TABLE 3 Comparison of subfield thickness, number of injections and treatment interval before and after cataract surgery

	Before surgery	After surgery	<i>P</i> -value ^a
CST μm , mean (SD)			
Cases	341 (106)	360 (124)	.08
Controls	316 (92)	315 (102)	.89
<i>P</i> -value ^a	.01	<.001	
Injections, mean (SD)			
Cases	2.4 (1.9)	2.1 (1.8)	.09
Controls	1.6 (1.7)	1.5 (1.7)	.42
<i>P</i> -value ^a	<.001	<.001	
VEGF injections, mean (SD) ^b			
Cases	2.2 (1.6)	1.9 (1.9)	.06
Controls	1.6 (1.7)	1.5 (1.7)	.60
<i>P</i> -value ^a	<.001	.01	
Treatment interval, median days (Q1, Q3)			
Cases	36 (28, 49)	41 (35, 52)	.22
Controls	42 (30, 66)	42 (35, 56)	.50
<i>P</i> -value ^a	.12	.51	

Abbreviations: CST, central subfield thickness; Q1, first quartile; Q3, third quartile.

^a*P*-values in columns compares within-group changes before and after surgery and *P*-values in rows compares between cases and controls.

^bVery few eyes had received intravitreal injections of steroids.

15 letters (41.3 [20.3] vs 65.2 [11.6] and 65.4 [16.0] letters for gaining ≥ 15 letters vs gaining 1-14 letters and no gain or loss ≥ 1 letter, respectively; $P < .001$ for global comparison; Table 4). Eyes that received treatment with an intravitreal injection in the 4 weeks preceding the surgery or at the time of cataract surgery were likely to gain vision (72% and 70% vs 56%; $P = .02$ for global comparison; Table 4). Other factors that were analysed, including age at cataract surgery, duration of diabetes, macular thickness and the degree of macular oedema, were not significantly associated with the outcome (Table 4).

4 | DISCUSSION

This study analysed changes in VA and CST after cataract surgery in eyes receiving intravitreal injections for DMO. Macular thickness and number of injections before and after surgery were compared with matched unoperated phakic controls. There was a mean improvement of 10.6 letters 6 months after cataract surgery; 28% gained ≥ 15 letters and the proportion of eyes with VA of ≥ 70 letters (approximately 6/12) increased from 36% 6 months before surgery to 60% 6 months later. The operated eyes had thicker maculae and received more injections than their matched controls during the 6-month period both before and after surgery. An increased requirement for injections could conceivably have contributed to cataract progression in eyes that underwent surgery. Eyes with

TABLE 4 Predictive factors for visual acuity change 6 months after cataract surgery (from preoperative) in patients with diabetic macular oedema at the time of surgery

	Gained ≥ 15 letters, n = 64	Gained 1 to 14 letters, n = 83	No gain or lost >1 letter, n = 61	<i>P</i> -value ^a
Age at cataract, years, mean (SD)	70 (8)	69 (10)	66 (10)	.19
Duration of diabetes, years mean (SD)	18 (10)	19 (9)	18 (11)	.56
VA prior to surgery mean letters (SD)	41.3 (20.3)	65.2 (11.6)	65.4 (16)	<.001
CST before surgery, μm mean (SD)	337 (115)	335 (100)	358 (96)	.19
CSMO degree (%)				
Centre involving	56	60	66	.26
Non-centre involving	22	27	26	
No CSMO	22	13	8	
Intravitreal injection 4 weeks before the surgery ^b (%)				
Yes	72	70	56	.02
No	28	30	44	

Abbreviations: CSMO, clinically significant macular oedema; CST, central subfield thickness; VA, visual acuity; VEGF, vascular endothelial growth factor.

^a*P*-values are global tests from multinomial regression model comparing characteristics between eyes that gained ≥ 15 letters, gained 1 to 14 letters and those that did not gain or lost letters.

^bOne hundred and thirty-eight eyes (66%) received intravitreal injections (VEGF inhibitors in 112 eyes [81%], few received steroid) in the 4 weeks period before the surgery or at the time of cataract surgery.

worse vision before cataract surgery and those that received treatment with an intravitreal injection of VEGF inhibitor in the 4 weeks preceding or time of surgery were more likely to gain vision.

Previous studies of VA outcomes after cataract surgery in eyes with DMO have also found good improvements in vision.^{7,14} Moshfeghi et al⁷ found a mean gain of 14.5 letters 3 months after cataract surgery (from the preoperative mean VA of 54.2 letters) in monthly ranibizumab-treated eyes in the RIDE and RISE study while the sham injection group gained 12.8 letters (from the preoperative mean VA of 46.9 letters). A pilot study of 63 eyes from the Diabetic Retinopathy Clinical Research Network (DRCR.net) group observed a mean gain of 12 letters at 16 weeks from a preoperative mean of 55 letters.¹⁴ The proportion of eyes with VA of ≥ 70 letters was 43% and 6% gained three or more lines while 1% lost three lines.¹⁴ The mean gain of 10.6 letters (from preoperative mean of 58 letters) observed in the present study was lower than the mean gains reported by Moshfeghi and DRCR.net.^{7,14} However, the mean VA 6 months after surgery (68.8 letters) was similar to the mean VA observed by Moshfeghi at 3 months and DRCR.net group at 16 weeks after surgery.^{7,14} The mean VA 6 months after surgery was similar to their matched controls, suggesting that eyes on treatment with DMO with visually significant cataract do generally benefit from cataract surgery.

Previous studies have reported worsening of macular oedema after cataract surgery.^{4,6} Denniston et al⁶ found the proportion of DMO eyes with $\text{CST} \geq 400 \mu\text{m}$ in the UK diabetic retinopathy electronic medical record users group cohort increased from 2.9% in the year before cataract surgery to 5.3% in the year after surgery. The peak period for the increase was observed in the 3- to 6-month period after the surgery.⁶ The DRCR.net study reported that the mean central macular thickness before and 16 weeks after cataract surgery were similar.¹⁴ In this study we identified that eyes undergoing cataract surgery had greater CST and received more intravitreal injections than their matched controls in the 6-month periods both before and after surgery. This suggests that cataract progression and DMO are associated and systemic factors like hyperglycaemia have been linked to both.^{15,16}

Reported outcomes of intravitreal injections (steroids or VEGF inhibitors) at the same time as cataract surgery or a few weeks before it in eyes with DMO are variable.¹⁷⁻¹⁹ Takamura et al¹⁸ found greater improvements in VA and macular thickness 3 months after cataract surgery in eyes treated with intraoperative bevacizumab in a prospective analysis. Rauen et al¹⁷ observed similar macular thickness before and 11 weeks after cataract surgery which included an intraoperative intravitreal injection of

ranibizumab. Lim et al²⁰ reported that a VEGF inhibitor or steroid injection at the time of cataract surgery improved VA at 6 months after the surgery, though eyes receiving steroid had a more sustained reduction in macular thickness and required fewer injections. We found in the present study that eyes receiving intravitreal treatment in the 4 weeks preceding or at the time of cataract surgery were more likely to gain vision 6 months after cataract surgery.

We also examined some other variables that may have influenced the development of cataract. Few eyes in each group received focal laser treatment before cataract surgery. Vitreous haemorrhage, which was found at some point before surgery in 18 eyes in the cataract surgery group and two eyes in the control group suggests that more eyes with cataract in our cohort had more severe diabetic retinopathy. There were fewer intravitreal steroid treatments before surgery in each group (8% vs 3% in the phakic control group) to make a reasonable comparison on cataract progression with steroid treatment.

There are several limitations of the present study. Treatment decisions, including choice of treatment, were at the discretion of the physician. There were no details on systemic diabetes control (HbA1C, insulin, oral anti-diabetic medication, and presence of end-organ disease), grading of cataract, rationale for cataract surgery, or perioperative events such as surgical complications. There was no information on the type and duration of anti-inflammatory agents used after surgery, which can influence macular oedema. In addition, it may be difficult to distinguish pseudophakic macular oedema from DMO. Also, we have no information on why or why not a patient received intravitreal treatment prior to cataract surgery.

The main strengths of this study are the evaluation of VA and macular oedema at each visit, inclusion of a comparison group and the analysis of factors that predict these outcomes in eyes receiving treatment for DMO. Observational studies such as the present study improve our understanding of the outcomes of cataract surgery in eyes with DMO for which a clinical trial that randomized eyes with cataract to no treatment might pose ethical issues.

In conclusion, cataract surgery in eyes receiving intravitreal treatment for DMO can be associated with good visual and anatomic outcomes with an increased injection burden in the pre- and postoperative period. Macular oedema in these eyes did not increase significantly 6 months after the surgery. However, maculae were thicker than their phakic controls in both the 6-month period before and after surgery. Intravitreal injection therapy in the 4 weeks preceding or at the time of

cataract surgery was associated with better visual outcomes at 6 months.

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CONFLICT OF INTEREST

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