Cataract Surgery Outcomes in Retinitis Pigmentosa A Comparative Clinical Database Study

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• PURPOSE: To report visual acuity (VA) outcomes, intraoperative and postoperative complications of isolated cataract surgery in eyes with retinitis pigmentosa (RP), compared with non-RP-affected eyes.

• DESIGN: Retrospective clinical cohort study.

• METHODS: A total of 113,389 eyes underwent cataract surgery between July 2003 and March 2015 at 8 clinical sites in the United Kingdom. Eyes with RP as the only comorbid pathology and eyes without any ocular comorbidities (controls) undergoing cataract surgery were compared. VA at 4 to 12 weeks postoperatively and rates of intraoperative and postoperative complications are reported.

• RESULTS: Seventy-two eyes had RP. The mean age in the RP group was 57 ± 15 compared to 75 ± 10 in controls ($P < .001$). Females represented 46% of RP cases and 60% of controls ($P = .06$). Preoperative VA (mean LogMAR = 1.03 vs 0.59, $P < .001$) and postoperative VA (0.71 vs 0.14, $P < .001$) were worse in RP group. The mean VA gain was 0.25 ± 0.60 LogMAR in RP vs 0.43 ± 0.48 LogMAR in controls ($P < .001$). There were no significant differences in the rate of intraoperative pupil expansion use, posterior capsular tears, or zonular dialysis. Postoperative cystoid macular edema developed in 6.9% of RP eyes and 1% of controls ($P < .001$). The need for IOL repositioning or exchange was not statistically different between the two groups.

• CONCLUSION: Cataract surgery can improve vision in eyes with RP and cataract. Intraoperative complications were similar to control eyes; however, RP eyes experienced more frequent postoperative cystoid macular edema. (Am J Ophthalmol 2024;262: 34–39.

INTRODUCTION

Retinitis pigmentosa (RP) is the most common inherited retinal disease phenotype, inherited as an autosomal dominant (AD), autosomal recessive (AR) or X-linked trait.[1] RP is characterized by nyctalopia and a gradual constriction of the visual field, with eventual loss of central vision, progressing to legal blindness.[2,3] The management of RP is mainly symptomatic, with the 2 most common vision-limiting complications being cystoid macular edema (CME) and cataract.

Cataract surgery in RP-affected eyes is considered a high-risk procedure due to reports of higher incidence of intraoperative complications.[4] In addition, visual acuity (VA) gains can be limited by retinal degeneration, and removing the physiologic photoprotection provided by the crystalline lens may theoretically accelerate retinal degeneration.[4,5] The therapeutic landscape of RP is rapidly evolving, with multiple ongoing clinical trials of novel therapeutics, many of which show promising preclinical or early clinical efficacy signals.[6] These novel therapeutics include gene therapy products developed for subretinal delivery, leading to an expected increase in the number of vitrectomy surgeries in younger individuals with RP, thereby increasing the need for subsequent cataract surgery at a younger age. However, there is insufficient evidence to inform patients with RP about their prognosis after cataract surgery. Only a few studies have been published evaluating the visual outcomes in these patients postsurgery, and these studies are limited because they are noncomparative and include eyes with coexisting ocular comorbidities such as pseudoexfoliation and epiretinal membrane.[5,7] This makes it difficult to precisely

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quantify the impact of RP on visual outcomes or complication rates.

In this study, we utilize a large clinical database of patients who underwent cataract surgery to assess the safety of cataract surgery in RP in a comparative fashion. We report rates of intraoperative complications both in RP-affected and nonaffected eyes.

MATERIALS AND METHODS

• **DATA CAPTURE:** The study period covered a 12-year span (July 2003-March 2015). Anonymized data pertaining to cataract surgery were automatically extracted from eight United Kingdom (UK) National Health Service centers and consolidated into a single database. All centers had large ophthalmology departments with a representative mix of patients undergoing cataract surgery and utilized the same electronic medical record (EMR) system (Medisoft Ophthalmology; Medisoft Limited).

In summary, all sites performed day-case phacoemulsification surgery. Routine postoperative care at each site included at least 1 visit conducted by a specialist nurse or an optometrist 4 to 12 weeks postoperatively. All patients received a tapering postoperative course of topical steroid and antibiotic drops for 4 weeks. The standards of care at the study sites and the data extraction process have been described in detail in previous publications.[8-11] Data fields extracted from preoperative and postoperative visits included: age, gender, laterality, diabetic status, preexisting copathology, preoperative and postoperative VA, and the presence of postoperative CME diagnosis. Data on the date of surgery and the type of all surgeries or procedures conducted prior to or after cataract surgery were also available. Fields extracted from the operative record for cataract surgery included pupil size, type of surgery performed, and details of intraoperative complications. The recording of complications in the EMR was a required field, and surgeons were mandated to report any intraoperative complications for proper closure of the operation record. If a complication occurred, the surgeon reported it by selecting it from a prespecified list of well-recognized cataract surgery complications, including posterior capsule (PC) tear, zonular dialysis, and dropped nucleus.

This study was conducted in accordance with the Declaration of Helsinki. The extracted patient information was deidentified; therefore, it was not classified as human subject research, and institutional board review was waived.

• **STUDY POPULATION:** The total dataset included 178,856 eyes. We excluded all patients who underwent any surgery other than isolated phacoemulsification and those with ocular pathologies other than RP and cataract, including patients with a preoperative history of CME, epiretinal membrane, uveitis, vascular events, or diabetic macular edema in either eye. We divided the remaining eyes into two groups: (1) those affected with RP, (2) those not affected by RP (controls). Supplementary Figure 1 details the inclusion and exclusion of patients in the cohort.

• **OUTCOMES AND COVARIATES:** We compared the two groups in terms of VA at 4 to 12 weeks postoperatively, change in VA from the preoperative level per eye, and the incidence of intraoperative and postoperative complications. Visual acuity was recorded using Snellen fractions and automatically converted to a logarithm of the minimal angle of resolution (LogMAR) before the extraction process. Due to the retrospective nature of the study, we defined VA as the best uncorrected or corrected distance VA achieved at each period. The preoperative VA in our analysis was the VA recorded closest to the date of cataract surgery, and none were obtained more than 3 months before surgery. Similar to other recent studies by our group, we defined CME based on clinical diagnosis within 90 days of cataract surgery.[12] The study centers performed imaging studies, including optical coherence tomography (OCT) or fluorescein angiography (FA), at the clinicians' discretion, typically in patients with unexpected VA outcomes following cataract surgery. Therefore, postoperative CME in our study reflects visually significant CME rather than subclinical disease. Intraoperative complications reported include the need for the use of a pupil expansion device, PC tear, and zonular dialysis. We defined postoperative intraocular pressure (IOP) spike as a postoperative IOP greater than 21 mmHg recorded within the first three months after surgery. We also calculated the rate of YAG laser capsulotomy for posterior capsule opacification (PCO) within the first 6 months postoperatively.

Due to the heightened risk of postoperative CME in the fellow eye when the first operated eye has previously exhibited CME,[12] and the potential intrasample correlation between both eyes within the same patient, we conducted an additional analysis of only the right eye of individuals in both the RP and control groups who underwent bilateral sequential surgery.

• **STATISTICAL ANALYSIS:** For statistical comparisons of continuous and categorical variables, we employed the Kruskal-Wallis Rank Sum test and chi-square test. We analyzed the data using the R statistical software package version 3.5.3 (R Foundation for Statistical Computing, Vienna, Austria. www.R-project.org) and set the significance level for all statistical tests at $P < .05$.

RESULTS

• **STUDY POPULATION:** We screened a total of 178,856 eyes for eligibility. After excluding patients undergo-

TABLE 1. Demographics and Visual Acuity

Parameter	Retinitis Pigmentosa	Control	*P* Value
eyes, *n*=	72	113,317	
patients, *n*=	52	83,468	
Mean Age ± SD, years	57 ± 15	75 ± 10	<.001
Female	46%	60%	.06
Preoperative VA	1.03 ± 0.82	0.59 ± 0.50	<.001
Postoperative VA at 4-12 weeks	0.71 ± 0.75	0.14 ± 0.25	<.001
VA Gain	(-) 0.25 ± 0.60	(-) 0.43 ± 0.48	<.001
% eyes with ≥20/40 VA at 4-12 weeks	89.0%	41.7%	<.001

SD, standard deviation; VA, visual acuity in LogMAR units.

ing combined surgeries (eg, phaco-vitrectomy), surgeries for trauma or nonphacoemulsification cataract surgeries, 172,662 eyes remained eligible. After further excluding eyes with other ocular pathologies such as glaucoma, congenital cataract, diabetic retinopathy, age-related macular degeneration, central or branch vein occlusion, central or branch artery occlusion, pseudoexfoliation syndrome, previous retinal detachment repair, and epiretinal membrane, only 113,389 eyes (83,520 patients) remained eligible. The control group consisted of 113,317 eyes from 83,468 patients who underwent isolated phacoemulsification without RP, and the study group consisted of 72 eyes from 52 patients who underwent isolated phacoemulsification and had RP.

• **DEMOGRAPHIC DATA:** Females represented 46.2% of RP patients and 59.9% of the control group (chi-squared, $P = .06$). The mean age (SD) at surgery for the RP group was 57.2 ± 15.0 years old (range; 31-85 years). Mean age (SD) in the control group was 75.0 ± 10.1 years old (range; 18-99 years). The age at cataract surgery was significantly lower for the RP group (Kruskal-Wallis rank sum test, $P < .001$). The mean axial length was 23.33 mm for the control group and 23.42 mm for the RP group (Kruskal-Wallis rank sum test, $P = .53$). None of the patients in the RP group had brunescent or white cataract, while 3.1% of the cataracts in the control group had this grade of cataract.

• **VISUAL ACUITY:** Preoperative mean VA (SD) was 0.59 (20/78 Snellen) ± 0.50 LogMAR and 1.03 (20/214 Snellen) ± 0.82 LogMAR for the control and RP groups, respectively (Kruskal-Wallis rank sum test, $P < .001$). Postoperative mean VA (SD) was 0.14 (20/27 Snellen) ± 0.25 LogMAR and 0.71 (20/102 Snellen) ± 0.75 LogMAR for the control and RP groups, respectively (Table 1 and Supplementary Figure 2). Mean postoperative VA was significantly worse in the RP group, but postoperative VA significantly improved after surgery in both groups compared to baseline. The proportion of patients with VA reaching ≤0.3 LogMAR (≥20/40 Snellen) at 4 to 12 weeks was 89.0% for the control group and 41.7% for RP ($P < .001$).

TABLE 2. Complications

Complication	RP ($n = 72$)	Control ($n = 113,317$)	RR	*P*
Pupil expansion	0	0.40%	NA	1
Posterior capsular tear	0	1.60%	NA	.52
Dropped nucleus	0	0.20%	NA	1
Zonular dialysis	0	0.50%	NA	1
Postoperative CME	6.90%	1%	7.36	<.001
IOL dislocation	1.4%	0.2%	7.19	.13
YAG capsulotomy	13.9%	3%	4.68	<.001

RP, retinitis pigmentosa; CME, cystoid macular edema; IOP spike, intraocular pressure > 21; RR, relative risk; IOL, intraocular lens; YAG, YAG laser capsulotomy.

• **INTRAOPERATIVE COMPLICATIONS:** As compared to the control group, there was no statistically significant difference in the rates of intraoperative pupil expansion use (0% in RP vs 0.40% in the control group), PC tears (0% vs 1.60%), zonular dialysis (0% vs 0.50%), or dropped nucleus (0% vs 0.20%).

• **POSTOPERATIVE COMPLICATIONS:** Table 2 summarizes the complication rates between the two groups. Postoperative IOP spike was similar between the two groups (4.8% in RP vs 2.6% in the control group). The need for intraocular lens (IOL) repositioning or exchange was similar between the two groups (1.4% vs 0.2%, respectively). YAG capsulotomy was significantly higher ($P < .001$) in patients with RP compared to the control group (13.9% vs 3%), within the first six months after surgery.

Postoperative CME developed in 6.9% of RP eyes and 1% of controls ($P < .001$). The relative risk for CME was 7.36 times greater for eyes with RP. Further analysis of only the right eyes in patients that had bilateral cataract surgery, CME developed in 7.7% of RP eyes, and 1% of controls ($P < .001$), and the RR was 7.66 times greater for eyes with RP. Of the RP patients who underwent bilateral surgery

($n = 20$), none had bilateral CME, and 2 experienced unilateral CME.

DISCUSSION

Despite RP being the most common phenotype of inherited retinal diseases, only a limited number of studies have reported visual outcomes and complications risk of cataract surgery for the disease.[4,5,13] Our results provide insights and may aid in patient management and counseling in the evolving therapeutic landscape for inherited retinal diseases.

In the current study, VA was worse at baseline for patients with RP, with RP patients also undergoing cataract surgery at the age of 57 years, which is 18 years younger than the control group. A multicenter international study reported an average age of cataract surgery of 56 years for RP patients, externally validating the accuracy of our current database. Their reported VA also mirrored our cohort with a baseline VA of 1.03 LogMAR (Snellen equivalent 20/200), improving to 0.81 LogMAR (20/130).[5] While retinal pathology limits achieving full visual acuity recovery in RP patients, cataract surgery may still enhance vision.[7,14,15] In our RP group, approximately 40% of eyes reached a VA of 0.30 LogMAR (20/40 Snellen) or better by 4 to 12 weeks. However, as anticipated, postoperative vision and VA gain were notably inferior to the control group. The early onset of cataracts and the associated visual disability in the RP patient group highlight the need for early identification and prompt discussion with the patient regarding the risks and potential benefits of cataract surgery. It is crucial for cataract surgeons to emphasize this distinction in visual potential when discussing VA outcomes with RP patients as part of managing their expectations before cataract surgery.

In the present study, the rates of intraoperative complications, including zonular dialysis and PC rupture in RP eyes, were comparable to routine cataract surgery. A major distinguishing difference of the current study from other retrospective series is excluding eyes with any other ocular pathology that may confound the risks of surgery or the VA outcomes. Similar to the current report, a study investigating the axial length and the risk for complications during cataract surgery did not identify axial length as an independent risk factor for complications when coexisting ocular pathology was excluded.[16] The compulsory nature of reporting of intraoperative complications by the EMR used in our study with 100% completeness of this data point, increases the accuracy of our results. Nguyen et al. recently reported a zonular dialysis rate of 5% ($n = 15/295$).[5] A large case study conducted in the UK with patients undergoing phacoemulsification or extracapsular cataract extraction ($n = 142$ eyes), also did not report an increased rate of zonular dialysis.[7] In the study with the largest reported rate of phacodonesis, fifteen eyes (18.8%) of 10 patients (21.3%); 3 eyes were noted preoperatively, 8 intraoperatively, and 4 postoperatively.[14] Disparities in zonular dialysis rates may be attributed to variations in the complication reporting systems and differences in the genetic subtypes of RP.

In our study, 6.9% of the eyes with RP developed postoperative CME, significantly higher than in the control group. The greater prevalence of CME in patients with RP after cataract surgery follows the disease's natural history and pathogenetic mechanism.[17] CME is most prevalent in patients with AD inheritance (71.4% with CME in at least one eye), followed by AR/sporadic inheritance (58.9%), and least common in X-linked inheritance (12.5%).[18] Several studies have reported higher rates of CME after cataract surgery, ranging from 5.8% to 14%.[4] A recent database study that included 124 eyes with RP and 615 521 without RP reported an incidence of 5.8% in the RP group.[13] The difference in reported rate post cataract CME surgery in patients with RP may reflect the different inheritance/genetic backgrounds of the cases in various cohorts. The higher rate of CME reported herein and in the literature[4,13] highlights the need for careful preoperative and postoperative evaluation of patients with RP to mitigate the risk. Early recognition of pre-existing CME in RP patients with OCT before surgery can help advise the patients of the risk of worsening CME after surgery and initiate treatment of pre-existing CME before surgery. Patients with RP also need close follow-up for longer periods of time, both for early recognition and treatment of CME. Treatment approaches for CME include topical carbonic anhydrase inhibitors (CAIs), oral CAIs, periocular and intravitreal steroids, and intravitreal anti-VEGF agents.[19-21]

Similar to CME, we found a higher rate of YAG capsulotomy in RP patients compared to the control group (14% vs 3%). Other studies in eyes with RP reported a higher rate of YAG capsulotomy, ranging from 41% to 52%.[7,14,22] It is of note that our reported rate reflects only the frequency of YAG capsulotomy within the first 6 months postoperatively. Jackson et al. reported an increasing incidence of PCO after postoperative month six, reporting a rate of 51% for eyes with longer than 6 months of follow-up.[7] Dikopf et al. also report a mean time for YAG capsulotomy of 10.8 months which is also greater than the 6-month interval in the current study, with an incidence of 52%. Yoshida et al. report a rate of 41.1% within a mean follow-up time of 3 years. It is clear from the current report and the literature that the rate of PCO is significantly higher for patients with RP, and this should be communicated to the patient during the discussion of their cataract surgery.

The main limitation of our study is the retrospective design with variable follow-up time. Surrogate markers of RP severity, such as OCT structural changes, extent of retinal atrophy, disease duration, and visual field data, were lacking. Also, molecular confirmation and genotypic data were unavailable, which precluded further investigation of complication rates for specific genotypes or inheritance modes.

CME was assessed clinically, with patients with reduced VA outcomes receiving imaging studies to confirm the diagnosis of CME; however, subclinical disease may not have been detected in this study.

Despite the limitations, this study has certain strengths. The study was comparative and excluded eyes with coexisting ocular co-pathology that can confound intraoperative complication rates and VA outcomes, including epiretinal membrane, pre-existing CME, and uveitis. Since the data were pragmatically collected as a byproduct of routine clinical care and the data extraction was automated, the risk of recall bias is expected to be minimal. Additionally, we expect that rates of under-reporting bias for intraoperative complications were minimal because reporting surgical complications in the EMR was mandatory to close the operative record. Surgeons could only omit recording a complication if they made a false declaration.

In summary, this study quantified the complications of cataract surgery in patients with RP in a comparative fashion. We found that cataract surgery can improve vision in this patient population. While intraoperative complications were similar to those in control eyes, RP eyes experienced more CME. Our findings provide prognostic and counseling information for patients with RP, both for their current clinical management and their participation in clinical trials or future therapeutics that result in cataract development. Prospective studies with more in-depth phenotypic characterization, including RP severity and genotype, may further provide greater insight into the genotypic-phenotypic correlation of complications during cataract surgery and VA outcomes.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

MICHALIS GEORGIOU: Writing – original draft, Investigation, Formal analysis, Conceptualization. **AHMED F. SHAKARCHI:** Writing – original draft, Software, Resources, Formal analysis. **ABDELRAHMAN M. ELHUSSEINY:** Writing – review & editing, Visualization, Methodology, Investigation. **MICHEL MICHAELIDES:** Writing – review & editing, Supervision, Formal analysis. **AHMED B. SALLAM:** Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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