The Royal College of Ophthalmologists' National Ophthalmology Database Audit

RCOphth NOD National Cataract Audit Vision Loss statistical model

Sixth year of the prospective National Cataract Audit

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2 Abbreviations

Abbreviation	Description
AMD	Age-related Macular Degeneration
AUROC	Area under the receiver operating curve
CF	Count fingers
CNS	Central nervous system
CQC	Care Quality Commission
CV	Comparator Value
DR	Diabetic Retinopathy
EMR	Electronic Medical Record
GIRFT	Getting It Right First Time Programme
HM	Hand movements
IMD	Index of multiple deprivations
LogMAR	Logarithm of the Minimum Angle of Resolution
NHS	National Health Service
NOD	National Ophthalmology Database
NPL	No perception of light
PCR	Posterior capsule rupture
PL	Perception of light
RCOphth	The Royal College of Ophthalmologists
SD	Standard Deviation
UK	United Kingdom
VA	Visual Acuity
VEGF	Vascular Endothelial Growth Factor

3 Acknowledgements

The National Ophthalmology Database Audit (NOD) is conducted under the auspices of the Royal College of Ophthalmologists (RCOphth) and conducts the National Cataract Audit focusing on publicly funded cataract surgery.

We acknowledge the support of the hospitals that are participating in the RCOphth NOD and thank our medical and non-medical colleagues for the considerable time and effort devoted to data collection. All participating centres are listed on the RCOphth NOD website (www.nodaudit.org.uk).

We acknowledge with thanks the contribution of Professor John Sparrow who provided diligent clinical and academic oversight and leadership of the NOD over many years to bring it to its current stature. It is with gratitude that we remember our friend and colleague Robert Johnston, who sadly died in September 2016. Without his inspirational vision, determination and career long commitment to quality improvement in ophthalmology this work would not have been possible.

4 Introduction

The Royal College of Ophthalmologists (RCOphth) is the governing authority for the National Ophthalmology Database Audit (NOD) and conducts The National Cataract Audit on data concerning cataract surgery. The audit is open to all providers of National Health Service (NHS) funded cataract surgery and providers of private funded cataract surgery in England, Scotland, Northern Ireland, Wales and the Channel Islands. The data is collected as part of routine clinical care on electronic medical record (EMR) systems or in-house data collection systems and the analysis is performed by the RCOphth NOD Audit statisticians based in Cheltenham General Hospital.

Every year, around 400,000 patients in England and 20,000 patients in Wales undergo NHS cataract surgery – the most frequently performed incisional surgical procedure in the UK. A widely accepted indicator of surgical quality is the frequency of posterior capsule rupture with or without vitreous prolapse into the anterior chamber of the eye, or zonule rupture with vitreous loss, abbreviated as PCR. This operative complication arises on average in approximately 1 operation in 100 but the risk of this event varies by as much as 50-fold depending on preoperative risk factors associated with the patient, their eye and the grade of the surgeon. When this surgical complication occurs, there is a 6-10-fold higher chance of significant Vision Loss after surgery.

Case-complexity adjustment is therefore necessary for fair comparisons between surgeons and centres performing cataract surgery. Case complexity adjusted PCR and postoperative Vision Loss were chosen as the two primary outcome measures of cataract surgery in the National Cataract Audit.

This document contains the methodology used to create the case complexity adjusted postoperative Vision Loss model which will be applied to the prospective cataract audit. The model was created from 'legacy' data extracted from 40 contributing centres, 34 of which contributed cataract surgery data.

Full details of the RCOphth NOD can be found on the RCOphth NOD website (www.nodaudit.org.uk).

5 Statistical methods

Data were extracted from participating centres that used the Medisoft (Medisoft Ophthalmology, Medisoft Limited, Leeds, UK) electronic medical record (EMR) system in November 2015 and all analysis was conducted using STATA version 11, (StataCorp. 2009. Stata Statistical Software: Release 11. College Station, TX: StataCorp LP). Centre participation was approved by the Caldicott Guardian (responsible for data protection) and Clinical Lead for Ophthalmology.

A mixed effects logistic regression model was fitted to all eligible cataract operations performed during the 2011 – 2014 NHS years (01 April 2011 – 31 March 2015). The criteria for an eligible cataract operation can be found on the RCOphth NOD website (https://www.nodaudit.org.uk/resources/methodology) and the outcome variable was postoperative Vision Loss which was defined as;

A loss of ≥0.30 LogMAR (doubling or worse of the visual angle) between the preoperative and postoperative VA measurements, where:

- Preoperative visual acuity was defined as the better measurement of corrected distance visual acuity or uncorrected distance visual acuity that is closest to the date of surgery, including the day of surgery and within 90 days prior to surgery. Pin hole visual acuity measurements were not used for preoperative visual acuity. For the second prospective year of the audit the preoperative visual acuity time period was increased to 'within 4 months prior to surgery', and for the third prospective year of the audit to "within 6 months prior to surgery". These changes were in order to better account for the variability between centres in terms of the time from initial assessment / listing for surgery and the cataract surgery.

- Postoperative visual acuity was defined as the best measurement of corrected distance visual acuity, uncorrected distance visual acuity or pin hole visual acuity between 14 days and 4 months (inclusive) post-cataract surgery. For the third prospective year of the audit these time periods were changed to '8 days and 6 months (inclusive) of cataract surgery'. This change was to better account for the variability between centres in terms of the time of post-surgery assessment.

Since the second year of the audit the Vision Loss definition has been changed to the following;

Pre-operative visual acuity	Postoperative visual acuity loss
<1.00 LogMAR	A loss of ≥0.30 LogMAR
≥1.00 to <CF	Postoperative visual acuity of HM, PL, or NPL
CF	Postoperative visual acuity of PL or NPL
HM	Postoperative visual acuity of NPL
PL	Vison Loss not considered
NPL	Vision Loss not considered

Where, CF = count fingers, HM = hand movements, PL = perception of light and NPL = no perception of light.

All covariates of interest were fitted to the model as fixed effects and the individual surgeons were fitted as the random effect. An identity matrix was used to model the covariance structure; this sets equal variances for the random effects and all covariances to be zero and is the appropriate structure when factor variables are specified.

Covariates of interest were first investigated on the univariate level using Pearson's Chi-squared tests. Covariates that were significant at the 10% level were fitted to the multivariate models on a 'test sample' using backwards selection and a significance level of 5% to remain in the model. The final model from the 'test' sample was then applied to a 'validation' sample for comparison.

To create the 'test sample' and the 'validation sample' a random number generating allocation from a multivariate normal distribution was used, where negative random numbers allocated an operation to the 'test sample' and positive random numbers allocated an operation to the 'validation sample'. Before the random number allocation was performed the data was sorted (ordered) on all covariates under consideration.

Model diagnostics utilised were comparing the deviance residuals to the model predicted values and the model fitting automatically performs a comparison with a fixed effects logistic regression model to ascertain if the random effects are needed.

From the final model on the 'test' sample case complexity adjusted Vison Loss graphs for surgeons and centres are created using funnel plots for the audit period being reported (see annual reports at https://www.nodaudit.org.uk). The case complexity adjusted Vision Loss graphs include 95% and 99.8% confidence limits plotted using the logit transform and a comparator value of 0.9% for Vison Loss which has been reduced from 1.5% used in the 'legacy' analysis and the first prospective year of the audit. This updated comparator value better reflects the current average rates for the reference group, i.e. the consultant surgeons. The categorisation of each covariate under investigation in the Vision Loss mixed effects logistic regression model are detailed in Table 1.

Table 1: Variables for consideration in the mixed effects logistic regression model

Variable	Categorisation	Additional information
Surgeon grade	Consultant	
	Career grade non-consultant	Staff grade Associate Specialists Trust doctors
	Experienced trainee	Fellows registrars specialty registrars' years 3 - 7 specialty trainees' years 3 – 7
	Inexperienced trainee	SHO specialty trainees' years 1-2 specialty registrars' years 1 - 2 foundation doctors years 1 - 2
Patient variables		
Age at surgery	<70 years 70 – 74 years 75 – 79 years 80 – 84 years 85 – 89 years ≥90 years	If missing data constitutes <2% of the sample, then impute the mean age of patients with data using first treated eyes for missing first treated eye age and second treated eyes for missing second treated eye age. If missing age constitutes ≥2% of the sample then fit into the models as a variable level.
Gender	Female Male	If missing gender or gender recorded as "Not Specified" allocate as "Female" unless missing data constitutes ≥2% of the sample, if so fit as a variable level in the models
Index of multiple deprivations (IMD) score	Quintiles	If missing, infer within each centre the mean IMD score for that centre.
Patient taking any alpha-blockers	No Yes	"No" if no medication recorded or "Not taking medication" is recorded "Yes" if patient taking any of; Alfuzosin Doxazosin Indoramin Prazosin Tamsulosin Terazosin

Patient ability to lie flat	No Yes	If missing, assume "Yes"
Patient ability to co-operate	No Yes	If missing, assume "Yes"
Eye variables		
First eye surgery	No Yes	Bilateral surgery can be included with "Yes" for both eyes under the assumption that any difference in PCR likelihood between a first and second eye operation from the patients age and grade of operating surgery do not apply to bilateral surgery. If missing and only one operated eye per patient, assume "Yes"
Pupil size	Large Medium Small	If missing, assume "Large"
Axial length	<20 mm 20 – 28 mm >28 mm	If missing data constitutes <2% of the sample allocate to "20 – 28 mm", if ≥2% of the sample fit as a variable level in the models.
PCR	No Yes	"Yes" if Occurring during cataract surgery, see the RCOphth NOD website for the definition of PCR, www.nodaudit.org.uk.
Preoperative visual acuity (LogMAR)	<0.00 0.00 – 0.30 0.31 – 0.60 0.61 – 0.90 0.91 – 1.20 >1.20	
Ocular co-pathology / know risk indicator		
	AMD	In the legacy data Wet AMD and Dry AMD could not be separated, in the prospective data this is now possible
	Amblyopia	

	Brunescent / White Cataract	
	Corneal Pathology	
	DR	
	Glaucoma	
	High Myopia	
	Inherited eye disease	
	No fundal view / Vitreous Opacities	
	Optic nerve / CNS disease	
	Other Macular pathology	Including 'Epiretinal Membrane' and 'Macular Hole' as recorded ocular co-pathology.
	Other Retinal vascular pathology	
	Previous Trabeculectomy	
	Previous Vitrectomy*	Any previous operation that included a Pars Plana Vitrectomy, plus 'Retinal Detachment' as a recorded ocular co-pathology.
	Psuedoexfoliation / Phacodenesis	In the legacy analysis these could not be separated, in the prospective data this is now possible
	Uveitis / Synaechiae	
	Other	

In the 'legacy' data Epiretinal Membrane, Macular Hole and Retinal Detachment were recorded as ocular co-pathologies without specifying if with or without a previous vitrectomy surgery. In the model fitting both Epiretinal Membrane and Macular Hole were classified as "Other macular pathology" while Retinal Detachment was classified as "Previous vitrectomy". In the prospective analysis these terms can be recorded and specified as with a previous vitrectomy surgery or not and could be fitted into any model of prospective data separately.

6 Vision Loss case complexity adjustment modelling results

In total, 34 centres recorded 602,459 cataract operations on the RCOphth NOD, 287,093 of which were performed since the start of the 2011 NHS year. Of these, 159,910 operations were performed in eyes that had both preoperative and postoperative visual acuity measurements and were eligible for Vison Los case complexity adjustment model development. Vision Loss was experienced by 1,600 (1.0%) eyes. The rates of Vision Loss for each covariate under consideration in the model are shown in Table 2, by the random allocation of operations to the 'test' and 'validation' samples and with univariate analysis on the whole sample.

There were discrepancies between the proportion of eyes with Vision Loss in the 'test sample' and 'validation sample' for the following covariates, patient ability to lie flat, patient ability to cooperate, extreme axial length measurements, high myopia, inherited eye disease, optic nerve / CNS disease, other maculopathy pathology, other retinal vascular pathology, previous trabeculectomy surgery, previous vitrectomy surgery and uveitis / synaechiae. Discrepancies in the outcome variable between samples used for model fitting are not ideal, but the allocation was random and the covariates with a discrepancy were low prevalence conditions.

The covariates that were significant at the 10% level from the univariate Chi-Squared tests were as follows; surgeon grade, patient gender, age at surgery, patient ability to lie flat, patient taking alpha-blocker medication, pupil size, axial length, pre-operative visual acuity, PCR, AMD, amblyopia, brunescent / white cataract, corneal pathology, DR, glaucoma, high myopia, inherited eye disease, optic nerve / CNS disease, other macular pathology, other retinal vascular pathology, previous trabeculectomy, previous vitrectomy, psuedoexfoliation

/ phacodenesis, uveitis / synaechiae and unspecified other co-pathology. These covariates were all investigated in the VA loss mixed effects model.

Table 2: Covariates under consideration in the Vision Loss model with rates of Vision Loss for each covariate by the 'test sample' and the 'validation sample', and with univariate hypothesis testing on the whole sample.

	Test sample N = 80,030		Validation sample N = 79,880		Overall Vision Loss N = 159,910		
	No Vision Loss	Vision Loss	No Vision Loss	Vision Loss	No Vision Loss	Vision Loss	p-value
Number of eyes	**79,221**	**809 (1.0)**	**79,089**	**791 (1.0)**	**158,310**	**1,600 (1.0)**	**N/A**
Surgeon grade							
Consultants	48,762	487 (1.0)	48,379	481 (1.0)	97,141	968 (1.0)	
Career grade non-consultants	10,023	85 (0.8)	10,143	82 (0.8)	20,166	167 (0.8)	0.001
Experienced trainees	17,876	218 (1.2)	18,060	204 (1.1)	35,936	422 (1.2)	
Inexperienced trainees	2,560	19 (0.7)	2,507	24 (0.9)	5,067	43 (0.8)	
Patient details							
Age (years)							
<70	20,045	134 (0.7)	20,064	149 (0.7)	40,109	283 (0.7)	
70 – 74	12,458	93 (0.7)	12,604	88 (0.7)	25,062	181 (0.7)	
75 – 79	17,166	126 (0.7)	16,971	149 (0.9)	34,137	275 (0.8)	<0.001
80 – 84	16,494	226 (1.4)	16,256	202 (1.2)	32,750	428 (1.3)	
85 – 89	9,756	146 (1.5)	9,800	133 (1.3)	19,556	279 (1.4)	
≥90	3,302	84 (2.5)	3,394	70 (2.0)	6,696	154 (2.2)	
Gender							
Female	46,167	458 (1.0)	45,959	421 (1.0)	92,126	879 (0.9)	0.009
Male	33,054	351 (1.1)	33,130	370 (1.1)	66,184	721 (1.1)	
Index of multiple deprivations							
First quintile	16,993	165 (1.0)	16,803	178 (1.0)	33,796	343 (1.0)	
Second quintile	15,911	172 (1.1)	16,036	153 (1.0)	31,947	325 (1.0)	0.215
Third quintile	15,402	150 (1.0)	15,587	132 (0.8)	30,989	282 (0.9)	

Fourth quintile	16,004	159 (1.0)	15,945	163 (1.0)	31,949	322 (1.0)	
Fifth quintile	14,911	163 (1.1)	14,718	165 (1.1)	29,629	328 (1.1)	
Taking alpha-blockers							
No	73,712	734 (1.0)	73,439	728 (1.0)	147,151	1,462 (1.0)	0.014
Yes	5,509	75 (1.3)	5,650	63 (1.1)	11,159	138 (1.2)	
Able to lie flat							
Yes	78,687	805 (1.1)	78,508	790 (1.0)	157,195	1,595 (1.0)	0.062
No	534	4 (0.7)	581	1 (0.2)	1,115	5 (0.4)	
Able to cooperate							
Yes	78,606	800 (1.0)	78,442	786 (1.0)	157,048	1,586 (1.0)	0.728
No	615	9 (1.4)	647	5 (0.8)	1,262	14 (1.1)	
Eye details							
1st or 2nd treated eye							
1st treated eye	52,049	518 (1.0)	51,893	505 (1.0)	103,942	1,023 (1.0)	0.150
2nd treated eye	27,172	291 (1.1)	27,196	286 (1.0)	54,368	577 (1.1)	
Pupil size							
Large	60,727	581 (1.0)	60,516	574 (1.0)	121,243	1,155 (0.9)	
Medium	15,623	187 (1.2)	15,543	169 (1.1)	31,166	356 (1.1)	<0.001
Small	2,871	41 (1.4)	3,030	48 (1.6)	5,901	89 (1.5)	
Axial Length							
< 21 mm	107	2 (1.8)	99	4 (3.9)	206	6 (2.8)	
21 – 28 mm	78,285	802 (1.0)	78,170	779 (1.0)	156,455	1,581 (1.0)	0.019
>28 mm	829	5 (0.6)	820	8 (1.0)	1,649	13 (0.8)	
PCR							
No	78,210	717 (0.9)	78,115	709 (0.9)	156,325	1,426 (0.9)	<0.001
Yes	1,011	92 (8.3)	974	82 (7.7)	1,985	174 (8.1)	
Preoperative visual acuity							
<0.00	301	46 (13.3)	284	54 (16.0)	585	100 (14.6)	
0.00 – 0.30	11,251	141 (1.2)	11,418	111 (1.0)	22,669	252 (1.1)	<0.001
0.31 – 0.60	34,808	340 (1.0)	34,620	328 (0.9)	69,428	668 (1.0)	

0.61 – 0.90	20,155	149 (0.7)	19,960	156 (0.8)	40,115	305 (0.8)	
0.91 – 1.20	5,495	43 (0.8)	5,533	50 (0.9)	11,028	93 (0.8)	
>1.20	7,211	90 (1.2)	7,274	92 (1.2)	14,485	182 (1.2)	
Ocular co-pathology / known risk indicator							
Age-related macular degeneration							
No	70,232	613 (0.9)	69,998	584 (0.8)	140,230	1,197 (0.8)	<0.001
Yes	8,989	196 (2.1)	9,091	207 (2.2)	18,080	403 (2.2)	
Amblyopia							
No	77,916	792 (1.0)	77,774	770 (1.0)	155,690	1,562 (1.0)	0.025
Yes	1,305	17 (1.3)	1,315	21 (1.6)	2,620	38 (1.4)	
Brunescent / white cataract							
No	76,294	768 (1.0)	76,215	757 (1.0)	152,509	1,525 (1.0)	0.030
Yes	2,927	41 (1.4)	2,874	34 (1.2)	5,801	75 (1.3)	
Corneal pathology							
No	77,082	766 (1.0)	76,754	736 (1.0)	153,836	1,502 (1.0)	<0.001
Yes	2,139	43 (2.0)	2,335	55 (2.3)	4,474	98 (2.1)	
Diabetic retinopathy							
No	73,945	706 (1.0)	73,931	707 (1.0)	147,876	1,413 (1.0)	<0.001
Yes	5,276	103 (1.9)	5,158	84 (1.6)	10,434	187 (1.8)	
Glaucoma							
No	71,989	670 (1.0)	71,959	665 (1.0)	143,948	1,335 (0.9)	<0.001
Yes	7,232	139 (1.9)	7,130	126 (1.7)	14,362	265 (1.8)	
High Myopia							
No	75,563	796 (1.0)	75,604	762 (1.0)	151,167	1,558 (1.0)	<0.001
Yes	3,658	13 (0.4)	3,485	29 (0.8)	7,143	42 (0.6)	
Inherited eye disease							
No	79,123	805 (1.0)	78,970	788 (1.0)	158,093	1,593 (1.0)	0.001
Yes	98	4 (3.9)	119	3 (2.5)	217	7 (3.1)	
No fundal view / vitreous opacities							

No	78,465	803 (1.0)	78,282	785 (1.0)	156,747	1,588 (1.0)	0.339
Yes	756	6 (0.8)	807	6 (0.7)	1,563	12 (0.8)	
Optic nerve / CNS disease							
No	78,906	804 (1.0)	78,805	785 (1.0)	157,711	1,589 (1.0)	0.046
Yes	315	5 (1.6)	284	6 (2.1)	599	11 (1.8)	
Other macular pathology							
No	77,798	777 (1.0)	77,653	764 (1.0)	155,451	1,541 (1.0)	<0.001
Yes	1,432	32 (2.2)	1,436	27 (1.8)	2,859	59 (2.0)	
Other retinal vascular pathology							
No	78,371	779 (1.0)	78,209	765 (1.0)	156,580	1,544 (1.0)	<0.001
Yes	850	30 (3.4)	880	26 (2.9)	1,730	56 (3.1)	
Previous trabeculectomy							
No	78,844	801 (1.0)	78,713	786 (1.0)	157,557	1,587 (1.0)	0.052
Yes	377	8 (2.1)	376	5 (1.3)	753	13 (1.7)	
Previous vitrectomy							
No	77,814	786 (1.0)	77,667	775 (1.0)	155,481	1,561 (1.0)	0.051
Yes	1,407	23 (1.6)	1,422	16 (1.1)	2,829	39 (1.4)	
Pseudoexfoliation / phacodenesis							
No	78,400	794 (1.0)	78,280	772 (1.0)	156,680	1,566 (1.0)	<0.001
Yes	821	15 (1.8)	809	19 (2.3)	1,630	34 (2.0)	
Uveitis / Synaechiae							
No	78,553	798 (1.0)	78,437	777 (1.0)	156,990	1,575 (1.0)	0.001
Yes	668	11 (1.6)	652	14 (2.1)	1,320	25 (1.9)	
Unspecified other co-pathology							
No	75,915	760 (1.0)	75,727	745 (1.0)	151,642	1,505 (1.0)	0.001
Yes	3,306	49 (1.5)	3,362	46 (1.3)	6,668	95 (1.4)	

‘Test sample’ model fitting;

The best fitting model (‘test sample’) did not include surgeon grade, gender, patient ability to lie flat, patient taking alpha-blocker medication, pupil size, axial length, brunescent / white cataract, optic nerve / CNS disease, previous trabeculectomy, psuedoexfoliation / phacodenesis or uveitis / synaechiae, Table 3. The comparison with a fixed effect logistic regression model yielded a p-value of <0.001 in favour of the inclusion of the random effect.

‘Validation sample’ model fitting;

The best fitting model from the ‘test sample’ was applied to the ‘validation sample’, Table 4. The comparison with a fixed effects logistic regression model yielded a p-value of <0.001 in favour of inclusion of the random effect.

Vision Loss model comparisons;

There were two big differences between the model estimates from the ‘test sample’ and the ‘validation sample’, these were for the presence or absence of high myopia and previous vitrectomy surgery which were both significant for the ‘test’ sample but non-significant in the ‘validation’ sample. These are rare ocular co-pathologies and both covariates displayed discrepancies in the proportion of eyes with Vision Loss between the random allocation to the ‘test’ and ‘validation’ samples. The discrepancy may be sample size and sample allocation related, but is of concern given the nature of the difference.

There was one minor difference between the model estimates from the ‘test sample’ and the ‘validation sample, which was for the presence or absence of an inherited eyes disease which was borderline non-significant in the ‘validation’ model. Concern over this difference is limited due to the rare prevalence of this ocular co-pathology within the sample.

Neither of the ‘test sample’ or ‘validation sample’ Vision Loss models were perfect fits to the data, as can be seen in Figures 1 and 2, there is curvature in the graphs of the deviance residuals against the model predicted values. The ‘test sample’ estimates as predictors for the ‘validation sample’ fitted adequately considering that the outcome variable is a ‘rare’ event and some surgeons have a small number of operations, these two aspects can introduce zero inflation to a sample, Figure 3.

Table 3 Fixed effect estimates from the Vision Loss model on the 'test sample'

Covariate	Odds ratio	coefficient	P>z	95% CI for coefficient
Constant term	N/A	-2.308	<0.001	-2.664 to -1.951
Preoperative visual acuity				
<0.00	REF	0	N/A	N/A
0.00 – 0.30	0.054	-2.911	<0.001	-3.285 to -2.537
0.31 – 0.60	0.035	-3.340	<0.001	-3.696 to -2.983
0.61 – 0.90	0.024	-3.727	<0.001	-4.105 to -3.348
0.91 – 1.20	0.024	-3.726	<0.001	-4.184 to -3.267
>1.20	0.035	-3.355	<0.001	-3.760 to -2.949
Age at surgery (years)				
Aged <70	REF	0	N/A	N/A
Aged 70 – 74	1.141	0.132	0.345	-0.142 to 0.405
Aged 75 – 79	1.129	0.121	0.351	-0.134 to 0.376
Aged 80 – 84	2.114	0.749	<0.001	0.517 to 0.980
Aged 85 – 89	2.278	0.823	<0.001	0.567 to 1.080
Aged ≥90	3.591	1.278	<0.001	0.975 to 1.582
PCR	9.786	2.281	<0.001	2.042 to 2.520
Presence of an ocular co-pathology / known risk indicator				
Age-related macular degeneration	2.244	0.808	<0.001	0.631 to 0.986
Amblyopia	1.826	0.602	0.019	0.101 to 1.103
Corneal pathology	2.132	0.757	<0.001	0.435 to 1.079
Diabetic retinopathy	2.546	0.935	<0.001	0.714 to 1.156
Glaucoma	1.938	0.662	<0.001	0.468 to 0.856
High myopia	0.448	-0.804	0.005	-1.363 to -0.244
Inherited eye disease	6.352	1.849	<0.001	0.814 to 2.884
Other macular pathology	1.713	0.538	0.007	0.148 to 0.929
Other retinal vascular pathology	2.757	1.014	<0.001	0.619 to 1.410
Previous vitrectomy surgery	2.293	0.830	<0.001	0.369 to 1.291
Unspecified other co-pathology	1.498	0.404	0.009	0.102 to 0.706

Table 4 Fixed effect estimates from the Vision Loss model on the 'validation sample'

Covariate	Odds ratio	coefficient	P>z	95% CI for coefficient
Constant term	N/A	-2.020	<0.001	-2.351 to -1.690
Preoperative visual acuity				
<0.00	REF	0	N/A	N/A
0.00 – 0.30	0.035	-3.350	<0.001	-3.718 to -2.983
0.31 – 0.60	0.029	-3.540	<0.001	-3.879 to -3.199
0.61 – 0.90	0.022	-3.815	<0.001	-4.175 to -3.454
0.91 – 1.20	0.025	-3.707	<0.001	-4.137 to -3.278
>1.20	0.030	-3.499	<0.001	-3.889 to -3.110
Age at surgery (years)				
Aged <70	REF	0	N/A	N/A
Aged 70 – 74	0.976	-0.025	0.861	-0.298 to 0.249
Aged 75 – 79	1.215	0.194	0.113	-0.046 to 0.435
Aged 80 – 84	1.702	0.532	<0.001	0.300 to 0.763
Aged 85 – 89	1.733	0.550	<0.001	0.292 to 0.807
Aged ≥90	2.473	0.905	<0.001	0.592 to 1.218
PCR	8.936	2.190	<0.001	1.939 to 2.442
Presence of an ocular co-pathology / known risk indicator				
Age-related macular degeneration	2.558	0.939	<0.001	0.764 to 1.114
Amblyopia	1.903	0.643	0.006	0.188 to 1.099
Corneal pathology	2.862	1.051	<0.001	0.763 to 1.340
Diabetic retinopathy	2.092	0.738	<0.001	0.498 to 0.978
Glaucoma	1.863	0.622	<0.001	0.420 to 0.824
High myopia	1.044	0.043	0.829	-0.344 to 0.429
Inherited eye disease	3.182	1.158	0.054	-0.022 to 2.337
Other macular pathology	1.888	0.635	0.003	0.222 to 1.048
Other retinal vascular pathology	2.530	0.928	<0.001	0.512 to 1.346
Previous vitrectomy surgery	1.155	0.144	0.602	-0.398 to 0.686
Unspecified other co-pathology	1.414	0.346	0.029	0.036 to 0.657

Figure 1: A graph of the deviance residuals vs. predicted values for the 'test sample' model

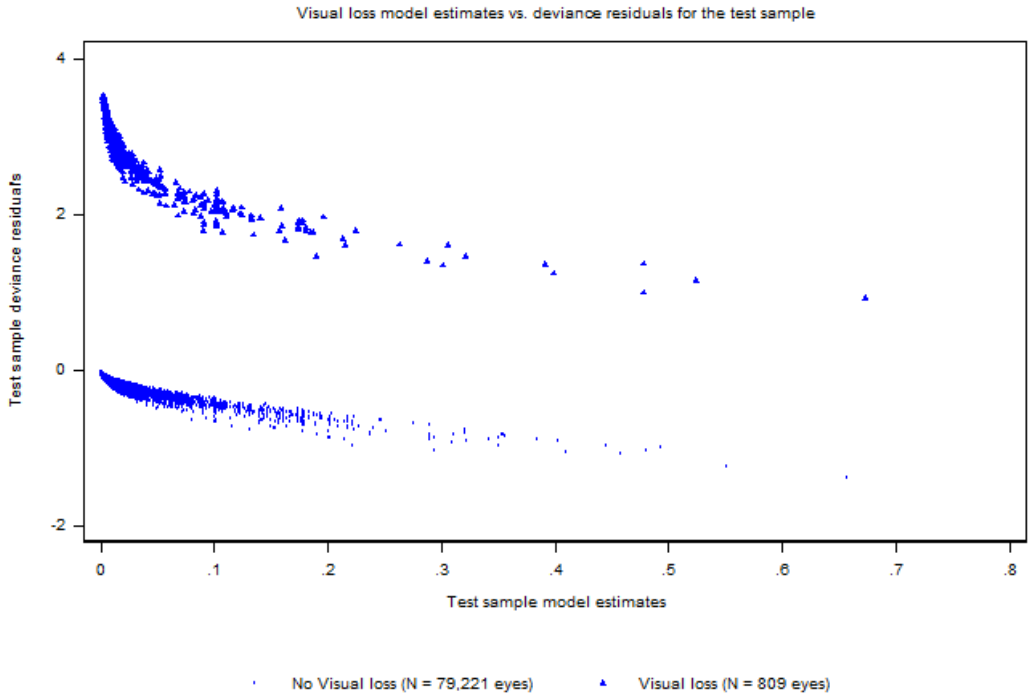


Figure 2: A graph of the deviance residuals vs. predicted values for the 'validation sample' model

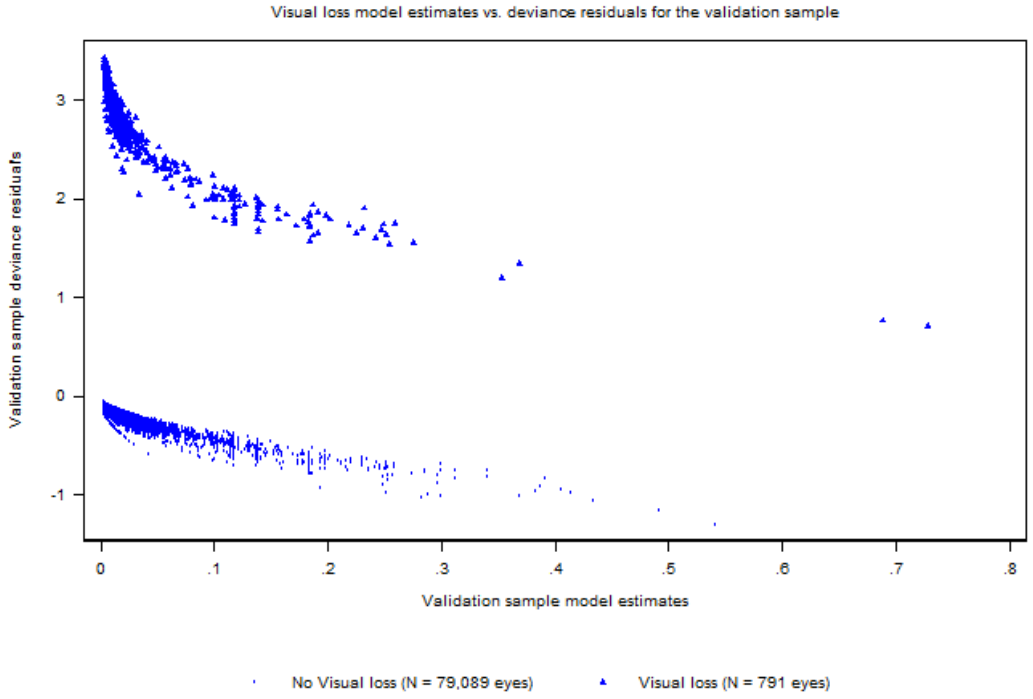
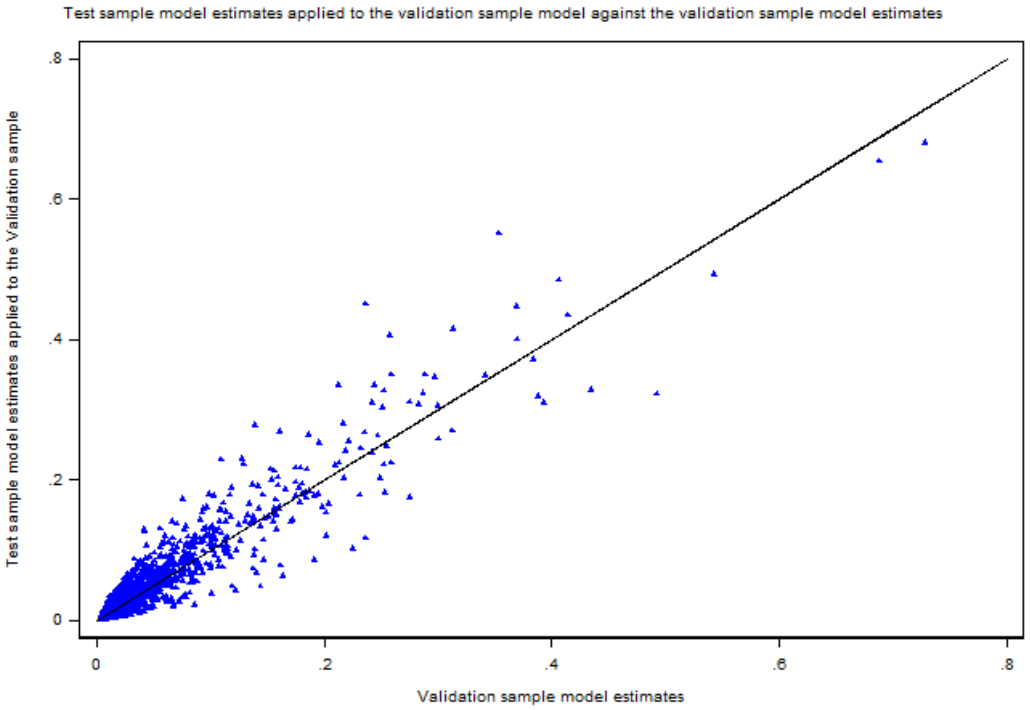


Figure 3: A graph of the 'test sample' estimates applied to the 'validation sample' against the estimates from the 'validation sample'



Missing data imputations used in the model;

For this sample the patient's gender was not recorded for 119 (<0.1%) operations and were assigned as female. The patient's age was missing for 2 (<0.1%) operations and the mean age by treated eye was inferred respectively using the mean age of patients with age data in that cohort (1 first treated eye and 1 second treated eye). The axial length was missing for 73 (<0.1%) eyes and was assigned as 21 – 28 mm. The patient's IMD score was not calculable for 5,177 (3.2%) operations and each contributing centre had at least 16 operations where the IMD score was not calculable. Within each centre the mean IMD score was inferred for these eyes.

Otherwise no missing data imputations were used. For many variables the non-recording of data is assumed to indicate absence of the issue, for example: no record of the patient taking alpha blockers is assumed to indicate that the patient is not taking alpha blockers and no record of a patient not being able to lie flat or co-operate is assumed to indicate that these were not problems during the operation.

Vision Loss model example

Examples of unadjusted and adjusted for case complexity Vision Loss graphs are shown for consultant surgeons and career grade non-consultant surgeons in Figures 4 and 5 and for centres including data from trainee surgeons in Figures 6 and 7. These graphs use data submitted for the completed prospective audit year 3.

Figure 4: Unadjusted for case complexity Vision Loss graph for consultant and career grade non-consultant surgeons; data for audit year 3.

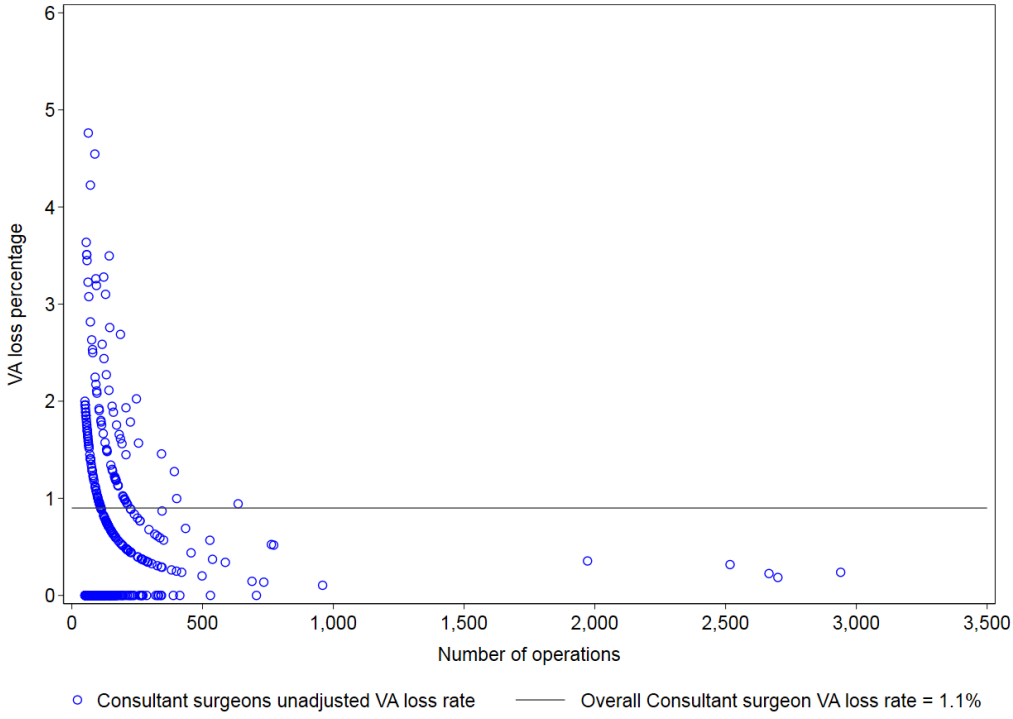


Figure 5: adjusted for case complexity Vision Loss graph for consultant and career grade non-consultant surgeons; data for audit year 3.

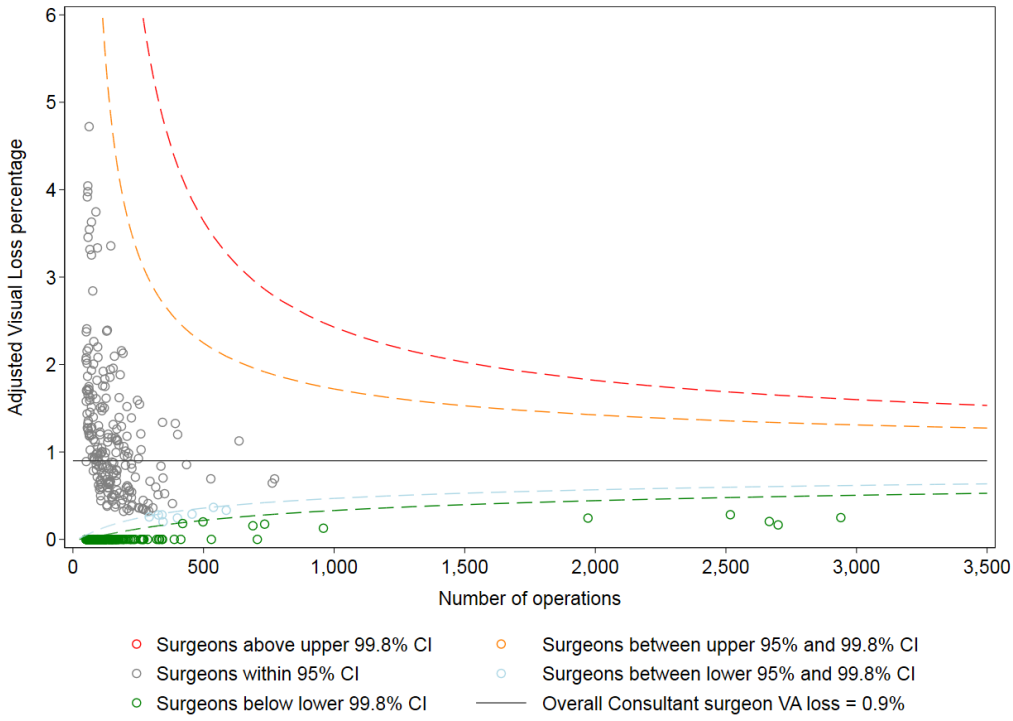


Figure 6: Unadjusted for case complexity Vision Loss graph for centres including all grades of surgeon; data for audit year 3.

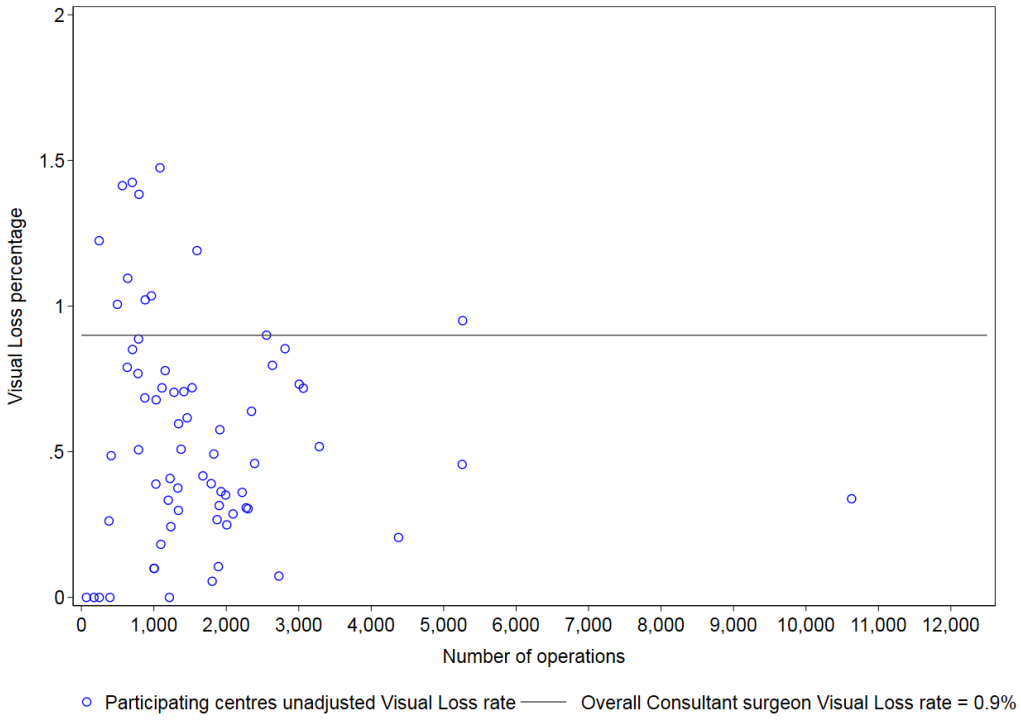
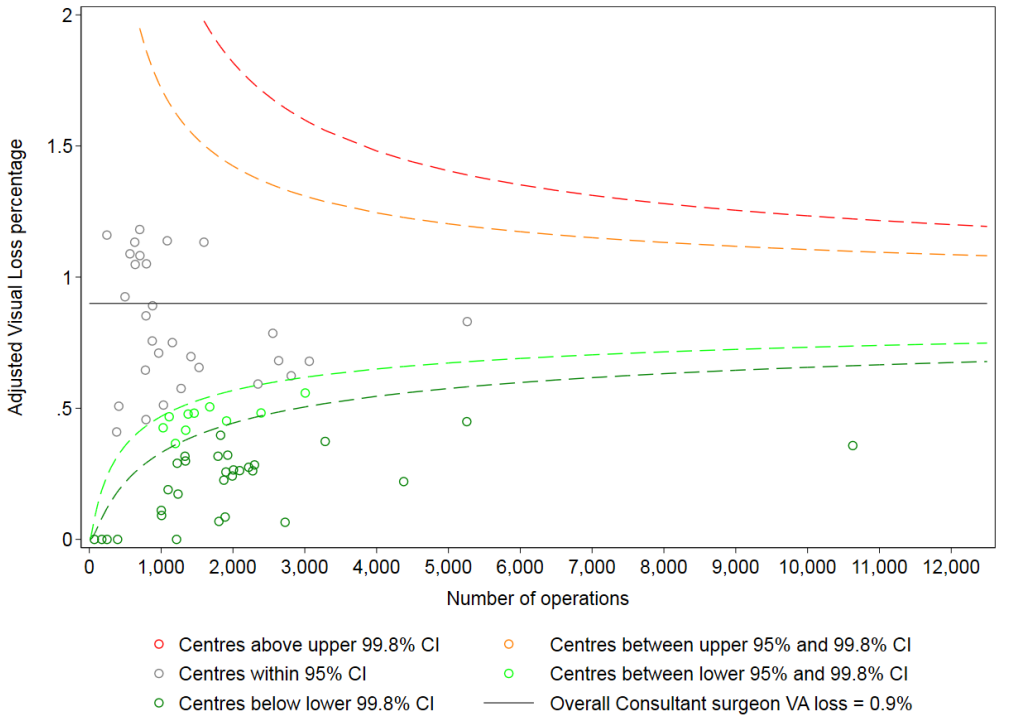


Figure 7: Adjusted for case complexity Vision Loss graph for centres including all grades of surgeon; data for audit year 3.



7 Possible refinements to the Vision Loss model

The current case complexity adjusted Vision Loss model is not a perfect fit to the data and could potentially be improved by the following actions:

- Testing for over dispersion and exploring different methodology to estimate the confidence intervals may improve the model and interpretation of the output; these have not been done due to time constraints.
- The model contains dichotomised variables, patient age and preoperative visual acuity. In both cases the dichotomisation process leads to a loss of information and an alternative approach would be to fit these as continuous variables, although this would greatly increase the computational demands of model fitting. If patient age remains as a categorical variable then the current categories could be altered. The model does provide some evidence that Vision Loss is linked to higher age and thus the lower age categories could be condensed.
- The appropriateness of the comparator value of 1.5% should be reviewed given that the overall Vision Loss rate was 1% and there were no differences between the grades of surgeon, as is the case for PCR, this was changed for the second prospective audit year, where the comparator value was reduced from 1.5% to 0.9%.
- The Vision Loss definition was changed for the second year of the audit and the visual acuity time periods before and after surgery for the third year of the audit. These alterations affect the definitions used for model fitting, and better reflect the variation between centres regarding the timing of visual acuity measurements.

The biggest problem with the Vision Loss model is that only 55.7% (159,910/287,093) of eligible cataract operations for the model time period had both preoperative and postoperative visual acuity measurements recorded. Any improvements in the number of operations with both a preoperative and postoperative visual acuity would increase the sample for future re-fitting of the model; this in turn would decrease parameter estimation errors due to the increased sample. For the second year of the prospective audit the preoperative visual acuity time period was changed from within 90 days to within 4 months. For the third year of the prospective audit the preoperative time period was changed to 'within 6 months prior to surgery', and the postoperative time period to 'within 8 days and 6 months (inclusive) of cataract surgery'. These increases in the time periods considered for a valid audit visual acuity measurement have increased the proportion of operations from many centres with visual acuity data.

In the prospective cataract audit, there are changes to the collection of some of the covariates considered as possible risk factors for Vision Loss, these are as follows:

- Lack of postoperative visual acuity has been identified as a weakness and a web portal has been developed to allow community optometrists to record visual acuity data for the patients discharged to the community optometrist services.
- Pseudoexfoliation / phacodenesis can be recorded as separated terms.
- Age-related macular degeneration can be recorded separately for geographic atrophy / dry AMD and neovascular / wet AMD.
- Uveitis / Synaechiae can be recorded as separate terms.
- Vitreoretinal co-pathologies (macular hole, epiretinal membrane, retinal detachment and vitrectomy) can be recorded with or without a previous vitrectomy.

The reason for altering the above ocular co-pathology data is to provide more information on these ocular conditions which may improve the model fitting. There is data that can now be collected in the prospective cataract audit which was not being recorded when the risk factor models were fitted, for example sub-type of cataract, floppy iris syndrome, anaesthesia data and previous anti-VEGF therapy. These changes are in preparation for future re-fitting of the risk factor models.

Any risk model can only be as good as the quality of data collected and it is unlikely that all theoretically plausible risk factors can be investigated, due to data collection, funding and time constraints. The RCOphth NOD is committed to using risk models based on scientific evidence that reflect current practice as accurately as possible. If new risk factors are discovered the RCOphth NOD will attempt with the resources available at that time to account for this new information. When time is available the RCOphth NOD plan to re-fit the risk models.

8 Vision Loss case complexity adjustment calculation

Analysis of large sets of cataract surgery data allows the risk indicators for Vision Loss to be identified and quantified through construction of a statistical model. This statistical model can then be 'reversed' for use as a prediction tool to calculate the predicted probability of Vision Loss occurring for an individual operation on the basis of the preoperative risk indicators identified in the model. The risk indicators can be thought of as representing a measure of the 'case complexity' or surgical difficulty for that particular operation.

To adjust for the case complexity of a series of operations undertaken by a surgeon, the predicted probability that a complication will arise is calculated for each of their operations. An average of the individual operation predicted probabilities is then calculated for the operative series and this is the surgeon's expected complication rate. To adjust for the surgeon's case complexity (i.e. give credit for how complex or difficult their cases are), this expected rate is compared against the actual observed complication rate by dividing one by the other. If the surgeon is performing to exactly the standard expected for their case complexity then the ratio would be 1.0, if better than expectation the ratio would be <1.0 and if less well the ratio would be >1.0. This ratio is then multiplied by the comparator value (underlying consultant rate) to set the case complexity adjusted estimates in contextual comparison to the underlying rate for consultant surgeons.

This adjusted rate is plotted on the funnel plot vertical axis with the number of operations on the horizontal axis. Calculations at the surgeon level are performed differently for each grade at which an individual surgeon has data recorded, i.e. if a surgeon has data for operations they performed as a trainee surgeon and as a consultant surgeon, they will have adjustments

applicable to the relevant grade at the time that each of their operations was performed. Results for centres include all grades of surgeon (consultant and trainees).

Details of case complexity adjustment method

The process of converting the Vision Loss risk model output into an adjusted Vision Loss rate per surgeon and surgeon grade is as follows;

The first two steps are on the operation level:

1: For each operation sum the Vision Loss risk model coefficients (including the constant term) relating to the operation to calculate Y, where Y = ∑relevant model coefficients for each operation plus the constant term.

2: Using the logit transformation convert Y to calculate Z, where Z = exp(Y) / (1 + exp(Y)) and exp = the exponential function.

The remaining steps are on the surgeon level are calculations are performed separately for each surgeon.

3: Calculate the expected Vision Loss rate (E_{VL}) where $E_{VL} = \sum Z / n$ and

n = the number of operations that surgeon has performed

4: Calculate the observed Vision Loss rate (O_{VL}) where $O_{VL} = n_{VL} / n_{operations}$ and

N_{VL} = the number of operations performed by a surgeon that had Vision Loss

$n_{operations}$ = the number of operations that surgeon performed

5: Calculate the adjusted Vision Loss rate (A_{VL}) where

A_{VL} = Comparator value multiplied by (O_{VL} / E_{VL})

To convert the adjusted Vision Loss rates to the percentage scale multiple A_{VL} by 100.

To calculate adjusted Vision Loss rates per contributing centre repeat steps 3 – 5 for contributing centres instead surgeons.

Example: A consultant surgeon performs a cataract operation on the left eye from an 80 year old patient. The patient's operated eye has a preoperative visual acuity of 0.45 LogMAR and the following ocular co-pathologies, Age-related macular degeneration, Amblyopia, Corneal pathology and Other macular pathology. In this case;

Y = -2.308 + 0.749 + -3.340 + 0.808 + 0.602 + 0.757 + 0.538

Y = -2.194

And Z = exp(-2.194) / (1 + exp(-2.194)) =0.100

Let's say that this consultant surgeon performed 9 further operations with the following Z values: 0.515; 0.098; 0.052; 0.349; 0.013; 0.009; 0.083; 0.703; 0.006

For this surgeon the equivalent sum of the Z values would be ∑Z = 1.928 and their expected Vision Loss rate would be E_{VL} = 1.928 / 10 = 0.1928 or 19.3%

The adjusted Vision Loss rates for this surgeon are shown in Table 5 for each possible observed Vision Loss rate based on the possible number of operations they performed that could have led to Vision Loss.

Table 5: Adjusted Vision Loss rates for each number of operations that could have led to Vision Loss for the example surgeon

Number of operations with Vision Loss	CV*	O_{VL}	E_{VL}	A_{VL}	A_{VL} (%)
0	0.009	0.0	0.1928	0.0	0.00
1	0.009	0.1	0.1928	0.0047	0.47
2	0.009	0.2	0.1928	0.0093	0.93
3	0.009	0.3	0.1928	0.0140	1.40
4	0.009	0.4	0.1928	0.0187	1.87
5	0.009	0.5	0.1928	0.0233	2.33
6	0.009	0.6	0.1928	0.0280	2.80
7	0.009	0.7	0.1928	0.0327	3.27
8	0.009	0.8	0.1928	0.0373	3.73
9	0.009	0.9	0.1928	0.0420	4.20
10	0.009	1.0	0.1928	0.047	4.67

*CV = the comparator value 0.9% used for Vision Loss rate

Any rounding of estimates is only performed for the adjusted Vision Loss rate and not at any earlier point in the calculations.

Estimating the 95% and 99.8% confidence intervals

1: The 95% and 99.8% confidence intervals are created using the following equation;

$y = x \pm \alpha(se(x))$ where

$x = \ln (p / (1 - p))$

p = the comparator value and ln = the natural logarithm

α = the z-values from the normal distribution corresponding to the 95% and 99.8% cut-off points used for the confidence intervals, these are 1.96 and 3.01 respectively.

se(x) = the standard error of x which is calculated from the following equation;

$se(x) = \sqrt{(1 / (n(x)(1-x))}$ where n = the number of operations performed

2: By using the logit transformation convert to the appropriate scale to create the confidence interval values (CI) where

$CI = \exp(y) / (1 + \exp(y))$ and exp = the exponential function.

To convert the confidence interval values to the percentage scale multiple CI by 100.

The confidence intervals are calculated for the range of the number of operations performed by the surgeons in the sample. When producing adjusted Vision Loss rates for contributing centres, the confidence intervals are produced for the range of operations performed by the contributing centres and the upper boundaries of the 95% and 99.8% confidence intervals equate to alert and alarm levels in public reporting and these are displayed in Table 6 for the comparator values used in the audit.

Table 6: Upper boundaries of the 95% (alert level) and 99.8% (alarm level) confidence intervals for the RCOphth NOD comparator values

	Vision Loss (comparator value = 0.9%)	
Number of operations	**Alert level (+2 SD)**	**Alarm level (+3 SD)**
50	14.60	45.16
100	6.75	18.03
150	4.71	10.92
200	3.79	7.96
300	2.92	5.41
400	2.50	4.28
500	2.25	3.64
600	2.08	3.23
700	1.95	2.94
800	1.86	2.73
900	1.78	2.56
1,000	1.72	2.43
1,100	1.67	2.32
1,200	1.63	2.23
1,300	1.59	2.15
1,400	1.56	2.08
1,500	1.53	2.03
2,000	1.42	1.82
3,000	1.31	1.60
4,000	1.25	1.48
5,000	1.20	1.41
6,000	1.17	1.35
7,000	1.15	1.31
8,000	1.13	1.28
9,000	1.12	1.25
10,000	1.11	1.23
15,000	1.06	1.16

9 Fixed effects only model

As a further model diagnostic, the final Vision Loss model covariates were fitted to a fixed effects only model and the area under the receiver operator curve (AUROC) produced. The AUROC should only be interpreted as a rough guide to the contribution the fixed effects make to the final model and not an exact measure of this contribution as the final model contains both fixed effects and random effects, the combination of both types of effects cannot be measured using AUROC.

The AUROC for a fixed effect only model using the final Vision Loss model covariates is displayed in Figure 8 for the 'test' sample and Figure 9 for the 'validation' sample.

Figure 8: AUROC graph from a fixed effects only model of the final Vision Loss model covariates using the 'test' sample

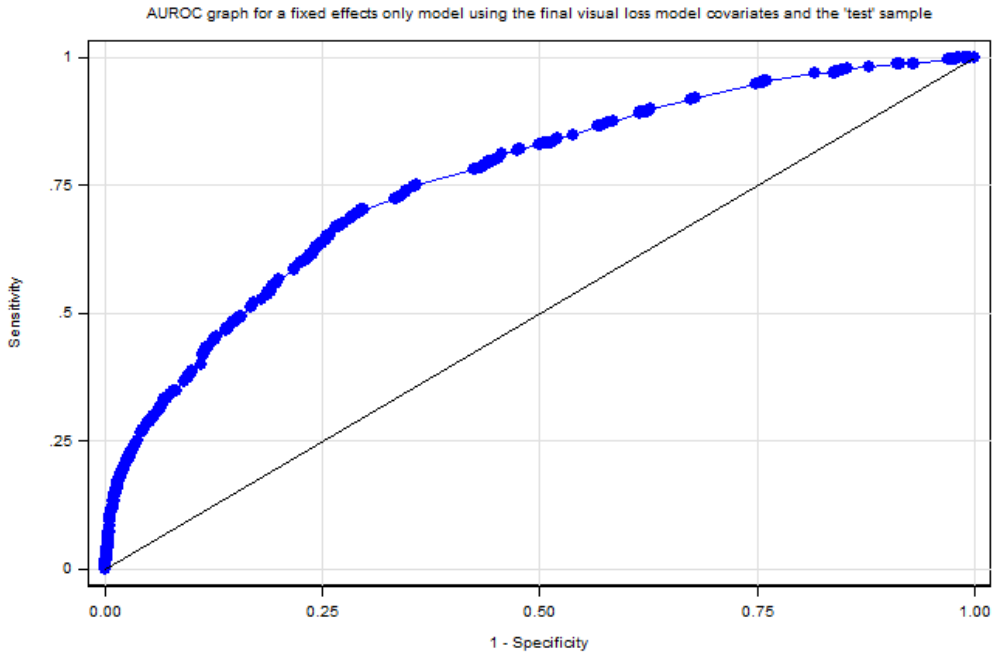
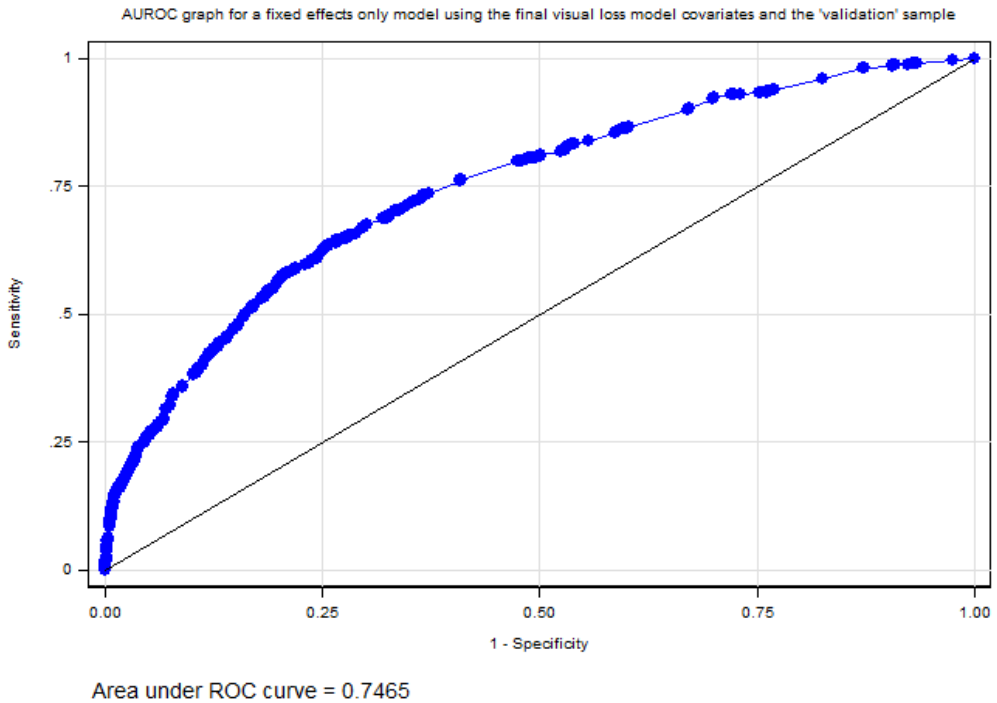


Figure 9: AUROC graph from a fixed effects only model of the final Vision Loss model covariates using the 'validation' sample



10 Changes to the Vision Loss model in the prospective audit

Two of the covariates used in the development of the Vision Loss case complexity adjustment model are not used in the calculation of reported adjusted Vision Loss rates in the prospective national cataract audit, these are;

- the presence of high myopia
- the occurrence of PCR

The presence of high myopia was not used due to concerns raised by surgeons that the Vision Loss risk model suggested a protective effect against Vision Loss. This view is considered to be counter-intuitive by many ophthalmologists and as this result was based on small numbers, it is possible that the seemingly protective effect was an artefact of the rareness of the condition in the model sample. There are optical explanations for the protective effect of myopia, in that spectacles for myopes minify images, hence creating an artefactual poor visual acuity and explaining the superior acuity gained by contact lens use in myopes. In axial myopia there is some compensation for this minimisation as the retina is further away from the lens, hence there is relative magnification of the image at the retina. After cataract surgery, in which the refractive aim will usually be closer to emmetropia than pre-operatively, the magnification of images due to greater axial length remains, but the spectacle minimisation does not, hence myopes derive greater acuity gains from cataract surgery which could protect them from appearing as cases of visual loss in the audit. We therefore anticipate including high myopia in a future re-fitted Vision Loss model.

Adjustment for the occurrence of PCR in the Vision Loss model has not been made as doing so would artificially reduce the adverse visual acuity impact of this event on the Vision Loss outcome. A further stipulation on the Vision Loss risk adjusted results is a criterion for less

than 40% of eligible operations having missing visual acuity data and at least 50 eligible operations with visual acuity data.

The comparator value used for the case complexity adjustment of Vision Loss has been lowered from 1.5% used in the 'legacy' analysis and the first prospective year of the audit to 0.9%. This decision was made after looking at the rates of Vision Loss for the equivalent audit year periods from 2010 to 2017. The chosen value closely reflects the current average for the reference group, i.e. consultant surgeons. The Vision Loss definition has been changed to reduce the number of eyes with a poor preoperative visual acuity being designated as Vision Loss, and the time periods used for a valid visual acuity have been increased.

11 Audit reporting destinations

Reporting destinations

The prospective national cataract audit results are published in annual reports available on the RCOphth NOD website. Results for centres are supplied to the Care Quality Commission (CQC) and on the completion of an audit year; a data set is uploaded to data.gov and is accessed by the Getting It Right First Time Programme (GIRFT).

Annual reports – Centre adjusted Vision Loss results are provided for all operations performed in a centre including operations performed by trainee surgeons. A minimum of 50 eligible operations with visual acuity measurement data and less than 40% of eligible operations with missing visual acuity data are required for inclusion. Case mix adjusted graphs will display the 99.8% confidence interval, but not the 95% confidence interval.

For the CQC - Centre adjusted Vision Loss results are provided for all operations performed in a centre including operations performed by trainee surgeons. A minimum of 50 eligible operations with visual acuity measurement data and less than 40% of eligible operations with missing visual acuity measurement data are required for inclusion. The CQC will have the data for displaying both the 95% and 99.8% confidence intervals.

For the RCOphth NOD website (www.nodaudit.org.uk):

Behind the secure log-in - Centre and surgeon unadjusted and adjusted Vision Loss results are available behind a secure log-in for access by relevant staff in participating centres. Date searching functionality is available when the data covers a period longer than the official prospective audit period. Filtering results by surgeon grade and location of surgery are planned future website developments. The adjusted graphs display the 95% and 99.8% confidence intervals. The aim is for clinical staff from participating centres to be able to use these results for internal audits and revalidation.

Public facing – The RCOphth NOD website has a public facing section where centres and individual surgeons adjusted Vision Loss results for the audit period are available. All surgeons' data is included in the centres' results, while named surgeons results do not include trainee surgeons.

For data.gov – Once reporting of the data to all sources has been completed the audit data sets are uploaded to data.gov.

For GIRFT – Once the data sets have been uploaded to data.gov, the GIRFT programme are informed so that the GIRFT team can access the data for their use.