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1 What was known before

2 Large datasets on cataract outcomes are limited by incomplete collection of key primary
3 outcome indicators, which in turn may affect the quality of the data.

4 What this study adds

5 This study demonstrates that fully paperless ophthalmology units can be achieved in the
6 NHS and that these have the ability to produce comprehensive cataract surgery outcome
7 data.

8 The comprehensiveness of the data and the absence of selection bias mean that these data
9 can be used with confidence in benchmarking and audit.

10

11 Going paperless: Improved cataract surgery outcome data quality in
12 a new fully electronic unit

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31 work described.

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36 Abstract

37 Objectives: To report outcome data on the first 5,000 consecutive cataract cases at a new
38 paperless eye unit and benchmark against the Royal College of Ophthalmologists' National
39 Ophthalmology database (RCOphth NOD).

40 Methods: Using the in-built audit tool of the electronic medical records system, data from
41 all cataract operations performed between 1st April 2014 and 13th January 2017 were
42 compiled.

43 Results: 5,008 cases were recorded of which the overall intra-operative complication rate
44 was 2.4%, the most common being posterior capsular rupture – 1.14%. Follow-up data on
45 post-operative complications were recorded in 98.6% of cases. Pre-operative visual acuity
46 and post-operative visual acuity was measured in 98.0% of cases. 40.8% of eyes achieved a
47 visual acuity of 6/6 or better and 90.7% achieved 6/12 or better.

48 Conclusions: A dataset of over 5,000 consecutive cataract operations was obtained in this
49 eye department. The recording of pre-operative and post-operative visual acuity in 98% of
50 cases compare very favourably to the RCOphth NOD Audit Report 2017 where pre-operative
51 and post-operative visual acuity were recorded in only 57.1% of operations. Despite this
52 difference, the outcome measures from this unit and RCOphth NOD were very similar,
53 validating the results of the RCOphth NOD audit reports. Significantly, when applying the
54 RCOphth NOD audit criteria for measuring post operative visual acuity, approximately 15%
55 of cases were excluded from the dataset; reducing the completeness of the dataset.

56 Paperless ophthalmology units are feasible in today's NHS and can produce near complete
57 cataract datasets; this can ultimately lead to more comprehensive and reliable aggregate
58 cataract outcome data.

59

60 Introduction:

61 Cataract surgery is the most common surgical procedure in the UK, where 330,000 cataract
62 operations are performed per year in the English National Health Service (NHS) in the UK
63 (1). In recent years there has been increasing emphasis on publication of aggregate and

64 individual surgical outcome data in cataract surgery (2). Publication of surgical outcomes is
65 an important driver of quality improvement and helps patients to make informed decisions
66 about their care.

67 The primary dimensions of data quality have been defined as completeness, uniqueness,
68 timeliness, validity, accuracy and consistency (3). In many reports on cataract outcomes to
69 date there appears to be actual or potential data quality issues both in terms of the
70 accuracy (representativeness) of the data and the completeness of the dataset. Although
71 some databases have been able to capture a large number of operations, the results have
72 been limited by incomplete collection of key primary outcome indicators, which in turn may
73 affect the quality of the data. In addition, when outcome databases are dependent on input
74 of data that is separate from the clinical record there is selection bias and potential loss of
75 representativeness of the data.

76 The European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO)
77 reported outcomes on 523,921 cataract extractions but long-term follow-up data (7 to 60
78 days) were available in only 46% of cases (4). The Royal College of Ophthalmologists'
79 National Ophthalmology Database (RCOphth NOD) aims to provide robust evidence on
80 cataract surgery outcomes and in its first report has audited the outcomes of 75,827
81 cataract operations in 34 centres in England (2). However, the results drawn from this first
82 report indicate that data on pre-operative and post-operative visual acuity (VA) were
83 recorded in the database in only 52.7% of cases. In the second RCOphth NOD audit report
84 in 2017 this figure improved to 57.1% of cases (5). An estimate of the proportion of cataract
85 operations performed in each participating centre that was included in the RCOphth NOD
86 audit report ranged from 7.7% to 99.9% (overall 73%).

87 In the case of RCOphth NOD, the incompleteness of the dataset is due partly to the time-
88 based definition of post-operative visual acuity (only cases with an acuity measured at
89 between 2 weeks to 4 months post-surgery are included). A more important factor is the
90 fact that, although many ophthalmology units in the UK use electronic medical records
91 (EMR), very few use EMR *exclusively*. The ongoing partial use of paper records is the main
92 reason for data leaching from multicentre electronic datasets such as the RCOphth NOD
93 through the patients' cataract pathways. The NHS in England plans to be paperless by 2023

94 (6). In 2014 Moorfields Eye Hospital NHS Foundation Trust established a new paperless
95 ophthalmology unit at Croydon University Hospital. We present outcomes data on the first
96 5,008 consecutive cataract surgery cases performed at this new unit.

97 Our specific aims were:

- 98 1) To benchmark our cataract surgery results against the RCOphth NOD results using
99 the RCOphth NOD definition of post-operative visual acuity in order to assess the
100 representativeness of our data
- 101 2) To investigate whether including data from patients seen and discharged within 2
102 weeks of surgery made a material difference to the visual outcomes
- 103 3) To report outcomes on this more inclusive and almost complete dataset of 5,008
104 consecutive cases

105

106 Methods:

107 Moorfields Eye Centre at Croydon University Hospital uses a single electronic medical
108 records (EMR) system to record cataract encounters (Medisoft Ophthalmology, Medisoft
109 Limited, Leeds, UK).

110 All cataract operations were performed between 1st April 2014 and 13th January 2017. These
111 dates represent the opening date of the new eye unit and the date at which the 5,000th
112 cataract operation was performed.

113 All duplicate records and records not belonging to patients (eg test patients) were removed
114 by Medisoft technical staff. Thereafter, the in-built audit tool in the EMR was used to
115 acquire data. The search was conducted on the 12th Dec 2017.

116 Baseline data on demographics, pre-operative visual acuity (VA), ocular co-morbidities and
117 whether the surgery was on a first or second eye were collected. Outcome data on intra-
118 operative complications, post-operative complications, post-operative VA and deviation
119 from predicted post-operative refraction were collected. Pre-operative VA data was
120 defined as the better value of uncorrected distance visual acuity (UDVA) or corrected
121 distance visual acuity (CDVA). Post-operative 'best-measured' VA was defined as the best

122 CDVA measurement when present and the best measurement of UDVA or pinhole VA when
123 CDVA was absent. Post-operative VA data were acquired in two ways: first, using the
124 RCOphth NOD timescale of 2 weeks to 4 months post-surgery and second, using a more
125 inclusive timescale of 1 day to 6 months post-surgery.

126

127 Results:

128 5,008 cataract operations were recorded between 1st April 2014 and 13th January 2017 at
129 Moorfields Eye Centre at Croydon University Hospital. 2,902 (57.9%) were female and 2,106
130 (42.1%) were male and the mean age was 73.6 years. 41.2% of operations were performed
131 by consultants, 38.6% by career grade non-consultant surgeons, 15.5% by experienced
132 trainees and 4.7% by less experienced trainees.

133 The presence or absence of ocular co-pathology was documented in 100% of cases. 3,519
134 (70.3%) operations were in patients with no recorded ocular co-pathology and 1,489
135 (29.7%) were in patients with recorded ocular co-pathology.

136

137 *Intra-operative Complications*

138 The intra-operative complication rate was 2.4% (119 cases), the most common being
139 posterior capsular rupture (PCR) which occurred in 1.14% of cases (see Table 1). The
140 RCOphth NOD uses the definition of PCR to include PCR with and without vitreous loss *and*
141 zonular rupture with vitreous loss.

142

143 *Post-Operative Complications*

144 Follow-up data on post-operative complications were recorded in 4,938 (98.6%) of operated
145 eyes. The overall post-operative complication rate was 9.8%, the most common being post-
146 operative uveitis (129 cases, 2.6%) and cystoid macular oedema (99 cases, 2.0%) see Table
147 2.

148

149 *Visual Acuity*

150 The pre-operative VA was recorded in 4,927 (98.4%) out of 5,008 cases.

151 Overall, 4,906 eyes (98%) had documented VA before and after cataract surgery. Using the
152 RCOphth NOD time criteria of measuring post-operative VA between 2 weeks to 4 months
153 post-surgery, 4,156 (83%) eyes had documented visual acuity before and after cataract
154 surgery. 15% of cases were reviewed and discharged within 2 weeks of surgery.

155 Overall, 2,004 (40.8%) of patients achieved a post-operative VA of 6/6 or better and 4,449
156 (90.7%) achieved 6/12 or better after surgery (see Table 3). There was broad agreement in
157 visual outcomes between our comprehensive data, our data limited to RCOphth NOD time
158 criteria for post-operative acuity and the RCOphth NOD data (Table 4).

159

160 Discussion:

161 This single-centre study provides a high-quality dataset of over 5,000 consecutive cataract
162 operations from a new ophthalmology unit. The completeness of these data compares
163 favourably with previous reports using data from EMR in the UK, not least because this
164 dataset includes 100% of the cataract operations performed in our unit within these dates.
165 In the RCOphth NOD Audit Report 2017 no pre-operative VA data were recorded in 19.5% of
166 cases and no post-operative complication data were recorded in 64.4%. Pre-operative and
167 post-operative VA data were recorded in only 57.1% of cases (5). Incompleteness of visual
168 acuity data has been a historical problem in national datasets in the UK (1, 2, 7) and the
169 RCOphth NOD audit report 2017 acknowledges that *“completeness of pre-operative VA and
170 post-operative VA outcome remain variable and an area for improvement in many centres.”*
171 We anticipate that the increasing adoption of paperless EMR will bring about this
172 improvement. In the meantime, our (98% complete) data appear to validate the
173 benchmarks for visual acuity outcomes reported in the RCOphth NOD audit reports. One
174 way of improving the completeness of VA outcome would be to include data on all patients.
175 This would require a change in the time-based definition of post-operative visual acuity
176 defined by RCOphth NOD. We note an approximate 15% loss of post-operative VA data in
177 our cases when adhering to RCOphth NOD criteria for reporting post-operative VA. Our data

178 suggests that including data on all patients would not materially change the visual acuity
179 outcomes.

180 When analysing intra-operative complications, this study found a posterior capsule rupture
181 rate of 1.14%, which compares well with the 1.5% and 1.8% PCR rate from RCOphth NOD
182 2017 and 2016 respectively. Of note, our dataset is comprehensive and we have not
183 excluded cataract cases which RCOphth NOD defines as ineligible in its statistical analysis
184 plan. The overall rate of post-operative complication was 9.8% in this study with post-
185 operative uveitis and corneal oedema accounting for 4.2%. Although our rate of major
186 intra-operative complication (posterior capsule rupture) was lower than that recorded in
187 the RCOphth NOD, our rate of recorded post-operative less serious complications (9.8%)
188 was higher than the 5.8% reported in RCOphth NOD 2016 and lower than the 11.4%
189 reported in RCOphth NOD 2017. These differences between our results and those of the
190 RCOphth NOD and between successive RCOphth NOD reports raise an interesting issue
191 about the definition of complications and recording in electronic records. At the first post-
192 operative review, our electronic record forces documentation of the presence or absence of
193 the findings listed in Table 2. Corneal oedema and post-operative uveitis, for example, are
194 present in almost all patients at some point after cataract surgery and whether these are
195 recorded as a complication depends both on the timing of post-operative review and the
196 ability or inclination of the clinician reviewing the patient to distinguish between
197 complication and normal post-operative course. Many of our patients were reviewed at 1-2
198 weeks post-surgery rather than the usual 3 weeks and this may account for some of the
199 reported cases of corneal oedema and post-operative uveitis. Similarly, recorded rates of
200 cystoid macular oedema will depend on whether patients have post-operative optical
201 coherence tomography scans of the retina and whether cystoid macular oedema is defined
202 clinically or tomographically. In order to accurately benchmark rates of post-operative
203 complications, these complications need to be defined.

204 In some units in the UK patients are followed up by community opticians and not seen by
205 the operating unit post-operatively. This is a further reason for loss of electronic data
206 during the cataract pathway. Our centre invites all of our patients to attend for post-
207 operative review after cataract surgery and records data exclusively electronically. Hence
208 we have been able to record follow up in 98.6% of operations and record post-operative VA

209 in 98.0% of operations. This represents an almost complete dataset. We attribute the small
210 data loss to non-attendance for follow up, inability to record VA (learning
211 difficulties/cognitive impairment) and human error in neglecting or forgetting to enter data.
212 In some fields we have recorded 100% data completeness. This is usually because the EMR
213 forces the user to make an entry for this field. Forced choice data entry leads to high levels
214 of data completeness but not necessarily data accuracy. One of the forced choice data fields
215 in Medisoft Ophthalmology is the presence or absence of ocular co-pathology. An answer
216 was recorded in 100% of cases but, in our cohort, co-pathology was recorded as present in
217 just 29.7% of cases compared with 46.7% of cases in the RCOphth NOD audit report 2017.
218 Our cataract patient cohort is comprehensive containing both new referrals and patients
219 who already attend the clinic with other eye conditions so we were surprised to see the
220 relatively low level of recorded ocular co-pathology. One explanation for this is that our
221 cohort does in fact contain a lower proportion of patients with ocular co-pathology
222 compared to the RCOphth NOD audit. Another explanation is that we have not recorded the
223 presence of co-pathology accurately in our patients. This raises an important issue in
224 paperless systems: In order to enter data in mandatory fields faithfully, those data must be
225 easily accessible whilst the field is being filled. In our software it is difficult to access the past
226 ophthalmic history and findings whilst completing the operation note. This barrier may
227 explain the tendency for surgeons to tick the “no ocular co-pathology” mandatory field
228 when filling the operation note in order to maintain efficiency in the operating theatre.

229 The easy availability of high-quality fully-representative outcome data is just one benefit of
230 the move to paperless record-keeping. It provides real time feedback and the ability to
231 audit results rapidly and comprehensively and then instigate improvements. However data
232 will always be limited to accurate record keeping by the clinician regardless of how it is
233 recorded.

234 Our study represents one of the most comprehensive and complete datasets on cataract
235 surgery to be reported and appears to validate the outcome benchmarks reported by the
236 RCOphth NOD audit reports.

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238

239

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243

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266

Table 1. Intra-operative complications compared to RCOphth NOD 2017

Intra-operative complications	n (%)	RCOphth NOD 2017 %
No intra-operative complications	4889 (97.6)	96.7
One or more intra-operative complications	119 (2.4)	3.3
PCR*	57* (1.14)	1.5*
Corneal epithelial abrasion	13 (0.3)	0.3
Zonule dialysis	10 (0.2)	0.4
Endothelial damage/Descemet's tear	7 (0.1)	0.1
Phaco burn/wound problems	6 (0.1)	<0.1
Torn iris / damage from phaco	3 (0.1)	0.2
Hyphaema	2 (<0.1)	<0.1
IOL exchange	1 (<0.1)	0.1
Iris prolapsed	1 (<0.1)	<0.1
Operation cancelled	1 (<0.1)	-
Other IOL problem	1 (<0.1)	0.1
Other	25 (0.5)	0.4

*Posterior capsular rupture (PCR) figure includes zonule rupture with vitreous loss and lens fragment into vitreous

Table 2. Post-operative complications compared to RCOphth NOD 2017

Presence or absence of post-operative complications	Recorded in 4938 of eyes (98.6%) n (%)	RCOphth NOD 2017 for operations with recorded data (35.6%) %
No post-operative complications	4454 (90.2)	88.6
One or more post-operative complications	484 (9.8)	11.4
Post-operative uveitis	129 (2.6)	3.2
Cystoid macular oedema	99 (2.0)	2.7
Corneal oedema/striae/Descemet's folds	78 (1.6)	2.7
Raised IOP (>21mmHg)	60 (1.2)	1.6
Reduction in vision*	50 (1.0)	
Macular oedema	33 (0.7)	0.0
Corneal decompensation	17 (0.3)	0.2
Unexpected refractive outcome	14 (0.3)	0.2
Vitreous in AC	9 (0.2)	0.3
Leaking wound (Seidel +ve)	7 (0.1)	<0.1
Hypotony<5	6 (0.1)	<0.1
Retained soft lens matter	6 (0.1)	0.4
IOL decentred	5 (0.1)	0.2

Iris to wound	5 (0.1)	<0.1
Vitreous to the section	4 (0.1)	0.1
Choroidal effusion/haemorrhage	3 (0.1)	<0.1
Retinal tear	3 (0.1)	<0.1
Posterior capsule opacification – YAG indicated	3 (0.1)	0.1
Corneal epithelial defect	2 (<0.1)	<0.1
Endophthalmitis	2 (<0.1)	<0.1
Hyphaema	2 (<0.1)	<0.1
Post-operative eyelid oedema	2 (<0.1)	<0.1
Anterior capsulophimosi	1 (<0.1)	<0.1
Diplopia	1 (<0.1)	<0.1
Iris prolapse	1 (<0.1)	<0.1
Post-operative ptosis	1 (<0.1)	<0.1
Posterior capsule opacification	1 (<0.1)	0.3
Progression of diabetic retinopathy	1 (<0.1)	<0.1
Retinal detachment	1 (<0.1)	<0.1
Vitreous haemorrhage	1 (<0.1)	<0.1
Other	69 (1.4)	1.3

*Note reduction of vision was reported by the clinician using EMR and is not the same as the RCOphth NOD definition of doubling of the visual angle or worse. We report a 1.26% rate of reduction in vision according to the RCOphth NOD criteria.

Table 3. Post-operative visual acuity (VA) by pre-operative VA, intra-operative complications and posterior capsular rupture (PCR) for cases where pre-operative and post-operative VA are recorded

		Post-operative Snellen visual acuity		
Percentages (N)		≤ 6/6	≤6/12	≤6/24
All eyes (4906)		40.8 (2004)	90.7 (4449)	96.8 (4750)
Presenting Snellen VA				
≤ 6/6	2.8% (137)	70.8 (97)	99.3 (136)	100 (137)
≤6/12	36.2% (1778)	49.7 (883)	98.0 (1743)	99.8 (1774)
≤6/24	67.6% (3316)	43.0 (1425)	94.5 (3134)	99.1 (3287)
Intra-operative complications				
No	97.6% (4789)	41.2 (1972)	90.9 (4354)	96.9 (4642)
Yes	2.38% (117)	27.4 (32)	81.2 (95)	92.3 (108)
PCR (RCOphth NOD definition)				
No	98.9% (4850)	41.0 (1989)	90.8 (4405)	96.9 (4702)
Yes	1.14% (56)	26.8 (15)	78.6 (44)	85.7 (48)

Table 4. Post-operative visual acuity in different post-operative time brackets and compared with RCOphth NOD benchmarks from 2017.

	Cases with visual acuity measurement within 14 days to 4 months post-operative	Cases with visual acuity measurement within 1 day to 6 months post-operative	RCOphth NOD Benchmarks (using 14 days to 4 months)
Percentage of eyes with pre- and post-operative data in our cohort	83%	98%	
≤6/6	39.1%	40.8%	39%
≤6/12	89.9%	90.7%	88.6%
≤6/24	96.5%	96.8%	95.9%