Original Investigation

The Royal College of Ophthalmologists' National Ophthalmology Database Study of Vitreoretinal Surgery
Report 6, Diabetic Vitrectomy

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IMPORTANCE Patients and clinicians need to accurately assess the risks and benefits of pars plana vitrectomy for proliferative diabetic retinopathy, but clinical trial data may not reflect real-world experience.

OBJECTIVE To prospectively audit the complications of vitrectomy for proliferative diabetic retinopathy and help establish benchmarks.

DESIGN, SETTING, AND PARTICIPANTS Royal College of Ophthalmologists' National Ophthalmology Database study of 939 eyes of 834 patients undergoing primary vitrectomy for proliferative diabetic retinopathy at 16 different vitreoretinal units in the United Kingdom. Data were obtained for the period from January 2001 to November 2010.

INTERVENTIONS Pars plana vitrectomy with or without delamination/segmentation.

MAIN OUTCOMES AND MEASURES Descriptions of the primary procedures performed, intraoperative complication rate, and proportion of eyes undergoing further surgery. An exploratory analysis of visual outcome was undertaken, with visual success and visual loss defined as a gain or reduction of 0.3 logMAR or more, respectively (approximately 2 Snellen lines), 6 to 12 months after surgery.

RESULTS Of 420 eyes (among 408 patients) that underwent vitrectomy without delamination, the intraoperative complication rate was 13.1% (95% CI, 10.2%-16.7% [55 of 420 eyes]), with 126 eyes (30.0%) requiring an intravitreal tamponade and 49 eyes (11.7%) undergoing further vitrectomy (median follow-up, 6.9 months); 17.9% of 127 phakic eyes developed cataracts within a year, with 63.6% achieving visual success and 8.2% visual loss. Of 519 eyes (among 463 patients) that underwent vitrectomy with delamination, the intraoperative complication rate was 30.4% (95% CI, 26.6%-34.5% [158 of 519 eyes]), with 299 eyes (57.6%) requiring an intravitreal tamponade and 78 eyes (15.0%) undergoing further vitrectomy (median follow-up, 7.1 months); 21.2% of 126 phakic eyes developed cataracts within a year, with 62.8% achieving visual success and 14.9% visual loss.

CONCLUSIONS AND RELEVANCE Diabetic vitrectomy has an appreciable complication rate, particularly if delamination or segmentation are required. Nonetheless, the data available on visual acuity suggest that a majority of patients achieve clinically meaningful gains in vision.

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Invited Commentary

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Proliferative diabetic retinopathy can lead to vitreous hemorrhage and, in severe cases, tractional retinal detachment. Not all patients need surgery, but persisting vitreous hemorrhage or tractional retinal detachment involving or threatening the macula are 2 of the most common indications for pars plana vitrectomy (PPV).[1] For vitreous hemorrhage, PPV primarily aims to clear the visual axis by removing blood-stained vitreous. For tractional retinal detachment, PPV is combined with delamination or segmentation of the preretinal fibrovascular membranes, to relieve retinal traction.

Using the Royal College of Ophthalmologists' National Ophthalmology Database (RCOphth NOD), we aim to describe diabetic PPV techniques and surgical complication rates to allow benchmarking. The RCOphth NOD collects anonymized, pragmatic surgical audit data from hospitals across the United Kingdom, with the aim of providing benchmark surgical outcomes for both surgeons and patients.[1-6]

At a Glance

- The United Kingdom's National Ophthalmology Database prospectively collects pragmatic "real-world" surgical data, including 11 618 vitreoretinal surgical procedures.
- This report details the subset of 420 eyes undergoing diabetic vitrectomy and 519 eyes undergoing diabetic vitrectomy with delamination or segmentation.
- The intraoperative complication rate for diabetic vitrectomy without delamination was 13.1%, with 11.7% of eyes requiring further vitrectomy, and 70 of 110 eyes (63.6%) gaining 2 Snellen lines.
- The intraoperative complication rate for diabetic vitrectomy with delamination was 30.4%, with 15.0% eyes requiring further vitrectomy, and 59 of 94 eyes (62.8%) gaining 2 Snellen lines.
- Diabetic vitrectomy has an appreciable complication rate, but despite this, a majority of patients gain vision.

Methods

Data Extraction

Our database study relates to primary vitrectomies for diabetic vitreous hemorrhage or tractional retinal detachment that were performed during the period from January 2001 to November 2010, using data supplied to the RCOphth NOD, as reported previously.[1,2,4,5] Data were extracted from 13 vitreoretinal units using the same electronic medical record (EMR) system (Medisoft Ophthalmology; Medisoft Limited) up to November 2010, and from 3 vitreoretinal units using a noncommercial database (VITREOR database; Guy's and St Thomas' NHS Foundation Trust) up to October 2013. Data analysis started in November 2013, but the majority of the analysis was conducted in 2014, with additional analysis conducted in 2015. Our study was conducted in accordance with the Declaration of Helsinki and the United Kingdom's Data Protection Act. The lead clinician and Caldicott Guardian (who oversees data protection) at each hospital gave written approval to extract the data. Anonymized database analyses of this type do not require ethical permission because they are viewed as audit or service evaluation.[7] Eyes were divided into those undergoing PPV with or without delamination/segmentation of fibrovascular membranes.

Complications of Pars Plana Vitrectomy

The EMRs required surgeons to record whether or not there were any surgical complications, before they could save the operation note. If a complication occurred, then the surgeon had to select from a prepopulated list of well-recognized complications specific to that operation or select "other" and record the complication using free text. All the hospitals using the commercial EMR for vitreoretinal surgical procedures recorded cataract surgery using the same system, while the centers that used the noncommercial database had a tendency for postvitrectomy cataract operations to be performed in other units, so it was not possible to accurately determine the postvitrectomy cataract rate for these patients. Therefore, only the commercial EMR data were used to estimate the incidence of postvitrectomy cataract surgery.

Statistical Analysis

The operations were grouped into diabetic vitrectomy with or without delamination. Although our study primarily aimed to provide benchmark complication rates (using mandated data collection during surgery), some centers also used the EMR to record postoperative visual acuity (VA), and an exploratory VA analysis was undertaken using the logMAR scale, where count fingers (CF), hand motions (HM), light perception (LP), and no LP (NLP) were assigned values of 2.1, 2.4, 2.7, and 3.0, respectively.[1,4,5] Visual acuity values less than 6 weeks after primary PPV were excluded. The main VA result was considered as the best-recorded VA between 6 and 12 months after surgery, with data also displayed graphically for the best-recorded VA within 1 to 4 weeks, 1 to 3 months, and 3 to 6 months after surgery. Visual success at 6 to 12 months was defined as a gain of 0.3 logMAR or more (approximately 2 Snellen lines), and visual loss was defined as a loss of 0.30 logMAR or more.

The time to postvitrectomy cataract surgery was modeled using the Kaplan-Meier[8] method, in which the failure event was cataract surgery. Eyes were censored at the last date on which follow-up data of any type were recorded in the EMR, if the patients had not had cataract surgery. Eyes with less than 3 months of follow-up, with lens touch during vitrectomy, or requiring a further vitrectomy were excluded. Potential differences between the 2 treatment groups in terms of the equality of survival functions for postvitrectomy cataract surgery, the presence of operative complications, and visual success and loss were compared using the log-rank test or the Fisher exact test when appropriate. For each treatment group, postvitrectomy cataract surgery was investigated by the use of gas with primary vitrectomy and age at primary vitrectomy using the log-rank test or the *t* test with the Wald approximation when appropriate. The Pearson χ^2 test and the *t* test were used when appropriate to compare the sex, ethnicity, and age at vitrectomy between patients with and patients without recorded VA data, and to compare the presenting VA between patients with and patients without eligible postoperative VA data. The *P* value

Table 1. Patient Demographics

Characteristic	Pars Plana Vitrectomy		Total
	Without Delamination	With Delamination	
Eyes, No.	420	519	939
Operation, No. (%) of eyes			
First	393 (93.6)	441 (85.0)	834 (88.8)
Second	27 (6.4)	78 (15.0)	105 (11.2)
First operation, No. of patients	393	441	834
Sex, No. (%) of patients			
Male	226 (57.5)	250 (56.7)	476 (57.1)
Female	167 (42.5)	191 (43.3)	358 (42.9)
Ethnicity, No. (%) of patients			
White	222 (56.5)	176 (39.9)	398 (47.7)
Asian	10 (2.5)	10 (2.3)	20 (2.4)
African-Caribbean	9 (2.3)	38 (8.6)	47 (5.6)
Other	1 (0.3)	7 (1.6)	8 (1.0)
Not recorded	151 (38.4)	210 (47.6)	361 (43.3)
Age, y, median (IQR)	63.8 (52.2-72.9)	54.4 (42.4-64.2)	58.2 (46.2-69.2)
Diabetes mellitus, No. (%) of patients			
Type 1	99 (25.2)	138 (31.3)	237 (28.4)
Type 2	185 (47.1)	220 (49.9)	405 (48.6)
Not recorded	109 (27.7)	83 (18.8)	192 (23.0)

Abbreviation: IQR, interquartile range.

threshold used for statistical significance was .05. All analyses were conducted using Stata, version 11 (StataCorp), except for 95% CIs, which were calculated using Confidence Interval Analysis.[9]

Results

Patient Demographics

There were 15 667 vitreoretinal surgical procedures recorded in the RCOphth NOD over the study period. Of these, 939 (6.0%) were primary PPVs for diabetes (939 eyes, 834 patients, and 64 surgeons). Of these 939 PPVs, 482 (51.3%) were for the left eye and 457 (48.7%) were for the right eye; 420 (44.7%) vitreoretinal surgical procedures were diabetic vitrectomies without delamination, and 519 (55.3%) were diabetic vitrectomies with delamination (**Table 1**). In total, 105 patients had surgery performed on both their eyes, 68 of whom had both eyes in the same surgical treatment group.

Surgical Technique and Anesthesia

Of the 420 diabetic vitrectomies without delamination (among 408 patients), 76 (18.1%) were PPVs only, 344 (81.9%) were PPVs that included intraoperative laser surgery, 126 (30.0%) were PPVs that included an intravitreal tamponade (33 with sulfur hexafluoride, 9 with hexafluoroethane, 16 with octafluoropropane, 54 with air, and 14 with silicone oil), and 99 (23.6%) were PPVs combined with cataract surgery. General anesthesia was used for 150 diabetic vitrectomies (35.7%), and local anesthesia was used for 268 diabetic vitrectomies (63.8%) (3 with sedation); for 2 diabetic vitrectomies (0.5%), anesthesia was not recorded.

Of the 510 diabetic vitrectomies with delamination (among 463 patients), 42 (8.1%) were PPVs only, 477 (91.9%) were PPVs that required intraoperative laser surgery, 299 (57.6%) were PPVs that required an intravitreal tamponade (98 with sulfur hexafluoride, 25 with hexafluoroethane, 66 with octafluoropropane, 53 with air, and 57 with silicone oil), and 105 (20.2%) were PPVs combined with cataract surgery. General anesthesia was used for 333 diabetic vitrectomies with delamination (64.2%), and local anesthesia was used for 183 diabetic vitrectomies with delamination (35.3%) (4 with sedation); for 3 diabetic vitrectomies with delamination (0.6%), anesthesia was not recorded.

Intraoperative Complications

Of the 939 PPVs, 726 (77.3%) were recorded as having no intraoperative complication. The overall operative complication rate was 22.7% (95% CI, 20.1%-25.5% [213 of 939 PPVs]). The 2 most commonly reported complications were iatrogenic tear (213 PPVs [19.4%]) and lens touch (13 PPVs [1.4%]) (**Table 2**).

The overall complication rates were 13.1% (95% CI, 10.2%-16.7% [55 of 420 PPVs]) for the diabetic vitrectomies without delamination and 30.4% (95% CI, 26.6%-34.5% [158 of 519 PPVs]) for the diabetic vitrectomies with delamination, which were more likely to have an intraoperative complication (odds ratio, 2.9 [95% CI, 2.1-4.1]; $P < .001$), mainly owing to having more iatrogenic tears (144 of 519 PPVs [27.7%] vs 38 of 420 PPVs [9.0%]; $P < .001$); otherwise, the individually reported complications were not significantly different (Table 2).

Excluding the complications associated with cataract surgery, we found that the overall complication rate attributable to PPV was 21.7% (95% CI, 19.2%-24.5% [204 of 939 PPVs]).

Table 2. Intraoperative Complications

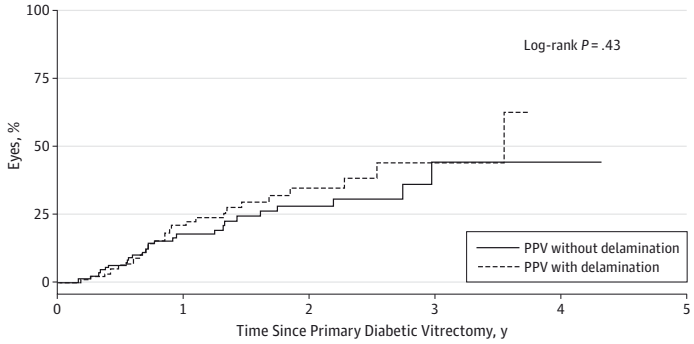
Complication Status	Pars Plana Vitrectomy		Total (N = 939)	*P* Value[a]
	Without Delamination (n = 420)	With Delamination (n = 519)		
Operations, No.				
With no reported complications	365 (86.9)	361 (69.6)	726 (77.3)	<.001
With reported complications	55 (13.1)	158 (30.4)	213 (22.7)	
Reported complications, No. of operations				
Iatrogenic tear	38 (9.0)	144 (27.7)	182 (19.4)	<.001
Lens touch	9 (2.1)	4 (0.8)	13 (1.4)	.09
Posterior capsule rupture (no vitreous loss)[b]	6 (1.4)	3 (0.6)	9 (1.0)	.31
Conjunctival buttonhole	2 (0.5)	1 (0.2)	3 (0.3)	.59
Retinal hemorrhage	0 (0.0)	3 (0.6)	3 (0.3)	.26
Choroidal/suprachoroidal hemorrhage	2 (0.5)	0 (0.0)	2 (0.2)	.20
Corneal epithelial abrasion	2 (0.5)	0 (0.0)	2 (0.2)	.20
Subretinal hemorrhage	0 (0.0)	1 (0.2)	1 (0.1)	>.99
Nuclear/epinuclear fragments into vitreous[b]	1 (0.2)	0 (0.0)	1 (0.1)	.45
Subretinal heavy liquid	0 (0.0)	1 (0.2)	1 (0.1)	>.99
Other	0 (0.0)	3 (0.6)	3 (0.3)	.26
Total No.[c]	61	160	221	

[a] Derived from the Fisher exact test comparing the rate of a specific complication between the 2 treatment groups.

[b] Lens-related complications occurring in eyes with combined cataract surgery.

[c] More than 1 intraoperative complication could be reported for each operation, and therefore the sum of the individual complication percentages exceeds the percentage of operations with a complication.

Figure 1. Rates of Postvitrectomy Cataract Surgery



No. at risk					
PPV without delamination	127	66	32	7	2
PPV with delamination	126	58	22	5	0

Kaplan-Meier curves of postvitrectomy cataract surgery, with cataract surgery modeled as the failure event. PPV indicates pars plana vitrectomy.

The complication rate (excluding cataract-related complications) was 11.7% (95% CI, 8.9%-15.1%) for diabetic vitrectomies without delamination (49 of 420 PPVs) and 29.9% (95% CI, 26.1%-33.9%) for diabetic vitrectomies with delamination (155 of 519 PPVs) (odds ratio, 3.2 [95% CI, 2.2-4.6]; $P < .001$).

Further PPV

At least 1 further PPV was performed on 127 of 939 eyes (13.5%) (95% CI, 11.5%-15.9%) after a median of 2.8 months (interquartile range, 2 days to 7.1 years) after primary surgery, comprising 49 of 420 eyes (11.7%) that underwent PPV without delamination and 78 of 519 eyes (15.0%) that underwent PPV with delamination ($P = .08$). Retinal detachment occurred in 19 of 939 eyes (2.0%) (95% CI, 1.3%-3.1%) after a median of 2.7 months (interquartile range, 25 days to 1.1 years), including 7 of 420 eyes (1.7%) after PPV without delamination and 12 of 519 eyes (2.3%) after PPV with delamination ($P = .32$).

Postvitrectomy Cataract Surgery

Of the 939 eyes, 686 were excluded from the postvitrectomy cataract surgery analysis: 238 because they were not recorded in the commercial EMR, 66 because of previous cataract surgery, 149 because they had combined cataract surgery, 5 because of lens touch, 48 because they underwent a further PPV, and 180 because they had less than 3 months of follow-up. Of the remaining 253 eyes eligible for analysis, the median follow-up was 1.2 years (interquartile range, 3 months to 4.3 years), and 58 (22.9%) were subsequently recorded as having cataract surgery (28 after PPV without delamination and 30 after PPV with delamination). The 1-, 2-, and 3-year postvitrectomy cataract surgery rates were 17.9%, 28.0%, and 44.1%, respectively, for 127 eyes that underwent PPV without delamination and 21.2%, 34.6%, and 43.9%, respectively, for 126 eyes that underwent PPV with delamination ($P = .43$) (**Figure 1**).

For both groups of patients, those who underwent postvitrectomy cataract surgery were older than those who did not; the mean ages at vitrectomy were 67.1 vs 59.5 years, respectively (P = .002), for the patients who underwent PPV without delamination and 60.3 vs 47.8 years, respectively (P < .001), for the patients who underwent PPV with delamination. The use of gas during diabetic vitrectomy without delamination did not have a significant effect on subsequent cataract surgery; 26 of 113 gas-filled eyes (23.0%) and 2 of 14 eyes without gas (14.3%) underwent cataract surgery (P = .64). For the patients who underwent PPV with delamination, a higher proportion of eyes that had gas subsequently underwent cataract surgery: 14 of 34 eyes that had gas (41.2%) vs 16 of 92 eyes that did not have gas (17.4%) (P = .047).

Visual Acuity

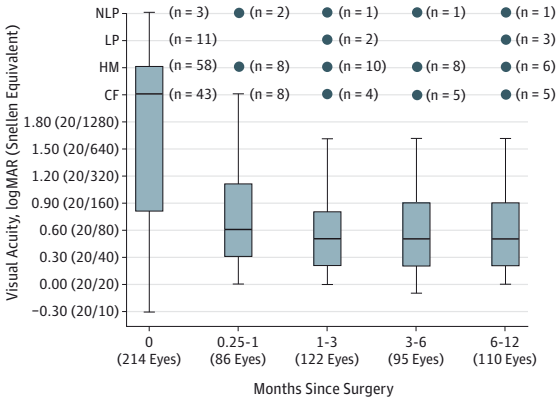
Of the 939 eyes, 730 (77.7%) had a presenting VA recorded in the EMR. Of these 730 eyes, the median and mean VAs were CF and 1.55 logMAR (Snellen equivalent of 20/693), respectively (interquartile range, −0.30 logMAR to NLP), which included 157 eyes with a VA of CF (21.5%), 182 eyes with a VA of HM (24.9%), 34 eyes with a VA of LP (4.7%), and 4 eyes with a VA of NLP (0.5%). The logMAR VA (and Snellen equivalent) was 0.30 (20/40) or better for 71 eyes (9.7%) and 1.00 (20/200) or worse for 499 eyes (68.4%). Of the 730 eyes with a presenting VA in the EMR, 204 were excluded from postoperative VA analysis (53 had no further VA data, and 151 had <6 weeks of follow-up). Of 526 eyes eligible for postoperative VA analysis, the median and mean presenting logMAR VAs (and Snellen equivalents) were CF and 1.54 (20/693), respectively. Of these 526 eyes, 204 had VA outcomes at 6 to 12 months after surgery with a median and mean VA of 0.50 and 0.76 logMAR, respectively (with Snellen equivalents of 20/63 and 20/115, respectively). The logMAR VA (Snellen equivalent) was 0.30 (20/40) or better for 88 of 204 eyes (43.1%) and 1.00 (20/200) or worse for 52 of 204 eyes (25.5%).

Of the 420 eyes that underwent PPV without delamination, 323 (76.9%) had a presenting VA. The median and mean VAs were CF and 1.64 logMAR (Snellen equivalent of 20/873), respectively (interquartile range, −0.30 logMAR to NLP). Of 214 eyes eligible for postoperative VA analysis, the median presenting VA was CF, and the mean VA was 1.58 logMAR (Snellen equivalent of 20/760). Of these 214 eyes, 110 had a median and mean VA of 0.50 and 0.74 logMAR, respectively (with Snellen equivalents of 20/63 and 20/110, respectively) 6 to 12 months after surgery (**Figure 2**). The logMAR VA (Snellen equivalent) was 0.30 (20/40) or better for 50 of 110 eyes (45.5%) and 1.00 (20/200) or worse for 27 of 110 eyes (24.5%).

Of the 519 eyes that underwent PPV with delamination, 407 (78.4%) had a presenting VA recorded in the EMR; the median and mean VAs were 1.60 and 1.49 logMAR, respectively (Snellen equivalents of 20/796 and 20/618, respectively) (interquartile range, 0.00 to LP). Of 312 eyes eligible for postoperative VA analysis, the median and mean presenting VAs were 1.60 and 1.52 logMAR, respectively (Snellen equivalents of 20/796 and 20/662, respectively). At 6 to 12 months after surgery, the median and mean VAs were 0.5 and 0.78 logMAR, respectively (Snellen equivalents of 20/63 and 20/120, respectively) for 94 eyes (**Figure 3**). The logMAR VA (Snellen equivalent) was 0.30 (20/40) or better for 38 of 94 eyes (40.4%) and 1.00 (20/200) or worse for 25 of 94 eyes (26.6%).

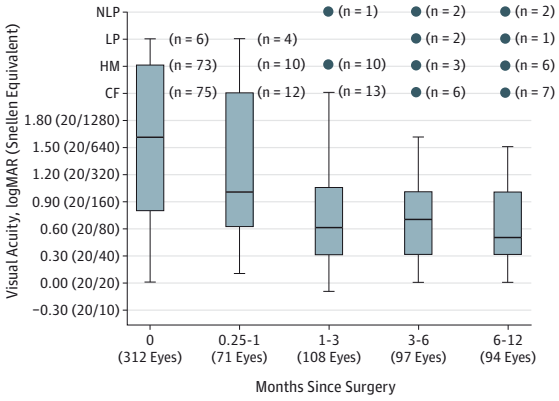
At 6 to 12 months after surgery, visual success (≥0.30 logMAR gain) was achieved by 129 of the 204 eyes (63.2% [95%

Figure 2. Visual Acuity in Eyes That Underwent Pars Plana Vitrectomy Without Delamination



Box plots of logMAR visual acuity before and after surgery. The horizontal line in the middle of each box indicates the median, while the top and bottom borders of the box mark the 75th and 25th percentiles, respectively. The whiskers above and below the box mark the 90th and 10th percentiles, respectively. The numbers in parentheses refer to the numbers of eyes with visual acuity at the level shown on the y-axis, for that time period (shown on the x-axis). The points beyond the whiskers are outliers beyond the 90th percentile. CF indicates counting fingers; HM, hand motions; LP, light perception; and NLP, no light perception.

Figure 3. Visual Acuity in Eyes That Underwent Pars Plana Vitrectomy With Delamination



Box plots of logMAR visual acuity before and after surgery. The horizontal line in the middle of each box indicates the median, while the top and bottom borders of the box mark the 75th and 25th percentiles, respectively. The whiskers above and below the box mark the 90th and 10th percentiles, respectively. The points beyond the whiskers are outliers beyond the 90th percentile. The numbers in parentheses refer to the numbers of eyes with visual acuity at the level shown on the y-axis, for that time period (shown on the x-axis). CF indicates counting fingers; HM, hand motions; LP, light perception; and NLP, no light perception.

CI, 56.4%-69.6%]) eligible for postoperative VA analysis, and visual loss (≥0.30 logMAR) occurred in 23 of the 204 eyes (11.3% [95% CI, 7.6%-16.3%]). Of 110 eyes that underwent PPV without delamination, visual success was achieved by 70 eyes (63.6% [95% CI, 54.3%-72.0%]), and visual loss occurred in 9 eyes (8.2% [95% CI, 4.4%-14.8%]). Of 94 eyes that underwent PPV with delamination, visual success was achieved by 59 eyes (62.8% [95% CI, 52.7%-71.9%]), and visual loss occurred in 14 eyes (14.9% [95% CI, 9.1%-23.5%]).

There was no difference in the proportion of eyes with visual success (P = .90) or visual loss (P = .13) between the eyes that underwent PPV with delamination and the eyes that underwent PPV without delamination. The occurrence of intraoperative complications or further PPV did not influence visual outcome, except for eyes that underwent PPV with delamination undergoing further PPV, which had a greater risk of 0.3 logMAR (approximately 2 Snellen lines) or more visual loss (6 of 14 eyes [42.9%] vs 8 of 80 eyes [10.0%]; P = .001).

Using the last recorded VA (from 6 to 12 months) rather than best-recorded VA (6-12 months) produced no change in the median VA. The mean logMAR VA (Snellen equivalent) changed relatively little, from 0.74 to 0.81 (20/110 to 20/130) in the eyes that underwent PPV without delamination and from 0.78 to 0.83 (20/121 to 20/135) in the eyes that underwent PPV with delamination.

To assess the risk of bias in the VA data set (because it was incomplete), we compared the demographics of the patients with VA data recorded in the EMR with the demographics of the patients without VA data recorded in the EMR and found no difference in sex, ethnicity, or age at time of surgery. There was no difference in the mean presenting VA between eyes with (1.54 logMAR [Snellen equivalent of 20/800]) and eyes without eligible postoperative VA (1.58 logMAR [Snellen equivalent of 20/800]) (P = .57).

Discussion

Our database study reviewed a large number of PPVs undertaken for diabetic eye disease. The majority of eyes had a measurable improvement in vision, but the complication rate was appreciable, particularly in the eyes that underwent PPV with delamination.

With expanding digital data collection, database studies and national audits are increasingly being used to document clinical outcomes in a real-world environment.[10] They provide a new type of clinical data, and the method and interpretation are very different from those of clinical trials. For example, the analysis is limited to whatever data are collected, with the expectation that data sets are sometimes incomplete. However, they facilitate the collection of large data sets, and because the patients are not within the confines of a clinical trial, the results may be more generalizable. By contrast, interventional clinical trials typically involve novel interventions, mandated treatment regimens, and external monitoring of outcomes, and they often occur in select university hospitals.

Our database study differs from many in that it was set up to prospectively collect audit data rather than retrospectively analyze data that were already collected. The RCOphth NOD's predefined aim was to establish national benchmarks that can be used by clinicians for local audit, in the expectation that this will enable patients and physicians to identify issues of concern and drive quality improvement. Clinicians provided prospective data anonymously to facilitate pooled analysis. In many UK specialties, NHS clinician-level outcome data are released into the public domain, but results need to be measured against national standards, and large database studies may be better suited to setting "real-world" service benchmarks than "idealized" clinical trials.

The complication rate in the eyes that underwent PPV with delamination was approximately 3 times higher than the complication rate in eyes that underwent PPV without delamination, with almost 1 in 3 operations associated with a complication. This was mainly related to retinal tears. This was reflected in the use of postoperative tamponade; overall, 43% of eyes had some sort of tamponade, with a greater use of long-acting gases and silicone oil in the eyes that underwent PPV with delamination. Silicone oil was used in approximately 6% of cases, similar to some studies[11,12] but lower than the 23% rate reported by Ostri et al.[13] Despite the higher tear rate in the delamination group, the postoperative retinal detachment rate was acceptable (2% in both groups), consistent with previous series (eTable in the Supplement).[11-13]

Our VA analysis should be considered exploratory because, unlike the surgical complication data, VA data collection was not mandated, and not all hospitals used EMRs to record postoperative VA. Overall, 63% of eyes improved by at least 0.3 logMAR (approximately 2 Snellen lines) after surgery, with little difference between the eyes that underwent PPV with delamination and the eyes that underwent PPV without delamination. The magnitude of visual improvement is relatively similar to that reported in the literature (eTable in the Supplement).[11-13]

The strengths of our study include its large size, multicenter data collection, and prospective design. Database studies may be less subject to selection or publication bias than case series. The EMRs forced clinicians to record whether or not a complication occurred and this, combined with anonymized data collection, may facilitate the recording of surgical complications. Complication data were therefore 100% complete, in that all operation records noted whether a complication did or did not occur; however, some clinicians may have elected not to record all complications. The data on the surgical elements are likely to be relatively complete, but it is possible that some clinicians failed to enter all procedure elements. Another limitation of our study is that the exploratory VA data had much lower levels of completeness. Most database studies do not include VA data because VA is not usually linked to reimbursement, so in this respect our study is better than many; however, incomplete VA data collection raises the prospect of bias, and the results need to be interpreted accordingly.

To look for bias, we compared the baseline demographics and VAs in eyes of patients with VA outcome data with the baseline demographics and VAs in eyes of patients without VA outcome data, and none was suggested, but this does not eliminate the possibility of bias. We suspect that data collection reflects variations in the use of the EMR systems among hospitals, with some using EMRs for both the clinic and the op-

erating room, and others using EMRs just in the operating room and relying on paper notes in the clinic. Future database studies might consider the collection of core, mandated data sets, including VA outcomes, from consecutive patients. Our results may not be generalizable to other countries, but the method that we used may serve as a useful template.

Conclusions

In conclusion, the VA data need to be interpreted with caution, but they suggest that, despite an appreciable complication rate, most patients benefit from diabetic vitrectomy.

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Study concept and design: Jackson, Johnston, Donachie, Williamson, Sparrow.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Jackson, Donachie, Steel.
Critical revision of the manuscript for important intellectual content: All authors.
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