

1 Risk of complications of vitrectomy for floaters, based on  
2 presence or absence of posterior vitreous detachment.

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18

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- 20 1. R Rahman: Conception and design of study, acquisition and analysis of data,  
21 revising article critically and approval of the version to be published.  
22 2. J Gormley: Preparation of manuscript.  
23 3. J Stephenson: Statistical analysis of the data, revising the article and final approval  
24 of published version.

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## 29 Abstract

30 **Purpose:** To ascertain whether vitreous status (attached versus detached) affects the risk of  
31 intraoperative retinal breaks and number of operations in patients undergoing vitrectomy for  
32 floaters.

33 **Methods:** Consecutive, comparative single-surgeon case series. All patients undergoing  
34 vitrectomy for visually disabling floaters between July 2003 and June 2016 were included in  
35 this study. Data was collected prospectively into a vitreo-retinal database and reviewed  
36 retrospectively for the purpose of the study. The following data was collected on each patient:  
37 Age in years, sex, axial length (mm), presence of myopia, pre and post-operative visual acuity  
38 in LogMAR. The status of the posterior hyaloid face was ascertained using preoperative clinical  
39 and OCT assessment which was confirmed intraoperatively. The primary outcome measure  
40 was considered to be the presence or absence of a retinal tear. Significant visual loss  
41 (Reduction in  $\geq$  log units visual acuity), number of operations and time from surgery to  
42 discharge were considered to be secondary outcomes. Sequential multiple logistic and Cox  
43 regression analyses were conducted.

44 **Results:** Data was collected on 97 patients (55 males, 42 females). Indications for surgery  
45 were Fuchs heterochromic cyclitis (9 patients); asteroid hyalosis (12 patients); vitreous  
46 syneresis (76 patients). 21 patients were pseudophakic on presentation, while 76 underwent  
47 combined phacovitrectomy. Vitreous status was significantly associated with retinal  
48 tears/breaks ( $p=0.010$ ). Controlling for other parameters, the odds of a retinal break in  
49 patients with vitreous attached were about 5.5 times those in patients with vitreous detached  
50 (95% confidence interval [CI] 1.52 to 20.4). Number of operations was also significantly  
51 associated with this outcome ( $p=0.027$ ); the odds of a retinal tear increase by 6.28 times  
52 (95% CI 1.23 to 32.1).

53 A substantive difference in the proportion of patients with retinal breaks was observed  
54 between the two groups, with a 50% prevalence rate in the attached group and a 90.91%  
55 prevalence rate in the detached group. **(to change this line):**

56 Controlling for other parameters, the odds of a retinal tear or break in patients with vitreous  
57 attached were about 5.5 times those in patients with vitreous detached (95% confidence  
58 interval [CI] 1.52 to 20.4). Number of operations was also significantly associated with this  
59 outcome ( $p=0.027$ ); the odds of a retinal break increase by 6.28 times (95% CI 1.23 to 32.1).

60 Vitreous status was not associated with either secondary outcome measure. Number of  
61 operations was also significantly associated with improvement in visual acuity ( $p=0.017$ ; odds  
62 ratio 15.8 [95% CI 1.65 to 151]) in a multiple logistic regression model; and with time to  
63 discharge ( $p=0.008$ ; hazard ratio 2.78 [95% CI 1.30 to 5.91]) in a multiple Cox model. Hence  
64 an increasing number of operations is associated with higher odds of visual improvement; and  
65 with longer time to discharge. **Was there any association with Axial length or presence or  
66 absence of myopia?**

67 **Conclusion:** The analysis has found evidence to link vitreous status with the primary outcome  
68 of the presence of a retinal break. However, the risk of retinal detachment was zero in both  
69 groups. Number of operations is of substantive importance with respect to all measured  
70 outcomes.

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## 73 Introduction

**Commented [JS1]:** There was no association with axial length. I don't think myopia was recorded

74 The human vitreous undergoes significant macroscopic changes with age, namely liquefaction  
75 (synchysis) and collapse (syneresis).<sup>1</sup> As a result, posterior vitreous detachment (PVD) occurs  
76 causing visually significant floaters.<sup>1,2</sup> However, visually debilitating floaters can occur in the  
77 absence of a PVD, due to age-related liquefaction which is accelerated in myopia. PVD, followed  
78 by myopic vitreoretinopathy and asteroid hyalosis are the most common cause of floaters.<sup>3,4</sup>  
79

80 Recent studies suggest that floaters can have a negative impact on quality of life and are  
81 perceived by patients as a significant health problem.<sup>5,2</sup> While treatment options are limited  
82 to Nd:YAG (Yttrium aluminium garnet) vitreolysis or vitrectomy,<sup>6</sup> primary vitrectomy is  
83 increasing in popularity.<sup>7</sup>  
84

85 Patients undergoing this procedure have given good satisfaction scores (85% satisfied / very  
86 satisfied) as measured using QOLVFQ (Quality of Life visual function questionnaire) suggesting  
87 that it can enhance quality of life.<sup>7</sup>  
88

89 With the more widespread use of transconjunctival small gauge vitrectomy, reports have  
90 declared the improved safety profile of pars plana vitrectomy for floaters,<sup>4,7,8</sup> encouraging  
91 surgeons to offer it to patients more readily.  
92

93 Performing pars plana vitrectomy for floaters is associated with certain risks, such as iatrogenic  
94 retinal breaks, retinal detachment and cataract formation. These risks have been reported to  
95 occur at rates between 0 – 16.4% for breaks, 0 - 10.9% for detachment and 22 - 60% for  
96 cataract<sup>2,7-10</sup>. It has been identified that induction of PVD during surgery is associated with  
97 higher complications, especially of retinal breaks and detachment<sup>9,11</sup>. Preoperative OCT  
98 analysis provides accurate visualisation of vitreous status at the optic disc, hence enabling  
99 surgeons to plan surgery and counsel patients appropriately.<sup>12</sup>  
100

101 In this study we aimed to examine the outcomes in patients undergoing combined  
102 phacovitrectomy/vitrectomy for floaters. We compared two similar groups varying in vitreous  
103 status: attached versus detached; and reported their outcomes in terms of retinal break/tears,  
104 posterior segment complications, significant visual deterioration and time to discharge.  
105

105

## 106 **Materials and Methods**

107 This study was a comparative, single surgeon series. Data was collected prospectively in a  
108 vitreo-retinal database and reviewed retrospectively. All patients presenting with visually  
109 disabling floaters requiring vitrectomy between July 2003 and June 2016 at Calderdale Royal  
110 Hospital, UK were included. The local Research and Development department confirmed that  
111 no ethical approval was required as there was no deviation from the usual standard of care.

112 The surgical procedure was a standard 23 gauge transconjunctival sutureless vitrectomy (TSV)  
113 +/- combined phacoemulsification and IOL insertion. From July 2015, 27g TSV was used. In  
114 all cases a three port pars plana approach was used with sclerostomies 3.5 mm from the  
115 limbus. For patients with an intact posterior hyaloid face (PHF), separation was induced with  
116 a 23 or 27-gauge cutter probe using suction.

117 Baseline demographics including sex, age and indication for surgery (asteroid hyalosis, Fuchs  
118 heterochromic cyclitis or floaters) were recorded. Posterior hyaloid status was assessed using  
119 OCT (Optovue RTVue – 100 with V. 4.0 software, Freemont, California, USA) and slit lamp  
120 biomicroscopy; this was confirmed intraoperatively with the use of the BIOM viewing system

121 (Oculus, Wetzlar, Germany). In addition to demographic data, we recorded axial length, and  
122 pre-operative visual acuity in LogMAR. We recorded the number and type of operation  
123 (vitrectomy or phacovitrectomy), tamponade used (none, air, C<sub>2</sub>F<sub>6</sub>, SF<sub>6</sub> or Silicone oil. We also  
124 recorded whether the vitreous was attached or detached (*Vitreous*); considered to be the  
125 explanatory variable of primary interest. The primary outcome measure was whether or not the  
126 patient experienced a retinal break (*Break*) as a direct consequence of intra-operative  
127 separation of posterior hyaloid face. The secondary outcome measures were time from surgery  
128 to discharge in days (*Time*) and any significant visual loss (2 or more logmar units loss from pre-  
129 operative level). Other variables were considered to be controlling variables. Some levels of  
130 categorical variables were combined before analysis due to low frequencies.

131 The sample was summarised descriptively. Sequential logistic regression analysis was  
132 conducted on the primary outcome measure of *Break*. All controlling variables were entered in  
133 the first block, with a parsimonious subset of variables derived using backward elimination.  
134 These were added to the key *Vitreous* variable which was forced entered in the second block.  
135 A second sequential logistic regression analysis was conducted on the secondary outcome  
136 measure of *Improvement*, utilising the same modelling strategy. Semi-parametric time-to-  
137 event analyses (Cox regression) were conducted on the secondary outcome of *Time*, again  
138 utilising the same modelling strategy.

139 Odds ratios (logistic regression analyses) or hazard ratios (Cox regression analyses), with  
140 associated confidence intervals; and p-values were reported for all analyses. For the logistic  
141 regression analyses, model goodness-of-fit was assessed using Nagelkerke's pseudo-  
142 R<sup>2</sup> statistic and classification tables, and model calibration was assessed using Hosmer and  
143 Lemeshow's test statistic.

144 All statistical analysis was conducted using SPSS statistical software (Version 22.0).

145

## 146 Results

147 A total of 97 patients were included in the study. 42 patients (43.3%) had vitreous attached;  
148 55 patients (56.7%) had vitreous detached. Majority of the patients undergoing simultaneous  
149 cataract surgery had non-clinically significant cataracts. The age range of the analysed patients  
150 was 23-94 years, with a mean age of 60.1 years (SD 13.2 years). 55 patients were male  
151 (56.7%). Both groups were similarly matched in terms of gender and age, and type of surgery  
152 performed (vitrectomy versus phacovitrectomy). Vitreous syneresis was a more common  
153 indication for surgery in the vitreous detached patient group. Other indications were more  
154 common in the vitreous attached patient group.

155 Tamponade agents varied between the two groups, with a higher number of patients with  
156 vitreous detached requiring air (46 out of 55 patients (83.6%) detached versus 24 out of 42  
157 patients (57.1%) attached); with higher rates of utilization of other agents in the attached  
158 group. The association between agent and vitreous status was statistically significant at the  
159 5% significance level ( $\chi^2_{(1)}=8.32, p=0.004$ ). The magnitude of the effect was medium  
160 ( $\phi=0.293$ ). ~~Was this statistically significant?~~ An imbalance between groups was also noted  
161 needed, with 100% of patients with detached vitreous needing only a single posterior segment  
162 surgery—; compared with 76.9% in patients with attached vitreous needing only a single  
163 (5 patients (17.9%)) (5) needing 2 surgeries and (2 patients) (5.1%) needing 3 surgeries).

164 The outcomes of time from surgery to discharge and changes in visual acuity were very similar  
 165 between the two groups. A substantive difference in the proportion of patients with retinal  
 166 tears or breaks was observed between the two groups, with a 50% prevalence rate in the  
 167 attached group and a 90.9.1% prevalence rate in the detached group.

168 A small amount of missing data was recorded for the variables corresponding to number of  
 169 operations and improvement in vision after surgery. Missing values were not imputed.

170 A full descriptive summary of the sample is provided in Table 1.

171

172 Table 1: Descriptive summary of data

Categorical Variable	All (n=97)	Vitreous attached (valid%) (n=42)	Vitreous detached (valid%) (n=55)
	Frequency (valid %)	Frequency (valid %)	Frequency (valid %)
Gender			
Male	55 (56.7%)	23 (54.8%)	32 (58.2%)
Female	42 (43.3%)	19 (43.3%)	23 (41.8%)
Indications for surgery			
Vitreous syneresis	76 (78.4%)	30 (71.4%)	46 (83.6%)
Asteroid hyalosis	12 (12.4%)	7 (16.7%)	5 (9.1%)
Fuchs heterochromic cyclitis	9 (9.3%)	5 (11.9%)	4 (7.3%)
Type of operation			
Vitrectomy	21 (21.6%)	7 (16.7%)	14 (25.5%)
Phacovitrectomy	76 (78.4%)	35 (83.3%)	41 (74.5%)
Tamponade medium			
None reported	7 (7.2%)	1 (2.4%)	6 (10.9%)
Air	70 (72.2%)	24 (57.1%)	46 (83.6%)
C <sub>2</sub> F <sub>6</sub>	2 (2.1%)	2 (4.8%)	0 (0.0%)
SF <sub>6</sub>	13 (13.4%)	10 (23.8%)	3 (5.5%)
SO	5 (5.2%)	5 (11.9%)	0 (0.0%)
Number of posterior segment operations (n=94)			
1	83 (88.3%)	30 (76.9%)	53 (96.4%)
2	9 (9.6%)	7 (17.9%)	2 (3.6%)
3	2 (2.1%)	2 (5.1%)	0 (0.0%)
Vision after surgery (n=95)			
Improved		19 (47.5%)	26 (47.3%)
Stayed the same	45 (47.4%)	18 (45.0%)	28 (50.9%)
Worsened	46 (48.4%)	3 (7.5%)	1 (1.8%)
4	4 (4.2%)		
Retinal tear or break			
No tear or break	71 (73.2%)	21 (50.0%)	35 (90.9%)
Tear or break	26 (26.8%)	21 (50.0%)	5 (9.1%)

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Covariate	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	60.1 (13.2) Range: (23, 94)	59.1 (14.9) Range: (31, 94)	60.8 (9.09) Range: (38, 80)
Pre-operative visual acuity (LogMAR)	0.202 (0.231) Range:(-0.10, 1.0)	0.230 (0.250) Range: (-0.10, 1.00)	0.188 (0.238) Range: (-0.10, 1.00)
Time from surgery to discharge or last observation <sup>1</sup> days	125 (88) Range: (0, 60)	124 (75.2) Range: (0, 360)	126 (107) Range: (0, 600)
Axial length (mm)	24.9 (1.82) Range: (20.1, 29.0)	24.6 (2.01) Range: (20.1, 29.0)	25.2 (1.74) Range: (21.7, 28.6)

173

174 Five patients required two surgeries for removal of silicone oil (ROSO)-a, as they had multiple  
175 retinal breaks, including inferior breaks on PVD induction initial surgery, which necessitated  
176 use of silicone oil.

177 Of these 2 patients required a further operation, one for a symptomatic epiretinal membrane  
178 (ERM) and another for a post ROSO vitreous haemorrhage wash out.

179 Those requiring further surgery often had ocular comorbidities (lattice degeneration, myopia,  
180 diabetic retinopathy).

181 A sequential logistic regression analysis conducted on the *Break* outcome retained age and  
182 number of operations from the block of controlling variables. Number of operations, plus the  
183 primary vitreous status variable, were found to be significantly associated at the 5%  
184 significance level with retinal breaks or tears in a final parsimonious multiple model ( $p=0.027$   
185 for number of operations;  $p=0.010$  for vitreous status). Age was substantively associated  
186 with the outcome but was not statistically significant at the 5% significance level ( $p=0.128$ ).

187 Controlling for other parameters, the odds of a retinal tear or break in patients increase by  
188 about 6.3 times with each additional operation conducted. Controlling for other parameters,  
189 the odds of a retinal tear or break in patients with vitreous attached were about 5.5 times the  
190 odds of a retinal tear or break in patients with vitreous detached.

191 Nagelkerke's pseudo- $R^2$  statistic for the final model was 0.366; indicating that the model was  
192 a good fit to the data. A classification table revealed that 80.5% of cases were correctly  
193 classified. Hosmer and Lemeshow's test for calibration revealed no evidence that the final  
194 model was not well calibrated ( $\chi^2_{(8)}=3.50$ ,  $p=0.899$ ).

195 Full model parameters are given in Table 2 below.

196 **Table 2: Model parameters of parsimonious logistic regression model of retinal**  
197 **break**

Variable	Odds ratio	95% CI	p-value
Age (years)	0.96	(0.91, 1.01)	0.128
Number of operations	6.28	(1.23, 32.1)	0.027
Vitreous status (reference category <i>Detached</i> )	5.56	(1.52, 20.4)	0.010

198

199 A sequential logistic regression analysis conducted on the *Improvement* outcome retained  
200 indications for surgery and number of operations from the block of controlling variables.  
201 Number of operations was found to be significantly associated at the 5% significance level with  
202 improvement in visual acuity in a final parsimonious multiple model ( $p=0.017$ ). Indications for  
203 surgery was substantively associated with the outcome but was not statistically significant at  
204 the 5% significance level ( $p=0.056$ ). There was no evidence for any association between  
205 vitreous status and the outcome ( $p=0.793$ ). Controlling for other parameters, the odds of  
206 improvement in visual acuity increases by about 15.8 times with each additional operation  
207 conducted.

208 Nagelkerke's pseudo- $R^2$  statistic for the final model was 0.219; indicating that the model is a  
209 fairly good fit to the data. A classification table revealed that 63.8% of cases were correctly  
210 classified. Hosmer and Lemeshow's test for calibration revealed no evidence that the final  
211 model was not well calibrated ( $\chi^2_{(3)}=1.62$ ,  $p=0.655$ ).

212 Full model parameters are given in Table 3 below.

213 **Table 3: Model parameters of parsimonious logistic regression model of visual**  
214 **improvement**

Variable	Odds ratio	95% CI	p-value
Indications for surgery	3.93	(0.97, 15.9)	0.056
Number of operations	15.8	(1.65, 151)	0.017
Vitreous status (reference category <i>Detached</i> )	0.87	(0.31, 2.43)	0.793

215

216 A sequential Cox regression analysis conducted on the *Time* outcome retained number of  
217 operations from the block of controlling variables. Number of operations was found to be  
218 significantly associated at the 5% significance level with time to discharge in a final  
219 parsimonious multiple model ( $p=0.008$ ). There was no evidence for any association between  
220 vitreous status and the outcome ( $p=0.934$ ). Controlling for other parameters, the "hazard" of  
221 discharge increases by about 2.8 times with each additional operation conducted.

222 Full model parameters are given in Table 4 below.

223 **Table 4: Model parameters of parsimonious Cox regression model of time to**  
224 **discharge**

Variable	Hazard ratio	95% CI	p-value
Number of operations	2.78	(1.30, 5.91)	0.008
Vitreous status (reference category <i>Detached</i> )	0.87	(0.61, 1.58)	0.934

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227

228 **Discussion:**

229 Research suggests that patient satisfaction from vitrectomy for floaters is high, with the  
230 majority of patients being satisfied and very satisfied. <sup>6, 10</sup> While there is significant data  
231 available on satisfaction, there is limited and variable data available on complication rates and  
232 visual outcomes. <sup>9</sup>

233 This study aimed to investigate the incidence of complications such as retinal tear/detachment  
234 following PPV for floaters, to ascertain if there was any difference between patients with  
235 vitreous attached or detached prior to surgery. Additionally we looked at the post-operative  
236 complications and time to discharge in these two groups.

237 A large proportion of patients (47.5% vitreous attached; 47.3% vitreous detached) had an  
238 improvement of vision after surgery. There were also a large proportion of patients (45.0%  
239 vitreous attached; 50.9% vitreous detached) for whom vision was unchanged. These outcomes  
240 were expected, as most patients undergoing surgery had normal or near normal visual acuity  
241 on Snellen's chart, the standard clinical test for visual function. Improvement in the visual  
242 disability secondary to floaters is best determined by QOLVFQ as patients' distress does not  
243 correlate with visual acuity. <sup>10</sup>

244 16.7% of the vitreous attached group and 25.5% with vitreous detached group were already  
245 pseudophakic. All patients were pseudophakic following vitrectomy; therefore the visual  
246 outcome were not cofounded by post-operative cataract which has been reported in high  
247 proportions (22.5-75%) in other studies. <sup>4, 7-10</sup>

248 **A major concern following vitrectomy is iatrogenic retinal breaks leading to rhegmetogenous**  
249 **retinal detachment if missed. In our series of 97 eyes there were no cases of post-operative**



250 retinal detachment (both vitreous attached or detached); this is similar to Mason et al. 2014  
251 (168 eyes) and Sebag et al. 2014 (49 eyes). In contrast to other studies<sup>8, 9</sup> however, we had  
252 a high proportion of intra-operative retinal breaks requiring retinopexy 36.2% (25 eyes). This  
253 was much higher in the group with vitreous attached (51.4%) than in the group with vitreous  
254 detached (21.2%). (to mention proportion requiring retinopexy and gas tamponade) This  
255 difference has been noted previously by Rahman et al. 2013 who studied 137 patients  
256 undergoing PPV and PHF separation; iatrogenic retinal breaks were found in 18.2%. Tan et al.  
257 2011 found a statistically significant relationship between retinal breaks and PVD induction.  
258 Where PVD was induced, breaks were found in 30.5% of cases and only 11.6% of cases where  
259 PVD pre-existed (P =0.019). Better intraoperative detection of breaks due to excellent  
260 peripheral view afforded by combined phakovitrectomy and prospective data collection may  
261 have contributed to a higher incidence of peripheral breaks in this study.

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262 The analysis has revealed strong evidence for a link between vitreous status and the occurrence  
263 of retinal breaks or tear, with no evidence revealed to link vitreous status with any of the  
264 secondary outcomes. All available patients were included in the analysis; no formal power  
265 calculation was undertaken. However, it is unlikely that findings would be substantively  
266 different from a larger sample.

## 267 **Conclusion**

268 This study suggests that when offering PPV as a treatment for floaters, surgeons must be  
269 mindful of vitreous status. Having to induce a PVD as part of the vitrectomy is associated with  
270 increased retinal breaks, post-operative complications and potentially a worse visual outcome.  
271 Patients should therefore be made aware of this and be counselled appropriately about the  
272 possibility of retinopexy and a longer acting tamponade when considering treatment.

**Commented [JS3]:** Could re-word to stress the strong relationship between vitreous status and the probability of a retinal tear/break

## 273 **Summary Box**

274 What was known before:

- 275 • Transconjunctival sutureless vitrectomy (TSV) is an effective treatment for floaters
- 276 • TSV is associated with high patient satisfaction scores on QOLVFQ
- 277 • Induction of PVD during vitrectomy is associated with an increased risk of iatrogenic
- 278 retinal breaks.

279 What this study adds:

- 280 • Retinal breaks are significantly likely in patients with vitreous attached, however they do
- 281 not lead to postoperative retinal detachment, if properly managed at the time of surgery.
- 282 • Patient with vitreous detached are more likely to undergo retinopexy and tamponade
- 283 compared to vitreous detached.

284 • There is no significant difference in time to discharge or levels of improvement of VA  
285 between those with vitreous attached or detached before surgery

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