United Kingdom National Ophthalmology Database Study of Vitreoretinal Surgery: Report 2, Macular Hole

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Purpose: To study macular hole (MH) surgery in terms of baseline demographics, intraoperative complications, post-vitrectomy cataract, reoperation, and visual outcome.

Design: National Ophthalmology Database study.

Participants: A total of 1078 eyes from 1045 patients undergoing primary MH surgery.

Methods: Participating centers prospectively collected clinical data using a single electronic medical record (EMR) system, with automatic extraction of anonymized data to a national database, over 8 years. The following data were extracted for eyes undergoing MH surgery: demographics, procedure elements, intraoperative complications, visual acuity (VA), and further surgery.

Main Outcome Measures: Description of the primary procedures performed, intraoperative complication rate, change in VA, proportion of eyes undergoing subsequent surgery for persisting MH, cataract, or retinal detachment.

Results: The median age was 70.3 years, with a 2.2:1 female preponderance. All operations included a pars plana vitrectomy (PPV)—41.1% with hexafluoroethane (C_2F_6), 25.6% with perfluoropropane (C_3F_8), 24.5% with sulfahexafluoride (SF_6), 2.2% with air, and 0.4% with silicone oil. A PPV was combined with internal limiting membrane (ILM) peel in 94.1% and cataract surgery in 40.5%. One or more intraoperative complications occurred in 12.4%. The median presenting logarithm of the minimum angle of resolution (logMAR) VA improved from 0.80 to 0.50 after a median follow-up of 0.6 years; 57.8% of eyes improved ≥0.30 logMAR units (~2 Snellen lines). The choice of gas tamponade did not significantly influence the visual outcome, but eyes undergoing ILM peel were significantly more likely to gain ≥0.30 logMAR units, as were eyes with poor presenting VA. Subsequently, 4.2% of eyes underwent repeat surgery for MH and 2.4% for retinal detachment, and, excluding pseudophakic eyes, 64.6% underwent cataract surgery within 1 year.

Conclusions: This study provides pooled, anonymized data on the demographics, complications, and visual outcome of MH surgery. This may enable vitreoretinal surgeons to benchmark their case-mix and outcomes, and facilitate risk–benefit and cost–benefit analyses.

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Macular hole (MH) has a reported prevalence of 0.02% to 0.8%, with 7.8 new cases per 100 000 population per year.[1–6] Multiple studies have shown a female preponderance, and the peak incidence is thought to be in the seventh decade of life.[7]

The standard treatment for MH is pars plana vitrectomy (PPV) combined with intravitreal gas tamponade, with randomized controlled trials showing benefit for stage 2, 3, and 4 MHs.[8,9] Studies suggest that peeling of the internal limiting membrane (ILM) during PPV increases the MH closure rate,[10,11] although it is not known what percentage of MH operations include an ILM peel.

The outcome of MH surgery is usually defined in terms of anatomic success (proportion of MHs that close with primary surgery) and visual success (proportion of eyes gaining at least 2 Snellen lines of visual acuity [VA]). Mester and Kuhn's literature review[10] reported anatomic success in 58% to 100% of cases and visual success in 33% to 100% of cases.

It is difficult to gather accurate, pragmatic, and representative clinical data, because much of the published evidence comes from single centers, small case series, and retrospective case-note review. In addition, there is a risk of publication bias, in that clinicians may be reluctant to report low success rates.[12] It would be preferable to prospectively collect pooled, anonymized, pragmatic clinical data from a large number of surgeons. Robust data would enable individual surgeons to benchmark their own success rate and allow patients to make an informed decision about the risks and benefits of surgery.

The National Ophthalmology Database (NOD) was established in the United Kingdom under the auspices of The Royal College of Ophthalmologists. It was established to prospectively collect anonymized surgical data during routine clinical care by using electronic medical records (EMRs). Previous studies that led to the creation of the NOD collated large, high-quality, pragmatic cataract data sets, with high levels of data completeness.[13–16]

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The NOD was subsequently used to study vitreoretinal surgery and has reported a pooled analysis of 11 618 operations.[17] The present study analyzed the MH subset of the NOD vitreoretinal study to gain an insight into current MH surgery. Specifically, we aimed to describe the baseline demographics, surgical techniques, intraoperative complication rate, and change in VA. We also aimed to estimate the rate of MH reoperation and subsequent cataract surgery.

Materials and Methods

Data Extraction

The NOD received data from 31 contributing National Health Service hospitals, as reported in another publication.[17] This report relates to MH operations performed between December 2002 and November 2010. The NOD was designed specifically to prospectively collect pragmatic surgical data with the aim of reporting pooled analysis. All data were captured using one EMR system (Medisoft Ophthalmology, Medisoft Limited, Leeds, UK). The lead clinician and Caldicott Guardian (who oversees data protection) at each center gave written approval for the data extraction, and on this basis an ethics committee determined that ethics approval was not required. This study was conducted in accordance with the declaration of Helsinki and the UK's Data Protection Act.

Complications of Macular Hole Surgery

The EMR required surgeons to record whether or not there were any surgical complications before they could save the operation note. If the surgeon indicated that a complication occurred, then he or she had to select from a pre-populated list of well-recognized complications specific to that operation or select "other" and record the complication using free text.

All hospitals using the EMR for vitreoretinal procedures also recorded cataract surgery using the same system, with data submitted to the NOD. It was therefore possible to analyze the incidence of post-vitrectomy cataract surgery (PVCS).

Statistical Analysis

The time to PVCS was modeled using the Kaplan–Meier[18] method with PVCS modeled as failure. Eyes were censored at the last date on which follow-up data of any type were recorded on the EMR if they had not had cataract surgery. The log-rank test was used to investigate any differences in failure between the type of gas used (sulfahexafluoride [SF6] vs. hexafluoroethane [C_2F6] vs. perfluoropropane [C_3F8]) and MH stage (stage 2 vs. stage 3 vs. stage 4).

Visual acuity data were expressed on the logarithm of the minimum angle of resolution (logMAR) scale where VA was categorized as ≤0.30, >0.30–0.60, >0.60–0.90, >0.90–1.20, or >1.20 at the time of presentation and the last VA measurement record. Visual success was defined as eyes improving by ≥0.30 logMAR units from presentation and is reported at 12 and 52 weeks and the last recorded VA measurement (final review). Visual acuity values less than 6 weeks after primary MH surgery were excluded. We chose to primarily report the median VA as the most appropriate VA outcome, but to allow comparison with the literature we also reported the mean VA by substituting counting fingers (CF), hand movement (HM), and perception of light (PL) with 2.1, 2.4, and 2.7, respectively.[19] Both the median and mean VA were reported at presentation and final review. The Pearson's chi-square test was used to test for any differences in the proportion of eyes achieving visual success at final review between the types of gas used, MH stage, and whether ILM was performed during primary MH surgery. Analysis was conducted using STATA version 11 (StataCorp, College Station, TX).

Results

Patient Demographics, Presenting Visual Acuity, and Macular Hole Stage

There were 11 618 vitreoretinal operations recorded on the NOD within the 8-year study period, and of these, 1078 were for primary MH. Of these, 26 were not the first vitreoretinal operation in the eye; 20 had a previous retinal detachment surgery, 5 had previous epiretinal membrane peel surgery, and 1 had previous vitrectomy for diabetic eye disease. These 26 operations were conducted at a median of 0.4 years (range, 0.1–3.6 years) before the primary MH surgery. The 1078 primary MH operations were performed on 512 left eyes and 566 right eyes of 1045 patients. Patient demographics are presented in Table 1. The EMR did not reliably record the duration of symptoms or MH size. Of the MHs, 1 was classified as stage 1, 52 were classified as stage 2, 199 were classified as stage 3, 66 were classified as stage 4, and 760 had no classification. Thirty-three patients had surgery on both eyes.

Table 1. Demographic Details

Variable (Column %)	Male	Female	Not Specified	Total
n	330	714	1	1045
Age at first vitreoretinal operation (yrs)				
Median	72.7	69.1	59.8	70.3
Interquartile range	67.1–77.4	64.1–74.6	—	65.0–75.6
Range	17.4–92.1	33.5–99.8	—	17.4–99.8
Diabetic status				
Diabetic	38 (11.5)	51 (7.1)	1 (100.0)	90 (8.6)
Not diabetic	150 (45.5)	319 (44.7)	0 (0.0)	469 (44.9)
Not recorded	142 (43.0)	344 (48.2)	0 (0.0)	486 (46.5)
Ethnicity				
Caucasian	161 (48.8)	354 (49.6)	0 (0.0)	515 (49.3)
Mixed race	1 (0.3)	4 (0.6)	0 (0.0)	5 (0.5)
Asian	4 (1.2)	4 (0.6)	0 (0.0)	8 (0.8)
Black	9 (2.7)	12 (1.7)	0 (0.0)	21 (2.0)
Other	0 (0.0)	2 (0.3)	0 (0.0)	2 (0.2)
Not recorded	155 (47.0)	338 (47.3)	1 (100.0)	494 (47.3)

Table 2. Reported Intraoperative Complications

(%) = Column Percentage	Total (N = 1078)
Operations with no reported complications	944 (87.6%)
Operations with ≥1 reported complications	134 (12.4%)
Frequency of specific intraoperative complications	
Iatrogenic retinal tear	74 (6.9)
Iatrogenic retinal trauma	18 (1.7)
Lens touch	12 (1.1)
Conjunctival buttonhole	7 (0.6)
Retinal hemorrhage	7 (0.6)
Posterior capsular rupture, no vitreous loss*	6 (0.6)
Other	6 (0.6)
Choroidal/suprachoroidal hemorrhage	4 (0.4)
Posterior capsular rupture, vitreous loss*	3 (0.3)
Corneal epithelial abrasion	2 (0.2)
Subretinal hemorrhage	2 (0.2)
Nuclear/epinuclear fragment into vitreous*	1 (0.1)
Infusion cannula in subretinal/suprachoroidal space	1 (0.1)
Zonule dialysis*	1 (0.1)
Corneal edema	1 (0.1)
Retinal incarceration	1 (0.1)
Total intraoperative complications†	146

*Lens-related complications occurring in eyes with combined cataract surgery.
†More than 1 intraoperative complication can be reported for each operation, and the sum of the individual complication percentages therefore exceeds the percentage of operations with a complication.

The presenting VA was recorded for 884 eyes (82.0%), with a median logMAR VA of 0.80 and mean logMAR VA of 0.90. The logMAR VA was ≤0.30 in 46 eyes, >0.30 to 0.60 in 213 eyes, >0.60 to 0.90 in 233 eyes, >0.90 to 1.20 in 295 eyes, and >1.20 in 87 eyes, including 53 eyes with CF and 10 eyes with HM. No eyes had PL or no PL.

Surgical Technique and Anesthesia

All operations undertaken for primary MH included a PPV; 1014 (94.1%) also included ILM peel, 437 (40.5%) included cataract surgery, 1008 (93.5%) included gas tamponade, 4 included silicone oil tamponade, and in 66 (6.1%) the tamponade used was not recorded. Of the gases used, 265 (24.5%) of operations used SF_6, 443 (41.1%) used C_2F_6, 276 (25.6%) used C_3F_8, and 24 (2.2%) used air. General anesthesia was used for 349 operations (32.3%), local anesthesia with sedation was used for 22 operations (2.0%), local anesthesia without sedation was used for 687 operations (63.7%), and for 20 operations (1.9%) the anesthesia used was unknown.

Intraoperative Complications

Of 1078 operations, 944 (87.6%) were recorded as having no intraoperative complication. Of the 134 eyes (12.4%) having a complication, the most common were iatrogenic retinal tears, iatrogenic retinal trauma, and lens touch (Table 2). Two intraoperative complications occurred in 12 eyes. If the complications associated with cataract surgery were excluded, then the complication rate attributable to MH surgery alone was 11.6% (125/1078).

Further Surgery

At least 1 further PPV and tamponade was undertaken for a diagnosis of MH in 45 eyes (4.2%) at a median of 2.5 months (range, 0.4–44.4 months) after the primary MH surgery, and 2 eyes (0.2%) had a third operation for MH.

Twenty-six eyes (2.4%) underwent surgery for retinal detachment at a median of 2.9 months (range, 0.2–7.6 months) after primary MH surgery. Twenty-one eyes had 1 retinal detachment operation, 4 eyes had 2 retinal detachment operations, and 1 eye had 4 retinal detachment operations. Five eyes had both a persistent MH and a retinal detachment after their primary MH surgery, and 16 eyes had further surgery that was neither for an MH nor a retinal detachment.

Of the 1078 eyes undergoing primary MH surgery, 696 were excluded from the PVCS analysis: 75 because the NOD indicated that they had previous cataract surgery, 437 because they had combined MH and cataract surgery, 12 because they experienced a lens touch complication during primary surgery, and 172 because they had <3 weeks follow-up. Of the remaining 382 eyes eligible for analysis, the median follow-up was 0.5 years (range, 22 days to 3.7 years), and 198 (51.8%) were subsequently recorded as having cataract surgery. The 1-, 2-, and 3-year PVCS rates were 64.6%, 88.8%, and 92.0%, respectively (Fig 1). No statistical differences in the PVCS rate was observed for the type of gas used (P = 0.2807).

Change in Visual Acuity

Of the 884 eyes with a presenting VA recorded, 117 had no further VA measurements and 291 had less than 6 weeks of follow-up data, leaving 476 of the original cohort of 1078 eyes (44%) available for analysis. At 12 weeks after primary MH surgery, 245 eyes had a VA record and 119 eyes (48.6%) achieved visual success (≥0.3 logMAR improvement), improving to 58.3% (207/355) at 52 weeks. At 52 weeks, 8% of eyes (29 eyes) had deteriorated by >0.30 logMAR units.

The last recorded VA ranged from 6 weeks to 3.7 years (median, 0.6 years) after primary MH surgery. At this time, the median VA was 0.50, the mean VA was 0.61, and 57.8% of eyes (275/476) had achieved visual success. Forty-eight eyes (10.1%) lost >0.30 logMAR units from presentation to final review. Of these, 17 had repeat surgery within this timeframe, at a median of 3.6 months (range, 0.0–1.0 year): 7 for MH, 8 for retinal detachment, and 2 underwent PPV for unknown reasons. The worst

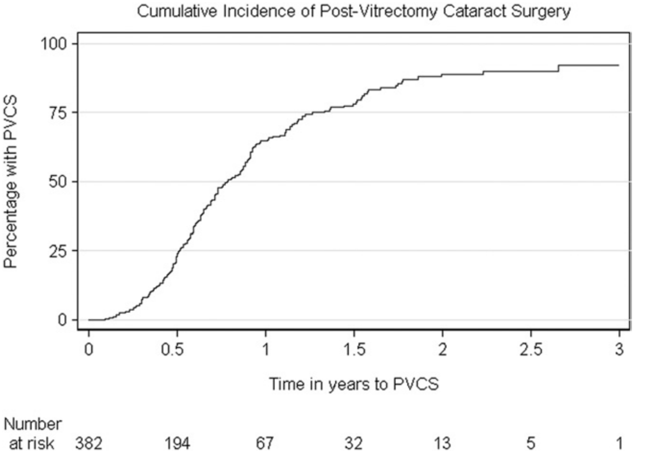

Figure 1. Kaplan–Meier failure graph of PVCS, with cataract surgery modeled as failure. The rates are those after primary macular hole (MH) surgery, excluding eyes known to be pseudophakic, eyes with lens touch recorded during vitrectomy, or cases with <3 weeks follow-up. PVCS = post-vitrectomy cataract surgery.

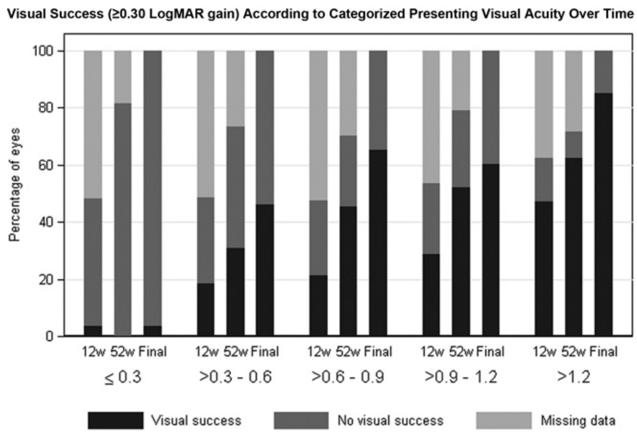

Figure 2. The percentage of eyes achieving visual success at 12 weeks, 52 weeks, and final review. Visual success was defined as those gaining ≥0.3 logMAR units (~2 Snellen lines) from presenting logMAR acuity. logMAR = logarithm of the minimum angle of resolution.

visual outcomes were CF in 18 eyes, HM in 7 eyes, and PL in 1 eye. More eyes with poorer presenting VA achieved visual success than eyes with a better presenting VA at 12 weeks, 52 weeks, and final review (Figs 2 and 3). Eyes that underwent ILM peel with primary surgery were more likely to achieve visual success (P = 0.027) than eyes without ILM peel. There was no difference in the proportions of eyes achieving visual success comparing the type of gas or MH stage.

Of the 476 eyes eligible for VA analysis, 23 were known to be pseudophakic at the time of primary MH surgery. These eyes had a median presenting VA of 0.80 (range, 0.20 to CF) that improved to 0.50 (range, 0.10–1.20) at final review.

Discussion

This study provides anonymized, pragmatic data on MH surgery, including the intraoperative risks, surgical techniques, visual outcomes, and likelihood of post-vitrectomy cataract, by using data collected from a national database over 8 years.

The most commonly selected intravitreal gas was C_2F_6, with approximately equal numbers of eyes receiving SF_6 and C_3F_8. The choice of gas did not significantly alter the visual outcome or the rate of PVCS. Taken in isolation, this result seems to support the use of shorter-acting gases, which led to faster visual rehabilitation. This conclusion is not necessarily valid, because there may be confounding variables. For example, surgeons might select a longer-acting gas in cases at risk of failure, such as large or long-standing MHs. For the same reason, caution is needed in interpreting our data showing that ILM peel is associated with a better VA outcome, although this is consistent with the literature.[10,11]

The complications seen in this study are also consistent with the literature. Most studies indicate that retinal breaks are the most common intraoperative complication of PPV, with figures varying widely from 0% to 24%.[20] A large (n = 409), single-center, database study by Dogramaci et al[20] reported iatrogenic retinal breaks occurring in 16% of eyes undergoing 20- or 23-gauge PPV for MH. Another single-center, retrospective review included 144 eyes undergoing 20-gauge primary PPV for MH and reported a figure of 18%.[21] Both rates are higher than in the present series (7%), but they emanated from large, inner-city vitreoretinal teaching units that may attract more difficult cases, and where vitreoretinal fellows undertake a high proportion of the operations. The present series may be more representative of surgical case mix and service delivery in the United Kingdom.

As with retinal breaks, the reported rates of post-vitrectomy retinal detachment vary widely, from 0% to 16%.[20] Ramkissoon et al[21] reported that new or missed retinal breaks led to retinal detachment in 1.7% of eyes undergoing 20-gauge vitrectomy for MH. Rizzo et al's[22] large database study included 957 eyes undergoing 20-, 23-, or 25-gauge PPV for the treatment of MH, with a reported retinal detachment rate of 2.2%, similar to our own figure of 2.4%.

For the purposes of this study, we defined visual success as a ≥0.30 logMAR improvement, equivalent to a gain of approximately 2 Snellen lines. This occurred in 58.3% of eyes over 12 months. A meta-analysis of 98 eyes undergoing primary MH surgery with ILM peel reported a 2 Snellen line improvement in 81% of eyes.[10] It is well known that publication bias increases the likelihood of reporting favorable results,[12] and it is possible that the present findings are more representative than the 4 relatively small case series included in the meta-analysis.

Although a 2–Snellen line improvement is an accepted outcome measure, the capacity for a 2-line improvement is limited by the ceiling effect imposed by a substantial number of eyes with good presenting VA (Fig 3). Further, VA does not assess other beneficial effects of surgery, such as reduction in distortion, elimination of central scotomas, or reduction in interference with the fellow eye,

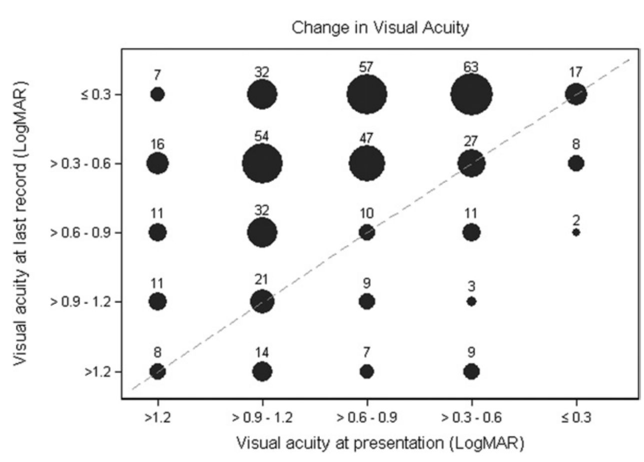

Figure 3. The logMAR visual acuity (VA) at presentation compared with the measurement at final review in 476 eyes. The area of each data point reflects the numbers of eyes in that category. An eye that has an increase in VA appears above the *diagonal gray line* of identity, eyes with no change in VA appear on the line, and eyes with a decrease in VA appear below the line. The VA improved by at least 1 category in 330 eyes, remained in the same category for 83 eyes, and decreased by at least 1 category for 63 eyes. logMAR = logarithm of the minimum angle of resolution.

which are known to be important to patients undergoing surgery for MH.[23]

It is not possible to determine the anatomic success rate of MH surgery in this study, but 4.2% of eyes underwent further MH surgery in the same eye at a median of 2.5 months after primary PPV. It is reasonable to assume that most of these were due to failure to close the MH, although some late surgeries may have been for treatment of a reopened MH. Conversely, not all patients with failed surgery will elect to undergo reoperation, and this proportion is likely to be greater than the approximately 6% of eyes with late reopening of a MH.[24] Taken together, these uncertainties mean that that the present data offer little certainty about the anatomic success rate of MH surgery, beyond noting that it is likely to be less than 96%.

In more than 40% of cases, cataract surgery was undertaken as part of primary MH surgery. In eyes that did not undergo primary surgery, approximately two-thirds progressed to cataract surgery within 1 year. These findings are similar to those of other studies.[7,25]

A strength of this study is that the data were nonselective, pooled, and anonymized, so they may be more generalizable than data obtained from randomized controlled trials and less subject to publication bias than a single-center case series.[12] Another strength is that the EMR required surgeons to record whether or not there was a complication before they could save the operation record and to detail any complications that occurred. However, the system had no way of forcing them to record postoperative complications, unless these led to further surgery that was also recorded on the EMR. Another weakness is that some parameters had more complete data than others. For example, 18% of cases did not have presenting VA recorded on the NOD. Therefore, the data on surgical techniques and intraoperative complications are likely to be reliable, and data on post-vitrectomy cataract, retinal detachment, and VA change are moderately reliable, but no firm conclusion can be drawn with respect to the anatomic success rate.

In conclusion, this study presents the largest clinical database study of MH surgery to date. The results suggest that the benefits of surgery outweigh the risks, with more than half of eyes achieving meaningful VA gains. Retinal breaks were the most frequent intraoperative complication, but postoperative retinal detachment occurred in only 2.4% of eyes. By contrast, cataract surgery occurs in a majority of eyes and needs to be considered as part of any risk–benefit and cost–benefit analysis.

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