The Effect of Postoperative Face-Down Positioning and of Long-versus Short-Acting Gas in Macular Hole Surgery

Results of a Registry-Based Study

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Purpose: To determine whether sulfur hexafluoride (SF6) gas is noninferior to longer-acting gases in macular hole surgery and whether withholding postoperative face-down positioning (FDP) is noninferior to FDP.

Design: Registry-style, prospective, nonrandomized, observational cohort study.

Participants: Patients with idiopathic macular holes undergoing primary surgery.

Methods: Surgeons were invited to submit clinical details of all macular hole cases receiving surgery. Baseline demographic and clinical information were collected, as well as details of surgical intervention and postoperative posturing advice. Primary follow-up data were collected 3 months postoperatively.

Main Outcome Measures: Macular hole closure at 3 months. A noninferiority approach was used, with a noninferiority margin set at 5% decreased frequency of success.

Results: A total of 2456 eyes of 2367 patients were included in the study. Outcomes were available in 94.9% of cases (2330/2456). The rate of macular hole closure was 95.0% (2214/2330). Sulfur hexafluoride gas was found to be noninferior to longer-acting gases (95% confidence interval [CI] for adjusted effect on success, −1.76 to +2.25), and noninferiority was demonstrated regardless of macular hole size. Although withholding FDP was found to be noninferior to FDP for the study population as a whole (95% CI for adjusted effect on success, −4.21 to +0.64), the result was inconclusive in holes >400 μm in diameter (95% CI, −9.31 to +1.04). Lack of internal limiting membrane (ILM) peel, increasing hole size, hole duration ≥9 months, increasing age, and 20-gauge surgery all were associated with lower odds of success. Vitreous attachment to the hole margin was not associated with outcome when corrected for hole size, and combined phacovitrectomy surgery was not observed to affect the odds of success in phakic eyes.

Conclusions: Sulfur hexafluoride gas tamponade was noninferior to longer-acting gases in the surgical management of macular hole. Withholding FDP was noninferior to FDP in holes ≤400 μm in diameter. In holes >400 μm in diameter, noninferiority of withholding FDP could not be concluded. We would advise caution if posturing is withheld in this group on the basis of the results of this study and of others. Ophthalmology 2016;123:1129-1136 © 2016 by the American Academy of Ophthalmology.

Supplemental material is available at www.aaojournal.org.

Macular hole surgery was first described in 1991 by Kelly and Wendel' and Wendel et al.2 Randomized controlled studies subsequently demonstrated the superiority of surgery over conservative management. These studies used perfluoropropane (C3F8) gas as a tamponade agent, rather than the originally described sulfur hexafluoride (SF6), and advised 2 weeks of face-down positioning (FDP).3-5 The surgical technique has been refined over the past 2 decades.6 Recent studies have demonstrated the additional benefit of internal limiting membrane (ILM) peeling at the time of surgery, and hole closure rates in most recent series are greater than 90%.7-10 There remains broad variability in clinical practice and management of this condition, with no consensus regarding the best surgical approach, particularly regarding the choice of intravitreal tamponade and duration of FDP.11-13 Many investigators have reported good results without FDP.14-25 Various mechanisms of action of the gas tamponade are...
postulated in macular hole surgery,\textsuperscript{26} with all assuming that bubble-fovea contact is relevant. Therefore, it would seem intuitive that a larger, longer-acting bubble combined with FDP should be beneficial because this would both facilitate and prolong this apposition. However, there is optical coherence tomography evidence that hole closure occurs very early in the postoperative period, often within the first 24 hours.\textsuperscript{27–29} As such, longer-acting gases and prolonged (or indeed any) FDP may be unnecessary.

By using a noninferiority study design applied to a large prospective (nonrandomized) registry-based cohort, we aimed to observe whether withholding FDP was noninferior to FDP (of any duration) and whether SF6 gas was noninferior to longer-acting gas tamponades. The present article presents the anatomic outcomes.

**Methods**

All surgeons who were members of the Australian and New Zealand Society of Retinal Specialists were invited to participate. The study was approved by the ethics committee of the Royal Australian and New Zealand College of Ophthalmologists, and local institutional review boards where relevant, and adhered to the tenets of the Declaration of Helsinki.

Primary idiopathic macular holes as determined by the surgeon were included. Holes that had already undergone surgery were excluded. Traumatic holes, holes associated with pathologic myopia, eyes with refractive errors $\leq -6$ diopters spherical equivalent, and “stage 1 macular holes” (i.e., no full-thickness retinal defect) also were excluded, as were those for which the surgeon documented the cause to be “other.”

Surgeons prospectively completed a data sheet at the time of surgery, collecting key baseline demographic and clinical features, and surgical information including tamponade used and FDP advice (Table 1, available at www.aaojournal.org). Surgeons were asked to measure hole size as the minimum hole width at the narrowest hole point in the mid retina, as defined by the Vitreomacular Traction study group.\textsuperscript{30} The study commenced in November 2008 using a paper-based system and then transitioned to an online data-entry system in June 2012.

The primary outcome was hole closure at 3 months with 1 surgery, chosen to avoid the confounding effects of cataract on visual outcome. Hole closure was the absence of a full-thickness retinal defect at the site of the original hole. Secondary outcomes were visual acuity and safety outcomes (retinal detachment and endophthalmitis). These secondary outcomes are not the subject of the present article and will be reported in a separate publication. If the hole failed to close after the primary procedure and subsequent surgery had been successfully performed, this was still regarded as a failure, and the acuity at the time of the failure was used as the outcome acuity. Retrospective data entry was allowed provided the robustness of the conclusions of the primary analysis. First, a reduced model without the nonsignificant predictors ($P > 0.05$) was considered. Second, multiple imputation was used as an alternative approach to handle missing data. Finally, patient and surgeon clustering effects, due to bilateral eyes and repeated cases from each site, respectively, were explored using generalized estimating equations methodology.

**Results**

There were 2689 macular holes in the dataset. Of these, 87 were persistent, 5 were recurrent, 29 were traumatic, and 84 were “other” (including 47 with pathologic myopia). These were excluded from the dataset. Five cases received air as a postoperative tamponade, and 13 cases received silicone oil, and these were also excluded. An additional 6 cases were found to be duplicates and 4 had almost total lack of data, leaving a total of 2456 primary idiopathic holes from 2367 patients (89 bilateral), contributed by 50 surgeons and 3 institutions (i.e., 53 sites). The median number of cases per site was 29 (range, 1–173). Seven sites contributed >100 cases, and 9 sites contributed less than 5 cases.

The baseline characteristics of the group are summarized in Table 2, and operative intervention is shown in Table 3 and Figure 1. Numbers of cases with missing data also are presented. Refraction was recorded in only 367 cases (mean $-0.46$ diopters) and could not be included in the analysis. The majority of cases were submitted from private practices, receiving surgery from consultant surgeons rather than trainees. The median duration of macular hole at the time of surgery (estimated by the operating surgeon) was 3 months. Median hole size was 281 $\mu$m, and less than one quarter were $>400$ $\mu$m in diameter. Two thirds received SF6 gas tamponade. Vitreous was attached to the hole margin in
49.8%, and the breakdown of attachment by hole size is shown in Table 4.

The baseline characteristics of cases with no FDP are compared with those who were advised any duration of FDP in Table 5 (available at www.aaojournal.org). The groups were well balanced with respect to all baseline features except vitreous attachment to hole margin, which was slightly less common in the FDP group (47% vs. 56%, \( P < 0.001 \)). Patients who were advised not to posture face-down postoperatively were more likely to receive SF6 gas. They were also more likely to have small-gauge surgery, be operated on by a trainee, and to have the ILM peeled. The statistical analysis for the primary outcomes (i.e., the adjusted effects of no FDP and of SF6 gas use) corrects for any imbalances in baseline covariates.

### Primary Outcome

Outcome was available in 94.9% of cases (2330/2456), and the rate of primary macular hole closure among these was 95.0% (2214/2330). There was complete baseline and outcome data in 82.2% of cases (2019/2456), and this group was used for the primary analysis.

The 95% confidence interval (CI) for the adjusted effect of no FDP was a 4.21% worse success rate to a 0.64% better success rate compared with FDP. This does not cross the predetermined 5% noninferiority margin, demonstrating that withholding FDP was noninferior to FDP for the study population as a whole. When the effect of posturing was estimated by hole size category (<250 \( \mu \)m, 251–400 \( \mu \)m, and >400 \( \mu \)m), the 95% CI straddled the non-inferiority margin in holes >400 \( \mu \)m (Fig 2). Noninferiority in larger holes cannot be concluded. We did not observe FDP to be superior to no FDP at any hole size (all CIs also straddled zero effect).

Sulfur hexafluoride gas use was noninferior to longer-acting gas tamponades (95% CI for adjusted effect on success, -1.76 to 0.47).

### Table 2. Baseline Demographic and Clinical Features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Missing</th>
<th>2456</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (yrs, SD; range, 37–95)</td>
<td>69.1</td>
<td>13</td>
</tr>
<tr>
<td>Gender n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>844 (34.5%)</td>
<td>6</td>
</tr>
<tr>
<td>Female</td>
<td>1606 (65.6%)</td>
<td>9</td>
</tr>
<tr>
<td>Side</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>1242 (50.8%)</td>
<td>9</td>
</tr>
<tr>
<td>Left</td>
<td>1205 (49.2%)</td>
<td>9</td>
</tr>
<tr>
<td>Duration of hole (months)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;9 mos</td>
<td>2059 (87.4%)</td>
<td>99</td>
</tr>
<tr>
<td>≥9 mos</td>
<td>298 (12.6%)</td>
<td>99</td>
</tr>
<tr>
<td>Median hole size (( \mu )m)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤250 ( \mu )m</td>
<td>1021 (44.5%)</td>
<td>159</td>
</tr>
<tr>
<td>251–400 ( \mu )m</td>
<td>741 (32.1%)</td>
<td>159</td>
</tr>
<tr>
<td>&gt;400 ( \mu )m</td>
<td>535 (23.4%)</td>
<td>159</td>
</tr>
<tr>
<td>Vitreous attached to hole edge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not attached</td>
<td>420 (18.8%)</td>
<td>383</td>
</tr>
<tr>
<td>Attached</td>
<td>588 (26.4%)</td>
<td>337</td>
</tr>
</tbody>
</table>

*Percent of number with both hole size and vitreous attachment recorded in dataset (\( N = 2231 \)).

### Table 3. Operative Intervention

<table>
<thead>
<tr>
<th>Feature</th>
<th>Missing</th>
<th>2456</th>
</tr>
</thead>
<tbody>
<tr>
<td>ILM peel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2392 (97.7%)</td>
<td>7</td>
</tr>
<tr>
<td>No</td>
<td>57 (2.3%)</td>
<td></td>
</tr>
<tr>
<td>Tamponade used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF6</td>
<td>1653 (67.7%)</td>
<td>14</td>
</tr>
<tr>
<td>C2F6</td>
<td>87 (3.6%)</td>
<td></td>
</tr>
<tr>
<td>C3F8</td>
<td>702 (28.8%)</td>
<td></td>
</tr>
<tr>
<td>Postoperative FDP (any duration)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1806 (74.2%)</td>
<td>22</td>
</tr>
<tr>
<td>No</td>
<td>628 (25.8%)</td>
<td></td>
</tr>
<tr>
<td>Combined cataract and vitrectomy surgery</td>
<td>250 (13.3%) of 1880 phakic eyes</td>
<td>29</td>
</tr>
<tr>
<td>Grade of surgeon Consultant</td>
<td>2282 (94.9%)</td>
<td>50</td>
</tr>
<tr>
<td>Trainee</td>
<td>124 (5.2%)</td>
<td></td>
</tr>
<tr>
<td>Gauge of instruments used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20G</td>
<td>79 (3.3%)</td>
<td>23</td>
</tr>
<tr>
<td>23G</td>
<td>1353 (55.6%)</td>
<td></td>
</tr>
<tr>
<td>25G</td>
<td>1001 (41.1%)</td>
<td></td>
</tr>
</tbody>
</table>

C3F8 = perfluoropropane; FDP = face-down positioning; ILM = internal limiting membrane; SF6 = sulfur hexafluoride.

### Table 4. Preoperative Optical Coherence Tomography Grading of Macular Holes

<table>
<thead>
<tr>
<th>Hole Size</th>
<th>( \mu )m</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤250</td>
<td>420 (18.8%)</td>
<td>383 (17.2%)</td>
</tr>
<tr>
<td>251–400</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;400</td>
<td>588 (26.4%)</td>
<td>337 (15.1%)</td>
</tr>
</tbody>
</table>

*Percent of number with both hole size and vitreous attachment recorded in dataset (\( N = 2231 \)).
The noninferiority of SF6 gas was observed at all macular hole sizes (Fig 2).

The effects of the other covariates on the odds of success are presented in Table 6. Lack of ILM peel, increasing hole size, hole duration ≥ 9 months, increasing age, and 20-gauge surgery all were associated with lower odds of success. The number of eyes in which the ILM was not peeled (n = 57, 2.3%) and with 20-gauge surgery (n = 79, 3.3%) was small. Vitreous attachment to the hole margin was not associated with outcome when corrected for hole size.

Removing nonsignificant predictors from the model had no effect on these conclusions, nor did accounting for intrasurgeon correlations (which were found to be negligible: +0.011) or intrapatient correlation (also low: –0.077). Analyses using multiple imputation as an alternative method for managing missing data also did not affect the conclusions.

**Combined Phacovitrectomy Surgery**

A separate analysis was performed on phakic eyes to investigate the effect of combined phacovitrectomy surgery on closure rate. The numbers undergoing combined surgery were relatively small (n = 250/1880 phakic eyes). Combined surgery was not observed to have any effect on the odds of hole closure overall (odds ratio, 0.95; 95% CI, 0.48–1.86; P = 0.875). There was no interaction observed between combined surgery and gas choice (P = 0.20) or FDP (P = 0.12), although we had low power to estimate these interactions with confidence. A further analysis was performed on the entire study group using “lens status at the end of the procedure” as a covariate. Again, pseudophakia and combined surgery were not associated with anatomic outcome, and the significance of the other covariates was not affected (results not shown).

**Discussion**

The present study has demonstrated the noninferiority of SF6 gas in macular hole surgery (when compared with longer-acting gases) and that withholding FDP...
postoperatively is noninferior to FDP in holes \( \leq 400 \, \mu m \) in diameter. Noninferiority of no FDP could not be concluded in holes \( >400 \, \mu m \) in diameter.

A noninferiority approach is the appropriate way to investigate a treatment if “...it is expected to cause fewer side effects, or lead to improved quality of life...” when compared with the standard treatment.\(^\text{32}\) This is the case for withholding FDP (compared with FDP) and for SF6 gas (compared with longer-acting gas). Only 1 previous study\(^\text{33}\) has used a noninferiority design to investigate whether withholding posturing is noninferior to a more intrusive FDP regimen. However, the investigators chose a noninferiority margin of \(-15\%\), which in our opinion was far too generous. At the commencement of the present study, the study steering committee determined that a \(-5\%\) noninferiority margin was most appropriate, and Yorston et al\(^\text{31}\) have subsequently independently published sample size calculations using the same \(-5\%\) noninferiority margin. This margin balances the desire for hole closure with the onerous nature of FDP, which itself has potential adverse outcomes (reviewed by Gupta\(^\text{26}\)).

Attempts to study the effect of withholding FDP have been made difficult by the generally high success rates of surgery, the fact that most studies have been small and lacked sufficient power, and the confounding effects of hole size and concomitant cataract surgery.\(^\text{31,33–41}\) The majority of published series state that no differences could be observed between the posture and nonposture groups then state or imply that there is no difference. The lack of a noninferiority approach in many of these studies invalidates these conclusions. Attempted (overlapping) meta-analyses have been challenging because of differing study designs and lack of randomization, and have yielded conflicting results regarding the benefits of FDP.\(^\text{42–44}\) The present study failed to demonstrate noninferiority of withholding FDP in holes \( >400 \, \mu m \) in diameter. Two small randomized studies have concluded that FDP is associated with better hole closure rates in holes \( >400 \, \mu m \) in diameter.\(^\text{37,38}\) On the basis of the results of these 2 studies\(^\text{37,38}\) and this study, the authors would advise caution in withholding postoperative FDP for eyes with holes \( >400 \, \mu m \).

Although others have suggested that FDP may have a differential effect depending on whether or not combined phacovitrectomy surgery is performed, the present study failed to identify any interaction between combined surgery and the effect of FDP on outcome.\(^\text{51,57}\) In addition, the present study failed to demonstrate a beneficial effect of combined surgery itself or pseudophakic lens status on hole closure.

Less attention has been given in the literature to the choice of gas tamponade. Most studies are not randomized, all are small, and several confound the question by using different surgical techniques in the treatment groups (e.g., cataract surgery or differing posturing advice).\(^\text{15,36,45–51}\) Most studies fail to demonstrate any difference between SF6 and longer-acting gas, although they are again flawed by the lack of a noninferiority design. Tognetto et al\(^\text{7}\) found a higher success rate (uncorrected) with SF6 gas in their large retrospective study. The present study presents strong evidence supporting the noninferiority of SF6 gas. Although we did not find SF6 gas to be superior to longer-acting gases, it is logical to prefer the shorter-acting SF6 gas in light of our results.

We found that lack of ILM peel and increasing hole size were associated with a lower odds of success. The importance of ILM peel has been well demonstrated by other investigators.\(^\text{5,29–31}\) As has the effect of hole size.\(^\text{5,29,29}\)

Longer hole duration was observed to be associated with a lower probability of success by Wendel et al\(^\text{2}\) in their 1993 article, and Tognetto et al\(^\text{7}\) observed longer duration of symptoms to be associated with a lower odds of success. Our results support these earlier findings. The effect of hole duration was not consistently recorded in the UK National Ophthalmology Database.\(^\text{13}\) However, good success rates are still reported for chronic holes.\(^\text{54}\)

Increasing age was reported by Tognetto et al\(^\text{7}\) to be associated with a lower odds of success, and our results are consistent with this finding. Smaller studies have failed to observe an effect with age,\(^\text{5}\) but these lacked the power to detect a small effect. It is unclear whether this association is present at the extremes of the age range, particularly in younger patients in whom pathogenesis may differ from the more typical idiopathic macular holes. It is important to emphasize that increasing patient age and duration of hole are not contraindications for surgery: Surgeons and patients simply should be aware that the probability of a successful outcome is moderately reduced.

We observed patients receiving 20-gauge surgery to have a lower odds of success; however, the numbers of patients receiving 20-gauge surgery were small (3.3%), and this result may be anomalous or confounded by other unmeasured factors (e.g., socioeconomic). We are not aware of other published studies documenting better macular hole outcomes with small-gauge surgery.

The international vitreomacular traction study group has recommended that vitreous attachment to hole margin be included in the optical coherence tomography—based grading system of macular hole.\(^\text{30}\) This is particularly relevant to pharmacologic vitreolysis with ocriplasmin, but we failed to observe any association between vitreomacular attachment and hole closure postvitrectomy.\(^\text{55}\) In this study, 41.5% of eyes in the dataset had vitreomacular attachment and hole size less than 400 \( \mu m \) and would have been eligible for the Microplasmin for Intravitreous Injection—Traction Release without Surgical Treatment (MIVI-TRUST) studies. Our observed (unadjusted) surgical success rate was 97.0% in this subgroup (data not shown).

**Study Limitations**

The present study is not randomized. It is possible that there is selection bias in the dataset and that patients with a higher risk of failure preferentially received longer-acting gases or were allocated to FDP. If this were the case, it could mask a beneficial effect of these interventions. However, the dataset includes many baseline covariates that are all included in the logistic regression. Logistic regression corrects for any imbalance providing there are no unmeasured determinants of outcome that are also imbalanced between the study groups. This cannot be known and would be addressed only by a randomized study. It was reassuring to observe that the
observed baseline covariates including hole size were reasonably well balanced in the FDP and no FDP groups. The initial sample size calculation for this study was based on an observed ratio between the nonposture and posture groups of 1:9. During the course of the study, this evolved to closer to 1:3. This, combined with a push encouraging surgeons to catch up with their missing data and cases, resulted in us collecting a dataset more powerful than was necessary to address the primary study questions. This did not present any ethical issues because no patients were inconvenienced in any way by the study. However, power calculations were made for the study group as a whole and did not consider subgroup analyses.

The raw (unadjusted) success rates in holes ≤250 μm, 251 to 400 μm, and >400 μm were 97.8%, 95.6%, and 88.8%, respectively. The adjusted estimate of the effect of FDP in the large hole group was a 4% improvement in success rate, but with a CI that extended from a 9% benefit to 1% worse. By using this as the basis for a sample size calculation (using a type 1 error rate of 5% and a power of 80%), a study designed to demonstrate this 4% difference would require 2070 participants with holes >400 μm in diameter. Such a study is unlikely ever to occur, and for now we are left with the present study and others on which to base our clinical decisions. Ongoing data collection using this and other registries, such as the IRIS registry and the UK National Ophthalmology Database, may better inform us in time. It is important these registries collect posturing information, gas use, and hole size in their datasets in addition to other baseline covariates known to be relevant to outcome. Ongoing data collection is vital to better inform our decision making.

We have demonstrated the noninferiority of SF6 gas tamponade in the surgical management of macular hole. We also have demonstrated the noninferiority of withholding postoperative FDP in holes ≤400 μm in diameter. We cannot offer definitive advice regarding the efficacy of FDP in holes >400 μm, but would advise caution if posturing is withheld in this group on the basis of the results of this study and others. Measurement of the hole size using optical coherence tomography is an important component of the preoperative assessment of patients with macular hole.

References

Footnotes and Financial Disclosures

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Pictures & Perspectives

Ectopic Lacrimal Gland Underlying a Caruncular Nevus

A 55-year-old man presented with an asymptomatic left pigmented caruncular lesion (Fig 1). The lesion was excised and histopathology (H&E) revealed non-keratinizing squamous epithelium containing goblet cells. Numerous large nests of bland-appearing nevus cells are seen in the superficial substantial propia (Fig 2, black arrows) creating pseudopapillae. Densely populated nevus cells (Fig 2, white arrow), pilosebaceous units, and lacrimal gland acini (Fig 2, asterisks) are seen below the nests. Ectopic lacrimal gland tissue is rare but has been reported in the orbit, lids, adnexa, and within the globe. Neoplastic transformation of the ectopic tissue may occur.

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