

**PREFERRED PRACTICE PATTERN®**



**Idiopathic  
Macular Hole**

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# RETINA/VITREOUS PREFERRED PRACTICE PATTERN® DEVELOPMENT PROCESS AND PARTICIPANTS

The **Retina/Vitreous Preferred Practice Pattern® Panel** members wrote the Idiopathic Macular Hole Preferred Practice Pattern® (“PPP”) guidelines. The PPP Panel members discussed and reviewed successive drafts of the document, meeting in person twice and conducting other review by e-mail discussion, to develop a consensus over the final version of the document.

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The **Preferred Practice Patterns Committee** members reviewed and discussed the document during a meeting in March 2014. The document was edited in response to the discussion and comments.

## **Preferred Practice Patterns Committee 2014**

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The Idiopathic Macular Hole PPP was then sent for review to additional internal and external groups and individuals in June 2014. All those returning comments were required to provide disclosure of relevant relationships with industry to have their comments considered. Members of the Retina/Vitreous Preferred Practice Pattern Panel reviewed and discussed these comments and determined revisions to the document.

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## FINANCIAL DISCLOSURES

In compliance with the Council of Medical Specialty Societies' Code for Interactions with Companies (available at [www.cmss.org/codeforinteractions.aspx](http://www.cmss.org/codeforinteractions.aspx)), relevant relationships with industry are listed. The Academy has Relationship with Industry Procedures to comply with the Code (available at <http://one.aao.org/CE/PracticeGuidelines/PPP.aspx>). A majority (86%) of the members of the Retina/Vitreous Preferred Practice Pattern Panel 2013–2014 had no financial relationship to disclose.

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The disclosures of relevant relationships to industry of other reviewers of the document from January to August 2014 are available online at [www.aao.org/ppp](http://www.aao.org/ppp).



# TABLE OF CONTENTS

<b>OBJECTIVES OF PREFERRED PRACTICE PATTERN GUIDELINES</b> .....	2
<b>METHODS AND KEY TO RATINGS</b> .....	3
<b>HIGHLIGHTED FINDINGS AND RECOMMENDATIONS FOR CARE</b> .....	4
<b>INTRODUCTION</b> .....	5
Disease Definition .....	5
Patient Population .....	5
Clinical Objectives .....	5
<b>BACKGROUND</b> .....	5
Epidemiology.....	5
Natural History .....	6
<b>CARE PROCESS</b> .....	7
Patient Outcome Criteria .....	7
Diagnosis.....	7
History .....	7
Physical Examination .....	7
Ancillary Tests.....	7
Management .....	8
Prevention and Early Detection .....	8
Early Stages.....	8
Later Stages.....	8
Surgical Management .....	9
Preoperative Discussion .....	9
Vitrectomy .....	9
Detaching the Posterior Vitreous .....	9
Internal Limiting Membrane Removal and Dyes.....	10
Positioning .....	11
Outcomes of Surgery .....	11
Predictors of Visual Results .....	11
Complications of Vitrectomy .....	12
Follow-up Evaluation after Surgery.....	13
Vitreopharmacolysis.....	13
Provider and Setting.....	14
Counseling and Referral .....	14
Socioeconomic Considerations.....	14
<b>APPENDIX 1. QUALITY OF OPHTHALMIC CARE CORE CRITERIA</b> .....	15
<b>APPENDIX 2. PREFERRED PRACTICE PATTERN RECOMMENDATION GRADING</b> .....	17
<b>SUMMARY BENCHMARKS</b> .....	21
<b>RELATED ACADEMY MATERIALS</b> .....	22
<b>REFERENCES</b> .....	22



# OBJECTIVES OF PREFERRED PRACTICE PATTERN® GUIDELINES

As a service to its members and the public, the American Academy of Ophthalmology has developed a series of Preferred Practice Pattern® guidelines that **identify characteristics and components of quality eye care**. Appendix 1 describes the core criteria of quality eye care.

The Preferred Practice Pattern® guidelines are based on the best available scientific data as interpreted by panels of knowledgeable health professionals. In some instances, such as when results of carefully conducted clinical trials are available, the data are particularly persuasive and provide clear guidance. In other instances, the panels have to rely on their collective judgment and evaluation of available evidence.

**These documents provide guidance for the pattern of practice, not for the care of a particular individual.** While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Adherence to these PPPs will not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients' needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.

**Preferred Practice Pattern® guidelines are not medical standards to be adhered to in all individual situations.** The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.

References to certain drugs, instruments, and other products are made for illustrative purposes only and are not intended to constitute an endorsement of such. Such material may include information on applications that are not considered community standard, that reflect indications not included in approved U.S. Food and Drug Administration (FDA) labeling, or that are approved for use only in restricted research settings. The FDA has stated that it is the responsibility of the physician to determine the FDA status of each drug or device he or she wishes to use, and to use them with appropriate patient consent in compliance with applicable law.

Innovation in medicine is essential to ensure the future health of the American public, and the Academy encourages the development of new diagnostic and therapeutic methods that will improve eye care. It is essential to recognize that true medical excellence is achieved only when the patients' needs are the foremost consideration.

All Preferred Practice Pattern® guidelines are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly. To ensure that all PPPs are current, each is valid for 5 years from the "approved by" date unless superseded by a revision. Preferred Practice Pattern guidelines are funded by the Academy without commercial support. Authors and reviewers of PPPs are volunteers and do not receive any financial compensation for their contributions to the documents. The PPPs are externally reviewed by experts and stakeholders, including consumer representatives, before publication. The PPPs are developed in compliance with the Council of Medical Specialty Societies' Code for Interactions with Companies. The Academy has Relationship with Industry Procedures (available at <http://one.aao.org/CE/PracticeGuidelines/PPP.aspx>) to comply with the Code.

The intended users of the Idiopathic Macular Hole PPP are ophthalmologists.



## METHODS AND KEY TO RATINGS

Preferred Practice Pattern® guidelines should be clinically relevant and specific enough to provide useful information to practitioners. Where evidence exists to support a recommendation for care, the recommendation should be given an explicit rating that shows the strength of evidence. To accomplish these aims, methods from the Scottish Intercollegiate Guideline Network<sup>1</sup> (SIGN) and the Grading of Recommendations Assessment, Development and Evaluation<sup>2</sup> (GRADE) group are used. GRADE is a systematic approach to grading the strength of the total body of evidence that is available to support recommendations on a specific clinical management issue. Organizations that have adopted GRADE include SIGN, the World Health Organization, the Agency for Healthcare Research and Policy, and the American College of Physicians.<sup>3</sup>

- ◆ All studies used to form a recommendation for care are graded for strength of evidence individually, and that grade is listed with the study citation.
- ◆ To rate individual studies, a scale based on SIGN<sup>1</sup> is used. The definitions and levels of evidence to rate individual studies are as follows:

I++	High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias
I+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
I-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
II++	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
II+	Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
II-	Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
III	Nonanalytic studies (e.g., case reports, case series)

- ◆ Recommendations for care are formed based on the body of the evidence. The body of evidence quality ratings are defined by GRADE<sup>2</sup> as follows:

Good quality	Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Insufficient quality	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate Any estimate of effect is very uncertain

- ◆ Key recommendations for care are defined by GRADE<sup>2</sup> as follows:

Strong recommendation	Used when the desirable effects of an intervention clearly outweigh the undesirable effects or clearly do not
Discretionary recommendation	Used when the trade-offs are less certain—either because of low-quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced

- ◆ The Highlighted Findings and Recommendations for Care section lists points determined by the PPP Panel to be of particular importance to vision and quality of life outcomes.
- ◆ All recommendations for care in this PPP were rated using the system described above. To locate ratings for specific recommendations, see Appendix 2 for additional information.
- ◆ A literature searches to update the PPP was undertaken in June 2013 in PubMed and the Cochrane Library. Complete details of the literature search are available at [www.ao.org/ppp](http://www.ao.org/ppp).



## HIGHLIGHTED FINDINGS AND RECOMMENDATIONS FOR CARE

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People with vitreous traction and no macular hole (stage 1-A or 1-B) should be observed, because they often remain stable or even improve. Currently, there is no evidence that treatment improves the prognosis.

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Most people with stage 2–4 macular holes have a poor prognosis without treatment; with successful macular hole closure, however, visual prognosis is usually good. Therefore, an ophthalmologist should discuss treatment options that include the opportunity for macular hole closure and the associated visual benefits.

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Recent studies report that approximately 90% of recent macular holes that are 400  $\mu\text{m}$  or smaller are closed by means of vitrectomy surgery.

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Careful removal of the internal limiting membrane (ILM) during vitrectomy surgery increases the macular hole closure rate without adversely affecting the visual acuity. Removal of the ILM is likely to lead to both higher closure and lower reoperation rates, resulting in more cost-effective care.

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Macular holes that have been present for over 6 months have a lower closure rate following vitrectomy, and such patients have less return of vision.

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Macular holes are more common in females than males and usually occur after age 55. There is a high rate of macular hole formation in the fellow eye (10% to 15%) in the 5-year period after a macular hole occurs in the first eye.

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Cataract is a frequent complication of vitrectomy surgery to repair macular holes. This risk should be discussed with patients preoperatively, and postoperative monitoring is advised.

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Approximately 40% of holes 400  $\mu\text{m}$  or smaller that are associated with vitreous traction were closed following an intravitreal injection of ocriplasmin.

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To prevent visual field loss, prolonged air flow during the air-fluid exchange should be minimized.

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## INTRODUCTION

### DISEASE DEFINITION

Macular cyst, hole, or pseudohole (ICD-9 #362.54; ICD-10 #H35.34- [(-) = 1, right eye; 2, left eye; 3, bilateral])

A macular hole is a discontinuity of the neurosensory retina, located at the fovea.

### PATIENT POPULATION

The patient population consists of adults, most of whom are women, who have idiopathic macular holes.

### CLINICAL OBJECTIVES

- ◆ Identify patients at risk for macular hole.
- ◆ Educate high-risk patients about the reason for periodic monocular self-assessment and follow-up examination, the symptoms of a macular hole, and the need to return promptly should symptoms occur.
- ◆ Follow patients who are at risk for vision loss from macular hole.
- ◆ Inform patients of the risks and benefits of the treatment options for macular hole.
- ◆ Optimize central vision recovery.



## BACKGROUND

A macular hole is an anatomic discontinuity of the neurosensory retina that develops in the center of the macula or fovea. Typically, the patient will experience metamorphopsia and decreased visual acuity.<sup>4,5</sup> Most investigators believe that macular holes are caused by pathologic vitreoretinal traction at the fovea.

Uncontrolled series also suggest that trauma may be responsible for a minority of macular hole cases.<sup>6,7</sup> A lamellar macular hole is a partial-thickness defect in the neurosensory retina, whereas a macular pseudohole is an epiretinal membrane with a circular or oval configuration that gives the false clinical appearance of a full-thickness macular hole.

### EPIDEMIOLOGY

The Beijing Eye Study is a population-based cross-sectional study of 4346 subjects that found a prevalence of macular holes of  $0.09 \pm 3.04\%$ .<sup>8</sup> Another population-based cross-sectional study in rural India found a macular hole prevalence of  $0.20 \pm 0.05\%$  of people.<sup>9</sup> In the United States, a population-based retrospective study of the largely Caucasian residents (>90%) of Olmsted County, Minnesota, estimated the age- and sex-adjusted incidence of macular holes to be 7.8 people and 8.7 eyes per 100,000 people per year.<sup>10</sup> In a case-control study, the majority (72%) of idiopathic macular holes occurred in women; more than 50% of holes were found in individuals 65 to 74 years of age and only 3% in those under the age of 55.<sup>11</sup> The 5-year risk of a patient with a full-thickness macular hole (FTMH) of developing an FTMH in the fellow eye is approximately 10% to 15%.<sup>12-18</sup> Fellow eyes with a complete posterior vitreous detachment have a lower risk of developing an FTMH. In one study, it was observed that no fellow eye with a complete posterior vitreous detachment developed an FTMH during a median follow-up period of 33 months (range, 9 to 99 months).<sup>15</sup>

## NATURAL HISTORY

The formation of a macular hole typically evolves over a period of weeks to months through the clinically defined stages first described by Gass,<sup>19</sup> although some macular holes may develop more rapidly. In both cases, macular holes are frequently detected when the patient's symptoms change relatively abruptly.<sup>19,20</sup> The anatomic findings from optical coherence tomography (OCT) support Gass' original observations, and an updated classification of FTMH is described in Table 1.

Importantly, a retinal defect is not present in stages 1-A and 1-B. Therefore, these stages may be better classified as impending macular holes.

**TABLE 1 STAGES AND CHARACTERISTICS OF MACULAR HOLES**

Stage	Characteristics
1-A (impending)	<ul style="list-style-type: none"> <li>• Loss of the foveal depression and a yellowish foveal spot (100–200 <math>\mu\text{m}</math> in diameter)</li> <li>• Localized shallow detachment of the perifoveal vitreous cortex with persistent adherence to the foveola</li> <li>• Vitreofoveolar traction may horizontally separate (split) the retina at the fovea (pseudocyst) that corresponds to the yellow spot<sup>21</sup></li> <li>• Epiretinal membranes are uncommon</li> <li>• Visual acuity ranges from 20/25 to 20/80</li> <li>• Surgical intervention is not recommended</li> </ul>
1-B (impending)	<ul style="list-style-type: none"> <li>• Yellow ring 200–350 <math>\mu\text{m}</math> in diameter</li> <li>• Posterior extension of the pseudocyst with disruption of the outer retinal layer<sup>21-23</sup></li> <li>• The retinal roof remains intact with persistent adherence of the posterior hyaloid to the retina<sup>21-23</sup></li> <li>• Epiretinal membranes are uncommon</li> <li>• Visual acuity ranges from 20/25 to 20/80</li> <li>• Surgical intervention is not recommended</li> </ul>
2	<ul style="list-style-type: none"> <li>• Small full-thickness (&lt;400 <math>\mu\text{m}</math> in diameter) retinal defect</li> <li>• Epiretinal membranes are uncommon</li> <li>• Visual symptoms include metamorphopsia and decreased vision</li> <li>• Visual acuity 20/25 to 20/80</li> </ul>
3	<ul style="list-style-type: none"> <li>• Full-thickness hole <math>\geq 400</math> <math>\mu\text{m}</math> in diameter</li> <li>• The posterior hyaloid is separated from the macula but may remain attached at the optic disc and be attached more peripherally<sup>21</sup></li> <li>• An operculum or a flap is present on the posterior hyaloid over the hole and is visible clinically or by means of optical coherence tomography</li> <li>• A cuff of subretinal fluid may be detected along with intraretinal edema and cysts</li> <li>• Drusen-like deposits* may be occasionally seen in the base of the hole</li> <li>• A rim of retinal pigment epithelium hyper/hypopigmentation is often present at the junction between edematous or detached retina and normal-appearing attached retina in long-standing cases<sup>24</sup></li> <li>• Epiretinal membranes may be present</li> <li>• Visual acuity usually ranges from 20/100 to 20/400<sup>17,24</sup></li> </ul>
4	<ul style="list-style-type: none"> <li>• A full-thickness hole with a diameter usually larger than stage 3 (&gt;400 <math>\mu\text{m}</math> in diameter)</li> <li>• A complete posterior vitreous detachment with a Weiss ring<sup>20,23</sup></li> <li>• A cuff of subretinal fluid, intraretinal edema, and cystoid changes are usually present</li> <li>• Drusen-like deposits* may be occasionally seen in the base of the hole</li> <li>• Epiretinal membranes are more frequent<sup>25</sup></li> <li>• Visual acuity is more profoundly decreased to 20/100 to 20/400<sup>17,24</sup></li> </ul>

\* Drusen-like or yellow deposits may represent macrophages at the level of the retinal pigment epithelium, suggesting chronicity of disease.

Recent evidence provided by OCT,<sup>21,22,26-29</sup> retinal thickness analyzer,<sup>30</sup> scanning laser ophthalmoscopy,<sup>31</sup> and observations made during vitrectomy<sup>32,33</sup> suggests that vitreomacular traction or adhesion (VMA) is likely responsible for a stage 1-A hole. Some of the pseudocysts may resolve spontaneously and completely;<sup>34,35</sup> a few evolve into a lamellar or partial-thickness hole. The pseudocysts progress over a period of weeks to months to an FTMH, often passing through stage 1-B. Approximately 75% of stage 2 macular holes progress to a stage 3 or stage 4 macular hole.<sup>16,36-39</sup>

The prognosis of untreated FTMHs is poor. Only 5% will have 20/50 visual acuity or better, approximately 55% will have visual acuity of 20/100 or better, and 40% will have visual acuity of 20/200 or worse.<sup>14,17,24,40,41</sup> Sixty percent of eyes with FTMH lose 2 or more lines of vision over 5 years of follow-up.<sup>17,40</sup> After a follow-up of 3 to 5 years, 70% to 80% of eyes will have 20/200 or worse visual acuity, and the visual acuity in the remaining 20% to 30% will usually be 20/70 to 20/100.<sup>14,24,40,41</sup> In about 3% to 11% of cases, a FTMH will close spontaneously.<sup>16,17,42-44</sup> If the hole closes spontaneously, the visual acuity may recover dramatically. The vast majority of eyes with untreated macular holes deteriorates to the 20/100 to 20/400 range and then stabilizes with good peripheral vision.



## CARE PROCESS

### PATIENT OUTCOME CRITERIA

Patient outcome criteria include the following:

- ◆ Prevention of visual loss and functional impairment
- ◆ Improvement of visual function
- ◆ Maintenance or improvement of quality of life

### DIAGNOSIS

The initial evaluation of a patient with symptoms and signs suggestive of macular hole includes all features of a comprehensive adult medical eye evaluation, with particular attention to those aspects relevant to macular hole.<sup>45</sup> Conditions often mistaken for the various stages of macular hole include cystoid macular edema, central serous retinopathy, a subfoveal druse, lamellar macular hole, epiretinal membrane with pseudohole, and solar maculopathy.<sup>46-48</sup>

#### History

A complete history includes the following elements, although the exact composition varies according to the patient's particular symptomatology and specific needs.

- ◆ Duration of symptoms
- ◆ Ocular history: glaucoma, retinal detachment or tear, other eye disease, injuries, ocular surgery, or sun or eclipse gazing
- ◆ Medication use that may be related to macular cystoid edema (e.g., systemic niacin, topical prostaglandin analogues)

#### Physical Examination

Physical examination includes the following elements:

- ◆ Slit-lamp biomicroscopy of:
  - ◆ The macula and vitreoretinal interface
  - ◆ The optic disc to rule out an optic pit or advanced cupping
- ◆ An indirect peripheral retinal examination
- ◆ Amsler grid test

#### Ancillary Tests

Optical coherence tomography is extremely helpful and offers detailed information about the anatomy and size of the macular hole and the presence of vitreous traction or an epiretinal membrane. This information aids in the diagnosis, staging, and follow-up.<sup>49</sup> Optical coherence tomography images are also helpful with patient education. However, full-thickness macular holes are readily apparent with slit-lamp biomicroscopy of the fundus.

## MANAGEMENT

### Prevention and Early Detection

At this time, there is no known prevention for the development of an idiopathic macular hole. The initial evaluation should include a careful assessment of the fellow eye. Fellow eyes are at higher risk of developing a macular hole when there is not a definite posterior vitreous detachment. The early detection of a macular hole is associated with both a higher closure rate after vitrectomy surgery as well as better postoperative visual acuity, perhaps because of the smaller size of the hole and a more limited compromise of border retinal elements. For these reasons, it is important to diagnose a macular hole in the fellow eye as soon as possible. Thus, patients should be educated about warning signs such as metamorphopsia or mild decrease in central visual acuity. An OCT may also help to identify at-risk eyes, evident by the presence of vitreous traction at or near the center of the macula.

### Early Stages

Some people with stage 1-A or 1-B macular holes have foveal cysts that may resolve completely without treatment.<sup>34,35</sup> One study reported that patients with foveal cysts can remain stable with good vision for up to 5 years.<sup>16</sup> The visual acuity of patients with foveal cysts may improve when the posterior vitreous detaches from the central macula. Most patients who present with good central visual acuity can be followed and asked to return promptly if symptoms worsen.<sup>34</sup> Although stage 1-A and early stage 1-B lesions have been referred to as early or impending macular holes, only about 50% progress to an FTMH.<sup>37</sup> The vitreous attachment separates from the fovea in the other 50%, and then the appearance of the fovea either returns to normal or appears as a reddish spot. If the vitreous spontaneously detaches from the fovea, there is often a rapid improvement in visual symptoms.<sup>19,34</sup>

### Later Stages

When the macular hole progresses beyond stage 2, further vision loss will occur if the patient does not receive treatment. Moreover, as the macular hole enlarges, epiretinal membranes may develop and the success rate of hole closure may decrease.<sup>50</sup>

Table 2 delineates management recommendations for each of the stages of macular hole.

**TABLE 2 MANAGEMENT RECOMMENDATIONS FOR MACULAR HOLE**

Stage	Management	Follow-up
1-A and 1-B	Observation <sup>34</sup>	<ul style="list-style-type: none"> <li>Follow-up at 2–4 month intervals in the absence of new symptoms</li> <li>Recommend prompt return if new symptoms develop</li> <li>Encourage monocular visual acuity testing with Amsler grid</li> </ul>
2	Vitreoretinal surgery <sup>39</sup> *	<ul style="list-style-type: none"> <li>Follow-up at 1–2 days postoperatively, then 1–2 weeks</li> <li>Frequency and timing of subsequent visits varies depending on the outcome of surgery and the patient's clinical course</li> <li>If no surgery, follow up every 2–4 months</li> </ul>
2	Vitreopharmacolysis <sup>†</sup>	<ul style="list-style-type: none"> <li>Follow-up at 1 week and 4 weeks, or with new symptoms (i.e., retinal detachment symptoms)</li> </ul>
3 or 4	Vitreoretinal surgery <sup>39,43</sup>	<ul style="list-style-type: none"> <li>Follow-up at 1–2 days postoperatively, then 1–2 weeks</li> <li>Frequency and timing of subsequent visits varies depending on the outcome of surgery and the patient's clinical course</li> </ul>

\* Although surgery is usually performed, observation may also be appropriate in selected cases.

† Although ocriplasmin has been approved by the U.S. Food and Drug Administration for vitreomacular adhesion, its use for treatment of idiopathic macular hole without vitreomacular traction or adhesion would currently be considered off-label use.

## Surgical Management

### Preoperative Discussion

The preoperative discussion should include the following information:

- ◆ The usual natural history of a macular hole, if untreated, usually results in poor central visual acuity (20/200 to 20/400) with normal peripheral vision. Delays in repair may also result in a lower anatomic success rate.
- ◆ The risk of developing a macular hole in the fellow eye when the vitreous remains attached is 10% to 15%; there is a lower risk when the vitreous appears detached.
- ◆ There is a remote chance for spontaneous macular hole closure and the associated visual benefit depending on the duration and size of the macular hole.
- ◆ The possible option to use intravitreal ocriplasmin to treat a macular hole with associated VMA, as compared to vitrectomy surgery, including the detailed risks and benefits for each option.<sup>51,52</sup>

### Vitrectomy

For surgery, the discussion should include the following:

- ◆ The type of anesthesia required. (Usually, monitored anesthesia care is provided with a local anesthetic.) Macular hole surgery can be performed under general anesthesia for anxious or claustrophobic patients.
- ◆ Avoiding the use of nitrous oxide gas at least during the last 10 minutes of the air fluid exchange when general anesthesia is used because it may result in an unpredictable gas fill postoperatively.
- ◆ The risks (e.g., cataract, retinal tears) versus benefits of vitrectomy surgery.
- ◆ Instructions about the need for intraocular gas, facedown positioning postoperatively to tamponade the hole, as well as the likely development of a cataract in phakic eyes. The surgeon should inform patients who have glaucoma about the possibility of an increase in postoperative intraocular pressure (IOP). The surgeon is responsible for formulating a postoperative care plan and should inform the patient of these arrangements.<sup>51,52</sup>

### Detaching the Posterior Vitreous

An important anatomic goal of the pars plana vitrectomy is to separate the posterior cortical hyaloid from the retinal surface. Triamcinolone acetonide can be injected into the vitreous following a core vitrectomy to highlight the posterior vitreous. Various surgeons have individual preferences or techniques to accomplish the surgical objectives. Retina breaks may develop in eyes with macular holes, and this is believed to be due to the creation of a posterior vitreous detachment.<sup>53</sup> Thus, an examination of the peripheral retina for breaks or tears should be performed prior to every air-fluid exchange.

Retinal tamponade may be created using different agents at the conclusion of macular hole surgery to achieve anatomic closure of the macular hole. Tamponade options include the use of air (days), SF<sub>6</sub> (2 to 4 weeks), C<sub>3</sub>F<sub>8</sub> (1 to 3 months), or silicone oil (long term). Two early studies found that better results were achieved by using C<sub>3</sub>F<sub>8</sub> gas when compared with SF<sub>6</sub> gas.<sup>54,55</sup> A later study found no difference in results.<sup>56</sup> A recent study found a 98% rate of closure using SF<sub>6</sub> gas.<sup>57</sup> High closure rates have been reported when air tamponade and internal limiting membrane (ILM) peeling are used.<sup>58</sup> Most patients with gas tamponade are generally instructed to remain prone, facedown, during the immediate postoperative period. In general, there is no consensus about the best choice of tamponade agent.

Silicone oil may be used for patients who cannot position facedown.<sup>59,60</sup> In one study, 86% of 40 holes were closed using silicone oil;<sup>59</sup> however, these same investigators later concluded that the anatomic and visual results are better with gas tamponade.<sup>61</sup> Using silicone oil also requires a second operation to remove oil. The optimal duration of facedown is also debated. The consensus is that 1 week of facedown positioning is optimal, whereas some surgeons advocate less or even none.<sup>62</sup> Some studies have monitored the status of macular hole closure by means of early postoperative OCT (through the gas-filled vitreous cavity) and used that information to curtail positioning.<sup>63,64</sup>

### Internal Limiting Membrane Removal and Dyes

Another unsettled controversy is the value of removing the ILM during surgery. The ILM may act as a scaffold for cellular proliferation or attachment of contractile tissue elements that may cause persistent vitreomacular traction. Thus, failure of the original surgery or late reopening of initially successfully closed holes may occur without removal of the ILM.<sup>65</sup> On the other hand, loss of its structural role or secondary collateral nerve fiber layer loss during removal may be detrimental.

Table 3 summarizes three large case series and two randomized controlled trials (RCTs) that compared macular hole closure rates following vitrectomies when the ILM was either peeled or not peeled. Margherio et al found little difference with ILM removal,<sup>66</sup> while Tognetto et al found statistical evidence that ILM peeling is associated with higher rates of macular hole closure.<sup>67</sup> Brooks et al reported an 18% difference in favor of ILM peeling with a statistically significant difference in visual acuity between the peeling and non-peeling groups.<sup>58</sup> Interestingly, they noted a rather high rate (25%) of macular holes reopening in the non-peeled eyes compared with no reopening in ILM peeled macular holes.<sup>58</sup> Lastly, Christensen et al presented outcome data that macular holes were much less likely to reopen if the ILM was peeled during the initial surgery.<sup>68</sup> Both the Christensen et al and Lois et al RCTs reported a greater difference in hole closure rates in favor of ILM peeling.<sup>68,69</sup> However, these RCTs were small and subject to some potential biases.

A recent Cochrane review that included the studies listed in Table 3 concluded that ILM peeling in the treatment of idiopathic full-thickness macular hole (FTMH) is associated with higher rates of macular hole closure.<sup>70</sup> Both the Cochrane review and an individual patient data meta-analysis found that ILM peeling achieves higher anatomical success with a reduced need for additional surgical interventions when compared to non-peeling in treating patients at stages 2, 3, and 4.<sup>70,71</sup>

A cost-effectiveness analysis was also performed alongside a RCT and concluded that ILM treatment is a cost-effective treatment of FTMH compared with no-peeling technique over a 6-month period and was based on the higher number of reoperations required in the no-peel arm of the trial.<sup>72</sup>

**TABLE 3 MACULAR HOLE SURGICAL OUTCOMES – NO PEEL VS. PEEL OF ILM**

Study (Author, Year)	ILM Peeled/Not	% Macular Holes Closed
Margherio et al, <sup>66</sup> 2000	No peel; n=59	92%
	Perifoveal tissue dissection; n=48	86%
Tognetto et al, <sup>67</sup> 2006	No peel; n=527	89%
	Peel; n=1100	94%
Brooks, <sup>58</sup> 2000	No peel; n=46	82% no peel (25 reopened)
	Peel; n=116	100% (no reopening)
Christensen et al, <sup>68</sup> 2009	No peel; n=25	44%
	Peel with ICG; n=34	94%
	Peel with TB; n=18	89%
Lois et al, <sup>69</sup> 2011	No peel; n=64	48%
	Peel; n=67	84%

ICG = indocyanine green; ILM = internal limiting membrane; TB = trypan blue

Indocyanine green (ICG), trypan blue (TP), brilliant blue (BB), and other dyes, as well as triamcinolone acetonide (TA), have been reported to optimize visualization of the ILM during surgery.<sup>73-77</sup> When ICG was used initially, reports of visual field defects and retinal pigment epithelium abnormalities in the foveal center raised concerns for possible toxicity.<sup>78,79</sup> Subsequent studies have suggested either a slight decrease in postoperative

visual acuity using ICG compared with using no dye, or no difference between the various dyes.<sup>74,75,77,79-85</sup> A meta-analysis concluded that there is no difference in the rate of macular hole closure between eyes with ILMs that were peeled without dye or with use of ICG or BB. The authors found a slight decrease in visual acuity outcomes using ICG for ILM peeling during the first postoperative year; however, there was no difference thereafter and no difference even during the first year when a concentration of  $\leq 0.05\%$  ICG was used.<sup>5</sup> A recent retrospective study of 351 patients found that the closure rate of ICG-assisted ILM peels (73.2%) was statistically lower than the closure rate using BB.<sup>86</sup> Unfortunately, there has not been a large randomized trial comparing dyes in ILM peeling. Triamcinolone acetonide has been safely used for visualization of residual vitreous to facilitate removal of the ILM with good results and low concerns for toxicity.<sup>73,77</sup>

Importantly, when the surgeon prefers ICG to stain the ILM, the lowest possible concentration of ICG should be used. And, in summary, definitive recommendations about the use of specific dyes to peel the ILM in macular hole surgery simply do not exist in the literature.

### **Positioning**

In the early days of macular hole surgery, patients were instructed to maintain a facedown position for 10 to 14 days postoperatively to optimize macular hole closure. Postoperative prone positioning is uncomfortable. In some cases, positioning may be extremely difficult or even impossible due to neck, back, or body habitus constraints. Recent studies have reported excellent results using facedown positioning for 1 to 3 days.<sup>57,87,88</sup> Surgeons have reported closure rates with no facedown positioning that are similar to the rates seen in series requiring longer facedown positioning.<sup>62,89-94</sup> In all of these studies, however, the patient was told to avoid the face-up or supine positioning. Specifically, recommendations were for an upright position that avoided the head tilting back.<sup>92,94</sup>

Therefore, there is no clear consensus regarding duration of facedown positioning to seal macular holes following vitrectomy surgery, but longer positioning may be required for holes larger than 400  $\mu\text{m}$  or those with inadequate tamponade.<sup>92</sup>

### **Outcomes of Surgery**

Two multicenter randomized controlled trials provide evidence for the efficacy of surgery compared with observation for FTMH.<sup>39,43</sup> One study of patients with stage 3 and stage 4 macular holes reported a benefit from vitrectomy surgery in the closure rate and final visual acuity.<sup>43</sup> However, results with stage 2 macular holes did not demonstrate a similar benefit.<sup>39</sup> Nevertheless, the consensus of the vitreoretinal community is to recommend surgery for a stage 2 macular hole, not only because the visual acuity results are good with surgery but also to minimize further visual loss that accompanies progression to a stage 3 or stage 4 macular hole.

However, 60% of early or stage 1 macular holes may not progress to more advanced stages. Therefore, cautious observation is recommended.<sup>34</sup> With OCT imaging, the physician is able to monitor the progress of early-stage macular holes and make appropriate treatment recommendations.

Surgical studies in the last 5 years have reported closure rates of 91% to 98%.<sup>57,80,87,94</sup> Most articles have reported that the median postoperative visual acuity of sealed macular holes is approximately 20/40,<sup>57,74,80,87,94-97</sup> clearly better than the visual acuity of untreated macular holes.<sup>14,17,24,40,41</sup>

### **Predictors of Visual Results**

In case series, many authors have reported better closure rates and better final visual acuities when the duration of symptoms is less than 6 months.<sup>98-102</sup> Findings from case series indicate that a macular hole that has been present for more than 2 to 3 years may be closed, yet the success rate is lower (63%) and visual acuity outcomes are worse than for a macular hole of shorter duration.<sup>58,98,103-108</sup>

Patients whose macular holes fail to seal after the first surgery usually have a less favorable visual acuity outcome when compared with primary closure. Two studies have shown that up to 70% of the holes seal following additional surgery but have an improvement of only one line in visual acuity and an approximate visual acuity of 20/100.<sup>109,110</sup> On the other

hand, patients whose macular holes closed following successful initial surgery, but then later reopened, did better. A study reported that 21 holes were closed with additional surgery and the mean visual acuity after this additional surgery was 20/45.<sup>109</sup>

## **Complications of Vitrectomy**

### ***Cataract***

The vast majority of phakic eyes in adults develop cataracts after macular hole surgery. Clinically significant cataract develops in over 80% of phakic eyes within the first few years after pars plana vitrectomy<sup>111,112</sup> One study found that the median time to cataract surgery postvitrectomy was 14 months and that 98% of eyes needed cataract surgery during a mean of 91 months after vitrectomy.<sup>113</sup> One study showed a high rate of closed macular holes reopening after cataract surgery and that the development of cystoid macular edema after surgery increased the risk by sevenfold.<sup>114</sup> Given the rate of cataract formation and risk of reopening of the macular hole, some surgeons advocate combining macular hole surgery with phacoemulsification and placement of an intraocular lens.<sup>62,114-116</sup> A combined procedure eliminates the need for two operations and may allow for a more complete gas fill.<sup>62,114,115</sup> The potential complications of combining cataract surgery with vitrectomy include hypotony, intraocular lens-iris capture, and possibly an increased risk of macular edema in some patients. Up to 10% of successfully closed macular holes later reopen, although the risk might be less when the ILM is peeled during the vitrectomy to close the hole.<sup>18,113,117-122</sup>

### ***Retinal Tears***

Intraoperative retinal tears have been reported in 3% to 17% of macular hole operations, and most occur inferiorly.<sup>120,123-126</sup>

### ***Retinal Detachment***

Although postoperative retinal detachment has been reported to be as high as 14% of cases, most series report an incidence of 1% to 5%.<sup>62,66,74,120,123,124,127</sup> The detachment is typically located inferiorly and caused by small flap tears at the posterior vitreous base. Fortunately, most detachments can be repaired without reopening of the hole.<sup>126</sup>

### ***Visual Field Loss***

In the past, up to 20% of patients were noted to have a permanent temporal visual field loss after macular hole surgery.<sup>128-132</sup> Most believe that this field loss is caused by either mechanical injury (such as trauma to the peripapillary retinal vasculature or nerve fiber layer<sup>131</sup>) or dehydration damage to the retina as a result of air streaming from the temporally placed infusion cannula during the air-fluid exchange.<sup>133</sup> It is unknown whether the following recommendations have reduced the incidence of visual field loss: surgeon awareness to minimize prolonged air flow at high pressure, secure closure of the sclerotomies to minimize air flow through the eye during the air-fluid exchange, leaving a puddle of fluid posteriorly until the final aspiration,<sup>134</sup> humidifying the air,<sup>135</sup> or using a low infusion pressure during air-fluid exchange.<sup>136,137</sup> In addition, it is possible that the air flow through the vitreous cavity is decreased in small gauge vitrectomy.

### ***Endophthalmitis***

Endophthalmitis has been reported in less than 0.05% of vitrectomies, including those performed for macular holes.<sup>120,121</sup>

### ***Gas-related Complications***

Patients who have retinal tamponade achieved by an intravitreal gas bubble must avoid air travel. Physicians should also discuss the implications of travel to higher altitudes. For example, driving to or ascending to a higher altitude in some regions may result in gas expansion, increased IOP, and related intraocular complications. Therefore, patients must be informed about the implications of such travel for the postoperative gas-filled eye. Bubble expansion at higher altitude causes increased IOP that could risk arterial occlusion, wound dehiscence, gas leakage, or other IOP-related injury.<sup>138</sup> Most surgeons require their patients to wear a wristband warning alert that states that the wearer's eye contains intraocular gas and that anesthetic (e.g., nitrous oxide) should be avoided, since it may result in a dangerous rise in IOP.

### **Follow-up Evaluation after Surgery**

Patients who have surgery are usually examined on postoperative day 1 or 2 and again approximately 1 to 2 weeks following surgery. The frequency and timing of subsequent postoperative visits varies, depending on the outcome of surgery and the patient's symptoms. Components of the follow-up visit should include the following:

- ◆ Interval history, including new symptoms
- ◆ Measurement of IOP
- ◆ Visual acuity measurement
- ◆ Slit-lamp biomicroscopy of the anterior chamber and central retina, and indirect binocular ophthalmoscopy of the peripheral retina
- ◆ Optical coherence tomography to document the postoperative macular anatomy when indicated

### **Vitreopharmacolysis**

#### ***Ocriplasmin***

Ocriplasmin is a recombinant protease that was approved by the FDA in 2012 for enzymatic dissection of the vitreous from the retinal surface. Approval by the FDA was based on the results of a randomized study.<sup>139</sup> The study's inclusion criteria encompassed all eyes with vitreous traction on the macula, including a subset of eyes with stage 2 macular holes. In this subset, the closure rate of macular holes was 40% when the protease was used compared with 10% when the macular holes were injected with an intravitreal saline placebo.<sup>139</sup> The FDA approved the use of intravitreal ocriplasmin for VMA, although the use of ocriplasmin for the treatment of macular hole alone (without VMA) would still be considered off-label. On average, stage 2 macular holes have a 90% chance of closure when vitrectomy techniques are used.<sup>57,87,88,92</sup>

#### ***Complications of Ocriplasmin***

There are postmarket concerns regarding the safety of ocriplasmin. Acute vision loss, electroretinographic abnormalities, macular detachment, and dyschromatopsia have been described.<sup>139</sup> The benefits and risks associated with vitrectomy surgery versus intravitreal ocriplasmin require continued investigation. In addition, there are no long-term data on the efficacy or possible toxicity of ocriplasmin. At the time of this publication, there is a large postmarket study that will better define the safety profile of this agent.

The reported complications associated with ocriplasmin are as follows:

- ◆ Retinal tears
- ◆ Floaters (usually due to progression of the PVD)
- ◆ Blue-yellow vision, dyschromatopsia or dark vision
- ◆ Photopsias
- ◆ Visual field abnormalities
- ◆ Electroretinography changes
- ◆ Weakening of zonular fibers and possible lens subluxation

## PROVIDER AND SETTING

Diagnosis and management of macular hole requires expertise, skills, and specialized equipment to detect alterations in the retina and then select, perform, and/or monitor the appropriate treatment regimen. Referral to an ophthalmologist who has expertise and experience in managing this condition is recommended. The performance of certain diagnostic procedures is often delegated to appropriately trained and supervised personnel. However, the interpretation of the results of the diagnostic procedures, as well as the medical and surgical management of a macular hole, require medical training, clinical judgment, and experience.

## COUNSELING AND REFERRAL

Patients should be informed to notify their ophthalmologist promptly when they have symptoms such as an increase in floaters, a loss of visual field, metamorphopsia, or a decrease in visual acuity.<sup>140-142</sup> The goal of vision rehabilitation is to restore functional ability.<sup>143</sup> Patients with function-limiting postoperative visual impairment should be referred for vision rehabilitation and social services.<sup>137,144</sup> More information on vision rehabilitation, including materials for patients, is available at [www.aao.org/smartsight](http://www.aao.org/smartsight).

## SOCIOECONOMIC CONSIDERATIONS

The economic considerations related to treatment and management of idiopathic macular hole have not been comprehensively studied. Measures of patient satisfaction after surgery correlate with the visual and anatomic results.<sup>145-147</sup> Vision-related quality of life, assessed by the National Eye Institute Visual Function Questionnaire 25, has been reported to improve following surgery for idiopathic macular hole.<sup>145</sup> Research to explore the costs and risks associated with the use of ocriplasmin in this population (relative to the costs and risks of vitrectomy surgery) is ongoing.



# APPENDIX 1. QUALITY OF OPHTHALMIC CARE CORE CRITERIA

*Providing quality care  
is the physician's foremost ethical obligation, and is  
the basis of public trust in physicians.  
AMA Board of Trustees, 1986*

Quality ophthalmic care is provided in a manner and with the skill that is consistent with the best interests of the patient. The discussion that follows characterizes the core elements of such care.

The ophthalmologist is first and foremost a physician. As such, the ophthalmologist demonstrates compassion and concern for the individual, and utilizes the science and art of medicine to help alleviate patient fear and suffering. The ophthalmologist strives to develop and maintain clinical skills at the highest feasible level, consistent with the needs of patients, through training and continuing education. The ophthalmologist evaluates those skills and medical knowledge in relation to the needs of the patient and responds accordingly. The ophthalmologist also ensures that needy patients receive necessary care directly or through referral to appropriate persons and facilities that will provide such care, and he or she supports activities that promote health and prevent disease and disability.

The ophthalmologist recognizes that disease places patients in a disadvantaged, dependent state. The ophthalmologist respects the dignity and integrity of his or her patients and does not exploit their vulnerability.

Quality ophthalmic care has the following optimal attributes, among others.

- ◆ The essence of quality care is a meaningful partnership relationship between patient and physician. The ophthalmologist strives to communicate effectively with his or her patients, listening carefully to their needs and concerns. In turn, the ophthalmologist educates his or her patients about the nature and prognosis of their condition and about proper and appropriate therapeutic modalities. This is to ensure their meaningful participation (appropriate to their unique physical, intellectual, and emotional state) in decisions affecting their management and care, to improve their motivation and compliance with the agreed plan of treatment, and to help alleviate their fears and concerns.
- ◆ The ophthalmologist uses his or her best judgment in choosing and timing appropriate diagnostic and therapeutic modalities as well as the frequency of evaluation and follow-up, with due regard to the urgency and nature of the patient's condition and unique needs and desires.
- ◆ The ophthalmologist carries out only those procedures for which he or she is adequately trained, experienced, and competent, or, when necessary, is assisted by someone who is, depending on the urgency of the problem and availability and accessibility of alternative providers.
- ◆ Patients are assured access to, and continuity of, needed and appropriate ophthalmic care, which can be described as follows.
  - ◆ The ophthalmologist treats patients with due regard to timeliness, appropriateness, and his or her own ability to provide such care.
  - ◆ The operating ophthalmologist makes adequate provision for appropriate pre- and postoperative patient care.
  - ◆ When the ophthalmologist is unavailable for his or her patient, he or she provides appropriate alternate ophthalmic care, with adequate mechanisms for informing patients of the existence of such care and procedures for obtaining it.
  - ◆ The ophthalmologist refers patients to other ophthalmologists and eye care providers based on the timeliness and appropriateness of such referral, the patient's needs, the competence and qualifications of the person to whom the referral is made, and access and availability.

**Idiopathic Macular Hole PPP:  
Appendix 1. Quality of Ophthalmic Care Core Criteria**

- ◆ The ophthalmologist seeks appropriate consultation with due regard to the nature of the ocular or other medical or surgical problem. Consultants are suggested for their skill, competence, and accessibility. They receive as complete and accurate an accounting of the problem as necessary to provide efficient and effective advice or intervention, and in turn they respond in an adequate and timely manner. The ophthalmologist maintains complete and accurate medical records.
- ◆ On appropriate request, the ophthalmologist provides a full and accurate rendering of the patient's records in his or her possession.
- ◆ The ophthalmologist reviews the results of consultations and laboratory tests in a timely and effective manner and takes appropriate actions.
- ◆ The ophthalmologist and those who assist in providing care identify themselves and their profession.
- ◆ For patients whose conditions fail to respond to treatment and for whom further treatment is unavailable, the ophthalmologist provides proper professional support, counseling, rehabilitative and social services, and referral as appropriate and accessible.
- ◆ Prior to therapeutic or invasive diagnostic procedures, the ophthalmologist becomes appropriately conversant with the patient's condition by collecting pertinent historical information and performing relevant preoperative examinations. Additionally, he or she enables the patient to reach a fully informed decision by providing an accurate and truthful explanation of the diagnosis; the nature, purpose, risks, benefits, and probability of success of the proposed treatment and of alternative treatment; and the risks and benefits of no treatment.
- ◆ The ophthalmologist adopts new technology (e.g., drugs, devices, surgical techniques) in judicious fashion, appropriate to the cost and potential benefit relative to existing alternatives and to its demonstrated safety and efficacy.
- ◆ The ophthalmologist enhances the quality of care he or she provides by periodically reviewing and assessing his or her personal performance in relation to established standards, and by revising or altering his or her practices and techniques appropriately.
- ◆ The ophthalmologist improves ophthalmic care by communicating to colleagues, through appropriate professional channels, knowledge gained through clinical research and practice. This includes alerting colleagues of instances of unusual or unexpected rates of complications and problems related to new drugs, devices, or procedures.
- ◆ The ophthalmologist provides care in suitably staffed and equipped facilities adequate to deal with potential ocular and systemic complications requiring immediate attention.
- ◆ The ophthalmologist also provides ophthalmic care in a manner that is cost effective without unacceptably compromising accepted standards of quality.

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## APPENDIX 2. PREFERRED PRACTICE PATTERN RECOMMENDATION GRADING

The grades herein report the SIGN grade associated with the included studies supporting each recommendation (I++; I+; I-; II++; II+; II-; III), the GRADE evaluation of the body of evidence (Good, Moderate, Insufficient), and the GRADE assessment of the strength of the recommendation (Strong, Discretionary). Details of these grading systems are reported in the Methods and Key to Ratings section.

### Highlighted Findings and Recommendations for Care

Page 4: People with vitreous traction and no macular hole (stage 1-A or 1-B) should be observed, as they often remain stable or even improve. Currently, there is no evidence that treatment improves the prognosis: I+; Good; Strong

Page 4: An ophthalmologist should discuss treatment options that include the opportunity for stage 2–4 macular hole closure and the associated visual benefits: III; Good; Strong

Page 4: Cataract is a frequent complication of vitrectomy surgery to repair macular holes. This risk should be discussed with patients preoperatively, and postoperative monitoring is advised: III; Good; Strong

### Care Process

Page 7: The initial evaluation of a patient with symptoms and signs suggestive of macular hole includes all features of a comprehensive adult medical eye evaluation, with particular attention to those aspects relevant to macular hole: II++; Good; Strong

Page 7: A complete history includes duration and location of symptoms: III; Good; Discretionary

Page 7: A complete history includes ocular history: III; Good; Discretionary

Page 7: A complete history includes medication use that may be related to macular cysts: III; Good; Discretionary

Page 7: Physical examination includes slit-lamp biomicroscopy of the macula and vitreoretinal interface, and the optic disc to rule out an optic pit or advanced cupping: III; Good; Strong

Page 7: Physical examination includes and indirect peripheral retinal examination: III; Good; Strong

Page 7: Physical examination includes Amsler grid test: III; Good; Strong

Page 7: Optical coherence tomography offers detailed information about the anatomy and size of the macular hole and the presence of vitreous traction or an epiretinal membrane, all of which aid in the diagnosis, staging and follow-up: III; Moderate; Discretionary

Page 8: The initial evaluation should include a careful assessment of the fellow eye: III; Good; Strong

Page 8: It is important to diagnose a macular hole in the fellow eye as soon as possible, and patients should be educated about warning signs such as metamorphosia or mild decreases in central visual acuity: III; Good; Strong

Page 8: An OCT may also help to identify at risk eyes evident by vitreous traction at or near the center of the macula: III; Insufficient; Discretionary.

Page 8: In most cases presenting with good central visual acuity, patients with Stage 1-A or 1-B macular holes can be followed and asked to return promptly should symptoms worsen: I+; Good; Strong

**Idiopathic Macular Hole PPP:  
Appendix 2. PPP Recommendation Grading**

Page 8: Patients with Stage 1 holes should be followed and asked to return promptly if their symptoms worsen: III; Good; Strong

Page 8: Table 2: Management recommendation for stage 1-A or 1-B macular holes: Observation: III; Good; Strong

Page 8: Table 2: Follow-up recommendation for stage 1-A or 1-B macular holes: Follow-up at 2–4 month intervals in the absence of new symptoms: III; Good; Discretionary

Page 8: Table 2: Follow-up recommendation for stage 1-A or 1-B macular holes: Recommend prompt return if new symptoms develop: III; Good; Strong

Page 8: Table 2: Follow-up recommendation for Stage 1-A or 1-B macular holes: Encourage monocular visual acuity testing with Amsler grid: III; Good; Strong

Page 8: Table 2: Management recommendation for stage 2 macular holes: Vitreoretinal surgery: I++; Good; Strong

Page 8: Table 2: Follow-up recommendation for stage 2 macular holes treated by vitreoretinal surgery: 1–2 days postoperatively, then 1–2 weeks: III; Good; Strong

Page 8: Table 2: Follow-up recommendation for stage 2 macular holes treated by vitreoretinal surgery: Frequency and timing of subsequent visits varies depending on the outcome of surgery and the patient's clinical course: III; Good; Discretionary

Page 8: Table 2: Follow-up recommendation for stage 2 macular holes: If no surgery, every 2–4 months: III; Good; Discretionary

Page 8: Table 2: Management recommendation for stage 2 macular holes: Vitreopharmacolysis: III; Insufficient; Discretionary

Page 8: Table 2: Follow-up recommendation for stage 2 macular holes treated by vitreopharmacolysis: 1 week and 4 weeks, or with new symptoms: III; Good; Discretionary

Page 8: Table 2: Management recommendation for stage 3–4 macular holes: Vitreoretinal surgery: I++; Good; Strong

Page 8: Table 2: Follow-up recommendation for Stage 3–4 macular holes treated by vitreoretinal surgery: 1–2 days postoperatively, then 1–2 weeks: III; Good; Discretionary

Page 8: Table 2: Follow-up recommendation for Stage 3–4 macular holes treated by vitreoretinal surgery: Frequency and timing of subsequent visits varies depending on the outcome of surgery and the patient's clinical course: III; Good; Discretionary

Page 9: The preoperative discussion should include the usual natural history of a macular hole, if untreated: III; Good; Strong

Page 9: The preoperative discussion should include the 10% to 15% risk of developing a macular hole in the fellow eye, especially when the vitreous remains attached or a lower risk when the vitreous appears detached: III; Good; Strong

Page 9: The preoperative discussion should include the duration and size of the macular hole, and help facilitate a discussion of the chance for spontaneous macular hole closure and the associated visual benefit: III; Good; Strong

Page 9: The preoperative discussion should include the suitability of intravitreal ocriplasmin for a macular hole with associated VMA as compared to vitrectomy surgery, including the risks and benefits of each option: III; Insufficient; Discretionary

**Idiopathic Macular Hole PPP:  
Appendix 2. PPP Recommendation Grading**

Page 9: For surgery, the discussion should include the type of anesthesia required (usually monitored anesthesia care with a local anesthetic): III; Good; Strong

Page 9: Nitrous oxide gas should be avoided during the last 10 minutes of the air fluid exchange when using general anesthesia because it may result in an unpredictable gas fill postoperatively: III; Good; Strong

Page 9: For surgery, the discussion should include the risks (e.g., cataract, retinal tears) versus benefits of vitrectomy surgery: III; Good; Strong

Page 9: The surgeon should instruct the patient about the need for intraocular gas, facedown positioning postoperatively to tamponade the hole, as well as the likely development of a cataract in phakic eyes: III; Good; Strong

Page 9: Patients with glaucoma should be informed of the possibility of an increase in postoperative IOP: III; Good; Strong

Page 9: The surgeon is responsible for formulating a postoperative care plan and should inform the patient of these arrangements: III; Good; Strong

Page 9: Retinal tamponade may be created using different agents at the conclusion of macular hole surgery in order to achieve anatomic closure of the macular hole: III; Moderate; Discretionary

Page 9: Tamponade options include the use of air (days), SF<sub>6</sub> (2 to 4 weeks), C<sub>3</sub>F<sub>8</sub> (1 to 3 months), or silicone oil (long-term): II-; Moderate; Discretionary

Page 9: Silicone oil may be used for patients who cannot position facedown: II-; Moderate; Discretionary

Page 9: Using silicone oil also requires a second operation for oil removal: III; Good; Strong

Page 10: Evidence from studies suggests a beneficial outcome with ILM peeling in macular hole surgery: I-; Moderate; Discretionary

Page 11: When the surgeon prefers ICG to stain the ILM, the lowest possible concentration of ICG should be used: III; Good; Strong

Page 11: There is no clear consensus regarding duration of facedown positioning to seal macular holes following vitrectomy surgery. Longer positioning may be required for holes larger than 400 μm or those with inadequate tamponade: I+; Good; Discretionary

Page 11: The consensus of the vitreoretinal community is to recommend surgery for a stage 2 macular hole, not only because the visual acuity results are good with surgery, but also to minimize further visual loss that occurs with progression to a stage 3 or stage 4 macular hole: I++; Good; Strong

Page 11: Cautious observation of stage 1 macular holes is recommended: I+; Good; Strong

Page 11: With OCT imaging, the physician can monitor the progress of early-stage macular holes and make appropriate treatment recommendations: III; Good; Discretionary

Page 12: With the high rate of cataract formation and risk of reopening of the macular hole, some surgeons advocate combining macular hole surgery with phacoemulsification and placement of an intraocular lens: III; Moderate; Discretionary

Page 12: It is unknown whether surgeon awareness to minimize prolonged air flow at high pressure has reduced the incidence of visual field loss after macular hole surgery: III; Insufficient; Discretionary

Page 12: It is unknown whether secure closure of the sclerotomies to minimize air flow through the eye during the air-fluid exchange has reduced the incidence of visual field loss after macular hole surgery: III; Insufficient; Discretionary

**Idiopathic Macular Hole PPP:  
Appendix 2. PPP Recommendation Grading**

Page 12: It is unknown whether leaving a puddle of fluid posteriorly until the final aspiration has reduced the incidence of visual field loss after macular hole surgery: II-; Insufficient; Discretionary

Page 12: It is unknown whether humidifying the air has reduced the incidence of visual field loss after macular hole surgery: II-; Insufficient; Discretionary

Page 12: It is unknown whether using a low infusion pressure during air-fluid exchange has reduced the incidence of visual field loss after macular hole surgery: II-; Insufficient; Discretionary

Page 12: Patients who have retinal tamponade achieved by an intravitreal gas bubble must avoid air travel: III; Good; Strong

Page 12: Physicians should also discuss the implications of travel to higher altitudes. Patients must be informed about the implications of such travel for the postoperative gas-filled eye: III; Good; Strong

Page 12: Most surgeons require their patients to wear a wristband warning alert that states that the eye contains intraocular gas and anesthetic such as nitrous oxide should be avoided and may result in a dangerous rise in IOP: III; Good; Discretionary

Page 13: Patients who have surgery are usually examined on postoperative day 1 or 2 and again approximately 1–2 weeks following surgery. The frequency and timing of subsequent postoperative visits varies, depending on the outcome of surgery and the patient's symptoms: III; Good; Discretionary

Page 13: The follow-up visit should include interval history, including new symptoms: III; Good; Strong

Page 13: The follow-up visit should include measurement of IOP: III; Good; Strong

Page 13: The follow-up visit should include measuring visual acuity: III; Good; Strong

Page 13: The follow-up visit should include slit-lamp biomicroscopy of the anterior chamber and central retina, and indirect binocular ophthalmoscopy of the peripheral retina: III; Good; Strong

Page 13: The follow-up visit should include OCT to document the postoperative macular anatomy: III; Good; Strong

Page 13: Referral to an ophthalmologist who has expertise or experience in managing macular holes is recommended: III; Good; Strong

Page 13: The performance of certain diagnostic procedures is often delegated to appropriately trained and supervised personnel. However, the interpretation of the results of the diagnostic procedures, as well as the medical and surgical management of a macular hole, requires the medical training, clinical judgment, and experience of an ophthalmologist: III; Good; Strong

Page 14: Patients should be informed to notify their ophthalmologist promptly when they have symptoms such as an increase in floaters, a loss of visual field, metamorphopsia, or a decrease in visual acuity: III; Good; Strong

Page 14: Patients with function-limiting postoperative visual impairment should be referred for vision rehabilitation and social services: II++; Good; Strong



## SUMMARY BENCHMARKS

### Idiopathic Macular Hole (Initial Evaluation and Therapy)

#### Initial Exam History (Key elements)

- Duration of symptoms
- Ocular history: glaucoma, retinal detachment or tear, other prior eye diseases or injuries, ocular surgery, or prolonged sun or eclipse gazing
- Medications that may be related to macular cystoid edema

#### Initial Physical Exam (Key elements)

- Visual acuity
- Slit-lamp biomicroscopic examination of the macula and the vitreoretinal interface, and the optic disc
- Indirect peripheral retinal examination

#### Management Recommendations for Macular Hole

Stage	Management	Follow-up
1-A and 1-B	Observation	Follow-up at 2–4 month intervals in the absence of new symptoms Recommend prompt return if new symptoms develop Encourage monocular visual acuity testing with Amsler grid
2	Vitreoretinal surgery*	Follow-up at 1–2 days postoperatively, then 1–2 weeks Frequency and timing of subsequent visits varies depending on the outcome of surgery and the patient's clinical course If no surgery, follow up every 2–4 months
2	Vitreopharmacolysis†	Follow-up at 1 week and 4 weeks, or with new symptoms (i.e., retinal detachment symptoms)
3 or 4	Vitreoretinal surgery	Follow-up at 1–2 days postoperatively, then 1–2 weeks Frequency and timing of subsequent visits varies depending on the outcome of surgery and the patient's clinical course

\* Although surgery is usually performed, observation may also be appropriate in selected cases.

† Although ocriplasmin has been approved by the U.S. Food and Drug Administration for vitreomacular adhesion, its use for treatment of idiopathic macular hole without vitreomacular traction or adhesion would currently be considered off-label use.

#### Surgical and Postoperative Care if Patient Receives Treatment

- Inform the patient about relative risks, benefits, and alternatives to surgery, and the need for use of expansile intraocular gas or facedown positioning postoperatively
- Formulate a postoperative care plan and inform the patient of these arrangements
- Inform patients with glaucoma of possible postoperative increase in IOP
- Examine postoperatively within 1 or 2 days and again 1 to 2 weeks after surgery

#### Patient Education

- Inform patients to notify their ophthalmologist promptly if they have symptoms such as an increase in floaters, a loss of visual field, metamorphopsia, or a decrease in visual acuity
- Inform patients that air travel, travel to high altitudes, or general anesthesia with nitrous oxide should be avoided until the gas tamponade is nearly completely gone
- Inform patients who have had a macular hole in one eye that they have a 10% to 15% chance of macular hole formation in the fellow eye, especially if the vitreous remains attached
- Refer patients with functionally limiting postoperative visual impairment for vision rehabilitation (see [www.aao.org/smartsight](http://www.aao.org/smartsight)) and social services



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Retina Informed Consent Video Collection (2013)

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**Idiopathic Macular Hole PPP:  
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