

## Ophthalmic Anesthesia Liability

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### DISCLAIMER

*Recommendations presented here should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. The ultimate judgment regarding the propriety of any specific procedure or treatment must be made by the ophthalmic in light of the individual circumstances presented by the patient. This information is intended solely to provide risk management recommendations. It is not intended to constitute legal advice and should not be relied upon as a source for legal advice. If legal advice is desired or needed, an attorney should be consulted. This information is not intended to be a modification of the terms and conditions of your OMIC policy of insurance. Please refer to your OMIC policy for these terms and conditions.*

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Ocular anesthesia is challenging for both the ophthalmologist and the anesthesiologist. Special concerns include patient anxiety about decreased vision, eye surgery, and pain or movement during eye surgery; multiple medical co-morbidities, especially in elderly patients; pediatric patients, some premature with congenital syndromes; limited access to the patient and need for immobility during surgery; problems with intraocular pressure and anesthetic agents; and oculocardiac reflexes.<sup>1,2</sup>

OMIC conducted a review of claims and lawsuits related to anesthesia and sedation in order to identify issues that can be modified through proactive risk management. When patients sue physicians for medical malpractice, the entire process of care is scrutinized. Attention to the following aspects of care will promote patient safety and reduce the ophthalmologist's professional liability exposure.

- Indications for surgery
- Even if the anesthesia complication is disclosed during the informed consent process, promptly recognized, and properly managed, it will be difficult to defend the physician if the surgery is deemed medically unnecessary.
- Conduct and disclose a risk/benefit analysis for the surgery, and document the decision-making process.
  - Clarify why surgical intervention is indicated, especially in patients who are (functionally) monocular, or those with glaucoma or pterygium.
  - Ascertain the impact of cataracts and other ocular conditions on activities of daily living, and document both subjective comments and objective data such as near and distant VA, glare, etc.

<sup>1</sup> Stead SW and Bell, SB, Focal Points: Ocular Anesthesia, The Foundation of the American Academy of Ophthalmology, March 2001: Vol. XIX, No. 3.

<sup>2</sup> Tables based upon information provided in Stead SW and Bell, SB, Focal Points: Ocular Anesthesia, The Foundation of the American Academy of Ophthalmology, March 2001: Vol. XIX, No. 3; Anesthesia Alternatives for Ocular Surgery, American Academy of Ophthalmology, 2001.

- Determine, disclose, and document reasons for choice of which eye to treat first in patients with bilateral disease.
- Medical comorbidities
- Carefully screen patients for medical comorbidities, such as those that increase the potential for:
  - Bleeding (hemophilia, hypertension, and conditions requiring anticoagulant therapy)
  - Cardiovascular events
  - Floppy iris syndrome (e.g., Flomax. See “Flomax-Induced Floppy Iris Syndrome” for more recommendations).
- Obtain preoperative clearance as needed from primary care physicians.
  - Communicate both the proposed surgical procedure and type of anesthesia.
  - Ask about need for preoperative tests. Review results, such as coagulation studies, ECGs, and chest x-rays. Discuss pertinent abnormalities with the PCP and anesthesia provider.
  - Inquire about need to continue anticoagulant therapy, medications such as Flomax, etc.
  - See “Preoperative History and Physical Examinations” for a discussion of signing or co-signing updates to the preoperative evaluation.
- Type of anesthesia
- See chart below for alternatives, risks, benefits, contraindications
- Discuss with patient, PCP as needed, and anesthesia provider.
- Document decision-making process, especially if choice differs from that of patient, PCP, or anesthesia provider.
- Informed consent
- Obtain and document the patient’s informed consent for both the surgical procedure and the type of anesthesia, even if it will be administered by an anesthesia provider.
- See the OMIC website for sample consent forms and “Obtaining and Verifying Informed Consent.”
- Anesthesia/sedation provider
- Respect scope of practice, licensure, and competency when providing, delegating, and supervising anesthesia and sedation.
  - Ophthalmologists are usually held vicariously liable for care rendered by their employees, such as nurses and technicians.
  - As a general rule, they are not held liable for the negligent acts or omissions of anesthesiologists, or of Certified Registered Nurse Anesthetists (CRNAs), even if—for billing and regulatory purposes—they are deemed to be their “supervisors.”
    - Unless the ophthalmologist controls or directs the actions of the anesthesia provider
- LOCAL
- Verify that Certified Registered Nurse Anesthetists (CRNA) and anesthesiologists have current competency in ophthalmic injection anesthesia.
- Communicate any pertinent information (e.g., long or wide eye, staphyloma, ocular or medical comorbidities) both orally and by including it in the preoperative orders.
- SEDATION (see “Outpatient Surgical Facility Recommendations” and “Office-Based Surgery for Adults” for more information).

- Determine the patient's ASA Physical Status in order to decide when an anesthesia provider is needed, or where the procedure should be performed.
  - The American Society of Anesthesiologists (ASA) has a Physical Status Classification System that assigns a category after the physician completes a history and physical examination
    - P1: normal, healthy patient
    - P2: mild systemic disease
    - P3: severe systemic disease
    - P4: severe systemic disease that is a constant threat to life
    - P5: a moribund patient who is not expected to survive without the operation
    - P6: a declared brain-dead patient whose organs are being removed for donor purposes
  - The ASA does not elaborate on what these classifications mean. The ophthalmologist must use professional judgment, and consult with an anesthesiologist or the patient's primary care physician as needed, to determine if patients have particular ocular or medical comorbidities that require the services of an anesthesia provider (as opposed to the ophthalmologist or his/her staff), ambulatory surgery center, or hospital. Particular attention should be paid to patients with hypertension or those with cardiovascular disease or its risk factors. For example, patients with more than one mild systemic disease may be considered ASA P3 (e.g., a patient with hypertension and diabetes that requires medication for control, or one with both hypertension and coronary artery disease, etc.).
- Evaluate the desired and potential level of sedation in order to decide when an anesthesia provider is needed, or where the procedure should be performed.
  - The ASA guidelines note that because sedation is a continuum, it is not always possible to predict how an individual patient receiving sedation will respond. Sufficient qualified individuals must be present both to perform the procedure and to monitor the patient throughout the administration of sedation and recovery from it.
  - The ASA has defined levels of sedation/analgesia.
    - Minimal sedation ("anxiolysis") is defined as "a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected."
      - Examples of minimal sedation for ADULTS includes peripheral nerve blocks, local or topical anesthesia and either 1) less than 50% N<sub>2</sub>O or 2) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.
    - Moderate ("conscious") sedation is defined as a "drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation."
      - NOTE: reflex withdrawal from a painful stimulus is NOT considered a purposeful response
      - No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
    - Deep sedation/analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation.

- NOTE: reflex withdrawal from a painful stimulus is NOT considered a purposeful response
  - The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.  
Cardiovascular function is usually maintained.
- Do not administer moderate (“conscious”) sedation in an office unless an anesthesia provider is present (i.e., an anesthesiologist or certified registered nurse anesthetist).
  - Patients receiving moderate sedation risk slipping into deep sedation, where the ability to maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.
  - Most ophthalmic personnel lack the skill, training, and licensure to monitor and rescue patients receiving moderate sedation. Moreover, office surgical suites are rarely adequately equipped to monitor and rescue these patients.
  - If moderate (“conscious”) sedation is administered, the office must have appropriate emergency and monitoring equipment.
- Do not prescribe or administer medications for conditions you do not normally treat and follow (e.g., sublingual Procardia for management of hypertension before blepharoplasty).
- Verify dosages and choice of medication in pediatric, pregnant, and elderly patients.
- Management of complications
- Be mindful of your own limits. Consider obtaining consultations and referring the patient to subspecialists as needed.
- Disclose the complication to the patient as soon as possible, and document the discussion. If the complication puts the patient at increased risk for other complications or could lead to additional surgery, inform the patient. Stay in touch with the patient. (See “Responding to Unanticipated Outcomes” for detailed suggestions on disclosure, documentation, event analysis, reporting, and healing the healthcare team)
- Document the complication and its management in the Operative Note (if during surgery) and/or medical record.
- Provide written discharge instructions to the patient that include symptoms that should be reported to you, contact information, diet, wound care, activity restrictions, and the date and time of the follow-up appointment. Document the instructions.
- Institute a follow-up system for missed appointments and noncompliance (see “Noncompliance” for recommendations on tracking systems and sample letters).
- Instruct staff to consider calls from postoperative patients as high-risk situations (see “Telephone Screening of Ophthalmic Problems” for sample screening guidelines and contact forms).
- Document all after-hours calls from patients, and consider postoperative patients with known complications to be high risk. Inform call partners of such patients (see “Telephone Screening of Ophthalmic Problems” for more recommendations and sample after-hours contact forms).

## RESOURCES

- American Society of Anesthesiologists [www.asahq.org](http://www.asahq.org)
  - ASA Physical Status Classification System, [www.asahq.org/clinical/physicalstatus.htm](http://www.asahq.org/clinical/physicalstatus.htm), accessed 2/18/05
  - Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, approved 13 October 1999, accessed 2/18/05,

- <http://www.asahq.org/publicationsAndServices/standards/20.pdf>
  - Office-Based Anesthesia Guidelines <http://www.asahq.org/Washington/oba.htm>
  - Basic Standards for Pre-Anesthesia Care, Basic Anesthesia Monitoring, and Post-Anesthesia Care <http://www.asahq.org/publicationsAndServices/standards/02.pdf>
  - Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists <http://www.asahq.org/publicationsAndServices/sedation1017.pdf>
  - Practice Guidelines for Preoperative Fasting and the Use of Pharmacological Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures <http://www.asahq.org/publicationsAndServices/npoguide.html>
- American College of Emergency Physicians [www.acep.org](http://www.acep.org)
  - ACED AED Fact Sheet <http://search.acep.org:8080/PortalInABox460/portlets/autosuggest.jsp?username=e8e9e6e5f9e0f8&pib=true&threshold=50&numresult=10&defaultlogo=htm.gif&display=775&url=http%3A%2F%2Fwww.acep.org%2F1%2C2891%2C0.html&links=A&command=getoriginal>
- American Heart Association [www.americanheart.org](http://www.americanheart.org)
  - BLS for Healthcare Providers <http://www.americanheart.org/presenter.jhtml?identifier=3011775>
  - AED Implementation Guide
  - <http://www.americanheart.org/presenter.jhtml?identifier=3027225>

**OMIC policyholders who have additional questions or concerns about practice changes are invited to call OMIC's confidential Risk Management Hotline at (800) 562-6642, extension 641.**

TYPE	ADVANTAGES	DISADVANTAGES	INDICATIONS	CONTRA-INDICATIONS	COMPLICATIONS
General	<ul style="list-style-type: none"> <li>• Complete ocular akinesia</li> </ul>	<ul style="list-style-type: none"> <li>• More episodes of intraoperative oxygen desaturation, hemodynamic fluctuation, postoperative nausea and vomiting, initial postoperative pain than ocular injection techniques</li> <li>• Causes hormonal stress response</li> <li>• Slower return to ambulation</li> </ul>	<ul style="list-style-type: none"> <li>• Vitreoretinal surgery</li> <li>• Pediatric strabismus surgery</li> <li>• Can't cooperate with MAC (children, adults with mental or psychological problems, tremor, inability to lie supine)</li> <li>• Need complete ocular akinesia</li> <li>• Lengthy procedure (&gt; 3-4 hours)</li> <li>• Surgical field not amenable to injection or topical anesthesia</li> <li>• Technically difficult; large, myopic globe, coagulopathy</li> <li>• Following inadvertent intrathecal or intravascular injection of local</li> <li>• Surgeon or patient preference</li> </ul>	<p>Prudent to avoid in:</p> <ul style="list-style-type: none"> <li>• Patients with severe cardiovascular or pulmonary disease</li> <li>• Patients prone to postoperative nausea and vomiting</li> </ul>	<ul style="list-style-type: none"> <li>• Hemodynamic fluctuations</li> <li>• Changes in blood pressure, heart rate or rhythm</li> <li>• Myocardial infarction</li> <li>• Stroke</li> <li>• Death</li> <li>• Oculocardiac reflex (bradycardia, bigeminy, ectopic beats, nodal rhythms, AV block, asystole)</li> <li>• Nausea and vomiting</li> <li>• Significant rise in IOP during emergence, tracheal stimulation</li> <li>• Increase or decrease in IOP from anesthetic agents</li> <li>• Some agents can increase IOP to point of extravasation of intraocular contents in open globe injury</li> </ul>

TYPE	ADVANTAGES	DISADVANTAGES	INDICATIONS	CONTRAINDICATIONS	COMPLICATIONS
Orbital Injection: Peribulbar, Retrobulbar	<ul style="list-style-type: none"> <li>• Complete anesthesia of eye and extraocular structures of orbit</li> <li>• No sensitivity to light or IOP fluctuation</li> <li>• Requires less communication with patient, cooperation from patient</li> </ul>	<ul style="list-style-type: none"> <li>• Blind injection technique</li> <li>• Patching of eye during recovery from anesthesia</li> <li>• Dealing with anticoagulant or platelet-modifying therapy</li> <li>• Complications</li> <li>• May require IV sedation</li> </ul>	<ul style="list-style-type: none"> <li>• Patients who prefer no sensation, or not qualified for local or local plus intracameral</li> <li>• Patients who are anxious, young, or those with mental or psychological problems</li> <li>• Complicated surgical procedures with extensive intraocular manipulation</li> <li>• Lengthy procedures (&gt; 30-40 minutes)</li> </ul>	<p>Care must be taken in patients with:</p> <ul style="list-style-type: none"> <li>• Adverse anatomical features, particularly large, myopic globe with an axial length greater than 26 or 27 mm</li> <li>• Severe or inadequately controlled systemic vascular disease</li> </ul>	<ul style="list-style-type: none"> <li>• Globe perforation</li> <li>• Retrobulbar hemorrhage</li> <li>• Increased IOP</li> <li>• Scleral perforation</li> <li>• Postoperative strabismus from anesthetic myotoxicity</li> <li>• Retinal vascular occlusion</li> <li>• Optic nerve trauma</li> <li>• Intravascular injection with CNS excitation and convulsions</li> <li>• Subarachnoid extension with unconsciousness and respiratory arrest</li> <li>• Apnea</li> <li>• Anesthetic blemish</li> <li>• CNS anesthesia</li> <li>• Unintended bilateral ocular anesthesia</li> </ul>

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<p>Sub-Tenon's</p> <p>Under direct visualization</p> <p>Uses blunt irrigation cannula to deliver anesthetic directly into sub-Tenon's space (see video)</p>	<ul style="list-style-type: none"> <li>• Easy to administer</li> <li>• Rapid onset of anesthesia</li> <li>• Excellent long-lasting anesthesia</li> <li>• Relatively good akinesia</li> <li>• Essentially eliminates risk of retrobulbar hemorrhage</li> <li>• Essentially eliminates risk of strabismus from anesthetic myotoxicity</li> </ul>	<ul style="list-style-type: none"> <li>• 5-10 minutes may be needed for maximum akinesia</li> <li>• Patient may sense pressure and/or burning from anesthetic as it is passed behind globe but is usually quite tolerable</li> </ul>	<ul style="list-style-type: none"> <li>• Appropriate for any patient who would otherwise require injection anesthesia</li> <li>• High-risk patients (monocular, on anticoagulants) who need to avoid needle block</li> <li>• Patients made anxious by sight of approaching needle</li> <li>• When there is a need for deeper level of anesthesia</li> </ul>	<p>Relative:</p> <ul style="list-style-type: none"> <li>• Previous scleral buckling with extensive conjunctival scarring related to retinal surgery since difficult to place cannula safely behind eye</li> <li>• Preexisting glaucoma filtering bleb</li> <li>• Some physicians feel patients on anticoagulants are poor candidates</li> </ul>	<ul style="list-style-type: none"> <li>• Serious complications are rare</li> <li>• Limited subconjunctival hemorrhage (20 to 25% of cases)</li> <li>• Chemosis</li> <li>• Damage to vortex vein</li> <li>• Superior oblique tendon damage from "buttonhole" scissors</li> <li>• Sight-threatening complications (e.g., closure of central retinal artery if anesthetic delivered through cannula against connective tissue in back of eye)</li> </ul>



TYPE	ADVANTAGES	DISADVANTAGES	INDICATIONS	CONTRA-INDICATIONS	COMPLICATIONS
Topical  (including deep topical with sponge soaked in anesthetic, and topical augmented by intracameral)	<ul style="list-style-type: none"> <li>• Safe</li> <li>• Easily administered</li> <li>• Avoids pain and risks of injection anesthesia</li> <li>• Eliminates need for patching following surgery</li> <li>• Can be used on patients on anticoagulant or antiplatelet drugs</li> <li>• Allows patient to assist surgeon with extraocular movements, thus providing advantageous exposure</li> </ul>	<ul style="list-style-type: none"> <li>• Leaves patient conscious of surgery in progress</li> <li>• Makes patient aware of speculum and operating microscope light</li> <li>• May lead to inadvertent or inappropriate patient movement of eye</li> <li>• Leaves patient susceptible to pain or discomfort associated with intraocular manipulation or IOP changes</li> </ul>	<ul style="list-style-type: none"> <li>• Small incision, anterior-segment procedure (90 to 95% of cataract surgery)</li> <li>• Patient able to tolerate lid speculum and bright light</li> <li>• Patient able to respond to instructions to move eye in desired directions</li> </ul>	<ul style="list-style-type: none"> <li>• Young children</li> <li>• Decreased mental capacity, dysphasic, otherwise incapable of understanding or communicating with surgeon during procedure</li> <li>• Deaf or hearing-impaired patients</li> <li>• Anxious patients</li> <li>• Potentially complicated or prolonged cases (&gt; 30-40 minutes)</li> <li>• Coarse nystagmus</li> <li>• Ocular conditions, e.g., cannot fixate above or below microscope light due to dense cataracts; small pupils, hard lenses, weak zonules</li> <li>• Patients with strong blink reflex, unable to tolerate light, uncomfortable with speculum</li> <li>• Surgical need to keep extraocular eye muscles completely paralyzed</li> </ul>	<ul style="list-style-type: none"> <li>• Damage of ocular structures due to inadvertent movement</li> <li>• Drying of cornea, leading to superficial punctate keratopathy (SPK)</li> <li>• Irritation at site where anesthetic-soaked sponge used: need to remove at end of procedure</li> </ul>

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