ANESTHESIA & the LAW
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PPM

Ophthalmic Regional Blocks: Defending Vision Loss Litigation

Introduction

Opthalmic surgical procedures comprise a significant percentage of all surgeries performed worldwide.[1] In the United States, nearly 4 million cataract extractions are performed annually.[2] There are a variety of anesthetic techniques employed to facilitate ophthalmic surgery including topical eye drops, monitored anesthesia care with varying degrees of sedation, ophthalmic regional blocks, and general anesthesia. Depending upon practice location, surgical procedures performed, and surgeon preferences, anesthesia professionals may be requested to administer ophthalmic regional blocks. As with all regional blocks, there are known risks and complications associated with ophthalmic regional anesthesia. While major complications include brainstem anesthesia and oculocardiac reflex, vision loss caused by needle penetration and perforation of the globe is the most common allegation against PPM's insureds. The following case studies highlight some of the allegations and expert criticisms against PPM's insureds during the course of vision loss litigation.

Case Study One

A 50-year-old male with a medical history significant for Parkinson's disease, placement of two brain stimulator electrodes, and a left visual impairment (acuity 20/100) due to a central corneal ulcer with fungal etiology, corneal transplant, and left corneal graft rejection presented for a left cataract extraction with lens implantation.

The PPM insured anesthesiologist performed the pre-anesthesia assessment. The patient did not report his history regarding uveitis, corneal graft rejection, or the recent loss of corneal sutures. The plan was for regional anesthesia with sedation. The anesthesiologist discussed the risks, benefits, and alternatives of the anesthetic plan and answered all of the patient's questions. The anesthesiologist administered a peribulbar block as that was the ophthalmologist's anesthetic preference and no contraindications were noted.

Shortly after placing the block, the anesthesiologist observed that the patient's left eye became soft. The anesthesiologist notified the surgeon who evaluated the patient and concluded that the suture line from the previous corneal transplantation dehisced. The surgeon undertook an immediate repair of the corneal wound that was 180-degrees dehisced. During the procedure the lens protruded and was expelled through the dehisced tear. After the repair, the patient was cared for in the PACU. Approximately 5 1/2 hours later, the anesthesiologist administered another peribulbar block so the surgeon could re-evaluate the patient's eye. During this procedure, the surgeon and another ophthalmologist revised the repair. Postoperatively, the patient had continued complaints of decreased and blurred vision in his left eye (acuity 20/70).

The patient and his wife sued the anesthesiologist, the ophthalmologist, his practice group, and the surgery center. The plaintiffs contended that the defendants' negligence caused the plaintiff to experience a left globe perforation, dehiscence of penetrating keratoplasty, loss of vision in the left eye, peripheral vision loss, aphakia,

scarring of the left cornea, decreased ability to use an automobile, and pain and suffering. The plaintiffs also claimed that the defendants' negligence impacted the plaintiff's ability to conduct his daily living activities. However, the plaintiff's Parkinson's disease was significantly disabling with worsening symptoms that rendered him unable to perform his work duties as an attorney.

The plaintiffs argued two theories of negligence against the defendants at trial: (1) failure to adequately obtain informed consent, and (2) failure to administer general anesthesia (GA) instead of performing a regional block due to the risk of dehiscence. Regarding the allegations that there was an inadequate informed consent process, defense counsel indicated the plaintiff executed three informed consent forms relating to the procedure and the anesthesia plan. The defense also highlighted the fact that both the plaintiff and his wife, who was present on the day of her husband's procedure, were attorneys. Accordingly, they should have appreciated the importance of carefully reading the documents before they were signed.

"Regarding the allegations that there was an inadequate informed consent, the plaintiff executed three informed consent forms relating to the procedure and the anesthesia plan. The defense also highlighted the fact that both the plaintiff and his wife, who was present on the day of her husband's procedure, were attorneys."

The anesthesiologist testified that during his 35-year career, he had performed between 25,000 and 30,000 peribulbar blocks and only a couple of his patients had experienced a severe complication. He explained that when he discusses informed consent with his patients, he only addresses the most likely complications such as bruising and bleeding, not rare complications that he had never personally seen over the course of several decades practicing medicine.

The co-defendant ophthalmologist testified that he provides his patients with an extensive informed consent form listing numerous risks, including death and vision loss. He testified that following his informed consent discussion with the plaintiff, he handed him the form, and watched him read and sign it. He also testified that this was the first time he had experienced, heard of, or read about a peribulbar block potentially causing a corneal transplant to dehisce.

The plaintiffs' anesthesiology expert, Artem Grush, M.D., Boston, Massachusetts, testified that the anesthesiologist violated the standard of care (SOC) by not providing a more extensive list of risks to the patient, including globe perforation, wound dehiscence, and optic nerve perforation.

On cross-examination, defense counsel presented Dr. Grush with a copy of the anesthesia informed consent that he used at his facility. Defense counsel asked him to show the jury on his own facility's informed consent where he discusses all of the risks that he testified the anesthesiologist should have covered with the plaintiff. None of those specific risks were listed on the informed consent form. Defense counsel also asked the plaintiffs' expert if he was familiar with New York law governing informed consent that requires a physician to disclose the "reasonably foreseeable" risks and benefits involved in a procedure. He conceded he was not familiar with that requirement, but still maintained the anesthesiologist should have included the specific risks and complications that occurred in this case. He also admitted that while he had placed 20,000 blocks during his career, only one or two of his patients had experienced a complication such as a hemorrhage or dehiscence.

Regarding plaintiffs' allegation that GA should have been administered instead of a peribulbar block, the surgeon testified that he chose the anesthetic for the cataract removal. He also testified that he did not feel GA was required due to the implants to control his Parkinson's symptoms.

The defense anesthesiology expert testified that the risks of undergoing GA outweighed the risks of a peribulbar block. He conceded that the placement of the block caused the corneal transplant to dehisce. However, that was not a foreseeable risk, and he had personally never seen that complication happen.

Plaintiffs' counsel asked the jury to award $2,600,000 to his clients. Following an 11-day trial, the jury returned a unanimous defense verdict in favor of the defendants. Vincent Nagler, Esq. of Dorf, Nelson & Zauderer, LLP,

Rye, New York, represented the PPM insured anesthesiologist. Tracey Dujakovich, JD, Lead Claims Professional & Risk Advisor, managed the file on behalf of PPM.

Case Study Two

A 55-year-old female patient presented for cataract extraction with lens implantation. The PPM insured anesthesiologist administered a peribulbar block for the surgery. During placement of the block the patient suffered a perforated globe. The patient was referred to a retina specialist who attempted to repair the patient's eye, but the efforts were unsuccessful.

The patient and her husband subsequently sued the anesthesiologist, the ophthalmologist, and the eye clinic. She alleged the anesthesiologist improperly performed the peribulbar block that resulted in her vision loss. The patient claimed the ophthalmologist and the eye clinic were vicariously liable for the anesthesiologist's alleged negligence.

Plaintiffs' ophthalmology expert testified that there were three deviations from the standard of care by the anesthesiologist: (1) he utilized an improper technique and perforated the eye twice, (2) he not did not recognize the initial perforation when it occurred, and (3) he failed to obtain an adequate informed consent. He testified that it was not permissible for the surgeon to obtain the informed consent for the peribulbar block. Instead, the expert indicated that the anesthesiologist should have had a verbal conversation with the patient about the risks, benefits, and alternatives of performing the block and documented the same in the informed consent form. He was also critical of the performance of the block in that the anesthesiologist had the patient look up as well as angling the needle upwards once it was underneath the eye. He conceded that a perforation injury can occur in the absence of negligence. However, he stated that the fact that there were two different perforations signified that there was negligence. He testified further that it is very rare for there to be an injury in the absence of an unusual eye anatomy or patient movement.

The defense anesthesiology expert testified that the technique used by the PPM insured anesthesiologist was well within the standard of care. In his deposition, our insured anesthesiologist testified that he had performed the same block "thousands of times" during his career and never had a patient experience a perforation. He used a short 5/8-inch, 25-gauge needle that was directed perpendicular to the eye just at the orbital rim and in a fashion parallel to the orbital rim. Once the needle was in place, he tilted the needle 10 degrees toward the orbital apex. The anesthesiologist used a single peribulbar technique instead of a 2-injection technique whereby the second injection is administered in the superonasal orbit. He was clear in his testimony that he had the patient looking in the neutral position while administering the injection, which decreases the risk for inadvertent ocular penetration.

The defense expert testified that all injectable regional anesthesia for ocular surgery is known to be associated with the risk of ocular penetration. And while the risk of ocular penetration is significantly lower with peribulbar technique rather than retrobulbar technique, the risk still exists and is a known potential complication of peribulbar anesthesia. With regard to the allegation that the anesthesiologist failed to obtain a separate consent, he conceded that he would anticipate that an anesthesiologist would obtain consent for the anesthesia. However, he indicated that the choice of the anesthesia would be left up to the surgeon to decide. He also conceded that he primarily relied on the anesthesiologist's deposition and his version of the facts to form his opinions.

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The plaintiff claimed she had no vision in her left eye and experienced pain as a result of the complication. The plaintiff's eye was cloudy and showed a shrunken deformity. She testified she was unable to work and had anxiety for which she is unable to get psychological help. Plaintiffs' economic expert produced a report that calculated a total economic loss of $256,044. Plaintiffs initially claimed damages in the amount of $12,000,000.

Defense counsel's evaluation indicated this was likely a case of liability based on the number of perforations as well as the location of same. He estimated a jury range of $1,000,000 to $1,500,000, but also a real possibility of an excess verdict. Settlement range was estimated to be between $600,000 to $900,000. Estimated chance of a defense verdict was 40-45%. Based on the potential

exposure beyond the insured's available insurance policy limits, defense counsel recommended settlement, if possible.

With our insured's consent to settle, PPM engaged in settlement negotiations. Plaintiffs' opening global demand to all defendants was $2,500,000. The parties participated in mediation. Plaintiffs' settlement demand to our insured was $2,200,000. Following several rounds of settlement negotiations, PPM settled this case on behalf of our insured for $850,000. The remaining co-defendants were dismissed from this case.

Michael McBride, Esq. of Mattia & McBride, P.C., Fairfield, New Jersey, represented PPM's insured. Shelley Strome, Senior Claims Professional & Risk Advisor, managed the file on behalf of PPM.

Case Study Three

A 56-year-old female presented for right eye pars plana vitrectomy. The patient's history was significant for decreased visual acuity secondary to age-related macular degeneration. She had undergone a cataract extraction with lens replacement 10 years earlier. At that time, the patient's axial length was measured at 27.05 mm. This information was contained in the referring neuro-ophthalmologist's records, but it wasn't part of the patient's record on the date of the underlying procedure.

The anesthesiologist underwent training in both the retrobulbar and peribulbar approaches during his residency. Over the course of his 15-year career, the anesthesiologist performed approximately five-hundred regional ophthalmic blocks; of which, he estimated 80% were retrobulbar and 20% were peribulbar. The retina surgeon did not express a preference regarding the type of block to be performed for the patient's case. Based on his experience working with the surgeon, the anesthesiologist understood he preferred the retrobulbar approach because it provides better akinesia and patients rarely require an additional block after surgery start time. Shortly before the underlying procedure, the retina surgeon informed the anesthesiologist that the patient had a "large eye" and "to be careful [performing the block]."

After obtaining the patient's informed consent, the anesthesiologist performed a retrobulbar block. There were no apparent complications during the block, and the patient was brought to the operating room for surgery. Upon looking through the microscope, the surgeon observed a hemorrhage in the back of the patient's eye. He was also concerned that there might have been damage to the optic nerve. He attempted to repair the injury and was initially hopeful that the patient would not experience any long-term effects.

The patient and her husband filed a lawsuit against the PPM insured anesthesiologist. The plaintiff alleged that the retrobulbar block was contraindicated based on the patient's history of myopia, and the anesthesiologist's technique in performing the block was not consistent with the standard of care. The plaintiffs pursued general damages based on the patient's total loss of vision in her right eye.

Plaintiff's anesthesiology expert, Elizabeth Baker, M.D., of Albuquerque, New Mexico, testified that the retrobulbar approach was contraindicated due to the patient having a myopic eye. Instead, Dr. Baker opined the anesthesiologist should have performed a peribulbar block or administered general anesthesia for the procedure. She also stated the anesthesiologist's description of the needle's path was inconsistent with the globe perforation described in the operative report. On cross-examination, the plaintiff's expert was forced to acknowledge globe perforations can occur absent negligence, and it is a recognized risk of both the retrobulbar and peribulbar approaches.

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The defense anesthesiology expert testified the anesthesiologist's decision to perform a retrobulbar block was a judgment call, not a departure from the standard of care. He characterized the degree of the patient's myopia as moderate, not severe. He also highlighted the fact that the axial length was not part of the perioperative records available for the anesthesiologist to review before the procedure. The defense anesthesiology expert explained that clinicians must rely on landmarks and feel when performing regional ophthalmic blocks as there is no way to know exactly where the needle is being placed.

During closing arguments, the plaintiff attorney asked the jury to award his clients $2,000,000. The jury deliberated for less than three hours before returning a verdict in favor of the anesthesiologist.

Gary Fadell, Esq. of Fadell, Cheney & Burt, PLLC, Phoenix, Arizona, represented PPM's insured. Paul Lefebvre, JD, Lead Claims Professional & Risk Advisor, managed the file on behalf of PPM.

Risk Management Strategies and Considerations

Based on PPM's experience in defending vision loss litigation, the expert opinions in those cases, and the medical literature, we offer the following risk management strategies and considerations:

- Patient selection should include a detailed medical history including the ability for the patient to remain motionless in the supine position, communicate with the surgical team, use of any anticoagulant or antithrombotic medications, and previous eye procedures.[3]
- Expressly disclose and document the risk of globe perforation and vision loss during the informed consent process and discuss the benefits and reasonable alternatives with the patient. This is particularly important if the ophthalmic regional block is to be performed for a cataract extraction and lens replacement, as topical anesthesia is now the anesthetic of choice in most parts of the country.[1(p58)]
- If available in preoperative records, review optical biometry measurement or ultrasound report of the eye's axial length. Retrobulbar approach may be contraindicated in patients with severe myopia.[4]
- Patients with a history of staphyloma are at a much higher risk of globe perforation than the average patient population (staphyloma is commonly found in patients with severe myopia).[5]
- Peribulbar approach has a lower risk of globe perforation according to the medical literature.[5] If the ophthalmic surgeon prefers a retrobulbar approach, explain and document specific risks and benefits to the patient to ensure approach is a shared decision (e.g., benefits: better akinesia of the eye can reduce the risk of surgical complication, requires less injectate volume, typically won't require second block; risks: intraconal approach carries a greater risk of globe perforation and injury to the optic nerve).
- Use appropriate gauge and length of needle for desired approach.[5]
- Hold patient's eyelid open during block and instruct patient to maintain a neutral gaze. Avoid Atkinson gaze position (upward and inward), it can pull the optic nerve towards path of the needle.[6]
- Use hyaluronidase as adjunct for local anesthetic, which spreads the injectate. Undiluted local anesthetic has a more toxic effect and can injure the extraocular muscles and nerves, which may result in diplopia (double vision).[6]

Table 1: Eye Procedure Complications and Management Strategies[3(p102)] (Reproduced and modified with permission from the APSF)

Complication	Manifestation	Treatment
Retrobulbar Hemorrhage (compartment syndrome)	Tense orbit with significant resistance to retropulsion, no ocular motility, decrease in visual acuity, bulbar chemosis and complete ptosis.	Lateral canthotomy, Inferior cantholysis, Inferolateral anterior orbitotomy
Eye perforation/penetration	Hypotonic eye, loss of vision on postoperative evaluation, evidence of retinal detachment and/or laceration on exam	Consult with a retina specialist, vitrectomy most likely needed
Intra-arterial injection of local anesthetic	Brainstem anesthesia (Symptomatology can differ between each case of brainstem anesthesia and it can include different combinations of confusion, unconsciousness, irregular breathing, apnea, numb throat, dysphagia, hypotension, hypertension, bradycardia, tachycardia, cardiovascular instability, convulsions, shivering, dysarthria, and hemi-, para- or quadriplegia). Symptoms appear 2-10 minutes after injection	May require cardiopulmonary resuscitation, intubation, and vasopressor support. Recovery with appropriate support may take 10 to 60 minutes
Intrathecal injection of local anesthetic	Brainstem anesthesia	May require cardiopulmonary resuscitation, intubation, and vasopressor support
Allergic reaction to local anesthetic	Very uncommon but possible. Clinical symptoms of anaphylaxis	Follow anaphylaxis resuscitation
Allergic reaction to hyaluronidase	Immediate reactions may present with periorbital edema and chemosis developing within a few minutes of administering the anesthetic mixture with the enzyme. Delayed reaction may mimic periorbital inflammation (up to 36 hours after block with the enzyme)	Surgical treatment may be needed due to the increased IOP. Systemic steroids may be needed
Venous air embolism	Hemodynamic instability, pulseless electrical activity (PEA), arrest	Hemodynamic support, follow PEA algorithm
Intramuscular injection	Diplopia due to myositis. Most commonly due to inferior rectus injection	Avoid lidocaine in concentrations higher than 2%. May need surgical or mechanical correction
Oculocardiac reflex	Severe bradycardia with asystole in some cases. May last less than 30 seconds	Stop stimulation, may need atropine in rare occasions
Gas injection	Potential increase in intraocular pressure due to gas expansion in the eye	Avoid nitrous oxide and identify patients who are receiving or have received intraocular injection of gas

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In This Issue

PPM has defended nine lawsuits in the past five years involving vision loss allegedly caused by ophthalmic regional blocks, including retrobulbar and peribulbar blocks. In this issue, we highlight three case studies involving vision loss arising from complications from eye blocks and some common allegations of negligence against our insured anesthesia professionals. We also offer risk management strategies to consider when performing elective ophthalmic regional blocks and treatment strategies for eye procedure complications.

Thanks for reading,

Brian J. Thomas, Editor