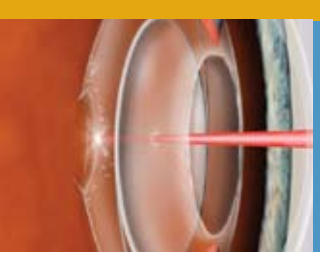

Closed Claim Study

Off-Label Use of ICG Dye During Vitrectomy for Floaters

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ALLEGATION

Lack of informed consent for off-label use of ICG dye during vitrectomy.

DISPOSITION

The case settled for $30,000.

Case Summary

A patient with a past history of LASIK OU and floaters OU presented to an OMIC insured complaining that the floaters were worse OD than OS. The insured noted the patient's vision at 20/20 OU and recommended a vitrectomy. During a preoperative work up the next day, LASIK scars were discovered on both corneas. A fundus exam displayed an unusual vitreous opacity with waves of vitreous material that obscured the view of the posterior pole. The left eye displayed the same abnormal vitreous but was somewhat less significant than the right eye. A vitrectomy was performed that same day. The operative note indicated that the insured used ICG dye on two separate occasions to visualize residual vitreous and then lavaged the eye each time to remove all remaining dye. Immediately following surgery, the patient complained of a large blind spot in the center of vision on the operated eye. He was evaluated by a retinal specialist, who measured the patient's vision at 20/300 OD with no improvement. There was no other therapy available to improve the patient's visual acuity.

Analysis

According to the expert witnesses in this case, at the time this care was delivered, the insured's decision to perform a vitrectomy to treat floaters and use ICG dye to better visualize residual vitreous was a controversial one. Furthermore, the insured did not have a detailed informed consent signed by the patient. Rather, he had a dictated risk/benefit note in the hospital record of a conversation with the patient in which the ophthalmologist explained and the patient understood the risks of surgery, including hemorrhage, infection, retinal detachment, loss of vision, risk of cataract progression, and the visual limitations of pseudophakia. The surgeon was careful to report the patient's acknowledgment that some individuals are not bothered in the same way he was by vitreous opacities and that the surgery was being performed to address the patient's unhappiness with the quality of his vision. However, the dictated note did not address the off-label use of ICG dye and the risk of retinal toxicity. Accordingly, the patient not only alleged a lack of informed consent but also contended that the ophthalmologist minimized the risks, stating that the procedure to remove the floaters was "more simple than LASIK" and would not threaten his vision. The patient recalled only the risk of infection and the doctor's assurance that an infection could easily be treated with antibiotics. It was certainly helpful that the insured had documented the discussion in the hospital record, but the case would have been more defensible if he had also used a procedure-specific consent form signed by the patient. The absence of any documentation on the use of ICG and the patient's poor outcome supported the decision to settle the case on behalf of the insured.

Risk Management Principles

As this case and the lead article demonstrate, patients often forget or misinterpret what they are told and have a hard time recalling risks that the ophthalmologist disclosed to them during the informed consent discussion. Staff can improve patient understanding by using educational aids such as brochures, handouts, and videos. Having the patient sign a procedure-specific form can also help the defense in several ways. First, it serves as further evidence that the consent discussion took place. Second, patients can be given a copy of the form, and encouraged to read it again at home with their family and to call back if they have any questions. Finally, if patients experience a complication, physicians can use the document to help them come to terms with the outcome. In this case, the insured should have modified a procedure-specific form for vitrectomy to include information about the off-label use of ICG and asked the patient to sign it following a thorough discussion of the risks and benefits of the procedure. OMIC policyholders who need assistance developing forms that are not already available on our web site may call the **Risk Management Hotline**.