PA PSRS
Pennsylvania Patient Safety Reporting System

Patient Safety Advisory

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Focusing on Eye Surgery

Two distinct patterns emerge from a number of Serious Events and Incidents reported to PA-PSRS involving eye surgery: wrong side surgery and problems with intraocular lens (IOL) implants.

While marking the surgical site has received much attention as a promising safety practice, marking the eye—by virtue of its unique anatomy—may present a problem for clinicians. Any mark placed near or around the eye may be obscured by surgical drapes and may not be visible during a pre-procedure time out.

Problems associated with intraocular lenses reported to PA-PSRS concern the implantation of a different lens than the clinical team intended. IOLs may vary by size, power and type. After reviewing case studies of several reports, we discuss protocols that may help to promote positive outcomes.

Case Studies in Wrong-Side Procedures

Case #1—In this well documented report, a patient undergoing surgery was asked to identify the operative site, which the scrub nurse marked with an "X" above the eye. A physician finished the surgical prep and draped the site. Several members of the surgical team verified the operative site, and all sources of information were consistent regarding the correct side for surgery. As the procedure progressed team members believed they were operating on the correct eye. Intraoperative and postoperative documentation listed the correct eye as having surgery. However, when the patient arrived in the PACU, the wrong eye was draining and surgically tender.

Several elements of this case may have contributed to this error. First, the use of an "X" as the surgical mark is nonspecific. It could indicate the surgical site, but could easily be misinterpreted as a warning indicating the non-operative site. In a follow-up contact, the Patient Safety Officer at this facility stated that their policy is to use the surgeon's initials as the surgical mark, consistent with guidance from other organizations.[1]

As stated previously, the surgical mark was obscured after the operative site was draped. The mark was placed above the eye rather than in a location that would still be visible after draping, which is an element of the guidance on site marking published by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[1] Just beyond the eye's medial or lateral angles might be a suitable alternative in some cases. Another alternative could be to mark the eyelid of the operative eye, and to verify the presence of the surgical mark on the right or left side when applying lid clamps. The lid clamps could then be a proxy for the surgical mark.

The scrub nurse (who made the initial surgical mark) was not present during the operative site verification. We can only conjecture whether the scrub nurse might have caught this error had she been present, but a possible systems solution to this problem would include having all team members present for a pre-procedure time out. Another preventive measure might include making the surgeon responsible for making the surgical mark. The American Association of Ophthalmologists (AAO) suggests that "the surgeon/assistant surgeon marks the skin next to the operative eye with his/her initials."[2] JCAHO's Universal Protocol, which has been endorsed by AAO and the American Society of Ophthalmic Registered Nurses (ASORN), also specifies that the person performing the procedure be responsible for site marking.[1] Yet, a June 2004 survey conducted by ASORN found that 58% of respondents from 216 sites reported that markings are being performed by RNs, and only 22% reported that markings are being performed by physicians.[3]

Case #2—A patient having cataract surgery verified the side for surgery with a nurse. The operating room schedule, the permit, and the history and physical were in agreement with the patient. The nurse proceeded to mark the site for surgery

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Focusing on Eye Surgery (Continued)

and dilated the eye. A physician administering a local anesthetic placed the needle in the wrong eye. The nurse stopped the physician just before the anesthetic was administered. Thereafter, the procedure proceeded correctly.

The report of this case does not mention a final time out before beginning the procedure, and the surgical mark may also have been obscured in this case. We previously reported on the JCAHO Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery[1] in the September 2004 *PA-PSRS Patient Safety Advisory*. The hallmarks of this protocol are pre-operative verification, marking the operative site, and conducting a time out immediately prior to beginning the procedure. The AAO has developed the following guidance, consistent with the Universal Protocol:

Your ophthalmology staff and surgeons will want to know if your facility changes IOL vendor. Variations in the A-constant across different manufacturers' lenses may invalidate their calculations for the correct diopter for the patient.

- Prior to administration of anesthetic injection or sedation, the anesthesia staff/surgeon verifying the operative eye with the patient, informed consent and/or the ophthalmic history and exam, and confirming that they all match.
- Immediately prior to incision, the surgeon verifying the operative eye with the ophthalmic history and exam.
- In the event of any discrepancy among the patient's response, the informed consent, the doctor's order, and the ophthalmic history and exam, the surgeon making the final determination and correcting the discrepancy before proceeding with the procedure.
- Developing a checklist for verification that all documents are congruous and that all parties involved, including the patient, agree on the location of surgery.[2]

In any complex environment, the potential always exists for human error. Patient safety protocols, such as site marking and the time out, do not necessarily reduce the rate of human error. Rather, they are mechanisms by which we aim to make human error more observable and by which we build redundancy into the system, hopefully mitigating the consequences of errors by catching them before they reach the patient.

Intraocular Lens (IOL) Problems

PA-PSRS has received several reports in which the wrong intraocular lens was implanted in the patient's eye. Half of the reports indicate that the patient returned to the OR for implantation of the correct lens. In one case the patient was satisfied with the level of correction obtained even with the incorrect lens. One report refers to the physician's selection of the incorrect lens from a cart.

Table 1. Suggestions for Minimizing Wrong IOL Implantation

1. The ophthalmic history and exam and form that contains keratometry and axial length, primary and alternate lens/es for each patient are available in the operating room.
2. The surgeon/assistant surgeon selects the primary and alternate IOL/s before the start of the case. The surgeon verifies the IOL number, diopter, optic, A constant, and length against the appropriate form or documentation and/or patient medical record.
3. When the surgeon requests the IOL, the circulating nurse shows the IOL box to the surgeon and verbally states the IOL model number and lens power and the surgeon acknowledges the communication.
4. The circulating nurse then repeats this procedure with the scrub nurse/technician (i.e., shows the IOL box and verbally states the model number and lens power).
5. The scrub nurse/technician verbally states the model number and lens power as he/she passes the lens to the surgeon for implantation.
6. The surgeon performs visual inspection of the IOL under the microscope for appropriateness and any lens defect or deposit.
7. If there is a discrepancy the surgeon reviews the ophthalmic history and exam and/or designated institute form.
8. The circulating nurse puts the IOL labels on the IOL card, operative record/patient chart right after the surgeon implants the IOL.
9. Have good communications among the surgeon/assistant surgeon and operating room personnel, and check the lens power against the medical record in the operating room.
10. The correct lens should be in the operating room prior to sedation/anesthesia.

Source: American Association of Ophthalmologists. Reprinted with permission.

Focusing on Eye Surgery (Continued)

The magnitude of the problem is evident from a review of a decade of claims. The Ophthalmic Mutual Insurance Company reviewed 168 claims which occurred from 1987 to 1997. Cataract procedures represented 33% of all closed claims during this period, and IOL cases were the largest group in the sample.[4] Causative factors identified with implanting the wrong IOL include: use of an outdated IOL formula for the patient, incorrect biometry or keratotomy readings, mistakes in entering data into an IOL calculation program, incorrect IOL labeling or packaging, and mistakes in providing the IOL during surgery.[5]

Different formulas can be used to determine the correct IOL, and each formula includes a variable known as a "lens constant." A widely used formula uses the "A-constant," which is dependent on the specifics of the IOL design" and, as required by the FDA, is printed on the IOL packaging by the manufacturer.[6,7] This A-constant is used in a string of interconnected calculations to determine the best lens for each patient. A quick review of five companies' products revealed A-constants ranging from 114.2 to 119, with different A-constants for the same lens diopter.

If your facility changes vendors or lens manufacturers, it would be helpful to notify all ophthalmologists so the calculations can be adjusted accordingly. Ideally, the surgeon would select the lens prior to entering the operating room and note the change in vendor. However, this is often a delegated responsibility, and surgeons may unknowingly implant a different manufacturer's lens, not recognizing that a formula change is necessary because of differences in the A-constant between different manufacturers' products.[8]

Suggestions for IOL verification in the operating room advocated by the American Academy of Ophthalmology, the American Society of Ophthalmic Registered Nurses, and the American Association of Eye and Ear Hospitals are presented in Table 1.[5]

Notes

1. Joint Commission on Accreditation of Healthcare Organizations. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery [online]. 2003 Jul 18 [Cited 12 Nov 2004]. Available from Internet: http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/wss_universal+protocol.htm.

2. American Association of Ophthalmologists. Eliminating wrong site surgery, patient safety bulletin 1 [online]. [Cited 10 Nov 2004.] Available from Internet: http://www.aao.org/education/library/safety/site.cfm.

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5. American Association of Ophthalmologists. Minimizing wrong IOL placement, patient safety bulletin number 2 [online]. [Cited 10 Nov 2004.] Available from Internet: http://www.aao.org/aao/education/library/safety/iol.cfm.

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An Independent Agency of the Commonwealth of Pennsylvania

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI, as contractor for the PA-PSRS program, is issuing this newsletter to advise medical facilities of immediate changes that can be instituted to reduce serious events and incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority's website at www.psa.state.pa.us.

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