The Case of the Double-Edged Protector

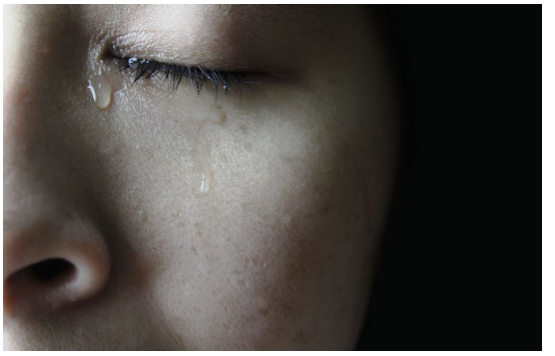
This article is part of an occasional series of patient safety cases, written by the American Board of Ophthalmology (ABO) and appearing in Morning Rounds.

Angela Lee* was tired of dabbing away her tears and looked forward to the dacryocystorhinostomy (DCR) that she hoped would allow her to put away the tissue box that was always by her side. Although she had more bleeding than usual, the procedure was otherwise uncomplicated. Her eye was covered with a pressure dressing, and after routine observation in the surgery center, she was discharged home in the care of her husband.

The surgeon called Mrs. Lee on the evening of her procedure, but no one answered the phone. Because of the intraoperative epistaxis, the patient had been instructed to arrange an office appointment within 48 hours after surgery, so the surgeon was not highly concerned. However, no appointment was scheduled.

The ophthalmologist next heard about Mrs. Lee four days after surgery, when her husband called the office to report that his wife couldn't see out of the eye and was experiencing mild discomfort. He described what he saw when he parted his wife's eyelids: "Everything looks white." This information was relayed to the surgeon, who asked the staff to arrange an office visit the following day. At the beginning of that exam, the technician who was screening Mrs. Lee quickly discovered that the metallic corneal protector used during surgery was still in place within the palpebral fissure.

When the protector was removed, Mrs. Lee's visual acuity, which had been 20/20-1, was now decreased to counting fingers at 2 feet. The cornea was edematous, and keratometry showed 8 D of central corneal flattening. The surgeon immediately apologized and took full responsibility for the retained corneal protector. She referred Mrs. Lee to a cornea specialist and offered to pay the cost of the cornea specialty care. Over the next several months, Mrs. Lee's cornea gradually regained a more normal shape, and her final visual acuity was 20/25.



DCR. *A dacryocystorhinostomy led to important lessons for one practice.*

Safety Event Investigation/ Root Cause Analysis

An adverse event or near miss should automatically prompt a formal investigation to determine the root cause of the incident, followed by intervention and changes in processes to reduce the risk for repeated events. Larger health care facilities have reporting systems and designated safety specialists to coordinate such an investigation. However, these resources were not available at either the surgery center or in the practice of Mrs. Lee's ophthalmologist.

A review of this case shows that several factors might have contributed to the retained corneal protector and subsequent corneal injury:

- There was no "counting" process during the DCR to ensure that the corneal protector had been removed from the patient's eye at the end of the procedure.
- The surgeon might have been distracted while managing the increased epistaxis during the DCR.
- The surgeon did not examine the eye at the completion of surgery.
- Someone other than the surgeon might have placed the eye patch at the end of the case, being unaware the protector had been used.
- There was no office protocol to ensure that the patient was examined shortly after surgery, as requested by the physician.
- Cultural and language barriers

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might have inhibited the patient or family from contacting the ophthalmologist sooner after surgery. (See "Health Literacy" section, below.)

- The surgeon did not recognize the significance of the problem when the husband called four days after surgery.

Root cause. The root cause for this adverse event was determined to be inadequate intraoperative protocols to ensure that corneal protectors are always removed at the completion of a procedure. Inadequate office processes for appropriate scheduling of postoperative appointments and handling of phone calls contributed to patient harm by prolonging the duration of the corneal injury.

Discussion of Patient Safety Principles

Failure to remove the corneal protector is considered a preventable medical error. The unintended retention of foreign objects (URFOs)—also called retained surgical items (RSIs)—is a well-recognized medical error in other surgical specialties. There are many reports of sponges, needles, and whole instruments or broken parts inadvertently left in surgical fields. Most of these cases result in additional care and/or prolonged hospital stays for the patients; some are fatal. Lawsuits are common. Typical root causes for these mistakes include 1) inadequate policies or inconsistent adherence to those policies and 2) poor staff education or team communication.[1] Certain types of cases carry an increased risk of URFOs, including emergency procedures, operations involving multiple surgical teams, and situations in which the surgical plan changes unexpectedly.

It would be wise for all ophthalmology surgery centers to institute a counting policy for protectors and other temporary external or internal devices used during ophthalmic procedures.

Operating room protocols are used to ensure that any item at risk for being inadvertently retained is counted both when introduced to the case and at the end of the procedure. Counts are also advised whenever there is a change in the scrub nurse. Any inconsistency in these counts must be rectified prior to the completion of surgery.

Eye surgery safety procedures. The true incidence of URFOs in ophthalmology is unknown. Although failure to remove a corneal-scleral protector might seem like a rare occurrence, the authors are aware of similar events having occurred at other institutions. It would be wise for all ophthalmology surgery centers to institute a counting policy for protectors and other temporary external or internal devices used during ophthalmic procedures. Examining the status of the globe at the completion of surgery should be part of every operation.

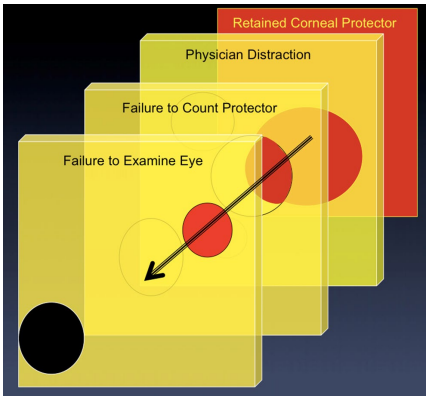
Communication. Poor communication between providers, staff, patients, and families is a common cause of medical adverse events. Each medical office should have protocols to ensure that appointments are scheduled, documented, and communicated to the patient. Postoperative patients who miss appointments should be contacted in a timely fashion to reschedule or verify their status.

Additional office protocols must be implemented to manage phone calls from patients who are having unexpected symptoms. When Mrs. Lee's husband called to report her discomfort and decreased vision, the "white appearance" was attributed to Bell's phenomenon, and neither staff nor physician recognized the significance of the postoperative visual change.

Health literacy. Poor health literacy can make it difficult for patients both to communicate symptoms and to understand instructions, contributing to poor health care. Mrs. Lee and her husband might not have completely understood their postoperative instructions, as English was not their primary language. In addition, cultural factors might have contributed to their delay in reporting visual loss after surgery. It is important to identify those patients who have educational or language barriers that may hinder their ability to understand and follow instructions or to communicate with providers.[2]

Culture of medical facility. All members of the health care team must be mindful of the potential for medical errors. Adverse medical events can occur in a variety of health care settings, including physician offices and freestanding surgery centers. Reliable and standardized processes of care, as well as communication and teamwork, can decrease the risk of dangerous mistakes. Continual education, vigilance,

Swiss Cheese



"Swiss cheese" is a metaphor proposed by James Reason[1] to explain medical mishaps. Considering that redundant checks are put in place to prevent mistakes, it follows that medical errors often involve mistakes at multiple levels, often by different providers. Hazards are supposed to be prevented by a series of barriers; however, each barrier has weaknesses, or "holes." If by chance the holes align as they constantly open, close, and shift, the patient can be harmed. Mr. Reason writes, "When an adverse event happens, the important issue is not who blundered, but how and why the defenses failed." In the case of Mrs. Lee, the physician might have been distracted, there was no protocol to count the protector, and the eye was not checked at the completion of the case.

1 Reason J. *BMJ*. 2000;320(7237):768-770.

and process improvement are needed to identify and reduce the risk of errors.

Investigation. Each entity should have a designated person to coordinate patient safety activities. In a small office, this person may be an office manager or lead technician who wears multiple hats, including compliance and safety. Adverse events, near misses, and at-risk behavior should be reported and investigated. Once the underlying root causes are identified, changes in protocol can then be instituted. Open, nonpunitive communication is essential to create an atmosphere that fosters a team approach to reducing medical error and improving patient care.

*Patient name is fictitious.

1 *The Joint Commission Sentinel Event Alert.* Preventing unintended retained foreign objects. 2013;51:1-5. www.jointcommission.org/assets/1/6/SEA_51_URFOs_10_17_13_FINAL.pdf.
2 Dewalt DA et al. *J Gen Intern Med.* 2004;19(12):1228-1239.

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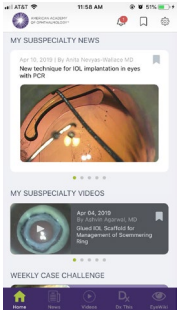

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A Risk Management Perspective

HONESTY. *For clear errors, a forthright account from the surgeon can help mitigate risk.*

Dealing with unanticipated outcomes is one of the most difficult aspects of medical practice, especially if an error contributed to the result. Ophthalmologists have been sued for failure to remove shields, trocars, clips, scleral plugs, and Weck-Cel sponges. Leaving an object in the eye is considered a preventable error, as are operating on the wrong eye and implanting the wrong IOL. Sometimes, as in this case study, it is clear that an error occurred. At other times, it is necessary to review the care before determining the cause of the unexpected outcome. When you ascertain that an error has been made, you need to respond. The following discussion explores disclosure and payment for subsequent care.

Honest acknowledgment. Although ophthalmologists are understandably wary of admitting liability, risk managers advise them to handle clear errors differently from other types of adverse events. It is best to admit the error and apologize to the patient, as the ophthalmologist in this case study did. Communicating in a sympathetic and nondefensive way with the patient or patient's family about the error may help dispel much of the anger, confusion, and distrust. It is when patients believe that they are not being told the whole story, or are not being given the opportunity to ask the physician questions and vent feelings, that they may seek the advice of an attorney and pursue a medical malpractice claim. An honest approach can prevent allegations of fraudulent concealment, for which attorneys may seek punitive damages.

Payment considerations. Acknowledge that the patient is likely to require care that would not have been needed without the error, and discuss who will pay for this care. Not surprisingly, patients do not feel it is fair to incur additional charges after an error. The surgeon in the case study offered to pay for the corneal care when she referred the patient to a cornea specialist. Taking such a step may not prevent a lawsuit, but it does show the patient that you care.

Note that you may choose to waive or refund your own fees, but you do not have the authority to waive those of other providers who were involved in the care, such as the nurses at an ambulatory surgery center or the anesthesiologist. Contact your professional liability carrier if you want to pay for care provided by another physician. Your carrier can advise you on whether fee refunds or payments need to be reported to your state board of medicine or the National Practitioner Data Bank. Discuss whether you want to pay for the care yourself or would like any payments to be made on your behalf by the carrier. Arrange to pay other physicians directly, rather than the patient. Clarify the extent of the care that you will pay for. Many patients have chronic eye conditions that require ongoing care, and they may believe they will not have to pay for it.

For detailed guidance on disclosure, preserving evidence, documentation, analyzing the error, and healing the health care team, see www.omic.com/unanticipated-outcomes-steps-for-responding.

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