Surgical Confusions in Ophthalmology

John W. Simon, MD; Yen Ngo, MD; Samira Khan, MD; David Strogatz, PhD

Objective: To investigate the hypothesis that surgical confusions rarely occur but are unacceptable to the public; occur in predictable circumstances; involve a wrong lens implant more often than a wrong eye, procedure, or patient; and can be prevented using the Universal Protocol.

Methods: A retrospective series of 106 cases, including 42 from the Ophthalmic Mutual Insurance Company and 64 from the New York State Health Department. We investigated how the error occurred; when and by whom it was recognized; who was responsible; whether the patient was informed; what treatment was given; what the outcome and liability was; what policy changes or sanctions resulted; and whether the error was preventable using the Universal Protocol.

Results: The most common confusion was wrong lens implants, accounting for 67 cases (63%). Wrong-eye operations occurred in 15 cases, wrong-eye block in 14, wrong patient or procedure in 8, and wrong corneal transplant in 2. Use of the Universal Protocol would have prevented the confusion in 90 cases (85%).

Conclusions: Surgical confusions occur infrequently. Although they usually cause little or no permanent injury, consequences for the patient, the physician, and the profession may be serious. Measures to prevent such confusions deserve the acceptance, support, and active participation of ophthalmologists.

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SURGICAL CONFUSIONS (IE, wrong patient, wrong site, wrong procedure) are an increasingly recognized cause of morbidity, recently representing the most common category of reportable medical error.1-5 In July 2004, the Joint Commission on Accreditation of Healthcare Organizations, in concert with many professional organizations, including the American Academy of Ophthalmology, promulgated the Universal Protocol in an effort to prevent such confusions in all surgical procedures.28,29 This protocol includes consistent preoperative verification, site marking, and a time-out immediately before incision.

Surgical confusions are relatively common in orthopedics, podiatry, urology, and neurosurgery, but their incidence in ophthalmology is uncertain. They are clearly more frequent if cases of wrong implants are included with cases of wrong site, procedure, and patient.22-26,33,36,37 The most infamous cases involve enucleation of the incorrect eye.26 This study was designed to estimate the incidence of surgical confusions in ophthalmology, to assess factors contributing to their occurrence, to discover their consequences to both patients and ophthalmologists, and to examine the potential effectiveness of the Universal Protocol in their prevention.

METHODS

We retrospectively reviewed 106 cases of surgical confusions in ophthalmology that occurred between 1982 and 2005. Of these, 42 (40%) were closed cases from the Ophthalmic Mutual Insurance Company (OMIC), the largest liability carrier in ophthalmology, that occurred between 1982 and 2003. The other 64 (60%) cases had been reported to the New York State Department of Health's New York Patient Occurrence Reporting and Tracking System (NYPORTS) program between 2000 and 2005. None of the OMIC cases occurred in New York state. Access to the data was granted by OMIC and NYPORTS officials under agreements protecting the identities of all patients, surgeons, and institutions. The institutional review board of the Albany Medical Center approved this investigation.

All cases were one of the following: (1) wrong implant, (2) wrong-eye block, (3) wrong patient or procedure, (4) wrong eye, or (5) wrong transplant. These categories were mutually exclusive. Data were abstracted from each record and factors contributing to the confusions were identified.
Each case was assigned one of the following injury severity scores, adapted from Kwaan and associates: 1, temporary or insignificant (eg, scar only); 2, temporary or minor (eg, delayed recovery, return to the operating room [OR], 3 diopters [D] of overcorrection or undercorrection); 3, mild but permanent (moderately to severely delayed recovery, >3 D of overcorrection or undercorrection); and 4, severe permanent injury or uncorrectable vision loss. Scores were determined by 3 independent observers. In cases in which there was a disagreement, a consensus decision was reached by discussion.

In OMIC cases, the final legal outcome, including liability payment, if any, was recorded. In NYPORTS cases, whether review concluded that relevant policies were followed correctly, whether they were changed as a result, and whether sanctions were imposed on the surgeon were documented.

### RESULTS

**Tables 1, 2, 3, 4, 5, and 6** detail, for each category of confusion, who recognized the error and when it was recognized; who was responsible; whether the patient and/or family was informed; the severity of the error; and whether application of the Universal Protocol would have likely prevented the error. For statistical analyses, data were combined into the following 2 groups: group I (wrong implant or transplant) and group II (wrong eye, patient, or procedure). **Tables 7, 8, and 9** compare these 2 groups by who was responsible for the error, its severity, and its preventability using the Universal Protocol.

<table>
<thead>
<tr>
<th>Person Who Recognized the Error</th>
<th>No. (%)</th>
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<tbody>
<tr>
<td>Wrong Implant</td>
<td>Wrong Eye Block</td>
</tr>
<tr>
<td>Surgeon</td>
<td>44 (66)</td>
</tr>
<tr>
<td>Staff</td>
<td>10 (15)</td>
</tr>
<tr>
<td>Patient</td>
<td>0</td>
</tr>
<tr>
<td>Unknown</td>
<td>13 (19)</td>
</tr>
<tr>
<td>Total</td>
<td>67</td>
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<table>
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<tr>
<th>Time of Error Recognition</th>
<th>No. (%)</th>
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<tr>
<td>Wrong Implant</td>
<td>Wrong Eye Block</td>
</tr>
<tr>
<td>Preoperatively</td>
<td>0</td>
</tr>
<tr>
<td>Intraoperatively</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Postoperative recovery</td>
<td>37 (55)</td>
</tr>
<tr>
<td>Postoperative follow-up</td>
<td>22 (33)</td>
</tr>
<tr>
<td>Unknown</td>
<td>6 (9)</td>
</tr>
<tr>
<td>Total</td>
<td>67</td>
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<table>
<thead>
<tr>
<th>Person Responsible for Error</th>
<th>No. (%)</th>
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</thead>
<tbody>
<tr>
<td>Wrong Implant</td>
<td>Wrong Eye Block</td>
</tr>
<tr>
<td>Surgeon alone</td>
<td>10 (15)</td>
</tr>
<tr>
<td>Surgeon and others</td>
<td>48 (72)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Unknown</td>
<td>6 (9)</td>
</tr>
<tr>
<td>Total</td>
<td>67</td>
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<table>
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<tr>
<th>Was Patient Informed?</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong Implant</td>
<td>Wrong Eye Block</td>
</tr>
<tr>
<td>Yes</td>
<td>46 (69)</td>
</tr>
<tr>
<td>No</td>
<td>5 (7)</td>
</tr>
<tr>
<td>Unknown</td>
<td>16 (24)</td>
</tr>
<tr>
<td>Total</td>
<td>67</td>
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</table>
Wrong power of an intraocular lens constituted by far the most common error in both data sets. Overall, the wrong implant was used in 67 of 106 cases (63%): 26 of the 42 OMIC cases (62%) and 41 of the 64 NYPORTS cases (64%). In 17 cases, the error occurred preoperatively. Incorrect A-scans were used in lens-power calculations in 8 cases, in 3 of these because a new machine had not been correctly programmed. In 2 cases, surgeons were criticized for not performing A-scans concurrently on the fellow eye, which might have alerted them to an incorrect power measurement. In 6 cases, 2 patients’ lens orders records were transposed, and in 1 case, the patient’s eye scans were transposed.

Two cases occurred because the ophthalmologist’s office staff switched the order of operations, but this change was not communicated to the OR nurse. In both cases, the second patient, who was operated on first, received the implant intended for the first patient. In 2 cases, the surgeon forgot the plan that was agreed on with the patient, to perform monovision correction. In all of these cases, the lens powers were checked against incorrect order forms on the day of the operation.

Errors committed intraoperatively accounted for 46 of 67 wrong-implant cases (69%). The cause in almost every case was failure to check the lens specifications properly before implantation. Typically, the OR clerk or circulator...
pulled the wrong lens and its parameters were not verified in the OR before implantation. Contributing factors were often identified. The OR schedule or staff assignment was changed in 6 cases. The nursing staff was unfamiliar with the eye operations or was changed in the middle of the procedure in 8 cases. In 1 case, the surgeon simply confused 2 patients. In another, the surgeon dropped a pile of charts, which were reassembled out of order.

Problems reading the label on the implant package contributed to confusion in 3 cases: labels were damaged, difficult to read in the dimly lit OR, or stored upside down. In 1 case, the surgeon ordered a −4 D lens, but the staff was unaware that negative lenses were available and ordered a +4 D lens. In only 1 case was it recorded that the surgeon simply refused to follow the policy designed to prevent surgical errors.

The most serious injuries resulted from difficulty during lens exchange. Two patients developed corneal edema. In 1, the best-corrected final visual acuity was 20/80. In the other, penetrating keratoplasty was required, but the patient’s final corrected visual acuity was 20/25. Glaucoma occurred in 1 patient, who required an Ahmed valve and had a final visual acuity of 20/40 with visual field loss.

Information regarding liability payments was available in the 26 OMIC cases. Four lawsuits were never filed, 1 was withdrawn by the plaintiff, 2 were dismissed, and 2 were decided in favor of the surgeon. In 1 case, the surgeon was excused and the OR alone was held responsible. Six cases were closed without payment by the insurer, but liability payments were made by surgeons in 2 cases from their own funds ($6000 and $6500). A total of 9 cases were settled by the insurance company, with liability payments ranging from $36 667; median, $30 000). One case of forgotten monitoring and the surgeon who refused to follow the policy was investigated for professional misconduct. One surgeon was required to undergo 3 months of monitoring and the surgeon who refused to follow the policy was investigated for professional misconduct.

<table>
<thead>
<tr>
<th>Confusion Group</th>
<th>Group I: Wrong Implant or Transplant</th>
<th>Group II: Wrong Eye, −Eye Block, Patient, or Procedure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>51 (77)</td>
<td>35 (97)</td>
<td>86 (84)</td>
</tr>
<tr>
<td>No</td>
<td>15 (23)</td>
<td>1 (3)</td>
<td>16 (16)</td>
</tr>
<tr>
<td>Unknown</td>
<td>3</td>
<td>1</td>
<td>4</td>
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*a P = .009 for comparison of groups I and II, based on the χ² test.

### WRONG PATIENT OR PROCEDURE

The wrong patient was operated on or the wrong procedure was performed in 8 cases, 4 from OMIC and 4 from NYPOR. Most had no site markings indicating the correct eye for operation. The purple mark was not visible on the darkly pigmented skin of 1 vitrectomy patient and the mark was covered by the OR hat of 1 cataract patient. Another cataract patient had the correct eye marked, but the anesthesiologist and resident initiated peribulbar anesthesia on the other eye after the patient stated that it was the eye to be operated on.

In all 14 cases, the anesthetic effect dissipated and operation on the correct eye was performed without complication, generally on the same day and often without delay. In the case with the undetected purple mark, a payment of $5500 was made by the surgeon’s liability carrier. Policy changes were made after administrative review in 8 of 12 NYPOR cases. Two surgeons had their practices monitored.

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specified conjunctival incision in the incorrect eye. In most cases, appropriate site markings had not been made and a time-out had not been performed.

In 2 lacrimal cases, probings on the correct eye were performed the same day, in the first before the child awoke from anesthesia and in the second, 2 hours later. One dacryocystorhinostomy incision was sutured before the operation was completed and the correct eye was operated on before the patient left the OR. One dacryocystorhinostomy and 1 laser lacrimal procedure was completed on wrong eyes.

When a cataract operation was commenced on the wrong eye, 1 patient complained of pain because the correct eye had been blocked. A second patient informed the nurse that the incorrect eye was to undergo the operation, which was then operated on; after an otherwise uneventful cataract operation, she asked why the wrong eye had been operated on. A third patient had the correct eye marked and site verifications were performed 3 times, but viscoelastic material was injected into the wrong eye.

In another case, a patient undergoing a penetrating keratoplasty had the correct eye marked with tape and was prepared for the operation, but the surgeon then draped the wrong eye, which underwent corneal transplantation. The OR staff then prepared the wrong eye for the retinal detachment operation. After opening the conjunctiva, the surgeon recognized the error, sutured the incision, and performed the operation on the correct eye. After a skin incision in the wrong upper eyelid was made in a patient scheduled for gold weight implant, the surgeon sutured the incorrect incision and completed the operation on the correct eyelid.

Legal outcomes were available for 10 OMIC cases. Three patients did not bring liability actions and 3 cases were closed without payment. In the 4 remaining cases, liability payments were as follows: $40,000 for a glaucoma case, $20,000 for a lacrimal probing case, $6500 for a dacryocystorhinostomy case, and $6000 for the conjunctival incision in the retinal detachment case. In all 5 of the NYPORTS cases, policies were changed to require more effective site verification. The 2 Nd:YAG capsulotomy errors resulted in practice monitoring. The surgeon who performed the penetrating keratoplasty on the wrong eye was temporarily suspended, given counseling, and eventually the individual’s staff privileges were reinstated with practice monitoring.

**WRO ng TRANSPLANTS**

The wrong tissue was transplanted during penetrating keratoplasty in 2 NYPORTS cases. In both, the incorrect tissue was stored in the OR refrigerator. The circulator called out the donor’s identifying information in the OR, but it is unclear whether the surgeon heard or responded in either case. In both cases, policies were revised to require more thorough donor tissue identification.

**STATISTICAL ANALYSIS**

There were 69 cases in group I (wrong implant or transplant) and 37 cases in group II (wrong eye, patient, or procedure). Confusions in group I were more often the shared responsibility of the surgeon and another member of the surgical team than those in group II (P = .001). Confusions in group I had higher injury severity scores (21% vs 3% for injury severity scores of ≥ 3, P = .001) and were less often preventable using the Universal Protocol (P = .009).

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**COMMENT**

The 62 NYPORTS cases represent all of the surgical confusions reported from 900,000 eye operations performed in New York state between 2001 and 2005. These statistics suggest an incidence of 69 surgical confusions per 1 million eye operations. Some believe underreporting of as much as 90% may occur in Florida’s mandatory reporting system. Even without accounting for underreporting, an incidence of 69 cases per 1 million (69 sigma) is more than 10 times the quality-defect standard (6 sigma) accepted by the manufacturing industry. The 42 malpractice incidents, claims, and lawsuits identified by OMIC were taken from a closed case file containing 2256 cases from 1982 through 2003. Surgical confusions therefore appear to account for only about 2% of malpractice cases in ophthalmology. Once initiated, however, such cases are relatively likely to result in an indemnity payment. On average, 21% of malpractice cases brought against OMIC-insured ophthalmologists resulted in an indemnity payment. During the same period, there was a payment in 48% of lawsuits that involved surgical confusions.

The incidence of surgical confusions in ophthalmology compared with other specialties depends largely on the categories that are included. Of 52 wrong-site, wrong-patient, and wrong-procedure cases reported to NYPORTS in 2003-2005, ophthalmology did not account for a single case. In a similar tabulation of 126 cases from the Joint Commission on Accreditation of Healthcare Organizations (August 1998 to December 2001), only 2 cases were in ophthalmology.

Ophthalmology figures much more prominently if cases of incorrect equipment, especially intraocular lenses, are tabulated. Wrong equipment accounts for 15% of all surgical confusions in the NYPORTS program. Of 20 cases reported in 2003-2005, 14 (70%) were wrong intraocular lenses. Thus, ophthalmology was first among surgical specialties in errors involving equipment. Wrong-knee components were in second place, accounting for only 4 cases (20%). In a listing that included wrong equipment along with other confusions, cataract operations were second only to radiology procedures among 494 adverse event procedures reported to the Florida Agency for Health Care between 1990 and 2003.

Of the 106 cases analyzed, 67 (63%) represented wrong-power intraocular lenses. Operation on the wrong eye was the second most common confusion, representing only 15 cases. An additional 14 cases were wrong-eye blocks, which were, fortunately, recognized before operation on the incorrect eye was initiated. Wrong procedure or patient errors accounted for 6 cases. Two cases were wrong corneal transplants.
In 16 of 106 cases, application of the Universal Protocol would have been unlikely to prevent the error. Many had their genesis in the surgeon’s office. Clearly, vigilance is required throughout the process surrounding an eye operation, beginning in the office with the planning of the procedure, calibration and performance of A-scans, preparation and transmittal of lens orders, execution of informed consents, and scheduling of the operation. A-scans should be performed on both eyes concurrently and should be repeated if asymmetric. Lens orders and operating schedules should be checked against original office notes, preferably by more than one participant, before an operation is initiated. As hypothesized, such factors as switched schedules; distracted, inexperienced, or changing personnel; inadequate preoperative verification procedures; lack of uniform site marking; and breakdown of communication between the surgeon and the patient and his or her family were identified in most cases.

Several problems with application of the Universal Protocol were uncovered. Preoperative verification can become confused if patients are themselves confused or if only 1 patient identifier is used.6,40 Site marking can be useless if the mark is not visible on the patient’s skin, if it is covered by OR caps or drapes, or if it is removed in the course of the surgical preparation. The final time-out can be ineffective if the surgeon and other participants do not consider it seriously. A preoperative checklist, such as the one developed by the American Academy of Ophthalmology and based on the Universal Protocol, should be used consistently.23 Although there has been considerable resistance in the past, most surgeons have agreed with an editorial from the American Journal of Orthopedics that “the most grievous errors in surgery are to operate on the wrong patient, do the wrong procedure, or operate on the wrong site.”71 Regardless of how rare, benign, or treatable, such errors may have serious negative consequences for the patient, the surgeon, the institution, and the profession. The public finds such errors shocking and simply do not consider them to be an acceptable risk of their medical care.31,35

Some injuries were not benign. Severity scores of 3 or 4 were assigned in 14 cases, which included a permanent decrease in vision from new-onset glaucoma and corneal decompensation; unnecessary corneal transplantation on the only good eye; and severe refractive error in 1 or both eyes. Many patients reported annoying asthenopia or diplopia, even though they had severity scores of 2.

Involved surgeons typically faced intramural and external investigations, official sanctions, medical liability, and embarrassment, even in cases without significant injury. The Florida Board of Medicine has imposed severe penalties on surgeons, including suspended licenses, fines as high as $20,000, community service, and giving lectures to colleagues.31,35,54 Perhaps the strongest sanctions are imposed by the surgeon’s conscience owing to loss of the patient’s trust. Finally, the reputation of the profession as a whole is called into question whenever such cases, no matter how mild or rare, come to public light.

For these reasons, procedures designed to prevent surgical errors deserve the acceptance, support, and active participation of ophthalmologists. Even if they seem burdensome at times and even if the errors prevented are mild, these procedures may prevent serious consequences if applied consistently. In the unfortunate circumstance of having committed a surgical confusion, the ophthalmologist is well advised to treat the patient as medically indicated and to make a prompt, full, and honest disclosure to the patient and family. Although embarrassing, such apologies probably decrease liability.55-57

The causes of these confusions were faulty systems, processes, and conditions that led people to make mistakes, more often than an individual’s recklessness. Indeed, broadly accepted principles in the error literature recognize that physicians inevitably make errors, that errors are almost always multifactorial, and that systems can be designed to prevent them.53,56-70 The traditional response to medical error, “blame, shame, and train,” therefore misses the point. Humiliating or otherwise disciplining caregivers tends to perpetuate a culture of secrecy that impedes effective root-cause analysis and future improvement. A more enlightened approach is entirely nonpunitive, drawing on methods of crew resource management adapted from the airlines and the defense department.52,71,72
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From the Archives of the Archives

Römer reports three cases of intraocular infection in which iodoform was introduced into the anterior chamber. In the first case, one of staphylococcus infection after a myopia operation, there was complete recovery and V=½ was obtained. In the second case, a perforating injury from a bit of stone, with traumatic cataract and beginning panophthalmitis, the iodoform was efficacious and the panophthalmitis passed off....In the third case there was infection with a peculiar bacillus after a cataract extraction, and the clinical course did not resemble that of purulent infection. Iodoform was of no service.