PREVENTING SURGICAL CONFUSIONS IN OPHTHALMOLOGY (AN AMERICAN OPHTHALMOLGICAL SOCIETY THESIS)

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ABSTRACT

Purpose: Surgical confusions have been rarely studied, especially in ophthalmology. The author hypothesized that such confusions occur rarely but are unacceptable in the public, legal, and regulatory arenas; often occur in circumstances presenting predictable risk; more often involve wrong lens implant than wrong eye, procedure, or patient; and can be prevented by following the Universal Protocol.

Methods: A retrospective series of 106 cases occurring between 1982 and 2005 included 42 closed files from the Ophthalmic Mutual Insurance Company and 64 cases reported to the New York State Health Department. Records were grouped by procedure planned and analyzed to answer these questions: How did the error occur? By whom and when was the error recognized? Who was responsible? Was the patient informed? What was done to the patient? What was the outcome? What liability payments were made? What policy changes or sanctions resulted? Was the error preventable by following the Universal Protocol?

Results: The most common confusion was wrong lens implant, accounting for 67 (63%) of the 106 cases. Wrong eye surgery occurred in 15 cases, wrong eye blocks in 14, wrong patient/procedure in 8, and wrong corneal transplant in 2. In 16 cases, the Universal Protocol would have been unlikely to prevent the confusion.

Conclusions: Surgical confusions occur infrequently and usually cause little or no permanent injury, but they may be devastating to the patient, the physician, and the profession. Measures to prevent such confusions, including the Universal Protocol and related checklists, deserve the acceptance, support, and active participation of ophthalmologists.

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INTRODUCTION

Surgical confusions (wrong patient, wrong site, wrong procedure) are an important and potentially preventable cause of morbidity in the United States that is becoming more recognized.[1-56] Relatively little information is available regarding the incidence and severity of the problem in ophthalmology.[7,13,21-26] The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), in concert with many professional organizations, including the American Academy of Ophthalmology, has promulgated a "Universal Protocol" in an effort to prevent such confusions in all surgical procedures (Appendix).[27,28] This protocol, which took effect in July 2004, provides a consistent approach involving preoperative verification, site marking, and a "time-out" immediately before incision. 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.

Although rarely mentioned in the medical literature, surgical confusions have frequently been the subject of reports in the lay press.[1,29-31] Their overall incidence is difficult to determine, however, because most cases are unreported. In Veterans Administration facilities, where records are relatively reliable, such errors occur once in approximately 25,000 surgical procedures, accounting for about 1 case each month nationwide.[15] The Physician Insurance Association of America has files on nearly 1000 liability claims involving wrong-site surgery. The JCAHO identifies wrong-site surgery as the most commonly reported error causing patient injury, accounting for 531 of 4074 "sentinel events."[28]

One survey of 560 hand surgeons indicated that, at some time in their careers, 16% of respondents had prepared to operate on the wrong site but noticed the error prior to incision.[4] An additional 21% acknowledged actually performing wrong-site surgery at least once. In 46% of errors, the surgeon alone was deemed at fault; in 41% another hospital staff member was held partly accountable. The problem was more common with busier and more experienced surgeons. Permanent disability resulted in 9% of cases, and legal action that led to a monetary settlement resulted in 38%. Wrong-site surgical errors are typically indefensible, and 84% of the suits reported in this survey of hand surgeons resulted in an indemnity award (compared to 30% of all orthopedic liability cases).

Risk factors for surgical confusions, identified in a number of studies, include breakdown in communication between the surgeon and the patient or family; lack of consistent patient and procedure verification procedures; lack of a uniform site-marking procedure; lack of a uniform preoperative checklist; incomplete patient assessment; staffing issues; distraction or lack of available information in the operating room (OR); and cultural or language barriers.[15,21,32-34]

Confusions are more likely in emergencies, when there are time pressures, when unusual patient characteristics force a break in routine, and when there are multiple surgeons or procedures. In many cases, the error occurs simply because 2 patients have similar names. In other cases, OR staff have positioned the patient incorrectly or prepared the wrong side for surgery. In some instances, patients themselves supplied incorrect information preoperatively.[5] Of cases reported to JCAHO, 58% involved patients undergoing ambulatory surgery and 29% involved inpatients. The wrong site was involved in 76%, the wrong patient in 13%, and the wrong procedure in 11% of cases.

Surgical confusions are most common in orthopedics and podiatry, urology, and neurosurgery. The incidence in ophthalmology is

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uncertain, but it is clearly higher if cases of wrong implants are included in addition to cases of wrong site/procedure/patient.[21,22,32,35] Insertion of an incorrect IOL accounted for one-third of liability claims related to cataract extractions in the 1980s.[11]

The consequences of surgical confusions in ophthalmology can be devastating. The most infamous cases involve enucleation of the incorrect eye.[19,23,36] The author heard anecdotally of a series of errors caused when an OR nurse prepared all of the IOLs for the dozen cataract surgeries to be performed that day but had them out of order because the schedule was changed. Most of the lenses required removal when the error was discovered at the end of the day.

The American Academy of Ophthalmology, the American Society of Ophthalmic Registered Nurses, and the American Association of Eye and Ear Hospitals have all endorsed a preoperative checklist incorporating JCAHO's Universal Protocol.[22,27,36,37] The checklist includes the following: (1) Informed consent is executed without abbreviations; (2) The history and physical examination document is available in the OR; (3) Before medications are administered, the circulator asks the patient or family which eye will be operated upon; (4) The patient/family response, the surgical consent form, the orders, the equipment to be used (including IOL), and the history and physical examination document are all matched against the OR schedule; (5) The surgeon or assistant marks the eye to be operated upon with his or her initials using indelible ink; (6) Before the patient is sedated, the surgeon personally verifies the operative eye with the patient or family, the consent, and the history and physical; (7) Just before making the incision, the surgeon verifies the procedure with the active involvement of the entire team, including anesthesiology and nursing staff. If there is any discrepancy, the surgeon resolves it before proceeding. Similar protocols have been recommended by the American College of Surgeons, the American Academy of Orthopaedic Surgeons, the Veterans Health Administration, the American College of Obstetricians and Gynecologists, and the Association of Perioperative Registered Nurses (AORN).[37-45]

Clearly, surgical confusions are preventable. In 1997, Canadian orthopedic surgeons initiated a program requiring that the surgeon initial the operative site. In the subsequent 5 years, the incidence of wrong-site surgery lawsuits decreased by 65%.[4] And yet there has been considerable resistance on the part of some surgeons, who may believe that such errors cannot occur in their ORs, that procedures designed to prevent them are unduly disruptive, or that site marking may give a negative impression to patients. Only 48% of the hand surgeons surveyed regularly marked the surgical site preoperatively.[4] Those who had committed errors tended to become the most compliant.

The author performed this study to test the hypothesis that surgical confusions in ophthalmology:

1. occur rarely but are unacceptable to the public and in the legal and regulatory arena;
2. often occur in circumstances presenting predictably higher risk;
3. more often involve wrong lens implant than wrong eye, procedure, or patient; and
4. could be prevented by appropriate application of the Universal Protocol.

METHODS

The Institutional Review Board of the Albany Medical Center granted its approval for this investigation.

SOURCES OF DATA

For this study, the author retrospectively reviewed 106 cases of surgical confusions in ophthalmology that occurred between 1982 and 2005. Of these, 42 (40%) were closed cases of the Ophthalmic Mutual Insurance Company (OMIC), the largest liability carrier in ophthalmology, provided under an agreement that protects the identity of patients, institutions, and surgeons. Dates of occurrence for the OMIC cases were 1982 through 2003. The other 64 (60%) of the 106 cases had been reported to the New York State Department of Health NYPORTS (New York Patient Occurrence Reporting and Tracking System) program, which began in 2000. Names were masked to protect the anonymity of patients, institutions, and surgeons. Dates of occurrence for the NYPORTS cases were 2000 through 2005. None of the OMIC cases occurred in New York State.

DATA ABSTRACTION AND ANALYSIS

The cases were first grouped according to the type of confusion: (1) Wrong Implant; (2) Wrong Eye Block; (3) Wrong Patient or Procedure; (4) Wrong Eye; and (5) Wrong Transplant. These categories were mutually exclusive and did not overlap. For each case, data abstracted from available records included the following: the planned procedure, type of error, and how it occurred; who recognized the error and when it was recognized; whether the error occurred preoperatively or intraoperatively; who was responsible for the error; whether the patient/family was informed; what treatment was given; the eventual medical outcome; and whether application of the Universal Protocol would have prevented the error.

In order to compare outcomes, each case was assigned an injury severity score of 1, 2, 3, or 4. The four levels of injury severity were adapted from Kwan and associates[14]: 1, temporary/insignificant (eg, scar only); 2, temporary/minor (eg, delayed recovery, return to the operating room, < 3 diopters of over/undercorrection); 3, mild but permanent (eg, moderate to severely delayed recovery, > 3 diopters of over/undercorrection); and 4, severe permanent injury (eg, uncorrectable vision loss). The injury severity score was determined by the author and 2 independent observers. In cases where there was a disagreement, a consensus decision was reached by discussion.

In the OMIC cases, the final legal outcome, including liability payment, if any, was also recorded. In the NYPORTS cases, the policies in place at the facility, whether these were followed correctly, whether they were changed as a result of review of the error, and whether sanctions were imposed on the surgeon were also tabulated.

STATISTICAL ANALYSES

For statistical analyses, data for the 5 groups into which the cases were initially sorted were combined into 2 groups: group I (Wrong Implant or Transplant) and group II (Wrong Eye/Eye Block/Patient/Procedure). Intergroup differences in the distribution of who was responsible for the error, the injury severity score, and whether following the Universal Protocol would have prevented the error were analyzed using a chi-square test, with the Fisher exact test employed for comparisons involving inadequate cell sizes. The level of significance for all analyses was $P < .05$. For the hypotheses involving the comparison of a proportion to the null value (eg, % surgical confusions due to wrong lens implant > 50%; % preventable surgical confusions > 50%), the sample size of 106 provided sufficient statistical power (one minus $\beta = .8$) for detecting true proportions of 60% or greater.

RESULTS

A. WRONG IMPLANTS

Wrong-power IOL constituted by far the most common error in both data sets. Overall, the wrong implant was used in of 67 (63%) of the 106 cases, 26 (62%) of the 42 OMIC cases and 41 (66%) of the 64 NYPORTS cases. This group of errors was sorted and described according to whether the confusion occurred before or after the patient reached the OR.

Preoperative Errors

In 17 of the 67 wrong-implant cases, the error occurred during the preoperative period. In 8 of these, incorrect A-scans were used in lens power calculations. In 3 cases, the clinic where the scans were performed used a new machine, which had been not been programmed by the service representative and therefore reverted to a default A-constant (116.8, rather than 118.7). In 2 cases, records of 2 patients' A-scans were transposed in the ophthalmologist's office, leading to the incorrect lens powers being ordered for the OR. In another case, a left eye's A-scan was substituted for the right eye's scan because of a transcription error in the preoperative area. In 2 cases, the surgeons were criticized for not performing A-scans concurrently on the fellow eye, which might have alerted them to an incorrect power measurement. In one of these cases, a 5-year-old A-scan was used, despite a discrepancy between eyes of 22.6 D OS vs 25.1 D OD.

In another case, the surgical coordinator in the OR ordered a +17.50 D lens instead of a +7.50 D lens because of a transcription error. In 2 cases, the resident transposed the powers determined for 2 separate patients when faxing IOL orders from the ophthalmology clinic to the OR. On the day of surgery, the power was not verified against the patient chart, but only against the order form, so the error was not discovered until 5 days postoperatively. In 2 cases, the preregistration nurse in the OR switched patient identification stickers, containing the preoperative orders and lens calculation sheets, in 2 patient records.

Two cases occurred because the ophthalmologist's office staff switched the order of surgeries but this change was not communicated to the OR nurse. As a result, the second patient, who was operated upon first, received the implant intended for the first patient. In 2 cases, the surgeon simply forgot the plan agreed upon with the patient to perform monovision correction.

Intraoperative Errors

Errors committed intraoperatively accounted for 46 (69%) of the 67 wrong-implant cases. 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 the parameters of the lens were not verified in the OR before implantation. Contributing factors were identified in several cases. The OR schedule or staff assignment was changed in 6 cases. Nursing staff was changed in the middle of the procedure in 2 cases, and nurses were multitasking and distracted in another case. A circulator unfamiliar with eye surgery substituted in 1 case and put the wrong lens on the tray. In another case, the circulator switched the lenses between 2 patients. In 2 cases, the incorrect chart was used to verify the lens power, and in 1 case the clerk labeled the lens with the incorrect patient's name. In 1 case, the surgeon dropped a pile of charts, which were out of order when reassembled. In another the surgeon simply confused 2 patients.

Problems reading the label on the implant box caused the confusion in 7 cases. In 1 case, the label on the box containing a 26 D lens was damaged, leading several observers to read the label as 20 D. In a second case, the surgical assistant misread the lens power, interpreting a 26.5 D as a 21.5 D, and the stronger lens was incorrectly implanted. In a third case, the circulator pulled the wrong lens because it was stored upside down and she misread the label on the box. In 2 cases, the OR technician transposed IOL powers. In the sixth case, the OR clerk pulled the incorrect power lens because she could not see the label in the dimly lit OR. In the seventh case, the surgeon ordered a -4 D lens but the staff members were unaware that minus 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.

By Whom and When Was the Error Recognized?

Records demonstrated who discovered the error in 54 of the 67 wrong-implant cases (Table 1). In 44 (81%) of these, the error was discovered by the surgeon. Seven errors were discovered by OR nurses, 2 by the resident assistant, and 1 by a second ophthalmologist.

In 61 cases, it was possible to determine when the error was discovered (Table 2). In 39 (64%) of these, the error was discovered on the day of surgery when documentation was checked, either while the patient was still in the OR (2 cases) or when the patient was in the recovery room (37 cases). In 22 cases (36%), poor uncorrected vision or ametropia was noted during the first days or weeks postoperatively.

Who Was Responsible?

Responsibility for the error could be assigned by review of available records in 61 of the 67 wrong-implant cases (Table 3). Inasmuch as it is standard care for the surgeon to check the IOL before implantation, the surgeon bears at least partial responsibility in almost all cases. In 3 cases, the error was the result of A-scans incorrectly calibrated by the manufacturer. In 10 cases (16%), the surgeon alone was responsible. In the remaining 48 cases (84%), the surgeon shared responsibility with office or OR staff. Included were circulators (38 cases), clerical staff in the OR (4 cases), resident surgeons (3 cases), fellows (1 case), office staff (7 cases), and A-scans (3 cases).

TABLE 1. WHO RECOGNIZED THE ERROR, BY TYPE OF OPHTHALMIC SURGICAL CONFUSION

WHO RECOGNIZED ERROR?	WRONG IMPLANT	WRONG EYE BLOCK	WRONG PATIENT OR PROCEDURE	WRONG EYE	WRONG TRANSPLANT
Surgeon	44 (66%)	8 (57%)	4 (50%)	8 (53%)	2 (100%)
Staff	10 (15%)	3 (21%)	4 (50%)	2 (13%)	0
Patient	0	1 (7%)	0	3 (20%)	0
Unknown	13 (19%)	2 (14%)	0	2 (13%)	0
Total	67	14	8	15	2

TABLE 2. WHEN WAS THE ERROR RECOGNIZED, BY TYPE OF OPHTHALMIC SURGICAL CONFUSION

WHEN WAS ERROR RECOGNIZED?	WRONG IMPLANT	WRONG EYE BLOCK	WRONG PATIENT OR PROCEDURE	WRONG EYE	WRONG TRANSPLANT
Preoperatively	0	14 (100%)	0	0	0
Intraoperatively	2 (3%)	0	1 (13%)	6 (40%)	0
Postoperative recovery period	37 (55%)	0	6 (75%)	8 (53%)	2 (100%)
Postoperative follow-up period	22 (33%)	0	1 (13%)	0	0
Unknown	6 (9%)	0	0	1 (6%)	0
Total	67	14	8	15	2

TABLE 3. WHO WAS RESPONSIBLE FOR THE ERROR, BY TYPE OF OPHTHALMIC SURGICAL CONFUSION

WHO WAS RESPONSIBLE?	WRONG IMPLANT	WRONG EYE BLOCK	WRONG PATIENT OR PROCEDURE	WRONG EYE	WRONG TRANSPLANT
Surgeon alone	10 (15%)	9 (64%)	4 (50%)	10 (67%)	2 (100%)
Surgeon and others	48 (72%)	2 (14%)	4 (50%)	4 (27%)	0
Someone besides surgeon	3 (4%)	3 (21%)	0	0	0
Unknown	6 (9%)	0	0	1 (7%)	0
Total	67	14	8	15	2

Was the Patient Informed?

In 51 cases, records specified whether the patient or family or both were informed of the error by the surgeon (Table 4). In 46 cases (90%), this disclosure was made. The surgeon elected not to confess the error in 5 cases because of embarrassment or because patients experienced only minimal symptoms. One patient was informed of the error by a second surgeon, whom he had consulted on his own.

What Was Done to the Patient?

Lens exchange was at least attempted in 28 of the 67 patients (42%). In 1 case, removal of the lens was attempted but could not be accomplished because the capsule ruptured and the incorrect lens would not prolapse easily into the anterior chamber. Piggyback lenses were implanted in 2 cases, and laser refractive surgery was performed in 1 case. The incorrect lens was left in place with spectacle or contact lens correction in 27 cases (40%), generally with only minimal ametropia. In 8 cases, the data available for review did not include information about subsequent treatment.

TABLE 4. WAS THE PATIENT INFORMED OF THE ERROR, BY TYPE OF OPHTHALMIC SURGICAL CONFUSION

WAS PATIENT INFORMED?	WRONG IMPLANT	WRONG EYE BLOCK	WRONG PATIENT OR PROCEDURE	WRONG EYE	WRONG TRANSPLANT
Yes	46 (69%)	12 (86%)	5 (63%)	15 (100%)	2 (100%)
No	5 (7%)	0	0	0	0
Unknown	16 (24%)	2 (14%)	3 (38%)	0	0
Total	67	14	8	15	2

What Was the Outcome?

The severity of injury, based on information from the last follow-up visit recorded in the data set, could be identified in 60 of the 67 cases (Table 5). The injury severity score was 1 (temporary/insignificant, eg, scar only) in 8 cases; the score was 2 (temporary/minor, eg, delayed recovery, return to the OR, or to ≤3 diopters of overcorrection or undercorrection) in 39 cases; the score was 3 (mild but permanent, eg, moderate to severely delayed recovery or >3 diopters overcorrection or undercorrection) in 11 cases; and in 2 cases the score was 4 (severe permanent injury/uncorrectable vision loss). In 7 cases, records did not indicate the outcome.

Prompt and successful IOL exchange, piggyback lens placement, and laser refractive surgery all generally resulted in good outcomes, but cases were assigned an injury severity score of 2 if a return to the OR was required. In 4 patients, the error was recognized and the lens was exchanged before the patient left the OR. In 3 cases, a lawsuit was filed before corrective surgery could be performed.

The most serious injuries included glaucoma and corneal decompensation resulting 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 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.

TABLE 5. WHAT WAS THE SEVERITY OF INJURY SCORE, BY TYPE OF OPHTHALMIC SURGICAL CONFUSION*

WHAT WAS SEVERITY OF INJURY SCORE?	WRONG IMPLANT	WRONG EYE BLOCK	WRONG PATIENT OR PROCEDURE	WRONG EYE	WRONG TRANSPLANT
1	8 (12%)	14 (100%)	5 (63%)	6 (40%)	0
2	39 (58%)	0	3 (38%)	7 (47%)	2 (100%)
3	11 (16%)	0	0	1 (7%)	0
4	2 (3%)	0	0	0	0
Unknown	7 (10%)	0	0	1 (7%)	0
Total	67	14	8	15	2

*Scores adapted from Kwan and associates[14]: 1, temporary/insignificant (eg, scar only); 2, temporary/minor (eg, delayed recovery, return to the operating room, < 3 diopters of over/undercorrection; 3, mild but permanent injury (eg, moderate to severely delayed recovery, > 3 diopters of over/undercorrection); 4, severe permanent injury (eg, uncorrectable vision loss).

What Liability Payments Were Made?

Information regarding liability payments was available in the 26 OMIC cases. In 4, suits were never filed, and in 1 an impending suit was withdrawn by the plaintiff. Two cases were dismissed. Two cases were decided in favor of the surgeon. The first case was

brought to small-claims court to cover the expense of a radial keratotomy performed to correct what the patient claimed was the incorrect implant. The judge was unconvinced and granted a verdict for the defense. In the second case, the surgeon recognized during cataract surgery that he had implanted an IOL that was 2 D too strong. He decided not to explant the lens, reasoning that a slight myopia might actually be of benefit to the patient. The patient experienced diplopia, however, and demanded $350,000, representing herself in the proceeding. The judge granted a motion for summary judgment by the defense, negating the plaintiff's lawsuit.

Six cases were closed without payment by the insurer, but liability payments were made by the surgeons in 2 cases from their own funds. In the first of these, the OR technician had transposed the lens powers of 2 patients, resulting in an unexpected hyperopia of 0.5 D. The surgeon agreed to pay $6500 to settle the claim. In the second, the surgeon had difficulty centering the implant. The patient self-referred to another ophthalmologist, who repositioned the implant successfully but later noted that it was 8 D too hyperopic. The first surgeon agreed to pay $6000 to reimburse the patient's medical expenses and to obtain a release from the liability claim.

A total of 9 cases were settled by the insurance company, the liability payments ranging from $7500 to $87,500 (mean $36,667, median $30,000). In one case, the surgeon was excused and the OR alone was held responsible for ordering the wrong implant. Prompt and uncomplicated lens exchange generally resulted in the smallest settlements. One case of forgotten monovision was settled for $50,000. The 2 cases of corneal edema were settled for $20,000 and $30,000, respectively. The glaucoma case was settled for $87,500.

What Policy Changes or Sanctions Resulted?

Information regarding changes in OR policy and sanctions against surgeons was available in 41 NYPORTS cases. In all but 1 of these, OR policies were amended following administrative review. In this 1 case, the circulator pulled the incorrect lens, but the power was not verified by the surgeon according to established OR protocol. The reviewer determined that the OR policy was adequate to have prevented the error had the policy been followed. Education of the surgeon and the OR staff was recommended. In 23 other cases, the policies in place, although deemed adequate, were nevertheless strengthened following administrative review. In addition, staff education was recommended.

In 4 cases there was no OR policy in place to prevent the confusion, and in 10 cases the relevant policies were deemed inadequate. One surgeon simply refused to follow the OR policy and was reported for professional misconduct. In 1 case, the patient returned to the OR for exchange of an incorrect lens that had been implanted because the lens request form was not in the OR, the nursing record did not include the required signature and lens power, and the side/site verification form was not completed prior to surgery. The surgeon in this case was required to undergo 3 months of monitoring of his compliance with OR policies. In 2 cases, the reviewers concluded that effective policies were in place and were followed, but no explanation was given as to why the errors occurred.

Was the Error Preventable?

Adequate information to assess the potential impact of the Universal Protocol was available in 64 of the 67 cases (Table 6). In 49 (77%) of these 64 cases, the error could have been prevented had the Protocol been applied conscientiously. In the remaining 15 cases (23%), the errors were committed preoperatively and were of a type that could not have been recognized using the Universal Protocol. For example, A-scans incorrectly calibrated or lens order forms labeled with the wrong patient's lens power in the surgeon's office would not be identifiable in the OR.

TABLE 6. WAS THE ERROR PREVENTABLE UNDER UNIVERSAL PROTOCOL, BY TYPE OF OPHTHALMIC SURGICAL CONFUSION

WAS ERROR PREVENTABLE?	WRONG IMPLANT	WRONG EYE BLOCK	WRONG PATIENT OR PROCEDURE	WRONG EYE	WRONG TRANSPLANT
Yes	49 (73%)	14 (100%)	7 (88%)	14 (93%)	2 (100%)
No	15 (22%)	0	1 (13%)	0	0
Unknown	3 (4%)	0	0	1 (7%)	0
Total	67	14	8	15	2

B. WRONG EYE BLOCKS

Injection of anesthesia to the incorrect eye was reported in a total of 14 (13%) of the 106 cases, 2 of the 42 OMIC cases and 12 of the 64 NYPORTS cases. Almost all of these errors resulted from inadequate site verification: either the site was not marked or there was no time-out before surgery. In 1 patient, the purple mark identifying the eye to undergo vitrectomy was not visible on the darkly pigmented skin and the fellow eye was blocked. In another patient, the surgical mark was covered by the OR hat, and the eye not scheduled for cataract surgery received a block.

In 1 case, a patient with glaucoma who was scheduled for bleb revision in one eye received a lid block to the other eye. Although the consent form indicated that surgery was planned for the right eye, the patient, his wife, and the OR schedule indicated the left eye. When questioned, the surgical fellow verified that the left eye was to be operated upon, but he had not checked the surgeon's office note. Only after the block had been administered to the patient's left eye did the surgeon recognize that the bleb in the left eye was

functioning and that the right eye was the one that required surgery.

In another case, a cataract procedure was planned for the patient's right eye. Although the preoperative orders, surgical booking form, OR schedule, and patient all indicated the correct eye, the consent form did not specify the eye to be operated upon. The nurse in the preoperative area asked that the surgeon supply this information on the consent form. The surgeon, when interviewing the patient, confused the patient with her next case of the day and confirmed with the patient, who had cataracts in both eyes, that the left eye was to be operated upon. The block was administered to the left eye. The surgeon discovered the error after discussion with the nurse and the assistant.

In another case, a patient with bilateral cataracts was admitted for surgery on the right eye. The correct consent was obtained and the correct right eye was marked. The anesthesiologist and resident initiated peribulbar anesthesia to the left eye after consulting with the patient, who stated that this was the eye to be operated upon. The error was recognized by the circulator after only a small amount of anesthetic had been administered. The injection was halted and the right eye was anesthetized and operated upon without complication.

A patient with dementia scheduled for cataract surgery on the left eye inadvertently received a retrobulbar block in the right eye because the surgeon happened to be standing on the patient's right side. The error occurred despite the appropriate preoperative check by the OR nurse and the appropriate time-out verifying the correct side with the entire OR team.

By Whom and When Was the Error Recognized?

In 8 of the 14 cases of wrong eye block, the error was discovered by the surgeon (Table 1). One case each was discovered by the anesthesiologist, the fellow, the circulator, and the patient. In 2 cases, the person recognizing the error was not identified. In all 14 cases, the errors were discovered before an incision was made (Table 2).

Who Was Responsible?

In 11 of the 14 cases of wrong eye block, the surgeon was considered at least partly responsible for the error (Table 3). In 1 case, an anesthesiologist blocked the incorrect eye. The surgeon alone was responsible in 9 cases; in 5 cases, the anesthesiologist, the OR staff, the resident, or the fellow shared responsibility for the error.

Was the Patient Informed?

The records indicated that the patient or family or both were informed of the error in 12 of the 14 cases of wrong eye block (Table 4). In the other 2 cases there was no record of such notification.

What Was Done to the Patient?/What Was the Outcome?

In all 14 cases of wrong eye block, the anesthetic effect dissipated and surgery on the correct eye was performed without complication, generally on the same day and often without delay. All 14 of these injuries were thus assigned an injury severity score of 1 (Table 5).

What Liability Payments Were Made?

In the case in which the purple ink used for site marking was masked by the patient's dark skin, a payment of $5500 was made by the surgeon's liability carrier.

What Policy Changes or Sanctions Resulted?

Policy changes were made after administrative review in 8 of the 12 NYPORTS cases. In 2 of these 8 cases, it was required that the surgeons who injected the incorrect eye have their procedures monitored by another surgeon for 6 months.

Was the Error Preventable?

In all 14 cases, following the Universal Protocol could have prevented administering the block to the wrong eye (Table 6).

C. WRONG PATIENTS/PROCEDURES

The wrong patient was operated on or the wrong procedure was performed in 8 of 106 cases, 4 cases in the NYPORTS series and 4 in the OMIC series. Five cases involved laser procedures.

In 1 case, a patient with a diagnosis of retinal detachment came to the glaucoma clinic for a visual field examination. Another patient, with the same last name, was concurrently awaiting a laser trabeculoplasty. When the patient's name was called for the trabeculoplasty, the perimetry patient responded and underwent the laser procedure.

In a similar case, a patient visited a glaucoma clinic for a laser iridotomy on the right eye. While recovering in the waiting room from this procedure, he was mistaken for another patient and underwent iridoplasty on the same eye.

In another case, a patient who had been scheduled for laser iridotomy was mistakenly given a consent form for laser trabeculoplasty. Although the surgical plan clearly indicated an iridotomy was to be performed, as had been performed several months earlier on the fellow eye, the surgeon performed a trabeculoplasty.

Two cases involved LASIK. In the first case, 2 patients with the same first name were present concurrently in the laser center. The second responded when the first was called for the procedure, resulting in overcorrection of myopia in both eyes. In the second case, 2 patients were scheduled for LASIK procedures: the first for astigmatism and the second for hyperopia. At the last minute, the astigmatism patient cancelled and the parameters for his procedure were mistakenly used to treat both eyes of the patient with hyperopia.

In another case, a child who was scheduled for surgery to correct esotropia instead underwent a procedure to correct exotropia. The surgeon recognized the error while the child was still in the hospital and returned the child to the OR, where he reversed the first procedure and performed the intended surgery for esotropia.

In another case, a patient who had undergone removal of silicone oil from the vitreous was to have received a postoperative subconjunctival injection of gentamicin and dexamethasone. Inadvertently, this injection was performed intravitreally. Another patient, who was undergoing cataract surgery, had limbal relaxing incisions intended for a different patient.

By Whom and When Was the Error Recognized?

In 4 of the 8 cases of wrong patient/procedure, the error was recognized by the surgeon. In 7 cases the problem was discovered before the patient left the facility (Tables 1 and 2). The clinic staff recognized the errors in the case of the patient who had laser surgery on the iris repeated in the same eye and the patient who had laser trabeculoplasty performed instead of perimetry when the last patients in the clinic inquired why they had not been called for their procedures. In the case in which unplanned relaxing incisions were made, the surgical nurse recognized the problem intraoperatively. In the case of the patient undergoing trabeculoplasty instead of iridotomy, the error was recognized by a second surgeon.

Who Was Responsible?

The surgeon alone was responsible for the errors in 4 of the 8 cases of wrong patient/procedure (Table 3). In the remaining 4 cases the surgeon shared responsibility, with residents in 3 cases and with the surgical staff in 1 case.

Was the Patient Informed?

In 5 of the 8 cases of wrong patient/procedure, the patient or family were informed of the error (Table 4). In the remaining 3 cases, the records available for review did not indicate whether the error was disclosed.

What Was Done to the Patient?/What Was the Outcome?

The injuries in 5 of the 8 cases of wrong patient/procedure were assigned an injury severity score of 1 (Table 5). The patients who underwent wrong procedures for glaucoma suffered no long-term damage. The iridotomy was performed a month later on the patient who had the unnecessary trabeculoplasty. The incorrect relaxing incisions were simply closed without harm to the patient. The intravitreal medications were removed by vitrectomy, likewise with no damage to the patient.

In the 2 cases of error related to LASIK, a second procedure was required, resulting in both cases being assigned an injury severity score of 2. In the first case, enhancement of the incorrect procedure resulted in an excellent outcome. In the second case, in which surgery was performed to correct astigmatism rather than hyperopia, the patient suffered severe astigmatism, moderately high hyperopia, and photophobia. This patient later underwent lensectomy followed by retreatment with LASIK and eventually attained 20/20 or better vision in each eye.

An injury severity score of 2 was also assigned in the case of the patient with strabismus. After a second procedure, the patient had exotropia, hypertropia, and scar tissue over the muscle insertions. Further surgery was performed by a different surgeon to treat both the strabismus and scarring.

What Liability Payments Were Made?

Liability outcomes were documented for 4 of the 8 cases of wrong patient/procedure. In 2 cases, there was no action brought on behalf of the patient. The LASIK case involving astigmatism was settled for $85,000. The strabismus case was settled for $95,515.

What Policy Changes or Sanctions Resulted?

The case in which iridoplasty was performed on the same eye that had undergone iridotomy resulted in a new policy requiring more thorough patient identification. None of the other 3 NYPORTS cases resulted in policy changes, and no case resulted in sanctions against the surgeon.

Was the Error Preventable?

Application of the Universal Protocol would have prevented 7 of the 8 cases of wrong patient/procedure (Table 6). The incorrect intravitreal injection would not have been prevented by following the Protocol.

D. WRONG EYES

A total of 15 (14%) of the 106 cases involved surgery on the wrong eye; there were 5 such cases in the NYPORTS series and 10 in the OMIC series. All cases involved inadequate preoperative site verification. Included were 5 lacrimal drainage procedures, 3 cataract procedures, 2 yttrium-aluminum-garnet (YAG) laser capsulotomies, 1 penetrating keratoplasty, 1 retinal detachment repair, 1 eyelid implant, and 1 glaucoma procedure. One patient had an unspecified conjunctival incision in the incorrect eye, but no further information was available regarding this case.

The first of the 5 lacrimal cases involved a child scheduled for a probing on the right eye who inadvertently underwent the procedure on the left eye. No site marking had been performed. The surgeon recognized the error immediately after the procedure, and lacrimal probing was performed on the correct side before the child awoke from anesthesia. In the second case, lacrimal probing was performed on the right eye when intended for the left eye. The error was recognized postoperatively, and the child was brought back to the OR, 2 hours later, for probing on the left eye with silicone intubation. In the third case, a patient scheduled for dacryocystorhinostomy on the left eye underwent the procedure on the right eye. Fortunately, the patient required the same procedure

in both eyes. In the fourth case, a dacryocystorhinostomy incision intended for the left side was performed on the right side. The surgeon closed the incision and immediately proceeded to operate on the left side. In the fifth case, a laser lacrimal procedure intended for the left eye was completed on the right eye.

In the first of the 3 cataract cases, peribulbar anesthesia was administered correctly to the left eye. When surgery was commenced on the right eye, the patient complained of pain and the procedure was halted. In the second case, the left eye was scheduled for surgery. The right eye had previously undergone cataract surgery. Although the correct eye was marked and site verifications were performed three times, the right eye was draped and viscoelastic material was injected into the right eye. The error was discovered, the viscoelastic material was removed, and the procedure was rescheduled for a later date on the left eye. In the third case, the patient was admitted for removal of a cataract in the right eye, which had preoperative best-corrected visual acuity of 20/200. The left eye was correctable to 20/25. Consent was obtained for surgery on the correct right eye, which was dilated. When the patient was brought into the OR, however, the patient informed the nurse that it was the left eye that was to undergo surgery. The nurse proceeded to dilate the patient's left eye, peribulbar anesthesia was administered to the left eye, and uneventful cataract surgery with lens implantation was performed on the left eye. After surgery, the patient asked the surgeon why the incorrect eye had been operated on.

The 2 YAG capsulotomies on the wrong eye both occurred because of inadequate site verification. In 1 case, the patient asked after the procedure why the left eye had been treated, although the right eye had been dilated. Both patients were scheduled to undergo treatment to the correct eye subsequently.

The patient scheduled to undergo penetrating keratoplasty had given consent for the correct left eye, which was marked with a tape in the preoperative area. The tape was moved and the correct eye was prepared for surgery. However, the surgeon then proceeded to drape the right eye and performed corneal transplantation on that eye.

The patient scheduled for retinal detachment repair on the left eye gave the correct consent, but the OR staff prepared the right eye for surgery. The surgeon first recognized the error after opening the conjunctiva of the incorrect eye. The conjunctival incision was sutured, and the retinal detachment repair proceeded uneventfully on the correct eye. The patient scheduled for a gold weight implant in the left upper lid had a skin incision made in the right upper lid. The surgeon recognized the error at this point, sutured the incorrect incision, and proceeded to complete the surgery on the correct left upper eyelid.

The patient scheduled for glaucoma surgery on the right eye had undergone similar surgery on the left eye several years earlier. The surgery was inadvertently repeated on the same left eye.

By Whom and When Was the Error Recognized?

In 8 of the 15 cases, the surgeon recognized the error (Tables 1 and 2). Two errors were recognized by nurses, 3 were recognized by the patient, and in 2 cases it was unclear who recognized the error. In 6 cases the error was recognized intraoperatively, in 8 cases the error was recognized postoperatively, and in 1 case the time of recognition could not be determined.

Who Was Responsible?

In 10 of the 15 cases, the surgeon alone was responsible for the error (Table 3). The surgeon shared responsibility with a resident in 1 case and with the OR staff in 3 cases. In 1 case, no information regarding responsibility was found in the available documents.

Was the Patient Informed?

In all 15 cases, patients were promptly informed of the error (Table 4).

What Was Done to the Patient?/What Was the Outcome?

In 6 of the 15 wrong eye cases, no damage was sustained except for surgical scars in 1 of the 5 lacrimal cases and in the patient who had the incision in the wrong eyelid. All were assigned an injury severity score of 1 (Table 5). Seven patients were considered to have injuries of severity level 2, in all cases because a return to the OR was required for surgery on the correct eye. The patient with glaucoma who mistakenly underwent a second surgery on the same eye claimed to have decreased visual acuity and light sensitivity, although his visual acuity was unchanged after the incorrect surgery.

In the case in which penetrating keratoplasty was performed on the wrong eye, the patient clearly suffered permanent damage, but the final visual acuity was not recorded in the records available for this case. Based on the information available, an injury severity score of 3 was assigned in this case, although it is recognized that a higher score could have been warranted.

What Liability Payments Were Made?

Legal outcomes were available for 10 OMIC cases. No actions were brought by 3 patients, and 3 cases were closed without payment. In the 4 remaining cases liability payments were as follows: $40,000 for the glaucoma case, $20,000 for 1 of the lacrimal probing cases, $6500 for 1 of the dacryocystorhinostomy cases, and $6000 for the conjunctival incision in the retinal detachment case.

What Policy Changes or Sanctions Resulted?

In all 5 of the NYPORTS cases, policies were changed to require more effective site verification. The 2 YAG capsulotomy errors resulted in notes being placed in the surgeons' administrative records, and their practices were monitored. The surgeon who performed the penetrating keratoplasty on the wrong eye was temporarily suspended, was given counseling, and was eventually reinstated with monitoring of his practice.

Was the Error Preventable?

In 14 of the wrong eye cases, the error could have been prevented by appropriate application of the Universal Protocol (Table 6). In 1 case, the information available for review did not permit this determination.

E. WRONG TRANSPLANTS

The wrong tissue was transplanted during penetrating keratoplasty in 2 cases, both in the NYPORTS series. In both cases, the incorrect tissue intended for tectonic transplant was stored in the OR refrigerator, with correct identifying information from the eye bank. In both cases, the circulator called out the donor's age in the OR, but it is unclear whether the surgeon heard the technician or responded.

By Whom and When Was the Error Recognized?

Both errors were discovered by the surgeon while the patient was still in the recovery room (Tables 1 and 2).

Who Was Responsible?

The surgeon alone was responsible in both cases (Table 3).

Was the Patient Informed?

In both cases, the patient was informed immediately (Table 4).

What Was Done to the Patient?/What Was the Outcome?

In both cases the patient was returned to the OR for removal and replacement of the incorrect corneal transplant tissue. Both were assigned an injury severity score of 2 (Table 5).

What Liability Payments Were Made?

No information regarding liability was available from the records reviewed.

What Policy Changes or Sanctions Resulted?

In both cases, policies were revised to require more thorough donor tissue identification.

Was the Error Preventable?

In both cases, the wrong transplant was potentially preventable if the Universal Protocol had been followed (Table 6).

RESULTS OF STATISTICAL ANALYSES

There were 69 cases in group I (Wrong Implant/Transplant) and 37 cases in group II (Wrong Eye/Patient/Procedure). Tables 7, 8, and 9 summarize data on the association between type of confusion and who was responsible, the injury severity score, and whether the injury could have been prevented by following the Universal Protocol. Almost 80% of the confusions in group I were the shared responsibility of the surgeon and another member of the surgical team, whereas the majority of confusions in group II were attributed solely to the surgeon. This difference in the assignment of responsibility for group I vs group II errors was highly significant (P = .001). The injury severity scores were significantly higher for confusions in group I (eg, 21% vs 3% for injury severity scores of 3 or greater, P = .001), and confusions in group I were significantly less often considered to have been preventable if the Universal Protocol had been followed (77% vs 97%, P = .009).

TABLE 7. ASSOCIATION BETWEEN WHO WAS RESPONSIBLE AND TYPE OF OPHTHALMIC SURGICAL CONFUSION, BY GROUP*

WHO WAS RESPONSIBLE?	GROUP I WRONG IMPLANT/TRANSPLANT	GROUP II WRONG EYE/EYE BLOCK/PATIENT/PROCEDURE	TOTAL
Surgeon alone	12 (19%)	23 (64%)	35 (35%)
Surgeon and others	48 (76%)	10 (28%)	58 (59%)
Someone besides surgeon	3 (5%)	3 (8%)	6 (6%)
Unknown	6	1	7

*P = .001 for comparison of Group I and Group II, based on the Fisher exact test.

TABLE 8. ASSOCIATION BETWEEN WHAT WAS THE SEVERITY OF INJURY SCORE AND TYPE OF OPHTHALMIC SURGICAL CONFUSION, BY GROUP*

WHAT WAS SEVERITY OF INJURY SCORE?†	GROUP I WRONG IMPLANT/TRANSPLANT	GROUP II WRONG EYE/EYE BLOCK/PATIENT/PROCEDURE	TOTAL
1	8 (13%)	25 (69%)	33 (34%)
2	41 (66%)	10 (28%)	51 (52%)
3	11 (18%)	1 (3%)	12 (12%)
4	2 (3%)	0	2 (2%)
Unknown	7	1	8

*The association between type of error and these characteristics was tested using a chi-square test, with the Fisher exact test employed for comparisons involving inadequate cell sizes. $P < .001$ for comparison of Group I and Group II, based on Fisher exact test.

†Scores adapted from Kwan and associates[14]: 1, temporary/insignificant (eg, scar only); 2, temporary/minor (eg, delayed recovery, return to the operating room, < 3 diopters of over/undercorrection; 3, mild but permanent injury (eg, moderate to severely delayed recovery, > 3 diopters of over/undercorrection); 4, severe permanent injury (eg, uncorrectable vision loss).

TABLE 9. ASSOCIATION BETWEEN WAS THE ERROR PREVENTABLE UNDER UNIVERSAL PROTOCOL AND TYPE OF OPHTHALMIC SURGICAL CONFUSION, BY GROUP*

WAS ERROR PREVENTABLE?	GROUP I WRONG IMPLANT/TRANSPLANT	GROUP II WRONG EYE/EYE BLOCK/PATIENT/PROCEDURE	TOTAL
Yes	51 (77%)	35 (97%)	86 (84%)
No	15 (23%)	1 (3%)	16 (16%)
Unknown	3	1	4

**P* = .009 for comparison of Group I and Group II, based on chi-square test.

DISCUSSION

The 62 cases in the NYPORTS data set represent all of the surgical confusions reported to the NYPORTS program from a total of 900,000 eye surgeries performed in New York State between 2001 and 2005 (Janet Mannion, New York State Department of Health Bureau of Hospital Services, Division of Primary and Acute Care Services, Troy, New York; written communication, September 2006). These statistics suggest an incidence of 6.9 per 100,000 or 69 surgical confusions per million eye surgeries.

On the other hand, the New York State Health Department suspects, on the basis of focused reviews, that some reportable incidents escape referral to NYPORTS, despite the fact that it is a mandatory reporting system (Janet Mannion, New York State Department of Health Bureau of Hospital Services, Division of Primary and Acute Care Services, Troy, New York; written communication, September 2006). Some believe underreporting of as much as an order of magnitude may occur in Florida's mandatory reporting system, especially in cases where the surgeon is able to conceal the error.[18] It deserves emphasis that, even without accounting for underreporting, an incidence of 69 cases per million (69 sigma) is 10 times the quality-defect standard (6 sigma) accepted by the manufacturing industry.[18] If half of the cases are unreported, the true incidence rises to 138 sigma, and if 90% are unreported, the true incidence is 690 sigma. Depending on one's view of what constitutes a "rare" occurrence, in this context, the hypothesis was therefore not corroborated. In any case, the goal should be to prevent all of these confusions.

The 42 malpractice incidents, claims, and suits identified by OMIC were taken from a closed-case file containing 2256 cases from 1982 through 2003. Surgical confusions, including wrong implant, wrong eye blocks, wrong patient/procedure, wrong eye, and wrong transplant, therefore appear to account for only about 1.86% of malpractice cases in ophthalmology.

Surgical confusion cases, however, are much more likely than other ophthalmology liability cases to result in an indemnity payment once they are initiated. As noted previously, such cases are difficult, if not impossible, to defend.[4] On average, 21% of malpractice cases brought against ophthalmologists insured by OMIC resulted in an indemnity payment. In suits involving surgical confusions during the same time period, there was a payment in 48%. This finding is consistent with the hypothesis that such errors are unacceptable in the legal system and to the public at large.

The incidence of surgical confusions in ophthalmology compared to other specialties depends largely on the categories that are included. In one accounting of 52 cases reported in 2003-2005 to the NYPORTS program, wrong surgical site and wrong patient or procedure cases were tabulated by surgical specialty (John Morley, presentation at the Procedural and Surgical Site Verification Panel Conference, Albany, New York, April 24, 2006). Included were 25% in orthopedic surgery, 21% in general surgery, 16% in neurosurgery, 14% in urology, and 12% in cardiovascular-thoracic surgery. One case (2%) each occurred in otolaryngology, vascular surgery, obstetrics/gynecology, transplant surgery, plastic surgery, and pain management. Ophthalmology did not account for any case in this listing. In a similar tabulation of 126 cases from JCAHO, 41% were orthopedic/podiatric surgery, 20% general surgery, 14% neurosurgery, and 11% urologic surgery. The remaining 14% were divided among dental/oral maxillofacial, cardiovascular-thoracic, ear-nose-throat, and ophthalmologic surgery.[32]

Ophthalmology figures much more prominently if cases of incorrect equipment are tabulated, especially IOLs. Wrong equipment accounts for 15% of the total surgical confusions in the NYPORTS program (Janet Mannion, New York State Department of Health Bureau of Hospital Services, Division of Primary and Acute Care Services, Troy, New York; Office of Health Systems Management Report, 2002-2004; September 2006). A total of 20 cases of wrong equipment were reported to the NYPORTS program in 2004-2005. Of these, 14, or 70%, were wrong IOLs. Ophthalmology thus has the dubious distinction of occupying first place 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 surgery was second only to radiology procedures among 494 adverse event procedures reported to the Florida Agency for Health Care between 1990 and 2003.[18]

Data from the current study mirror this trend and are in agreement with its hypothesis. The author believes that the data set described is sufficiently large and geographically diverse to be representative of ophthalmic surgical confusions in the United States. Of the 106 cases analyzed, 67 cases, fully 64%, represent wrong-power IOLs. Wrong eye surgery was the second most common confusion, accounting for only 15 cases. An additional 14 cases represented wrong eye blocks, fortunately recognized before surgery on the incorrect eye was initiated. Wrong procedure/patient errors accounted for 6 cases. Two cases were wrong corneal transplants.

In 16 of the 106 cases, application of the Universal Protocol was considered unlikely to have prevented the error, a finding that was not anticipated in the hypothesis. Many of these confusions had their genesis in the surgeon's office. For example, 18 of the 67 incorrect implants were ordered because of such factors as incorrectly programmed A-scans, transposed lens orders, and surgery schedules switched by the ophthalmologist's office.

Clearly, vigilance is required throughout the process surrounding eye surgery, 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 surgery. A-scans should be performed on both eyes concurrently and should be repeated if asymmetric. Lens orders and operating schedules should be checked with reference to original office notes before surgery is initiated, preferably by more than one participant. Some hospitals have had success insisting that surgeons bring a list to the OR that specifies the name, eye, and lens parameters for each cataract patient, which is posted in the OR for the staff to see. 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 family were identified in a majority of the cases analyzed in this study.

Several problems with application of the Universal Protocol have been uncovered. Preoperative verification can become confused if patients are themselves confused or if only 1 patient identifier is used.[5,46] This study demonstrates that site marking can be useless if the mark is too dark on pigmented skin, if it is covered by the OR cap 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. Confusions generated by different site-marking protocols in different hospitals should be avoided by all institutions following the same protocol, as has recently been promulgated in New York State. In the past, some facilities specified that an "X" be marked on the incorrect eye, potentially causing exactly the confusion that the system was intended to avoid (Albert Biglan, MD, written communication, February 16, 2006; unpublished data).[1,10]

Some evidence suggests that enforced redundancy can become counterproductive.[14] For example, routine violations of protocol may occur because multiple checks take on the character of "busy work" or because they delay patient flow so that violations are considered necessary or at least acceptable. Additionally, steps may be skipped because of interruptions and distractions. Vigilance against such violations should be maintained, but the safety protocol should be as simple and straightforward as possible without sacrificing its effectiveness. A preoperative checklist, such as the one advocated by the American Academy of Ophthalmology, should be used consistently.[22]

One would expect that there may have been a decrease in the reported incidence of surgical confusions in ophthalmology during the period after the Universal Protocol became effective in July 2004. During the 49 months before this date, a total of 52 cases were reported to NYPORTS. During the 14 months between this date and September 2005, there were a total of 10 cases, representing an improvement from 7.4 to 5.0 cases per 100,000 procedures. Although this 33% decrease is encouraging, it did not reach statistical significance ($P = .26$). There could be several reasons why the difference was not significant. First, the New York State Department of Health had already, in 2001, made its own equivalent protocol, including preoperative verification, site marking, and time-out, the standard of care throughout the State. Second, enhanced awareness of the problem of surgical confusion may have increased reporting of such incidents during the period after the Protocol became effective. Third, the Universal Protocol simply was not universally applied, as clearly demonstrated in the cases included in this analysis. Indeed, NYPORTS officials believe that both the state protocol and the Universal Protocol have had a positive impact (Janet Mannion, New York State Department of Health Bureau of Hospital

Services, Division of Primary and Acute Care Services, Troy, New York; written communication, September 2006).

Had it been conscientiously applied, the Universal Protocol or its equivalent would likely have been effective in a large majority of the cases analyzed in this study. Proper preoperative verification, site marking, and final time-out represent the necessary beginning. In ophthalmology, verification of lens implant or corneal transplant is an important component to be included in both preoperative verification and final time-out. Although there has been considerable "push-back" in the past, most surgeons have come to accept the process.[14,47-55]

It would be preferable for more injurious errors to be easier to prevent. Unfortunately, the results of this study suggest just the opposite trend: errors in group I (incorrect implant or transplant) were, compared to errors in group II (wrong patient/procedure/eye), more likely to cause serious injury but less likely to be preventable using the Protocol (Tables 8 and 9). One reason for this trend is that a disproportionate number of wrong-implant errors, which caused relatively serious injuries, had their genesis during the preoperative period. Patient involvement in helping to prevent an incorrect implant is unlikely to be effective, because patients do not typically know what power lens should or is being used. It is also noteworthy that staff members other than the surgeon alone were more likely to have contributed to the error in group I cases (Table 7), presumably because others are more often involved in the process of procuring the implant and bringing it to the operating table.

Importantly, most errors result in relatively minor or effectively treatable injures. Of 96 patients in our series who had a definable injury, the injury severity score in 33 cases was 1, in 51 cases the score was 2, in 12 cases the score was 3, and in 2 cases the score was 4. Wrong implants could often be explanted and replaced without damage to the eye or could be compensated with piggyback lenses or refractive surgery. Wrong eye blocks simply wore off without damage. Incorrect glaucoma laser procedures were harmless. Laser refractive correction could be repeated with good visual outcomes. Incorrect strabismus surgery could be reversed with a second surgery. Surgery on the wrong eye, although often requiring a return to the OR, was itself harmless in most of the cases of lacrimal surgery, cataract surgery, and YAG capsulotomy. Although indemnity payments were more common in cases of surgical confusion, the average payment was only $29,426, compared to an average of $91,000 in all OMIC cases for the period covered.

On the other hand, ophthalmologists would generally agree 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."[10] Regardless of how rare, benign, or treatable, such errors may have serious negative consequences for the patient, the surgeon, the institution, and the profession as a whole. The public find such errors shocking and simply do not consider them to be an acceptable risk of their medical care.[30,34]

Some of the injuries analyzed in this study were not benign. There were 14 cases in which an injury severity score of 3 or 4 was assigned. The injuries in these cases included permanent decrease in vision due to new-onset glaucoma and corneal decompensation following attempted explantation of incorrect IOLs, unnecessary corneal transplantation on the only good eye, and severe refractive error in 1 eye following implantation of an incorrect IOL and in both eyes following incorrect refractive surgery. Many patients reported annoying asthenopia and diplopia, even though the outcome met criteria for an injury severity score of 2.

All of these confusions were associated with consequences to the surgeon, who typically faced intramural and external investigations, official sanctions, medical liability, and embarrassment, even in cases without significant patient injury. These outcomes were predicted in the hypothesis. In Florida, the Board of Medicine has imposed severe penalties on surgeons, including suspended licenses, fines as high as $20,000, community service, and required lectures to be given to colleagues.[30,34,56] Perhaps the strongest sanctions are imposed by the surgeon's conscience and the loss of the patient's trust (A. Zeal, written communication from presentation, "When the unimaginable happens to you." Wrong Site Surgery Conference, Joint Commission on Accreditation of Healthcare Organizations, Chicago, Illinois, December 2, 2003). Finally, the reputation of the profession as a whole is called into question whenever such cases come to public light, no matter how mild or infrequent.

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, they 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. The essential components of an apology in this setting are to acknowledge the harm, to take responsibility for it, to explain what happened, to show remorse, and to make amends. Patients often need to hear that steps will be taken to ensure that other patients will not suffer the same error. This discussion is embarrassing to surgeons in many cases; some report difficulty getting the necessary words out. On the other hand, such disclosure probably decreases liability, especially if a problem is already apparent to the patient.[57-59]

Medical error is commonly considered the portion of injuries resulting from medical care that are preventable. The Institute of Medicine defines medical errors as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.[3] Surgical confusions are only a small subset of the broader problem, which includes adverse drug events, improper transfusions, suicides, restraint-related injuries or death, falls, burns, and pressure ulcers. Such errors cause the death of 44,000 to 98,000 people each year in the United States, more than motor-vehicle accidents, breast cancer, and AIDS. The cause, more often than an individual's recklessness, is predominantly faulty systems, processes, and conditions that lead people to make mistakes. The surgical confusions analyzed in this study fit this pattern.

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.[43,60-71] 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.[11] The caregiver who commits an error has even been considered "the second victim" in the recent literature.[72] Using methods of crew resource management employed by airlines and the defense department to foster team interactions and develop safety checks is demonstrably effective in preventing errors. Computerized bar codes and other technological advancements may provide the ultimately effective safety check to prevent surgical errors of the sort analyzed in this study.

Improving patient safety requires raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of health care. It also requires new standards for collection, coding, classification, and dissemination of patient safety information.[73,74] Currently, only 15 states maintain a mandatory reporting system comparable to NYPORTS, and only 13 of these apply to free-standing ambulatory care settings.[75] Such reporting should be expanded. Safe practices must be ensured by safety systems implemented at the delivery level by health-care organizations. A "culture of safety" must be adopted by all involved in providing health care. Hopefully, the information in this study will be helpful to those seeking to advance the cause of patient safety in ophthalmology.

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APPENDIX

THE UNIVERSAL PROTOCOL[27]

PREOPERATIVE VERIFICATION PROCESS

The health care team ensures that all of the relevant documents and studies are available prior to the start of the procedure and that they have been reviewed and are consistent with each other, with the patient's expectations and with the team's understanding of the intended patient, procedure, site and, as applicable, any implants. The team must address missing information or discrepancies before starting the procedure.

Times to verify the correct person, procedure, and site:
* When the surgery or procedure is scheduled.
* When the patient is admitted to the facility.
* Any time the patient is transferred to another caregiver.
* Before sedation, with the patient awake and aware, if possible.
* Before the patient enters the surgery or procedure room.

Consider using a preoperative checklist to ensure the availability of:
* Relevant, complete documentation, such as the history and physical, informed consent, etc.
* Relevant images—properly labeled and displayed.
* Any required implants and special equipment.

MARKING THE OPERATIVE SITE

The health care team, including the patient (if possible), identifies unambiguously the intended site of incision or insertion.

Mark all cases involving laterality, multiple structures (fingers, toes, lesions), or multiple levels (spine). Note: For the spine, in addition to preoperative marking of the general region (cervical, thoracic or lumbar), special intraoperative radiographic techniques are used to mark the exact vertebral level.
* Use your organization's defined method and type of marking.
* The person performing the procedure should mark the site.
* Mark the site with the patient awake and aware, if possible.
* Mark at or near the incision site.

* Use marks that are unambiguous or cannot be misinterpreted. (Consider that "X" may be ambiguous).
* Non-operative site(s) should not be marked, unless necessary for some other aspect of care.
* Adhesive site markers should not be used as the only means of marking the site.
* Use a permanent marker that remains visible after skin prep.
* Make sure the mark is visible after the patient is prepped and draped.
* Know your organization's procedure for patients who refuse site marking.

Exceptions to marking:
* Single organ cases.
* Premature infants.
* Interventional cases for which the catheter/instrument insertion site is not predetermined.
* Teeth. Indicate operative tooth name(s) on documentation or mark the operative tooth/teeth on the dental radiographs or dental diagram.
* For non-OR settings/bedside procedures—cases in which the individual doing the procedure is in continuous attendance with the patient from the time of decision to do the procedure and consent from the patient through to the conduct of the procedure. The requirement for a "time out" final verification still applies.

"TIME OUT" BEFORE STARTING THE PROCEDURE

The operative team conducts a final verification of the correct patient, procedure, site and, as applicable, implants.

Conduct the time out in the surgery/procedure room, just before starting the procedure.
* Involve the entire operative team in the time out using active communication.
* Know your organization's procedure for reconciling differences in staff responses during the "time out."

Consider using a checklist to briefly document the time out, including
* Correct patient identity.
* Correct side and site.
* Agreement on the procedure to be done.
* Correct patient position.
* Availability of correct implants and any special equipment or special requirements.

Know your organization's verification, site marking and "time out" procedures, including those for non-OR settings/bedside procedures.