

Recommendations of American Academy of Ophthalmology Wrong-Site Task Force

Background

The recommendations described here are designed to minimize the incidence of preventable surgical errors regarding surgical site (e.g. wrong eye) and surgical procedure (e.g. wrong intraocular lens implant). This report is the result of collaborative efforts from members of the following organizations:

American Academy of Ophthalmology; American Association of Pediatric Ophthalmology and Strabismus; American Board of Ophthalmology; American Glaucoma Society; American Society of Cataract and Refractive Surgery; American Society of Ophthalmic Plastic and Reconstructive Surgery; American Society of Ophthalmic Registered Nurses; Association of University Professors of Ophthalmology, Ophthalmic Mutual Insurance Company; Outpatient Ophthalmic Surgery Society; Retina Society.

Introduction

Ophthalmologists perform many different types of surgeries in many different types of settings. The correct performance of some surgeries (e.g. cataract, LASIK, strabismus) is dependent upon very specific refractive or prismatic calculations (e.g. intraocular lens power, refractive change, strabismic measurement), while others are not (e.g. blepharoplasty, dacryocystorhinostomy, trabeculectomy). For that reason, this document will outline general guidelines initially, and then will make recommendations for more measurement-specific surgeries at the end.

The task force recognizes that surgeons currently operate in different surgical settings, ranging from full-service hospitals to ophthalmology-only ambulatory surgery centers and office-based clean rooms. The fact that wrong-site and wrong-surgery errors are infrequent indicates that proper safeguard systems are currently in place and are working. The purpose of this document is to create a list of suggestions to help surgeons evaluate their own systems to minimize preventable surgical errors further.

Although the task force tried to be as comprehensive as possible in devising this document, it is aware that the goal of decreasing preventable surgical errors may be met by other protocols outside the specifics of this document, and in no way should this document be misconstrued as being the only proper way of minimizing errors.

There will be circumstances where the rules defining how surgeons perform certain tasks (e.g. marking the operative eye, performing the time-out) are strictly defined by the hospital or ASC. This may be so because accreditation bodies (e.g. JCAHO, AAAHC), state legislatures (e.g. New York), or the governing bodies of the hospital or ASC itself have clearly defined how these should be performed. In these situations, it is the responsibility of the surgeon to understand what the policies and procedures are, and to adhere to them.

However, in situations where specific policies have not been so defined, surgeons and administration should work together to devise policies and procedures that they believe will

result in an error-free environment. It is important to understand that acceptable policies and procedures may be devised that differ from those written by accreditation bodies and state legislatures, at sites where these bodies do not have jurisdiction (i.e. in ASC's that are not accredited by an outside body, and states where no specific legislation has been enacted).

This document outlines the basic tenets that should help all surgeons to devise their procedures where appropriate. It is divided into three main sections: 1) Steps taken prior to surgery day, 2) Steps taken on the day of surgery; and 3) Procedures dependent upon pre-operative calculations.

STEPS TAKEN PRIOR TO SURGERY DAY

The order for surgery

The decision to perform surgery should be entered into the patient's medical record as a written order. This order should be as specific as possible, with all pertinent surgical data being available. Examples of things in this order may include the surgical procedure, operative eye, adjunctive medications (e.g. mitomycin C), post-operative refractive result (e.g. monovision), strabismus surgery measurements, and/or intraocular implant (IOL) style if appropriate.

Communication with surgery staff

While the pre-operative workup is typically performed in a clinic setting, the surgery is usually performed in a hospital or ambulatory surgery center. In some practices, the clinic and operating suite may share an electronic medical record (EMR) system, while in others they may not.

Regardless, it is important for information to pass back-and-forth between these two sites as seamlessly as possible.

In systems where the clinic and surgery areas share a common EMR system, minimal if any additional communication may be necessary, as clinic notes can be used by operating room staff in scheduling and preparing for surgery. Potential communication errors are naturally lessened in this type of system, and it is likely that it will become more prevalent in the future as EMR becomes more widely used.

More rigorous steps should be considered by those working in systems that either use a paper system in clinic, or where the clinic uses a different EMR system than the hospital or ASC. In these situations, it is recommended that specific data be passed between sites via written documentation rather than verbal whenever possible. Examples of written communication may include printed lists, spreadsheets, or photocopies of office records that are mailed, couriered, or telefaxed. It should be understood that every added step increases the potential likelihood of a transcription error.

STEPS TAKEN ON THE DAY OF SURGERY

Consent

The informed consent process will vary from site to site, but there are many aspects of it that are consistent. It is not the purpose of this document to describe the informed consent process in any detail, except for how it pertains to preventing wrong-site and wrong-surgery errors. The patient (or patient's representative) should be actively involved in the informed consent process. The consent form should be written at a level that the patient is able to understand, and interpreters should be available where appropriate. If only one eye is to be operated upon, the proper eye should clearly be notated on the consent form.

Hard Stop

Hospitals and ASC's should consider having written policies describing a "hard stop" process whereby any member of the staff can halt the process of preparing the patient for surgery if an inconsistency or error is discovered. The hard stop can be reversed once the inconsistency or error is resolved. A culture should be established where surgery staff understand that they will not be punished or reprimanded by the surgeon, colleagues, or administration for calling a hard stop.

Marking the Operative Eye

As stated above, specific ways to mark the operative eye are defined by various accreditation bodies (e.g. JCAHO, AAAHC), and state statute (e.g. New York). In these cases, surgeons must follow the rules outlined by these bodies, and therefore the surgeon must be the one to physically place the identifying mark on the patient. However, more leeway exists for surgeons working in ASC's that are not accredited by these bodies, in states that do not have specific statutes defining how a patient's eye should be marked. In these situations, surgeons should work with administration to establish a policy in marking the appropriate eye that fits well with the culture of the surgery center. In these situations, it may be appropriate to establish a system where a member of the pre-operative staff (as designated by the policy developed by the surgeon and administration of the center), and not the surgeon, marks the appropriate eye.

If only one eye is to have surgery, it should be clearly marked prior to surgery, with the active involvement of the patient whenever possible. The person who marks the eye should use written documentation with verbal verification by the patient or guardian to determine the operative eye. Any discrepancy should result in a hard stop as described above. If the surgeon is not the one to physically place the mark on the patient, the surgeon should verify that the correct eye is marked at some point during the pre-operative preparation. Hospitals and surgery centers should use marking protocols that work well for them. Examples include using marking pens or stickers around the eye that is to be operated on. . If the eye is to be dilated for surgery, it may be beneficial to have the appropriate eye marked prior to the institution of dilating drops.

If it is customary for the surgeon to put a towel over the patient's forehead in the operating room prior to placing of the clear surgical drape, it may be beneficial for the identifying mark to be placed on the cheek rather than the forehead. In this way, the surgeon can visualize the identifying mark immediately before placing the surgical drape.

Time-Out

The time-out is an opportunity for the surgeon, along with both the entire operating room staff and the patient, to ensure that they are all preparing for the proper surgical procedure on the proper eye. This step is typically performed in the operating room, and the patient is actively involved if they are able (NB: they may be unable due to age, mentation, etc.). All members of the surgical team, including surgeon, scrub person, circulating nurse, and anesthetist or anesthesiologist should be engaged in the time-out. Any discrepancies uncovered while performing the time-out should result in a hard stop as described above. Examples of data that are typically reviewed in the time-out include: patient name, patient birthdate, operative eye(s), and procedure. Using two patient identifiers (e.g. name and birthdate) is recommended over merely using the patient's name, as this will help ensure that the proper chart is being used if two patients share the same name.

PROCEDURES DEPENDENT UPON PRE-OPERATIVE CALCULATIONS

Background

Many procedures performed by ophthalmologists require surgical manipulation that is dependent upon specific data that are gathered pre-operatively. Examples include intraocular lens power for cataract or lens-based refractive surgery, refractive change for keratorefractive surgery, and millimeters of resection or recession for strabismus surgery. Extra care must be taken to ensure that these preoperative data are measured properly and accurately communicated from the clinic to surgery center, and that the proper measurements are available for the surgical team at the time of surgery.

Specific considerations for intraocular lens surgery

- Surgeons should consider establishing a process whereby all intraocular powers are double-checked by either the surgeon or a separate “QA” technician. In cases where calculations are felt to be inaccurate, they should be rechecked, often by a different technician or using different equipment (e.g. IOLmaster and immersion a-scan)
- It may be helpful to have intraocular calculations performed for both eyes, even when surgery in the fellow eye is not anticipated, as a way to double-check the IOL power of the surgical eye.
- In the surgery order, the surgeon should document the IOL type that is requested, and should also document the post-operative refractive target and astigmatism management if appropriate.
- Surgeons should consider having some form of written documentation regarding the case available to them to view when scrubbed, gowned and gloved, and seated at the surgical microscope. Examples include writing the patient’s name, eye, and IOL power on a white-board or having a copy of the operative plan taped to the operating microscope.

Specific considerations for keratorefractive surgery

- Surgeon may wish to include post-operative refractive target (e.g. monovision) when performing the time-out.
- Surgical plan should be visually available for the surgeon and team during the procedure.

Specific considerations for strabismus surgery

- Surgeon should consider having some form of written documentation regarding the case available to them to view when scrubbed, gowned, and gloved. Examples include writing the patient’s name and surgical plan on a white-board in the operating room.

Appendix A. Checklist for the surgery chart

What follows is one example of how to document in the surgery chart that all the appropriate steps have been taken in preventing wrong-site and wrong-surgery. Surgeons and administration may wish to include something similar in their charts to ensure that steps are being followed appropriately for every patient. Individuals who perform each task check off the appropriate box, and the surgeon and nurse sign the bottom. -----

Pre-operative Area

- The informed consent form describes the procedure and operative eye. Abbreviations are not acceptable.
- Prior to administration of eye drops, the nurse asks the patient which eye is to be operated on. The patient's operative eye is appropriately marked in the pre-operative holding area.
- The pre-operative nursing staff ensures the patient's response, informed consent, and doctor's orders for dilation all match for the operative eye.
- The surgeon discusses with the patient the appropriate procedure and ensures that the appropriate eye is marked.

Operating Room

- The office chart notes are available in the operating room.
- Prior to draping, a time out is performed verifying:
 - Patient's name
 - Patient's birth date
 - Procedure
 - Operative eye
 - Lens implant style
 - Lens implant power
- Prior to draping, circulating nurse ensures that operative plan is visible so that the surgeon can read it while gowned and gloved.
- The circulating nurse writes the patient's name, operative eye, IOL style, and IOL power on the white board.

_____ Nurse's signature

_____ Doctor's signature