

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 (IOL) implant). This report is the result of collaborative efforts from members of the following organizations:

American Academy of Ophthalmology; American Association for 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; American Uveitis Society; 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., IOL 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 also recognizes that surgeons currently operate in different surgical settings, ranging from full-service hospitals and multispecialty ambulatory surgery centers (ASCs) to ophthalmology-only ASCs and office-based procedure rooms. The fact that wrong-site and wrong-surgery errors are infrequent indicates that correct safeguard systems are currently in place and 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 strove 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 the only correct way to minimize 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 because external accreditation bodies, state legislatures, or the governing bodies of the hospital or ASC itself have clearly defined how these should be performed within institutions under their jurisdictions. In these situations, it is the responsibility of the surgeon to understand what the policies and procedures are and 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 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.

This document outlines the basic tenets to help all surgeons 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 formally entered into the patient's medical record. This order should be as specific as possible with all pertinent surgical data made available. Examples of things in this order may include the surgical procedure, operative eye, adjunctive medications (e.g., mitomycin C), post-operative refractive target, strabismus surgery measurements, and/or IOL implant 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 ASC. In some practices, the clinic and operating suite may share an electronic health record (EHR) 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 EHR system, minimal if any additional communication may be necessary, as clinic notes can be directly accessed by surgery staff in scheduling and preparing for surgery.

Extra steps should be considered by those working in systems that either use a paper system in clinic, or where the clinic uses a different EHR system than the hospital or ASC. In these situations, it is recommended that specific data pass between sites via written or electronic documentation rather than verbally whenever possible. Examples of written communication may include printed lists, spreadsheets, or photocopies of office records that are mailed, couriered, e-mailed or telefaxed. It should be understood that every added step increases the potential likelihood of a transcription error, so checks and balances must be in place to minimize errors of this sort.

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 correct eye should clearly be notated on the consent form.

Hard stop

Hospitals and ASCs 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 procedures for marking the operative eye are defined by various accreditation bodies and state statutes. In these cases, surgeons must follow the rules outlined by these bodies. However, more leeway exists for surgeons working in ASCs 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.

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 it is customary for the surgeon to put a towel over the patient's forehead in the operating room prior to placement 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 clear surgical drape.

Time-out

The time-out is an opportunity for the surgeon, along with the entire operating room staff and the patient, to ensure that they are all preparing for the correct surgical procedure on the correct 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, sedation, 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 typically reviewed in the time-out include: patient name, patient birthdate, operative eye(s), procedure, IOL model number and power. Using two patient identifiers (e.g., name and birthdate) is recommended over merely using the patient's name as this will help avoid errors in cases where 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 IOL 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 pre-operative data are measured correctly and accurately communicated from the clinic to the surgery center, and that the correct measurements are available for the surgical team at the time of surgery.

• Specific considerations for intraocular lens surgery

- O Surgeons should consider establishing a process whereby all IOL 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., both optical and ultrasound biometry).
- o 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 written 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.

• Specific considerations for oculofacial plastic and reconstructive surgery

Surgeons should personally mark the correct surgery site in the pre-operative area to avoid inappropriately placed marks, which interfere with important resection or incision marks.

Approvals

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