

Preventing Retained Items during Eye Surgery

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ABSTRACT

Introduction: Retained surgical items continue to occur, including during eye surgery. This series of root cause analysis (RCA) reports provides detailed information on the causes of such events and ideas on how to prevent future occurrences.

Methods: The Veterans Health Administration conducts RCAs on reported adverse events such as retained surgical items. We reviewed this data base (2006-2016) for reported retained surgical items during eye surgery. We coded these cases for root causes, event type and characteristics and conducted a descriptive analysis.

Results: There were 7 reported cases of retained surgical items during eye surgery. All resulted in some degree of monitoring, intervention or harm. Root causes overall focused on the need for increased awareness of the possibility of a retained item during eye surgery and the need to routinely implement interventions to prevent retained surgical items in ophthalmic surgery.

Conclusions: Although retained items during ophthalmic surgery are rare, such events do occur often with patient harm. Careful visualization of the wound including with a microscope, may be one the strongest preventative measures intraoperatively. Increased awareness of the risk of these retained items may help with situational awareness and consistent implementation of such measures.

Introduction:

Retained surgical items (RSIs) have been defined as “items or parts thereof not intended to remain and are found in any part of the patient’s body after the patient has been taken from the operating or procedure room [1].” RSIs occur in about 0.3-1.0 of 1000 abdominal operations. They are preventable, can cause patient harm and have serious legal consequences for healthcare providers and organizations. Risk factors include emergency, complex, or abdominal procedures; procedures that are prolonged, or involve several body cavities, multiple surgical teams, or a large number of instruments [2]. Countermeasures to prevent, capture, and mitigate RSIs include the surgical

count, methodical wound exploration, intraoperative X-ray, patient safety education, and team training (e.g. minimizing distractions during count) [1,2]. One of the largest literature reviews on RSIs, included cases from the abdomen, retroperitoneum, pelvis, chest, and extremities, but did not include a single RSI case from the eye [2].

Retained lens fragments following cataract surgery, however, have been studied and may occur in 0.1-1.6% of cataract operations [3]. In a study of malpractice claims retained lens fragments most likely to result in a verdict for the patient were often associated with complications (including increased intraocular pressure, visual field damage, retinal detachment, corneal edema, vitreous hemorrhage) and worsening of visual acuity (< 20/200) compared to baseline [4]. The average payment for these latter cases was \$117,688.

Reports of actual retained instruments or soft goods in the eye are sparse in the literature. A Hong Kong hospital examined its patient safety reporting system for the years 2007-2014 and found 12 sentinel events involving eye surgery which included only 2 cases of RSIs [4]. The RSIs included a 1 mm piece of a soaked sponge in one case and a missing scleral plug (assumed to not be in the patient) in the other case. There are also some single case studies reported in the literature of retained foreign items such as cannulas, cotton fibers and suture needles [5-7]. As in the case of RSIs in general, the authors recommended increased awareness of this possibility, consistent use of the surgical count, and intraoperative X-rays as useful actions.

The Veterans Health Administration (VHA) performs over 70,000 ophthalmology operations annually representing one of the most frequent operations, providing a unique platform for studying rare events such as RSIs for eye surgery. Furthermore, the VHA has an established, keen interest in preventable complications in eye surgery which have led to eye specific updates to safety policies, safety alerts, and inclusion of serious adverse events in eye surgery as part of a Surgical Lessons Learned Program [1,8-10]. The purpose of this study was to examine reported patient safety cases of RSIs among eye surgeries in the VHA, to determine the root

causes of these reported eye RSIs, and to develop recommendations for strong solutions for their prevention. This is the largest study and case series of RSI in the eye.

Methods

The Veterans Health Administration (VHA) uses an adverse event reporting system as part of its patient safety program. Clinicians at each facility submit reports of adverse events and close calls to the National Center for Patient Safety (NCPS). Each VHA facility has a patient safety manager who reviews submitted incident reports (also referred to as safety reports) and codes their severity. Those cases with the highest actual or potential harm undergo a root cause analysis (RCA) [11]. During an RCA, an interdisciplinary team examines what happened, why it happened and what can be done to prevent it from happening again.

We searched the National Center for Patient Safety (NCPS) database from between 2006-2016 for safety reports and RCAs where an item was retained during eye surgery.

We developed a code book based upon key elements in the VHA Prevention of Retained Surgical Items Directive [1]. Elements in the codebook included completion of a surgical count, methodical wound exploration and if an x-ray was done. We also included patient age, gender, time to discovery of retained item, which provider discovered the item and where it was discovered. The codebook is available upon request.

A retained surgical item was defined as the patient left the operating room with an unintentionally retained item. We included all types of foreign items (including but not limited to needle fragments, fibers, cannulas etc.).

One of the authors (DP) coded the cases for these elements and type of eye surgery, description of retained item, root causes and contributing factors to the event, actions suggested by the facility that reviewed the event and harm to the patient. We used the "National Coordinating Council for Medication Error Reporting and Prevention"(NCC-MERP) guidelines to code harm [12,13]. We provided a narrative

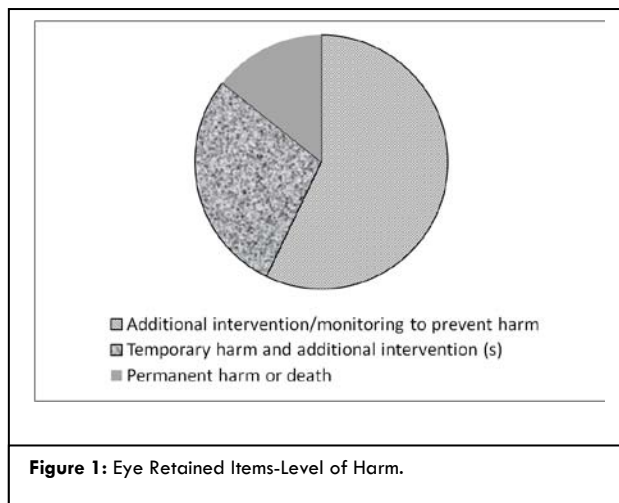
Table 1: Foreign Items.

Foreign Object Retained	Description	Gender	Physician level	Who Discovered	Location of discovery	Symptoms of RSI	Time until discovery - Days	Root Causes/Contributing Factors	Level of Harm (NCC MERC Index) A-1 ¹²	Primary Actions
	A patient had a left eye phacoemulsification with lens implant. During post-op clinic follow up visit a white fiber was identified in his eye. It was removed without complications.	No Info	No Info	Physician	clinic	None	6	None identified in report	D	None reported
	During a post-op cataract follow up visit in clinic a metallic fragment was noted in patient's eye. Physician stated this will occasionally occur if sinsky hook and phaco tip touch during nuclear chopping and should remain inert in the eye.	Male	Attending	Physician	clinic	None	7	Attending suggested this happens when the Sinsky hook and Phaco tip touch during nuclear chopping	D	None reported
	A corneal protector was used during eyelid surgery. This was placed on sterile field without scrub nurse's knowledge. There was confusion over whether the surgeon wanted that corneal protector. It was used without scrub nurse's knowledge, became dislodged was thought to have traveled into the ocular space, hidden from view. No one questioned it because corneal protector was a non-counted item. He returned to the hospital with complaints of eye irritation. Discovered corneal protector. Corneal abrasion occurred. Corneal protector was removed.	Male	Attending	Clinic Staff	clinic	Pain/Blindness	3	Communication about removing corneal protector flawed and the corneal protector was not on count sheet.	E	Corneal protector will be placed on count sheet

Foreign Object Retained	Description	Gender	Physician level	Who Discovered	Location of discovery	Symptoms of RSI	Time until discovery - Days	Root Causes/Contributing Factors	Level of Harm (NCC MERC Index) A-J ¹²	Primary Actions
	A patient had cataract surgery. During the procedure he had floppy iris syndrome. The surgeon placed a suture with a tiny needle, which was difficult to detect with the naked eye. Counts were done at the end of the case. During follow up surgery staff found a tiny piece of needle in patient's eye. Patient was returned to OR for removal. On follow up with a microscope, the needle fragment was detected. Patient reported doing well after this procedure.	Male	Attending	Physician	clinic	None	1	Not doing methodical wound exploration and this was a 10-0 needle used to deal with "floppy iris" during index operation so the tip of needle must of broken off; and the Patient had "floppy iris" syndrome due to chronic use of medication Flomax	D	Standardize visual inspection and wound exploration
	The patient had a complex clinical situation of detached retina with two prior surgeries for this problem. On his second follow up visit the surgeon discovered two cannulas in the patient's eye. They were removed without incident and the patient's comfort and vision improved. He healed with no infection.	Male	Resident	Physician	clinic	Pain blindness and drainage	4	Distractions, not following policy, Cannulas not part of the count	G	Revise eye briefing guide to mandate wound exploration; Implement count sheet in eye
	During a two procedure operation (cataract and lens implant with pars plana vitrectomy, membranectomy (macula), pan-retinal Laser, SF6 gas, and intra-vitreous steroid) a cannula was left behind. This was discovered on a follow up visit. During a scheduled traction retinal detachment procedure the cannula tip was elevated with suction and could no longer be seen.	Female	Attending	Physician	clinic	Poor Vision but Expected	22	No requirement to examine instruments upon removal	E	New policy/procedure to check tips of instruments before/after procedure
	On post-operative visit for eye surgery, on slit lamp exam, a piece of thread/lint was found embedded in main wound. The item was scheduled for removal in the OR under topical/MAC.	No Info	No Info	Physician	clinic	None	7	None identified in report	D	None reported

D=an error that occurred that reached the patient and required monitoring to confirm no harm and/or required intervention to preclude harm
 E= an error that may have contributed to or resulted in temporary harm to the patient and required intervention
 G= an error occurred that may have contributed or resulted in permanent patient harm.

description of the cases and conducted a descriptive analysis of the events.



Results

There were 7 reported cases of retained items after eye surgery between July, 2006 and November 2016 (Table 1). Table 1 describes the details of the cases along with root causes and contributing factors. Four cases involved males, one female and the remaining had no information on gender. Four cases were done by an attending; one by a resident with the remaining cases had no information on the provider doing the case. The physician discovered six of the items and clinic staff the remaining one. All cases resulted in some degree of monitoring, intervention or harm to the patient (Figure 1). There was not enough information to report on age, whether or not a count or methodical wound exploration was done, if an x-ray was taken or if there was a change in personnel during the case.

Discussion

This is the largest study to date of retained items from eye surgery. This ten year review revealed 7 reported cases of retained items after eye surgery. While such events are rare it is significant to note that in all of these cases the patient suffered harm. Others have also reported non-biologic items retained from eye surgery [5-7].

The root causes focused on instruments touching each other and breaking, two cases of instruments being on the field but not on the count sheet, careful visualization not completed, distractions, no requirement to examine

instruments, and patient clinical factors. This highlights the need for increased awareness of the value of applying accepted patient safety techniques for preventing RSI in the OR such as instrument counts, instrument inspection and methodical wound exploration for cases such as eye surgery.

In discussions with the surgical community during the Lessons Learned process, VHA staff have expressed resistance to implementing routine measures to prevent RSI due to a bias that a RSI would never happen within the ocular operative field [9]. There is also production pressure with eye surgeries and they are so brief that there are competing commitments between production and safety. However, this study provides evidence that while rare, it is possible for RSI to occur in eye surgery resulting in patient harm. Our goal is to provide potential solutions to prevent this adverse event and spare the patient additional procedures and harm. The VHA directive [1] requires a methodical wound exploration before closing the wound which could be complemented by the use of a microscope to visualize the wound to help prevent retained items.

Our findings are consistent with the findings of Kieval [14] who recommended methodical wound exploration. To address the question of x-rays to detect foreign items for eye surgery Kieval et al. [14] embedded 10-0 nylon suture needles in porcine eyes and then x-rayed the eyes. They found that in only ten of the twenty embedded eyes were the needles identified. They suggest that expert ophthalmologist surgical exploration may be more effective. Microscopic evaluation can aid in a more thorough careful visualization of the wound for the intraoperative prevention of RSIs.

Limitations

This review has several limitations. First, the summary is based on voluntary reporting and the number of cases reported is small, so it is highly likely there was under reporting of events. Despite this limitation, however this case series still represents, to our knowledge, the largest cases series of retained surgical items from eye surgery. Therefore, this report heightens awareness of the possibility of retained items from eye surgery to help

combat the tendency for providers to think “it will never happen to me” and to share preventative actions.

The reports were also de-identified without access to medical records and therefore contained minimal information on patient details. We were dependent upon the analysis conducted by the facility based staff. In some cases these reviews were thorough and in others they were less so. Our goal is that this review provides suggestions for actions and re-emphasizes the value of methodical wound exploration.

Despite these limitations this report provides, in-depth information on RSIs in the eye that ophthalmologists may use to increase awareness that these adverse can happen and to implement techniques that have proven successful in mitigating the possibility of a RSI in other specialties.

Conclusion

In summary, items can be retained after eye surgery and increased awareness of this possibility may help prevent such occurrences. Methods to detect such items can vary from expert ophthalmologist evaluation to detailed intraoperative microscopic evaluation with a closing pause, which could be included as part of a debriefing process. Continuing to review reports of such cases including close calls will strengthen our knowledge of how to best detect and prevent these retained items.

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