Incidence and Characteristics of Potential and Actual Retained Foreign Object Events in Surgical Patients

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BACKGROUND: Incidence of retained foreign objects (RFOs) after operations is unknown, as many can go unrecognized for years. We reviewed the incidence and characteristics of surgical RFO events at a tertiary care institution during 4 years.

STUDY DESIGN: All RFO events, near misses and actual, reported on an adverse event line during 2003 to 2006 were reviewed.

RESULTS: During 2003 to 2006, there were 191,168 operations performed, with 68 reported events resulting in a potential RFO defect rate of 0.356/1,000 patients. After review, 34 patients had no RFOs (near misses) and 34 were actual RFOs, resulting in a true RFO defect rate of 0.178/1,000 operations or approximately 1:5,500 operations. In the near-miss patient, needles were miscounted 76% of the time. In the 34 actual RFO patients, items retained were 23 sponges (68%), 7 miscellaneous other items (20%), 3 needles (9%), and 1 instrument (3%). The 34 actual RFOs occurred in incidents where the count had been reported as correct in 21 patients (62%). In 18 patients where an RFO was eventually discovered, intraoperative imaging detected only 12 objects (67%). In operations involving a body cavity, our practice is to obtain a high-resolution x-ray survey film, in a dedicated x-ray suite, before entering the recovery room. Twenty RFOs were identified from survey films and all occurred in patients with correct counts. No RFOs occurred during emergency or high blood-loss procedures and none resulted in demonstrable clinical harm. Two patients left the hospital with an RFO. Twenty-two patients (64.8%) underwent reoperation, with 1 object not removed, 6 (17.6%) retrieved without operation, and 6 (17.6%) where the clinical decision was not to remove.

CONCLUSIONS: RFOs at an institution that routinely performs postprocedure x-rays indicate that RFOs can occur more frequently than expected from the literature. The majority occur in patients with correct counts. Relying on counting as the primary mechanism to avoid RFOs is unreliable, and investigating new technologies designed to achieve reliable counts is warranted. (J Am Coll Surg 2008;207:80–87. © 2008 by the American College of Surgeons)
Limitations of previous studies are that they rely on administrative databases and reports of harm occurring as the result of RFOs. There are numerous case reports of RFOs discovered years or decades after the index operation. These RFOs were detected in patients being treated for chronic symptoms related to the presence of the RFO or incidentally. Lack of reliable systems to account for surgical instruments, needles, and sponges at the time of operation, or infrequent use of screening postoperatively to detect RFOs, most likely leads to an underestimate of the true incidence of RFOs reported in the current literature.

In this article, we present a single high-volume tertiary care institution’s experience with surgical RFOs. We describe the incidence, characteristics, and outcomes related to RFOs. Our institutional practice is to routinely screen patients who undergo operations involving a body cavity with a postoperative high-resolution x-ray survey film, in a dedicated x-ray suite, before entering the recovery room (Figs. 1A, 1B). This practice allows us to assess the use of routine postoperative survey x-rays in detecting unexpected RFOs.

METHODS
A retrospective review of all potential or actual RFOs reported to a sentinel event phone line or Web site at the Mayo Clinic, Rochester (MCR), during 2003 to 2006 was performed. Review and publication of the data were approved by the Institutional Review Board. Our institutional definition of an RFO is any object that was unintentionally retained in a patient at the time of final wound closure or in procedure without a wound when the operating team has completed the procedure. All RFO events that originated in the main operating rooms and labor and delivery unit were analyzed for type of object; patient characteristics, including age, gender, and body mass index; details of the operations, including duration, number of surgical teams involved, and volume of blood lost; if counts were documented as correct; cavity involved; circumstances of the event; means of detection; and clinical outcomes. Procedures started before 6:00 AM or completed after 4:00 PM were categorized as late procedures. Operations were classified as either emergency (need to be performed within hours) or scheduled (elective). For patients with an actual RFO, we documented the type of foreign body (sponge, needle, or instrument), the way it was detected (intraoperative x-ray, standard postoperative survey x-ray before recovery room admission, or chance discovery after leaving the postoperative recovery area), and the corrective action to address the RFO.
There are 98 main operating rooms, 3 obstetrical operating rooms, and 8 labor and delivery birthing rooms on the MCR campus, which are distributed between 2 acute care hospitals. All operating rooms are staffed by MCR physicians, nurses, and allied health staff. All staff members are under one organizational leadership structure, with a unified policy and procedure manual for operating room conduct, including instrument, needle, and sponge counting. Statistical analysis was performed using Minitab software (version 14.2).

RESULTS
During the 4-year analysis period, 191,168 operations were performed at MCR. Sixty-eight RFO events were reported to the sentinel event line. This represents a potential RFO defect rate of 0.356/1,000 cases. After additional review of the 68 reported events, 46 were reported because of incorrect counts at the end of the procedure, and 22 were reported as correct counts, but an RFO was discovered after the procedure as the result of routine postprocedure screening practices or in subsequent followup at the MCR. In 34 of 68 RFO events reported to the sentinel event line, no RFO could be detected using high-resolution postprocedure imaging. These 34 events were classified as “near misses.” The remaining 34 events represented true RFOs, because some type of object had been retained and was discovered after the patient had left the operating room. A schematic diagram of the two types of events (near misses and true RFOs) and the types of objects retained are shown in Figure 2.

In the 34 near-miss events, 31 were associated with incorrect counts of needles, instruments, or sponges. In three events, it was not the policy at the time to routinely count sponges or instruments for the particular procedure type being performed. In these three events, a missing object investigation was initiated intraoperatively because of a concern that a sponge, instrument, or needle was missing, despite having what was thought to be a “correct” reconciliation of all objects. Incorrect needle counts represented 76% of the near-miss events, although instruments and sponges accounted for 12% and 12%, respectively (Fig. 3A).

In the 34 true RFOs, cotton sponges were by far the most commonly retained object (n = 3 [68%]), followed by miscellaneous other items (n = 7 [20%]), needles (n = 3 [9%]), and instruments (n = 1 [3%]) (Fig. 3B). Distribution of RFOs and where they were located are shown in Table 1. Of these 34 incidents, 3 (9%) occurred where there was no established policy for counting in that partic-

![Figure 2. A flow diagram of the total number of retained foreign object (RFO) events called into the sentinel event line and the subsequent classification of the event and the type of retained object.](image-url)
ular type of procedure or for those items. In 21 events (62%), the count was recorded as correct. In 2 events (6%), needle counts were reported as incorrect and sponge counts were documented as correct, but 2 sponges were later identified as being retained. Two incidents (6%) involved equipment that had small portions of the equipment that broke off and were left in the patient. Six events (18%) were associated with an incorrect count at the conclusion of the procedure. In these six events with an incorrect count, an intraoperative x-ray was obtained in four patients, which identified the RFO; in one patient the retained sponge was found before the x-ray being performed, and in the sixth patient the decision was to not look for the RFO, as the patient was deemed too unstable to delay conclusion of the case. Of these 34 RFO incidents, 20 RFOs (59%) were found on routine postoperative survey film, where there was no suspicion of an RFO, as all counts had been reported as correct at the completion of the case. A schematic representation of how the 34 true RFOs were discovered is shown in Figure 4.

The operative circumstances and possible contributing factors under which the 34 near-miss and 34 true RFOs occurred were analyzed using a root cause analysis process as part of the sentinel event review. The important characteristics for the all RFO events, both nearmisses and true RFOs, in our operating rooms are summarized in Table 2. This includes a side-by-side comparison of near misses versus true RFOs. Probability values between near-miss events and RFO events are given in Table 2 and were found not to be statistically significant.

In the 34 true RFO events, none occurred during an emergency case, there were no unplanned changes in operations, the attending surgeon was not participating in concurrent procedures, and there were no multiteam procedures. In addition, a majority of incidents did not involve excessive blood loss (> 500 mL), and there were no after-hour procedures. We were unable to determine from our data the number and relationship of personnel changes during the course of the operation in which an RFO occurred. Management of RFOs after identification varied according to the nature of the retained object, its location, and patient condition. In 6 patients (18%), the object was removed without the need for repeat operation, and in another 6 (18%) patients, it was decided not to attempt removal, because the procedure to remove the RFO posed a greater risk than leaving it in place. Twenty-two patients (65%) were returned to the operating room to have the object removed, which was success in all but 1 patient.

Table 1. Location and Type of Actual Retained Foreign Objects (n = 34)

<table>
<thead>
<tr>
<th>Location</th>
<th>Sponge</th>
<th>Needle</th>
<th>Other</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdomen/pelvis</td>
<td>11</td>
<td>3</td>
<td>—</td>
<td>1</td>
</tr>
<tr>
<td>Thoracic cavity/mediastinum</td>
<td>4</td>
<td>—</td>
<td>4</td>
<td>—</td>
</tr>
<tr>
<td>Head and neck</td>
<td>2</td>
<td>—</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Cranium</td>
<td>1</td>
<td>—</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Joint space</td>
<td>1</td>
<td>—</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Soft tissue</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Obstetrical/vagina</td>
<td>2</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Oropharynx</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>23</td>
<td>3</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>

Types of sponges retained: 7 Raytec sponges (Johnson&Johnson), 11 laparotomy sponges, 1 cottonoid/peanut sponge, 4 unable to determine from record. Instrument retained: malleable retractor. Other miscellaneous items retained: portion of vascular stent, shunt, device marker, bulldog clamp, aneurysm clip, drill bit, pedicle marker.
In that patient, although reoperation was performed, the object was not able to be retrieved because of an inability to remove it from behind a critical structure without major revision of the primary procedure. Thirty (88%) of the RFOs were discovered within 24 hours of operation, with the majority discovered immediately after operation and before entry into the recovery room. This was possible because of our practice of postoperative survey films. Four (12%) were discovered 24 hours after operation, with 2 RFOs reported after hospital discharge. The 2 events reported after discharge included a sponge left in a patient’s vagina for 3 weeks after a vaginal delivery, and a retained needle found on a routine followup x-ray 1.5 years after a laparoscopic gastric bypass operation. It was decided to follow the patient without reoperation.

The role of intraoperative and routine postprocedure survey x-ray imaging was analyzed. In the 68 events, both near misses and actual RFOs, 46 (67%) had intraoperative x-rays performed. Twenty-eight intraoperative x-rays were obtained in the near-miss events. None of these revealed any RFOs. In 18 incidents where an RFO was eventually detected, intraoperative x-ray identified only 12 of those objects. This results in true yield for intraoperative imaging of 67%. In addition, there were three incidents where an x-ray was obtained to find a missing object, specifically, missing needles, but another type of unexpected retained object was detected: a sponge in two patients and one instrument in the third. Our routine postoperative survey x-ray before entering the recovery area detected 20 RFOs. All of these were unexpected findings, as none was associated with any incorrect needle, sponge, or instrument count. Of these 20 incidents, 17 (85%) were retained sponges, a bulldog clamp (5%), a malleable retractor (5%), and 1 (5%) needle. Additionally, survey films detected two RFOs in patients where intraoperative imaging had been performed to rule out the presence of an RFO and it had failed to detect the retained objects. Both of these items were needles.

![Figure 4](image.png)

**Figure 4.** A flowchart of the true retained foreign objects (RFOs) (n = 34) and how they were discovered or handled by the care team.

**Table 2.** Characteristics of Retained Foreign Object Events (Near-Miss and True Retained Foreign Objects)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All (n = 68)</th>
<th>Near miss (n = 34)</th>
<th>True RFO (n = 34)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y), mean ± SD</td>
<td>62.5 ± 19.3</td>
<td>67.6 ± 14.2</td>
<td>57.6 ± 22.5</td>
<td>0.033</td>
</tr>
<tr>
<td>Female, n/total, (%)</td>
<td>25/68 (37)</td>
<td>11/34 (32)</td>
<td>14/34 (41.2)</td>
<td>0.4505</td>
</tr>
<tr>
<td>Count of sponges and instruments performed n/total (%)</td>
<td>65/68 (95.6)</td>
<td>34/34 (100)</td>
<td>31/34 (91.2)</td>
<td>0.765</td>
</tr>
<tr>
<td>Counts considered correct, n/total (%)</td>
<td>26/68 (38.2)</td>
<td>3/34 (14.7)</td>
<td>21/34 (61.8)</td>
<td>—</td>
</tr>
<tr>
<td>Body mass index,‡ mean ± SD</td>
<td>29.0 ± 6.8</td>
<td>28.1 ± 5.2</td>
<td>29.9 ± 8.1</td>
<td>0.285</td>
</tr>
<tr>
<td>Duration of operation (min), mean ± SD</td>
<td>345.6 ± 120.2</td>
<td>342.8 ± 82.7</td>
<td>348.3 ± 148.7</td>
<td>0.85</td>
</tr>
<tr>
<td>Estimated volume of blood lost (mL), mean ± SD</td>
<td>480.8 ± 430.6</td>
<td>416.2 ± 317.3</td>
<td>468.1 ± 486.2</td>
<td>0.788</td>
</tr>
<tr>
<td>Blood loss of &gt; 500 mL or patient on autotransfusion, n/total (%)</td>
<td>32/68 (47.1)</td>
<td>18/34 (52.9)</td>
<td>14/34 (41.1)</td>
<td>0.3311</td>
</tr>
<tr>
<td>Operations performed on emergency basis</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Operations performed after hours, n/total (%)</td>
<td>32/68 (47.1)</td>
<td>18/34 (52.9)</td>
<td>14/34 (41.1)</td>
<td>0.3311</td>
</tr>
<tr>
<td>Unexpected change in operation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>More than one surgical team involved, n/total (%)</td>
<td>6/68 (8.8)</td>
<td>4/34 (11.8)</td>
<td>2/34 (5.9)</td>
<td>0.3925</td>
</tr>
</tbody>
</table>

*Near-miss versus retained foreign object event (Minitab software, version 14.2).

†In three cases, formal counting was not done, as there was no existing policy for counts for those specific procedures. In these cases, the team in the operating room believed that there was a discrepancy, despite having a correct count at the end of the procedure.

‡Body mass index is calculated as weight (kg) divided by height (m²) of patient.

§Operations that were started before 6:00 AM or completed after 4:00 PM.

RFO, retained foreign object.
DISCUSSION
RFOs after surgical or invasive procedures continue to challenge surgeons and operating room staff as major errors that must be avoided. In this article, we analyzed the experience of the high-volume surgical practice at MCR during a 4-year period. During the study period, 191,168 operations were performed, with 68 total events reported to our adverse event line, of which 34 represented true RFOs. This resulted in an overall incidence of actual RFOs of 0.178 RFOs/1,000 operations, or approximately 1 RFO per 5,500 operations.

Our institutional RFO incidence rate of 1:5,500 is in agreement with other estimated rates reported in the literature. In some respects, our experience might be a more accurate reflection of real-world incidence. Our article is different, because the true incidence is measured, as we know the totality of procedures that were performed and the actual number of RFOs that occurred. In addition, because most other reports base their estimates on legal claims filed for substantial clinical harm as the result of an RFO, they might not capture all RFOs in their study population. Assuming that many RFOs are detected during hospitalization and treated before considerable clinical harm is incurred, these events might not rise to the level of legal claims being filed. In our data set, no demonstrable short- or longer-term clinical harm resulted from the RFO event, because the vast majority of RFOs were detected within a few minutes to hours after completion of the original procedure. In these 34 patients, only 4 RFOs were discovered > 24 hours after the procedure, and 2 were discovered after discharge from the hospital.

A disturbing finding from our review is that 59% of our RFOs were found unexpectedly through our routine use of postoperative x-rays. In all of these patients, the sponge, instrument, and needle counts were reported as correct at the completion of the procedure. Although these items might have caused patients to become symptomatic during or shortly after their hospitalization and be detected, there are numerous reports of RFOs becoming evident years after the initial operation. Assuming these data of unsuspected RFOs are representative of other institutions, there might be a large number of patients currently in the US with RFOs that are causing nonspecific symptoms or that remain asymptomatic for years.

Similar to other studies, our data demonstrate that sponges are the most common RFO. The location where the RFO occurs is most commonly the thoracic or abdominal cavity. There were RFOs discovered in the oropharynx and the vagina. Our analysis, unlike other reports in the literature, discussed both near-miss events and true RFOs. Surprisingly, needles were very infrequently the cause of a true RFO, but they were the major causes of near misses in the operating room. From our root cause analysis of these events, we believe the reason that needles are rarely true RFOs is that they are handled in the operating room quite differently from both sponges and instruments. Needles, as sharps, are often directly passed from the scrub nurse to the surgeon and back immediately after being used. They are then placed into a numbered position in a dedicated needle box, which permits ease of counting. Also, as our data would suggest, if a needle is missing, the ability to detect it in the patient is extremely difficult, even with intraoperative x-ray. This is why we favor postoperative surveillance high-resolution x-rays to resolve situations involving missing needles, as they are clearly more sensitive for such items. Even this does not ensure that the needle is not actually in the patient. As such, some of our near-miss events might truly be RFOs, but because of our inability to detect the missing needle within the patient, even using high-resolution imaging, we are unable to accurately classify them. If we were to include a proportion of our missing needles as true RFO events, then our incidence of RFOs would increase from our estimate of approximately 1 in 5,500 operations. Unlike needles, sponges and instruments can be passed or taken by the surgeon or assistant without the scrub nurse’s knowledge and not returned to the scrub nurse directly or in a short period of time. Also sponges and instruments might not always be in the direct control of an individual, which allows them to be moved into areas of the body or in the operative field other than where they were
formed before the procedure is completed. In our experience, the majority of RFOs occur despite a "correct" count being performed during the case.

Unlike other studies that have identified potential risk factors for RFOs, including emergency procedures, high blood loss, multiple operative teams, and increased body mass index, we did not find any such association with our RFO events. This might be a limitation of our study, as we did not perform any matched comparison to similar cases that did not experience an RFO. In the detailed review of each of these RFOs, none of those specific factors was thought to contribute to the event. In addition, because of the nature of our practice, which involves a high number of complex cases that often involve multiple specialties and large blood loss, our staff and support systems might be more sensitive to the risk associated with these procedures, which might contribute to increased vigilance and avoidance of an RFO. Given the nature of our high-volume tertiary care complex surgical practice, we have developed a number of systems, including use of high-resolution postoperative survey films, to try to reduce the number of RFOs. Our findings might not be representative of the more general surgical practices throughout the country. One could assume that we might have a higher incidence of RFOs because we perform more complex, high blood loss, multispecialty procedures than most operating rooms; but we found no association with any of those variables. Actually, the converse is true for our experience, because RFOs occurred most commonly in routine surgical procedures. Assuming this is representative of the general operating room environment in this country, our data might approximate true RFO incidence, which would be a higher incidence than reported in other series.

In our analysis of 34 RFOs, the most commonly cited contributing factor was a breakdown in communication. The two most common findings were failure to communicate placement of the item within a body cavity to other team members or failure to remember that action by the person performing the action later in the procedure. In any complex system in which people interact and perform within that system, communication failures are commonly cited as one of the most important factors when errors do occur. These findings highlight the importance of human factors in contributing to both the successes and failures in the operating theaters.

This study also confirms the findings of others: that the majority of RFOs occur despite a "correct" count being performed before the procedure is completed. In our experience, the count was reported correct in nearly 62% of events. Surprisingly, those items that are routinely counted most frequently during an operation, sponges, were the items most commonly missed. This most likely has to do with the fact that even a relatively simple task, such as counting discrete items, has a low but predictable error rate. The more times the count is performed, the incidence of a possible error increases exponentially. This is compounded by performing this "simple" counting process in a very complex environment, with multiple distractions and competing tasks. In other similar environments and in psychologic testing situations, the success rate of routine or easy tasks is considerably impaired by minor distractions or by increasing the number of items the person is required to attend to while also performing the task. The fact that cotton sponge products are the most common RFOs across multiple reports, and that an important component of this problem might be related to nonmodifiable human factors, a technologic solution to sponge counting might be desirable. Recently, both barcode and radiofrequency identification technology have been incorporated into cotton sponge products to help improve the reliability of counting these products. The initial small trials using radiofrequency identification technology to account for cotton sponges have been reported with mixed results. Given the reliance on counting by operating room personnel to avoid sponge and instrument RFOs, additional evaluation of new technologies to improve counting performance is warranted.

In a limited number of patients, we were able to evaluate the impact of radiographic imaging in detection of RFOs. Intraoperative imaging using portable x-ray equipment identified only 12 RFOs of 18 actual RFOs. In addition, in two patients the intraoperative x-ray failed to detect objects that were subsequently seen in postoperative survey films. Similar to our study, Kaiser and colleagues reported that intraoperative imaging failed to detect RFOs in 3 of 29 patients in whom it was used. Analysis of those patients indicated poor image quality, multiple foreign objects in the field, and failure to communicate the purpose of the film to the radiologist as contributing to the false-negative reading. In our experience, all of these reasons were similarly cited for failures to detect RFOs. Additional concerns about relying on intraoperative imaging to detect RFOs is that operating tables and portable x-ray equipment were not designed specifically to maximize imaging for an RFO, which results in poor image quality. In addition, intraoperative imaging is very poor for certain items, such as needles. In 1 study looking at the sensitivity of portable x-rays in detecting surgical needles, 75 clinicians and allied health professionals reviewing the films could identify needles > 19 mm 100% of the time, but only 13% could detect needles < 13 mm, and none could detect needles of 10 mm. Absence of an RFO, especially a missing needle, on intraoperative im-
aging obtained in a situation where the counts are incorrect should not be considered a definitive test.

An important finding of our study is that 20 RFOs were detected on postoperative survey films in patients for whom there was no suspicion of an RFO. All of these patients were immediately returned to the OR for removal of the object. Unlike other series, where symptoms or complications developed related to the presence of the RFO, use of postoperative survey films avoided any substantial clinical harm to the patient from the RFO. In addition, because the majority of RFOs occurred in the setting of a correct count of instruments, sponges, and needles, we believe that use of routine postoperative survey imaging in all patients undergoing surgical procedures is a very important safety process. Given the unreliability of portable x-ray imaging, ideally the survey x-ray should be performed with dedicated high-resolution radiographic equipment in a dedicated imaging area. Adoption of this practice needs to be weighed against the very low incidence of RFOs, the logistics of obtaining high-quality films, radiation exposure to the patient and hospital personnel, and additional expense of this practice. In our institution, the operating room infrastructure, both facilities and dedicated personnel, is designed to accommodate the ability to obtain survey x-rays and does not impede operating room workflow or expose operating room personnel to additional radiation.

In conclusion, RFOs after operations continue to be a patient safety and surgical quality issue. Although certain patient and operative risk factors might predispose to RFOs, both human and system factors contribute to these events considerably. Additional studies of the interactions between the operating room environment and personnel performance need are necessary to develop systems that mitigate human errors that result in RFOs. The impact of new technology designed to improve the reliability of accounting for surgical instruments, needles, and sponges needs to be thoroughly investigated. Incorporation of new technology into an already complex environment might cause unforeseen opportunities for errors. Finally, serious consideration for expanding use of postoperative imaging surveillance in dedicated imaging units in the operating suite should be considered as a best practice, as it can decrease risk of complications related to RFOs by early detection.

Author Contributions
Study conception and design: Cima, Kollengode, Deschamps Acquisition of data: Kollengode, Garnatz, Storsveen Analysis and interpretation of data: Cima, Kollengode, Storsveen, Weisbrod, Deschamps

Drafting of manuscript: Cima, Kollengode
Critical revision: Kollengode, Storsveen, Weisbrod, Deschamps

REFERENCES