ABSTRACT

Failure to account for all sponges, sharps, and instruments postoperatively may lead to the inadvertent retention of a foreign object. The retention of a foreign object may cause serious patient harm and often requires further medical treatment. Surgeons and operating teams routinely rely on the practice of a sponge, sharp, and instrument count to reduce the risk of a retained foreign object. Surgical counts are intended to prevent the retention of a sponge, sharp, or instrument, yet despite the highly regulated nature of the process, discrepancies in the surgical count occur. In 2008, the Pennsylvania Patient Safety Authority received 2,228 reports involving an incorrect sponge, sharp, or instrument count. The Authority also received 194 reports of retained foreign objects (RFOs). Preventing RFOs requires a multipronged strategy, including reliable counting methods. However, counting alone may be insufficient. This article examines risk factors for RFOs following surgery and addresses the role of human factors analysis to uncover system vulnerabilities. Risk reduction strategies include improved perioperative processes, perioperative team communication, and the use of assistive technology. (Pa Patient Saf Advis 2009 Jun;6[2]:39-45.)

Introduction

Foreign objects can be left behind following a surgical procedure in any part of the body—most frequently in the abdominal cavity and thorax—although no body cavity is invulnerable.1 Authority reports and a case-control study of retained foreign objects (RFOs) in surgical patients show that sponges are the items most frequently reported as retained, followed by instruments.2 RFOs may lead to serious complications, such as sepsis, fistula or small bowel obstruction, or visceral perforation.2 The retention of a foreign object is considered a serious preventable event by the National Quality Forum.1 The Centers for Medicare & Medicaid Services (CMS) includes the retention of a foreign object in its list of hospital-acquired conditions for which reimbursement will not be provided.4 The Joint Commission categorizes the unintended retention of a foreign object as a sentinel event.3 Estimates of the incidence of RFOs vary.2,6,7 It may be difficult to arrive at a true estimate of the incidence of RFOs since an RFO can remain undetected for years.7 A 2003 study involving claims and incident reports related to RFOs over a 10-year period estimated that RFOs are rare, occurring at a rate of 1 in 8,801 to 1 in 18,760 inpatient operations.2 Two later studies estimated that RFOs occur more frequently. In an analysis of administrative and event reporting data, the authors determined that of 153,263 operations, the rate of RFOs was 1 in 7,000 surgeries.6 A study involving 191,168 surgical procedures in an institution that performed routine postoperative radiographs reported that the incidence of RFOs was 1 in 5,500.7 The costs related to an RFO can be significant. According to CMS, the cost of an RFO after surgery is $62,631 per hospital stay.8 In addition to hospital costs, RFOs can generate significant litigation costs. Kaiser et al.’s review of 9,729 closed malpractice claims demonstrated 40 retained surgical sponge cases over a 7-year period from 1988 through 1994 with an average expenditure of $66,110 for legal defense costs and indemnity payments,9 or approximately $103,504 adjusted to current dollars. Thus, the total cost for an RFO, including legal defense, indemnity payments, and surgical costs unreimbursed by CMS, would be approximately $166,135. At the previously quoted incidence of 1 in 5,500 operations,7 the cost of an RFO amortizes to about $30 per operation.

Counting objects before, during, and after surgery is a common method for screening for and preventing RFOs. When count discrepancies occur, reconciliation of the count may involve additional time and cost. The effect of count discrepancies on the cost of treatment has been estimated. A study reviewed all coronary artery bypass graft (CABG) procedures conducted at a major academic health center between 2000 and 2004.6 The total cost of CABG procedures and the additional cost related to count discrepancies, including extended operating room (OR) time and the additional cost of imaging, were calculated. In 153,263 surgical procedures, 1,062 discrepancies were reported. The incremental OR cost for CABG because of a count discrepancy was $932. On the basis of the national volume of CABG operations per year (347,570 in 2004), the estimated national cost of count discrepancies for CABG procedures is $24 million. Moreover, the rate of RFOs was 1 in 70 discrepancy cases;6 therefore, the cost of detecting an RFO from a count discrepancy can be calculated to be $65,240, demonstrating the importance of reliable counting and reconciling count discrepancies in RFO prevention.

Risk Factors Related to Retention of a Foreign Object

RFOs may cause serious injury.2 Knowledge of the factors that increase the chance that an RFO may occur can improve preventive practices. The infrequency of RFOs has been described as limiting observational and single-institution studies of risk factors and patterns of causation.2 Nonetheless, retrospective studies of closed claims and medical records have cited several risk factors, including emergent surgery, unexpected changes in the operative procedure, high
Before the procedure, to establish a baseline

Before the closure of a cavity within a cavity

Consistently perform surgical counts according to

Before wound closure begins

At the time of permanent relief of either the scrub

At skin closure

At the time of permanent relief of either the scrub person or circulating nurse

After wound closure and whenever a count discrepancy is noted.

Counting as a Risk Reduction Strategy

Counting procedures to prevent RFOs are in place in most hospitals. However, regulations do not prescribe how counts should be performed, who should perform them, and when they should be performed. Guidelines have been provided by the American College of Surgeons (ACS), the Association of peri-Operative Registered Nurses (AORN), and the Joint Commission. The guidelines recommend counting of all sponges, sharps, and instruments at the following times:10,11,12

- Before the procedure, to establish a baseline
- Before the closure of a cavity within a cavity
- Before wound closure begins
- At skin closure
- At the time of permanent relief of either the scrub person or circulating nurse

Adding to the count sheet any sponge, sharp, or instrument subsequently introduced to the operative field and performing counts to coincide with personnel handoffs is also recommended.11 AORN, with the support of ACS, published the best practices for preventing the retention of a foreign object. Best practices related to the surgical count are as follows:11

- Consistently perform surgical counts according to national standards and facility policy.
- Conduct a methodical wound exploration before wound closure and whenever a count discrepancy is noted.
Document the outcomes of the surgical count, items intentionally used for packing, and actions taken to rectify a count discrepancy.

Develop and review count policies and procedures through a collaborative process to promote consistency in practice across disciplines.

Make count policies and procedures readily available in the practice setting.

Reliability of Surgical Counts
Surgical teams routinely rely on discrepancies in the surgical count procedure to screen for the presence of a potential RFO. However, several studies suggest that reliance on the surgical count for this purpose may not be sufficient. One of the earliest studies that evaluated the likelihood of an RFO in the presence of a count discrepancy demonstrated that 88% of RFOs were associated with a count that was erroneously thought to be correct. Cima et al. also demonstrated that counting procedures may have limitations. In an analysis of RFO events and near misses, 62% of the true RFO events involved a correct sponge, sharp, and instrument count. Egorova et al. determined that of 1,062 count discrepancies among 153,263 surgical procedures, 17 were true positives in which the foreign object was inside the patient. For that reason, AORN and ACS recommend methodical wound exploration in addition to a surgical count. A recent study evaluated whether surgical counts successfully detect potential RFOs. Researchers observed 148 elective general-surgery procedures. A count discrepancy, defined as a count that does not agree with a previous count, occurred once in eight observed cases. In 51% of these discrepancies, a misplaced item, one that was lost on the floor, in the trash, or in the drapes, was detected and represented the possibility of an RFO. Sponges were the items most frequently retained. Forty-one percent of discrepancies were attributed to human errors, such as addition, incorrect documentation, or miscounting. The author concludes that despite recognized limitations in manual counts, any count discrepancy should prompt a thorough search and reconciliation and never be ignored.

The Egorova et al. study evaluated count discrepancy data from a four-year period derived from the event reporting system and administrative data at a major academic healthcare institution to estimate the rate of RFOs and the ability of counting to detect RFOs. The authors report the rate of RFOs was 1 of 70 discrepancy cases. The study demonstrated that accuracy of the count was affected by the following:

1. The complexity of the surgery (number of nursing teams and duration)
2. The emergent or urgent nature of the surgery
3. The surgical team’s fatigue and workload (duration and late-day procedures)

The authors suggest that the reduced reliability of counting in certain circumstances argues for adoption of additional safety measures and technological support. Counting is not reliable enough to be used without concurrent manual visual checks.

Human Factors in the Counting Process
Daily activities in the OR environment can increase the risk of errors during the counting process. Communication failures, distractions from multiple competing interests, pressure for increased productivity, and lack of sufficient personnel are all factors that may contribute to errors in the surgical count. The counting procedure is dependent to a great degree on human performance, and it has been estimated that in the event of a count and subsequent recount, the chance that the counts will not match is substantial, representing inherent potential for human error in the process.

Communication in the OR can be effected by cultural factors. The OR team consists of individuals with specific roles, requiring specific expertise and skills, performing interdependent tasks. Teams are prone to conflicts, such as a dispute, disagreement, or difference of opinion related to patient management, requiring some decision or action. In addition, the culture of the OR often is hierarchical, contributing to communication failures. Hierarchical relationships between individuals or groups include the following:

- Cross-cultural: nurse to surgeon
- Gender-related: male to female
- Captain to crew: surgeon to OR team
- Structural: medical staff to hospital staff

Environmental factors can influence human performance during the counting process. Interruptions, equipment noise, conversations, and OR traffic can all distract participants in the count procedure. Transfer of responsibility between staff members during change of shift or breaks can also create distractions, interfering with the transfer of information between OR team members. In addition, the length of surgery can contribute to fatigue.

ElBardissi et al. studied the transferability to the OR of a human factors model originally developed in the aviation industry. Potential areas of error causation identified by OR team members that may affect the counting process are summarized as follows:

- Routine violation and bending of rules
- High staff turnover, necessitating recruitment of inexperienced team members
- Performance of too many jobs by OR staff
- Consistent underestimation by OR management of the time-consuming nature of scrub technician and registered nurse duties
- Effect of extended operative time on OR members

Communication and handoff issues were also demonstrated in a prospective study involving observation and systems analysis of 10 complex surgical cases. Handoffs of patient care across physical locations and
Additional Risk Reduction Strategies

As the literature regarding the reliability of counting suggests, counting alone may not prevent postoperative retention of a foreign object. The integration of multiple methods of prevention has been recommended.9 Consideration of human factors that may affect the count as well as adherence to a standardized counting procedure are important ways to reduce the risk of RFOs. Additional strategies to consider include radiographic screening, multidisciplinary approaches, and the use of assistive technology.

Radiographic Screening

Some institutions conduct surveillance using routine postoperative screening radiographs. Instruments made of stainless steel are likely to be detected successfully on screening radiographs; however, radiographs are less sensitive in detecting sponges and needles.13,14 Sponges may be difficult to detect because they may become twisted or folded, distorting visualization of the marker, or a sponge without a radiopaque marker may have been used.13,14 Needles may be difficult to visualize due to their size.13,14

A limited number of studies have been undertaken to evaluate the effectiveness of intraoperative and postoperative radiographs. Cima et al. demonstrated that in 34 cases of an actual RFO in which the count was correct, 20 (60%) of the RFOs were detected on a postoperative high-resolution radiograph survey film.7 In 68 events of near misses and actual RFOs, 46 (67%) had intraoperative radiographs performed. In 18 incidents in which an RFO was eventually detected, intraoperative radiographs identified 12 of those objects. The authors conclude that given the unreliability of portable intraoperative radiographs, postoperative survey radiographs should be performed with dedicated high-resolution radiograph equipment in a dedicated imaging area.7 Kaiser et al. demonstrated that in 3 of 29 (10%) cases in which intraoperative radiographs were taken to detect radiopaque sponges, the radiograph was falsely negative. Poor-quality radiographs, multiple foreign objects in the field, and failure to communicate the purpose of the radiograph to the interpreting radiologist were cited as factors involved.9 In an abstract, Devgan et al. concluded that the net cost of a routine intraoperative screening was $450. The calculated cost of a routine intraoperative radiographic screening of all surgical patients to detect an RFO would be approximately $11.5 million.19 Detection of needles on radiograph screening depends on the needle size. A recent study evaluated the accuracy of plain abdominal films in the detection of retained surgical needles of varying sizes in the peritoneal cavity. Radiologists identified 195 needles in 360 abdominal segments. Abdominal radiographs had high sensitivity in the detection of retained surgical needles that were more than 10 mm in length.20 Earlier studies are inconsistent; one study reported detection of needles as small as 6 mm, while another reported that needles smaller that 13 mm could not be detected.21,23

Gawande et al. have recommended radiographic screening at the end of cases involving an emergent procedure, unexpected change in procedure, or high patient BMI.2 Conversely, citing the low quality of portable radiographs and the “large logistical and financial commitment” that would accompany a mandatory radiograph policy, Gibbs et al. have recommended obtaining an radiograph if the count is incorrect and before wound closure.24 In addition, intraoperative radiographs should be reviewed by a radiologist.24 ACS recommends the use of radiographs “as indicated.”10 A 2006 Department of Veterans Affairs multistakeholder directive on the prevention of RFOs suggests that when a radiograph is requested to locate a missing item, the type of foreign object that is missing and the OR suite number and telephone number must be specified in the radiology request.24

Multidisciplinary Approaches and the Counting Process

A multidisciplinary, multiphase approach to RFO prevention has been implemented at the Mayo Clinic. Its three-phase quality improvement program began with policy review and analysis of true and near-miss RFOs to identify patterns of failures. The second phase involved multidisciplinary educational programs. The third phase included monitoring and the response of rapid leadership response teams to any event. The program has resulted in an increase in the interval between RFO events from every 16 days to every 69 days sustained over a 2-year period. Highlights of the program related to the surgical count are summarized as follows:25

- Implementation of a “Conscientious Count Campaign”—an educational program that includes the in-house production of a video documenting the correct counting process, team training in a simulation center, and in-room audits
- Daily reminders of appropriate counting techniques in staff morning reports
- Use of a counting whiteboard with standardized documentation criteria
- Introduction of “red rules” that are prominently displayed in all ORs
  - Any team member can invoke a red rule to stop the procedure, including the rule that all counts must be performed by two team members. During the closing pause, the surgeon and residents are required to stop all activity other than appropriate wound exploration to avoid any interruption of the count process.
Deployment of a rapid response leadership team to any near-miss or real RFO event to analyze the event (A memo describing the event and findings must be shared with all OR personnel within 24 to 48 hours of the event.)

Use of posters to track the number of days since the last RFO event

A multidisciplinary approach to RFO prevention is also suggested in a national RFO prevention initiative, “No Thing Left Behind,” a surgical patient safety project aimed at encouraging all members of the OR team to reduce the incidence of RFOs. A summary of the highlights related to the surgical count are as follows:26

Use a standardized counting process.

- Develop a standardized method that must be used by all OR personnel for all ORs in the facility.
- Allow sufficient time for the count.
- Perform the count using audible and visual confirmation between two team members.
- Use a standardized counting process using hanging sponge holders.
- Document the count for all personnel to see.
- Develop a standard nomenclature for all sponges used in the OR.
- Develop a standard, visual means to record and display the surgical count, such as a dry-erase board.
- Unless absolutely necessary, avoid disturbing the nursing staff while they are counting.
- Take recommended steps to explore the wound during procedures in the abdomen and pelvis and mediastinum or thorax.
- Inform the scrub team about all additional items added to the count.

Verify that sponges are accounted for through the following actions:

- Actively ask whether appropriate counting procedures have been performed at the end of the procedure.
- Verify the final count before the patient leaves the OR.

If there is an incorrect count, take the following actions:

- Stop closing the wound.
- Remove enough sutures to allow a visual and tactile exploration.
- Obtain a radiograph of the complete operative field, and provide a description of the missing item to the radiologist to aid in detection.
- Enlist the assistance of additional personnel.
- Locate the missing item before the patient leaves the OR.
- The surgeon should consider dictating what actions were taken in response to the incorrect count and the results of the search.

Assistive Technology

Technological aids to assist the OR team in the detection and prevention of the retention of sponges, gauze towels, and laparotomy pads include radio-frequency (RF) detectable sponge systems, radio-frequency identification (RFID)-detectable sponge systems, and bar-coded sponge systems.27 These aids are intended to augment the manual count, not replace it. RF sponge detection systems operate as “detect only” and involve a surgical sponge with an embedded RF tag, along with an antenna or a wand RF reader to detect the RF tag. During and/or after the surgery, the user passes the wand over and around the surgical site to detect the presence of a retained surgical sponge.27,28 RFID-tagged sponge systems count and detect. The sponges are scanned before surgery, and a running count of sponges is kept during the procedure. The wand can be used to detect a missing sponge; however, scanning of the patient has been recommended regardless of the outcome of the sponge count.27 Potential benefits of RF/RFID technology include early identification of a sponge and prevention of the need for additional surgery and the reduction or elimination of the need to take radiographs to detect the presence of a sponge.27 The cost of RF systems using a wand scanned over the patient to detect RF tags embedded in sponge, gauze, and towels is estimated to be $50 to $55 per open procedure.29 The cost associated with RFID sponge systems is estimated to be $35 to $50 per case on average.29 However, the costs may decrease as newer RF and RFID technologies becomes available.

Bar-code scanning is another technology available to reduce the likelihood of a retained sponge. Bar-code technology for this application became available in early 2006.30 The process involves labeled sponges or towels that are passed under a bar-code reader, providing a count of each sponge. A recent randomized controlled study compared a bar-code-assisted surgical count with a manual count in 300 general-surgery procedures.30 The bar-code system detected significantly more counting discrepancies involving sponges than the traditional counting method. The benefit of a bar-code system is that using the system decreases the risk of an incorrect count.27 However, bar-code sponge systems have limitations when compared with RF-detectable sponge technology. Bar-code technology will not detect misplaced or retained sponges, and scanning a bar-coded label covered in blood may be difficult.27 The cost of bar-code systems has been estimated to be $12 to $14 per procedure.30
Conclusion
As reports to the Authority demonstrate, incorrect counts occur frequently. Incorrect counts may lead to the inadvertent retention of a foreign object after surgery, which may result in serious harm to a patient. The counting process is highly dependent on human performance in an increasingly complex environment. However, the risk of RFOs can be reduced by a multifaceted and multidisciplinary approach, including strict adherence to a standardized counting process, consistent and methodical wound exploration before closing, attention to human factors contributing to error, and use of assistive technology.

Notes


29. Getting the whole team on board to prevent retained foreign bodies. OR Manager 2008 Sep;24(9):1,15-8.


**Self-Assessment Questions**

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. Which of the following factors has NOT been associated with an increased risk of retention of a foreign object following surgery?
   a. Emergency surgery
   b. Size of the sponge
   c. Multiple major surgical procedures
   d. High body mass index

2. All of the following statements about factors that can affect the accuracy of the surgical count are true EXCEPT:
   a. High music volume, excessive conversation, and equipment noise can interfere with the transfer of information between operating room (OR) team members.
   b. The transfer of responsibility between staff members during change of shift or breaks can create distraction.
   c. In the event of a miscount and subsequent recount, there is a substantial chance that the counts will be reconciled.
   d. Routine violation and bending of rules are potential areas of error causation identified by OR team members that may affect the counting process.

3. Which of the following are NOT risk reduction strategies that will reduce the risk of a retained foreign object (RFO)?
   a. Develop a standard, visual means to record and display the surgical count, such as a dry-erase board.
   b. When a radiograph is requested to identify or rule out a suspected RFO, the type of suspected foreign object should be specified on the request.
   c. Verify the count before the patient leaves the OR only if there has been a discrepancy between the baseline and final count.
   d. Actively ask whether appropriate counting procedures have been done at the end of the procedure.

4. A patient has undergone an open abdominal procedure. During closure of the abdomen, the scrub nurse reports an incorrect needle count; a 13 mm needle is missing. Select the evidence-based response to this incorrect count.
   a. Stop closing the wound, cover the wound, and obtain a radiograph of the abdomen.
   b. Conduct a visual inspection. If the needle is not seen in the abdominal cavity, continue to close the wound because the needle is too small to be detected on a radiograph.
   c. Stop closing the wound, remove enough sutures to allow a visual and tactile exploration, and request and obtain a radiograph of the complete operative field, communicating to the radiologist that the team is searching for a needle.
   d. Continue closing the wound, send the patient for an abdominal radiograph, indicating to the radiologist that a needle is missing, and return the patient to the OR immediately.

5. All of the following are potential advantages of the use of radio-frequency (RF) surgical sponge detection systems EXCEPT:
   a. RF surgical sponge detection can replace manual counting.
   b. RF surgical sponge detection has the potential to reduce or eliminate the need for radiographs to detect the presence of a retained sponge.
   c. Studies have shown that RF systems detected significantly more counting discrepancies involving sponges than the traditional counting method.
   d. It has been demonstrated that RF wands have a very high success rate in detecting RF tagged sponges.