Retained surgical instruments (RSIs), which primarily consist of retained surgical sponges (RSSs), can have a profound effect on patient outcomes, health care costs, and provider and institutional reputation.\(^1\)\(^-\)\(^3\) Traditional methods of accounting for sponges, such as manual sponge counting and intraoperative radiography before surgical site closure, are unreliable and prone to error.\(^2\)\(^-\)\(^4\)

Inadvertently leaving behind a sponge or instrument at the end of an operation is an uncommon but serious medical error (Figure 1).\(^1\) The incidence of RSIs, sometimes referred to in the medical literature as gosypiboma, varies markedly among different reports, possibly due, in part, to the reluctance of hospitals and clinicians to disclose these errors for privacy, adverse publicity, or liability reasons, or because some patients may remain asymptomatic for long periods of time and therefore go undetected.\(^1\)\(^,\)\(^2\)\(^,\)\(^3\)\(^,\)\(^5\)\(^,\)\(^6\)

Regardless, a representative national sample of inpatient administrative claims suggests that the RSI rate may actually be as high as 1 per 7,000 surgical admissions.\(^7\) Wan and colleagues reviewed 254 cases of RSIs published between 1963 and 2008, and found the abdominal/pelvic cavity/vaginal vault (74%) was the most common site for RSIs, followed by the thoracic cavity (11%).\(^8\) Furthermore, in a study of nearly 300 surgical patients, surgical sponges comprised 69% of all cases of RSIs, which is consistent with results from other studies.\(^1\)\(^,\)\(^9\)

The body’s pathophysiologic response to RSSs can consist of an exudative or an aseptic fibrous tissue
reaction. The exudative reaction occurs earlier in the postoperative period and may manifest as infection secondary to bacterial contamination. The aseptic fibrous type of reaction occurs later and involves fibroblasts, leading to formation of adhesions, granulomas, or pseudotumors, with patients potentially remaining asymptomatic for many years.

The clinical presentation of RSIs such as sponges, varies and depends on the site and type of tissue reaction elicited. Early reactions can consist of unexplained pain or signs and symptoms of abscess formation or sepsis. More delayed clinical presentations include wounds that do not heal, or signs and symptoms of intestinal obstruction or fistulization. Sponges can migrate transmurally and enter nonsterile compartments (eg, intestine, bladder, airway/lung, stomach), further increasing the risk for RSS-related infection, sepsis, or death.

In a study of medical records associated with all claims or incident reports of an RSI filed between 1985 and 2001 with a large malpractice insurer representing one-third of the physicians in Massachusetts, Gawande and colleagues reported that RSIs resulted in serious sequelae, including reoperation for removal (69%), readmission to the hospital or prolonged hospital stay (59%), sepsis or infection (43%), fistula or small bowel obstruction (15%), visceral perforation (7%), and even death (2%). Among other studies, the mortality rate associated with RSSs was much higher and ranged from 10% to 35%. Economic Effects of Retained Surgical Objects

Complications of RSIs result in a marked increase in health care costs. The average per-incident costs for an RSI is approximately $63,631 for unreimbursed procedural costs and an additional $25,000 for associated secondary infections that are not otherwise reimbursed by the Centers for Medicare & Medicaid Services (CMS). Legal costs, including legal defense fees and malpractice settlements, are estimated to be on average $370,000 per incident. There are also time consideration costs to searching for missing sponges as well as administering X-rays. The indirect costs of an RSI (eg, related to absence from employment or school, the need for caregiver support) have not been quantified. Although liability and litigation are often described as adverse consequences of RSIs, perhaps less recognized is the profound effect of RSI-related complications on the patient’s emotional health and trust in the health care system, as well as the negative publicity and distress for the providers and institutions involved.

Risk Factors

Several groups of investigators have attempted to characterize risk factors related to the occurrence of RSIs, particularly sponges (Table). For example, in a multivariate analysis of patients with RSIs by Gawande and colleagues, factors that significantly increased the risk for retention of a foreign body were emergency surgery (risk ratio [RR], 8.8; 95% confidence interval [CI], 2.4-31.9), unplanned change in the operation (RR, 4.1; 95% CI, 1.4-12.4), and body mass index (RR for each 1-unit increment, 1.1; 95% CI, 1.0-1.2). In a similar multivariate analysis by Lincourt and colleagues, factors associated with a significantly higher risk for RSIs were the total number of major procedures performed (odds ratio [OR] 1.6; 95% CI, 1.1-2.3), as well as an incorrect count (OR, 16.2; 95% CI, 1.3-197.8). In a root-cause analysis, Steelman and Cullen reported that distraction, time pressures, multitasking, and not following standardized procedures were the most frequent factors related to the risk for RSSs.

A. Postoperative Day 1  
B. Postoperative Day 12

Figure 1. An unintentional retained surgical sponge on postoperative day 1 and postoperative day 12.
Based on these and other data, the Joint Commission classifies the unintended retention of a foreign object in a patient after surgery or other invasive procedure as a reviewable sentinel event. Furthermore, an RSS is included in the list of 29 adverse events issued by the National Quality Forum. In 2007, the CMS announced its decision to deny reimbursement to hospitals for the costs associated with objects left in patients during surgery.

Strategies To Prevent Retained Surgical Sponges

To prevent RSSs, surgeons and operating room (OR) staff have relied on manual counting protocols and “cavity sweeps”; however, each method is prone to human error. Current practices for counting sponges have a 10% to 15% error rate. Additionally, nearly 88% of all RSSs occur when sponge counts are thought to be correct. According to the sentinel event data, an incorrect or “discrepant” count in 52 of the 772 SSI sentinel events was reported to the Joint Commission. The Pennsylvania Patient Safety Authority’s Reporting System database shows that 22.3% of RSIs were associated with a discrepant count. Furthermore, Egorova and colleagues retrospectively analyzed count discrepancy data stored in a web-based “near-miss” and patient-harm reporting system over a 4-year period (2000-2004), and reported that the sensitivity and specificity of surgical counting as a screening method were 77.27% and 99.32%, respectively.

The Association of periOperative Registered Nurses (AORN) recommends a multidisciplinary approach to the prevention of RSIs that includes a standardized approach and global accountability for all team members. Although the AORN stresses that minimization of distractions is key to reducing error in manual counting protocols, this goal is not always achievable in the operating suite, especially with the increasing complexity of surgical procedures or in the setting of urgent or emergent procedures or unstable patients. Therefore, the AORN recommends that perioperative staff supplement manual count procedures with adjunct technologies. Similarly, the Joint Commission recommends using a standardized counting system to account for all surgical items, whereas the American College of Surgeons (ACS) recommends the use of x-rays, barcoding, or radiofrequency to prevent the retention of surgical instruments. The ideal system should be highly accurate and reliable, simple to use, rapid, and cost-effective.

Intraoperative Radiography

Radiography has been the primary method of screening for RSIs, and best practices include the use of radiopaque (x-ray–detectable) surgical items to facilitate visualization. Although some facilities obtain radiographs on all patients undergoing an open-cavity operation, most use radiography only when the count is incorrect. Radiographs can be expensive and time-consuming. They expose the patient to ionizing radiation, and they are not always reliable, especially when looking for needles and sponges.

Table. Risk Factors for Retained Surgical Instruments Identified in 2 Retrospective Case–Control Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Risk Factors for Retained Surgical Instruments</th>
<th>P Value</th>
<th>Risk Ratio (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gawande 2003</td>
<td>Emergency procedures</td>
<td>&lt;0.001</td>
<td>8.8 (2.4–31.9)</td>
</tr>
<tr>
<td></td>
<td>Unexpected change in operation</td>
<td>0.01</td>
<td>4.1 (1.4–12.4)</td>
</tr>
<tr>
<td></td>
<td>BMI (per 1-unit increment)</td>
<td>0.01</td>
<td>1.1 (1.0–1.2)</td>
</tr>
<tr>
<td></td>
<td>Multiple surgical teams</td>
<td>0.1</td>
<td>3.4 (0.8–14.1)</td>
</tr>
<tr>
<td></td>
<td>Estimated blood loss (per 100-mL increment)</td>
<td>0.19</td>
<td>1.0 (1.0–1.0)</td>
</tr>
<tr>
<td></td>
<td>Change in nursing staff during procedure</td>
<td>0.24</td>
<td>1.9 (0.7–5.4)</td>
</tr>
<tr>
<td></td>
<td>Counts of sponges and instruments</td>
<td>0.76</td>
<td>0.6 (0.0–13.9)</td>
</tr>
<tr>
<td>Lincourt 2007</td>
<td>Number of major procedures performed</td>
<td>0.008</td>
<td>1.6 (1.1–2.3)</td>
</tr>
<tr>
<td></td>
<td>Incorrect counts recorded</td>
<td>0.02</td>
<td>16.2 (1.3–197.8)</td>
</tr>
<tr>
<td></td>
<td>Multiple surgical teams</td>
<td>&gt;0.05</td>
<td>5.4 (0.9–33.1)</td>
</tr>
</tbody>
</table>

BMI, body mass index
Based on references 1 and 20.
Indeed, the sensitivity of intraoperative radiographs for detecting a retained item has been found to be 67% effective, while another 10% of radiographs have been found to be falsely negative for radiopaque sponges. Steelman and colleagues used radiography on morbidly obese patients to assess the presence of a retained sponge in the abdomen, and found that it often required 2 overlapping radiographs, an estimated 30-minute extension to the OR time, and also an increased risk for contamination of the surgical drapes. Furthermore, a key clinical study showed the probability of detecting an RSI as being 3.9 per 100,000 operations, the cost of performing routine intraoperative radiography to prevent RSIs, including sponges is estimated at $11.5 million for every clinically harmful object detected (based on a cost of $450 screening x-ray, which includes technician time and radiology fees). 

**Barcoded Sponges**

Some hospitals also use barcoded sponges, which consist of a scanning device, and 2-dimensional, matrix-labeled sponges that are individually identified. Before the surgical procedure, the sponge packs are scanned in with the sponges then individually scanned off the sterile field. Because this is essentially a computer-assisted physical counting system, it is a time-consuming activity and also can be just as vulnerable to some of the same types of human errors otherwise associated with current manual counting approaches. For example, failure to manually scan a sponge or sponge pack before placing it within the operative field can result in a false-negative count when removing sponges from the field. Furthermore, the sponges must be found and removed from the patient in order to count them because the scanner cannot read through or detect the presence of a sponge inside the body. Although this system can account for sponges placed in or removed from the operative field, it cannot localize the missing sponge within the patient or elsewhere in the operating suite.

As a result, when the manual and barcode counts do not match, intraoperative x-rays are still needed to localize the missing sponge, therefore obviating the time, cost, and radiation minimization benefits of otherwise avoiding the use of intraoperative x-rays. Additionally, the direct line of sight between the barcode scanner and the item’s barcode label may be compromised by blood and fluid, thereby requiring manual wiping and removal of particulate before rescanning the sponge, which could lengthen the process and make it more cumbersome. Furthermore, the barcode label can separate from the sponge when irrigation warmers are used or in cases where bone cement is used, such as in orthopedic procedures.

**Radiofrequency Detection Technology**

Another option in preventing RSSs involves the use of radiofrequency (RF) detection technology (RF Assure Detection System X; Figure 2). Using a low-energy RF signal for the purpose of compatibility with existing OR equipment, this technology is engineered to detect misplaced surgical sponges before closing the wound. RF sponges have a small RF chip sewn into a pocket in the sponge. RF tags do not contain specific information, so the system cannot distinguish one sponge from another and cannot quantify the number of sponges; rather, its focus is to detect whether a sponge is in proximity to the receiver. The technology is used at the end of the procedure to supplement manual counts and to determine via detection whether a sponge has been retained inside the patient cavity. Visual proximity is not required with RF systems, and sponges with the passive RF tag can be detected when a receiver is within 16 to 24 inches of it.

RF-based technologies typically use a detection mat (Antennae Array Body Scanner), a handheld wand (Room Scanner), or a combination of both. The Body Scanner, which is placed under the patient on the OR table, reduces the chance of human error with 1-button automatic scanning. The Body Scanner is used to quickly scan the patient (12 seconds) before completing the procedure to ensure that no surgical sponges are retained in the patient. In the event of a miscount, the Room Scanner is used to determine the location of an errant sponge, including within the patient if so used or the surrounding operating suite (eg, trash bags, linen bags). Per suggested manufacturer protocol, the Body Scanner is the first mode of scan (passive scan), with the ability to follow up with the Room Scanner (dynamic scan) as a secondary measure or if the Body Scanner detects the presence of an RF-tagged item. Additionally, the Room Scanner can be used for patient scanning, but is principally recommended as a supplement to the Body Scanner for morbidly obese patients.

Furthermore, a recent RF component has been made available for clinical specialty use, the ArQ-Sphere Peripheral Scanner. This device offers in vivo detection that is ideally designed to address procedures where the Body Scanner may not be an option (eg, orthopedic and spine cases). The ArQ-Sphere enables clinicians to ensure the detection and removal of surgical sponges without compromising the integrity of the sterile field. The ArQ-Sphere offers motion-free scanning, and a triaxial overlapping detection field to create an optimal detection zone.

Because the RF system does not require direct line of sight, as is otherwise needed with barcode-scanning technology, the RF system has the advantage of being able to detect RF-tagged sponges both inside and outside of the operative field. For example, the Room Scanner can be passed over the sterile field or linen, as well as trash bags, to locate a missing sponge. Unlike the barcode-scanning technology, RF-based technology can detect misplaced surgical sponges through blood, dense tissue, bone, and near metal.

The localization features of this system have the potential to obviate the need for detection of missing sponges via intraoperative x-ray, thereby avoiding the associated costs, time, and radiation exposure of this technique, which are major advantages when compared with other adjunct technologies for the detection of an RSS.

**Clinical Studies Using Radiofrequency-Based Technology**

As reviewed here, several strategies designed to prevent RSSs (eg, manual counting, intraoperative radiography, and barcoded sponge systems) have drawbacks that limit their overall clinical usefulness. By contrast, the characteristics of the RF-based sponge-detection technology appear well suited for the prevention of RSSs in surgical patients relative to other strategies.
Several studies have investigated the clinical utility, time and resource utilization, and cost–benefit of this RF-based approach. For example, Steelman and colleagues performed a prospective, crossover, double-blind study in which 203 study participants (63% of whom were morbidly obese) reclined in a supine position on top of an RF Body Scanner.31 Four surgical sponges were sequentially placed on top of the torso in locations approximating the abdominal quadrants, or 4 surgical sponges were sequentially placed underneath the torso, and an RF wand was passed over the abdomen.31

The sensitivity and specificity of the RF detection scanner was 98.1% and 100%, respectively, and that of the Room Scanner was 100% and 100%, respectively, which the investigators noted was much higher than those of surgical sponge counts or published findings on the use of intraoperative radiographs to identify RSSs.30 Furthermore, the RF Room Scanner was slightly more sensitive for detecting sponges in morbidly obese patients than the RF Body scanner.31

The investigators noted that the RF scanning procedure to detect the presence of a sponge took less than 1 minute.31 Additionally, the RF Room Scanner located a sponge in a linen or trash receptacle without any line of sight.31 The investigators concluded that the use of the RF-based technology saved significant time and additional OR costs associated with resolving discrepant counts. With predicated use for the device, most implants, patient adornments, or appliances did not interfere with RF readings.4

Rupp and colleagues prospectively studied the use of the RF-based sponge detection technology versus standard counting protocols among 2,285 patients (Figure 3).38 Thirty-five surgical sponge miscounts (rate, 1.53%) resulting from standard counting procedures occurred.38 Several variables evaluated were found to be associated with miscounts through statistical analysis: higher estimated volume of blood lost (P<0.0001), change of surgical team during the operation (P<0.0001), open surgical approach (P=0.004), higher number of laparotomy sponges (per 10 sponges opened used (P<0.0001), unanticipated change in operative procedure during the surgery (P<0.0001), longer duration of operation (P<0.0001), emergency cases (P<0.0001), operations performed after 5 PM but before 7 AM ("after hours": P=0.005), and operations occurring on a weekend or holiday (P=0.03).38

The investigators noted that the incorporation of the RF-based technology assisted in the resolution of a near-miss event (1 of 2,285) not detected by manual counting protocols and assisted in the resolution of the 35 surgical sponge miscounts resulting from standard counting procedures.38 Thus, they concluded that the incorporation of the RF-based sponge detection technology resulted in the prevention of RSSs over a 10-month period in a large surgical population.38

The study culminated with a questionnaire given to the circulating nurses at the completion of each procedure.38 The majority of respondents reported that confidence in the final count improved with the RF-based system was as follows: 95% responding agreed or strongly agreed; the RF system improved the time to resolve a count discrepancy (83% agreed); the RF system was easy to use (97% agreed); and the process of body cavity closure/operative conclusion was not prolonged by the use of the RF system (99.5% agreed).38

**Time and Cost Savings**

Without adjunct detection technology, the time and cost associated with reconciliation of the surgical sponge count can be significant. One group of investigators retrospectively evaluated...
analyzed 13,322 surgical cases. Accordingly, additional effort for reconciliation was required in 212 (ie, 1 in 63 procedures) surgical sponge counts, and of these, 143 were first closing counts and 63 were final closing counts. Type of sponges missing included 108 radiopaque 4×4s, 82 laparotomy sponges, and 4 episiotomy sponges. The most frequently reported steps taken for reconciliation were searching the sterile (77.4%) and nonsterile fields (58.5%). The time required to conduct such a search ranged from 1 to 90 minutes, with 9 searches taking longer than 30 minutes. Thus, the cumulative reported time required for reconciliation was 1,700 minutes. The results showed that 25% of cases required an x-ray with an average time of 30 minutes. Costs associated with this process were quantified as follows: time required to find the sponge at $62 per minute; time to administer intraoperative radiography at $62 per minute; and cost of x-rays, at $286 per x-ray. Using these costs, Steelman and colleagues found that the annualized operating time spent on sponge counting reconciliation with the added expense of x-rays was $70,267. Additionally, the investigators concluded that the total annualized cost of searching for missing sponges and ruling out the presence of a retained sponge using radiography was $218,326.

However, they also cautioned in their findings that these estimated costs are likely lower than actual costs. Hence, they noted that the staff likely did not report every search performed due to “documentation fatigue.” Additionally, the number of minutes for searches was at times recorded as “greater than 30” minutes and were treated as a 30-minute value in their analysis; moreover, an estimate of nonproductive OR time spent searching for a sponge at 50% was considered to be conservative.

In their cost–benefit analysis of adopting an RF technology defined as having a Body Scanner that is placed under the patient on the OR table inclusive of a Room Scanner that is passed over the patient, Williams and colleagues reported

**Figure 3.** Algorithm of a counting process incorporating RF-based technology for the prevention of retained surgical sponges.

RFDS, radiofrequency detection system

that 5 organizations that implemented the technology between 2008 and 2012 collectively demonstrated a 93% reduction in the rate of reported RSSs. \textsuperscript{17} Institutions that used the RF technology showed a significant reduction in OR time per case (16 minutes per procedure). \textsuperscript{17} The time saved was likely due to obviation of need for intraoperative radiography and less time searching for sponges.

If RF technology is more efficient and effective in finding missing sponges, then the costs associated with operating suite time and x-rays should decline. To determine the annual savings in x-rays, the cost of a portable x-ray was derived from organizational data and multiplied by the estimated number of count discrepancies annually. The number of discrepancies was determined from an occurrence rate in the literature. To calculate the OR time saved, information on average time to reconcile a count discrepancy and the cost per minute of OR time was obtained from the literature. The following formula was used:

\textbf{Annual Savings in OR Time} = \text{number of minutes needed to reconcile a count discrepancy} \times \text{the cost per minute} \times \text{the number of discrepancies.}

Based on this formula, investigators calculated an average of 18 minutes (note: the model used 16 minutes as the average range) saved per case, while the cost savings in x-ray and operating suite time totaled $157,024. \textsuperscript{17,18}

To determine the medical and legal costs avoided, information on the average cost of readmission and surgery, as well as malpractice claims, was obtained from the literature. The average number of RSSs annually was calculated from an occurrence rate in the literature, and the estimated costs avoided was determined at $441,534. \textsuperscript{17,30} Therefore, the 1-year cost–benefit analysis showed that the savings in x-rays and time spent in the OR and in the medical and legal costs (estimated at $598,558 annually) outweighed the cost of deploying RF technology ($191,352; Figure 4). \textsuperscript{17}

\textbf{Conclusion}

An RSS is a serious medical error associated with significant complications and high health care costs. This phenomenon is entirely preventable, but the current detection and avoidance of an RSS through manual counts and intraoperative x-rays are prone to error, present labor-intensive and time-consuming work, and are costly. By contrast, the use of RF detection-based technology as reported is quick and cost-effective in detecting RSSs, while providing efficiency-based cost savings to institutions.

As recommended by the Joint Commission, AORN, and ACS, institutions should consider integrating the use of adjunct technologies, such as the RF-based system, into their sponge-counting process. Implementation should benefit hospitals and surgical facilities by avoiding complications and reducing overall costs.

\textbf{Figure 4.} Annual cost–benefit analysis for the use of RF technology for the prevention of retained surgical sponges.

\textbf{RF}, radiofrequency

Based on reference 17.


Disclosures: Dr. Boyd reported that he is a consultant for Covidien and RF Surgical Systems, Inc. Dr. Lottenberg reported that he is a consultant for Haemonetics, RF Surgical Systems, Inc., Synthes, and Teleflex.

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