Bar-coding Surgical Sponges To Improve Safety
A Randomized Controlled Trial

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Objective: A randomized, controlled trial was performed to evaluate a computer-assisted method for counting sponges using a bar-code system.

Background: Retained sponges are a rare and preventable problem but persist in surgery despite standardized protocols for counting. Technology that improves detection of counting errors could reduce risk to surgical patients.

Methods: We performed a randomized controlled trial comparing a bar-coded sponge system with a traditional counting protocol in 300 general surgery operations. Observers monitored sponge and instrument counts and recorded all incidents of miscounted or misplaced sponges. Surgeons and operating room staff completed postoperative and end-of-study surveys evaluating the bar-code system.

Results: The bar-code system detected significantly more counting discrepancies than the traditional protocol (32 vs.13 discrepancies, $P = 0.007$). These discrepancies involved both misplaced sponges (21 vs. 12 sponges, $P = 0.17$) and miscounted sponges (11 vs. 1 sponge, $P = 0.007$). The system introduced new technical difficulties (2.04 per 1000 sponges) and increased the time spent counting sponges (5.3 vs. 2.4 minutes, $P < 0.0001$). In postoperative surveys, there was no difference in surgical teams' confidence that all sponges were accounted for, but they rated the counting process and team performance lower in operations randomized to the bar-code arm. By the end of the study, however, most providers found the system easy to use, felt confident in its ability to track sponges, and reported a positive effect on the counting process.

Conclusions: Use of automated counting using bar-coded surgical sponges improved detection of miscounted and misplaced sponges and was well tolerated by surgical staff members.

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Inadvertently leaving behind a sponge or instrument at the end of an operation is a rare but persistent and serious medical error. A conservative estimate based on malpractice claims suggests that it occurs in 1 in 9000 to 19,000 inpatient operations,[1] although the rate was estimated as high as 2.4 per 10,000 surgical admissions among a representative national sample of inpatient administrative claims data.[2] Retained sponges and instruments (RSIs) tend to result in serious sequelae, including reoperation for removal (69%–83%), bowel perforation, fistula or obstruction (10%–22%), and even death (0%–2%).[1,3] These episodes also frequently lead to litigation, negative publicity, and distress for the providers involved.[1,4]

Standard procedures for prevention of RSI depend on 2 members of the surgical team concurrently counting every item as it is introduced into the sterile field, and again at the end of the operation. When the totals match (known as a "correct count"), the team is reassured that all sponges and instruments have been accounted for. A discrepancy occurs any time a subsequent count does not agree with a previous count. For the purposes of this study, we defined 2 types of discrepancies: miscounts and misplaced items. A miscount occurs when the number of sponges counted does not reflect the number of sponges that are actually present, such as with a double count or undercount, and is usually resolved by recounting. A misplaced sponge is one that is unintentionally lost on the floor, in the trash, or on the sterile field. A retained sponge is a specific type of misplaced sponge that is located within the patient's body cavity, either before the patient leaves the operating room (representing a near miss) or postoperatively (representing an adverse event). If it cannot be located, radiographs must be obtained to confirm that no sponges are retained inside the patient.[5]

Although these protocols are labor-intensive (they occupy as much as 14% of the operative time[6]) failure to follow them seems uncommon. Instead, the weak link has been the deception of a falsely correct count (72% to 88% of cases of retained surgical equipment occur in operations with correct counts).[1,3,7] In these cases, the count lends a false sense of security because a manual counting error has allowed the team to believe all sponges have been identified when in fact a misplaced sponge has been left in the patient. There is currently no estimate of how frequently incorrect counts are mistakenly interpreted as correct. By depending solely on the

diligence of operating room personnel, standard protocols thus remain susceptible to human error, especially in emergencies and in operations with an unexpected change in procedure.[1,6]

When a discrepancy does occur, the risk of a RSI is increased because there is no longer an accurate record of the number of sponges in the field. A recent report suggests that a RSI is more than 100 times more likely to occur in a case with a discrepant count.[8] One approach to preventing RSIs is to improve the accuracy of counting to more consistently detect counting discrepancies when they occur. Because the majority of retained objects are surgical sponges, and current protocols have failed to eliminate the problem, sponges have been a primary target for innovation.[1,3] Recently, technological adjuncts to manual sponge counting have emerged as potential solutions.[9] Small pilot studies have demonstrated the feasibility of imbedding radiofrequency (RF) identification tags in sponges.[10–12] One radiofrequency detection system is already on the market and is being implemented in a number of centers (J. Port, RF Surgical, personal communication). Passive approaches to tracking such as RF detection or radiographic screening are appealing because they alleviate the need for counting altogether. However, these are as yet untested technologies with their own failure rates, and it is not certain that they will function more reliably than our current manual counting approach. Another approach is the placement of bar codes on surgical sponges to allow computer-assisted sponge counting as a supplement to manual counts. Bar-code technology is promising because it has already proven effective in improving the safety of medication administration, reducing the risk of potential adverse drug events by 97%.[13] A bar-coded sponge system has been introduced in the United States and, according to a hospital system that has put it in use in 50 operating rooms, the system has proved feasible and inexpensive, with total increased costs of 9 dollars per case (James Bennan, University of California at San Francisco, personal communication).

Although a bar-coded sponge system may be promising, it is not certain to reduce errors. We therefore sought to perform a randomized controlled trial of the system. A central difficulty for such trials is that the sample size required to detect a reduction in retained sponge incidence is unattainably large. Given the known association between discrepancies (miscounts and misplaced sponges) and RFBs, the frequency with which the system recognizes when sponges have been miscounted or misplaced can serve as an effective proxy.[8] A system that significantly increases detection and reconciliation of these high-risk situations, and reduces the likelihood of a misplaced sponge going undetected, would be expected to reduce the risk of a retained sponge in surgical patients.

METHODS

Protocol

Study Population

We conducted a randomized, controlled trial comparing a bar-coded sponge system (SurgiCount Medical, Temecula, CA) to the standard sponge-counting protocol at the Brigham and Women's Hospital in Boston, under the approval of the hospital's Human Research Institutional Review Board (clinicaltrials.gov #: NCT00282750). Patients undergoing an elective, weekday procedure in a general surgery operating room by a general surgeon, surgical oncologist, or colorectal surgeon were eligible for randomization. Letters introducing the study were mailed to the patients in advance of their procedure, and consent was obtained in the preoperative holding area. The surgical nurses and technologists involved in the operations were trained ahead of time in the use of the bar-coded sponge system. A total of 56 circulating nurses and surgical technologists (STs) and 36 surgeons participated in the study.

Intervention and Timing

The teams followed the standard Association of Perioperative Registered Nurses protocol[6] for counting instruments and sponges at the start of the case in both arms, including a simultaneous manual count by the ST and circulating registered nurse (RN) and a complete written record. The same sponges, each of which contained a unique Data Matrix symbology tag annealed to the gauze, were used in both arms. In the intervention arm, the sponges were also scanned using a handheld bar-code reader as they were added to the sterile field, and again as they were removed, while the control arm was limited to the manual count.

When sponges were removed from the sterile field, they were counted and placed in plastic bags with 10 sponges per bag, according to standard protocol. In the control arm, this count was performed manually by both the ST and RN. In the bar-code arm, it was done by the RN manually and using the computer-assisted bar-code system. Concurrent counts with the ST were not required in the intervention arm; however, they were allowed at the discretion of the team.

Outcome Measures

The primary end point was the number of incidents of miscounted or misplaced sponges detected in each arm. Secondary outcomes included the total time devoted to counting activities, the number of miscounts, and the number of misplaced or retained sponges, the number of operations with any discrepancy and each type of discrepancy, and the number of x-rays required to resolve discrepancies. Qualitative assessments of the counting protocol, team performance, and confidence that the count was correct were compared.

Sample Size

Using a Fisher exact test and assuming a discrepancy rate of 40% in the nonintervention arm, we have 80% power to detect a change of 50% in the discrepancy rate in the intervention arm with 150 patients per arm of the trial.[6] In the subset of patients who have a discrepancy in the counts, assuming that this $n = 60$ in each arm, we have 80% power to detect a 10-minute difference in time to resolve the counts, assuming a conservative standard deviation of 20 minutes. We were not powered to detect a difference in the number of x-rays requested or of retained sponges.

Statistical Analysis

Statistical analysis was performed using SAS version 9.1 (SAS Corp., Cary, NC). Case characteristics and outcome variables are reported as means or counts. Transformations were used to approximate normal distributions for non-normal data. Hypothesis testing was performed with exact Poisson tests when the counting activity was the unit of analysis, Fisher exact test tests when the case was the unit of analysis, Wilcoxon rank sum tests for time analyses, and Poisson regression for secondary outcomes related to frequencies. Survey analyses used generalized estimating equations for trend to account for clustering among multiple providers within each case.

Assignment

Randomization to either the bar-coded sponge or control arm was performed at the patient level using a 4 block randomized permutation on the day of surgery before any counting activities began.

Data Acquisition

Observations

Three physician-observers were trained in observational techniques and use of the standardized data intake forms. Data collection commenced with set-up for the operation and continued until all counting activities were concluded and the patient left the operating room. Data collected for each counting activity included start and end time, team members involved, phase of the counting protocol ("count-in" or "count-out"), and number and type of item being counted. Whenever the team detected a discrepancy between starting and subsequent counts (indicating a misplaced or miscounted sponge), this was recorded, as was the amount of time required to identify and reconcile the discrepancy, a freehand minute-to-minute record of all activities involved in the reconciliation, and whether an x-ray was required to resolve the discrepancy. The observers also recorded whether any counting difficulty resulted from the technology itself, events that were excluded from the tally of miscounts, and misplaced sponges.

Survey of Frontline Providers

At the end of each case, an immediate postoperative survey was administered to the attending surgeon and nursing team members asking them to evaluate the counting process, team function, and their level of confidence that no sponge was left behind. A final survey assessed providers' evaluations of the system at the completion of the study. The questions included in each survey are provided in Table 1.

Medical Record Review

Observers collected demographic, clinical, and procedural data for each patient on the day of surgery. We reviewed patients' paper and electronic medical records 60 days after surgery to assess whether a retained sponge was found postoperatively.

TABLE 1. Staff Survey

Immediate postoperative survey

1. How well do you think the sponge counting process went?
   1 (poorly) to 10 (perfectly)
2. How well do you think that you and the other caregivers in the OR functioned as a team during this case?
   1 (poorly) to 10 (perfectly)
3. How confident are you that no sponges were left behind? ___%

End of study assessment

1. How easy do you think the bar-coded sponge system was to use?
   1 (very difficult) to 10 (very easy)
2. How confident do you feel in the ability of the bar-coded sponge system to accurately track sponges?
   1 (not at all confident) to 10 (very confident)
3. How do you think the Safety Sponge System affects the counting protocol?
   −5 (makes it worse) to +5 (improves it)

An immediate postoperative survey was administered to the attending surgeon and nursing team members. A final survey assessed providers' evaluations of the system at the completion of the study.

TABLE 2. Case Characteristics

	Traditional (N = 148)	Bar-Code System (N = 150)
Age (yr)	51.9	52.4
BMI	31.8	32.7
Male	65%	71%
Duration of operation	2.68 h	2.90 h
EBL	289 mL	298 mL
Sponges used	29.0	29.0
Counting activities	16.9	16.8
Sponge counting activities	11.6	11.9

Results are presented as the mean value per operation, stratified by arm. *P* values were derived using the t test for normally distributed data. No *P* value was significant ($P > 0.10$ for all variables).

Transformations were used to approximate normal distribution for EBL (log) and total sponges (square root).

BMI indicates body mass index; EBL, estimated blood loss.

RESULTS

Observational Findings

There were no differences between the patients assigned to the control and the bar-code arms of the study with regard to age, gender, body mass index, duration of their operation, amount of estimated blood loss, number of sponges used, total counting activities, and counting activities related to sponges (Table 2). There was also no difference in the number of discrepancies detected for instrument counts, which were not altered by the introduction of the bar-code system (11 vs. 10 discrepancies, $P = 0.99$) (Table 3).

The detection of sponge count discrepancies, which involved miscounted or misplaced sponges and were not a direct result of the new technology, was significantly higher in the bar-code versus the control arm (32 vs.13 discrepancies, $P = 0.007$) (Table 3). With the operation as the unit of

TABLE 3. Comparison of Traditional Counting Protocol and Bar-coded Sponge System

	Traditional (N = 148)	Bar-coded System (N = 150)	*P*
Analyses by event			
Instrument discrepancy	10	11	0.99
Sponge discrepancy	13	32	0.008
Retained or misplaced sponges	12	21	0.17
Miscount of sponges	1	11	0.007
Mean time to resolve discrepancy	12.7 min (±3.3)	13.0 min (±2.9)	0.61
Difficulties due to technology	—	17	—
Analyses by case			
Cases with any sponge discrepancy	12	24	0.049
Cases with retained or misplaced sponge	11	17	0.32
Cases with miscount of sponges	1	9	0.036
X-ray required to resolve discrepancy	1	2	0.99
Count abandoned	1	0	0.29
BCS abandoned	—	5	—
Total time spent on counts	8.6 min (±11.3)	12.0 min (±12.6)	<0.0001
Time spent on sponge counts	2.4 min (±7.7)	5.3 min (±7.6)	<0.0001

P values were derived using exact Poisson test for analyses by event, Fisher exact test for analyses by case, and Wilcoxon rank sum test for time analyses.

analysis, the bar-code system detected a discrepancy in twice as many operations (24 vs. 12 operations, $P = 0.049$) as well.

A total of 33 incidents of misplaced sponges were detected during the study. Of those misplaced, 30 sponges were found in the trash, under the drapes, on the floor, or elsewhere on the sterile field outside of the patient, and 3 sponges were found retained inside the patient. All incidents of retained sponges occurred in the bar-code arm and were found before the patient left the operating room. Overall, there were nearly twice as many misplaced sponges detected in the bar-code arm as in the control arm, although this difference did not reach statistical significance (21 vs. 12, $P = 0.17$). At chart review after 60 days, we found no cases of retained sponges identified postoperatively.

There were a total of 12 miscounts identified in the study: 11 in the bar-code arm and 1 in the control arm ($P = 0.007$). In analyzing the miscounts in the bar-code arm, we found at least 4 of the 11 involved "technological saves." For example, in one case, the ST attempted to recount 3 sponges that had already been counted. The bar-code system alerted her to the duplication and avoided a potential error in the count.

The bar-code system improved the ability of the surgical team to recognize discrepancies in the sponge count, but did not change the amount of time required to resolve discrepancies or the likelihood of requiring an x-ray to resolve a discrepancy (Table 3).

There were 17 incidents of technological difficulties because of the bar-code system (2.04 per 1000 sponges counted). These difficulties included "background scanning"—scanning sponges that were lying on the table behind the sponge that the provider was intending to scan—and attempting to scan a sponge out while the scanner was still set to "scan in." The time spent counting sponges was significantly higher for the bar-code arm (5.3 vs. 2.5 minutes, $P < 0.0001$). The bar-code system was abandoned at the discretion of the surgical team in 5 of 150 operations because of time constraints.

Results of Provider Surveys

A total of 727 postoperative surveys (response rate 82%) were available for analysis. Frontline providers were less likely to give perfect ratings (10 on a scale of 1–10) for both the sponge count process (rating 10 on a scale of 1–10; 71% vs. 86%, $P < 0.0001$) and team performance (77% vs. 84%, $P = 0.03$) among operations involving the bar-code system; however, there was no difference between the 2 arms in the providers' confidence that all sponges were accounted for (98% vs. 97%, $P = 0.65$).

Forty-one providers (20 nurses, 8 STs, and 13 surgeons) returned the end-of-study survey rating their overall experience with the system for a response rate of 44%. Most providers found the system easy to use (mean rating: 7.3 ± 2.3 on a scale of 1–10) and felt confident in the ability of the bar-code system to track sponges (mean rating: 7.5 ± 2.5 on a scale of 1–10). In aggregate, providers also reported that the bar-code system had a positive effect on the counting protocol, although individual responses varied widely (mean rating: +1.6 ± 3.0 on a scale of −5 to +5). This variation in responses was also reflected in the individual written comments about the system. For example, some providers felt that the system was especially useful in large operations with high blood loss and many sponges, whereas others felt that the system was difficult to use in these types of operations.

DISCUSSION

Retained sponges and instruments are a persistent and dreaded occurrence in surgery. We have traditionally relied solely on the diligence of surgical personnel to prevent leaving behind any of the myriad surgical instruments and sponges introduced to the operative field. Because of inevi-

table fallibility in this approach,[6,14] we have failed to prevent the occurrence of this problem. Technological adjuncts to standard counting protocols have been discussed,[9,11] and proof-of-principle has been demonstrated for certain devices,[10,11] but this is the first clinical trial to evaluate the effect of such an innovation on counting discrepancies, efficiency, and safety in the operating room.

In this randomized, controlled trial, we found that computer-assisted counting with a bar-coded sponge system significantly increased the detection of occurrences of misplaced and miscounted sponges, compared with the traditional manual counting protocol. Our findings indicate that misplacement and miscounting of sponges occur frequently with manual counting and go undetected despite continued diligence with counting procedures. By increasing detection of these occurrences, the bar-code system has the potential to meaningfully decrease the risk of a retained sponge in surgery.

Before implementing such a technology, however, it is important to consider its secondary effects on workflow and team performance in the operating room.[14] The bar-code system did appear to introduce occasional new technical difficulties to the counting process, to decrease perceived team performance, and to increase the time devoted to sponge counts by approximately 3 minutes per case. Nonetheless, despite lower perceived performance on a case-by-case basis, the results of the final survey indicate that, by the end of the study, the majority of providers found the system easy to use, felt confident in its ability to track sponges, and reported a positive effect on the counting process.

There are several limitations in the design of this study. We were unable to determine whether the bar-code system could decrease the rate of retained sponges because of the impossibly large sample size required. The current analysis was also limited to elective general surgery operations and did not test emergency operations, which are recognized to be at higher risk for retained sponges.[1,7]

The study period coincided with the introduction of the technology, and the learning curve for using it may have influenced both qualitative and quantitative results. Although we observed no trend suggesting improved counting times during the trial, only 44% of providers reported personal experience with more than 10 operations using the bar-code system. Most staff members easily adapted to using it, but we subjectively noted some staff members struggling through the learning curve. Several of the negative aspects of the new technology (new difficulties, longer counting times, and lower evaluation by some providers) may improve with increased personnel experience, and with modifications to improve the performance and utility of the system.

The introduction of computer-assisted sponge counting with a bar-code system seems to improve the detection of incidents of misplaced sponges and offers a technological defense against human errors, such as miscounts. The system was easily implemented and well-accepted by frontline providers. Our results suggest that bar-coded sponges have a strong potential to decrease the risk of retained sponges.

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