Initial Clinical Evaluation of a Handheld Device for Detecting Retained Surgical Gauze Sponges Using Radiofrequency Identification Technology

Alex Macario, MD, MBA; Dean Morris, MBA; Sharon Morris, RN, BSN, CNOR

Hypothesis: A handheld wand-scanning device (1.5 lb, battery powered, 10 × 10 × 1.5 in) has been developed to detect commonly used surgical gauze sponges, which have been tagged with a radiofrequency identification (RFID) chip. We tested the hypothesis that this wand device has a successful detection rate of 100%, with 100% specificity and 100% sensitivity.

Design: Prospective, blinded, experimental clinical trial.

Setting: Stanford University Medical Center, Stanford, Calif.

 Patients: Eight patients undergoing abdominal or pelvic surgery.

Interventions: Eight untagged sponges (1 control per patient) and 28 RFID sponges were placed in the patients. Just before closure, the first surgeon placed 1 RFID sponge (adult laparotomy tape; 18 × 18 in, 4-ply) in the surgical site, while the second surgeon looked away so as to be blinded to sponge placement. The edges of the wound were pulled together so that the inside of the cavity was not exposed during the detection experiments. The second (blinded) surgeon used the wand-scanning device to try to detect the RFID sponge.

Main Outcome Measures: A successful detection was defined as detection of an RFID sponge within 1 minute. We also administered a questionnaire to the surgeon and nurse involved in the detections to assess ease of use.

Results: The RFID wand device detected all sponges correctly, in less than 3 seconds on average. There were no false-positive or false-negative results.

Conclusions: We found a detection accuracy of 100% for the RFID wand device. Despite this engineering success, the possibility of human error and retained sponges remains because handheld scanning can be performed incorrectly.

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NADVERTENTLY LEAVING SPONGES inside patients who undergo surgery continues to occur despite manual counting of sponges by operating room (OR) personnel. A landmark retrospective study of claims and incident reports of retained sponges or instruments filed with a Massachusetts insurer estimated the incidence as approximately 1 in every 10,000 surgical procedures that involve an open cavity. Two thirds of the reported cases were for surgical sponges. The risk factors for retained foreign bodies were emergencies, with unplanned changes in procedure and patients with higher body mass indexes.

Retained sponges may cause no adverse effects in patients and may remain undiscovered for decades. Alternatively, retained sponges may lead to serious sequelae, including sepsis, intestinal obstruction, fistulization, and death. The Agency for Healthcare Research and Quality used patient safety indicators to identify medical injuries in 7.45 million hospital discharge abstracts from 994 acute care hospitals across 28 states in 2000; a discovered foreign body added 4 days to the average hospital stay, with 57 patients dying because of this error in 2000. A better system to prevent retained foreign bodies before the patient leaves the OR would improve patient safety. For example, detecting retained surgical sponges by electronic article surveillance via magnetomechanical technology (often used to prevent theft in retail stores) may help solve this problem.

For the first time, a handheld wand-scanning device (1.5 lb, battery powered, 10 × 10 × 1.5 in) has been developed (ClearCount Medical Solutions Inc, Pittsburgh, Pa) to detect commonly used gauze sponges, which have been tagged with a radiofrequency identification (RFID) chip.
nurse involved in the detections to assess perceived ease of use and its ability to improve patient safety and reduce medical errors. We also asked what would be a reasonable price for the hospital to pay to have the RFID wand device available to all its surgical patients. This was done to try to assign a monetary amount to the perceived value of the device. We left space open at the bottom of the survey for free text, asking for suggestions to improve the device and for general comments.

**METHODS**

Table 1. Characteristics in 8 Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height, mean (SD), cm</td>
<td>173.4 (10.1)</td>
</tr>
<tr>
<td>Weight, mean (SD), kg</td>
<td>76.0 (13.6)</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>48.8 (18.1)</td>
</tr>
<tr>
<td>Female, %</td>
<td>50</td>
</tr>
<tr>
<td>Case duration, mean (SD), min</td>
<td>254.0 (100.5)</td>
</tr>
<tr>
<td>Surgical procedures, No.</td>
<td></td>
</tr>
<tr>
<td>Removal of pancreatic or ampulla mass</td>
<td>2</td>
</tr>
<tr>
<td>Removal of pelvic mass</td>
<td>1</td>
</tr>
<tr>
<td>Total abdominal hysterectomy</td>
<td>1</td>
</tr>
<tr>
<td>Kidney transplantation</td>
<td>2</td>
</tr>
<tr>
<td>Colon resection</td>
<td>1</td>
</tr>
<tr>
<td>Radical prostatectomy</td>
<td>1</td>
</tr>
</tbody>
</table>

*Sponge Type:* Control, Single, Double

After approval from Stanford University’s Human Subject Panel, 8 patients were enrolled after written informed consent was obtained. This convenience sample of 8 patients underwent a variety of elective abdominal and pelvic procedures while under general anesthesia. An RFID tag that measured 20 mm in diameter and 2 mm in width was sewn securely into each sponge and sterilized in the usual manner with the ethylene oxide technique. 

Once the surgical procedure was finished and just before closure of the incision, the first surgeon (either the randomly selected resident or the attending surgeon) placed 1 RFID surgical sponge (adult laparotomy tape; 18 × 18 in, 4-ply) in the surgical site while the second surgeon looked away so as to be blinded to sponge placement. The second surgeon remained blinded for all the sponge placements in each patient.

A computer-generated random-number table (http://www.random.org/nform.html) was used to randomly select 1 of the 4 quadrants in the abdomen for the location of sponge placement. No suture material was used to close the wound until the detection experiments were finished. The edges of the wound were pulled together so that the inside of the cavity was not exposed during the detection experiments. After sponge placement, the second (blinded) surgeon used the handheld wand device to try to detect the RFID sponge. The scan technique was standardized, following the sequence of right upper quadrant, right lower quadrant, left lower quadrant, left upper quadrant, and then midline.

We recorded the time from the wand device (enclosed in a sterile, plastic, disposable sheath) being given to the surgeon until detection. Three other random placements of sponges were performed in each patient. For each patient, one of these detection experiments was with an untagged sponge (as a control) to determine the false-positive rate (the device indicating the presence of an RFID sponge when there was none). We also computed the false-negative rate, defined as the device not indicating the presence of an RFID sponge when one had been placed. In 5 of the patients (determined by random-number generator), we placed 2 RFID sponges simultaneously to determine if the wand device would detect a concurrent second RFID sponge.

After completion of the detection experiment, we administered a 1-page survey to the surgeon and nurse who had used the RFID wand device. Questions related to the wand device’s overall quality, its ease of use, and its ability to contribute to efficiency and patient safety, and responses were based on a 0 to 100 visual analog scale. We also asked what would be a reasonable price for the hospital to pay to have the RFID wand device available to all its surgical patients. This was done to try to assign a monetary amount to the perceived value of the device. We left space open at the bottom of the survey for free text, asking for suggestions to improve the device and for general comments.

**RESULTS**

Table 2. Time to Detect Gauze Sponges Placed in the Surgical Site

<table>
<thead>
<tr>
<th>Sponge Type</th>
<th>No. of Sponges Placed</th>
<th>Time, Mean (SD), s</th>
<th>Time, Median (Range), s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>8 (8)</td>
<td>14.5 (13.4)</td>
<td>12.0 (2.0-45.0)</td>
</tr>
<tr>
<td>Single</td>
<td>18 (8)</td>
<td>2.7 (1.8)</td>
<td>2.0 (1.0-7.0)</td>
</tr>
<tr>
<td>Double</td>
<td>10 (5)</td>
<td>2.6 (1.7)</td>
<td>3.0 (1.0-5.0)</td>
</tr>
</tbody>
</table>

*Time for surgeon to indicate that there were no radiofrequency identification sponges in the site.

Characteristics of the 8 patients enrolled are given in Table 1. Eight untagged sponges (1 per patient) and 28 RFID-tagged sponges were placed in the 8 patients. The RFID wand device detected all sponges correctly. There were no false-positive or false-negative results. The RFID sponges were detected by the surgeon using the wand in less than 3 seconds on average (Table 2). Both surgeons and nurses rated the RFID wand device highly for ease of use and its ability to improve patient safety and lowest for its ability to increase efficiency (Table 3). Feedback obtained via written comments described the users’ preference for a smaller wand device (Table 4). Concern was also expressed that human error would persist in the detection of RFID sponges unless the technology was designed to be failsafe.

**COMMENT**

Retained sponges may be referred to as either a textiloma (from the Latin term textile and oma, meaning “swelling”) or a gossypiboma (from the Latin Gossypium, the

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genus of cotton plants, and bona, a Kiswahili term meaning "place of concealment".14 The inflammatory reaction to the nonabsorbable cotton sponge leads to a variety of costs to society, including pain and emotional distress experienced by the patient, imaging studies to diagnose the problem, a subsequent hospitalization for reoperation, and litigation expenses and patient compensation for perceived negligence of the facility and staff.

The currently recommended OR nursing procedure requires 3 separate counts of potential foreign bodies: once before the surgery, then again during the surgery, and finally once the incision is closed.15 However, use of this requires 3 separate counts of potential foreign bodies: once

Table 3. Results of Questionnaire Survey

<table>
<thead>
<tr>
<th>Question</th>
<th>Surgeon</th>
<th>Circulator</th>
<th>Nurse</th>
</tr>
</thead>
<tbody>
<tr>
<td>How would you rate the overall quality of this wand device?</td>
<td>81 (12)</td>
<td>74 (21)</td>
<td></td>
</tr>
<tr>
<td>How easy do you think this wand device was for you to use?</td>
<td>85 (9)</td>
<td>93 (6)</td>
<td></td>
</tr>
<tr>
<td>How well do you think this device contributes to your efficiency (ie, ability to do more in less time)?</td>
<td>66 (23)</td>
<td>73 (21)</td>
<td></td>
</tr>
<tr>
<td>How well do you think this wand device adds to patient safety (ie, avoids complications)?</td>
<td>78 (30)</td>
<td>94 (3)</td>
<td></td>
</tr>
<tr>
<td>What is a reasonable price for such a product per patient?</td>
<td>$144 ($158)</td>
<td>$88 ($107)</td>
<td></td>
</tr>
<tr>
<td>Who should do the scan once commercially available?</td>
<td>Surgeon</td>
<td>75 50</td>
<td></td>
</tr>
<tr>
<td>Scrub technician, %</td>
<td>25 25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgeon and scrub technician, %</td>
<td>0 25</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*On a scale of 0 to 100. Data are presented as visual analog scale scores unless otherwise indicated.

tags have an antenna for receiving and sending signals to and from the reader and an encapsulation that protects the circuit and antenna from the external environment. The RFID tag also has an integrated circuit that contains specific item-level data (eg, what the item is, its inventory number, and the date of manufacture). This is unlike the larger (45 × 10-mm) electronic article surveillance tag used to prevent theft in stores, which cannot contain or relay such data.

It is unknown whether RFID technology can be used as a failsafe tool for reducing the incidence of retained foreign bodies. The RFID system we studied exhibited no electronic interference from OR equipment such as the anesthesia machine.

When an RFID chip sewn into the sponge receives a certain radio query, the sponge responds with a unique identification code back to the scanner. The RFID tags are powered by the radio signal from the scanner. These broadcast signals are designed to be read between a few inches and several feet away, depending on the size of the tags and the size and power of the scanner antenna. As an added safety precaution, the RFID tags were checked to be in working condition before our experiments. The RFID tags used in this study have a failure rate due to malfunctioning of less than 3 per million.

In the 8 patients we studied who underwent a variety of surgical procedures, 8 untagged control sponges (1 per patient) and 28 RFID-tagged sponges were placed. We found a detection accuracy for the RFID wand device of 100%, with a 0% false-positive rate and a 0% false-negative rate. Despite this engineering success, the clinical trial raised important user issues, such as the risk of human error and retained foreign bodies. For example, if the scan is performed incorrectly (eg, the wand scan is performed farther away than a few inches from the skin.
or the device does not cover the entire surface area of the surgical site), retained sponges can be missed. Retained sponges could also be missed, even if the technical detection works accurately, if the scan were performed too early, such as if an additional sponge were placed in the wound to help with closure after the final RFID scan had been performed.

Ideally, the sponge scan system would pinpoint the exact location of the sponge so that if the sponge needed to be retrieved, it would be easier to find without disrupting the surgical repair. Certainly, an economic analysis of such a sponge detection technology is necessary to justify the additional acquisition costs of an RFID system and tagged sponges for use in the OR. Surgeons who used the device suggested a wide range of reasonable prices for acquisition of such a product, with the average being approximately $144 per patient.

The cost to manufacture the RFID wand device once commercialized is unknown. Comparison of the potential benefits of RFID technology to the price hospitals pay to acquire it will have to factor in the number of ORs in which the sponge-tracking technology is deployed, the baseline incidence of a retained foreign body (Does the facility perform a lot of high-risk cases, such as major abdominal cancer surgery, or low-risk cases, such as breast biopsies?), the amount of counting time nurses can save with tagged sponges, and liability costs.

The long-term objective may be to have sponge tracking as part of an overall OR supply-tracking system, including metal surgical instruments. Ultimately, for any device or drug, the gold standard for showing effectiveness is a randomized clinical trial. However, such a study on whether RFID sponges can reduce the incidence of retained foreign bodies would require thousands of patients. For example, if we assumed a retained sponge incidence of 1 per 5000 population and the aim was to determine if RFID sponge use halves this incidence to 1 per 10,000 population, then more than 50,000 patients would need to be enrolled in each of the 2 groups.

The true scope of retained foreign bodies after surgery may be underreported in the medical literature, perhaps because of medical privacy and legal concerns. Since 2003, Minnesota hospitals are required by law to report 27 categories of preventable accidents, as defined by the National Quality Forum, known as “never events” (eg, amputating the wrong limb or sending a newborn home with the wrong family). More than half of the 99 reported mistakes occurred during surgery. Of those, 31 involved retained foreign objects. Hospitals had between 0 and 6 retained sponge or instrument incidents during the 15-month reporting period. On the basis of such available published data, a typical hospital annually performing 10,000 open body cavity operative procedures can expect 1 to 2 retained foreign-body cases per year.

The surgical team will remain responsible for inspecting the surgical site and avoiding retained foreign bodies. Technologies to increase safety in the OR, such as the RFID wand device described in this article, deserve further study to assess if they should be added to manual counting (rather than replace it). However, related human and system factors need to be addressed as well because it is likely that technology alone will not be foolproof in solving the retained foreign-body problem.

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Financial Disclosure: Dean and Sharon Morris own several patents and have patents pending related to RFID-tagged sponges. Dean Morris is a director and Sharon Morris is a nursing consultant for ClearCount Medical Solutions Inc.

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REFERENCES