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SURGICAL ENDOSCOPY
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Radio frequency identification (RFID) applied to surgical sponges

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Abstract
Use of gauze sponges that have been embedded with passive radio frequency identification (RFID) tags presents a high probability of reducing or eliminating instances of gossypiboma, or retained surgical sponge. The use of human counts during surgical operations, especially during instances where unexpected or emergency events occur, can result in errors where surgical instruments, most often gauze sponges, are retained within the patient's body, leading to complications at a later date. Implementation of an automatic inventory record system, for instance, RFID, may greatly reduce these incidences by removing the human factor and would improve patient safety by eliminating the current sponge count protocol. Experiments performed by placing RFID-labeled sponges within an animal and removing them have demonstrated that tags are at least partially readable inside the body cavity and fully readable once removed, suggesting the possibility of an automated sponge count system pending further development of this technology.

Key words: Laparotic sponge — Gossypiboma — RFID — Automated inventory

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The importance of ensuring the removal of all foreign bodies from a patient after surgery can not be overstated. Retention of surgical instrumentation, most often surgical sponges, inside body tissues is an inconvenience for the patient at best and can lead to severe physiologic consequences in extreme cases. Most operating rooms use a count of sponges, sharps, and instruments to prevent this occurrence, but in the heat of surgery, especially when unforeseen circumstances occur during an operation that require emergency measures to be taken, mistakes can and do happen. These occasional mistakes in the sponge count, while rare, can result in both physical harm to the patient and damage to the surgeon via consequential malpractice suits. Furthermore, the sponge count protocol itself has been implicated as a hazard to patient safety [1].

The long-term objective of this research is the development of a radio frequency identification (RFID) system embedded within surgical sponges that will allow for a fast and accurate count during surgical operations. The overall objective of this system would be to eliminate errors in the sponge count by removing the human error factor and applying an automated, non-line-of-sight inventory system. RFID's power to inventory unique frequency signals for multiple items as well as the removal of the line-of-sight requirements of other technologies (i.e., barcodes) gives this technology the potential to meet the requirements of the surgical environment.

A recent study has estimated that as many as 1 in 1000-1500 surgeries worldwide may result in a retained surgical instrument [2]. When a retained surgical sponge is involved, the result is a generalized group of symptoms called gossypiboma, which includes development of abscess or granuloma around the sponge itself. A majority of hospitals use some form of sponge, sharps, and instrument count to prevent this, but no standardized method exists. In many cases the count procedure is defined by the individual hospital and is frequently omitted in cases of emergency or transvaginal surgery or for vaginal deliveries. Any number of factors can contribute to this possibility, including but not limited to surgical packs used during fascial closure, hurried counts at the end of long operations [3], emergency surgeries, or surgeries where complications arise over the course of the proceedings [2].

Typically, surgical sponges are embedded with radiopaque strips, allowing them to be visualized by postoperative X-ray. However, while this has reduced gossypiboma, it has not eliminated it. In one study 3 of 29 cases in which X-ray was used to screen for radiopaque sponges resulted in a false negative [4]. More

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importantly, these X-rays must be performed postoperatively, meaning that any sponges discovered must be removed via a second operation, exposing the patient to an even larger degree of risk for infection or trauma.

Accurate data regarding incidents of retained surgical instrumentation from surgery is difficult to discover. The Joint Commission for Accreditation for Healthcare Organizations (JCAHO) policy mentions that instances of "unintentionally retained foreign body without major permanent loss of function" do not require reporting. This leads to a gross underestimation of the incidents and incurred costs of retained surgical instruments, confounding efforts to compile numbers regarding them. Published popular press studies list worldwide surgical instrument retention rates ranging between 1 in 15,000 operations to as many as 1 in 100 operations. Of these, roughly two thirds consist of incidents of retained surgical sponges.

Presentation of gossypiboma is either acute or delayed, with acute symptoms resulting in abscess or granuloma and delayed symptoms resulting typically in adhesion formation and encapsulation, resulting in a subacute intestinal obstruction months or even years after the initial operation [3]. In some extreme cases, complications have been observed including perforation of the bowel, sepsis, and, in very rare instances, death [2].

RFID systems use individual transponders, typically referred to as tags, which emit a specific identification signal. Nearby antennae emit radio waves that are absorbed by the tag, converted to electrical energy, and then re-emitted at the tag's specific frequency [5]. These frequencies are then read by the antennae, creating an active inventory of each item read by the system [6, 7]. This inventory information is then usable by a variety of middleware applications, opening options for IMS, portal checkpoints, logistics, and access control systems.

An RFID sponge system would reduce gossypiboma by using a small handheld device to perform an automated count of inventoried sponges before, during, and after the operation, minimizing human error in surgical tool counts, and allowing for immediate discovery and retrieval of surgical sponges within the peritoneum.

A recent study performed by researchers at Stanford presented encouraging results for the application of RFID technology in surgical settings [8]. In a double-blind test involving RFID-embedded gauze sponges, surgeons were able to detect and remove sponges hidden within the abdominal cavity using a simple handheld device. Both the wand and sponge were created by ClearCount Medical Solutions (Pittsburgh, PA).

Materials and methods

The first objective of our study, testing the current RFID technology's ability to function within the requirements of an operating room setting, consisted of a series of experiments involving submersion of RFID tags in body fluids (primarily water). Tags were affixed with standard adhesive to the consumer-bought gauze sponges and submerged in water to test for tag readability when wet. Once that information had been obtained, the next objective was to design a prototype "smart sponge." Issues that needed to be addressed during this step included identifying the existing RFID tag/reader combination which resulted in the desired accuracy and determining optimum placement of the RFID tags on the sponge surface for optimum readability and resistance to mechanical stress. Assembly of this prototype was tested by placing the RFID-labeled surgical sponges within the abdominal cavity of a euthanized pig cadaver and then retesting readability upon removal.

Once all of these objectives are met, the entire system will be assembled for final experimental confirmation of function and fine-tuning via implementation in a simulated or actual operating theatre.

Results

The initial experiment indicated that water would prove to be the primary obstacle to overcome for project success. While the porcine test resulted in positive read rates when the sponge was placed inside the body cavity and removed, full submersion or the sponge into water caused much more disruption in reads. Specifically, the read range seemed to be reduced sharply from an average of 18–20 in. between the reader and sponge to 4-6 in. as a result of full submersion and removal, along with a slight decrease in overall tag readability.

Experiments comparing performance with labels on the exterior of the sponge versus embedded showed a much better performance for tags on the outside of the sponge, presumably as a result of the removal of the intervening layer of liquid between reader and sponge. Additional testing demonstrated a positive correlation between this relationship. Initial concern arose from the possibility of separation of the RFID tag from the sponge, but further testing has shown this to be unlikely. Any weakening of the adhesive can be compensated for in later prototypes through use of water-resistant adhesives and/or through printing the RFID antenna directly onto the sponge itself.

Release of second-generation RFID technology (Gen 2) during the testing phase of our study opened the possibility for utilization of more rugged RFID transponders in the smart sponge system. Gen 2 technology features better range along with a more consistent read rate and resistance to various factors that hinder RFID read accuracy (such as water). In actual practice, this translated into a greatly increased read accuracy, even with the tag placed inside of the sponge.

One initial goal of the project was to allow readability of the RFID tags through a patient's skin, thus allowing mobile RFID readers to be used to locate missing sponges within a patient's body cavity. No Generation 1 RFID tags that were tested were capable of fulfilling this criterion. However, upon repeating the experiment with Gen 2 technology, tags were read effectively and accurately while in the pig's body cavity through the intervening layer of skin. Additional testing will be required to determine an accurate failure rate for these devices, but initial results suggested that, in many cases, this failure rate may be extremely low.

X-rays taken of sponges embedded with RFID tags were clearly visible because of the highly metallic content of the antenna inks. Thus, if an RFID tag is damaged or otherwise rendered unreadable, they should be able to perform the same task as the radiopaque-labeled sponges until such time as RFID technology improves to allow for 100% reliable location within the patient's body cavity.

Discussion

Early experimental results strongly suggest that current RFID technology can be used to inventory surgical sponges accurately during an operation and with minimal human error. Specifically, Gen 2 Alien Squiggle T Tags (Morgan Hill, CA) have repeatedly demonstrated a 99% read accuracy when wet, even when submerged within water for up to an hour. In addition, these tags demonstrated the ability to be read with a reliable level of accuracy through the skin of a patient, even while wet from blood.

Given these data, an RFID sponge inventory system can be envisioned wherein each sponge is read entering the OR, as it is being placed within the patient, and finally at the end of the operation itself. A list of each sponge's ID number from the beginning of the operation and at the end could be compared, with any discrepancies visible immediately. If a sponge is missing, the patient's body can then be scanned with the same handheld RFID reader to locate the approximate location of the tag within the patient's body. If for some reason the tag can not be located, the metallic ink used for printing the RFID antenna will allow for tag identification via X-ray, much like the currently used radiopaque strips. With a high enough level of sophistication, this system can be fine tuned to a level of accuracy where the human sponge count will not be necessary, as the automated inventory system will be more accurate and free of human bias. This will result in an overall increase in efficiency for the operating room and an increase in patient safety.

The immediate reduction in gossypiboma cases would result in an increase in patient safety and efficiency in the OR and a reduction in malpractice suits for the medical community at large. Any sponges that are left within a patient would be identified immediately, allowing retrieval before the surgeon closes up, thus eliminating the need to perform a second operation to retrieve the sponge. Moreover, there would be a direct benefit for the surgeon because the operating room would be more efficient because of the elimination of lengthy counts and recounts at the end of each operation. A reduction in the number of miscounts would also reduce the need to X-ray the site of the operation to locate the sponge, decreasing the amount of time spent on this tedious task and minimizing the patient's radiation exposure.

An RFID reader such as the MC-9000G (Symbol Technologies, now part of Motorola), which was used for this study, typically costs $5000. Estimates indicate that the cost to place an RFID tag onto a surgical sponge during the manufacturing process would be negligible. As such, the $5000 price tag should be representative of the cost of a basic RFID system for sponge identification in the operating room. When compared to the 2 million dollars in indemnities paid to patients with retained surgical sponges during a seven-year period [4], the financial benefits for hospitals become clear.

Once the necessary technology is developed and further testing completed, the smart sponge system should be capable of fulfilling this requirement. In addition, a similar methodology can be used to radiolabel other surgical instruments. With all of the surgical tools in an operating room tagged by RFID, it will require only a small step on the part of hospital organizers to branch into an RFID-managed inventory control system, smart shelf technology, real-time location systems, and numerous other applications.

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