Gynecology & Obstetrics
ISSN: 2161-0932

Chapa, Gynecol Obstet (Sunnyvale) 2014, 4:11
DOI: 10.4172/2161-0932.1000252

Case Report Open Access

An Unwanted Postpartum Gift: The Issue of Retained Vaginal Sponges and Gauzes after Vaginal Birth

Hector Chapa*

Womens' Specialty Center Dallas, USA

Abstract

Gossyphiboma refers to surgical items, including surgical gauzes and sponges, unintentionally left inside a patient during a surgical or other invasive procedure. The exact incidence is unknown as wide underreporting is suspected. Published evidence places the incidents between 1/7000 to 1/100 surgical procedures. It is been estimated that there are 1500 to 2000 retained surgical item cases a year in the United States. The incidence of retained surgical items is also linked to decreased patient satisfaction scores regarding the respective admission. The collection of patient satisfaction surveys for healthcare facilities in the US is not a new concept. Medicare began publishing patient satisfaction scores on its Hospital Compare website in 2008. Additionally, under the Center for Medicare and Medicaid services "value-based purchasing" proposal, Medicare introduced withholding of 1% of its payments to hospitals based on the facilities' patient satisfaction scores. For this reason, along with the desire to pursue quality patient acre, healthcare institutions are focusing on the prevention of retained surgical items. While much of the attention has historically been in the main operating theater, new focus has been placed on the prevention of retained items in the Labor and Delivery Suites.

Keywords: Retained vaginal items; Glossyphiboma; Postpartum

Case Presentation

A 23-year-old Hispanic gravida 1 para 1 presents to the clinic setting two weeks post-partum. She had an uncomplicated labor, proceeding to a spontaneous vaginal delivery of a newborn male infant. The perineum sustained a second degree laceration. Laceration was repaired by the attending physician in the usual manner. Stated estimated blood loss was within normal limits at approximately 500 ml by visual inspection. Presenting symptom to the office was malodorous vaginal discharge and pressure in the vagina. She was afebrile and otherwise in no acute distress. Vaginal examination revealed a desiccated 4×4 gauze located in the posterior cervico-vaginal fornix. The foreign body was removed, and patient released home on an empiric 5 day course of oral metronidazole.

The Current Reality

Among the pressures of maintaining current, evidence-based treatment plans and keeping up with the newest in robotic surgical equipment, healthcare facilities are finding themselves more and more keenly aware of the impact of patient satisfaction scores.

The collection of patient satisfaction surveys for healthcare facilities in the US is not a new concept. Medicare began publishing patient satisfaction scores on its Hospital Compare website in 2008. Additionally, under the Center for Medicare and Medicaid services "value-based purchasing" proposal, Medicare introduced withholding of 1% of its payments to hospitals based on the facilities' patient satisfaction scores.

According to Hospital Consumer Assessment of Healthcare Providers and Systems, or HCAHPS, such patient oriented surveys are designed to produce comparable data based on patient perspectives on care received in order to function as working comparisons between hospital institutions. Secondly, public reporting of the survey results is designed to create incentives for hospitals to improve quality care [1]. While intended to improve quality measures in hospitals throughout the United States, healthcare providers and institutions alike are feeling the impetus to not only provide medicine at or above the standard of care, but also ensure that the patient experience is beyond expectation.

Recently, I unexpectedly learned that a fellow physician in our busy private practice inadvertently "gifted" a used 4×4 ray-tec (Pearson Surgical, Sylmar, CA, USA) gauze to his treated parturient in the form of a retained vaginal foreign object. On case review, the scenario played out in typical form: after spontaneous vaginal delivery of the newborn, the physician placed three 4×4 sponges in the vaginal vault to tamponade supra-cervical bleeding during a perineal laceration repair. At the end of the repair, all gauze was removed from the vaginal cavity, or so it was thought. This occurred despite a count being performed and confirmed as "correct". The patient presented after release from the hospital to our clinic setting with a chief symptom of vaginally malodor.

Behold, the retained gauze was found and removed. As this event occurred within the first two weeks of her hospitalization, within the timeframe of when patient satisfaction surveys are mailed to our newly discharged patients, I began to think of how this occurrence would impact her overall rating not only of her treating physicians but also of her treating institution. As an academic physician and researcher, I began the process of what I do best: examining the evidence.

Objective

To Review the incidence, risk factors for, morbidity of, and implications to the healthcare system of retained foreign objects after surgical or other invasive procedure, with a focus on the field of Obstetrics. Secondarily, a review of a current FDA cleared RF technology for prevention of retained foreign objects will be presented.

***Corresponding author:** Hector Chapa, Womens' Specialty Center Dallas, 2042 Marydale Drive, Dallas, TX-Texas 75208, USA, Tel: 21-334-8116, 2146933324; E-mail: ChapaMD@icloud.com

Received September 06, 2014; **Accepted** October 20, 2014; **Published** October 26, 2014

Citation: Chapa H (2014) An Unwanted Postpartum Gift: The Issue of Retained Vaginal Sponges and Gauzes after Vaginal Birth. Gynecol Obstet (Sunnyvale) 4: 252. doi:10.4172/2161-0932.1000252

Background and Incidence

Gossyphiboma refers to surgical items, including surgical gauzes and sponges, unintentionally left inside a patient during a surgical or other invasive procedure. The retained foreign object is also known by that term textiloma [2]. The exact incidence is unknown as wide underreporting is suspected. Published evidence places the incidents between 1/100 to 1/7000 surgical procedures [3]. It is been estimated that there are 1500 to 2000 retained surgical item cases a year in United States [3]. In a published article by Verna Gibbs for the National Surgical Patient Safety Project (No Thing Left Behind), these numbers are further explained. "There are over 6000 hospitals with operating and procedure rooms in the US...Every year more than 45 million inpatient procedures are performed in the US and 234 million operations are performed globally" [3]. Any one of these procedures presents an opportunity for a retained foreign object. These retained foreign objects have variable time to discovery. In a published study by Rappaport and According to Rappaport and Haynes, retained foreign objects had a mean of 21 days to detection. 26% remained undetected for >60 days, 40% were discovered within 1 year, and an alarming 50% were identified greater than 5 years post index procedure [4].

The issue of Retained Surgical items (RSIs) received focused attention in 2003 with the release of a landmark publication by Gawande et al. In this review, the authors analyzed medical records associated with all claims or incident reports pertaining to retain surgical sponges or instruments files between 1985 and 2001. Fifty four patients with a total of 61 retained foreign bodies (69% sponges, 31% instruments) were evaluated [5]. Table 1 reflects the body cavities in which a foreign body remained.

In 2009, data from the Minnesota Adverse Health Events Reporting System also shed light on the incidence of retained surgical items. Since approximately 2004 when the Minnesota Department of Health began collecting information about adverse health events, retained foreign objects have been among the most reported events [6].

According to this State's data, the type of procedure most commonly linked to retain for an object was obstetrical, generally vaginal deliveries or cesarean birth. These procedures accounted for 25% of retained foreign objects, followed by digestive system procedures, inguinal hernia repairs, colectomies, and gastrectomy's [6]. Interestingly, the same organization published updated findings in January 2013. As of 2012, 31 cases of retained foreign objects had been reported to the Minnesota Department of Health. This was a decline of 16% from 2011 [7]. However, 19% of retained objects remained under the banner of gynecology, with the majority being sponges following cesarean section and vaginal hysterectomies.

According to the Joint Commission review of sentinel events for the first two quarters of 2014 (January 2014-June 2014), the most frequent sentinel event was unintended retention of a foreign body 957 events out of 394 total reported events) [8]. As stated in the summary data presented by the Joint Commission, "the reporting of most sentinel events is voluntary and represents only a small proportion of actual events" [9]. Therefore, this must not be construed as actual epidemiological data, and may be an underestimation of true incidence.

Body cavity affected	N (%)
Abdomen or pelvis.	29 (54)
Vagina.	12 (22)
Thorax	4 (7)
Other.	9 (17)

Gawande data (2003): 54 patients with a total of 61 retained foreign bodies (of which 69% were sponges and 31% instruments)

Table 1: Location of retained foreign objects per body cavity.

Morbidities Associated with Gossyphiboma

Subsequent complications of retained foreign objects are primarily related to the area in which they remain as well as the length of time they have remained in vivo. For retained surgical sponges/gauzes, variable clinical presentations have been reported. Patients may present with a mass or abdominal pain or more commonly, on an incidental finding on a routine radiograph done for a separate indication, variable time frames after the index case. Sponges initially placed in the thorax or abdomen have been associated with fistulous tract formation, walled off abscesses, and have even presented as spontaneous passage through bowel movements [10,11]. Zantvoord et al. published a case report in which a retained surgical sponge eroded from the intra-abdominal space into the intestinal lumen, migrated distally, and spontaneously passed with defecation 12 weeks after cesarean section [12]. After a systematic review of the literature, the authors cite 64 cases of transmural migration of a gossyphiboma (as of 2008), occurring mainly after intra-abdominal surgery. However, patient morbidity due to retained surgical sponges has even been described after transvaginal surgery. Kato et al. described a case of a refactory urge incontinence despite medical therapy, in a 72-year-old woman. Plain abdominal X-ray followed by cystoscopy demonstrated a large stone (43×37 mm) in the bladder. At suprapubic cystotomy to remove the stone, a surgical sponge was found with the stone encapsulating the item. The patient had undergone transvaginal hysterectomy two years previously. As explained by the authors, "the sponge had most likely eroded the bladder wall and migrated into the cavity" [13].

Although significant life-threatening morbidity from retained vaginal sponges after vaginal birth is unlikely, unequivocal reported adverse effects have been documented in the literature. Symptoms of malodorous vaginal discharge, use of empiric or therapeutic antibiotics, loss of confidence in providers as well as the medical system, and subsequent litigation are all potential sequelae of the retained vaginal item [14].

Risk Factors for Retained Surgical Items

According to Hariharan and Lobo, published in the 2013 Annals of the Royal College of Surgery England, identifiable risk factors for the occurrence of retained surgical items could fall into one of four categories:

1) Failure to perform accurate sponge an instrument counts (or failure to have accounting policy in place), 2) operations with unexpected change in surgical procedure, 3) invasive procedures in patients with raised body mass index, and 4) emergent surgical procedures [15]. Additional risk factors are greater number of major surgical procedures at the same time and the presence of multiple surgical teams during one index operation [16].

Strikingly, published evidence has reported that in cases in which incongruences were found at the intraoperative surgical count, 3 of 29 intraoperative X-rays employed to detect radiopaque sponges produced a false negative result [12]. False negative X-ray interpretations could occur with either densely packed surgical sponges, or more likely, in those with higher body mass index for whom the X-ray beam may have difficulty penetrating.

In the Minnesota Adverse Health Events Reporting System, retained surgical items occurred despite a correct surgical count being reported in the operative record in 83% of cases [6].

The Association of Perioperative Registered Nurses (AORN) has published a Health Failure Model and Effects Analysis for retained surgical items (HFMEA). Published in 2011, frequency of causes of potential failures and sponge management were found in the following decreasing order of frequency: 21% operating room team distraction, 18% multitasking, 18% time pressure and emergency procedure status, 14% systemic breakdown of standard procedures, 5% surgeon when closure prior to complete now, and 4% was attributed to the Circulator unable to see the surgical field from their standing position [13].

Related specifically to the occurrence in labor and delivery, the following root causes for retained vaginal sponges have been identified: lack of counting policies after vaginal birth, loss or miscount of non-tagged 4×4 sponges agglutinated together with vaginal blood, communication gaps when a 4×4 gauze is packed into the vagina, and unexpected postpartum vaginal bleeding. Alarmingly, fatigue of the healthcare provider accounted for 11% of cases [6]. This latter statistic, in theory, should decrease as hospitals across United States continue to adopt an in-house laborist/hospitalist model.

Healthcare Policy Effects

According to a study by the Center for Disease Control and Prevention (CDC), common medical errors total more than $4.5 billion in additional health spending a year [14]. The Center for Medicaid and Medicare (CMS), as of 2007, no longer issues payment for the extra cost of treating select conditions that occur while the patient is in the hospital. Among the list of "no pay" conditions is the retained foreign object [14].

Precedent for this began in the landmark study issued by the Institute of Medicine titled, "To Err is Human: Building a Safer Health System" [15]. Based on the results from this publication, the national quality forum created a list of 29 "serious reportable events", commonly referred to as "never events". These never events are defined as "an error in medical care that is concern to both the public and healthcare professionals and providers, clearly identifiable and measurable, and of the nature such at the risk of recurrence is significantly influenced by the policies and procedures of the health care organization [16]. Listed among the 29 is "unintended retention of a foreign object in a patient after surgery or other invasive procedure".

Related to the field of obstetrics and gynecology, the Joint Commission Sentinel Event Report commented that a "retained vaginal sponge is a reviewable sentinel event and is reportable as a breach in quality and patient safety" [17]. To this end, the Institute for Clinical Systems Improvement (ICSI) released their protocol summary entitled, "retained foreign objects during vaginal deliveries, prevention of unintentionality". It is available on their website: www.ICSI.org/guidelines. Table 2 lists the Societies and National care organizations who have drafted policies regarding prevention of retained foreign objects.

Cost and Legal Implications

The direct impact to a healthcare facility due to retained surgical items can be significant. It may lead to patient increased length of stay, and secondary procedures. According to Becker's Healthcare review, retained surgical items are the most frequent and most costly surgical "never event". Due to Medicare's implement of policy since 2008 to no longer reimburse hospitals for consequential surgical procedures and charges associated with his hospital related error, the financial hardship undertaken by affected institutions is massive [18].

Indirect costs due to surgical miscounts have also been addressed. According to publish reports, count discrepancies occur in one and eight surgical cases and take an average of 13 minutes of valuable operating room time to address. Counting errors were seen across all surgical service specialties and were more frequent as length of surgery increased. Prolonged operating room presence time also adds to the increase to healthcare costs [19].

Additionally, it has been estimated that each retained surgical sponge incident costs providers more than $250,000 per incident due to subsequent litigation [20]. The American College of Obstetricians and Gynecologists concluded through a multidisciplinary group that 87% of the quality problems in labor and delivery or preventable. Additionally, a review of 90 closed claims related to obstetrical care concluded that 78% had a preventable cause [21]. Therein lays the impetus for improved strategies not only in the main operating theaters the labor and delivery as well.

Outside of the calculated dollar amounts associated with an incident of retained surgical items, what is difficult to calculate is the indirect reputation effects a hospital/institution sustains from such an incident. As stated in the Becker's Hospital Review, "the damage to a hospital's reputation complicity surrounding a retained foreign object is harder to calculate an exact dollar figures, but surely considerable" [22]. As public reporting groups such as the Leapfrog Group make the "Hospital "Safety Score" open access, healthcare facilities are acutely aware of the implications. Currently, the hospital safety score is designated with an A-F letter grade based on the methodology that includes the occurrences of retained surgical items. This category compromises 6% of that total score [23].

Strategies and Tools for Prevention

The occurrence of a retained surgical item has varied and multiple root causes; therefore, multiple prevention efforts are needed to avoid this never event [24]. A key element to successful implementation of the recommended practices for prevention of RSIs in an organization is a consistent multidisciplinary approach during all surgical and invasive procedures [25]. All members of the operating theater, or delivery suite, must share in the responsibility of RSI prevention: physician, first assistant, circulator, etc. All involved personnel should become aware of the published evidence to aid in prevention. In a 2009 systematic review of risks and preventative strategies for retained surgical objects, the authors concluded that prevention should focus on three main categories. First, is knowledge and awareness of attributable risk factors. Second is use of modern technology as an ancillary tool. And thirdly, improved operative team communications and training [26].

Organization	Policy/statement obtainable at:
American College of Surgeons	https://www.facs.org/about-acs/statements/51-foreign-bodies
Association of periOperative Registered Nurses	http://isgweb.aorn.org/ISGWeb/downloads/CEA12506-0001.pdf
Joint Commission	http://www.jointcommission.org/assets/1/6/SEA_51_URFOs_10_17_13_FINAL.pdf
Institute for Clinical Systems Improvement	https://www.icsi.org/_asset/3xvmi8/RFO.pdf
National Quality Forum	http://www.qualityforum.org/Press_Releases.aspx

Table 2: Societies and National care organizations with drafted policies and/or statements on prevention of procedural retained foreign objects.

Physically counting surgical items by the operating room staff before and after procedures is the most common policy. However, as exemplified in the Minnesota Safety Report, a correct count was recorded in 83% of cases where a retained item occurred [6]. While work continues on behavioral changes of the operating room team and enhanced communication techniques, modern technologies have been developed and may improve the efficacy and workflow of the operating room, as well as the labor and delivery suite [27]. In 2007, RF Surgical Systems (Carlsbad, CA; USA) launched the FDA approved device for detection of Radiofrequency (RF) tagged surgical sponges and gauzes. Through the development of Cardiothoracic Surgeon, Dr. Jeffrey Port and chief engineer William Blair, the low frequency Radiofrequency (RF) detection system was granted FDA marketing clearance in 2006. According to the manufacturer website, the patented system currently exists in more than 4,500 operating rooms, trauma and labor and delivery suites nationwide [28]. The use of such adjuvant technology has been recognized by the Joint Commission. In the Sentinel Event Alert Report released by the Joint Commission in 2013, it was stated that, "Organizations should research the potential of using assistive technologies to supplement manual count procedures and methodical wound exploration" for the prevention of retained foreign object.

The detection system (Figure 1) employs low energy radio frequency wavelengths for the detection of misplaced surgical sponges (embedded with a Radio Frequency (RF) tag) through blood, dense tissue, bone and near metal, without exposing patients to harmful radiation [28]. The hand held wand has two functions: 1) as an antenna to transmit magnetic impulses that stimulate the RF tag on the corresponding sponge or gauze, and 2) acts as a receiver to detect residence signal returning from the tag. Coil design of the wand is optimized by specific scan patterns and, as such, is motion based as the one wand "floats" above the patient surface. Per suggested manufacturer protocol, the mat scan is the first mode of scan (passive scan), with the ability to follow up with a wand (dynamic scan) as a secondary measure or if the mat scan detects presence of an RF tagged item (Figure 2).

More recently, this same unique technology has been modified for use in the Labor and Delivery arena. This modification is the first system specifically designed for use in the delivery suite. Engineering has successful merged the functions of the wand and the ConformPlusII Mat into the Verisphere, a single portable handheld scanner for use over the perineum for detection of retained vaginal items [28]. This has been FDA cleared for use as a component of the low frequency detection system (Figure 3). This modification allows for both patient scanning (static scan) and as well as a room scan (dynamic scan), should the patient scan reflect an inconsistency. Instructions for patients scanning are illustrated in Figure 4. Similar to the original wand and mat design, a visual confirmation code is displayed on the device console once confirmation of absence of retained items is reached [28].

Although the low frequency technology is the first to be modified specifically for Labor and Delivery use, it is not the sole device for adjunct use. In 2010, the use of High Frequency wand-capable RF sponge detection system (ClearCount System; Medline Industies, Inc. Dallas, TX; USA) was approved by the FDA. This approach uses Radio-Frequency Identification (RFID) technology coupled with chips embedded in sponges to allow surgeons and nurses to count and detect sponges used in operations. The first generation of this high frequency

*Image used with permission RF Surgical Systems, Inc.

Figure 1: Low Frequency RF Detection System.

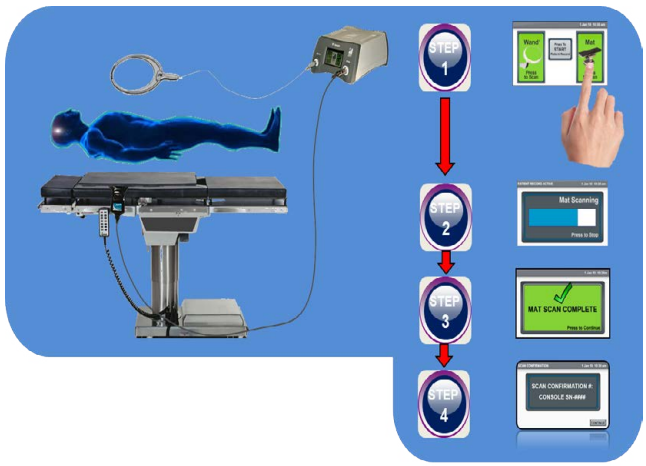

*Image used with permission RF Surgical Systems, Inc.

Figure 2: Low Frequency RF Detection System in Use.

Console:Touch Screen, Visible Scan Result, Displays Confirmation Code

Verisphere Hand Held Scanner; Static and Dynamic Scan ability

Mobile, Light-weight portable stand

*Image used with permission RF Surgical Systems, Inc.

Figure 3: Low Frequency RF Delivery System for Labor and Delivery Prevention of retained Vaginal Sponges and Gauze

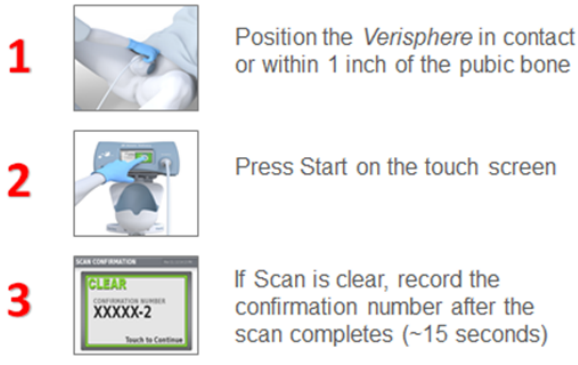

*Image used with permission RF Surgical Systems, Inc.

Figure 4: Verisphere Vaginal Static Scan after Vaginal Birth and Perineal Repair.

system was originally approved in 2007. In the original design, a count of sponges to be used in an operation was performed before procedure initiation, and then reconciliation was performed of that first number with the sponges returned to a receptacle after surgery completion [29]. With this "Smart Sponge System", sponges are *scanned in* by swiping each unopened pack to the In-Scanner. The data on each sponge is validated and the inventory counts are updated on the screen. Alternatively, sponge counts can be verified through a scan over sponge packs with the associated wand handheld device. As sponges are used and discarded into the system receptacle, the sponges are automatically scanned out. At any point in the surgery, the handheld wand may be used to perform a patient scan or scan of the surgical area to reconcile any discrepancies, if needed.

In addition to radiofrequency detection is a textile barcode identification system. This system (Stryker Surgicount System© (Stryker Corps, Kalamazoo, MI; USA) incorporates three components: a portable scanner, barcodes textiles, and an associated computer database program. Each sponge is barcode scanned in and scanned out during the surgical case. Each barcode represents a unique identifier number per sponge/gauze for tracking. This prevents one item from being scanned in or out more than once, thereby reducing erroneous double reads [30].

Examining the Evidence

Low frequency radio-detection

Clinical performance of the low radiofrequency detection system has been evaluated in various clinical trials. In 2011, Steelman investigated the sensitivity of detection of radiofrequency surgical sponges in a prospective, crossover study. An observer blinded study design was employed. Subjects served as their own controls. With the patient supine, four surgical sponges were sequentially placed behind the subjects' torsos in locations approximating the four quadrants. 210 subjects were enrolled. Half were morbidly obese. There were no false positive or false negative readings. The sensitivity and specificity of detection of the RF sponges through the torso of subjects of varying body habitus is were 100% [31].

The same author further assessed the radiofrequency device sensitivity for retained sponges in patients with morbid obesity, in 2012. Steelman and Alasaqheirin conducted the prospective, crossover, double blinded study and a large Midwestern academic medical center. Two phases of this study were completed [32]. The first phase of the study enrolled 203 subjects, 63% of whom had morbid obesity. 117 of the same 203 subjects were enrolled in the second phase of the study. As described in the publication, "participants lie in a supine position on top of the radiofrequency mat. Four surgical sponges were sequentially placed on top of the torso in locations approximating the abdominal quadrants. The torso was scanned for sponges. In the subset of participants, four surgical sponges are sequentially placed underneath the torso, and the radiofrequency wand was passed over the abdomen. The objective was to compare the sensitivity and specificity of the wand and mat. Twelve false-negative readings were obtained with the mat, exclusively in patients with super morbid obesity (BMI>50). Overall, the sensitivity of the mat was 98.1% and the specificity of the mat was 100%. In the subset of 117 patients in whom wand use was employed, the sensitivity and specificity of the wand were each 100% [32]. The authors concluded that RF wand is more sensitive than the mat in individuals with morbid obesity.

Rupp et al. similarly published a prospective trial of 2,285 patients. The low frequency Detection System detected a sponge in one case in which the count was reported as correct, and rectified 35 cases with incorrect accounts. No false negatives or false positives were reported during the study period. No true retain surgical items occurred throughout the investigation [33].

In September 2014, the first published study to analyze the occurrence of retained surgical items, the methods of prevention and the cost involved was published in the Journal of the American College of Surgeons. Williams at all conducted a review of the University Health Systems Consortium (UHC) Safety Intelligence database on incorrect surgical counts [34]. The UHC intelligence group is an organization providing comparative data and benchmark testing to guide clinical, operational, and financial decision-making for health related industries [35]. Reported cases of retained surgical sponges at organizations that use radiofrequency technology were compared to centers without its use. A cost-benefit analysis of the employment of low frequency radiofrequency technology was conducted. In this review, five organizations that implemented radiofrequency technology between 2008 and 2012 collectively demonstrated a 93% reduction in the rate of retained surgical sponges. Based on the cost-benefit analysis, the savings in X-rays and operating room time, as well as medical and legal costs which were avoided, outweighed the initial expense of radiofrequency technology integration. The authors state, "the data showed that over a two-year period, OR time for radiofrequency users was on average about 16 minutes shorter" [34]. The projection was that 82% of the implementation cost of RF use was offset by the gain in workplace efficiency from time not lost from duplicating manual count and/or incorporating additional X-ray intervention.

High frequency radio-detection

We found one peer review publication for this system. Macario and Morris published a prospective, blinded, experimental clinical trial for this system. In this analysis, eight patients undergoing abdominal/pelvic surgery had a RFID tagged sponge placed into the surgical site. A separate blinded surgeon then used the system to detect the "lost" sponge. The authors documented detection accuracy of 100% for the RFID wand device [36].

Barcode technology

The peer reviewed clinical trial of this data- matrix-coded sponge system was published in 2011. This multicenter investigation was conducted in two phases, phase I for efficacy and phase II as a validation analysis. The authors state that prior to implementation; one retained surgical item occurred within the institution an average of one out of every 64 days. No incidents were reported after device incorporation over the 18 months of investigation [37-40].

A summary comparison between the current FDA cleared technologies for the prevention of retained foreign objects is shown in Table 3. No ancillary device reviewed yet possesses clinical data in the Labor and Delivery unit. However, expected similar performance as shown in the main operating theater may be expected as detection is for inadvertent "cavitary retention" (i.e., vaginal cavity vs intraabdominal/pelvic cavity are not variedly different). The authors of this manuscript wish to disclose that a clinical investigation for the performance of the low radiofrequency detection system in Labor and Delivery is being planned for 2015. We choice this system for study due to the device's unique modification specific for use in the L&D space [41-45].

Although it would seem that RF detection systems are superior to manual counting, it should be emphasized that an RF detection system is not a substitute for manual counting, but rather an adjunct

	Low Frequency RF Scanning (RF Surgical Systems Inc)	High Frequency RFID Scanning (ClearCount Medical Solutions)	Manuel Barcode Scanning (SurgiCount Medical, Inc)
Published peer reviewed studies	4 [31-34]	1 [36]	2 [19,37]
Sensitivity	100% [31]	100% [36]	Not reported
Specificity	100% [31]	100% [36]	Not reported
Bariatric subjects	Yes [32]	No	No
Reduction in procedure time studied	Yes [34]	No	No [19]
Cost Savings over Implantation Costs	Yes [34]	No	No
Reported Staff Satisfaction with system	97% [33]	85-93% [36]	60% [37]
Avoidance of biohazard material prior to scan	Yes [28]	Yes	No
Diameter of Detection wand	14'' [28]	21'' [40]	NA
In-Vivo sponge detection ability	Yes [28,33]	Yes [29]	No
Validated performance in tissue and fluids	Yes [28]	No [39]	No [30]
Operative Field sponge detection ability	Yes [28,33]	Yes [29]	No
Effective through bone cement	Yes [28]	Yes	No [38]

Numbers correspond to listed citations

Table 3: Comparative Review of FDA Cleared Technologies for Prevention of retained Foreign Items Source: www.Rfsurg.com.

to manual counting.

Conclusion

Beyond healthcare facilities aesthetic competition one with another, and the pursuit of the latest in surgical innovations, lies the determination and dedication to quality patient care. As healthcare institutions and healthcare providers alike are increasingly under public scrutiny, the traditional adage of "first do no harm" is paramount.

While attention is mainly focused on the prevention of retained surgical items in the operating theaters, similar focused attention is being placed in the Labor and Delivery wards. It is best summarized by Becker's Health Review: "when it comes to retained surgical sponges, the incentives for taking action, coupled with the availability of new technology, provide an excellent opportunity to make this avoidable error an extremely rare hazard in the near future" [18].

References

1. Hospital Consumer Assessment of Healthcare Providers and Systems: Hospital patient satisfaction scores.
2. Kim CK, Park BK, Ha H (2007) Gossypiboma in abdomen and pelvis: MRI findings in four patients. AJR Am J Roentgenol 189: 814-817.
3. Gibbs VC (2011) Retained surgical items and minimally invasive surgery. World J Surg 35: 1532-1539.
4. Rappaport W, Haynes K (1990) The retained surgical sponge following intra-abdominal surgery. A continuing problem. Arch Surg 125: 405-407.
5. Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ (2003) Risk factors for retained instruments and sponges after surgery. N Engl J Med 348: 229-235.
6. Spotlight on patient safety: data, trends, and learning from that Minnesota adverse health event reporting system.
7. Adverse health events in Minnesota, ninth annual public report.
8. Becker's ASC Review for 2014.
9. The Joint Commission. Summary data of sentinel events reviewed by the joint commission.
10. McIntyre LK, Jurkovich GJ, Gunn ML, Maier RV (2010) Gossypiboma: tales of lost sponges and lessons learned. Arch Surg 145: 770-775.
11. Erdil A, Kilciler G, Ates Y, Tuzun A, Gulsen M, et al. (2008) Transgastric migration of retained intraabdominal surgical sponge: gossypiboma in the bulbus. Intern Med 47: 613-615.
12. Zantvoord Y, van der Weiden RM, van Hooff MH (2008) Transmural migration of retained surgical sponges: a systematic review. Obstet Gynecol Surv 63: 465-471.
13. Kato K, Kawai T, Suzuki K, Sai S, Murase T (1998) [Migration of surgical sponge retained at transvaginal hysterectomy into the bladder: a case report]. Hinyokika Kiyo 44: 183-185.
14. Lutgendorf MA, Schindler LL, Hill JB, Magann EF, O'Boyle JD (2011) Implementation of a protocol to reduce occurrence of retained sponges after vaginal delivery. Mil Med 176: 702-704.
15. Hariharan D, Lobo DN (2013) Retained surgical sponges, needles and instruments. Ann R Coll Surg Engl 95: 87-92.
16. Lincourt AE, Harrell A, Cristiano J, Sechrist C, Kercher K, et al. (2007) Retained foreign bodies after surgery. J Surg Res 138: 170-174.
17. Kaiser CW, Friedman S, Spurling KP, Slowick T, Kaiser HA (1996) The retained surgical sponge. Ann Surg 224: 79-84.
18. Steelman VM, Cullen JJ (2011) Designing a safer process to prevent retained surgical sponges: a healthcare failure mode and effect analysis. AORN J 94: 132-141.
19. Fact sheets: eliminating serious, preventable, and costly medical errors – never events.
20. Institute of medicine (1999) To Err is Human: Building A Safer Health System.
21. Health Quality Ontario (2010) KRAS Testing for Anti-EGFR Therapy in Advanced Colorectal Cancer: An Evidence-Based and Economic Analysis. Ont Health Technol Assess Ser 10: 1-49.
22. The joint commission sentinel event alert.
23. Becker's ASC Review: 10 things to know about retained search for sponges.
24. Greenberg CC, Regenbogen SE, Lipsitz SR, Diaz-Flores R, Gawande AA (2008) The frequency and significance of discrepancies in the surgical count. Ann Surg 248: 337-341.
25. 2006 annual report of national practitioner data Bank, US health and human services. Legal: $234,000 average medical malpractice payment since 1990.
26. Abuhamad A, Grobman WA (2010) Patient safety and medical liability: current status and an agenda for the future. Obstet Gynecol 116: 570-577.
27. The high cost of in action: retain surgical sponges are draining hospital finances and harming reputations.
28. Leapfrog hospital ratings: the leapfrog group.
29. Moffatt-Bruce SD, Cook CH, Steinberg SM, Stawicki SP (2014) Risk factors for retained surgical items: a meta-analysis and proposed risk stratification system. J Surg Res 190: 429-436.
30. Goldberg JL, Feldman DL (2012) Implementing AORN recommended practices for prevention of retained surgical items. AORN J 95: 205-216.
31. Stawicki SP, Evans DC, Cipolla J, Seamon MJ, Lukaszczyk JJ, et al. (2009)

Retained surgical foreign bodies: a comprehensive review of risks and preventive strategies. Scand J Surg 98: 8-17.

32. Coleman J, Wolfgang CL (2013) Detection of a gossyphiboma. J Nurs Practition 9: 277-282.
33. www.rfsurg.com.
34. Clearcount (2010) pittsburgh's clearcount gets fda approval for lower cost sponge detection system.
35. The SurgiCount Safety-Sponge® System.
36. Steelman VM (2011) Sensitivity of detection of radiofrequency surgical sponges: a prospective, cross-over study. Am J Surg 201: 233-237.
37. Steelman VM, Alasagheirin MH (2012) Assessment of radiofrequency device sensitivity for the detection of retained surgical sponges in patients with morbid obesity. Arch Surg 147: 955-960.
38. Rupp CC, Kagarise MJ, Nelson SM, Deal AM, Phillips S, et al. (2012) Effectiveness of a radiofrequency detection system as an adjunct to manual counting protocols for tracking surgical sponges: a prospective trial of 2,285 patients. J Am Coll Surg 215: 524-533.
39. Williams TL, Tung DK, Steelman VM, Chang PK, Szekendi MK (2014) Retained surgical sponges: findings from incident reports and a cost-benefit analysis of radiofrequency technology. J Am Coll Surg 219: 354-364.
40. www.UHC.edu/solutions-for/physicians.
41. Macario A, Morris D, Morris S (2006) Initial clinical evaluation of a handheld device for detecting retained surgical gauze sponges using radiofrequency identification technology. Arch Surg 141: 659-662.
42. Cima RR, Kollengode A, Clark J, Pool S, Weisbrod C, et al. (2011) Using a data-matrix-coded sponge counting system across a surgical practice: impact after 18 months. Jt Comm J Qual Patient Saf 37: 51-58.
43. US Department of Health and Human Service (2014) MAUDE Adverse Event Report: Surgicount Surgicount Lap Sponge Sponge-Lap.
44. Rivera, ASSIST Project, 2008 International Conference on RFID.
45. www.medline.com/sku/item/MDPMDSCCDTXRWAND.