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Identifying lost surgical needles with visible and near infrared fluorescent light emitting microscale coating

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ABSTRACT

Background. Retained foreign bodies (RFOs) have substantial clinical and financial consequences. In laparoscopic surgery, RFOs can be a cause of needing to convert a minimally invasive surgery (MIS) procedure to an open operation. A coating for surgical models was developed to augment localization of needles using fluorescence appropriate for open and minimally invasive surgeries procedures.

Methods. An epoxy matrix containing both dansyl chloride and indocyanine green was coated as visible and near infrared labels, respectively. With ultraviolet excitation, dansyl chloride emits green fluorescence and with NIR excitation, the ICG dye emits radiation observable with specialized near infrared capable laparoscopes. To evaluate the coatings, open and laproscopic surgeries were simulated in rabbits. Surgeons blinded to the type of needles (coated or non-coated) were timed while finding needles in standard conditions and with the use of the adjunct coatings. Control needles not located within 300 seconds were researched with the corresponding near infrared or ultraviolet light. Localization time was evaluated for statistical significance, $P < .05$.

Results. All dual dye coated needles searched utilizing the near infrared camera ($n = 26$) or ultraviolet light ($n = 26$) were located within 300 seconds. Conversely, 9 needles in both control settings (no dye usage) were not located within 300 seconds. Mean time to locate control needles in open surgery and laparoscopic surgery was statistically 2-3× greater than time to localization with the use of dye as an adjunct ($P = .0027$ open, $P < .001$ laparoscopic).

Conclusion. Incorporation of a dual-dye fluorescent coating on surgical needles improved the efficiency of locating needles, may minimize the need to convert minimally invasive surgeries procedures to open, and may decrease the consequences of a missed RFO.

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Surgical retained foreign objects (RFOs) have substantial potential consequences for patients and hospitals.[1,2] Substantial research and strict protocols have been implemented to minimize the risks of RFOs but despite best efforts, an estimated 1 in 5,500 to 1 in 18,760 inpatient operations result in an RFO.[3-8] Clinical consequences for RFOs can range from sepsis, to wound infections, and even to death in rare circumstances. The majority of patients, estimated between 69% to 83%, require additional operative interventions to remove the RFO.[1,2,5,9-12] Many of these cases lead to malpractice suits, and even when minimal direct patient harm is documented, the estimated cost lies between $37,000 and 2.3 million.[1,6]

The mainstay of preventing RFOs relies on surgical staff counting all sponges, instruments, and needles once before incision, and twice after closure.[4] Unfortunately, counting is prone to errors and recent studies show that counting is only 77% sensitive and 99% specific.[13,14] When discrepancies in the counting occur, which can be as often as 1 in 8 operations, protocols dictate that the operation be paused and that all participating personnel search for the object in and around the surgical field including within the body.[4,15] If the miscount cannot be remedied, it is recommended that an x-ray be obtained to exclude an RFO prior to leaving the operating room, assuming the condition of the patient permits.[3,4] While x-rays are used commonly as a backup for counting errors, studies show that x-ray images are neither particularly specific nor sensitive

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intraoperatively, and they are particularly poor for location of needles.[16,17] Additional technologies have been developed to optimize locating lost sponges, including radiofrequency identification (RFID) of sponges and barcoding systems (BCS). While both have been shown to be effective at decreasing retained sponges, neither are infallible and these methods are not adaptable to address miscounted needles due to size restrictions.[5,18,19] Thus, current protocols aimed to decrease retained needles rely on counting and x-rays, both of which, as noted, have been proven to be particularly flawed for preventing needles as RFOs.[13,15,20]

Current understanding of the clinical consequences of RFOs relies primarily on case reports and retrospective reviews and suggest the consequences can be severe. Currently there is a paucity of knowledge as to the long-term implications of retained needles, although case reports suggest that larger needles can on occasion lead to psychologic and physical discomfort.[10-12,21-23] In addition, during laparoscopic and other minimally invasive surgeries (MIS), lost needles can have immediate consequences because many surgeons will convert to an open procedure to maximize the probability of finding the lost needle.[3,24]

Because RFOs are preventable and should be considered a reportable "never event" by the National Quality Forum, a new technique was developed to minimize the impact of miscounted needles and to prevent needles as being overlooked and thus considered as an RFO in both open and laparoscopic settings. A new technique was needed, because RFID and BCS are impractical for locating surgical needles. To accomplish this need, a fluorescent dual-purpose film was developed for standard surgical needles to allow rapid localization of needles with ultraviolet (UV; black light) in open procedures and with near infrared (NIR) light in operations using a minimally invasive surgery (MIS) approach with the aid of specialized fluorescent laparoscopes.

Methods

Coating development and testing

Standard 11 mm (Ethicon, Somerville, NJ) 7-0 reverse cutting needles were coated with the dual layer coating. Epoxy glue was used to apply the dansyl chloride (DC) and indocyanine green (ICG) dyes that were used as fluorescence and NIR labels, respectively, with the metal surface of needles. Methanol was added to dilute the glue and dissolve the dyes. The needles were coated with the mixture by dip coating and cured in air at room temperature to form a hard polymer-dye film. After curing, the content of DC and ICG in the cured glue were 10 mg/g and 0.15 mg/g, respectively. The final coating was clear in color and ranged from 10 to 30 μm thick and both dyes were able to be incorporated in the standard needle coating without disrupting the brittleness of the coating or the sharpness of needle. To verify this, several tests were done comparing standardly coated needles to the needles coated with the addition of the dye. These tests included passing the needle through thin vasculature tissue and imaging the defects created in the tissue with optical microscope. The coating did not appear to alter the size of the tissue defect (see supplemental figure). During illumination under a black light source with a wavelength of 390 nm, DC emits green fluorescence with a wavelength near 520 nm. With the ICG dye, illumination with a 980 nm NIR light source emits NIR light with a wavelength greater than 1,000 nm. An additional fluorescent (rubrene) coating was developed to evaluate if the color of the fluorescent needles influences recognition retrieval time in an open setting. Under a black light, rubrene emits orange fluorescence with a wavelength near 560 nm. To enhance the binding of the film with the surface of needle, the needles were pretreated with N^1-(3 trimethoxysilylpropyl) diethylenetriamine (DETA) by dipping needles into 1% DETA methanol solution for 4 h before drying at room temperature overnight. The silane group in DETA reacts with surface hydroxyl groups on the metal, and the amine groups can react with glycidyl groups of the epoxy resin to better anchor the polymer chains to the metal surface.

During the development of the coating, tests to evaluate the adherence of the dye to the needle were performed. Needles were passed through tissue up to 20 times to evaluate for any disruption or flaking of the coating. In addition, the needles were clamped with standard needle holders >30 times to insure the coating could withstand standard manipulation in an operating room. The coating was also evaluated for any degradation or photo bleaching to ensure that prolonged storage would not lead to decreased fluorescence.

Animals

This study was approved by the Institutional Animal Care and Use Committee of the University of California San Diego. In vivo studies were performed to evaluate the utility and efficacy of the fluorescence and ICG coated needles in 10 female New Zealand White rabbits, aged 20 to 30 weeks. All animals were housed in an approved animal housing facility and kept at 20°C with a 12-hour light/dark cycle and were fed a commercial pelleted diet (Harlan Tecklad, Indianapolis, IN) ad libitum. Rabbits were anesthetized with isoflurane gas with oxygen during the open and laparoscopic operations. At the conclusion of the experiments, the animals were killed with sodium pentobarbital injection and bilateral thoracotomies. All rabbits were between 3 to 4 kg at time of operation. Only female rabbits were employed, because many of the animals had been recruited initially for an unrelated experiment that mandated all female rabbits.

Searching protocol

To evaluate the effectiveness of the coating in a clinical setting, 2 separate Institutional Animal Care and Use Committees approved experiments were completed. To simulate the setting of an open laparotomy setting, a standard laparotomy incision from xyphoid to pubis was made and subsequently a total of 52 needles were placed in the abdomen, one at a time, in random locations to which the surgeon was blinded. All needles were searched for by 2 residents under the direct supervision of an attending physician. Both residents had several years of both open and laparoscopic surgical experience and were deemed appropriate for the testing by the attending physicians. The location of each needle was recorded. The surgeon searched for 26 needles with standard light as controls and for 26 with the use of a black light. Time to location of the needle by the surgeon was recorded. To simulate a laparoscopic setting, a standard laparoscopic tower and equipment set was used to establish a pneumoperitoneum. A standard 5 mm zero-degree camera was used for access and replaced with a specialized 30 degree FDA-approved laparoscope that can detect ICG and NIR wavelengths (VisionSense NIR Imaging System, Stryker, Kalamazoo, MI). A total of 52 needles were searched for in a laparoscopic setting, 26 with a standard camera (control) and 26 with an ICG capable-laparoscope. Maximum time allotted for location of all needles in both open and MIS procedures was 300 seconds. If at 300 seconds the surgeon had not found the needle, the search was repeated with black light or an ICG fluoroscope, as appropriate. The open protocol was also repeated with the orange fluorescent, rubrene-coated needles to assess for time variance secondary to color.

Statistics

Because of the limited number of subjects studied (n = 2), the statistical analyses here are purely descriptive. Mann-Whitney nonparametric tests were used to compare the time to location of

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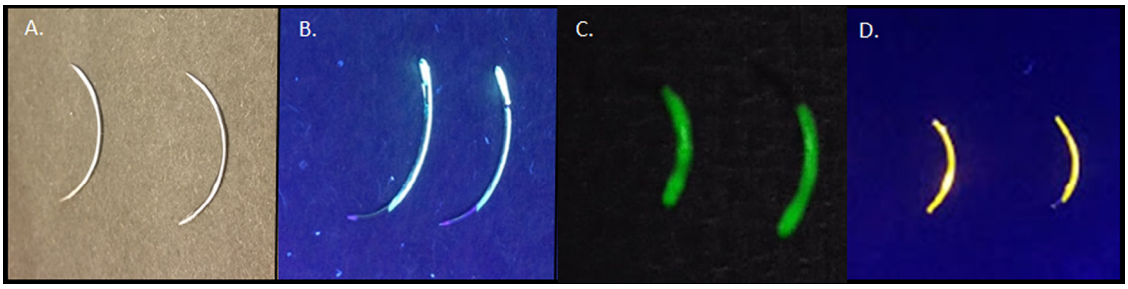

Fig. 1. To minimize the risk of retained needles 11 mm needles were coated with fluorescent dye. (*A*) Image of the dual-coated needles under standard light, (*B*) UV light for excitation of the DC coating, (*C*) and with the ICG-capable laparoscope highlighting the excitation of the ICG coating. (*D*) Image of 11 mm needles coated with orange fluorescent rubrene under black light.

fluorescent and ICG-coated needles against their respective controls at a *P* value of .05. Statistics were calculated in SPSS Statistics for Macintosh, version 22.0 (IBM, Somers, NY). and figures were created in GraphPad Prism 7 (GraphPad Software, Inc., La Jolla, CA).

Results

Needle coating

After coating the 11 mm needles with the dual DC and ICG dyes, the needles did not have any notable alterations to their appearance or texture. The orange fluorescent coating resulted in an orange hue in standard lighting unlike the DC coating. The fluorescent coatings were found to withstand extensive testing involving passing the needles through tissue 20 times and repetitive needle manipulation with standard steel needle holders without evidence of flaking or chipping. Images of the dual-coated needles in standard light, UV light, and with NIR light can be seen after 20 passes through tissue with standard needle holders (Fig 1, *A* to *C*). The orange fluorescent needles under a black light can be seen Fig 1, *D*.

Open laparotomy UV fluorescent needles

On average, the surgeon required 149 ± 47 seconds to locate the 26 dual-coated control needles in normal lighting (Fig 2, *A*). A total of 9 control needles (35%) could not be located within the maximum allotted 300 seconds. All 9 of the "lost" control needles were then located with the use of the UV light and fluorescent coating within 300 seconds (mean 52, range 2–70 seconds). All the coated needles searched for under black light were found within 300 seconds (mean time 54 ± 47 s). The time to locate the needles with the use of the fluorescent coating was less than the time to locate the needles in the control setting ($P = .0027$). The time to locate the needles with the aid of green fluorescence was decreased by 64% with an overall 100% success rate. Example images of the coated needles without and with the aid of the UV light can be seen in Fig 3, *A* and *B*.

To evaluate for any influence of color on the effectiveness of the fluorescent coating, a separate experiment was completed utilizing the orange fluorescent coating on 26 of the same 11 mm sized needles (Fig 3, *C*). On average, the surgeon took 44 ± 60 seconds to locate the orange fluorescent needle under black light illumination (Fig 2, *B*). One needle could not be found within the allotted time with this coating. No significant difference was found between the time to location of the dual-coated green fluorescent needles and the orange fluorescent needles ($P = .1786$). Relative to control settings, the fluorescent orange coating decreased the time to retrieval of the needle ($P < .0001$).

Laparoscopic needles

In the laparoscopic setting, the surgeon required on average 165 ± 117 seconds to locate the needles with a standard laparoscope. A total of 9 of the control needles could not be located within 300 s and 8 of these 9 could be located with the ICG-capable

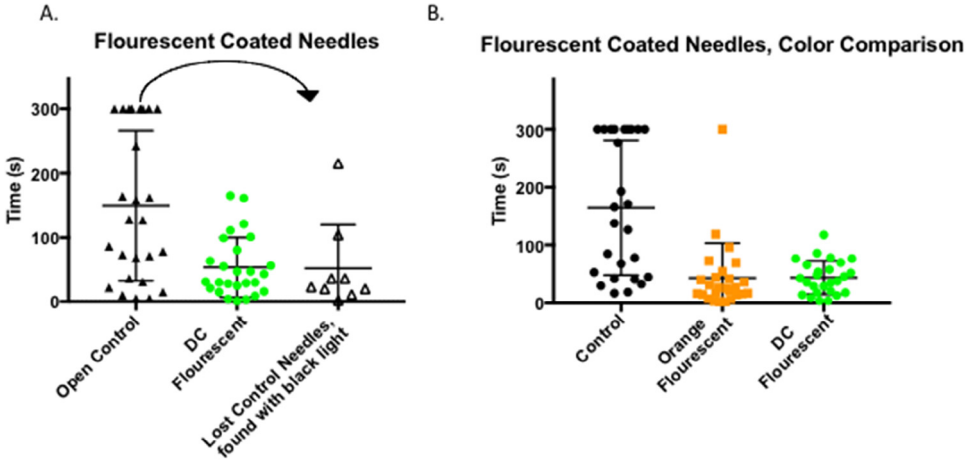

Fig. 2. (*A*) Dual coated 11 mm needles were searched for with UV light ($n = 26$) and control light ($n = 26$). The needles were found significantly faster with the black light using the fluorescent coating (53 ± 47 seconds) than in standard conditions (149 ± 116 seconds, $P = .00027$). All 9 needles that were not located during the control setting within 300 seconds were located with the help of the black light within 51 ± 67 seconds on average. (*B*) Orange fluorescent rubrene coated needles were found in a similar amount of time as the green DC coated needles with UV light ($P = .1786$) and significantly faster than the control needles (43 ± 60 seconds, $P < .0001$).

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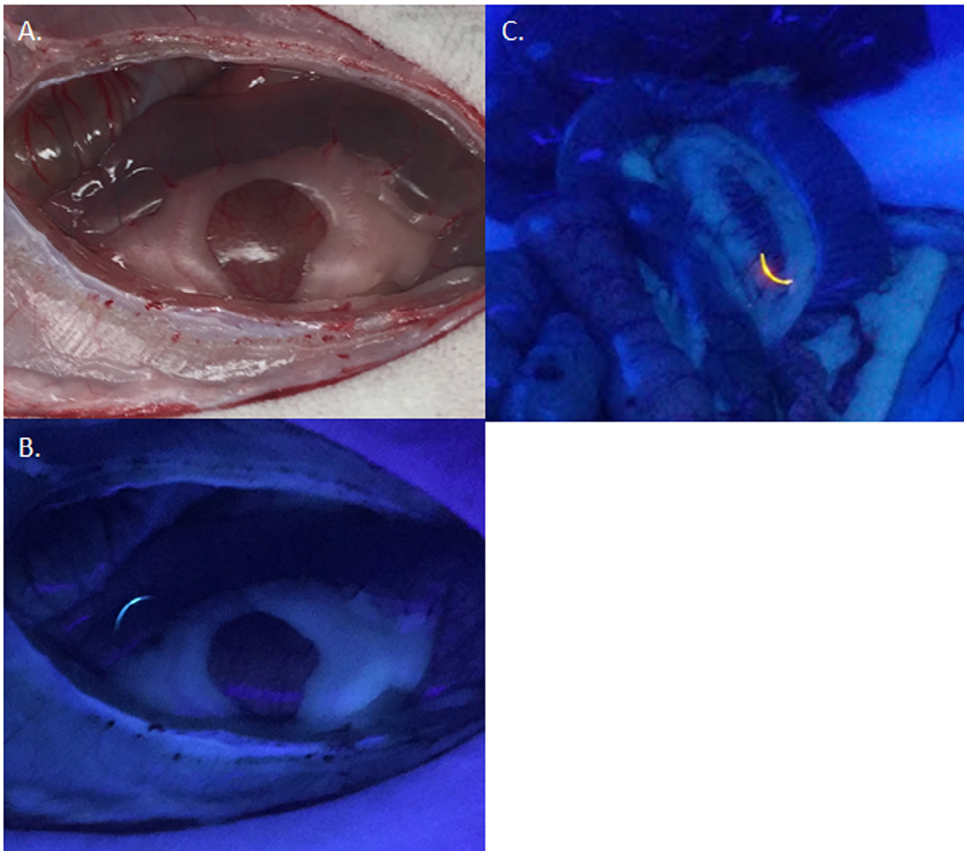

Fig. 3. (*A*) Dual coated needle in open laparotomy setting under standard lighting and (*B*) the same needle under UV light demonstrating the fluorescent coating. (*C*) Image of rubrene coated needle in surgical setting under UV light.

laparoscope within an average of 75 ± 90 s (range 2–90 s; Fig 4). All the needles searched for initially with the ICG laparoscope were located within 300 s in an average of 44 ± 29 s. The needles searched for with the dual coating were found faster and more frequently than the control needles ($P < .0001$). Example images of the ICG-coated needles in the peritoneal cavity with the control and ICG scope and the laparoscopic set up can be seen in Fig 5. Overall, while the dual coating significantly improved the frequency of locating the needle in both settings, the ICG coating was found to have a more marked decrease in time to retrieve the needle (Table). Altogether, the time to locate the coated needles with the aid of ICG was reduced by 74% with an overall 100% success rate.

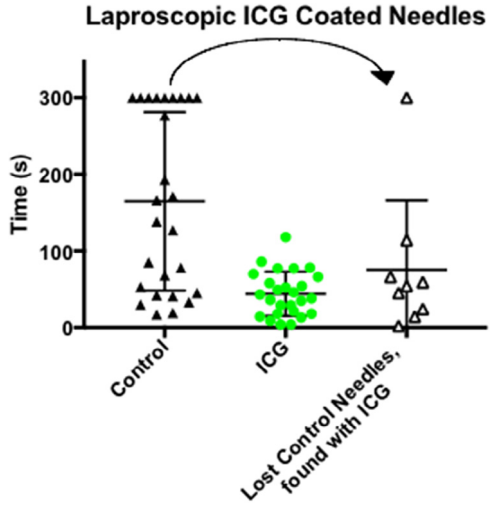

Fig. 4. (*A*) Dual coated 11 mm needles were searched for in a laparoscopic surgery setting with a standard scope ($n = 26$) and ICG capable scope ($n = 26$). The needles were found significantly faster with the ICG capable fluorescent coating (44 ± 29 seconds) than in standard conditions (164 ± 116 seconds, $P < .0001$). Eight of the 9 needles not found during the control setting were located within 300 s with the help of the ICG coating in an average of 75 ± 90 seconds.

Discussion

Retained foreign bodies may lead to have serious medical consequences for patients and the potential for an expensive lawsuit for the hospital. Multiple retrospective and a few prospective studies support the idea that RFOs are costly, common, and lead to high rates of reoperation.[1,6,9,15,23,25] In addition, these studies and additional case reports support the belief that the clinical consequences of RFOs can be severe. Incorrect counts put patients at significantly increased risk for having an RFO and can lead to longer operations because of conversion of laparoscopic operations to open operations.[1,3,6] Miscounts of surgical needles are considered a relatively common occurrence and current protocols rely on repeated counting and intraoperative x-rays, which are known to be prone to errors and are neither sensitive or specific for finding lost needles.[3,5,14,20]

This report describes our initial experience with a dual-dye fluorescent needle coating for both open and laparoscopic operations in an in vivo setting. The incorporation of a dual-dye led to a marked improvement in both the time required for a surgeon to retrieve a needle and the overall success in both a laparoscopic and open operative setting in a live animal. All needles that were initially searched with the adjunct dye were found within 5 minutes, while only 65%

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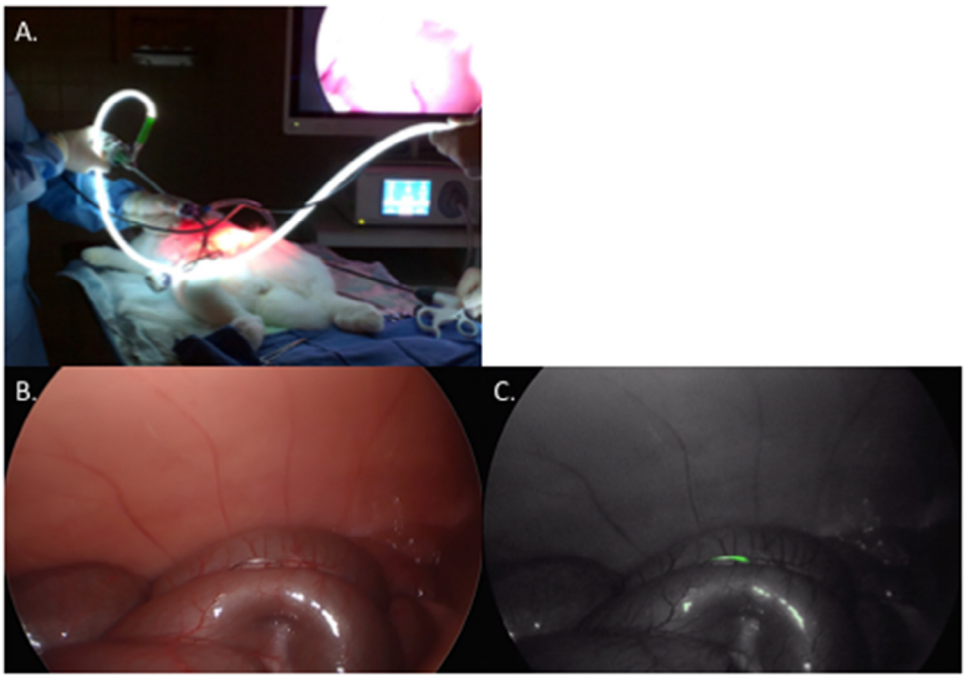

Fig. 5. (*A*) The laparoscopic surgery setting was simulated in rabbits with standard OR equipment and an ICG capable scope. (*B*) A needle with peritoneum on top of bowel can be seen with the standard scope and (*C*) the ICG capable scope.

of the control uncoated needles were retrieved. The dual fluorescent coating assisted the surgeon in locating 100% of needles not found in the open control setting and 89% of unfound control needles in a laparoscopic surgery scenario. Furthermore, the fluorescent dye coating resulted in a 64% decrease and a 74% decrease in the total needle-recovery time in the open and laparoscopic settings, respectively. Overall, without the coating, the surgeon was 2.9 times more likely to fail in attempting to find the 11-mm needle. In addition, we found the florescent coating was effective, irrespective of the color of the fluorescent marker in the open setting.

Current literature supports that larger retained needles have the potential for physical and psychological consequences for patients, while controversy still exists over the long-term clinical consequences of small needles.[3,10-12,19,22,23,25,26] Most of what is known about the long-term consequences of all RFOs relies on retrospective reviews and case reports documenting that even for larger items, such as surgical sponges, the effects can take years to manifest and the can vary greatly.[2,6,8,11] While it remains unlikely that true extent of the consequences of retained needles will be ever fully delineated, some things are certain. Currently the national goal is to make RFOs a "never event" irrespective of the size of the item. Furthermore, for specific operations the consequences of lost needles can be immediate. In laparoscopic and other minimally invasive operations, an unfound needle can leave surgeons with the following dilemma: convert to a larger incision and loose the benefits of a minimally invasive approach or potentially leave a needle behind. The limited visual field afforded by the camera, the small size of the needles and the difficultly in manipulating tissues with the instruments makes finding a needle in a laparoscopic setting particularly challenging.[3,23-25] Ruscher et al found that when surveyed 55% of surgeons would convert a minimally invasive procedure to open one if a needle could not be found, while the others report they would leave the needle in the abdomen.[24] In response to this known dilemma, different designs of assist devices, including magnets, have been proposed but currently, none are used widely, and none of these designs translate well to an open setting.[26,27]

Studies of cost analysis studies agree that even costly systems like RFID and BCS for surgical sponges can be overall cost effective for hospitals due to the associated high clinical and litigative costs of RFOs.[3,8,18] The dual coating provides surgeons with an additional way to locate lost needles other than the relatively insensitive intraoperative x-rays, decreasing the potential for expensive litigation, which can average between $52,581 to $95,000 per RFO incident.[1,6,9,13,15,20] Our results also support that this coating can decrease the time required to rectify needle miscounts, which are estimated to account for 21% to 79% of all counting errors.[13,15,28] With the cost of 1 minute of operating room time estimated at $20 to $60, Egorova et al found that every miscounted needle added an

Table
Time required to locate lost needles with and without the use of fluorescent coatings.

	Percent not located within 300 s*	Max time (s)	Mean time (s)	Mean time to locate lost control needles (s)	Total time searched (min, % control)	*P* value (compared to controls)
Open surgery						
Control ($n = 26$)	35%	300*	149 ± 116	51 ± 67 ($n = 9$)	64.68 (100%)	—
Black light assisted (green) ($n = 26$)	0%	165	53 ± 47	n/a	23.18 (36%)	.0027
Black light assisted (orange) ($n = 26$)	4%	300*	43 ± 60	n/a	18.75 (28%)	<.0001
Laparoscopic						
Control ($n = 26$)	35%	300*	164 ± 116	75 ± 90† ($n = 9$)	71.38 (100%)	—
ICG assisted ($n = 26$)	0%	118	44 ± 29	n/a	19.03 (26%)	<.0001

* Maximum time allotted = 300 s.
† Of note: 1 needle that was unable to be located initially via visible light also was not able to located with ICG.

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average $932/case in OR time alone.[3,13] Because not all lost needles are within the body cavity, the dual nature of this coating could further minimize the time required to locate a needle by utilizing the UV fluorescent marker to search the surrounding drapes and Mayo stand.[4,14,16] At this time, ICG-capable laparoscopes are not standard but an increasing number of companies are adapting current platforms to integrate this technology. Both the acquisition of an ICG laparoscope and the purchase of standard black lights would need to be taken into consideration for further cost analysis. While this analysis should be completed, our initial in vivo data supports that the operating room costs, clinical costs of converting a laparoscopic procedure to an open one, and potential litigation costs could quickly substantiate the cost of adding the dual coating to needles.

Although this dual-dye coating allows for more rapid location of lost needles in the open and laparoscopic setting, the main limitation of this technology because it requires the coating to be activated by the appropriate light (UV or near IR) to emit the associated fluorescence. Therefore, if the lost needle remains behind a segment of bowel or other tissue, the surgeon must still manipulate the tissue to allow for any small portion of the needle to serve as a beacon. It is standard procedure for surgeons to move tissue to locate lost needles, and only a small segment of the needle must be exposed to the excitation light thus this technology does not require anything beyond the standard care and has the potential to decrease the time required to locate the needle. Furthermore, if the needle is superficial but just small and difficult to find, the technology allows for the needle to be located without the normal manipulation and moving of tissue.

The technology will function as long as some portion of the needle is not completely submerged in blood. Although the UV/DC coating and blood have overlapping spectral absorption, due to the hydrophobic coating, if any portion of the needle is exposed, the coating can be activated rapidly by the UV light. Although there may be some blood within the field during the process of searching for needles, the majority of surgeons use tools such as suction or lap pads to minimize the amount of settled blood within the field. Therefore, although this technology requires exposure of the coating to UV or near IR light, the needles with coating can be located rapidly in an active surgical field using the standard searching strategies.

The initial experiments with the dual fluorescent needle coating technology, while promising, are not without limitations. First, the experiments were designed to approximate lost needles by placing the needle randomly within the abdomen in a blinded fashion. While this likely approximated a scenario in which the procedure involved the entire abdomen, in some operations the included area may be smaller, hence the surgeon may have a better idea as to where the needle may be located. In addition, because only 1 size needle, 11 mm, was evaluated, it is likely that the dual coating provides less obvious efficacy for larger needles and greater efficacy for smaller needles as overall larger needles are easier typically to find without adjuncts. Third, the time to locate the needle was capped at 5 minutes, and some of the needles that were not able to be located in the control setting may have been found by the surgeon if given an extended time period. Fourth, this preliminary data only evaluates the efficacy of this technology in the abdomen.

The initial in vivo data described here support that a dual coating consisting of UV fluorescent markers that are visible with UV and NIR light allows for needles to be consistently and quickly retrieved safely in an open and laparoscopic abdominal surgical setting. While this study was performed in an in vivo manner, further studies are required to validate that these results can be translated to the operating room and what the associated costs will be. Given the alternatives, the promising results, and the cost of RFOs, our data supports strongly that this dual-dye could lead to a relevant decrease in the immediate and long-term consequences of needle miscounts and help make progress toward the national goal of RFOs becoming "never events."

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Supplementary data

Supplementary data related to this article can be found online at https://doi.org/10.1016/j.surg.2017.10.025.

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