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


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 fluorescent and with NIR excitation, the ICG dye emits radiation observable with specialized near infrared capable laparoscopes. To evaluate the coatings, open and laparoscopic 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 2-3x 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. Existing 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. 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. 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.

The mainstay of preventing RFOs relies on surgical staff counting all sponges, instruments, and needles once before incision, and twice after closure. Unfortunately, counting is prone to errors and recent studies show that counting is only 77% sensitive and 99% specific. 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. 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. While x-rays are used commonly as a backup for counting errors, studies show that x-ray images are neither particularly specific nor sensitive
intraoperatively, and they are particularly poor for location of
eedles.\textsuperscript{10-12,21-23} Additional technologies have been developed to opti-
mize locating lost sponges, including radiofrequency identification
\textbf{(RFID)} of sponges and barcoding systems \textbf{(BCS)}. While both have
been shown to be effective at decreasing retained sponges, neither
of these methods have been proven to be particularly flawed for
preventing needles as \textbf{RFOs}.\textsuperscript{13,15,20}

Current understanding of the clinical consequences of \textbf{RFOs} relies
primarily on case reports and retrospective reviews and suggest
the consequences can be severe. Currently there is a paucity of knowl-
dge as to the long-term implications of retained needles, although
case reports suggest that larger needles can have immediate consequences because many sur-
geons will convert to an open procedure to maximize the probability
of finding the lost needle.\textsuperscript{13,15}

Because \textbf{RFOs} are preventable and should be considered a re-
portable “never event” by the National Quality Forum, a new
\textbf{RFID} was developed to minimize the risk of miscounted
needles and to prevent needles as being overlooked and thus con-
sidered as an \textbf{RFID} in both open and laparoscopic settings. A new
\textbf{RFID} was needed, because \textbf{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 \textbf{(MIS)} approach with the aid of spe-
cialized fluorescent laparoscopes.

\textbf{Methods}

\textbf{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 sharp-
ness 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 vas-
culature tissue and imaging the defects created in the tissue with
an 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,
iluminated with a 980 nm NIR light source emits NIR light with a
wavelength greater than 1,000 nm. An additional fluorescent
dye was developed to evaluate if the color of the flu-
orescent needle influences recognition retrieval time in an open
setting. Under a black light, rubrene emits orange fluorescence with
a wavelength near 650 nm. To enhance the binding of the film with
the surface of needle, the needles were pretreated with N\textsuperscript{4}-
(trimethoxyisilylpropyl) diethylenetriamine (DETA) by dipping needles
into 10% DETA methanol solution for 4 h before drying at room tem-
perature 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 ad-
herence of the dye to the needle were performed. Needles were
passed through tissue up to 20 times to evaluate for any disrup-
tion 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.

\textbf{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 thoracoto-
 mies. 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 man-
dated all female rabbits.

\textbf{Searching protocol}

To evaluate the effectiveness of the coating in a clinical setting,
2 separate Institutional Animal Care and Use Committees ap-
proved 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 physi-
cian. 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 re-
corded. The surgeon searched for 26 needles with standard light
as controls and for 26 with the use of a black light. Time to loca-
tion of the needle by the surgeon was recorded. To simulate a
laparoscopic setting, a standard laparoscopic tower and equip-
ment 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, Striker,
Kalamazoo, MI). A total of 52 needles were searched for in a lapa-
roscopic 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 fluorescense, as appro-
riate. The open protocol was also repeated with the orange fluores-
cent, rubrene-coated needles to assess for time variance secondary to color.

\textbf{Statistics}

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

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. 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. 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.

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%
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 fluorescent 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.\cite{3,10-12,22,23,25,26} 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.\cite{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 lose 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 difficulty in manipulating tissues with the instruments makes finding a needle in a laparoscopic setting particularly challenging.\cite{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.\cite{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.\cite{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.\cite{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.\cite{16,9,15,26} 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.\cite{15,26} 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. |

<table>
<thead>
<tr>
<th>Percent not located within 300 s*</th>
<th>Max time (s)</th>
<th>Mean time (s)</th>
<th>Mean time to locate lost control needles (s)</th>
<th>Total time searched (min, % control)</th>
<th>P value (compared to controls)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Open surgery</strong></td>
<td></td>
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</tr>
<tr>
<td>Control (n = 26)</td>
<td>35%</td>
<td>300*</td>
<td>149 ± 116 (n = 9)</td>
<td>64.68 (100%)</td>
<td>—</td>
</tr>
<tr>
<td>Black light assisted (green) (n = 26)</td>
<td>0%</td>
<td>165</td>
<td>53 ± 47 (n = 9)</td>
<td>23.18 (36%)</td>
<td>.0027</td>
</tr>
<tr>
<td>Black light assisted (orange) (n = 26)</td>
<td>4%</td>
<td>300*</td>
<td>43 ± 60 (n = 9)</td>
<td>18.75 (28%)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td><strong>Laparoscopic</strong></td>
<td></td>
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</tr>
<tr>
<td>Control (n = 26)</td>
<td>35%</td>
<td>300*</td>
<td>164 ± 116 (n = 9)</td>
<td>71.38 (100%)</td>
<td>—</td>
</tr>
<tr>
<td>ICG assisted (n = 26)</td>
<td>0%</td>
<td>118</td>
<td>44 ± 29 (n = 9)</td>
<td>19.03 (26%)</td>
<td>.0001</td>
</tr>
</tbody>
</table>

* 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.
average $932 case in OR time alone.3,3 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.14,18 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 alternative 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

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