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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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