

Development of a handheld wireless device for fluorescence imaging

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Minimally invasive platforms with built-in fluorescence imaging systems have facilitated the widespread implementation of fluorescence guided surgery. The use of fluorescent dyes, such as indocyanine green, have a wide range of applications in gynecologic oncology and have improved the accuracy of lymphatic mapping and identification of sentinel lymph nodes. However, near infrared imaging systems for open surgeries lack portability and mobility due to size and connections of cables and/or mechanical arms between the handheld component and the image processor/monitor, or even because of the need for a connection to the electric power supply.

Given that current guidelines for the management of early stage cervical cancer recommend the open abdominal approach and the aforementioned issues for the fluorescence imaging systems currently available on the market, we conceptualized our homemade device, Easy Light, as a low cost user friendly system for targeted procedures in open surgeries. In brief, this device is an open field handheld wireless fluorescence imaging system for real time visualization of fluorescence in smartphones and tablets that are accessible to many health professionals. The handheld system is a rechargeable device responsible for excitation of the operative field with infrared lighting and for capturing the fluorescence emitted by fluorescent dye, visualized via wi-fi on smartphones and tablets using pre-installed application software (ie, mobile app) (Figure 1).

We next focused our efforts on developing a handheld prototype that could avoid physical connections. Electric and electronic parts were acquired from online markets and assembled into a pistol shaped case. Near infrared excitation was provided with high power light emitting diodes with a lens arranged in a circular way around a wi-fi micro-camera equipped with optical filters. A rechargeable battery was also added to allow up to 6 hours of continuous use. Proof of concept tests were first developed as preclinical experiments,

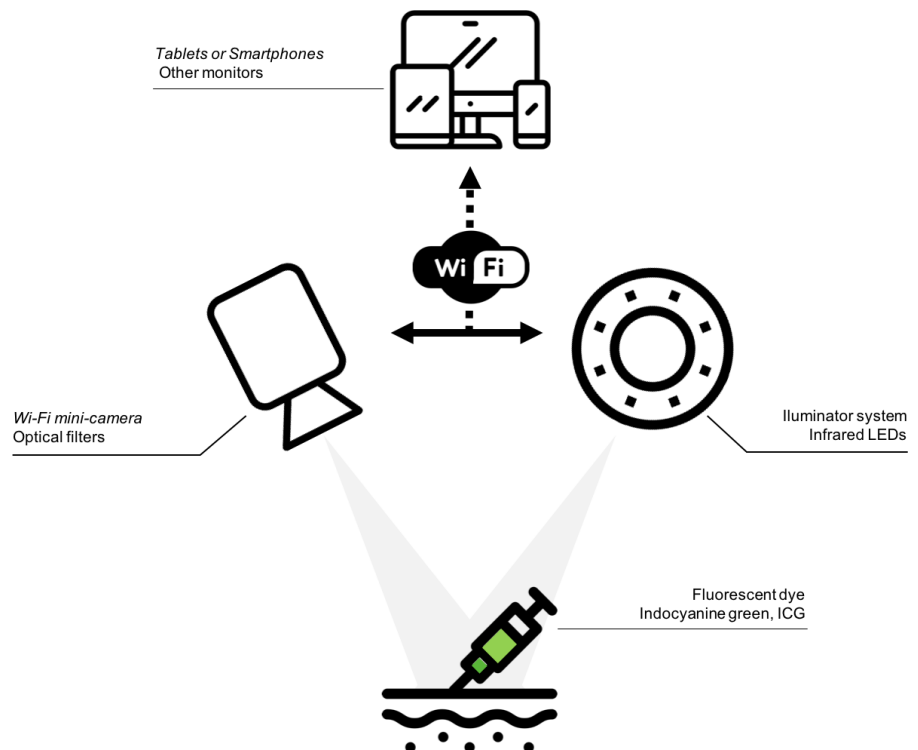


Figure 1 Overview of electronic components and functionality of the homemade handheld wireless device for fluorescence imaging, Easy Light. For the proof of concept tests, we used the mobile app BXCAM (BXCAM Inc, V.1.0.1, 2020) for real time visualization of the fluorescence images in an iOS based smartphone (ie, iPhone X, 256 GB). For the commercial version of our device, a specific application software will be available for both iOS and Android based smartphones and tablets. LEDs, light emitting diodes.

injecting an indocyanine green solution into fresh chicken wings (Figure 2). Thereafter, we performed ex vivo evaluations of fresh surgical specimens removed during robotic surgeries (online supplemental picture 1). Finally, we also developed an early feasibility study (NCT05004623) to evaluate the functionality of our device in a clinical setting, and also to guide future adjustments and improvements. Intraoperative detection of at least one sentinel lymph node was achievable in all five patients recruited to participate (online supplemental video 1), with bilateral detection in two patients (Figure 3).

We consider that it is important to report this innovative device that may help to disseminate the use of fluorescence lighting for targeted procedures in medicine. At this point, we have already filed a patent in Brazil (BR 10 2021 014051 8) and we are adding improvements to our prototype to initiate a manufacturing process. Finally, we hope our approach may serve as motivation to increase the involvement of surgeons in the process of producing surgical innovations and medical devices.

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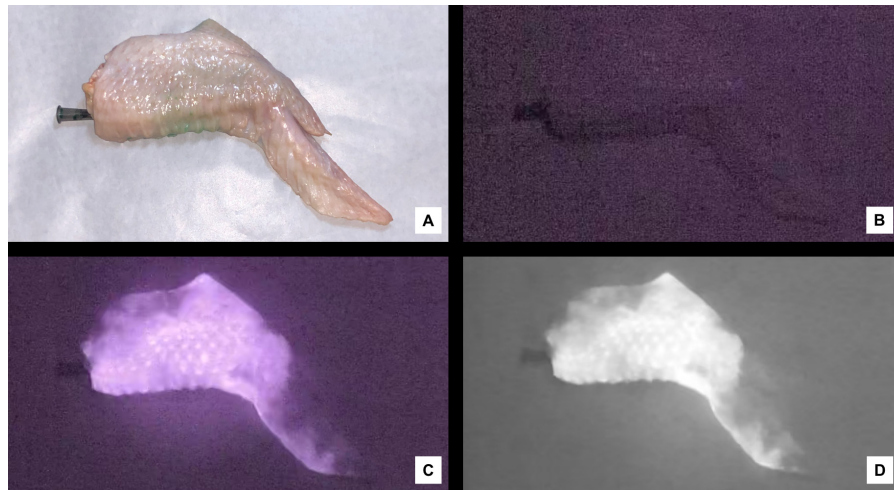


Figure 2 Preclinical tests for visualization of indocyanine green fluorescence in fresh chicken wings. For this experiment, we injected 0.3 mL of a 1.25 mg/mL indocyanine green solution into the root of fresh chicken wings, and then real time images were collected from a distance of 20 cm using a prototype of our device. (A–D) A fresh chicken wing and the corresponding real time visualizations using our device. (B) Near infrared lighting is turned off, whereas (C) and (D) show detection of the fluorescent dye using the original 'color' and 'black and white' modes of the micro-camera, respectively.

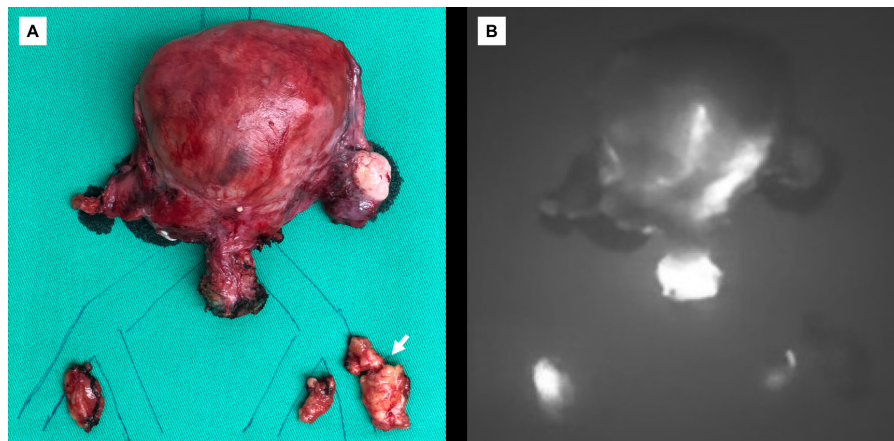


Figure 3 Ex vivo examinations of fresh surgical specimens from patients who underwent open surgical staging for endometrial cancer in our early feasibility study. In this case, the standards of near infrared fluorescence imaging for detection of sentinel lymph in gynecologic malignancies were applied by injecting deeply and superficially 2 mL of a 1.25 mg/mL indocyanine green solution at both sides of the cervix (total dose 5 mg) just before starting the surgical procedure. (A, B) Fresh uterine specimen with the sentinel pelvic lymph nodes, in the same patient, with the corresponding real time visualization of the fluorescent dye using our device. In the left hemipelvis, enlarged lymph nodes (arrow in A) were also removed at the surgeon's discretion as non-sentinel nodes (no fluorescence in the real time examination) because of their clinical appearance suggesting spread of the disease. The final pathological processing confirmed no lymphatic metastasis in all nodes in this particular case.

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