


Development of a handheld wireless device for fluorescence imaging

Thales Paulo Batista , Recife, Brazil, Recife, Brazil; Anderson Stevens Leônidas Gomes , Recife, Brazil and Avishek Das , Recife, Brazil

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,

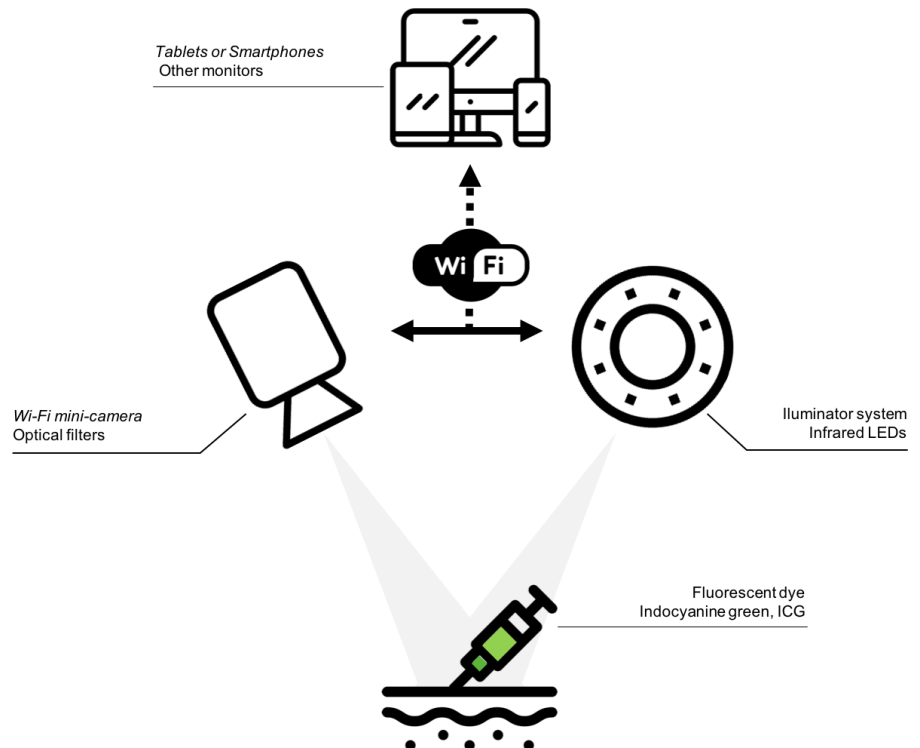


Figure 1 Overview of electronic components and functionality of the homemade handheld wireless device for fluorescence imaging, Easy Light. For the proof of concept tests, we used the mobile app BXCAM (BXCAM Inc, V.1.0.1, 2020) for real time visualization of the fluorescence images in an iOS based smartphone (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.

Correspondence to Dr Thales Paulo Batista, Surgery/Oncology, Instituto de Medicina Integral Professor Fernando Figueira, Recife, Pernambuco, 50070-902, Brazil; t.paulo@outlook.com

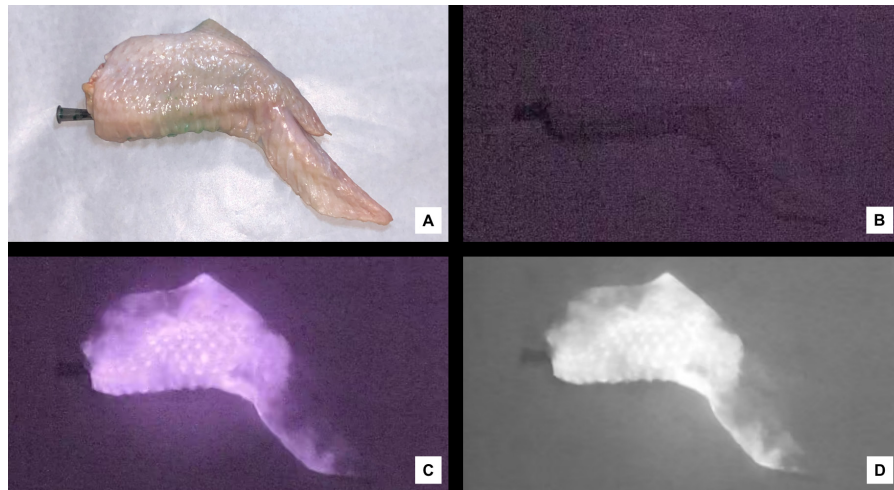


Figure 2 Preclinical tests for visualization of indocyanine green fluorescence in fresh chicken wings. For this experiment, we injected 0.3 mL of a 1.25 mg/mL indocyanine green solution into the root of fresh chicken wings, and then real time images were collected from a distance of 20 cm using a prototype 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.

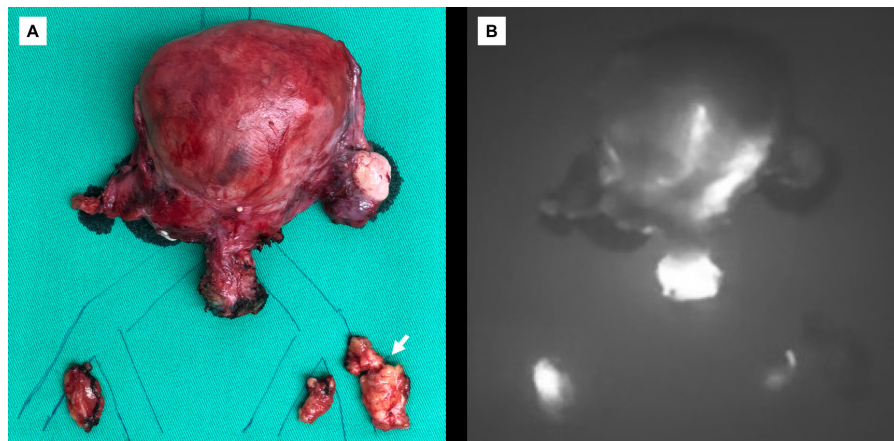


Figure 3 Ex vivo examinations of fresh surgical specimens from patients who underwent open surgical staging for endometrial cancer in our early feasibility study. In this case, the standards of near infrared fluorescence imaging for detection of sentinel lymph in gynecologic malignancies were applied 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.

Twitter Thales Paulo Batista @BatistaTP

Acknowledgements We acknowledge Professor Francisco de AC Barbosa for providing us with the first bottles of indocyanine green that allowed us to start our initial experiments, and Professor Romulo AV Silva for designing an initial pistol shaped case

for our device. We also thank Dr Mário R Martins for supporting us during the ex vivo examinations of the fresh surgical specimens removed via minimally invasive robotic surgery, and Dr Vandrê CG Carneiro and Dr Diógenes FS Fontão for helping us with patient recruitment during our early feasibility study. Thanks also to residents in general surgery from the Instituto

de Medicina Integral Professor Fernando Figueira for helping us with data collection.

Contributors Study concept and design: all authors, mainly TPB. Device physical set-up and optoelectronics tests: AD. Acquisition of the data: all authors, mainly TPB. Analysis and interpretation of the data: TPB. Drafting of the manuscript: TPB. Critical revision of the manuscript for important intellectual content: ASLG and AD. Administrative support: TPB. Material support: all authors, mainly TPB. Study supervision: TPB and ASLG.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial, or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval The study protocol was reviewed by the Ethics Research Committee of IMIP-Instituto de Medicina Integral Professor Fernando Figueira (Reference No CAAE 45814621.5.0000.5201, acceptance protocol No 4.735.768; May 26, 2021) and registered on ClinicalTrials.gov (NCT05004623).

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

© IGCS and ESGO 2021. No commercial re-use. See rights and permissions. Published by BMJ.

► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/ijgc-2021-003150>).

Some data from this study were presented as an oral presentation during the XV Congress of the Brazilian Society of Surgical Oncology (virtual meeting, November 17-20, 2021).



To cite Batista TP, Gomes ASL, Das A. *Int J Gynecol Cancer* Published Online First: [please include Day Month Year]. doi:10.1136/ijgc-2021-003150

Accepted 17 November 2021
Int J Gynecol Cancer 2021;0:1–2.
doi:10.1136/ijgc-2021-003150

ORCID iDs

Thales Paulo Batista <http://orcid.org/0000-0001-5320-3205>
Anderson Stevens Leônidas Gomes <http://orcid.org/0000-0001-6536-6570>
Avishek Das <http://orcid.org/0000-0002-9250-8287>