OBSTETRICS & GYNECOLOGY

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Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: Nov 13, 2020
To: "Halis Kaan Akturk" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-2869

RE: Manuscript Number ONG-20-2869

A Novel and Easy Method to Locate Hormone-Releasing Contraceptive Implants Using Near-Infrared Light

Dear Dr. Akturk:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Dec 04, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Overall I think this is a clever idea for locating non-palpable contraceptive implants however I have several major concerns with the study. This case series should contain more information about the patients involved beyond what is listed. For example, what were the BMIs of these patients? Were there significant weight changes between when the Nexplanon was inserted and when it was removed as this could change the difficulty and length of the procedure. I also think the paper could benefit from more description about what happens after the Nexplanon is located. It is located so that a provider can remove it. Description about how this imaging can or cannot help with the removal is very important to discuss. For example, I would love to know if the light was ever turned back on to help with the removal. Was ultrasound used if needed during the removal process or did the patients never receive an ultrasound? Ultrasound is not just used to identify where the contraceptive implant is but it can also help guide practitioners with removal. It tells them about depth of device and proximity of the device to other structures. Without commenting further on if/ how the near-infrared light was used for removal, the utility of this imaging technique is limited. Therefore more information on whether or not this method assists with both tasks would be helpful. After it is identified, how did the providers go about removing the Nexplanon devices? What is their standard technique and did this help them? There is no information about exactly how long the removal procedures took. Ultimate it would be good to know if the device helps shorten removal time of the non-palpable implants. It would also be great to have a description of provider satisfaction with the imaging device. Were there any complications with removal given that standard of care was not used? To answer many of the above questions, you could either make your case series more comprehensive with details, or, I would recommend considering an alternative study design to compare your procedure to the standard of care.

I also have concerns about protections for these patients/research subjects. Given that this deviates from the standard of care, were ultrasounds performed on these patients first? There is no mention about patient protections other than "all patients gave written consent for medical photography and the procedure". This does not discuss if the patients were aware that this is not standard of care and more description about the details of this consent process are needed. Should near-infrared imaging improperly locate the devices, it could have placed the patients at risk for additional incisions and procedures. It needs to be clear in the text that the patients were aware of the experimental nature of this imaging.

I have several smaller suggestions for the paper. The wording in lines 77-78 is unclear. Did the contraceptive implant migrate 3cm? If so, in what direction? Your use of the term "in seconds" is unclear. Any amount of time can be measured in seconds. A year can be measured in seconds. Actually quantifying the amount of time from when the light is turned on to identification of the device would be more exact. It seems more appropriate to move the information from lines 81 to 85 where you described your previous study on using near-infrared light to locate implanted glucose sensors to the introduction to inform the reader that there is precedent for this imaging technique. Additionally, in your discussion you mention the use of near-infrared to avoid blood vessels and the possible risks of complications from non-palpable implant removals. If you are going to include this in the discussion, I would mention if any of the patients in your case series

experienced any complications with their removals to place this discussion into context. In the discussion, you should also include the limitation that this imaging modality does not provide information on depth of the implant or location of any other non-superficial structures.

Lastly, there are several typos in this article. Line 99 should read "it is used by turning on" not "it is used with turning on". Line 100 should say "implants are visualized in seconds" not "implants are visual in seconds".

Reviewer #2: Nexplanon removal can be challenging in some women, especially if it was placed deep, has migrated, or patient has gained weight. Ability to locate the nexplanon can prevent complications associated with removal.

Since ultrasound needs training & can be expensive, finding alternate modality can be helpful.

Authors should be commended for this study and the innovative idea. Ability of the infrared light to locate nexplanon within 5sec is very impressive finding. If proven in Larger cohort, this technique can help providers in many ways.

However, major limiting factor of this study is its sample size. This manuscript is better suited as a case series
Did these patients also have radiological data for comparison

-any potential side effects of infrared rays that authors encountered?

Reviewer #3: This is a description of using near-infrared light to locate contraceptive implants for removal.

1. Abstract Background: Instead of "preferable" would say "highly effective option". Would say "In a minority of cases, the implants cannot be located..."

2. Abstract Method: I don't understand what you mean by "perpendicularly with 33 cm to the possible implant location". Do you mean perpendicular to the implant location and hold the device 33 cm away from the arm? This is confusing.

3. Abstract Experience: This states 5 women but the manuscript states 4 women.

4. Introduction: Line 45: Change to "The etonogestrel implant is highly effective in preventing pregnancy". Then whenever you say "implants", change to "the etonogestrel implant" e.g the etonogestrel implant is a single flexible rod 4 cm long and 2 mm in diameter.

5. Introduction: Line 48: change to a "minority of implants cannot be located easily".

6. Introduction: Line 51, would not use reference 6 as the migration into the pulmonary vasculature had nothing to do with a removal procedure but happened beforehand.

7. Method: Line 66, again I don't understand the 33 cm direction, please clarify.

8. Experience: Don't use Nexplanon, use etonogestrel implant.

9. Figures: Please clarify if this is the same patient with different waves and what waves you recommend. Should the implant be a shadow or a white line? Please explain more in Method how to use the device and what settings are recommended.

10. Discussion: Line 90, please rewrite the sentence starting with "However", to be more clear. Is ultrasound really not used in family medicine clinics? I don't think you can say that.

11. Discussion: Line 92. How is it not known how near-infrared light locates implants?? Wouldn't it be related to light reflecting back?

12. Discussion: Need to discuss how people are going to access the vein finder. Our anesthesia department has one in the preop area but most physicians do not have this in their office. What is the cost of this device, how do you recommend providers access it?

13. Discussion: Is there evidence that vein finders only work in people with white skin? There must be studies on this that you could add here.

EDITOR COMMENTS:

1. Please if possible in your revision expand a little on the nature of the consent process.

2. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

4. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." *The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

5. Your manuscript states that all 4 women were White. Could you comment on whether this would work on women of color, who could have darker skin tones.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Procedures and Instruments articles should not exceed 8 typed, double-spaced pages (2,000 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

8. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

9. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

10. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Procedures and Instruments is 200 words. Please provide a word count.

11. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com /ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

12. The commercial name (with the generic name in parentheses) may be used once in the body of the manuscript. Use the generic name at each mention thereafter. Commercial names should not be used in the title, précis, or abstract.

13. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top).

14. Figures 1-3: Please renumber these figures as 1A, 1B, and 1C and update the legend to describe the difference between each. Are better versions of these images available?

15. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at https://wkauthorservices.editage.com/open-access/hybrid.html.

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16. If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Dec 04, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD, MSPH

2019 IMPACT FACTOR: 5.524
2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals
