

OBSTETRICS & GYNECOLOGY



NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

**The corresponding author has opted to make this information publicly available.*

Personal or nonessential information may be redacted at the editor's discretion.

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

Date: May 07, 2019
To: "Melissa C. Matulich" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-636

RE: Manuscript Number ONG-19-636

Referral Center Experience with Non-palpable Contraceptive Implant Removals

Dear Dr. Matulich:

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 May 28, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: In this descriptive retrospective study, authors presented clinical-demographic data and outcomes on 50 patients that had non-palpable etonogestrel implant removal performed in the office by a team of family planning specialists.

1. Précis; Authors statement " women with non-palpable contraceptive implants should be referred to specialty center" is not demonstrably supported by the data presented. This was not a comparative analyses of their outcomes and referral sources, rather, a presentation of their experience with non-palpable implants.
2. Abstract can be better articulated; lines 58-60 is unnecessary in the abstract section and lines 64-66 is confusing.
3. Introduction; please provide citation for line 90
4. Materials and Methods; Are the 3 patients reported by authors in a previous (2015 Obstet Gynecol) publication included in this cohort?
 - a. More than half of the patients in this cohort had at least 1 attempt at removal by referring providers (some of whom may have experienced difficult procedures) and 1 in 5 had "neuropathic pain" post operatively. How did authors systematically document pain and sensory & motor evaluation of the upper extremities before attempting a second or third procedure in these patients?
 - b. Further, with incisions less than 5mm, how did authors systematically avoid nerve injuries especially in the patients that had subfascial implant location? Was the US done during the procedures?- if not, the risk for damaging medial antebrachial cutaneous nerve or the median/ulnar nerve would seem substantial. Often, these implants are encased in fibrous sheaths that can make them indistinguishable from nerve bundles. Were any electrodiagnostic tests conducted and if not, why?
 - c. How did authors evaluate for nerve injury post operatively? When did patients return for post op evaluation and for how long were they evaluated? What exactly was "limited" neuropathic pain?
 - d. How many family planning specialists participated in the removal and what is their average number of past removals?
5. Results; Authors may just wish to present their data according to the flow diagram. It will make it easier for readers to follow. Table 2 seems overdone and superfluous; if authors are making the point that thinner women and those with a previous use of incision were more likely to have a subfascial location of implant- just say so.

- a. Why were patients referred for implant removal counseled not remove them? (lines 142-144)
- b. Lines 149-154 is confusing as written and may not be necessary.
6. Discussion; are there any particular strengths and limitations of your study?
7. Table 1; data on prior attempts at removal is worth including in the abstract . Table 2 can be eliminated.

Reviewer #2: This is a well written manuscript about a very timely and important clinical topic.

It would have improved the manuscript to show the arm marking and US images, perhaps along with the small incision so that the reader would have a better chance of implementing difficult removals in their own clinics.

Reviewer #3: SUMMARY

This study is a retrospective case series describing patient characteristics and outcomes when referred for removal of non-palpable contraceptive implants.

PRECIS

I'm not sure the data presented here actually support the Precis as currently written, seems more of a presumption. The data would support a Precis statement like, "For patients with non-palpable contraceptive implants, high proportion of successful localization and in-office removal can occur at a referral specialty center."

ABSTRACT

1-- Objective should really be targeted at the primary outcome. Suggest changing to: To describe proportion of successful in-office removals for patients referred with non-palpable contraceptive implants.

2-- Suggest replacement of "women" with "patients" throughout the abstract and manuscripts

3-- Please describe what limited means in line 64 (remitted prior to leaving clinic? This is not clear).

4-- Suggest statistical analysis of the primary outcome (proportion of successful removals) based on non-palpable implant suprafascial v. subfascial location (see comments in Results)

5-- How many non-palpable suprafascial implants had been inserted during removal-reinsertion procedure? Suggest statistical analysis of this secondary outcome as well (comments in Discussion section).

6-- The results section is very wordy. Please try to simplify.

INTRODUCTION

7. Line 78: replace with "triceps muscle, with the intent to minimize neurovascular injuries...."

8. Line 98: change "We feel this information" to "This information"

9. Lines 97-100:

MATERIALS & METHODS

10. Lines ost-procedure neuropathic pain complaints were mentioned in the abstract, is this also a secondary outcome?

RESULTS

11. Suggest analysis of the primary outcome (proportion of successful office removals by implant location as below). P value for the Fischer's exact for this 2x2 table is 0.11 suggesting no difference in removal success by location at this referral specialty center.

	Removal Y	Removal N
Subfascial Y	19	4
Subfascial N	21	0
	40	4

12. Line 146: please describe what "limited" post procedure neuropathic pain is... is limited 5 minutes, 30 minutes, 3 days,

4 weeks? The presumption in reading this is prior to leaving clinic. Did all pain subside by clinic discharge? If no, do you have any subsequent follow up data for the patients who reported neuropathic pain regarding total duration?

13. Line 149: Stated as "Table 2" but titled "Table 1" in Figures section.

DISCUSSION

14. Suggest more natural flow of results would be current paragraph 3 (Lines 170-176) following current paragraph 1 (Lines 157-162).

15. Line 171: Delete the sentence "Providers without advanced..."

16. Lines 172-174: what proportion of non-palpable suprafascial implants had been removed and reinserted?

17. Reasonable to calculate Fischer's exact test here to start to examine the biological plausibility you mention in line 174.

Removal reinsert Y Removal reinsert N
Subfascial Y 7 18 25
Subfascial N ?? ?? 22 (23 if you include the intrafascial one as well)

18. Suggest deleting current paragraph 4 (Lines 177-189). Could retain sentence that begins, "We have found new 15 and 18 MHz transducers..." and add it after the first sentence of current paragraph 5.

19. Line 199: "location of such a center is unknown, pharmaceutical company representatives should be contacted..."

STATISTICAL EDITOR'S COMMENTS:

1. lines 63-65: Should use Fisher's test for comparison, the exact p-value = .048, not .0002'

2. lines 65-66: Should use Fisher's test, the exact p-value = .0002, not .0001.

3. Table 1: Since the entire sample was N = 55, should round the % to nearest integer, cannot cite precision to nearest .1% from these data. Were age, BMI and distance traveled all normally distributed (line 134)? If not, should cite as median (IQR or range), rather than as mean \pm SD.

4. Table 2: If BMI not normally distributed, then should cite as median (IQR or range) and test non-parametrically. Since average BMI were significantly different, suggest testing proportions in each BMI stratum, as well (except for overweight category, they each are significantly different).

5. General: The subsets have modest counts, esp for adverse outcomes, so Fisher's test should be used. Also, citing proportions of events should include more CIs to put the results in context. Also, do the results necessarily support the conclusion of referral to a specialty center? There is no data re: use of ultrasound for guidance prior to referral.

6. lines 112-116 and 184-186: Why would not U/S guidance in the clinic or radiology suite at the time of removal be the preferred approach?

EDITORIAL OFFICE COMMENTS:

1. 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, as well as subsequent author queries. 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:

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. 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.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

3. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

4. 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 and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 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.

6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

- * All financial support of the study must be acknowledged.
- * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- * If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

7. 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."

8. 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 limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

9. 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.

10. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

11. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

12. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

13. 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 <http://edmgr.ovid.com/acd/accounts/ifaauth.htm>.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at <http://ong.editorialmanager.com>. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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 May 28, 2019, we will assume you wish to withdraw the manuscript from further consideration.


Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>) Please contact the publication office if you have any questions.



June 10, 2019

Editor
Obstetrics and Gynecology
409 12th Street, SW
Washington, DC 20024-2188

RE: Manuscript Number ONG-19-636

To the Editor,

Enclosed are the responses to the reviewers' and editors' comments for the manuscript titled "Referral Center Experience with Non-palpable Contraceptive Implant Removals". The comments were very constructive and thoughtful, and we are appreciative of the time they took to help improve this manuscript.

All authors have contributed to this revised manuscript and agree on this submitted version. The comments are addressed as outlined below. The manuscript is submitted with changes marked as well as a clean version; the line numbers refer to the clean version.

Thank you for your further consideration of our manuscript.

Sincerely,



Melissa C. Matulich, MD
Family Planning Fellow
University of California, Davis

REVIEWER COMMENTS:

Reviewer #1:

1. Précis; Authors statement "women with non-palpable contraceptive implants should be referred to specialty center" is not demonstrably supported by the data presented. This was not a comparative analyses of their outcomes and referral sources, rather, a presentation of their experience with non-palpable implants.

RESPONSE: We appreciate this observation and have changed the Précis to better reflect the manuscript's message.

Précis Lines 43-44:

Old text: Women with non-palpable contraceptive implants desiring removal should be referred to a specialty center.

New text: At a specialty referral center, non-palpable suprafascial implants and most subfascial implants can be removed in the office after ultrasound localization.

2. Abstract can be better articulated.

a) Lines 58-60 are unnecessary in the abstract section.

RESPONSE: If this information is removed, patient numbers do not add up in the Results section. Accordingly, we have changed the abstract to be more concise while also maintaining internal consistency.

Abstract Lines 57-60:

Old text: Non-palpable implants were suprafascial (n=22), subfascial (n=25) and intrafascial (n=1).

One patient with a suprafascial implant and the patient with an intrafascial implant chose to continue use; two patients with subfascial implants opted to delay removal. In the office, we successfully completed attempted removal of all palpable (n=6), all non-palpable suprafascial (n=21), and 19/23 (83%) subfascial implants.

New text: Non-palpable implants were suprafascial (n=22), subfascial (n=25) and intrafascial (n=1); four of these patients opted to delay removal. Of 50 attempted office removals, all palpable (n=6), all non-palpable suprafascial (n=21 [100%, 95% CI 83-100%]), and 19/23 (83%, 95% CI 67-98%) subfascial implants were successful.

b) Lines 64-66 are confusing.

RESPONSE: In an effort to better articulate these observations, we have restructured the sentences that are confusing and adjusted the order that these findings appear in the abstract. Also, the p-values have been adjusted using Fisher's exact tests.

Abstract Lines 63-67:

Old text: Patients had limited post-procedure neuropathic pain complaints after 7/23 (30%) subfascial implant removals and 1/21 (5%) suprafascial implant removal (P=.0002). Non-palpable implants were subfascial in 1/13 (8%) obese and 24/34 (71%) non-obese women (P=.0001). Seven (28%) of the 25 subfascially located implants had been inserted during a removal-reinsertion procedure through the same incision.

New text: Transient post-procedure neuropathic complaints were noted in 7/23 (30%, 95% CI 12-49%) subfascial and 1/21 (5%, 95% CI 0-13%) suprafascial removals (P=.048). Non-palpable implants were more likely to be subfascial in non-obese (24/34, 71%) as compared to obese (1/13, 8%)

patients (P=.0002). Seven (28%) of the 25 subfascially located implants had been inserted during a removal-reinsertion procedure through the same incision.

3. Introduction; please provide citation for line 90.

RESPONSE: Such centers have been in place in the UK for more than a decade. We did not originally reference this information because we felt it was factual, however in response to the reviewer's comment, we have amended the text and added a reference.

Old text: In the United Kingdom, the Faculty of Sexual and Reproductive Healthcare have established a formal network of expert removal centers; however, only in the past few years has a similar specialty removal network been developed in the United States.

*New text: In the United Kingdom, the Faculty of Sexual and Reproductive Healthcare have established a formal network of expert removal centers **more than a decade ago**¹⁷; however, only in the past few years has a similar specialty removal network been developed in the United States.*

New reference: 17. Mansour D. UK provision for removal of non-palpable contraceptive implants. J Fam Plann Reprod Health Care 2009;35(1):3-4

4. Materials and Methods; Are the 3 patients reported by authors in a previous (2015 Obstet Gynecol) publication included in this cohort?

RESPONSE: Yes, these three patients are included in this larger analysis. For clarity we have added this information in lines 105-106.

*New Materials and Methods text: **The first three patients in this series have been previously reported.**⁶*

5. More than half of the patients in this cohort had at least 1 attempt at removal by referring providers (some of whom may have experienced difficult procedures) and 1 in 5 had "neuropathic pain" post operatively. How did authors systematically document pain and sensory & motor evaluation of the upper extremities before attempting a second or third procedure in these patients?

RESPONSE: All patients were interviewed for history of removal attempt(s) including what procedure had been attempted and any ongoing issues. The neuropathic symptoms we report in this paper are new symptoms that started after our procedure. Only eight patients admitted to self-limited or "transient" neuropathic symptoms (mostly tingling or mild numbness) after our procedure and none of them had pre-procedure neuropathic complaints. Of note, one patient presented to our referral center with complaints of severe neuropathic symptoms and had extreme pain during ultrasound localization of her implant; decision to delay her implant removal procedure until further evaluation and collaboration with our orthopedic surgeon was made. Unfortunately, this procedure was not authorized by the patient's insurance and patient sought care elsewhere; this information was originally reflected in Figure 1 (referral flowsheet), now Figure 2 in new version of manuscript. The eight patients with neuropathic complaints after our implant removal attempt included complaints that either resolved before leaving clinic that day (n=1), within 24 hours (n=1), within 1 week (n=3), within 1 month (n=1), within 4 months (n=1) or within 6 months (n=1). Some of these complaints were identified immediately post-procedure and follow-up phone calls were made by our Family Planning team to ensure improvement and ultimate resolution, while other complaints were reported within one week of the procedure via a patient call to our clinic. At the time of initial identification of the post-procedure complaint, reassurance was provided and once improvement was documented, our team would recommend further contact and evaluation only if symptoms did not resolve completely within the next several weeks. For clarification, we have added this information to the Materials and Methods section of

the manuscript to better explain our process. Information regarding specifics of the neuropathic complaints and their resolution was added to the Results section.

Materials and Methods Lines 112-114:

Old text: For a typical appointment, the patient first meets with the specialist who assesses if the implant is palpable.

New text: For a typical appointment, the patient first meets with the specialists who assess reasons for removal, ongoing symptoms or problems related to any prior removal attempts, and if the implant is palpable.

Materials and Methods Lines 133-134:

New text: We arranged follow-up by phone or in the office for women that had post-procedure complaints until resolution or a diagnosis was made.

Results Lines 156-160:

Old text: Limited post-procedure neuropathic pain was reported after 7/23 (30%) subfascial and 1/21 (5%) suprafascial removals (P=.0002).

New text: Transient post-procedure neuropathic complaints were noted in 7/23 (30%, 95% CI 12-49%) of the subfascial implant removals and 1/21 (5%, 95% CI 0-13%) of the suprafascial implant removals (P=.048). Neuropathic complaints included mild tingling of fingers or numbness in ulnar distribution of arm. These complaints all spontaneously resolved within 6 months with the majority (6/8, 75%) resolving within one month.

6. Further, with incisions less than 5mm, how did authors systematically avoid nerve injuries especially in the patients that had subfascial implant location? Was the US done during the procedures? - if not, the risk for damaging medial antebrachial cutaneous nerve or the median/ulnar nerve would seem substantial. Often, these implants are encased in fibrous sheaths that can make them indistinguishable from nerve bundles. Were any electrodiagnostic tests conducted and if not, why?

RESPONSE: Thank you for the comment. However, in our experience, the Implanon/Nexplanon is rarely encased in a significant fibrous sheath as was encountered with Norplant. The implant is round and firm as compared to a relatively flat nerve. While removing the implant, sharp instruments were only used for skin and fascial incisions. Dissection was then performed with blunt forceps or modified vasectomy clamp. At times, we did encounter the nerve, (as demonstrated through patient reported pain or tingling during dissection) and would then identify and release the nerve. Also, nerves are not completely distinguishable on ultrasound examination. Electrodiagnostic tests were not routinely conducted as they were not clinically indicated since all issues resolved spontaneously. One patient with persistent symptoms beyond 3 months had a consultation with a planned a nerve conduction study (NCS), but never presented for this examination and had spontaneous resolution of her symptoms by 6 months after the procedure. To address these points, the following additional text has been added:

Materials and Methods Lines 121-122:

New text: While removing the implant, sharp instruments are only used for skin and fascial incisions. Dissection is performed with blunt forceps or modified vasectomy clamp.

7. How did authors evaluate for nerve injury post operatively? When did patients return for post op evaluation and for how long were they evaluated? What exactly was "limited" neuropathic pain?

RESPONSE: We did not schedule routine follow up visits as is our practice for all minor procedures. We encouraged patients to call if they had any healing concerns and this is how we discovered post-procedure complaints in three of the eight patients. The other five patients noted immediate post-procedure issues, one resolved prior to leaving clinic, two were counseled to contact our office if

symptoms had not completely resolved within one week, and two had provider initiated follow up phone calls. See response #5 for full details of the patients with post-procedure neuropathic complaints. Again, for clarity, this follow up process has been added to the Materials and Methods section of the manuscript (see response #5 “new text”). “Limited” was meant to mean time-limited and therefore we have changed the word “limited” to “transient” throughout the manuscript.

Abstract Results Line 63:

Old text: Patients had limited post-procedure neuropathic pain complaints after 7/23...

*New text: **Transient** post-procedure neuropathic **complaints were noted in 7/23...***

Abstract Conclusion Line 70:

Old text: Some patients may experience limited post-procedure neuropathic pain.

*New text: Some patients may experience **transient** post-procedure neuropathic pain.*

Results Lines 156:

Old text: Limited post-procedure neuropathic pain was reported after 7/23...

*New text: **Transient** post-procedure neuropathic **complaints were noted in 7/23...***

Discussion Lines 175-177:

Old text: However, nearly one-third of these women reported post-procedure neuropathic complaints, albeit limited in duration; this information should be incorporated into pre-procedure counseling.

*New text: However, nearly one-third of these **patients** reported **transient** post-procedure neuropathic complaints, albeit limited in duration; this information should be incorporated into pre-procedure counseling.*

8. How many family planning specialists participated in the removal and what is their average number of past removals?

RESPONSE: Three Family Planning specialist attendings and four Family Planning fellows participated in the removals over the four-year time period. Most removals were performed or supervised by Dr. Creinin who has more than 25 years of experience dating back to Norplant (including removal publications related to that implant). A second attending was also one of the fellows who learned the techniques as a fellow under Dr. Creinin’s direct supervision and guidance. A third attending gained experience during her fellowship at the University of Colorado. We have added general information about the experience in training, see below.

Materials and Methods, Lines 106-108:

*New text: **All patients were seen by a Family Planning fellow supervised by a Family Planning attending with fellowship training in non-palpable implant removals.***

9. RESULTS

- a. Authors may just wish to present their data according to the flow diagram. It will make it easier for readers to follow.

RESPONSE: We have presented the text and the figure to be complimentary to each other to avoid repetition.

- b. Table 2 seems overdone and superfluous; if authors are making the point that thinner women and those with a previous use of incision were more likely to have a subfascial location of implant - just say so.

RESPONSE: Thank you for this suggestion. Table 2 has been simplified to focus on BMI. The primary reason for requesting removal was originally present in both Table 1 and Table 2, and therefore the

information for our entire referral population remains present in Table 1. The implant removal-reinsertion data was already present in the Results section of the original manuscript and is still present in new version with minor adjustments, see below.

Results Lines 165-169:

Old text: Fifteen women had used a contraceptive implant in the past, eight of whom were known to have reinsertion of the index implant through the removal incision. Seven (88%) of these eight had subfascial placement; six (86%) of these seven women had a BMI of less than 30 kg/m².

*New text: Fifteen **patients referred to our specialty referral center** had used a contraceptive implant in the past, eight of whom were known to have reinsertion of the index implant through the removal incision. **One of these implants was found to be palpable on our initial examination, while the other seven (88%) were non-palpable and subfascial. Six (86%) of the seven non-palpable subfascial implants were in patients with a BMI of less than 30 kg/m².***

Old table:

Table 2

Comparison of BMI, reinsertion and removal event and reasons for removal between suprafascial non-palpable and subfascial non-palpable implants

	Non-palpable suprafascial (n = 22)	Non-palpable subfascial (n = 25)	P-value
Body Mass Index (kg/m²)	34.0 ± 9.4	23.1 ± 3.8	<0.01
Underweight to Normal (< 25 kg/m ²)	4 (18.2%)	17 (68.0%)	
Overweight (25 kg/m ² to < 30 kg/m ²)	6 (27.3%)	7 (28.0%)	
Obese (≥ 30 kg/m ²)	12 (54.5%)	1 (4.0%)	
Current implant inserted through removal incision[†]	0 (0.0%)	7 (29.2%)	0.01
Primary reason for requesting removal			0.64
Device expiration	10 (45.5%)	7 (28.0%)	
Desires pregnancy	2 (9.1%)	5 (20.0%)	
Bleeding complaints	1 (4.5%)	3 (12.0%)	
Systemic side effects	5 (22.7%)	5 (20.0%)	
Other [‡]	4 (18.2%)	5 (20.0%)	

All data presented as n (%) and mean ± standard deviation

* Fisher's exact test used for categorical comparisons

[†] Index implant reinserted through removal incision at time of prior implant removal

[‡] Other includes pain/neuropathy, location/migration concerns, partially removed fragment, acute cellulitis

New table:

Table 2

Comparison of BMI, reinsertion and removal event and reasons for removal between suprafascial non-palpable and subfascial non-palpable implants

	Non-palpable suprafascial (n = 22)	Non-palpable subfascial (n = 25)	P-value
Body Mass Index (kg/m²)	34.0 ± 9.4	23.1 ± 3.8	<.001*
Body Mass Index Categories			<.001*
Underweight to Normal (< 25 kg/m ²)	4 (18%)	17 (68%)	

Overweight (25 kg/m ² to < 30 kg/m ²)	6 (27%)	7 (28%)	
Obese (≥ 30 kg/m ²)	12 (55%)	1 (4%)	

All data presented as n (%) and mean ± standard deviation

* Student t test used for means and Fisher's exact test used for categorical comparisons

10. Why were patients referred for implant removal counseled not to remove them? (lines 142-144)

RESPONSE: The reviewer is asking about three specific patients. We have detailed the reasons for opting to continue use of their current implant in the footer for the Figure, see below.

Old Figure 1 footer:

* Two implants initially not localized by US, identified using XR, repeat US located implants with minimal shadowing

† Subfascial implant identified with XR then localized with CT; patient ultimately lost to follow up due to insurance authorization issues

‡ Referred due to non-palpable implant with acute cellulitis immediately after insertion

§ One subfascial and one suprafascial implant required removal in US suite for direct US-guidance, while all others successfully removed with skin mapping technique in office

New footer (now Figure 2):

* Two implants initially not localized by US, identified using XR, repeat US located implants with minimal shadowing

† Three patients opted to continue use of implant; one palpable implant had one additional year of extended use; intrafascial implant continued use due to time constraints after evaluation and counseling and aware she must return to specialty center at time of desired removal; suprafascial implant referred with acute cellulitis immediately after insertion but at consultation cellulitis was resolved and implant partially palpable (ultrasound localization confirmed implant location as suprafascial)

‡ Subfascial implant identified with XR then localized with CT; patient ultimately lost to follow up due to insurance authorization issues

§ One subfascial and one suprafascial implant required removal in US suite for direct US-guidance, while all others successfully removed with skin mapping technique in office

11. Lines 149-154 is confusing as written and may not be necessary.

RESPONSE: Table 2 has been simplified and therefore this paragraph has been adjusted to reflect the new table, see comment #9b. We feel as though this paragraph is necessary to emphasize the interesting findings related to BMI and removal-reinsertion events.

Results Lines 163-169:

Old text: Table 2 compares the impact of BMI, reinsertion through removal incision and reason for removal as predictors of subfascial location. Non-palpable implants were more likely to be subfascial in non-obese (24/34, 71%) as compared to obese (1/13, 8%) women (P=.0001). Fifteen women had used a contraceptive implant in the past, eight of whom were known to have reinsertion of the index implant through the removal incision. Seven (88%) of these eight had subfascial placement; six (86%) of these seven women had a BMI of less than 30 kg/m².

New text: Table 2 compares the impact of BMI as a predictor of subfascial location. Non-palpable implants were more likely to be subfascial in non-obese (24/34, 71%) as compared to obese (1/13, 8%) patients (P=.0002). Fifteen patients referred to our specialty referral center had used a contraceptive implant in the past, eight of whom were known to have reinsertion of the index implant through the removal incision. One of these implants was palpable on our initial examination, while the other seven

(88%) were non-palpable and subfascial. Six (86%) of the seven non-palpable subfascial implants were in patients with a BMI of less than 30 kg/m².

12. DISCUSSION: are there any particular strengths and limitations of your study?

RESPONSE: These points are already incorporated into the Discussion (see lines 207-208). Strengths of our case series include the relatively large cohort and consistent set of providers and technique used for removals. Weaknesses include generalizability and the overall small numbers which did not allow for multivariable analyses.

13. Tables

a. Table 1: data on prior attempts at removal is worth including in the abstract.

RESPONSE: Although we too believe this is important information, due to word limitations, we were unable to include this data in the abstract.

b. Table 2 can be eliminated.

RESPONSE: See response #9b.

Reviewer #2:

14. It would have improved the manuscript to show the arm marking and US images, perhaps along with the small incision so that the reader would have a better chance of implementing difficult removals in their own clinics.

RESPONSE: Additional figure with photos of skin mapping and removal incision added. Ultrasound images previously published from our group in 2015⁶ showing ultrasound localization which we felt would be redundant in this manuscript. New text referencing the new Figure is shown below with the new Figure and Figure title included here as well.

Materials and Methods Lines 115-118:

Old text: Patients with non-palpable, partially palpable or questionably palpable implants have ultrasound localization in the radiology suite using a 15-18 MHz linear array transducer to evaluate implant relationship to fascia and neurovascular structures; during localization, the Family Planning specialist maps the implant location on the skin with a surgical marker.

New text: Patients with non-palpable, partially palpable or questionably palpable implants have ultrasound localization in the radiology suite using a 15-18 MHz linear array transducer to evaluate implant relationship to fascia and neurovascular structures; during localization, the Family Planning specialists map the implant location on the skin with a surgical marker (Figure 1).

New Figure 1:

Figure 1. Skin mapping and removal incision of subfascial implant in patient with prior removal attempt by general surgeon at outside institution.



Reviewer #3:

15. PRECIS: I'm not sure the data presented here actually support the Precis as currently written, seems more of a presumption. The data would support a Precis statement like, "For patients with non-palpable contraceptive implants, high proportion of successful localization and in-office removal can occur at a referral specialty center."

RESPONSE: See response #1. Précis has been changed.

16. ABSTRACT: Objective should really be targeted at the primary outcome. Suggest changing to: To describe proportion of successful in-office removals for patients referred with non-palpable contraceptive implants.

RESPONSE: We respectfully disagree. This was a descriptive study with the primary objective of describing our relatively robust experience at our specialty referral site. We not only wanted to describe the primary and secondary outcomes as stated in the manuscript, but also wanted to describe the complex clinical care process. The abstract conclusion is "At a specialty referral center, non-palpable suprafascial implants and most subfascial implants can be removed in the office after ultrasound localization. Some patients may experience post-procedure neuropathic pain. Providers should have a higher suspicion of subfascial location in non-obese patients with non-palpable implants." which directly addresses the objective as originally stated. The reviewer's suggestion is valid, but we feel as though changing the objective oversimplifies this paper.

17. Suggest replacement of "women" with "patients" throughout the abstract and manuscripts.

RESPONSE: This change has been made throughout the abstract and manuscript.

18. Please describe what limited means in line 64 (remitted prior to leaving clinic? This is not clear).

RESPONSE: See responses #5,6 and 7 for more details related to the post-procedure neuropathic complaints. The word "limited" has been changed to "transient" to show that we meant "limited in time" (see response #7).

19. Suggest statistical analysis of the primary outcome (proportion of successful removals) based on non-palpable implant suprafascial vs. subfascial location (see comments in Results).

RESPONSE: See response to #24.

20. How many non-palpable suprafascial implants had been inserted during removal-reinsertion procedure? Suggest statistical analysis of this secondary outcome as well (comments in Discussion section).

RESPONSE: Zero non-palpable suprafascial implants had been inserted during removal-reinsertion procedure. This information was originally presented in Table 2, but has since been removed based on other reviewer comments. Overall, 8 implants were removal-reinsertion events, 1 of which was palpable, the other 7 were non-palpable and all non-palpable were subfascial. New text has been added to better outline this information. See also statistical analysis comment in response #27.

Results Lines 165-169:

Old text: Fifteen women had used a contraceptive implant in the past, eight of whom were known to have reinsertion of the index implant through the removal incision. Seven (88%) of these eight had subfascial placement; six (86%) of these seven women had a BMI of less than 30 kg/m².

New text: Fifteen patients referred to our specialty referral center had used a contraceptive implant in the past, eight of whom were known to have reinsertion of the index implant through the removal incision. One of these implants was found to be palpable on our initial examination, while the other seven (88%) were non-palpable and subfascial. Six (86%) of the seven non-palpable subfascial implants were in patients with a BMI of less than 30 kg/m².

21. The results section is very wordy. Please try to simplify.

RESPONSE: We've done our best to streamline the information.

22. INTRODUCTION

- a. Line 78: replace with "triceps muscle, with the intent to minimize neurovascular injuries...."
- b. Line 98: change "We feel this information" to "This information".

RESPONSE: Suggested changes made.

Line 78:

Old text: ...triceps muscle, with the intention that this location will minimize neurovascular injuries should deep insertion...

New text: ...triceps muscle, with the intent to minimize neurovascular injury should deep insertion...

Line 97:

Old text: *We feel this information is important for all...*

New text: *This information is important for all...*

23. MATERIALS & METHODS: Post-procedure neuropathic pain complaints were mentioned in the abstract, is this also a secondary outcome?

RESPONSE: The objective is to describe our experience thus complications are an outcome. We added this to our Materials and Methods section.

Materials and Methods Lines 130-133:

Old text: Secondary outcomes included the proportion of women referred versus those seen in the clinic as well as evaluation of the impact of body mass index (BMI), reinsertion of index implant through removal incision and reason for removal as predictors of subfascial location.

New text: Secondary outcomes included the proportion of patients referred versus those seen in the clinic as well as evaluation of the impact of body mass index (BMI) and reinsertion of index implant through removal incision on subfascial location, and clinical outcomes including post-procedure complications.

24. RESULTS: Suggest analysis of the primary outcome (proportion of successful office removals by implant location as below). P value for the Fischer's exact for this 2x2 table is 0.11 suggesting no difference in removal success by location at this referral specialty center.

Removal Y Removal N

Subfascial Y 19 4 23

Subfascial N 21 0 21

40 4

RESPONSE: This information is represented in the 2x2 table below.

	REMOVAL – Y	REMOVAL - N	Totals
Subfascial – Y	19	4	23
Subfascial – N	21	0	21
Totals	40	4	44

This information has been added to our Results section.

Results Lines 153-156:

New text: Of the 44 non-palpable implants, successful removal rates for suprafascial implants (21/21, [100%, 95% CI 83-100%]) did not differ compared to subfascial implants (19/23, [83%, 95% CI 67-98%]), p=0.11.

25. RESULTS

- a. Line 146: please describe what "limited" post procedure neuropathic pain is... is limited 5 minutes, 30 minutes, 3 days, 4 weeks? The presumption in reading this is prior to leaving clinic. Did all pain subside by clinic discharge? If no, do you have any subsequent follow up data for the patients who reported neuropathic pain regarding total duration?

RESPONSE: See response #7.

- b. Line 149: Stated as "Table 2" but titled "Table 1" in Figures section.

RESPONSE: The reviewer was in error. The Table reference was correct and correctly titled in the tables and figure section.

26. DISCUSSION

- a. Suggest more natural flow of results would be current paragraph 3 (Lines 170-176) following current paragraph 1 (Lines 157-162).

RESPONSE: Paragraph #3 has been moved.

- b. Line 171: Delete the sentence "Providers without advanced..."

RESPONSE: The reviewer pointed out a statement which, as originally written, was unclear. The intent was to point out that providers without advanced training should not attempt removal of non-palpable implants. Rather than simply removing the statement, we have amended it to clarify our message.

Discussion Lines 178-180:

Old text: Our findings support that a non-palpable implant in non-obese women is highly likely to be subfascial. Providers without advanced removal training should avoid attempting removal and refer to a specialty center.

*New text: Our findings support that a non-palpable implant in non-obese patients is highly likely to be subfascial. **For that reason, providers** without advanced removal training should avoid attempting removal **of non-palpable implants** and refer to a specialty center.*

- c. Lines 172-174: what proportion of non-palpable suprafascial implants had been removed and reinserted?

RESPONSE: See response to #20.

- d. Suggest deleting current paragraph 4 (Lines 177-189). Could retain sentence that begins, "We have found new 15 and 18 MHz transducers..." and add it after the first sentence of current paragraph 5.

RESPONSE: We respectfully disagree for the following reasons: 1) there are providers that claim they can see implants with lower frequency transducers, however the relationship of the implant to the fascia is of utmost importance prior to removal attempts and is not well captured until using frequencies of at least 10 MHz or higher, ideally using 15 and 18 MHz transducers; 2) providers must understand the cost of such a transducer is often prohibitive for general ObGyn clinics because deep implant placements are rare, therefore the existence of Centers of Experience with the appropriate experience and technology is essential; and 3) real-time ultrasound guidance is mentioned in this paragraph, addressing other reviewer comments, and we specifically explain why in our system we were unable to perform the removals in our ultrasound suite and therefore developed the skin mapping technique. This paragraph demonstrates the complexity of this process, which as mentioned earlier, is an important part of the paper's objective.

- e. Line 199: "location of such a center is unknown, pharmaceutical company representatives should be contacted..."

RESPONSE: Word added.

Discussion Line 213:

Old text: When the location of such a center is unknown, company representatives should be contacted for more information.

*New text: When the location of such a center is unknown, **pharmaceutical** company representatives should be contacted for more information.*

27. Reasonable to calculate Fischer's exact test here to start to examine the biological plausibility you mention in line 174.

Removal reinsert Y Removal reinsert N

Subfascial Y 7 18 25

Subfascial N ?? ?? 22 (23 if you include the intrafascial one as well)

RESPONSE: The appropriate comparison group would be a group of women who had a second implant placed through a separate incision and not the removal incision. The denominator for these events must only be women receiving another implant at time of prior implant removal. Only 15 patients in our series had used an implant in the past, some of whom used an implant years before their index implant that prompted referral to our site. Eight of these 15 women had known removal-reinsertion events through the same incision. One was found to be palpable and the other 7 were non-palpable and subfascial. Additional text added to both Results section (see response #20) and Discussion sections (see below) for clarity.

Discussion Lines 182-184:

*New text: **To test this hypothesis the appropriate comparison group would be a group of women who had a second implant placed through a separate incision.***

STATISTICAL EDITOR'S COMMENTS:

28. Lines 63-65: Should use Fisher's test for comparison, the exact p-value = .048, not .0002.

RESPONSE: Apologies for this oversight. Rechecked calculation and you are correct. Sentence also restructured for better flow.

Abstract Lines 63-64:

Old text: Patients had limited post-procedure neuropathic pain complaints after 7/23 (30%) subfascial implant removals and 1/21 (5%) suprafascial implant removal (P=.0002).

*New text: **Transient post-procedure neuropathic complaints were noted in 7/23 (30%, 95% CI 12-49%) subfascial and 1/21 (5%, 95% CI 0-13%) suprafascial removals (P=.048).***

29. Lines 65-66: Should use Fisher's test, the exact p-value = .0002, not .0001.

RESPONSE: Again, apologies for this oversight. Rechecked calculation and p-value changed to .0002. Sentence also restructured for better flow.

Abstract Lines 64-66:

Old text: Non-palpable implants were subfascial in 1/13 (8%) obese and 24/34 (71%) non-obese women (P=.0001).

*New text: Non-palpable implants were **more likely to be subfascial in non-obese (24/34, 71%) as compared to obese (1/13, 8%) patients (P=.0002).***

30. Table 1: Since the entire sample was N = 55, should round the % to nearest integer, cannot cite precision to nearest .1% from these data. Were age, BMI and distance traveled all normally distributed (line 134)? If not, should cite as median (IQR or range), rather than as mean \pm SD.

RESPONSE: We have rounded to the nearest 1% in the tables. We have also added information about the normality assessments of certain variables in our Materials and Methods section.

Materials and Methods Lines 135-136:

New text: *We assessed normality of age, BMI and distance traveled by histograms and QQ plots; all data were normally distributed.*

31. Table 2: If BMI not normally distributed, then should cite as median (IQR or range) and test non-parametrically. Since average BMI were significantly different, suggest testing proportions in each BMI stratum, as well (except for overweight category, they each are significantly different).

RESPONSE: Thank you for the suggestion regarding the BMI strata. However, we (including our statistician) feel the significant result for the omnibus test is sufficient to indicate the effect of BMI. Pairwise comparisons do not significantly add information because the reader can see the comparisons for themselves and note whether the differences appear to be important from a real-world context, i.e., 18% versus 68% is clearly an important difference, whereas 27% versus 28% is not.

32. General:

- a. The subsets have modest counts, especially for adverse outcomes, so Fisher's test should be used.

RESPONSE: We apologize for this statistical oversight. The calculations have been rechecked and adjusted as appropriate.

- b. Also, citing proportions of events should include more CIs to put the results in context.

RESPONSE: We think with the small numbers in this paper, the CI's detract from the descriptive observations. However, we have added CI's to several event proportions as we deemed appropriate. If the editors feel that these CI's are "too much" than we give permission to delete them.

Abstract Lines 58-64 (also reflected in Results section:

Old text: In the office, we successfully completed attempted removal of all palpable (n=6), all non-palpable suprafascial (n=21), and 19/23 (83%) subfascial implants. Three of four women with failed subfascial implant office removal had successful operating room removal with a collaborative orthopedic surgeon; the other patient sought removal elsewhere. Patients had limited post-procedure neuropathic pain complaints after 7/23 (30%) subfascial implant removals and 1/21 (5%) suprafascial implant removal (P=.0002).

New text: Of 50 attempted office removals, all palpable (n=6), all non-palpable suprafascial (n=21 [100%, 95% CI 83-100%]), and 19/23 (83%, 95% CI 67-98%) subfascial implants were successful. Three of the four patients with failed subfascial implant office removal had successful operating room removal with a collaborative orthopedic surgeon; the other patient sought removal elsewhere. Transient post-procedure neuropathic complaints were noted in 7/23 (30%, 95% CI 12-49%) subfascial and 1/21 (5%, 95% CI 0-13%) suprafascial removals (P=.048).

- c. Also, do the results necessarily support the conclusion of referral to a specialty center? There is no data re: use of ultrasound for guidance prior to referral.

RESPONSE: We believe that this conclusion is supported by the fact that 50% of patients had providers attempt removal for a nonpalpable implant without success, yet we were able to remove all suprafascial and 83% of subfascial implants in the office.

33. Lines 112-116 and 184-186: Why would not U/S guidance in the clinic or radiology suite at the time of removal be the preferred approach?

RESPONSE: Real-time ultrasound guidance during removal can be beneficial, but systems issues prevented our team from being able to utilize the ultrasound suite for the procedure or to use the high frequency ultrasound probes in our clinic. This case series shows that real-time ultrasound guidance throughout the procedure is not necessary if skilled localization and skin-mapping is performed prior to removal attempt. Our institution has since purchased a high-frequency probe to use in our clinic during implant removal, but we still localize, skin map and only use direct ultrasound guidance if necessary. Originally, the manuscript discussed this in Discussion paragraph #4 *"Unfortunately, implant removal at our institution cannot be performed under direct ultrasound guidance in the radiology suite due to scheduling limitations and cost-effectiveness concerns. Clinicians could avoid potential scheduling complexity and perform more complicated procedures under real-time ultrasound guidance by having their own high-frequency ultrasound probe. However, the high price of such a probe precludes feasibility for most clinics due to the rarity of deep insertions,"* but this has since been removed as we added a more concise statement as shown below:

Discussion Lines 204-206:

Old text: Our experience with subfascial implant removal in the office is especially unique.

New text: Our experience with subfascial implant removal in the office is especially unique, which we have developed due to scheduling limitations for implant removals under direct ultrasound guidance in the radiology suite.

EDITORIAL OFFICE COMMENTS:

1. 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, as well as subsequent author queries. 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:

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

RESPONSE: We choose OPT-IN.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. 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.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

RESPONSE: You are welcome to remove these after submission. Thank you.

3. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

RESPONSE: Our case series does not fit any of the above validated checklists.

4. 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 and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

RESPONSE: We have reviewed and confirmed that we are following any applicable definitions from reVITALize.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 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.

RESPONSE: The current length of the entire submission is 18 pages including everything listed above.

6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

- * All financial support of the study must be acknowledged.
- * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- * If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

RESPONSE: We acknowledge meeting all the above listed rules and guidelines.

7. 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."

RESPONSE: The précis word count is 21 and meets the described criteria.

8. 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 limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

RESPONSE: We have reviewed the abstract carefully and your guidelines. The word count is 296.

9. 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.

RESPONSE: We follow these guidelines.

10. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

RESPONSE: We have not used this symbol in this manuscript.

11. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

RESPONSE: We do not make any claims of first reports.

12. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

RESPONSE: We have checked the table checklist and assure the tables meet the journal's style. No changes were made.

In addition, we made these changes to the manuscript to maintain consistency throughout:

Results Lines 149-152:

Old text: Figure 1 outlines the outcomes of our assessments and removal attempts. Overall, three women with either a palpable, intrafascial or suprafascial implant opted to keep their implant after counseling, and two with subfascial implants did not have removal attempts by our team after initial evaluation.

*New text: Figure 2 outlines the outcomes of our assessments and removal attempts. Overall, three **patients** with either a palpable, intrafascial or suprafascial implant opted to **continue use** after counseling, and two with subfascial implants did not have removal attempts by our team after initial evaluation.*

Reference labels changed due to additional reference #17.

Old text: We use ultrasonography for primary implant localization which provides the ability to mark the position of the implant and identify nearby vascular structures. Transducers with a frequency of 5 or 7.5 MHz, which are commonly available in an Obstetrician-Gynecologist's office, can be used to identify correctly placed implants.¹⁷ Frequencies of 10 MHz or greater are more useful with non-palpable implants, since these frequencies can identify an implant in both suprafascial and subfascial locations.¹⁸

New text: Transducers with a frequency of 5 or 7.5 MHz, which are commonly available in an Obstetrician-Gynecologist's office, can be used to identify correctly placed implants.¹⁸ Frequencies of 10 MHz or greater are more useful with non-palpable implants, since these frequencies can identify an implant in both suprafascial and subfascial locations.¹⁹