

OBSTETRICS & GYNECOLOGY



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- 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.*

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Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:

obgyn@greenjournal.org.

Date: Feb 13, 2020
To: "Chetna Arora" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-138

RE: Manuscript Number ONG-20-138

Comparing Surgical Experience and Skill Using a High-Fidelity Total Laparoscopic Hysterectomy Model

Dear Dr. Arora:

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 Mar 05, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Abstract

Line 76 - Include the secondary objective (assessment of the model).

Introduction

Line 110- ACGME does not require a minimum number of surgical cases for a resident to graduate. A resident can graduate with less than the ACGME minimum number of cases for a specific procedure. ACGME can issue a citation or an AFI (area for improvement) to the program if all residents in a graduation class fail to perform the minimum number of cases for a particular procedure.

Line 110 & Line 112 - need to give full name of each organization (ACGME & ABOG)

Line 116 - eliminate last sentence

Last paragraph should be replaced with lines 178-183 - this paragraph clearly states your primary and secondary aims of your study.

Methods

Line 178 to Line 183 - move to introduction as outlined above

Line 185 - Remove "blinded" as the videos were de-identified.

Line 185 - Why did you elect not to have the expert reviewers have a training session to standardize their evaluation of each video to inter-rater reliability?

Results

Suggest shortening the narrative by referring the reader to the tables to highlight important points related pre-simulation questionnaire, OSATS scores, surgical time, and post-simulation questionnaire.

Eliminate lines 267-270.

Discussion

Lines 279-281 - Your assertion is not supported by your reference. The reference is 11 years old and does not analyze patient outcomes for minimally invasive hysterectomies.

Line 299 - as previously noted in my review, residents do not have to complete a minimum number of TLH/BSO procedures to graduate

Last sentence beginning on Line 301 should be removed. This statement is speculation and the "issue is outside the scope of this study." (line 302)

Line 305 - clarify "complexity"- Are you referring to surgeons "handling" more complex surgical cases?

Reviewer #2: The authors present a prospective cohort study comparing OSATS scoring of technical skills on a high fidelity laparoscopic simulation hysterectomy model. They use blinded reviewers to compare scores broken down by task and level of training. The study design was well planned and executed however it is not clear if the primary objective on discriminating between the cohorts is an appropriate outcome vs. construct validation of the model itself, which is a very important outcome in it's own right. This is the on going debate about using FLS vs. EMIG's in high stakes assessment for basic skills. A chicken or egg argument. Having worked with the ACOG simulation working group this model has been used for several years at our ACOG ACM and it needs to be clearly stated what cohorts were already exposed to the simulator. This may confound any results.

Abstract:

Line 85 Although I appreciate the 2nd objective to look at contained morcellation, I don't think using a 250 gm specimen should have been the target given most would remove vaginal with little difficulty. I find this bias towards MIG's cohort which may focus more on laparoscopic cuff closure which is neither evidence based or cost effective. Given controversy of cuff dehiscence and learning curve with robotics or laparoscopic closure there is an assumption being made this is the gold standard. More generalist of 19 yrs experience evolved from early days of LATVH to LAH and are more likely to remove specimen vaginally and close vaginally as shown in the survey.

Line 96 The standardized model should be explicitly stated as a simulation model.

Introduction:

Line 102-103 To always champion innovation over status quo regarding outcomes is misleading. Too many examples to list but to name a few power morcellation, vaginal mesh, TVH vs. LAH/Robotics, stage 1b cervical cancer and outcomes of open vs. robotic radical hysterectomies LACC Trial. N Engl J Med 2018; 379:1895-1904 DOI: 10.1056/NEJMoa180639 I would suggest saying sometimes improve outcomes with an emphasis on RCT to support tech advances.

Line 109-117 As a program director I do think there needs to be more discussion of both ACOG and AAGL position statement of TVH first. I don't think this gets the attention it deserves as its is the ultimate minimally invasive approach. Although FLS is roughly a transferable task to LAH there is no requirement transferable to TVH as a requirement for ABOG certification.

Line 118-121 This is my point made above regarding surgical skills vs. construct validation of the simulation model.

Line 129 There should be more information on resident recruitment. Were all in or going into generalist practice or other non surgical fellowships like MFM? I think the skills and interest are quite variable and the cohort should be those in generalist practice. I do see the breakdown in table 1

Line 131-132 There is a big difference in the cohort of specialist practicing the breadth of ob/gyn vs. generalist doing gyn only. This is also reflected in the reported case volume.

Line 135 The exclusion criteria of using the model is very important. Teaching to the test. That being said using vs. having seen or used other laparoscopic simulators may also bias the results. Is there information on involvement in any simulation course or model?

Line 138 The local recruitment bias may make the study less generalizable particularly to resident variable training and local generalist practice patterns.

Methods:

Line 163 What uterine manipulator was provided? Was there a colpotomizer or Koh ring?

Line 167 Providing vs. requiring two assistants may bias some of the quantitative outcomes. This should have been standardized regardless of preference.

Line 168 Were the fellow assistants blinded to the level of training of the participants?

Line 171 What choices if any were given for cuff closure? V-lock suture, running etc.?

Line 173 What was the training or instruction given regarding ExCITE technique and what was the pre testing use of this technique?

Line 185 The expert reviewers should have included other subspecialties ie urogyn or experience gyn only surgeons.

Line 192 The separate tissue extraction simulator sounds similar to models used at the ACOG ACM and probably other AAGL courses. What was the exposure or experience with the model for each cohort?

Line 201 I understand using the MIGS specialist as control but I would not have necessarily kept one sided.

Line 211-212 If 20% of generalist were gyn only what percent of the total 448 hysterectomies were done by gyn only vs. full scope ob/gyn?

Line 216-217 The preferred route of hysterectomies in the generalist group toward TAH should be further broken down into the gyn only sub cohort vs. full scope. These are really two different cohorts in practice.

Results:

Line 258-262 The content and construct validation are perhaps the most important findings

Line 265 Of the 24/25 who had prior simulation exposure what cohorts were they in? This addresses the concerns previously mentioned and potential bias.

Table 1 The resident cohort had almost 25% who were going into non surgical or laparoscopic specialties limiting comparison.

The wide range of hysterectomies for generalist should look at both mean and median.

There is also an a priori difference in experience or preference for vaginal cuff closure.

Discussion:

Line 272-274 There is a little bit of teaching to the test in regards to what is gold standard. The domains being assessed should have been given choices or made to preform the case by different methods ie vaginal closure vs. laparoscopic. V-lock vs. intracorporal closure. The results may have varied by technique and year of training. That is not to say the results are not important but the primary outcome may be more about validating the model than assessment or comparison of cohorts.

Line 290 It is a leap to make assumptions about gyn surgery in general vs. the specific focus of this study on a laparoscopic simulated hysterectomy. I would suggest being more specific and qualify with translational research from simulation to OR.

Many of the concerns above were addressed in the limitation section.

Reviewer #3:

1. This is an original prospective cohort study looking at a large group of diverse participants representing many different levels of training/surgical experience. The primary objective was aimed at comparing skills and scores of the participants on a standardized TLH/BSO simulation. Strengths include the prospective nature of the study, the use of an objective validated scoring system (OSATS), blinding of reviewers, and the use of a standardized model with standardized surgical assistants. Limitations include the uncertainty of inter-rater reliability among reviewers, as well as possible lack of generalizability in the "generalist" cohort given that they were largely recruited from academic settings or an academic district meeting.

2. The manuscript is well written and I would like to commend the authors for a thorough and comprehensive evaluation performed.

3. Methods: The fellow and resident cohorts have generally a similar range of skills/training within their respective groups. However, in the generalist cohort there is a wide range of experience in terms of number of years in practice; it may be interesting to further stratify generalists by years in practice (e.g. less than vs more than 10 years) to see if there

is any difference in performance on the tasks.

4. Lines 161-163: The use of a standardized myomatous uterus without any pelvic pathology may make the results less generalizable for cases with endometriosis or adhesive disease. Maybe this could be acknowledged in the discussion section.

5. Lines 184-186: When the videos are assigned to blinded reviewers, do all five expert reviewers review every video, or is each video assigned to only a few of the reviewers from the pool of five? And if all 5 reviewers score each video, did you perform any statistical analyses to assess the inter-reviewer variability in scoring for each video? You partially addressed this in the discussion section but maybe you could say if you have any plans to analyze the inter-rater reliability.

6. Discussion: I think you do a good job of addressing the possible lack of generalizability for using a more "academic" generalist cohort as opposed to non-academic generalists who may perform more surgery in areas with fewer specialists. Do you think that having readily-available subspecialists that can perform more advanced or complicated minimally invasive surgeries may negatively impact the ability or performance of generalists who are more likely to refer these cases to their MIGS or Gyn Onc colleagues?

Reviewer #4: Thank you, authors, for the submission of this most interesting study and the accompanying manuscript. I have included a few questions and suggestions that should help the readability and clarity of your paper.

METHODS, Page 6, Line 135. Any specific reason the GyneSim model was chosen, over others?

RESULTS, Page 9, Line 210. You mention that the average Generalist in the study had performed 29.9 hysterectomies a year. How was this obtained? Was this self-reported? And (in the Discussion) what biases does that introduce?

REFERENCE SECTION:

I would recommend you review the "Instructions for Authors" regarding References. There are sections of the 44 references that seem to be done correctly, and most are done with the same format (but not following the OG format). The main rules that seem to have been overlooked are as follows (please review ALL 44 references...)

1. The names of the cited journal should be abbreviated in the manner accepted by the journals in Pub Med, using the Index Medicus. For instance, 'Obstetrics and Gynecology' should be 'Obstet Gynecol'.
2. The names of the cited journal should be capitalized, like any publication or book. ie. The journal of reproductive medicine should be 'J Reprod Med'.
3. In citing journal articles, there is no maximum number of authors that should be listed. Therefore, REFERENCE #4, That lists, "Urban RR, Ramzan AA, Doo DW, et al." should list all the authors.
4. The proper way to list the authors' names are last name first, then first initial of first and middle name; comma; then repeat which each subsequent author. REFERENCE #16 lists "Cohen SL and Emily Hinchcliff" instead of 'Cohen SL and Hinchcliff E.'
5. The journal titles should be italicized uniformly throughout the Reference section (example: References #16 and 17 are not)
6. The J Obstet Gynaecol Can : JOGC is listed twice in every reference in which it is cited, for some reason. It should not be.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1: The column totals range from 15 to 19, so the %s should all be rounded to nearest integer %, not to 0.1% precision. The years in practice should include some measure of variability, such as range. I assume the averages and ages are in terms of means, but should clarify.

Table 2: Need units for BMI. The comparisons all need a referent. The numbers cited are based on a Likert scale and should be cited as median(range), since the samples are relatively small and the comparisons should be non-parametric. lines 201-202: There is no a priori basis for using a one-sided p-value, should use a two-sided. lines 195-197: The power calculation is correct, but is based on only one primary outcome, namely comparing the residents vs MIGS. All other

comparisons are secondary, unless the Authors wish to compare multiple groups as the primary outcome(s), in which case the sample size/power calculation is incorrect and multiple comparisons are underpowered. lines 204-206: The statement re: the meaning of R^2 is accurate, but incomplete. Whether $R^2 = 0.75$ is statistically significant depends on the sample size.

Table 3: Need to clearly separate the primary outcome (resident total OSAT score vs MIGS total score) from the rest. The study was not powered to evaluate all the subsets. The scores should be cited with some measure of variability and since non-parametric tests were used, should be median(range). Should round scores and times to nearest 0.1, not to nearest 0.01.

Table 4: Should cite differences as mean difference with CI. Could summarize p-values in footnote. No correction for multiple hypothesis testing (30 comparisons in this Table, so only those with $p < .001$ retain statistical significance, but again, these are mostly secondary outcomes, not the primary outcome by study design.

Table 5: Need to include CIs for mean differences, round time to nearest 0.1 minute, not 0.01 minute and clarify that minutes are the time unit used. Same issue as in Table 4 with multiple hypothesis testing, only the 3 out of 4 of the MIGS vs resident differences are statistically significant.

Table 6: Need to cite scores as median(ranges) and correct for multiple hypothesis testing.

EDITOR COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting.

Line 27: please mention what the people you are acknowledging did.

Line 51: The précis is a single sentence of no more than 25 words, written in the present tense and stating the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstracts conclusion. Précis should be the "hook" for people who scan the Table of Contents to see what to read. It shouldn't include statements like "in this study" or "we found". Please make sure you mention that this was a simulation study—"Standardized" doesn't quite capture that for the average reader. As well, ACOG prefers to describe "generalists" as "specialists" in distinction to "subspecialists". Here and on line 131 and thereafter, please use "specialists in Ob GYN".

Line 85: The use of "novel" implies a primacy claim: yours is the first, biggest, best study of its kind. Perhaps best to delete this in the abstract. In the manuscript, in order to make such a claim, please provide the data bases you have searched (PubMed, Google Scholar, EMBASE for example) and the search terms used. If not done, please edit it out of the paper as well.

I am a bit unclear about what the purpose of the study is. Perhaps it will be clearer when I get to the manuscript but the abstract needs to be able to stand alone. Usually simulations are done for educational purposes but this seems to be set up as a contest almost between different groups. Was the purpose to begin with educational or comparative like this?

Line 108: The surgical experience for most graduating residents is more likely to be minimally invasive than abdominal as I understand it. Is "particularly minimally invasive" true in this context?

Line 112 Please spell out all abbreviations on first use in both the manuscript and abstract. If you never use the term again, you don't need to include the abbreviation.

Line 118: How does your study, as described in the abstract, address "continued post graduate Ob GYN surgical training"? Other than including one group of MIGS fellows?

Line 129: Please add how long the AAGL-approved MIGS fellowships are. As I understand them, its 2 years—so is 6 months before graduation (3/4 of the way through) comparable to 3 months before finishing Ob GYN residency 3/4's of the way through a good comparison?

Line 135: please describe the Gynsim simulator in a bit more detail.

Line 158-60: Please describe how the operator was de-identified for anonymous scoring.

Line 167: What is a consistent FMIGS fellow? Do you mean the same 2 fellows were available for each of the participants?

Line 196-200: Please note the important information by the statistical editor regarding your power analysis and primary outcome.

Line 207: PRESENTATION OF STATS INFORMATION

P Values vs Effect Size and Confidence Intervals

While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

This is true for the abstract as well as the manuscript, tables and figures.

Please provide absolute values for variables, in addition to assessment of statistical significance.

We ask that you provide crude OR's followed by adjusted OR's for all relevant variables.

Lines 214-216: How many of the residents and fellows had completed that segment of their training (you had said they could be up to 3 and 6 months post fellowship and residency).

Line 222. Do not begin a sentence w/ a numeral. Either spell out or edit your sentence to avoid the need to start w/a number.

Line 225. We do not allow authors to describe variables or outcomes in terms that imply a difference (such as the terms "trend" or "tendency" or "marginally different") unless there is a statistical difference. Please edit here and throughout to indicate that there is no difference.

Line 245: What do you mean they were the fastest? Please provide the comparison data. You've given 2 data points, presumably that of the MIGS specialist and the fellow with a non significant p value, so no different. Also even if these were different, is 3 minutes clinically relevant?

Line 259: Let the data speak for itself, and avoid perception of self aggrandizement, by deleting the phrase "the most skilled surgeons". Inclusion of this speaks to my concerns about the purpose of the study.

Line 275: Since this is a simulator, while a reasonable proxy for surgical skill, perhaps best to say here that MIGS specialists scored highest rather than stating "more skilled".

Line 289: I'm not sure I'm following you here. This study showed that specialists in practice did score better than the residents, didn't it? So one can reasonably assume there is improvement over time. The study does not address whether they are "less prepared" (less prepared compared to who?) as it shows that there is improvement with additional experience. Are they "less prepared" than residents trained in prior years? You haven't studied this and can't conclude this. Are they "less prepared" than a MIGS subspecialist in practice for 9 years? I dare say you didn't need a study to show this. You really need to dial this whole section way back.

You've shown a "dose response" of experience vs performance on a simulation.

Line 293: how do you know "only after many years of practice? You didn't study that. Maybe the biggest gains are in the first 3 years and then a plateau.

Line 296: By whose criteria is this reasonable for all gyn surgeons who do laparoscopic surgery?

Line 297: I'm and MFM so I'm not sure I understand how laparoscopic suturing is considered "advanced laparoscopy".

Lines 300-304: as noted, this is out of scope...I'd recommend leaving it there.

Line 312: or is it a time to develop over confidence? Also please provide a reference for this sentence.

Line 333: This is known as a primacy claim: yours is the first, biggest, best study of its kind. In order to make such a claim, please provide the data bases you have searched (PubMed, Google Scholar, EMBASE for example) and the search terms used. IF not done, please edit it out of the paper.

Line 352—seems like this sentence is incomplete.

Line 356: The journal style does not support the use of the virgule (/) except in mathematical expressions. Please remove here and elsewhere.

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. 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.

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.

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

3. Please submit a completed STROBE checklist.

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 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.

11. 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.

12. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

13. 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.

14. 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.

15. 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 via the Clinical Guidance & Publications page at <https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance>.

16. Figures

Figure 1: Current figure file may be resubmitted with the revision as-is.

Figure 2: Please provide a version of this figure without the A–D labels. These will be added back per journal style.

Figure 3: Please provide a letter of permission to use this figure in print and electronic formats. Also please provide a high resolution version of this figure (text should be crisp when you zoom in)

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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.

18. 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.

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 Mar 05, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 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.

February 22, 2020

Re: Submission of manuscript, “Comparing Surgical Experience and Skill Using a High-Fidelity Total Laparoscopic Hysterectomy Model”

The Editors
Obstetrics & Gynecology
409 12th Street, SW
Washington, DC 20024-2188

Dear Editors:

On my behalf of my co-authors, I am pleased to submit our revised manuscript, “Comparing Surgical Experience and Skill Using a High-Fidelity Total Laparoscopic Hysterectomy Model” for consideration for publication as original research in *Obstetrics & Gynecology*. Our manuscript is the first to determine differences in surgical skills and confidence in the completion of a standardized and simulated total laparoscopic hysterectomy with bilateral salpingo-oophorectomy between Ob-Gyns with different levels of training and expertise. Individual responses to the reviewer’s and editor’s comments are detailed below on a point-by-point basis. We confirm that we have read and abided by the complete Instructions for Authors to the best of our ability.

The work from this study was presented at the American Association of Gynecologic Laparoscopists (AAGL) Annual Meeting in Vancouver, CA in November 2019 as an oral presentation for which it also received the AAGL Jay M. Cooper Award for best minimally-invasive gynecologic surgery manuscript. This manuscript has solely been submitted to *Obstetrics & Gynecology* is not under consideration elsewhere.

Each author participated actively in conducting analyses, drafting sections of the manuscript, editing, and approving the final, submitted version. The lead author, Chetna Arora, M.D., 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. All persons noted in the acknowledgements have given written permission to be named.

This study was approved by our institutional review board (IRB-AAAR5527). Permission has been obtained by all persons named in the acknowledgements.

Support from Applied Medical, Medtronic, CooperSurgical and Karl Storz in the form of in-kind equipment were obtained through unrestricted educational grants. Industry had no involvement in study design; collection, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication.

We look forward to your comments and critique of the manuscript. We would like to suggest that Figure 2d (active participant performing cuff closure with standardized assistant) be considered as cover art.

If you have any questions about the manuscript, I will be serving as the corresponding author. Thank you for your consideration.

Sincerely,

Chetna Arora, MD, FACOG

RE: Manuscript Number ONG-20-138

Comparing Surgical Experience and Skill Using a High-Fidelity Total Laparoscopic Hysterectomy Model

REVIEWER COMMENTS:

Reviewer #1:

Abstract

Line 76 - Include the secondary objective (assessment of the model).

[Included in revisions.](#)

Introduction

Line 110- ACGME does not require a minimum number of surgical cases for a resident to graduate. A resident can graduate with less than the ACGME minimum number of cases for a specific procedure. ACGME can issue a citation or an AFI (area for improvement) to the program if all residents in a graduation class fail to perform the minimum number of cases for a particular procedure.

[Changed the terminology from "requirements" to "expectations."](#)

Line 110 & Line 112 - need to give full name of each organization (ACGME & ABOG)

[Included in revisions.](#)

Line 116 - eliminate last sentence

[Included in revisions.](#)

Last paragraph should be replaced with lines 178-183 - this paragraph clearly states your primary and secondary aims of your study.

[Included in revisions.](#)

Methods

Line 178 to Line 183 - move to introduction as outlined above

[Included in revisions.](#)

Line 185 - Remove "blinded" as the videos were de-identified.

[Clarified in revisions.](#)

Line 185 - Why did you elect not to have the expert reviewers have a training session to standardize their evaluation of each video to inter-rater reliability?

[We acknowledge this as a limitation in our study. That would have been ideal, for both the primary and secondary objectives. As mentioned in our discussion, we attempted to mitigate this limitation by employing only fellowship-trained experts in practice at least 10 years. We also included not just benign gynecologic surgery with MIGS, but also Gynecology Oncology in an effort to be more inclusive of surgical practices.](#)

Results

Suggest shortening the narrative by referring the reader to the tables to highlight important points related pre-simulation questionnaire, OSATS scores, surgical time, and post-simulation questionnaire.

Text has been shortened where appropriate.

Eliminate lines 267-270.

Included in revisions.

Discussion

Lines 279-281 - Your assertion is not supported by your reference. The reference is 11 years old and does not analyze patient outcomes for minimally invasive hysterectomies.

You are correct, this sentence is actually an extension of the topic sentence. The references reflecting our statement have been expanded.

Line 299 - as previously noted in my review, residents do not have to complete a minimum number of TLH/BSO procedures to graduate

Included in revisions.

Last sentence beginning on Line 301 should be removed. This statement is speculation and the "issue is outside the scope of this study." (line 302)

Included in revisions.

Line 305 - clarify "complexity"- Are you referring to surgeons "handling" more complex surgical cases?

Yes. The sentence has been rephrased to say, "The ability of a surgeon to progressively handle procedures of increasing complexity directly translates to confidence and objective skill." The following sentences from this topic sentence explain further. Please let me know if further clarification/rephrasing is required.

Reviewer #2: The authors present a prospective cohort study comparing OSATS scoring of technical skills on a high fidelity laparoscopic simulation hysterectomy model. They use blinded reviewers to compare scores broken down by task and level of training. The study design was well planned and executed however it is not clear if the primary objective on discriminating between the cohorts is an appropriate outcome vs. construct validation of the model itself, which is a very important outcome in it's own right. This is the on going debate about using FLS vs. EMIG's in high stakes assessment for basic skills. A chicken or egg argument. Having worked with the ACOG simulation working group this model has been used for several years at our ACOG ACM and it needs to be clearly stated what cohorts were already exposed to the simulator. This may confound any results.

Thank you for your expertise. We did consider separating the paper into two parts—one focusing on the primary objective comparing the cohorts on a TLH-BSO, and the other paper with the new primary objective of the model validation itself. When trialed, the data became less impactful. More work needs to be done to complete the validity framework of the Gynesim™ model itself, and we acknowledge that this is just the beginning of the validity argument. We are establishing further studies with the model itself to better focus on its validation using the Messick model (reference 14, Cook et al). Five sources of evidence are necessary when approaching the validation of an instrument. By also performing further studies focusing on this, we can improve its validation by allowing for its use in several different contexts and applications.

No study participant had previous exposure to this hysterectomy model. In fact, we reference in the methods at the end that one fellow's data was lost due to technical issues. We could not let them repeat that portion of the study due to inherent advantages from immediately previous exposure to the model. In the first paragraph of the methods, we state this in our exclusions. (Of note, this commentary was recommended to be removed by another reviewer, but you can see it in our tracked changes).

Abstract:

Line 85 Although I appreciate the 2nd objective to look at contained morcellation, I don't think using a 250 gm specimen should have been the target given most would remove vaginal with little difficulty. I find this bias towards MIG's cohort which may focus more on laparoscopic cuff closure which is neither evidence based or cost effective. Given controversy of cuff dehiscence and learning curve with robotics or laparoscopic closure there is an assumption being made this is the gold standard. More generalist of 19 yrs experience evolved from early days of LATVH to LAH and are more likely to remove specimen vaginally and close vaginally as shown in the survey.

Important points. We established the methodology a priori to find as many objective points of difference between the cohorts and acknowledge that not all data collected may be helpful.

With that being said, we chose to ask very specific questions in our pre-simulation survey (Table 1). We specifically ask each cohort their preference to cuff closure in a TLH. The majority of the generalists chose a laparoscopic closure. 60% with suturing, 6.7% with the Endostitch, and 33.3% vaginal. We chose not to have a larger and more pathologic specimen in order to fairly compare surgical skills across all included study participants.

As shown in Table 3, statistical differences were seen in OSATS score when compared to the MIGS subspecialist for all categories of participants, not just the generalists. We also now have added in a calculation to correct for multiple comparisons with a Bonferroni adjustment. Those changes are highlighted in the tables and text where appropriate. In Table 4, we wanted to ensure a more clarified break-down when comparing individual cohorts, and we do objectively note there is no difference between the resident and the generalist in tissue extraction OSATS score. In Table 5, we further objectively note there is no difference between the resident or the fellow and the generalist in tissue extraction time.

Line 96 The standardized model should be explicitly stated as a simulation model.

Included in revisions.

Introduction:

Line 102-103 To always champion innovation over status quo regarding outcomes is misleading. Too many examples to list but to name a few power morcellation, vaginal mesh, TVH vs. LAH/Robotics, stage 1b cervical cancer and outcomes of open vs. robotic radical hysterectomies LACC Trial. N Engl J Med 2018; 379:1895-1904 DOI: 10.1056/NEJMoa180639 I would suggest saying sometimes improve outcomes with an emphasis on RCT to support tech advances.

Good point! Not our intent to be misleading. We have included the terminology "evidence-based" in revisions.

Line 109-117 As a program director I do think there needs to be more discussion of both ACOG and AAGL position statement of TVH first. I don't think this gets the attention it deserves as its is the ultimate minimally invasive approach. Although FLS is roughly a transferable task to LAH there is no requirement transferable to TVH as a requirement for ABOG certification.

We agree. If a TVH is feasible and appropriately selected for a patient, it should be the first-line surgical approach. This study was inspired by changes from the ACGME, resident readiness upon graduation, and growing value in MIGS as a subspecialty for complex pathology. We chose not to address the TVH

[conversation here as that is its own study in its own right.](#)

[We reference the Choosing Wisely statement in response here.](#)

[Choosing Wisely. Five things patients and providers should question.](#)

https://www.choosingwisely.org/wp-content/uploads/2017/11/AAGL_5things-List_Updated101119.pdf

Line 118-121 This is my point made above regarding surgical skills vs. construct validation of the simulation model.

[Understood. Response above addresses your comment as well. This sentence has also been replaced by the aims statement from the methods. Please see revisions.](#)

Line 129 There should be more information on resident recruitment. Were all in or going into generalist practice or other non surgical fellowships like MFM? I think the skills and interest are quite variable and the cohort should be those in generalist practice. I do see the breakdown in table 1

[In an effort to consolidate data and abide by word restrictions, we placed all the demographic data including the information you seek explicitly in Table 1.](#)

Line 131-132 There is a big difference in the cohort of specialist practicing the breadth of ob/gyn vs. generalist doing gyn only. This is also reflected in the reported case volume.

[We agree. We further analyzed the data due to this exact point by performing a linear regression model to determine if a difference in generalists and MIGS specialists were noted when controlling for surgical volume and years of practice. An \$R^2\$ value of 0.75 was noted, indicating that the model explains 75% of the variance when the dependent variable represents the OSATS score and the independent variables represent surgical volume and years in practice. This is included in our methods section. Of note, 20% of our generalists, while a small \(n\), were gyn-only as well. We also did include low and high-volume generalists \(whether gyn-only or not\) completing an average of 29.87 hysterectomies/year \(range of 2-75\).](#)

Line 135 The exclusion criteria of using the model is very important. Teaching to the test. That being said using vs. having seen or used other laparoscopic simulators may also bias the results. Is there information on involvement in any simulation course or model?

[Understood. No participants had ever performed on the TLH-BSO model specifically \(any component or altogether\). Given that is how the demographics were specifically collected, that is how the data was reported. Anecdotally, all participants were new to the Gynesim models altogether themselves, or had only heard of/seen presentations of advertisement/viewed Gynesim of some sort at an exhibition hall from a conference.](#)

Line 138 The local recruitment bias may make the study less generalizable particularly to resident variable training and local generalist practice patterns.

[We do acknowledge this in our limitations paragraph in the discussion.](#)

Methods:

Line 163 What uterine manipulator was provided? Was there a colpotomizer or Koh ring?

[We used the disposable Advincula Delineator uterine manipulators provided by Cooper Surgical's education grant. This has a colpotomy ring. We revised the information regarding uterine manipulator to include information about the colpotomy ring to the methods.](#)

Line 167 Providing vs. requiring two assistants may bias some of the quantitative outcomes. This should have been standardized regardless of preference.

[We allowed the study participant to choose if they wanted assistance. One assist was standardized to the uterine manipulator and another was standardized as a laparoscopic assist. Not all participants elected to](#)

use both. The manuscript has been edited for more clarity.

Line 168 Were the fellow assistants blinded to the level of training of the participants?

No. As one can imagine, recruitment and collection of data in and of itself was extremely challenging, time consuming, and required mobilization of essentially travel operating rooms to regional and national sites. It would be hard then to standardize two assistants that do not recognize participants as they have to physically be present and can see the study participant. The standardized assistants had explicit orders on what they could provide as aid (only tasks such as holding the camera, grasping or retraction), and had to be directly told by the study participant for each step. The expert reviewers were blinded. These details are included in the methods.

Line 171 What choices if any were given for cuff closure? V-lock suture, running etc.?

They were given a choice between V-lock or Vicryl suture for closure. Figure 2 demonstrates several of the instruments provided.

Line 173 What was the training or instruction given regarding ExCITE technique and what was the pre testing use of this technique?

The tissue extraction station was readied with their specimen while the study participant performed their cuff closure. The specimen was placed in a bag, brought through the simulated umbilicus, and held in place with a self-retaining retractor (Figure 2c). Several instruments to grasp and cut the specimen was provided. No training was provided. We did not assess the use of this technique prior.

Line 185 The expert reviewers should have included other subspecialties ie urogyn or experience gyn only surgeons.

We tried to mitigate bias by employing only high-volume gyn-only experts in both benign and oncology. We did not want to have too many expert reviewers as this could worsen inter-rater reliability. We do mention this in our limitations.

Line 192 The separate tissue extraction simulator sounds similar to models used at the ACOG ACM and probably other AAGL courses. What was the exposure or experience with the model for each cohort?

We did investigate this prior, and the tissue extraction models used at ACOG ACM and other AAGL courses are the SimSei made by Applied Medical. We did not use that simulator box. See Figure 2c.

Line 201 I understand using the MIGS specialist as control but I would not have necessarily kept one sided.

We acknowledge this and did do various direct comparisons between the cohorts for both OSATS and time scores (Table 4 and 5). We have also now incorporated a Bonferroni adjustment to account for the multiple comparisons.

Line 211-212 If 20% of generalist were gyn only what percent of the total 448 hysterectomies were done by gyn only vs. full scope ob/gyn?

This breakdown of data was not reported in the paper in an effort to not overload the tables. But of those that were gyn-only, they performed an average of 55 hysterectomies per year.

Line 216-217 The preferred route of hysterectomies in the generalist group toward TAH should be further broken down into the gyn only sub cohort vs. full scope. These are really two different cohorts in practice.

The purpose of this study was to look at a collective group of generalists who we sought to represent the spectrum of clinical practice. Doing a much more granular analysis would have required a significantly larger cohort thus decreasing the feasibility of study execution.

Results:

Line 258-262 The content and construct validation are perhaps the most important findings

We do agree that those are very important components to validation of a simulator, but understand that more proof is required. We used the Messick model for validity framework when studying this model. See reference 14 by Cook et al for further details.

Line 265 Of the 24/25 who had prior simulation exposure what cohorts were they in? This addresses the concerns previously mentioned and potential bias.

25 participants had exposure to “a” hysterectomy simulator, but not the Gynesim simulator. Of those, 96% felt the Gynesim model was superior for surgical education at the completion of the study. This has been clarified in the text.

Table 1 The resident cohort had almost 25% who were going into non surgical or laparoscopic specialties limiting comparison.

While true, and important information to collect in order to objectively analyze the data, this does argue the reverse that 77.8% of residents participating in the study do, in fact, intend on performing laparoscopic surgery in the future. Importantly this also highlights, that while the majority intend to further their surgical training with fellowship, 38.9% will graduate as surgical generalists.

The wide range of hysterectomies for generalist should look at both mean and median.

The mean is 29.87. The range is reported at 2-75. Median, ranges and confidence intervals have now been reported in the tables where appropriate.

There is also an a priori difference in experience or preference for vaginal cuff closure.

Understood. We collected all the data for the demographic table to be as transparent as possible.

Discussion:

Line 272-274 There is a little bit of teaching to the test in regards to what is gold standard. The domains being assessed should have been given choices or made to preform the case by different methods ie vaginal closure vs. laparoscopic. V-lock vs. intracorporal closure. The results may have varied by technique and year of training. That is not to say the results are not important but the primary outcome may be more about validating the model than assessment or comparison of cohorts.

In an effort to compare exact components of the TLH/BSO, we did limit the study to a purely intra-corporeal laparoscopic closure. The participants were given the option of V-lock or Vicryl. Understanding that this might not be everyone's preference, we did collect that data within the pre-simulation questionnaire to be fair. It is also within our discussion that we address that those who complete a surgical fellowship are more likely to be consistently exposed to higher volumes and more complicated pathology, thus allowing for a translation in skill preference to close laparoscopically over vaginally. This model does offer the capacity for a transvaginal hysterectomy. It would be interesting to replicate this study with a TVH as well.

Line 290 It is a leap to make assumptions about gyn surgery in general vs. the specific focus of this study on a laparoscopic simulated hysterectomy. I would suggest being more specific and qualify with translational research from simulation to OR.

While we do agree that translational research is necessary, we do state that these are our inferences from our data with the direct purpose to invoke the reader to make their own perspectives. This is also why we did not separate this study into two manuscripts. The arguments for validation of this simulation model are directly tied into how we can interpret the results and move toward in-vivo comparisons from simulation to the operating room.

[In addition, we have extended the conversation of this paragraph to include commentary regarding the resident's trajectory. Please see revisions.](#)

Many of the concerns above were addressed in the limitation section.

Reviewer #3:

1. This is an original prospective cohort study looking at a large group of diverse participants representing many different levels of training/surgical experience. The primary objective was aimed at comparing skills and scores of the participants on a standardized TLH/BSO simulation. Strengths include the prospective nature of the study, the use of an objective validated scoring system (OSATS), blinding of reviewers, and the use of a standardized model with standardized surgical assistants. Limitations include the uncertainty of inter-rater reliability among reviewers, as well as possible lack of generalizability in the "generalist" cohort given that they were largely recruited from academic settings or an academic district meeting.

2. The manuscript is well written and I would like to commend the authors for a thorough and comprehensive evaluation performed.

[Thank you.](#)

3. Methods: The fellow and resident cohorts have generally a similar range of skills/training within their respective groups. However, in the generalist cohort there is a wide range of experience in terms of number of years in practice; it may be interesting to further stratify generalists by years in practice (e.g. less than vs more than 10 years) to see if there is any difference in performance on the tasks.

[Given the small \(n\), we, including our statistician, elected not to further break down the data to not skew results. Only 4 generalists were in practice less than 10 years. Their average years out of practice was 6.25 years.](#)

[We do agree that these were important data points to collect and thus were included in the pre-simulation survey for demographic purposes.](#)

4. Lines 161-163: The use of a standardized myomatous uterus without any pelvic pathology may make the results less generalizable for cases with endometriosis or adhesive disease. Maybe this could be acknowledged in the discussion section.

[Although that is an interesting point, the development of such a standardized model is very difficult. We would also argue that a myomatous uterus does constitute pelvic pathology. Also, our four cohorts of study participants are more likely to manage a myomatous uterus over an advanced endometriosis or extensive pelvic adhesive disease case.](#)

5. Lines 184-186: When the videos are assigned to blinded reviewers, do all five expert reviewers review every video, or is each video assigned to only a few of the reviewers from the pool of five? And if all 5 reviewers score each video, did you perform any statistical analyses to assess the inter-reviewer variability in scoring for each video? You partially addressed this in the discussion section but maybe you could say if you have any plans to analyze the inter-rater reliability.

[The videos were randomized and divided up between the reviewers. This phase was extremely time intensive for the expert reviewers. We do acknowledge in our limitations that no test subject was provided and thus we cannot prove the internal structure. We do try to mitigate this by employing only fellowship-trained experts in practice at least 10 years who focused in only gynecology surgery. We also included not just benign gynecologic surgery with MIGS, but also Gynecology Oncology in an effort to be more](#)

inclusive of surgical practices. While we could consider a comparison of an existing and randomized study participant to all the previous reviewers to analyze their inter-rater reliability, we consulted with an expert in validity research in surgical simulation and a retrospective analysis would not be acceptable and would have needed to be done at the outset of the study.

6. Discussion: I think you do a good job of addressing the possible lack of generalizability for using a more "academic" generalist cohort as opposed to non-academic generalists who may perform more surgery in areas with fewer specialists. Do you think that having readily-available subspecialists that can perform more advanced or complicated minimally invasive surgeries may negatively impact the ability or performance of generalists who are more likely to refer these cases to their MIGS or Gyn Onc colleagues? This is quite possible as this construct of subspecialists working in tandem with generalists is prevalent nationwide, particularly in academic institutions with residency programs. With the growing integration of minimally-invasive gynecology as a subspecialty and evidence to support better outcomes with higher-volume surgeons, we foresee referrals of complex benign gynecologic cases to become more commonplace. As a result, those specific exposures for those generalists would proportionally decrease, likely translating to less confidence and objective skill over time.

Reviewer #4: Thank you, authors, for the submission of this most interesting study and the accompanying manuscript. I have included a few questions and suggestions that should help the readability and clarity of your paper.

METHODS, Page 6, Line 135. Any specific reason the GyneSim model was chosen, over others? This model had the closest "likeness" to a live patient, similar to a cadaver, but was a fraction of the cost. We were able to design in it such a way that it was standardized to the exact number, location, and size of the myomas, the surrounding anatomy, and inclusion of vital structures key for evaluating objective skill. In addition, a consistent representative of Gynesim was able to travel to all the recruitment sessions to ensure model integrity. We are not aware of another model similar in these features.

RESULTS, Page 9, Line 210. You mention that the average Generalist in the study had performed 29.9 hysterectomies a year. How was this obtained? Was this self-reported? And (in the Discussion) what biases does that introduce?

This was self-reported. We understand that this may include a recall bias. This has been added to the limitations section of our discussion.

REFERENCE SECTION:

I would recommend you review the "Instructions for Authors" regarding References. There are sections of the 44 references that seem to be done correctly, and most are done with the same format (but not following the OG format). The main rules that seem to have been overlooked are as follows (please review ALL 44 references...)

1. The names of the cited journal should be abbreviated in the manner accepted by the journals in Pub Med, using the Index Medicus. For instance, 'Obstetrics and Gynecology' should be 'Obstet Gynecol'. Corrected.

2. The names of the cited journal should be capitalized, like any publication or book. ie. The journal of reproductive medicine should be 'J Reprod Med'.

Corrected.

3. In citing journal articles, there is no maximum number of authors that should be listed. Therefore, REFERENCE #4, That lists, "Urban RR, Ramzan AA, Doo DW, et al." should list all the authors.
Corrected.

4. The proper way to list the authors' names are last name first, then first initial of first and middle name; comma; then repeat which each subsequent author. REFERENCE #16 lists "Cohen SL and Emily Hinchcliff" instead of 'Cohen SL and Hinchcliff E.'
Corrected.

5. The journal titles should be italicized uniformly throughout the Reference section (example: References #16 and 17 are not)
Corrected.

6. The J Obstet Gynaecol Can : JOGC is listed twice in every reference in which it is cited, for some reason. It should not be.
Corrected.

All references have been edited to follow author guidelines. The Obstetrics and Gynecology endnote style was downloaded and used. Each reference was then double-checked to ensure it was appropriately written. Please let me know if there were any unforeseen errors.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1: The column totals range from 15 to 19, so the %s should all be rounded to nearest integer %, not to 0.1% precision. The years in practice should include some measure of variability, such as range. I assume the averages and ages are in terms of means, but should clarify.

Corrected in tables.

Table 2: Need units for BMI. Corrected.

The comparisons all need a referent. The numbers cited are based on a Likert scale and should be cited as median(range), since the samples are relatively small and the comparisons should be non-parametric.

Corrected.

lines 201-202: There is no a priori basis for using a one-sided p-value, should use a two-sided.

Corrected. All results adjusted accordingly.

lines 195-197: The power calculation is correct, but is based on only one primary outcome, namely comparing the residents vs MIGS. All other comparisons are secondary, unless the Authors wish to compare multiple groups as the primary outcome(s), in which case the sample size/power calculation is incorrect and multiple comparisons are underpowered.

Given that there is no literature from which to calculate a power analysis for the remaining categories (MIGS specialist vs. generalist and MIGS specialist vs. fellows), we have elected to extrapolate the data from the reference study (MIGS subspecialist vs. resident). We chose to do this given the importance of establishing a reference point for outcomes. With that being said, we acknowledge that this extrapolation requires us to be conservative in our interpretations and have adapted our results to abide by the rule of multiple comparisons. By performing a Bonferroni adjustment, we recalculated the p-value for each test to be equal to the alpha divided by the number of tests. Where appropriate, each table has been corrected

to reflect this and the comparisons that remain statistically significant have been highlighted with superscripts. Please see footnotes within the tables for details.

lines 204-206: The statement re: the meaning of R^2 is accurate, but incomplete. Whether $R^2 = 0.75$ is statistically significant depends on the sample size.

A p-value has been added to provide more information regarding statistical significance. We understand our sample size is small, and our goal was to show percentage of correlation. We calculated a corresponding p-value of <0.001 .

Table 3: Need to clearly separate the primary outcome (resident total OSAT score vs MIGS total score) from the rest. The study was not powered to evaluate all the subsets. The scores should be cited with some measure of variability and since non-parametric tests were used, should be median(range). Should round scores and times to nearest 0.1, not to nearest 0.01.

Clarification regarding primary outcomes addressed above. Bonferroni adjustment used for tables where appropriate. Methods adjusted accordingly as well.

Table 4: Should cite differences as mean difference with CI. Could summarize p-values in footnote. No correction for multiple hypothesis testing (30 comparisons in this Table, so only those with $p < .001$ retain statistical significance, but again, these are mostly secondary outcomes, not the primary outcome by study design.

Revisions as described above completed. Multiple hypothesis testing performed. Footnote added with recommended changes.

Table 5: Need to include CIs for mean differences, round time to nearest 0.1 minute, not 0.01 minute and clarify that minutes are the time unit used. Same issue as in Table 4 with multiple hypothesis testing, only the 3 out of 4 of the MIGS vs resident differences are statistically significant.

Revisions as described above completed. Multiple hypothesis testing performed. Footnote added with recommended changes.

Table 6: Need to cite scores as median(ranges) and correct for multiple hypothesis testing.

Revisions as described above completed. Multiple hypothesis testing performed. Footnote added with recommended changes.

EDITOR COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting.

Line 27: please mention what the people you are acknowledging did.

Included in revisions.

Line 51: The précis is a single sentence of no more than 25 words, written in the present tense and stating the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstracts conclusion. Précis should be the "hook" for people who scan the Table of Contents to see what to read. It shouldn't not include statements like "in this study" or "we found". Please make sure you mention that

this was a simulation study—"Standardized" doesn't quite capture that for the average reader. As well, ACOG prefers to describe "generalists" as "specialists" in distinction to "subspecialists". Here and on line 131 and thereafter, please use "specialists in Ob GYN".

Included in revisions. Precis is 25 words.

Line 85: The use of "novel" implies a primacy claim: yours is the first, biggest, best study of its kind. Perhaps best to delete this in the abstract. In the manuscript, in order to make such a claim, please provide the data bases you have searched (PubMed, Google Scholar, EMBASE for example) and the search terms used. IF not done, please edit it out of the paper as well.

The terminology "novel" has been removed from the abstract.

Within our extensive literature search, all models in alternative studies used were either low-fidelity or non-biologic or both. In addition, the focus of the current published studies is on virtual reality simulation or a specific portion of a total laparoscopic hysterectomy (i.e. colpotomy) and not an entire total laparoscopic hysterectomy with bilateral salpingo-oophorectomy. Studies with high-fidelity models for a vaginal cuff closure alone have been published. The novelty of the study arises not only from the use of this biologic model itself (given its likeness to a real patient or even a cadaveric specimen), but also from its design as the only prospective study of its kind to compare four separate cohorts of study participants with various degrees of training and expertise while also using a validated scoring tool (OSATS). Search engines include: PubMed, Google Scholar, EMBASE, PMC and our Columbia university library Search terms: "Gynesim," "hysterectomy simulation," "laparoscopic hysterectomy," "laparoscopic hysterectomy simulation," "biologic hysterectomy," "biologic hysterectomy specimen," "prospective laparoscopic hysterectomy simulation," "OSATS laparoscopic hysterectomy"

I am a bit unclear about what the purpose of the study is. Perhaps it will be clearer when I get to the manuscript but the abstract needs to be able to stand alone. Usually simulations are done for educational purposes but this seems to be set up as a contest almost between different groups. Was the purpose to begin with educational or comparative like this?

While we would not call it a "contest," this is a comparative study between the four cohorts of study participants. The purpose of this study was to stratify surgical skill level and confidence in the performance of a core gynecologic procedure applicable to all. With confirmation of our hypothesis that those who are fellowship-trained would score better objectively in surgical skill and subjectively with confidence, we aim to highlight the benefit of surgical sub-specialization in benign gynecologic surgery.

Line 108: The surgical experience for most graduating residents is more likely to be minimally invasive than abdominal as I understand it. Is "particularly minimally invasive" true in this context?

This phrasing is ultimately an inference from the studies cited and thus has been narrowed to just say, "There is rising concern that graduating Ob-Gyn residents are not prepared or confident in their surgical ability."

Line 112 Please spell out all abbreviations on first use in both the manuscript and abstract. If you never use the term again, you don't need to include the abbreviation.

Included in revisions.

Line 118: How does your study, as described in the abstract, address "continued post graduate Ob GYN surgical training"? Other than including one group of MIGS fellows?

These lines were removed by recommendation of a reviewer above. To answer your question though, this study highlights the importance of post-graduate Ob-Gyn surgical training in the sense that those who have pursued more surgical training in general were more confident and skilled when performing a TLH-BSO on standardized, high-fidelity biologic models. As the goal was to describe the benefit of post-graduate surgical training for benign gynecologic surgery, the focus was on minimally-invasive gynecology surgery fellowship over say, gynecology oncology. We elected to not include urogynecology

[as we endeavored to focus the conversation on the growing regard and acknowledgement of minimally-invasive gynecologic surgery as a subspecialty in its own right.](#)

Line 129: Please add how long the AAGL-approved MIGS fellowships are. As I understand them, its 2 years—so is 6 months before graduation (3/4 of the way through) comparable to 3 months before finishing Ob GYN residency 3/48's of the way through a good comparison?

[AAGL-accredited FMIGS programs are either two or three years in length. Only one program \(Columbia\) is three years in length with the extra year representing a purely research year without clinical responsibility. Two study participants were recruited from this site.](#)

[To clarify, you do mean ¾ of the way through a FMIGS fellowship and 45/48 way through an Ob-Gyn residency, correct? The goal was to score the study participants as close to the point of graduation \(whether immediately before or immediately after\) in order to represent how they would surgically be upon starting the next phase of their careers. The reason we chose 6 months for FMIGS fellows was purely for feasibility. There are not many FMIGS programs and they are scattered all over the US. In addition, most programs only have one fellow per year. The 6 months allowed us to encompass our annual AAGL conference where many fellows would be in one location for recruitment.](#)

[Clarification of the length of AAGL-accredited fellowship programs was included in the manuscript revisions.](#)

Line 135: please describe the Gynesim simulator in a bit more detail.

[The specimen is described in more detail in the following paragraphs in lines 165-168. Figure 2 also displays the model. It is also further mentioned in the discussion on how the model is made. Please let me know if this location is not acceptable and needs to be moved up.](#)

Line 158-60: Please describe how the operator was de-identified for anonymous scoring.

[Included in revisions.](#)

Line 167: What is a consistent FMIGS fellow? Do you mean the same 2 fellows were available for each of the participants?

[Yes, the same two FMIGS fellows were present for every single recruitment. One was available as the assistant holding the uterine manipulator and another was available for non-essential laparoscopic tasks as explicitly directed by the operator. This has been rephrased for clarity in the manuscript revisions.](#)

Line 196-200: Please note the important information by the statistical editor regarding your power analysis and primary outcome.

[Reviewed and revisions and/or explanations provided.](#)

Line 207: PRESENTATION OF STATS INFORMATION

P Values vs Effect Size and Confidence Intervals

While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

This is true for the abstract as well as the manuscript, tables and figures.

Please provide absolute values for variables, in addition to assessment of statistical significance.

We ask that you provide crude OR's followed by adjusted OR's for all relevant variables.

[Revisions made where appropriate in the abstract, tables and manuscript regarding recommendations above.](#)

Lines 214-216: How many of the residents and fellows had completed that segment of their training (you had said they could be up to 3 and 6 months post fellowship and residency).

[If I am following this correctly---All residents and fellows surveyed in this study met eligibility criteria and thus had completed all the specified segments of training required.](#)

Line 222. Do not begin a sentence w/ a numeral. Either spell out or edit your sentence to avoid the need to start w/a number.

[Included in revisions.](#)

Line 225. We do not allow authors to describe variables or outcomes in terms that imply a difference (such as the terms “trend” or “tendency” or “marginally different”) unless there is a statistical difference. Please edit here and throughout to indicate that there is no difference.

[We have carefully combed through the manuscript to ensure trends are no longer described. Only statistically significant data is included in our descriptions. We have also adjusted the results accordingly with the recommended changes in description of our data per the statistical editor’s recommendations.](#)

Line 245: What do you mean they were the fastest? Please provide the comparison data. You’ve given 2 data points, presumably that of the MIGS specialist and the fellow with a non significant p value, so no different. Also even if these were different, is 3 minutes clinically relevant?

[When modifying the data in the appropriate format as specified in these reviews, our statistician noted 4 values of the fellow’s total TLH time to be in seconds and not minutes in the R software. This skewed results. This has been corrected in all the tables, text and concepts. We then double-checked all entries to ensure no further technical errors. The raw data can be provided at your request.](#)

[Given we have modified our data to be two-sided and report medians with ranges, we have also clarified the phrasing of the data in the manuscript revisions to read: “MIGS subspecialists showed statistical significance in speed when compared to residents in all categories, with an overall median time of 40.4 min and 65.7 min, respectively \(\$p < 0.001\$ \). Comparisons between the cohorts can be seen in Table 5. MIGS subspecialists were significantly faster than fellows in overall TLH-BSO time \(\$p < 0.05\$ \), but not in sub-categories of cuff closure or tissue extraction. Similarly, specialists in Ob-Gyn were faster than residents in overall TLH-BSO time \(\$p < 0.05\$ \), but not in sub-categories of cuff closure or tissue extraction. There were no statistical differences between the fellow and the specialist in Ob-Gyn.”](#)

Line 259: Let the data speak for itself, and avoid perception of self aggrandizement, by deleting the phrase “the most skilled surgeons”. Inclusion of this speaks to my concerns about the purpose of the study.

[Understood. This has been removed from the manuscript. Please see above for clarifications on study purpose.](#)

Line 275: Since this is a simulator, while a reasonable proxy for surgical skill, perhaps best to say here that MIGS specialists scored highest rather than stating “more skilled”.

[Included in revisions.](#)

Line 289: I’m not sure I’m following you here. This study showed that specialists in practice did score better than the residents, didn’t it? So one can reasonably assume there is improvement over time. The study does not address whether they are “less prepared” (less prepared compared to who?) as it shows that there is improvement with additional experience. Are they “less prepared” than residents trained in

prior years? You haven't studied this and can't conclude this. Are they "less prepared" than a MIGS subspecialist in practice for 9 years? I dare say you didn't need a study to show this. You really need to dial this whole section way back.

You've shown a "dose response" of experience vs performance on a simulation.

What we intended to relay was the correlation between those who chose to obtain further post-graduate surgical training in the form of a MIGS fellowship had higher OSATS scores and surgical confidence. Those who did not elect to pursue this would, at the outset of their career, likely be less confident and surgically-exposed and as a result, less prepared. While it is very clear that the MIGS subspecialists did better than the residents, this is not the only focus of the conversation and we agree a study focusing on just that piece would likely be an unnecessary study.

The phrasing has been adjusted to reflect that less prepared means less confident and surgically-exposed. We have also added the text at the end to say, "Although the residents score the lowest, the study did not answer whether or not over time they could obtain the same performance outcome as the MIGS subspecialist or the FMIGS fellows, and if so, over what time frame. How a graduating resident tailors their practice and continued surgical education will likely dictate that trajectory."

Line 293: how do you know "only after many years of practice? You didn't study that. Maybe the biggest gains are in the first 3 years and then a plateau.

This sentence segment has been deleted from the manuscript.

Line 296: By whose criteria is this reasonable for all gyn surgeons who do laparoscopic surgery?

Given changes in practice and the use of more conservative therapies, i.e. Mirena IUD and endometrial ablation, the pathology presenting to surgeons for intervention are often larger and/or more complex. As no standardized criteria exists regarding average uterine weight removed by a practicing gynecologic surgeon, 250 grams was chosen as it is the break point in CPT coding subdivisions for a laparoscopic hysterectomy with bilateral salpingo-oophorectomy (Code 58571).

Line 297: I'm and MFM so I'm not sure I understand how laparoscopic suturing is considered "advanced laparoscopy".

It is an advanced laparoscopic skill. Maybe that is a better way to phrase it. Revisions in the manuscript.

Lines 300-304: as noted, this is out of scope...I'd recommend leaving it there.

Removed after review of a previous comment from a reviewer above.

Line 312: or is it a time to develop over confidence? Also please provide a reference for this sentence.

Due to word limit restrictions this comment has been removed. But more references have been added to strengthen our statements (Glaser, Gabbe, Naveiro) and the conversation regarding this has been consolidated in the 3rd paragraph of the discussion to aid in decreasing word count. You can see our modifications through our tracked changes.

Line 333: This is known as a primacy claim: yours is the first, biggest, best study of its kind. In order to make such a claim, please provide the data bases you have searched (PubMed, Google Scholar, EMBASE for example) and the search terms used. IF not done, please edit it out of the paper.

Response from above pasted here for reference as previously discussed.

Within our extensive literature search, all models in alternative studies used were either low-fidelity or non-biologic or both. In addition, the focus of the current published studies are on virtual reality simulation or a specific portion of a total laparoscopic hysterectomy (i.e. colpotomy) and not an entire total laparoscopic hysterectomy with bilateral salpingo-oophorectomy. Studies with high-fidelity models

for a vaginal cuff closure alone have been published. The novelty of the study arises not only from the use of this biologic model itself (given its likeness to a real patient or even a cadaveric specimen), but also from its design as the only prospective study of its kind to compare four separate cohorts of study participants with various degrees of training and expertise while also using a validated scoring tool (OSATS).

Search engines include: PubMed, Google Scholar, EMBASE, PMC and our Columbia university library
Search terms: "Gynesim," "hysterectomy simulation," "laparoscopic hysterectomy," "laparoscopic hysterectomy simulation," "biologic hysterectomy," "biologic hysterectomy specimen," "prospective laparoscopic hysterectomy simulation," "OSATS laparoscopic hysterectomy"

Line 352—seems like this sentence is incomplete.

Included in revisions.

Line 356: The journal style does not support the use of the virgule (/) except in mathematical expressions. Please remove here and elsewhere.

Included in revisions.

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. 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.

We elect to 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.

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

3. Please submit a completed STROBE checklist.

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.

[Attached for submission.](#)

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.

[Reviewed and no concerns.](#)

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.

[Revisions tracked in manuscript. Of note, the title page is two pages given the multiple components required. As a result, all the pages are numbered accordingly \(i.e. the précis is now on page 3 and not page 2, and so forth\).](#)

[Our word count for the title page, précis, abstract, text, tables, boxes and figure legends is <5,500 words.](#)

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).

[Reviewed and no concerns.](#)

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."

[Revisions made, as above. Please see manuscript.](#)

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.

[Reviewed and revisions made accordingly.](#)

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.

[Reviewed and no concerns. Abstract is 276 words.](#)

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.

[Revisions made accordingly, please see manuscript.](#)

10. 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.

[Reviewed and no concerns.](#)

11. 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.

[Revisions made accordingly, please see manuscript.](#)

12. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

[Revisions made accordingly, please see manuscript.](#)

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

[Not applicable to this study.](#)

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

[Revisions made accordingly, please see manuscript.](#)

13. 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.

[Comment previously made by Editor and response provided above.](#)

14. 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://edm-gr.ovid.com/ong/accounts/table_checklist.pdf.

[Revisions made accordingly, please see manuscript.](#)

15. 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 via the Clinical Guidance & Publications page at <https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance>.

[Reviewed and no concerns.](#)

16. Figures

Figure 1: Current figure file may be resubmitted with the revision as-is.

[Attached as a separate JPG file. Figure legends within manuscript following tables.](#)

Figure 2: Please provide a version of this figure without the A–D labels. These will be added back per journal style.

[Revisions made accordingly, attached as a separate JPG file. Figure legends within manuscript following tables.](#)

Figure 3: Please provide a letter of permission to use this figure in print and electronic formats. Also please provide a high resolution version of this figure (text should be crisp when you zoom in)

[Still awaiting response from author regarding permission. If not permitted or we still do not hear back, it can be easily removed from the manuscript without incident. The methods section carefully explains the scoring system and a reference is provided. It was included to be comprehensive, but is not mandatory.](#)

[Revisions made accordingly, attached as a separate excel file. Figure legends within manuscript following tables.](#)

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- * 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.

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 Mar 05, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief