

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 19, 2020
To: "Malcolm G. Munro" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-36

RE: Manuscript Number ONG-20-36

Essentials in Minimally Invasive Gynecology (EMIG) Manual Skills Construct Validation Trial

Dear Dr. Munro:

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 11, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

Review of Manuscript ONG-20-36 "Essentials in Minimally Invasive Gynecology (EMIG) Manual Skills Construct Validation Trial"

Munro and colleagues on behalf of the EMIG Steering Committee have reported results of a series of skills performed among surgeons of different levels (and skills), including nearly 150 residents, in an attempt to determine if this approach may be a more "valid" assessment of minimally invasive surgical skills, as compared to current utilization of the Fundamentals in Laparoscopic Surgery. As noted, the authors use, for lack of a better word, normative data from a pilot study to help design the study in terms of maximal time allowed per task. I have the following questions and comments.

Title - No comments

Précis - No comments

Abstract - I think it is important to list that this was an IRB approved project in the abstract as it does involve residents, "students", that can be considered a vulnerable population. Are there numerical results that can be provided in the results section and/or the statistical test results which support these observations?

Introduction - While the introduction is very comprehensive and highlights many of the issues related to the subject matter it was too long in my opinion. Is there a way to condense some of this information such that the introduction itself can be shortened? For instance, lines 135-147 can either be shortened or much if not all of this might be able to be moved to the discussion. Lines 149-163 - do you need to single out a individual for this over and above the organization?

Methods - Line 231-3 - why was only two hysteroscopic tests selected? Line 275- since subjects were collected from multiple sites how did you control, if at all, for the Orientation proctor? While the descriptions of the procedures are quite comprehensive, they again contribute to the significant length of the article. Is it possible that these can be shortened in some fashion, and/or the similar elements elucidated with the remainder in an appendix? Perhaps a much shorter description be created with subsequent reference to an appendix which perhaps could be lengthened and/or listed in bullet points for all details of each of the tasks. Line 438 - What protections were in place, especially for the residents, that if they elected not to participate this was not punitive for them? Line 536 - Interesting that Excel was the statistical program utilized. While the trainer seems reasonable, one concern that is difficult to deal with perhaps is that the "entry" points for the ports may in fact not be consistent with real human anatomy (trainer ports closer together and there is no anterior "abdominal wall thickness" to speak of versus a real anterior abdominal wall as well as ports that are often further apart).

Results - Line 560 - With the proficient, non-FMIGS, group there were only 33 participants and not the goal of 40 as noted in the methods. Line 572 - why did you present the same data in both tabular and figure form. If you want to use the figure, can you make the full table an appendix with a reference to the most important findings, time, etc., in the manuscript and/or figure legend? The hysteroscopic portion almost seems an afterthought to the paper based not only on the limited exercises performed but the scant portion of the results which address this.

Discussion - Like much of the paper, and at first glance, the discussion seems too long. Line 655 - Is it possible that not only the easier aspect of the HSC tests but the relative paucity of these (5 LSC vs. 2 HSC)? Line 695 is important about this being a process. Is there a way to shorten the conclusions to one or two paragraphs? Again, there is almost too much information included.

Tables - Table 1 - no issues. Did you consider combining Tables 2-4 into one table. It seems like with this type of data which has a limited number of variables that perhaps that would be a reasonable way to present the data. Table 3 is a bit overwhelming and again should be supplementary.

Figures - Since the data is predominantly related to LSC rather than HSC, may consider putting the figures dealing with HSC in an appendix in order to allow the LSC ones to remain.

REVIEWER #2:

This is an excellent long awaited report of validation studies on the minimum requirement of GYN graduates for performing Minimally Invasive Gynecology surgery and should be published.

To strengthen the paper, please include the following reference which provides the appropriate historical reference to highlight the importance of the project so the readers would appreciate the tasking nature of this activity. Below is the reference:

[https://www.jmig.org/article/S1553-4650\(09\)00128-9/abstract](https://www.jmig.org/article/S1553-4650(09)00128-9/abstract)

(may also be found here) <https://endometriosispecialists.com/nezhatmedicalcenter/wp-content/uploads/2012/12/Proposal+of+a+formal+gynecologic+endoscopy+curriculum.pdf>

Additionally, a reference to the recent JAMA article (<https://jamanetwork.com/journals/jama/fullarticle/2758269>) highlighting the importance of "The responsibility of physicians to maintain competency" may add to the usefulness of this project even in cases of maintenance of certification for practicing minimally invasive Gynecology surgery.

REVIEWER #3:

This is a well designed prospective multicenter trial evaluating whether EMIG performance correlated with participants' training level. The paper was well written and provided excellent figures, tables and videos.

1. In Study Design line 412, can authors clarify what "aggregate experience with operative laparoscopy and operative hysteroscopy = 0" means? Did PG1 residents who participated in this study have NO laparoscopic or hysteroscopic experience?
2. Could an explanation for the less pronounced differences in performance of hysteroscopic exercises among the four cohorts be that PGY1 residents are immediately exposed to hysteroscopy at the start of their training? Could the results have to do more with exposure to the procedure versus ease of the tasks assigned?
3. In Discussion, could the authors comment on future applications of the EMIG laparoscopic and hysteroscopic simulation systems? Are these systems available to Ob/gyn residency training programs? What is their cost and could these systems be made available to ABOG-certified obstetrican gynecologists who want to improve their skills?

STATISTICAL EDITOR'S COMMENTS:

1. lines 438-444: Should expand on the recruitment process to address any bias that might prevent extrapolation of these results to the cohorts that are represented (PGY-1, PGY-3, proficient and FMIGS).
2. Table 2: No need to include the SEM, since the N and SD are already reported. No need to include the Cohen's d, could be in supplemental material if desired. Suggest that showing the mean difference (with CIs) would be more informative for contrasting the completion times for PGY-1 vs PGY-3, Proficient vs FMIGS, or could summarize all 4 categories by use of ANOVA, then compare pairwise for each exercise.
3. Table 3: Same comment re: citing SEM and Cohen's d. Also, since most of these comparisons were NS and there were 42 comparisons in all, likely some of those could be spurious due to multiple hypothesis testing. Should include this in

supplemental material. Is there a more concise summary of error rates for the various cohorts that could be used? If so, again, summarizing by use of ANOVA and comparison across the 4 groups by use of mean differences (with CI) would seem a more efficient summary of the error rates.

ASSOCIATE EDITOR - GYN

We acknowledge the importance of the submission in future training of minimally invasive surgical skills. However, a resubmission would need to address a series of items in addition to the manuscript being too lengthy. Better synchrony with the pilot validation trial published in JMIG is also needed.

1 - The Abstract as written has no data provided in the Results section - which is not acceptable for an 'Original Research' submission

2 - Intro at about 5 pages is far too long (number pages 7-11) and would need to be condensed

3 - Methods (numbered pages 11-26) is far too lengthy - which led to some discussion whether this manuscript would be better split into 2 separate papers: 1 showing the devices/models and methodological details and another with a focus on the original research validation. Yet, the figures with the devices/models are already pictured in the pilot trial paper published in JMIG and thus too repetitive to warrant a stand-alone P&I submission. We would suggest this section reference the pilot trial more, move some of the figures to Supplementary content and shorten significantly.

4 - Results - brief and with no notable data in the actual text - we would encourage a better synchrony here with the figures/tables

5 - Discussion at 7 pages also could be shortened significantly to highlight the main points

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. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

4. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works. Variance is needed in the following sections:

- a. Lines 180-204 appear to be mostly a quote from another source. If any sections of this quote are not verbatim, please be sure to put them in brackets.
- b. Additionally, 20% of the entire manuscript matches the previous pilot study. We do understand that there will be overlap; however, variance should be added to lines 462-511. Additionally, lines 721-728.
- c. The first paragraph of the conclusions section should be original, and not taken from the pilot study. Please add more variance.

5. 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.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric 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.

7. 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.

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

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

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

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

11. 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%).

12. 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.

13. 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.

14. The Journal's Production Editor had the following comments about the figures in your manuscript:

"All figures: Please upload as figure files on Editorial Manager.

Figure 4: Note that the person visible in this image will need to sign a release form since she can be identified. We will provide this form.

Figure 9: Please provide the graph and image as separate figure files.

Please consider moving some figures to supplemental digital content, as this many figures may not fit in print."

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate

file to Editorial Manager (do not embed the figure in your manuscript file).

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce.

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

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

If you choose to revise your manuscript, please submit your revision 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 11, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

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.



Malcolm G. Munro, MD, FACOG, FRCSC
Chair, FIGO Menstrual Disorders Committee

Clinical Professor, Department of Obstetrics & Gynecology
David Geffen School of Medicine at UCLA

March 17, 2020

Dr Nancy Cheshire
Editor
Obstetrics & Gynecology

Re: Essentials in Minimally Invasive Gynecology (EMIG) Manual Skills Construct Validation Trial:
Revision-1.

Dear Dr Cheshire,

Please accept this revised manuscript. We include a point-by-point response ([in blue type](#)) to the reviewer's and editors' comments and requests and have now modified our submission to conform to the requirements for *Obstetrics & Gynecology* which is the only journal to which this manuscript has been submitted. Indeed, we have read the instructions for authors as a prerequisite to formatting this revision. The manuscript is not under consideration elsewhere and will not be submitted elsewhere until or unless a final negative decision is made by the Editors of *Obstetrics & Gynecology*.

The revision has been reviewed by the co-authors and those in the acknowledgements have had the opportunity to review the manuscript and provide permission to use their names.

Regards,

Mac

A handwritten signature in blue ink, appearing to read "Munro".

Malcolm G. Munro MD
Principal Investigator, EMIG Manual Skills Construct Validation Trial
Essentials in Minimally Invasive Gynecology (EMIG) Manual Skills Construct Validation
Trial

REVIEWER COMMENTS:

REVIEWER #1:

Review of Manuscript ONG-20-36 "Essentials in Minimally Invasive Gynecology (EMIG) Manual Skills Construct Validation Trial"

Munro and colleagues on behalf of the EMIG Steering Committee have reported results of a series of skills performed among surgeons of different levels (and skills), including nearly 150 residents, in an attempt to determine if this approach may be a more "valid" assessment of minimally invasive surgical skills, as compared to current utilization of the Fundamentals in Laparoscopic Surgery.

[This was not a comparative study. There are no study-based comparisons to FLS. Of course, FLS has no hysteroscopic component.](#)

As noted, the authors use, for lack of a better word, normative data from a pilot study to help design the study in terms of maximal time allowed per task. I have the following questions and comments.

Title - No comments

Précis - No comments

Abstract - I think it is important to list that this was an IRB approved project in the abstract as it does involve residents, "students", that can be considered a vulnerable population.

[We have added the documentation of IRB approval in the abstract.](#)

Are there numerical results that can be provided in the results section and/or the statistical test results which support these observations?

[We have added primary outcome data to the abstract.](#)

Introduction - While the introduction is very comprehensive and highlights many of the issues related to the subject matter it was too long in my opinion. Is there a way to condense some of this information such that the introduction itself can be shortened? For instance, lines 135-147 can either be shortened or much if not all of this might be able to be moved to the discussion.

[The introduction has been shortened. See track changes version for changes](#)

Lines 149-163 - do you need to single out a individual for this over and above the organization?

This individual did have the vision and the organizational skills to launch and guide this process initially, but we have eliminated the name from the text and left it in the acknowledgement section.

Methods - Line 231-3 - why was only two hysteroscopic tests selected?

Indeed, four hysteroscopic exercises were developed. Our other tests included a simulated rollerball resectoscope model as well as a tubal cannulation model. It was the opinion of our Steering Committee and the two exercises selected would be adequate for resident level testing. We believe that this is an acceptable approach for these levels of resident training, but for assessment of more demanding hysteroscopic psychomotor skills, it would be necessary to use additional testing.

Line 275- since subjects were collected from multiple sites how did you control, if at all, for the Orientation proctor?

First of all, there were only three proctors for the entire study. In all instances, two or three of the proctors travelled to the sites. Each would function as a Training or Orientation Proctor for a given subject. The Training Proctor would never be the Orientation Proctor for a single individual. The subsequent central review described in the methods section further minimized variation in proctor based evaluation as a potential confounder.

While the descriptions of the procedures are quite comprehensive, they again contribute to the significant length of the article. Is it possible that these can be shortened in some fashion, and/or the similar elements elucidated with the remainder in an appendix? Perhaps a much shorter description be created with subsequent reference to an appendix which perhaps could be lengthened and/or listed in bullet points for all details of each of the tasks.

We have shortened these descriptions and added some components to the digital supplementary material. We are uncertain, from the review, whether or not the reviewer looked at the videos of these exercises which were submitted as supplemental digital material.

Line 438 - What protections were in place, especially for the residents, that if they elected not to participate this was not punitive for them?

The informed consent waiver and instructions, both to the local PI and to the potential participant emphasized this. Participation was anonymous.

Line 536 - Interesting that Excel was the statistical program utilized.

Microsoft Excel is not a statistical program. However, Excel does contain time-tested graphing and statistical capabilities appropriate to the computational and analytical tasks contemplated in the study. It provided the benefit of allowing data to be

organized, managed, evaluated and analyzed all within the same digital file, thus minimizing data transfer errors.

While the trainer seems reasonable, one concern that is difficult to deal with perhaps is that the "entry" points for the ports may in fact not be consistent with real human anatomy (trainer ports closer together and there is no anterior "abdominal wall thickness" to speak of versus a real anterior abdominal wall as well as ports that are often further apart).

Thank you for this comment. The trainer box is the one used for FLS and is, therefore, available throughout the country for general surgical programs. As a result, it allows simulation centers to use the same context within which to perform and assess these fundamental psychomotor skills. The FLS system for general surgery has used this type of system for all of the studies that have contributed to the process of validation for general surgery residents over the last 15 years or so. Yes, there would or could be advantages to having realistic abdominal walls, or of realistic tissue targets, but these surrogates have been demonstrated capable of supporting exercises that appear to discriminate amongst individuals with different levels of training and experience.

Results - Line 560 - With the proficient, non-FMIGS, group there were only 33 participants and not the goal of 40 as noted in the methods.

This is correct. The reason for the goal of 40 was to ensure that we reached the desired minimal sample size of 30 defined by our statistical consultants. Thirty observations is a standard documented in statistical literature that will allow a dataset to minimally approximate a normal distribution, and thus allow the valid use of more robust statistical measures in its analysis. The Proficient v. 2-year FMIG pairwise analyses were actually secondary outcomes. We anticipated that we might have difficulty in reaching the goal for the Proficient cohort as it is the one least represented in the medical centers throughout the two countries. However, our data attrition was very low in this group, a circumstance that allowed us to reach our minimum sample size.

Line 572 - why did you present the same data in both tabular and figure form. If you want to use the figure, can you make the full table an appendix with a reference to the most important findings, time, etc., in the manuscript and/or figure legend?

Only selected data are presented as figures. The selected figures we believe are superior ways to convey the results of selected data elements, but don't provide all the variables tested - the specific values, the SDs, the 95% confidence intervals - and don't include the granularity of statistical components of the analysis. There are quite a few data elements here that are not included in the figures and we think it best to include them with the main manuscript.

The hysteroscopic portion almost seems an afterthought to the paper based not only on the limited exercises performed but the scant portion of the results which address this.

The hysteroscopic portion is not an afterthought, but there are only two relatively rudimentary exercises each of which have fewer measured variables. This doesn't undermine the value of the hysteroscopic component of the EMIG systems, but it does result in a smaller data set. There are other hysteroscopic exercises developed and in future studies we think that they would be useful additions to the menu of tests for prospective gynecological surgeons.

Discussion - Like much of the paper, and at first glance, the discussion seems too long.

We have shortened the discussion – see the marked up text.

Line 655 - Is it possible that not only the easier aspect of the HSC tests but the relative paucity of these (5 LSC vs. 2 HSC)?

It is possible, but the level of difficulty would appear to be the major reason.

Line 695 is important about this being a process. Is there a way to shorten the conclusions to one or two paragraphs? Again, there is almost too much information included.

We understand, but these concepts are likely new to the majority of readers. We have made adjustments and hopefully the reviewer will find this to be satisfactory.

Tables - Table 1 - no issues.

Noted

Did you consider combining Tables 2-4 into one table. It seems like with this type of data which has a limited number of variables that perhaps that would be a reasonable way to present the data.

Table 2 are all time-based variables, so we feel that these should stand alone. We have combined Tables 3 and 4 and removed some of the outcomes that were infrequent and non-discriminatory.

Table 3 is a bit overwhelming and again should be supplementary.

See above

Figures - Since the data is predominantly related to LSC rather than HSC, may consider putting the figures dealing with HSC in an appendix in order to allow the LSC ones to remain.

We wouldn't be happy with this because of the importance of hysteroscopy to the specialty. It is our opinion that the value of hysteroscopy as an access method and technique for directing the performance of surgical procedures has generally been

minimized; even trivialized. We already have only two exercise – moving the data to supplementary material would only serve to reinforce this notion.

REVIEWER #2:

This is an excellent long-awaited report of validation studies on the minimum requirement of GYN graduates for performing Minimally Invasive Gynecology surgery and should be published.

To strengthen the paper, please include the following reference which provides the appropriate historical reference to highlight the importance of the project so the readers would appreciate the tasking nature of this activity. Below is the reference:
[https://www.jmig.org/article/S1553-4650\(09\)00128-9/abstract](https://www.jmig.org/article/S1553-4650(09)00128-9/abstract)

We appreciate this comment and suggestion – there was a mistaken reference that was placed to make this point. The correct reference is now in place.

(may also be found here) <https://endometriosispecialists.com/nezhatmedicalcenter/wp-content/uploads/2012/12/Proposal+of+a+formal+gynecologic+endoscopy+curriculum.pdf>

Additionally, a reference to the recent JAMA article (<https://jamanetwork.com/journals/jama/fullarticle/2758269>) highlighting the importance of "The responsibility of physicians to maintain competency" may add to the usefulness of this project even in cases of maintenance of certification for practicing minimally invasive Gynecology surgery.

REVIEWER #3:

This is a well designed prospective multicenter trial evaluating whether EMIG performance correlated with participants' training level. The paper was well written and provided excellent figures, tables and videos.

1. In Study Design line 412, can authors clarify what "aggregate experience with operative laparoscopy and operative hysteroscopy = 0" means? Did PG1 residents who participated in this study have NO laparoscopic or hysteroscopic experience?

Yes, that is what it means. We have altered the wording to clarify the statement. Also see Supplementary Digital material - Appendix 1.

2. Could an explanation for the less pronounced differences in performance of hysteroscopic exercises among the four cohorts be that PGY1 residents are

immediately exposed to hysteroscopy at the start of their training? Could the results have to do more with exposure to the procedure versus ease of the tasks assigned?

We don't think so. The exposure had to be 0 or 1 for simulation and 0 for surgical procedures so we excluded those with higher scores than this very restrictive threshold. We also excluded sites that provided "boot camps" or early exposure in their training programs to minimize the risk of exposure. Furthermore, we performed the study within 100 days of the start of their first year, an approach that largely eliminated this issue in the programs included in the trial.

3. In Discussion, could the authors comment on future applications of the EMIG laparoscopic and hysteroscopic simulation systems? Are these systems available to Ob/gyn residency training programs? What is their cost and could these systems be made available to ABOG-certified obstetrician gynecologists who want to improve their skills?

Future applications of the EMIG laparoscopic and hysteroscopic simulation systems include both training and testing, with the latter ranging from local assessments, a national formative test analogous to the CREOG in-training examination, and an addition to, or replacement for the FMIGS examination currently used by ABOG. The systems are not yet available, and a cost structure is not yet established.

STATISTICAL EDITOR'S COMMENTS:

1. lines 438-444: Should expand on the recruitment process to address any bias that might prevent extrapolation of these results to the cohorts that are represented (PGY-1, PGY-3, proficient and FMIGS).

We have expanded on this in a number of sections – see "Study Sites" and "Cohort Groups". Also note the addition to Table 1, where we have demonstrated that all of the ACOG regions have been represented by at least one site.

2. Table 2: No need to include the SEM, since the N and SD are already reported. No need to include the Cohen's d, could be in supplemental material if desired. Suggest that showing the mean difference(with CIs) would be more informative for contrasting the completion times for PGY-1 vs PGY-3, Proficient vs FMIGS, or could summarize all 4 categories by use of ANOVA, then compare pairwise for each exercise.

We modified Table 2 removing SEM, and Cohen's d and added a difference of mean comparison with associated confidence intervals.

3. Table 3: Same comment re: citing SEM and Cohen's d. Also, since most of these comparisons were NS and there were 42 comparisons in all, likely some of those could be spurious due to multiple hypothesis testing. Should include this in supplemental material. Is there a more concise summary of error rates for the various cohorts that could be used? If so, again, summarizing by use of ANOVA and comparison across the 4 groups by use of mean differences (with CI) would seem a more efficient summary of the error rates.

Table 3 has been modified remove SEM, Cohen's d and have added a comparison of mean differences with confidence intervals.

Our methodology was designed to reduce the effects of multiple comparisons within and between each group. Using ANOVA will summarize whether significant differences exists between one or more groups in multiple comparisons, but it will not indicate which pairings have significant differences. Inasmuch as the primary comparison of interest was between the Novice cohort and the Mid-Level cohort, we tested that pairing for every data point. Comparisons between Proficient and FMIG cohorts were secondary findings. Any other comparisons were deemed out of scope for this project.

ASSOCIATE EDITOR - GYN

We acknowledge the importance of the submission in future training of minimally invasive surgical skills. However, a resubmission would need to address a series of items in addition to the manuscript being too lengthy.

Better synchrony with the pilot validation trial published in JMIG is also needed.

We have endeavored to increase the synchronization with the pilot study but it is difficult since it was a pilot and there were important differences in design.

1 - The Abstract as written has no data provided in the Results section - which is not acceptable for an 'Original Research' submission

The exercise time data from the primary outcomes are now included in the Results section.

2 - Intro at about 5 pages is far too long (number pages 7-11) and would need to be condensed

We have substantially reduced the length of the introduction

3 - Methods (numbered pages 11-26) is far too lengthy - which led to some discussion whether this manuscript would be better split into 2 separate papers: 1 showing the devices/models and methodological details and another with a focus on the original research validation. Yet, the figures with the devices/models are already pictured in the

pilot trial paper published in JMIG and thus too repetitive to warrant a stand-alone P&I submission. We would suggest this section reference the pilot trial more, move some of the figures to Supplementary content and shorten significantly.

The descriptions of each exercise have been reduced to the level that we feel comfortable with referring to the pilot and figures adjusted with more detailed descriptions in the supplementary material.

4 - Results - brief and with no notable data in the actual text - we would encourage a better synchrony here with the figures/tables

We had wanted to save space following the principal of avoiding duplication in the text of data from the tables. However, we have inserted the exercise time data for the primary and main outcomes for both the laparoscopic (L-1 to L-5) and hysteroscopic (H-1, H-2) exercises in the Results section.

5 - Discussion at 7 pages also could be shortened significantly to highlight the main points

The Discussion section has been shortened.

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.

A. 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.

Noted

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

This has been done

3. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

The first set of data were entered in the field directly to a web-based and backed up secure server by the trained proctors as described in the methodology section. These data comprised both continuous variables (time) and categorical variables, typically accuracy or yes/no errors. All exercises were video recorded, and all specimens were labeled, stored and transported to the study center. A second review was performed by a second Proctor using the videos and stored specimens, and another set of data entered and uploaded to the same server. If there was a discrepancy (as described in methodology) a third review was performed, with data entered. In virtually all instances the third reviewer agreed with one or the other initial assessment, but it was generally the second assessment. These data were then exported to an Excel workbook with subjects labeled only by their anonymous ID and the institution. Statistical and other analyses were conducted on neighboring worksheets within the same workbook, so as not to endanger the integrity of the data. Any consolidation or other manipulation of data was done via one-way reference within Excel and working with the reference or copy rather than the original data. Access to the master Excel workbook was protected, allowing access only to senior researcher, data manager and statistical team.

4. All submissions that are considered for potential publication are run through CrossCheck for originality.

The following lines of text match too closely to previously published works. Variance is needed in the following sections:

a. Lines 180-204 appear to be mostly a quote from another source. If any sections of this quote are not verbatim, please be sure to put them in brackets.

These lines have been removed as part of the editing process

b. Additionally, 20% of the entire manuscript matches the previous pilot study. We do understand that there will be overlap; however, variance should be added to lines 462-511. Additionally, lines 721-728.

Lines 462 to 511 and 721-728 have been revised to increase variance; see the text.

C. The first paragraph of the conclusions section should be original, and not taken from the pilot study. Please add more variance.

This paragraph has been largely rewritten; see the text

5. 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.

Please see the included STROBE checklist for cohort comparative studies

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric 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.

We believe that we are compatible with reVITALize

7. 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.

We have done our best to reduce the length of the manuscript. We checked with the office and were informed that the title page, acknowledgements and references were not included in the 5,500 word limit (Currently, the overall manuscript is 20 pages net references and supplemental material, the body of the manuscript is 5,169 words, the Abstract including required headings is 3000 words, the Figure Legends 681 words).

We agree with the editors that there was the possibility of creating two manuscripts, particularly because there are important concepts here that are new for readers and, consequently, framing the study both in the introduction and the discussion was difficult to compress further without compromising its integrity.

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.

The modified abstract matches the body text

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.

The abstract is now at 300 words, including headings

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

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

We believe that we have removed each virgule

11. 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.

We have made these changes – focusing on mean differences and 95% confidence intervals

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

We don't believe that this applies to this manuscript

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%).

12. 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.

The only example we could see was on original line 726 relating to the first publication of hysteroscopic simulation. While we believe that this is correct, we have modified the text to eliminate this term.

13. 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.

We have adjusted the table to fit the requirements documented in the checklist.

14. The Journal's Production Editor had the following comments about the figures in your manuscript:

"All figures: Please upload as figure files on Editorial Manager.

Figure 4: Note that the person visible in this image will need to sign a release form since she can be identified. We will provide this form.

This figure has now been modified so that there is no opportunity to identify the subject

Figure 9: Please provide the graph and image as separate figure files.

This comment refers to what is now Figure 7. We have submitted two separate files including one labeled as "Inset"

Please consider moving some figures to supplemental digital content, as this many figures may not fit in print."

We have moved two figures to supplemental digital content.

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

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If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures were generated via MS Excel and modified in MS PowerPoint

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

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- * A point-by-point response to each of the received comments in this letter.