

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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obgyn@greenjournal.org.

Date: Jul 01, 2021
To: "Paul Marshburn" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-1184

RE: Manuscript Number ONG-21-1184

A Fluid Management Drape for Hysteroscopy: Innovation for Improved Patient Safety and Surgical Care

Dear Dr. Marshburn:

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).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

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 Jul 22, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

This manuscript would benefit from attention to the concerns, questions, comments, suggestions and questions listed below.

- * The Study appears to meet the definition of a clinical trial cited in the Obstetrics and Gynecology Instructions for authors (<http://edmgr.ovid.com/ong/accounts/authors.pdf>). Please include information regarding pre-trial registration in a public trials registry.
- * It appears that this manuscript greatly exceeds the limitations for a "Procedures and Instruments" article.
- * Is the TCD drape currently FDA "cleared" and commercially available?
- * Line 92 - You might explain the functioning of the Olympus, HysteroFlow II, fluid management system as this system is critical to your experimental design.
- * Line 146-148 - If the above Fluid Management System is accurate, why do you state "We found no significant differences for fluid management system outcomes between the TCD and the standard drape groups, however, there were fewer cases of fluid on the floor or in blankets with the TCD". This appears to suggest that the fluid management system is not accurately recording outflow fluid volumes.
- * Line 217 - You mention "minimal cost". What is the cost difference between the Standard and TCD drapes?
- * Figure 2 - Why were 37 patients excluded from participation in the study?
- * The differences in patient groups (operative time and myomectomy cases both being greater in the TCD group) are problematic.
- * It seems like your paper has three different outcomes:
 1. Proof of concept in a simulation model
 2. Steep learning curve in applying the TCD to the patient
 3. Only demonstration of TCD efficacy in "long" cases, e.g., myomectomies

Perhaps you might consider repeating this study using only surgeons familiar with the technique of TCD application and limiting the case type to planned myomectomies or other operative hysteroscopies with a planned surgical time exceeding 30 minutes.

Reviewer #2:

This a descriptive study for a novel hysteroscopic drape that seeks to capture more fluid than the current drapes in use. The subject matter is an important GYN safety matter as the authors described in their paper. It is a suitable topic for the Green Journal in the category of "procedures and instrumentation". The major criticism I have of the manuscript is that I do not fully understand the novelty if the new drape without a picture, a more detailed sketch or a more detailed description.

Reviewer #3:

Description of a novel device to better measure patient fluid absorption related to operative hysteroscopy. The device is designed to collect unabsorbed distention fluid that is not absorbed by the patient. This paper describes a simulation study that compares the new drape to a standard drape using a pelvic model and then a prospective, randomized trial with 68 participants. Fluid capture efficiency was superior for the new device compared to the standard drape.

1. Lines 112-113: Can "Human factors" be defined more clearly?
2. Line 119: Please define "verbal confusion".
3. Lines 123-125: Why was no initial pre-surgical training provided?
4. Line 149: How does one interpret the SUS scores in table 4 (higher score is better?)?
5. Lines 183 -187: So both brief procedure times and lengthy procedure times with the TCD limit the ability to detect differences in fluid capture?
6. The following reference may be of interest:
AAGL Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media: (Replaces Hysteroscopic Fluid Monitoring Guidelines. J Am Assoc Gynecol Laparosc. 2000;7:167-168.).
AAGL Advancing Minimally Invasive Gynecology Worldwide, Munro MG, Storz K, Abbott JA, Falcone T, Jacobs VR, Muzii L, Tulandi T, Indman P, Istre O, Jacobs VR, Loffer FD, Nezhat CH, Tulandi T.
J Minim Invasive Gynecol. 2013 Mar-Apr;20(2):137-48. doi: 10.1016/j.jmig.2012.12.002.

STATISTICS EDITOR COMMENTS:

Tables 1, 2: Need units for age, BMI. When the comparison is between two groups, the ANOVA is a t-test, so should simply label as a t-test. But more fundamentally, the groups were randomized and there is no need to statistically test the two groups. Any difference is due to random chance. All the %s should be rounded to nearest integer, not formatted to

0.1% precision. Also, many of the factors are binary (yes vs no, with few missing values. Therefore, could simply cite the "no category" as n(x%), rather than citing both the No and the Yes) and then indicate in footnote when there were missing data. Omitting this redundancy would make the Tables much more concise.

Table 3: Need units for volume and for the primary fluid deficit. The primary outcome should be given more emphasis. Suggest incorporating the primary and secondary outcomes into the current Table 5 (re-labelled as Table 4) and placing the primary outcome first, then clearly demarcated from the other items. Again the %s should be rounded to nearest integer %. Can volumes be accurately measured to nearest 0.1 (I presume mL)? If not, then should round to nearest integer. Also, since the primary outcome was formatted as an effect size for purposes of the sample size calculation (lines 129-131), then the primary outcome should also be formatted in the same way and it should be made clearer that the primary outcome was negative.

lines 117-121 and current Table 4: Need to clarify in text how many individuals evaluated the Standard and TCD metrics. If I understand the study design, there were 4 surgeons and 68 procedures. So my 1st and 5th use, were these the 1st and 5th for each of the 4 surgeons? In other words, how many observations were evaluated to calculate the means, SD? If only 4, then should summarize as a range, since $n = 4$ is too few to precisely estimate the SD. If there were multiple operations for each surgeon that were in the calculation, then would need to account for intraclass correlation of scores for each individual surgeon. Was there any significant change from the 1st to the 5th use score? It appears not.

lines 142-144: Since the $n = 3$, one cannot generalize the simulation results. Also, despite there being no fluid loss observed in the 3 simulation studies, in actual practice (Table 3), the control and treatment groups showed no difference.

lines 148-149: The $p = 0.07$ is NS, so the "fewer cases" cannot be generalized, per the stipulation on line 134.

Fig 1, Table 3: Despite the schematic, the difference in fluid balance in this series seems trivial.

EDITOR COMMENTS:

Reviewer 2 highlights the difficulty in understanding the drape without an actual picture - this is important - rather than a sketch. The RCT for this 'early phase' study is not registered in clinicaltrials.gov and the authors are advised to simply provide descriptive data as their 'experience' with it

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased 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. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

3. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the

manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

4. Figure 1: Is this figure original to the manuscript? Does any illustrator need to be credited?

Figures 2-3: okay

Tables, figures, and supplemental digital content should be original. The use of borrowed material (eg, lengthy direct quotations, tables, figures, or videos) is discouraged. If the material is essential, written permission of the copyright holder must be obtained.

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Increasingly, publishers will not grant permission for modification of their material. Creative Commons licenses and open access have also made obtaining permissions more challenging. In order to avoid publication delays, we strongly encourage authors to link or reference to the material they want to highlight instead of trying to get permission to reprint it. For example, "see Table 1 in Smith et al" (insert reference number) or "see Table 1 in the document available at [insert URL]." For articles that the journal invites, such as the Clinical Expert Series, the journal staff does not seek permission for modifications of material — the material will be reprinted in its original form.

When you submit your revised manuscript, please upload 1) the permissions license and 2) a copy of the original source from which the material was reprinted, adapted, or modified (eg, scan of book page(s), PDF of journal article, etc.).

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), observational studies using ICD-10 data (ie, RECORD), 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, RECORD, 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 data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions> and the gynecology data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions>.

informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Procedures and Instruments articles 2,000 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

8. 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).
- * If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

9. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

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

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

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

12. The 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.

13. 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%).

14. Your manuscript contains a priority claim. 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 it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

15. 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.

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

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and 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.

17. Figure 1: Is this figure original to the manuscript? Does any illustrator need to be credited?
Figures 2-3: okay

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.

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

- * A confirmation that you have read the Instructions for Authors (<http://edmgr.ovid.com/ong/accounts/authors.pdf>), and

- * A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jul 22, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

John O Schorge, MD
Associate Editor, Gynecology

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd 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.

August 18, 2021

To the Editorial Staff of OBSTETRICS & GYNECOLOGY:

We are most pleased to re-submit, for your review, our study entitled, "A Fluid Management Drape for Hysteroscopy: Innovation for Improved Patient Safety and Surgical Care." We have made every attempt to comply with the requirements and standards set forth by the Editorial Board of OBSTETRICS & GYNECOLOGY as stated in the instructions to authors and revise the manuscript as recommended by the reviewers and Editors. We pledge that:

- 1) If the manuscript is accepted for publication, the corresponding author will sign the License to Publish where they will then own the copyright but grant Wolters Kluwer Health (WKH), the journal's publisher, a license to publish the article and identify itself as the original publisher. Each author has completed the journal's Copyright Transfer Agreement.
- 2) We have made all efforts to comply with the manuscript text, format, length, and references for the "Procedures and Instruments" sections recommended in the Instructions for Authors.

Please find below and attached a point-by-point response to each of the received comments and questions.

We are very excited to be submitting our revised manuscript for the prestigious journal, OBSTETRICS & GYNECOLOGY, and look forward to the results of your review.

Sincerely,

Paul B. Marshburn, M.D.

Lead Author

POINT-BY-POINT RESPONSE TO REVIEWERS AND EDITORS

Reviewer #1:

This manuscript would benefit from attention to the concerns, questions, comments, suggestions and questions listed below.

1) The Study appears to meet the definition of a clinical trial cited in the Obstetrics and Gynecology Instructions for authors (<http://edmgr.ovid.com/ong/accounts/authors.pdf>). Please include information regarding pre-trial registration in a public trials registry.

Prior to formally testing the fluid capture efficiency of the Total Capture Drape (TCD) in a clinical trial, we wanted to proceed with a pre-trial early phase clinical study to assess measures of drape usability and technology assessment. As stated by the first Editor, "The RCT for this 'early phase' study is not registered in clinicaltrials.gov and the authors are advised to simply provide descriptive data as their 'experience' with it." This is exactly what we wanted to do. We did not provide pre-surgical training of OR staff and physicians on the use of the TCD so we could obtain their initial impressions for iterative improvements of the TCD prior to a formal clinical trial. We recognize that randomizing patients to the TCD, with *no training* on its use, versus the standard drape, with *prior training and experience* with its use, would bias the surgeons and OR staff towards expressing difficulties with the TCD. This is what we found. What we sacrificed in not offering pre-surgical training of staff in the use of the TCD, we gained by obtaining a rich source of observational data to guide improvements in the TCD design prior to a formal RCT. A true RCT would have provided balanced control for pre-trial training of surgeons and OR staff for both the TCD and the standard drape. We inform the reader about these differences in pre-use training in the METHODS lines 130-131 and DISCUSSION lines 187-189 and lines 206-208.

In full transparency, our IRB requested after data collection started that that we submit our results to the clinicaltrials.gov site to post any potential adverse events for our 'early phase' study. We had no adverse event for either the TCD or the standard group. We are in the process of providing those results in the public trials registry.

2) It appears that this manuscript greatly exceeds the limitations for a "Procedures and Instruments" article.

Thank you for this comment. We have ensured our manuscript meets the requirements for word length of the Abstract and text of the body of the manuscript.

3) Is the TCD drape currently FDA "cleared" and commercially available?

The drape is not yet commercially available, but we are currently engaged with commercial entities for TCD development and production. The drape does have FDA clearance under the 510(k) clause because: 1) all women require a sterile drape for hysteroscopy and 2) the drape use does not involve an invasive process. Therefore, a trial for safety by the FDA is not required.

4) Line 92 - You might explain the functioning of the Olympus, HysteroFlow II, fluid management system as this system is critical to your experimental design.

To address this reviewer's recommendation, we have included a description of functioning of the HysteroFlow II on lines 89-94. The statement was the following: "The Olympus HysteroFlow II Fluid Management System provides a measurement of patient fluid absorption by weighing a bag of normal saline used for the inflow fluid medium and subtracting from it the weight of the outflow fluid that is returned to a canister in the FMS. The methodology allows the calculation of the hysteroscopic fluid deficit (HFD) which is digitally displayed in real time. The flow rate of the inflow volume is adjusted to maintain a given regulated intrauterine pressure."

5) Line 146-148 - If the above Fluid Management System is accurate, why do you state "We found no significant differences for fluid management system outcomes between the TCD and the standard drape groups, however, there were fewer cases of fluid on the floor or in blankets with the TCD". This appears to suggest that the fluid management system is not accurately recording outflow fluid volumes.

Fluid lost from the fluid management system (FMS) by a failure of capture of outflow fluid in the collection bag will not be returned to the outflow container. Because the FMS will only calculate the hysteroscopic fluid deficit (HFD) based on the inflow fluid volume and the fluid volume returned to the outflow container, the calculated HFD will be falsely higher if fluid is lost from the system and spills on the floor or in OR blankets. This condition is true even though the FMS is accurately calculating the inflow volume minus the outflow volume it receives. We appreciate the opportunity to clarify our statement of "there were fewer cases of fluid on the floor or in blankets with the TCD" by adding "noted by observations from the OR design researcher" on line 154-155.

6) Line 217 - You mention "minimal cost". What is the cost difference between the Standard and TCD drapes?

Because the TCD has yet to be manufactured for clinical use, we cannot calculate the cost difference between the TCD and the standard drape. The modifications made to a standard drape, however, involve only an extension of a polypropylene sheet above the capture bag along with the addition of a coated, moldable wire at the periphery of the sheet extension. The Reviewer raises an important point, so we removed any mention of cost and added the statement, "with modifications requiring a modest amount of additional materials" on line 229.

7) Figure 2 - Why were 37 patients excluded from participation in the study?

We have provided the data on these patients into the Patient Flow Diagram (Figure 2, referenced by the asterisk).

8) The differences in patient groups (operative time and myomectomy cases both being greater in the TCD group) are problematic.

We clarify that there was “no statistical difference between drape groups with regards to myoma resections or surgery duration” on lines 196-197. We presented the absolute numbers for the operative times and numbers of myomectomy cases for the TCD versus the standard to give a measure of the magnitude of difference between groups even though the numbers for myomectomy and long case lengths were low in number.

9) It seems like your paper has three different outcomes:

1. Proof of concept in a simulation model

2. Steep learning curve in applying the TCD to the patient

3. Only demonstration of TCD efficacy in "long" cases, e.g., myomectomies

Perhaps you might consider repeating this study using only surgeons familiar with the technique of TCD application and limiting the case type to planned myomectomies or other operative hysteroscopies with a planned surgical time exceeding 30 minutes.

The reviewer is absolutely correct, and for that reason, we state in the DISCUSSION section lines 234-236, “A larger, prospective hysteroscopy trial, with the updated TCD design versus standard, could provide important data by stratifying hysteroscopies for different procedure lengths and the invasiveness of hysteroscopic procedures.” These considerations were learned from our study and should certainly be controlled by stratification, as stated, in a subsequent RCT.

Reviewer #2:

This a descriptive study for a novel hysteroscopic drape that seeks to capture more fluid than the current drapes in use. The subject matter is an important GYN safety matter as the authors described in their paper. It is a suitable topic for the Green Journal in the category of "procedures and instrumentation". The major criticism I have of the manuscript is that I do not fully understand the novelty of the new drape without a picture, a more detailed sketch or a more detailed description.

We have provided two pictures (Figure 2, A and B) to address the recommendations of Reviewer #2 and the Editor. This is referenced in lines 85 and 86. The text below will be placed as legends under the respective pictures.

Figure 2A - Specially designed hand pouches under the extension sheet above the collection bag allow the surgeon to situate the sheet beneath the patient's buttocks without violating sterile field.

Figure 2B – The plastic extension sheet, which continues with the collection bag has a “bowl” shape design to funnel unabsorbed fluid into the collection bag while restricting its lateral flow to prevent fluid loss unto the floor and into the blankets.

Reviewer #3:

Description of a novel device to better measure patient fluid absorption related to operative hysteroscopy. The device is designed to collect unabsorbed distention fluid that is not absorbed by the patient. This paper describes a simulation study that compares the new drape to a standard drape using a pelvic model and then a prospective, randomized trial with 68 participants. Fluid capture efficiency was superior for the new device compared to the standard drape.

1. Lines 112-113: Can "Human factors" be defined more clearly?

We are happy to define the field of human factors and have provided the following definition on lines 115-116: Human factors is a scientific field dedicated to studying and improving human system interactions.

2. Line 119: Please define "verbal confusion".

We have clarified the term verbal confusion with the following example on lines 121-122: and verbal confusion (e.g., participants verbally indicating they were unsure about how to use the drape, place the drape, etc.).

3. Lines 123-125: Why was no initial pre-surgical training provided?

This is a crucial component of the usability portion of the study, and we thank you for raising the concern that this aspect was not clear. We have provided detailed rationale to this query in our response to Reviewer #1, Question #1.

4. Line 149: How does one interpret the SUS scores in table 4 (higher score is better)?

Yes, in general, higher scores indicate better usability of the device and have clarified this on line 156 in the manuscript with the following statement: Higher scores indicate better overall usability of a system.

5. Lines 183 -187: So both brief procedure times and lengthy procedure times with the TCD limit the ability to detect differences in fluid capture?

We have clarified this on lines 191-195 by stating: "In the simulated trial and hysteroscopy cases, the adhesive attachment of the operative opening of the standard drape progressively failed over time allowing more fluid to be lost from the FMS onto the blankets and the OR floor. Therefore, with the standard drape, procedures that require longer procedure lengths for any reason, such as myoma resections, would have progressively worsening fluid loss over time."

6. The following reference may be of interest:

AAGL Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media: (Replaces Hysteroscopic Fluid Monitoring Guidelines. J Am Assoc Gynecol Laparosc. 2000;7:167-168.).

AAGL Advancing Minimally Invasive Gynecology Worldwide, Munro MG, Storz K, Abbott JA, Falcone T, Jacobs VR, Muzii L, Tulandi T, Indman P, Istre O, Jacobs VR, Loffer FD, Nezhat CH, Tulandi T.

J Minim Invasive Gynecol. 2013 Mar-Apr;20(2):137-48. doi: 10.1016/j.jmig.2012.12.002.

We appreciate the knowledge in this reference and have included it in our reference #4, lines 246-248.

STATISTICS EDITOR COMMENTS:

1) Tables 1, 2: Need units for age, BMI. When the comparison is between two groups, the ANOVA is a t-test, so should simply label as a t-test. But more fundamentally, the groups were randomized and there is no need to statistically test the two groups. Any difference is due to random chance. All the %s should be rounded to nearest integer, not formatted to 0.1% precision. Also, many of the factors are binary (yes vs no, with few missing values. Therefore, could simply cite the "no category" as n(x%), rather than citing both the No and the Yes) and then indicate in footnote when there were missing data. Omitting this redundancy would make the Tables much more concise.

Thank you for your recommendations. Reviewer's advice was taken, and the following changes were made as suggested: 1) added units for age and BMI. 2) deleted p value column as statistical test is not needed since this study was randomized. 3) rounded %s to nearest integer. 4) simplified rows as "no category" in table 1 and "yes category" in table 2.

2) Table 3: Need units for volume and for the primary fluid deficit. The primary outcome should be given more emphasis. Suggest incorporating the primary and secondary outcomes into the current Table 5 (re-labelled as Table 4) and placing the primary outcome first, then clearly demarcated from the other items. Again the %s should be rounded to nearest integer %. Can volumes be accurately measured to nearest 0.1 (I presume mL)? If not, then should round to nearest integer. Also, since the primary outcome was formatted as an effect size for

purposes of the sample size calculation (lines 129-131), then the primary outcome should also be formatted in the same way and it should be made clearer that the primary outcome was negative.

We appreciate your advice and have made the following changes in table 3: 1) added units. 2) rounded %s to nearest integer. 3) placing the primary outcome in the first row and clearly demarcated from other info. 4) All our fluid volumes data were entered as integers, yet we kept a 0.1 precision for calculated mean and standard deviation. 5) added effect size as a note, considering that mean and standard deviation enables everyone to calculate an effect size if needed, and more importantly mean and standard deviation are easier for general physicians and other audiences to understand.

3) lines 117-121 and current Table 4: Need to clarify in text how many individuals evaluated the Standard and TCD metrics. If I understand the study design, there were 4 surgeons and 68 procedures. So my 1st and 5th use, were these the 1st and 5th for each of the 4 surgeons? In other words, how many observations were evaluated to calculate the means, SD? If only 4, then should summarize as a range, since $n = 4$ is too few to precisely estimate the SD. If there were multiple operations for each surgeon that were in the calculation, then would need to account for intraclass correlation of scores for each individual surgeon. Was there any significant change from the 1st to the 5th use score? It appears not.

Thank you for the opportunity to provide further clarification regarding administration of the SUS. We sincerely apologize as we realized we did not detail some of the missing data we had for this measure. We have provided this clarification in the manuscript on lines 124-128.

We revised table 4 values as median and interquartile range to reflect small sample size. N was also filled in. We did not observe any significant change from 1st to 5th usability score.

4) lines 142-144: Since the $n = 3$, one cannot generalize the simulation results. Also, despite there being no fluid loss observed in the 3 simulation studies, in actual practice (Table 3), the control and treatment groups showed no difference.

We thank you for your feedback. We agree that 3 simulated trials is not a large number as that in usual population studies, however, we reached saturation of information similar to data saturation in qualitative studies. In other words, we would gain same information even if we continue with more simulation trials. Thus, we transparently reported results from both simulation and patient studies.

5) lines 148-149: The $p = 0.07$ is NS, so the "fewer cases" cannot be generalized, per the stipulation on line 134.

Thank you for your comment. We agree that $p = 0.07$ is NS. Due to the limitation and critiques

of using p value alone in recent years, we further considered effect size difference and 95%CI. The TCD group has 23% lower chances of leak than the standard group, with a confidence interval of (-46%, 1%). The 95%CI suggested a large possibility of few cases though there is still a low chance that this difference is above 0.

6) Fig 1, Table 3: Despite the schematic, the difference in fluid balance in this series seems trivial.

We thank the reviewer for the observation. It is true that the difference is small, so we claimed no significant difference of fluid between the two groups.

EDITOR COMMENTS:

Reviewer 2 highlights the difficulty in understanding the drape without an actual picture - this is important - rather than a sketch. The RCT for this 'early phase' study is not registered in clinicaltrials.gov and the authors are advised to simply provide descriptive data as their 'experience' with it

We have complied with the Editor's recommendation and included Figure 2 (A-B).

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased 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:

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To my knowledge, all of the co-authors have confirmed their authorship in the manuscript. I understand that they agree with the "electronic Copyright Transfer Agreement." If this is not received by your office, then please notify me to request specific co-authors to go back and redo their authorship verification.

3. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

The "Other" category used for the Race variable in Table 1 was a prespecified formal category in our RedCap database which extracted information directly from the patient's electronic medical record. We have included this in the legend under Table 1.

4. Figure 1: Is this figure original to the manuscript? Does any illustrator need to be credited?

The image was created through modification of original illustration found on the Milton Keynes University Hospital (MKUH) website. It can be found via URL is <https://www.mkuh.nhs.uk/wp-content/uploads/2021/03/Untitled-31.jpg>. The MKUH copyright protected material may be reproduced free of charge in any format or medium for research, private study or for internal circulation within an organization.

Figures 2-3: okay

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We have completed the STROBE checklist for observational studies as it closely fits the early phase trial conducted and described on our manuscript. We respectfully submit it as part of the attachments.

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

We have made every attempt to comply with the standard obstetric and gynecology data definitions.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Procedures and Instruments articles 2,000 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

The word limit of 2,000 was exceeded when including additional text for revisions requested by reviewers and the Editors. We did word count on other published articles in the Procedures & Instruments in OBSTETRICS & GYNECOLOGY and found that our manuscript length was similar to these articles. We respectfully submit this manuscript for your consideration at the current word length.

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

- * All financial support of the study must be acknowledged.**
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We have read the rules and complied accordingly.

9. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

A Fluid Management Drape for Hysteroscopy

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revision, please check the abstract carefully.

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The abstract is 205 words. We feel like eliminating other words would compromise the communication.

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

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12. 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.

The manuscript has been thoroughly revised and no virgule symbol is used.

13. 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.

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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%).

The manuscript has been revised and presentation of data has been standardized as

recommended.

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We do not make a priority claim and have reviewed the manuscript to not include language indicating otherwise.

**15. 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.**

The checklist has been reviewed and tables formatted accordingly.

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