

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.*

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

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

Date: Nov 21, 2019
To: "Sarah C. Lassey" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-2021

RE: Manuscript Number ONG-19-2021

A Double-Blind Randomized Controlled Trial of a Cephalic Elevation Device for Second Stage Cesarean Delivery

Dear Dr. Lassey:

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

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Dec 12, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This is an interesting manuscript with a purpose to "evaluate whether a cephalic elevation device, the Fetal Pillow (Safe Obstetrics System, Essex UK), reduces time to delivery after hysterotomy and lowers morbidity in cesarean deliveries during the second stage." This was a randomized, double-blind, controlled trial.

1. The authors note that "The circulating nurse accessed the Fetal Pillow (both groups) and deflated it if indicated (FPI group)." How did the circulating nurse access the fetal pillow? What were the indications for deflating the pillow?
2. Could the authors expand on how Estimated blood loss was determined?
3. In the results section could the authors also discuss that there was no statistical difference in length of second stage or fetal station between their two groups?
4. Was the survey they gave to the obstetricians following delivery an investigator-developed survey? How was the survey validated?
5. Line 196: "estimated fetal blood loss" Should this be maternal?

Reviewer #2: Well designed study evaluating a potentially useful device.

Specifically:

1. Line 11: The company name is Safe Obstetric Systems. Not Obstetrics. This error is repeated throughout the manuscript and should be corrected.
2. Line 107: Patient legs are laid flat, but what is the position of the patient? The image provided appears to be semi-recumbent. This may be important, as the angle of impingement on the fetal head by the device, and its efficacy, may be affected.
3. Line 115: Why include only nulliparous women?
4. Line 119-121: Good to include ethical consideration related to informed consent. The double edged sword this creates of identifying a patient to all concerned as a possible study participant is described below.

5. Line 150: Decreasing the delivery time 41.2 sec to 20 seconds was "considered clinically meaningful" based on what?
6. Lines 168-171: Perhaps I am reading this incorrectly, but looking at Table 1, the p values for "higher rate of CS for FTP and non-reassuring fetal heart rate tracing, and BWt differences are 0.30, 0.36, 0.24 which do not reach significance. These statements and the p-values should concur. Please clarify.
7. Line 205: Thoughtful study design.
8. Table 1: See earlier comments. Evidently some patients had more than one indication for CS; would point this out.
9. Table 2: Specify "Incision to delivery time" as skin to delivery or uterine incision to delivery.
10. Table 3: One FPI inflation was reported as difficult. More information about this case may be enlightening.
11. Figure 1: Would orient with maternal head on the left of the image in accord with standard imaging protocol for ease of readers' orientation. Rather than labeling " Image of the Fetal Pillow", which negates the woman and fetus who comprise most of the picture, suggest "Image of the Fetal Pillow in Situ" or something along those lines.
12. The newborn weight for the FPI is about the median percentile for term babies, and the FPNl newborn birthweight average is smaller. This is notable since most CS were performed for "failure to progress". Why is this? Are these birthweights close to your institution's average birthweights for babies delivered by CS due to FTP? This is important, as the Fetal Pillow is designed to help elevate heads that may be impacted during the second stage of labor, a problem which is theoretically related to fetal size. General use of this device may include large babies, but the largest reported in this series is 3805g. The mean second stage of labor length for the two groups complies with definition of prolonged second stage. However, one wonders if all was done to effect vaginal delivery of these women, all but one of whom had epidurals and likely needed coaching, that would have been done had they not been consented for inclusion in this study: a possible source of bias favoring inclusion of smaller babies. I would like to see something in your discussion addressing the small to medium size of infants.

Reviewer #3: This study is a double-blind, randomized control trial evaluating whether the use of the Fetal Pillow at the time of cesarean section would result in shorter time to delivery and decreased maternal and neonatal morbidity.

The authors found that the use of the Fetal Pillow at the time of unplanned primary cesarean section in the second stage of labor resulted in a significant decrease in time to delivery of the neonate as well as fewer extensions of the hysterotomy.

These are the reviewer's comments:

1. The abstract is well-written and thorough, while remaining easy to understand. The primary outcome and secondary outcomes were clearly stated, as was the hypothesis.
2. In your introduction, you address studies which evaluate similar primary and secondary outcomes as your study, including an RCT. Why did you choose to repeat using the same or similar outcomes?
3. The materials and methods section is well-done. Inclusion, exclusion criteria are clear, as is the technique used in order to ensure the delivering physician remained blinded.
4. The RN and anesthesiologist in the OR are aware of which group the patient has been randomized to (lines 126-135). Is it possible that these two groups could have unknowingly indicated which group the patient was a part of?
5. The study was powered to evaluate the primary outcome - time from hysterotomy to delivery. Are uterine extensions common enough to evaluate this has a statistical decrease, or is it still a relatively rare event?
6. It is great that lines 200-203 address the potential impact of the difference between the two groups in regards for indications for cesarean delivery (failure to progress vs non-reassuring fetal heart tones).
7. The tables and figures are clear, concise, and comprehensive.

STATISTICAL EDITOR'S COMMENTS:

1. lines 148-152 and Abstract: The abstract should conform to our template for a RCT. Specifically, the primary outcome needs to be stated in the sample size calculation and clearly separated from the secondary outcomes in the Results. Missing from the analysis in Methods is the estimated SD for delivery time. To be consistent with the sample size and

other criteria cited, it would have to be ~ 28 secs.

2. lines 70-71: "an approximate 50% reduction in time ..." would be less confusing. The "decrease in several measures of maternal morbidity" is questionable

3. lines 155-156: Need to expand this sentence.

4. Table 1: These cohorts were randomized, so there is no need for stats testing of baseline characteristics. Any difference is thought to be due to random chance. Since 15 stats tests were done, there is ~ 54% probability of at least one characteristic being different at $p < .05$ level $(1 - 0.95^{15}) = .54$. Since each cohort had $n = 30$, the %s should be rounded to nearest integer %, not to nearest 0.1%. Need units for age, BMI, GA and bwgt.

5. Table 2: Need to clearly separate the primary outcome from the rest, which are all secondary. Again, need to round the %s to nearest integer %. For uterine extension (p-value cited as 0.05, lines 174-175), need to state whether this was < 0.05 . If not $< .05$, then by lines 155-156, the difference is NS. The difference in extensions was a stats test for overall difference among types 1, 2, 3, which had $p = .02$. A specific test for rates of uterine extension into cx/bladder/vagina (0 vs 4) has $p = 0.11$ by Fisher's test, so the statement on lines 175-177 or on lines 65-66 are incorrect and need to be modified or removed. The secondary outcomes were infrequent, not powered in the analysis and cannot be generalized from these samples to be generally non-significant.

6. Table 3: Need to round %s to nearest integer %.

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. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

4. Obstetrics & Gynecology follows the Good Publication Practice (GPP3)* guideline for manuscripts that report results that are supported or sponsored by pharmaceutical, medical device, diagnostics and biotechnology companies. The GPP3 is designed to help individuals and organization maintain ethical and transparent publication practices.

(1) Adherence to the GPP3 guideline should be noted in the cover letter.

(2) For publication purposes, the portions of particular importance to industry-sponsored research are below. In your cover letter, please indicate whether the following statements are true or false, and provide an explanation if necessary:

(2a) All authors had access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.

(2b) All authors take responsibility for the way in which research findings are presented and published, were fully involved at all stages of publication and presentation development and are willing to take public responsibility for all aspects of the work.

(2c) The author list accurately reflects all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors are disclosed in the acknowledgments.

(2d) The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research has

been fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings has also been disclosed.

(2e) All authors have disclosed any relationships or potential competing interests relating to the research and its publication or presentation.

(3) The abstract should contain an additional heading, "Funding Source," and should provide an abbreviated listing of the funder(s).

(4) In the manuscript, a new heading—"Role of the Funding Source"—should be inserted before the Methods and contain a detailed description of the sponsor's role as well as the following language:

"The authors had access to relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or non-financial, relating to this research and its publication have been disclosed." Authors should only include the above statement if all of it is true, and they should attest to this in the cover letter (see #2, above).

*From Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good publication practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med* 2015;163:461-4.

5. Tables, figures, and supplemental digital content should be original. The use of borrowed material (eg, lengthy direct quotations, tables, figures, or videos) is discouraged, but should it be considered essential, written permission of the copyright holder must be obtained. Permission is also required for material that has been adapted or modified from another source.

Both print and electronic (online) rights must be obtained from the holder of the copyright (often the publisher, not the author), and credit to the original source must be included in your manuscript. Many publishers now have online systems for submitting permissions request; please consult the publisher directly for more information.

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.).

6. 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.

7. 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.

8. 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.

9. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

10. 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).

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

12. 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.

13. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

14. 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.

15. 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.

16. 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%).

17. 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.

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

"Figure 1: Is this figure original to the manuscript? "

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.

19. 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/ifauth.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 Dec 12, 2019, 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.

December 11, 2019

Nancy C. Chescheir
Editor in Chief
Obstetrics and Gynecology
The American College of Obstetricians and Gynecologists
409 12th St, SW
Washington, DC 20024

Dear Dr. Chescheir:

Please find enclosed our manuscript titled “A Double-Blind Randomized Controlled Trial of a Cephalic Elevation Device for Second Stage Cesarean Delivery” which we are pleased to submit for publication as original research in Obstetrics and Gynecology. The corresponding author of this manuscript is Dr. Sarah C Lassey.

With the submission of this manuscript I would like to undertake that all authors have participated in the review of this research and have read and approved the final version submitted. I would also like to disclose that the contents of this manuscript are not under consideration for publication elsewhere and will not be submitted while acceptance is under consideration.

The authors adhere to the GPP3 guidelines. The authors had access to relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or non-financial, relating to this research and its publication are below.

Michaela K. Farber is a member of the North America Patient Blood Management Scientific Advisory Committee for Instrumentation Laboratory and is an investigator on grants to Brigham and Women's Hospital from Pacira Biosciences and Gauss Surgical. Otherwise, the authors have no conflicts of interest to declare and no financial disclosures. We affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

This study occurred at Brigham and Women's Hospital. It was approved by the Partners IRB and registered with ClinicalTrials.gov (NCT 03342508). The CONSORT guidelines have been followed and the checklist has been attached to the submission.

After initial submission, the reviewers and editors requested certain revisions. They are as follows with our responses by-line in bold and italics.

Reviewer #1: This is an interesting manuscript with a purpose to "evaluate whether a cephalic elevation device, the Fetal Pillow (Safe Obstetric System, Essex UK), reduces time to delivery after hysterotomy and lowers morbidity in cesarean deliveries during the second stage." This was a randomized, double-blind, controlled trial.

1. The authors note that "The circulating nurse accessed the Fetal Pillow (both groups) and deflated it if indicated (FPI group)." How did the circulating nurse access the fetal pillow? What were the indications for deflating the pillow?

The sentence has been edited to "The circulating nurse accessed the Fetal Pillow (both groups) by the catheter to the side of the patient's legs and either deflated it, or carried out a mock deflation, after delivery of the fetus (FPI vs. FPNI group). The Fetal Pillow was removed by the delivering provider at the end of the procedure in both groups."

2. Could the authors expand on how Estimated blood loss was determined?

The estimated blood loss was a subjective determination carried out by the delivering provider, which is the normal practice for our LD during this time. We realize this is a limitation (compared to a quantitative blood loss system) which is addressed in the discussion (line 261). "At the time of the study the hospital was using maternal estimated fetal blood loss as opposed to quantitative blood loss; given the difference in delivery time and the greater incidence of uterine extension between the two groups, the latter technique may have been more likely to show a difference in blood loss."

3. In the results section could the authors also discuss that there was no statistical difference in length of second stage or fetal station between their two groups?

This discussion piece has been added. "There was no difference in the length of the second stage or fetal station at delivery between the two groups."

4. Was the survey they gave to the obstetricians following delivery an investigator-developed survey? How was the survey validated?

It was an investigator-developed survey that was validated and assessed in a peer reviewed research meeting within our institution and approved by the Institutional IRB. It was piloted with 15 physicians prior to initiation of the study. We would be happy to include this in the manuscript if the reviewers feel this is needed.

5. Line 196: "estimated fetal blood loss" Should this be maternal?

Estimated blood loss was maternal in origin. This has been clarified in the manuscript to read "maternal estimated blood loss." Thank you for bringing this error to my attention.

Reviewer #2: Well designed study evaluating a potentially useful device.

Specifically:

1. Line 11: The company name is Safe Obstetric Systems. Not Obstetrics. This error is repeated throughout the manuscript and should be corrected.

This had been edited throughout the manuscript.

2. Line 107: Patient legs are laid flat, but what is the position of the patient? The image provided appears to be semi-recumbent. This may be important, as the angle of impingement on the fetal head by the device, and its efficacy, may be affected.

This has been clarified to "the patient's legs are laid flat and adducted on the operating room table with the patient in the supine position with left lateral tilt."

3. Line 115: Why include only nulliparous women?

This study was limited to nulliparous women due to the requirements of the informed consent process. Overall, second stage arrest cesarean deliveries in multiparous women are quite rare and per the IRB all women had to be consented when they were admitted in labor (prior to the knowledge if they would require a second stage arrest cesarean delivery). As a result, this would have required many more women to be consented without significant change in enrollment. For example, we consented 439 women for a study of 60 patients, an incidence rate of 13%. The rate of second stage arrest in multiparous patients would be much lower and is conceivable that the number of women needed to be consented would be in the thousands.

4. Line 119-121: Good to include ethical consideration related to informed consent. The double edged sword this creates of identifying a patient to all concerned as a possible study participant is described below.

We interpret this comment as not needing a response. However if it is felt a response is needed we would be happy to do so with some clarification as to any issue.

5. Line 150: Decreasing the delivery time 41.2 sec to 20 seconds was "considered clinically meaningful" based on what?

A survey of delivering providers was performed prior to study initiation, which deemed a 50% decrease in time from hysterotomy to delivery as being clinically meaningful. In short, it is a subjective determination, but an objective measure was not obvious to us.

6. Lines 168-171: Perhaps I am reading this incorrectly, but looking at Table 1, the p values for "higher rate of CS for FTP and non-reassuring fetal heart rate tracing, and BWt differences are 0.30, 0.36, 0.24 which do not reach significance. These statements and the p-values should concur. Please clarify.

Based on feedback from the statistical editor both the p-values and the standardized difference have been removed from Table 1. While the p-value was not statistically significant the standardized difference of 0.31 and 0.36 shows a moderate effect size which is why it was included originally in the manuscript.

7. Line 205: Thoughtful study design.

We appreciate this comment.

8. Table 1: See earlier comments. Evidently some patients had more than one indication for CS; would point this out.

A note has been made following the table reading, "Women were able to have more than one indication for cesarean delivery coded."

9. Table 2: Specify "Incision to delivery time" as skin to delivery or uterine incision to delivery.

This has been changed to "hysterotomy to delivery time."

10. Table 3: One FPI inflation was reported as difficult. More information about this case may be enlightening. ***This patient is briefly described in the results section (line 216) and the Fetal Pillow was unable to be inflated following insertion. The analysis was performed with intention-to-treat and the patient remained in the fetal pillow inflated group despite this difficulty. This difficulty with inflation was indicated by the provider on the survey as well. If the reviewer would like more clarification in the prose we would be happy to oblige.***

11. Figure 1: Would orient with maternal head on the left of the image in accord with standard imaging protocol for ease of readers' orientation. Rather than labeling "Image of the Fetal Pillow", which negates the woman and fetus who comprise most of the picture, suggest "Image of the Fetal Pillow in Situ" or something along those lines.

The title of the figure has been changed to "Image of the Fetal Pillow in Situ (maternal head right)." The copyright of the photo has been added per the editorial reviews below as the authors do not have the ability to edit the orientation of the figure.

12. The newborn weight for the FPI is about the median percentile for term babies, and the FPNI newborn birthweight average is smaller. This is notable since most CS were performed for "failure to progress". Why is this? Are these birthweights close to your institution's average birthweights for babies delivered by CS due to FTP? This is important, as the Fetal Pillow is designed to help elevate heads that may be impacted during the second stage of labor, a problem which is theoretically related to fetal size. General use of this device may include large babies, but the largest reported in this series is 3805g. The mean second stage of labor length for the two groups complies with definition of prolonged second stage. However, one wonders if all was done to effect vaginal delivery of these women, all but one of whom had epidurals and likely needed coaching, that would have been done had they not been consented for inclusion in this study: a possible source of bias favoring inclusion of smaller babies. I would like to see something in your discussion addressing the small to medium size of infants.

In 2018, the median birthweight at our institution for nulliparous women greater than 39 weeks was 3400 grams and the birthweights for both the FPI and FPNI are close to this median. As mentioned, the rates of epidural anesthesia were similar between the two groups. Women were coached routinely during the second stage of labor by both nurses and physicians on the labor floor with a goal for vaginal delivery. The majority of the patients in the study were managed by independent practitioners and the investigator was not part of the management team. We think it is very unlikely for study participation to bias the occurrence of a second stage cesarean delivery.

A statement regarding small to medium size infants has been added to the limitations of our discussion as follows “Another limitation of our study is that our median birthweight for the FPI group was 3502 grams and 3385 grams for the FPNI group. While this is consistent with the median birthweight for nulliparous women at term at our institution (3400 grams), our results may not be generalizable to a population with a larger median birthweight.”

Reviewer #3: This study is a double-blind, randomized control trial evaluating whether the use of the Fetal Pillow at the time of cesarean section would result in shorter time to delivery and decreased maternal and neonatal morbidity.

The authors found that the use of the Fetal Pillow at the time of unplanned primary cesarean section in the second stage of labor resulted in a significant decrease in time to delivery of the neonate as well as fewer extensions of the hysterotomy.

These are the reviewer's comments:

1. The abstract is well-written and thorough, while remaining easy to understand. The primary outcome and secondary outcomes were clearly stated, as was the hypothesis.

Due to the addition of the funding statement and the word count limitation, the abstract has been significantly shortened. Please let us know if you would like us to make any changes to these edits.

2. In your introduction, you address studies which evaluate similar primary and secondary outcomes as your study, including an RCT. Why did you choose to repeat using the same or similar outcomes?

None of the prior studies were blinded. We thought that design of our study was particularly innovative as all participants had a fetal pillow placed but the inflation was randomized and blinded. We also chose a different primary outcome (time to delivery) than the prior studies due to the rare event of uterine hysterotomy extension and the data that described time to delivery as a proxy for fetal well being. We thought that both providers and patients would easily understand a difference in time during counseling about potential use of the Fetal Pillow.

3. The materials and methods section is well-done. Inclusion, exclusion criteria are clear, as is the technique used in order to ensure the delivering physician remained blinded.

4. The RN and anesthesiologist in the OR are aware of which group the patient has been randomized to (lines 126-135). Is it possible that these two groups could have unknowingly indicated which group the patient was a part of?

Yes this is possible. However, in preparation of the trial and during the trial, great emphasis was placed on the importance of maintaining blinding. Before the start of the trial, mock procedures were performed to ensure blinding was effective and it appeared to be so. We acknowledge in any trial using a clinical device it is almost impossible to ensure that blinding is 100% effective. We could not think of any other methodology to make the blinding more opaque.

5. The study was powered to evaluate the primary outcome - time from hysterotomy to delivery. Are uterine extensions common enough to evaluate this has a statistical decrease, or is it still a relatively rare event?

The study was not powered to find a difference in uterine hysterotomy extension. We found there was both a trend toward significance of occurrence and a significant difference in the ease of suturing hysterotomy extension with women in the FPNI group having more severe uterine extensions.

6. It is great that lines 200-203 address the potential impact of the difference between the two groups in regards for indications for cesarean delivery (failure to progress vs non-reassuring fetal heart tones).

7. The tables and figures are clear, concise, and comprehensive.

STATISTICAL EDITOR'S COMMENTS:

1. lines 148-152 and Abstract: The abstract should conform to our template for a RCT. Specifically, the primary outcome needs to be stated in the sample size calculation and clearly separated from the secondary outcomes in the Results. Missing from the analysis in Methods is the estimated SD for delivery time. To be consistent with the sample size and other criteria cited, it would have to be ~ 28 secs.

The abstract has been reviewed to comply with the template for RCT. The primary outcome is stated in the methods section and the sample size has been clarified.

2. lines 70-71: "an approximate 50% reduction in time ..." would be less confusing. The "decrease in several measures of maternal morbidity" is questionable

This has been edited to "...delivery led to an approximate 50% reduction in time from hysterotomy to delivery, a decrease in maternal hysterotomy extension and improvement..."

3. lines 155-156: Need to expand this sentence.

This sentence has been expanded to "Univariate analyses for outcomes were performed similarly with Fischer exact, chi-square testing, and Wilcoxon rank sum tests where appropriate. The risk difference between groups was calculated with 95% confidence interval."

4. Table 1: These cohorts were randomized, so there is no need for stats testing of baseline characteristics. Any difference is thought to be due to random chance. Since 15 stats tests were done, there is ~ 54% probability of at least one characteristic being different at $p < .05$ level $(1-0.95^{15}) = .54$. Since each cohort had $n = 30$, the %s should be rounded to nearest integer %, not to nearest 0.1%. Need units for age, BMI, GA and bwgt.

Both the p-value and the standardized difference have been removed from Table 1 (track changes is unable to show deletion of columns). The percentiles have been rounded to the nearest integer and changed in the manuscript. Units have been added.

5. Table 2: Need to clearly separate the primary outcome from the rest, which are all secondary. Again, need to round the %s to nearest integer %. For uterine extension (p-value cited as 0.05, lines 174-175), need to state whether this was < 0.05 . If not $< .05$, then by lines 155-156, the difference is NS. The difference in extensions was a stats test for overall difference among types 1, 2, 3, which had $p = .02$. A specific test for rates of uterine extension into cx/bladder/vagina (0 vs 4) has $p = 0.11$ by Fisher's test, so the statement on lines 175-177 or on lines 65-66 are incorrect and need to be modified or removed. The secondary outcomes were infrequent, not powered in the analysis and cannot be generalized from these samples to be generally non-significant.

We would be willing to separate the primary outcome however the statistical editor thinks best. We did not want to insert a blank line into the table due to the journal's requirements of tables. The percentiles have been rounded to the nearest integer and changed in the manuscript. We have changed the manuscript so that uterine extension is trending toward significance as the p-value was not < 0.05 . We performed a Fischer exact test comparing easy to suture extensions which has been added to the results section of the manuscript.

6. Table 3: Need to round %s to nearest integer %.

This has been changed in both the table and the manuscript.

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.

The authors opt-in.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

All conflicts of interest have been correctly disclosed.

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

A data sharing statement has been added to the manuscript following the references section.

4. Obstetrics & Gynecology follows the Good Publication Practice (GPP3)* guideline for manuscripts that report results that are supported or sponsored by pharmaceutical, medical device, diagnostics and biotechnology companies. The GPP3 is designed to help individuals and organization maintain ethical and transparent publication practices.

(1) Adherence to the GPP3 guideline should be noted in the cover letter.

(2) For publication purposes, the portions of particular importance to industry-sponsored research are below. In your cover letter, please indicate whether the following statements are true or false, and provide an explanation if necessary:

(2a) All authors had access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.

(2b) All authors take responsibility for the way in which research findings are presented and published, were fully involved at all stages of publication and presentation development and are willing to take public responsibility for all aspects of the work.

(2c) The author list accurately reflects all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors are disclosed in the acknowledgments.

(2d) The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research has been fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings has also been disclosed.

(2e) All authors have disclosed any relationships or potential competing interests relating to the research and its publication or presentation.

The adherence to the GPP3 has been included in the cover letter and all of the above statements are true.

(3) The abstract should contain an additional heading, "Funding Source," and should provide an abbreviated listing of the funder(s).

This has been added to the abstract.

(4) In the manuscript, a new heading—"Role of the Funding Source"—should be inserted before the Methods and contain a detailed description of the sponsor's role as well as the following language:

"The authors had access to relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or non-financial, relating to this research and its publication have been disclosed." Authors should only include the above statement if all of it is true, and they should attest to this in the cover letter (see #2, above).

*From Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good publication practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med* 2015;163:461-4.

The role of the funding source as well as the above paragraph has been added to the manuscript. It has been attested in the cover letter.

5. Tables, figures, and supplemental digital content should be original. The use of borrowed material (eg, lengthy direct quotations, tables, figures, or videos) is discouraged, but should it be considered essential, written permission of the copyright holder must be obtained. Permission is also required for material that has been adapted or modified from another source.

Figure 1 has been adapted from Safe Obstetric Systems material. The company has provided written permission for the use of the material.

Both print and electronic (online) rights must be obtained from the holder of the copyright (often the publisher, not the author), and credit to the original source must be included in your manuscript. Many publishers now have online systems for submitting permissions request; please consult the publisher directly for more information.

Both print and online rights have been obtained by Safe Obstetric System and uploaded to the revision.

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.).

The permissions license has been uploaded. The original source was digital media.

6. 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.

The CONSORT guidelines were followed and the checklist has been uploaded with the submission.

7. 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.

The definitions have been reviewed..

8. 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.

Our manuscript adheres to the above length restrictions.

9. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

Our title adheres to the above length restrictions.

10. 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).

The above rules have been reviewed and are up to date with the current manuscript.

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

A short title has been added to the footer.

12. 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 abstract and the manuscript have been reviewed to ensure there are no inconsistencies.

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 has been reviewed to journal guidelines. The word count for the abstract is 297 words.

13. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here:

http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

The abstract has been reviewed to meet the journal's standard format. The methods and results section include the above specifications.

14. 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.

The abbreviations and acronyms have been reviewed and are up to date with the current manuscript.

15. 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.

This symbol does not appear in the manuscript.

16. 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.

In table 2 we include both the p-value and the mean difference between groups. The reasons we included both was due to the different statistical analysis performed as the p-value compared the medians. If the editors would like us to remove one of these statistical tests, we would happily oblige.

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.

Number needed to treat with regards to uterine hysterotomy extension is included in the discussion.

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 presentation of data has been standardized throughout the manuscript.

17. 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 tables conform to the journal style as described.

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

"Figure 1: Is this figure original to the manuscript? "

This figure is not original to the manuscript. The permissions license has been uploaded.

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.

The figure is saved as a high-resolution TIFF file.

Sincerely,

Sarah C. Lassey, MD
Fellow, Maternal Fetal Medicine