

# 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](mailto:obgyn@greenjournal.org).

**Date:** Apr 10, 2020  
**To:** "Ankita Gupta" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-20-677

RE: Manuscript Number ONG-20-677

Candy Cane vs. Boot Stirrups in vaginal surgery (STIRUPPS): A Randomized controlled trial

Dear Dr. Gupta:

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).

\*\*\*Due to the COVID-19 pandemic, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by May 10, 2020, we will assume you wish to withdraw the manuscript from further consideration.\*\*\*

#### REVIEWER COMMENTS:

##### Reviewer #1: Abstract

- It's better to say "women" than "patients" since that implies somehow tied to their care which can be coercive - please update this in the body of the manuscript as well
- Did you administer the PROMIS questionnaire prior to surgery as well as after? This would be important since baseline function level would obviously affect postop function level.

##### Intro

- Line 82 - I am surprised that you don't mention avoiding hyperflexion of the hip as a recommendation to avoid nerve injury. Is this not cited in the literature? Please add this information.

##### Methods

- Line 106 - State more clearly that the PROMIS questionnaire was completed at baseline and 6 weeks postop.
- Line 112 - Why did you not ask about sacral pain? This is not uncommon after pelvic surgery positioning.
- Line 119 - Why did you not exclude women with chronic pain? Surgery can exacerbate pain and skew the results.
- Line 129 - You mention "satisfactory positioning" - please list exactly what protocol you followed and who performed the positioning. This is critical to the study design, as improper positioning can occur with either type of stirrup and could bias your results.
- Line 131 - Please clarify that you measured hip flexion. This is not clear.
- Line 140 - Why did you decide to do VAS for pain scores when some of your patients would have to complete a verbal pain score instead? How did you account for this variation?
- Line 169 - Why did you not do an intent to treat analysis? Please include this in your manuscript.
- Line 170 - "For the calculation of PFDI scores, we only include patients that answered more than half of the 20 171 questions. For the remaining patients that did not respond to all of the questions, we proportionally inflate their scores based on the number of questions that were completed." Is this the proper way to interpret PFDI-20 scores? Please refer to scoring protocol for this questionnaire.

##### Results

- Line 182 - When you say two participants were re-positioned, do you mean with a different type of stirrup? Was any re-positioning not allowed?
- Please be consistent with the use of "participant" rather than "patient".
- Line 215 - Please omit this statement, as it was not significant and shows bias: "Three patients (4.5%) in the candy cane group reported that they were no different or very much worse compared to 0/63 (0%) in the boot group, but the numbers were too small to demonstrate significance."

- Line 218 - please list the variables included in the regression models
- You introduce the number of neuropathies in the Discussion section. Those finding should be listed here. Give more details about these cases.

#### Discussion

- How do you account for the difference in PROMIS scores if both groups had the same positioning angles? What is inherent to the candy cane stirrups that led to a difference in overall patient functioning?
- Line 288 - Please expand on the fact that your primary outcome of physical functioning does NOT direct correlate to neurologic injury. Physical function is a very general assessment and cannot replace nerve injury as a recommendation for type of leg stirrup used. This needs to be highlighted more clearly.

Reviewer #2: Is the material written in a text box following the methods section intended to be there or will that ultimately be incorporated in the methods section text?

In at least two places in this manuscript you have a claim of primacy ("this is the first report of..."). Can you describe in your methods section the search process you undertook to justify these claims?

Was the positioning standardized? Specifically were the angles at the hips and knees, the placement of brackets (distance from end of bed rails), the position of the patient on the table (degree of buttock overhang) standardized?

Although not statistically significant, the OR time using booted stirrups was longer than candycanes (112 vs 98 minutes). Do you think that candy cane stirrups offer any advantage over booted stirrups that might lead to shorter operating time? How about in a teaching situation where there might be three surgeons rather than one or two?

I think you should report the number of sacrospinous suspensions and uterosacral ligament suspensions separately as these operations have different risks of postoperative pain and if unequally distributed could confound your results.

Finally, the logistic regression shows a lower physical function score with candy cane stirrups but no difference in pain intensity or interference. If the lower physical function is not due to pain, how do you explain it?

Reviewer #3: Review of Manuscript ONG-20-677 "Candy Cane vs. Boot Stirrups in vaginal surgery (STIRUPPS): A randomized controlled trial"

Gupta and colleagues have submitted results from an RCT that evaluated physical functioning at 6 weeks following the performance of vaginal surgery in women that had these surgeries in either (A) a boot stirrup or (B) a candy cane stirrup. Although not impacting the data in the manuscript, there does appear to be a faint leftover "highlight" for instance most of lines 109-122 among other places. Was there no funding whatsoever - even institutional (departmental or otherwise) funding for data assessment? I have the following questions and comments.

Title - No comments.

Précis - No comments unless you can add it how this was assessed - PROMIS.

Abstract - Line 44 - consider "masked" rather than "blinded" as it is often a more preferred term in RCTs (Blinding referring to the loss of sight).

Line 47 - I don't think you need justification for sample size in your abstract. Since this can be removed yo can comment on IRB approval and consent or other issues.

Introduction - Line 77 - maybe range rather than lie.

Line 95-6 - Can you comment more in the introduction on how the use of PROMIS will allow you to evaluate your primary outcome? Any similar evaluations or even quasi-similar meaning how do we know, based on previous experience/evaluations, that using PROMIS will answer the question that you are trying to answer?

Methods - Line 118 - How would you treat a patient that ended having to be repositioned intra-operatively?

Line 113 - as noted above, what information is currently available to demonstrate that PROMIS is the instrument that should be used for the primary outcome as compared to form 3a, form 8a and/or PFDI-20?

Results - Line 178 - why were the excluded and not left in for ITT principles?

Line 183 - How did the patient get enrolled in not fluent in English?

Discussion - Line 278-9 - Why not follow them up longer 3 months, 6 months, 12 months for instance?

Tables - Table 1 - could eliminate the p values since all non-significant which strongly suggest that your randomization

worked.

Figures - No comments.

#### STATISTICAL EDITOR COMMENTS:

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

1. Lines 176-186, Fig 1: Should compare the 72 vs 67 pts who were randomized and had 6 week follow-up, ie, as an ITT analysis to contrast with the PP analysis.
2. Table 1: Since the groups were randomized, there is no need to statistically compare the pre-operative variables. Any difference is thought to be due to random chance. Since the samples were  $n = 68$  and  $64$  (actually the ITT should be cited here) there is no need to format the %s to nearest 0.1% level of precision. Should round to nearest integer %.
3. Table 2: The primary outcome (lines 148-149) needs to be clearly separated from the secondary ones. This appears to be the between group difference in PROMIS physical function SF-20a, not all the other comparisons. Also, the sample size calculation was based on specifying a Cohen's effect size = 0.5, so should format the primary outcome in terms of effect size and in terms of the minimum clinically important difference of 2.
4. Lines 48-51: Not sure why this analysis was included, since age, BMI, CCI and duration of surgery were random (and NS different in Table 1) and why would one adjust for intraoperative complication? That would seem to bias the results.

#### EDITOR 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. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author\* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained."

\*The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

4. 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).

5. 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.

6. 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.

7. 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).

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

9. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

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 limits for Original Research articles is 300 words. Please provide a word count.

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

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.

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

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

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

12. 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](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

13. 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. 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.

14. Please provide a reference for the Clavien-Dindo scoring system, if possible.

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

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

\*\*\*

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

- \* A confirmation that you have read the Instructions for Authors (<http://edmgr.ovid.com/ong/accounts/authors.pdf>), and
- \* A point-by-point response to each of the received comments in this letter.

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

\*\*\*Again, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by May 10, 2020, we will assume you wish to withdraw the manuscript from further consideration.\*\*\*.

Sincerely,

The Editors of Obstetrics & Gynecology

2018 IMPACT FACTOR: 4.965

2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

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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.

April 22<sup>nd</sup>, 2020

*The Editors*

*Obstetrics & Gynecology,*

Re: Submission of manuscript, “Candy Cane vs. Boot Stirrups in vaginal surgery (STIRUPPS): A Randomized controlled trial”

Dear Editors,

On behalf of my co-authors, I am pleased to submit our manuscript, “Candy Cane vs. Boot Stirrups in vaginal surgery (STIRUPPS): A Randomized controlled trial” for consideration for publication in *Obstetrics & Gynecology*. All authors participated actively in design, recruitment, drafting and editing of this study.

In this randomized trial, we sought to investigate physical function at 6 weeks after vaginal surgery between patients positioned in candy canes and boot stirrups. The manuscript has not been previously published and is not submitted to another journal for publication. It will not be submitted to another journal unless a final negative decision is made by the Editors of *Obstetrics & Gynecology*.

I, the lead author, 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. I also certify that, when applicable, a statement has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; all human subjects provided written informed consent with guarantees of confidentiality. This study was approved by the IRB at the University of Louisville (protocol number: 18.0061) and registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), (NCT03446950).

Thank you for your consideration.

Sincerely,

Ankita Gupta, MD, MPH

**Thank you for your thoughtful and thorough review of our manuscript. Please find below our point-by-point responses to the reviewers. Our updated manuscript is attached and line numbers in our responses correspond to the tracked changes version of our manuscript.**

## REVIEWER COMMENTS:

Reviewer #1: Abstract

- It's better to say "women" than "patients" since that implies somehow tied to their care which can be coercive - please update this in the body of the manuscript as well

**Thank you for this important suggestion. Both, the abstract and manuscript have been updated with the words “women” and “participants” instead of “patients” where appropriate.**

- Did you administer the PROMIS questionnaire prior to surgery as well as after? This would be important since baseline function level would obviously affect postop function level.

**Thank you for your question. Yes the PROMIS question was administered at baseline and at 6 weeks after surgery and the primary outcome was change in PROMIS score. This is noted in the abstract Lines 50-52 “The primary outcome was change in Patient-Reported Outcomes Measurement Information System (PROMIS) physical function short form-20a from baseline to 6 weeks after surgery.”**

Intro

- Line 82 - I am surprised that you don't mention avoiding hyperflexion of the hip as a recommendation to avoid nerve injury. Is this not cited in the literature? Please add this information.

**Thank you for your comment. Data cited in the literature does not specify different recommendations for low versus high lithotomy. Although some recommendations, including the cited guidelines by Fleisch *et al*, suggest avoiding hip flexion greater than 90**



degrees and hip abduction between 30-45 degrees (only in the presence of hip flexion), these recommendations usually pertain to low lithotomy positions. Other texts (Tollefson MK, Boorjian SA, Leibovich BC. Chapter 20 - COMPLICATIONS OF THE INCISION AND PATIENT POSITIONING. In: Taneja SS, ed. Complications of Urologic Surgery (Fourth Edition). Philadelphia: W.B. Saunders; 2010:225-236.) have suggested that hip flexion should be limited to 80-100 degrees in high lithotomy. We have revised lines 81-83 of the manuscript to read “Recommendations for lithotomy positioning include avoiding: excessive hip flexion or abduction, direct pressure on the peroneal neck, leg contact with support rods, and positions that do not align the thigh, knee and heel to the contralateral shoulder.”

#### Methods

- Line 106 - State more clearly that the PROMIS questionnaire was completed at baseline and 6 weeks postop.

Thank you for your comment. We have edited line 106-107 to read “The PROMIS physical function short form-20 was administered at baseline and at 6 weeks after surgery, with the primary outcome as change in PROMIS score.” Additionally, lines 116-117 now read “Participants also completed PROMIS physical function-20a, pain intensity-3a, pain interference-8a and Pelvic Floor Disability Index (PFDI-20) at baseline.”

- Line 112 - Why did you not ask about sacral pain? This is not uncommon after pelvic surgery positioning.

**Thank you for your question. Since we were asking participants to rate pain in lower back, hips, buttocks and thighs, we felt that asking patients about sacral pain might be too specific and would not add information relevant to our primary outcome.**

- Line 119 - Why did you not exclude women with chronic pain? Surgery can exacerbate pain and skew the results.

**Thank you for your question. Since we were looking for change in PROMIS scores from baseline to 6 weeks, we did not exclude patients with pain at baseline. We acknowledge that participants with chronic pain may have a differential reaction to surgery but, due to the virtue of randomization, expected equitable distribution across our groups.**

- Line 129 - You mention "satisfactory positioning" - please list exactly what protocol you followed and who performed the positioning. This is critical to the study design, as improper positioning can occur with either type of stirrup and could bias your results.

**Thank you for your question. Patient positioning was performed by the attending Female Pelvic Medicine and Reconstructive Surgery surgeon in conjunction with the rest of the surgical team. Although there was no set protocol, all faculty and fellows were briefed on guidelines surrounding appropriate patient positioning. This has been updated on lines 131-134: "After allocation, participants were positioned in the assigned stirrup by the attending surgeon with assistance from the surgical team. Next, the operating surgeon measured the angle of flexion at the hip and knee joints in a standardized fashion using a goniometer."**

- Line 131 - Please clarify that you measured hip flexion. This is not clear.

**Thank you for your comment. Please see our edits mentioned for line 131-134 above.**

- Line 140 - Why did you decide to do VAS for pain scores when some of your patients would have to complete a verbal pain score instead? How did you account for this variation?

**Thank you for your question. Since we were looking at differences in score and all of our baseline questionnaires were completed in person, we opted to have participants complete VAS score. At the completion of the study, we had 8 participants (8/139, 5.7%) who completed the questionnaires over the phone. Since the VAS scores were not a primary outcome, we did not correct for this discrepancy.**

- Line 169 - Why did you not do an intent to treat analysis? Please include this in your manuscript.

**Thank you for your question. Per your recommendation, we performed an intention to treat analysis and have changed all the results, tables and figures in the manuscript to reflect the results of this analysis. We found negligible change in our results. The per protocol analysis has been removed.**

- Line 170 - "For the calculation of PFDI scores, we only include patients that answered more than half of the 20 171 questions. For the remaining patients that did not respond to all of the questions, we proportionally inflate their scores based on the number of questions that were completed." Is this the proper way to interpret PFDI-20 scores? Please refer to scoring protocol for this questionnaire.

**Thank you for your comment. We revised our calculation of PFDI per the scoring manual. Missing data were dealt with by using a mean from answered questions only. We excluded 4**

**participants who had not answered at least one question in each subscale. Please see lines 176-178 in the methods “To calculate PFDI scores, we only include participants that answered at least one question on each subscale. Missing items were dealt with by using the mean from answered items only.”**

## Results

- Line 182 - When you say two participants were re-positioned, do you mean with a different type of stirrup? Was any re-positioning not allowed?

**Thank you for your questions. Once positioning and angle measurement was completed, participants could not be repositioned to standardize protocols, especially for the candy cane group where participants cannot be switched from high to low lithotomy position with the same ease as boot stirrups. The two participants in the candy cane group were repositioned from candy cane to boot stirrups during surgery and the two participants in boot stirrups were moved from high to low lithotomy position intraoperatively.**

- Please be consistent with the use of "participant" rather than "patient".

**Thank you for your suggestion. This has been changed throughout the manuscript as noted above.**

- Line 215 - Please omit this statement, as it was not significant and shows bias: "Three patients (4.5%) in the candy cane group reported that they were no different or very much worse compared to 0/63 (0%) in the boot group, but the numbers were too small to demonstrate significance."

**Thank you for your comment. This line has been removed.**

- Line 218 - please list the variables included in the regression models

**Thank you for your comment. The variables included have been listed in methods and have been added to the results section. Please see lines 224-226 “For the linear regression model, fit to predict PROMIS scores using stirrup group and controlling for confounders (age, BMI, CCI and duration of surgery), the change in PROMIS physical score between groups was -4.0 (95% CI -6.7 to -1.4,  $p<0.01$ ) favoring boot stirrups.”**

- You introduce the number of neuropathies in the Discussion section. Those finding should be listed here. Give more details about these cases.

**Thank you for your comment. Details about the two neuropathies have been listed on lines 204-208 in the results section: “There were two participants, one in each group, who reported neurological injury in the postoperative period (2/132, 1.5%). The participant in the candy cane group reported sensory femoral neuropathy which resolved spontaneously. The participant in the boot stirrups group reported unilateral foot numbness along the peroneal nerve distribution which was persistent at 6 weeks after surgery.”**

## Discussion

- How do you account for the difference in PROMIS scores if both groups had the same positioning angles? What is inherent to the candy cane stirrups that led to a difference in overall patient functioning?

**Thank you for your question. Although both groups had similar angles of flexion, the patients in the candy cane group had a significantly greater angle between the femurs which**

**was a marker of abduction and external rotation as compared to the patients in the boot stirrups group. We hypothesize that this increased abduction was associated with lower physical function at 6 weeks after surgery. Additionally, although non-significant between groups, pain intensity within the boot stirrups group (Table 2) was significantly improved 6 weeks after surgery which could also play a role in improved physical function.**

**Please see lines 271-274: “In order to identify abduction and external rotation, we recorded the angle between the femurs and found that participants positioned in candy canes had greater hip abduction than those positioned in boot stirrups, which could provide a rationale for our findings.”**

- Line 288 - Please expand on the fact that your primary outcome of physical functioning does NOT direct correlate to neurologic injury. Physical function is a very general assessment and cannot replace nerve injury as a recommendation for type of leg stirrup used. This needs to be highlighted more clearly.

**Thank you for your commen. The line 292-296 have been modified and now read “Lastly, physical function is a general measure of physical well-being and has not been directly correlated to neurological injury in this population. We would have liked to power this study to neurological injuries as well as to patient-reported outcomes, but due to the low incidence of neurological injury, this was not feasible.”**

Reviewer #2: Is the material written in a text box following the methods section intended to be there or will that ultimately be incorporated in the methods section text?

**Thank you for your question. The text box has been moved to the end of the manuscript, after the references, as requested by the Editor.**

In at least two places in this manuscript you have a claim of primacy ("this is the first report of...").

Can you describe in your methods section the search process you undertook to justify these claims?

**Thank you for your question. We have added lines 109-111 “A review of literature and clinicaltrials.gov was performed in February 2018 and repeated in February 2020 to confirm the novelty of this trial.” We have also modified lines 263-265 to read “This is novel data, as this is the first study *to our knowledge*, on intraoperative positioning in vaginal surgery to report on all of these patient-centered outcomes.”**

Was the positioning standardized? Specifically were the angles at the hips and knees, the placement of brackets (distance from end of bed rails), the position of the patient on the table (degree of buttock overhang) standardized?

**Thank you for your question. The positioning of brackets, the angles at hips and knees and the degree of buttock overhang were not standardized. Since one of our secondary outcomes was the relationship between angles and physical function, if any, we decided not to standardize the angles but instead allow the attending surgeon to position the patient as they normally would for their vaginal surgery.**

Although not statistically significant, the OR time using booted stirrups was longer than candycanes (112 vs 98 minutes). Do you think that candy cane stirrups offer any advantage over

booted stirrups that might lead to shorter operating time? How about in a teaching situation where there might be three surgeons rather than one or two?

**Thank you for your questions. While physician comfort and ease of access is certainly important during vaginal surgery, we did not specifically survey the operating surgeons or look at the number of surgeons per surgery. Since the study was randomized, we did not expect operating times to differ significantly and did not further investigate operating time. We did find it interesting that candy canes had non-significantly shorter operating operating times and still had worse physical function when compared to boot stirrups, despite previous data suggesting a link between operating time and neurologic injuries. We therefore included operating time in our regression model which reaffirmed the difference in physical function scores.**

I think you should report the number of sacrospinous suspensions and uterosacral ligament suspensions separately as these operations have different risks of postoperative pain and if unequally distributed could confound your results.

**Thank you for your comment. This has been added to Table 1 and these procedures were equally distributed across both groups.**

Finally, the logistic regression shows a lower physical function score with candy cane stirrups but no difference in pain intensity or interference. If the lower physical function is not due to pain, how do you explain it?

**Thank you for your question. Please see our response to reviewer #1 above.**



Reviewer #3: Review of Manuscript ONG-20-677 "Candy Cane vs. Boot Stirrups in vaginal surgery (STIRUPPS): A randomized controlled trial"

Gupta and colleagues have submitted results from an RCT that evaluated physical functioning at 6 weeks following the performance of vaginal surgery in women that had these surgeries in either (A) a boot stirrup or (B) a candy cane stirrup. Although not impacting the data in the manuscript, there does appear to be a faint leftover "highlight" for instance most of lines 109-122 among other places. Was there no funding whatsoever - even institutional (departmental or otherwise) funding for data assessment?

**Thank you for pointing out the “highlight”- this has been corrected.**

**This study did not receive any funding, institutional or otherwise.**

I have the following questions and comments.

Title - No comments.

Précis - No comments unless you can add it how this was assessed - PROMIS.

**Thank you for your comment. To maintain brevity, since Patient-Reported Outcomes Measurement Information System (PROMIS) will add 6 words, we would prefer to leave the précis as is, unless requested by the Editor.**

Abstract - Line 44 - consider "masked" rather than "blinded" as it is often a more preferred term in RCTs (Blinding referring to the loss of sight).

**Thank you for your comment. This has been changed in the abstract and the manuscript.**

Line 47 - I don't think you need justification for sample size in your abstract. Since this can be removed you can comment on IRB approval and consent or other issues.

**Thank you for your comment. We included the sample size in our abstract per the Green Journal instructions for authors-January 2020 and the sample RCT abstract provided. We are happy to change the abstract if the Editor feels that it needs to be changed.**

Introduction - Line 77 - maybe range rather than lie.

**Thank you for your suggestion. This line been changed and now reads “Neurological injuries often go unrecognized and studies report rates between 1.1-1.9%”**

Line 95-6 - Can you comment more in the introduction on how the use of PROMIS will allow you to evaluate your primary outcome? Any similar evaluations or even quasi-similar meaning how do we know, based on previous experience/evaluations, that using PROMIS will answer the question that you are trying to answer?

**Thank you for your questions. The goal of our study was to assess the impact of patient positioning on physical health and the ability to perform activities of daily living, rather than specific pelvic floor outcomes. As stated by Hays *et al*, physical function, which is a subdomain of physical health, is an important predictor of health. The physical function questions assess the ability to perform basic and instrumental activities of daily living and are comparable to and less cumbersome than existing questionnaires. Studies in the urogynecologic population are limited but have shown correlation of the PROMIS scores with pelvic floor questionnaires (PFDI and PFIQ). To further demonstrate the utility of this questionnaire, we have added the citation by Schalet *et al* who studied the PROMIS physical**

**function scale among a diverse clinical population and found that the questionnaire was sensitive to change over time and responsive to interventions. Please reference lines 91-99 in the manuscript.**

Methods - Line 118 - How would you treat a patient that ended having to be repositioned intra-operatively?

**Thank you for your questions. Patients who were repositioned intraoperatively were included in the intention to treat analysis but excluded from the per protocol analysis.**

Line 113 - as noted above, what information is currently available to demonstrate that PROMIS is the instrument that should be used for the primary outcome as compared to form 3a, form 8a and/or PFDI-20?

**Please see our response above.**

Results - Line 178 - why were the excluded and not left in for ITT principles?

**Thank you for your question. We have updated our manuscript with ITT results. Please see our response to reviewer #1 above.**

Line 183 - How did the patient get enrolled in not fluent in English?

**Thank you for your question. The patient presented with a family member who acted as her interpreter and it was not clear, until her post-operative visit, that the patient was not fluent in English. Since the ability to speak English was an inclusion criteria, this patient was excluded entirely from the study and the text and Figure 1 have been updated to reflect that.**

Discussion - Line 278-9 - Why not follow them up longer 3 months, 6 months, 12 months for instance?

**Thank you for your question. We allow our patients to return to work at 6-weeks after surgery and thus that was our primary outcome. We typically do not have patients return to the office at 3 or 6 months unless they require additional care. We have mentioned this as a limitation of our study.**

Tables - Table 1 - could eliminate the p values since all non-significant which strongly suggest that your randomization worked.

**Thank you for your comment. The p values have been removed from Table 1.**

Figures - No comments.

**Thank you.**

STATISTICAL EDITOR COMMENTS:

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

1. Lines 176-186, Fig 1: Should compare the 72 vs 67 pts who were randomized and had 6 week follow-up, ie, as an ITT analysis to contrast with the PP analysis.

**Thank you for your question. We have changed the methods, results and figures in the manuscript to reflect ITT analysis. Since the results did not change significantly, we have not reported the PP analysis.**

2. Table 1: Since the groups were randomized, there is no need to statistically compare the pre-operative variables. Any difference is thought to be due to random chance. Since the samples were  $n = 68$  and  $64$  (actually the ITT should be cited here) there is no need to format the %s to nearest 0.1% level of precision. Should round to nearest integer %.

**Thank you for your questions. The tables and manuscript have been changed to reflect ITT analysis. P values from Table 1 have been removed. All % have been rounded to the nearest integer.**

3. Table 2: The primary outcome (lines 148-149) needs to be clearly separated from the secondary ones. This appears to be the between group difference in PROMIS physical function SF-20a, not all the other comparisons. Also, the sample size calculation was based on specifying a Cohen's effect size = 0.5, so should format the primary outcome in terms of effect size and in terms of the minimum clinically important difference of 2.

**Thank you for your comments. We have added a footnote to table 2 identifying that the primary outcome was the between group differences. We have also added lines 211-213 in the manuscript formatting the primary outcome in terms of effect size “This difference of 3.8 between the groups was greater than the minimum clinically important difference of 2 and Cohen’s effect size value was  $d=0.51$ .”**

4. Lines 48-51: Not sure why this analysis was included, since age, BMI, CCI and duration of surgery were random (and NS different in Table 1) and why would one adjust for intraoperative complication? That would seem to bias the results.

**Thank you for your comments. We preselected the variables in this model based on existing literature. Studies by Gummus *et al*, Bohrer JC *et al* and Cardosi *et al* have identified that age, BMI, pre-existing comorbidities and duration of surgery can all significantly impact the risk of neurologic injury after gynecologic surgery. Thus, although they were equitably distributed by virtue of randomization, we wanted to mitigate their potential effect on our outcome. Intraoperative complications was removed from the regression model per your suggestion with negligible impact on the results. Additionally, as requested, we have removed the regression model from the abstract but would prefer to leave it in the manuscript.**

**EDITOR 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 choose to opt in.**

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on

"Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

**All disclosures have been listed on the title page.**

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows:

"The lead author\* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." \*The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

**This statement is included in the cover letter.**

4. 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).

**The data sharing statement is located at the end of the article.**

5. 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://nam03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2FAbout-ACOG%2FACOG-Departments%2FPatient-Safety-and-Quality-Improvement%2FreVITALize&data=02%7C01%7Cankita.gupta%40louisville.edu%7Cc24ccef50cd04acab61b08d7dd8eff0c%7Cdd246e4a54344e158ae391ad9797b209%7C0%7C0%7C637221479136052927&sdata=to3hqvdyRXeblHPy%2F765YFdpwQCJz9gc7BMYWxhuLi4%3D&reserved=0>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

**The reVITALize definitions have been reviewed.**

6. 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 is less than 5,500 words.**

7. 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).

**We have adhered to the above guidelines.**

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

**A running title has been provided and added as a footer.**

9. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

**A précis has been provided.**

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 limits for Original Research articles is 300 words. Please provide a word count.

**The abstract has been reviewed and meets the length criteria.**

11. 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:  
[https://nam03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Fsampleabstract\\_RCT.pdf&data=02%7C01%7Cankita.gupta%40louisville.](https://nam03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Fsampleabstract_RCT.pdf&data=02%7C01%7Cankita.gupta%40louisville)

edu%7Cc24ccef50cd04acab61b08d7dd8eff0c%7Cdd246e4a54344e158ae391ad9797b209%7C0%7C637221479136052927&data=1lTyQAtTsG86HJk1K5j0D7lcp3iqADDkq%2FJyt8FGOKY%3D&reserved=0. Please edit your abstract as needed.

**The abstract meets the above requirements.**

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 reviewed and (/) symbol removed as requested.**

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

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts. Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

**The manuscript has been reviewed and changes made as appropriate.**

12. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here:

[https://nam03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Ftable\\_checklist.pdf&data=02%7C01%7Cankita.gupta%40louisville.edu%7Cc24ccef50cd04acab61b08d7dd8eff0c%7Cdd246e4a54344e158ae391ad9797b209%7C0%7C0%7C637221479136052927&sdata=xGAUVAlA3W6TTdN00chigupxBmm%2F%2FB36Ww6nJ5KCqcw%3D&reserved=0](https://nam03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Ftable_checklist.pdf&data=02%7C01%7Cankita.gupta%40louisville.edu%7Cc24ccef50cd04acab61b08d7dd8eff0c%7Cdd246e4a54344e158ae391ad9797b209%7C0%7C0%7C637221479136052927&sdata=xGAUVAlA3W6TTdN00chigupxBmm%2F%2FB36Ww6nJ5KCqcw%3D&reserved=0).

**The checklist has been reviewed and adhered to.**

13. 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. 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.

**Figure one has been provided as a word document.**

**Figures 2 and 3 have been provided as tiff files.**

14. Please provide a reference for the Clavien-Dindo scoring system, if possible.

**Thank you for your question. References for the Clavien-Dindo scale had been provided in the methods section and have been added to the results section as well.**