

OBSTETRICS & GYNECOLOGY



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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

**The corresponding author has opted to make this information publicly available.*

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

Date: Oct 17, 2019
To: "Ida Bergman" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1742

RE: Manuscript Number ONG-19-1742

Perineorrhaphy versus pelvic floor muscle therapy in women with perineal body defects – a randomized controlled trial

Dear Dr. Bergman:

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 Nov 07, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The authors report an RCT between PT and perineorrhaphy for non-healed second degree laceration.

Abstract

- I do not understand what the 66% treatment effect is referring to. Could you clarify this?

Intro

- Can you provide more discussion of treatment success rates after postpartum PT for pelvic floor symptoms and treatment success rates for perineorrhaphy?

Methods

- Were patients referred for bothersome pelvic floor symptoms or were they recruited from a general Ob population?
- Was enrollment restricted to primiparous women, or were multiparas also included? Multiparas likely had prior pelvic floor trauma which could affect the results.
- Did the patients have to have a specific symptom to meet enrollment criteria?

Results

- Please add p values to Table 1

Discussion

- No changes

Reviewer #2:

Overall impression: useful study of a contemporary, important clinical problem

Eligibility: the study subjects were identified if they requested help for symptoms that related to a clinically detectable second-degree perineal injury.

Inclusion: patients with symptoms and clinical findings (definition needs to be clarified).

Exclusions: adequate, included AS tear on ultrasound.

Big problems:

What defines "defectively healed" perineum? How can we identify patients who would benefit from this data?

The authors use 3 different terms early in the manuscript and throughout the introduction. They use perineal body defects in the title, defectively healed second-degree perineal tears in the précis, and second degree obstetrical injury in the abstract and introduction. The terminology should be consistent and well defined. The clearest definition appears in the methods section and is listed after 'eligibility' above. However, the authors need to include the concept of "defectively healed" second-degree perineal injury. Basically, as I understand the manuscript, the study subjects are women with bothersome pelvic floor symptoms that relate to a poorly healed second-degree perineal injury.

One can infer that PB <2cm is the defect under study here. Were there any other characteristics noted such as asymmetry, granulation tissue, inflammation, foreign body reaction? Can any representative images be included other than the video? Note: the patient in the video looks fairly unremarkable and I believe many clinicians would not spot a problem. The authors might consider raising this point: that we examine in context of the presenting concerns and should be on the look out for short perineum, bulging of the perineum and/or descent, combined abnormal vaginal and DRE findings, asymmetry, contraction, etc.

It should be stated clearly that there was little/no standardization as to what is meant by "defectively healed" perineum. If there were 5 clinicians seeing these patients then this is an even bigger problem.

Small problems:

How much time elapsed between laceration occurrence and determination of study eligibility? This does not appear to be part of the protocol. Therefore, I believe the authors should at least report a minimum value for the subjects. This will help clarify what is meant by "defectively healed". It is important for the authors to indicate that these patients had healed and were not likely to improve with time.

Questionnaires: were these in English? If so, than inclusion criteria should include that patients can read English. If not, were the questionnaires used validated in Swedish? If not all then which ones?

Line 100: suggest "one of 5 urogynecologists", unless each patient did in fact have 5 surgeons attend their case.

Line 171: One patient in the physiotherapy group did not meet inclusion criteria (had a history of a 4th degree perineal tear) . Why was this patient randomized in the first place? Please clarify in the manuscript.

Tables 1 and 4

Please give unit of measures where appropriate, for example, age (years), perineal body height on ultrasound (cm), TVL (cm), change in GH (cm), etc.

References

- #3- was the entire reference used? If not please provide page numbers.
- #8 please recheck this reference and provide publication data, if known.
- #14 what does "discussion 8" mean listed after the citation?
- #21 is not properly cited.
- #29 is incompletely cited please complete.

Reviewer #3: Review of Manuscript ONG-19-1742 "perineorrhaphy versus pelvic floor muscle therapy in women with perineal body defects - a randomized controlled trial"

Bergman and colleagues report results from a single center open label RCT evaluating 2 differing approaches for improperly healed second degree obstetrical lacerations. The authors appropriately provided the CONSORT checklist. The authors reported that they standardized the surgical procedures and also recorded the procedures with a representative one submitted as an appendix. Overall this is a well written manuscript that does not appear to oversight its findings. I have the following comments/questions.

Title - No comments.

Précis - Seems incomplete as written, consider modifying to something similar to - "Surgery was significantly more effective than physiotherapy in providing symptom relief in women with defectively healed second degree perineal tears."

Abstract - If space allows, note informed consent obtained. Any other data like age, parity, prior lacerations, etc. that can be included?

Introduction - Good summary

Methods - line 80 - if their delivery was prior to age 18 were they potentially eligible? Authors provide exclusion criteria

which seem appropriate. Line 107 - was there a rationale regarding differences in scheduled follow-up 1 vs. 2 vs. 3 in the physiotherapy group? How much data imputation was performed? Line 110 - was thought given to additional follow-up at either 1 or 2 years?

Results - Reasonable breakdown provided.

Discussion - Authors point out findings as well as potential limitations. Any thoughts to having physiotherapy for all and then patients randomized to surgery?

Tables - As noted in the results all baseline characteristics were similar. I presume this means that all were $p < 0.05$? Add units to genital hiatus and perineal body height in table 1. Other tables seem fine, although some of the tables could be supplementary for instance table 4 and either table 3 or 5.

Figure - Flow diagram appropriate.

STATISTICAL EDITOR COMMENTS:

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

Table 1: Since the continuous variables were tested with Mann-Whitney U test, should format those characteristics as median(range or IQR). If desired, could also cite the variables as mean \pm SD, either in this Table or in supplemental appendix.

Table 2: Since "success" and "failure" are complementary values, no need to cite each, should simplify the Table with just the % success, which was how the primary outcome was defined (lines 38-39, 110-116, 144-149). Also, given the sample sizes for the two cohorts ($n = 35$ and 35), there is no justification for reporting the % success to nearest 0.1%, should round to nearest integer %. While the reader may be interested in ITT analysis by subset on the 7-point Likert scale, that is not how the primary was defined and should be either in supplemental material or with the secondary outcomes. The 4 comparisons, 3 ITT and 1 PP are more than sufficient for the primary outcome.

Tables 3,4: Again, since the test used was Wilcoxon's and Mann-Whitney U, should format as median(range or IQR). Could include the mean \pm SD as supplemental material.

Table 5: Given the cohort sizes, should round the %s to nearest integer %, not nearest 0.1% precision.

Fig 1: Were the women who either declined or who were not invited different in baseline characteristics from the randomized group? Why not simply use the intention to treat with worst case imputation (ie, all $n = 35$ for each group) as the primary outcome analysis, since it included all women, then contrast with the PP analysis in Table 1?

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- Your title, precis and objective of the abstract need to make it clear that the injury occurred about 6 months prior to randomization.

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

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

P Values vs Effect Size and Confidence Intervals

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

This is true for the abstract as well as the manuscript.

- please tell us what time frame the obstetrical injury occurred within. Is this acute injury? First 42 days? 5 years previously? Tell us.

- what do you mean by "improperly healed"? See reviewer comments about this.

- what is level 3 support?

- what is the posterior compartment? Recall that many readers are general Ob GYN's and not urogynecologists so this type of terminology needs to be defined.

- Its not clear as you have written this that you are talking about remote history of obstetrical injury. Please edit.

- Your introduction should at least mention physical therapy as an option for treatment of chronic obstetrical injury. It sort of comes out of nowhere that your comparison group here is physical therapy.

- from October 15, 2015 to....

- I'm not sure what this means. The terminology "second degree perineal injury" refers to the acute obstetrical injury, at least that the way I read it. Could you clarify that you are talking about residual perineal body injury following a 2nd degree obstetrical laceration or episiotomy?

- Clarify in which plane thickness of the perineal body measured.

- By "independent physician" do you mean they were unaware of the treatment arm allocation? Were patients asked not to tell her or him? Who recruited patients and at what point in their presentation for care? Were there any inducements?

- performed under local anesthesia...

2. 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.

3. 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.

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. 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.

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

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

8. 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).

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

10. 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."

11. 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.

12. 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.

13. 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.

14. 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.

15. 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%).

16. 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.

17. Figure 1: Please confirm that the number included in the intention-to-treat analysis for those allocated to surgery is 32.

18. 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.

19. 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 Nov 07, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965

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

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>). Please contact the publication office if you have any questions.



Stockholm, October, 2019

To: The Editor of *Obstetrics and Gynecology*

Dear Editor,

We hereby submit a revised version of our manuscript “Perineorrhaphy versus pelvic floor muscle therapy in women with late consequences of a poorly healed second degree perineal tear – a randomized controlled trial” for consideration to be published in *Obstetrics and Gynecology*. We thank you for being willing to give further consideration to a revised version. This cover letter includes the comments made by the reviewers and the editor followed by our response. We have thoroughly read the instructions for authors and formatted the manuscript, tables and figures according to the rules.

The Corresponding Author grants to *Obstetrics and Gynecology* the exclusive rights to publish this article (if accepted). The manuscript is not under consideration to be published elsewhere and will not be submitted elsewhere until a final decision is made by the Editors of *Obstetrics & Gynecology*. The study was approved by the Research Ethics Committee at Karolinska Institutet, Stockholm, Sweden, and conforms to the CONSORT guidelines for reporting randomized trials. The study protocol was registered at ClinicalTrials.gov ([NCT02545218](https://clinicaltrials.gov/ct2/show/study/NCT02545218)) prior to recruitment and the trial was conducted in accordance with the protocol.

I also certify that all authors fulfill the requirements for authorship according to the Vancouver guidelines. 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 authors have no conflicts of interest to declare.

We believe that our paper is of interest to the readers of *Obstetrics and Gynecology* and look forward to your response.

Yours sincerely,

Ida Bergman, MD



We thank the Editorial Board and reviewers for constructive commentaries and suggestions on how to further improve our manuscript. The issues raised are addressed in order of appearance below.

REVIEWER COMMENTS:

REVIEWER #1: The authors report an RCT between PT and perineorrhaphy for non-healed second degree laceration.

Abstract

- I do not understand what the 66% treatment effect is referring to. Could you clarify this?

Reply

The 66% treatment effect refers to the delta value in percentage points when comparing treatment success rates between the groups. We have now also reported the effect size in odds ratios as suggested by the comments from the editor. Please see line 71-72 and 284-285.

Intro

- Can you provide more discussion of treatment success rates after postpartum PT for pelvic floor symptoms and treatment success rates for perineorrhaphy?

Reply

We have now added a paragraph about postpartum physiotherapy to the Introduction section, as well as, results from previous studies evaluating perineorrhaphy. Please see line 120-124 and 125-132.

Methods

- Were patients referred for bothersome pelvic floor symptoms or were they recruited from a general Ob population?

Reply

All patients were referred to our urogynecological outpatient clinic due to bothersome pelvic floor symptoms. We have clarified this in the methods section, please see line 144-146.

- Was enrollment restricted to primiparous women, or were multiparas also included? Multiparas likely had prior pelvic floor trauma which could affect the results.

Reply

Enrollment was not restricted to primiparous women. We have clarified this in the methods section. Please see line 144. The median parity in both groups was 2 as demonstrated in Table 1 (non-significant difference between the groups). We agree that multiparous women might have a higher degree of pelvic floor injuries resulting from childbirth. However, we did not want to exclude multiparous women since this would have further decrease the generalizability of the results.

- Did the patients have to have a specific symptom to meet enrollment criteria?

Reply

The symptomatology related to a poorly healed second degree perineal tear is not well described. We did therefore not want to restrict enrollment to a specific symptom or symptoms. Our starting point was the anatomical findings of a thin/short perineum on bidigital palpation, where a clinical examination and ultrasound demonstrated a detachment of the bulbocavernosus plus/minus the transversus perinei muscles in women with bothersome pelvic floor dysfunction symptoms and no anterior or apical prolapse or sphincter defects. We have tried to clarify this in the methods section. Please see line 146-163.

Results

- Please add p values to Table 1

Reply

We did not present p-values in Table 1 as many journal currently discourage to do so in randomized trials (<http://www.consort-statement.org/checklists/view/32-consort/510-baseline-data;>). We have, however, now included a version of Table 1 where the p-values are presented in the right column. The editorial office may choose which version they prefer.

Discussion

- No changes

Reviewer #2:

Overall impression: useful study of a contemporary, important clinical problem

Eligibility: the study subjects were identified if they requested help for symptoms that related to a clinically detectable second-degree perineal injury.

Inclusion: patients with symptoms and clinical findings (definition needs to be clarified).

Exclusions: adequate, included AS tear on ultrasound.

Big problems:

What defines "defectively healed" perineum? How can we identify patients who would benefit from this data?

Reply

Thank you for a highly relevant comment. We have now edited the methods section in the manuscript aiming to clarify this. Please see line 146-163.

The authors use 3 different terms early in the manuscript and throughout the introduction. They use perineal body defects in the title, defectively healed second-degree perineal tears in the précis, and second degree obstetrical injury in the abstract and

introduction. The terminology should be consistent and well defined. The clearest definition appears in the methods section and is listed after 'eligibility' above. However, the authors need to include the concept of "defectively healed" second-degree perineal injury. Basically, as I understand the manuscript, the study subjects are women with bothersome pelvic floor symptoms that relate to a poorly healed second-degree perineal injury.

Reply

We agree and as requested we now use the term "poorly healed second degree perineal tear" throughout the manuscript.

One can infer that PB <2cm is the defect under study here. Were there any other characteristics noted such as asymmetry, granulation tissue, inflammation, foreign body reaction? Can any representative images be included other than the video? Note: the patient in the video looks fairly unremarkable and I believe many clinicians would not spot a problem. The authors might consider raising this point: that we examine in context of the presenting concerns and should be on the look out for short perineum, bulging of the perineum and/or descent, combined abnormal vaginal and DRE findings, asymmetry, contraction, etc.

It should be stated clearly that there was little/no standardization as to what is meant by "defectively healed" perineum. If there were 5 clinicians seeing these patients then this is an even bigger problem.

Reply

We agree, however, there is currently no established standardized definition of a "poorly healed second degree perineal tear". We have now included a more detailed description of how the diagnosis was made during enrollment of the patients in the present study, please see line 146-164. We have also included a representative image to illustrate the anatomical findings (please see Figure 1).

Small problems:

How much time elapsed between laceration occurrence and determination of study eligibility? This does not appear to be part of the protocol. Therefore, I believe the authors should at least report a minimum value for the subjects. This will help clarify what is meant by "defectively healed". It is important for the authors to indicate that these patients had healed and were not likely to improve with time.

Reply

As stated in the methods section line 166 exclusion criteria were "less than six months postpartum, lactational amenorrhea...". The median duration between the last delivery and enrollment in this study was 10 months. The precis, abstract and manuscript have been edited to highlight this, please see line 32, 53, 56, 92, 136.

Questionnaires: were these in English? If so, than inclusion criteria should include that patients can read English. If not, were the questionnaires used validated in Swedish? If not all then which ones?

Reply

We used questionnaires validated into Swedish language (please see reference number 32). We have now edited the inclusion criteria paragraph in the Methods section, line 144.

Line 100: suggest "one of 5 urogynecologists", unless each patient did in fact have 5 surgeons attend their case.

Reply

We have now edited the manuscript. Please see line 184.

Line 171: One patient in the physiotherapy group did not meet inclusion criteria (had a history of a 4th degree perineal tear) . Why was this patient randomized in the first place? Please clarify in the manuscript.

Reply

The patient with a previous 4th degree tear was randomized by mistake. This mistake was noticed post randomization, when baseline characteristics were compiled into the study dataset. We have made a clarification in the manuscript. Please see line 275.

Tables 1 and 4

Please give unit of measures where appropriate, for example, age (years), perineal body height on ultrasound (cm), TVL (cm), change in GH (cm), etc.

Reply

The Tables have been edited as requested.

References

#3- was the entire reference used? If not please provide page numbers.

#8 please recheck this reference and provide publication data, if known.

#14 what does "discussion 8" mean listed after the citation?

#21 is not properly cited.

#29 is incompletely cited please complete.

Reply

We sincerely apologize for the improperly cited references. We have now edited the reference list.

Reviewer #3: Review of Manuscript ONG-19-1742 "perineorrhaphy versus pelvic floor muscle therapy in women with perineal body defects - a randomized controlled trial"

Bergman and colleagues report results from a single center open label RCT evaluating 2 differing approaches for improperly healed second degree obstetrical lacerations. The authors appropriately provided the CONSORT checklist. The authors reported that they standardized the surgical procedures and also recorded the procedures with a representative one submitted as an appendix. Overall this is a well written manuscript that does not appear to oversight its findings. I have the following comments/questions.

Title - No comments.

Précis - Seems incomplete as written, consider modifying to something similar to - "Surgery was significantly more effective than physiotherapy in providing symptom relief in women with defectively healed second degree perineal tears."

Reply

We have now edited the Précis as suggested.

Abstract - If space allows, note informed consent obtained. Any other data like age, parity, prior lacerations, etc. that can be included?

Reply

The abstract has been edited. We have now included information about informed consent and mean age and number of months postpartum at enrollment, please see line 57, 66-68.

Introduction - Good summary

Methods -

- line 80 - if their delivery was prior to age 18 were they potentially eligible?

Reply

Yes, they were potentially eligible if their delivery was prior to the age of 18. The eligibility criteria states that they had to be 18 or above at enrollment in the study. However, the youngest participant was 21 years at enrollment.

Authors provide exclusion criteria which seem appropriate.

Line 107 - was there a rationale regarding differences in scheduled follow-up lvs. 2 vs. 3 in the physiotherapy group?

Reply

The follow-up visits in the physiotherapy group were scheduled approximately 1-2 month apart. The aim or purpose of the follow-up visits were to encourage the patients to keep up their training and to provide an opportunity for the physiotherapist to check that the patients used an appropriate training technique (and make

adjustments if needed) and for the patients to ask questions if needed.

How much data imputation was performed?

Reply

Data was imputed only for the three drop-out patients. Baseline characteristics were used in a regression model to predict the missing values. A pooled estimate of ten iterations was used.

Line 110 - was thought given to additional follow-up at either 1 or 2 years?

Reply

Yes. We have planned for a 2 year follow-up which also includes a 3-dimensional ultrasound of the levator ani muscles in order to evaluate if treatment failure or lack of symptom relief is correlated to injuries in these muscles.

Results - Reasonable breakdown provided.

Discussion - Authors point out findings as well as potential limitations. Any thoughts to having physiotherapy for all and then patients randomized to surgery?

Reply

We have planned to do a follow-up of the patients who were randomized to physiotherapy and subsequently were scheduled for surgery and compare them with the group that were randomized directly into surgery. We hypothesize that a combination of the two treatments leads to the most optimal result. We agree that it would be very interesting to refer the women who received initial surgery to subsequent physiotherapy to assess if this leads to further symptom improvement.

Tables - As noted in the results all baseline characteristics were similar. I presume this means that all were $p < 0.05$? Add units to genital hiatus and perineal body height in table 1. Other tables seem fine, although some of the tables could be supplementary for instance table 4 and either table 3 or 5.

Reply

Yes, all baseline characteristics were similar (p -value > 0.05), we have clarified this in the manuscript, please see line 277. We have now also submitted a version of Table ,1 where p -values are listed in a separate column as requested by reviewer number 1. The editorial office may chose which version they prefer. The tables have now been edited and appropriate units are added.

Figure - Flow diagram appropriate.

STATISTICAL EDITOR COMMENTS:

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

Table 1: Since the continuous variables were tested with Mann-Whitney U test, should format those characteristics as median(range or IQR). If desired, could also cite the variables as mean±SD, either in this Table or in supplemental appendix.

Reply

Thank you. We have now revised Table 1 and changed means (SD) to medians (IQR). Reviewer nr 1 requested a column in Table 1 showing the results (p-values) from the statistical tests. We have now submitted two versions, one with and one without p-values. The editorial office may choose which version they prefer.

Table 2: Since "success" and "failure" are complementary values, no need to cite each, should simplify the Table with just the % success, which was how the primary outcome was defined (lines 38-39, 110-116, 144-149). Also, given the sample sizes for the two cohorts (n = 35 and 35), there is no justification for reporting the % success to nearest 0.1%, should round to nearest integer %. While the reader may be interested in ITT analysis by subset on the 7-point Likert scale, that is not how the primary was defined and should be either in supplemental material or with the secondary outcomes. The 4 comparisons, 3 ITT and 1 PP are more than sufficient for the primary outcome.

Reply

As requested, we have now revised the table according to the suggestions above. We have omitted the rows including "treatment failure" and rounded the % to the nearest integer (for example 3 instead of 2.9). We have moved the PGI 7-point Likert scale to table 4. According to the instructions from the Editor we have replaced the "p-value" column with an "OR (95% CI)" column.

Tables 3,4: Again, since the test used was Wilcoxon's and Mann-Whitney U, should format as median(range or IQR). Could include the mean±SD as supplemental material.

Reply

We have now revised Table 3 and 4 and changed means (SD) to medians (IQR).

Table 5: Given the cohort sizes, should round the %s to nearest integer %, not nearest 0.1% precision.

Reply

We have now rounded the %s to nearest integer %.

Fig 1: Were the women who either declined or who were not invited different in baseline characteristics from the randomized group? Why not simply use the intention to treat with worst case imputation

(ie, all n = 35 for each group) as the primary outcome analysis, since it included all women, then contrast with the PP analysis in Table 1?

Reply

As suggested, we have now used the "worst case imputation" results as the primary analysis. We have now revised figure 2, abstract and manuscript.

The table below shows a comparison of baseline characteristic when comparing included an non-included eligible patients. Statistically, but probably not clinically, significant differences were found regarding parity and BMI. This information has been added to the manuscript, please see line 261-265.

	Included n=70	Not included n=39	p-value	Statistical test
Age, median (IQR)	35 (6)	36 (7)	0.08	MWU
BMI, median (IQR)	22 (5)	24 (4)	0.03	MWU
Parity, median (IQR)	2 (1)	2 (1)	0.008	MWU
Laceration			0.74	Fisher exact
2 nd degree (n%)	58 (83)	31 (80)		
3 rd degree (n%)	12 (17)	8 (20)		
Smoker n (%)	6 (9)	4 (10)	0.80	Fisher exact

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- Your title, precis and objective of the abstract need to make it clear that the injury occurred about 6 months prior to randomization.

Reply

We agree that it has to be clear to the reader that we are studying women who present with late symptoms and signs (at minimum six months postpartum). We have now edited the title, precis and objective, please see line The precis, abstract and manuscript have been edited to highlight this, please see line 2, 32, 53, 56, 92, 136.

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

Reply

We have studied the instructions in great detail and tried to format the manuscript, tables and figures according to the requirements.

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

P Values vs Effect Size and Confidence Intervals

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

This is true for the abstract as well as the manuscript.

Reply

We fully agree that effect sizes and confidence intervals makes the results from a statistical test more clinically relevant. We have now included odd ratios and confidence intervals in our abstract (line 71-72), manuscript (line 285-286) and table 2.

- please tell us what time frame the obstetrical injury occurred within. Is this acute injury? First 42 days? 5 years previously? Tell us.

Reply

Exclusion criteria in this study was "less than six months postpartum, lactational amenorrhea" as stated in the methods section (please see line 166). We have now added this information also to the precis, abstract and manuscript please see line 32, 53, 56, 92, 136. The mean (SD) duration postpartum among the women included in this study was 35 (\pm 56)months and the median (IQR) was 10 (37) months. The median duration postpartum in both groups are presented in the abstract (line 67-68), result section (line 279) and in the table 1.

- what do you mean by "improperly healed"? See reviewer comments about this.

Reply

As suggested by the editor and reviewer we have now elaborated on the anatomical findings referred to as a poorly healed second degree perineal tear. Please see methods section line 146-164.

- what is level 3 support?

Reply

In 1992 DeLancy described three levels of vaginal support. Level I suspends the upper third of the vagina and is supported by the uterosacral and cardinal ligaments. Level II is the middle third of the vagina and is supported by the endopelvic fascia including the pubocervical and rectovaginal fascia and attaches laterally to the arcus tendineus. Level III is the most distal portion, which is supported by the levator ani muscles and the perineal body. The perineal body acts as the final mechanism for preventing prolapse beyond the hymen. We have now edited the introduction by defining the term level III support (line 107-108).*

*DeLancey JO. Anatomic aspects of vaginal eversion after hysterectomy. Am J Obstet Gynecol 1992;166:1717-24

- what is the posterior compartment? Recall that many readers are general Ob GYN's and not urogynecologists so this type of terminology needs to be defined.

Reply

The posterior vagina wall together with the the perineal body are often referred to as the posterior compartment. We have now edited the manuscript, please see line 116-117.

- Its not clear as you have written this that you are talking about remote history of obstetrical injury. Please edit.

Reply

We have now tried to clarify in the title, precis, abstract and manuscript that the study aims to assess results of conservative and surgical treatments of late sequelae from poorly healed second degree perineal tears. Please see line please see line 2, 32, 53, 56, 92, 136 and Figure 1.

- Your introduction should at least mention physical therapy as an option for treatment of chronic obstetrical injury. It sort of comes out of nowhere that your comparison group here is physical therapy.

Reply

As suggested, we have now added a few sentences about postpartum physiotherapy in the introduction section. Please see line 125-132.

- from October 15, 2015 to....

Reply

We have now edited the manuscript by changing the date format to the suggestion above (line 143-144).

- I'm not sure what this means. The terminology "second degree perineal injury" refers to the acute obstetrical injury, at least that the way I read it. Could you clarify that you are talking about residual perineal body injury following a 2nd degree obstetrical laceration or episiotomy?

Reply

We apologize for the confusing terminology. We have now tried to be more consistent throughout the manuscript.

- Clarify in which plane thickness of the perineal body measured.

Reply

We have now clarified that the plane of the perineal body thickness measurements is the level of the caudal part of the external anal sphincter, please see line 152-153.

- By "independent physician" do you mean they were unaware of the treatment arm allocation? Were patients asked not to tell her or him? Who recruited patients and at what point in their presentation for care? Were there any inducements?

Reply

By independent physician we meant that the outcome assessor was not the patients surgeon (manuscript edited, line 179). The outcome

assessor was not blinded to the treatment allocation, which is a limitation of the study (limitations section edited, line 396). However, the primary outcome was solely patient reported and did not include parameters assessed by a physician. The primary outcome was collected using a questionnaire which the patient filled in without involvement of a caregiver (line 197-198). Patients were recruited when presenting at the outpatient clinic due to bothersome symptoms. The patients come on referral from other physicians to our pelvic floor outpatient clinic (please see line 144-145). No inducements were used. We have revised the manuscript trying to clarify this, please see line xxx.

- performed under local anesthesia...

Reply

The manuscript has been edited according to the suggestion above, please see line 183.

2. 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.

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Reply

A. OPT-IN: Yes, please publish my point-by-point response letter.

3. 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.

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).

Reply

We have included a data sharing statement table after the reference list.

5. 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.

Reply

Our study was not company sponsored.

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

Reply

The terminology in the present study adheres to the terminology and definitions included in the reVITALize definitions

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

Reply

We have not exceeded the length restrictions for the manuscript type, original research.

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

- * All financial support of the study must be acknowledged.
- * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- * If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

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

10. 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."

11. 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.

12. 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.

Reply

The abstract has been edited.

13. 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.

14. 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.

15. 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%).

16. 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.

17. Figure 1: Please confirm that the number included in the intention-to-treat analysis for those allocated to surgery is 32.

Reply

We have revised Figure 1 (now labeled Figure 2 since a new figure has been added to the manuscript) according to the suggestion from the statistical reviewer. The main analysis is the ITT analysis with worst case imputation. The number included in the intention-to-treat analysis for those allocated to surgery is thus 35.

18. 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>.

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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.

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- * 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 Nov 07, 2019, we will assume you wish to withdraw the manuscript from further consideration.