

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)*
- Email correspondence between the editorial office and the authors*

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

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

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:

obgyn@greenjournal.org.

Date: Jan 04, 2019
To: "DANIEL DUGI" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-2212

RE: Manuscript Number ONG-18-2212

Implementation of a Pelvic Floor Physical Therapy Program for Transgender Women Undergoing Gender-Affirming Vaginoplasty

Dear Dr. DUGI:

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 Jan 25, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

This is a descriptive study outlining the experience of vaginoplasty patients at a single institution with pelvic floor physical therapy and pelvic floor disorders before and after surgery. This is not a common surgery and usually performed in specialized centers, therefore, this data may be more relevant for a subspecialty journal. In addition, the retrospective nature and small numbers limit conclusions. On the other hand, it is a reminder that pelvic floor physical therapists can help with vaginal dilation for any indication.

1. Methods: So that distance can be compared, please state that the "local" group is within x miles of the hospital rather than within a three-county area.
2. Methods: If this is a retrospective chart review, please provide more detail about follow up at 3 and 12 months. Was this passive or active? In other words, if patients happened to show up at 3 and 12 months, then the data was documented, but if they did not show up, we have no information? Could they have gone to a pelvic floor physical therapist closer to home and do you have access to that information?
3. Results: Please check tables and report missing data, for example Table 1: Distance to facility adds up to 78 subjects but only 77 were enrolled, Table 5 Data is reported on 65 subjects, presumably 12 subjects did not respond to the question or it is not documented, missing data numbers should be reported in a Table footnote. Similarly Table 6, clarify that numbers reported are for those who showed up to the visits, everyone else was lost to follow up.
4. Discussion: This should be shortened. Lines 254-267 can be deleted for example.
5. Discussion: Agree that randomization is not feasible but a larger prospective study at multiple centers could be performed.

REVIEWER #2:

1. This single institution study is retrospective, and yet there is a paucity of information in the literature on this subject, and this paper offers information that I believe is clinically useful.
2. The introduction is very well done and is necessary, as many readers likely have a very superficial understanding of the

topic.

3. My first instinct was that the study should be prospective and that there should be a comparison group ie there should be a group that receives no preoperative PFPT or postoperative PFPT, a group that receives only postoperative PFPT, and a group that receives both.

4. The paper was not designed in this way, but I feel that the authors did the next best thing. For example, table 4 show that for patients who did not attend the preoperative PFPT their rate of pelvic floor muscle dysfunction was worse. Ideally, the numbers would be greater, and if they were, the authors might be able to show a difference in urinary and bowel dysfunction between these two groups as well.

5. Table 6 shows no significant differences, but the numbers for 1 year follow up are small and I think this would be a very interesting area for further study, as it would answer some of the questions regarding the long term benefits of PFPT.

6. The paper is very well written, and criticisms regarding the retrospective nature and lack of randomization aside, I think the content is unique, and it will be a useful contribution to the literature and our understanding of the topic. The information may not directly apply to the majority of the readers of the Green Journal, but I think it will be of great interest nonetheless.

REVIEWER #3:

The authors present their outcomes in trans women undergoing perioperative pelvic floor PT before and after vaginoplasty surgery. Use of PT perioperatively in transgender patients is becoming more common in academic centers performing vaginoplasty surgery and the authors are the first to study it.

I have the following comments to the authors:

1- In the introduction, the authors should discuss the role of PFPT in high tone pelvic floor disorders, aka myogascial syndrome - this is where PT is the most applicable with regard to this surgery

2- The authors do not state true objectives of this paper/study - they should add this at the end of their introduction

3- In the methods, the authors should be very clear about their design - based on how they describe their methods, we can figure it out. But, is this a case series of 77 women who underwent vaginoplasty or is this a designed retrospective cohort study with primary and secondary outcomes studied - the way that the methods and results are presented, this is not clear

4- The authors lack strict definitions of their outcomes for this study; these should be described in the methods; how did the PTs diagnose pelvic floor dysfunction, etc - "yes" "no" answers to certain questions? validated PF questionnaires? How were these assessed? How was "success of dilation" defined?

5- In their description of vaginal dilation and dilator size the authors make it sounds as though data were collected prospectively. How were these data captured in the medical record if this was a retrospective study?

6- In the last sentence of the first paragraph of the results - line 166 - the authors say "other affirming" surgeries - how many patients had previous vaginoplasty surgery? Or were all patients primary surgeries? This should be described in the inclusion criteria in the methods.

7- In the second paragraph of the results - the authors should present the data as % n/N - so that it is clear which subset of the patients the authors are referring to

8- Again - how were pelvic floor symptoms defined a priori to conducting the study? This is vague.

9- The authors determine why only 65% of patients went to PT postoperatively? Did they not like the preoperative PT? Was preoperative PT enough?

10- When did patients do preop PT in relation to their surgery date? Please specify in the methods .

11- Please also specify in the methods the PT protocol used for preop and postop patients.

12- The authors should comment further on the patients who improved postop - is it possible that there is a regression to the mean situation? Also - most of these patients only had 1 PT visit

13- in the cisgender community, 1 PT session for PFD usually is not curative. How do the authors explain this?

14- Also the authors should be forthcoming in their discussion: PT did not statistically improve ease/success of dilation - this may be the main goal of therapy. May not mean PT doesn't help - they are simply not powered to determine this.

15- The authors should consider doing a post hoc power analysis to determine how many patients they needed in their cohort to show that PT is efficacious

16- The authors again report improvement in baseline PFD postoperatively - do they think this is from the surgery, from 1 session of PT?

17- I think that one of the main points of this paper is that the incidence of PFD in trans women seeking surgery is not negligible - do the authors know how this incidence compares in the cis gender world? Are PFD common amongst women?

18- The authors spend a lot of time discussing that PT helped patient's with baseline PFD but they do not really spend too much time discussing how it enhances the surgery and recovery process

19- I urge the authors to retract their statement about it being unethical to perform a RCT to study this - this is simply not true. PFPT is not currently gold standard therapy for postop vaginoplasty patients - it is new and people are considering it. The authors have not shown a true improvement in patient outcomes using their methodology - so they can hardly say that it would be wrong to study this intervention with the most robust study design known to researchers. In fact, before we urge insurance companies to routinely cover this type of therapy, I would argue that we must study it this way to show that it truly is better than no therapy and that patients' outcomes are better with it.

STATISTICAL EDITOR'S COMMENTS:

1. lines 62-64: In Table 4, this appears to be incorrectly stated, the comparison was between post-op only and cohort with both pre and post op attendance, not simply pre vs only post.

2. Table 1: Need units for BMI, age, distance to facility. If there are any missing data characteristics, then need to enumerate.

3. Table 2: Need to include a flow diagram or Venn diagram, clearly showing 4 groups: attended no PFPT, Pre-op only, post-op only and cohort with both pre and post-op.

4. Table 3: If any comparisons are inferred, then should include CIs. All comparisons are NS, mostly due to low stats power.

5. Tables 4, 5, 6: Although most comparisons are NS, the counts are so few that there is little power to generalize the NS findings.

6. Table 7: Should format as n(%) or show number used in denominator at top of column

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. 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:

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

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.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

3. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality

improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

4. 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.

5. 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 26 typed, double-spaced pages (6,500 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.

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

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. 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.

10. 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.

11. 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.

12. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

13. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

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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 via Editorial Manager for Obstetrics & Gynecology at <http://ong.editorialmanager.com>. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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 Jan 25, 2019, we will assume you wish to withdraw the manuscript from further consideration.


Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

In compliance with data protection regulations, please contact the publication office if you would like to have your personal information removed from the database.



Dear Dr. Editors of Obstetrics & Gynecology,

Please find a revised manuscript; below are responses to each comment by the reviewers.

REVIEWER #1:

This is a descriptive study outlining the experience of vaginoplasty patients at a single institution with pelvic floor physical therapy and pelvic floor disorders before and after surgery. This is not a common surgery and usually performed in specialized centers, therefore, this data may be more relevant for a subspecialty journal. In addition, the retrospective nature and small numbers limit conclusions. On the other hand, it is a reminder that pelvic floor physical therapists can help with vaginal dilation for any indication.

1. Methods: So that distance can be compared, please state that the "local" group is within x miles of the hospital rather than within a three-county area.

RESPONSE: *updated in the manuscript to be "approximately within 20 miles"*

2. Methods: If this is a retrospective chart review, please provide more detail about follow up at 3 and 12 months. Was this passive or active? In other words, if patients happened to show up at 3 and 12 months, then the data was documented, but if they did not show up, we have no information? Could they have gone to a pelvic floor physical therapist closer to home and do you have access to that information?

Response: *This retrospective review was passive; if they did not attend follow-up, we examined their electronic charts to see if they saw physical therapy in electronic care system. If they did not have physical therapy follow-up, then they were deemed to not have seen PT. Transgender patients often have negative healthcare experiences from places inexperienced in transgender care; thus, we encourage majority of care be done at our institution and expect rates of follow-up with PT elsewhere would be low.*

3. Results: Please check tables and report missing data, for example Table 1: Distance to facility adds up to 78 subjects but only 77 were enrolled, Table 5 Data is reported on 65 subjects, presumably 12 subjects did not respond to the question or it is not documented, missing data numbers should be reported in a Table footnote. Similarly Table 6, clarify that numbers reported are for those who showed up to the visits, everyone else was lost to follow up.

Response: *Thank you, we clarified this in the tables.*

4. Discussion: This should be shortened. Lines 254-267 can be deleted for example.

Response: *Below there are two statements wanting to know more about the PT interventions. We moved most of the discussion about intervention into the methods. (lines 171-193).*

5. Discussion: Agree that randomization is not feasible but a larger prospective study at multiple centers could be performed.

Response: *We appreciate this comment and we added this to the discussion (lines 331-335)*

REVIEWER #2:

1. This single institution study is retrospective, and yet there is a paucity of information in the literature on this subject, and this paper offers information that I believe is clinically useful.

2. The introduction is very well done and is necessary, as many readers likely have a very superficial understanding of the topic.

3. My first instinct was that the study should be prospective and that there should be a comparison group ie there should be a group that receives no preoperative PFPT or postoperative PFPT, a group that receives only postoperative PFPT, and a group that receives both.

4. The paper was not designed in this way, but I feel that the authors did the next best thing. For example, table 4 show that for patients who did not attend the preoperative PFPT their rate of pelvic floor muscle dysfunction was worse. Ideally, the numbers would be greater, and if they were, the authors might be able to show a difference in urinary and bowel dysfunction between these two groups as well.

RESPONSE to both 3 and 4: *We agree that lack of randomization is one of the major flaws of our study; however, randomization of patients to receive or not receive PFPT is difficult in this patient population when these patients have previously been marginalized in society and healthcare. In addition, the PFPT program was started in response to surgeon-perceived apprehension of and pain/difficult with dilation observed in other centers. In the future, prospective randomized study would be valuable in determining more objective data on how PFPT affects outcomes. We also agree that this is a preliminary study to understand baseline characteristics of these patient in terms of their pelvic floor dysfunction. In the future, we hope to continue accruing patients to increase the power of our study.*

5. Table 6 shows no significant differences, but the numbers for 1 year follow up are small and I think this would be a very interesting area for further study, as it would answer some of the questions regarding the long term benefits of PFPT.

RESPONSE: *We agree that we need to improve the power of our study. We hope to have a follow up study once we have over a few hundred patients with longer follow up.*

6. The paper is very well written, and criticisms regarding the retrospective nature and lack of randomization aside, I think the content is unique, and it will be a useful contribution to the literature and our understanding of the topic. The information may not directly apply to the majority of the readers of the Green Journal, but I think it will be of great interest nonetheless.

REVIEWER #3:

The authors present their outcomes in trans women undergoing perioperative pelvic floor PT before and after vaginoplasty surgery. Use of PT perioperatively in transgender patients is becoming more common in academic centers performing vaginoplasty surgery and the authors are the first to study it.

I have the following comments to the authors:

1- In the introduction, the authors should discuss the role of PFPT in high tone pelvic floor disorders, aka myogasial syndrome - this is where PT is the most applicable with regard to this surgery

Response: *This was our original thought " they need to learn how to relax for dilation. But what we learned is that there is also a surprisingly high rate of pre-existing Pelvic floor muscle dysfunction of urinary incontinence and fecal incontinence and constipation. Correcting those before surgery potentially reduces infection, straining, and pain. Yet there are other important factors to healing such as the presence of low tone pelvic conditions, particularly fecal incontinence, which could contribute to infection risk in the post-op period.*

2- The authors do not state true objectives of this paper/study - they should add this at the end of their introduction

Response: *The goal of our study is to describe baseline pelvic floor characteristics of transgender women undergoing gender affirming vaginoplasty as well as preliminary results of pelvic floor physical therapy program. This has been added to the end of the introduction. Thank you. (lines 113-116)*

3- In the methods, the authors should be very clear about their design - based on how they describe their

methods, we can figure it out. But, is this a case series of 77 women who underwent vaginoplasty or is this a designed retrospective cohort study with primary and secondary outcomes studied - the way that the methods and results are presented, this is not clear

Response: Agree, we have added the first line in the methods section to make sure that readers are clear that this is a case series. (line 119)

4- The authors lack strict definitions of their outcomes for this study; these should be described in the methods; how did the PTs diagnose pelvic floor dysfunction, etc - "yes" "no" answers to certain questions?

Response: Pelvic floor dysfunction was diagnosed based on patient complaint of urinary incontinence and fecal incontinence, straining to stool as an activity limitation. If the patient consented to an internal pelvic floor muscle exam via the rectum, the diagnosis was further confirmed with the presence of, 1. localized muscle weakness of pelvic floor muscles (messink scale nil, weak, normal, strong) single repetition, 2. muscular incoordination, inability to do an isolated contraction of the pelvic floor muscles without breath holding or co-contraction of the gluteal muscles, or difficulty relaxing after contraction 3. Levator myalgia Pain with internal exam or difficulty relaxing after contraction. Lines 155-170 has been added to further clarify.

5- In their description of vaginal dilation and dilator size the authors make it sound as though data were collected prospectively. How were these data captured in the medical record if this was a retrospective study?

Response: We apologize for the confusion, we have added "retrospectively collected" on line 194.

6- In the last sentence of the first paragraph of the results - line 166 - the authors say "other affirming" surgeries - how many patients had previous vaginoplasty surgery? Or were all patients primary surgeries? This should be described in the inclusion criteria in the methods.

Response: These patients have often previously had other non-genital gender affirming surgeries. We have added the word non-genital gender-affirming surgery at the end of the first paragraph in the results (line 216)

7- In the second paragraph of the results - the authors should present the data as % n/N - so that it is clear which subset of the patients the authors are referring to

Response: We have updated this. Thank you.

8- Again - how were pelvic floor symptoms defined a priori to conducting the study? This is vague.

Response: We added an additional section in the methods section to clarify this. Lines 155-170.

9- The authors determine why only 65% of patients went to PT postoperatively? No Did they not like the preoperative PT? possibly but not asked. Was preoperative PT enough? I think sometimes the pre-op PT and the affirming surgery were enough

Response: As it is common for transgender people to be averse to receiving health care due to previous poor experiences in the health care setting, it was important in our program that the patient was educated in the rationale for involving PFPT, by the surgical team and by the physical therapist. It was equally important to us that the patient was empowered to choose whether to pursue additional pre-operative PT or post-operative PT. As transgender people seeking medical and surgical transition intervention already have multiple requirements of genital hair removal and mental health visits and letters, we did not want this PT examination and treatment to seem like a barrier or obstacle to them receiving their gender-affirming care. (lines 130-138)

10- When did patients do preop PT in relation to their surgery date? Please specify in the Methods section.

Response: The timing of the pre-operative consultation can be variable: patients who live locally sometimes have a consultation well in advance of their surgery, especially if they are thought by the surgical team to have special need for PFPT. Patients coming from afar usually have their preoperative consultation in the week prior to surgery. Line 123-127 mention this.

11- Please also specify in the methods the PT protocol used for preop and postop patients.

Response: The methods have been reinforced significantly to clear up this question. Lines 155-193 were added.

12- The authors should comment further on the patients who improved postop - is it possible that there is a regression to the mean situation? Also - most of these patients only had 1 PT visit

Response: *Due to the small study size and retrospective nature of the study, we agree that we should exercise caution with over-interpretation of statistical results; however, due to the extensive nature of the PT visit, we do not think that patients would have been diagnosed with pelvic floor dysfunction by chance as suggested by the reviewer (regression to the mean). We acknowledge that there might be other factors unique to transwomen that may contribute to pelvic floor dysfunction which may be resolved with simple pelvic floor PT interventions or with the surgery itself. We have added discussion lines 290-296.*

13- in the cisgender community, 1 PT session for PFD usually is not curative. How do the authors explain this?

16- The authors again report improvement in baseline PFD postoperatively - do they think this is from the surgery, from 1 session of PT?

Response to 13 and 16: *Lines 290-296 were added. The emphasis of the PT intervention was exercise and independent changes. Clear written instructions were given to support teaching at the visit. When the dysfunction with poor isolation of the pelvic floor muscle from the gluteal muscles or if the pelvic floor muscle contraction was timed with breath holding, frequently the patients were able to correct the coordination with simple cueing. It is possible the termination of the use of anti-androgen medication or no longer needing to "tuck", or pulling the penis and scrotum backwards between the legs to conceal them under clothing, contributed to the resolution of subjective complaints.*

14- Also the authors should be forthcoming in their discussion: PT did not statistically improve ease/success of dilation - this may be the main goal of therapy. May not mean PT doesn't help - they are simply not powered to determine this.

Response: *PT may have a significant role with dilation but we agree that we were not powered to determine this and we have added lines 324-328 to emphasize this point.*

15- The authors should consider doing a post hoc power analysis to determine how many patients they needed in their cohort to show that PT is efficacious

Response: *This is an excellent point and we will look into this for our follow up study.*

17- I think that one of the main points of this paper is that the incidence of PFD in trans women seeking surgery is not negligible - do the authors know how this incidence compares in the cis gender world? Are PFD common amongst women?

Response: *We appreciate this helpful comment and we have made appropriate comparisons to the cis-gender population in the discussion. Lines 278-282*

18- The authors spend a lot of time discussing that PT helped patient's with baseline PFD but they do not really spend too much time discussing how it enhances the surgery and recovery process

Response: *We agree that PT helps with additional preparation of the surgery as well as the recovery process. We commented on lines 318-324.*

19- I urge the authors to retract their statement about it being unethical to perform a RCT to study this - this is simply not true. PFPT is not currently gold standard therapy for postop vaginoplasty patients - it is new and people are considering it. The authors have not shown a true improvement in patient outcomes using their methodology - so they can hardly say that it would be wrong to study this intervention with the most robust study design know to researchers. In fact, before we urge insurance companies to routinely cover this type of therapy, I would argue that we must study it this way to show that it truly is better than no therapy and that patients' outcomes are better with it.

Response: *We appreciate the feedback on this and we have retracted the strongly worded statement.*

STATISTICAL EDITOR'S COMMENTS:

1. lines 62-64: In Table 4, this appears to be incorrectly stated, the comparison was between post-op only and cohort with both pre and post op attendance, not simply pre vs only post

Response: *we have updated this in the abstract. Thank you.*

2. Table 1: Need units for BMI, age, distance to facility. If there are any missing data characteristics, then need to enumerate.

Response: *we have updated the units and the enumeration of each category. Thank you.*

3. Table 2: Need to include a flow diagram or Venn diagram, clearly showing 4 groups: attended no PFPT, Pre-op only, post-op only and cohort with both pre and post-op.

Response: *we made a flow diagram which is now called: Figure 1.*

4. Table 3: If any comparisons are inferred, then should include CIs. All comparisons are NS, mostly due to low stats power.

Response: *we are not comparing two groups, we are simply stating the rate of resolution for each issue at the first postop visit.*

5. Tables 4, 5, 6: Although most comparisons are NS, the counts are so few that there is little power to generalize the NS findings.

Response: *we have made caution statements in the manuscript (lines 326-328).*

6. Table 7: Should format as n(%) or show number used in denominator at top of column

Response: *we have made the aforementioned changes in table 7.*

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Daniel Dugi:III MD". The signature is written in a cursive, flowing style.

Daniel Dugi III, MD



Daniel Mosier

From: Dave Jiang [REDACTED]
Sent: Friday, February 8, 2019 12:10 PM
To: Daniel Mosier
Cc: Daniel Dugi
Subject: RE: Manuscript Revisions: ONG-18-2212R1
Attachments: Figure 1.docx

Dr. Mosier, we apologize for not uploading it. We did make the figure as requested. It is attached to this email.

Thank you.

-Dave Jiang & Daniel Dugi

From: Daniel Mosier [dmosier@greenjournal.org]
Sent: Friday, February 08, 2019 8:27 AM
To: Dave Jiang
Cc: Daniel Dugi
Subject: RE: Manuscript Revisions: ONG-18-2212R1

Drs. Jiang and Dugi,

Thank you very much for the timely turnaround. I've forwarded it to the editor on your manuscript, and I will send you any follow-up questions if he has any.

One quick question: In your revision letter, you responded to one of the Statistical Editor's questions by noting: "We made a flow diagram which is now called: Figure 1." This figure was not uploaded with your revision, although there was a citation to it in the original version of the revision. Could you send me a copy of this figure, or have you decided not to include it in your final paper?

Sincerely,
-Daniel Mosier

Daniel Mosier
Editorial Assistant
Obstetrics & Gynecology
Tel: 202-314-2342

From: Dave Jiang [REDACTED]
Sent: Thursday, February 7, 2019 8:02 PM
To: Daniel Mosier <dmosier@greenjournal.org>
Cc: Daniel Dugi [REDACTED]
Subject: Re: Manuscript Revisions: ONG-18-2212R1
Importance: High

Dr. Mosier,

We apologize for the error in accepting the changes with our return correspondence. Here are our responses to the edits.

1. We agree with all the changes.
2. I have attached a strobe checklist to this email
3. We approve the running title
4. Thank you for making the change, this is ok.
5. We changed it to "or" from "and/or" (there are no other places where and/or is used)
6. We have attached new versions of tables 4 and 5 (with track changes on)
7. We changed it to sacral *flexion*

With this email, I have attached the manuscript with all changes tracked (no change has been accepted on word). We have also attached the strobe list and a tables 4 and 5.

Thank you for your patience.

-Dave Jiang and Daniel Dugi

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 18: Please provide a completed STROBE checklist. The checklist is available at <http://ong.editorialmanager.com>.
3. LINE 30: Do you approve the running title?
4. LINE 66 (Deleted text): This sentence was deleted, since the editor prefers not to end the abstract with statements that suggest further research.
5. LINE 208: Please revise "and/or" to mean either "and" or "or." Be sure this is done throughout your paper.
6. LINE 221 (Deleted text): Please instead put footnote with Tables 4, 5 highlighting that Fisher's exact test was used.
7. LINE 278: Is there another, more familiar word to use here – not many will have see
- 1.
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From: Daniel Mosier [<mailto:dmosier@greenjournal.org>]

Sent: Thursday, February 07, 2019 8:43 AM

To: Daniel Dugi

Subject: RE: Manuscript Revisions: ONG-18-2212R1

Importance: High

Dr. Dugi,

Thank you for responding in a timely manner. However, it appears that in the manuscript file you "Accepted All Changes" and turned off the tracking changes before submitting to us. Do you have a version of the manuscript without the changes accepted? It's very important for us to be able to track every single edit that has been made to the paper. If you do not have another version of the paper, please send us a document listing every change that has been made to the paper, along your responses to the queries in my initial email.

Please let me know if you have any questions or concerns.

Sincerely,

-Daniel Mosier

Daniel Mosier
Editorial Assistant
Obstetrics & Gynecology
Tel: 202-314-2342

From: Daniel Dugi [REDACTED]
Sent: Tuesday, February 5, 2019 4:50 PM
To: Daniel Mosier <dmosier@greenjournal.org>
Subject: FW: Manuscript Revisions: ONG-18-2212R1

Hi,

Please see the attached documents. Let me know if there is anything missing.

daniel

From: Dave Jiang
Sent: Monday, February 04, 2019 9:07 PM
To: Daniel Dugi
Subject: Re: Manuscript Revisions: ONG-18-2212R1

Dr. Dugi, I have all the files for the edits that were discussed. The files are attached to this email. You can send it to Daniel Mosier or if you want, I can do it.

On Feb 4, 2019, at 12:47 PM, Daniel Dugi [REDACTED] wrote:

Thank you. I'm ok with the edits throughout and the running title, as well as the other suggested changes.

It seems like the STROBE checklist is more of a guide for how the manuscript is constructed than a simple checklist. Can you give more information on what we need to do with this now?

Should we make the requested changes (numbers 5, 6, 7) in the document and email that back or re-submit through the website?

Regarding #7, our physical therapist recommends we just remov

e "sacral nutation" as it is a somewhat arcane concept, difficult to explain, and not critical to understanding.

Thank you,

Daniel Dugi III, MD, FACS

Associate Professor, Department of Urology
Transgender Health Program
Oregon Health & Science University

[REDACTED]

Pronouns: he/his/him

From: Daniel Mosier [<mailto:dmosier@greenjournal.org>]
Sent: Monday, February 04, 2019 12:15 PM
To: Daniel Dugi
Subject: RE: Manuscript Revisions: ONG-18-2212R1

CORRECTION: The last line of my message should read: "....please respond no later than COB on **Wednesday, February 6th**".

Apologies,
-Daniel Mosier

Daniel Mosier
Editorial Assistant
Obstetrics & Gynecology
Tel: 202-314-2342

From: Daniel Mosier
Sent: Monday, February 4, 2019 3:13 PM
To: [REDACTED]
Subject: Manuscript Revisions: ONG-18-2212R1

Dear Dr. Dugi,

Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 18: Please provide a completed STROBE checklist. The checklist is available at <http://ong.editorialmanager.com>.
3. LINE 30: Do you approve the running title?
4. LINE 66 (Deleted text): This sentence was deleted, since the editor prefers not to end the abstract with statements that suggest further research.
5. LINE 208: Please revise "and/or" to mean either "and" or "or." Be sure this is done throughout your paper.
6. LINE 221 (Deleted text): Please instead put footnote with Tables 4, 5 highlighting that Fisher's exact test was used.
7. LINE 278: Is there another, more familiar word to use here – not many will have seen this

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on **Tuesday, February 5th**.

Sincerely,
-Daniel Mosier

Daniel Mosier
Editorial Assistant
Obstetrics & Gynecology

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Web: <http://www.greenjournal.org>

From: [REDACTED]
To: [Eileen Chang \(Temp\)](#)
Subject: RE: O&G Figure Revision: 18-2212
Date: Tuesday, February 19, 2019 11:14:13 AM

Hi Eileen,

Those are fine with me. I replied immediately previously, not sure why that didn't go through.

Daniel Dugi III, MD, FACS

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

From: Eileen Chang (Temp) [mailto:echang@greenjournal.org]
Sent: Tuesday, February 19, 2019 6:50 AM
To: Daniel Dugi
Subject: RE: O&G Figure Revision: 18-2212

Hello,

I am writing to follow up about your figure (18-2212). The figure and legend still needs to be reviewed promptly and I would appreciate it if you could back to me with any necessary edits. This is to ensure that there is no delay in the publication of your article.

Thank you!

Best,

Eileen

From: Eileen Chang (Temp)
Sent: Tuesday, February 12, 2019 9:55 AM
To: 'dugi@ohsu.edu' [REDACTED]
Subject: O&G Figure Revision: 18-2212

Good Morning,

Your figure (18-2212) has been edited, and a PDFs of the figure and legend are attached for your

review. Please review the figure and legend CAREFULLY for any mistakes.

PLEASE NOTE: Any changes to the figures must be made now. Changes made at later stages are expensive and time-consuming and may result in the delay of your article's publication.

To avoid a delay, I would be grateful to receive a reply no later than Friday, 2/15. Thank you for your help.

Best wishes,

Eileen