OBSTETRICS & GYNECOLOGY

NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

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

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

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

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

Date: Apr 23, 2020
To: "Erin A Brennand" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-709

RE: Manuscript Number ONG-20-709

Mid-Urethral Sling Tensioning (MUST): a randomized trial comparing two intraoperative techniques

Dear Dr. Brennand:

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

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

Due to the COVID-19 pandemic, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by May 23, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Review of Manuscript ONG-20-709 "Mid-Urethral sling Tensioning (MUST): a randomized trial comparing two intraoperative techniques"

Brennand and colleagues have submitted results from a RCT that evaluated two distinct ways that a mid-urethral sling could be "tightened" in order to determine if one was preferred based on a composite outcome. As described, the trial was multicenter, double-blind (masked) and utilized block randomization. I have the following questions and comments. In Line 37-8 it is noted that the remaining authors have no relevant disclosures but do they have disclosures?

Title - Perhaps note that the techniques being evaluated were tightening or tensionsing techniques.

Précis - Ok.

Abstract - Since the methods note the study was designed to demonstrate superiority for the Babcock approach especially in the objective.

Introduction - Fairly concise review of current issues related to performance of MUS. Line 105 - minor issue but by definition an RCT is prospective.

Methods -
Line 123 - for clarification had patients already decided to pursue TVT before learning of the study? Was the study discussion at the same visit as the decision for surgery, a different visit or did it vary from the different centers?

Line 132-3 - nice touch having someone other than the surgeon consent them.

Line 144-5 - For the Mayo scissor approach, can you provide more detail about this - like very snug but able to remove, tight enough to keep scissors in place without holding them, etc.?

Line 161 - When was cystoscopy performed? Prior to the sling, after the sling or possibly both?

Line 168-70 - Did you consider a phone call sooner than 6 weeks? I presume if there was documentation of an issue prior to 6 weeks that the patient did not discuss with their surgeon that it was still included?

Line 177 - For women that reported having " a comfortably full bladder" did you perform U/S assessment to make sure the

volume was at least similar to the 300 for those who had their bladder artificially filled?

Line 225 - I presume you mean a superiority design?

Line 226 - What did you utilize a 90% CI rather than the more common 95%?

Results -
Line 273-6 - Was this pre-specified in the protocol that it would occur?

Line 283 - there is a typo as the Babcock procedures did not take 5 minutes.

Line 294 - Since as designed the study wanted to demonstrate the superiority of the Babcock approach should you rephrase this sentence to make it a positive and supportive of the Babcock approach?

Discussion -
Line 322 - How about it being multicentered as well?

Line 326-7 - So this gets to a previous point about the standardization of the scissors approach. Is there not really a "standard" approach for the scissors as compared to the Babcock which as described appears to be standardized?

Line 333 - Did you consider secondary or exploratory analyses in individuals that were smokers, concomitant surgery, etc. that have higher risk for poor outcomes to see if that happened?

Line 419 - Do you want to confirm the study met its primary endpoint here?

Tables -
Table 1 seems a little long but ok otherwise. Table 2 - I believe that when a stats program gives a p value of 0.000 that it is acceptable and preferred to say that it is $p < 0.005$ (since it would not round up if this in fact was the case)?

Table 2-4 - has 95% CIs but in the methods, it was noted that 90% CI were being used.

Figures - Consort is fine as are the medical illustrations.

Reviewer #2: This manuscript describes an RCT comparing two tensioning techniques used during midurethral sling placement. I have a few comments / questions:

Congratulations on designing and completing a large surgical RCT. That's never an easy thing to accomplish!

ABSTRACT:
Well done. Very descriptive and inclusive

INTRODUCTION:
1) You should include (either here or in your DISCUSSION section) a description of the "cough test" technique and the published results from same

METHODS:
2) I assume you went to some lengths to take away the technique variability. Especially for the scissor technique, there would be a large amount of variability in the degree of tension that COULD be applied with the scissors in place. By the same token, the Babcock technique was a function of the length of the loop. What specific details of tensioning did you use but leave out of this manuscript? I think you should be as descriptive as possible.

RESULTS:
3) I appreciate your brevity, but perhaps you could include a little more of the data rather than force the reader to glean all from the tables. For example, stating the actual number of exposures per group would be nice.

CONCLUSIONS:
Appropriate - well written
4) Did any surgeon change his / her management because of these results?

Reviewer #3: This is a randomized, double-blind multi-center clinical trial comparing two tensioning methods for synthetic midurethral sling placement (which are commonly used). Their primary outcome is a composite outcome that include persistent stress urinary incontinence, bothersome overactive bladder and post-operative urinary retention. These are the

key outcomes after this type of surgery and is an appropriate primary outcome.

They found a difference in their primary outcome at 12 months. In the scissors group (ie tighter tightening) more interventions for obstruction and urgency were seen (and strangely more +cough stress test). In the babcock group (or looser option), fewer interventions were but there was a higher rate of mesh erosion.

This trial was reported a clinicaltrials.gov and followed the consort guidelines as reported on the consort checklist. They have good follow-up of 91.2% at 12 months (though not all components were completed by every subject).

Below is a point-by-point critique.

Abstract.
1. The conclusion does not report the primary outcome.

Introduction
1. Consider adding a sentence about why the two techniques were chosen (ie manufacturer recommended vs commonly used techniques).

Methods
2. Line 138. Be consistent when describing the questionnaires. For some of them a description is included in parentheses and is absent in others (ISI).

Results
3. The result that the scissor group had higher rates of positive cough stress test but more post-op retention and intervention is surprising (even after your sensitivity analysis). Are these the subjects that had repeat sling, bulking, other? See my comment #7 below as well.
4. The mesh exposure rate in the Babcock group is interesting, Can you provide any narrative description about where the erosions were located (incision site, laterally?) and what surgery they required?

Discussion
5. The discussion is wordy and could be shortened and more focused. The second and third paragraphs could be combined (ie the explanation of characteristics that impact the external validity and recruitment bias etc are an elaborated discussion of strengths and limitations and could be better organized into the above paragraph.
6. Line 372. I disagree with the mesh shrinkage sentence and suggest considering removing this sentence.
7. There is is no comment on the higher rate of a positive cough stress test in the scissor group. Please address.
8. Additionally I am unsatisfied with the discussion of mesh erosion. There is no possible explanation given for seeing higher rates in the Babcock group other than the mesh erosion rate in the scissor group may be underreported or delayed. But why? Does the babcock tensioning leave the mesh "closer" to the vaginal epithelium or incision?
9. Line 398. I recommend putting the caveats that you have lower in your paragraph in your sentence about advocating for the Babcock technique. Ie are there certain subjects that you would advocate this technique in, or are you really saying all subject?

Tables
10. The first two lines of Table 3 can be consolidated. Ie I don't think you need to state the number/percentage of subjects that had the primary outcome and then list the ones that didn't (we know it will add to 100%).

Figures
11. The figures both seem to show the Babcock technique and not the scissor technique.

STATISTICAL EDITOR COMMENTS:

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

General: Although the results show a significant difference in frequency of the primary outcome for the two cohorts, the Authors need to provide more material to answer whether the loss to follow-up at 12 months might have selectively biased the results. That is, were those that were lost to follow-up materially different from those who provided results at 12 months? In the worst case scenario (assuming all who did not follow-up had adverse outcomes), then the results would have been 71/159 (44.7%) vs 57/159 (35.8%), which is nominally different but has p = 0.11, ie, NS.

Abstract: Need to conform to our template for RCTs. Specifically, need to elaborate on the power/sample size calculation. The conclusion should re-iterate the main finding, ie, that the primary outcome (abnormal bladder function at 12 months) was 12.9% different. Since the hypothetical clinical difference of interest was 10% (lines 227-230), then why is not the

conclusion that the scissor tensioning is superior, both statistically and by pre-determined metric of meaningful clinical difference, rather than stating in Abstract conclusion and precis that "similar cure" was obtained by the two techniques? Also, if the goal was to establish that there was equivalence, then why was the study not designed as "non-inferiority" rather than as testing for superiority?

Table 1: Need units for age, BMI. Since these cohorts were randomized by block, any difference at baseline is thought to be due to random chance. No need to test for statistical differences. If enough variables were tested, then it would be expected that at least one would be statistically different at $p < .05$ threshold. Several characteristics are binary events, so no need to cite both (e.g., concomitant prolapse surgery yes or no, pre menopause or post menopause or constipation yes or no.

Table 2: The presence or absence of complications is a binary event, to report both is unnecessary and redundant.

Table 3: The presence or absence of "abnormal bladder function" is a binary event, to report both is unnecessary and redundant. Need to more clearly separate the primary from all of its components.

Table 4: For "Pad test (g)", the designation < 1 g and ≥ 1 g is a binary event, so to report both is unnecessary and redundant. Similarly for flow pattern unobstructed vs obstructed.

EDITOR'S COMMENTS:

Please take special care with addressing the Statistical Editor's comments, especially this comment :"the primary outcome (abnormal bladder function at 12 months) was 12.9% different. Since the hypothetical clinical difference of interest was 10% (lines 227-230), then why is not the conclusion that the scissor tensioning is superior, both statistically and by pre-determined metric of meaningful clinical difference, rather than stating in Abstract conclusion and precis that "similar cure" was obtained by the two techniques?"

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 relevant topics. Adherence to these requirements with your revision will avoid delays during the revision process by avoiding re-revisions on your part in order to comply with formatting. One area to address is the use of abbreviations that are non standard, such as MUS. We generally avoid these as they can be difficult for readers to keep track of.

Numbers below refer to line numbers.

Abstract-Results and Results sections:
PRESENTATION OF STATS INFORMATION (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, tables and figures.

Please provide absolute values for variables, in addition to assessment of statistical significance.

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

Please limit p values to 3 decimal places.

47. Thank you for the clear statement of funding source role

62. This is the sample abstract for RCT's which you should use as a template for yours.
Note that abstracts for RCTs should be structured similarly to the provided example (see http://edmgr.ovid.com /ong/accounts/sampleabstract_RCT.pdf).

85. The journal style does not support the use of the virgule (/) except in mathematical expressions. Please remove here and elsewhere.

105. For the non-urogynecologist, could you indicate whether these 2 techniques are commonly used in this procedure? Are they recommended by the company that manufactures the mesh?

115. Be careful of words spelled differently in British vs American English, such as “centre” vs “center” and adjust for American English use.

218.Should this be “estimated” rate?

283> Should this be “35.8” for the Babcock method?

376: “Stretchy forces” sounds colloquial. IS there are different term? Even “stretch force” sounds better.

404. Spell out MSK

412. I assume you mean you find the Babcock technique to be valuable, but the antecedent to “it” in this sentence is “both techniques”.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

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

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

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

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

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

(2) For publication purposes, the portions of particular importance to industry-sponsored research are below. In your cover letter, please indicate whether the following statements are true or false, and provide an explanation if necessary:
(2a) All authors had access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.
(2b) All authors take responsibility for the way in which research findings are presented and published, were fully involved at all stages of publication and presentation development and are willing to take public responsibility for all aspects of the work.
(2c) The author list accurately reflects all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors are disclosed in the acknowledgments.
(2d) The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research has been fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings has also been disclosed.
(2e) All authors have disclosed any relationships or potential competing interests relating to the research and its publication or presentation.

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

funder(s).

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

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

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

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

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

7. 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.

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. 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. 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.

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

12. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

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

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

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

14. 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.

15. Figures: Figures should be numbered in the order that they appear in the manuscript. Please update the text.

Figure 1: This file may be resubmitted as-is.

Figures 2-3: Please provide a letter of permission from the illustrator allowing us in print and electronic formats. Email is okay.

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

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

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

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

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

Again, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by May 23, 2020, 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

UNIVERSITY OF CALGARY
FACULTY OF MEDICINE

[redacted]

April 28, 2020

Dear Dr. Chescheir,

Please accept the revisions to our manuscript, submission ONG-20-709. As requested, this cover letter outlines review comments and our responses/edits.

Reviewer #1: Review of Manuscript ONG-20-709 "Mid-Urethral sling Tensioning (MUST): a randomized trial comparing two intraoperative techniques"

Brennand and colleagues have submitted results from a RCT that evaluated two distinct ways that a mid-urethral sling could be "tightened" in order to determine if one was preferred based on a composite outcome. As described, the trial was multicenter, double-blind (masked) and utilized block randomization. I have the following questions and comments. In Line 37-8 it is noted that the remaining authors have no relevant disclosures but do they have disclosures?

Response: Confirming that the other authors (Wu, Gagnon, Globerman, Robert, Al-Shankiti, Kim-Fine) do not have disclosures.

Title - Perhaps note that the techniques being evaluated were tightening or tensionsing techniques.

Response: have added “to “tighten” retropubic slings for stress incontinence” to the title (Line 2).

Précis - Ok.

Abstract - Since the methods note the study was designed to demonstrate superiority for the Babcock approach especially in the objective.

Response: We had added “planned to achieve power for a superiority trial” to line 69.

Introduction - Fairly concise review of current issues related to performance of MUS. Line 105 - minor issue but by definition an RCT is prospective.

Response: This word has been removed.

Methods -
Line 123 - for clarification had patients already decided to pursue TVT before learning of the study? Was the study discussion at the same visit as the decision for surgery, a different visit or did it vary from the different centers?

Response: Correct, women had already decided to undergo TVT before being informed of the study. Discussion occurred after the OR consent form had been completed. This may have occurred on the same day as the decision for surgery, or a different encounter, depending on availability of the team study to go through the study consent process on the same day as the surgical consult/decision making. This variability existed at all centres.

Line 132-3 - nice touch having someone other than the surgeon consent them.

Response: Thank you. Our team wanted to ensure the decision to participate was separate from the clinical encounter to minimize risk of patients feeling unable to decline.

Line 144-5 - For the Mayo scissor approach, can you provide more detail about this - like very snug but able to remove, tight enough to keep scissors in place without holding them, etc.?

Response: We have added the descriptor: “spacer with the midline of the sling pulled flush but without tension against the hub of the scissors” to line 147. Additionally we have put in a reference to our methodology paper which describes the technique in detail. We have not repeated those paragraphs in this paper for ensure brevity.

Line 161 - When was cystoscopy performed? Prior to the sling, after the sling or possibly both?

Response: Intra-operative cystoscopy was performed after passage of the retropubic MUS needles. Some of these patients may have undergone pre-operative cystoscopy as part of their work up for incontinence, but this was not a routine requirement.

Line 168-70 - Did you consider a phone call sooner than 6 weeks? I presume if there was documentation of an issue prior to 6 weeks that the patient did not discuss with their surgeon that it was still included?

Response: Yes, patients were free to call their surgeon at any time after surgery (routine post-operative care) and issues that occurred within that 6 week window were captured in the 6 week outcome.

Line 177 - For women that reported having " a comfortably full bladder" did you perform U/S assessment to make sure the volume was at least similar to the 300 for those who had their bladder artificially filled?

At the 12-month follow-up appointment, only 5 women attended their appointment with an empty bladder and required a retrofill. Mean instillation volume was 301 ml (95% CI 293 – 310 mls). The remaining women attended with a self-reported comfortably full bladder, which was measured by bladder scanner prior to cough stress testing. The mean volume in this group was 408 ml (95% CI 382 – 435 ml). Women in the scissor group had a lower volume in their bladder during cough stress test (Scissor: 375 ml; Babcock: 432 ml, p=0.0333). Despite this, proportions of positive cough stress test was actually higher in the Scissor group.

Line 225 - I presume you mean a superiority design?

Response: Typo has been corrected.

Line 226 - What did you utilize a 90% CI rather than the more common 95%?

Response: Apologies this is a typo, alpha=0.05 indicating a 95%CI. Has been corrected.

Results -
Line 273-6 - Was this pre-specified in the protocol that it would occur?

Response: Yes, as per line 243 this was a planned interim analysis. It was included in the open-access publication of the trial protocol.

Line 283 - there is a typo as the Babcock procedures did not take 5 minutes.

Response: “3” has been added back in and matches the table

Line 294 - Since as designed the study wanted to demonstrate the superiority of the Babcock approach should you rephrase this sentence to make it a positive and supportive of the Babcock approach?

Response: This sentence has been rephrased as suggested, and now reads: A statistically significant difference was found for the primary outcome, in favor of the Babcock technique given that a lower proportion of women in the “Babock” group experienced an “abnormal bladder outcome” at 12-month. (line 303)

Discussion -
Line 322 - How about it being multicentered as well?

Response: This has been added.

Line 326-7 - So this gets to a previous point about the standardization of the scissors approach. Is there not really

a "standard" approach for the scissors as compared to the Babcock which as described appears to be standardized?

Response: The authors agree with this reviewer. Perhaps the term “reproducible” best describes how the Babcock performs, and we have attempted to update our sentence to be more articulate: While the authors attempted to standardize the Scissor technique for all participating surgeons[9], we expect there was inherent variation both within an individual surgeon’s cases and between study surgeons given that subtle differences in the tension of the sling against the spacer scissor is could not be measured. As such, the authors experience is that the Scissor technique is less reproducible between cases. (starts on line 358)

Line 333 - Did you consider secondary or exploratory analyses in individuals that were smokers, concomitant surgery, etc. that have higher risk for poor outcomes to see if that happened?

Response: These secondary analysis were not part of the original study protocol. Since drafting the manuscript, we have developed a number of secondary and exploratory hypothesis that we plan to explore. This will require another Ethics application as per the requirements of our IRB.

Line 419 - Do you want to confirm the study met its primary endpoint here?

Response: We have updated to include this, and the paragraph now reads: The MUST trial met it’s primary endpoint of a superior rate of “abnormal bladder function” at 12-months post-operative. (Line 430).

Tables -
Table 1 seems a little long but ok otherwise. Table 2 - I believe that when a stats program gives a p value of 0.000 that it is acceptable and preferred to say that it is $p < 0.005$ (since it would not round up if this in fact was the case)?
Response: We have updated to read <0.001

Table 2-4 - has 95% CIs but in the methods, it was noted that 90% CI were being used.

Response: We have updated the typo as per the comment above. The PI attests that 95% CIs were used throughout.

Figures - Consort is fine as are the medical illustrations.

Reviewer #2: This manuscript describes an RCT comparing two tensioning techniques used during midurethral sling placement. I have a few comments / questions:

Congratulations on designing and completing a large surgical RCT. That's never an easy thing to accomplish!

Response: The authors are appreciative of the recognition regarding the magnitude or work that goes into an RCT of this size.

ABSTRACT:
Well done. Very descriptive and inclusive

INTRODUCTION:
1) You should include (either here or in your DISCUSSION section) a description of the "cough test" technique and the published results from same

Response: We have described this in detail and compared it to the International Continence Society’s recommendations on how a cought test should be performed. Line 187: Objective evidence of persistent SUI was obtained using a cough-stress test (CST) in supine position, being instructed to cough once forcefully. If no leakage was observed, they were instructed to cough three additional times. If leakage was not seen in supine

lithotomy position, women were re-examined standing. The paramters of this CST is in keeping with the uniform Cough Stress Test endorsed by the International Continence Society (new reference=Guralnick M, et al).

METHODS:
2) I assume you went to some lengths to take away the technique variability. Especially for the scissor technique, there would be a large amount of variability in the degree of tension that COULD be applied with the scissors in place. By the same token, the Babcock technique was a function of the length of the loop. What specific details of tensioning did you use but leave out of this manuscript? I think you should be as descriptive as possible.

Response: This reviewer's comments echo those of Reviewer #1 and should be addressed with the changes to line 147. We did not attempt to leave any details regarding tensioning out of the manuscript, but recognized early on in the development of the study that these should be published elsewhere or the final manuscript would become too long to keep a reader's attention. So these details were published in an Open Access journal so that any interested reader can read the technique details in full.

This reviewer's comment was also used to inform the edits to line 358 (listed under Reviewer #1 comment).

RESULTS:
3) I appreciate your brevity, but perhaps you could include a little more of the data rather than force the reader to glean all from the tables. For example, stating the actual number of exposures per group would be nice.

Response: The authors have attempted to reduce repetition to keep the paper a reasonable length. And have complied with the Instructions to Authors document which stated "take care to minimize duplication between the text and tables or figures" (page 231, http://edmgr.ovid.com/ong/accounts/authors.pdf). As a result of the edits above, the Results section now contains more written data than the original submission.

CONCLUSIONS:
Appropriate - well written
4) Did any surgeon change his / her management because of these results?

Response: At the time of study development, none of the surgeons who designed the trial used the Babcock technique in their practice. Since concluding the trial, how a sling is tensioned is now tailored with the recommendations beginning on line 440. For those surgeons in the trial who teach MUS to learners (residents, fellows, generalists) the Babcock technique is how these low volume learners are taught to tension their slings.

Reviewer #3: This is a randomized, double-blind multi-center clinical trial comparing two tensioning methods for synthetic midurethral sling placement (which are commonly used). Their primary outcome is a composite outcome that include persistent stress urinary incontinence, bothersome overactive bladder and post-operative urinary retention. These are the key outcomes after this type of surgery and is an appropriate primary outcome.

They found a difference in their primary outcome at 12 months. In the scissors group (ie tighter tightening) more interventions for obstruction and urgency were seen (and strangely more +cough stress test). In the babcock group (or looser option), fewer interventions were but there was a higher rate of mesh erosion.

This trial was reported a clinicaltrials.gov and followed the consort guidelines as reported on the consort checklist. They have good follow-up of 91.2% at 12 months (though not all components were completed by every subject).

Below is a point-by-point critique.

Abstract.
1. The conclusion does not report the primary outcome.

Response: Line 84 has been updated to include: "Abnormal bladder" outcomes were less frequent in MUS tensioned by Babcock.

Introduction

1. Consider adding a sentence about why the two techniques were chosen (ie manufacturer recommended vs commonly used techniques).

Response: This has been updated on line 110: These two techniques were selected as they represent the most commonly employed tensioning method (Scissor) and a highly reproducible technique (Babcock) that could be utilized for teaching and standardized between surgeons.[9]

Methods

2. Line 138. Be consistent when describing the questionnaires. For some of them a description is included in parentheses and is absent in others (ISI).

Response: On line 139, a description has been added for the ISI: [a two item tool to assess frequency and amount of leakage]

Results

3. The result that the scissor group had higher rates of positive cough stress test but more post-op retention and intervention is surprising (even after your sensitivity analysis). Are these the subjects that had repeat sling, bulking, other? See my comment #7 below as well.

Response: We have clarified that after the sensitivity analysis, the rates of positive cough test remained higher in the Scissor group. Line 304: When excluding cases that underwent sling lysis, rates of positive cough stress test remained statistically different between Scissor and Babcock groups (Scissor 14.7%; Babcock: 6.9%; p=0.0431). To better answer this reviewer's questions about the retreatment groups, another sensitivity analysis was performed excluding retreatment cases: Exclusion of both cases that underwent sling lysis and/or retreatment resulted in the difference in positive cough stress test to no longer be statistically significant (Scissor: 13.5%; Babcock: 6.9%, p=0.0856).

4. The mesh exposure rate in the Babcock group is interesting, Can you provide any narrative description about where the erosions were located (incision site, laterally?) and what surgery they required?

Response: This has been added to line 315: All mesh erosions occurred in the midline, in the region of the original vaginal incision. Removal of erosion in these cases occurred in the operating room to facilitate the retraction and visualization required to dissect off vaginal epithelium, trim exposed mesh and suture the defect for hemostasis.

Discussion

5. The discussion is wordy and could be shortened and more focused. The second and third paragraphs could be combined (ie the explanation of characteristics that impact the external validity and recruitment bias etc are an elaborated discussion of strengths and limitations and could be better organized into the above paragraph.

Response: The paragraphs have been edited down for length. They were not combined, as the concepts of strengths & limitations vs external validity and bias are subtly different. Additionally, having a paragraph of this length felt cumbersome to read when we attempted to combine it.

6. Line 372. I disagree with the mesh shrinkage sentence and suggest considering removing this sentence.

Response: The authors recognize that this is a contentious topic in the field of Urogynecology/Female Pelvic Reconstructive Surgery. As such as have updated line 372 to recognize this controversy. We gave strong consideration to removing the sentence as suggested, but we also recognize there will be readers in the field of FPMRS who strongly believe that mesh shrinkage does occur. This has been a topic of discussion and many talks at relevant national and international FPRMS meetings. Given there is some in vtiro data about shrinkage, the authors elected to leave this sentence in at present. We are open to further discussion as needed.

7. There is is no comment on the higher rate of a positive cough stress test in the scissor group. Please address.

Response: More exploration of the CST finding has done based on the comments above, and can be found on line 322.

We have also expanded our thoughts on this issue on line 412: It is difficult to explain how a technique that appeared to be more obstructive can also result in more objective failures by Cough Stress Test. It is possible that our result is a Type I statistical error. The p-value of the sensitivity analysis excluding sling lysis cases indicates the probability of the difference we observed in CST findings (or one more extreme) is 4.31% assuming that the null hypothesis of no difference is actually true. The additional sensitivity analysis excluding sling lysis and/or retreatment of SUI cases results in a non-statistically significant p-value of 0.0856. The authors have interpreted these values and secondary analyses to mean that clinically the Scissor and Babcock techniques provide similar rates of SUI cure.

This is congruent with line 425 where we clearly state that we think cures are similar, and not inferior with Scissor technique.

8. Additionally I am unsatisfied with the discussion of mesh erosion. There is no possible explanation given for seeing higher rates in the Babcock group other than the mesh erosion rate in the scissor group may be underreported or delayed. But why? Does the babcock tensioning leave the mesh "closer" to the vaginal epithelium or incision?

Response: Line 447 has now been updated to address this: While the reason for this is not clear, the thought is that the volume of mesh present in the suburethral space is larger with the Babcock technique resulting in the mesh being closer to the original vaginal incision during healing

9. Line 398. I recommend putting the caveats that you have lower in your paragraph in your sentence about advocating for the Babcock technique. Ie are there certain subjects that you would advocate this technique in, or are you really saying all subject?

Response: Our paragraphs (lines 464-486) discuss the options of using the Babcock technique as a universal practice or tailored approach. None of our data suggest the Babcock technique provides inferior SUI cure, and so we do think a universal approach of Babcock in a patient who has no other special considerations (such as prior surgery) would be reasonable – particularly for low volume surgeons who are known to need higher rates of mesh revision (Brennand EA, Quan H).

Tables

10. The first two lines of Table 3 can be consolidated. Ie I don't think you need to state the number/percentage of subjects that had the primary outcome and then list the ones that didn't (we know it will add to 100%).

Response: The authors looked at a number of surgical RCTs recently published, to see how others have presented binary (yes/no). We have seen it done both ways. Our group would prefer to leave this table as it is. Our work in other research domains (sociologic work on medical decision making) has helped us understand that there are large differences in how individuals read and process numerical information, in terms of positive and negative findings, even among highly educated individuals such as health care professionals. We believe that by presenting the positive and negative proportions, we improve the inherent understandability of our data.

Figures

11. The figures both seem to show the Babcock technique and not the scissor technique.

Response: This is correct. Our experience is that Scissor technique is well known among those who do MUS, where as Babcock is not well known. Therefore we have only provided medical illustration of this technique. When we have presented this data, all questions have been about how to do Babcock tensioning, no one has ever asked how to do Scissor technique**. If the Editor feels strongly that a illustration of the Scissor technique is required to accompany this manuscript, please let the Corresponding Author know. We will pay for additional medical illustration, and expect this could require an addition 4 weeks of time to complete.**

STATISTICAL EDITOR COMMENTS:

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

General: Although the results show a significant difference in frequency of the primary outcome for the two cohorts, the Authors need to provide more material to answer whether the loss to follow-up at 12 months might have selectively biased the results. That is, were those that were lost to follow-up materially different from those who provided results at 12 months? In the worst case scenario (assuming all who did not follow-up had adverse outcomes), then the results would have been 71/159 (44.7%) vs 57/159 (35.8%), which is nominally different but has p = 0.11, ie, NS.

Response: We have analyzed for baseline differences, and updated the paper with this information. It is found on Line 300 of Results.

Abstract: Need to conform to our template for RCTs. Specifically, need to elaborate on the power/sample size calculation. The conclusion should re-iterate the main finding, ie, that the primary outcome (abnormal bladder function at 12 months) was 12.9% different. Since the hypothetical clinical difference of interest was 10% (lines 227-230), then why is not the conclusion that the scissor tensioning is superior, both statistically and by pre-determined metric of meaningful clinical difference, rather than stating in Abstract conclusion and precis that "similar cure" was obtained by the two techniques? Also, if the goal was to establish that there was equivalence, then why was the study not designed as "non-inferiority" rather than as testing for superiority?

Response: The sample size information is now updated further in the Abstract.

We have repeated the relative difference again from line 78 (results section of the abstract) to line 85 (conclusions of the abstract) as requested.

The 10% difference that was used to determine sample size was for superiority in the domain of “abnormal bladder” outcomes (aka complications). This was the primary outcome of the trial.
“Cure” is a secondary outcome of this trial, and we have intentionally described the cure rates as similar because while the positive CST rates may have differed between the two groups, the patient reported outcomes did not. As such the question is whether the CST findings are Type 1 error. Even if they are not, CST is not the only outcome to define cure. Equal if not more weighting should be given to patient reported outcomes.

Table 1: Need units for age, BMI. Since these cohorts were randomized by block, any difference at baseline is thought to be due to random chance. No need to test for statistical differences. If enough variables were tested, then it would be expected that at least one would be statistically different at p < .05 threshold. Several characteristics are binary events, so no need to cite both (e.g., concomitant prolapse surgery yes or no, pre menopause or post menopause or constipation yes or no.

Response: We have added years and kg/m^2 units to the table. At present we have left the tests of significance in the table, as we wanted to show that none of the differences in baseline characteristics that occurred by chance were large enough that we should change our statistical plan (such as stratification of results by menopausal status, or modelling for age or BMI). **If the Statistical Editor and Editor genuinely prefer to have the tests of significance removed after the explanation we can either remove the most righthand column or the copy editing team can do this at their direction.**

Table 2: The presence or absence of complications is a binary event, to report both is unnecessary and redundant.

Response: Have removed the complications “no” line from Table 2.

Table 3: The presence or absence of "abnormal bladder function" is a binary event, to report both is unnecessary and redundant. Need to more clearly separate the primary from all of its components.

Response: We understand the Statistical Editor and Reviewer #3’s comment on this. However, this is our primary outcome table and we feel strongly that we want to make sure the information is easily interpretable to everyone.

Please see the above comment in response to Reviewer #3. We hope the Editors will allow us this line in Table 3 to remain.

We have attempted to clearly separate the composite from its components through use of a subheading and dividing line in the table.

Table 4: For "Pad test (g)", the designation < 1 g and ≥ 1 g is a binary event, so to report both is unnecessary and redundant. Similarly for flow pattern unobstructed vs obstructed.

Response: We have updated the table as suggested.

EDITOR'S COMMENTS:

Please take special care with addressing the Statistical Editor's comments, especially this comment :"the primary outcome (abnormal bladder function at 12 months) was 12.9% different. Since the hypothetical clinical difference of interest was 10% (lines 227-230), then why is not the conclusion that the scissor tensioning is superior, both statistically and by pre-determined metric of meaningful clinical difference, rather than stating in Abstract conclusion and precis that "similar cure" was obtained by the two techniques?"

Response: We have addressed the fact that these numbers relate to different outcomes. The 12.9% is related to “abnormal bladder” (essentially a poor outcome after surgery). This infact is not related to cure of SUI (absence of incontinence on exam, patient report of SUI symptoms at 1 year). What our study has shown is that cure is relatively the same with the two approaches, but women have different types and proportions of abnormal events post-operatively. It is up to the individual surgeon to decide which complication “pattern” they are comfortable with.

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 relevant topics. Adherence to these requirements with your revision will avoid delays during the revision process by avoiding re-revisions on your part in order to comply with formatting. One area to address is the use of abbreviations that are non standard, such as MUS. We generally avoid these as they can be difficult for readers to keep track of.

Response: We have converted all use of the acronym MUS to the phrase “mid-urethral sling”. The only acronyms used are on the permitted list, and we have attempted to minimize how ofter the acronym is used in the text, favoring the full word.

Numbers below refer to line numbers.

Abstract-Results and Results sections:
PRESENTATION OF STATS INFORMATION (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, tables and figures.

Please provide absolute values for variables, in addition to assessment of statistical significance.

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

Please limit p values to 3 decimal places.

Response: We can confirm the relative difference and 95% CI are reported as our tests of statistical significance. ORs are not reported, as the primary audience of this manuscript are clinicians. To improve the readability of the findings, we have used probabilities rather than odds. P-values are limited to 3 decimals.

47. Thank you for the clear statement of funding source role

62. This is the sample abstract for RCT's which you should use as a template for yours.
Note that abstracts for RCTs should be structured similarly to the provided example
(see http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf).

Response: We have updated our abstract, and edited some of the information presented in results to control word count.

85. The journal style does not support the use of the virgule (/) except in mathematical expressions. Please remove here and elsewhere.

Response: Removed.

105. For the non-urogynecologist, could you indicate whether these 2 techniques are commonly used in this procedure? Are they recommended by the company that manufactures the mesh?

Response: We have updated the introduction section to indicate the Scissor technique is commonly used, and the Babcock is not. Line 125: These two techniques were selected as they represent the most commonly employed tensioning method (Scissor) and a less commonly known but highly reproducible technique (Babcock) that could be utilized for teaching and standardized between surgeons.[9]

115. Be careful of words spelled differently in British vs American English, such as "centre" vs "center" and adjust for American English use.

Response: We have adjusted to American English.

218.Should this be "estimated" rate?

Response: Updated. Now line 255.

283> Should this be "35.8" for the Babcock method?

Response: Updated

376: "Stretchy forces" sounds colloquial. IS there are different term? Even "stretch force" sounds better.

Response: Updated.

404. Spell out MSK

Response: Completed.

412. I assume you mean you find the Babcock technique to be valuable, but the antecedent to "it" in this sentence is "both techniques".

Response: This has been updated for clarification

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process,

in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

Response: OPT-IN to publish the point by point letter.

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

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

Response: This confirms our adherence to the Good Publication Practice (GPP3) guideline.

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

(3) The abstract should contain an additional heading, "Funding Source," and should provide an abbreviated listing of the funder(s).
Response: This is included at time of submission under the Clinical Trial Registration

(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).

Response: This was included above the abstract and has now been moved into the position requested.

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

Response: We are using the terminology developed through revitalize (stress incontinence).

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

Response: We adhere to word and page counts.

7. 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.

Response: In order to respond to one of the reviewers we added “to “tighten” retropubic slings for stress incontinence” on line 2. This took our character count from 86 to 133. If the Editors prefer the original title please delete the addition.

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.

Response: Word count added, 300.

10. 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.

Response: Editted as per the sample.

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

Response: We have removed the MUS acronym and replaced it each time with the phrase “mid urethral sling”. The OAB acronym is on the allowed list, but have removed it from the text of the manuscript and left it only in tables (where it is explained directly underneath). SUI is on the allowed list and has been left in the manscript and tables, although we ensure to define the acryonym repeatedly through the body of the text.

12. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid

using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

Response: Removed

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

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

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

Response: Differences, 95% CI and 3 decimal places are used. NNTb, NNTh, OR, RR are not applicable.

14. 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.

15. Figures: Figures should be numbered in the order that they appear in the manuscript. Please update the text.

Response: Updated.

Figure 1: This file may be resubmitted as-is.

Figures 2-3: Please provide a letter of permission from the illustrator allowing us in print and electronic formats. Email is okay.

Response: This will be uploaded as a supplement.

Thank you for giving us the opportunity to revise our manuscript for further consideration by Obstetrics & Gynecology. We look forward to hearing your decision regarding our work.

Sincerely,

Erin Brennand MD, FRCSC
Assistant Professor & Program Director
Section of Female Pelvic Medicine & Reconstructive Surgery (Urogynecology)
Department of Obstetrics & Gynecology
University of Calgary

Date: May 21, 2020
To: "Erin A Brennand" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-709R1

RE: Manuscript Number ONG-20-709R1

Mid-Urethral Sling Tensioning (MUST): a randomized trial comparing two intraoperative techniques

Dear Dr. Brennand:

Your revised manuscript has been reviewed by the handling Editor. Before a final decision can be made, we need you to address the following comments. Please make the requested changes to the latest version of your manuscript that is uploaded to your Author account in Editorial Manager (5-21-20v2). Please contact me by email if you cannot locate this file.

Please track your changes and leave the ones made by the Editorial Office. Your next version should be uploaded to Editorial Manager with a point-by-point reply letter to the comments below.

Your next version will be due by June 18.

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.

2. The title and running title were edited per journal style. The study name ("MUST") can be used in the abstract and body text.

3. Author Byline: Please list the authors' names in the byline in this way: First name, middle initial, last name, academic degrees (up to two).

4. Electronic Copyright Transfer Agreement Form: It appears not all of the authors in the author list in Editorial Manager were added to your manuscript record. The ones we received are:

- Erin A. Brennand
- Guosong Wu, MSc
- Sara Houlihan, MD
- Dobrochna Globerman, MD
- Louise Gagnon
- Colin Birch
- Hanan Al-Shankiti
- Magali Robert
- Darren Lazare
- Shunaha Kim-Fine

What are Drs. Hyakutake and Carlson's email addresses? We will add their names to the manuscript and send them the electronic Copyright Transfer Agreement by email.

5. Line 40: Please add Dr. Carlson's first name.

6. Line 90 and elsewhere: Note that the slings did not experience symptoms, patients did. Could you edit please?

7. Line 91 and elsewhere: We prefer you not describe patients or participants as "cases".

8. Line 97 (Body Text Length): Your paper is about 1200 words over the limit as described in the Instructions for authors. Your introduction length is fine, but the Methods and Discussion section need to be significantly shortened. If you wish, some could be moved to the Supplemental Digital content.

9. Line 104: Is the only reason there is interest in improving it that these bodies worldwide are issuing statements? It seems that you could delete this entire sentence as there must certainly be other reasons to want to improve our outcomes AND concerns about mesh are well known by our readers.

10. Line 107: For this non FPMRS specialist would you please define "to tension"? Tension is a noun so I don't understand its' use as a verb. You use it as a verb here and elsewhere, and also as an adjective.

11. Line 171: In your letter revision letter you indicated that you could provide an image of the scissor technique. I do think that would be useful. I understand that it will delay the return of your manuscript.

12. Line 177: By who?

13. Line 183: I'm going to highlight some "extra" words you could easily edit out to help shorten your paper without impairing meaning. Of course, please don't accept these if they do change your meaning or emphasis while realizing you need to cut about 1/6 of your length. For instance, the readers will understand that the patients' preference and surgical requirements are involved in deciding about type of anesthesia. Valuing patient choice is important but is not key to reporting your study.

14. Line 195: Please clarify if the surgeon's recorded these or did study personnel abstract from surgeon's notes?

15. Line 210: It looks like a reference number should be inserted here.

16. Line 223: I think we can assume that you scored the questionnaires

17. Line 319: For all data, in lieu of an isolated p value, we strongly prefer provision of a hazard ratio or effect size measures +/- 95% CI's. Please refrain from reporting p values alone; given your space limitations, you could exclude these altogether, as previously suggested, in your tables and the manuscript.

18. Line 321: You could shorten this to read: "Fewer women experienced an "abnormal bladder outcome" at 12 months who were allocated to the Scissors (31.3%) compared to the Babcock (18.4%) technique".

19. Line 326: Please be consistent with capitalization: sometimes you capitalize Scissor group and sometimes not.

20. Line 329: You could shorten this to read " As the positive cough-stress findings in the scissor group could be the result of higher proportions of women undergoing sling lysis for urinary retention, we performed a sensitivity analysis excluding individuals who underwent this procedure"

21. Line 349: What do you mean by less low grade of urinary retention? Less low grade may mean more high grade?

22. Line 353: Is this sentence necessary for your study?

23. Line 355 (Discussion): Your discussion should be about 750 words; it is currently 1719 words. Again, I'll highlight some possible editing.

24. Line 358: You've used the word "mid-urethral sling procedure" twice in the same sentence. Could you edit?

25. Line 362: Do you need this sentence? That's what your questionnaires, cough test and pad tests showed, isn't it? You could shorten this by saying: "Women in both groups experienced high rates of objective and subjective cure, as shown by similar pad testing and standardized questionnaire scores".

26. Line 399: This paragraph needs to be and can be significantly shortened. What is the key message or 2 key messages you are trying to say in this paragraph? Distill it down to these 2 key messages.

27. Line 402: Arm of what?

28. Line 405: As most readers won't know the difference between a UDI6 and an ISI you could just say "The difference could be explained by use of different questionnaires for patient-reported outcomes"

29. Line 424: As this paragraph has a lot of speculation in it, it should be significantly edited.

30. Line 442: Similarly, in this paragraph, you are speculating about rates of mesh erosion after 12 months. Please eliminate much of this and focus on the results you have of your study.

31. Line 461: What is the MUST Study? Why are you bringing it up here?

32. Line 474: ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

33. Line 569: Please incorporate this reference into your references list and fix the numbering in the text.

Best,
Randi Zung for Dr. Chescheir

[redacted]

UNIVERSITY OF CALGARY
FACULTY OF MEDICINE

CUMMING SCHOOL OF MEDICINE
Dr. Erin Brennand MD, FRCPC
Department of Obstetrics and Gynaecology
[redacted]

May 26, 2020

Dear Dr. Chescheir,

Please accept the revisions to our manuscript, submission ONG-20-709R1. As requested, this cover letter outlines review comments and our responses/edits.

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1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.
Response: I have edited the title and short title further. Word count complies with the instructions for authors, and it fits the formatting with the Randomized Controlled Trial listed last. We hope this title is acceptable.

Line 80 – the word "add" has been removed. In this context is not added to the sling, but rather the amount of tensioning in determined. I have tried to reword, and stay within the 25 word count.

2. The title and running title were edited per journal style. The study name ("MUST") can be used in the abstract and body text.
Response: This has been updated.

3. Author Byline: Please list the authors' names in the byline in this way: First name, middle initial, last name, academic degrees (up to two).
Response: This has been updated.

4. Electronic Copyright Transfer Agreement Form: It appears not all of the authors in the author list in Editorial Manager were added to your manuscript record. The ones we received are:
- Erin A. Brennand
- Guosong Wu, MSc
- Sara Houlihan, MD
- Dobrochna Globerman, MD
- Louise Gagnon
- Colin Birch
- Hanan Al-Shankiti
- Magali Robert
- Darren Lazare
- Shunaha Kim-Fine

What are Drs. Hyakutake and Carlson's email addresses? We will add their names to the manuscript and send them the electronic Copyright Transfer Agreement by email.
Response: Dr. Momoe Hyakutake can be reached at: [redacted] and/or [redacted] Dr. Kevin Carlson can be reached at: [redacted]

5. Line 40: Please add Dr. Carlson's first name.

Response: This has been added

6. Line 90 and elsewhere: Note that the slings did not experience symptoms, patients did. Could you edit please?
Response: Edited.

7. Line 91 and elsewhere: We prefer you not describe patients or participants as “cases”.
Response: Edited.

8. Line 97 (Body Text Length): Your paper is about 1200 words over the limit as described in the Instructions for authors. Your introduction length is fine, but the Methods and Discussion section need to be significantly shortened. If you wish, some could be moved to the Supplemental Digital content.
Response: We have cut the length down by over 1200 words.

9. Line 104: Is the only reason there is interest in improving it that these bodies worldwide are issuing statements? It seems that you could delete this entire sentence as there must certainly be other reasons to want to improve our outcomes AND concerns about mesh are well known by our readers.
Response: Sentence removed as per these recommendations.

10. Line 107: For this non FPMRS specialist would you please define “to tension”? Tension is a noun so I don’t understand its’ use as a verb. You use it as a verb here and elsewhere, and also as an adjective.
Response: It is generally used as a verb in FPMRS. I have tried to clarify language and added a reference to how this word is used in our specialty.

11. Line 171: In your letter revision letter you indicated that you could provide an image of the scissor technique. I do think that would be useful. I understand that it will delay the return of your manuscript.
Response: This has been added as an additional figure.

12. Line 177: By who?
Response: This has been updated to reflect it was the study coordinator (JV)

13. Line 183: I’m going to highlight some “extra” words you could easily edit out to help shorten your paper without impairing meaning. Of course, please don’t accept these if they do change your meaning or emphasis while realizing you need to cut about 1/6 of your length. For instance, the readers will understand that the patients’ preference and surgical requirements are involved in deciding about type of anesthesia. Valuing patient choice is important but is not key to reporting your study.
Response: I have made the changes suggested.

14. Line 195: Please clarify if the surgeon’s recorded these or did study personnel abstract from surgeon’s notes?
Response: Clarified. Line 286.

15. Line 210: It looks like a reference number should be inserted here.
Response: Added

16. Line 223: I think we can assume that you scored the questionnaires
Response: Deleted

17. Line 319: For all data, in lieu of an isolated p value, we strongly prefer provision of a hazard ratio or effect size measures +/- 95% CI's. Please refrain from reporting p values alone; given your space limitations, you could exclude these altogether, as previously suggested, in your tables and the manuscript.
Response: I have changed this to the effect size.

18. Line 321: You could shorten this to read: "Fewer women experienced an "abnormal bladder outcome" at 12 months who were allocated to the Scissors (31.3%) compared to the Babcock (18.4%) technique".
Response: I have shortened this further and refer to the tables for absolute numbers and effect size.

19. Line 326: Please be consistent with capitalization: sometimes you capitalize Scissor group and sometimes not.
Response: Edited to be consistently capitalized.

20. Line 329: You could shorten this to read " As the positive cough-stress findings in the scissor group could be the result of higher proportions of women undergoing sling lysis for urinary retention, we performed a sensitivity analysis excluding individuals who underwent this procedure"
Response: Change has been made.

21. Line 349: What do you mean by less low grade of urinary retention? Less low grade may mean more high grade?
Response: I have clarified further by listing the parameters a clinician would use to assess for urinary retention. Line 493. This loops into the edits on line 503.

22. Line 353: Is this sentence necessary for your study?
Response: No, it is not. It was not in the original manuscript but was the request of one of the original reviewers. I prefer the manuscript without it and have removed it as per your suggestions.

23. Line 355 (Discussion): Your discussion should be about 750 words; it is currently 1719 words. Again, I'll highlight some possible editing.
Response: Edited as per suggestions.

24. Line 358: You've used the word "mid-urethral sling procedure" twice in the same sentence. Could you edit?
Response: Edited. Lines 497-499.

25. Line 362: Do you need this sentence? That's what your questionnaires, cough test and pad tests showed, isn't it? You could shorten this by saying: "Women in both groups experienced high rates of objective and subjective cure, as shown by similar pad testing and standardized questionnaire scores".
Response: Edited, Lines 500-502.

26. Line 399: This paragraph needs to be and can be significantly shortened. What is the key message or 2 key messages you are trying to say in this paragraph? Distill it down to these 2 key messages.
Response: The most important messages are an exploration of what is happening with the primary outcome, and comparing our results to clinical trials related to mid-urethral slings that are considered high quality evidence of the cure rate of these procedures. Therefore sentences at the start of the

paragraph were removed.

27. Line 402: Arm of what?
Response: As a result of editing the paragraph, this sentence was entirely removed.

28. Line 405: As most readers won't know the difference between a UDI6 and an ISI you could just say "The difference could be explained by use of different questionnaires for patient-reported outcomes"
Response: As a result of editing the paragraph, this sentence was entirely removed.

29. Line 424: As this paragraph has a lot of speculation in it, it should be significantly edited.
Response: This paragraph has been edited out, for clarity and word count.

30. Line 442: Similarly, in this paragraph, you are speculating about rates of mesh erosion after 12 months. Please eliminate much of this and focus on the results you have of your study.
Response: This paragraph has been edited out, for clarity and word count.

31. Line 461: What is the MUST Study? Why are you bringing it up here?
Response: This is the name of the study, the title with which the study protocol has already been published. It was edited out of the manuscript as part of the review process. We would like to keep the use of the study name and acronym visible in the paper.

32. Line 474: ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.
Response: This has been replaced with "surgeons". I searched within the document and could not find another use of this term to replace.

33. Line 569: Please incorporate this reference into your references list and fix the numbering in the text.
Response: New references incorporated, numbering in text updated and reference list renumbered.

Thank you for giving us the opportunity to revise our manuscript further. We appreciate the time and consideration Obstetrics & Gynecology has shown our work, and hope that it is deemed acceptable for publication in the Green Journal.

Sincerely,

Erin Brennand MD, FRCSC
Assistant Professor & Program Director
Section of Female Pelvic Medicine & Reconstructive Surgery (Urogynecology)
Department of Obstetrics & Gynecology
University of Calgary