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.
RE: Manuscript Number ONG-19-601

A Randomized Trial of Closed Incision Negative Pressure Therapy in Morbidly Obese Women Undergoing Cesarean Delivery

Dear Dr. Roberts:

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 May 27, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Hussamy and colleagues present the results of a randomized controlled trial of closed incision negative pressure wound therapy in obese women undergoing cesarean delivery. The topic should be of significant interest to readers of the journal. I have the following comments/questions for the authors:

1. Remove the acronym in the Short Title.
2. The Abstract could be reworked to improve clarity—were all women or only some women in labor (line 74)? The term "sensitive skin disorders" (lines 76-7) is vague. What is the definition of "prolonged postoperative hospitalization for wound concerns" (lines 80-1)? Do you mean all hospital readmissions (line 81), and if so, why so specific on the prior variable and not on this one?
3. The first sentence in the Introduction needs a reference.
4. Let the reader decide how "dramatically increased" (line 119) by providing data in the second sentence of the Introduction.
5. Replace "shows" with "show" in line 121—the word "data" is plural.
6. The Introduction, particularly the third paragraph, should be reworked to improve clarity. Is the focus on wound complications overall or just wound infections?
7. The fact that negative pressure wound therapy has been effective in some types of operations should be acknowledged and cited in the last paragraph of the Introduction.
8. Consider inserting the word "label" after the word "open" in line 164.
9. The term "sensitive skin disorders" again is used in line 174. Like in the Abstract, it is vague and not defined. At least give a few examples.
10. The word gentamicin is misspelled in line 182.
11. Were women randomized before or after the completion of the cesarean delivery?
12. What is the definition of "prolonged postoperative hospitalization for wound concerns" (line 215)?
13. Data about the secondary outcomes described in the paragraph starting on line 276 should be included.

14. Was there any crossover, or was the adherence to randomized treatment 100%?

15. In line 296, change Table 5 to Table 4.

16. This reader would like to see data from the patient satisfaction survey rather than summary reports.

17. Please attend to consistent formatting—some references listed have all authors, while others have three then et al.

18. Table 2: What proportion of the skin incisions of Pfannenstiel abdominal incisions were made in the subpannicular fold as opposed to suprapannicular?

19. Table 2: The variables "labor" and "induction" are confusing and seem to imply that less than half of the patients had spontaneous or induced labor, though only about a third had a scheduled cesarean.

Reviewer #2: This is a well designed RCT investigating the possibility of wound complication reduction with closed incision negative pressure therapy (ciNPT) as compared to standard wound closure. The manuscript is well written and easy to follow, with most of the relevant information presented clearly. I would recommend consideration of the following:

ABSTRACT: Please add a comment about the effect of ciNPT on wound complications in other surgical populations; is the 50% reduction for which this study was powered consistent with what has been seen with other applications?

METHODS:
Did the study protocol guide the following, or were these decisions left to the managing physician: the decision to proceed to cesarean; subcutaneous closure (in either group), technique for wound closure in the standard therapy group?

Was GBS colonization and prophylaxis considered at all in the study?

For the patient's 30 day telephone follow-up, was there any attempt to validate the presence or absence of wound complications with chart review or administrative data review?

RESULTS, DISCUSSION, REFERENCES, TABLES/FIGURES: Very well written, clear, and great as is.

Reviewer #3: This is a prospective randomized study assessing the use of a closed incision negative pressure therapy (ciNPT) to decrease postoperative wound morbidity in class III obese women undergoing cesarean delivery in a single institution.

Key findings of the study: Prophylactic ciNPT use did not reduce postoperative wound morbidity compared to a standard surgical dressing in women with class III obesity.

1. Novelty: not new. The literature on this topic is heterogenous with some studies showing no effect (2015 B. Anglim et al, Ruhstaller et al 2017), one study showing increased infection with NPT (Gibbs et al 2014) and one showing decreased infection (2015 Mark et al.) Similar to another RCT( Ruhstaller et al 2017), this study demonstrates no effect. This study would be the largest PROSPECTIVE, RANDOMIZED trial of this intervention and warrants consideration on this basis, with 3X higher numbers than Ruhstaller et al.

2. Methodology: line 164 “a pragmatic” RCT, recommend moving explanation of this term to methods section. Of 850 eligible patients identified, 409 were excluded. Seems high, consider addressing. Primary outcomes well delineated. External validity: results likely applicable to general population as obesity and cesarean rates continue to increase across the board.

3. Significance: given the increasing obesity rates nationally, the increasing cesarean rates and associated maternal morbidity rates for these patients, this is clinically relevant

4. Presentation: overall clear and concise

5. Length: appropriate
Abstract: purpose is clearly stated, methods outlined, conclusions supported by data

Intro: well written, appropriate references, objectives and outcomes clearly stated

Materials and Methods: clearly outlined methods, statistical analyses and primary outcomes reasonable.

Results: No difference in intervention group (line 293) compared to standard therapy. Post hoc analysis (line 290) was unable to delineate differences explaining lack of effect. Unclear meaning of "No heterogeneity in the treatment effect" (line 293). Consider rewording to clarify.

Consider re-wording of the post hoc analysis rationale: "As no benefit was seen (lines 296-299) the entire study cohort was evaluated to identify what, if any, risk factors were likely to lead to postoperative wound morbidity in this patient population" to make more clear.

Skin reactions and patient satisfaction included: first study I have seen to include these variables.

Discussion: points well made, counter arguments considered

Tables and figures: Figures and tables are clear and informative (with the exception of reference to table 5 that does not exist, suspect mean table 4 (line 296)

References: reasonable, appropriate and inclusive

Reviewer #4:
Overall: This is an original research report that compares wound morbidity among obese women undergoing cesarean delivery. The intervention is negative pressure wound therapy. The paper is succinct and well written and follows the CONSORT guidelines. There are some places where the manuscript could be stronger. The major flaw is the use of the term "composite outcome" yet not really defining how what that was - a combination of the listed outcomes or at least one of the listed a-priori outcomes?

The abstract provides good overview of the study and includes important information. The conclusion of the abstract matches the manuscript.

There are other papers on this topic in the literature including one, stated below, with the exact same title. The authors should emphasize the value their paper brings to the literature and in particular will this paper ANSWER this clinical question especially given the current epublication of a very similar study.

There is another paper that is epub ahead of print - Hyldig et al conclusions are different from the authors here. Hyldig N, Vinter CA, Kruse M, et al.

Prophylactic incisional negative pressure wound therapy reduces the risk of surgical site infection after caesarean section in obese women: a pragmatic randomised clinical trial [epub ahead of print] BJOG (England), Aug 01 2018, p

The authors report no conflicts, funding sources are stated.

IRB/Ethics approval was stated and was obtained.

This trial was registered on Clinical Trials NCT02289157.

First posted Nov 13, 2014. Last update July 2 2018. The primary outcome stated on the NCT site is not a composite outcome. The anticipated sample size is the same on the NCT site as in the manuscript.

The title is appropriate

PRECIS: The precis is fine

INTRODUCTION:
1. The introduction would be stronger if the authors described the controversy in this particular topic. This is thoroughly discussed in the discussion, but it would help set the stage of the potential importance of this submitted manuscript.

2. Please be clear what the outcome was. At least one of the morbidities? If it’s a composite outcome why?
MATERIALS AND METHODS:
3. The primary outcome should be more clearly stated. Any or at least one morbidity? Line 213

4. The blistering as a side effect or potential adverse event should be more clearly described and talked about. Any other adverse events? Were they recorded?

DISCUSSION:
5. Lines 340-341. This is an important concept - please expand about the fulltility stated here and why the authors still went ahead with their own RCT.

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

Table 2: Estimated blood loss often has a skewed distribution. If not normally distributed, should cite as median(IQR) and test non-parametrically.

Table 3: The components of the primary outcome were under powered and the NS results for the components cannot be generalized due to low power.

Table 4: The counts of adverse events by treatment group were too few to allow for sufficient power to generalize the NS findings and too few to allow for enough stats power to adequately test for interaction terms.

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

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

- Note that abstracts for RCTs should be structured similarly to the provided example (see http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf ) and should include the primary outcome and sample size justification in the Methods. The Results should begin with the dates of enrollment to the study, a description of demographics and the primary outcome analysis.

- Please consult the Instructions for Authors regarding the use of abbreviations, and what constitutes an acceptable abbreviation. This is not an acceptable abbreviation. Please spell out all abbreviations on first use. It is reasonable to not use abbreviations for words that are seldom used in the paper. We try to limit “unique” abbreviations so that readers don’t have to frequently refer back to the first notation of the abbreviation to remember its meaning. We realize that this may affect word count but believe it makes it easier in most cases for the reader. clNPT would not be an acceptable abbreviation, for instance.

- Please state "This is a randomized, controlled trial....." to begin with in methods. Can drop "prospective" because an RCT has to be prospective.

- did this include only women admitted for delivery w/ plan for vaginal birth or were those admitted for scheduled cesarean also included?

- were the latter two only if the reasons for readmit or reop were wound issues?

- When you write that a study occurred between date 1 and date 2, it literally excludes those boundary dates. For instance, "This study was performed between Feb 2018 and Jan 2019" would mean it was performed from March 2018 to Dec 2018. Do you instead mean that the study was performed from date 1 to date 2? If so, please edit.

- In both the abstract and the paper, please provide absolute numbers as well as which ever effect size you are reporting (if appropriate) + Confidence intervals. P values may be omitted for space concerns. We strongly prefer CI’s as they give
more information about strength of association than do P values. By absolute values, I mean something like xx (outcome in exposed)/yy(outcome in unexposed) (zz%) (Effect size= ; 95% CI=. ) An example might be: Outcome 1 was more common in the exposed than the unexposed 60%/20% (Effect size=3;95% CI 2.6-3.4)

- As most of the readers will be aware of the rise in obesity rates in pregnancy, rise in CS rates, perhaps you could edit this portion of your introduction substantially down. Perhaps you could provide some information instead about the conflicts in literature about utility of using closed systems prophylactically for CS incisions? There is quite a bit of conflicted data about this, which is what is defining the knowledge gap that your study is seeking to fill.

- For all manuscripts with corporate funding, we require that the following information be included in the materials and methods of the manuscript: The role of the sponsor in the design, execution, analysis, reporting and funding (ie, what did the sponsor provide).

- We do not require that initial submissions adhere to the Green Journal publication requirements. Articles for which a revision is requested however, do require that the revised submission adhere to all Green Journal formatting requirements. We strongly recommend that you read the Instructions for Authors to be able to present your revised submission in a format that is likely to allow for a prompt final decision. It is available as a PDF download from the login page for EditorialManager. It has information for formatting, required elements, word limits, reference style and other necessary items. For example, we do not use subheadings like the one highlighted here.

- In your discussion section, you will need to define a "pragmatic open randomized controlled trial" as I think many reviewers will be thrown off by this. The best that I know of is:

According to Califf and Sugarman, there are "three key attributes of PCTs: (1) an intent to inform decision-makers (patients, clinicians, administrators, and policy-makers), as opposed to elucidating a biological or social mechanism; (2) an intent to enroll a population relevant to the decision in practice and representative of the patients or populations and clinical settings for whom the decision is relevant; and (3) either an intent to (a) streamline procedures and data collection so that the trial can focus on adequate power for informing the clinical and policy decisions targeted by the trial or (b) measure a broad range of outcomes. https://rethinkingclinicaltrials.org/chapters/pragmatic-clinical-trial/what-is-a-pragmatic-clinical-trial-2/

You may of course have a different or better one.

- see earlier note.

- not sure what this means. I can't imagine a pregnant woman not "committed to delivery". As the risks of wound infection in general are higher in women who labor than those who have scheduled cesarean births, it is important for the reader to know what population of people you are talking about. Just tell us. Are these women admitted in active labor or with PPROM at > 34 weeks or with medical /obstetrical indications for IOL? Did it include women for scheduled cesarean birth? Just tell us.

- Do you mean "if" or "When"?

- please describe the standard surgical dressing

- describe components of standard surgical dressing.

- delete highlighted. Standard of care at Parkland may differ from elsewhere.

- presumably within 60 minutes of skin incision but please describe

- what about hair clip v shave? What about incision closure? Temp regulation?

- you use "per" a lot. Could you substitute to "according to" in these instances instead of "per"?

- were study personnel blinded to allocation? IF not, why not?

- at least is pretty broad. What was the outer bound?

- administered by phone?

- "wound disruption" is a bit vague. Could this include needing to apply steristrips for skin separation as well as a wound infection requiring debridement, or dehiscence altogether? These would all be included the way you define wound disruption.

- A 50% decrease in rates of post op wound infection is very high. In your discussion, when you compare your negative trial to other studies which have looked at this same question, it will be important to give the %
change being studied in the other trials. Since yours is a negative trial, it will need to be put into context when comparing to the other trials.

- The highlighted items are not part of the statistical analysis and should be moved to around lines 175-179. Its confusing that you describe there a 1:1 allocation but here you have block sizes. This needs to be made more clear.

- Sentence line 230-232 can be deleted.

- how could delivery at an outside facility occur if patients were screened when "committed to delivery" at admission to L&D?

- Did all women who were randomized get the intended intervention?

- were all women weighed and have height measured at delivery?

- please provide denominators for your data

- your paper is not that long. Please provide this data.

- this should be part of methods. You don't include anything in methods about this at all--not listed as a primary or secondary outcome.

- please provide denominators

- This is not described in your methods section and should be.

- In both the abstract and the paper, please provide absolute numbers as well as which ever effect size you are reporting (if appropriate) + Confidence intervals. P values may be omitted for space concerns. We strongly prefer CI's as they give more information about strength of association than do P values. By absolute values, I mean something like xx (outcome in exposed)/yy(outcome in unexposed) (zz%) (Effect size= ; 95% CI=. ) An example might be: Outcome 1 was more common in the exposed than the unexposed 60%/20% (Effect size=3;95% CI 2.6-3.4).

- were there skin reactions in the control group?

- give day range

- by 50% or more compared to the control group. This needs to be included here.

- neither table 2 nor table 4 indicate that the vertical midline skin incision group was at higher risk. Also, the BMI and EBL differences as reported above do no include RR and CI data. The absolute differences (BMI and EBL) really don't look clinically significant)

- This is called a primacy claim: yours is the first, biggest, etc...In order to assert that, you need to provide the search terms used and the data base (s) searched (PubMed, Google Scholar, etc) to substantiate the claim. Otherwise, it needs to be deleted. It wouldn't belong in the abstract anyway, so make sure you address this in the manuscript body.

- please complete your table with RR and CI's.

2. There are several areas of some concern with your manuscript.

A. The primary outcome differs in your manuscript compared to what it is clinical trials.gov and there is no explanation for this.

Clinical trials: The primary outcome will be wound complication defined as wound disruption or wound infection. A wound disruption will be defined as the partial or complete opening of the deep subcutaneous space, not to include superficial skin separation. Underlying causes will include seroma, hematoma, abscess, and facial dehiscence. Wound infection will be defined as a physician diagnosis of wound infection with erythema and warmth extending beyond the immediate area adjacent to the incision and requiring treatment with antibiotics.

Manuscript: You have a composite including any of the following wound disruption, prolonged hospitalization for wound concerns, hospital readmission, or reoperation within 3 days.

You do not provide the definition of wound infection in manuscript.

B. You provide no information about the 2 week visit: How many attended? What were the results?

C. Please explain how you managed allocation concealment for the post operative wound examinations? If those
examining the wounds are aware of allocation, there could be substantial bias.

D. Please explain role of the funder.

E. I have completed a CONSORT checklist as I reviewed the paper. Please address deficiencies. My version is uploaded to the PDF at the end.

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

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

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

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.

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

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

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

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

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

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

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

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


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

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

8. 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.

9. 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).

10. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

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

12. 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.

13. The commercial name (with the generic name in parentheses) may be used once in the body of the manuscript. Use the generic name at each mention thereafter. Commercial names should not be used in the title, précis, or abstract.

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

15. Line 344: 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.

16. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist

17. Figure 1:

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

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

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

19. If you choose to revise your manuscript, please submit your revision 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 May 27, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: http://ong.edmgr.com/login.asp?a=r) Please contact the publication office if you have any questions.
May 31, 2019

Re: Manuscript ONG-19-601, Negative Pressure Wound Therapy in High Risk Patients Undergoing Cesarean

To the Editor:

Thank you very much for your helpful comments and suggestions. We appreciate the careful review of our manuscript and agree with many of the areas of concern raised by the reviewers. In our revision, we note that several of the reviewers have similar concerns and we have revised accordingly. We believe that the revised manuscript is much improved and hope that it is now worthy of publication in Obstetrics & Gynecology. Your questions on “areas of concern” seem most relevant and will be responded to first. We have listed each area of concern using and responded directly to each using bold font.

Editor
- Please state “This is a randomized, controlled trial.....” to begin with in methods. Can drop "prospective" because an RCT has to be prospective
Done

Did this include only women admitted for delivery w/ plan for vaginal birth or were those admitted for scheduled cesarean also included?
Potential subjects were identified and provided written consent in the outpatient Maternal-Fetal Medicine Clinic, the hospital during antepartum hospitalization, in the preoperative area prior to scheduled cesarean delivery, and prior to indication for cesarean at the beginning of labor (including scheduled inductions). Study participants provided written informed consent. If the decision was made to proceed with cesarean delivery, enrolled women were randomized using block randomization and for labor using a computer-generated random sequence.

Were the latter two only if the reasons for readmit or reop were wound issues?
No, this captured all obese gravidas whether having elective surgery or cesarean after labor had started and cesarean was performed for obstetric indications.

When you write that a study occurred between date 1 and date 2, it literally excludes those boundary dates. For instance, “This study was performed between Feb 2018 and Jan 2019” would mean it was performed from March 2018 to Dec 2018. Do you instead mean that the study was performed from date 1 to date 2? If so, please edit.
Done
- In both the abstract and the paper, please provide absolute numbers as well as which ever effect size you are reporting (if appropriate) + Confidence intervals. P values may be omitted for space concerns. We strongly prefer CI's as they give more information about strength of association than do P values. By absolute values, I mean something like xx (outcome in exposed)/yy(outcome in unexposed) (zz%) (Effect size= ; 95% CI=. ) An example might be: Outcome 1 was more common in the exposed than the unexposed 60%/20% (Effect size=3; 95% CI 2.6-3.4)

Table 4 and ‘new listed table 3’ lend themselves to RR with CI as you suggest and are changed. Denominators are included.

As most of the readers will be aware of the rise in obesity rates in pregnancy, rise in CS rates, perhaps you could edit this portion of your introduction substantially down. Perhaps you could provide some information instead about the conflicts in literature about utility of using closed systems prophylactically for CS incisions? There is quite a bit of conflicted data about this, which is what is defining the knowledge gap that your study is seeking to fill.

We agree with this suggestion and have removed explanation from Conner, et al. We have modified the introduction to make it little lighter on obesity as you have suggested and have and added Dr. Rouse’s advice to test ciNPT in clinical setting prior to adoption. We believe this addresses your concerns and are open to additional editing if you believe further is warranted.

For all manuscripts with corporate funding, we require that the following information be included in the materials and methods of the manuscript: The role of the sponsor in the design, execution, analysis, reporting and funding (ie, what did the sponsor provide).

Kinetics Concept Incorporated (KCI) donated iNPWT devices for the study and provided initial in-service on use and trouble shooting. They did not pay for any other clinical services for these patients. They were given access to the manuscript but did not provide any input or editing to the manuscript. They did not censor the presentation of the findings. We have added this to the methods section of the manuscript.

We do not require that initial submissions adhere to the Green Journal publication requirements. Articles for which a revision is requested however, do require that the revised submission adhere to all Green Journal formatting requirements. We strongly recommend that you read the Instructions for Authors to be able to present your revised submission in a format that is likely to allow for a prompt final decision. It is available as a PDF download from the login page for EditorialManager. It has information for formatting, required elements, word limits, reference style and other necessary items. For example, we do not use subheadings like the one highlighted here. We have removed the subheadings and reviewed for compliance with the formatting for Obstetrics & Gynecology.

In your discussion section, you will need to define a "pragmatic open randomized controlled trial" as I think many reviewers will be thrown off by this. The best that I know of is:

According to Califf and Sugarman, there are “three key attributes of PCTs: (1) an intent to inform decision-makers (patients, clinicians, administrators, and policy-makers), as opposed to elucidating a biological or social mechanism; (2) an intent to enroll a population relevant to the decision in practice and representative of the patients or populations and clinical settings for whom the decision is relevant; and (3) either an intent to (a) streamline procedures and data collection so that the trial can focus on adequate power for informing the clinical and policy decisions targeted by the trial or (b) measure a broad range of outcomes.
You may of course have a different or better one.

We appreciate the suggestion and agree it provides clarity for the reader. We do not have a better one than you have provided. In an attempt for brevity we have added the following to the discussion. If you believe the full definition should be included, we are happy to have it added.

The pragmatic trial has as its focus: an intent to enroll a population relevant to the decision in practice and representative of the patients or populations and clinical settings for whom the decision is relevant, and an intent to focus clinical and policy decisions.

- Not sure what this means. I can't imagine a pregnant woman not "committed to delivery". As the risks of wound infection in general are higher in women who labor than those who have scheduled cesarean births, it is important for the reader to know what population of people you are talking about. Just tell us. Are these women admitted in active labor or with PPROM at > 34 weeks or with medical /obstetrical indications for IOL? Did it include women for scheduled cesarean birth? Just tell us.

We apologize for the lack of clarity and believe we have edited to improve comprehension. The trial included women undergoing elective cesarean and those undergoing cesarean after labor as noted in the methods section. The allocation was stratified by the presence or absence of labor. We are open to further edits for clarity at the Editors discretion.

- Do you mean "if" or "When"?
  “If” replaced with “When”

- please describe the standard surgical dressing
  Describe components of standard surgical dressing.
  Add to methods section: Participants were randomized to either a standard surgical dressing (Telfa Adhesive Island Dressing 4” X 10” and Steri-strips) or ciNPT upon completion of surgery.

- Delete highlighted. Standard of care at Parkland may differ from elsewhere. Done.

- Presumably within 60 minutes of skin incision but please describe
  - What about hair clip v shave? What about incision closure? Temp regulation?

The methods section has been revised to address these concerns, it now includes:

All women received infection-prevention measures. These include prophylactic preoperative antibiotics of two grams of cefazolin (unless a penicillin allergy was noted, in which gentamycin and clindamycin were administered) within 60 minutes of skin incision, pubic hair shaving, as well as an abdominal skin preparation of 2% chlorhexidine gluconate / 70% isopropyl alcohol solution. In addition, all scheduled cesarean deliveries were given a 4% chlorhexidine gluconate wash to be used prior to presenting for surgery. In laboring and patients with ruptured membranes GBS prophylaxis was used according to hospital practices.11 No preoperative vaginal preparation was used.

and
Intraoperative incision measurements were obtained for all study participants including skin incision length and the subcutaneous tissue depth at the deepest location along the incision using a sterile marked surgical pen. Subcutaneous tissue (ST) was closed with 3-0 plain gut if depth was greater than 2 cm. The skin was approximated with subcuticular 4-0 vicryl and or staples (1 PROXIMATE PLUS MD@ 35 REGULAR).

- You use "per" a lot. Could you substitute to "according to" in these instances instead of "per"?
  We have removed the majority of the “per” and replaced them as suggested.

- were study personnel blinded to allocation? IF not, why not?
  All study personnel were blinded to allocation prior to completion of the surgical case. At the time of closure of the wound blinding was no longer possible. The type of surgical dressing was not included in the 2 week post op follow up data collection. To the extent that served as allocation concealment it was performed.

- At least is pretty broad. What was the outer bound?
  Added in the methods (line 290)

All participants were appointed to a two-week postpartum appointment to examine the incision site and were contacted by telephone 30 – 60 days after delivery to assess whether they had a surgical-site complication and whether additional emergency department or clinic visits were necessary.

- administered by phone?

The 30 day follow-up visit was a phone call as noted in the methods (see above)

- "wound disruption" is a bit vague. Could this include needing to apply steristrips for skin separation as well as a wound infection requiring debridement, or dehiscence altogether? These would all be included the way you define wound disruption.

We understand the concern and have added to the outcomes section for clarity:

The primary outcome was wound complication defined as wound disruption or wound infection (cellulitis was included). A wound disruption was defined as the partial or complete opening of the deep subcutaneous space (dehiscence - underlying causes include seroma, hematoma), NOT to include only superficial skin separation. Surgical Site Infection (SSI) required antibiotics and wound care and required physician diagnosis conforming to CDC guidelines concerning SSI\(^2\). Cellulitis required antibiotics and follow up.

- A 50% decrease in rates of post op wound infection is very high. In your discussion, when you compare your negative trial to other studies which have looked at this same question, it will be important to give the % change being studied in the other trials. Since yours is a negative trial, it will need to be put into context when comparing to the other trials.
  We have addressed this in the discussion section. The largest trial, Hyldig, was powered for a 50% reduction in SSI – whereas our trial was powered for a 50% reduction in wound complication. This has been added to the discussion as below:

Recently Hyldig K, et al completed a multiinstitutional trial with iNPWT in which SSI in cesareans, not wound complications, was the specific outcome measure. The trial was powered to detect a 50% difference in SSI and found this benefit with use of iNPWT vs
standard surgical dressing (4.6% - 9.2%, RR 0.5 [0.3 – 0.84]). We note our findings for iNPWT vs standard surgical dressing were 9.5% versus 11.4%, RR 0.8 (0.8 – 1.5). We were not adequately powered to look at a 50% difference in the rate of SSI. Further, Hyldig N, et found the use of iNPWT to be dominant over standard surgical dressing in preventing SSI’s using data from their trial in a cost effectiveness analysis.32

- The highlighted items are not part of the statistical analysis and should be moved to around lines 175-179.
  Done

It’s confusing that you describe there a 1:1 allocation but here you have block sizes. This needs to be made more clear.

We understand have changed the wording as follows:

In methods:
If the decision was made to proceed with cesarean delivery (cesareans were performed for obstetric indications), enrolled women were randomized using block randomization. The allocation was stratified for the presence of labor. A computer-generated random sequence was utilized for each of the strata using randomized blocks of sizes 4, 6, 8 and 10.

In statistical analysis:
A randomization schedule for each of the strata (labor vs no labor) was computer generated by randomized blocks of size 4, 6, 8, and 10.

- Sentence line 230-232 can be deleted.
  Done

- How could delivery at an outside facility occur if patients were screened when "committed to delivery" at admission to L&D?
  We appreciate the question and have revised lines 220 – 224 so that delivery of informed consent is reworded for clarity.

- Did all women who were randomized get the intended intervention?
  Yes

- were all women weighed and have height measured at delivery?
  All women had their height and weight recorded within two weeks of delivery. This has been added to the methods section

- please provide denominators for your data
  The denominators are in each of the tables. They are also listed below:
  Table 1. iNPWT denominator 222, std dsg 219
  Table 2. ciNPT denominator 222, std dsg 219
  Table 3. ciNPT denominator 37, std dsg 42
  Table 4. ciNPT denominator 222, std dsg 219
  Table 5. Not really lend itself to denominators
  Table 6. Denominators given each morbidity and risk factor
  Table 7. iNPWT denominator 222, std dsg 219

- this should be part of methods. You don't include anything in methods about this at all--not listed as a primary or secondary outcome.
We appreciate this was not included and have now revised the methods to include reference to the CDC guidelines concerning SSI, as follows:

Surgical Site Infection (SSI) required antibiotics and wound care and required physician diagnosis conforming to CDC guidelines concerning SSI. Cellulitis required antibiotics and follow up. Secondary outcomes were length of postoperative hospital stay, readmission length of stay, number of emergency department visits, and number of additional clinic visits for wound complications.

- In both the abstract and the paper, please provide absolute numbers as well as which ever effect size you are reporting (if appropriate) + Confidence intervals. P values may be omitted for space concerns. We strongly prefer CI's as they give more information about strength of association than do P values. By absolute values, I mean something like xx(outcome in exposed)/yy(outcome in unexposed) (zz%) (Effect size= ; 95% CI=. ) An example might be: Outcome 1 was more common in the exposed than the unexposed 60%/20% (Effect size=3;95% CI 2.6-3.4).
  Done

- were there skin reactions in the control group?
  No skin reactions occurred in the control group

  - give day range
  Done, as noted above

  - by 50% or more compared to the control group. This needs to be included here.
  Done as follows: The use of ciNPT did not reduce the frequency of postoperative wound morbidity by at least 50% in morbidly obese women undergoing cesarean delivery in our population

  - neither table 2 nor table 4 indicate that the vertical midline skin incision group was at higher risk. Also, the BMI and EBL differences as reported above do not include RR and CI data. The absolute differences (BMI and EBL) really don't look clinically significant
  The RR and CI's are now included. As you have noted, the absolute differences are not significant. We have removed this sentence from the manuscript.

  - This is called a primacy claim: yours is the first, biggest, etc...In order to assert that, you need to provide the search terms used and the data base (s) searched (PubMed, Google Scholar, etc) to substantiate the claim. Otherwise, it needs to be deleted. It wouldn’t belong in the abstract anyway, so make sure you address this in the manuscript body.
  We understand and have added this to the discussion as requested. If the Editors would prefer, we are comfortable also deleting the primacy claim.

“This is the first adequately-powered, and fully conducted RCT comparing iNPWT dressing to a standard dressing to address efficacy in preventing post-caesarean wound morbidity in women with class III obesity (Pub Med May 31, 2019 using terms “cesarean delivery, closed incision, negative pressure therapy”).

- please complete your table with RR and CI's.

We have added these as appropriate. If additional RRs and Cis are needed we would be happy to add as the Editors desire.

2. There are several areas of some concern with your manuscript.
a. The primary outcome differs in your manuscript compared to what it is clinical trials.gov and there is no explanation for this.

Our intent was to evaluate the wound morbidity which causes extra care in our postoperative cesarean population. There was more than just surgical site infections (SSI) in this group. As you noted the definition of the primary outcome in Clinicaltrials.gov was:

“The primary outcome will be wound complication defined as wound disruption or wound infection. A wound disruption will be defined as the partial or complete opening of the deep subcutaneous space, not to include superficial skin separation. Underlying causes will include seroma, hematoma, abscess, and facial dehiscence. Wound infection will be defined as a physician diagnosis of wound infection with erythema and warmth extending beyond the immediate area adjacent to the incision and requiring treatment with antibiotics. We have addressed this in the Abstract Methods:

“The primary outcome was wound complication: a wound disruption or wound infection within 30 days of delivery”

And in Methods Outcomes in the body of the paper:

“The primary outcome was wound complication defined as wound disruption or wound infection. A wound disruption was defined as the partial or complete opening of the deep subcutaneous space (dehiscence - underlying causes include seroma, hematoma), not to include only superficial skin separation. Surgical Site Infection (SSI) required antibiotics and required physician diagnosis conforming to CDC guidelines concerning SSI². Cellulitis was considered wound infection (complication) but not classified as SSI.

b. You provide no information about the 2 week visit: How many attended? What were the results?

We have addressed this in Results and also Tables 4 and 5.

“A total of 397 (90%) of women were successfully evaluated in clinic at their 2 week followup visit, and 411 women (93%) were successfully contacted by telephone at least 30 days postoperatively to assess for wound morbidity and to complete a brief patient satisfaction survey (table 6).”

c. Please explain how you managed allocation concealment for the post operative wound examinations? If those examining the wounds are aware of allocation, there could be substantial bias.

“Type of surgical dressing was not evaluated at and allocation was concealed at 2 week post operative visits.”

d. Please explain role of the funder.

Kinetics Concept Incorporated (KCI) donated iNPWT devices for the study and provided initial in-service on use and trouble shooting. They did not pay for any clinical services for these patients. They did not censor the presentation of our findings. They were given access to the manuscript but did not provide any input or editing to the manuscript. The study is listed in IRB documents as being Department Funded. We are very grateful for the opportunity to perform this pragmatic trial without outside input.

e. Consort Document: see Comparison

STATISTICAL EDITOR COMMENTS:
The Statistical Editor makes the following points that need to be addressed:
Table 2: Estimated blood loss often has a skewed distribution. If not normally distributed, should cite as median (IQR) and test non-parametrically.

The statistician is correct. This has been corrected in table 2.

a. Table 2: Estimated blood loss often has a skewed distribution. If not normally distributed, should cite as median (IQR) and test non-parametrically.

The statistician is correct. This has been corrected in table 2.

b. Table 3: The components of the primary outcome were under powered and the NS results for the components cannot be generalized due to low power.

We believe wound complication involves several factors and powered our study on this composite measure. And while SSI as an outcome would have required many more patients (only half of wound complications noted in this study), it was never our intention to focus on that one aspect of wound complication. Our composite outcome was listed poorly in Abstract Methods and Methods Outcomes and the language describing this outcome has been modified. This may not allay all the concerns of the statistician but we feel it was a very reasonable outcome to study in this pragmatic trial; and powering for such was also reasonable.

c. Table 4: The counts of adverse events by treatment group were too few to allow for sufficient power to generalize the NS findings and too few to allow for enough stats power to adequately test for interaction terms.

This follows from the statistician’s initial concern. We used interaction to see if any subgroup stood out which might show some benefit from icNPT in our population. A two sided alpha of 0.20 was used to test this interaction and nothing was significant at this level. This is a standard way to look at interaction. Since we defend our initial use of outcome measure as reasonable to power the study, we also defend this analysis of interaction.

Reviewer #1:
Hussamy and colleagues present the results of a randomized controlled trial of closed incision negative pressure wound therapy in obese women undergoing cesarean delivery. The topic should be of significant interest to readers of the journal. I have the following comments/questions for the authors:

1. Remove the acronym in the Short Title.
Done: Short title: Negative pressure wound therapy in high risk patients undergoing cesarean

2. The Abstract could be reworked to improve clarity—were all women or only some women in labor (line 74)? The term "sensitive skin disorders" (lines 76-7) is vague. What is the definition of "prolonged postoperative hospitalization for wound concerns" (lines 80-1)? Do you mean all hospital readmissions (line 81), and if so, why so specific on the prior variable and not on this one? Abstract has been reworked to provide clarity. Thank you.

3. The first sentence in the Introduction needs a reference.
Done: same reference as the second sentence

4. Let the reader decide how "dramatically increased“ (line 119) by providing data in the second sentence of the
Done: reader can see 2005 7.6%, and 2014 9.8%

Introduction.
5. Replace "shows" with "show" in line 121—the word "data" is plural.  
Done

6. The Introduction, particularly the third paragraph, should be reworked to improve clarity. Is the focus on wound complications overall or just wound infections?  
Done

7. The fact that negative pressure wound therapy has been effective in some types of operations should be acknowledged and cited in the last paragraph of the Introduction.

Added:
Hyldig, et al identified and described decreased wound infection and seroma in multiple types of surgery including orthopedic, median sternotomy, abdominal wounds, and breast reductions in her Meta-Analysis.

8. Consider inserting the word "label" after the word "open" in line 164.  
OK

9. The term "sensitive skin disorders" again is used in line 174. Like in the Abstract, it is vague and not defined. At least give a few examples.
That term has been eliminated. Was never used and confusing even to investigator when had discoverable allergies acrylic and silver.

10. The word gentamicin is misspelled in line 182.  
Corrected

11. Were women randomized before or after the completion of the cesarean delivery?  
Participants were randomized to either a standard surgical dressing (Telfa Adhesive Island Dressing 4” X 10” and Steri-strips) or ciNPT upon completion of surgery.

12. What is the definition of "prolonged postoperative hospitalization for wound concerns" (line 215)?
Greater than 5 days; see # 389, table

13. Data about the secondary outcomes described in the paragraph starting on line 276 should be included  
Done, see new table 5

14. Was there any crossover, or was the adherence to randomized treatment 100%?  
There was 100% adherence to randomized treatment of those who had cesarean section.

15. In line 296, change Table 5 to Table 4.  
Table designations corrected

16. This reader would like to see data from the patient satisfaction survey rather than summary reports.  
See new Table 7
17. Please attend to consistent formatting—some references listed have all authors, while others have three then et al.
   **Have corrected**

18. Table 2: What proportion of the skin incisions of Pfannenstiel abdominal incisions were made in the subpanniculal fold as opposed to suprapannicular?
   **Did not differentiate midline abdominal incisions in data as to infraumbilical, periumbilical, supraumbilical, subpannicular, or suprapanicular. Incision type was not our primary focus. Don’t want to infer any causation from this secondary measure. Could go back and scour med records but not at this time.**

19. Table 2: The variables "labor" and "induction" are confusing and seem to imply that less than half of the patients had spontaneous or induced labor, though only about a third had a scheduled cesarean.
   **Have corrected labor to be spontaneous labor. So you can be in spontaneous labor or you can be induced: no overlapping**

**Reviewer 2:**

**ABSTRACT:** Please add a comment about the effect of ciNPT on wound complications in other surgical populations; is the 50% reduction for which this study was powered consistent with what has been seen with other applications?

**Other applications have used 50% reduction in power calculations. These measurements are usually made for SSI’s, not overall wound morbidity. See comments to editor.**

**METHODS:**

Did the study protocol guide the following, or were these decisions left to the managing physician: the decision to proceed to cesarean; subcutaneous closure (in either group), technique for wound closure in the standard therapy group?

**Cesareans were performed for obstetric indications**

Subcutaneous tissue (ST) was closed with 3-0 plain gut if depth was greater than 2 cm. Number of layers of 3-0 gut used to close ST was at the discretion of the operating surgeon.

**Allocation assignment was concealed until after closure to assure standard closure technique.**

Was GBS colonization and prophylaxis considered at all in the study?

**In laboring and patients with ruptured membranes GBS prophylaxis was used according to hospital practices.**

For the patient’s 30 day telephone follow-up, was there any attempt to validate the presence or absence of wound complications with chart review or administrative data review?

**Patient charts were reviewed to assure as complete of follow up as possible.**

**RESULTS, DISCUSSION, REFERENCES, TABLES/FIGURES:** Very well written, clear, and great as is.
Thank you

Reviewer 3
Results: No difference in intervention group (line 293) compared to standard therapy. Post hoc analysis (line 290) was unable to delineate differences explaining lack of effect. Unclear meaning of "No heterogeneity in the treatment effect" (line 293). Consider rewording to clarify.

**Heterogeneity changed to interaction for clarification**

Consider re-wording of the post hoc analysis rationale: " As no benefit was seen ( lines 296-299) the entire study cohort was evaluated to identify what, if any, risk factors were likely to lead to postoperative wound morbidity in this patient population" to make more clear.

We have removed this as noted in the comments to the editor.

Skin reactions and patient satisfaction included: first study I have seen to include these variables.

Thank you

Discussion: points well made, counter arguments considered

Thank you

Tables and figures: Figures and tables are clear and informative (with the exception of reference to table 5 that does not exist, suspect mean table 4 (line 296)

**Tables added, correctly designated**

References: reasonable, appropriate and inclusive

Thank you

Reviewer 4
Overall: This is an original research report that compares wound morbidity among obese women undergoing cesarean delivery. The intervention is negative pressure wound therapy. The paper is succinct and well written and follows the CONSORT guidelines. There are some places where the manuscript could be stronger. The major flaw is the use of the term "composite outcome" yet not really defining how what that was - a combination of the listed outcomes or at least one of the listed a-priori outcomes?

We appreciate the concerns raised by the reviewer and have addressed them in the manuscript as follows:

**Abstract methods: The primary outcome was wound morbidity**

**Body Paper methods:** The primary outcome was wound complication defined as wound disruption or wound infection (cellulitis was included). A wound disruption was defined as the partial or complete opening of the deep subcutaneous space (dehiscence - underlying causes include seroma, hematoma), NOT to include only superficial skin separation.

Surgical Site Infection (SSI) required antibiotics and wound care and required physician diagnosis conforming to CDC guidelines concerning SSI\(^2\).

The abstract provides good overview of the study and includes important information. The conclusion of the abstract matches the manuscript.

Thank you
There are other papers on this topic in the literature including one, stated below, with the exact same title. The authors should emphasize the value their paper brings to the literature and in particular will this paper ANSWER this clinical question especially given the current epublication of a very similar study.

There is another paper that is epub ahead of print - Hyldig et al conclusions are different from the authors here.
Hyldig N, Vinter CA, Kruse M, et al.

Prophylactic incisional negative pressure wound therapy reduces the risk of surgical site infection after caesarean section in obese women: a pragmatic randomised clinical trial [epub ahead of print]
BJOG (England), Aug 01 2018, p

After review, we note that the report by Hyldig, et al is exceptional in design and conduct. Its positive findings are listed in the body of the paper as good evidence for the benefit of iNPWT decreasing SSI’s in obese gravidas who undergo cesarean. We have added this reference and incorporated it into the discussion

The authors report no conflicts, funding sources are stated.

IRB/Ethics approval was stated and was obtained.

This trial was registered on Clinical Trials NCT02289157.

First posted Nov 13, 2014. Last update July 2 2018. The primary outcome stated on the NCT site is not a composite outcome. The anticipated sample size is the same on the NCT site as in the manuscript.
We appreciate this and have revised to address this concern.

The title is appropriate

PRECIS: The precis is fine

INTRODUCTION:
1. The introduction would be stronger if the authors described the controversy in this particular topic. This is thoroughly discussed in the discussion, but it would help set the stage of the potential importance of this submitted manuscript.
We have focused the controversy a little better in introduction. We have addressed the positive study by Hyldig, et al.

2. Please be clear what the outcome was. At least one of the morbidities? If it’s a composite outcome why?
It is a composite, but we consider it a pragmatic outcome for our service. SSI’s aren’t the only wound complications that require extra wound management. Everything listed as making up wound morbidity in our definition does. The dehiscence often requires more wound care than a superficial SSI. Cellulitis often is the first presenting symptom of SSI.
MATERIALS AND METHODS:
3. The primary outcome should be more clearly stated. Any or at least one morbidity? Line 213
Done

Listed in Methods: Study Outcome
The primary outcome was wound complication defined as wound disruption or wound infection (cellulitis was included). A wound disruption was defined as the partial or complete opening of the deep subcutaneous space (dehiscence - underlying causes include seroma, hematoma), NOT to include only superficial skin separation. Surgical Site Infection (SSI) required antibiotics and wound care and required physician diagnosis conforming to CDC guidelines concerning SSI\textsuperscript{30}. Cellulitis required antibiotics and follow up.

4. The blistering as a side effect or potential adverse event should be more clearly described and talked about. Any other adverse events? Were they recorded?

Although Howell et al reported a 63% blistering rate with ciNPT use after knee arthroplasty \textsuperscript{30}, this complication has been reported elsewhere in the surgical literature.\textsuperscript{31} We found similar skin reactions, but not as frequently (28% of women who received ciNPT). No complications arose from these blisters and they were never noted at 2 week follow-up visit.

DISCUSSION:
5. Lines 340-341. This is an important concept - please expand about the futility stated here and why the authors still went ahead with their own RCT.
The authors from Wihbey KA, et al performed an interim analysis due to difficulty in achieving their stated goal of enrolling 200 in each group. After randomizing 166 patients total, their initial of SSI rate in each group (NPWT 15 % vs Standard 10%) demonstrated that if there was similar prevalence in the remaining 244 women then the power to detect a difference was 29%. The DSMB recognized the futility of continuing the study and asked for its' closure. Difficult to describe futility determined this way in paper.

This statement is added to discussion:
Enrollment was slow, incidence similar, and would lead to a power of only 29% to detect differences. DSMB advised stopping for futility. We felt we could achieve this number (440) at our institution and were interested in the pragmatic result as it affects the care our morbidly obese population (wound morbidity vs SSI).

We believe we have addressed all of the concerns of the editors and reviewers. We appreciate all of the insight and believe the manuscript is much stronger as a result of this process. We hope our revised manuscript is now suitable for publication in Obstetrics and Gynecology. We appreciate all of the effort the Journal has devoted to our manuscript. Please do not hesitate to contact me if any further revisions are needed.

Sincerely,

Scott Roberts, MD