Author's response to reviews

Title: Extubation Force Depends Upon Angle of Force Application and Fixation Technique: A Study of 7 Methods

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Version: 4 Date: 31 May 2014

Author's response to reviews: see over
Resubmission for MS: 1163346797120438

Dear Reviewers and Referees,

Thank you for your time and detailed review of the manuscript. Thoughtful input and valuable suggestions were appreciated and helpful during the revision process. The work has certainly benefited from your input with the resubmission being more understandable and effective at communicating the work, methods and pertinent results.

Please find below the referee’s letters with details on how the feedback was addressed. All three letters and responses are provided below.

Please feel free to contact me at Jennifer.wagner@ucdenver.edu with any additional concerns, questions or suggestions.

Sincerely,

Jennifer Wagner
Reviewer's report
Title:
Extubation Force Depends Upon Angle of Force Application and Fixation
Technique: A Study of 7 Methods
Version:3
Date:26 March 2014
Reviewer:Kamil Toker

Reviewer's report:
1. There are no major compulsory revisions.
2. There are some minor typing errors. In the first line of the first page 'used' should be instead of 'use'. 'endotracheal tube fixation' has been duplicated as a keyword. In the sixth line of Material and Methods, page 7, the company name of the manikin has been indicated as 'Laderal', probably it should be as 'Laerdal'

Corrective Action:
The typos, duplication and name errors were all corrected

3. It is an interesting study with a different point of view to the ET tube restraint methods. For sure it should be a manikin study because of ethical issues. As the authors has indicated that manikin cannot reflect or simulate living human body. The presence of saliva and temperature gradients were given as the differences between manikin and the living human body. Presence of beard and moustache can affect the security of ET tube, too. Probably all restraint methods will be affected by an unshaved face. Manikins do not have beards. Moreover, but not sure, there can be some differences between genders because of the different skin structure?
Last but not the least, concerning the patients in ICU and/or in ED, perspiration should be taken into consideration for the security of ET tube. Besides the presence of saliva and temperature gradients, it is better to emphasize the other points between manikin and human body mentioned above.

I appreciate your input on this and am glad the valid points you brought up were added into the paper. Thank you!

Corrective Action:
The first paragraph of the discussion section was updated to include limitations outlined above.

Level of interest:
An article whose findings are important to those with closely related research interests

Quality of written English:
Acceptable

Statistical review:
No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests' below.
Reviewer's report
Title: Extubation Force Depends Upon Angle of Force Application and Fixation
Technique: A Study of 7 Methods
Version: 3 Date: 4 April 2014
Reviewer: Thomas Bluth

Reviewer's report:
This prospective study of Wagner and colleagues aims at comparing seven endotracheal tube-restraint combinations with regard to mechanical forces needed for tube removal in an ex-vivo model of unplanned extubation. The strength of their work derives from the standardization of 13 different tube removal directions, covering a hemisphere on the plane of the face and reflecting typical clinical scenarios. The authors found relevant differences in the efficacies of these fixation techniques, particularly depending on the angle of force application.

The scientific question and hypothesis is well defined and might be of importance for both clinicians and manufacturers. However, due to the use of an intubation mannequin at room temperature without salivation transfer of these data to the clinical setting might be done cautiously.

Major compulsory revisions:
1) Seven tube-restraint combinations were analyzed to allow for a broad view on currently available devices. As the authors state, the use of adhesive tape following the Lillehei method and umbilical cotton twill is common. However, the authors may provide a rationale for investigation of advanced tube restraint devices like Thomas™ tube holders, Anchor fast devices (please provide the manufacturer for clarity) and the newly introduced SolidAIRity® system.
Corrective Action:
Additional information and reasoning was provided in paragraph 2 of the methods section.

Moreover, one might wonder if the combination of adhesive tape and the Securisyn endotracheal tube, although designed for use with a special fixation device is of interest from a practical point of view.
Corrective Action:
Additional information and reasoning was provided in paragraph 2 of the methods section.

2) The authors may provide a rationale for performing 3 attempts at each angle and each tube restraint combination. Was any calculation of sample size done before conducting the experiments?

Rationale:
A study was conducted by an independent lab on behalf of Securisyn Medical. After looking at the study, their statisticians determined a sample size of 3 would provide enough data to show
significant differences between the methods of fixation. Initially, this information was not included since the testing and report are confidential/proprietary.

Corrective Action:

Background and reasoning for sample size was provided in the first paragraph of the methods section.

The 5th paragraph of the methods section was updated to reflect information mentioned above, however; a reference to the lab/report is not provided as the information is confidential.

3) With regard to data presentation, the primary outcome of this investigation was the mechanical force needed to remove an endotracheal tube by 2 and 5 cm, respectively. Secondary endpoints are not presented systematically in the results section but could be of special interest. The authors state, that tube occlusion or device failure occurred during some experiments. These outcomes may be even more important considering clinical practice, since they could occur earlier and probably easier than the tube removal itself. The authors are kindly asked to first provide a more detailed description of each device failure.

Second, device failure and airway occlusion should be reported systematically for each position and device by providing the force needed to provoke this event, e.g. by using a table if appropriate.

Unfortunately, occlusion events were not recorded during testing. What information was recorded was added in, however; the level of detail requested is not possible from testing records. A new sub-section was added to the end of the results section dedicated to failure modes. General descriptions and observations were added along with a table describing failure modes and adding in what data was recorded.

Corrective Action:
A sub-section of failure modes was added to the end of the results section. Additional details were provided along with a table.

4) Please consider revision of the statistical part of the study. For statistical analysis fixation methods were compared using t-test. This would require 21 possible comparisons. However, there are no p-values presented on the graphs or within the text. I recommend using ANOVA test for seven groups and possible post hoc analysis, together with adequate presentation of the statistical results.

Furthermore, presentation of the force data (table 1, figure 4, 5 and 6) seems to be redundant. I recommend to show mean + standard deviation values of forces at each position for each device and to present mean + standard deviation for each device independent of the position. Be careful not to mix usual parametric (mean ± standard deviation) and nonparametric (box plot) means of data presentation. Please provide adequate description of the figures and tables to ensure understanding without reading the text.
I appreciate these comments and suggestions. The general flow of the data presentation has been described in a more logical way with this revision.

Corrective Action:
All of the figure captions were expanded upon to aid in interpretation. The figures in the results section were re-organized, with the scatter plot being added as an additional figure. The boxplot was moved to the first paragraph of the results for use in explaining the statistical methods chosen. Tables were re-formatted and a data summary table was added as suggested.

5) The study is supported financially by Securisyn Medical, LLC. Against this background, the authors must take care to avoid selective outcome reporting. This includes aiming at a well-balanced presentation and discussion of the results between the several tube-restraint combinations, as is not yet the case. I further recommend not to mention the SolidAIRity® system in the abstract but to write the abstract more universal, for example by comparing conventional vs. device fixation techniques.

I really like your suggestion of comparing traditional methods versus device performance. Taking that perspective also helped me look at the dataset in different ways making interpreting of the results more meaningful.

Corrective Action:
The abstract was edited as suggested. The results and discussions sections were also re-worked to incorporate a more coherent and organized framework for discussing observations and results. Additional observations and comments were added to each of the subsections to address referee 3’s comments.

6) The authors are kindly asked to revise the manuscript regarding typos and to streamline the text. The discussion section might be structured to first provide the main results. Second, the results should be discussed concerning previously published studies. At least, limitations of the study should be addressed and implications for clinical users might be drawn.
Corrective Action:
Several typos were identified and corrected.

Minor Essential Revisions
At this time there are no minor essential revisions. Please respond to major compulsory revisions until minor issues will be discussed.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I declare that I have no competing interests
Reviewer's report

Title: Extubation Force Depends Upon Angle of Force Application and Fixation Technique: A Study of 7 Methods

Reviewer: Thomas Kiss

Reviewer's report:
Wagner et al present the results of a small comparative experimental study to assess extubation forces with respect to the angle of force application. 13 different angles forming nearly a full hemisphere on the plane of the face have been tested. Combinations of seven different tube fixation techniques with two different endotracheal (ET) tubes have been compared, namely: SolidAIRity system, Thomas Tube Holder, Anchor Fast device, adhesive Tape and non-adhesive cotton tie. A Laerdal intubation mannequin in a load frame was used to measure the prevalent extubation forces with a load cell. Extubation forces were recorded at 2cm and 5cm tube displacement, respectively.
The authors measured three values per tube – angle - restraint combination for a 2 cm and 5 cm tube displacement, in total 546 single values. New tubes and devices were used for every pull test.
Measurements for each tube-angle-restraint combination were converted to means and averaged to allow for comparison across all different fixation methods.
The SolidAIRity system required the highest force to displace the tube. The performance of the other tube restraints is not summarized in the text.
The posed question of this study is well defined; the methods seem to be appropriate. The raw data looks reasonable. The introduction is well written except of some difficult sentences. The statistical analysis needs major revision also to corresponding figures/tables. The authors should revise this part on the basis of consultation with a local statistician. The Material & Methods section needs some minor revisions for better readability. The Results section should contain data and should be readable and understandable without the figures/tables. The Discussion section would benefit from a clear structure. I would like to evaluate this manuscript again after the revision.

Major Compulsory Revisions

1) During my reading I noticed that none of the figures and tables has a legend. This makes it extremely difficult to understand the results and to follow the statistics. Please try to include all facts that are important to understand the figure in the legend. Generally speaking, a figure should be understandable without reading the full text and the full text should be understandable without looking at the figures.
Thank you for pointing this out. A lot of information required for meaningful interpretation of the figures was present only in the text.

Corrective Action:
Figure captions (legends) were updated to further describe content/purpose.
Figure 1, 2, 3 and 4 are essential and beneficial for the article. Figure 5 doesn’t give me much more information than Figure 4.

**Rational:**
Figure 5 is intended to supplement figure 4 by providing a spatial relationship between force values and angle of application. Figure 4 was also included so anyone who wanted to see the raw data set could.

**Corrective Action:**
Figure 4 was replaced by a table and moved to the appendix as a supplementary figure.

Figure 6 is not understandable for me at the moment - does the Boxplot show median, interquartile range with minimum and maximum?

**Rational:**
Figure 6 is a traditional boxplot showing median and interquartile ranges along with min/max values. For this figure, data is grouped by fixation method. In other words, all tests for a given device were grouped to include all test angles. This figure is intended to illustrate differences in force value distributions across the devices. It is also intended to provide a basis for using t-tests as opposed to ANOVA.

**Corrective Action:**
The boxplot was moved to the first paragraph of the results section. Additional description/rational for the statistical methods was also added to the same section.

Please revise this for a better understanding. Table 1 is not labelled and the text states 95% confidence intervals – but usually confidence intervals are reported as [x;y] and not x±y.

**Corrective Action:**
Table was updated as requested. Additionally, calculation of the confidence intervals was changed to use the Satterthwaite's approximation for degrees of freedom. This test is sometimes called Welch's t-test. In the revised version of this table, calculations were performed by MATLAB’s ttest2 function (version R2013a) with the unequal variance flag set.

2) The statistical analysis is based on raw data that is shown in Figure 4. I agree, it makes sense to transform all values of a restraint method to a mean that can be compared with one of the other restraint types. To my understanding there are 7 different groups of tube restraints that have to be compared. Assuming that the data fulfill the criteria for a
parametric test, a comparison of means for more than two groups would be done by ANOVA.

**Rational:**
First, thank you for pointing this out. After re-evaluating the method, calculation of confidence intervals was updated to reflect the assumption that variances are not equal among all devices. It was decided to keep using t-tests for fear of violating 2 assumptions/guidelines for using ANOVA:
1. Large sample sizes to accurately characterize variance.
   - Small sample sizes (n=3), appear to leave too much room for inaccurate representation of variance.
2. Variances among the groups should be equal.
   - Asymmetries in the box plots indicate the dataset could violate the assumption of equal variance.

**Corrective Action:**
Confidence interval calculations were adjusted to match the inability to prove equal variance among fixation methods.

With the current description in the full text and the tables/figures I cannot follow your statistics. The full text states „mean force and standard deviation at each test point“, in the table you depict confidence intervals and in Figure 6 you show a Boxplot that normally shows a median. I recommend consulting a local statistician to clarify these points.

**Minor Essential Revisions**

- **Results:** Can you please describe your results in the text and not only refer to the figures/table. You should not only refer to the SolidAIRity System but compare all of the tested systems with each other.

  **Corrective Action:**
The presentation of results was framed in a different manner, incorporating the comparison of traditional methods of fixation (tape and twill) with commercially available devices. Additional observations were discussed in each of the subsections in the results section.

- **Discussion:** I recommend to have a clear structure in the discussions section:
  1. summary of the results
  2. comparison with other literature
  3. limitations
  4. conclusion - summary of the results in context of the discussion and clinical routine

I agree. Thank you for the input on discussion structure.
Corrective Action: The discussion section was re-organized for better flow.

- Methods, paragraph 1, sentence „a series of discrete angles covering a hemisphere on the plane of the face..“. Can you please try to describe the angles in the text and not only refer to the figure?
  Corrective Action: Description added to paragraph 1 of the methods section.

- Methods, paragraph 5, sentence „Forces were compared at each of the 13 test points“ Can you please define test point in the first paragraph of the methods section - together with the description of the tested angles
  "test point" is described quite late in the text, although you refer to it much earlier (same in the abstract).
  Corrective Action: Description added to paragraph 1 of the methods section and a reference to the test point terminology was added to the abstract methods section.

- Material and Methods, first paragraph, sentence "Angles were chosen to simulate possible extubation scenarios while balancing material costs and statistical requirements." I don't understand the meaning of this sentence. Can you please explain more?
  Corrective Action: Background and reasoning for sample size was provided in the first paragraph of the methods section.

- Introduction, last paragraph, sentence „This study is comparative in nature with precedence given to maintaining consistency across force tests as opposed to replication of clinical conditions.“ Too complicated – can you please write simpler?
  Corrective Action: Last paragraph of the introduction was re-written for clarity.

- Introduction, last paragraph, sentence „A quantitative framework for analysis of current ET tube restraint methods, along with qualitative observations of fixation performance when subjected to different force vectors, may aid in the reducing unplanned extubation.“ Too complicated – can you please write simpler?
  Corrective Action: Last paragraph of the introduction was re-written for clarity.

- Material and Methods, second paragraph sentence „All testing was performed on a Laderal intubation mannequin..“ It is called „Laerdal“.
  Corrective Action:
Change was made to the second paragraph of the methods section.

- If you use the MATLAB program you should state the software producer and the program version.
  
  **Corrective Action:**
  
  Version information was added to the last paragraph of the methods section.

**Level of interest:** limited interest

**Quality of written English:** acceptable

**Statistical review:** I recommend consultation between a local statistician and the authors.

**Declaration of competing interests:** None.