Author’s response to reviews

Title: Titanium vs Absorbable tacks Comparative Study (T.A.C.S.): a multicenter, non-inferiority prospective evaluation during laparoscopic repair of ventral and incisional hernia. Study protocol for randomized controlled trial

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Version: 2 Date: 21 May 2015

Author’s response to reviews: see over
Dear Sirs,

We are pleased to submit a revised version of the manuscript “Titanium vs absorbable tacks comparative study (T.A.C.S.): A multicenter, non-inferiority prospective evaluation during laparoscopic repair of ventral and incisional hernia: study protocol for randomized controlled trial” (it was: “titanium vs absorbable tacks comparative study (T.A.C.S. Trial) during laparoscopic repair of ventral and incisional hernia: study protocol for multicenter, non-inferiority randomized controlled study” by Silecchia G, Cavallaro G, Raparelli R, Olmi S, Baldazzi G, Campanile FC, for publication on Trials

We are grateful to Editors and the reviewer for their appraisal of our paper.

The reviewers correctly pointed out some concerns that required several modifications. The revised manuscript includes all the suggested changes and all the modifications required by the handling editor. The explanation of what we have changed in response to the reviewer concerns is marked in a different color within the text and also reported in the “Response to Reviewers” file. The language has also been extensively reviewed and submitted again to a mother tongue professional editing.

The reviewer support has been very constructive and allowed us to better clarify the importance of our trial and its rigorous methodology. This is the first randomized controlled trial designed to compare absorbable fixing devices vs. titanium helicoidal tacks (the gold standard) for mesh fixation in laparoscopic repair of ventral hernias. We agree with you and the reviewer that the explanation of the study protocol must be stringent.

The protocol is now better explained in accordance with the standard items of the SPIRIT and CONSORT guidelines, and we strongly believe that it would be of great interest for the readership of Trials.

We would like to take this opportunity to express our sincere thanks to the reviewer who identified necessary corrections to our report. We would like also to thank you for allowing us to resubmit a revised copy of the manuscript.

We hope that the revised manuscript is accepted for publication on Trials. We confirm that this paper has not been published elsewhere and is not under consideration by another journal.

All authors have approved the revised manuscript and agree with its submission to Trials.

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Thank you for receiving our manuscript. We appreciate your time and look forward to hearing you at your earliest convenience.

Sincerely,

Fabio Cesare Campanile, M.D., F.A.C.S.,
Reviewer's report
Title: Titanium vs absorbable tacks comparative study (T.A.C.S. trial) during laparoscopic repair of ventral and incisional hernias: study protocol for multi center non-inferiority randomized controlled trial
Version: 1
Date: 6 April 2015
Reviewer: Jane Blazeby

>Reviewer's report: It is interesting to read this trial protocol. I have a number of concerns about the description of the design which require clarification.

Thank you very much for your excellent appraisal. Your comments have been highly helpful to improve our manuscript, we introduced all the changes that you suggested: they are marled with a light blue color in the manuscript

> In addition it would benefit from work on the language and writing to improve readability

We extensively revised the language aspect and again had a professional, mother tongue, review of the manuscript after the changes were made.

> Major issues 1. The rationale for the study is confusing and I think it needs to critique the current evidence in terms of descriptors of previous studies and their design.

As you suggested, the “Background” section has now been completed with a critique of the current evidence and of the design of previous literature about the use, safety and efficacy of absorbable devices for mesh fixation.

> 2. The primary end point is unclear in the abstract which states a hypothesis but no clear focus this – elsewhere it appears that the primary endpoint is recurrence rates but at three time points - this requires clarification.

We clarified the primary endpoint both in the abstract and in the “methods” section. The recurrence rate will be measured at 3 years, but an interim evaluation is planned at 1 and 2 year.

> 3. There is a need to avoid the use of ‘double concealment’ – because of confusion of this terminology - although it is noted that it is possible to blind patients and outcome assessors which should reduce bias in this trial.
We completely agree with your considerations. The new manuscript does not use that terminology and the methods for blinding patients and outcome assessors are better explained in the “Randomization, allocation concealment, and blinding” paragraph.

>4. The discussion in the abstract repeats the aim and it appears that this study is aiming to ‘demonstrate’ something, rather than test a hypothesis - therefore I have concerns about bias.

We would like to thank you for having stressed this very important aspect. It is now clearly stated that the aim of the study is to test the hypothesis that absorbable tacks are non-inferior to titanium tacks for fixing lightweight meshes in LIVHR.

>5. It is unclear whether the patient will be expected to provide informed consent for the research and randomisation or whether this protocol describes simple informed consent used for clinical practise.

The patient will be expected to provide informed consent for the research and randomization. The research and randomization informed consent form has been approved by the mentioned Ethical Committee. This aspect has been clarified in the manuscript.

>6. It is unclear how allocation concealment will be maintained, I am not sure what restricted access means?

The sentence “restricted access” meant that the members of each surgical unit have access only to the records of their own unit. Your comment made us realize that such detail was unnecessary and potentially confusing. Therefore, we eliminated it altogether. The methods of allocation concealments have been further specified in the “Randomization, allocation concealment, and blinding” paragraph in the “Methods” section.

>7. Methods to analyse videos on the surgeons are not described

The quality control on the videos will be performed according to a checklist including all necessary items of the approved surgical technique. We are thankful for having underlined that this aspect was lacking. The methods are now well specified in the “Intervention, preoperative and postoperative management” paragraph.