Author’s response to reviews

Title: A Collagen-Fibrin Patch (Tachosil(R)) for the Prevention of Symptomatic Lymphoceles after Pelvic Lymphadenectomy in Women with Gynecologic Malignancies: a Randomized Clinical Trial

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Author’s response to reviews:

To the
Editor-in-Chief
March 17th, 2014
Re: revised manuscript submission

Dear Editor,

Please find enclosed our revised manuscript “A Collagen-Fibrin Patch (Tachosil®) for the Prevention of Symptomatic Lymphoceles after Pelvic Lymphadenectomy in Women with Gynecologic Malignancies: a Randomized Clinical Trial ”, which we re-submit for publication in your Journal.

The present clinical trial is of high scientific interest, as pelvic lymphadenectomy is a very common procedure in women with gynecologic malignancies. Lymphoceles are one of the major complications after pelvic lymphadenectomies. Symptomatic lymphoceles typically require medical interventions and lead to reduced quality of life and increased patient’s discomfort. Additionally, they can also cause postoperative treatment delay impairing the oncologic treatment effect. Despite their prevalence and importance as a postoperative complication very little is known with respect to lymphocele prevention. The present study is the largest randomized controlled trial evaluating the effect of Tachosil® in the prevention of pelvic lymphoceles in women with gynecologic malignancies.

The present study has not been externally funded. Thus, it has not undergone a peer-review by a funding body. The study’s present status is “ongoing”. Neither the present study nor any parts of it have been published or submitted for publication.
We addressed all requested changes:

1. Please include an Ethics statement in the manuscript, with the full name of the Committee that approved the study and a reference number.

   The study has been approved by the Ethics Committee of the Medical University of Vienna, Austria by September 9th, 2011 (EC no.: 740/2011). This information has been added to the manuscript (Materials and Methods, page 12, para 3).

2) Please include details of funding in the Acknowledgments section.

   We added information with respect to the funding of the study to the Acknowledgements section (Acknowledgements, page 16, para 1).

3) Funding - Can you please confirm whether your study protocol has undergone peer-review by the funding body.

   A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/ award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the 'competing interests' section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board.

   The study has not undergone a peer-review process by a funding body. This has been clarified in the manuscript (Acknowledgements, page 16, para 1).

4) Study status - The protocol must be for a study that is ongoing. An 'ongoing' study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.

   The current study status is "ongoing" as patient recruitment is currently ongoing. This has been stated in the cover letter.

5) Related Articles - Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.

   No results of the present study have been submitted or published at any journal. This has been stated in the cover letter.

Thank you for reviewing our manuscript.

Yours sincerely,

Christoph Grimm, M.D.