Reviewer's report

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

Version: 4 Date: 16 June 2014

Reviewer: Florian Heitz

Reviewer's report:

Minor Essential Revisions

Dear editor!

The study designed by Grimm et al. focuses on a very urgent and frequent problem in gyneco-oncologic patients undergoing lymphadenectomy. The paper is well written and the hypotheses are scientifically blameless. However, I believe there are two aspects which should be covered up from the beginning: the technical removal of the lymphatic tissue. Is it just cut by scissors, by Powerstar scissors, by Ligasure or any other sealing technique? There should be tremendous differences between these techniques which might influence the primary outcome on the study. The authors should harmonize and clarify the technique planned to use and should go into literature, if the existing literature describes the techniques used, that they do not overestimate frequency of symptomatic lymphocysts due to inadequate resection technique. Another important aspect seems to be the number of removed lymph nodes, which should be at least counted very thoroughly and the pathologists should be advised to workup the tissues very thoroughly, too. The problem seems to be that the surgeons, aware of the intervention group, might reduce radicality in patients designated to Tacosil patches. This bias should be reduced as much as possible.

Some further notes to be covered:

Background:

1st paragraph: What is the reasons for two licenses in Europe in 2004 and 2007, please clarify.

2.8. Are there Ethics committee approvals for the two other hospitals in Prague and Bochum?

2.8.4 Thrombosis in the lower limb should be taken into account for secondary outcome variable, as it reflects quite often presentations of lymphocysts.

2.11 How do the authors want to make sure, that symptomatic lymphoceles will be treated in their departments and not somewhere else?

2.12 At what time point will the anonymization will take place? How do the authors want to link follow-up data of patients to the surgical intervention, if patients are anonymized?
Level of interest: An article of importance in its field

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'