Author’s response to reviews

Title: Self-expanding nitinol stents of high vs. low chronic outward force in de-novo femoropopliteal occlusive arterial lesions (BIOFLEX-COF trial): study protocol for a randomized controlled trial

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Editorial requirements:

1) Report the title as follows: “Self-expanding nitinol stents of high vs. low chronic outward force in de-novo femoropopliteal occlusive arterial lesions (BIOFLEX-COF trial): study protocol for a randomized controlled trial”

Title has been changed as suggested.

2) Remove the word “cohort” when describing the study design in abstract and in full text.

The word "cohort" was removed.

3) Describe the randomization in the abstract.

Randomization now described in the abstract.

4) Precise the main type of analysis: intention to treat or per protocol?

Changes were made on page 19 (Statistical analysis): “Primarily, analysis will be based on intention-to-treat. If protocol deviations occur, the analysis will be performed both on an intention-to-treat and on a per-protocol basis.”

Reviewer #3:
1) Page 9 - there are values of RRF but not physical definition: is it N/mm²?

Thank you for advice: physical definition for values of RRF and COF are now included (N/mm²).

2) Page 10 - "In patients undergoing TLR the amount of in-stent neointima will be assessed ...." assessed by? By calibrated quantitative angiography?

Sentence has been changed: "In patients undergoing TLR the amount of in-stent neointima will be assessed by calibrated quantitative angiography..."