Reviewer's report

Title: Dental materials' interaction with peri-implant soft tissue: study protocol for a prospective, randomized clinical pilot-trial

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Reviewer: Rubens Albuquerque

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General comments:

The study protocol entitled “Dental materials' interaction with peri-implant soft tissue: study protocol for a prospective, randomized clinical pilot-trial” aims at analyzing the interactions between peri-implant soft tissues and zirconia, lithium disilicate or titanium as abutment materials employing a crossover design. The authors hypothesize that the respective interface differs biomolecularly and immunohistochemically depending on the specific abutment material. The use of biomolecular methods for proteins detection in the peri-implant crevicular fluid, immunohistochemical analysis and the evaluation of clinical parameters, such as plaque index, gingival index, probing depth and bleeding on probing, in a crossover design trial, is proposed to test that hypothesis.

Peri-implant disorders are reported to have high prevalence and little is known about soft tissue interactions with abutment materials for dental implant/prosthesis. Therefore, studies on this matter are of clinical and scientific relevance.

Overall, the proposal is clearly described and feasible.

Specific comments:

Minor Essential Revisions:

1. Despite the protocol being clear, it would benefit from a grammar revision.

2. The main issue with this protocol is related to its crossover design. While there is clear potential for carry over, period and time effects, no explanation has been presented on how these problems are going to be dealt with. Moreover, while statistical methods exist to minimize these problems a sample size of 4 patients per group may not render satisfactory results and so the hypothesis might not be adequately tested. The use of washout periods should be considered and some sort of sample size calculation or power test could perhaps be performed based on similar outcomes of previous investigations as an attempt to minimize the negative impact of those factors. Another possibility for consideration is the withdrawal of one of the three test materials from the investigation.

3. On the methodology, the authors should give further explanation on how the
supragingival plaque will be removed (p. 8, l. 17), what temperature the paper strips will be frozen at (p. 9, l. 9), how the PICF extracts will be analyzed for biomolecular detection of specific markers (p. 9, l. 15), and provide more details on the immunohistochemical/morphometric analyses. Lack of this information could preclude the replication of the work or comparison with related analyses.

4. In addition, there seems to be conflict between the number of PICF samples reported to be collected from the 24 participants (page 11, line 5; 24 samples), and the weekly PICF sampling described on page 8, line 21, considering that the patients will wear each abutment for one month (p. 8, l. 25). Please, revise.

5. The 2nd phrase on page 13, “Due to the huge amount…” is either not clear or out of context.

Discretionary Revisions

1. The title could be more specific since “dental materials” implies a very wide range of materials while only three of them will be investigated.

2. The Background section is interesting but relatively short. Since no results are presented, the content of Discussion could be moved to that section as a complement of the literature review. I see no need for a Discussion topic.

3. The 2nd paragraph of page 10 is repetitive and should be removed.

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