Author’s response to reviews

Title: Comparison of dental plaque reduction after use of electric toothbrushes with and without QLF-D-applied plaque visualization: A 1-week randomized controlled trial

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Author’s response to reviews:

Reviewer reports:

Monique Van Der Veen (Reviewer 1): The paper describes a simple straight forward study on how monitoring plaque during toothbrushing can help to improve plaque removal. It is a first step. Limitations to the study are many. Follow up with a more realistic setting and sample is necessary. Also needed is a longterm evaluation. After how much time does the use of the monitor wear off?

Reply to comment:

Thank you for your comments. If the objective of this study was to evaluate the effect of the newly developed toothbrush on gingivitis, i.e., the biological response, we should have conducted a long term study (of at least 2 weeks). However, the aim of this study was to evaluate the effect of the toothbrush on plaque removal, i.e., the mechanical effect. Moreover, we revealed a statistical difference between the intervention and control groups after only 1 week. Thus, we consider that the study duration was sufficient.

Title: May I suggest that the authors choose a more catching title based on the outcome of the study, while following CONSORT?
Reply to comment:
We have changed the title as follows: Comparison of dental plaque reduction after use of electric toothbrushes with and without QLF-D-applied plaque visualization: A 1-week randomized controlled trial

Abstract:
- The results can be condensed to two sentences. Knowing the 1 week and baseline PHP values for both groups is sufficient. The reader can calculate the change in PHP himself.

Reply to comment:
In accordance with your suggestion, the medians of 1 week and baseline PHP values for the monitor-none-use group were added to the abstract of the revised manuscript.

Introduction:
- no comments. One question: is the bristle distribution in the bristle head of the electric toothbrush with QLF-D monitoring built in different than that of the bristlehead of an oscillating/rotating toothbrush from say Oral-B?

Reply to comment:
Yes, the bristlehead of new device was manipulated using the ready-made bristlehead of an oscillating/rotating toothbrush such as those from Oral-B.

Methods:
- Why was a parallel design chosen, and not a cross-over one?
Reply to comment:
As there was no disadvantage in monitor-none-use group, the parallel design was chosen.

- Why was smoking not an exclusion criterion?
Reply to comment:
None of the participants were smokers. However, we have added smoking as an exclusion criterion (p7, line 7).

What do you expect of the amount of bias caused by:
a) The fact that blinding of the study participants was not possible? Irrespective of your claim that participants were blinded for treatment intervention: "To ensure blinding with regard to monitor usage, the monitor-non-use group first performed the procedures for 1 week, followed by the monitor-usage group."

Reply to comment:
Although the monitor-use group used the monitor, participants recognized that the aim of this study was to evaluate the effect of the toothbrush on plaque removal. Moreover, neither group was aware of the toothbrush used in the other group. We have added this statement in the methods section (p10, line 10).
b) The dependence of the dental students on the researchers for their grades at dental school?

Reply to comment:
All participants were school of dentistry students. All researchers were staff members of the school of oral health sciences. As such, the students did not depend on the researchers for their grades.

- What is the need for determining the amount of plaque AND the change in amount of plaque?

Reply to comment:
As you have indicated, the change in amount of plaque was superfluous. Table 3 has been deleted.

- Why is the gingival index determined when having gingivitis was an exclusion criterion?

Reply to comment:
The gingival index was evaluated to ensure that the toothbrush used in this study had no harmful effect on the gingiva.

- Did participants use the toothbrush at home or at the dental school?

Reply to comment:
Participants used the toothbrush at home. This was added to the methods section (p10, line 11).

- Why do you choose to present all values as mean ± standard deviation or median with upper and lower limits, when only non-parametric tests are used for comparison between groups or changes in time.

Reply to comment:
As you have indicated, the mean ± standard deviation is not necessary. The mean ± standard deviation values were deleted.

Results:
- Demographics of the two groups (age and sex) can simply be mentioned in the text. There is no need to include this in a data table. Data in Tables 1 and 2 can be combined. Table 3 is not needed. There was no change observed in GI and SEOH, then testing a difference between groups for this (non-existent) change is superfluous.

Reply to comment:
It is important to keep Tables 1 and 2 separate to indicate that there was no statistical difference between the intervention and control groups. Similarly, although no change in GI or SEOH was observed in the two groups, we believe that all statistical data should be included. As you have indicated, Table 3 is superfluous. We deleted it in the revised manuscript.
Discussion:
- What effect on the gingiva was anticipated from the QLR-brush, that could be reflected in the GI?

Reply to comment:
Due to the camera device, the height of head of the toothbrush was higher than that of a common electric toothbrush. However, the unique shape did not have a harmful effect. Moreover, irradiation of light with a wavelength of 400 nm did not induce inflammation or scalding of the gingiva.

- You state that: "Participants in the present study were not provided with any educational information on oral health behavior and tooth brushing was done individually." However the participants were dental students.

Reply to comment:
It may be difficult for users to properly interpret the data from the QLR-D-applied monitor system. The results of this study imply that educational information may be needed even for dental students to accurately operate this new electronic toothbrush with a monitor. On the contrary, visual information from the monitor may have a slight impact on the user’s health behaviour.

- Among the limitations of the study I am missing a discussion on bias induced by hawthorn effect (1 week of study duration) and the non-blinding of the participants. Participants must have been aware that the QLR brush was subject of study and a non-monitor was not. Interventions must have been announced to participants in the information letter prior to giving informed consent. If not international standards for scientific integrity and ethics are not met.

Reply to comment:
We expected the Hawthorne effect in the two groups to be similar. The monitor-non-use group was informed that the toothbrush was newly developed and that the aim of this study was to evaluate the plaque-removable effect of this toothbrush. The monitor-non-use group did not know about the QLR-D visualizing system, as the toothbrush used by the monitor-non-use group did not emit light.

Bernd W. Sigusch (Reviewer 2): Dear authors,
Thank you for this interesting study. It was shown that optical control has a great influence on the efficiency of mechanical plaque removal. Overall, the study is of sufficient quality. Only, minor spell checks are required.

Reply to comment:
Thank you for your comments. The manuscript has been checked by an English editorial service.