Author's response to reviews

Title: The NTI-tss device for the therapy of bruxism, temporomandibular disorders, and headache: where do we stand? A qualitative systematic review of the literature

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Author's response to reviews: see over
Stapelmann / Türp:
“The NTI-tss device for the therapy of bruxism, temporomandibular disorders, and headache – where do we stand? A qualitative systematic review of the literature”

Dear Dr Graham,

We would like to thank the referees for their peer reviews and their valuable suggestions. In the following, we shall address their comments point by point.

Sincerely,

Professor

Referee 1
Major compulsory revisions
(1) Revision of the abstract.
Answer: We have made the changes suggested by the reviewer. However, in the last sentence – “as an emergency device in patients with acute temporomandibular pain and, possibly, restricted jaw opening” –, we have not changed “temporomandibular pain” to “TMD”, because both “temporomandibular pain” and “restricted jaw opening” are symptoms embraced in the term “TMDs”.

(2) On top of page 16:
Answer:
As suggested by the reviewer, we have added “with follow-up appointments” after the word “compliant”.
Discretionary revisions
(1) Table 9: N.N.
Answer: N.N. stands for “Nomen Nescio” (latin: “I do not know the name”, here: unknown author).

Referee 2
Major compulsory revisions
(1) Methods: What were the specific selection criteria?
Answer: Our aim was identifying ALL relevant articles that have been published regarding (a) the efficacy and/or effectiveness and (b) complications and/or side effects related to the use of the NTI-tss device.
Accordingly, we have made the following change:
- Last paragraph of the introduction: we have replaced “to summarize the identifiable documented cases” by “to summarize all identifiable documented cases”.
Since our approach was very broad, the two selection stages typical for conventional systematic reviews with a narrow and focused question, did not apply in our case.

(2) Methods: Side effects and MAUDE database
Answer: The reviewer raises an important point. We agree that the case reports are documents with a low level of evidence. However, no other sources are available thus far that report about possible side effects associated with the use of the NTI-tss device. Therefore, we have added the following part in the discussion: “In the hierarchy of scientific evidence, case reports represent a low level (cf., Table 10). Nonetheless, considering the absence of other data we believe that the publications summarized in Tables 20 and Table 21 deliver valuable information and convey an important message to the clinician (as well as to the patient), namely that the use of the device is not free of risks. Unfortunately, no risk quantification is possible at this point in time.”

(3) Conclusions: “be more cautious when talking about side effects”
Answer: We concur with the reviewer that the subordinate clause “since the risk of potential side-effects appears to be greater for the NTI-tss device as compared to a stabilization appliance” is not based on very hard data. Hence, we have modified the sentence as follows: “However, to avoid potential side-effects, it must be ensured that the patient is willing to return regularly to the dentist’s office for control sessions and, if needed, re-adjustments.”

(4) Conclusions: “the first dotted conclusion – “A therapy with an occlusal stabilization appliance aimed at reducing temporomandibular pain was unsuccessful (i.e., no change or even increase of pain)” – is not supported by evidence presented in this review”.
Answer: We have deleted this conclusion.

Minor essential revisions
(1) Abstract: “modify when applicable as per my suggestions”
Answer: We have made appropriate modifications.

(2) Results: Flow diagram
Answer: We believe a flow diagram is not needed because we have considered every published article related to the NTI-tss device. We have presented our search
strategy with maximum transparency allowing the reader to repeat the search if needed.

(3) Results: Typo in the second paragraph of results (Figure 2).
Answer: We have replaced “(Figure 2)” by “(Figure 3)”. Thank you for this hint.

(4) Results: Only one reference is cited.
Answer: We have replaced “[22]” by “[9, 10, 21, 22]”. Thanks!

(5) Discussion: “I suggest to remove the last sentence of paragraph one.”
Answer: We agree with the reviewer and have removed the following sentence:
“Consequently, Straus et al [28] noted that “[i]f the study wasn’t randomized, we’d suggest that you stop reading it and go on to the next article in your search” [28].”

(6) Discussion: Side effects.
Answer: Please see point (2) in Major compulsory revisions. In Table 20, we have mentioned the side effects reported in RCTs.

Referee 3
Major compulsory revisions
(1) “Figure 2 cannot be accepted”
Answer: There are definitely no carious lesions in the dentition of the depicted lady (a dental hygienist). On the upper right canine, she has a small jewel.

(2) “the tables are extended, needing to be summarized”
Answer: We agree that the tables are extended. However, for the sake of traceability and transparency, such a detailed description is necessary.

(3) “the second conclusion is inconsistent”
Answer: The rationale for the second conclusion has been laid out in the Discussion. Hansen et al [22] and Kavaklı [21] have shown that insertion of the NTI-tss device leads to a significant reduction in EMG activity of jaw closing muscles during clenching or grinding. Data from clinical investigations [38] suggests that a decrease of EMG activity may be associated with a pain reduction in patients with masticatory muscle pain.