Author’s response to reviews

Title: Clinical complications during treatment with a modified Herbst appliance in combination with a lingual appliance

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Author’s response to reviews: see over
Dear Prof. Stamm,

we are grateful for the opportunity to revise our manuscript. Changes or additions to the manuscript text and tables have been highlighted using a red font.

We would like to address the comments made by the three reviewers as follows:

**Reviewer #1 / Thomas Stamm:**

**Comment:**

*Ethical approval is mentioned in the method section. However a reference number is missing. Please provide.*

**Answer:**

A reference for ethical approval has been added: (#1220-2011; MHH, Hannover, Germany).

**Comment:**
The authors emphasized the comparison with data reported in the literature. However, there is no search strategy mentioned in the method section to ensure that all studies which reported complications are included for comparison. Please provide information which studies were retrieved and which were included or excluded.

Answer:

The following section has been added to the ‘Method’ chapter:

“Literature screening strategy

In order to retrieve relevant data related to the subject of complications following Herbst appliance treatment, an unrestricted electronic search of PubMed was performed in December 2014. In an attempt to compensate for a holistic, systematic review of the literature using all available databases, the PubMed search query [(Herbst) AND orthod* AND (fract* OR compli* OR fail*)] used here was provided with robust truncations, as suggested earlier by Stamm and Hohoff.22 Title and abstract screening was performed in order to eliminate those papers not relevant to the subject of fracture rates following Herbst appliance treatment. Of a total of 39 publications, seven were identified as being relevant for a potential comparison with the findings of this study. In addition, electronic search was followed by a manual search up of the list of references in those manuscripts identified as being relevant to the subject of Herbst appliance failures”.

In addition, the following information has been added:

“Latkauskiene et al. reported a total of 46 Herbst appliance fractures for a sample of 175 subjects (26.3%) undergoing fixed functional pre-treatment prior to initiation of multi-bracket treatment in some cases.24 “

We are adding the following publications to the list of references:


Reviewer #2 / Dennis Boettcher:

Comment:
The subjects and methods are well described. But there is not mentioned how the patients were chosen. Were there any exclusion or inclusion criteria? The further information about the study group is sufficient and the work could be carried out again.

Answer:
Consecutive patients during or following completion of treatment with the WIN-Herbst appliance were included. The existing section on patient recruitment has been complemented as follows:

“The files of all patients currently in active treatment or having undergone complete treatment using the WIN Herbst appliance with a corresponding lingual appliance (Figures 2 und 3) in one orthodontic center (Bad Essen, Germany) were included and screened with a caesura made on September 9, 2014. That is, the single inclusion criterion was treatment with the WIN Herbst appliance. There were no exclusion criteria other than absence of active or completed WIN Herbst treatment. The initial Angle-Class II malocclusion extended to at least 3/4 cusps of distal occlusion in all subjects”.

Comment:
The results were compared to data from other authors and well weighted. But there is no information given about the search strategy.

Answer:
A section on the search strategy used here has been added to the ‘Method’ chapter.
Please see also my reply to the respective comment of reviewer #1.

Comment:
Table 3 contains data about different publications but there is no distinction between WIN and Incognito in the column „Lingual Apparatur + Herbst“.

Answer:
The information that the sample used by O’Keefe was based on Incognito-treated subjects has been given in the text:
“Compared to a different combination of a Herbst appliance with a lingual appliance (Incognito), the fracture rate could be significantly lowered.21“
In addition, informations on the system used (Incognito or WIN) have been added to Table 3.

Comment:
Further it would be fine if there would be the English expression (Lingual appliance + Herbst).

Answer:
Thanks for making us aware of having used a German term, accidentally. It has now been translated.

Comment:
On page 8 there is a missing „)“.
Thanks! It is now provided.

Reviewer #3 / Heike Korbmacher-Steiner:

Comment:
Thank you for your paper! Although it is clearly written, I have some complaints about some issues.

MINOR ESSENTIAL REVISIONS

1. I recommend professional editing for the manuscript.

2. The manuscript should be submitted, according to Head and Face Journal style, in block set.

3. Please maintain to the recommended citation style of Head and Face Magazine. 
   http://www.head-face-med.com/authors/instructions/research#formatting-references
   „All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends.“

Answer:

ad 1. Prior to submission, the manuscript has been sent to a (British) native speaker, for professional editing. However, if there may be still some major linguistic deficiencies, we should be very thankful for making us aware of those particular sections.

ad 2. The manuscript has now been set to block set.

ad 3. We have corrected the style of citation to conform with the author guidelines provided by Head and Face Medicine.

Comment:

MAJOR COMPULSORY REVISIONS

1. In this study only a lingual WIN-Herbst modification was tested. However the authors state in their clinical conclusion, that “the WIN-Herbst appliance was found to be superior to comparable vestibular Herbst appliances”. According to the authors this conclusion is based on comparative studies.
In the present study all patients were treated in one orthodontic practice, which is specialized in lingual therapy. The limitation of such a single-center approach results in the expected superior qualification of the technical staff and the clinicians. A multi-center design would have been desirable at this point, best case with a comparison of a buccal anchored Herbst-appliance in different practices to ensure better comparability for the reader. If this is not possible, the authors should mention this limitation in their manuscript.

**Answer:**

We have addressed this limitation by adding a new section „Study limitation“ (see my response to comment #2 below, for details).

**Comment:**

2. References and contents of cited sources:

   Silva et al.: Page 3 original publication Fulltext-pdf: „For all patients, the Herbst appliance was activated initially to an edge-to-edge incisor relationship and was used for a mean of 12 months (SD 2.15 months; range, 10 to 18 months)“. This different activation might have an impact on complications and should at least be stated in the table.

**Answer:**

Thank you very much for this comment! Indeed, a section on the subject of differences in activation has been part of the first draft of the manuscript, but was omitted prior to submission. This was, in part, due to a lack of reporting of the mode of activation by some of the author groups whose studies have been used for a comparison with our findings.

I am happy to provide a section on the subject in a response to your request. Also, differences in appliance specifications and also modes of activation have now been reported in Table 3 for those studies providing respective details.

**Added section:**
"Study Limitations"

This study reports the proportions of complications experienced with the lingual WIN-Herbst appliance, and compares the findings to proportions of complications resulting from the use of vestibular Herbst appliances. While the type of appliance activation (stepwise advancement, or bite jumping) may be seen as a factor that has a potential impact on appliance fractures, this has not been given consideration in our comparisons as the reporting of the mode of activation has not been provided by all author groups publishing on the subject. The classical description of Herbst activation includes an initial edge-to-edge or 'bite-jump' activation [6; 7; 10]. This type of activation was, for instance, adopted by Silva et al. [16]. As previously reported elsewhere [14], a step-wise mode of activation (as has been performed in the patients of this trial) may potentially have an impact on the duration of getting accustomed to the appliance, as well as on lower muscular counter-force activities, and thereby may contribute to a decrease in proportions of appliance failure.

An additional limitation to generalisability of our findings may be seen in the fact that all participants of the present study have been treated in one orthodontic center specialised in lingual orthodontic therapy, with a resulting superior qualification of the technical staff and clinicians, compared to centers that are not providing lingual orthodontic therapy, on a routine basis. On the other hand, the findings on proportions of vestibular Herbst appliance fractures have also been derived from orthodontic offices whose staffs have been trained in the use and maintenance of vestibular Herbst appliances. In general, attempts to interpret or generalise findings on proportions of orthodontic appliance failures should consider the fact the data are mostly based on treatments performed by experienced orthodontic professionals, and may differ in quality from treatment results of inexperienced teams.

Comment:

Furthermore, I may remark that (see table 1 in the cited article) 58.8% of the lower cantilever Herbst group had 0 „complex complications". In order to clarify the different appliances (a
removable mandibular splint versus a fixed WIN-system) a comment on the different designs should be mentioned in the table file.

**Answer:**

*We are happy to provide details on differences in appliance specifications in the revised Table 3 for those studies providing respective details.*

<table>
<thead>
<tr>
<th>Appliance specifications</th>
<th>Vestibular appliance + Herbst</th>
<th>Lingual appliance + Herbst</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Upper / lower cast-splint</td>
<td>Upper / lower fully customised WIN Herbst / bracket system</td>
</tr>
<tr>
<td></td>
<td>Upper / lower cast-splint</td>
<td>Upper / lower fully customised WIN Herbst / bracket system</td>
</tr>
<tr>
<td>(A) Upper steel crowns (1st molars), lower removable acrylic splint</td>
<td>(A) Upper steel crowns (1st molars), lower removable acrylic splint</td>
<td>(A) Upper steel crowns (1st molars), lower removable acrylic splint</td>
</tr>
<tr>
<td>(B) Upper / Lower steel crowns (1st molars)</td>
<td>(B) Upper / Lower steel crowns (1st molars)</td>
<td>(B) Upper / Lower steel crowns (1st molars)</td>
</tr>
<tr>
<td>Mode of appliance activation</td>
<td>Not reported in detail</td>
<td>Not reported in detail</td>
</tr>
<tr>
<td>Number of patients (n)</td>
<td>28</td>
<td>316</td>
</tr>
<tr>
<td>Frequency of severe complications (n)</td>
<td>94</td>
<td>755</td>
</tr>
<tr>
<td>Proportion of subjects with severe complications (%)</td>
<td>82.1</td>
<td>63.3</td>
</tr>
<tr>
<td>Duration of Herbst treatment (months)</td>
<td>6-7</td>
<td>7</td>
</tr>
<tr>
<td>Cumulative treatment time (months)</td>
<td>189</td>
<td>2.212</td>
</tr>
<tr>
<td>Mean interval without severe complications (months)</td>
<td>2.0</td>
<td>2.9</td>
</tr>
</tbody>
</table>

**Comment:**

Although taking all these issues into account, I can highly suggest to accept this manuscript, because -as the authors stated- lingual therapy is up to date and the modification of the Win-
system is interesting for many readers. However, I have to return this manuscript to the authors with minor revision because the above mentioned limitation (especially the conclusion “Win-Herbst is superior to competing systems”), necessarily needs to be attenuated throughout the whole paper to allow an appliance independent comparison.

Answer:
The statement as given above has been used only with the restriction ‘in terms of clinical sturdiness’ and was not meant to be extended to the quality of clinical treatment results. In order to make this clear, we have added the limitation to the conclusions in the abstract and manuscript text as follows:

“Evaluated in terms of severe or treatment-intensive complications, a mean complication-free interval of 27.8 months has been calculated. Taking into consideration the step-wise mode of activation used here as well as the differences in the design of the various Herbst appliances, the Herbst appliance which we investigated appears superior to conventional band- or splint-supported appliances when compared in terms of clinical sturdiness”.

(Original:

- Evaluated in terms of severe or treatment-intensive complications, a mean complication-free interval of 27.8 months has been calculated, which makes the Herbst appliance which we investigated appear superior to conventional band- or splint-supported appliances when compared in terms of clinical sturdiness.

Likewise, the conclusion of the abstract has been complemented as follows:

“Conclusion: In terms of clinical sturdiness, and taking into consideration the step-wise mode of activation used here as well as the differences in the design of the various Herbst appliances, the WIN-Herbst appliance was found to be superior to comparable vestibular Herbst appliances”
We highly appreciate the time all three reviewers have devoted to the improvement of our submission, and would like to express our thank for the opportunity to revise our manuscript.

Sincerely,

Michael Knösel