Author’s response to reviews

Title: In-vivo durability of a fluoride-releasing sealant (OpalSeal) for protection against white-spot lesion formation in orthodontic patients

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

thank you for giving us the opportunity of revising our manuscript. We would like to address the comments by the two reviewers as follows:

Replies to the Reviewer’s reports

Reviewer: Gero GK Kinzinger

Reviewer’s report:
This is a paper of elevated clinical relevance as it approaches the problem of decalcification during orthodontic bracket treatment from a new direction, which is the problem of bracket periphery sealant abrasion. The paper provides clinical data of abrasion of one sealant. As has correctly been pointed out by the authors, no investigation of white spot occurrence was
performed, so loss of sealant does not necessarily mean that decalcification will occur. Oral hygiene was screened before incorporation of brackets, and then at 14 days after incorporation of brackets. It should be mentioned under study limitation that subjects were allocated to the groups of adequate or inadequate oral hygiene based on these two assessments, not considering potential improvement or deterioration afterwards.

**Answer:**

The following section has been added to the section „Advantages and drawbacks of the study design“:

*Also, oral hygiene was screened before placement of brackets, and then again 14 days following incorporation of brackets. That is, subjects were allocated to the groups of adequate or inadequate oral hygiene based on these two assessments, not considering potential improvement or deterioration afterwards.*

**Reviewer:** Athanasios Athanasiou

**Reviewer’s report:**

Manuscript "In-vivo durability of a fluoride-releasing sealant (OpalSeal) for protection against white-spot lesion formation in orthodontic patients"

This is a prospective clinical trial which aims to assess in vivo the durability of a sealant for a period of 26 weeks. Although the sealant is used for improving protection against white-spot lesion formation in orthodontic patients, its effect was not part of the present investigation. The study concluded that one single application of the sealant is unlikely to last throughout the entire orthodontic treatment by fixed appliances.

My main reservation with this report relates to the absence of assessing the method’s error of the two highly subjective indices used, namely API (approximal plaque index) and ARI (adhesive remnant index).

**Answer:**
We are quite aware of the possible objection that chair-side assessments instead of judging
photographies are lacking the opportunity of performing method-error assessments, but also
bring the opportunity of increasing the sample size during collection of clinical data, in turn.
We therefore acknowledged and highlighted the situation in the section „Advantages and
drawbacks of the study design“:

“Integrity and condition of the OpalSeal layers was assessed chair-side by a clinician who
was blinded to the patient’s trial time schedule, while notes were made by a study nurse,
similar to previous studies on the topic of WSL formation in orthodontic patients [4]. The
assessment of photos would not have been feasible here, as every single tooth would have
to be photographed while being illuminated by the black-light lamp. However, as an
advantage, the trial sample size and numbers of performed assessments are remarkable”.

We are convinced that the findings based on our methodology may nonetheless –and within
the limitation of taking into consideration potential errors in classifying extents of sealant
residues at least in those cases with some sealant left- contribute to the knowledge on the
topic, as did previous studies on e.g. white-spot caries prevalence and incidences
implementing the same chair-side technique of data collection [4].

If the editor overcomes this serious short-back and decides to accept the paper for
publication the following should be also taken into consideration:

1. The exclusion and inclusion criteria applied should be written clearly and listed separately.
For example the sentence “Single teeth exclusion criteria were extractions and teeth that
were not bracketed” does not make sense.

Answer:

The section has been rewritten as follows:

Subjects were included upon meeting the following inclusion criteria:

- upcoming indirect Damon-3 (Ormco, Orange, CA, USA) bracket placement of least of
  sixteen teeth,
• application of a sealant (OpalSeal, Ultradent Products, South Jordan, Utah) on that same appointment, and
• having given consent for participation and accepting follow-up assessments during recall visits.

Subject were excluded upon refusal of sealant application, or less than sixteen teeth bracketed, or if they disagreed to participate. Other than exclusion of subjects, single teeth of included trial subjects were not assessed by this study in case they were not bracketed on the same appointment, or in case they were subject to upcoming extraction.

2. The text “,. and subsequent bonding application, followed by indirect bonding ......” confuses since there was only one bonding procedure. This sentence should be rewritten.

Answer:
We agree that the use of the term 'bonding' may have been misleading here, as it refers to both the bonding of fixed appliances, but also to the bonding material that is part of the composite adhesive system used here.

The section has been rewritten as follows:

Following cleaning of tooth surfaces with fluoride-free pumice, the bonding adhesive and sealant application routine was carried out following manufacturer’s instructions and included a 15 s interval of etching with 37 % phosphoric acid of the complete labial enamel surface, and subsequent bonding application, followed by indirect bonding of fixed appliances using chemically-cured Monolok2 composite adhesive system (Rocky Mountain Orthodontics, Denver, Colo, USA). Adhesive residues have been removed prior to sealant application. According to the manufacturer’s instructions, OpalSeal was gently air-dried following application, prior to light-curing for 20s per tooth (Bluephase C8, 800mW/cm2, IvoclarVivadent, Schaan, Liechtenstein).
3. In Parameter 1, the API (approximal plaque index) was mentioned without any reference, information regarding its validity and previous application information.

**Answer:**

The text is complemented by the following information and references:

*The approximal plaque index (API) has been introduced in dentistry for a quick assessment of oral hygiene status [8]. Although being based on more or less subjective decisions that are made chair-side, API assessments have been established as a basic clinical methodology used in research on the subject of cariology and periodontology [9]. Oral hygiene status was screened using the API (approximal plaque index) for each bracketed tooth, as a yes/no decision (results given in % of teeth with plaque) prior to bracket placement and sealant application at T0, and after 14 days in treatment (T1).*


4. Since ARI (adhesive remnant index) was introduced in the bibliography many years ago for assessing bonding material remaining its name should not be used in this study. Authors may state that they used the same scale for quantity material description as in ARI, for measuring the remaining varnish.

**Answer:**

The text has been changed as follows:

*Abatement of the varnish was parameterized using a classification from 0 to 3 that was derived concepted in analogy to from the adhesive remnant index (ARI, [8]): (3=sealant*
Assessment of the fluorescing sealant preservation was by a black-light lamp, using a classification that was concepted in analogy to the modified ARI index:

The authors use many terms derived from German orthodontic terminology, which are not used in the English orthodontic literature. Therefore, these terms should be corrected as follows:

- multi-bracket treatment: fixed appliances orthodontic treatment
- fixed orthodontic treatment: fixed appliances orthodontic treatment - bracketing: bonding of fixed appliances
- fixed orthodontics: orthodontic treatment with fixed appliances.

**Answer:**

Terminology has been changed as suggested.

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**Further changes**

The section "Ethical approval" has been complemented by details on the subject including provision of the corresponding registration number.

We would like to thank both reviewers for the time they devoted to an evaluation of our manuscript. We believe that the corrections and alterations to the manuscript which we have undertaken are in accordance with the reviewers’ requirements and have added to the quality of our manuscript. We hope that the revised manuscript is now suitable for publication.

Sincerely,

Michael Knösel