Author's response to reviews

Title: Statin using periodontitis patients have markedly fewer periodontal lesions - a retrospective study

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Author's response to reviews: see over
Helsinki, March 6, 2008

Dear Editor,

Thank you for your prompt answers to our enquiries and brisk elaboration on the manuscript. Please do find in this Word-document both our cover letter and point-to-point answers to the reviewer’s comments.

We feel confident to remind and point out that the statistical experts of the Journal [Reviewer 3 and Reviewer 4] do have opposing opinions of the cross-sectional design of the study.

Please do contact by e-mail if you have any further questions or suggestions,

Yours,

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In the following pages you will find our responses to the comments of the four (4) referees.

Referee 1 Björn Klinge  
Referee 2 Francesco D’Aiuto  
Referee 3 (statistical expert) Girdhar Agarwal  
Referee 4 (statistical expert) Francisco Gude

We would be grateful if you could address the comments in a revised manuscript and provide a cover letter giving a point-by-point response to the concerns. As you will see from the reports, Referee 3 raised several concerns regarding the design of your study, and the conclusions drawn. While we acknowledge that at this point you cannot change your study design to a case-control study, it is not possible to draw conclusions on a causal relationship based on a cross-sectional study, as both statistical referees point out. For this reason we would like you to limit your discussion to association relationships which are able to be inferred from a cross-sectional study, as pointed out by Referee 4.
Point-to point anwers to referee 1 of manuscript

Version: 3 Date: 06 March 2008

Referee Name: Björn Klinge

Comment: accept without revision

Response: we accept the acception without further response.
Point-to-point answers to referee 2 of manuscript

Version: 3 Date: 06 March 2008

Reviewer Name: Francesco D’Aiuto

Major essential revisions: none

Minor essential revisions:

1. The title word 'cross-sectional' is changed to 'retrospective' as suggested by the reviewer

2. The need for a properly designed study to address the relationship of PIBI and is stated clearly in the last sentence of the revised conclusion:

Page 11 Lines 11-12 ’...if confirmed by consecutive prospective studies.’

3. The reviewer states that it was "probably not possible" to have a calibration exercise of the examiners, and this should be mentioned in the discussion on the limitations.

Page 8 Lines 20-23
"The retrospective nature of the study places limits to external calibration of the measurements, and limits the interpretation of our measurements to the realm of a university dental clinic and the results are not necessarily applicable to a local dentist’s practice.”
Comment 1: The reviewer points out that this is a retrospective study.

Response to comment 1:
The title of the manuscript is changed accordingly, and the text revised as suggested.

Comment 2: The study should be planned as a case-control study.

Response to Comment 2:
As the Editor suggests in the editorial communication letter, we do not change the study design to a case-control design.

Comment 3: The possible confounding factors should be used to match controls to cases.

Response to comment 3:
As outlined by the Editor, there is no need to this matching.

Comment 4: The possible confounding factors are age, sex, diabetes, smoking etc.

In the light of previously published literature, all the above mentioned factors are considered increasing the risk of periodontal tissue injury. Thus we do not have a need to adjust for these factors.

Comment 5: The distribution is uneven.
Yes it is, please see the above response. Yes, the results will be biased so that the 'cases' do have more risk factors and a better outcome than the 'controls'.

Comment 6: The observations are count data. so t-test would not be proper.

Response to comment 6.
A count follows Poisson distribution that approaches normal distribution. We feel that with the data, the t-test is robust enough since the counts in a data set this large follows approximately the normal distribution. The additional raw data tables are provided on request.

Comment 7. Table 2 is very confusing.
Response to comment 7. We apologise the for the difficult nature of the terminology of the field.

Comment 8. Table 3 is not required.
response to comment 8: Table 3 was asked for by the reviewers during the process. We shall not remove it.

Comment 9. From an observational study, the conclusive inferences cannot be drawn.
Response to comment 9: conclusions revised accordingly, to with draw any speculation.
Comment 1 Study of association should be clearly mentioned in the objectives.

Response to Comment 1 The manuscript objectives and conclusions have been revised:
Title: cross-sectional study -> retrospective study
Objective: effect on [clinical markers] -> "The aim of this study was to examine the association of statin use and clinical markers of chronic periodontitis."

Comment 2 Statin use should be included in the linear regression analysis.

Response to Comment 2: During the review process, the fact that the periodontal indices measured do [approximately] follow normal distribution may have been obscured from the statistical experts. Having plotted the raw data, and having examined the distributions, we have not used distribution-free tests for the comparison. In essence, we do not consider the linear regression most appropriate for our data but only wish to comply to the suggestions of the reviewers.

Comment 3 Table 3 is lacking footnote for RA. What is RA?

Response to Comment 3: Footnote added.
"RA stands for rheumatoid arthritis."

Discretionary revision:
Comment to discretionary revision:
"effect of statins" has been replaced by "association of statin use"