Author’s response to reviews

Title: Minimizing risk of customized titanium mesh exposures – a retrospective analysis

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Author’s response to reviews:

Submission of manuscript

`Minimizing risk of customized titanium mesh exposures – a retrospective analysis`

Dear Mrs McMillan,

On behalf of my coauthors, thank you again for considering our research article `Minimizing risk of customized titanium mesh exposures – a retrospective analysis` for publication in your journal BMC oral health. The manuscript has been revised to address your comments, and a detailed point-by-point response to each point is attached. A clean version of our manuscript is also attached.

Yours sincerely,

Dr. Amely Hartmann

Dear Editor/Reviewer,

Thank you for critically assessing our manuscript for publication in BMC oral health.

We wish to thank you for suggested improvements.
1. We note that there are images of mouths in the manuscript but apparently no consent or ethical approval required for this study.

For all research involving human subjects, informed consent to participate in the study should be obtained from participants (or their parent or guardian in the case of children under 16) and a statement to this effect should appear in the ‘Ethics approval and consent to participate’ section of the Declarations including whether the consent was written. When reporting on such studies, individual patient data should not be made available unless consent for publication has also been obtained.

If the need for informed consent has been waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this with details, including the name of the Board or a reference to the relevant legislation in the ‘Ethics approval and consent to participate’ section of the Declarations.

Response:

We apologize for this inaccuracy. All patients accepted the publication of the images of their mouths and signed written informed consent. No patients under 16 (18) years were enrolled.

According to your suggestion we added this information to the Ethics approval and consent to participate section.

p.15, l.2-l.15:

Ethics approval and consent to participate

This is a clinical non-interventional monocentre study. It was performed retrospectively during the clinical routine without any further consequences for the patient. Data were anonymized and processed in accordance with the 2013 Declaration of Helsinki on medical protocol and ethics (Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks 2016). Due to the character of the study no approval by the local ethics committee was necessary (Regulatory of the ethic committee of Rhineland-Palatinate and described in Gaus et al.[24]). No administrative permissions and/or licenses were acquired by the team to access the data used in the research due to the character of the study. Using a human study design, written informed consent was obtained from patients.

Consent for publication

Using a human study design, written informed consent was obtained from patients.