Author’s response to reviews

Title: Factors affecting the early failure of implants placed in a dental practice with a specialization in implantology – a retrospective study

Authors:

Johannes Krisam (johannes.krisam@imbi.uni-heidelberg.de)
Larissa Ott (larissa.ott@med.uni-heidelberg.de)
Stephanie Schmitz (dr.stephanie.schmitz@web.de)
Anna-Luisa Klotz (anna-luisa.klotz@med.uni-heidelberg.de)
Aida Seyidaliyeva (aida.seyidaliyeva@med.uni-heidelberg.de)
Peter Rammelsberg (peter.rammelsberg@med.uni-heidelberg.de)
Andreas Zenthöfer (andreas.zenthoefer@med.uni-heidelberg.de)

Version: 1 Date: 11 Jul 2019

Author’s response to reviews:

Dear Prof Messin,

please find attached our revised manuscript “Factors affecting the early failure of implants placed in a general dental practice – a retrospective study” for publication in BMC Oral Health.

We want to thank you and the reviewers for the helpful and important comments which we all have addressed and listed point-by-point.

We think that the manuscript considerably improved due the revision.

We are looking forward to you decision.

Yours sincerely

Andreas Zenthöfer
Factors affecting the early failure of implants placed in a general dental practice – a retrospective study

Ref: OHEA-D-19-00188

Responses to reviewers:

Reviewer 1

Comment 1: It is important to point out the retrospective nature of this study as a major limitation. This is mentioned in the discussion but should be emphasized more.

Response to comment 1: Thank you for this comment. You are right we now have emphasized the possible bias of the retrospective nature of the study in more detail, e.g. in discussion (strength and weakness of the study).

Added on page 13, second paragraph: “...Nevertheless, when target variables and statistical approaches are selected retrospectively for existing data, a certain fuzziness might well be expected; for smokers, for example, the quantity of cigarettes smoked per day was not available. Another bias caused by the retrospective study design can be found in ‘non-responding participants’; controlling for drop-outs is more transparent in prospective studies. In fact, our study achieved a high response rate of approx. 90%, which means that the bias is lower than that usually accepted in retrospective studies.”

Comment 2: Smoking and diabetes are mentioned in the discussion but comparison of implant failure rates related to diabetes and smokers should be included in the results. Additionally, any data on the level of diabetic control (HbA1c levels) and quantity of smoking should be included in the analysis.
Response to comment 2: Thank you for this comment. We now address / explain this point in materials & methods, in the results as well as in the discussion section. Again, a limitation of the retrospective study design, e.g. the exact number of cigarettes smoked by the patients or their glycemic values were not available in the medical records and therefore not for statistical analysis. Thus, these variables were only assessed dichotomously (yes / no).

We added on page 5 (Target variables): “For the variables smoking, diabetes, and history of periodontitis, only their presence or absence was noted and used in statistical analysis(each considered as yes/no). A more detailed breakdown (for example, of the number of cigarettes smoked or glycemic values) was not available.”

We added on page 9, first paragraph (Results): “None of the other target variables, including smoking (failure rate: 6.8%; p = 0.484) and diabetes (failure rate: 5.3%; p = 0.977), reached a level of statistical significance or a statistical trend (p > 0.1). Detailed numbers of failures and comparisons of implant losses are presented in Table 1.”

We added on page 13, last paragraph (strengths and weaknesses of the study): “Nevertheless, when target variables and statistical approaches are selected retrospectively for existing data, a certain fuzziness might well be expected; for smokers, for example, the quantity of cigarettes smoked per day was not available.”

Comment 3: The mean time until implant loading was 81.9 days. The reason for this timeline should be discussed and what clinical factors were used to determine when the implants were ready for prosthesis delivery should be described. Many publications advocate longer integration times prior to restoration so this should be discussed.

Response to comment 3: Thank you for this hint. This was an inaccuracy, sorry for this. 81.9 was the standard deviation of the mean healing time of 147.8 days.

We added / changed on page 8 (end of first paragraph): “The mean healing time for the implants before the final prosthesis was attached and loaded was 147.8 (81.9) days (154.3 (79.9) and 137.8 (91.2) days in the maxilla and the mandible, respectively).”
Nonetheless, a variety of studies – indeed - recommend a more prolonged healing time for implants in the maxilla and mandible. Therefore, we also added a discussion part on this issue on page 13 (first paragraph): “In our study, a torque of at least 20 Ncm was achieved; this is indicative of consistently acceptable implant stability at time of placement. Moreover, it can be assumed that the surgeon responded to poorer primary stability by allowing prolonged healing times. Conversely, some implants placed with an even higher torque and time of placement were immediately loaded. These implants consequently reduced the mean healing time in the study (approx. five months in the maxilla and 4.6 months in the mandible). However, none of the implants that were loaded immediately failed in this study. When comparing the healing times in this study with those in the literature, the average recommended healing time is six months in the maxilla and three months in the mandible, which should be prolonged in the case of augmentation. The mean healing time in this study is thus slightly shorter for implants placed in the maxilla and slightly longer for those placed in the mandible.”

Comment 4: Why were 7 implants with a diameter less than 2.8mm excluded from the analysis? This is mentioned in the results but no reason for the exclusion is given.

Response to comment 4: Thank you, yes this topic - of course - needs clarification and more detailed description.

We, therefore, added on page 8, first paragraph: “Seven implants with a reduced diameter (2.8 mm) placed in three participants had to be excluded from analysis. This was because these implants had a different design (one-piece tissue-level implants with, e.g., a ball welded onto the implant), and a sub-group analysis of n = 7 seemed insufficient to achieve meaningful results.”

Comment 5: The results mention a history of periodontitis in 26% of patients. The time since achieving periodontal health and stability in these patients should be described. The periodontal diagnoses of these patients should be included as well.

Response to comment 5: Thank you for this comment. Unfortunately, information of the exact classification of periodontal disease was not clear from the medical records and were therefore
only used dichotomously (present or not). With respect to the waiting time until implantations after periodontitis treatment / stable conditions we added additional information in material & methods.

We added on page 5 (Target variables): “For the variables smoking, diabetes, and history of periodontitis (each recorded as yes/no), only their presence or absence was noted and used in statistical analysis. A more detailed breakdown (for example, of the number of cigarettes smoked or glycemic values) was not available.”

We added on page 6, fourth sentence: “Patients with a history of periodontal disease were required to have a stable periodontal condition after treatment for a minimum of three months.”

We also added some discussion on this issue on page 13 (strengths and weaknesses): “Nevertheless, when target variables and statistical approaches are selected retrospectively for existing data, a certain fuzziness might well be expected; for smokers, for example, the quantity of cigarettes smoked per day or the exact periodontal diagnosis was not available.”

Comment 6: This study evaluated implants placed by general dentists, not periodontists or oral surgeons. This should be discussed, including what type of surgical training these dentists had received.

Response to comment 6: Thank you for this comment. You are right, information and discussion on experience and surgical training is needed to rank the study outcome.

To address this issue, we added this information on end of page 5 and beginning of page 6: “One of the participating dentists (Stephanie Schmitz, D1) graduated in 2008 and passed a specialized course in dental implantology offered by the German Society of Oral Implantology (‘Curriculum Implantology’). When treating the patient sample, her professional experience thus ranged between four and nine years. The other dentist (D2) passed their final exams in 2015. All implant treatments performed by D2 were supervised by D1.”

With respect to discussion we also added an additional part on page 13 (end of page): “With regard to bias, it should perhaps also be kept in mind that the professional experience of dentists
working in general practice will vary, which could affect the success or failure of surgical procedures. In this study, the two dentists had amassed professional experience of between two and nine years.”

Comment 7: Evaluation of the implants included "radiologically (attachment loss)." Radiographs will demonstrate bone loss. Attachment loss is a clinical measurement based on probing depth and location of the gingival margin relative to the CEJ - this needs to be corrected in the manuscript.

Response to comment 7: Thanks for this hint, of course you are right. We adjusted this topic accordingly.

We added / changed on page 6 (middle of page): “no clinical abnormalities (e.g., radiologically evaluated bone loss < 2 mm) were observed for the implants. The moment of loading was selected by the dentists (e.g., extent of augmentative measures/primary stability). Abutments were attached to implants by applying a torque of 25 Ncm. Before initiation of prosthetic management (impressions, maxillomandibular relationship), implants were evaluated clinically (resonance on percussion, probing depths, pain, loosening) and/or radiologically (bone loss).”

Comment 8: The second sentence in the discussion states that this study suggests early implant failure is manageable for dental implants placed in private practice. This study does not evaluate management of implant failures. It just evaluates the number of implant failures, not how they were managed. This sentence needs to be corrected.

Response to comment 8: Thank you for this comment. You are right. Management was not reported. Our wording was misleading and it should have expressed that early failures were rare / convenient.

Thus, we changed this part on page 11, second sentence: “The results of this study suggest that the early failure of dental implants placed in the general practice is in an acceptable range.”
We also added on page at the beginning of page 14 (Conclusions): “Within the limitations of this study, early failure rates of dental implants placed in the general practice are convenient even though the treatment was performed by dentists with clear professional experience…”

Comment 9: Was a measurement of the insertion torque at the time of placement obtained for the implants? If so, what was the minimum accepted torque and what was the insertion torque of the failed implants?

Response to comment 9: Thanks. Yes, this was done. This information was missing in our report. We added this information and are now also discussing this.

We added on page 6, first paragraph: “For each implant, the insertion torque applied at the time of placement was measured and documented. The minimum torque required was 20 Ncm.”

Added at the end of page 6: “Torque was categorized as follows: < 30 Ncm = 1; ≥ 30 Ncm = 0).”

Added on page 9, first paragraph: “The insertion torque used at the time of placement of the failed implants ranged between 20–45 Ncm (mean: 32 Ncm).”

Added on page 13, first paragraph: “Moreover, it can be assumed that the surgeon responded to poorer primary stability by allowing prolonged healing times. Conversely, some implants placed with an even higher torque and time of placement were immediately loaded.”

Reviewer 2:

Comment 1: This is an interesting, well written retrospective evaluation of factors affecting the early implants failure in a general dental practice that deserves to be published. However, there are some minor issues that must be corrected and/or improved.
Response to comment 1: Thank you for this estimation, we have tried to address all your comments to further improve the paper and make it ready publishable.

Comment 2: The words "healing of implants" could be change to "early implants failure" in the title. New title "Factors affecting the early implants failure in a general dental practice - a retrospective study". In the abstract and text too, healing could be replaced by early implant failure, lack/failure of osseointegration, survival rates etc.

Response to comment 2: Thank you. Indeed your recommendation fits better and we changed “healing of implants” consistently into “early failure” or “lack of osseointegration” where appropriate throughout the manuscript including the title and the abstract…

Comment 3: More information about the background of the dentists participating in clinical treatment is necessary, e.g. postgraduate studies, specialization, continued education, years in practice and years of placing implants before 2012 that data was assessed etc. This is necessary in order to generalize or not the results for every general dental practice. This information and possible implications must also be included in the discussion and the conclusions adjusted accordingly.

Response to comment 3: Thank you for this comment. Yes, this is important information which is needed to file the outcome.

Therefore, we added this information on end of page 5 and beginning of page 6: “One of the participating dentists (Stephanie Schmitz, D1) graduated in 2008 and passed a specialized course in dental implantology offered by the German Society of Oral Implantology (‘Curriculum Implantology’). When treating the patient sample, her professional experience thus ranged between four and nine years. The other dentist (D2) passed their final exams in 2015. All implant treatments performed by D2 were supervised by D1.”

We also added a discussion part on this issue on page 13 (end of page): “With regard to bias, it should perhaps also be kept in mind that the professional experience of dentists working in
general practice will vary, which could affect the success or failure of surgical procedures. In this study, the two dentists had amassed professional experience of between two and nine years.”

Comment 4: Predictor variables definition for Smoking (yes or no/number of cigarettes?), Diabetes (glycemic values for yes or no), Periodontitis (definition of what was considered yes or no), Bone augmentation, Healing method and Lower torque must be included in the M&M section (some explanations are included in the discussion and Table).

Response to comment 4: Thank you for this helpful comment. We totally agree with you that these issues/variables need (better) explanation, especially in materials & methods section.

For clarification we added on page 5 (Target variables): “For the variables smoking, diabetes, and history of periodontitis (each recorded as yes/no), only their presence or absence was noted and used in statistical analysis. A more detailed breakdown (for example, of the number of cigarettes smoked or glycemic values) was not available.”

Added on page 5, (again target variables): “All types of grafting, including bone spreading or bone splitting), and mode of healing (open: healing abutment with penetration through the mucous membrane; closed: implant cover screw below the mucous membrane, re-exposure of implants needed after healing period).”

Added on page 6, first paragraph: “For each implant, the insertion torque applied at the time of placement was measured and documented. The minimum torque required was 20 Ncm. Patients with a history of periodontal disease were required to have a stable periodontal condition after treatment for a minimum of three months.”

Comment 5: The manuscript will benefit from a minor English biomedical editing.
Response to comment 5: Thank you for this advice. After our revision now we sent the manuscript to a medical copy editor which is a native speaker. The editing was worthful (certification of editing attached).