Author's response to reviews

Title: Early loading of hydrophilic titanium implants inserted in low-mineralized (D3 and D4) bone: One year results of a prospective case report study.

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Author's response to reviews: see over
Dear Editor,

thank you for your e-mail with the enclosed referee reports.

We have now carefully studied the useful suggestions of the referees and revised our paper according to all of their comments. As requested, we improved the general style of the paper based on the STROBE statement. Important changes in the text are marked in yellow, and comments to the queries are enclosed underneath this letter.

Yours Sincerely,

D. Rothamel
Comments to Reviewer 1

- This study is not randomised and it has limited number of patients

Patient number was indeed limited, based on the ethics approval. However, this was a case report study and all patients were treated following the same protocol, therefore also no randomization of patients or implants was possible.

“This was an exploratory trial with no prospective sample size calculation. The number of tested implants and treated patients was selected empirically.” was added to materials and methods.

- This is a prospective study and it should be reported according to the STROBE statement for improving the quality of observational studies (http://www.strobe-statement.org). Please rewrite Material and Methods and Results sections according to STROBE statement.

The concerned parts of the manuscript have been modified. The level of compliance with the STROBE Statement was improved.

e.g. As primary outcome, implant survival rate and the proportion of patients released for loading 8 weeks after implant placement, was calculated. Insertion torque, tactile resistance and ISQ changes were recorded as supportive measurements.” was added to the introduction, and different other modifications were made.

- How did the Authors detect D3/D4 quality bone before implant placement???? What did they measure????

The diagnosis of cancellous jaw bone quality was established on the evaluation of CBCT scans, analogically to the criteria of Misch (D1 – D4) and also to Lekholm and Zarb (Class I – IV).

The text in Materials and Methods was modified for more clarity accordingly: „Bone quality diagnosis was established on CBCT scans that were taken in progress of implant planning”, and „The CBCT used in the presented study served the purpose of visual estimation of the bone quality according to Misch [18], as well as an estimation of the thickness of the compacta in relation to the spongiosa, similar to Lekholm and Zarb [19]. Misch [18] divided the bone into four different quality classes (D1 to D4) whereas each of the four classes were topologically matched and described according to their implantological value.” was added to the discussion.

- Specify better all the outcomes and report estimate means and CI95% for all the outcome variables.

Means and Confidence intervals were inserted in the respective tables.

- How did you use a probe to detect bone loss??? The right way is to perform x-rays.

Of course the golden standard for bone loss evaluation is to perform x-rays. However, conventional X-rays are limited to mesial and distal bone areas, and CBCT scans lead to intense irradiation exposure and metal-related artifacts. Since the abutment had to be removed anyway to place the Osstell abutment, a periodontal probe was used to evaluate the bone height on buccal, oral, mesial and distal sides. X-rays are the preferred method for long-term outcomes after final prosthetic rehabilitation, when the implant shoulder can clinically not clearly be identified.
Comments to reviewer 2

1. In the abstract, the authors inform that 35 implants were used. However, in the manuscript they talk about 36. This has to be clarified and amended.

   In one patient who received 2 implants one implant was placed in D2-bone. In line with the study protocol, this implant was excluded from further analysis hence 36 implants were placed within the study, 35 have been evaluated up to 1 year.

   Text was added accordingly for more clarity: "In one patient 1 of 2 implants was inserted in a site with D2-bone, it was therefore not included in the subsequent evaluation."

2. The statistical methods and software utilized must be included at the end of the Materials and Methods section (also in the Abstract)

   Since this is a case report study with only one group, no inductive statistical analysis requiring e.g. SPSS was necessary.
   Abstract was changed accordingly: "Means, standard deviations and 95% confidence intervals were calculated using Excel."

   and "Patient data were entered into a dedicated database. Descriptive statistics was calculated using commercially available software (Excel)." was added to Material and Methods.