Impact of the outcome of guided bone regeneration in dehiscence-type defects on the long-term stability of peri-implant health: clinical observations at 4 years

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Abstract

Objectives: To investigate the impact of residual defect height (RDH) following guided bone regeneration (GBR) in dehiscence-type defects on the long-term stability of peri-implant health after a period of 4 years.

Material and methods: The RDH values in dehiscence-type defects at titanium implants were clinically assessed after 4 months of submerged healing following augmentation using a natural bone mineral (NBM) and a randomized application of either a cross-linked- (VN) or a native collagen membrane (BG) (n = 12 patients each). The RDH values were classified as absent (0 mm, control; n = 8), minimal (1 mm, test 1; n = 8), or advanced (>1 mm, test 2; n = 8). Clinical parameters (i.e. bleeding on probing [BOP], probing pocket depth [PD], mucosal recession [MR]) were recorded (mesio-, mid-, and disto-buccal aspects) at 4 years after prosthesis installation.

Results: The mean PD (2.9 ± 0.7, 2.8 ± 0.7, 2.7 ± 0.8 mm) values at 4 years were comparable in all the groups investigated. The mean MR values tended to be increased in both the test groups (0.5 ± 0.7, 0.4 ± 0.6 mm, respectively), when compared with the control group (0.2 ± 0.3 mm) (P < 0.05, respectively). The mean BOP values were also increased in both the test groups (45.8 ± 30.5%, 54.1 ± 24.8%, respectively), even reaching statistical significance when comparing test 2 and control (29.1 ± 21.3%) (P = 0.02).

Conclusion: The present study indicated that (i) implants exhibiting RDH values >1 mm are at a higher risk of developing peri-implant disease and (ii) positive RDH values may be associated with an increase in MR and may therefore compromise the overall esthetic outcome of implant therapy.

Over the past few years, the principle of guided bone regeneration (GBR) has become a standard of care for localized ridge augmentation at deficient implant sites (Chiapasco et al. 2006; Donos et al. 2008; Jensen & Terheyden 2009). A common clinical indication to apply GBR refers to the treatment of dehiscence-type and fenestration-type defects encountered during implant placement. For these purposes, a variety of non-resorbable and resorbable barrier membranes were used either alone or in combination with different grafting materials. At present, the best-documented augmentation protocol includes either the application of a natural bone mineral (NBM) in combination with a barrier membrane, particulate autogenous bone with or without a resorbable membrane or a non-resorbable membrane alone (Jensen & Terheyden 2009). It was reported that the survival rate of implants placed in conjunction with a simultaneous GBR procedure at augmented dehiscence-type and fenestration-type defects may be on a level equivalent to the survival rate of implants placed in pristine bone [median 95.4%] (Donos et al. 2008; Jensen & Terheyden 2009). Basically, the success rate of GBR at dehiscence-type and fenestration-type defects is commonly defined as percentage defect resolution measured during re-entry. A complete defect fill was only observed in 56.4% of the cases receiving bone augmentation without GBR (control), and in 75.4–75.5% for the concomitant application of resorbable and non-resorbable barrier membranes, respectively (Jensen & Terheyden 2009). The consensus report of the sixth European Workshop on Periodontology has confirmed that peri-implant diseases are infectious in nature (Lindhe & Meyle 2008). Peri-implant mucositis describes an inflammatory lesion that resides in the mucosa, while peri-implantitis also affects the supporting bone.
The long-term stability of peri-implant health and concomitant GBR in dehiscence-type defects (RDH) following bone augmentation using NBM investigate the impact of residual defect height smooth surface implant parts. onging peri-implant diseases than non-dehisced or areas may be at a higher risk of accumulating equally, it might be suggested that residual defect areas on the maintenance of peri-implant health still remains unknown. Limited evidence suggests that rough surface implants (Sa: > 2 μm) are more likely to develop peri-implantitis than minimally rough implants once exposed to the oral environment [Renvert et al. 2011]. Accordingly, it might be suggested that residual defect areas may be at a higher risk of accumulating bacterial plaque biofilms and subsequently developing peri-implant diseases than non-dehisced or smooth surface implant parts.

Therefore, the aim of the present study was to investigate the impact of residual defect height (RDH) following bone augmentation using NBM and concomitant GBR in dehiscence-type defects on the long-term stability of peri-implant health after a period of 4 years.

Materials and methods

Study population and design

The present study reports on a long-term follow-up of 24 patients formerly participating in a prospective randomized-controlled double-blinded clinical multicenter trial, which was conducted to evaluate the amount of bone fill in dehiscence-type defects at titanium implants using two different types of GBR procedures. Each patient referred to the study Center Duesseldorf and was given a detailed description of the procedure and required to sign an informed consent before participation. The study was performed in compliance with Good Clinical Practice and the Helsinki Declaration of 1975, as revised in 2000. The extended study protocol was approved by the ethics committee of the Heinrich Heine University, Düsseldorf.

The study design, surgical procedure, and terminal point data have been reported in detail previously [Becker et al. 2009]. In brief, screw-typed titanium implants [Camlog Screw-Line Implant, Promote® plus, Camlog, Basel, Switzerland] were inserted with good primary stability (i.e. lack of clinical implant mobility) in a way so that the borderline between the transmucosal (0.4 mm) and the bony part of the implant coincided with the bone crest. Accordingly, the implant neck [IN] was located at 0.4 mm above the bone crest. In a parallel-group design, dehiscence-type defects at respective titanium implants were filled with NBM [particle size: 0.35–1 mm, Geistlich BioOss®, Geistlich Biomaterials AG, Wolhusen, Switzerland] and randomly assigned to either a chemically cross-linked collagen membrane [18006, Geistlich Biomaterials AG] [VN] or a native collagen membrane [Geistlich Bio-Gide®, Geistlich Biomaterials AG] [CM]. Both VN and CM membranes were identical (porcine-derived type I and type III collagen), except for the fact that VN has been chemically cross-linked during the production process. Changes in defect height and defect width (DW) as well as the quality of the newly formed tissue were evaluated after 4 months of submerged healing and defined as the primary outcome parameters [Becker et al. 2009].

All patients (n = 37) having completed the initial observation period of 4 months at the study Center Düsseldorf were categorized according to RDH as recorded during re-entry: [1] absent: 0 mm [control], [2] minimal: 1 mm [test 1], or advanced: > 1 mm [test 2]. In brief, RDH was assessed during implant uncovering at 4 months of healing and measured as the linear distance from the IN to the deepest point of the first bone-to-implant contact at the vestibular aspect in the apico-coronal direction by means of a calibrated periodontal probe (PCP 12, Hu-Friedy, Leimen, Germany). The corresponding horizontal DW was measured as the widest linear mesio-distal dimension of the adjacent vestibular bone walls using the same periodontal probe. In addition, the quality of newly formed tissue (TQ) occupying the formed defect area at re-entry was evaluated according to the following scores: (0) no bone formation and loss of the parietal alveolar bone, (1) NBM particles embedded in connective tissue, NBM particles (2) marginally, (3) partially, (4) or fully integrated in newly formed bone, (5) corticalization of newly formed bone, NBM particles well integrated [Becker et al. 2009].

Inclusion criteria

A total of n = 31 patients completed the 4-year follow-up observation period. Each patient had to fulfill the following inclusion criteria: [1] non-smoker, [2] no history of malignancy, radiotherapy, or chemotherapy within the last 4 years, [3] no disease that affects bone or connective tissue metabolism [i.e. uncontrolled or poorly controlled diabetes HbA1c ≤ 7], [4] implant restorations without overhangings or margins, [5] treated chronic periodontitis, [6] proper recall/periodontal maintenance, as provided by the referring dentist, and [7] good level of oral hygiene (plaque index [PI] ≤ 1) [Löe 1967]. Finally, a total of n = 24 patients were found to be eligible to participate in this follow-up examination. A summary of the patient characteristics is presented in Table 1. The frequency distributions of the RDH values in the test and the control groups are summarized in Table 2.

Clinical measurements

The following clinical measurements were recorded at 4 years after prosthesis installation (inter-individual variation ± 3 months) using a periodontal probe (PCP 12, Hu-Friedy): [1] PI

Table 1. Patient and defect characteristics (mean ± SD) in the test and control groups

<table>
<thead>
<tr>
<th>Patient number (n)</th>
<th>Control (0 mm)</th>
<th>Test 1 (1 mm)</th>
<th>Test 2 (&gt;1 mm)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>–</td>
</tr>
<tr>
<td>Male</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>–</td>
</tr>
<tr>
<td>Age (years)</td>
<td>44 ± 12.7</td>
<td>59.4 ± 11.9</td>
<td>50.5 ± 17.2</td>
<td>NS</td>
</tr>
<tr>
<td>RDH (mm)</td>
<td>0 ± 0</td>
<td>1 ± 0</td>
<td>3.6 ± 1.5</td>
<td>NS***</td>
</tr>
<tr>
<td>RDW (mm)</td>
<td>0 ± 0</td>
<td>1.5 ± 1.4</td>
<td>3.2 ± 1.2</td>
<td>*****</td>
</tr>
<tr>
<td>TQ</td>
<td>4.6 ± 0.7</td>
<td>3.5 ± 0.9</td>
<td>1.9 ± 1.9</td>
<td>NS**</td>
</tr>
</tbody>
</table>

| Comparisons between groups (one-way ANOVA): RDH: *** test 2 vs. control: P = 0.0; RDW: ** test 1 vs. control: P = 0.03; *** test 2 vs. control: P = 0.0; TQ: *** test 2 vs. control: P = 0.001. |

CM, native collagen membrane; VN, cross-linked collagen membrane; RDH, residual defect height; RDW, residual defect width; TQ, tissue quality; NS, not significant.
implant site was assessed as follows: peri-implant calibrated investigator (N.S.).

Distooral (do) by one blinded and previously
Buccal (b), mesiooral (mo), and
Buccal (b), midbuccal (mb), and
distovestibular (db) aspects mesiooral (mo), midoral (o), and
distooral (do) aspects.

Five patients, each showing two implants with
PDs ≥ 4 mm on at least one aspect, were used
to calibrate the examiner. The examiner evaluated
the patients on two separate occasions, 48 h
apart. Calibration was accepted as measurements
at baseline and at 48 h were within a millimeter
> 90% of the time.

Intra-examiner reproducibility
Five patients, each showing two implants with
PDs ≥ 4 mm on at least one aspect, were used
to calibrate the examiner. The examiner evaluated
the patients on two separate occasions, 48 h
apart. Calibration was accepted as measurements
at baseline and at 48 h were within a millimeter
> 90% of the time.

Statistical analysis
The statistical analysis was performed using a
commercially available software program (PASW
Statistics 19.0, SPSS Inc., Chicago, IL, USA). The
mean values and standard deviations were calculated
for each variable and group using the patient
as the statistical unit. The data rows were examined
using the Kolmogorov–Smirnov test. Analysis of variance (one-way ANOVA) and post hoc
testing with Bonferroni’s correction for multiple
comparisons were used for between-group compar-
isons of the mean RDH, RDW, TQ, as well as
PI (six aspects), BOP, PD, MR, and CAL values
(three buccal aspects). The α error was set at
0.05.

Results
The defect characteristics as assessed in the test
and the control groups are summarized in Table
1. Between-group comparisons revealed signifi-
cant differences in the mean RDH (P = 0), RDW (P = 0.03), P = 0, respectively) and TQ (P = 0)
values. In particular, test group 2 revealed the
highest RDH and RDW as well as the lowest TQ
values, which was followed by test group 1 and
the control group showing the lowest RDH and
RDW as well as the highest TQ values (Table 1).
At the follow-up examination, none of the ex-
perimental sites revealed any signs of swelling,
redness or purulence.

The mean MR, PD, and CAL values in different
groups as assessed at either buccal or oral
aspects are summarized in Fig. 1a and b. Basic-
ally, both test and control groups revealed com-
parable mean PD values at the buccal aspects. In
particular, the mean PD values ranged between
2.8 mm (b) and 3.1 mm (mb) in the control
group, 2 mm (b) and 3.4 mm (db) in test group
1, and 2.5 mm (b) and 2.9 mm (mb) in test group
2 (Fig. 1a). When evaluating the corresponding
oral aspects, slightly increased mean PD values
were observed in test group 1 [2.6 mm (o) to
3.3 mm (do)] and test group 2 [2.9 mm (mo) to
3.9 mm (do)], when compared with the control
group [2.1 mm (o) to 2.6 mm (mo/do)] (Fig. 1b).

Similar results at all aspects investigated were noted when comparing the mean MR values in
test 1 and control groups. In particular, the mean
MR values at the buccal aspects ranged between
0 mm (mb) and 0.4 mm (b) in the control group,
and 0.4 mm (mb) and 0.6 mm (b) in test group 1
(Fig. 1a). At the oral aspects, the mean MR
values at the buccal aspects ranged between
0 mm (mb) and 0.4 mm (b) in the control
group, 2 mm (b) and 3.4 mm (db) in test group
1, and 2.9 mm (mb) and 3.3 mm (db) in test group
2 (Fig. 1a). When evaluating the corresponding
oral aspects, slightly increased mean MR values
were observed in test group 1 [0.3 mm (mo) to
0.8 mm (do)] and test group 2 [0.5 mm (mo) to
0.9 mm (do)], when compared with the control
group [0.2 mm (mo) to 0.6 mm (mo/do)] (Fig. 1b).

When evaluating the corresponding oral aspects,
both test and control groups revealed comparable mean values at the buccal aspects. In
particular, the mean CAL values, both test and
control groups revealed comparable mean values
at the buccal aspects. In particular, the mean
CAL values ranged between 2.8 mm (b) and
3.1 mm (mb) in the control group, 2.9 mm (mb)
and 3.3 mm (b/db) in test group 1, and 2.9 mm
(mb) and 3.3 mm (db) in test group 2 (Fig. 1a).
When evaluating the corresponding oral aspects,
slightly increased mean CAL values were ob-
served in test group 1 [3 mm (mo) to 3.9 mm
(do)] and test group 2 [3.5 mm (mo) to 3.9 mm
(do)], when compared with the control
group [2.5 mm (o) to 3 mm (mo/do)] (Fig. 1b).

Between-group comparisons of the mean PI
(six aspects), BOP, PD, MR, and CAL values
(three buccal aspects) are presented in Table 3.
In particular, statistical analysis failed to reveal any significant difference in the mean PI, PD, MR, and CAL values between the test and the control groups ($P > 0.05$, respectively). However, the mean BOP tended to be increased in both test groups, even reaching statistical significance when comparing test 2 and control groups ($P = 0.02$). However, the absence of positive BOP scores at the buccal aspects was observed in two patients of the control group and one patient each in both test 1 and test 2 groups. According to the given definition, peri-implant mucositis was diagnosed for six patients in the control group, five patients in test group 1, and two patients in test group 2, respectively. Non-standardized radiographs taken from implants diagnosed for peri-implantitis (control: $n = 1$; test 1: $n = 2$, test 2: $n = 3$) revealed either no or slight to moderate signs of a crestal bone resorption at both the mesial and the distal aspects (Fig. 2).

Table 3. Between-group comparison of mean ($\pm$ SD) plaque index (PI) (six aspects), bleeding on probing (BOP) (%), probing depth (PD), mucosal recession (MR), and clinical attachment level (CAL) (mm) (three aspects: mesio-, mid-, and distobuccal aspects) measured at 4 years after prosthesis installation ($n = 24$ patients)

<table>
<thead>
<tr>
<th>Group</th>
<th>PI</th>
<th>BOP</th>
<th>PD</th>
<th>MR</th>
<th>CAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.4</td>
<td>29.1</td>
<td>2.9</td>
<td>0.2</td>
<td>3.1</td>
</tr>
<tr>
<td>Test 1 (1 mm)</td>
<td>0.5</td>
<td>35.1</td>
<td>2.8</td>
<td>0.5</td>
<td>1.2</td>
</tr>
<tr>
<td>Test 2 (&gt;1 mm)</td>
<td>0.5</td>
<td>54.1</td>
<td>2.7</td>
<td>0.4</td>
<td>3.1</td>
</tr>
</tbody>
</table>

$P$-value NS NS NS NS NS

Comparisons between groups (one-way ANOVA): $^\text{a}$Test 2 vs. Control: $P = 0.02$. NS, not significant.

Discussion

The present study was designed to evaluate the impact of RDH following GBR in dehiscence-type defects on the long-term stability of peri-implant health after a period of 4 years. Within its limitations, the long-term follow-up has indicated that implants exhibiting RDH values $>1$ mm may be at a higher risk of developing peri-implant diseases than implants exhibiting minimal $\leq 1$ mm or absent RDH values. This was substantiated by the assessment of clinical key parameters (BOP and PD values) commonly...
recommended for the diagnosis of peri-implant diseases [Lindhe & Meyle 2008]. According to the given definition, the present analysis revealed the diagnosis peri-implant mucositis and peri-implantitis for six and one patients in the control group, five and two patients in test group 1, and two and four patients in test group 2, respectively. Clinically healthy peri-implant conditions were diagnosed for one patient each in the control and test group 1 as well as for two patients in test group 2, respectively. The corresponding radiographs revealed either no or slight to moderate signs of a crestal bone resorption at both the mesial and the distal aspects. In this context, it is important to realize that conventional intraoral radiography only allows the assessment of crestal bone-level changes in two planes, thus preventing the evaluation of any buccal or oral bone resorption. Accordingly, the apical extension of the peri-implantitis lesion in these areas can only be estimated by the clinical assessment of PD. However, experimental data have shown that at healthy and mucositis sites, the probe penetration tended to stop at the histological level of connective tissue adhesion, but reached the base of the inflammatory lesion at peri-implantitis sites [Lang et al. 1994]. These findings may explain, at least in part, the moderate mean PD values as assessed at the buccal aspects of both test groups, which were on a level equivalent to that noted in the control group. However, when considering the mean RDH values, one must realize that this situation may not represent homeostasis following implant placement, as several factors have been proven to be associated with a physiologic remodeling of the supporting alveolar bone. After implant uncovering, these include a bacterial colonization of the micro-gap at the implant–abutment interface [Ericsson et al. 1995; Hermann et al. 2001], biologic aspects such as the establishment of an adequately dimensioned biological width (Berglundh & Lindhe 1996) or dis- and subsequent reconnections of the abutment component compromising the mucosal barrier [Abrahamsson et al. 1997]. Accordingly, the consensus report of the seventh European Workshop on Periodontology [Lang & Berglundh 2011] agreed that the time of prosthesis installation should be chosen to establish the baseline. In this context, it was recommended to obtain a radiograph to determine crestal bone levels after physiologic remodeling, which may also be combined with the assessment of PD values [Lang & Berglundh 2011]. Unfortunately, the original study protocol [Becker et al. 2009] and subsequently the ethics approval did not consider the assessment of either radiographic or clinical baseline recordings at the time of prosthesis installation. Even though the lack of proper clinical baseline values may be considered as a potential drawback of the present study, it must be realized that these are the first data reporting on a correlation between RDH and the long-term stability of peri-implant health. As mentioned above, previous studies on simultaneous GBR at dehiscence-type and fenestration-type defects mainly focused on the assessment of defect reduction and implant survival rates [Dahlin et al. 1995; Fugazzotto 1997; Lorenzoni et al. 1999; Zitzmann et al. 2001; De Boever & De Boever 2003; Juodzbalys et al. 2007; Llambes et al. 2007]. Only a few studies also focused on the assessment of BOP and PD values subsequent to the GBR procedure, but did not correlate these findings with RDH (De Boever & De Boever 2003; Juodzbalys et al. 2007). In particular, non-submerged implants with large buccal dehiscences were augmented with NBM and covered by a non-resorbable membrane in a one-stage approach. Surgical re-entry at 6 months revealed a complete defect fill in 14 out of 16 implants, while two implants were characterized by a defect resolution of 63% and 87%, respectively. Clinical monitoring after 12–114 months revealed negative BOP scores and mean PD values <3 mm for 15 out of 16 implants [De Boever & De Boever 2003]. These data corroborate the present findings, as the absence of RDH values was clinically also correlated with peri-implant health. In a similar study, Juodzbalys et al. [2007] used simultaneous GBR at dehiscence-type defects adjacent to titanium implants using NBM + CM in a non-submerged healing procedure of 4–6 months. Clinical assessment of a modified bleeding index revealed stable mean values at 1 and 5 years after prosthesis placement. However, the mean PD values significantly increased from 1.43 ± 0.51 mm at baseline to 3.39 ± 0.59 mm at 5 years. Unfortunately, the lack of a site-level analysis did not allow for any evaluation of PD changes in the former defect area. Moreover, the authors did not assess defect closure and, therefore, these values cannot be correlated with RDH [Juodzbalys et al. 2007]. In this context, it must also be emphasized that combining transmucosal implant placement with simultaneous GBR resulted in less favorable outcomes compared with those of implants placed in healed sites [Siciliano et al. 2009]. When evaluating the results of the present study, it was also noted that the mean MR values tended to be highest in test group 2. This was particularly observed at the midbuccal aspects, potentially pointing to a pronounced remodeling process of the mucosa in the absence of a bony support. This issue, however, needs to be supported by histological evidence. Basically, the RDH values noted in test groups 1 and 2 corroborate previous findings indicating that no complete defect fill at dehiscence-type and fenestration-type defects was only obtained in 75.4–75.5% of the cases [Jensen & Terheyden 2009]. As the mean defect fill appeared to be comparable at sites receiving either non-resorbable or resorbable barrier membranes [87% vs. 75.7%] [Jensen & Terheyden 2009], one may consider a one-stage GBR procedure per se as a potential risk indicator for peri-implant diseases.

In conclusion and within its limitations, the present study has indicated that (i) implants exhibiting RDH values >1 mm are at a higher risk of developing peri-implant disease and (ii) positive RDH values may be associated with an increase in MR and may therefore compromise the overall esthetic outcome of implant therapy.

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