Peri-implant Tissue Health in Bone-Level Implants with Repeated Abutment Replacements Versus Tissue-Level Implants with a Definitive Abutment: A Randomized Controlled Trial

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The present randomized controlled study was undertaken to evaluate and compare peri-implant hard and soft tissue changes between implants restored with multiple disconnections and reconnections of the abutment (control group) vs implants restored with a definitive abutment (test group). Twenty edentulous sites from 13 systemically healthy participants were selected for the study. The recorded clinical parameters were bleeding on probing (BOP) and peri-implant pocket depth (PIPD). The measured radiographic parameter was peri-implant marginal bone loss (PMBL). Two parameters were measured both clinically and by CBCT: distance from the cementoenamel junction to the alveolar crest and alveolar ridge width. At the time of surgery, sites were randomly assigned to either the control or test group. At 6 months, (1) BOP was absent in both groups, (2) PIPD increased in both groups and was significantly greater in the control group, and (3) the mean PMBL was significantly higher in the control group than the test group. Thus, it can be concluded that the use of implants with a definitive abutment could be more beneficial in achieving better maintenance of marginal peri-implant tissue health.


Bone supporting two-piece implants undergoes resorption during healing, after the connection and disconnection of the abutment, and delivery of the final prosthesis. An important aspect of bone-level implants relating to early crestal bone loss is the tissue reaction to the abutment shift. Standard protocols for the clinical use of dental implants include the placement of healing abutments prior to standard or custom-made abutments at the time of loading. It has been demonstrated in many animal and clinical studies that the abutment disconnection as part of the prosthetic treatment in bone-level implants results in disruption of the epithelial seal, causing bleeding and ulceration of the site. This mechanical disruption may be considered an exposure of connective tissue, which may result in epithelial migration that might adversely affect the marginal peri-implant bone. The loss of peri-implant bone may be critical, as it may trigger peri-implantitis in the long term, thereby compromising esthetics and function. In order to avoid numerous connections and disconnections of prosthetic components and/or abutments, it was suggested to connect the definitive abutment at the surgical stage and to leave it undisturbed.

Advanced diagnostic aids like CBCT can measure the bone levels

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Submitted January 2, 2020; accepted April 12, 2020.
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in three dimensions with more precision. The images obtained by CBCT, combined with clinical measurements, could definitely increase the ability to determine the treatment outcome. Among the various parameters involved in determining the success rate of implant-supported prostheses, evaluation of clinical parameters is the most common. Along with the above, results based on patient satisfaction are a crucial aspect in defining the success of any treatment.

The present study was designed to evaluate whether placement of a tissue-level implant with a definitive abutment at the time of the surgery would improve bone and soft tissue healing around implants and to compare it with the conventional protocol of repeated abutment disconnections and reconnections in bone-level implants. The secondary aim was to assess, by questionnaire, patient satisfaction regarding the treatment.

Materials and Methods

The present randomized controlled clinical trial comprised 20 edentulous sites requiring implant treatment. Systemically healthy patients within the age range of 21 to 70 years who were willing to sign a written informed consent form were included in this trial. Each patient demonstrated at least one missing tooth in the mandibular molar region. Implants inserted with an initial insertion torque of at least 35 Ncm, as assessed with a manual ratchet, were considered in the study. The study design was reviewed and approved by the Institutional Ethics Committee of the present authors’ institute and was performed between September 2018 to October 2019 in accordance with the 1975 Declaration of Helsinki, as revised in 2013. This clinical trial was registered at Clinical Trial Registry–India (CTRI/2018/09/015726).

Patients were excluded from the study if they met any of the following criteria: presenting with general contraindications to implant surgery; subjected to irradiation in the head and neck area within the last 6 months; received previous or current treatment with intravenous amnibisphosphonates; smokers; poor oral hygiene; having parafunctional habits; pregnant or lactating women; and any acute or chronic infection at the site intended for implant placement.

The sample size was determined using mean bone-level changes as the primary outcome. It was estimated that a sample size of 10 sites in each group would enable a Type II error level of $\beta = 0.20$ (80% power) and a Type I error level of $\alpha = 0.05$ (5% probability). It was decided to have 10 sites in each group.

Suitable sites in patients who required one or more implants and satisfied the inclusion criteria were divided into two groups: control (multiple disconnections and reconnections of abutment) and test (definitive abutment). Tapered implants with a spiral tap design and standard internal hex connection and built-in platform switching were used. Moreover, alumina oxide-blasted/acid-etched implants with a roughened micro- and nanostructure surface topography of neck and body were placed in both groups (Fig 1). All patients were subjected to presurgical hygiene therapy. For evaluation of oral hygiene and gingival health, Plaque Index (PI) and Gingival Index (GI) were obtained.

Surgical Procedure

After obtaining adequate local anesthesia, a midcrestal incision was made. A full-thickness mucoperiosteal flap was reflected, and the root surfaces of the adjacent tooth were scaled and planed using hand instruments. Participants were then randomly assigned to one of two treatment groups. In the definitive abutment group, implants (One, Adin Dental Implant Systems) were inserted such that the implant shoulder was placed at the crestal level. In the control group, implants (Touareg S, Adin Dental Implant Systems) were inserted to the level of the alveolar crest. The flaps were approximated and sutured without tension using 3-0 Mersilk sutures (Ethicon, Johnson & Johnson). Patients were placed on antibiotics and analgesics to control postsurgical discomfort (Figs 2 and 3).

Prosthetic Phase

In control group patients, the standard healing abutments were removed, and the impressions were made directly on the implant platform with a customized tray using standard prosthetic components.
Fig 1  Implant specifications. (a) Bone-level implant with a healing abutment. (b) Tissue-level implant with a definitive abutment.

Fig 2  Implant placement at a control site. (a) Preoperative clinical view. (b) Alveolar ridge after flap reflection. (c) Placement of a conventional implant and (d) healing abutment. (e) Flap approximation with sutures. (f) Placement of the final prosthesis.

Fig 3  Implant placement at test site. (a and b) Preoperative clinical view. (c) Alveolar ridge after flap reflection. (d) Placement of the implant with a definitive abutment. (e) Flap approximation with sutures. (f) Placement of the final prosthesis.
Abutments were then removed three more times: at the metal framework try-in, at the bisque try-in, and at the delivery of the final prosthesis, at which point they were substituted by new abutments. Patients enrolled in the test group underwent the “one abutment” protocol. Impressions were made directly on the abutments using a standard tray. During the manufacture of the final metal-ceramic restoration, the test group had the same number of try-ins as the control group, so the only difference was the number of abutment removals. All of the final prostheses were delivered approximately 3 to 4 months after implant placement.

The clinical outcome measures included:
1. Alveolar ridge width (2 mm and 4 mm from the ridge crest) measured by a ridge-mapping gauge (Bone Caliper BC35, GDC) and CBCT at baseline and 6 months (Figs 5 and 6); and
2. Distance from the CEJ to the alveolar crest, measured at mesial and distal sites by a manual periodontal probe and CBCT at baseline and 6 months (Fig 7). Readings were repeated by the same examiner (P.R.) to perform an intra-observer reproducibility analysis. An intra-class correlation (ICC) coefficient with two-way mixed effects model was obtained for each periodontal parameter. The ICC ranged between 0.92 to 0.99 in the groups (P < .0001), indicating excellent intra-observer reliability. The data analyses were performed using a statistical package (SPSS version 20.0, IBM), and the statistical significance was tested at a level of 5%.

Patient satisfaction was assessed via questionnaire containing 10 questions regarding chewing, esthetics, speaking, comfort, and overall satisfaction. The patients were instructed to choose a binary reply (yes/no) for each question.
Results

The study population consisted of 13 systemically healthy patients (8 men, 5 women) aged between 21 and 70 years. Twenty sites were taken into consideration from 13 patients and were equally distributed among the study groups. All 13 patients returned for clinical and radiographic examination at defined postsurgical intervals. This study achieved a 100% implant and prosthetic success rate at the 6-month follow-up for both groups.

**BOP and PIPD**

Table 1 shows the comparison of BOP and PIPD at different time points between two groups as well as the PIPD comparisons across multiple time points for each group.

At 6 months, all patients showed an absence of BOP. The mean PIPD at 6 months was significantly higher in the control group (2.10 ± 0.43 mm) than the test group (1.60 ± 0.32 mm).

**PMBL**

At 6 months posttherapy, the mean bone level change was significantly

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Fig 6 Ridge width at baseline, measured via CBCT images at 2 mm and 4 mm from the ridge crest in the (a) control and (b) test groups.

Fig 7 Distance from the CEJ to the alveolar crest in a control group patient, measured via CBCT images at (a) baseline and (b) 6 months.
higher in the control group (1.22 ± 0.2 mm) than the test group (0.74 ± 0.41 mm) (Table 2).

### CEJ to the Alveolar Crest

The clinical and CBCT measurements at mesial and distal sites at different time points are presented in Table 3. The mean differences between two time points were statistically significant in both groups for clinical and CBCT measurements.

### Alveolar Ridge Width

In the control group, the mean differences between 2-mm and 4-mm measurements were statistically significant for both time points (baseline and 6 months), as assessed by CBCT. However, at test sites, the clinical values failed to reach statistical significance between the two time points. In the control group, significant differences in mean width were seen for clinical and CBCT measurements at 2 mm and 4 mm from baseline to 6 months, whereas in the test group, significant differences were seen only for CBCT measurements at 2 mm and 4 mm. In the control group, for the ridge width at 4 mm from the crest, the mean width was 11.35 ± 2.16 mm at baseline and 11.00 ± 2.09 mm at 6 months. In the test group, the comparison between mean clinical and CBCT measurements was insignificant (P > .05). For CBCT measurements at both 2 mm and 4 mm in both test and control groups, the mean width at baseline was significantly higher than at 6 months (Table 4).
### Table 3 Comparison of Clinical and CBCT Height Measurements (CEJ to the Alveolar Crest) at Different Time Points for Both Groups and Across Time Points for Each Group

<table>
<thead>
<tr>
<th>Group</th>
<th>Side</th>
<th>Time point</th>
<th>Clinical</th>
<th>CBCT</th>
<th>Pa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mesial</td>
<td>Baseline</td>
<td>2.35 ± 0.71 (2.50)</td>
<td>2.53 ± 0.73 (2.75)</td>
<td>.5831 (NS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 mo</td>
<td>2.80 ± 0.67 (2.75)</td>
<td>2.97 ± 0.79 (3.15)</td>
<td>.6101 (NS)</td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td>Baseline</td>
<td>2.14 ± 0.85 (2.00)</td>
<td>1.84 ± 1.27 (1.40)</td>
<td>.6059 (NS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 mo</td>
<td>2.64 ± 0.63 (2.50)</td>
<td>2.26 ± 1.22 (1.90)</td>
<td>.4725 (NS)</td>
</tr>
<tr>
<td></td>
<td>Distal</td>
<td>Baseline</td>
<td>2.00 ± 0.78 (2.00)</td>
<td>2.66 ± 0.83 (2.55)</td>
<td>.0835 (NS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 mo</td>
<td>2.30 ± 0.86 (2.00)</td>
<td>2.90 ± 1.04 (2.80)</td>
<td>.1768 (NS)</td>
</tr>
<tr>
<td>Test</td>
<td>Mesial</td>
<td>Baseline</td>
<td>1.81 ± 0.80 (1.75)</td>
<td>2.29 ± 0.60 (2.10)</td>
<td>.2077 (NS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 mo</td>
<td>2.19 ± 0.46 (2.00)</td>
<td>2.50 ± 0.69 (2.35)</td>
<td>.3325 (NS)</td>
</tr>
</tbody>
</table>

CEJ = cementoenamel junction; HS = highly significant; S = significant; NS = nonsignificant.
Measurements are presented in millimeters as mean ± SD (median).

*Paired t test.

### Table 4 Comparison of Alveolar Ridge Width at Different Time Points for Both Groups and Comparison Between Clinical and CBCT Measurements Across Time Points for Each Group

<table>
<thead>
<tr>
<th>Group</th>
<th>Distance</th>
<th>Time point</th>
<th>Clinical</th>
<th>CBCT</th>
<th>Pa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 mm</td>
<td>Baseline</td>
<td>9.05 ± 1.32 (9.50)</td>
<td>9.19 ± 1.42 (9.65)</td>
<td>.8218 (NS)</td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td>6 mo</td>
<td>8.75 ± 1.32 (9.25)</td>
<td>8.94 ± 1.44 (9.50)</td>
<td>.7615 (NS)</td>
</tr>
<tr>
<td></td>
<td>4 mm</td>
<td>Baseline</td>
<td>11.35 ± 2.16 (11.75)</td>
<td>11.64 ± 2.18 (12.20)</td>
<td>.7683 (NS)</td>
</tr>
<tr>
<td></td>
<td>6 mo</td>
<td>11.00 ± 2.09 (11.25)</td>
<td>11.39 ± 2.13 (11.85)</td>
<td>.6844 (NS)</td>
<td></td>
</tr>
<tr>
<td>Test</td>
<td>2 mm</td>
<td>Baseline</td>
<td>8.35 ± 1.25 (8.25)</td>
<td>8.52 ± 1.39 (8.15)</td>
<td>.7768 (NS)</td>
</tr>
<tr>
<td></td>
<td>6 mo</td>
<td>8.25 ± 1.14 (8.25)</td>
<td>8.27 ± 1.27 (8.00)</td>
<td>.9708 (NS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 mm</td>
<td>Baseline</td>
<td>10.20 ± 1.40 (10.50)</td>
<td>10.44 ± 1.75 (10.60)</td>
<td>.7388 (NS)</td>
</tr>
<tr>
<td></td>
<td>6 mo</td>
<td>10.05 ± 1.34 (10.00)</td>
<td>10.18 ± 1.68 (10.35)</td>
<td>.8508 (NS)</td>
<td></td>
</tr>
</tbody>
</table>

HS = highly significant; S = significant; NS = nonsignificant.
Measurements are presented in millimeters as mean ± SD (median).

*Paired t test.
Patient Satisfaction

All patients were satisfied with the implant treatment in general, as assessed by a questionnaire. Table 5 shows the distribution of patients related to the satisfaction level for the procedure in two groups.

Discussion

The present study provided insight into various aspects of success for implants with a definitive abutment vs a conventional protocol for implants placed in healed ridges. This included outcomes and information concerning bone level changes, soft tissue changes, and patient satisfaction.

The absence of BOP at the 6-month follow-up confirmed that the peri-implant sites were healthy, as demonstrated by Lang et al.12 Later, Luterbacher et al reported that BOP alone yields higher diagnostic accuracy to clinically assess the health of soft tissues around implant sites than using the same method around tooth sites.13 According to Adell et al14 and Buser et al15 PIPD ≤ 3 mm around implants was considered healthy. The range in PIPD measurements in the present study is in accordance with a previously reported’ mean probing depth of 2.04 mm at the 5-year follow-up in cases treated with a “one-abutment, one-time” protocol.7

PMBL changes around implants were measured on CBCT scans at buccal, mesial, distal, and lingual sites, and the highest value was considered. The present results are in accordance with the study done by Molina et al,16 in which the authors reported similar mean bone loss values in both treatment groups, whereas a few other studies reported less bone loss in both test and control groups.17-19 The effect of abutment replacements on marginal bone level changes has been evaluated in an animal study,3 where it was demonstrated that abutment disconnection and reconnection, done five times, compromised the mucosal barrier and resulted in a more apically positioned zone of connective tissue and increased marginal bone resorption.

Luongo et al6 and Koutouzis et al17 reported less bone loss in both study groups, but the observation period was shorter. The present study reported the 6-month postloading data around implants restored with the conventional protocol vs implants placed with definitive abutments. Although this follow-up period is brief, it takes into account the fact that the major component of the marginal bone loss occurs before and immediately after abutment connection.

A few studies assessed the accuracy of CBCT in visualizing peri-implant bone, concluding that CBCT provides usable information about bone in all dimensions around

### Table 5 Distribution of Patient Responses According to Their Satisfaction Level for the Procedure

<table>
<thead>
<tr>
<th>Question</th>
<th>Group, n (%)</th>
<th>Control</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Yes</td>
<td>6 (100)</td>
<td>7 (100)</td>
</tr>
<tr>
<td>Q2</td>
<td>Yes</td>
<td>6 (100)</td>
<td>7 (100)</td>
</tr>
<tr>
<td>Q3</td>
<td>Yes</td>
<td>6 (100)</td>
<td>7 (100)</td>
</tr>
<tr>
<td>Q4</td>
<td>Yes</td>
<td>6 (100)</td>
<td>7 (100)</td>
</tr>
<tr>
<td>Q5</td>
<td>Yes</td>
<td>6 (100)</td>
<td>7 (100)</td>
</tr>
<tr>
<td>Q6</td>
<td>Yes</td>
<td>6 (100)</td>
<td>5 (71.43)</td>
</tr>
<tr>
<td>Q7</td>
<td>Yes</td>
<td>3 (50)</td>
<td>0</td>
</tr>
<tr>
<td>Q8</td>
<td>Yes</td>
<td>5 (83.33)</td>
<td>6 (85.71)</td>
</tr>
<tr>
<td>Q9</td>
<td>Yes</td>
<td>6 (100)</td>
<td>7 (100)</td>
</tr>
<tr>
<td>Q10</td>
<td>Yes</td>
<td>6 (100)</td>
<td>7 (100)</td>
</tr>
</tbody>
</table>

Q1 = Are you satisfied with the chewing ability of your implant-supported teeth?; Q2 = Are you satisfied with the appearance of your implant-supported teeth?; Q3 = Do you feel any difference between the natural teeth and implant-supported teeth?; Q4 = Do you feel comfortable with the implant-supported teeth?; Q5 = Is it comfortable to speak with your implant-supported teeth?; Q6 = Do you feel it easy to maintain cleanliness around your implants?; Q7 = Are you satisfied with the duration of the treatment?; Q8 = Do you find this treatment cost-effective?; Q9 = Would you undergo the same treatment again?; Q10 = Will you recommend the treatment to your friends or relatives?
implants with varying accuracy. Studies that evaluated bone loss using periapical radiographs reported less crestal bone loss after the follow-up period. Only one study, by Degidi et al, was similar to the present study, and those authors reported CBCT use and found no statistically significant difference between the two groups regarding vertical bone healing measurements. The present results are dissimilar to a small randomized controlled trial that included only 16 patients and reported no noticeable differences in the test and control groups.

One major difficulty is estimating the bone width, as the mucosal contour can mask the actual alveolar ridge dimensions. In order to overcome the limitations of conventional radiographic techniques, some clinical methods have been adapted to measure transversal alveolar bone, like the ridge mapping technique. Wilson registered this technique in 1989, and Traxler et al suggested it as a reliable method to evaluate bone availability for implant surgery. Following the present analysis, the results differ with those obtained by Luk et al, who reported significant differences between bone ridge measurements obtained on CBCT vs ridge mapping. The present study’s findings are in accordance with those reported by Castro-Ruiz et al, wherein both methods (ridge mapping and CBCT) showed no significant differences. Moreover, studies that performed measurements at 3 and 6 mm from the alveolar soft tissue crest found no significant differences in the measurements.

Overall, the patients were satisfied with the treatment outcome, as confirmed by the professional evaluation. There is a plethora of literature that evaluated patient-reported outcomes, each concluding high satisfaction of the patient receiving implant treatment. Previous studies evaluating the tissue dimensions with definitive and repeated abutment replacements in implants have noted patient-reported outcomes based on only three simple questions. However, the present clinical trial estimated patient-reported outcomes based on a comprehensive questionnaire, taking into account chewing, esthetics, phonetics, comfort, overall satisfaction, and willingness to undergo similar therapy again if required. Having considered a greater number of outcome measures makes the present clinical trial more reasonable.

Conclusions
The use of an implant with a definitive abutment could help achieve better PMBL results. The strict recall schedule and high motivation among the patients lead to an absence of BOP at all sites. The implants restored with multiple disconnections and reconnections of the abutment lead to greater PIPD measurements. These clinical findings are the most recent human study data incorporating the use of CBCT to detect crestal bone level changes around implants with definitive abutments and conventional two-piece implants that require abutment disconnections and reconnections for prosthetic rehabilitation.

Acknowledgments
The authors declare no conflicts of interest.

References