The Effect of Multi-unit or Implant-Level Fixed Partial Dentures on Peri-implant Tissues: 1-year Follow-up of a Randomized Clinical Trial

Imantas Vatenas¹, Tomas Linkevicius² and Rimgaile Rinkevičiute³

¹Siaulių Implantologijos klinika, Siauliai, Lithuania
²Institute of Odontology, Faculty of Medicine, Vilnius University, Vilnius, Lithuania
³Balciunų klinika, Marijampolė, Lithuania

Corresponding author: Tomas Linkevicius, Institute of Odontology, Faculty of Medicine, Vilnius University, Vilnius, Lithuania.


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Abstract

Evaluation of the impact of abutment disconnections / reconnections on peri-implant marginal bone loss (MBL) changes in partially edentulous patients, restored with screw retained fixed partial dentures (FPD) in mandibular posterior teeth region recorded again. The data was collected and subjected to statistical analysis. 120 dental implants were placed for 60 patients (13 males and 47 females, mean age 57.46 years) combining with 60 vertical soft tissue augmentation procedures, using connective tissue grafts from the palate.

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Introduction
Disconnection and reconnection of the healing or prosthetic abutments has always been a controversial topic in implant dentistry for many years. Becker, Schwarz F et al reported that disruption of the peri-implant mucosal seal affected marginal bone loses, when abutments were disconnected and reconnected twice from implants with internal conical connection [1,2]. It has been suggested that abutment level prosthetic approach does not disturb peri-implant seal and as a result has less bone resorption [3,4]. Canullo et al suggested on that ‘one abutment – one time’ concept - when you place the prosthetic abutment once and leave it till the delivery of the final restoration, might be a possible additional strategy to further minimize peri-implant crestal bone resorption. He reported 0,2mm greater marginal bone loss (MBL) in the provisional abutment (PA) group in 3 years period compared with the definitive abutment (DA) group [5].

Degidi et al reported no statistically significant difference between the one abutment one - time group and control group regarding the measurement of vertical bone healing in subcrestally (2mm) placed post extractive tapered single dental implants, which were restored immediately [6]. In contrast, Grandi et al showed opposite results- after 12 months period implants in the DA group lost an average of 0,11mm peri-implant bone, implants in PA group about 0,58mm peri-implant bone with statistically significant difference in bone level change between the groups [7]. In both studies dental implants were placed immediately and restored with immediate cemented temporary restorations without occlusive contact. From these presented articles it is unclear if “one abutment one time” protocol could be more beneficial for the MBL compared to the standard treatment protocol. Delayed approach in both research groups, ensuring adequate soft tissue thickness, using soft tissue friendly material as zirconium and screw retained final restorations in both research groups; research with more standardized treatment protocol could be beneficial [9].

The aim of the present study- evaluation of the impact of abutment disconnections/reconnections on peri-implant MBL changes in partially edentulous patients, restored with screw retained fixed partial dentures (FPD) in mandibular premolar and molar region. Treatment in the IL group involves two repeated abutment disconnections (ADs), T2, T3 time periods. The null hypothesis was that “one abutment one time concept” will lead to less crestal bone loss, compared to the traditional implant level approach that involves multiple abutment disconnections.

Keywords
Marginal bone loss (MBL); Final abutment (FA); Definitive abutment (DA); Final abutment placement (FAP); multiple abutment placement (MAP); Fixed partial dentures (FPD)

Two dental implants placed for every patient, leaving a tooth gap between them in the molar and pre-molar region, in the lower jaw.
Materials and Methods

Patients Participants of the study were enrolled in Oral Implantology clinic of Siauliai in Siauliai, Lithuania, who were partially edentulous and required dental implant therapy in the mandibular posterior region. The Kaunas Regional Ethical Committee for Biomedical Trials, Kaunas, Lithuania (2020 06 25 No. BE-2-52) approved the study's protocol. Patients required to meet the following inclusion requirements: no general illnesses, no medical conditions that would preclude implantation, edentulous lower jaw molar and pre-premolar region, volumetric computed tomography-measured bone height 8 mm, bone width 6 mm, and at least 4 mm of attached tissues at implant site buccally-lingualy. The following were listed as exclusion criteria: systemic diseases that can affect the healing of oral wounds; pregnancy; medications that can affect the healing of oral wounds; smoking more than 10 cigarettes per day; active periodontitis diagnosis; and poor oral hygiene (plaque index by O'leary > 20%). Before taking part in the study, each patient was given both verbal and written instructions and digitally signed the informed consent form, giving their assent to the use of the collected data for research.

The surgeon (IV) carried out each surgery. The dental implant site's keratinized gingiva was measured buccolingually for width. The 4% articaine/40 ml solution with adrenaline (Ubistesin, 3M ESPE, Seefeld, Germany) was used as local anaesthetic during the procedure. In the middle of the edentulous ridge, a cut was made with scalpel No. 15. A 0.5mm marked periodontal probe (UNC; Hu-Friendly, Chicago, IL, USA) was used to assess the vertical thickness of the soft tissues after raising the complete thickness of the buccal flap [Figure 1]. The prospective site of the dental implant was the bone crest center, and the probe was positioned there upright. The dental implant site was then fully exposed by raising a full-thickness lingual flap. Dental implants were positioned in the center of the crest, parallel to one another, at the level of the bone, "Neodent" (Brazil) dental implant system, PS, conical connection, Helix, Grand Morse, and Acqua "hydrophilic surface". The dental implants were attached with dental implant cover screws.

Figure 1: Marginal bone loss changes between groups and with-in groups at T0, T1, T2, T3 and T4 follow-up points together with means (ο) and 95% confidence intervals.
Soft Tissue Grafting
An incision was made 1 cm above the gingiva’s edge (dental gingival connection) between the first molar and canine after local anesthesia (4% articaine 40 ml solution with adrenaline; Ubistesin, 3M ESPE, Seefeld, Germany) was applied to the upper jaw, in the palate, on the same side. In order to use the inner portion as a connective tissue graft, the full-thickness flap was lifted, the flap was split in half, and the inner portion was taken. The wound was then sutured without tension using 4/0 sutures (PTFE nonabsorbable monofilament suture "Golnit"; Ukraine). A 0.5mm marked periodontal probe (UNC; Hu-Friendly, Chicago, IL, USA) was used to quantify the thickness of the connective tissue graft, which is then applied over the exposed dental implant site in the lower jaw to cover the exposed alveolar ridge. Following the creation of coronal periosteal releasing incisions, flaps were approximated and 4/0 sutures (PTFE nonabsorbable monofilament suture "Golnit"; Ukraine) were used to stitch them together without tension. Always, the primary wound was closed.

Following surgery, patients were given antibiotic prescriptions: 500 mg of ciprofloxacin twice day for one week, or 1g of amoxicillin (Ospamox; Biochemie, Kiel, Germany) for those who had a penicillin allergy. Ibuprofen 400 mg (G.L. Pharma GmbH, Lannach, Austria), used twice day for five days, is a pain reliever. For two weeks, patients were instructed to raise the surgical site for one minute with a 0.12% chlorhexidine digluconate solution (Eludril classic, Boulogne, France). For a period of four weeks, patients were instructed not to chew on or brush the surgical sites. 14 days following the procedure, the sutures were removed.

Implant Uncovering
The second step of the procedure was carried out three months after the first. An incision was created in the middle of the alveolar crest after local anesthetic 4% articaine 40 ml solution with adrenaline (Ubistesin, 3M ESPE, Seefeld, Germany) was applied to the dental implant site. A full-thickness buccal flap was raised, and a 0.5 mm periodontal probe (UNC; Hu-Friendly, Chicago, IL, USA) was used to assess the thickness of the augmented soft tissues across the center of the alveolar ridge. The cover screws were removed, healing abutments measuring 4.5 mm wide by 4 mm high or multi-units measuring 4.5 mm wide by 1.5 mm gingiva high were linked to the dental implants, and the lingual flap was raised to fully expose the implants. With single interrupted 4/0 sutures (PGLA braided, violet, fast absorbable polyglactin 910 sutures, coated, "Golnit," Ukraine), flaps were approximated and stitched. After 14 days, the sutures were removed.

Prosthetic Stage
After 2 weeks from the second surgery, the gingiva formers removed from the implants or from the multi units, impressions are taken, using the open tray methodology, using the silicone dental impression material. After 2 weeks three-unit zirconium bridge was permanently screwed to the dental implants with 25N/cm or to the multi units with the force of 10N/cm.
Radiographic Evaluation
When assessing the changes in the bone, RVG 5200 dental radiographs were calibrated using the Trophy Imaging software (Suarez Trophy, Uruguay). The diameter of the implant was used for internal calibration. Digital individual radiographs were taken in the high-resolution mode with a Rinn-like film holder using a long-cone paralleling technique to produce orthogonal radiograms of dental implants. The images were obtained in the way that non-distorted implant/abutment interface and implant threads would be clearly visible, as this confirms that radiographic image is parallel to the implant long axis and sufficient for accurate evaluation. Bone loss was calculated as a distance between implant neck and first radiographically visible bone-to-implant contact. The mean value of the medial and distal measurements was pooled for each implant. Radiograms were analyzed by an experienced dentist, who was not aware of the purpose and did not take a part in the study. Radiographic examination was performed:

[TO]- After dental implantation - anatomical structures evaluated, to check - if the cover screws are properly fixed.
[T1]- After the second implantation stage - bone contour evaluation, evaluation of proper gingiva formers and multi unit’s fixation. Marginal bone level changes.
[T2]- 2 weeks after the second stage of implantation - formation of biological width. Marginal bone level changes.
[T3]- 2 weeks after. After the final prosthetic stage - the prosthetic structure is monitored, is properly adapted. Marginal bone level changes.
[T4]- 1 year after final prosthesis were delivered - implant function. Marginal bone level changes.

Statistical Analysis
Statistical software (SPSS 15.0 for Windows, Chicago, IL, USA) was used to analyze the data. Means, SEs, SDs, medians, and ranges of the measurements were determined as descriptive statistics. One patient was considered to be a statistical unit. In order to use parametric analysis, the normality of the distribution had to be verified. If the test for normality was successful, one-way ANOVA analysis was used to compare the differences between the five treatment phases in light of the MBL alterations. When P 0.05, the mean differences were deemed statistically significant. Additionally, differences were graphically represented using 95% confidence intervals.

Results
In total 56 implants were placed in implant-level group (IL) and 64 implants in abutment level group (AL). Dental implants were restored using screwed fixed partial dentures (FPD), using standard 1.5mm gingiva height titanium bases or standard multi-units of 1.5mm gingiva height. At the 1-year follow-up implant success rate of 100% in both groups was reported. In the IL group, peri-implant bone levels were T0= 0.97mm ± 0.33mm, T1= 0.69mm ± 0.47mm, T2= 0.55mm ± 0.44mm, T3= 0.22mm ±0.35mm, T4= -0.08mm ±0.49mm. In the AL group, peri-implant bone levels were T0= 1.05mm ± 0.37mm, T1= 0.36mm ± 0.30mm, T2= 0.24mm ±0.31mm, T3= 0.09mm ±0.34mm, T4= -0.01mm ±0.36mm.
Statistically significant lower MBL were found at time period T1= 0.33mm and T2= 0.31mm for the AL group between the groups. In the AL group statistically significant (p-value is less than α = .05) lower MBL were found around the dental implants at the T0 period compared with time periods T1, T2, T3 and T4. Statistically significant lower MBL were found at time period T1 compared with time periods T3 and T4. Statistically significant lower MBL were found at time period T2 compared with time period T4.

In the IL group statistically significant lower MBL were found around the dental implants at the T0 period compared with time periods T1, T2, T3 and T4. Statistically significant lower MBL were found at time period T1 compared with time periods T3 and T4. Statistically significant lower MBL were found at time period T2 compared with time period T3 and T4. Statistically significant lower MBL were found at time period T3 compared with time period T4 [Table 1].

**Discussion**

Current research results revealed that there was no statistically significant difference in MBL between the groups after 1-year follow-up. respectively -0.01 ± 0.36mm in the AL group and -0.08 ± 0.41mm. in the IL group. However, that difference was present at early treatment stages – during T1 and T2 time periods. Although there is 8 times less MBL during 1-year follow-up in the AL group. the difference could not be confirmed statistically significant between the groups. Besides the difference may not have any clinical effect. Null hypothesis can be rejected. Higher MBL changes for the IL group can be explained by several factors. one of them- that the IL group underwent 2 abutment disconnections (T2, T3). while the AL group did not undergo any. It was suggested by Berglund and colleagues. that any disturbance of the zone of connective tissue interaction may affect the marginal peri-implant tissues. including bone [10-13].

**Table 1**: Marginal bone loss measurement parameters in both groups and with-in groups at T0, T1, T2, T3 and T4 follow-up points.

<table>
<thead>
<tr>
<th>Time periods</th>
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<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Standard Error of Mean</th>
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<td></td>
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<tr>
<td></td>
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<td>.35142</td>
<td>.03208</td>
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<tr>
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<td>.04063</td>
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<tr>
<td></td>
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<td>.05992</td>
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<tr>
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<td>.03997</td>
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<tr>
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<td>.03812</td>
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<tr>
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<td></td>
<td>Total</td>
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Implant/abutment connection stability is another important factor for MBL [14-17]. Therefore, bacterial leakage is probably more prone to happen at the weakly torqued implant-healing abutment junction at the IL group compared with the stable conical multiunit connection in the AL group [18]. Moreover, restoration delivery brings more stability to the implant-abutment junction because the definitive titanium abutment in IL group is as precise as multiunit abutment in AL group.

It might also be that the reduction of micro movement results in less bone irritation and subsequently enhances bone remineralization in the future. Finally, soft tissue thickness (STT) - very important factor for the MBL proven by many authors previously [19]. Puzio et al. declared that – the higher soft tissue thickness was, the lower marginal bone loss has occurred [20]. Critical value for tissue thickness was determined as no less than 2.88mm. In the current research the initial soft tissue thickness vertically of the participants was 2.27 ± 0.64mm. The soft tissue augmentation was necessary according to the recommendation and in order to prevent MBL. In the current study, after soft tissue augmentation procedure, using connective tissue graft from the palate, after 3 months, soft tissue thickness vertically increased from 2.27 ± 0.64mm to 4.35 ± 0.64mm [8,9]. Disconnections and reconnections of the healing abutments during the prosthetic treatment phase may influence MBL. The present study indicates that implants receiving a final abutment at the time of implant placement exhibited minimal marginal bone loss and were similar to implants subjected to abutment disconnection and reconnection two times (T2, T3). The same results were showed by other authors - disconnection and reconnection of the abutment two times did not cause negative dimensional changes in the peri-implant mucosa [21]. Immediate connection of the prosthetic abutments did not reduce bone loss in comparison with three disconnections of the healing abutments. At the end of 2 years, the mean bone level was -0.18 ± 0.12 mm for the definitive abutment group (DEF) group and -0.13 ± 0.13 mm for the healing abutment group (HEA). Resulting in a cumulative bone loss of -0.61 ± 0.10 mm and -0.81 ± 0.15 mm, respectively, with no statistical difference between groups (22). Between 6 and 12 months, the mean bone loss was 0.14 ± 0.21 mm for the DA group and 0.21 ± 0.27 mm for the PA group, also without statistical significance between the two groups [23].

Though other studies declared opposite results - at the end of 3 years, the MBL was -0.35 ± 0.69 mm for participants in the DEF group and -0.57 ± 0.80 mm for the HEA group, with significant statistical difference between groups [24, 25]. Similar results presented by Bressan et al - the mean MBL 3 years after loading was 0.07 (0.18) mm for the definitive abutment group and 0.50 (0.93) mm for the repeated abutment changes group (difference= 0.43mm; 0.13; 0.74; P=0.007) [11]. The implants in this study were placed subcrestally for 1mm, immediately flapless implant placement. Bone augmentation during immediate implant placement was accepted. Different implant diameters were used. Nevertheless, the single and multiple implant placement cases up to three implants were accepted in the groups. Similar results presented by Nader et al - DA group 0.84mm ± 0.45. PA group 1.0mm ± 0.39 in 1-year follow-up period. In this study one abutment one time and standard protocol was used in the same site for the same patient. Implants were placed 0.5mm subcortical. Only delay ment implant placement and prosthetic protocols were used. Final restorations were cemented. Conical connection implants used [26]. More over Toia at al
showed the significant difference of MBL between the IL (implant level) and AL (abutment level) groups (P=0.003). At 1 year, MBL was 0.084 ± 0.31mm and 0.005 ± 0.22mm in the IL and AL groups, respectively. The study reveals those final restorations- screw retained in both groups. The more concerning fact that in the study different gingiva high definitive abutments were used. that probably means that patients had different gingiva types [16].

Usually, healing or temporary abutments are connected and disconnected several times between implant placement and definitive restoration delivery. and soft tissue disruption occurs each time the abutment is disconnected and reconnected. This histologic event is supposed to cause bone resorption around the implant after second-stage surgery. To minimize this clinical scenario. immediately placing and never removing a definitive abutment the day of implant insertion (one-stage protocol) or at second-stage surgery in cases of submerged implants (two-stage protocol) would be suggested [27]. A limitation of the present study was that standardized periapical radiographs were not obtained ideally precisely every single time. While standardization of radiograms with individual paralleling devices remains the best available method to record bones levels. it is not possible to do in clinical study set-up [28,29]. Another limitation of the study was the difficulty to place every single dental implant at the bone level ideally as the alveolar ridge is very individual buco-lingual and mesio- distal direction. Alveolar ridge tended to rise up medially towards the tooth. in order to place the dental implant at the bone level- requires to do the alveolar ridge flattening at the areas were the implants need to be placed. But even after this procedure not every dental implant has the ideal and equal bone levels around itself [30].

**Conclusion**

The current trial suggests that abutment disconnections / reconnections have an influence to peri- implant marginal bone loss (MBL) changes-( T1). (T2) periods; although later - during final restoration delivery time (T3) and 1 year after (T4) the marginal bone level changes between the (IL) and (AL) groups become statistically insignificant. Besides 0.3mm difference may not have any clinical effect.

**References**


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