Crestal Bone Stability around Implants with Horizontally Matching Connection after Soft Tissue Thickening: A Prospective Clinical Trial

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ABSTRACT

Background: It has been shown that thin mucosal tissues may be an important factor in crestal bone loss etiology. Thus, it is possible that mucosal tissue thickening with allogenic membrane might reduce crestal bone loss.

Purpose: The purpose of this study was to evaluate how implants with traditional connection maintain crestal bone level after soft tissue thickening with allogenic membrane.

Materials and Methods: One hundred three patients received 103 internal hex implants of 4.6 mm diameter with regular connection. According to gingiva thickness, patients were assigned into A (thin tissues, \( n = 34 \)), B (thin, thickened with allogenic membrane, \( n = 35 \)), and C group (thick tissues, \( n = 34 \)). Groups A and C had one-stage approach, and in group B, implants were placed in two stages. Radiographic examination was performed after implant placement, 2 months after healing, after restoration, and after 1-year follow-up. Crestal bone loss was calculated medially and distally. Significance was set to 0.05.

Results: After 1-year follow-up, implants in group A had 1.65 ± 0.08 mm bone loss mesially and 1.81 ± 0.06 mm distally. Group B had 0.31 ± 0.05 mm mesially and 0.34 ± 0.05 mm distally. C group implants experienced bone loss of 0.44 ± 0.06 mm mesially and 0.47 ± 0.07 mm distally. Differences between A and B, and A and C were significant (\( p = .000 \)) both mesially and distally, whereas differences between B and C were not significant mesially (\( p = .166 \)) and distally (\( p = .255 \)).

Conclusions: It can be concluded that thin mucosal tissues may cause early crestal bone loss, but their thickening with allogenic membrane may significantly reduce bone resorption. Implants in naturally thick soft tissues experienced minor bone remodeling.

KEY WORDS: allogenic membrane, biological width, crestal bone loss, thickening of mucosal tissues, thin mucosal tissues

INTRODUCTION

Stable crestal bone remains one of the most wanted features of successful implant treatment. Many methods

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have been proposed to maintain crestal bone stability around implants, like platform switching\(^1\)-\(^3\) or laser-modified implant surface,\(^4\)-\(^5\) yet the most effective one is still to be established. Implants have improved dramatically since introduction of crestal bone resorption definition in 1986 by Albrektsson and colleagues\(^6\); however, despite all efforts, we still observe this “crater-like” bone loss pattern. Numerous factors are suggested as reasons for bone loss – polished implant collar,\(^7\) overload,\(^8\) microgap,\(^9\)-\(^11\) etc. Among them is initial mucosal tissue thickness, which as a factor for crestal bone loss was brought up by Berglundh and Lindhe.\(^12\) It was proposed that if tissue thickness is 2 mm or less, formation of biological width around implants will involve bone loss. Later, this concept was confirmed clinically by study of
Linkevicius and colleagues, showing that up to 1.35 mm of bone loss might be expected if implants are placed in thin mucosal tissues. As a possible solution, authors suggested investigating the option to thicken soft tissues before or during implant placement to reduce crestal bone loss.13

Wiesner and colleagues14 proposed to use palatal connective tissue grafts for thickening of the mucosa. It was reported that soft tissue thickness increased by 1.3 mm; however, this augmentation did not improve crestal bone stability. In addition, it was observed that palatal harvesting is difficult, it may cause serious morbidity of donor and recipient sites, and thus might be replaced with other materials. It would be rational to see if thickening of thin soft tissues with allogenic membrane would have a better outcome.

The aim of the study was to evaluate how implants with horizontally matching connection and laser-modified surface maintain crestal bone stability after soft tissue thickening with allogenic membrane. Null hypothesis was raised that tissue thickening does not have impact of crestal bone levels.

MATERIALS AND METHODS

Patients

Individuals for this 1-year controlled clinical trial were selected among partially edentulous patients who attended Vilnius Implantology Center Clinic (Vilnius, Lithuania) for implant treatment. The protocol of this study was approved by Vilnius regional ethical committee for biomedical trials (No. 158200-07-512-149). Inclusion criteria were: (1) no less than 18 years of age; (2) generally healthy patients, no medical contraindication for implant surgery; (3) missing teeth in lower jaw posterior area; (4) minimum of 6-mm bone width and 8 mm in height; (5) healthy soft tissue (bleeding on probing [BOP] < 20%, Plaque Index [PI] < 25% Community Periodontal Index for Treatment Needs < 2);15 (6) minimum 2-mm keratinized gingiva buccally and lingually; (7) no bone augmentation procedures before and during implant placement; (8) sufficient (>35 N) implant primary stability; and (9) signed informed consent form for participation and permission to use obtained data for research purposes. Patients were excluded if they did not meet the inclusion criteria and if they additionally (1) had a history of periodontitis; (2) are smoking; (3) had diabetes; (4) had alcoholism; (5) take medicine, influencing healing. Each patient received verbal and written instructions and signed the informed consent form before participating in the study.

Tissue Measurement, Implant Placement, Prosthetic Restoration

Study protocol was similar to preceding study by Linkevicius and colleagues.8 All patients received a prophylactic dose of antibiotics of 1 g amoxicillin (Ospamox, Biochemie, Kiel, Germany) 1 hour prior to the surgery. Placement of implants was planned after clinical and radiographic examination. After the administration of 4% articaine 40 ml solution (Ubistesin, 3 M ESPE, Seefeld, Germany) for local anesthesia, a midcrestal incision in the center of edentulous ridge was performed, leaving at least width 2 mm of keratinized gingiva buccally. After crestal incision, full thickness buccal flap was raised, whereas lingual part was not elevated. Thickness of soft tissues was measured with 1.0-mm marked periodontal probe (UNC, Hu-Friedy, Chicago, IL, USA) on the top of bone crest in the center of future implant placement. This ensured direct visibility of mucosal thickness during measurement. After measurement, full-thickness lingual flap was raised to completely expose implantation site.

If vertical soft tissue thickness was 2 mm or less, the tissues were considered as thin (Figure 1). Thick tissues were considered if mucosa thickness was more than

Figure 1 Vertical measurement of thin mucosal tissues before implant placement.
2 mm (Figure 2). Therefore, three groups were formed: A group, implants placed in thin soft tissues; B group, implants placed in thin soft tissues and thickened with allogenic membrane at the time of implant placement; and C group, implants placed in thick soft tissues. Internal hex implants in 4.6 mm diameter with horizontally matching implant/abutment connection and laser-modified surface (Tapered Laser Lock, BioHorizons, Birmingham, AL, USA) were positioned approximately 0.5 to 1 mm above bone crest by the same surgeon (A.P.) (Figure 3).

In group B, allogenic membrane (AlloDerm, BioHorizons) was used for soft tissue thickening. Standard dimension’s (20 × 40 mm) membrane with thickness varying from 0.89 to 1.65 mm was treated with sterile saline solution for 10 minutes. Then, membrane was folded one time to reach the thickness of 2 to 3 mm, individually adapted to the implantation site and positioned over implant, covered with the cover screw.

Membrane was extended mesiodistally to neighboring teeth, buccaly −10 mm, and lingually for 5 mm beyond the implant margin to completely close implantation site (Figure 4). Periosteal releasing incisions were made; flaps were approximated and sutured without tension with 5/0 sutures (Assucryl, Assut Medical Sarl, Lausanne, Switzerland). Primary wound closure was always achieved (Figure 5) For patients in this group 0.5 g of amoxicillin was prescribed 3 times daily for 2 weeks.

After 2 months of healing second stage surgery was performed. After infiltration of local anesthetic, incision was made in the center of the bone crest to preserve attached mucosa. Full thickness buccal flap was raised and thickness of soft tissues over the implant was measured with periodontal probe in a previously described manner (Figure 6). Then lingual flap was raised, healing abutment was connected to implant. Flaps were sutured without tension with single interrupted 5/0 sutures. No soft tissue excision was made.

Implants in groups A and C had one-stage surgery; thus, healing abutments were connected to implants immediately and tissues sutured with 5/0 sutures (Figure 7). Patients in this group received 0.5 g of amoxicillin three times daily for 5 days. Patients in all groups were instructed to rinse the operated site with...
0.12% chlorhexidine-digluconate solution (Perio-aid, Dentaid, Barcelona, Spain) twice a day for a week. For pain control, patients were prescribed 400 mg of ibuprofen to be taken as needed. Patients were advised to minimize trauma to the site, but no special diet was introduced. The sutures were removed 7 to 10 days after surgery. Patients were advised to clean healing abutments with very soft toothbrush.

Prosthetic procedures were performed 2 months after connection of healing abutments to implants by the same prosthodontist (T.L.). Cement- and screw-retained implant prosthesis was selected as a restorative option for implants. Single metal-ceramic restorations with occlusal openings were made by the same technician (R.A.) and cemented to standard abutments in the laboratory. Then, restorations were screwed to implants; screw access was isolated with polytetrafluoretylene tape and closed with light-cured composite (Gradia Anterior, GC, Tokyo, Japan) (Figure 8).
All patients received instructions for individual oral hygiene and particularities of cleaning around implant-supported restorations. In addition, all patients were recalled every 6 months after prosthetic rehabilitation for professional hygiene and monitored, so that during the study, periodontal health indices would be BOP < 20% and PI < 25%.

**Radiographic Examination**

Radiographs were taken using a paralleling technique with individualized film holder in high-resolution mode. Intraoral radiographs were performed at four times during the study: (1) after implant placement; (2) after 2 months of healing; (3) after prosthetic delivery; and (4) after 1-year follow-up postreconstruction. This was performed for A group implants (Figure 9, A–D), B group (Figure 10, A–D), and C group (Figure 11, A–D).

The images were obtained in the way that implant-abutment interface and the threads would be clearly visible. Before measurement, the parallelism of all intraoral radiographs was evaluated. Radiological evaluation and measurements were performed using software measurement program (RVG WINDOWS TROPHY 7.0, Trophy Radiologie, Paris, France) with a magnification (×20) by the blinded examiner. Before calculation of the crestal bone changes, the calibration of RVG images was performed using the calibration program in the software. The diameter of implant 4.6 mm was used for calibration as a reference point. The intraexaminer agreement was determined by second and third measurements,
which were performed with 1-month intervals. In total, 1,854 measurements were made. The mean difference between measurements was 0.1 mm ± 0.38, and the mean of three measurements was used. Bone loss and comparison between groups and within groups were reported separately, on distal and mesial sites.

**Statistical Analysis**

Prior commencing this study, power analysis was performed by an experienced statistician to calculate the sample size. It was determined that each group should have at least 32 patients with the 95% power to reflect general population. To compensate for possible dropouts, the sample size was increased at least to 34 patients per group. Data were analyzed using statistical software (SPSS 15.0 for Windows, IBM, Chicago, IL, USA). The single patient was treated as a statistical unit. Mean bone loss was calculated for each group with standard error. As variables appeared to be nonparametric, Mann–Whitney U test was applied to find differences between groups. The mean differences were considered statistically significant at \( p \leq .05 \) with a confidence interval of 95%.
RESULTS
Initially, 113 patients agreed to participate in the study and received 120 implants. Seven implants were removed from the study because radiographic images of implants were not sufficiently parallel to correctly calculate crest bone changes. Two implants were lost before loading, and two patients with two implants were excluded from the study on the basis of refusal to attend follow-up checkups. In addition, six patients received two implants; however, only one from two was included into the study to keep the patient as a statistical unit. Therefore, the final sample included 103 patients, consisting of 31 men and 72 women. Subjects’ average age was 45.3 ± 1.2 ranging from 21 to 55 years at the beginning of the experiment. One hundred two internal hex implants with traditional horizontally matching connection and laser-modified surface were placed by the same surgeon: 34 in group A, 35 in group B, and 34

Figure 11 Crestal bone levels after implant placement (A), 2 months after placement (B), after prosthetic rehabilitation (C), and after 1-year follow-up (D) in naturally thick tissue group.
implants in group C. Good primary stability (>35 N) was achieved in all implants. Overall, the implant survival rate after 1 year of function in all groups was 100%. No prosthetic complications were recorded at follow-up visits.

In A group and in B group before tissue thickening, an average tissue thickness was 1.51 ± 0.09 mm. In group B after soft tissue augmentation, thickness increased to 3.83 ± 0.13 mm, whereas group C with naturally thick soft tissues had thickness equal to 2.98 ± 0.08 mm. All 35 allografts survived and healed uneventfully but one membrane, which had spontaneous exposure. The exposed part of the allograft was trimmed with surgical scissors, site irrigated with 0.12% chlorhexidine-digluconate solution, and antibiotics intake was prolonged for an additional week. These measures led to normal wound healing afterwards. Crestal bone loss after 2 months, after prosthetic rehabilitation, and after 1-year follow-up can be seen in Table 1 to 3. Table 4 represents crestal bone loss differences in all groups between a period of 2 months after placement and 1-year follow-up.

**DISCUSSION**

This study evaluated whether the thickening of thin mucosal tissues with allogenic membrane would keep the bone stable around implants with traditional connection. The major finding of the study was that thickening of thin tissues with membrane reduces crestal bone loss from 1.81 mm to 0.44 mm after 1-year follow-up. On basis of these results, null hypothesis was rejected.

Implants in group A with soft tissues of 2 mm or less in thickness experienced the most evident bone loss up to 1.65 mm mesially and 1.81 mm distally after 1-year follow-up. This is in direct agreement with Linkevicius and colleagues' study, showing bone loss of 1.18 mm mesially and 1.35 mm distally around implants in thin soft tissues after the same period of time. Other study also had similar outcome, where bone resorption reached up to 1.81 mm. This similarity can be explained, as in two mentioned studies, implants with traditional connection were placed in thin tissues.

Biological scheme of bone resorption because of thin soft tissues was identified in the animal studies. First, it was shown that soft tissues around implants tend to be longer compared with teeth. This means that more tissues in height are required around implants

### Table 1: Crestal Bone Loss in All Groups after 2 Months of Healing (Mann–Whitney U Test)

<table>
<thead>
<tr>
<th>Group</th>
<th>Difference Mesially</th>
<th>Difference Distally</th>
</tr>
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<tbody>
<tr>
<td>A Thin (n = 34)</td>
<td>−0.86 ± 0.08 mm</td>
<td>−0.97 ± 0.09 mm</td>
</tr>
<tr>
<td>B Thin augmented</td>
<td>−0.17 ± 0.04 mm</td>
<td>−0.20 ± 0.05 mm</td>
</tr>
<tr>
<td>C Thick (n = 34)</td>
<td>−0.22 ± 0.05 mm</td>
<td>−0.25 ± 0.05 mm</td>
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<table>
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<tr>
<th>Group</th>
<th>Mesially</th>
<th>Distally</th>
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</thead>
<tbody>
<tr>
<td>A and B</td>
<td>p = .000</td>
<td>p = .000</td>
</tr>
<tr>
<td>B and C</td>
<td>p = .417</td>
<td>p = .329</td>
</tr>
<tr>
<td>A and C</td>
<td>p = .000</td>
<td>p = .000</td>
</tr>
</tbody>
</table>

**Bold values show statistical significance. Significant when p ≤ .05.**

### Table 2: Crestal Bone Loss in All Groups after Prosthetic Treatment (Mann–Whitney U Test)

<table>
<thead>
<tr>
<th>Group</th>
<th>Difference Mesially</th>
<th>Difference Distally</th>
</tr>
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<tbody>
<tr>
<td>A Thin (n = 34)</td>
<td>−1.39 ± 0.08 mm</td>
<td>−1.55 ± 0.08 mm</td>
</tr>
<tr>
<td>B Thin augmented</td>
<td>−0.25 ± 0.04 mm</td>
<td>−0.28 ± 0.05 mm</td>
</tr>
<tr>
<td>C Thick (n = 34)</td>
<td>−0.34 ± 0.05 mm</td>
<td>−0.36 ± 0.05 mm</td>
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<tr>
<th>Group</th>
<th>Mesially</th>
<th>Distally</th>
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<tbody>
<tr>
<td>A and B</td>
<td>p = .000</td>
<td>p = .000</td>
</tr>
<tr>
<td>B and C</td>
<td>p = .117</td>
<td>p = .193</td>
</tr>
<tr>
<td>A and C</td>
<td>p = .000</td>
<td>p = .000</td>
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</table>

**Bold values show statistical significance. Significant when p ≤ .05.**

### Table 3: Crestal Bone Loss in All Groups after 1-Year Follow-Up (Mann–Whitney U Test)

<table>
<thead>
<tr>
<th>Group</th>
<th>Difference Mesially</th>
<th>Difference Distally</th>
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<tbody>
<tr>
<td>A Thin (n = 34)</td>
<td>−1.65 ± 0.08 mm</td>
<td>−1.81 ± 0.06 mm</td>
</tr>
<tr>
<td>B Thin augmented</td>
<td>−0.31 ± 0.05 mm</td>
<td>−0.34 ± 0.05 mm</td>
</tr>
<tr>
<td>C Thick (n = 34)</td>
<td>−0.44 ± 0.06 mm</td>
<td>−0.47 ± 0.07 mm</td>
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<tr>
<th>Group</th>
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<th>Distally</th>
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<tbody>
<tr>
<td>A and B</td>
<td>p = .000</td>
<td>p = .000</td>
</tr>
<tr>
<td>B and C</td>
<td>p = .166</td>
<td>p = .255</td>
</tr>
<tr>
<td>A and C</td>
<td>p = .000</td>
<td>p = .000</td>
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**Bold values show statistical significance. Significant when p ≤ .05.**
Berglundh and Lindhe\textsuperscript{12} have shown that thinning the overlying bone and maintain hemostasis. Further, than around teeth for biological width to protect underneath lying bone and maintain hemostasis. Further, Berglundh and Lindhe\textsuperscript{12} have shown that thinning the soft tissues to 2 mm or less may result in more bone loss in histological specimens compared with implants placed in soft tissues with mean thickness of 3.3 mm. An indirect proof also can be found in other animal study about morphogenesis of peri-implant tissues, as authors observed that formation of peri-implant mucosa involved loss of marginal bone level.\textsuperscript{24} There-
colleagues' study, where implants placed in thick soft tissues experienced 0.26 mm on medial aspect and 0.09 mm distally. This outcome can be seen as other argument that thick soft tissues satisfy needed requirements for biological width formation, and peri-implant seal develops without significant bone resorption. In addition, currently used implants have laser-modified surface, which has been shown to keep stable soft tissue and prevent bone loss.

Traditional horizontally matching implant-abutment connection is considered less reliable in keeping bone stable compared with implants with platform-switched connection. The reason resides in implant placement technique, as usually, implants with traditional connection are positioned equally with bone crest. In that case, microgap is located near the bone, and bone resorption may start. In implants with platform switching, microgap is horizontally moved away from bone; thus, less bone loss occurs. Ericsson and colleagues have proved that microgap is contaminated, and inflammatory cell infiltrate forms in connective tissue zone, contacting implant-abutment interface. Thus, two-piece implants with regular connection should be placed slight supra-crestally to move away from bone microgap, and this exactly was performed in current trial. Current study has brought up some new concepts, which show that traditional implants can successfully keep bone stable with minimal 0.44-mm bone loss, which is very similar or sometimes even better than reported outcomes from platform switching studies. However, it must be stressed that such bone levels are possible to maintain only in naturally thick or thickened soft tissues. If traditional connection implants are placed supra-crestally in thin soft tissues, bone loss will occur due to insufficient tissue dimension, though microgap and polished neck will be kept away from the bone. Pilot study has shown that platform-switched implants may also experience bone resorption, thus proving that it is not effective in keeping bone stable, if soft tissues are thin.

Mucosal thickness as a factor for crestal bone loss has not been addressed in research very frequently. In fact, most of the studies on crestal bone loss did not evaluate initial soft tissue thickness at the time of implant placement. This means that majority of papers reporting bone loss figures may not carry accurate information. For example, the amount crestal bone loss in this study varied from 1.81 to 0.44 mm; thus, without soft tissue thickness evaluation, it would not be clear why such diversity exists. It should be emphasized that measuring of initial soft tissue thickness could be very advisable, if research will be focused on crestal bone loss evaluation.

Patients who smoke, had poor oral hygiene, or history of periodontitis were excluded from the study, as it was shown that these factors may have influence on crestal bone resorption. Implants were restored with screw-retained restorations to exclude cement remnants as a possible factor in crestal bone loss etiology. It was proved that undetected cement excess might cause early or delayed peri-implant disease.

The present study has several controversies. The major discussion could be the influence of different implant placement protocols between the groups on the final results of the study. It might be speculated that the difference seen in outcome between group A and B is not due to allograft and its effect on soft tissue thickness, but due to one-stage versus two-stage implant placement protocol. First, it must be stressed that numerous studies showed no difference in crestal bone loss between submerged and nonsubmerged implant placement. Recent randomized controlled 5-year multicenter study by Hammerle and colleagues evaluated crestal bone loss in transmucosal and submerged implant placement techniques. The mean differences of change in the bone levels between the two groups were not statistically significant, indicating the equivalence of both procedures. The same conclusions were made in many other clinical studies. Thus, it could be concluded that the differences in implant placement method could not have influenced the outcome of this study; therefore, implant placement method should not be considered as a factor for crestal bone loss. The reason to perform two-stage surgery in B group implants was to avoid possible exposure and infection of the membrane, as during one-stage implant, placement there may be contact of the allograft with saliva and oral environment. In addition, the exact measurement of soft tissue enlargement after augmentation with double layer membrane could be performed only during second-stage surgery. Furthermore, from the ethical point of view, it was not considered proper for patients from groups A and C to have unnecessary second-stage surgeries, which would be required to have no difference between groups in implant placement method. Results of this study also contradict the assumption that additional surgeries may increase bone loss as implants in group A, which had one-stage
approach, had significantly more bone resorption than B group implants, which had two-stage placement with allograft augmentation. On the other hand, the study would be stronger if all implants would be treated the same way; this might be the topic of future research.

CONCLUSION
Within limitation of this study, it can be concluded that vertical mucosal tissue thickness is a very important factor in early crestal bone loss etiology. When thin soft tissues were present during implant placement, crestal bone loss was most evident. Vertical thickening of soft tissues with allogenic membrane significantly reduced the amount of bone loss. Naturally thick tissues were able to induce only minor bone remodeling.

REFERENCES


