EVALUATION OF STABILITY AND CRESTAL BONE CHANGES AROUND IMPLANTS PLACED AT CRESTAL VERSUS SUBCRESTAL LEVEL IN CONTROLLED TYPE TWO DIABETIC PATIENTS (RANDOMIZED CLINICAL TRIAL)

Asmaa E. Elserity1* BDS, Abd Elaziz F. Khalil2 PhD, Maha R. Taalab3 PhD, Riham M. Fliefel4 PhD

ABSTRACT

INTRODUCTION: Peri-implant bone level preservation is the key to maintaining peri-implant soft tissue and stability. Many studies have discussed the role of placing dental implants at various depths on crestal bone loss, but they were debatable.

OBJECTIVES: To compare clinically and radiographically the effect of placing implants at crestal versus subcrestal levels on the crestal bone loss and stability evaluation in controlled type 2 diabetic patients.

MATERIALS AND METHODS: 22 controlled diabetic patients were randomized according to placement depth (group I: 11 implants were placed equicrestally) (group II: 11 implants were placed 1 mm subcrestally). Stability of implants, clinical and radiographical assessment were done for both groups.

RESULTS: 19 implants were included in our study (10 crestal and 9 subcrestal). There were no statistically significant differences in bleeding index and probing depth between the 2 groups while plaque index was greater among subcrestal group. Crestal bone loss mesiodistally was significantly higher in crestal group, while there was no significant difference buccolingually between crestal and subcrestal groups. Stability values were significantly greater in subcrestal group at loading time.

CONCLUSION: Sub-crestal implant placement is preferable for controlled type 2 diabetic patients as it decreases the probability of implant thread exposure provided that careful oral hygiene care is followed and regular periodic checks to maintain peri-implant soft tissue and dental bone health.

KEYWORDS: Crestal, Subcrestal, Stability, Type 2 diabetes mellitus.

INTRODUCTION

Dental implants have become a successful alternative in the treatment of partially or completely edentulous patients for restoring function and esthetics (1). It is considered that crestal loss up to 1.5 mm is a normal finding through the first year post the placement of the implant and then followed by less than 0.2 mm annually (2). A lot of studies have focused on the preservation of peri-implant bone level and soft tissue which are considered crucial factors for long-term implant stability and also for maintaining esthetics (3). There are a lot of local factors affecting the stability of marginal bone around the dental implant and subsequently implant survival such as biologic width formation, bone density, surgical trauma, peri-implantitis, gingival biotype, stress concentration at crestal bone level, and location of the implant-abutment connection. On the other hand, many systemic conditions may affect implant survival such as (diabetes, cardiovascular diseases, elderly populations, bisphosphonate therapy, and bleeding disorders) (4).
Diabetes Mellitus is considered one of the most common metabolic-related endocrine diseases that is characterized by hyperglycemia as a result of a deficiency in insulin secretion (type 1) or insulin resistance (type 2). Type 2 diabetes represents about 90%-95% of all those individuals who are suffering from Diabetes Mellitus (5). Implant therapy in patients with type 2 diabetes mellitus (T2DM) was considered a critical treatment option because of the increased risk of infections and delayed healing due to microangiopathy. Also, hyperglycemia may impair implant osteointegration and increase marginal bone loss by suppressing osteoblastic proliferation and differentiation (6). However, a lot of recent studies have suggested that dental implants can successfully survive functionally and esthetically under optimal glycemic control (7). Glycosylated hemoglobin is considered a diagnostic tool for T2DM and for detecting blood sugar regulation over a period of 2 to 3 months (8). It is approved that an HbA1C level of ≤ 7% is the optimal glycemic control level in the diabetic patients while for uncontrolled patients it is more than 7% (5).

The location of the implant-abutment interface plays a crucial role in the remodeling of the marginal bone (9). Rough implant surface exposure leads to accumulation of greater amounts of plaque in this area which results in mucositis and peri-implantitis so Welander and Madani et al suggested that placing an implant below the bone crest is beneficial (10,11). In contrast, other studies declared that there is much less loss in the peri-implant crestal bone that occurs with the implant placement at the bone crest level than subcrestally (12,13).

Several clinical and radiographic studies have focused on marginal bone reduction incase of implant placement at crestal and subcrestal levels among non-diabetic patients (14,15), but there were few and controversial data carried on diabetic patients. Several studies assessed the amount of crestal bone loss with conventional peri apical radiography which measures only mesial and distal aspects of the implant (16). However, it can’t measure the buccal or lingual aspects, despite the fact of buccal crestal bone assessment importance because it influences the location of mucosal marginal level and subsequently affects the esthetic outcome of the restoration (17) so, using cone beam computed tomography (CBCT) as a 3-dimensionaX-ray to assess buccolingual and mesiodistal crestal bone loss is of great importance so, we aim to compare clinically and radiographically the effect of the dental implant placement at the crestal and subcrestal levels in the crestal bone loss and the stability among T2DM patients. The null hypothesis is that there is no difference in the loss occurring in the crestal bone around the placed implants at either the crestal or subcrestal levels among T2DM patients.

**MATERIALS AND METHODS**

**Ethical Approval**

This study was a clinical trial that is conducted among patients chosen from the Oral and Maxillofacial Surgery Department’s outpatient clinic at Alexandria University’s Faculty of Dentistry and reported according to modified CONSORT guidelines (18). The Alexandria University Faculty of Dentistry’s Ethical Committee validated the research protocol (IRB number: 00010556-IORG 0008839). This study has been registered and granted on ClinicalTrials.gov with registration number: (NCT05125445) All of the involved patients matched with the inclusion criteria and then signed informed consent before going on surgical operations. The research was carried out in compliance with the Helsinki Declaration for Experimentation on Human subjects (19).

**Study design**

Our study is considered a randomized controlled clinical trial investigation as the involved Patients were chosen randomly from individuals present in the outpatient clinic, at the Faculty of Dentistry, Alexandria University, who met the inclusion criteria. All patients were evaluated clinically and radiographically.

**Study setting**

Oral and Maxillofacial Department, at Faculty of Dentistry in Alexandria University.

**Sample size estimation**

The sample size was estimated based on assuming a confidence level= 95% and study power= 80%. The mean ± SD loss in the marginal bone subsequently after succeeding 6 months when implants were placed 1 mm subcrestally = 0.68 ± 0.39. When the implants were positioned at the bone crest, the analyzed marginal bone mean ± SD loss= 0.15 ± 0.37. The calculated sample size was considered to be 10 implants per group. This will be increased to 11 to make up for the loss to follow-up. The total sample size= number of groups × number per group= 2× 11= 22.

**Inclusion criteria (20)**

Patients involved in the study were those with Type 2 controlled Diabetes Mellitus HBA1C ≤ 7 who were having healthy periodontium missing at least one tooth from the lower jaw with adequate height and width of the alveolar ridge and

Alexandria Dental Journal Volume 48 Issue 3 Section A

17
sufficient inter-occlusal distance that accepts any future restoration, were included in the study.

**Exclusion criteria (20)**
Smokers, patients doing para functional habits or having bad oral hygiene, Pregnant women, and individuals suffering from any local or systemic diseases that have the probability to compromise the surgical procedure healing or osteointegration process, were all excluded from the study.

**Methods**

**A. Presurgical Phase**
- The following data were collected from the patients including name, gender, age, medical and dental history. All patients were subjected to HbA1c monitoring. Only patients who met the eligibility criteria of glycosylated hemoglobin (HbA1C) levels ≤ 7% were included in this study.
- Clinical evaluation of all teeth and oral tissues was done.
- CBCT images were acquired with J.Morita R100 cone beam 3D imaging system and was used to measure the available bone, ensure the implant’s right size selection for optimal support and the precision of the implant placement in the bone also, their relation with the adjacent structures, and to evaluate the bone condition.

**B. Surgical Procedure (4) Fig (1,2)**

- Systemic antibiotic prophylaxis (amoxicillin + clavulanate, Augmentin, GlaxoSmithKline, Middlesex, UK) was given to patients 1 hour prior to surgery.
- All patients were informed to rinse their mouth for about 2 minutes using chlorhexidine antiseptic mouthwash before the surgery.
- Application of local anesthesia was done using 4% articaine (1:100,000 adrenaline).
- Mid crestal incision was done and an envelope flap with full thickness was raised to expose the alveolar crest.
- When required, ridge flattening was done.
- The implant site was well prepared as stated by the manufacturer’s instructions and performed under sterile copious irrigation. IS-II active implants, NeoBiotec were used with different lengths (8.5, 10, 11.5) mm and different widths (3.5, 4) mm.
- All involved implants were implanted at a minimum distance of 1.5 mm away from the adjacent teeth and a 3 mm distance between 2 implants.
- Implants were placed 1 mm subcrestally in the subcrestal group and at the bone crest in the crestal group.
- The stability of the implant was immediately measured after the surgery using was checked by Osstell (ISQ®) in a quotient scale (ISQ).
• The performed measurement will include 3 different directions: the buccal, mesial, and distal, therefore, the recorded readings were the mean of the three readings for each dental implant (21).
• A cover screw was connected to the implant and sutures were taken using 3/0 silk sutures.
• After about 3-4 months period of time from the surgery, an incision was performed directly over the fixed implant and the cover screw was taken out.
• The implant stability was remeasured by using the Osstell device.

Post-surgical phase (4)
After implant placement and suturing, patients were instructed to follow a soft diet and to avoid chewing at the surgery site until suture removal. They were advised to take the prescribed medications, which include 1 gm tablet of Augmentin (Amoxicillin 875 mg + Clavulanic acid 125 mg; GlaxoSmithKline, UK.) Orally every 12 hours for 7 days. Cataflam 50 mg tablets (Diclofenac. Potassium Novartis, Switzerland) as an analgesic every 8 hours and 0.12% chlorhexidine mouthwash (Arab drug company, ADCO) 3 times per day for 2 weeks long starting the day after surgery. Sutures were taken out 7 days post-surgery. Sutures were removed after one week and a clinical evaluation of the surgical site was done.

Follow-up phase (Fig 3,4)

A) Clinical evaluation
- At the permanent prosthesis placement, patients were informed by careful oral-hygiene instructions. The initial peri-implant clinical parameters (plaque index, peri implant probing depth and bleeding index) were taken 1 month (T1) and then after 3 months from loading time (T2) to assess:

1) Modified Plaque index (22)
- It was assessed 1 month after loading (T1) and 3 months after loading (T2) at four aspects around each performed implant (buccal, lingual, mesial and distal) then the assessed mean was calculated.
- It was done by visual inspection using a mouth mirror and a periodontal probe after the abutments air-drying.

2) Peri-implant probing depth (PPD) (23)
A graduated PDL probe (a manual UNC 15-mm periodontal probe (Hu-Friedy, Chicago, IL, USA) was placed parallel to the implant’s long axis and introduced lightly to the peri-implant sulcus. Measurements were taken around each implant from 6 sites which are the mesio- buccal, mid- buccal, disto- buccal, mesio- palatal, mid- palatal, and disto- palatal 1 month after loading (T1) then 3 months after loading (T2), and the mean will be calculated after that. The probe readings with 1 mm or less depth was registered as 1 mm while the probe reading of more than 1 mm, but less than 2 mm depth was considered about 2 mm.

3) Modified bleeding index (22)
A score of 0-3 was assigned at 4 points (buccal, lingual, mesial, and distal) around each implant and the mean was calculated 1 month after loading (T1) and then after 3 months from loading (T2).

B) Radiographic evaluation (Fig 5,6)

Both clinical and radiographical follow-ups were done for the patients for about 6 months.
Figure 6: Radiographic CBL of subcrestal group

CBCT was done 3 times: T0 was immediately post-surgery, T2 was at loading time (3 months after 1st stage surgery), and T3 was taken after 6 months from 1st stage surgery. The image was analyzed using OnDemand3D™ software CBCT analyzing software. The ruler tool was used to measure the height starting from the bone crest up to the implant apical end to evaluate any marginal bone loss occurring in all aspects (mesial, distal buccal, and lingual). During each follow-up period, the distance difference from the bone crest to the implant apical end was assessed then the mean was formed for both the mesial and distal and also for the buccal and lingual.

Statistical analysis
Normality was checked using the Shapiro-Wilk test, box plots, and descriptives. Variables were presented using all of the following values: Mean, Standard deviation, Median, Inter Quartile Range (IQR), and Minimum and Maximum values. Comparisons among the study groups were done using the Mann-Whitney U test regarding both the plaque and bleeding index and loss in crestal bone while Wilcoxon sign rank test was applied for intragroup comparisons. An independent-t test was performed to evaluate both the implant stability and probing depth differences between the study groups and paired t-test for before and after comparisons. The level of significance was set at a P value of about 0.05. All tests were two-tailed tests. Analysis was performed for the study recorded data using SPSS for windows version 23.

RESULTS
The selected patients' age range was 48.50 years in group I (crestal group) and 48.11 years in group II (subcrestal group). There was one implant failed in group II and two dropouts one in group I and one in group II who didn’t respond to their planned follow-up visits. As a result, the total sample was 19 patients (19 implants) 10 for group A and 9 for group B (Table 1).

Plaque index
There was no statistically significant difference among the 2 study groups (P=0.126) including the mean plaque index which was 0.00±0.00 in group I and 0.19±0.39 in group II 1 month after loading by (T1). Meanwhile, at (T2) the assessed plaque index was higher in subcrestal group exhibiting a difference that was considered statistically significant between the study groups (p= 0.001). In group I, the calculated mean was about 0.50±0.00, while in group II it was 0.77±0.19. (Table 2)

Modified bleeding index
At T1 the difference was statistically significant between the 2 study groups (P=0.023). The calculated mean of the bleeding index in group I was about 1.35±0.41 while in group II was 1.77±0.36. At T2 the difference was not statistically significant between the 2 groups. (P=0.493) the calculated mean was 2.35±0.53 and 2.22±0.44 in group I and II respectively. (Table 2)

Peri implant probing depth (PPD)
The difference between the two groups at T1 (P=0.117) and T2 (P=0.066) was not significant. At T1 the calculated mean of the probing depth in group I and group II were 3.43±0.08 and 3.68±0.47 respectively. At T2 the mean probing depth was 4.25±0.21 while in group II it was 4.44±0.22. (Table 2)

Implant stability
The difference found between the 2 groups immediately after implant placement (P=0.486) was not statistically significant. The mean implant stability quotient value was recorded as 61.10±2.71 in group I while in group II it was 62.44±5.25. The difference between the 2 groups (P=0.033) three months after the implant placement was statistically significant. The mean ISQ was 70.55±3.71 in group I while it was higher in group II with a mean of 76.75±7.49. (Table 2)
Crestal bone loss (Buccolingual)

The difference between the 2 study groups regarding the buccolingual CBL at T1 (loading time) (P= 0.870) and T2 (3 months after loading) (P=0.743) wasn’t significant. At T1 (in group I

CBL recorded a mean of -0.81±0.34 and -0.80±0.23 in group II. At T2 the calculated mean reached about -1.09±0.37 in group I and -1.03±0.25 in group II. (Table 3)

**Table 3:** Comparison of crestal bone loss between the study groups

<table>
<thead>
<tr>
<th></th>
<th>Crestal group (n=10)</th>
<th>Sub-crestal group (n=9)</th>
<th>Test (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loading (T1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>-0.81 (0.34)</td>
<td>-0.80 (0.23)</td>
<td>0.164 (0.870)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>(0.71)</td>
<td>(0.71)</td>
<td></td>
</tr>
<tr>
<td>Min - Max</td>
<td>-1.27 - -1.07</td>
<td>-1.03 - -1.07</td>
<td></td>
</tr>
<tr>
<td>Test (P value)</td>
<td>0.916*</td>
<td>0.25</td>
<td></td>
</tr>
<tr>
<td>3 months (T2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>-1.09 (0.37)</td>
<td>-1.03 (0.29)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>(0.69)</td>
<td>(0.69)</td>
<td></td>
</tr>
<tr>
<td>Min - Max</td>
<td>-1.55 - -1.42</td>
<td>-1.08 - -1.05</td>
<td></td>
</tr>
<tr>
<td>Test (P value)</td>
<td>0.327 (0.743)</td>
<td>0.29</td>
<td></td>
</tr>
</tbody>
</table>

**Crestal bone loss (Mesiodistal)**

The difference between the 2 study groups at T1(P=0.041) and T2 (P=0.004) was statistically significant. At T1 CBL mesiodistally recorded a mean of -0.75±0.30 in group I while for group II the calculated mean was -0.37±0.38. At T2 the mean of CBL reached -1.16 ±0.22 in group I and -0.79±0.36 in group II. (Table 3)

**DISCUSSION**

Although dental implants surpass other traditional restorations in terms of function and aesthetics, their usage could be an absolute or relative risk in
individuals with certain systemically related disorders, such as diabetes mellitus (25). The dental implants’ long-term survival and success require the peri-implant tissue stability state and crestal bone preservation. (26).

Regarding bleeding index and peri-implant probing depth, our results agreed with Pellicer et al results which disclosed that the differences between the 2 groups were not of statistical significance (20). Our results were inconsistent with the study by Boynueri et al who stated that BOP sites were lower in crestal group implants than in subcrestal group, but they used a polished neck implant in their study (27).

BOP is a significant indication of peri-implant health(20). BOP values were high throughout our study (at T1 and T2). At T2 the mean bleeding index reached 2.35 ±0.53 in crestal group and 2.22 ±0.44 in subcrestal group. There is an explanation for that as persistent hyperglycemia stimulates proinflammatory cytokines production such as IL-6 which is produced by the human gingival fibroblasts(28). Also, in T2DM oral hygiene conditions may impact inflammatory markers and consequently cause periimplantitis(29). Our results agreed with the meta-analysis by Lagunov et al who indicated a significant rise in BOP and PD when comparing the controlled T2DM (HbA1C 6.1%-8%) to healthy individuals in 4 studies (30).

Different probing depths have been recorded in numerous studies. Duarte et al recorded a mean PPD of 3.7 ± 0.8(31). Also, Pellicer et al recorded a mean of 2.97±0.90 mm and 3.06±0.88 mm in crestal and subcrestal groups respectively(20).

The mean of PPD in our study was 4.25 mm ±0.21 in crestal group and 4.44 mm ±0.22 in subcrestal group. Both of these values correspond to normal peri-implant tissues(32).

Among the subcrestal group, the probing depth was higher but with no significant difference. This outcome might be ascribed to Pellicer et al who claimed an association that reveals the fact that the deeper the implant location, the deeper the pocket depth would be(12).

Although plaque index was higher in subcrestal group, it was minimal throughout the study as it didn’t exceed score 1 (22) (Mombelli score) as the mean was 0.50±0.00 in crestal group and was 0.77±0.19 in subcrestal group 3 months after loading. The cause of the significant difference between the 2 groups may be related to deeper implant placement which leads to subgingival crown margin which makes hygiene control problematic as Saleh et al stated in their study(33). Also, it may be because of noncompliance with a proper technique of tooth brushing or following oral hygiene measures regularly (34).

Regarding the crestal bone loss and stability, at T2 our study showed that the mesiodistal CBL was significantly lower in the subcrestal group P= (0.004) while the difference between both groups in buccolingual CBL P= (0.743) was not statistically significant. In addition, ISQ values were higher with significance in the subcrestal group compared to crestal group (P=0.033).

The majority of studies have used conventional PA radiographs with paralleling techniques to assess mesiodistal (interproximal) marginal or crestal bone loss (35). Only very few studies examined the buccal and lingual aspects. To our knowledge, there is only one study by Koutouzis et al who assessed the marginal bone level on the buccal and lingual aspect in relation to implant placement depth using CBCT(36). In our study, we evaluated mesiodistal as well as buccolingual CBL using CBCT. According to the mesiodistal CBL, our results showed that subcrestal implant placement exhibited significantly less CBL compared to crestal group at T1 P= (0.041) and T2 P= (0.004). Our results have coincided with madani et al who stated in their study that platform-switched implants inserted subcrestally within 1 mm and 1.99 mm demonstrated that crestal bone loss occurs but to the least extent and that they were not related to any implant radiographical exposure over time(11). However, Ercoli et al found that there is no difference in mesio distal CBL between crestal and subcrestal implants although subcrestal placement decreased the odds of thread exposure with time (37).

Bucco lingual CBL differences displayed no significance between crestal and subcrestal groups at T1 P= (0.870) and T2 P= (0.743) respectively while there is less chance for the subcrestal group to be exposed at the alveolar crest (mean = -1.03 mm) compared to crestal group. Although buccolingual CBL was proved to be non-significant, exposed rough implant surfaces in crestal group might cause difficulties in peri-implant health as the visible roughsurface of an implant migh provide a microenvironment preferable to bacterial contamination as a result of infiltration via the peri-implant sulcus. When implants are inserted at the crestal level, early bone remodeling exposes the implant’s rough surface. This does not occur when implants are placed at subcrestal level because the starting point of the bone is already above the platform of the implant and its rough surface is trapped inside the peri-implant defect formed as a result of the drilling step (20).

Our results coincide with koutouzis et al who found that the percentages of buccolingual surfaces within bone is considerably greater in subcrestal group than epicrestal group(37).
The greater values in subcrestal group may be due to less mesiodistal CBL compared to crestal group, and all implant threads were within bone even if there is no difference between both groups in buccolingual CBL (mean=−1.03mm). Our result agreed with a study done by Guirado et al who stated that after 8 weeks, ISQ values were higher in subcrestal group 71.5 ± 0.67 compared with the crestal group 69.5 ± 0.12(38). While Romanos et al reported a non-significant difference for the Periotest values between crestal and subcrestal implants(39).

CONCLUSIONS
From our study results, we can conclude the fact that subcrestal implant placement is associated with less mesiodistal crestal bone loss, less thread exposure, and better stability than crestal implant placement so, placing an implant at a subcrestal level may be favorable to decrease the probability of implant thread exposure, provided that meticulous oral hygiene care and regular periodic checks are kept to maintain both peri-implant soft tissue and bone health in controlled T2DM.

CONFLICT OF INTEREST
The authors reveal that they have not experienced any financial or personal conflicts of interest.

FUNDING STATEMENT
There is not any specific funding received by the authors for this work.

REFERENCES


