

Clinical Impact of Early loading on Osseointegration Success of Acid Etched Dental Implants Used in Osteoporotic Patients

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Abstract: Problem statement: Osteoporosis is considered one of the relative contraindications to dental implant specially, when associated with early loading protocol. So, this study was directed to evaluate the clinical impact of early loading on osseointegration success of acid etched dental implants used in osteoporotic patients. **Patients and Method:** Sixteen patients are seeking replacement of their missing posterior mandibular tooth by dental implant. Patients were divided into two equal groups, 1st group consisted of eight mild osteopenic patients (t-score of DEXA < -2.5) while, 2nd group contained eight normal patients. All patients were subjected to early loading protocol within 6-8 weeks after implant installation. Patients were assessed clinically using periotest, modified sulcus bleeding index, modified plaque index, peri-implant pocket depth and marginal bone loss either at 3, 6 and 12 months postoperatively. **Results:** Regarding to implant stability assessment, statistical significant differences were recorded between both groups at all intervals either immediately or at 3, 6 and 12 months (P= 0.009, 0.007, 0.003, 0.002 respectively). No statistical significant differences were recorded between both groups at all intervals either immediately or at 3, 6 and 12 months regarding to peri-implant pocket depth (P= 1, 0.835, 0.068, 0.258). While, statistical significant differences were recorded among both groups at 6 and 12 months regarding to marginal bone loss (P= 0.004, 0.007). **Conclusion:** Although, clinical prognosis of implant placement in the posterior mandibular region of mild osteoporotic patient doesn't represent a challenge by itself with regard to their compromised osseous nature. However, it requires proper selection of suitable patients and compatible loading protocol.

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1. Introduction

It is unclear to identify the effect of health risks on the outcome of implant treatment, as there are few of randomized controlled trials (RCTs) figuring status of health as an indication of risk.^[1] Such health risks include for example; uncontrolled diabetes, bleeding disorders, a weakened immune system, or cognitive problems that got attention about postoperative care and raise the risk of implant failure.^[2]

Other relative contraindications were reported such as: smoking, osteoporosis, adolescence, diabetes, positive interleukin-1 genotype, aging, cardiovascular disease, hypothyroidism and Crohn disease, human immunodeficiency virus positivity.^{[3][4]}

Alternatively, there is a relation between osteoporosis/osteopenia and raised failure risk of dental implant has been established, but appropriately designed experimental studies found that this impact is limited. A few investigations found that there is no convincing academic or practical basis to suppose that osteoporosis act as a risk factor for implants.^[5] There is a limited information about confirming the relation

between jaw and skeletal BMD in patients with osteoporosis as stated in a systematic review.^[6]

A systematic review showed no relation between mandibular BMD status, bone quality, systemic bone mineral density (BMD) status, and implant loss, concluding that dental implant use in osteoporotic patients is not a contraindication.^[7]

Additionally, no correlation was revealed between peri-implantitis and osteoporosis,^[8] still the patients suffering severe osteoporosis have been treated effectively with dental implant supported prostheses.^{[9][10]} However, weak correlation between the risk of implant failure and osteoporosis was reported by some case-control studies.^[11] Moreover, limited proof to review showed that if osteoporosis has harmful impact on histological determined osseointegration or not.^[12]

A compatible treatment plan was reported for osteoporotic patients including modification of the implant geometry with large-diameter implants, treated surfaces rather than machined surface are required to guarantee better clinical outcomes.^[13]

Santiago Junior et al. identified a reduced amount of marginal bone loss for platform-switching implants when compared to implants with a regular platform.^[14] Based on the abovementioned data this study was carried out to estimate the clinical impact of early loading on osseointegration success of acid etched dental implants used in osteoporotic patients.

2. Patients and Methods

Sixteen patients seeking replacement of their missing posterior mandibular tooth by dental implant were selected from outpatients of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Mansoura University. Patients with history of bruxism, using glucocorticoid therapy more than 3 months or bisphosphonate treated were excluded from this study.

All patients were distributed into 2 identical groups. 1st Group; included eight patients diagnosed with mild osteoporosis of T score < 2.5 and received acid etched dental implant and loaded in an early protocol within 6-8 weeks. While, 2nd group included eight healthy patients suffering from single missing tooth in posterior mandible and received acid etched dental implant and loaded with an early protocol within 6-8 weeks.

Then, panoramic radiographs were used to evaluate the area of intended implant placement. Panoramic radiographs were used for screening osteoporotic patients by measuring panoramic mandibular index normal value (0.3 mm) mandibular cortical width normal value (3 mm).

Mild osteoporotic group

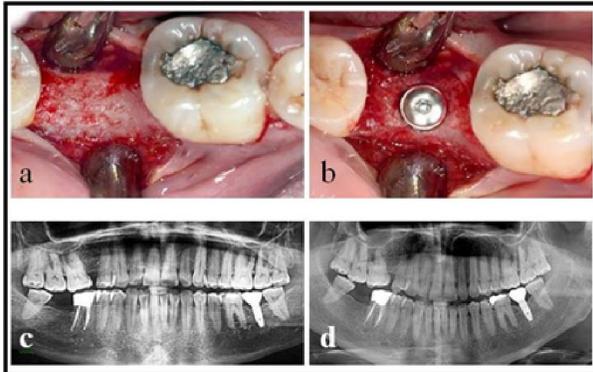


Fig 1.a Showing incision and flap reflection. **Fig 1.b** Implant in place. **Fig 1.c** A panoramic x-ray film revealing the MBL 6 months postoperatively. **Fig 1.d** A panoramic x-ray film revealing the MBL 12 months postoperatively.

Postoperative medication was prescribed including amoxicillin 500mg antibiotic every 8 hours for 5 days. Ibuprofen 400mg (Brufen Kahira Pharm. &

Surgical procedures

All patients were instructed to administrate Amoxicillin^o 500mg (Amoxil, Medical Union Pharmaceuticals Co., M.U.P., A.R.E.) every 8 hours for 2 days preoperatively as a prophylactic antibiotic. Then, rinse his/her mouth using chlorohexidine mouth wash ^π 0.12% (Hexitol, the Arab Drug Company, Cairo, Egypt) before the implant surgery and directly after 2% local anesthesia ^α administration (Mepivacaine HCL 2% with Levonordefrin 1:20,000. Alexandria Co. for pharmaceuticals Ind., A.R.E.). A gingival incision was made and the flap was reflected by mucoperiosteal elevator Fig. no. (1.a, 2.a).

Surgical motor (Xcube Implant motor, Saeshin Precision Co., LTD., Korea) with low speed, high torque contra angled hand piece was used. Drills were used according to the implant surgical kit sequence on speed range of 600-800 rpm with copious irrigation. An osteotomy was created in a diameter compatible with the selected dental implant diameter. Any bone fragments or tissue remnants were removed before placing the implant.

A sterilized implant was picked up from its package and then placed in the previously formed osteotomy site. Gently, the implant was screwed manually and then continued fixation by using ratchet till it reached to the bone level Fig. no. (1.b, 2.b).

Repositioning of the mucoperiosteal flap and primary closure was done by using interrupted sutures. A panoramic radiograph was taken to confirm that the implant was placed in the desired position.

Control group

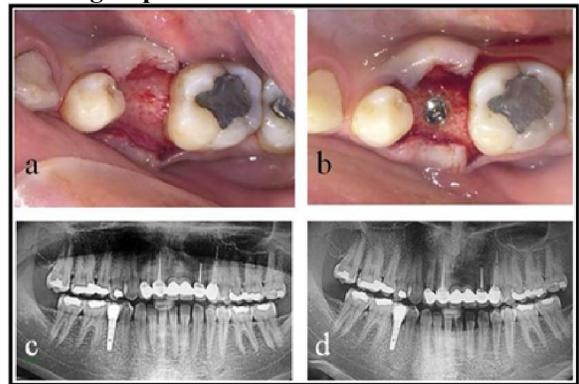


Fig 2.a Showing incision and flap reflection. **Fig 2.b** Implant in place. **Fig 2.c** A panoramic x-ray film revealing the MBL 6 months postoperatively. **Fig 2.d** A panoramic x-ray film revealing the MBL 12 months postoperatively.

Chem. Ind. Co) tablets have been used as anti-inflammatory and pain-relieving drug. Patients were instructed to have a good oral hygiene with

Chlorhexidine HCL (0.12 %), and not to project the placed implant to solid food. Sutures have been removed after surgery by the end of the first week after surgery.

Second stage surgery was performed after 6-8 weeks since implant was initially placed. A small incision was made over the implant and the cover screw was removed and then, the healing abutment was placed and fixed in its place and left for about 10 days.

Ten days after 2nd surgery, the healing abutment was detached from the implant. By using the impression copy and laboratory analogue, an impression was taken and then working cast has been formed. Then, porcelain fused to metal crown was constructed. Finally, crown was cemented to the implant abutment permanently.

Clinical Evaluation

Patients from both groups were checked at regular time intervals during the first year at 3, 6 and 12 months regarding the following parameters:

(1) Implant stability assessment

Periotest device (Periotest M, Medizintechnik Gulden, Germany) was used to assess the implant stability. The result was recorded and categorized by the following classes ^[15] **Class I**; when the result is between -8 & 0. It means that there is good osseointegration and the dental implant can be loaded. **Class II**; when the result is between +1 & +9. This means that the dental implant should be assessed clinically and it is not allowed to load the implant. **Class III**; when the result is between +10 & +20. This means that there is not enough osseointegration to allow the dental implant to be loaded.

(2) Modified sulcus bleeding index

Modified sulcus bleeding index was used to evaluate the health of the gingiva around the restored dental implants. The level was evaluated in accordance with the following grades^[16] Grade 0; revealing no blood when a periodontal probe is placed along the margin of the gingiva around the implant. Grade 1; revealing separate dots of bleeding are able to be seen. Grade 2; revealing a continuous red line of blood on margin. Grade 3; revealing more blood occurs.

(3) Modified plaque index

The result was classified in relation to the following grades^[16]. Grade 0; indicating no plaque has been detected. Grade 1; indicating that plaque can only be seen by moving a probe along the marginal surface of the dental implant. Grade 2; indicating that plaque can be easily seen by eyes. Grade 3; indicating large quantity of soft substances.

(4) Peri-implant Pocket depth

By using a graduated probe the depth of the pocket can be measured from the margin of the

gingiva and the bottom of the pocket. The probe was placed vertically beside the implant until the rounded boundary of the probe get in touch with the bottom of the pocket. The pocket depth was measured mesially and distally at the middle of each aspect. All measurements were documented to the nearest 0.5mm.^[17]

(5) Assessment of marginal bone level

Radiographic evaluation was done using panoramic x-rays to determine changes of marginal bone level immediately and at 3, 6 and 12 months postoperatively (Fig. no. 1.c, 1.d, 2.c, 2.d). The contact between implant and abutment was the reference position for measuring the level of bone. The tip of the interproximal bone level was determined and used as the other reference position mesially and distally of the implant. Distance was measured between these two reference points and the mean was calculated and documented. The real marginal bone loss was determined by correcting the error of magnification. This was done by multiplying the marginal bone loss on the radiograph by the actual length of the implant and then divided by the length of implant on the radiograph.^[18]

Statistical analysis

Data were fed and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using number and percent and Chi-square test was used to analyze it. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median and analyzed using simple t-test. Significance of the obtained results was judged at the 5% level.

3. Results

Sixteen female patients were included in this study for replacement of single missing mandibular posterior teeth. Patients were equally divided into two groups. Ten 1st molars, two 2nd molars, and four 2nd premolars were replaced. No statistical significant differences were recorded between both groups according to tooth number and implant specifications including length and diameter (P=0.108, 0.349, 0.769 respectively). Early loading protocol was applied on all patients included within this study 6 – 8 weeks after implant insertion.

All patients were evaluated clinically using the following parameters.

1. Implant stability

In control group, the PTVs at initial loading ranged from -5 to -2 with an average mean -3.57 ± 1.21 . After 3 months it ranged from -5 to -2 with an average mean value -3.86 ± 1.21 in comparison with periotest values at the time of initial loading and 3 months of follow up ranged from -3 to -2 and average

mean -2.14 ± 0.38 for mild osteoporotic group. While, after 6 and 12 months within control group, PTVs were ranged from -4 to -2 with a variation in the recorded average mean for same time intervals of follow up -3.14 ± 0.9 , -2.86 ± 0.69 respectively. Meanwhile, in mild osteoporotic group after 6 and 12 months, PTVs ranged from -2 to 0 with an average mean -1.0 ± 0.82 , -0.71 ± 0.76 respectively.

Significant differences were established among both groups at all intervals either immediately or at 3,

6 and 12 months ($P= 0.009, 0.007, 0.003, 0.002$ respectively) (table 1). No statistical significant differences were found between initially recorded PTVs versus those recorded at different assessment intervals of follow up of control group ($P= 0.317, 0.257, 0.096$). However, statistical significant differences were found between initial PTVs versus those recorded at 6, 12 months of follow up of mild osteoporotic group ($P= 0.023, 0.015$ respectively).

Table 1: Showing the mean PTVs, standard deviation and P values among patients of both groups during different assessment intervals.

| Patients Grouping/ Assessment Parameter | Implant stability assessment | | | |
|---|------------------------------|------------------|------------------|------------------|
| | Baseline | 3 months | 6 months | 12 months |
| Mild osteoporotic group | | | | |
| Mean \pm SD. | -2.14 ± 0.38 | -2.14 ± 0.38 | -1.0 ± 0.82 | -0.71 ± 0.76 |
| Control group | | | | |
| Mean \pm SD. | -3.57 ± 1.13 | -3.86 ± 1.21 | -3.14 ± 0.90 | -2.86 ± 0.69 |
| P | 0.009* | 0.007* | 0.003* | 0.002* |

2. Modified sulcus bleeding index (MSBI)

In control group, at the time of initial loading five patients recorded grade 0 and two patients recorded grade 1 in comparison with two patients recorded grade 0 and five patients recorded grade 1 in mild osteoporotic group. While, at 6 and 12 months two patients recorded grade 0 and five patients recorded grade 1 within control group. Meanwhile, in mild osteoporotic group after 6 and 12 months, one patient recorded grade 0 and six patients recorded grade 1 according to modified sulcus bleeding index.

Only one patient in each group included within this study suffered from extensive bleeding without pus formation with marked severity of the condition for the patient included in study group. Both patients didn't respond to proper gingival care through application of local antiseptics leading to their loss

No significant differences were established among both groups at all intervals of assessment regarding to modified sulcus bleeding index ($P=0.286, 1.0, 1.0$ respectively) (table 2).

Table 2: Showing patients distribution and P values among both groups regarding to modified sulcus bleeding index

| Patients Grouping/ Assessment Parameter | Modified sulcus bleeding index | | | | | | | |
|---|--------------------------------|-------|----------|------|----------|------|-----------|------|
| | Baseline | | 3 months | | 6 months | | 12 months | |
| | No. | % | No. | % | No. | % | No. | % |
| Mild osteoporotic group (n=7) | | | | | | | | |
| Grade 0 | 5 | 71.4 | 2 | 28.6 | 1 | 14.3 | 1 | 14.3 |
| Grade 1 | 2 | 28.6 | 5 | 71.4 | 6 | 85.7 | 6 | 85.7 |
| Control group (n = 7) | | | | | | | | |
| Grade 0 | 7 | 100.0 | 5 | 71.4 | 2 | 28.6 | 2 | 28.6 |
| Grade 1 | 0 | 0.0 | 2 | 28.6 | 5 | 71.4 | 5 | 71.4 |
| P | 0.462 | | 0.286 | | 1.000 | | 1.000 | |

3. Modified plaque index

In both group at the time of initial loading seven patients recorded grade 0. At 3 months five patients recorded grade 0 and two patients recorded grade 1 in control group against four patients recorded grade 0 and three patients recorded grade 1 in mild osteoporotic group. At 6 and 12 months two patients

recorded grade 0 and five patients recorded grade 1 in control group versus one patient recorded grade 0 and six patients recorded grade 1 in mild osteoporotic group according to modified plaque index.

No significant difference was declared among both groups at all intervals of assessment regarding to modified plaque index ($P=1.0$) (table 3).

4. Peri-implant pocket depth (PPD)

In control group, the peri-implant pocket depth at the time of initial loading ranged from 0.5 to 0.7mm with an average mean 0.54 ± 0.08 mm in comparison with a range of 0.5 to 0.7mm and average mean 0.54 ± 0.08 mm in mild osteoporotic group. After 3 months, PPD ranged from 0.5 to 0.8mm with an average mean 0.60 ± 0.14 in control group versus 0.5 to 0.7mm and average mean 0.6 ± 0.11 mm in mild osteoporotic group. After 6 months, it ranged from 0.5 to 0.9mm with an average mean 0.71 ± 0.20 mm in control group

against 0.7 to 1.1mm and average mean 0.90 ± 0.13 mm in mild osteoporotic group. After 12 months, it ranged from 0.5 to 1mm with an average mean 0.84 ± 0.19 mm in control group versus 0.7 to 1.3mm and average mean 0.97 ± 0.21 mm in mild osteoporotic group.

No significant difference was established among both groups at all assessment intervals either immediately or at 3, 6 and 12 months ($P= 1.000, 0.835, 0.068, 0.258$) (table 4).

Table 3: Showing patients distribution and P values among both groups regarding to modified plaque index

| Patients Grouping/ Assessment Parameter | Modified plaque index | | | | | | | |
|---|-----------------------|-------|----------|------|----------|------|-----------|------|
| | Baseline | | 3 months | | 6 months | | 12 months | |
| | No. | % | No. | % | No. | % | No. | % |
| Mild osteoporotic group | | | | | | | | |
| Grade 0 | 7 | 100.0 | 4 | 57.1 | 1 | 14.3 | 1 | 14.3 |
| Grade 1 | 0 | 0.0 | 3 | 42.9 | 6 | 85.7 | 6 | 85.7 |
| Control group | | | | | | | | |
| Grade 0 | 7 | 100.0 | 5 | 71.4 | 2 | 28.6 | 2 | 28.6 |
| Grade 1 | 0 | 0.0 | 2 | 28.6 | 5 | 71.4 | 5 | 71.4 |
| P | - | | 1.000 | | 1.000 | | 1.000 | |

Table 4: showing Mean PPD values, standard deviation and P values among patients of both groups during different assessment intervals.

| Patients Grouping/ Assessment Parameter | Pre-Implant Pocket Depth | | | |
|---|--------------------------|-----------------|-----------------|-----------------|
| | Baseline | 3 months | 6 months | 12 months |
| Mild osteoporotic group | | | | |
| Mean \pm SD. | 0.54 ± 0.08 | 0.61 ± 0.11 | 0.90 ± 0.13 | 0.97 ± 0.21 |
| Control group | | | | |
| Mean \pm SD. | 0.54 ± 0.08 | 0.60 ± 0.14 | 0.71 ± 0.20 | 0.84 ± 0.19 |
| P | 1.000 | 0.835 | 0.068 | 0.258 |

(5) Marginal bone loss (MBL)

In control group, at 3 months after loading the average mean MBL was 0.11 ± 0.07 mm versus an average mean MBL 0.13 ± 0.05 mm recorded in mild osteoporotic group. After 6 months, the average mean MBL was 0.14 ± 0.05 mm in control group in comparison with an average mean MBL 0.27 ± 0.05 recorded in mild osteoporotic group (Fig. no.1.c, 2c). After 12 months, the average mean MBL was $0.17 \pm$

0.05 mm in control group versus average mean MBL 0.29 ± 0.07 mm recorded in mild osteoporotic group (Fig. no.1.d, 2.d).

No statistical significant difference was established between both groups after three months of loading ($P= 0.705$). While, statistical significant differences were declared among both groups at 6 and 12 months regarding to marginal bone loss ($P= 0.004, 0.007$) (table 5).

Table (5): Showing the mean MBL values and standard deviations, and P values among patients of both groups during different assessment intervals.

| Patients Grouping / Assessment Parameter | Marginal bone loss | | |
|--|--------------------|-----------------|-----------------|
| | 3 months | 6 months | 12 months |
| Mild osteoporotic group | | | |
| Mean \pm SD. | 0.13 ± 0.05 | 0.27 ± 0.05 | 0.29 ± 0.07 |
| Control group | | | |
| Mean \pm SD. | 0.11 ± 0.07 | 0.14 ± 0.05 | 0.17 ± 0.05 |
| P | 0.705 | 0.004* | 0.007* |

Statistical significant differences were recorded when comparing baseline MBL values against those recorded at 6, 12 months ($P= 0.102, 0.014, 0.011$ respectively).

In harmony with these results, a statistical significant difference was declared between marginal bone loss values recorded at 3 months versus those declared at 6 months ($P=0.015$). Nevertheless, no statistical significant differences were established among MBL values of 6 months versus those of 12 months. ($P= 0.317$).

4. Discussion

Basically, no clear evidence proved that whether osteoporosis impairs clinical prognosis following dental implants treatment was found.^[19] Several studies have declared the clinical drawbacks associated with dental implants inserted in osteoporotic patients.^[20] Authors showed a high rate of implant failure in patients with osteoporosis^[21], and osteopenia^[22]. In contrary, another studies revealed that the rate of implant loss is not higher in patients with osteoporosis rather than those installed in normal individuals.^[23]

Based on the aforementioned controversial studies, only one patient within each group included in this study showed an early failure of implant secondary to an inflammatory cascade involving initially overlying gingiva and subsequently the underlying supporting bone with unsuccessful response to a meticulous local wound care measures. In the same way, Alsaadi et al. reported the limited impact of using antibiotics or even local application of antiseptic mouth in prevention of early implant failure in osteoporotic patient.^[24]

Additionally, only mild osteopenic patients ($Dexa < 2.5$) were included within this study in a trial to evaluate their clinical impact on osseointegration process in comparison with normal control individuals since osteoporotic patient with their variable grades of severity are considered theoretically as a relative contraindication and secondary due to the pattern of early loading protocol that was followed in this study.

Regarding to implant stability assessment using PTVs, statistical significant differences were recorded among both groups at all assessment intervals either immediately or at 3, 6 and 12 months ($P= 0.009, 0.007, 0.003, 0.002$ respectively). Moreover, statistical significant differences were found among initial PTVs versus those recorded at 6, 12 months of follow up of mild osteoporotic group ($P= 0.1, 0.023, 0.015$ respectively) in contrast with no statistical significant differences recorded within control group for same analytic variables and assessment intervals of follow up ($P= 0.257, 0.096$).

Such results can be regarded to the physiologic impact of mild osteoporotic condition on mandibular bone remodeling process of type II character following implant insertion. Additionally, the commonly fluctuation in the early recorded PTVs especially, when associated with applying of early loading protocol. This observation can be clarified by the explanation of Glauser et al.,^[25] whom suggested that, the initial drop is probably related to several factors such as bone relaxation following compression, biologic changes associated with early bone healing, initiation of marginal bone resorption.

Meanwhile, the lack of significance among both groups regarding to sulcus bleeding index at different time intervals can be explained in the lights of the study of McDermott et al.,^[26] whom suggested that, several factors affecting the peri-implant gingival and periodontal condition including either operator factors, prosthesis related factors and patient related factors. The operator related factor may be due to excessive pressure during examination. Fundamentally, soft tissue status, probing forces and probe dimension are considered as the factors that control probing penetration depth.^[27]

With regard to peri-implant pocket depth assessment, no statistical significant difference was documented among both groups at all intervals either immediately or at 3, 6 and 12 months ($P= 1, 0.835, 0.068, 0.258$). Such finding can be attributed to the explanation introduced by Abboud et al.^[28] who reported the role of provisional restoration in molding, contouring, and healing of the soft tissue with further adaptation to an anatomic form. Under guidance of this fact, early placement of provisional restoration in our study can be responsible on the lack of significant difference among both groups.

Additionally, regarding to marginal bone level assessment, no statistical significant difference was recorded between both groups after three months of loading. While, statistical significant differences were recorded among both groups at 6 and 12 months regarding to marginal bone loss ($P= 0.705, 0.004, 0.007$). In accordance with our findings, chow et al., 2016 declared weak correlation between probing depth and mean marginal bone in osteoporotic patients and attributed such findings to the small sample size, which is quite similar to our study. In addition, probing depths were measured from the gingival margins, which did not usually account for gingival recession.^[29]

On the other hand, in the mild osteoporotic group, a statistical significant difference was documented among marginal bone loss values recorded at 3 months versus those recorded at 6 months ($P=0.015$). Additionally, no statistical

significant differences were established between MBL values of 6 months versus those of 12 months. ($P=0.317$). Such findings can be explained by Von Wöhrn et al., in 2001 who reported an association between osseointegration and the risk of bone loss in implant area in osteoporotic patients.^[30]

Furthermore, Zhang et al. 2014 declared no statistical correlations between any of the clinical parameters and marginal bone loss in osteoporotic patient. Author also declared that greatest marginal bone loss and femoral neck T-score are not correlated.^[31] To the best of our knowledge, we believe that clinical outcomes associated with implant installation in osteoporotic patients are not related only to the compromised status of bone by itself but also it can be considered as a technique sensitive maneuver that require strict guide lines to enhance the overall prognosis.

Conclusion

Although, clinical prognosis of implant placement in the posterior mandibular region of mild osteoporotic patient doesn't represent a challenge by itself with regard to their compromised osseous nature. However, it requires proper selection of suitable patient and compatible loading protocol.

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