

Impact of Insertion Torque and Implant Neck Design on Peri-Implant Bone Level: A Randomized Split-Mouth Trial

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ABSTRACT

Purpose: The aim of this study is to assess the impact of insertion torque and implant neck design on peri-implant bone levels and gain insights into dynamic crestal tissue alterations by radiological, clinical, and biochemical examinations.

Material and Methods: In this prospective trial, a total of 84 implants (four implants in each patient) in the interforaminal region of 21 edentulous mandibles were randomly alternated according to a split-mouth design. Implant placement was performed using different insertion torques (≤ 20 Ncm vs > 50 Ncm). In each group, one machined and one anodized implant neck design (1.5 mm length) was used in the same jaw side. Evaluation of peri-implant tissues involved radiological, clinical examination and immunoassays for interleukin-1 β .

Results: No significant influence of insertion torque or implant neck design on peri-implant bone level was found. Protein levels of interleukin-1 β in the peri-implant crevicular fluid revealed no difference between both insertion torque groups and different neck designs.

Conclusion: Interactive effects of insertion torque and neck surface modification may exist; however, no clinically significant differences in marginal bone resorption after 1 year could be observed in the edentulous anterior mandible.

KEY WORDS: bone-implant interface, crestal bone loss, crevicular fluid analysis, edentulous mandible, implant neck design, implant stability, insertion torque, osseointegration, tapered implants

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DOI 10.1111/cid.12042

INTRODUCTION

Predictable success of dental implants has been reported because of enhanced implant surface modifications and improved understanding of osseointegration. Criteria for the evaluation of implant success are generally based on clinical and radiologic aspects such as probing depths, implant mobility, and peri-implant bone changes.^{1,2} Peri-implant bone level alterations are considered as a significant indicator of implant health showing the majority of bone loss within the first year of implant placement.²

Bacterial infection, surgical trauma, occlusal overload, patient characteristics as well as the implant neck design have been suggested as factors contributing to peri-implant bone level alteration. The crestal area receives the majority of occlusal forces that affect the surrounding tissue of an implant.³ Implant neck designs with a rough surface and/or microthreads may inhibit detrimental micro-motion at the bone-implant

interface and thus allow stress transfer to the surrounding tissue⁴⁻⁸ if stress does not exceed localized yield strength of the cortical bone.⁹ Mechanical stress below a certain threshold results in apposition of peri-implant bone, whereas bone loss is observed beyond this threshold.¹⁰⁻¹² Primary stability is considered as a prerequisite for proper osseointegration so that micromotions at the bone-implant interface do not jeopardize implant success. Higher insertion torque values are related to higher primary stability^{13,14}; however, excessive osseocompression can cause marginal bone loss.¹²

Detection of marginal bone loss by means of radiologic assessment offers information on the bone level of both mesial and distal sites only. Peri-implant crevicular fluid (PICF) analysis, by contrast, provides insights into the dynamic pathophysiological mechanisms around dental implants. Increased levels of inflammatory cytokines in PICF, such as interleukin-1 β , may reflect active stages of tissue alteration and thus can be used as a diagnostic and prognostic marker for peri-implant tissue destruction. Detection of peri-implant alterations as early as possible is of great importance for the prognosis of an implant.¹⁵

Detection of factors impairing dental implant success is the main goal of recent research in implant dentistry.¹⁶ Information on the influence of insertion torque and implant neck design are scarce in the literature and, to the best of the authors' knowledge, interactive effects have not been investigated yet. Therefore, the aim of the present randomized split-mouth trial was to evaluate the impact of insertion torque and neck design on tissue alterations at the crestal area by radiological, clinical, and biochemical examinations.

MATERIALS AND METHODS

Patients/Subject Sample

In this prospective study, a total of 84 implants (four implants per patient) were randomly alternated according to a split-mouth design in 21 edentulous mandibles in the interforaminal region using permuted-block randomization (Figure 1). Inclusion criteria involved: (1) edentulous mandibles, (2) teeth extracted for at least 6 months, (3) sufficient bone volume in height and width to allow for implant placement; and (4) without any augmentation procedure. Patients were excluded from the study if any medical or psychiatric contraindication to implant surgery was present. Patients were treated

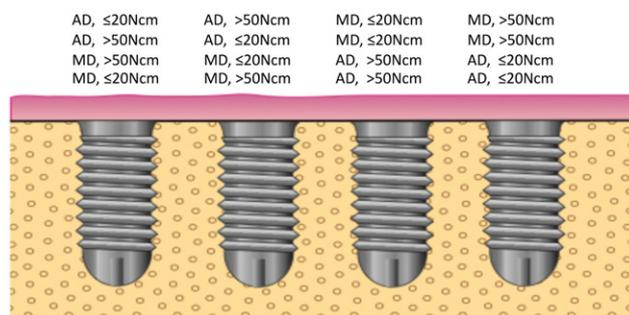


Figure 1 Random sampling in the lower mandible: possibilities of implant distribution (AD: anodized implant neck design, MD: machined implant neck design); insertion torque ($\leq 20\text{ Ncm}$, $>50\text{ Ncm}$).

between 2009 and 2011 at the Bernhard Gottlieb University Clinic of Dentistry in Vienna. Implant placement was performed using insertion torques of either $\leq 20\text{ Ncm}$ (L-group) or $>50\text{ Ncm}$ (H-group). Screw tapping was performed to achieve implant insertion torques of $\leq 20\text{ Ncm}$. Insertion torque was monitored through a surgical motor unit (Implantmed SI-923; W&H, Bürmoos, Austria) and verified by torque wrench measurements. In each group, one machined and one anodized implant neck design (1.5 mm length) was used per jaw side. For all implants, a submerged healing protocol was applied, and prosthetic restoration was performed by removable overdentures after a 3-month healing period. Patients were informed in detail and gave their informed consent. The study protocol was approved by the Ethics Committee of the Medical University of Vienna (EK-Nr. 561/2008) (Figure 2).

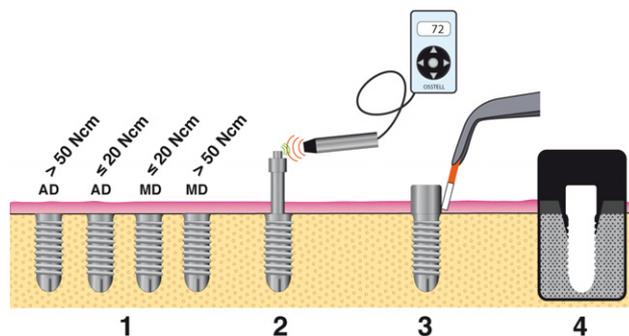


Figure 2 Schematic illustration of the study protocol: (1) implant placement with different insertion torques ($\leq 20\text{ Ncm}$, $>50\text{ Ncm}$) and different implant neck designs (AD: anodized design, MD: machined design), (2) implant stability measurements by resonance frequency analysis using Osstell® mentor and Smartpeg™ abutments, (3) collection of crevicular fluid for detection of interleukin-1 β , (4) radiographic assessment of peri-implant bone level.

Clinical and Radiographic Analysis

All patients were clinically examined postoperatively, at second stage surgery as well as after 6 and 12 months based on a standard protocol. The clinical monitoring included the assessment of bleeding on probing (4-point measurement) and peri-implant pocket depths (mesial, buccal, distal, and lingual). Implant stability measurements were performed immediately after implant placement, after implant uncovering (3 months) as well as at 6 and 12 months recall by resonance frequency analysis. Osstell® mentor (Integration Diagnostics AB, Gothenburg, Sweden) and Smartpeg™ abutments were used to measure implant stability quotient (ISQ) values.¹⁷ Removal of the suprastructure was performed at 6 and 12 months to allow for clinical and PICF analysis.

Peri-implant bone level changes were evaluated at the mesial and distal aspect of each implant by periapical radiographs after implant placement as well as after 3, 6, and 12 months (Figure 3). Radiographic bone loss was computed in duplicate using an individual magnification factor determined by comparison of actual and radiographic implant length. Bone level changes were analyzed separately on the mesial and distal side by subtracting the values of bone loss after implant placement.

Collection of PICF

PICF was collected at 3 and 12 months to monitor inflammatory alterations of interleukin-1 β .¹⁸ The gingiva around each implant was dried gently by air and isolated by cotton rolls. Paper strips (Periopaper, ProFlow, Amittyville, NY, USA) were inserted into the peri-implant pocket for 30 seconds. Samples were collected from the mesial and distal aspects of each implant and discarded if contaminated with blood or saliva. Determination of the adsorbed volume was performed by impedance measurements based on a calibration curve (Periotron 8000, Oralflow Inc., Plainview, NY, USA). Filter strips were placed in 1.5 mL plastic Eppendorf tubes containing phosphate-buffered

saline. The samples were stored at -80°C for subsequent analysis.

Interleukin-1 β Assay

Proinflammatory cytokine concentrations (interleukin-1 β) in PICF eluates were assessed using commercially available enzyme-linked immunosorbent assay kits according to manufacturer instructions (DuoSet® ELISA Development System R&D Systems Europe, Ltd., Abingdon, UK). Levels of interleukin-1 β were examined using a microplate reader at 540 nm wavelength (SpectraMax Plus 384, Molecular Devices, LLC, Sunnyvale, CA, USA). Concentrations of interleukin-1 β were determined by generation of a standard curve for comparison, corrected for PICF volume and defined as pg/mL. Total amounts of interleukin-1 β were expressed as pg/site.

Statistical Analysis

Sample Size Calculation. Since the present study design was developed as a prospective trial, a priori sample size calculation was performed. A difference of the mean peri-implant bone losses between 1 and 0.75 mm at 12 months after implant placement (assuming a standard deviation of the differences of 0.35) between implant surfaces can be detected with a two-sided significance level of 5% and a power of 87% if 21 patients are recruited in the study and if every patient receives both implant surfaces. As in this 2×2 factorial design, insertion torque is balanced over implant surfaces, and no interaction between implant surface and torque was assumed; the same difference can also be detected for insertion torque as every patient receives four implants of every surface-torque combination.

Statistical Methods. Continuous data are described with mean and standard deviation, and categorical data are described with absolute and relative frequencies. Continuous data are modeled by linear mixed models

Baseline	3months	6months	12months
Implant placement	-	-	-
Radiographic assessment	X-rays	X-rays	X-rays
Insertion Torque	-	-	-
Osstell	Osstell	Osstell	Osstell
-	-	Gingival Probing	Gingival Probing
-	Crevicular Fluid	-	Crevicular Fluid

Figure 3 Timetable of the prospective randomized split-mouth study.

with repeated measurements per patient where time is modeled as repeated measurement with first-order autoregressive variance–covariance matrices and implant region with an unstructured covariance matrix. Residuals were graphically inspected to check assumptions of normally distributed residuals and homoscedasticity. Generalized linear models with logit link were used to model binary dependent variables at 12 months with compound symmetry variance–covariance matrix for repeated measurements. Statistical calculations were performed with the statistical software SAS® (Version 9.3; SAS Institute Inc., Cary, NC, USA). All p values are two-sided and considered significant with $p \leq .05$.

RESULTS

A total of 84 implants were placed in edentulous jaws of 21 patients (13 women, eight men) with a mean age of 67.4 years at time of implant placement (range: 45–86 years). Implant lengths of 10 mm and 13 mm were used in 57% ($n = 48$) and 43% ($n = 36$) and a diameter of 3.5, 4.3, and 5 mm in 24% ($n = 20$), 74% ($n = 62$), and 2% ($n = 2$) of cases, respectively. During the observation period, one implant (insertion torque >50 Ncm, machined implant neck design) was lost after uncovering and successfully replaced after 3 months of healing. The resulting 1-year implant survival rate was 98.8%.

Mean probing depths after 6 and 12 months were 2.2 ± 1.0 and 1.9 ± 0.9 mm, respectively, and were not influenced by insertion torque values or type of implant neck design. Bleeding on probing was seen in 10% ($n = 26$) of the implant sites and was 2.5-fold higher for anodized implants with borderline significance of $p = .055$ (odds ratio [OR] = 2.5; 95% confidence interval [95% CI] 1.0–6.2). Logistic regression analysis showed that the likelihood for bleeding on probing increased from 6 to 12 months with an odds ratio of 2.2 (95% CI 0.9–5.4; $p = .071$). Bleeding on probing was associated with pocket depths on the mesial, distal, buccal, and lingual side with a likelihood of OR = 2.9 ($p = .007$), 4.4 ($p = .011$), 1.4 ($p = .029$), and 2.4 ($p = .381$), respectively.

Implant stability measurements at the time of implant placement revealed least square ISQ means of 75.5 and 78.5 for torque groups L (≤ 20 Ncm) and H (>50 Ncm), respectively. After 12 months, ISQ values were similar in both groups with mean values of 80.5 and 81.3 ($p = .029$), however, changed significantly over time (test for interaction $p = .029$).

TABLE 1 Qualitative Interaction of Insertion Torque (≤ 20 Ncm, >50 Ncm), and Implant Neck Design (Anodized and Machined) on Least Square Means of Peri-Implant Bone Level Changes

Insertion Torque	Implant Neck Design	Bone Level Changes
≤ 20 Ncm	Machined	0.57 mm
≤ 20 Ncm	Anodized	0.75 mm
>50 Ncm	Machined	0.73 mm
>50 Ncm	Anodized	0.62 mm

Peri-implant bone level changes revealed least square means of 0.30 mm, 0.71 mm, and 1.00 mm at 3, 6, and 12 months, respectively, and changed significantly over time (test for interaction $p < .001$). Peri-implant bone loss was 0.69 mm and 0.68 mm for insertion groups L and H, whereas least square means of 0.68 mm and 0.65 mm were observed for the anodized and machined design, respectively. No influence of insertion torque ($p = .912$) or implant neck modifications ($p = .682$) on peri-implant bone level was observed; however, a significant qualitative interaction of the combined factors torque and surface was seen ($p = .037$). The machined implant neck design revealed the lowest degree of bone loss in conjunction with low insertion torque (≤ 20 Ncm), whereas higher peri-implant bone loss was seen in cases of high insertion torque (Table 1).

Concentrations of the pro-inflammatory cytokine interleukin-1 β in PICF were 41.6 ± 1.2 pg/mL and 42.8 ± 1.3 pg/mL at 3 and 12 months, respectively. Higher concentrations of 44.9 ± 1.2 pg/mL were seen in the L group compared with 39.6 ± 1.2 pg/mL but did not reach the level of statistical significance. After 12 months of healing, higher pro-inflammatory concentrations were correlated with higher pocket depths ($p = .015$), whereas correlation between bleeding on probing and cytokine concentrations in PICF was not significant ($p = .081$).

No influence of insertion torque ($p = .560$) and implant neck design ($p = .345$) on interleukin-1 β concentrations was seen. Peri-implant bone level changes were not reflected by PICF measurements ($p = .669$).

DISCUSSION

In the present study, no significant influence of insertion torque value on peri-implant bone level was observed in the lower jaw of edentulous patients. These results,

however, are in contrast to generally accepted engineering principles of the relationship between stress and strain relationship. The amount of strain is dependent on both the applied mechanical stress as well as the properties of the surrounding bone.¹¹ Strain values of 1500–3000 microstrain are reported to result in bone apposition, whereas excessive strain values beyond this range may induce bone resorption or fracture.¹¹ Thus, it is reasonable to assume that higher insertion torques may result in peri-implant bone loss due to excessive osseocompression.¹⁹ Similar results were observed in an experimental implant design study where excessive strains at the crestal area may have contributed to peri-implant bone loss due to static load.¹⁴ In the present study, however, no significant influence of insertion torque on peri-implant bone loss was found. Different interpretations may be hypothesized: (1) compressive torque forces did not exceed the critical threshold in this anatomical region and (2) the surrounding tissue was not exposed to excessive dynamic load.

Static load was reported to induce structural adaptation of the peri-implant bone with absence of bone loss^{20–24}; dynamic load, by contrast, is seen to have detrimental effects on peri-implant bone behavior.²⁴

Implant insertion torque analysis is a valuable method for estimation of primary implant stability at surgery.^{25–27} Higher torque values were assumed favorable to obtain osseointegration, otherwise, implants were prone to failure because of decreased resistance of micromotions.^{12,13,28} Recently, an *in vitro* study showed that high insertion torque values in dense cortical bone did not induce implant failure but increased primary stability.²⁹ It was assumed that higher bone density reduced the strain in the marginal bone when subjected to loading and thus reducing peri-implant bone loss in the adaptation phase.¹¹ This is in line with the present study, as higher bone density of the mandible may have prohibited bone loss. However, one implant that exceeded insertion torque of 50 Ncm was lost due to fibrous encapsulation after a healing period of 3 months. The reason for the implant failure may only be hypothesized as it occurred for once. By contrast, peri-implant bone loss was reported to be significantly higher in the mandible due to less vascularization and slower bone adaptation compared with trabecular bone^{14,30} despite such biological tolerance of the mandibular bone against static forces.^{24,31} Further research is needed to gather more detailed information on implant-bone

interactions if subjected to different insertion torque forces and to different bone quality conditions.

Detection of early signs of disease initiation is of greatest importance for timely therapeutic intervention.³² Levels of interleukin-1 β around diseased implant sites were shown to be threefold higher than around stable peri-implant conditions thus providing evidence for the suitability of interleukin-1 β as a prognostic sensitive marker for detection of peri-implant bone alterations.³³ In the present study, detectable values of interleukin-1 β revealed no difference in both insertion torque groups and different neck designs. Concentrations of interleukin-1 β were comparable with those reported for healthy peri-implant control sites demonstrating no active stages of tissue destruction.³⁴ This underlines the homogeneity of the present study results. Peri-implant bone loss was measured within accepted values reported for the first year of implant function, and analysis of PICF was in line with data obtained from radiological evaluation. That bone level changes were not reflected by interleukin-1 β levels in the PICF suggests that these changes involved other than inflammatory processes.

Although several factors may be considered responsible for the etiology of peri-implant bone loss, subject variables can be excluded in the present study due to the split-mouth design. Implant neck modifications were reported to effect the stress–strain distribution on the implant-bone interface.^{2,35} A major decrease of shear stress was observed through retention elements that was asserted to counteract marginal bone resorption.³⁶ In direct comparison of rough and smooth surface modifications, higher bone loss was reported for machined surfaces,³⁷ whereas additional rough microthreads at the implant neck were considered favorable to show the least amount of bone loss.³⁸ In the present study, however, no significant differences were observed for both implant design groups suggesting insufficient roughness of the implant neck design to effect the stress distribution.^{39,40} This may also be due to the shorter observation period. By contrast, a qualitative interaction of both torque and surface was seen in the present study. The machined implant neck design revealed the lowest degree of bone loss in conjunction with low insertion torque; however, these data must be interpreted with caution due to clinically insignificant differences of peri-implant bone loss. However, interactive effects of insertion torque and neck surface modification may exist in other jaw regions such

as, for example, the anterior maxilla. Further research on the combined impact of different surface roughness modifications as well as on interactions of torque and surface modifications are needed to gather more detailed insights into crestal peri-implant tissue alterations. Furthermore, the impact of reduced implant length (shorter than 10 mm) needs to be investigated.⁴¹

To the best knowledge of the authors, this is the first clinical study evaluating the impact of insertion torque on peri-implant bone loss in a split-mouth design. The results of the present study suggest that both different insertion torque forces as well as implant neck designs did not influence stability of peri-implant tissue. Interactive effects of insertion torque and neck surface modification may exist; however, no clinically significant differences in marginal bone resorption after 1 year could be observed in the anterior mandible. Future research is indicated to gain more detailed insight into implant-bone interactions at early stages after implant placement due to higher incidence of peri-implant bone loss.

ACKNOWLEDGMENTS

The authors wish to thank Manuela Pensch, DDr. Martin Krainhöfner, and Assistant Professor DDr. Konstantin Zauza for their valuable contribution to the present study.

CONFLICTS OF INTEREST AND SOURCE OF FUNDING

The authors declare that they have no conflicts of interest. The study was supported by the Department of Oral Surgery, Bernhard Gottlieb University Clinic of Dentistry, Medical University of Vienna, Vienna, Austria.

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