

Article

# Factors Related to Early Marginal Bone Loss in Dental Implants—A Multicentre Observational Clinical Study

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**Abstract:** This study evaluated the effect of clinical and patient-related factors on marginal bone loss. The sample was composed of individuals who were treated at two dental schools in southern Brazil. The variables evaluated were divided into individual (age, sex, diabetes, hypertension and antihypertensive use), and implant levels (arch, position, brand, protection, torque, time). After implant installation and following the second stage, periapical radiographs were obtained to measure the distance between the peri-implant bone crest and implant platform. Measurements were performed using ImageJ software. Data were analyzed using linear and Poisson multilevel regression. Fifty-eight patients with 113 implants were evaluated. The mean marginal bone loss was  $0.45 \pm 0.48$  mm. Considering the linear multivariate model, age, diabetes, torque and time between surgery and reopening were found to be significant ( $p < 0.05$ ). In the dichotomous model (bone loss  $< 0.2$  mm and  $\geq 0.2$  mm), only high torques resulted in higher marginal bone loss ( $p = 0.033$ ). Marginal bone loss occurred before the second surgical stage and was greater in implants with high torque. Torque below 20 N, reopening performed after six months, diabetic status and young age all resulted in higher marginal bone loss, but these values are probably not clinically significant. These variables must be better explored in future studies.

**Keywords:** dental implants; marginal bone loss; insertion torque

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## 1. Introduction

The marginal bone loss (MBL) of implants is one criterion used to determine the success rate of rehabilitation [1]. A reduction in MBL can reduce other complications, such as soft tissue recession, peri-implantitis, fractures and implant loss. Historically, MBL from 1.2 mm to 2.0 mm is reported during the first year of function, with a further loss of 0.1 mm every year, with the greatest bone loss occurring during the first three months of occlusal loading [2]. Studies demonstrate that implants with a Morse taper connection can preserve the bone even after second-stage surgery and initial loading [3,4]. Recent implant systems, with one to five-year follow-ups reveal MBLs smaller than historically acceptable, as follows:  $0.2 \pm 1.2$  mm after one year with Morse taper [5];  $0.42 \pm 0.77$  mm after three years with Morse taper [4]; and  $0.47 \pm 0.65$  mm with external hexagon and  $0.15 \pm 0.33$  mm with internal hexagon, after four years.

Osseointegration has been defined as a direct and functional connection between the bone and an artificial implant. Both bone quality and quantity can influence the success of these procedures [6]. Height and density are two important parameters for a successful result in implantology. Bone compaction and the osseodensification technique positively

affect the primary implant stability values in cancellous bone, which permits a high insertion torque [7]. Insertion torque is the force required for the implant to lock in the bone structure, expressed in newton centimeters (Ncm) [8]. The optimal torque value depends on the manufacturer's recommendations, but it is usually between 30 and 40 Ncm [9], and the higher the insertion torque, the greater the tension in the region. This may be associated with peri-implant bone injury and difficulties in vascularization, contributing to osteocyte necrosis, and resulting in microfractures in the cortical bone, extensive bone remodeling and minimal bone formation [10].

According to some theories [1,11], the absence of the functional load on the implants during the healing period represented a fundamental factor for the bone formation. It has been established that a healing period with no functional load on the mandible for three to four months or on the maxilla for five to six months is necessary for osseointegration. However, studies report a high success rate of implants with early and immediate loading, with no difference in the success rate and MBL compared with conventional loading [12,13].

Diabetic patients show a trend for higher MBL. Chronic hyperglycemia can act on osteoblast synthesis and stimulate osteoclast function [14], reducing bone formation during the healing phase, which explains the higher failure rate during osseointegration.

Pre-prosthetic MBL has been previously evaluated [5,15], but the factors that influence early MBL (pre-prosthetic) are not often mentioned. The objective of the study is to evaluate the relationship of early MBL around implants with (a) installation torque, (b) time between surgery and reopening, (c) general health (hypertension, diabetes and anti-hypertensive use), (d) sociodemographic factors (age and sex) and (e) the implant location (maxilla or mandibular, anterior or posterior). The hypotheses tested are as follows: (1) early MBL occurs, (2) torques above 40 Ncm generate higher MBL compared with regular torques, (3) systemic and exogenous factors influence MBL, and (4) the location of the implant affects MBL.

## 2. Materials and Methods

The research ethics committees of the two dental schools involved in the study (#2.660.296 and #2.369.402) approved this multicenter prospective clinical study. This study was reported following the STROBE criteria ([www.strobe-statement.org](http://www.strobe-statement.org), accessed on 10 February 2020).

### 2.1. Sample

The sample includes individuals who sought dental replacement at two dental schools in southern Brazil, between April 2017 and December 2018.

### 2.2. Inclusion Criteria

The inclusion criteria were partial or total dental absence; good oral health; no active cavities, residual roots, periapical or periodontal infections; blood tests (blood count, coagulogram, fasting blood glucose, serum vitamin D); good general state of health, and cases of diabetes and hypertension were required to be managed; the patient signed a term of free, informed consent. Individuals who did not meet these criteria were automatically excluded. A total of 58 patients and 113 implants were included in the study.

### 2.3. Presurgical Procedures

For all individuals, a complete clinical examination was performed, and blood (including vitamin D) and imaging exams were requested. Periapical, panoramic and/or computed tomography radiographs were requested, according to the needs of the case, to guide the surgeon in their selection of the size and diameter of the dental implant. At this stage, the individual's personal information (age, sex, diabetes, hypertension, antihypertensive use) was recorded in a patient file, based on questionnaires and complementary

laboratory tests. For diabetes classification (yes or no), the patient's medical record was consulted. Since all diabetics were controlled, their fasting plasma glucose (FPG) was maintained at normal (100 mg/dL) or prediabetes (100 mg/dL to 125 mg/dL) levels, according to the American Diabetes Association. Rigid surgical guides were prior to the installation of dental implants for all individuals. The average result of fasting blood glucose was  $87.6 \pm 10.4$  mg/dL, and serum vitamin D was  $29.19 \pm 5.15$  ng/mL.

#### 2.4. Surgical Procedures

Morse taper and external hexagon implants from Neodent® (Curitiba, PR, Brazil) and Conexão® (Arujá, SP, Brazil) were used. The implants were installed after administering a local anesthesia, following the manufacturer's recommendations. The surgeries were performed by surgeons with at least two years of experience, assisted by two undergraduate students. A third student (MSc) was responsible for data tabulation. All implants were installed at the bone or infra bone level. Cover screws, healing abutments or immediate provisions were performed after the implant installation. After the suture, a periapical radiograph was obtained for the immediate control and verification of the distance between the bone crest and the implant platform (T0). Information related to surgery (implant brand, installation area and arch, installation torque, and type of protection) and the individual (age, sex, smoking, systemic diseases, systemic medication) were recorded. This moment was considered the baseline for the evaluation of the surgical aspects involved in the MBL. An average of  $1.95 \pm 1.34$  implants were installed per patient. Postoperative analgesic, anti-inflammatory, and antibiotic medications were prescribed. The antibiotics used followed the university protocols (Amoxicillin 500 mg or Azithromycin 500 mg for patients allergic to penicillin). One week after surgery, patients were recalled for suture removal and control. The dentures of completely edentulous patients were adapted to be used as temporary prosthesis.

#### 2.5. Postsurgical Procedures

Reopening and installation of healing abutments occurred at three and nine months after implant placement, in accordance with patient availability. During this stage, a new periapical radiograph (T1) was obtained to control the implant success/failure and measure the distance between the bone crest to the implant platform again. In cases where the healing abutments or provisional were installed with the implant installation (T0), prosthetic components were also selected at this stage.

#### 2.6. Measuring the Distance between the Crestal Bone and the Implant Platform

The radiographs were obtained by two calibrated operators (one per clinical center) and they were all performed using the long cone parallelism technique, with radiographic positioners (Indusbello, Londrina, Paraná, Brazil), and a radiographic film (Kodak, Rochester, NY, USA) with a standardized exposure time of 0.50 s. The radiographic film and the X-ray beam were positioned parallel to the long axis of the implants. The distance between the bone crest and the implant platform were obtained using ImageJ software (U. S. National Institutes of Health, Bethesda, MD, USA). Radiographs T0 and T1 were scanned (H.P., EUA, Palo Alto, CA, USA) and imported to the software, where the measurements were made. The known implant length was used for scale calibration, and the distance was measured in millimeters (mm) from the reference point, the implant platform, to the first visible bone level, on both the mesial and distal sides. MBL around the implant was calculated as the difference between the MBL of T0 and T1. The measurements were performed by a calibrated evaluator ( $\kappa > 0.8$ ) and blinded for predictor variables related to the implant or patient.

### 2.7. Predictor Variables

The following predictor variables were determined: implant installation torque, low torque (0–20 Ncm), intermediate torque (21–40 Ncm), high torque (above 40 Ncm); type of protection, cover screw, healing or provisional abutment; brand, either Neodent® or Conexão®; time between installation and reopening, ranging from three to nine months; implant region, mandibular or maxillary arch, anterior or posterior region; patient-related factors such as age, sex, diabetes, hypertension, and the use of antihypertensives.

### 2.8. Outcome

Degree of MBL, measured in millimeters, based on the difference between the measurements obtained at the first (T0) and second surgical stage (T1).

### 2.9. Statistical Analysis

The data were analyzed using the STATA 14.0 software. A descriptive analysis was conducted to determine the frequencies of the variables. For the analysis of the causal relationship between early MBL and variables of interest, multilevel linear regression and multilevel Poisson regression models were used. Mixed effects and three levels of organization of the variables were considered, i.e., the peri-implant site (level 1), implant (level 2) and individual (level 3). The outcome was analyzed by two approaches, namely, a dichotomous variable (bone loss <0.2 mm and ≥0.2 mm) and a discrete variable (in mm) approach. Only the variables showing  $p < 0.25$  in the dichotomous analysis were included in the adjusted models. Due to the non-normal distribution, the discrete outcome was log-transformed with base 10, and log of beta ( $\beta$ ) was obtained. An independent statistician reviewed the methodology and results sections.

## 3. Results

The features of the sample are described in Tables 1 and 2.

**Table 1.** Distribution of individuals according to the individual level variables (n = 58).

Variables	n	%
Sex		
Male	24	41.3
Female	34	58.6
Diabetes		
No	48	82.8
Yes	8	13.8
Uninformed	2	3.4
Hypertension		
No	41	70.7
Yes	15	25.9
Uninformed	2	3.4
Antihypertensive use		
No	47	81.0
Yes	11	18.9

**Table 2.** Distribution of individuals according to the implant level variables (n = 113).

Variables	n	%
Region		
Ant. Maxilla	17	15.0
Ant. Mandible	14	12.3
Post. Maxilla	29	25.6
Post. Mandible	53	46.9
Arch		
Maxilla	48	42.4
Mandible	65	57.5
Brand		
Neodent	87	76.9
Conexão	26	23.0
Protection		
Cover screw	87	77
Healing abutment	22	19.5
Provisional	4	3.5
Torque (N)		
0–20	22	19.4
21–40	38	33.6
Above 40	53	46.9
Time to reopen (months)		
3	12	10.6
4	14	12.3
5	30	26.5
6	32	28.3
7	7	6.2
8	3	2.7
9	15	13.2

Of the 226 sites analyzed, 77 (34.07%) showed MBL lower than 0.2 mm and 149 (65.93%) showed MBL higher than 0.2 mm at a mean follow-up of 6 months. The mean MBL for all the sites evaluated was  $0.45 \pm 0.48$  mm. The mean MBL in the mesial sites was  $0.44 \pm 0.46$  mm, and in the distal sites it was  $0.46 \pm 0.50$  mm, with no significant difference between them. The mean MBL measured at the implant sites with low torque was  $0.42 \pm 0.28$  mm, with regular torque it was  $0.32 \pm 0.39$  mm, and with high torque it was  $0.55 \pm 0.57$  mm. Considering the average difference in MBL between regular and high torque and the study sample size, the analysis showed a power of 89.8%.

Table 3 shows a multilevel linear regression model for the statistical association between MBL (continuous variable in mm) and the variables of interest. The final multivariate model shows that torque, time between surgery and reopening, diabetes and age had an effect on the outcome. Implants installed with torque below 20 N and above 40 N showed greater MBL compared with the regular torque group. Low torque increased MBL by 0.94 mm [ $\log\beta$  0.94 (95% CI 0.44–1.44);  $p < 0.001$ ] compared with regular torque. High torque increased MBL by 0.93 mm [ $\log\beta$  0.93 (95% CI 0.52–1.33);  $p < 0.001$ ], compared with regular torque. Implants that were reopened up to six months after the installation showed lower MBL [ $\log\beta$  0.46 (95% CI 0.10–0.81);  $p = 0.012$ ], and younger individuals showed greater MBL compared with older individuals [ $\log\beta$  -0.18 (95% CI -0.03–0.00);  $p = 0.047$ ]. Diabetic patients showed a higher MBL than non-diabetic patients, with an increase in the mean value of MBL of 0.55 mm [ $\log\beta$  0.55 (95% CI 0.08–1.02);  $p = 0.020$ ].

**Table 3.** Multilevel linear regression model with three levels of organization for implant MBL (continuous variable in mm) (n = 58 individuals, 113 implants, 226 sites).

Variable	Crude		Adjusted	
	log Beta (CI 95%)	p-Value	log Beta (CI 95%)	p-Value
Individual level				
Age (continuous variable)	-0.03 (-0.45–0.005)	0.015	-0.18 (-0.03–0.00)	0.047
Sex (ref = Fem)				
Male	0.47 (0.09–0.86)	0.016	-	-
Diabetes (ref = no)				
Yes	0.48 (-0.09–1.06)	0.098	0.55 (0.08–1.02)	0.020
Hypertension (ref = no)				
Yes	-0.10 (-0.56–0.35)	0.638	-	-
Antihypertensive use (ref = no)				
Yes	-0.12 (-0.62–0.38)	0.636	-	-
Implant level				
Arch (ref = maxilla)				
Mandible	-0.02 (-0.39–0.35)	0.907	-	-
Position (ref = anterior)				
Posterior	-0.05 (-0.46–0.36)	0.811	-	-
Brand (ref = neodent)				
Conexão	0.21 (-0.24–0.67)	0.352	-	-
Protection (ref = cover screw)				
Healing Abutment	-0.12 (-0.63–0.40)	0.661	-	-
Provisional	0.61 (-0.70–1.93)	0.365	-	-
Torque (ref = 21–40)				
0–20	0.49 (0.04–0.93)	0.032	0.94 (0.44–1.44)	<0.001
Above 40	0.53 (0.15–0.90)	0.006	0.93 (0.52–1.33)	<0.001
Time (ref = up to 6 months)				
Above 6 months	0.48(0.12–0.85)	0.009	0.46 (0.10–0.81)	0.012

Table 4 shows a multilevel Poisson regression model for the statistical association between implant MBL and the variables of interest, considering a dichotomous outcome (bone loss <0.2 mm and ≥0.2 mm). The final model showed that only a torque of above 40 N had an influence on the outcome [Risk Ratio 1.53 (95% CI 1.03–2.26); *p* = 0.033].

**Table 4.** Multilevel Poisson regression model with three levels of organization for implant MBL (dichotomous outcome <0.2 mm and ≥0.2 mm) (n = 58 individuals, 113 implants, 226 sites).

Variables	Crude		Adjusted	
	RR (CI 95%)	p-Value	RR (CI 95%)	p-Value
Individual level				
Age (continuous variable)	0.98 (0.97–0.99)	0.046	-	-
Sex (ref = female)				
Male	1.29 (0.93–1.78)	0.122	-	-
Diabetes (ref = no)				
Yes	1.03 (0.65–1.64)	0.889	-	-
Hypertension (ref = no)				
Yes	1.00 (0.70–1.44)	0.976	-	-
Antihypertensive use (ref = no)				
Yes	1.10 (0.75–1.60)	0.637	-	-
Implants level				
Arch (ref = maxilla)				

Mandible	1.02 (0.73–1.40)	0.916	-	-
Position (ref = anterior)				
Posterior	0.99 (0.69–1.43)	0.982	-	-
Brand (ref = neodent)				
Conexão	1.19 (0.82–1.70)	0.359	-	-
Protection (ref = cover screw)				
Healing Abutment	0.91 (0.60–1.39)	0.668	-	-
Provisional	1.49 (0.55–4.02)	0.435	-	-
Torque (ref = 21–40)				
0–20	1.54 (0.96–2.47)	0.071	1.54 (0.96–2.47)	0.071
Above 40	1.53 (1.03–2.26)	0.033	1.53 (1.03–2.26)	0.033
Time (ref = up to 6 months)				
Above 6 months	1.30 (0.94–1.80)	0.108	-	-

#### 4. Discussion

This study evaluated the influence of certain patient-dependent and surgical-dependent factors on early MBL. The overall mean of MBL was  $0.45 \pm 0.48$  mm at an average follow-up of six months after implant installation, confirming the first study hypothesis that early MBL occurs, even before prosthetic loading. These results were lower than the two-month follow-up mentioned by Cassetta et al. [16], for which the authors reported a mean MBL of 0.86 mm.

The MBL at implant sites with low and high torque was greater than MBL related to regular torque. Considering the dichotomous analysis, only high torque negatively influenced MBL ( $p = 0.033$ ), confirming the second hypothesis of the study. Barone et al. [17] suggested that MBL is statistically lower in implants installed with regular torque than with high torque 12 months after surgery. They reported  $1.01 \pm 0.57$  mm of MBL with high torque and  $0.68 \pm 0.46$  mm of MBL with regular torque, both in the maxilla. In the mandible, they observed  $1.33 \pm 0.33$  mm for high torque and  $0.70 \pm 0.28$  mm for regular torque. The authors considered high torque to be greater than 50 Ncm and regular torque lower to be than this value. In contrast, Grandi et al. [18] evaluated the MBL of implants with regular torque (30 to 45 Ncm) and high torque (up to 80 Ncm) after 12 months of installation, and observed no significant differences between the groups. To correctly mill the surgical site the bone type and implant macro and micro geometry should be considered. This presents a challenge, although this association does seem to be important in avoiding high torques.

In the multilevel linear regression model, the time for reopening was relevant: a period longer than six months increased the MBL by 0.46 mm. However, this difference was not observed in the dichotomous evaluation. The literature is scarce regarding the time between installation surgery and reopening. The manufacturers recommend at least three months for complete healing, but some studies report the success of implants with early and immediate loading [12,13]. According Gallucci et al. [19] conventional loading of dental implants is considered to be more than two months after the implant installation; early loading occurs between one week and two months; and immediate loading occurs within one week of implant installation. In the present study, the period before reopening varied, since some patients received bone grafts. Additionally, the implants were installed in university centers, where the vacation period can extend the time between implant installations and loading; many patients were from other cities, which also made callbacks difficult. Clinically, the time to reopening may vary, and this study aimed to demonstrate a realistic situation, which was found to be between three and nine months.

The process of healing and osseointegration in dental implants is a dynamic process. When an implant is installed, surgical preparation results in physiological MBL [20]. During the first healing phase, the recruitment and migration of osteogenic cells to the surface of the implant occurs. During the second healing phase, new bone is formed. Thereafter,

the bone tissue in contact with the implant is reabsorbed and replaced with a new viable bone [21]. In cases of successful treatment, this reaction reaches a balance with the body, and only in cases of disequilibrium is the MBL higher, thereby damaging peri-implant health [22]. In cases of implants without a load for a long period, the activation of cells that are responsible for bone loss will increase, and consequently bone resorption may occur [23]. An analysis of the results obtained here suggests an optimal reopening period of up to six months.

Diabetic patients presented higher MBL than non-diabetic patients ( $p = 0.020$ ) in the continuous analysis, but other factors such as smoking, hypertension and some form of systemic drug use, were not revealed to influence MBL, which only partially confirms the third hypothesis of the study. The significance of diabetes indicated in the continuous approach was not confirmed in the dichotomous approach, probably due to the small sample size of the group with diabetes. An increase in the sample size of this group would better illustrate the initial condition of MBL in diabetic patients. Some studies have also reported an association between diabetes and MBL [24]. In a prospective clinical study [25], no significant difference in the MBL of diabetic and non-diabetic subjects at six years of follow-up was detected; in this study, all diabetic individuals presented glycemic levels within the normal range (mean glycosylated hemoglobin levels of 4.86%). Fasting glucose was used as a reference, as it is accepted by the American Diabetes Association [26]. The glycemic levels of the group of diabetic patients ranged between 68.1 and 104 mg/dL, demonstrating that they were controlled.

In the analysis with the continuous variable, younger patients showed higher MBL compared with older individuals ( $p = 0.047$ ). The mean age of the patients included in the study was 54.1 years old. Most of the studies did not reveal a relationship between implant failure and MBL with patient age [27,28]. He et al. [29] reported that the bone density at implant sites is lower in older patients (>50 years) than in younger patients ( $\leq 50$  years). In this study, after analyzing the outcome using a dichotomous approach, patient age and sex were not found to be significant factors.

Factors such as the arch and position did not influence MBL, rejecting the fourth study hypothesis. The results obtained here are in agreement with the findings of Koller et al. [30] who evaluated 164 external hexagon implants five years after installation, and observed no difference between the regions. According to Barone et al. [17], the MBL measured after three months of Morse taper implants installation was 0 mm and 0.4 mm in the regular ( $\geq 50$  Ncm) and high (<50 Ncm) torque groups in the maxilla, and 0.03 mm and 0.96 mm for regular and high torque in the mandible, respectively.

Our clinical study associated the marginal bone loss with six patient-related factors and six clinical factors. It is very difficult to investigate the effect of numerous important variables in a single study; however, and the study has some limitations. The procedure steps were not randomized, since the main factor of the study 'torque' cannot be accurately predicted before the surgery. Moreover, despite evaluating 226 sites, the sample size can be considered low. Thus, any future studies that include a higher sample size and are focused on the variables of torque, time to reopening, diabetes and age, all of which showed significance in our study, are encouraged.

## 5. Conclusions

From this clinical study, the following can be concluded:

Marginal bone loss occurs before the second surgical stage and occurs more prominently in implants inserted with high torque (above 40 Ncm).

Marginal bone loss in implants with torque below 20 Ncm, reopening performed after six months, diabetic and young patients must be better explored.

The implant location does not affect the marginal bone loss.

We recommend that further studies on this topic are needed.

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## Abbreviations

MBL	marginal bone loss
Ncm	newton/centimeters

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