RETROSPECTIVE COHORT STUDY ON THE INFLUENCE OF BONE REMODELING ON MARGINAL BONE LOSS AND PERI-IMPLANTITIS AROUND IMMEDIATELY LOADED IMPLANTS SUPPORTING COMPLETE-ARCH RESTORATIONS

Abbreviated title: bone remodeling in immediately loaded implants

ABSTRACT

Purpose: The main objective of the present study was to assess the influence of bone remodeling on late marginal bone loss in immediately-loaded implant-supported complete-arch restorations and, secondarily, to determine its relation to peri-implant disease occurrence using a multilevel analysis.

Materials and Methods: A retrospective cohort study of patients treated consecutively in a private clinic with immediately-loaded full-arch restorations with at least 12 months' follow-up was conducted. Bone remodeling and marginal bone loss were determined through measurements made on panoramic X-rays by two calibrated examiners. Peri-implant health status was diagnosed in a visit for peri-implant maintenance. Descriptive, bivariate and multilevel analyses were performed with Stata/IC 15.1 software (StataCorp LLC, Lakeway Drive, USA).

Results: A total of 30 patients (11 men and 19 women, average age 63.3 ± 10.4 years), with a mean follow-up of 37.7 ± 19.6 months were included. Forty arches (20 maxillary and 20 mandibular) received 207 implants. Bone remodeling had an inversely proportional effect on marginal bone loss (*P* =.005) but was not related to peri-implantitis (*P* =.103; hazard rate (HR) = 2.1).

Conclusions: To conclude and taking into account the limitations of this study, bone remodeling around immediately-loaded dental implants supporting complete-arch restorations does not appear to increase marginal bone loss or peri-implantitis.

Key words: Immediate dental implant loading; dental prosthesis; implant-supported; bone remodeling; peri-implantitis; private practice.

INTRODUCTION

Full-arch implant-supported restorations have been an extensively documented procedure since the 1970s (1), while immediate loading protocols for totally edentulous patients constitute a predictable option which reduces treatment time and morbidity and improves patient comfort and esthetics (2). However, regardless of the loading protocol, dental implants can be subject to complications. Peri-implant diseases are common biological events with weighted prevalence rates ranging between 14% and 30% for peri-implantitis and between 32% and 54% for peri-implant mucositis (3).

Romanos (4) defined bone remodeling as a replacement mechanism of immature, former or damaged bone by new laminar bone. This process adapts the bone tissue to mechanical stimuli (4,5) and seems to depend on multiple factors such as the apico-coronal position of the implant, the macroscopic implant design (for example, platform-switching), the presence of buccal bone dehiscences, or repeated dis- and re-connection of abutments, among others (6,7). Degidi et al. (8) defined bone remodeling rate as the period of time needed by the bone to adapt to the new environment through a resorption-apposition process that prevents microdamage and increases fatigue strength. These authors stated that bone remodeling plays a crucial role in maintaining the bone level around implants in the long term. The latest World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions (2017) stated that the baseline peri-implant bone level is established at 1 year following the delivery of the definitive implant-supported prosthesis, thus considering the previous changes in the bone levels to be initial bone remodeling. However, progressive bone loss is considered pathological when associated with clinical signs of inflammation (9). Therefore, changes in peri-implant bone levels might be considered physiological (bone remodeling) or pathological (peri-implantitis), depending on the onset time (before or after the 1-year follow-up of the final restoration) and on the presence of inflammation (bleeding on probing and/or suppuration).

Galindo-Moreno et al. (10) questioned the limit between physiological and pathological bone loss. In a retrospective cohort study that included patients with single implants placed in posterior maxilla, they considered that bone remodeling (measured as the change in the bone levels after 6 months of loading) was related to long-term marginal bone loss. Conversely, Vervaeke et al. (2) found no association between bone remodeling and late bone loss in their prospective case series of patients restored with complete implant-supported prostheses. Consequently, the available evidence concerning the relation between bone remodeling and pathological marginal bone loss is still unclear. Furthermore, to the best of the present authors' knowledge, no data have been published regarding this association in immediately-loaded implants. In our opinion, bone remodeling could be associated with the onset of peri-implant diseases since it might lead to an exposure of the rough surface of the implant thus favoring biofilm accumulation (11,12).

For this reason, the main objective of the present study was to assess the influence of bone remodeling on late marginal bone loss in immediately-loaded implant-supported complete-arch restorations and, secondarily, to determine its relation to the occurrence of peri-implant diseases using a multilevel analysis.

The hypothesis was that bone remodeling is a predictor for marginal bone loss and peri-implantitis in patients with immediately-loaded implant-supported complete-arch restorations.

MATERIALS AND METHODS

This manuscript was written in accordance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement (13). The study protocol was approved by the ethical review board of the Dental Hospital of the University of XXX. The Declaration of Helsinki guidelines were followed throughout the trial.

An observational retrospective cohort study of patients treated consecutively with immediately loaded full-arch rehabilitations supported by a minimum of four implants (Replace® Tapered, Nobel Biocare AB, Gothenburg, Sweden) was conducted at a private clinic (XXX). Multi-Unit straight or angled conical abutments (MUA®, Nobel Biocare AB, Gothenburg, Sweden) were used in all cases and were connected to the implants during the surgical procedure. No age restriction was applied, and some patients required dental extractions as a part of the treatment plan. Informed consent was signed by all the patients. In order to be included in the study, the patients had to have completed a minimum 12-month follow-up period after delivery of the definitive implant-supported restoration.

The treatment protocol has been described in previous reports (14,15). In brief, implants were placed under local anesthesia and/or with conscious sedation. The smooth 1.5 mm implant collar was placed at bone level or slightly submerged, depending on the amount of soft tissue available to cover the intermediate abutment shoulder. No bone leveling was performed in the implants placed in fresh post-extraction sockets. Immediate loading was carried out when the insertion torque was > 35Ncm. Open-tray impression copings were placed before closing the wound and a polyether impression material (Impregum-Penta®, 3M Espe, MN, USA) was employed.

The patients were provided with a screw-retained acrylic full-arch provisional prosthesis 6 to 48 hours after implant placement that was performed by the same surgeon (ICI). The definitive cast-metal framework with acrylic or ceramic teeth was inserted after 12 to 16 weeks. All the patients were enrolled in a peri-implant maintenance program with visits every 6 months. Panoramic X-rays were taken at the time of immediate-loading insertion, once after delivery of the definitive prosthesis and at the control visits for the peri-implant maintenance with the same device (PaX-Flex 2D Digital Panoramic X-ray; Vatech; Barcelona; Spain).

Clinical and radiological data collection

Between January 2017 and January 2018, all the patients that complied with the inclusion criteria (n = 30) were recalled for a follow-up maintenance appointment. The sample size was calculated using the webpage www.sample-size.net. In order to detect a moderate correlation (r=0.5) between bone remodeling and marginal bone loss with a 5% alpha error and 80% power, 29 patients would be needed.

At this appointment, a panoramic X-ray was taken and one examiner (AST) disconnected the prostheses to collect variables for each implant and to perform the peri-implant maintenance. Patient characteristics (age, gender, arch, smoking habit [non-smoker / smoker ≥ 10 cig/day]); treatment variables (implant placement protocol [immediate / delayed], abutment angulation [straight / angled], abutment height [<2mm / ≥2mm], implant position [anterior / posterior], time of follow-up [months]); and outcome variables (bone remodeling [mm] and marginal bone loss [mm]) were recorded.

Two previously-calibrated researchers (AST, MM) recorded the peri-implant bone level, measured on the panoramic X-rays by means of EasyDentV4 Viewer (Version 4.1.1.3, Vatech, Hwaseong-si, Gyeonggi-do, Korea) software. The calibration consisted in measuring the mesial and distal aspects of 10 implants and correlating the data from both aspects through an intraclass correlation coefficient. An index greater than 0.71 was considered good agreement.

The peri-implant bone level was measured from the implant platform to the most apical bone to implant contact, on both the mesial and the distal aspect. The measurement of each implant was done after calibrating the radiograph by its length (Figure 1). Three different panoramic X-rays were taken of each patient: 1. Panoramic radiography on placing the immediately-loaded provisional prosthesis (PRx1); 2. Panoramic radiography when the patient received the definitive implant-supported restoration (when bone remodeling was considered to have finalized) (PRx2); 3. Panoramic radiography at the latest peri-implant maintenance visit (PRx3). The bone remodeling for each implant was calculated as the difference between the second (PRx2) and the first radiographies (PRx1), while marginal bone loss was defined as the difference between the second (PRx2) and the last radiography (PRx3). The final bone loss for each implant was calculated as the mean of the values obtained.

The criteria developed at the last Workshop on Periodontology (9) were used to diagnose the peri-implant health status. Specifically, the recommendations for epidemiologic studies were adopted in which peri-implantitis was defined as a bone loss ≥3 mm with the presence of bleeding on probing, in this case measured only in the last panoramic radiography (PRx3).

Stata/IC 15.1 software (StataCorp LLC, Lakeway Drive, USA) was used to perform the statistical analyses. Descriptive and bivariate analyses for dichotomic variables were carried out through a Student *t* test for marginal bone loss and a chi-square test for peri-implantitis. A Pearson correlation measured the strength of association between bone remodeling and marginal bone loss.

A multilevel approach was used because repeated observations (several implants) were nested within individuals (cluster effect). Firstly, three-level hierarchical linear modeling based on restricted likelihood estimation was used to evaluate the influence of bone remodeling on marginal bone loss. Secondly, a multilevel mixed effects parametric survival analysis was employed to assess the influence of bone remodeling on peri-implantitis. Akaike information criteria (AIC) were used to choose the best fit survival model. Both analyses were adjusted for potential confounders. The level of significance was set at $P < 0.05$.

RESULTS

Descriptive and bivariate analysis

The main exclusion criteria were patients that could not attend the follow-up appointment and that lacked radiographic assessment after the placement of the provisional or definitive prosthesis. Figure 2 shows a flow chart with the study participants. A total of 30 patients with placement of 207 implants were included in the study. Only one patient did not require dental extractions as part of the treatment plan. The sample was composed of 11 men and 19 women, with an average age of 63.3 years (standard deviation (SD) = 10.4; range = 43 to 88). Eleven patients smoked more than 10 cigarettes per day, while 19 were nonsmokers. Twenty maxillary and 20 mandibular arches were treated and a mean of 5.2 implants/arch were placed. Eighty-eight (42.5%) implants were placed in post extraction sockets. The average follow-up was 37.7 months (SD=19.6; range=12 to 72.2). Globally, the mean bone remodeling and marginal bone loss were 0.47 (SD= 0.87) mm and 0.47 (SD=0.83) mm, respectively. Table 1 shows the main characteristics of the study participants. The intraclass correlation coefficient was 0.981 thus indicating an excellent inter-examiner calibration.

Table 2 shows the peri-implant diagnosis by implants and patients. Of the 30 patients, 21 had one or more healthy implants, all had one or more implants with mucositis, and 6 had at least one implant with peri-implantitis. No implant failures were recorded in the entire study period.

The bivariate analysis, presented in Table 3, showed a significant increase in marginal bone loss for implants placed in anterior areas (*P* =.024) and in non-smokers (*P* =.045). However, peri-implantitis was significantly associated with implants placed in mandible (*P* =.011) and non-immediate implants (*P* =.005).

A negative correlation was found between bone remodeling and peri-implant bone loss, this last measured as a difference between the second (PRx2) and the last radiographic assessment (PRx3) (r = - 0.134; *P* =.051, near to significance).

Multivariate analysis

Effect of bone remodeling on peri-implant bone loss

The multilevel linear regression model included bone remodeling, arch, abutment height, abutment angulation, implant placement protocol and implant position as implant-level variables, and age, smoking habit and time of follow-up as patient-level variables (Table 4). Marginal bone loss was significantly affected by bone remodeling and implant position. Specifically, bone remodeling had an inversely proportional effect on marginal bone loss at implant- (*P* =.003) and patient level (*P* =.005), thus acting as a protective factor. Implants placed in anterior areas also experienced more bone loss at implant- (*P* =.008) and patient-level (*P* =.008).

Effect of bone remodeling on peri-implantitis

Table 5 presents the multilevel survival analysis adjusted for confounders. No relationship was found between bone remodeling and peri-implantitis (*P* =.103; hazard rate (HR) = 2.1 [0.86-5.14]) nor between any other variables.

DISCUSSION

This study aimed to assess the influence of bone remodeling on marginal bone loss and peri-implantitis. The results obtained show that bone remodeling seems to be inversely associated with marginal bone loss, thus indicating that immediately-loaded implants which have higher bone remodeling are likely to have less bone loss. In contrast, bone remodeling was not related to the presence of peri-implantitis.

The multilevel analysis showed that bone remodeling acts as a protective factor for marginal bone loss, as an inversely proportional significant relationship was found. Indeed, the globally accepted value of 2 mm of bone loss during the first year of loading highlights the major influence that the prosthetic loading of implants exerts (10,16) through its effects on the establishment of the supracrestal attached tissues (2,3,17). This is in accordance with some studies that have observed the existence of bone remodeling from implant installation to prosthesis placement, and to a more pronounced degree after prosthetic abutment placement, and further slow bone loss subsequent to the prosthetic connection which seems to be independent of the follow-up time (18,19). Tealdo et al. (20) compared the radiographic bone level changes in immediate- and delayed-loaded implants and found a significantly higher peri-implant bone loss in the delayed-loaded group (1.6 ± 0.9 mm Vs. 2.3 ± 1.1 mm) after a mean follow-up time of 40.5 months. As mentioned previously, a moderate peri-implant bone resorption was observed during the first year that stabilized in the subsequent follow-up appointments. In the present report, a lower degree of bone remodeling was observed (0.47 ± 0.83 mm).

Peri-implantitis appeared in 4.8% of implants and 20% of patients, values in accordance with the published literature (21-23). As all the patients included had a history of periodontal disease, the influence of this variable in peri-implantitis could not be studied. The fact that the patients' restorations were implant-supported full arches with more than 4 implants increased the risk of peri-implantitis, as published in previous reports (23,24). Interestingly, a retrospective cohort study by Fransson et al. (25) found through a multivariate analysis that the number of implants was the only variable with a significant impact on progressive bone loss around implants.

To date, few studies have centered on variables that could influence initial bone remodeling (2,10). A study published by Vervaeke et al. (2) aimed to assess predictive factors for early and late bone loss in patients with implant-supported full arches under immediate loading. They observed that bone remodeling was affected by reduced-height abutments, hence thin peri-implant mucosa, while late bone loss was influenced by a history of periodontitis and smoking. However, the object of the present study was slightly different, as it analyzed bone remodeling as a potential prognostic factor for marginal bone loss and/or peri-implantitis. In fact, one of the apparent advantages of the immediate loading protocol is the use of definitive intermediate abutments. As these abutments are placed during the surgical procedure, and in most cases are not changed during the fabrication of the definitive prosthesis, the marginal bone level and tissue sealing can be established from the very first moment. On the other hand, repeated dis/reconnection of abutments during the prosthetic phase has been associated with peri-implant bone resorption (26). In bone level implants, moreover, the critical abutment-prosthetic connection is moved coronally, which might prevent bone loss. Indeed, a study published by Galindo-Moreno et al. (27) has demonstrated that abutments of ≥ 2 mm in height protect implants from marginal bone loss as they allow the establishment of supracrestal attached tissues, particularly in the first 6 months after prosthetic loading.

Currently, the baseline for measuring the peri-implant bone level is considered to be 1 year after the definitive prosthetic loading, which results in considering all the previous bone loss as physiological remodeling (9). In the present authors' opinion, three periods with different behavior patterns may be distinguished for immediately loaded implants: 1. Bone level changes during the initial healing period with the provisional prosthesis, which should be considered physiological bone remodeling (up to 3-6 months); 2. Bone level 12 months after the definitive prosthesis delivery; and 3. Changes in marginal bone level in the long-term. It would be interesting to calculate the bone loss rate by periods of time in order to gain a better understanding of the bone loss pattern (10). Unfortunately, this information was not available in the present study as no intermediate clinical or radiological data had been gathered in most cases.

Although periapical radiographies are considered the gold-standard to measure interproximal bone levels, this study used panoramic radiographies which might be considered a limitation. However, panoramic X-rays have been used in other publications to assess bone loss (10,14). It should also be taken into account that performing several periapical radiographies to fully edentulous patients might not be feasible in a clinical setting and may have a reduced reliability in cases with atrophic maxillae. Moreover, an earlier cross-sectional study has demonstrated that periapical radiographs underestimate the size of the bone defect an average of 1.3 mm (28).

Although the present research has a retrospective design, the fact that many variables were recorded prospectively increases the accuracy of the data. Despite these drawbacks, the present research has high external validity, as the patients were treated in a private setting and the inclusion criteria did not restrict variables such as periodontal disease or smoking habit. In addition, the internal validity was guaranteed as all the implants were placed by the same surgeon and were of the same brand.

To conclude and taking into account the limitations of this study, bone remodeling around immediately-loaded dental implants supporting complete-arch restorations does not appear to increase marginal bone loss or peri-implantitis.

TABLES

Table 1. Main characteristics of the study participants

Baseline patients characteristics		
Age		63.3 (SD = 10.4)
Gender	Male	11
	Female	19
Arch	Maxilla	20
	Mandible	20
Smoking habit	Yes	11
	No	19
Treatment variables		
Implant placement protocol	Immediate	88
	Delayed	119
Implant position	Anterior	87
	Posterior	120
Abutment height	<2mm	121
	≥2mm	86
Time of follow-up		37.7 (SD = 19.6)
Outcome variables		
Bone remodeling		0.47 (SD= 0.87)
Marginal bone loss		0.47 (SD=0.83)

Table 2. Peri-implant diagnosis by implant and patient.

IMPLANT DIAGNOSIS	IMPLANT			PATIENT		
	N	% (95%CI*)	Mean follow-up (months)	N	% (95%CI)	Mean follow-up (months)
HEALTHY	46	22.2 (17.1-28.4)	33.8	-	-	-
MUCOSITIS	151	72.9 (66.5-78.5)	38.2	30	100 (88.7-100)	39
PERI-IMPLANTITIS	10	4.8 (2.6-8.7)	47.5	6	20 (9.5-37.3)	50.1

*CI: confidence interval.

Table 3. Bivariate analysis of the distribution by implants of marginal bone loss and peri-implantitis for dichotomic variables.

DICHOTOMIC VARIABLES		MARGINAL BONE LOSS †			PERI-IMPLANTITIS ‡		
		N	**Mean (SD§)**	***p* value**	**N**	**% (95% CI‖)**	***p* value**
Smoking habit	Yes	81	0.33 (0.7)	0.045*	2	20 (0.06-0.51)	0.204
	No	126	0.57 (0.9)		8	80 (0.49-0.94)	
Arch	Maxilla	102	0.43 (0.8)	0.503	1	10 (0.02 -0.4)	0.011*
	Mandible	105	0.51 (0.9)		9	90 (0.60-0.98)	
Abutment height	≥ 2 mm	86	0.50 (1)	0.747	3	30 (0.11-0.60)	0.448
	< 2 mm	121	0.46 (0.7)		7	70 (0.40-0.89)	
Abutment angulation	Straight	129	0.42 (0.7)	0.209	6	60 (0.31-0.83)	0.877
	Angled	78	0.58 (1)		4	40 (0.17-0.69)	
Implant position	Anterior	87	0.63 (0.8)	0.024*	3	30 (0.11-0.60)	0.430
	Posterior	120	0.36 (0.8)		7	70 (0.40-0.89)	
Implant placement protocol	Immediate	88	0.41 (0.8)	0.328	0	0 (0-0.28)	0.005*
	Delayed	119	0.52 (0.9)		10	100 (0.72-0.10)	

*significant (*P* <0.05); † results of Student *t* test; ‡ results of chi-square test; §SD: standard deviation; ‖CI: confidence interval

Table 4. Multilevel linear regression model adjusted for implant-level and patient-level predictors of marginal bone loss

		PERIIMPLANT BONE LOSS					
		Model 1		**Model 2**		**Model 3**	
		Coefficient (SE)†	*p value*	*Coefficient (SE)*	*p value*	*Coefficient (SE)*	*p value*
Implant fixed effects (level 1)							
Intercept		0.47 (0.06)	0.000	1.14 (0.30)	0.000	0.10 (0.72)	0.893
Bone remodeling				-0.19 (0.06)	0.003*	-0.18 (0.06)	0.005*
Arch	Mandible			0.15 (0.13)	0.267	0.14 (0.13)	0.306
	Maxilla			-	-	-	-
Abutment height	< 2 mm			0.16 (0.19)	0.402	0.13 (0.19)	0.512
	≥ 2 mm			-	-	-	-
Abutment angulation	Angled			0.30 (0.18)	0.101	0.25 (0.19)	0.180
	Straight			-	-	-	-
Implant placement protocol	Immediate			-0.14 (0.12)	0.261	-0.10 (0.12)	0.424
	Delayed			-	-	-	-
Implant position	Anterior			0.28 (0.10)	0.008*	0.28 (0.10)	0.008*
	Posterior			-	-	-	-
Patient fixed effects (level 2)							
Age						0.01 (0.01)	0.219
Smoking habit	Non-smoker					0.01 (0.21)	0.977
	Smoker					-	-
Follow-up time						0.01 (0.01)	0.201
Model Fit		*Log likelihood*	*p value*	*Log likelihood*	*p value*	*Log likelihood*	*P value*
LR‡ test		-255.27	-	-236.14	0.000*	-233.89	0.000*

*significant (*P* <0.05); †SE: standard error; ‡LR: likelihood ratio

Table 5. Hazard ratios for peri-implantitis based on multilevel mixed effects parametric survival analysis

COVARIATES	Number of implant failures (%)	Number of implant survivals (%)	Failure (%)	*p* value	HR† (95% CI ‡)
Bone remodeling	-	-	-	0.103	2.10 (0.86-5.14)
Age	-	-	-	0.095	1.12 (0.98-1.28)
Smoking habit					
Non-smoker	8 (80)	118 (59.9)	6.8	0.599	1
Smoker	2 (20)	79 (40.1)	2.5		1.77 (0.21-14.8)
Arch					
Maxilla	1 (10)	101 (51.3)	1.0	0.248	1
Mandible	9 (90)	96 (48.7)	9.4		4.33 (0.36-52.1)
Abutment height					
<2 mm	7 (70)	114 (57.9)	6.1	0.688	1
≥2 mm	3 (30)	83 (42.1)	3.6		0.61 (0.05-6.89)
Abutment angulation					
Straight	6 (60)	123 (62.4)	4.9	0.929	1
Angled	4 (40)	74 (37.6)	5.4		1.13 (0.07-18.4)
Implant placement protocol					
Delayed	10 (100)	109 (55.3)	9.2	1.000	1
Immediate	0 (0)	88 (44.7)	0		<0.000 (0-0)
Implant position					
Anterior	3 (30)	84 (42.6)	3.6	0.740	1
Posterior	7 (70)	113 (57.4)	6.2		1.45 (0.16-12.7)

†HR: hazard rate; ‡CI: confidence interval

FIGURES

Figure 1: Example of the radiographic measurements made during the study.

Figure 2: Flow-chart with the study participants.

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