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Single-Blind Randomized Trial to Evaluate Marginal Bone Loss of Immediate Implant Placement Supporting Metal Versus Peek Full Arch Prosthesis

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Abstract

Objectives: Immediately loaded implants have evolved due to the constant need to achieve more efficient and satisfactory prosthetic restorations for patients.

The main aim of this study was the radiographical assessment of peri-implant marginal bone loss when immediate load was applied to rehabilitate patients with partially edentulous (when the extraction of all remaining teeth was indicated) or edentulous mandible or maxilla, using full-arch fixed metal or peek prosthesis.

Methods: Prospective, single-blind clinical study with a control group (metal) used to be compared to the experimental material (peek). An initial descriptive analysis and a bivariate analysis were carried comprising all the statistical contrasts needed for the evaluation of the relationship to bone loss.

Results: In the radiographic study performed after 4 months in the maxilla and after 3 months in the mandible, a vertical bone loss of 0.07 mm and a horizontal bone loss of 0.02 mm were observed. It is noticeable that smokers and patients with parafunctions showed a greater bone loss, compared with those patients who did not have these habits. These results were also observed in cases with immediate post-extraction implants, where immediate loading with full-arch prosthesis was performed. On the other hand, the insertion torque and the materials used are factors that result in lower bone loss.

Conclusions: The material peek, as well as the insertion torque applied to the implants, are factors that protect against peri-implant bone loss, both the risk of suffering bone loss and the amount of bone loss.

Keywords: Immediate loading; osseointegration; bone loss; immediate implants after extraction

Introduction

Due to the large number of studies published (Mozzati, Arata, Gallesio, Mussano, & Carossa, 2013), rehabilitations with implants using immediate loading have been gaining ground in both dental clinics and dentistry schools. Surgical and prosthetic procedures designed for this purpose have been constantly evolving in order to provide more effective and satisfactory rehabilitation. This prompts us to search for alternatives both in the medical field and in new technologies and materials to improve our quality of life. In the field of dental care, our patients request shorter waiting times as well as more biocompatible materials.

The placement of dental implants requires accurate diagnosis and planning taking into account the vital anatomical structures and the restoration aims. The insertion of multiple implants is a challenge, especially in those patients with totally edentulous mandibles, due to the lack of anatomical landmarks.

Implants carried out with immediate loading provide a series of advantages to the patient thanks to an instant rehabilitation with teeth, although it can also lead to problems during osseointegration if the case is not properly studied or not indicated (Berglundh, Persson, & Klinge, 2002; Lee et al., 2012).

The prosthetic rehabilitation phase can be performed with different materials; conventionally, it has been made with an internal metal structure coated with resin or porcelain. However, patients and clinicians demand more biocompatible and metal-free materials due to an increasing population with sensitivity and allergies to metals. Scientific literature has shown that metal ions released in the mouth can cause damage to the cellular structure, alteration of cellular function (membrane permeability and enzymatic activity), alteration in immunity and inflammation, allergic effects and alteration of the genetic material (Becker, Lorenz, Strand, Vahl, & Gabriel, 2013; Rosentritt, Preis, Behr, Sereno, & Kolbeck, 2014). In recent years, the use of new biocompatible materials has been one of the scientific challenges, as well as their application in different medical disciplines. Among these new materials, there are high performance polymers. In this context it must be acknowledged that not all polymers are biocompatible. A biomaterial is any substance or combination of substances designed to interact with biological systems in order to evaluate, treat, improve or replace a tissue, organ or function of the human body (Amiji & Park, 1993).

These polymeric materials have moduli of elasticity more similar to the bone`s modulus of elasticity than metals or ceramics. From the mechanical point of view, rigid materials transmit forces directly to the bone, which has negative effects for osseointegration and is physiologically unfavorable for the antagonists.

The main aim of the present study was to evaluate the peri-implant bone loss in full-arch rehabilitations with immediate loading and the success rate. As well as assessing the influence of etiopathogenic factors on peri-implant bone loss in full-arch rehabilitations.

Methods

A prospective, single-blind clinical study was conducted between January 2015 and December 2016 to compare outcomes between a control group (metal framework) and an experimental group (PEEK framework). Patients who voluntarily and consecutively visited the clinic seeking immediate implant treatment were randomly assigned to either group using a computerized randomization method, which ensured balanced group sizes and minimized selection bias. The single-blind design ensured that participants were unaware of their group allocation, although the researcher knew the intervention administered.

All implants in each patient were restored using the same material, either metal or PEEK. The study was approved by the Ethics Committee of Cardenal Herrera University CEU and conducted in accordance with the Declaration of Helsinki on ethical principles for medical research involving human subjects.

The study sample consisted of 35 patients, receiving a total of 213 implants. The gender distribution was nearly balanced, with 18 women and 17 men. The mean age of participants was 58.2 years, ranging from 42 to 81 years.

Inclusion Criteria:

- Completely edentulous maxillary or mandibular arch.
- Partially edentulous arch requiring extraction of all remaining teeth.
- Indicated for full-arch, implant-supported fixed prosthetic rehabilitation.
- Minimum alveolar ridge width of 5 mm and height of 10 mm.
- Implants placed with an insertion torque ≥ 35 Ncm (implants with torque <35 Ncm were excluded and treated conventionally).

- Absence of systemic conditions contraindicating surgical intervention.
- Minimum follow-up of 12 months after placement of the definitive prosthesis.
- Minimum follow-up of 16 months after prosthetic loading of the implants.

Exclusion Criteria:

- History of chemotherapy or radiotherapy to the head or neck within the past 12 months.
- Severe alveolar bone deficiency (ridge width < 5 mm and height < 10 mm).
- Patients who smoke more than 10 cigarettes per day.
- Pregnant or breastfeeding women.

All patients included in the study provided written informed consent prior to participation.

Surgical protocol

All implant placement surgeries were performed by the same surgeon. Local anesthesia was applied to the part of the body that was to undergo surgery using articaine 4% with adrenaline 1: 100,000 (Articaina, Normon Laboratories, Madrid, Spain). Where tooth extraction was necessary, it was made as atraumatically as possible for the patient. Immediate post-extraction implants were placed making an intrasulcular incision on the teeth and a crestal incision on the edentulous ridge with elevation of a full-thickness flap. To place the implants in mature bone, crestal or crescent incisions were made and mucoperiosteal flaps were elevated to expose the alveolar ridge. The implant system used in this study was bredent® (Senden, Germany) thus the milling protocol recommended by the manufacturer was followed taking into account the diameter and length of the implant. The primary stability was assessed with the insertion torque values of the implants, obtained from the surgical motor.

Provisional and definitive prosthesis protocol

The implant positions were recorded intraoperatively. Impressions were taken using a conventional technique, and the vertical dimension and occlusion were verified using a reverse bite base plate. These records were then transferred to the diagnostic model in the laboratory for the fabrication of the provisional prosthesis.

The fabrication of the definitive prostheses began 13 weeks after implant placement, and they were fitted 16 weeks post-placement. Patients were randomly assigned to receive either type of prosthesis: the control group received screw-retained metal/composite prostheses, while the experimental group received screw-retained PEEK/composite prostheses. All prostheses were built on transepithelial abutments, with the material used for the definitive prosthesis being either metal (control group) or PEEK (experimental group), as illustrated in Figure 1.

Figure 1

Bone Loss Analysis

Periapical radiographs were taken using the long-cone paralleling technique. The radiographic field included at least 5 mm of bone on both sides of the implant, extending toward the adjacent fixations. The implant splines had to be clearly visible, allowing for evaluation of the interface between the screw base and bone tissue. All radiographs and measurements were performed by the same researcher.

Bone loss was assessed by measuring the difference in bone level across three time points:

- Baseline (at the time of surgery).
- Second measurement (at the time of definitive prosthesis placement: 4 months post-op in the maxilla and 3 months in the mandible).
- Final measurement (12 months after definitive prosthesis placement).

On the periapical radiograph, bone loss was measured mesially and distally, from a reference point at the implant-abutment junction to the point of contact between the bone and the titanium implant surface. Measurements at points where the bone contacted the abutment were excluded, as this area is not considered to be osseointegrated.

A total of four measurements were performed per implant:

- Vertical / Mesial.
- Vertical / Distal.
- Horizontal / Mesial.
- Horizontal / Distal.

Since all measurements were conducted by the same researcher, it was essential to determine the intra-observer error. This was assessed using Dahlberg's formula:

$$\text{Error} = \sqrt{(\Sigma d^2 / 2n)},$$

where d is the difference between repeated measurements and n = 30.

Measurements were repeated twice, with a 15-day interval between sessions. The result yielded a possible measurement error of 0.04 mm, which was considered minor and acceptable, as it did not alter the overall validity of the study's observations.

Statistical analysis

After collecting the general data of all patients, an initial descriptive analysis was conducted. This included basic statistics for the continuous variables—mean, standard deviation, minimum, maximum, and median—as well as the frequency and percentage distributions for the categorical variables. Subsequently, a bivariate analysis was carried out using the Wilcoxon and Mann-Whitney tests. A p-value was calculated for all cases, with values < 0.05 considered statistically significant. The analyses were performed using IBM SPSS Statistics, version 21.

Results

The study included 35 patients, in whom a total of 213 implants were placed—84 in the mandible and 129 in the maxilla. Mandibular rehabilitations were performed using metal frameworks in 40.9% of cases and PEEK frameworks in 38.4%. In the maxilla, 58.1% of rehabilitations used metal and 61.8% used PEEK.

Regarding implant location, 102 implants were placed in the anterior region and 111 in the posterior region. A total of 62% of implants were placed immediately post-extraction. Among these, 36.4% were rehabilitated with metal and 80% with PEEK.

Thirty-six implants were placed in patients with bruxism, with 16 rehabilitated using metal and 20 using PEEK. Of the 213 implants, 48 were placed with a 30º angulation, evenly split between metal and PEEK rehabilitations.

Implant diameter distribution was as follows:

- 3.5 mm diameter: 44.3% metal, 26.4% PEEK.
- 4.0 mm diameter: 25% metal, 68.8% PEEK.
- 4.5 mm diameter: 30.7% metal, 4.8% PEEK. (Table 1)

		MATERIAL					
		Total		***METAL***		***PEEK***	
		N	***%***	***N***	***%***	***N***	***%***
Arcade	Total	213	100.0%	88	100.0%	125	100.0%
	LOWER	84	39.4%	36	40.9%	48	38.4%
	UPPER	129	60.6%	52	59.1%	77	61.6%
Position	Total	213	100.0%	88	100.0%	125	100.0%
	Previous	102	47.9%	51	58.0%	51	40.8%
	Back area	111	52.1%	37	42.0%	74	59.2%
EXOD.	Total	213	100.0%	88	100.0%	125	100.0%
	NO	81	38.0%	56	63.6%	25	20.0%
	YES	132	62.0%	32	36.4%	100	80.0%
ANGLED	Total	213	100.0%	88	100.0%	125	100.0%
	NO	165	77.5%	64	72.7%	101	80.8%
	YES	48	22.5%	24	27.3%	24	19.2%
Diameter	Total	213	100.0%	88	100.0%	125	100.0%
	3.5 mm	72	33.8%	39	44.3%	33	26.4%
	4.0 mm	108	50.7%	22	25.0%	86	68.8%
	4.5 mm	33	15.5%	27	30.7%	6	4.8%

Table 1: Distribution of the sample (implants) according to superior/bottom arcade.

For the quantitative variables, the mean insertion torque of all implants was 46.22 Ncm. Specifically, the mean torque was 45 Ncm in the metal group and 47.08 Ncm in the PEEK group (Table 2). The mean implant length was 13.08 mm, with an average of 13.84 mm in the control group and 12.54 mm in the experimental group (Table 2).

As shown in Figure 2, the Wilcoxon test for related samples revealed no statistically significant differences between the first measurement (taken on the day of surgery and loading with the provisional prosthesis) and the second measurement (at 4 months in the maxilla and 3 months in the mandible). However, significant differences were found between the second measurement and the one taken after 12 months, indicating substantial bone loss following the placement of the definitive prosthesis.

		MATERIAL		
		Total	**METAL**	**PEEK**
Length	N	213	88	125
	Average	13.08	13.84	12.54
	SD	1.91	1.64	1.91
Torque	N	213	88	125
	Average	46.22	45.00	47.08
	SD	8.12	10.39	5.93

SD, standard deviation.

Table 2: Sample distribution according to implant torque insertion.

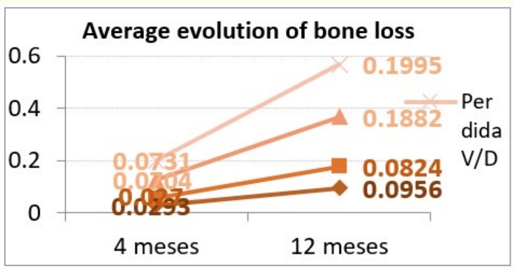

Figure 2: Average evolution bone loss.

The comparative analysis of different materials and related factors affecting bone loss (measured at four reference points) showed that vertical bone loss, both mesial and distal, was consistently greater than horizontal loss. A bivariate inferential statistical analysis was performed to correlate peri-implant bone loss with influencing variables related to surgical technique, implants, patients, and prostheses.

Table 3 summarizes the results including 0-values (i.e., cases with no bone loss), showing statistically significant relationships between bone loss and factors such as material, implant angulation, post-extraction placement, implant position, and smoking status in all four bone loss measurements using the Mann-Whitney test. Conversely, variables such as bruxism, type of antagonist, and dental arch showed no significant correlation.

LOST vs. FACTOR	**p-value M-W**								**p-value K-W**
	Material	**Arcade**	**Angled**	**Smokes**	**Exod.**	**Positión**	**Bruxism**	**Antagonist**	**Diameter**
Lost HM	0.031	0.369	0.000	0.806	0.553	0.033	0.125	0.385	0.006
Lost HD	0.023	0.289	0.299	0.006	0.002	0.278	0.450	0.647	0.241
Lost VM	0.000	0.883	0.000	0.716	0.480	0.088	0.156	0.134	0.000
Lost VD	0.006	0.832	0.002	0.002	0.012	0.017	0.296	0.403	0.017

MW. Mann-Whitney test KW. Wilcoxon test.

HM, horizontal/mesial; HD, horizontal/distal; VM, vertial/mesial; VD, vertial/distal.

Table 3: Bone loss values including 0 values (213 cases).

The Wilcoxon test relating bone loss measurements to implant diameter was also statistically significant.

When excluding 0-values (i.e., including only implants with measurable bone loss), the results in Table 4 indicate that bone loss was significantly associated with material, dental arch, implant angulation, smoking, and bruxism. The antagonist type remained statistically insignificant. Again, the Wilcoxon test confirmed a significant relationship between bone loss and implant diameter.

LOST vs. FACTOR	*p-value M-W*								*p-value K-W*
	Material	*Arcade*	*Angled*	*Smokes*	*Exod.*	*Position*	*Bruxism*	*Antagonist*	*Diameter*
Lost HM	0.630	0.551	0.364	0.386	0.432	0.076	0.195	0.574	0.856
Lost HD	0.029	0.048	0.152	0.045	0.194	0.674	0.590	0.133	0.157
Lost VM	0.000	0.544	0.000	0.645	0.735	0.619	0.035	0.306	0.000
Lost VD	0.000	0.044	0.034	0.284	0.003	0.937	0.384	0.186	0.338

Table 4: Bone loss values not including 0 values (loss >0).

The bivariate analysis provided a clearer understanding of how the material used for definitive full-arch prostheses—metal (control) versus PEEK (experimental)—affects peri-implant bone loss. Whether including or excluding 0-values, the results consistently showed greater average bone loss in the metal group, particularly in the vertical dimensions. When 0-values were excluded (i.e., only implants with measurable bone loss were considered), vertical bone loss was notably higher in the metal group across all measured points except for HM.

As illustrated in Figure 3 and Figure 4, three out of the four bone loss measurements showed statistically significant differences when comparing metal and PEEK framework materials, further supporting the conclusion that PEEK frameworks are associated with reduced peri-implant bone loss in immediate full-arch prostheses.

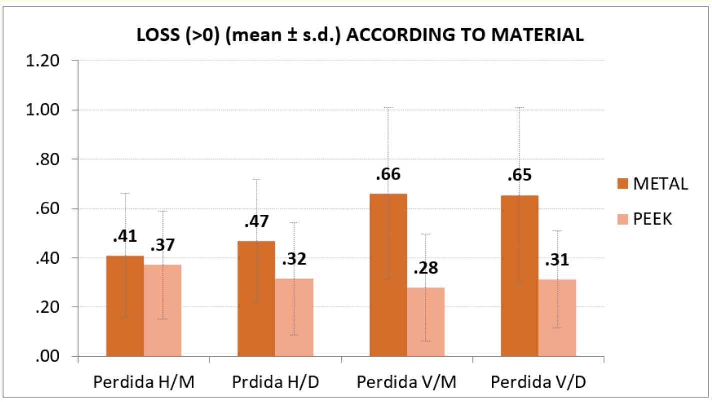

Figure 3: Average bone loss graph according to metal (control group) or peek (experimental group)/ Including 0.

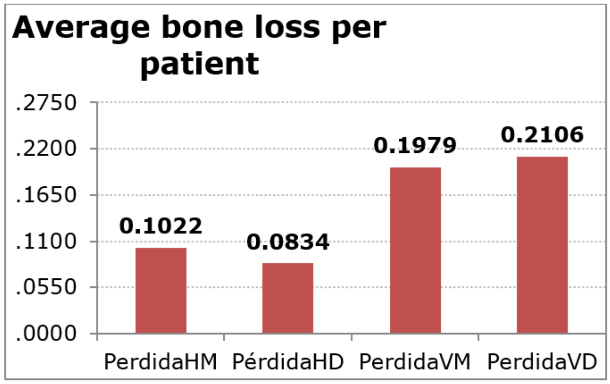

Figure 4: Distribution of average bone loss per patient.

Discussion

Immediate loading protocols offer the advantage of reduced treatment times, allowing patients to receive a fixed prosthesis within 48 hours after surgery (Glauser et al., 2001), which significantly enhances patient satisfaction. Proponents of immediate loading suggest that, in addition to time efficiency, this approach benefits peri-implant tissues, supports favorable esthetic outcomes, and promotes bone regeneration around the implants. The current literature supports the predictability and high survival rates of immediate loading protocols (Bergkvist et al., 2009; Grunder, 2001; Lindeboom et al., 2006).

The design of this study was informed by previous investigations (Bergkvist et al., 2009; Gallucci et al., 2004; Grunder, 2001), and our inclusion and exclusion criteria were based on those standards. We evaluated 213 implants placed with full-arch prostheses supported either by metal (control group) or PEEK (experimental group). This sample size is comparable to earlier studies, although most prior research focused on immediate loading in general rather than comparing framework materials (Balshi et al., 2005; Collaert & De Bruyn, 2008; Esposito et al., 2013; Horiuchi et al., 2000).

Digital periapical radiographs were used to assess peri-implant bone loss, employing individualized positioning guides and the long cone parallel technique, which remains the standard in the literature (Collaert et al., 2011). Several studies have validated this method's precision and reproducibility (Francetti et al., 2010; Pieri et al., 2009). For normalization, implant length was used as the reference, following the approach by Landázuri-Del Barrio et al. (2013). Other studies used implant diameter or thread pitch (Mozzati et al., 2013; Pieri et al., 2009), though these may introduce variability.

Unlike some studies that used panoramic radiographs (Strietzel et al., 2011), we avoided these due to their lower precision in assessing bone loss. Periodontal probing was also excluded to prevent tissue damage and ensure reproducibility, as probing forces must not exceed 0.2-0.25 N (Lang et al., 2004).

Immediate full-arch rehabilitations in both arches have shown high success rates (Balshi et al., 2005; Grunder, 2001), though more robust evidence exists for the mandible than the maxilla due to bone density differences (Lekholm & Zarb, 1999). Our 100% implant survival rate over a 12-month follow-up is consistent with previously reported rates of 95-97% for immediate loading protocols, especially when implants are splinted (Horiuchi et al., 2000). One exception in the literature is the study by Akça et al. (2007), where non-splinted implants were used with immediate loading.

The bivariate analysis revealed several significant factors influencing peri-implant bone loss. Smoking was consistently associated with increased bone loss, aligning with findings by Rocci et al. (2003) and Twito & Sade (2014). In contrast, bruxism did not show a statistically significant association with bone loss in our study when 0-loss values were included, despite being linked to higher failure rates in other works (Glauser et al., 2001; Weber et al., 2009). This supports the idea that parafunctional overloads do not necessarily cause localized crestal bone loss unless they compromise the entire implant structure (Wiskott & Belser, 1999).

Bone loss was found to be greater in the maxilla than in the mandible when excluding 0-values, consistent with the lower bone density in the maxilla. The mandible, particularly the anterior region, belongs to higher-density bone classes (Class 2-3), while the posterior maxilla includes Class 3-4 bone (Lekholm & Zarb, 1999), potentially explaining the observed differences.

Inclined implants placed at 30° demonstrated a statistically significant increase in bone loss, both with and without inclusion of 0-values. This supports findings from studies using the "All-on-Four" and "All-on-Six" concepts (Maló et al., 2003), which, while predictable, require surgical expertise and appropriate bone anatomy.

Our findings also indicate that larger implant diameters (4.0-4.5 mm) are associated with increased bone loss compared to narrower implants (3.5 mm). This contrasts with some biomechanical theories suggesting wider implants reduce stress (Vela-Nebot et al., 2006), but is supported by studies reporting higher failure rates for wider implants (Degidi & Piattelli, 2005).

Importantly, our results demonstrated lower average bone loss in the PEEK group compared to the metal group (Figures 3A and 3B). This can be attributed to PEEK's favorable biomechanical properties—its elasticity closely resembles that of bone, reducing stress transmission to peri-implant tissues. Reinforced PEEK (BioHPP), containing zirconium and aluminum oxides, is non-metallic, impact-resistant, and non-abrasive to antagonists, acting similarly to the periodontal ligament (Acocella et al., 2011). According to Kitamura et al. (2004), the modulus of elasticity and material resilience significantly influence bone remodeling and stress distribution. PEEK may thus harmonize force transmission and protect surrounding bone structures.

Limitations

The main limitation of this study is the relatively small sample size, despite an extended recruitment period. However, the randomized and single-blinded design enhances its internal validity and provides a strong methodological foundation for the conclusions drawn.

Conclusions

In this study, all implants achieved successful osseointegration, with no implant failures recorded. However, bone loss was observed in all implants at both the 4-month and 12-month follow-ups. Our findings indicate that age is a protective factor against the *risk* of experiencing bone loss, though it does not affect the *extent* of bone loss when it occurs. Tooth extraction sites, higher insertion torque, and the use of PEEK components were associated with a reduced risk and lesser degree of bone loss. Notably, the combination of PEEK and tooth extraction offered the greatest protective effect against the amount of bone loss. Conversely, a higher risk and greater degree of bone loss were observed in angulated implants compared to non-angulated ones, and in implants with diameters of 4.0-4.5 mm compared to those with a 3.5 mm diameter.

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