

# Early marginal bone loss around immediately loaded one-piece and two-piece dental implants following immediate or delayed loading. A prospective study

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## ABSTRACT

**Aim** This study was conducted to evaluate the marginal crestal bone loss around immediately loaded one-piece vs. two-piece dental implants associated with two different loading protocols during the first year after implant insertion.

**Materials and methods** 86 patients participated in the study. 90 dental implants (Zimmer Dental) were used. Of those, 30 were Tapered Screw Vent (TSV) implants with an immediate loading protocol (TSVi), 30 TSV with delayed loading (TSVd), and 30 were one-piece implants with an immediate loading protocol (OP). Crestal marginal bone loss in the coronal area of dental implants was evaluated radiographically at three months and one year post-implant insertion.

**Results** Marginal bone loss was significantly higher after one year post-surgery compared to three months post-surgery in all the study groups. The mean values of marginal bone loss obtained by TSV implants were higher than those obtained with OP implants at both follow-up points. TSVd implants experienced the higher crestal marginal bone loss among all the study groups at both three months and one year.

**Conclusions** Crestal marginal bone loss in the most coronal part of one-piece implants is significantly less than the marginal bone loss observed in tapered screw vent implants with either immediate or delayed prosthetic loading protocols with single implant crown rehabilitations. However, further studies with a longer observational time and larger sample are necessary.

patients, through aesthetic and functional improvement of their masticatory function (1). The placement of dental implants requires diagnosis and precise planning that considers vital anatomical structures and restoration goals (2,3).

Some factors like increased treatment time, restricted mastication, suboptimal aesthetics, and impaired phonetic function in the case of conventional loading, reduce the satisfaction and thereby interest of patients in following this procedure (4). Accelerated prosthetic recovery is usually found in both partial and fully edentulous patients when other protocols like immediate and early loading are performed (4,5). This reduced treatment duration has increased the interest of patients in these procedures (4,5). In addition, the loading protocol used also plays a role in bone remodeling around dental implants (6).

In order to achieve short-medium or long-term implant survival, osseointegration, which involves physiological processes that occur in the intimate bone-implant interface (1,7,8), is necessary (9). Many authors have stated that in order to achieve osseointegration, it is imperative to preserve the marginal bone and peri-implant soft tissue to the most significant possible degree (2,8,10). However, even when 90% of success rates are plausible with traditional techniques that stimulate osseointegration, dental implantology failures continue to exist (11). Physiological bone remodeling around dental implants during the first years of function has been studied in depth (3,6,12,13), and even though the nature of this phenomenon is not yet fully understood, some mechanical or biological risk factors have been proposed as possible reasons (4). This physiological process can result in marginal bone loss, which may eventually lead to complete loss of osseointegration (4,14).

Though they are regularly used, two-piece dental

## INTRODUCTION

Dental implant placement is a standard treatment nowadays, to improve the quality of life of edentulous

implants have some disadvantages that can promote peri-implant marginal bone loss; For instance, the presence of a mechanical implant-abutment joint, which has been described as structurally weak supporting functional chewing loads and causes micromovements (15). In this microgap between the prosthetic abutment and the implant platform, bacterial colonization occurs (5,6,16,17); during tissue manipulation for the fabrication of the definitive prosthesis, bacterial contamination also occurs (15). In this sense, OP implants have the advantage of lacking a microgap, diminishing the risk of bacterial colonization (5), and the absence of micromovements, which may be related to undesirable effects on the soft and hard peri-implant tissues (18).

However, very few randomized controlled clinical trials have been reported, which compared different implant systems i.e. one- and two-piece implants, and these have shown varying results (19,20). In addition, very few studies have focused on evaluating the marginal bone loss around the implants in one-stage and two-stage surgical techniques (2). Therefore, this study the marginal crestal bone loss obtained with OP with immediate loading is compared to that of TSV dental implants associated with immediate and delayed loading protocols.

## MATERIALS AND METHODS

### Study design

A prospective study with one year of follow-up for each patient was conducted at the Badal Centre in Valencia, Spain. Data collection took a period of 5 years. Ethical approval for the study was obtained from the ethics committee at Federico Henríquez y Carvajal University (Approval number: 2/3/2004), and it was conducted as per revised World Medical Association Declaration of Helsinki. A signed informed consent form was obtained from all the patients.

### Implants:

In total, 90 dental implants were used. Of those, 30 were Tapered Screw Vent (TSV) implants (Zimmer Dental®) with immediate loading protocol on the same day of the surgical intervention (TSVi), 30 TSV implants (Zimmer Dental®) were loaded 3 months after implant insertion (TSVd), and 30 were one-piece implants (Zimmer Dental®) with immediate loading protocol on the same day of the surgical intervention (OP). The implant lengths used were 10, 11.5, and 13 mm, and the diameters were 3, 3.7, and 4.7 mm respectively. All implants in the study presented a tapered design with apical cutting threads and the same endosseous topography, with a structural titanium alloy composition (Ti6Al4V) and a microtextured implant surface. TSV implants have a polished transmucosal zone of 2.5 mm, and OP implants also have a contoured abutment with prepared margins.

### Patient selection and inclusion/exclusion criteria

A total of 86 patients (49 men and 37 women; age range: 33 to 77 years) in need of single-implant prosthodontic rehabilitations were selected for this study. The following inclusion criteria were adopted: good overall health (American Society of Anesthesiologists physical status I and II); age above 20 years; presence of edentulous spaces with sufficient keratinized gingiva in maxilla and mandible; sufficient residual bone quantity in height and width for implant loading; edentulous gap from the anterior sector to the second premolars; tooth missing for more than three months; dental loss due, caries or trauma; and optimal dental hygiene.

The exclusion criteria were as follows: presence of systemic disorders; bone area destined for implant placement in need of regeneration; infectious pathology of the bone receptor area; contraindication for oral surgical procedures; individuals undergoing treatment for tumor or cyst of the oral cavity; individuals undergoing chemotherapy or radiotherapy; drug allergies; and (vii) pregnancy.

### Clinical and radiographic evaluation

An orthopantomography was performed for all patients to confirm the bone height was sufficient to allow for the placement of a minimum of 10 mm length implants. By a clinical evaluation, it was confirmed that the bone ridge width was no less than 6 mm horizontally.

### Surgical protocol

All dental implants were placed following the instructions provided by the manufacturer. For both OP and TSV implants, the same surgical kit was used. All the implants were placed by the same operator. A combination of articaine and epinephrine (1:200,000) was provided as local anesthesia. The incision was performed following the criteria for handling the remaining soft tissues, using a conventional flat-handled scalpel with sterile blade number 15 (Aesculap®), and keeping a minimum of 2 mm of gingival thickness. The protocol was then followed for the preparation of the implant site, and the osteotomy was performed following the manufacturer's instructions. Once the osteotomy was performed, the dental implants were placed depending on their type. In the case of TSVd, the cover screw was placed, and the flap was sutured with 3/0 non-absorbable silk. Following surgery, periapical radiography with parallelization technique and occlusal registration with heavy silicone was performed for control purposes and was set aside for subsequent radiographic review of crestal bone loss.

### Postoperative treatment

The postoperative pharmacological therapy for patients was 875 mg of amoxicillin and 125 mg of clavulanic acid at an interval of 8 hours over seven days; 600 mg of ibuprofen with arginine at an interval of 12 hours over three days; and chlorhexidine 0.2% gel applied over

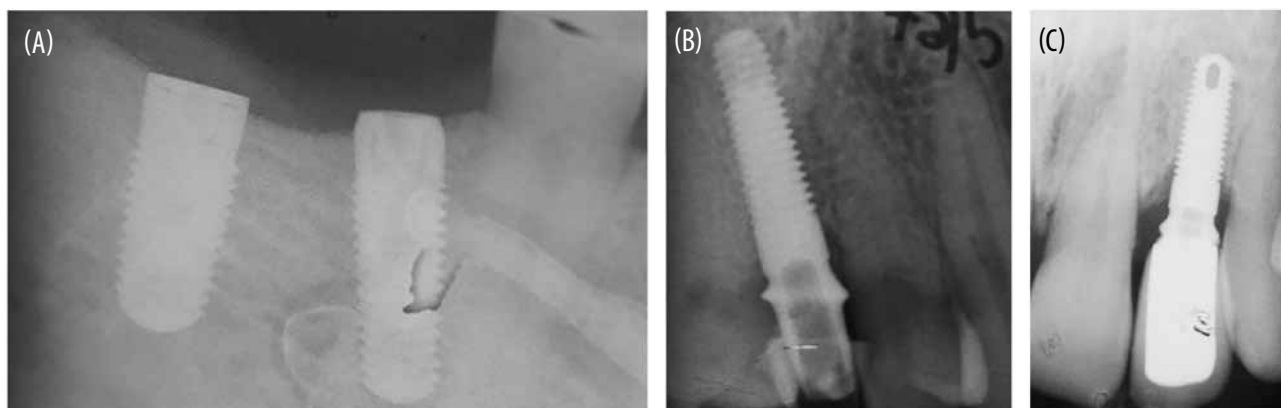


FIG. 1 Post-surgical radiography of VST implants (A); X-ray after 3 months of an OP implant (B); X-ray one year after implant insertion with its definitive rehabilitation (C).

the surgical wound every 12 hours for fifteen days. All drugs were administered orally, and a soft diet was also recommended, primarily in patients receiving implants with immediate loading.

The sutures were removed after seven days. Patients were instructed to maintain optimal oral and peri-implant hygiene, and patients were given a reminder regarding the next steps.

### Immediate loading protocol

In the case of TSVi and OP, a temporary acetate crown was adapted and refilled with autopolymerizable resin and adjusted in maximum intercuspation checking that there was no interference, prematurity, or contacts during excursive movements, implementing the preload tension recommended by the manufacturer. Once the abutment hole gave access to the fixing screw, it was filled with photopolymerizable composite resin, and the soft tissues around the crown were closed with sutures (3/0 non-absorbable silk).

### Implant follow-up and second surgery for implants with delayed loading

three months After implants placement, radiographic controls were performed with parallelization technique and occlusal registration.

In the case of the TSVd implants, articaine with epinephrine (concentration: 1:200,000) was administered, a subcrestal incision was performed, and a mucoperiosteal detachment was carried out to access the closure screw. The latter was removed, and the healing abutment was placed.

### Definitive prosthesis

Three months after the insertion of the implants, impressions were taken for the definitive prosthesis. Once prepared, the definitive crowns were adjusted over the definitive abutment. In the case of TSV implants, the abutment was attached to the definitive prosthesis with a torque wrench of 30 Nw.

The final single crown was then placed, reviewing its

occlusion, and performing cervical and interproximal adjustments. All crowns were attached with temporary material, in this case, Intermediate Restorative Material (IRM), to facilitate their removal if necessary and, more importantly, to perform follow-up at one-year.

### Clinical and radiological follow-up

A clinical evaluation system was implemented, with patients attending the consultation at one, three, six months, and one year after implant insertion. In order to evaluate the crestal marginal bone loss in the coronal area of the dental implants, periapical radiographs were taken the same day of surgery, after three months, and after one year of implant placement, using a negatoscope, a 5x magnifying glass, and a digital caliper (Fig. 1). The distance from the cervical edge of the implant to the residual bone crest was measured longitudinally on both mesial and distal surfaces. The mean obtained from both measurements was considered to be the radiographic crestal bone loss. For OP implants, the reference point for the cervical edge was the platform where convexity switches to concavity.

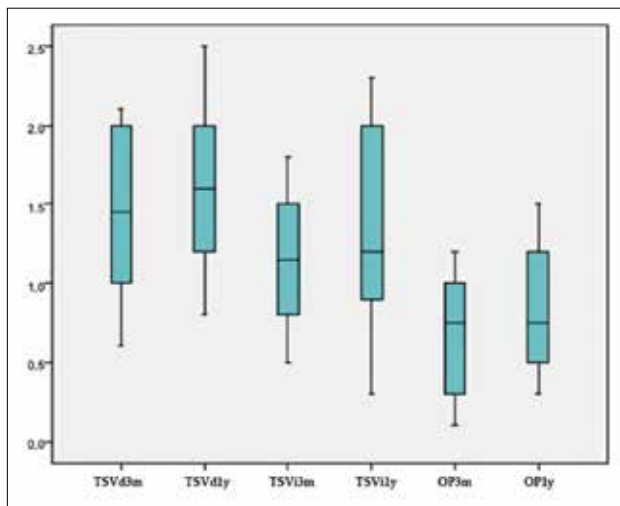
### Statistical analysis

For a comparative statistical analysis, Student's t-tests was performed. Kolmogorov-Smirnov non-parametric tests were applied to validate the normality of the measurements. F-test based on a Snedecor F distribution was performed to check for homogeneity of variance. A significance level of 5% ( $\alpha = 0.05$ ) was established to detect statistically significant differences. Microsoft Excel and IBM SPSS Statistics V.19 software were used to support data processing.

## RESULTS

### Healing and status of implants

All surgical sites in the study demonstrated uneventful healing, and all implants exhibited no looseness, peri-implantitis (peri-implant pockets  $\leq 3$  mm, no visible



**FIG. 2** Marginal bone loss expressed in mm for each implant group. TSVd3m: Tapered ScrewVent implants with delayed loading after three months; TSVd1y: Tapered Screw Vent implants with delayed loading after one year; TSVi3m: Tapered Screw Vent implants with immediate loading after three months; TSVi1y: Tapered Screw Vent implants with immediate loading after one year; OP3m: One-Piece implants after three months; OP1y: One-Piece implants after one year

plaque, no bleeding) (21), or fracture during the follow-up period.

**Population variance**

All the sample groups analyzed exhibited a normal probability distribution (Fig. 2). When tests for equality of variances were applied, all of the paired groups showed strong evidence that the statistical variable represented by them had the same population variance.

**Comparative marginal bone loss 3 months and 1 year post-surgery**

Data comparison between groups showed significant differences at both follow-up points (Tables 1, 2).

Group	N	Mean	SD	Mean differences	t-value	p-value
TSVd3m	30	1.4200	0.546	0.7467	6.2680	<0.001
OP3m	30	0.6733	0.357			
TSVi3m	30	1.1633	0.398	0.4900	5.0200	<0.001
OP3m	30	0.6733	0.357			

SD: Standard deviation

**TABLE 1** Comparison of mean data of marginal bone loss between two-piece and one-piece (OP) implants after three months of implant placement applying Student's t-test (95% CI). TSVd3m: Tapered ScrewVent implants with delayed loading after three months; TSVi3m: Tapered Screw Vent implants with immediate loading after three months. OP3m: One-Piece implants after three months.

**DISCUSSION**

Over the last twenty years, OP dental implants designed with a perspective of minimizing factors that may cause difficulties or complications in surgical placement or prosthetic restoration of traditional two-piece dental implants have gained increased use. OP implants require only one surgical intervention, avoiding the microgap formed at the implant-abutment interface and allowing the implant to be attached to the surrounding soft tissue when the implant is placed; this makes it more comfortable for the patients because it also reduces the treatment period and provides the patient immediate aesthetics and function (15,19). To the best of our knowledge, this is the first study, to evaluate two implant models with the same topography in terms of their intra-bone surface and design along with incorporating immediate loading variable being used in two-piece implants.

The present study shows marginal bone loss in all the groups which could be explained based on the study by Cochran et al., wherein they have shown that remodeling of marginal bone occurs during initial months of implant placement resulting in alteration of bone levels (22). Herein, we have further focused on the comparative bone loss around the fixtures using both techniques, since it is a criterion for evaluating implant success.

A marginal bone loss of less than 1.5 mm has traditionally been defined as a benchmark for successful implant treatment after one year of loading, but this should be redefined due to the availability of new surface technologies, new implant designs, and new research on factors affecting bone remodeling (11,23,24). It was also found that initial bone loss rates could determine marginal bone loss progression with time. A study showed that if the marginal bone loss is higher than the cutoff value of 0.44 mm at six months post-loading, marginal bone loss progression tends to be significantly higher, with an increased risk of implant failure (8). Thereby, to ascertain this, we have studied marginal bone loss in our study at

Group	n	Mean	SD	Mean differences	t-value	p-value
TSVd1y	30	1.5933	0.456	0.7833	7.3040	<0.001
OP1y	30	0.8100	0.371			
TSVi1y	30	1.3267	0.578	0.5167	4.1190	<0.001
OP1y	30	0.8100	0.371			

SD: Standard deviation

**TABLE 2** Comparison of mean data of marginal bone loss between two-piece and one-piece (OP) implants after one year of implant placement applying Student's t-test (95% CI) applying Student's t-test (95% CI). TSVd1y: Tapered Screw Vent implants with delayed loading after one year; TSVi1y: Tapered Screw Vent implants with immediate loading after one year; OP1y: One-Piece implants after one year

two time points. Moreover, the other reason for one year follow up is that many authors considered the one-year follow-up time adequate for their studies, as it is believed that the most significant bone resorption occurs in this timeframe (5,25).

Regarding crestal marginal bone loss, our results show a statistically significant decrease of this parameter in OP implants when compared to TSVd implants. Our results corroborated with a three-year multicenter study which showed that OP implants showed stable marginal bone levels (26). Although contradictory results were obtained by de Oliveira and coworkers in a systematic review, which indicated no difference between one- and two-piece implants in terms of marginal bone loss from a clinical perspective (27).

Our results were also found to be in accordance with Park et al., who showed statistically significant differences in one-stage and two-stage method in reference to alveolar bone loss after one year of implantation (28). One such study conducted by Gheisari et al. showed that the mean bone loss in the one-stage surgery technique was less than in the two-stage approach, however, this difference was not statistically significant. Besides, they suggested that, due to reduced treatment time, stress and discomfort associated with the procedure, the one-stage method is better (2). The only reason for the lower bone loss in OP implants compared to TSV implants in our study could be due to a higher susceptibility at the implant-abutment connection, which in turn can lead to inflammation of the surrounding tissue and further marginal bone loss (20,29). With regard to TSVd, which are the ones that recorded the greatest bone loss in the present study, it is possible that the bone loss targeted at three months is due to bacterial colonization around the cover screw (30) and the trauma caused by the performance of a second surgery is responsible for the increased assessment at one year of implant insertion (17).

Another study by Siadat et al. compared the crestal bone loss around implants placed through either one-stage or two-stage installation and found no significant differences between the approaches one year after functional loading (29). Less bone loss was seen for the one-stage approach, but after six and twelve months of functional loading, no significant differences in the marginal bone loss were observed. On the contrary, our data showed that comparing the differences in crestal marginal bone loss at three months and one year after implant placement in both groups, it was found to be less in OP implants. In few studies it was shown that OP implant design helps peri-implant soft tissues healing and prevents the damage of gingival seal when placing the final prosthesis. The design benefits described could justify our data wherein, OP implants showed less marginal bone loss (26,31).

It was observed in a study that during the second surgical phase, which is used to place the mucosal healing abutment of two-phase implants, an interface

is established between the most coronal part of the implant and the apical part of the prosthetic abutment, generating bone resorption of 1.5 to 2 mm. It has been said that this process occurs towards the apical portion of the implant due to chronic irritants such as bacteria and debris (16,32). Although it is known that the apical-coronal position of the implant has a fundamental role in remodeling of marginal bone, the available data are discordant (32). In our study, TSV implants suffered a considerable loss compared to the control group of OP implants. One reason for that could be closure screw removal and the abutment placement processes.

A review published in 2016 (33) compared the immediate versus conventional loading protocol of single implants in the posterior mandible. The included studies, with a follow-up of either 12 or 60 months, showed no statistically significant difference concerning marginal bone loss. According to their results, the immediate loading protocol is a reasonable alternative to the conventional loading protocol in terms of the marginal bone loss obtained. From a physiological point of view, the bone will rebuild when the implant is exposed to biomechanical loading induced by occlusal forces. As a result of this biomechanical loading, increased bone loss will occur. Therefore, when using the immediate loading protocol, the marginal bone is stimulated earlier by biomechanical loading without renewed bone remodeling after a few months (4,5,23,34). In our study, significant differences between the three study groups may suggest that marginal bone loss could be affected by the loading protocol alone or in relation with the the fixture configuration.

## CONCLUSIONS

This study deciphered that crestal marginal bone loss in the most coronal part of OP dental implants is significantly less than the marginal bone loss observed in TSV implants with either immediate or delayed prosthetic loading protocols with single implant crown rehabilitations. However, further studies with a longer observational time period and with larger sample size are necessary to establish the fact.

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This research received no external funding.

### Conflicts of Interest

The authors declare no conflict of interest.

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Angel Sánchez: data analysis and interpretation.

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