

ORIGINAL ARTICLE

Peri-Implant Marginal Bone Changes Using High-Speed Drilling With Irrigation Versus Low-Speed Drilling Without Irrigation: A Randomized Clinical Trial With 12 Months of Follow-Up

Juan Carlos Bernabeu-Mira¹ | Miguel Peñarrocha-Diago¹ | Luigi Canullo² | Fabio Camacho-Alonso³  | Julio Rojo-Sanchis¹ | David Peñarrocha-Oltra¹

¹Oral Surgery Unit, Department of Stomatology, Faculty of Medicine and Dentistry, University of Valencia, Valencia, Spain | ²University of Genova, Genova, Italy | ³Department of Oral Surgery, University of Murcia, Murcia, Spain

Correspondence: Juan Carlos Bernabeu-Mira (juan.c.bernabeu@uv.es)

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ABSTRACT

Objective: To analyse marginal bone level changes at implants placed using high-speed drilling (800 rpm) with irrigation versus low-speed drilling (150 rpm) without irrigation. Peri-implant soft-tissue parameters were assessed and the influence of bone density and vertical dimensions of supracrestal soft tissue on marginal bone level changes was evaluated.

Material and Methods: Patients with a single posterior edentulous area were included in a randomized parallel single-blinded clinical trial. The study groups were: high-speed drilling with irrigation (CG: control group) and low-speed drilling without irrigation (TG: test group). Marginal bone level changes were measured using parallelized periapical radiographs during 12-months. Probing depth, bleeding on probing, plaque index, buccal keratinized mucosa, suppuration and recession were measured. The mean total bone density was evaluated in Hounsfield Units. Mann–Whitney *U*-test for non-parametric variables and *t*-test for parametric variables were employed.

Results: A total of 66 patients were included (33 per group). The implant success rate was 100% for both groups according to Misch classification. No statistically significant differences were found regarding marginal bone loss (CG: -0.03 (0.17); TG: -0.01 (0.05)), bone remodeling (CG: 0.81 (0.64); TG: 0.86 (0.54)), or peri-implant soft tissue parameters ($p > 0.05$). Bone density showed no significant correlation with the peri-implant bone and soft-tissue changes. The vertical supracrestal soft tissue was inversely correlated to peri-implant bone remodeling.

Conclusions: Within the limits, high-speed drilling with irrigation and low-speed drilling without irrigation had no statistically significant influence on the peri-implant marginal bone and soft tissue changes during 12 months of follow-up. These variables were not significantly influenced by bone density.

Trial Registration: Unique identification number: NCT05286866

1 | Introduction

Implant bed preparation requires an atraumatic drilling technique to ensure implant success. High dental implant success rates have been described in the scientific literature over long periods of follow-up.

Irrigation is commonly used to reduce the frictional heat generated between the surgical drill and the osteotomy. Anitua, Carda, and Andia (2007) described a specific drilling technique involving low speed drilling without irrigation. Since then, several in vitro studies (Salomó-Coll et al. 2021; Oh et al. 2016; Fraguas de San José et al. 2020) have demonstrated that this drilling technique always produces temperature exposures below the critical threshold temperature of 47°C during 1 min (Eriksson and Albrektsson 1983).

Some advantages have been described for low-speed drilling without irrigation, such as better histomorphology and cellularity of harvested bone (Tabassum et al. 2020; Liang et al. 2017), a larger amount of harvested bone (Bernabeu-Mira, Peñarrocha-Diago, Canullo et al. 2024), and better patient-centered outcome measurements (Bernabeu-Mira, Peñarrocha-Diago, Peñarrocha-Diago et al. 2024). Despite these advantages, however, adequate performance in terms of marginal bone loss (MBL) and implant success rate must be ensured for low-speed drilling without irrigation.

According to a recent systematic review (Bernabeu-Mira et al. 2021), few clinical trials have described the MBL and implant success rates between high-speed drilling with irrigation and low-speed drilling without irrigation (Pellicer-Chover et al. 2017; Tabassum et al. 2021). Moreover, these studies involved small sample sizes and a high risk of bias (Bernabeu-Mira et al. 2021). Thus, randomized clinical trials with proper sample size calculation and a low risk of bias are needed to analyze the limited findings reported in the scientific literature to date.

The main objective of the present study was to compare the radiographic peri-implant bone changes between low-speed drilling without irrigation and high-speed drilling with irrigation. Implant success and soft tissue parameters were also studied, as well as the influence of bone density and supracrestal vertical soft tissue. The null hypothesis was that there are no significant differences in peri-implant bone changes, implant success, or soft tissue parameters between low-speed drilling without irrigation and high-speed drilling with irrigation.

2 | Material and Methods

2.1 | Study Design

The present randomized controlled, single-blind clinical trial was conducted between February 2022 and June 2023 in the Oral Surgery Unit (Faculty of Medicine and Dentistry, University of Valencia, Valencia, Spain). The study was carried out following the principles of the Declaration of Helsinki, and was approved by the Institutional Review Board of the University of Valencia (Ref. 1,937,615). All persons involved had provided their informed consent prior to inclusion in the study. The study was registered in ClinicalTrials.gov (NCT05286866) with the title: “Comparison

Between High-speed Drilling With Irrigation and Low-speed Drilling: a Randomized Clinical Trial”. The manuscript was written according to the CONSORT Guidelines (Schulz et al. 2010). The ID-COSM Project has been considered to conduct this clinical trial, specifically the section called “Pathophysiology harms: Surgical morbidity and complications” (Tonetti et al. 2023).

Patients requiring a single dental implant in the posterior maxilla or mandible were included. Each patient contributed one dental implant to the study. The patients were divided into two groups as follows:

- *Control group*: Implant bed preparation under high-speed drilling (800rpm) with irrigation.
- *Test group*: Implant bed preparation under low-speed drilling (150rpm) without irrigation.

2.2 | Eligibility Criteria

The patient inclusion criteria were: (1) single posterior edentulism; (2) completion of the growth phase; (3) plaque and bleeding index < 25% throughout the mouth; (4) sufficient height and width of bone for the placement of a dental implant (4mm in diameter and 8–10mm in length) without bone regeneration procedures; (5) keratinized mucosa of at least 2mm around the dental implant; (6) stable occlusion and a healthy periodontium; (7) no medical conditions contraindicating implant surgery, such as heavy smoking (< 10 cigarettes per day), severe bruxism, pregnant or breastfeeding patients, bisphosphonate therapy, patients receiving head and/or neck chemotherapy and radiation therapy; and (8) non-cooperative patients. The exclusion criteria were: (1) loss to follow-up; or (3) incorrect parallelized periapical radiography.

2.3 | Sample Size Calculation

The primary variable for calculating the sample size was mean MBL. The patient was considered as the analytical unit (one patient provided one position for dental implantation).

Pellicer-Chover et al. (2017) analyzed mean MBL in similar treatment groups, concluding a mean difference of 0.13mm and combined SD of 0.67mm. Using this variability estimation, a minimum of 60 patients (30 per group) were needed to detect as significant a mean difference of 0.5mm (Galindo-Moreno et al. 2015; Díaz-Sánchez et al. 2019) of MBL between test and control groups with a statistical power of 80%. The sample was increased in size by 10% to compensate for loss of power due to possible lack of follow-up or withdrawal of some patients. A total of 66 patients was calculated as the required sample size.

2.4 | Operational Procedure

2.4.1 | Surgical Procedure

Firstly, an anamnesis and oral examination and preoperative panoramic radiographic study were performed for every included patient. A radiological splint with a radiopaque marker

at the implant site was fabricated, and a cone-beam computed tomography (CBCT) scan was performed with it.

Each patient underwent prophylactic hygiene 7 days before the intervention, and 2g of oral amoxicillin was prescribed 1h before the operation as prophylaxis. All surgeries were performed by the same experienced operator (JCBM). The implants were IPX (Nueva Galimplant S.L., Sarria, Galicia, Spain) (4mm in diameter and 8–10mm length), placed 2mm subcrestally. Surgical drills with stops (K Fres Stop, Nueva Galimplant S.L., Sarria, Spain) were used to prepare the osteotomies with continuous drilling without pumping. A 2mm-longer drill than the implant length was used to ensure the 2-mm subcrestal implant position. A total of five surgical drills were used: pilot, 2mm Ø, 2.6mm Ø, 3.2mm Ø, and 3.6mm Ø. The pilot drill was used at 1200rpm with irrigation for both groups. The follow drills were used: 800rpm for the control group (high-speed drilling with irrigation) and 150rpm for the test group (low-speed drilling without irrigation). Two-mm high anti-rotational one-piece abutments were placed immediately after implant insertion; thus, healing was non-submerged (Figure 1).

Postoperative instructions were explained to the patients (manage pain with prescribed medications (1g Paracetamol on demand each 8h) and apply ice packs to the surgical area for 15–20min at a time during the first 24h to reduce swelling. Maintain oral hygiene by avoiding brushing the surgical site initially and instead using an antimicrobial mouthwash (chlorhexidine 0.2% three times per day during 15 days). Stick to a diet of soft, cold foods for the first 24–48h, and avoid hot, spicy, or

hard foods that may irritate the area. Rest and avoid strenuous physical activities to support the healing process. Refrain from smoking and consuming alcohol, as these can adversely affect recovery. Lastly, attend all follow-up appointments to ensure the implant is healing correctly and functioning well). The sutures were removed 7 days after surgery. Prosthetic loading was performed 10 weeks after implant placement.

2.4.2 | Prosthetic Treatment

The digital impressions were taken at the abutment level at 8 weeks from implant placement to fabricate a screw-cemented retained prosthesis. The digital impression was performed using Heron IOS (3di Dental Digital System, Spain). All the restorations were made of monolithic zirconia and were designed by the same dental technician. All screws were tightened with a torque of 25 Ncm according to the specifications of the manufacturer. The access hole of the cemented screw-retained crowns was closed with a Teflon pellet and a hybrid resin composite.

2.4.3 | Control Visits

Monitoring was performed at the first, third, sixth and twelfth month after implant placement. Periapical parallelized radiographs and clinical analysis (probing depth [PD], bleeding on probing [BoP], plaque index [PI], buccal keratinized mucosa, suppuration and recession) were performed (Figure 2).

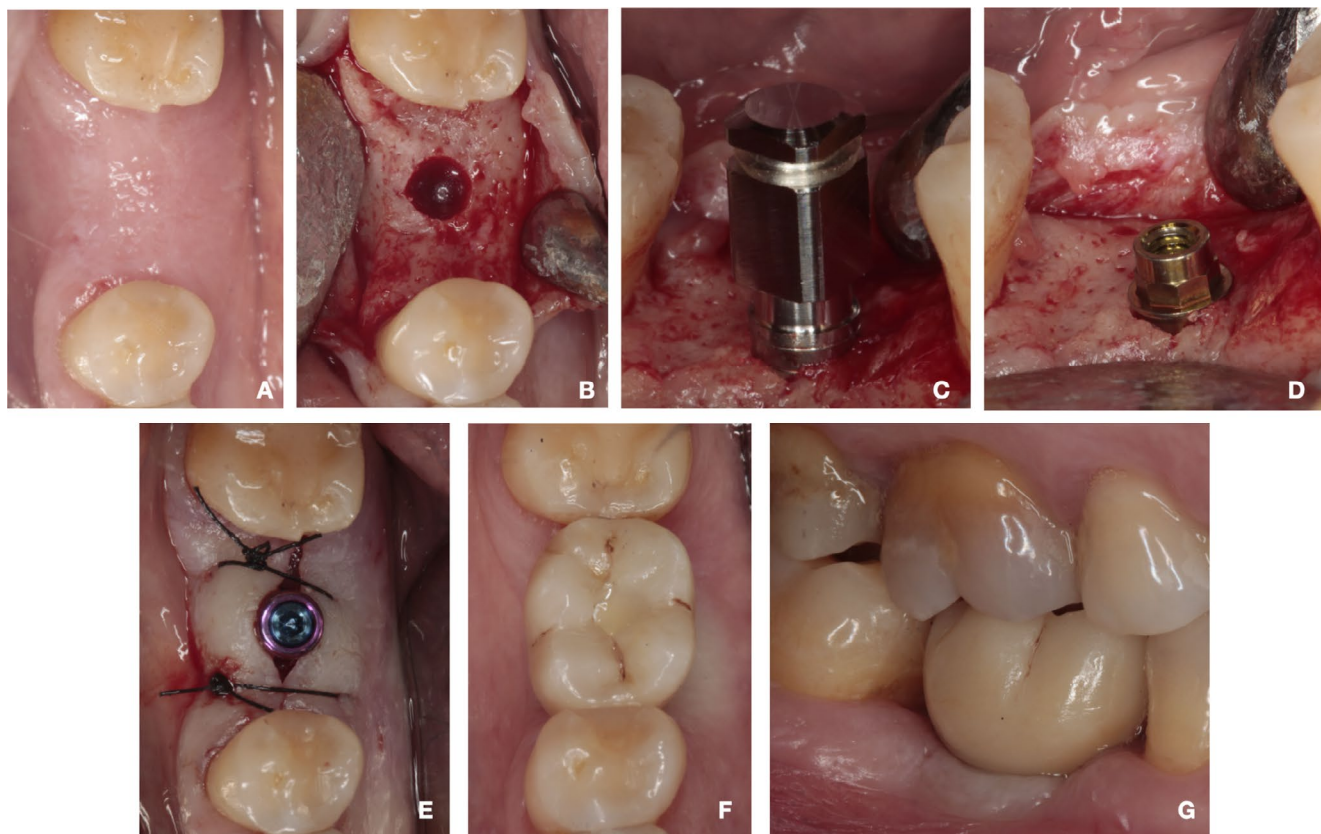


FIGURE 1 | Operational procedure. (A) Single posterior area. (B) Osteotomy. (C) Dental implant placed 2mm subcrestal. (D) 2mm abutment height. (E) Suture. (F) Occlusal view of monolithic zirconia crown. (G) Lateral view of monolithic zirconia crown.

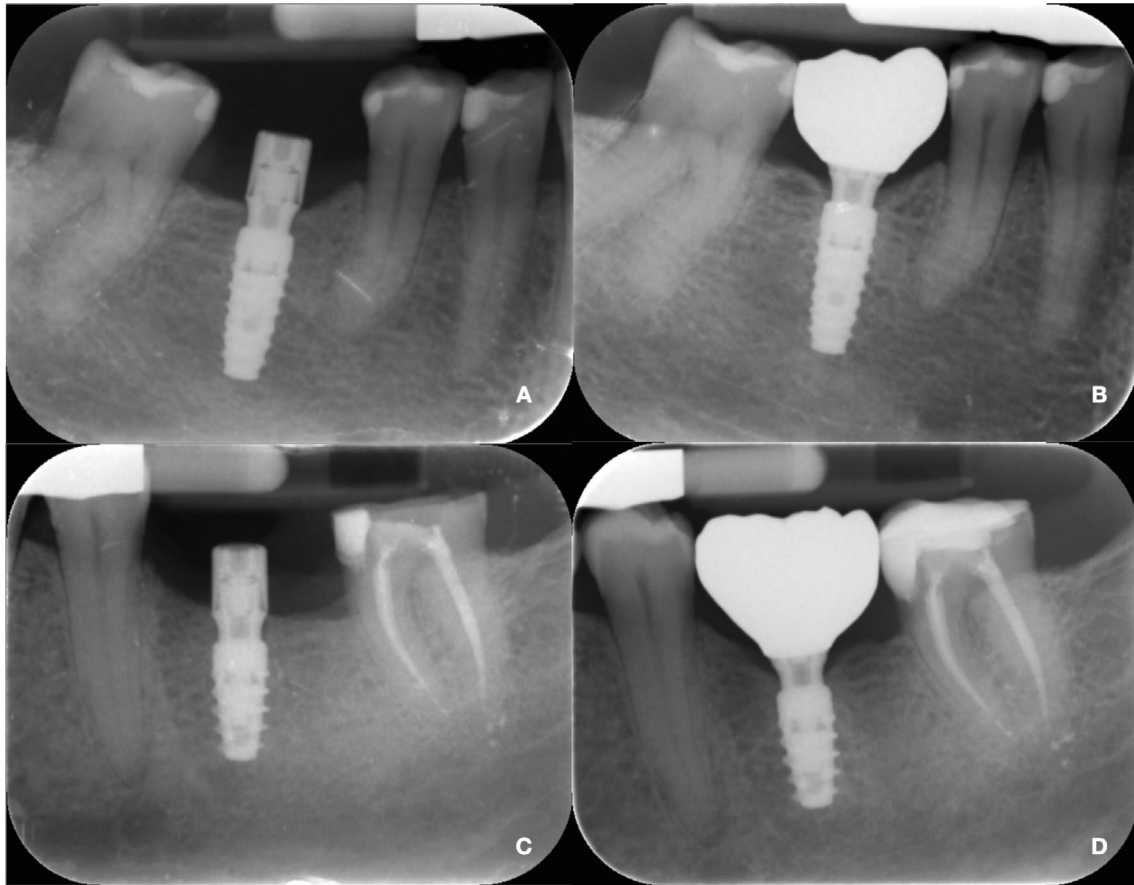


FIGURE 2 | Parallelized periapical radiography view of both groups. (A, B) Implant placement and 12 months of follow-up for the test group. (C, D) Implant placement and 12 months of follow-up for the control group.

2.5 | Outcome Measurements

2.5.1 | General Variables

Patient age and sex, smoking habit (no smoking or ≤ 10 cigarettes/day), brushing habit (0, 1–2, or 3 times/day), edentulism (interdental or free end), phenotype (thin, medium or thick), implant position (premolar or molar), antagonist (natural teeth, bridge on teeth, implant rehabilitation, or removable rehabilitation), cause of dental loss (caries, periodontitis or other), arch, implant dimension (4 × 8–10 mm), radiographic bone density (in HU) and vertical supracrestal soft tissue (in mm) were recorded.

2.5.2 | Changes in Peri-Implant Marginal Bone Level

Parallelized periapical radiographs were obtained at implant placement (T0) and at the first (T1), third (T3), sixth (T6), and twelfth month (T12). An XMIND intraoral system (GroupeSatelec-Pierre Rolland, Bordeaux, France) and an RVG intraoral digital receptor (Bür Dental, Bietigheim-Bissingen, Germany) were used. The paralleling radiographic technique was performed to reproduce the patient alignments using a rigid cross-arch bar and a Rinn XCP (Dentsply, Des Plaines, IL, USA). This process was performed by the same operator (Figure 2).

The peri-implant marginal bone level was measured to the closest 0.1 mm using ImageJ (National Institutes of Health, USA). Calibration was performed using the known abutment height (2 mm). For measurement purposes, a straight line was traced at implant platform level (this line represented zero height), and perpendicular lines were traced from the mesial and distal aspects of the implant platform.

Peri-implant MBL was defined as a bone-level change occurring in the apical direction with respect to the implant platform, thereby exposing rough implant surface. To calculate this variable, bone levels at each timepoint were determined from the implant platform to the first radiographic bone-implant contact. The difference in this bone level between implant abutment placement (T0) and each timepoint, that is, at the first (T1), third (T3), sixth (T6), and twelfth month (T12) after implant placement, was calculated. The mean between mesial and distal MBL was calculated for each implant.

Bone remodeling, as described by Linkevicius (Linkevicius et al. 2020), was defined as a bone-level change occurring in the area coronal to the implant platform, and thus not exposing rough implant surface. To calculate this variable, bone levels at each timepoint were determined from the implant platform to the marginal bone level following the vertical line of the mesial and distal aspects of the implant. The difference in this bone level between implant abutment placement (T0) and each

timepoint, that is, at the first (T1), third (T3), sixth (T6), and twelfth month (T12) after implant placement, was calculated. The mean between mesial and distal bone remodeling was calculated for each implant.

In cases where there was a double bone level (lingual/palatal and buccal), the worst (most apical) level was used as the measurement data.

The measurements were taken by two independent observers (JRS and DPO). The calibration was completed prior to the study using 15 patients who underwent treatment but who were not part of the study. The K-statistic was calculated to identify the reliability of the measurements performed by the two examiners in order to determine MBL. The result was $k=0.93$. According to the Landis and Koch categorization (Landis and Koch, 1977), this value of the K-statistic is “almost perfect” in terms of the peri-implant marginal bone change measurements.

2.5.3 | Peri-Implantitis and Mucositis

According to Caton et al. (2018), peri-implant mucositis is characterized by BoP and visual signs of inflammation. However, peri-implantitis was defined as a plaque-associated pathologic condition occurring in the tissue around dental implants, characterized by inflammation in the peri-implant mucosa and subsequent progressive loss of supporting bone. Herrera et al. (2023), recommended implementing interventions throughout implant placement and loading to prevent peri-implant diseases. Prevention should start at planning, placement, and loading stages. A structured care program with regular tissue health assessments is essential once implants are in function. If peri-implant mucositis or peri-implantitis arise, appropriate treatments should be applied.

2.5.4 | Peri-Implant Soft Tissue Condition

The peri-implant soft tissue condition was assessed by recording PD (in mm) and BoP (yes or no) at Month 3, 6, and 12 after implant placement. PD was measured at six surfaces per implant, and the mean of each implant was calculated. PI, buccal keratinized mucosa, mucosal recession and suppuration were also analyzed. The measurements were taken by two independent observers (JRS and DPO). The calibration was completed prior to the study using 15 patients who underwent treatment but who were not part of the study. The K-statistic was calculated to identify the reliability of the measurements performed by the two examiners in order to determine the PD. The result was $k=0.82$, which represents “almost perfect” according to Landis and Koch (1977) in terms of the probing measurements.

2.5.5 | Implant Success

The implants were evaluated according to Misch et al. (2008) based on three clinical conditions: success (no pain or tenderness on function, zero mobility, radiographic bone loss <2 mm since initial surgery, and no history of exudates); satisfactory survival (no pain on function, zero mobility, radiographic bone

loss 2–4 mm, and no history of exudates); compromised survival (possible tenderness on function, zero mobility, radiographic bone loss >4 mm [less than 1/2 of the implant length, PD >7 mm and a possible history of exudates]); and failure (if any of the following aspects are present: pain on function, mobility, radiographic bone loss >1/2 implant length, uncontrolled exudate, and absent from the oral cavity).

2.5.6 | Radiographic Bone Density Measurement and Bone Quality Assessment

Radiographic bone density was measured at the implant site using a radiopaque marker on the radiological splint according to Turkyilmaz et al. (2007). The region corresponding to the last surgical drill was carefully recorded. Newtom software (Cefla S.C., Bologna, Italy) was used to assess radiographic bone density. The results were given as CBCT pixel values expressed using Hounsfield Units (HU), just as an output unit, following previous methodologies (Cortes et al. 2015; González-García and Monje 2013). Following previously described methods (Salimov et al. 2014), bone quality was evaluated according to the Lekholm and Zarb classification (Lekholm 1985) after assessing the images from the CBCT scan.

2.6 | Randomization, Allocation and Blinding

Patients were randomized prior to the surgical procedure by simple randomization using www.randomization.com. This was a randomized, single-blind clinical trial in which the operator and the patient knew the group to which each subject had been assigned, but data collection and data analysis were blinded. The random allocation codes were sealed in sequentially numbered opaque envelopes. Allocation concealment was broken after raising of the flap, when the corresponding envelope was opened and the operator was informed whether to drill at 800 rpm with irrigation or at 150 rpm without irrigation. Regarding blinding, two independent researchers collected the outcomes (marginal bone changes and peri-implant soft tissue parameters). An independent blinded statistician was responsible for analyzing the data.

2.7 | Statistical Analysis

Firstly, homogeneity of groups through demographic and clinical variables was performed. Chi² and Fisher's exact tests were used to assess association of categorical variables and Mann-Whitney's test for continuous ones.

A Kolmogorov-Smirnov's test was used to check normality of outcomes, being accepted for PD, keratinized mucosa, and peri-implant bone changes and unaccepted for BoP (mean of six sites) and PI. Recession, suppuration and MBL were excluded from most of inferential analysis because their exceptional presence of positive cases (two patients as maximum).

A generalized linear model was estimated to assess the effect of group over time for normal outcomes. Main effects and interaction time-group was obtained.

Regarding non-normal outcomes, a non-parametric Brunner-Langer model for longitudinal data was estimated, including interaction term too.

Final outcomes at T12 months were correlated with independent factors (between-subjects comparisons) using 2-sample *t*-test, one-way ANOVA, Mann-Whitney's and Kruskal-Wallis tests depending on the specific distribution of the outcome. Some co-variables (age, bone density) were previously recoded into three intervals. Significant factors were considered for estimating multiple linear models.

The significance level was 5%, with a confidence level of 95%.

Mean: The average value of a data set. Standard Deviation (SD): A measure of the variability or dispersion of a data set relative to the mean. Median: The value that divides a data set into two equal halves. Interquartile Range (IR): The difference between the first (Q1) and third quartiles (Q3), measuring the dispersion of the central values in a data set.

3 | Results

A total of 66 dental implants were placed in 66 patients (33 men and 33 women) with a mean age of 54.5 (14.4) years. Thirty-three patients were included for each group. A 100% success rate was recorded. All the implants showed success according to the classification of Misch et al. (2008). Descriptive and analytical data are presented in Table 1 for each of the independent variables in the study, together with the correlations between bone changes and peri-implant soft tissue parameters. The homogeneity test results are also shown. The CONSORT flow chart is shown in the Figure 3.

Regarding the radiographic bone level changes (Table 2), the MBL was 0.0 (0.0) mm for both groups ($p > 0.05$). The mean difference in marginal bone remodeling was 0.81 (0.64) mm in the control group and 0.86 (0.54) mm in the test group ($p > 0.05$) after 12 months of follow-up. Thus, there were no statistical differences between groups with respect to the final follow-up mean and for each follow-up timepoint ($p > 0.05$) (intergroup comparison). In relation to the independent variables, the supracrestal vertical soft tissue was inversely correlated to marginal bone remodeling, with statistically significant differences (1.27 (0.52) mm for < 3 mm and 0.73 (0.53) mm for > 3 mm) (intragroup comparison). The differences in bone density were not significant correlated ($p = 0.102$) (intragroup comparison).

Regarding the peri-implant soft tissue parameters (Table 3), PD (2.62 (0.58) vs. 2.45 (0.57) mm), BoP, (0.0 vs. 0.0%) PI (0.0 vs. 0.0%), buccal keratinized mucosa (3.50 (1.34) vs. 3.03 (1.10) mm), suppuration (0 vs. 0%) and recession (0 vs. 0 mm) showed no statistically significant differences for control group and test group, respectively ($p > 0.05$) (intergroup comparison).

Regarding comparative of clinical and marginal bone changes over follow-up by group, only remodeling showed statistically significant changes throughout the study period ($p < 0.001$). The pattern of change was similar in both groups ($p = 0.629$).

Keratinized mucosa showed a tendency to increase during follow-up ($p = 0.096$); however, the magnitude was the same in both groups ($p = 0.270$).

The PI showed a tendency to decrease during follow-up ($p = 0.055$); however, the magnitude was the same in both groups ($p = 0.755$).

For the remaining parameters, no changes were observed over time, nor were there any differences between the groups (Table 4) (intragroup comparison).

The incidence of peri-implantitis and mucositis at 1 year of follow-up was 0%. So, the composite outcome of the presence of peri-implant mucositis and peri-implantitis was zero implants for 66 patients.

4 | Discussion

The comparative radiographic peri-implant bone changes between low-speed drilling without irrigation versus high-speed drilling with irrigation constituted the main outcome variable of the present study. Implant success and soft tissue parameters were also evaluated. No statistically significant differences were identified for MBL, marginal bone remodeling, implant success rate or soft-tissue parameters between the two drilling techniques. Radiographic bone density was not significantly correlated to any outcome variable. The supracrestal vertical soft tissue dimension showed an inverse correlation to marginal bone remodeling, though the differences did not reach statistical significance.

Several advantages have been described with low-speed drilling without irrigation versus high-speed drilling with irrigation, including superior osteogenic potential of the bone particles (Camacho-Alonso et al. 2024), a larger amount of harvested bone (Bernabeu-Mira, Peñarrocha-Diago, Canullo et al. 2024), and improved patient-centered outcome measurements (Bernabeu-Mira, Peñarrocha-Diago, Peñarrocha-Diago et al. 2024). However, the suitability of basic variables such as implant success rate and peri-implant MBL must also be ensured. These variables have been analyzed through preclinical and clinical studies with a high risk of bias (Bernabeu-Mira et al. 2021). The present study constitutes a clinical trial with correct randomization, allocation and blinding, together with correct sample size calculation and the use of standard methodology to measure peri-implant MBL.

The previous studies showed both techniques to have a high success rate of between 90% and 100% (Abdelsattar, El Khader, and Abdel Rassoul 2021; Tabassum et al. 2021; Pellicer-Chover et al. 2017). Our findings are consistent with those of the aforementioned studies, with a 100% implant success rate for both groups. These results are closely correlated to those of several preclinical studies in animal models that analyzed the osseointegration process with both techniques, and found no statistically significant differences between them. With regard to percentage bone-implant contact (BIC%) (Giro et al. 2011; Calvo-Guirado et al. 2015; Fujiwara et al. 2022), the percentage of old and new bone (Fujiwara et al. 2022; Favero et al. 2018), or bone area fraction occupancy (Giro et al. 2011) around the

TABLE 1 | Descriptive data for each variable at patient level.

Variable	Categories	High-speed <i>n</i> (%) or Δ (SD)	Low-speed <i>n</i> (%) or Δ (SD)	Sample homogeneity		Effect of variable	
				<i>p</i>	Statistical test	MBR (<i>p</i>)	Statistical test
Sex	Male	17 (51.5)	16 (48.5)	0.806	Chi ²	0.585	<i>t</i> -test
	Female	16 (48.5)	17 (51.5)				
Age	—	53 (14.5)	56 (14.4)	0.422	MW	0.547	<i>t</i> -test
Smoking habit	0 cig/day	27 (81.1)	27 (81.8)	1.000	Chi ²	0.047*	<i>t</i> -test
	≤ 10 cig/day	6 (18.2)	6 (18.2)				
Brushing habit	1 per day	2 (6.1)	2 (6.1)	0.460	Chi ²	0.365	<i>t</i> -test
	2 per day	16 (48.5)	13 (39.4)				
	3 per day	15 (45.5)	18 (54.5)				
Gingival phenotype	Thin	5 (15.2)	3 (9.1)	0.672	Chi ²	0.232	<i>t</i> -test
	Medium	23 (69.7)	26 (78.8)				
	Thick	5 (15.2)	4 (12.1)				
Position	Premolar	20 (60.6)	21 (63.6)	0.800	Chi ²	0.912	<i>t</i> -test
	Molar	13 (39.4)	12 (36.4)				
Arch	Upper	15 (45.5)	16 (48.5)	0.850	Chi ²	0.035*	<i>t</i> -test
	Lower	18 (54.5)	17 (51.5)				
Antagonist	Edentulism	0 (0)	0 (0)	0.427	FIS	0.556	<i>t</i> -test
	Natural teeth	28 (84.8)	31 (93.9)				
	Removable prosthesis	0 (0)	0 (0)				
	Fixed prosthesis	5 (15.2)	2 (6.1)				
Cause of dental loss	Periodontal disease	0 (0)	0 (0)	1.000	FIS	0.313	<i>t</i> -test
	Caries	31 (93.9)	32 (96.9)				
	Other	2 (6.1)	1 (3.1)				
Implant dimension	4×8 mm	17 (51.5)	18 (54.5)	0.805	Chi ²	0.528	<i>t</i> -test
	4×10 mm	16 (48.5)	15 (45.5)				
Final drill diameter	3.2	20 (60.6)	19 (57.6)	0.802	Chi ²	0.421	
	3.6	13 (39.4)	14 (42.4)				
Supracrestal vertical soft tissue	—	2.4 (1.5)	2.3 (0.7)	0.481	MW	<0.001*	<i>t</i> -test
Radiographic bone density	—	739.3 (328.6)	723.3 (319.3)	0.724	MW	0.102	<i>t</i> -test

Note: Homogeneity and statistical test and univariate lineal general multiple model.

Abbreviation: MBR, marginal bone remodeling.

**p* < 0.05.

implant, no statistically significant differences were recorded between the two techniques. Both procedures result in the bone trauma (neither insufficient nor excessive) needed to activate the osseointegration process (Piattelli et al. 1998).

Regarding peri-implant MBL, three clinical studies with a 12-month follow-up period demonstrated no statistically significant differences between the techniques (Abdelsattar, El Khader, and Abdel Rassoul 2021; Tabassum et al. 2021; Pellicer-Chover

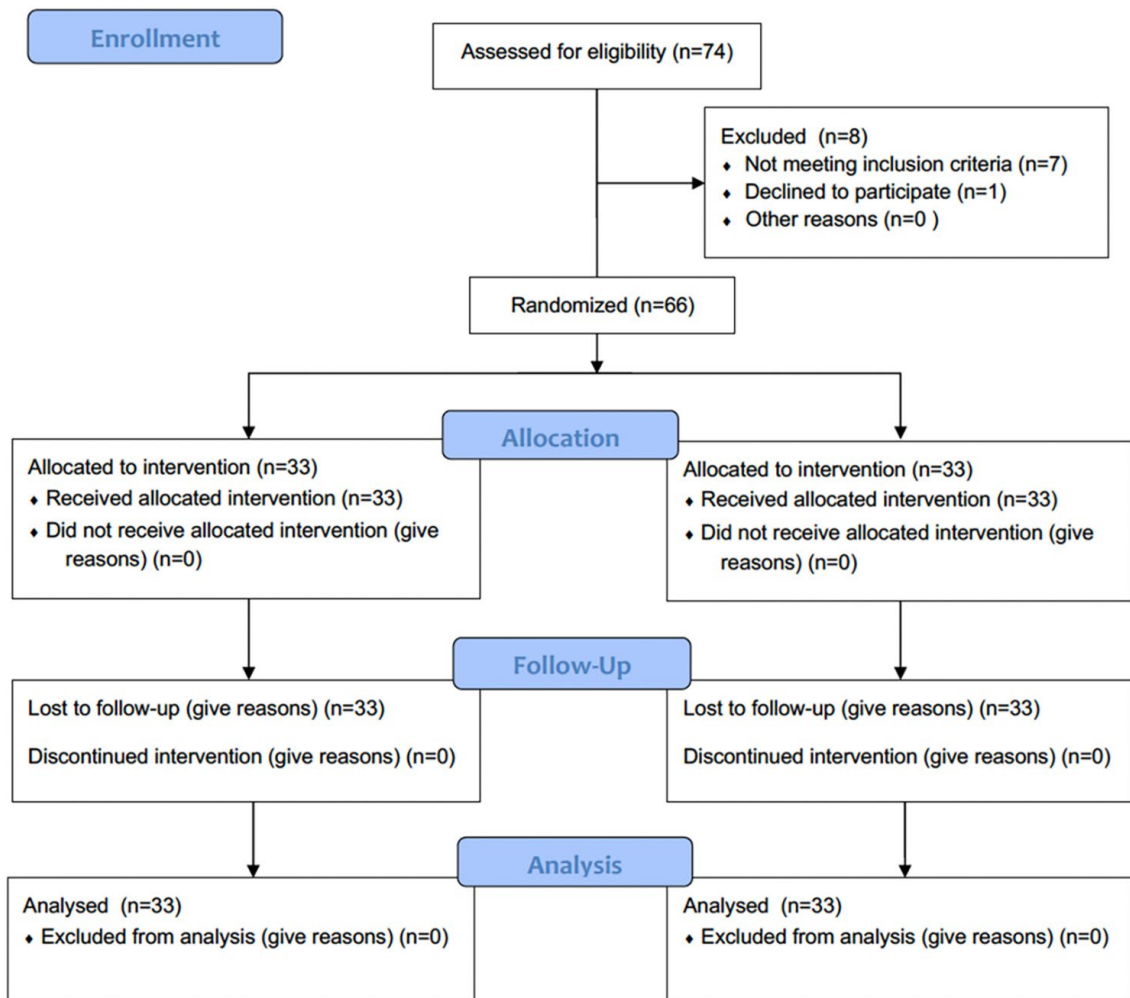


FIGURE 3 | CONSORT flowchart.

TABLE 2 | Comparative marginal bone changes between high-speed drilling with irrigation and low-speed drilling with irrigation at 12 months of follow-up.

	Marginal bone remodeling (Δ (SD))			Marginal bone loss (Δ (SD))		
	High-speed group	Low-speed group	Mean changes	High-speed group	Low-speed group	Mean changes
Baseline	1.93 (0.13)	1.93 (0.14)	0.0	0.00 (0.00)	0.00 (0.00)	0.0
1st month	1.21 (0.58)	1.13 (0.53)	0.08	0.00 (0.00)	0.00 (0.00)	0.0
3rd month	1.17 (0.56)	1.02 (0.57)	0.15	0.00 (0.00)	0.00 (0.03)	0.0
6th month	1.10 (0.65)	1.01 (0.55)	0.09	0.02 (0.10)	0.00 (0.03)	0.2
12th month	1.12 (0.63)	1.07 (0.54)	0.05	0.03 (0.17)	0.01 (0.05)	0.2
1st month (baseline—1 month)	0.73 (0.61)	0.70 (0.40)	0.03	0.00 (0.00)	0.00 (0.00)	0
3rd month (baseline—3 month)	0.68 (0.59)	0.79 (0.46)	0.11	0.00 (0.00)	0.00 (0.03)	0
6th month (baseline—6 month)	0.83 (0.67)	0.92 (0.53)	0.09	−0.02 (0.10)	0.00 (0.03)	0.02
12th month (baseline—12 month)	0.81 (0.64)	0.86 (0.54)	0.05	−0.03 (0.17)	−0.01 (0.05)	0.02

Note: Marginal Bone Loss: A downward change in bone level relative to the implant platform, exposing the rough surface of the implant. Marginal Bone Remodeling: a change in bone level above the implant platform, without exposing the rough surface of the implant.

TABLE 3 | Comparative clinical parameters between high-speed drilling with irrigation and low-speed drilling with irrigation at 12months of follow-up.

	High-speed group	Low-speed group	Mena changes
Probing depth (Δ (SD))	2.62 (0.58) mm	2.45 (0.57) mm	0.17 mm
Bleeding on probing (median)	0.00%	0.00%	0%
Buccal keratinized mucosa (Δ (SD))	3.50 (1.34) mm	3.03 (1.10) mm	0.47 mm
Plaque index	0.00%	0.00%	0%
Recession	0	0	0
Suppuration	0%	0%	0

TABLE 4 | Comparative of clinical and marginal bone changes over follow-up by group.

	Effect for TIME	Effect for GROUP	Interaction	Model
Probing depth	$p = 0.071$	$p = 0.447$	$p = 0.304$	GLM
Bleeding on probing	$p = 0.473$	$p = 0.732$	$p = 0.470$	B-L
Buccal keratinized mucosa	$p = 0.096$	$p = 0.295$	$p = 0.270$	GLM
Plaque index	$p = 0.055$	$p = 0.084$	$p = 0.755$	B-L
Recession	$p = 1$	$p = 1$	$p = 1$	B-L
Suppuration	$p = 0.932$	$p = 1$	$p = 1$	B-L
Marginal bone remodeling	$p < 0.001^{***}$	$p = 0.463$	$p = 0.629$	GLM
Marginal bone loss	$p = 0.317$	$p = 0.317$	$p = 0.317$	B-L

Note: Results of generalized linear model (GLM) and non-parametric Brunner-Langer model (B-L) for main effects and interactions.
*** $p < 0.001$.

et al. 2017). However, Abdelsattar, El Khader, and Abdel Rassoul (2021) measured MBL thorough CBCT scans, and parallelized periapical radiography (the gold standard) was not used. Pellicer-Chover et al. (2017) in turn performed a pilot study with a small sample size of 15 implants per group. Tabassum et al. (2021) conducted a study with a small sample size of 20 implants per group; healing was indistinctly submerged and non-submerged; and the transmucosal portion differed between the two groups. These variables may modify the peri-implant MBL measurements. Our study, performed with adequate sample size calculation, parallelized periapical radiographs and the same healing process and transmucosal portion for all implants, showed no statistically significant differences between the groups.

While studies have reported prevalence of peri-implant mucositis in the range of 27%–63% (Apaza-Bedoya et al. (2024)) The absence of peri-implant mucositis in this study may be contributed to the absence of plaque at the implant sites and the short follow-up. According to Caton et al. (2018) in the workshop was co-sponsored by the American Academy of Periodontology and the European Federation of Periodontology, the peri-implant mucositis shows strong evidence that this is caused by plaque, while there is very limited evidence for non-plaque induced peri-implant mucositis. The absence of peri-implantitis could be due to the application of fundamental concepts for preventing bone loss and peri-implant tissue stability in all aspects within a highly controlled university environment.

Single implants were placed 2mm subcrestally (Stacchi et al. 2023) in a favorable setting with at least 2 mm (Monje and Blasi 2019) of surrounding bone and peri-implant keratinized mucosa (Monje et al. 2019). The implant was a sub-crestal type with a switching platform and 2mm one-piece abutment placed using the one-abutment one-time technique (Calatrava et al. 2024). The cement-retained prosthesis was made of monolithic zirconia too (Valantijene et al. 2023). Additionally, patients were systemically healthy, periodontally stable or healthy, and closely monitored by the clinician throughout the short follow-up period.

Regarding the subcrestal position of the implants, subcrestal implant placement is a debated topic in the literature, with several studies showing variable results for this position. For example, Stacchi et al. (2023) found no significant differences in peri-implant marginal bone changes between implants placed 1 or 2mm subcrestally after 1 year of prosthetic loading. However, 2mm subcrestal placement showed deeper implant positioning without exposure of the treated surface, potentially preventing peri-implant pathology. Similarly, Barros et al. (2010) found that subcrestal placement of implants with Morse cone connection and platform switching helped preserve the interimplant crestal bone. In our study, we used implants with conical connections, platform switching, and a fully rough surface, which aligns with these findings. On the other hand, studies such as Cesaretti et al. (2015) and Mainetti et al. (2022) highlight that initial MBL is greater in

implants placed more subcrestally. However, the implants used in those preclinical studies with 3–4 months of follow-up had polished necks, no platform switching, and no internal conical connections, which may have significantly influenced the bone loss pattern observed. These differences in implant design could be crucial in explaining the variation in bone loss behavior.

Bone overheating during low-speed drilling without irrigation in patients presenting the highest bone densities is often suspected among clinicians. In this regard, Tabassum et al. (2021) and Pellicer-Chover et al. (2017) differentiated peri-implant MBL and implant success rate according to bone density. Both studies found no statistically significant differences, indicating that higher bone densities (mandible) versus lower bone densities (maxilla) do not appear to have an effect upon peri-implant MBL. However, Tabassum et al. (2021) suggested that the highest bone densities could produce implant failure. In the present study, bone density was measured objectively (CBCT scans and HU values), in contrast to Tabassum et al. (2021), who assessed bone density according to operator tactile sensation. Bone density was not seen to exert a statistically significant influence upon the implant success rate or MBL. In addition, Camacho-Alonso et al. (2024) measured the temperature profiles in a randomized clinical trial. Although the temperature of the drills was slightly higher in the case of low-speed drilling without irrigation, no statistically significant differences were observed. However, in relation to osteoblastic activity and osteogenic potential, greater cell proliferation, a larger number of cells in the G2/M and S phases, greater cell migration capacity, higher vascular endothelial growth factor (VEGF) concentration, and a larger amount of mineralized nodule formation were observed in the case of low-speed drilling without irrigation. These results provide solid evidence of low-speed drilling without irrigation as a safe drilling technique.

There are limitations to the present study. Each patient was periodontally healthy, with no history of periodontitis, and had abundant bone height and width, and sufficient keratinized mucosa. These conditions provide a stable foundation and promote optimal healing and maintenance of the peri-implant tissue, leading to reduced bone loss and enhanced bone remodeling over time. Likewise, fewer osteotomies were drilled in type D1 bone, since posterior areas were included in the study. Moreover, the nature of 2D periapical radiographs does not allow for a 3D radiographic analysis. Randomized clinical trials involving dental implants in type D1 bone are recommended in order to evaluate success rate and MBL. The peri-implant marginal tissue health status according to Tonetti et al. (2023) was followed in this study, however, number/proportion of implants presenting with changes of different magnitude was not reported. The follow-up could be considered short. A longer follow-up would be interesting to understand the status of these implants in the longer term.

5 | Conclusions

Within the limits of the present study, high-speed drilling (800rpm) with irrigation and low-speed drilling (150rpm) without irrigation had not significant influence upon the peri-implant marginal bone changes, soft tissue changes and success

rate during 12 months of follow-up. These variables were not significantly influenced by bone density, although fewer osteotomies were performed in type D1 bone due to the inclusion of posterior areas. Regarding limitations, all patients were periodontally healthy, with sufficient bone and keratinized mucosa, 2D periapical radiographs do not enable 3D analysis and the follow-up could be considered short.

Author Contributions

Juan Carlos Bernabeu-Mira: methodology, conceptualization, software, investigation, visualization, writing – original draft. **Miguel Peñarrocha-Diago:** conceptualization, visualization, writing – review and editing, investigation, supervision. **Luigi Canullo:** conceptualization, visualization, writing – review and editing, supervision. **Fabio Camacho-Alonso:** conceptualization, methodology, data curation, software, formal analysis, supervision, writing – review and editing. **Julio Rojo-Sanchis:** conceptualization, data curation, formal analysis, software, validation. **David Peñarrocha-Oltra:** conceptualization, writing – review and editing, project administration, software, validation.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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