

ORIGINAL ARTICLE

Marginal Bone Loss Around Bone-Level Fully Guided Implants With Direct Implant Connection Versus Intermediate Abutment: A Randomized Clinical Trial

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ABSTRACT

Objective: To determine the influence of an intermediate prosthetic abutment on peri-implant marginal bone loss (MBL) around two implant-supported fixed restorations in the posterior area.

Material and Methods: This study included patients with partial edentulism requiring two implants in the posterior maxilla or mandible. All implants were bone-level tapered implants, placed through a fully guided approach and finalized with a CAD/CAM temporary and final full zirconia restoration. The total sample comprised 30 patients (60 implants), divided into a Control group (direct to implant connection, non-intermediate abutment; 12 patients, 24 implants) and a Test group (intermediate abutment; 18 patients, 36 implants). The Test group was further divided into two abutment height subgroups: 1 mm (7 patients) and 2.5 mm (11 patients). MBL was measured using periapical x-ray imaging on the day of surgery, at definitive crown delivery, and at 4, 6, 12, and 24 months post-surgery.

Results: The Test group (intermediate abutment) had lower MBL (0.83 ± 0.25 mm) than the Control group (1.17 ± 0.35 mm; $p = 0.001$). The secondary analysis of the abutment height subgroups did not differ significantly in MBL, although values showed a trend towards a more favorable for the highest intermediate abutment.

Conclusions: This randomized clinical trial demonstrated that direct implant connection prosthesis induced greater MBL around implants in splinted crowns for an implant-supported fixed restoration when compared with the use of an intermediate abutment.

Trial Registration: [ClinicalTrials.gov](https://clinicaltrials.gov) ID: NCT06017115

1 | Introduction

Oral rehabilitation with dental implants following tooth loss has become one of the most common and predictable treatment modalities in dentistry. However, the long-term success of dental implants depends on multiple factors (Albrektsson and Wennerberg 2019). Most implants currently employed are

“two-piece” systems, consisting of an intermediate transepithelial definitive abutment (hereafter referred to as an intermediate abutment) that connects the prosthesis to the implant. This provides versatility to the implant restoration but also affects the biological behavior of the implant (Rodríguez et al. 2013). Two-piece bone-level implants are typically placed 1–1.5 mm into the bone to reduce or control initial bone remodeling. Nevertheless,

only minimal marginal bone loss (MBL) is considered to ensure the stability and long-term predictability of the implants (Bazrafshan and Darby 2014).

MBL is influenced by multiple factors, including inflammation from biomechanical stress caused by excessive occlusal loading (Rungsiyakull et al. 2011), foreign-body reactions to residual cement in cement-retained prostheses, patient habits (Qian et al. 2012), prosthetic design that compromises soft tissues (Galindo-Moreno et al. 2005), and various surgical factors such as excessive insertion pressure in marginal bone (Cardaropoli et al. 2006). Although many dental implants experience some degree of MBL, the definitive etiology remains unclear. Early marginal bone resorption around dental implants is often reported as physiological, mainly occurring after functional loading (Hermann et al. 2000); however, this interpretation remains controversial.

A key factor recently hypothesized to be involved in marginal bone remodeling is the establishment of supracrestal tissue attachment around dental implant restorations. This process is influenced by the trans-epithelial abutment height and the presence, size, and location of a micro-gap between the implant fixation and the trans-epithelial abutment or the final restoration (Blanco et al. 2018; Galindo-Moreno et al. 2014).

MBL around healthy implants can be attributed to the establishment of supracrestal tissue attachment or an inflammatory process induced by bacteria present in the micro-gap around the crown-implant connection. The latter issue may be associated with repeated connections and disconnections from the implant platform due to different surgical phases or to try-ins during the prosthesis elaborating process (Rodríguez et al. 2013). Accordingly, the concept of “one abutment, one time” has been proposed by Canullo et al. (2010), based on avoiding multiple disconnections from the implant platform by leaving the definitive abutment in place from the day of the surgery. Additionally, another factor that may influence marginal bone stability around implants is the height of the definitive intermediate abutment connecting the crown to the implant. The height of the abutment, relative to where the crown connects with the marginal bone, determines the available space for soft-tissue adaptation, potentially affecting bacteria-promoted inflammation (Galindo-Moreno et al. 2014).

Modern implantology involves the routine application of fully digital workflows, including 3D restorative and surgical pre-operative planning to final implant-supported restorations using computer-aided design and manufacturing (CAD/CAM) technology. Many publications highlight the importance of 3D pre-surgical planning in dental implantology to minimize errors and enhance patient comfort (Arisan et al. 2013; Pozzi et al. 2014). Furthermore, several randomized clinical trials have confirmed that static, fully guided surgery for dental implants offers the highest accuracy in the transfer of implant positioning from pre-surgical planning to the clinical setting (Farley et al. 2013; Vercruyssen et al. 2015; Younes et al. 2018; Gargallo-Albiol et al. 2020). Esquivel et al. (2021) and Hamilton et al. (2023) showed the impact of implant positioning on the emergence of prosthodontic profile design, affecting peri-implant bone and soft tissues and potentially contributing to peri-implant disease.

The primary objective of this prospective clinical study was to determine the influence of intermediate prosthetic abutments on peri-implant MBL around bone-level implants in implant-supported fixed restorations in the posterior mandible and maxilla. The secondary objective of this study was to evaluate the influence of different abutment heights (1 mm vs. 2.5 mm) on MBL.

2 | Materials and Methods

The study protocol was approved by the Research Medical Ethical Committee of the *Universitat Internacional de Catalunya* (Barcelona, Spain; registration number CIR-ECL-2016-03) and was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (ID NCT06017115).

2.1 | Patient Selection

Patients enrolled for this randomized controlled clinical trial were recruited from the Dental University Clinic of the *Universitat Internacional de Catalunya* between June 2017 and November 2020; all participants presented with partial edentulism and required placement of two implants in the posterior maxillary or mandibular area (molars and/or premolars). Written informed consent was obtained before study participation. Screening procedures included clinical and radiographic examinations. The following inclusion criteria were applied: (1) good general health (American Society of Anesthesiologists Physical Status I and II) (Daabiss 2011); (2) age ≥ 18 years; (3) patients requiring two implants in the molar and/or premolar area (maxilla or mandible); (4) adequate oral hygiene, defined as a full-mouth plaque score $< 15\%$; (5) ability to follow instructions and availability to attend regular appointments during the study period; (6) sufficient bone volume to place implants at least 3.3 mm in diameter with a minimum length of 8 mm with no requirement for bone augmentation; (7) completely healed ridge (all extraction sites older than 2 months). Patients meeting any of the following criteria were excluded: (1) acute local infection; (2) untreated periodontal disease; (3) patients who smoked more than 10 cigarettes per day; (4) substance use disorder (drug and/or alcohol); (5) medical conditions contraindicating implant surgery; (6) history of head and/or neck radiation; and (7) bisphosphonate therapy.

Each patient received two implants, placed in mesial and distal positions, and was randomly allocated to one of the two study groups (Control and Test) using Random Allocation Software (Informer Technologies Inc., Los Angeles, CA, USA; Saghaei 2004). Patients in the Test group required additional randomization to determine subgroup allocation according to the height of the intermediate abutment, considering the vertical height of the mucosa over the implant. Abutment height was randomly assigned as either 1 or 2.5 mm when sufficient mucosa was present over the coronal area of the placed implant. If the vertical distance between the most coronal part of the implant and the surface of the crestal mucosa was less than 3 mm, an intermediate abutment of 1 mm was selected. All implants were placed by residents of the International Master in Oral Surgery and Master in Periodontics of the *Universitat Internacional de Catalunya*.

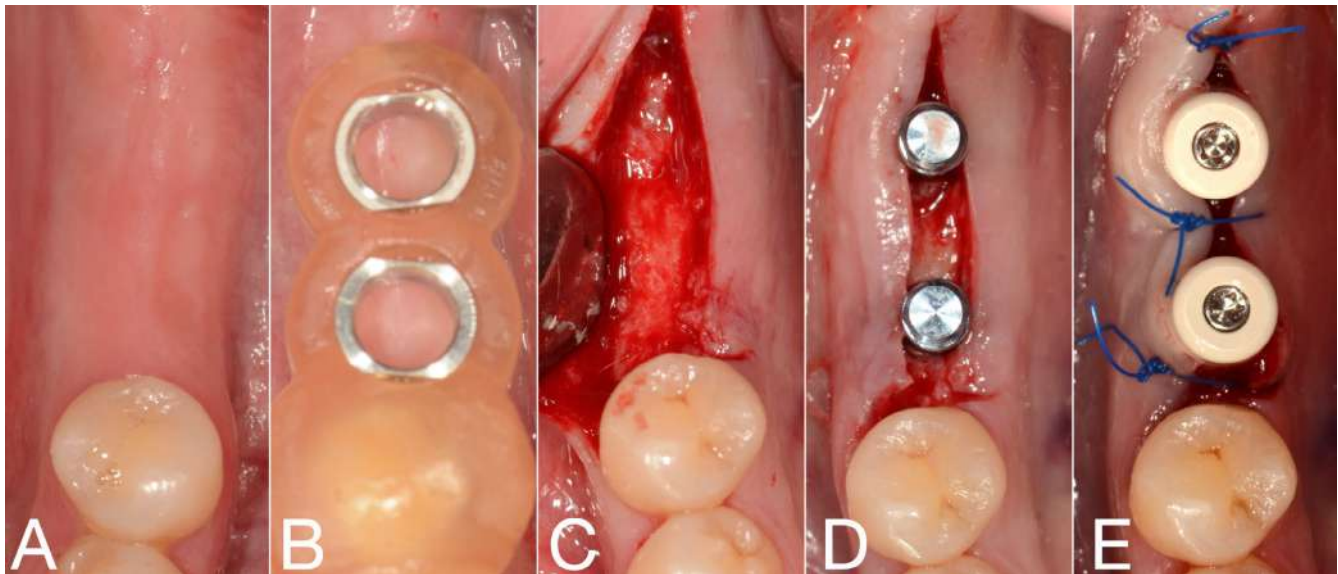


FIGURE 1 | Surgical steps of test group: Initial picture (A), Check surgical guide fitting (B), Full thickness flap (C), Guided drilling and positioning of the implants (D), intermediate of 2.5 mm height with their respective healing abutments (E).

2.2 | Preoperative Procedure

Preoperative cone-beam computed tomography (CBCT) was performed for each patient (Planmeca ProMax 3D Classic; Planmeca Oy, Helsinki, Finland). In addition, intraoral digital impressions were obtained (TRIOS MOVE; 3Shape A/S, Copenhagen, Denmark) to create a digital wax-up and facilitate presurgical planning for implant positioning. Digital Imaging and Communications in Medicine (DICOM) files obtained from CBCT were imported into guided-surgery planning software (coDiagnostix; Dental Wings Inc., Montreal, QC, Canada). Preoperative planning was performed by two operators (D.P. & M.Z.). Implants were planned to be as parallel as possible to maintain parallelism $<10^\circ$, planning to emerge on the center of the crown, to guarantee rehabilitation with straight screwed abutments. Measurements were performed to ensure appropriate distance from the gingival margin (3–4 mm), locating the final implant vertical position about 1 mm subcrestally, a minimum distance of 3 mm between implants, and 1.5 mm from adjacent teeth.

A fully guided surgical guide plan was exported as an STL file and sent to a dental laboratory (Odontecnic S.L., Barcelona, Spain) for printing directly from the planning software. After post-processing and printing of the surgical guides, metallic sleeves with an internal diameter of 5 mm (Institut Straumann AG, Basel, Switzerland) were inserted and sterilized at 121°C for 15 min (Autoclave Line B; W&H Dentalwerk Bürmoos GmbH, Bürmoos, Austria).

2.3 | Surgical Procedure

Prior to surgery, the accurate fitting of the surgical guide was confirmed. All procedures were performed under local anesthesia (Ultracain 4% with epinephrine 1:100,000; Laboratorios Normon, Madrid, Spain). A full-thickness envelope flap was elevated, and the drilling sequence was executed using the

Straumann Guided Surgery Kit for tapered implants (Institut Straumann AG) following a fully guided approach. The drilling sequence provided by the digital planning software was used as a reference (coDiagnostix). Each patient received two Straumann Bone Level Tapered implants (Institut Straumann AG). Implant diameters of 3.3, 4.1, or 4.8 mm, and implant lengths of 8, 10, or 12 mm were used. Insertion torque was measured using an iChiropro (Bien-Air Dental SA, Biel/Bienne, Switzerland). Subsequently, screw-retained abutments (Test group) or cover screws (Control group) were then placed (Figure 1). The flap was closed using 5–0 monofilament sutures. Post-operative antibiotic, analgesic, and anti-inflammatory medication was prescribed according to university recommendations and ethical committee regulations (Amoxicillin 500 mg every 8 h for 7 days or clindamycin 300 mg every 8 h in cases of penicillin allergy; ibuprofen 400 mg every 8 h for 3 days). Sutures were removed after 7–10 days, and the postoperative course was clinically evaluated.

2.4 | Prosthetic Phase

In the Control group, second-stage surgery was performed, and healing caps were placed. Intraoral digital impressions (TRIOS MOVE) were obtained 2 weeks after the second-stage surgery to initiate the prosthetic rehabilitation phase. In the Test group, intraoral digital impressions (TRIOS MOVE) were taken 2 months after implant placement, directly over the definitive abutments placed on the day of surgery. Final crowns were delivered without changing the intermediate abutment, thereby avoiding additional surgery or disconnections at the implant platform.

Digital impressions were taken using Straumann scan bodies placed either directly on the implant platform (Control group) or on multiunit abutments (Test group). STL files were sent to an external laboratory (Odontecnic, Barcelona, Spain) and processed using DentalCAD Software (Exocad, GmbH, Darmstadt, Germany) to design the metal framework. The designs were

transmitted to a milling center (Institut Straumann AG). After milling, the frameworks were tested on the patient. Temporary CAD/CAM PMMA restorations were provided in all cases to maintain posterior occlusion support throughout the prosthetic phase.

The milling center (Institut Straumann AG) fabricated the metal frameworks based on the definitive digital impressions. Passive fit was ensured using periapical X-rays, and adequate space for the ceramics was evaluated. If the framework met these criteria, it was returned to the laboratory technician, who performed the ceramic buildup. A biscuit try-in visit was performed for all patients to evaluate occlusion, contact points, and color. Upon approval, the final restoration was ordered. When definitive restorations were delivered, the prosthetic screws were tightened to a final torque of 15 Ncm for intermediate abutments and 35 Ncm for direct implant connections (Figure 2).

2.5 | Follow-Up

MBL was measured by one examiner (M.Z.) using periapical X-ray images (Planmeca Size 2) at six time points: the day of the surgery (T1); definitive crown placement (T2); and at 4

(T3), 6 (T4), 12 (T5), and 24 (T6) months after implant placement (Figure 3). Measurements were performed from the implant platform to the first detectable bone-to-implant contact using ImageJ software (Schneider et al. 2012), by one calibrated examiner. Standardization of measurements in the software was made with the known length of the implant (in mm). Posteriorly, measurements were performed from the first detectable bone-to-implant contact to the most coronal bone peak, drawing a line parallel to the implant position. Measurements from the six time points (T1–T6) were registered with periapical X-ray images, with two measurements for each implant, on the mesial and distal aspects. If the distance from the bone peak to the implant platform was coronally placed, the value was positive; if the bone peak was located apical to the implant platform, the value was negative.

2.6 | Statistical Analysis

Power calculation was conducted at the implant level. First, we estimated that 60 implants were necessary to reach a power of 85% to detect a large effect size ($d=0.8$) in assessing the difference in mean MBL between groups using the Student's *t*-test and 95% confidence intervals. Considering the dependence of

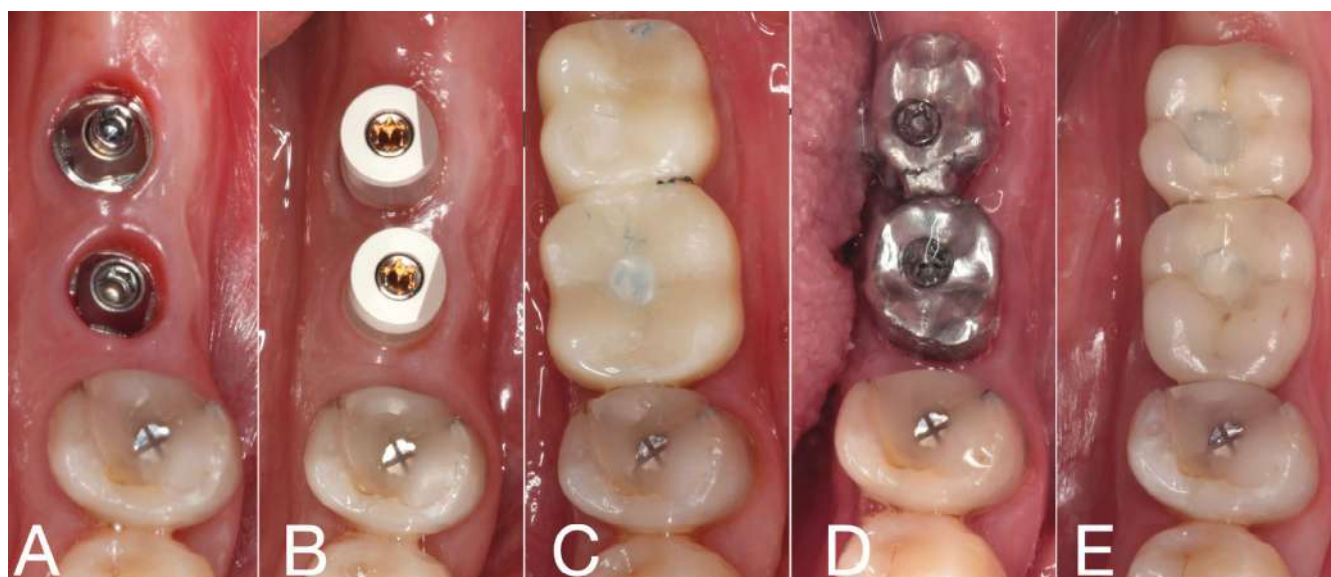


FIGURE 2 | Prosthesis steps of the test group: Profile impression (A), Scan bodies impression (B), Provisional (C), Metal framework (D), and definitive splinted crowns placement (E).



FIGURE 3 | Periapical x-rays in the test group at T1 (day of the surgery), T2 (definitive crown placement), T3 (4 months after implant placement), and T4 (6 months after implant placement).

the observations (two implants per patient) and an intraclass correlation coefficient of 0.5, effective power was penalized at 70% (Pandis 2012a, 2012b). The estimated sample size was then 30 patients, with two implants per patient, divided into two study groups: the (1) Control group (restoration direct to implant connection, no intermediate abutment, 12 patients); and the (2) Test group (restoration through an intermediate abutment, 18 patients). The Test group was divided into two abutment-height subgroups: (a) 1 mm abutment height (H1); and (b) 2.5 mm abutment height (H2.5). Power regarding comparisons between subgroups was calculated at 65% after correcting for dependent observations. Moreover, the true effect size in comparing the mean MBL between the Test group subgroups was estimated at $d=0.23$ (small). Therefore, the study's final sample size is limited in its ability to detect differences of that magnitude.

Descriptive analysis was performed for all variables using absolute and relative frequencies for categorical variables and median, standard deviation, range, and quartiles for continuous variables. Inferential analysis was performed using generalized estimating equation (GEE) linear models at the implant level to assess differences in overall MBL between groups and changes in MBL throughout follow-up, including comparisons between mesial and distal sites. The same approach was used to evaluate the effect of intermediate abutment height within the group. Estimates are expressed with 95% confidence intervals based on Wald Chi-squared statistics. Conventional association tests (Chi-squared and Fisher's exact test) were performed at the patient level to assess baseline comparability between the Control and Test groups. A significance level of 5% ($\alpha=0.05$) was applied.

This manuscript was prepared and structured in accordance with the CONSORT checklist for reporting randomized clinical trials.

3 | Results

3.1 | Descriptive Analyses

A total of 30 patients (73.3% men, 22.67% women; mean age, 63.4 years) were included in this study. Each patient received two implants placed in the posterior area, yielding a total of 60 implants. Most implants were placed in the mandible (83.3%). Complete data on sex, implant placement site, and group/subgroup distributions are presented in Table S1.

Random allocation to Test and Control groups resulted in a homogenous distribution, with no dropouts over the 2-year follow-up period. The Control group comprised 12 patients (24 implants), while the Test group included 18 patients (36 implants; 7 in H1 subgroup [14 implants], 11 in H2.5 subgroup [22 implants]).

3.2 | Peri-Implant MBL

Mean MBL values were 0.83 ± 0.25 mm in the Test group and 1.17 ± 0.35 mm in the Control group over the full observation period. These values represent the mean of the two implants placed in each patient. The greatest changes in MBL were seen

between T1 and T2. Thereafter, changes in MBL were minimal, regardless of group (Tables 1 and 2). Generalized estimating equation analysis showed that the MBL increased progressively and significantly throughout the whole observation period in both groups ($p<0.001$). The Test group showed significantly lower mean MBL than the Control group at each observation time point and all implant sites ($p=0.001$).

3.3 | Abutment Height and MBL

The mean MBL over the 2-year follow-up was 0.87 ± 0.22 mm for the H1 subgroup and 0.81 ± 0.29 mm for the H2.5 subgroup (Figure 4), with no statistically significant difference between groups (Table 3). Although no statistically significant differences were observed among the different abutment heights (1 vs. 2.5 mm), a trend toward lower MBL was noted with the larger abutment height.

Mesial implants showed mean MBL values of 0.96 ± 0.22 mm in the H1 subgroup and 0.97 ± 0.44 mm in the H2.5 subgroup. For distal implants, mean MBL values were 0.78 ± 0.29 mm and 0.66 ± 0.27 mm in the H1 subgroup and H2.5 subgroups, respectively. No significant differences were observed between subgroups within each implant location, but the MBL was significantly higher in mesial implants than in distal implants in both subgroups. Further, MBL increased progressively and significantly throughout the follow-up period (Figure 5). This increase was similar for the different abutment heights and implant positions.

3.4 | Implant Position and MBL Between Control and Test Groups

The mean MBL for mesial implants was 1.28 ± 0.47 mm in the Control group and 0.96 ± 0.36 mm in the Test group. For distal implants, mean MBL values were 1.06 ± 0.53 mm in the Control group and 0.71 ± 0.27 mm in the Test group (Figure 6). Table 4 shows changes in MBL over time for the mesial and distal implants in each group.

Generalized estimating equations confirmed that the mean MBL of mesial implants was significantly higher than that of distal implants ($p=0.008$) throughout the observation period in both groups.

4 | Discussion

This randomized clinical trial showed statistically significant differences in MBL between the Control (direct implant connection) group and the Test (intermediate abutment) group in implant-supported fixed restorations in the posterior mandible and maxilla. Intermediate abutments placed showed significantly lower MBL than direct implant connection prostheses without an intermediate abutment at all time points in the 2-year follow-up period. Thus, it can be concluded that direct implant connections induced greater MBL in splinted implant-fixed prostheses than bone-level implants. Additionally, although no statistically significant differences were observed among the

TABLE 1 | Change in MBL over each measurement interval according to study group (in mm).

	Group		
	Total	Control	Test
MBLT1-T2			
N	30	12	18
Mean	0.70	0.86	0.59
Standard deviation	0.28	0.25	0.25
Minimum	0.20	0.43	0.20
Maximum	1.23	1.23	1.18
Percentile 25	0.45	0.64	0.40
Median	0.65	0.93	0.54
Percentile 75	0.95	1.05	0.68
MBLT2-T3			
N	30	12	18
Mean	0.19	0.23	0.17
Standard deviation	0.12	0.16	0.08
Minimum	0.10	0.10	0.10
Maximum	0.68	0.68	0.45
Percentile 25	0.13	0.13	0.13
Median	0.15	0.20	0.14
Percentile 75	0.23	0.28	0.18
MBLT3-T4			
N	30	12	18
Mean	0.04	0.04	0.05
Standard deviation	0.07	0.10	0.03
Minimum	−0.18	−0.18	−0.03
Maximum	0.28	0.28	0.10
Percentile 25	0.03	0.03	0.03
Median	0.05	0.05	0.05
Percentile 75	0.08	0.06	0.08
MBLT4-T5			
N	30	12	18
Mean	0.04	0.04	0.04
Standard deviation	0.04	0.05	0.03
Minimum	0.00	0.00	0.00
Maximum	0.15	0.15	0.13
Percentile 25	0.03	0.00	0.03
Median	0.03	0.03	0.03
Percentile 75	0.05	0.05	0.05

(Continues)

TABLE 1 | (Continued)

	Group		
	Total	Control	Test
MBLT1-T5			
N	30	12	18
Mean	0.97	1.17	0.83
Standard deviation	0.34	0.36	0.26
Minimum	0.38	0.63	0.38
Maximum	1.68	1.68	1.35
Percentile 25	0.73	0.81	0.60
Median	0.88	1.24	0.80
Percentile 75	1.28	1.45	1.00

Abbreviations: MBL, marginal bone loss; T1, post-surgery; T2, after definitive crown placement; T3, 6-month follow-up; T4, 12-month follow-up; T5, 24-month follow-up; T1–T2, interval from T1 to T2; T2–T3, interval from T2 to T3; T3–T4, interval from T3 to T4; T4–T5, interval from T4 to T5; T1–T5, interval from T1 to T5.

different abutment heights (1 vs. 2.5 mm), a trend toward lower MBL was noted with the larger abutment height.

Our results are consistent with those of previous studies. Hamudi et al. (2021) compared implants placed with healing abutments at the time of surgery versus intermediate definitive abutments, finding statistically significant differences in MBL at a 3-year follow-up, with lower MBL in the definitive abutment group than the Control group with healing abutments. Similarly, studies published by Göthberg et al. (2014, 2018) showed significantly higher MBL in implants without intermediate abutments compared with those with abutments at 1- and 5-year follow-up. Although their reported MBL values were slightly higher than those observed in the present study, this difference may be explained by their use of an immediate loading group and external connection implants. In line with the evidence that the greatest MBL changes occur in the first few months after implantation, randomized controlled trials performed by Toia et al. (2019, 2022, 2024) showed a significantly lower MBL in an abutment-level group compared with an implant-level group at 1 year of follow-up (Toia et al. 2019). However, no significant differences in MBL values were observed between abutment- and implant-level screw-retained restorations at 3 years (Toia et al. 2022) and 5 years (Toia et al. 2024). In the present study, MBL increased the most in the interval from the day of implant placement surgery until the definitive prosthesis delivery. This observation aligns with the findings of Göthberg et al. (2014), who showed a significantly greater increase in MBL between the day of surgery and the final restoration placement than between other time points. In addition, the present results are in line with a clinical trial published by Blanco et al. (2018), which suggested that bone resorption of more than 0.45 mm from 6-months post-loading onward may be considered progressive MBL. In the present clinical trial, changes in MBL after 6 months post-loading were smaller than those observed earlier, showing predictable and stable evolution for this type of treatment. In contrast, Maceiras et al. (2023, 2024) showed

that bone-level implants with internal connection restored by CAD/CAM prosthesis with or without an intermediate abutment had similar MBL changes at 1 and 3 years of follow-up. These randomized studies prioritized the connection type and the quality of the prosthetic fitting to maintain soft and hard tissue stability around dental implants, minimizing the effects of intermediate abutments.

None of the aforementioned studies included fully guided surgery, which can improve implant positioning and facilitate better prosthetic profiles, minimizing the risk of marginal bone damage (Esquivel et al. 2021; Hamilton et al. 2023). Only

TABLE 2 | Changes in total MBL in each measurement interval using the simple linear model generalized estimating equations, unadjusted beta coefficient, and 95% CI with Bonferroni correction.

	Beta (group test)	95% CI	p
T1-T2	-0.27	-0.44 to -0.10	0.010*
T2-T3	-0.07	-0.16 to 0.02	0.608
T3-T4	0.00	-0.05 to 0.06	1
T4-T5	-0.01	-0.03 to 0.03	1
T1-T5	-0.34	-0.55 to -0.12	0.015*

Abbreviations: CI, confidence interval; MBL, marginal bone loss; T1, post-surgery; T2, after definitive crown placement; T3, 6-month follow-up; T4, 12-month follow-up; T5, 24-month follow-up; T1-T2, interval from T1 to T2; T2-T3, interval from T2 to T3; T3-T4, interval from T3 to T4; T4-T5, interval from T4 to T5; T1-T5, interval from T1 to T5.

* $p < 0.05$.

the studies of Maceiras et al. (2023, 2024) described a CAD/CAM final prosthesis but did not include a guided implant placement approach. To address this gap, the present study implemented a fully digital workflow, using guided implant placement with or without intermediate abutments on the day of the surgery and submerged or non-submerged approaches and using scanning impressions for CAD/CAM temporary and final restorations.

Therefore, in the present study, the Test group received definitive abutments placed on the day of surgery, following the “one abutment, one time” concept. Placement of a definitive intermediate abutment during initial surgery may promote the establishment of supracrestal tissue attachment, thereby contributing to the stability of hard and soft tissues (Moreira et al. 2021). This approach allows the prosthetic phase to be performed at the abutment level rather than at the implant platform level. However, a minimum insertion torque is intraoperatively required when executing this approach to ensure excellent abutment fit (Moreira et al. 2021). Depending on the implant brand and abutment torque recommendations, complete knowledge of the required torque of the definitive abutment is mandatory for safe insertion at the initial implant placement surgery.

Regarding the secondary objective of this clinical trial of comparing MBL between the use of two different abutment heights (1 and 2.5 mm), we found no difference in mean MBL. Accordingly, the secondary null hypothesis could not be rejected, and we cannot say that there are differences in MBL between the two abutment heights, especially considering the underpowered subgroup analysis. Nevertheless, more

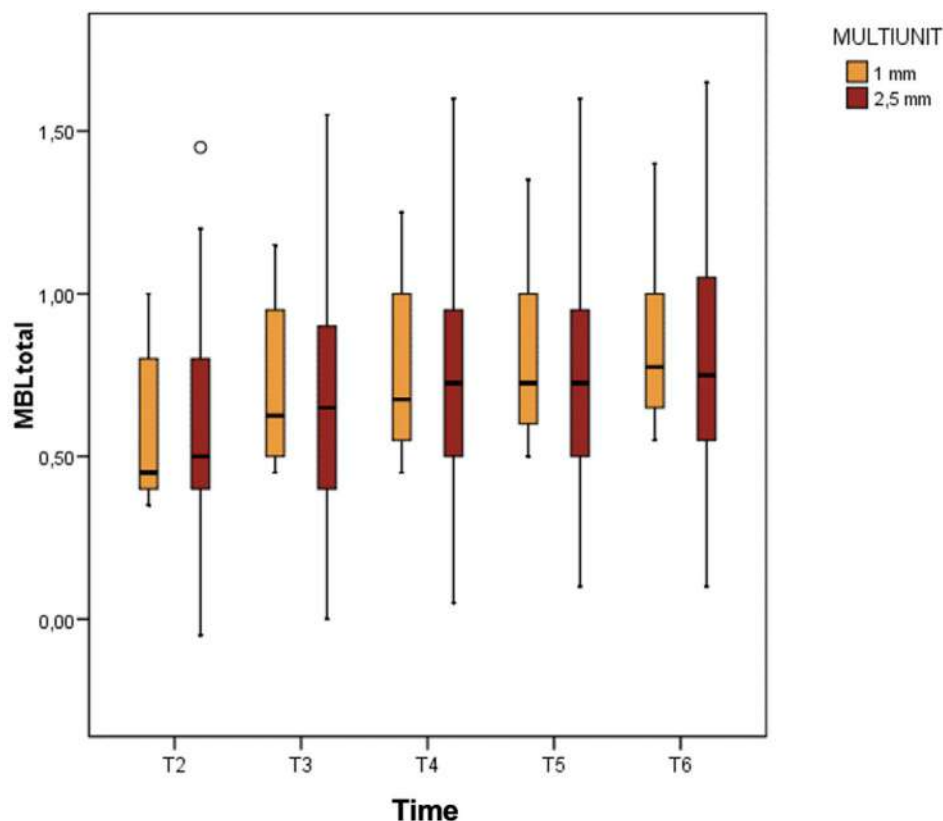


FIGURE 4 | Bar graphic showing MBL of mesial and distal implant.

TABLE 3 | MBL at each measurement time point (in mm; mean of mesial and distal implants), according to the intermediate abutment height subgroup.

	Intermediate abutment		
	Total	1 mm	2.5 mm
MBLT1-T2			
N	18	7	11
Mean	0.59	0.57	0.60
Standard deviation	0.25	0.20	0.28
Minimum	0.20	0.38	0.20
Maximum	1.18	0.95	1.18
Percentile 25	0.40	0.40	0.38
Median	0.54	0.53	0.55
Percentile 75	0.68	0.68	0.85
MBLT2-T3			
N	18	7	11
Mean	0.17	0.20	0.14
Standard deviation	0.08	0.12	0.03
Minimum	0.10	0.13	0.10
Maximum	0.45	0.45	0.20
Percentile 25	0.13	0.13	0.13
Median	0.14	0.15	0.13
Percentile 75	0.18	0.25	0.18
MBLT3-T4			
N	18	7	11
Mean	0.05	0.06	0.04
Standard deviation	0.03	0.03	0.03
Minimum	−0.03	0.03	−0.03
Maximum	0.10	0.10	0.10
Percentile 25	0.03	0.03	0.03
Median	0.05	0.05	0.05
Percentile 75	0.08	0.08	0.05
MBLT4-T5			
N	18	7	11
Mean	0.04	0.04	0.04
Standard deviation	0.03	0.05	0.03
Minimum	0.00	0.00	0.03
Maximum	0.13	0.13	0.10
Percentile 25	0.03	0.00	0.03
Median	0.03	0.03	0.03
Percentile 75	0.05	0.05	0.05

(Continues)

TABLE 3 | (Continued)

	Intermediate abutment		
	Total	1 mm	2.5 mm
MBLT1-T5			
N	18	7	11
Mean	0.83	0.87	0.81
Standard deviation	0.26	0.22	0.29
Minimum	0.38	0.58	0.38
Maximum	1.35	1.28	1.35
Percentile 25	0.60	0.78	0.58
Median	0.80	0.83	0.78
Percentile 75	1.00	0.98	1.08

Abbreviations: MBL, marginal bone loss; T1, post-surgery; T2, after definitive crown placement; T3, 6-month follow-up; T4, 12-month follow-up; T5, 24-month follow-up; T1-T2, interval from T1 to T2; T2-T3, interval from T2 to T3; T3-T4, interval from T3 to T4; T4-T5, interval from T4 to T5; T1-T5, interval from T1 to T5.

bone resorption was observed with the shorter abutment, although the differences were small and not statistically significant. These results are partially consistent with a study from Nóvoa et al. (2017) showing that shorter abutment height (1 vs. 2.5 mm) led to higher MBL at a 36-month follow-up, and with a study from Galindo-Moreno et al. (2016) showing similar bone loss values for an intermediate abutment group and higher values for abutments <2 mm in height. These findings may be explained by the fact that a significant amount of crestal bone loss can occur around two-piece implant designs, depending on the location of the interface (Hermann et al. 2000). Furthermore, higher intermediate abutments may be advantageous because they provide “space” for soft tissue and connective tissue insertion. Blanco et al. (2018) posited that there must be a minimum distance from the abutment to the implant platform to ensure the establishment of new supracrestal tissue attachment. This may explain why higher abutments have been associated with better bone-level maintenance and treatment stability (Galindo-Moreno et al. 2014). Previous studies have shown that an abutment height of 2 mm or more can be beneficial for preventing MBL over time (Blanco et al. 2018); however, Galindo-Moreno et al. (2016) reported that a height of 4 mm or more did not result in additional clinically significant differences in MBL.

Ultimately, the effect of implant position on MBL must be interpreted with caution, as this analysis was conducted post hoc, despite statistically significant differences observed between mesial and distal implants. MBL was significantly higher in mesial implants than in distal implants across both study groups (with and without intermediate abutments) and for the H1 and H2.5 subgroups at all follow-up time points. There was a vertical bone discrepancy between the distal bone-level of the neighboring tooth and the apico-coronal position of the implant in most cases. Therefore, marked MBL was observed in this area after the healing period. This could explain the observations herein, as higher bone resorption can be expected in the mesial area, near an

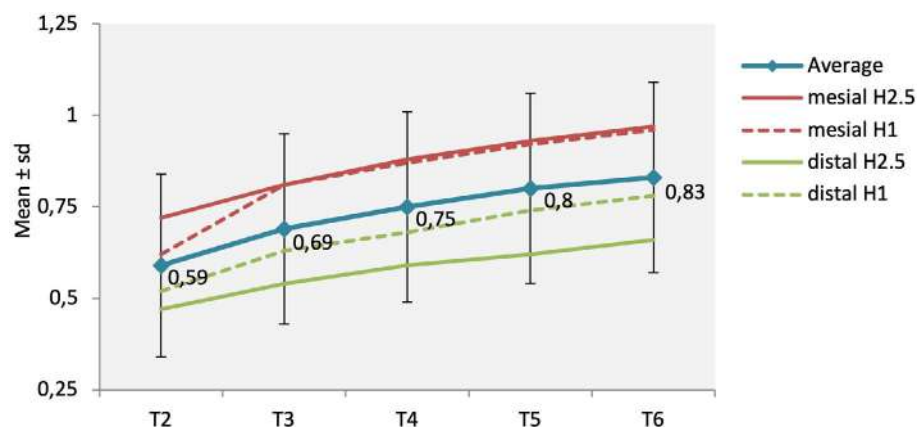


FIGURE 5 | MBL by abutment height and position.

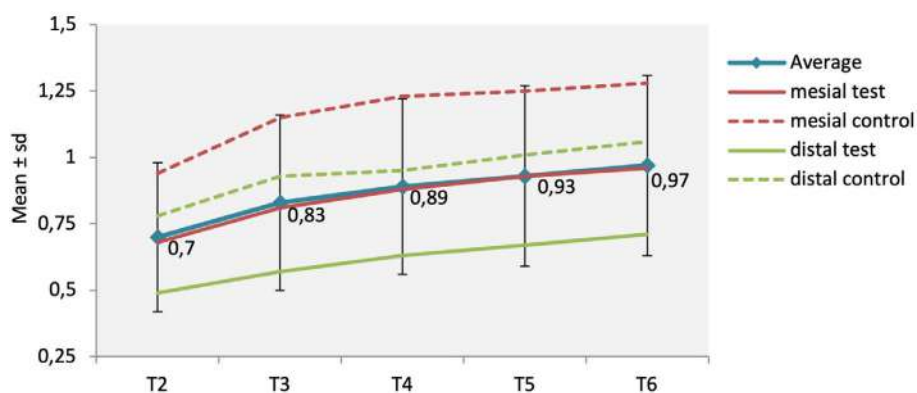


FIGURE 6 | Linear graphic showing MBL changes in time.

adjacent natural tooth, than on the distal aspect, without an adjacent distal tooth. Clinicians should consider this when placing implants, particularly in posterior areas in partially edentulous patients. Factors such as the vertical position of the implant in relation to the cemento-enamel junction of the adjacent tooth can affect peri-implant MBL, and implants placed deeper than 3 mm from the cemento-enamel junction of the adjacent tooth showed more MBL than those placed at less than 3 mm away (Mailloa et al. 2015). This variable was not evaluated in the present study and may have contributed to the observed differences.

The effects of platform switching should also be considered in relation to the maintenance of marginal bone around dental implants. The use of abutments with a narrower diameter than the implant platform may promote the deposition of connective tissue fibers coronal to the implant platform (Bilhan et al. 2021). The establishment of these fibers in healthy implants may help protect against bacterial infiltration and ensure correct supracrestal tissue attachment (Rodríguez et al. 2016).

Other factors that were not evaluated in the present study may also have influenced MBL outcomes, including soft tissue width and the amount of keratinized tissue. Several studies have an association between abutment and soft tissue width. Vervaeke et al. (2014) demonstrated that early bone remodeling is influenced by soft tissue thickness at the time of implant placement. In the present study, patients with thinner soft tissue were assigned shorter abutments and may therefore have experienced

greater MBL. Moreover, according to a systematic review by Chen et al. (2019), the height of the abutment induces more MBL irrespective of the soft tissue width.

In this study, postoperative medication was provided according to university recommendations (Salomó-Coll et al. 2018), as the optimal protocol for prescribing pre- or postoperative antibiotic therapy remains unclear (Lund et al. 2015; Radovic and Ouanounou 2025). Prophylactic antibiotics may not be justified, particularly in simple cases (Klinge et al. 2015). Consistent with the present study and findings by Salgado-Peralvo et al. (2024), amoxicillin is the most commonly prescribed postoperative antibiotic in Europe for dental implant placement, with clindamycin used as an alternative in patients with amoxicillin allergy. However, a double-blind randomized clinical trial by Durand et al. (2021) found that postoperative antibiotics after implant placement in healthy patients do not prevent postoperative complications or peri-implant bone loss. Overall, these findings highlight ongoing uncertainty and underscore the need for clearer clinical guidelines regarding antibiotic use in dental implant placement (Salgado-Peralvo et al. 2024; Peter et al. 2024).

This randomized prospective clinical study has several limitations. First, MBL was assessed using two-dimensional measurements (apical and mesial) to minimize ionizing radiation exposure; buccal and lingual measurements were not taken. Second, although all measurements were performed by a single examiner, surgical procedures were carried out by multiple

TABLE 4 | Marginal bone loss (in mm) in each measurement interval, according to implant location (mesial or distal) and study group.

	Mesial			Distal		
	Total	Control	Test	Total	Control	Test
MBLT1-T2						
<i>N</i>	30	12	18	30	12	18
Mean	0.79	0.94	0.68	0.61	0.78	0.49
Standard deviation	0.36	0.34	0.34	0.33	0.39	0.24
Minimum	0.20	0.45	0.20	−0.05	0.30	−0.05
Maximum	1.50	1.50	1.45	1.45	1.45	1.00
Percentile 25	0.45	0.70	0.40	0.40	0.43	0.40
Median	0.80	0.88	0.65	0.50	0.75	0.48
Percentile 75	1.10	1.15	0.85	0.90	1.00	0.65
MBLT2-T3						
<i>N</i>	30	12	18	30	12	18
Mean	0.23	0.29	0.19	0.15	0.17	0.14
Standard deviation	0.20	0.24	0.15	0.11	0.14	0.08
Minimum	0.05	0.05	0.05	0.00	0.00	0.00
Maximum	0.90	0.90	0.75	0.45	0.45	0.30
Percentile 25	0.15	0.15	0.15	0.10	0.08	0.10
Median	0.20	0.23	0.15	0.15	0.15	0.13
Percentile 75	0.25	0.30	0.20	0.20	0.28	0.15
MBLT3-T4						
<i>N</i>	30	12	18	30	12	18
Mean	0.04	0.03	0.05	0.05	0.06	0.04
Standard deviation	0.10	0.14	0.06	0.10	0.15	0.04
Minimum	−0.40	−0.40	−0.05	−0.10	−0.10	−0.05
Maximum	0.20	0.10	0.20	0.50	0.50	0.10
Percentile 25	0.00	0.05	0.00	0.00	0.00	0.00
Median	0.05	0.05	0.05	0.05	0.00	0.05
Percentile 75	0.10	0.10	0.05	0.05	0.08	0.05
MBLT4-T5						
<i>N</i>	30	12	18	30	12	18
Mean	0.04	0.03	0.04	0.04	0.05	0.04
Standard deviation	0.05	0.05	0.05	0.04	0.05	0.04
Minimum	−0.05	0.00	−0.05	0.00	0.00	0.00
Maximum	0.15	0.15	0.15	0.15	0.15	0.10
Percentile 25	0.00	0.00	0.00	0.00	0.00	0.00
Median	0.00	0.00	0.05	0.05	0.05	0.05
Percentile 75	0.05	0.05	0.05	0.05	0.10	0.05

(Continues)

TABLE 4 | (Continued)

	Mesial			Distal		
	Total	Control	Test	Total	Control	Test
MBLT1-T5						
N	30	12	18	30	12	18
Mean	1.09	1.28	0.96	0.85	1.06	0.71
Standard deviation	0.43	0.47	0.36	0.42	0.53	0.27
Minimum	0.35	0.65	0.35	0.10	0.40	0.10
Maximum	2.10	2.10	1.65	2.35	2.35	1.40
Percentile 25	0.75	0.98	0.70	0.55	0.68	0.55
Median	1.00	1.15	0.98	0.78	1.08	0.70
Percentile 75	1.50	1.68	1.15	1.05	1.18	0.85

Abbreviations: MBL, marginal bone loss; T1, post-surgery; T2, after definitive crown placement; T3, 6-month follow-up; T4, 12-month follow-up; T5, 24-month follow-up; T1-T2, interval from T1 to T2; T2-T3, interval from T2 to T3; T3-T4, interval from T3 to T4; T4-T5, interval from T4 to T5; T1-T5, interval from T1 to T5.

operators. However, good standardization was achieved by using a fully static guided implant placement surgery for all cases, preceded by complete 3D surgical and prosthodontic planning. Additionally, to further reduce variability, all restorations followed the same workflow, including intra-oral scanning, temporary screw-retained restorations, try-in, and final definitive metal-ceramic screw-retained restoration placement. Third, the relatively small sample size limited the subgroup analysis; therefore, comparisons of mesial and distal implants should be interpreted with caution as exploratory/post hoc findings. Finally, there was a lack of evaluation of clinical parameters and patient-reported outcomes in the present study. Important clinical parameters such as bleeding on probing, probing depth, soft tissue width, and the amount of keratinized tissue were not systematically evaluated. These limitations were related to the study setting and should be addressed in further studies.

5 | Conclusions

This randomized clinical trial demonstrated that the use of intermediate prosthetic abutments placed at bone-level implants on the day of implant placement surgery in splinted crowns for an implant-supported fixed restoration reduced peri-implant MBL compared with direct implant connection prostheses. Although no statistically significant differences were observed between 1- and 2.5-mm abutment heights, a trend towards lower MBL was noted with 2.5-mm abutments. Further studies are warranted to clarify the relationships between these variables and other clinical factors influencing MBL.

Author Contributions

Jordi Gargallo-Albiol: conceptualization, funding acquisition, writing – original draft, methodology, validation, writing – review and editing, project administration, supervision, visualization. **María José Zilleruelo-Pozo:** investigation, writing – original draft, formal analysis, data curation, methodology, software, visualization. **Anna Treserra-Parra:** investigation, data curation, visualization, software.

Ernest Lucas-Taulé: conceptualization, data curation, methodology, visualization, supervision, investigation. **Daniel Paternostro-Betancourt:** investigation, visualization, data curation, software. **Federico Hernandez-Alfaro:** funding acquisition, visualization, validation, project administration, supervision.

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Ethics Statement

The study protocol was approved by the Research Medical Ethical Committee (registration number CIR-ECL-2016-03) of the *Universitat Internacional de Catalunya*, Barcelona (Spain).

Consent

All patients provided written informed consent before participating in the study.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** Summary of marginal bone loss (MBL) data separated by sex (0 = male, 1 = female) and group (0 = Control group [direct implant connection], 1 = Test group [intermediate abutment]). In the intermediate abutment group, two abutment heights were used (0 = 1 mm, 1 = 2.5 mm). The maxilla and mandible are identified as 0 and 1, respectively. **Data S1:** CONSORT 2010 checklist of information to include when reporting a randomised trial.