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Subcrestal versus Bone-Level One-Stage Implants: Early Bone and Soft Tissues Modification: One-Year Randomized Clinical Trial

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Abstract: Reducing marginal bone resorption is a challenge in implant dentistry. Sub-gingival implant placement has been suggested as a suitable strategy to avoid long-term esthetic and biological complications. A total of 38 healthy patients received bone-level (BLG-Control) or 2 mm sub-crestal (SCG-Test) conical connection, platform-switched implants. The test group received an immediate tissue-level abutment, following the one-time abutment (OTA) concept. Marginal bone modification (MBM) was calculated on standardized radiographs at surgery (T0), loading (T1), and 6 (T2) and 12 (T3) months after loading and classified as bone loss (BL) if it occurred below the implant neck and bone remodeling (BR) if above. Pocket-probing depth (PPD), Bleeding on probing (BoP), and Plaque Index (PI) were collected. At 12 months, the mean MBM was 0.61 mm in the test group and 0.52 mm in the control group. In all the cases of the test group (SCG), MBM occurred only above the implant neck, therefore being classified as BR, and no BL was observed. In the control group (BLG), MBM occurred below the implant neck, thus corresponding entirely to BL. The test group had an average PPD of 2.38 mm compared to 3.04 mm in the control group, with BoP at 50% and 43%, and PI at 33% and 19.44%, respectively. At one year after loading, sub-crestal conical connection, platform-switched implants show comparable MBM to bone level implants; however, no bone loss was observed.

Keywords: sub-crestal implants; bone loss; one-time abutment; conical connection; mucosal tunnel depth

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1. Introduction

Dental implants are a widespread and reliable treatment for the replacement single and multiple missing teeth. Whilst short-term clinical success is commonly achieved, the real challenge is to maintain peri-implant hard and soft tissue stability in the long-term, which is crucial for functional and esthetic outcomes, as well as for the prevention of biological complications and, ultimately, implant success [1–7].

Early implant bone loss, defined as the loss of marginal bone occurring during the first year of the implant prosthetic function, is a multifactorial process which has traditionally been linked to factors such as the surgical procedure, the establishment of a supracrestal tissue attachment, the restorative protocol, and the presence of micro-gaps between the various components [8–10]. Whilst, historically, an early bone loss of up to 1.5 mm in the first year and 0.2 mm for every subsequent year has been deemed acceptable [11,12], recent evidence suggests that an early bone loss exceeding 0.5 mm represents a risk factor for

future peri-implantitis development and implant failure [7]. Therefore, several strategies and protocols have been tested with the aim of limiting implant bone loss.

Sub-crestal implant placement has been introduced with the rationale that anticipating the expected early bone loss by adjusting the apico-coronal position of the implant could prevent the exposure of the treated and threaded area of the fixture, lowering the risk of biological and esthetic complications [2,13–15]. Sub-crestal placement seems to be particularly important for patients with thin, soft tissues at the time of implant placement: a thin biotype seems to lead to more bone loss, possibly due to the space required for the establishment of a supracrestal tissue attachment of appropriate dimension [2,9,13,16].

Overall, the benefits of sub-crestal implant placement are still controversial, as recent publications found no significant difference in bone loss around sub-crestal and equi-crestal implants [2,17,18]. However, some authors have recently started arguing that not all bone loss bears the same clinical weight: bone resorption occurring below the implant neck increases the risk of thread exposure and complications, whilst bone resorption above the implant neck leaves the fixture safely covered. Therefore, Linkevicious et al. [19] and Spinato et al. [15] introduced the distinction between bone remodeling, observed above the implant collar, and bone loss, which instead exposes the implant neck and threads. It is worth mentioning that only implants placed sub-crestally present bone above the collar which could buffer the initial bone modification as bone remodeling, whilst equi-crestal implants inevitably fall into the bone loss category. With this distinction in mind, it seems that sub-crestal implant placement might not prevent bone modification, but it mostly occurs as bone remodeling, with minimal observed bone loss [19].

Sub-crestal implant placement is often used in conjunction with a one-time abutment (OTA). An OTA consists of an immediate abutment placement at time of implant placement, which will be left in situ for all the restorative procedures, avoiding the multiple disconnection and reconnection of regular abutments during traditional workflows [20–22]. The use of an OTA may reduce the risk of damaging the supra-crestal soft tissue complex and the implant-to-abutment connection wear and tear [20,23–25].

Other factors that seem to positively influence the initial bone modification relate to the implant design, specifically the choice of an internal conical connection and the platform switching. An internal conical connection between the fixture and the abutment seems to be less prone to bacterial infiltration and more stable under static and dynamic loads when compared to flat-to-flat connection systems [4,26–30]. Platform switching of the abutment diameter is thought to provide a horizontal space for soft tissue attachment during the formation of the supracrestal tissue attachment, therefore reducing bone modification [5,31,32]. Finally, the choice of a screw-retained restoration over a cemented one [33–35] and the careful positioning of the restorative margin through the correct prosthetic abutment height [36–38] are important considerations for peri-implant tissue stability. The aim of the present study was to compare the early bone changes around conical connection, platform-switched implants placed at bone level or 2 mm sub-crestally. These changes were measured as marginal bone modifications (MBMs), a term describing the apical repositioning of the peri-implant marginal bone, within which a distinction was made between bone remodeling (BR) above the implant neck and bone loss (BL) below it. A summary of the aforementioned evidence on surgical and implant design factors and their effect on hard and soft tissues is provided in Table 1.

Our hypothesis is that sub-crestal implant placement prevents or minimizes early interproximal bone loss, assessed on intra-oral radiographs. The secondary outcome was the evaluation of peri-implant tissue health through Probing Depth (PD), Bleeding on Probing (Bop), and Plaque Index (PI).

Table 1. Summary of the surgical and design implant factors, the relationship with the biotype, and their observed influence on the implant site.

Factor	Effect on Bone Levels	Influence of Soft Tissues Biotype	Reference
Subcrestal vs. Bone level implants	Average <1 mm of bone loss for both placements	In the presence of thin, soft tissues, subcrestal placement should be preferred.	Palacios-Garzón et al., 2019 [2]
	Comparable bone loss: mean mesial (m) bone loss was 1.41 (±1.65 mm) and 1.84 (±1.49 mm) for subcrestal and bone level, respectively, and mean distal (d) bone loss was 1.34 (±1.60 mm) and 1.73 (±1.31 mm).		Romanos et al., 2015 [18]
		Subcrestal implants show better bone levels in case of thin, soft tissues.	Vervaeke et al., 2018 [13]
	Implants placed 1 or 2 mm subcrestally show comparable bone remodeling (0.49 ± 0.32 mm and 0.46 ± 0.35 mm, respectively)		Stacchi et al., 2023 [14]
		Deeper subcrestal placement is advised in thin biotypes, as they exhibit higher mean marginal bone loss.	Spinato et al., 2022 [15]
Conical vs. flat connection	Less bone loss observed around conical connection implants in both human and animal models	Better soft tissue esthetics with internal hexagon.	Schmitt et al., 2014 [27] Vetromilla et al., 2019 [28] Weng et al., 2011 [29] Weng et al., 2011 [30]
Platform switching vs. platform matching	Less marginal bone loss observed for platform-switched implants, especially in case of larger mismatch		Annibali et al., 2012 [5]
One-time abutment (OTA) vs. repeated abutment removal	Implants restored with an OTA show less vertical bone change	Implants restored with an OTA show fewer soft tissues-level changes.	Wang et al., 2017 [20]
	No difference in peri-implant bone loss observed		Ríos-Santos et al., 2020 [23]

2. Materials and Methods

2.1. Patient Selection

The present study is a single-blind, parallel, randomized, controlled prospective clinical trial, the protocol of which was reviewed and approved by the local University/Hospital ethical committee (N4078) and recorded in public registry of clinical trials (www.clinicaltrials.gov, URL accessed on 27 December 2023—NCT06182670). The study was conducted according to the principles of Helsinki Declaration (as revised in Fortaleza 2013), following CONSORT (Consolidated Standards of Reporting Trials) guidelines. Patients were recruited from April 2021 to May 2023 at the Section of Periodontics, School of Dentistry, Department of Surgical Specialties, Radiological Science, and Public Health of the University of Brescia. The study flowchart is reported in Figure 1.

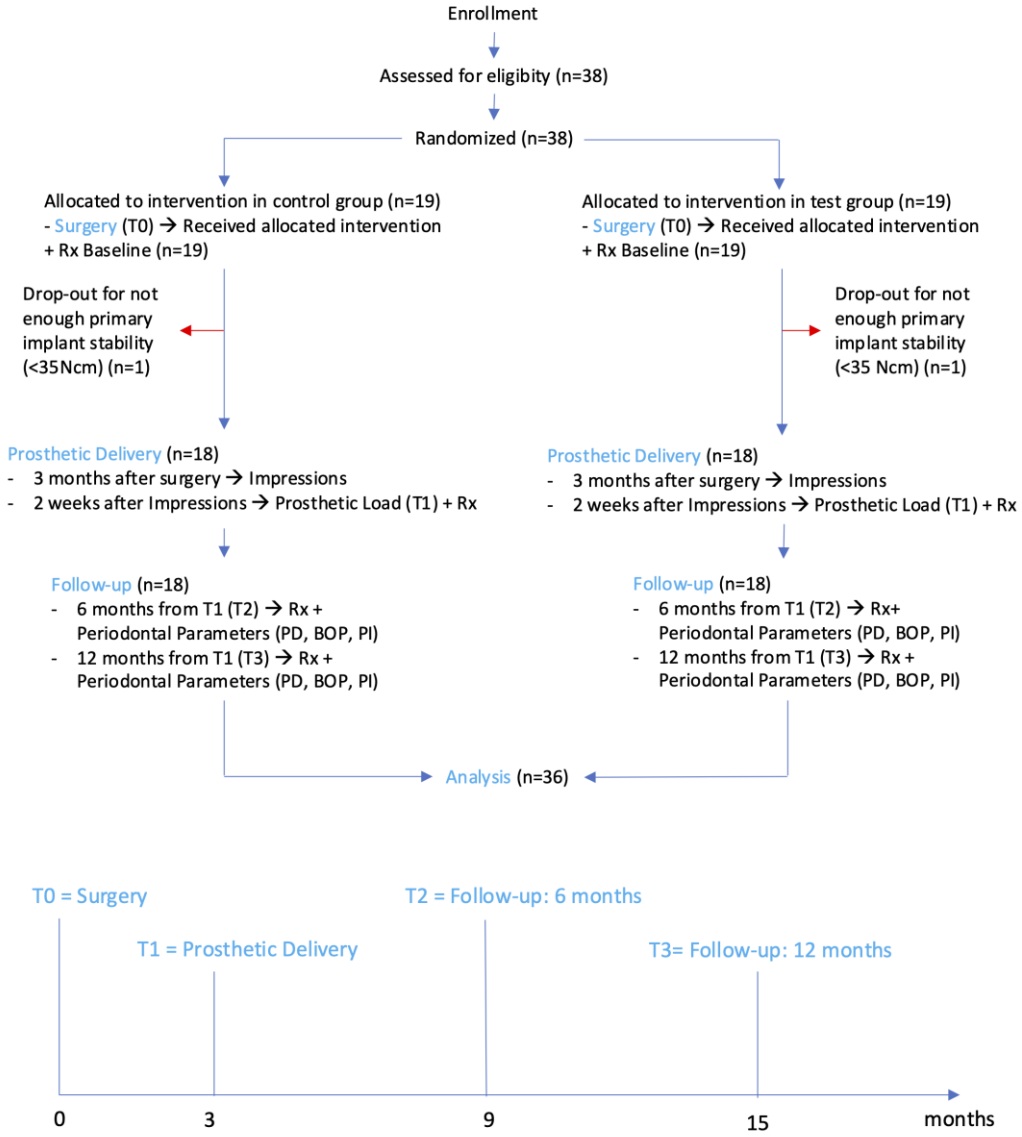

Figure 1. Study flowchart and timeline.

Patients needing a single tooth replacement in the upper and lower posterior areas (premolar and molar) by means of an implant-fixed rehabilitation were included in the present study. The implant site was assessed for bone volume and space based on the following requirements: 1.5 mm of residual buccal and lingual bone around the selected implant diameter, a minimum bone height of 10.5 mm in order to place an implant with a minimum length of 7.5 mm, and at least 1.5 mm of bone between the fixture and the adjacent tooth. Patients with systemic diseases; history of radiation therapy in the head and neck region; current treatment with steroids; neurological or psychiatric impairments that could interfere with good oral hygiene; immuno-compromised status, including infection with human immunodeficiency virus; severe clenching or bruxism; smokers (more than 10 cigarettes per day); drug or alcohol abuse; and inadequate compliance were excluded. All included patients gave their written consent after being informed in detail about the objectives of the study.

Before treatment, patients were clinically and radiographically evaluated. An orthopantomography and peri-apical radiographs were used as a first-level exam to evaluate the bone quantity before implant placement. A cone beam TC was also performed to plan for a prosthetically guided implant placement.

2.2. Surgical Procedures

All surgical and prosthetic procedures were performed by a single experienced operator (ES), and all cases have been treated with the same implant system (Advan GTB-Tzero, Advan S.r.l. Via Linussio 1, 33020—Amaro, Italy) provided with platform switching and conical hybrid connection. Under local anesthesia, an incision along the center of the ridge was performed. After elevating a mucoperiosteal buccal envelope flap, supra-crestal soft tissue height (STH) of the undetached lingual flap was measured using a periodontal probe (PC-PUNC 15 HU-Friedy, Milan, Italy). An independent investigator then opened the randomization envelope and communicated the patient's group allocation to the surgeon. The control group received a bone-level implant placement (BLG), whilst the test group received a 2 mm sub-crestal implant placement (SCG). (Figures 2–4).

Implant-site preparation was performed by following manufacturer's instructions. Insufficient implant primary stability (<35 Ncm) and, therefore, the necessity to bury the implant was considered an exclusion criterion for the present study. A minimum of 2 mm of distance was maintained between the fixture and the neighboring teeth, and a minimum of 1 mm of buccal bone was maintained.

Trans-mucosal healing abutments were inserted on the BLG implants, whilst a Gingival Former Abutment (GFA) for the one-time abutment technique was connected to the implants belonging to the SCG group. The flaps were repositioned and sutured, and post-operatory instructions were provided. Ibuprofen, 600 mg every 4–6 h, was prescribed for pain relief.

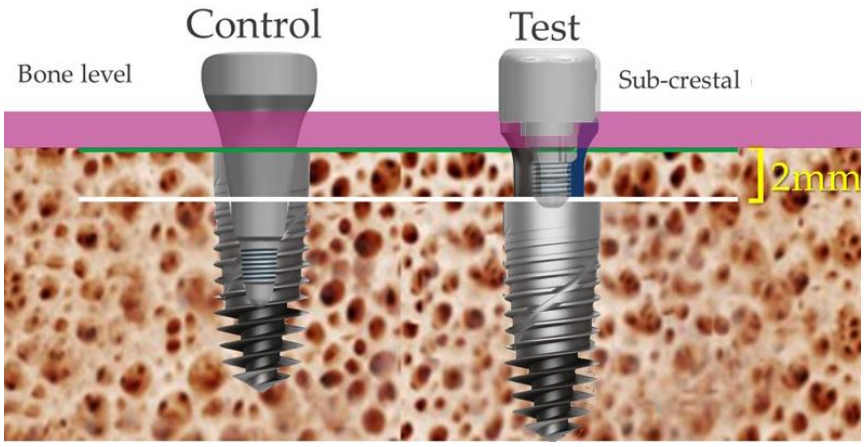

Figure 2. Bone-level implant (BLG—control group) and sub-crestal-level implant (SCG—test group) placement. Refer to Figures 3–11 for the full BLG and SCG workflow.

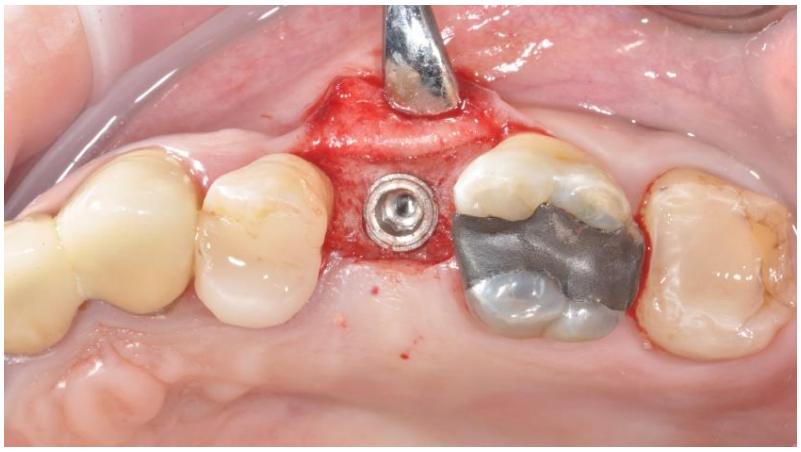

Figure 3. Bone-level implant (BLG—control group). Occlusal view.

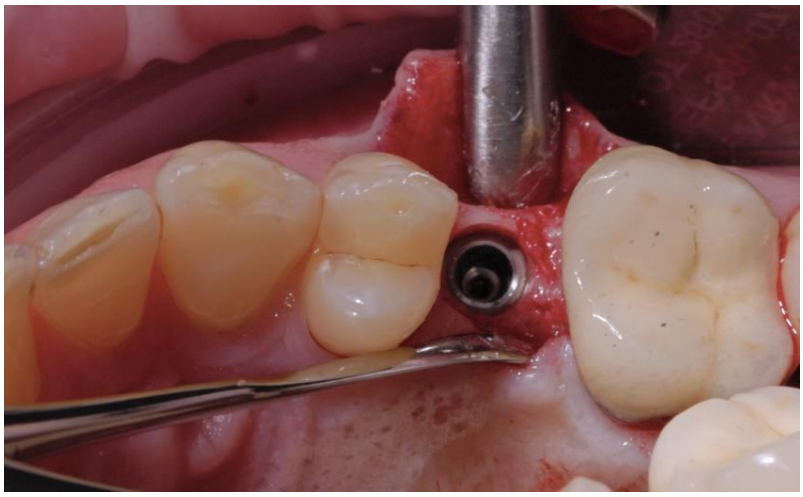

Figure 4. Sub-crestal implant (SCG—test group). Occlusal view.

2.3. Prosthetic Protocol

Three months after surgery, implant-level and abutment-level impressions were taken to provide for single-crown screw-retained restorations for the Control and test groups, respectively (Figures 5 and 6). The final crowns were inserted two weeks after impressions. All restoration margins were placed from 1 mm below the gingival margin to the juxta-gingival level by using the appropriate Ti-base and GFA transmucosal height (Figures 7 and 8). The crowns were tightened to the implants with a torque of 25 N/cm (Figures 9–11). An intraoral periapical radiograph of the restored implant site was taken, and peri-implant PPD, BoP, and PI were assessed. Refer to Figures 3, 5, 7 and 10 for the full BLG group workflow, and to Figures 4, 6, 8 and 11 for the full SCG workflow.

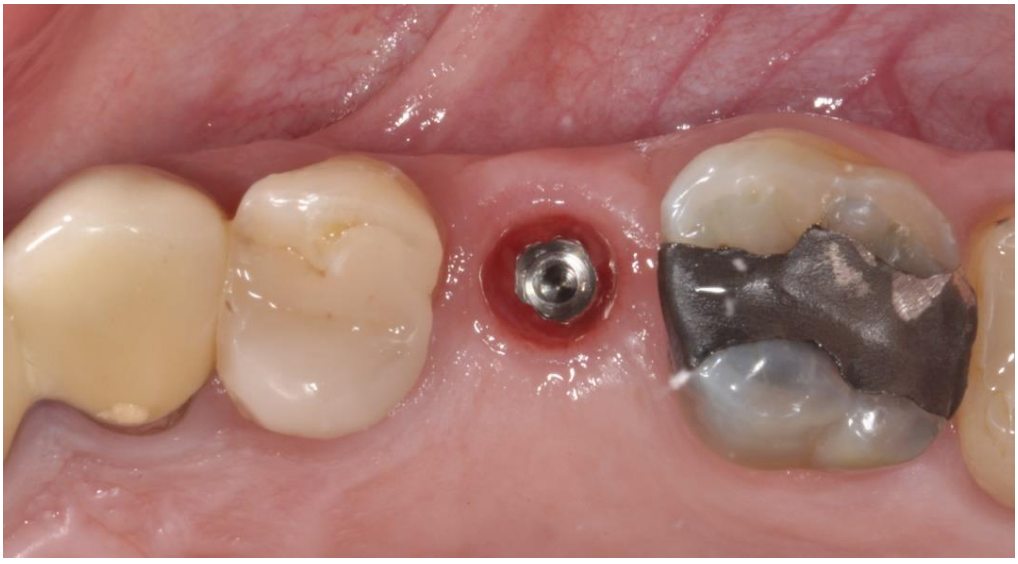

Figure 5. Peri-implant soft tissues at time of impression: BLG—control group.

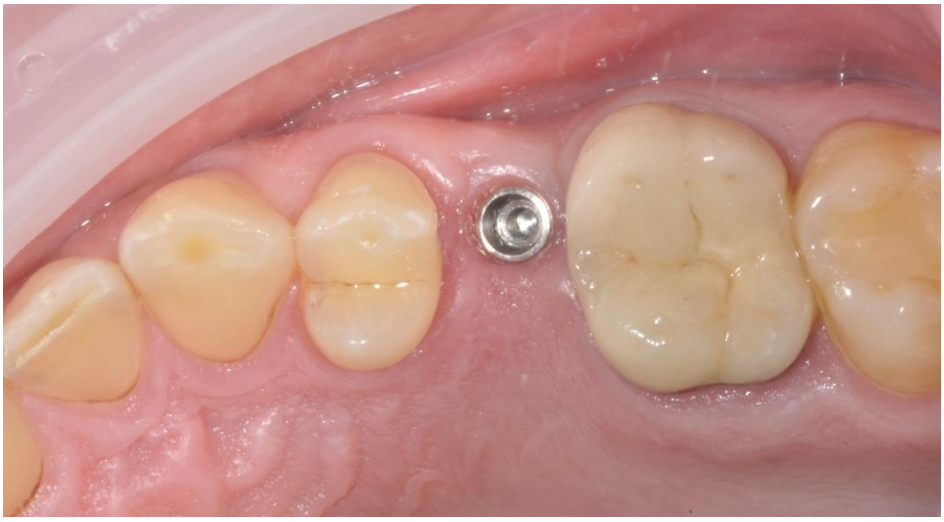

Figure 6. Peri-implant soft tissues at time of impression: SCG—test group.

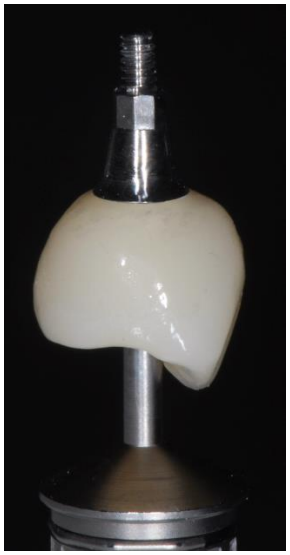

Figure 7. Screw-retained fixed prosthesis secured to the implant (BLG—control group): buccal to lingual emergence profiles.

Figure 8. Screw-retained fixed prosthesis secured to the GFA (SCG—test group): buccal to lingual emergence profiles.

Figure 9. Ti-Base titanium Grade V (**left**) used for one-piece restoration directly connected to the fixture. GFA (**right**) screwed to the implants and used for two-pieces restoration connected to the GFA.

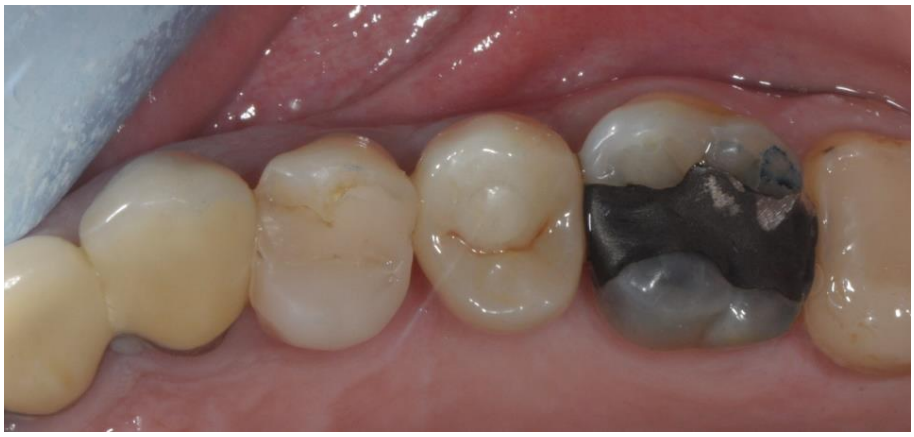

Figure 10. Screw-retained fixed prosthesis secured to the implant (BLG—control group) into position: occlusal view.

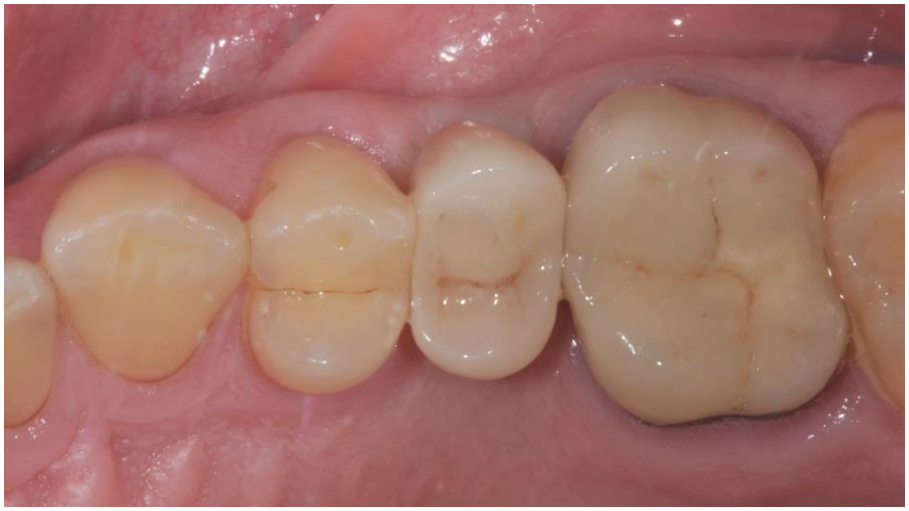

Figure 11. Screw-retained fixed prosthesis secured to the GFA (SCG—test group) into position: occlusal view.

2.4. Radiographic Evaluations

All peri-apical radiographs for the measurement of the marginal bone modification (MBM) were taken with a standardized parallel technique (FONA™ Dental Image Plates). The images were then analyzed with a computer software (Image J, National Institute of Health, Bethesda, MA, USA). Before measurement, each radiograph was calibrated by using the implant diameter as a reference to correct any distortion. Measurements were repeated twice by a single operator (MZ). Each measurement was repeated two times at three different time points. Calibration of the operator was performed by measuring MBM (BL and BR) on a sample of 10 radiographs not included in the study. Intra-examiner reliability was computed using Intra-class Correlation Coefficient (ICC = 0.86%). MBM measurements were taken at both mesial and distal crest.

For each implant, radiographs performed at the time of surgical implant placement (T0), restoration delivery (T1), and after 6 (T2) and 12 (T3) months of prosthetic function were analyzed. The most coronal extension of the crestal bone at the time of the surgical placement was identified as marginal bone level (MBL). The MBL in the BLG group corresponds to the level of the implant neck, being positioned coronal to it in the SCG group. In the assessment of the MBM, bone remodeling (BR) and bone loss (BL) were distinguished. Bone loss was measured as the distance between the initial MBL and first radiographically visible bone-to-implant contact apical to the implant neck, whilst bone remodeling as the distance from the initial MBL to first point of contact coronal to the implant neck. The mean value of the mesial and distal MBM measurements was pooled for each implant. Any apical MBM was expressed as negative number (Figures 12 and 13). MBM was measured at baseline (T0), at crown delivery (T1), and at 6- (T2) and 12-month (T3) follow-up visits (Figures 14 and 15).

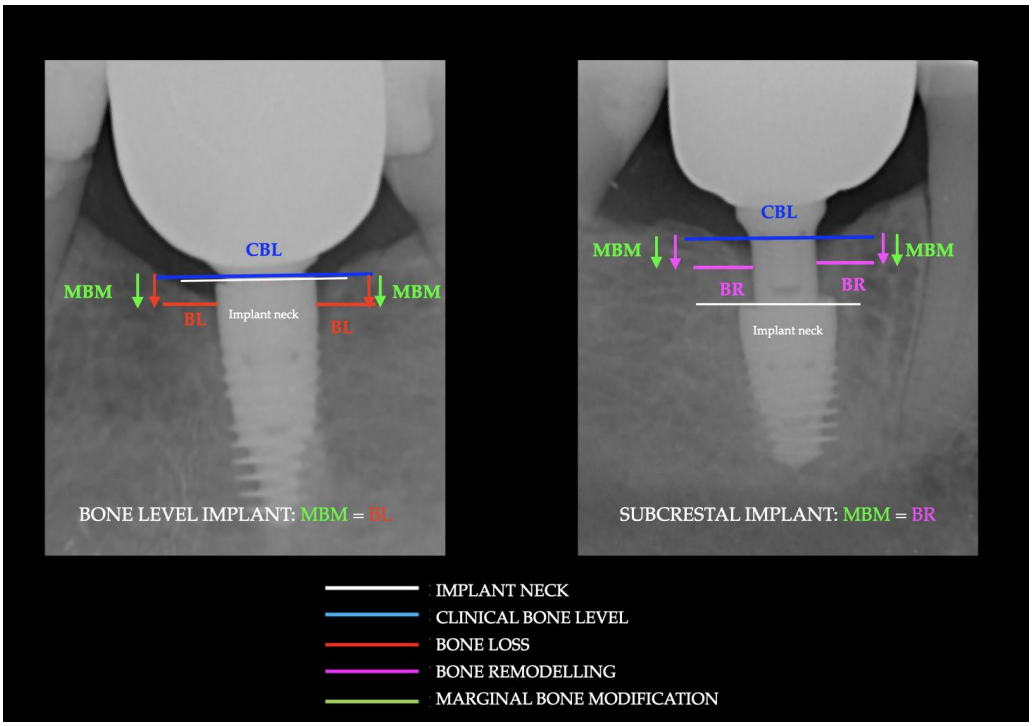

Figure 12. Example of marginal bone level (MBL), marginal bone modification (MBM), bone loss (BL), and bone remodeling (BR) in bone-level and sub-crestal implants.

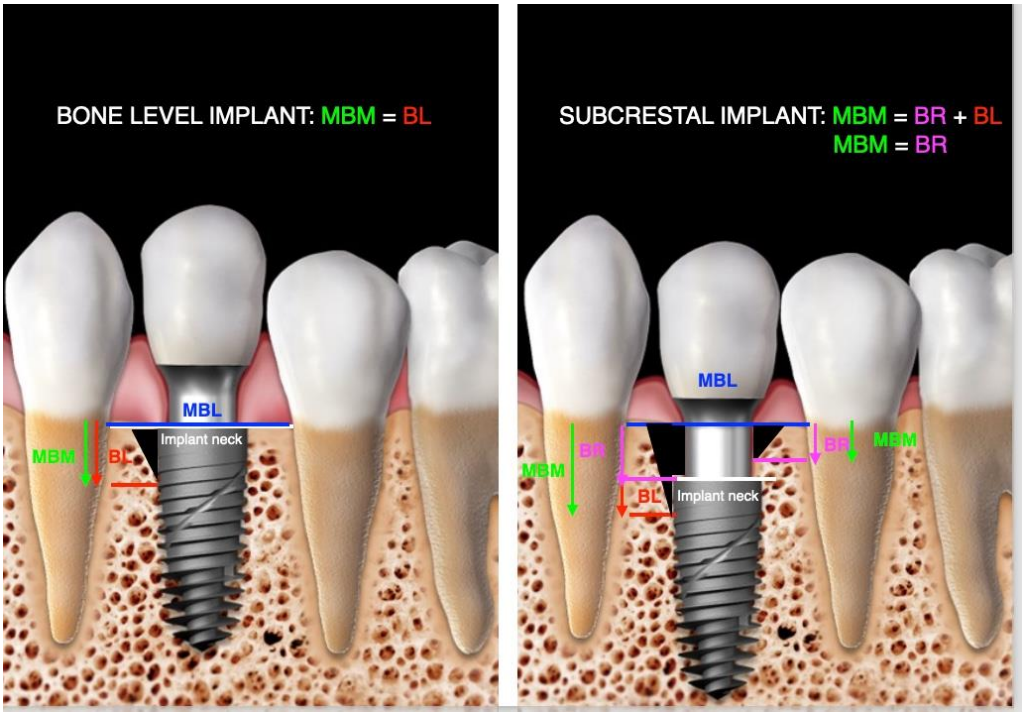

Figure 13. Graphical representation of marginal bone level (MBL), marginal bone modification (MBM), bone loss (BL), and bone remodeling (BR) in bone-level and sub-crestal implants. Refer to Figures 3, 5, 7 and 10 for the full BLG group workflow, and to Figures 4, 6, 8 and 11 for the full SCG workflow.

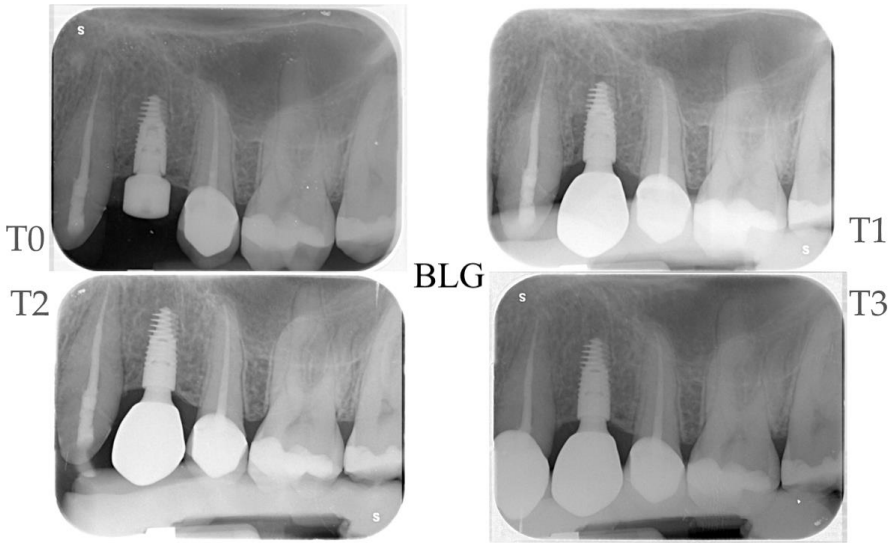

Figure 14. Radiographic control at (T0), (T1), (T2), and (T3) months, respectively. Control (BLG) group.

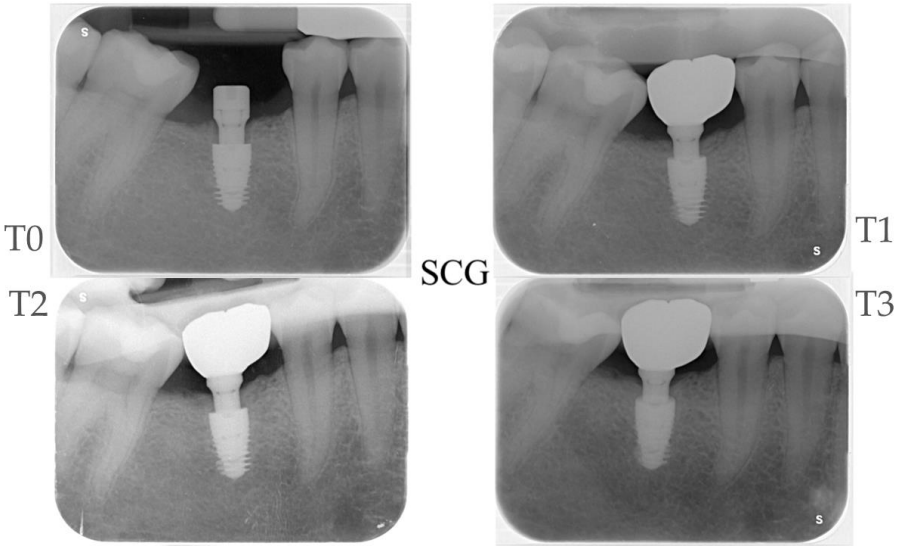

Figure 15. Radiographic control at (T0), (T1), (T2), and (T3) months, respectively. Test (SCG) group.

2.5. Clinical Evaluations

Peri-implant soft tissues parameters were collected using a calibrated probe (Vivacare TPS probe Vivadent, Scahaan, Liechtenstein) (Figure 16). The probing depth (PD) was measured at four aspects (mesial, distal, buccal, palatal) following the Mombelli and Lang (1994) classification [39]. The Bleeding on probing (BOP) and Plaque Index (PI) were measured at the implant site by following Trombelli et al. (2018) [40] and O'Leary (1972) classifications [41]. PD, BoP, and PI indexes were measured at 6 and 12 months after restoration delivery (Figure 1).

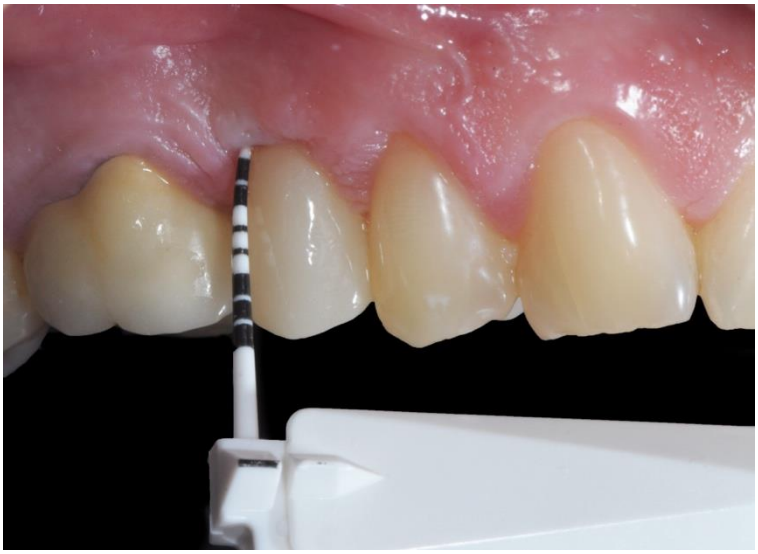

Figure 16. Calibrated probe used to assess peri-implant soft tissues parameters.

2.6. Sample Size and Randomization

Sample size was computed assuming a two-parallel-groups design with balanced groups and an independent sample *t*-test. We assumed a single implant and a single measurement for patients, a standard deviation of 0.5 mm, and an average difference of at least 0.5 mm. A total sample size of 34 patients provides a power of at least 80% at a 5% significance level. Assuming a 15% drop-out, the total sample size is N = 40 patients. The randomization list was built by a biostatistician using a random blocks randomization

algorithm (block size 4, 6, 8). The sequential allocation was performed using numbered envelopes containing the group code.

2.7. Statistical Analysis

Data are described using standard statistics, such as mean, median standard deviation, and IQR for quantitative variable, and counts and percentages for qualitative variables. Variation in MBL is modeled using both a simple *t*-test for independent samples (after averaging values within patients) as well as a multilevel model using GEEs (Generalized Estimating Equations) on individual site measurements and accounting for within subject correlation. Secondary continuous outcomes are modeled using GEE with ad hoc error distribution according to outcome (Gaussian for PPD, CAL, REC, binomial for BOP). Results are expressed as estimates and relative 95% confidence intervals. A significance level of 5% is used for all the comparisons, and all analysis are performed using R (version 3.6.3 or higher).

3. Results

Thirty-eight patients (15 males and 23 females, respectively) aged from 23 to 72 years (mean age 49.4 ± 32.4 years) were recruited in the present study, and 36 completed the study: two implants were considered as drop-outs due to insufficient implant primary stability (<35 Ncm) during the implant placement. Patients' demographic characteristics are reported in Table 2.

Table 2. Patient demographic characteristics.

Demographic Characteristics	Total N (%)	Control Group BLG N (%) **	Test Group SCG N (%) *
Subjects enrolled	38 (100%)	19 (50%)	19 (50%)
Drop Out	2 (5.3%)	1 (50%)	1 (50%)
Age (mean)	49.4 (23–72)	47.3 (23–69)	51.5 (33–72)
Sex	F: 22 (62%) M: 14 (38.9%)	F: 13 (72.2%) M: 5 (27.8%)	F: 9 (50%) M: 9 (50%)
Smokers	6 (16.7%)	4 (22.2%)	2 (11.1%)

* Subcrestal implant. ** Bone-level implant.

The implant and surgical site characteristics are reported in Table 3: 12 (33.3%) implants were positioned in the upper jaw; 21 implants (58.3%) were in molar region; 23 implants (63.9%) were 3.6 × 9 mm and 13 (36.1%) 4.3 × 7.5 mm. Observed STH was 3 mm in 21 patients (58.4%) and 2 mm in 12 (33.3%). No patient had an STH equal to 1 mm, and only 3 patients (8.3%) had 4 mm.

Table 3. Implant-site clinical features.

Sites	Total N (%)	Control Group BLG N (%) **	Test Group SCG N (%) *
Dental arch	Upper: 12 (33.3%) Lower: 24 (66.7%)	Upper: 7 (38.9%) Lower: 11 (61%)	Upper: 5 (33.3%) Lower: 13 (66.7%)
Site	Premolar: 15 (41.7%) Molar: 21 (53.8%)	Premolar: 9 (50%) Molar: 9 (50%)	Premolar: 15 (41.7%) Molar: 21 (53.8%)
STH § (mm)	1: 0 (0%) 2: 12 (33.3%) 3: 21 (58.4%) 4: 3 (8.3%)	1: 0 (0%) 2: 4 (22.2%) 3: 13 (72.2%) 4: 1 (5.6%))	1: 0 (0%) 2: 8 (44.4%) 3: 8 (44.4%) 4: 2 (11.2%)

Table 3. *Cont.*

Sites	Total N (%)	Control Group BLG N (%) **	Test Group SCG N (%) *
Implant (Diameter × Length)	3.6 × 9: 23 (63.9%) 4.3 × 7.5: 13 (36.1%)	3.6 × 9: 15 (83.3%) 4.3 × 7.5: 3 (16.7%)	3.6 × 9: 8 (44.4%) 4.3 × 7.5: 10 (55.6%)
Bone Density (Misch Classification)	D1: 0 (0%) D2: 4 (11%) D3: 25 (69.4%) D4: 7 (19.4%)	D1: 0 (0%) D2: 3 (16.7%) D3: 14 (77.8%) D4: 1 (5.6%)	D1: 0 (0%) D2: 1 (5.6%) D3: 11 (61.1%) D4: 6 (33.3%)
Healing Abutment (mm) control group		3.5: 6 (33.3%) 4.5: 12 (66.7%)	
GFA § (mm) test group			3.5: 7 (38.9%) 4.5: 9 (50%) 5.5: 2 (11.1%)

* Subcrestal implant. ** Bone-level implant. § Negative values referred to apical MBM.

MBM for both groups from the baseline (T0) to the prosthetic loading (T1), six-month follow-up visit (T2) and 1-year follow-up visit (T3) were statically significant ($p < 0.01$), as shown in Table 4. Particularly, after 1 year of loading, the mean MBM in the control group was −0.52 mm compared to the baseline (T0) and −0.60 mm in the test group. However, no significant difference was observed when the MBM values in the two study groups were compared ($p > 0.05$) (Table 4). The control group showed a mean bone loss (BL) equivalent to the MBM values, whilst no MBM below the implant neck was noted for the test group. Therefore, the bone loss for this group equals to zero at all time points.

Table 4. Marginal Bone Modification (MBM), bone loss (BL) and bone remodeling at different time intervals.

Time Points	MBM Control Group Δ (CI 95%) **	*p*-Value	Bone Loss Control Group Δ (CI 95%) **	MBM Test Group Δ (CI 95%) *	*p*-Value	Bone Loss Test Group Δ (CI 95%) **	MBM Test vs. Control Δ (CI 95%)	*p*-Value
T1–T0	−0.44 (−0.67; −0.21)	<0.01	−0.44 (−0.67; −0.21)	−0.65 (−0.89; −0.42)	<0.01	0	−0.21 (−0.54; 0.11)	0.195
T2–T0	−0.49 (−0.72; −0.26)	<0.01	−0.49 (−0.72; −0.26)	−0.72 (−0.95; −0.49)	<0.01	0	−0.23 (−0.55; 0.10)	0.168
T3–T0	−0.52 (−0.75; −0.29)	<0.01	−0.52 (−0.75; −0.29)	−0.60 (−0.83; −0.36)	<0.01	0	−0.07 (−0.40; 0.25)	0.657

* Subcrestal Implant. ** Bone Level Implant.

Clinical peri-implant parameters modification over time are reported in Table 5. In the control group, a mean PD of 3.04 mm was observed after 1 year (T3), while the mean PD was 2.38 mm in the test group, with a statistically significant difference ($p < 0.05$). The mean BoP at 1 year (T3), was 43.06% in the control group and 50% in the test group, with no statistically significant intergroup difference ($p > 0.05$). Comparably, the control and test group PI indexes after 1 year were 19.44% and 33.33%, respectively ($p > 0.05$).

Table 5. Clinical peri-implant parameters modification at different times intervals.

Clinical Parameter	Control Group **			Test Group *			TEST vs. Control	
	6 Months	1 Year	1 Year vs. 6 Months	6 Months	1 Year	1 Year vs. 6 Months	6 Months	1 Year
PPD (mm) (CI 95%)	3.18 (2.76; 3.60)	3.04 (2.64; 3.45)	0.04 (−0.72; 0.45) $p = 0.641$	2.33 (2.03; 2.63)	2.38 (2.13; 2.62)	0.04 (−0.35; 0.43) $p = 0.834$	−0.85 (−1.36; −0.33) $p = 0.001$	−0.67 (−1.14; −0.19) $p = 0.006$

Table 5. *Cont.*

Clinical Parameter	Control Group **			Test Group *			TEST vs. Control	
	6 Months	1 Year	1 Year vs. 6 Months	6 Months	1 Year	1 Year vs. 6 Months	6 Months	1 Year
BOP (%) (CI 95%)	55.56 (43.90; 70.31)	43.06 (33.54; 55.27)	0.78 (0.56; 1.08) [p = 0.134]	36.11 (24.51; 53.21)	50.00 (36.40; 68.68)	1.38 (0.86; 2.23) [p = 0.180]	0.65 (0.41; 1.02) [p = 0.0627]	1.16 (0.78; 1.74) [p = 0.4681]
PI (%) (CI 95%)	12.50 (4.90; 31.89)	19.44 (10.54; 35.86)	1.56 (0.49; 4.89) [p = 0.44979]	11.11 (5.03; 24.53)	33.33 (21.00; 52.91)	3.00 (1.33; 6.79) [p = 0.00837]	0.89 (0.26; 3.03) [p = 0.851]	1.71 (0.80; 3.69) [p = 0.168]

* Subcrestal Implant. ** Bone Level Implant. p = p value.

4. Discussion

The present study evaluates the marginal bone modification around one-stage, platform-switched, internal conical connection implants positioned 2 mm sub-crestally or equi-crestally. The results show that the mean MBMs of the test and control groups were comparable with values of 0.61 mm and 0.52 mm, respectively, at 12 months of prosthetic function. This is due to the apical remodeling of the marginal bone level according to the initial soft tissue height, which was not considered in this paper as an indicator for the apical position of the implant. So, it is possible that thinner phenotypes were included in the test group, compared to the control group. However, following the distinction made by Linkevicious et al. [19] and Spinato et al. [15], all the MBMs in the control group equi-crestal implants developed as bone loss below the implant neck level, whilst the MBM in the test group was limited to the area above the implant neck, due to the 2 mm of sub-crestal depth of the planned fixture position. Therefore, MBMs in the test group resulted in zero bone loss. This leaves, on average, 1.5 mm of coronal marginal bone that protects the treated and threaded portion of the fixture, helping to prevent future biological and esthetic complications [2,13–15]. In fact, in a recent 10-year prospective study, Windael and colleagues [7] demonstrated that implants with Early BL >0.5 mm during the first year of function showed 5.43 times higher odds of future peri-implantitis development than implants with Early BL < 0.5 mm.

Bone loss seems to have mostly occurred in the first 3 months after surgery for both groups, in agreement with other histological studies conducted on animals and humans [42–44]. Those studies also demonstrated that implant supra crestal soft tissues around implants then tend to stabilize after 8–12 weeks, achieving an average height of 3.6 mm height on average, which constitutes the new supracrestal tissue attachment. MBM seems to be a necessary step for the re-establishment of such a dimension [19]. As a consequence, mucosal thickness at the time of implant placement is a significant influencing factor on peri-implant marginal bone stability, and the soft tissue height seems to be inversely proportional to the early bone resorption. This is likely due to the necessary space for the formation of the aforementioned 3.6 mm of tissue height, which occurs at the expense of the bone [7,9,13,16,45,46]. In the present study, a soft tissue thickness ranged between 1 and 4 mm, with 2 and 3 mm being the most frequent values. Linkevicious et al. [45] analyzed the bone loss around bone-level implants in patients with thin (<2 mm) and thick (>2 mm) soft tissue and found a mean bone loss of 1.17 mm in the first group at 12 months after restoration. Despite one-third of the patients in our control group showing an STH of 2 mm, none of the implants exceeded 0.75 mm of bone loss. This difference might be due to other factors, such as implant type and design.

Our bone loss results are in line with the one obtained by Vervake et al. [16] and Linkevicious et al. [19], who measured 0.04 mm and 0.11 mm of bone loss, respectively, around sub-crestally placed platform-switched implants. Linkevicious et al. [19] also observed 0.33 mm of bone loss around equi-crestal implants, more than in the current study. However, they also performed a soft tissue augmentation procedure, which could have provided the extra space for the supracrestal tissue attachment re-establishment.

When assessing the soft tissues, the mean PD value in the test group was 2.38 mm at 12 months after loading and 3.04 mm in the control group, respectively. That difference was both statistically and clinically significant, considering the confidence interval of 2.13–2.62 for the test group and 2.64–3.45 in the control group. This means that in the test group, more than 2.62 mm of PD could not be found, while in the control group, values of up to 3.45 mm could be observed. The recent literature highlighted that the depth of the mucosal tunnel can be a crucial factor in the treatment of peri-implant mucositis, should it occur [25]. Chan et al. [25] showed that deeper mucosal tunnel depth ($\geq$3 mm) is associated with chronic inflammation. Crown removal and professional hygiene were needed to revert such mucositis. Differently, in the shallow tunnel depth $\leq$1 mm, just the oral hygiene practice was sufficient to revert the mucositis. Accessibility for biofilm removal around implant prosthesis is crucial for preventing and managing peri-implant diseases [47].

PI was slightly but not significantly higher in the test group (33.33% vs. 19.44% $p = 0.168$) because of the profiles of the restorations, but the plaque was just lying on the gum surface and not in the sulcus. The slightly but not significantly higher BoP (50% vs. 43.06% $p = 0.4681$) was due to the irritation of the mucosa and not to an inflammation of the mucosal tunnel, and this is an important factor.

An additional observation was made in the test group: one year after loading, in 18% of cases, BoP was observed without the presence of plaque. The authors' assumption is that the bleeding was due to compression of the soft tissues by the crown contour. In those cases, the crowns were unscrewed from the GFA, without interfering with the integrity of the mucosal barrier, remodeled, and polished to reduce the soft tissues compression. It was also possible to check the health of the free gingival sulcus around the GFA. The mean PD was 1.22 mm (IC 1.07–1.37 mm), and the juxtagingival position of the restoration margin was confirmed. This aspect may be important in patients with a history of periodontitis and high risk of implant diseases [48] in the posterior sectors where home hygiene procedures are difficult and esthetics is less important. Heitz–Mayfield and colleagues, in a recent randomized controlled clinical trial [36] on the management of peri-implant mucositis, showed that implants with supra-mucosal restoration margins yielded significantly greater reductions in probing depth following treatment compared to those with submucosal margins.

A limitation of the current study is that the BLG control group was restored with crowns directly screwed to the implant with Ti-base abutment, while in the test group, a definitive GFA was used, following a one-time abutment (OTA) prosthetic workflow. The rationale behind an OTA is to limit the disconnection and reconnection of the abutment from the fixture, which is shown to possibly negatively affect marginal bone levels [49]. However, the topic is still controversial: in fact, some papers seem to associate OTA technique with improved marginal bone stability when compared to traditional restorative procedures [20–22,49–51], whilst others failed to find significant advantages [23,52,53]. Another limitation is the short observation period, which might fail to capture progressive bone loss. Most of the initial adaptive peri-implant bone loss occurs in the first 12 months of prosthetic function, and it is strongly related to the risk of future peri-implantitis [7]. However, while the long-term survival rates of single implants are quite high, at 5 years, the cumulative rate of implants showing >2 mm of bone loss can reach 5.2%, and the soft tissue complications rate can reach 7.1% [54].

Linkevicious et al. [55] found that immediate abutments significantly reduce the amount of early bone loss at 1 month after prothesis delivery on sub-crestal implants. However, no difference is found with traditional abutments at 12 months. It also appears that bone gain was obtained around traditional implant-level restorations. Conversely, a slight bone gain was observed in the test group of the present study, where the average bone remodeling at 6 months was -0.72 mm, but was -0.60 mm at 12 months.

On the other hand, Molina et al. [50] found that the OTA significantly reduced the early bone loss around equi-crestal implants. Therefore, it appears that minimal disturbance of soft tissues might be of greater importance for equi-crestal implants. The bone loss observed by Molina et al. [50] around implants with traditional prosthetic workflow was

1.21 mm on average, higher than the one observed in the present group. This, again, could be due to differences in implant design. The choice to use the definitive GFA in the present study was due to the manufacturing company's recommendations, and to make the impression stage easier. However, it would be interesting to replicate in a future trial both protocols of Molina et al. and Linkevicious et al. [50,55]. Nevertheless, the authors believe it would be misleading to separately consider every single factor associated with implant failure or success. A more global comprehension of different clinical parameters interacting together with the peri-implant hard and soft tissues would be a more effective way to understand the crucial balance between patient biology and the implant [9,36,45]. The results of our study confirm the null hypothesis. It would be interesting to replicate the study by adjusting the apico-coronal position of the implant based on the soft tissue height, in order to verify the direct correlation between STH (soft tissue height) and MBM (marginal bone modification). In this scenario, the test group should ideally achieve MBM approaching zero and, consequently, BL equal to zero.

5. Conclusions

In the present study, the use of internal conical connection, platform-switching implants placed 2 mm sub-crestally and restored through a one-time abutment workflow with screw-retained crowns resulted in marginal bone modification comparable to bone-level implants, but with zero net bone loss in the short term. Further clinical studies will be necessary to better understand the role of the implant position in relation to the bone level, the OTA, and the relationship between STH and bone modification. Only long-term follow-ups will be able to demonstrate the theoretical reduction in the risk of biological complications.

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