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Marginal Bone Changes at Bone-Level Implants With Narrow or Standard Diameter Abutments: 1-Year Results of a Randomised Controlled Trial

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ABSTRACT

Aim: To evaluate changes in the peri-implant marginal bone level at implants restored with narrow or standard-diameter abutments after 12 months.

Material & Methods: Twenty-eight partially edentulous patients were randomly allocated to two groups. The test group consisted of 14 patients restored with a 2.9 mm diameter abutment (21 implants), while the control group included 14 patients restored with a 4.1 mm diameter abutment (17 implants). The primary outcome variable was the radiographic change in the peri-implant marginal bone level at 12 months, measured as the distance from the implant shoulder to the first bone-to-implant contact (fBIC). Secondary outcome variables included clinical peri-implant parameters, the papilla index, biological and mechanical complications, patient-reported outcomes (PROs) and professional aesthetic assessment.

Results: A per-protocol analysis was conducted on the 22 patients who completed all scheduled follow-up visits. At the patient level, the change in mean radiographic bone level from definitive prosthesis placement to 12 months showed a reduction in the distance from the implant shoulder to the fBIC of 0.16 ± 0.31 mm in the test group and 0.21 ± 0.34 mm in the control group, with no statistically significant differences between the groups. No statistically significant differences were observed between the two groups for any of the secondary outcomes.

Conclusions: Considering the limitations of this study, no significant differences in peri-implant marginal bone levels were found between bone-level implants restored with narrow and standard diameter abutments after 12-month follow-up. Additionally, no differences were observed in clinical variables, patient-reported outcomes, or complications.

1 | Introduction

The preservation of supracrestal peri-implant soft tissues plays a crucial role in maintaining bone tissue stability (Berglundh and Lindhe 1996; Gargiulo et al. 1961). In recent decades, it has been suggested that peri-implant marginal bone loss is influenced by several factors, including the surface characteristics of the implant neck (Penarrocha et al. 2004), the implant-abutment interface (Ericsson et al. 1995), abutment height (Blanco et al. 2018), platform switching (Strietzel et al. 2015), and abutment dis/reconnection (Molina et al. 2017). Limiting these disconnections has been shown to improve the maintenance of the peri-implant marginal bone level (Becker et al. 2012).

On the other hand, it has been observed that transmucosal abutments with convex designs can influence bone remodeling,

even with platform switching, when compared to straight or concave abutments (Alves et al. 2015; Souza et al. 2018). The hypothesis was that distancing the abutment-prosthesis interface from the implant shoulder and using narrower transmucosal abutments with platform switching could favor the maintenance of the peri-implant marginal bone level by reducing bone remodeling (Blanco et al. 2018; Novoa et al. 2017) and the apical migration of the "biological width" (Canullo et al. 2009).

Although there is evidence regarding the influence of platform switching or abutment height on the maintenance of the peri-implant marginal bone level, the evidence on the effect of abutment diameter is limited.

Therefore, the aim of this 12-month randomized clinical trial is to evaluate changes in the peri-implant marginal bone level at implants restored with narrow or standard diameter abutments after 12 months.

2 | Materials and Methods

2.1 | Study Design

This study was designed as a randomized, single-blinded, parallel-group, controlled clinical trial with a 12-month follow-up. All clinical procedures were performed at the Periodontology Unit (Faculty of Medicine and Dentistry) of the University of Santiago de Compostela, Spain. The trial was conducted from July 2021 to July 2023. The study protocol was approved by the local ethical research committee (CEIm-G. 2020/34). The study complies with the CONSORT 2010 guidelines checklist.

Additionally, the research was conducted in accordance with the principles established in the Declaration of Helsinki. The clinical trial was registered with the U.S. National Institutes of Health (Clinicaltrials.gov: NCT04385355).

2.2 | Patients

All participants were selected from patients treated at the Periodontology Unit of the University of Santiago de Compostela. The following inclusion criteria were established:

- Absence of systemic and periodontal pathology.
- Age ≥ 18 years.
- Plaque index < 25%.
- Absence of a tooth in any location, with adjacent natural teeth.
- Adequate bone quantity to allow the placement of 1 to 3 Ticare Inhex (Mozo-Grau S.A., Valladolid, Spain) implants with diameters of 3.75 or 4.25 mm and lengths of 8, 10, or 11.5 mm, without the need for hard or soft tissue grafting procedures.
- Presence of a natural tooth or an implant with a fixed restoration as anantagonist.

Patients were excluded based on the following criteria:

- Systemic medication that may affect bone metabolism.
- Untreated periodontitis or persistent intraoral infection.
- Dysfunction and deficiency of leukocytes, immunodeficiency syndromes, renal insufficiency, or metabolic bone disorders such as osteoporosis.
- Physical disability that may affect proper oral hygiene.
- Consumption of > 10 cigarettes/day, alcoholism, and/or drug addiction.
- Conditions or circumstances that could prevent compliance with study participation or interfere with the analysis of results.
- Pregnancy or breastfeeding.
- History of local radiotherapy.
- Bruxism or diseases affecting the oral mucosa.
- Patients requiring bone regeneration surgery for implant placement.

The patients were informed about the risks and benefits associated with their participation in the study, and their informed consent was obtained before its inclusion.

2.3 | Sample Size, Randomization and Blinding

The sample size was calculated based on data from Pico et al. (2019), which reported a difference of 0.83 mm in the distance from the implant shoulder to the fBIC between groups, with a standard deviation of 0.66. Assuming an alpha risk of 0.05 and a statistical power of 80%, a sample size of 22 participants was required to detect these differences. Taking into account a potential 20% drop-out rate during follow-up, the total number of patients to be included was increased to 28. (MACRO!NSize V2010.06.30 JM. Domenech and R. Granero 201 in IBM SPSS Statistics version 27).

Participants were randomly assigned to one of the two treatment groups using a block randomization method with a 1:1 allocation ratio. The randomization sequence was generated using IBM SPSS Statistics version 27 software (MACRO!RNDSEQ V2011.09.09 JM. Domenech). A single-blind design was adopted, in which both the patients and the data analyst were blinded to the group allocation.

2.4 | Examiners Calibration

For examiner calibration, 10 patients from the Unit of Periodontology at the University of Santiago de Compostela, who were not part of the study and had dental implants with a definitive prosthesis, were selected. All variables were calibrated by the same two independent examiners (L.M., L.N.). For the primary outcome variable, the examiners conducted two separate radiographic measurements on each patient within a 1-week interval. For the secondary outcome variables,

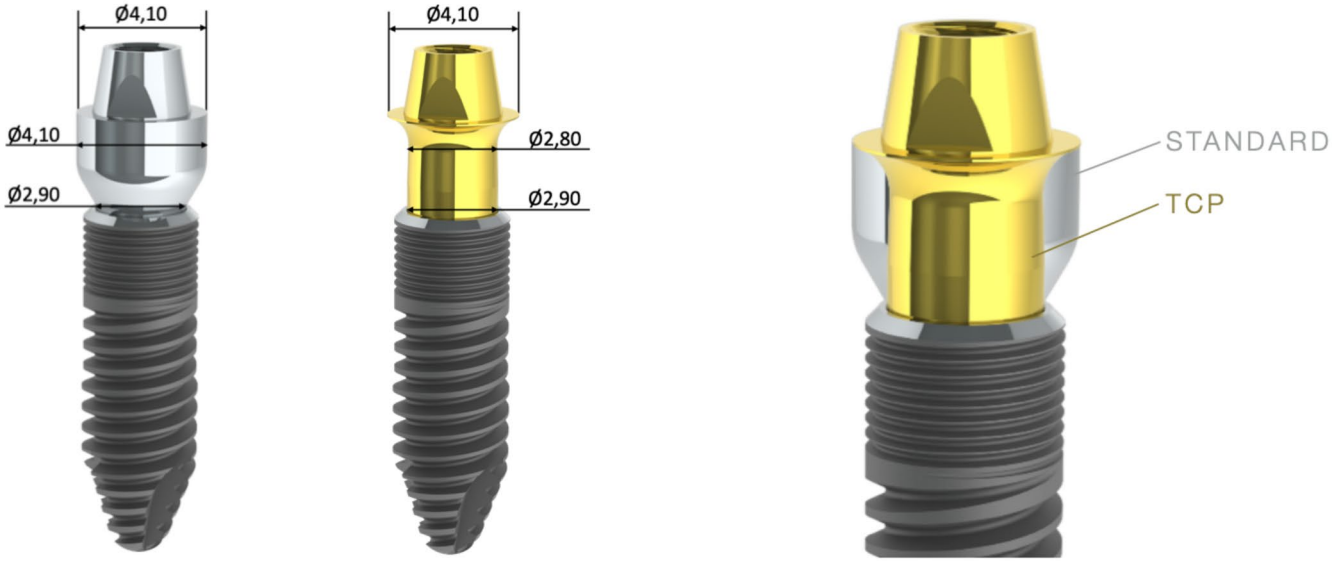

FIGURE 1 | Comparison of the dimensions and shapes of standard (STD) and narrow (TCP) abutments.

calibration of both quantitative and categorical parameters was performed using a Hu-Friedy CP15 UNC periodontal probe. In addition, calibration of the professional aesthetic evaluation was also carried out. These variables were recorded twice, with a 1 h interval between measurements. The examiners repeated the measurements until the intraclass correlation coefficient exceeded 0.75 for quantitative variables and the kappa index exceeded 0.75 for categorical variables at both intra- and inter-examiner levels.

2.5 | Intervention

Before inclusion in the study, informed consent was obtained, and demographic, clinical, and radiological data were recorded. Periapical radiographs were taken using the parallel technique with a long cone, and a cone-beam computed tomography (CBCT) with a radiological-surgical guide was used for implant evaluation and placement.

Participants were instructed to rinse with a mouthwash containing 0.12% chlorhexidine digluconate and 0.05% cetylpyridinium chloride (CPC) (Perio-aid; Dentaid, Spain) immediately before surgery. Surgical procedures were performed under local anesthesia using 20 mg/mL lidocaine with 0.0125 mg/mL epinephrine (Inibsa Dental, Barcelona, Spain). A crestal incision was made, and if necessary, intrasulcular incisions were performed on adjacent teeth to facilitate flap elevation. Lingual mucosal height was assessed using a periodontal probe (Hu-Friedy CP15 UNC).

Implant osteotomy was performed following the manufacturer's guidelines. After implant placement, the sealed envelope containing group allocation was opened. All implants used were Ticare Inhex (Mozo-Grau S.A., Valladolid, Spain) with diameters of 3.75 or 4.25 mm and lengths of 8, 10, or 11.5 mm. All implants received the definitive transmucosal abutment on the same day of surgery, following the "one abutment–one time" protocol. The control group received a standard Ticare Inhex (Mozo-Grau S.A., Valladolid, Spain) tapered abutment (3 mm height, 4.1 mm diameter), while the test group received a narrow Ticare Inhex TCP (Mozo-Grau S.A., Valladolid, Spain) tapered abutment (3 mm height, 2.9 mm diameter) (Figure 1). Mucoperiosteal flaps were repositioned and sutured using Supramid 5/0 (Aragó; Barcelona, Spain). All implants were placed 1 mm subcrestally, measured from the buccal aspect. Clinical and radiographic variables were recorded at the implant level.

Postoperatively, patients were prescribed a 15 mL chlorhexidine + CPC mouthwash (0.12% + 0.05%) (Perio-aid; Dentaid, Spain) twice daily for 7 days. Anti-inflammatory medication (600 mg Ibuprofen every 8 h as needed) and antibiotics (500 mg amoxicillin with 125 mg clavulanic acid every 8 h for 7 days) were also prescribed.

Sutures were removed 7–15 days after surgery. Clinical data, including implant survival, adverse effects, photographs, and oral hygiene instructions, were recorded at this visit. At 8 weeks, conventional impressions were taken using Impregum Penta (3 M; Madrid, Spain) with a customized open tray and a Ticare non-rotational impression coping (Mozo-Grau S.A., Valladolid, Spain) for 10° Inhex abutments STD to fabricate the definitive metal-ceramic prosthesis designed using CAD/CAM technology by Ticare Biocam (Mozo-Grau S.A., Valladolid, Spain).

After 12 weeks of healing, the definitive screw-retained cobalt-chromium (Co-Cr) ceramic prosthesis was connected and adjusted, and clinical and radiographic data were recorded in both groups. Patients received oral hygiene instructions with the new prosthesis. This appointment was considered the baseline visit for the study. Radiographs were taken using the parallel technique with an individualized long cone bite block and evaluated with ImageJ software (1.47 V Wayne Rasband; National Institutes of Health, Bethesda, MD, USA). Patient-reported outcomes (PROs) were assessed using a visual analog scale (VAS), along with evaluation of biological and mechanical complications. Professional aesthetics were subjectively assessed by the

investigators using a visual analog scale (VAS). Subsequent follow-up visits were conducted at 6 and 12 months after prosthesis placement, during which the same clinical and radiographic variables recorded at baseline were reassessed.

2.6 | Outcome Variables

2.6.1 | Changes in Radiographic Bone Level

Changes in the peri-implant marginal bone level were evaluated by measuring the distance from the implant shoulder to the fBIC on the mesial and distal surfaces of the implant, to the nearest 0.1 mm, using ImageJ software (1.47 V Wayne Rasband; National Institutes of Health, Bethesda, MD, USA). The mean of the two measurements was then calculated. In patients with more than one implant, the mean value of the implants was calculated. All radiographs were calibrated using the known height of the dental implant to determine a pixel/mm ratio. Radiographs were taken using the long-cone parallel technique with an individualized bite block for each patient at the following time points: baseline, 6–12 months after the placement of the definitive prosthesis.

2.6.2 | Clinical Evaluation

Peri-implant parameters, including probing pocket depth (PPD) (distance from the mucosal margin to the bottom of the peri-implant pocket), recession (distance from the margin of the peri-implant mucosa to the most apical position of the prosthesis), plaque index (0–3) (Mombelli et al. 1987) and bleeding on probing (BoP; 0–3) (Mombelli et al. 1987), were recorded for each implant at six locations. The mean values of these variables were then calculated for each patient. These variables were assessed by two independent examiners (L.M., L.N.) using a Hu-Friedy CP15 UNC periodontal probe. The position of interdental tissues was evaluated using the papilla index (Jemt 1997). The height of the lingual flap was also evaluated during surgery, before it was elevated, using a Hu-Friedy CP15 UNC periodontal probe.

Biological complications, such as mucositis and peri-implantitis (Renvert et al. 2018), as well as mechanical complications like loss of retention, seal or screw, and fractures of the abutment, prosthesis, or implant were evaluated dichotomously (yes/no) (Lang et al. 2012).

2.6.3 | Patient-Reported Outcomes (PROs) and Professional Aesthetic Assessment

Patient-reported outcomes were assessed using a 10-point visual analog scale (VAS). The PROs included overall satisfaction, aesthetics, phonation, masticatory function, and comfort (de Bruyn et al. 1997; Meijndert et al. 2007).

From a professional perspective, aesthetic evaluation was performed subjectively by two independent examiners (L.M., L.N.), using a 10-point VAS, based on the criteria established by the Pink Esthetic Score (PES) (which includes mesial papilla, distal papilla, soft-tissue level, soft-tissue contour, alveolar process deficiency, soft-tissue color and texture) and the White Esthetic Score (WES) (which includes crown form, volume, color, translucency and texture) (Cosyn et al. 2017). The contra-lateral or adjacent tooth was used as a reference for all aesthetic assessments.

2.7 | Statistical Analysis

The primary outcome variable of the study was the change in radiographic bone level, measured as the distance from the implant shoulder to the fBIC from the time of definitive prosthesis placement to the 12-month follow-up. The distribution of this variable was assessed using the Shapiro–Wilk test, and after verifying a normal distribution in both groups, the Student's *t*-test for independent samples was used for intergroup comparisons, while the Student's *t*-test for paired samples was applied for intragroup comparisons. However, intergroup comparisons at each individual visit did not follow a normal distribution. Consequently, non-parametric tests were used for these comparisons, specifically the Mann–Whitney *U*-test.

For the probing depth variable, the Student's *t*-test for independent samples was used for intergroup comparisons, while the Student's *t*-test for paired samples was applied for intragroup comparisons. For the clinical variables, recession, bleeding index, and plaque index, after verifying a non-normal distribution, the Mann–Whitney *U*-test was applied for intergroup analysis and the Wilcoxon signed-rank test for intragroup analysis. A mean value was calculated per patient for all continuous variables in cases where the patient presented with multiple implants.

For the patient-reported outcomes, professional aesthetic assessment, biological complications, and mechanical complications, the Chi-square test was used for intergroup comparisons. When the assumption of expected frequencies ≥ 5 was not met, Fisher's exact test was applied.

Regarding the analysis of papilla index data, the distribution of the different scores (i.e., 0, 1, 2, or 3) from all implants was aggregated separately within the test and control groups at each visit (baseline, 6 months, and 12 months). The Chi-square test or Fisher's exact test, as appropriate, was applied at each time point to compare mesial and distal papillae between the groups.

Statistically significant differences were established at $p < 0.05$. All analyses were performed using SPSS software, Version 29 (SPSS Inc., Chicago, IL, USA).

The analyzed data sets included the per-protocol study sample, comprising all patients who completed the study without major protocol deviations and attended the following visits: implant placement, definitive prosthesis placement, 6-month visit, and 12-month visit.

3 | Results

Twenty-eight partially edentulous patients were included in this study. Fourteen patients were assigned to the 2.9 mm diameter

abutment group (21 implants) and fourteen patients were assigned to the 4.1 mm diameter abutment group (17 implants) (Table 1). At the 6-month visit, two patients from the test group (5 implants) and three patients from the control group (4 implants) missed the appointment but attended the 12-month visit. At the 12-month visit, one patient from the test group (1 implant) did not attend, as she had moved away (Figure 2). We report the per-protocol analysis of the 22 patients who completed all scheduled visits.

TABLE 1 | Demographic data and patient characteristics.

	Abutment diameter 2.9 mm	Abutment diameter 4.1 mm
	***n* = 14**	***n* = 14**
Age (mean (SD))	56.92 (9.62)	58.12 (6.99)
Gender (*n*, female/male)	6/8	8/6
Smokers (*n*, (%))	0 (0%)	0 (0%)
No. of implants (*n*)	21	17
Implant diameter[a] (*n*, 3.75/4.25)	13/8	5/12
Height of the lingual flap (mm) (mean (SD))	3.21 (0.93)	3.04 (1.18)
Bone density	*n* = 14	*n* = 14
I (*n*, (%))	0 (0%)	0 (0%)
II (*n*, (%))	5 (35.71%)	2 (14.28%)
III (*n*, (%))	9 (64.29%)	12 (85.71%)
IV (*n*, (%))	0 (0%)	0 (0%)
Prosthesis location	*n* = 14	*n* = 14
Maxilla posterior (*n*, (%))	6 (42.85%)	6 (42.85%)
Mandible posterior (*n*, (%))	8 (57.14%)	8 (57.14%)
Prosthesis design	*n* = 14	*n* = 14
Presence of 1 Implant (*n*, (%))	8 (57.14%)	11 (78.57%)
Presence of 2 Implants (*n*, (%))	5 (35.71%)	3 (21.43%)
Presence of 3 Implants (*n*, (%))	1 (7.14%)	0 (0%)

Note: Statistically significant differences were considered for $p < 0.05$.
[a]Statistically significant differences between groups.

3.1 | Radiographic Evaluation of Interproximal Peri-Implant Bone Level

The distance from the implant shoulder to the fBIC at baseline was −0.40 ± 0.43 mm in the control group and −0.33 ± 0.47 mm in the test group. At 6 months, these values were −0.21 ± 0.22 mm and −0.27 ± 0.48 mm, respectively, and at 12 months, −0.19 ± 0.18 mm and−0.17 ± 0.39 mm, respectively. The change in mean radiographic bone level from definitive prosthesis placement to 12 months showed a reduction in the distance from the implant shoulder to the fBIC of 0.16 ± 0.31 mm in the test group and 0.21 ± 0.34 mm in the control group, with a mean difference of 0.051 mm (95% CI: −0.23 to 0.34). Statistical analysis showed no significant intergroup differences during the 12-month follow-up period, $p \geq 0.05$. Similarly, no statistically significant intragroup differences were observed, with a reduction of 0.21 ± 0.34 mm in the control group ($p = 0.071$) and 0.16 ± 0.31 mm in the test group ($p = 0.120$) (Figures 2 and 3; Table 2).

3.2 | Clinical Evaluation

In the evaluation of clinical parameters of the implants, the mean probing depth at baseline was 2.08 ± 0.14 mm in the control group and 2.23 ± 0.55 mm in the test group. At 12 months, the probing depth was 2.25 ± 0.37 mm in the control group and 2.29 ± 0.51 mm in the test group. The baseline recession was 0.07 ± 0.25 mm in the control group and 0.01 ± 0.02 mm in the test group. At 12 months, recession was 0 mm in the control group and 0.03 ± 0.06 mm in the test group. No statistically significant differences were observed between the two groups for any of the clinical variables evaluated, $p \geq 0.05$ (Table 3).

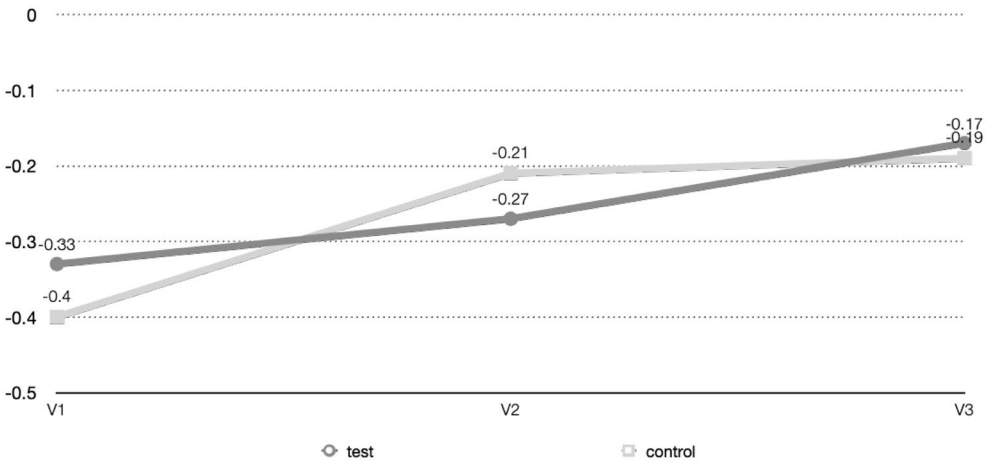

FIGURE 2 | Change in distance from the implant shoulder to the first bone-to-implant contact (fBIC) (mm) at the patient level. Data are shown for the test group (narrow abutment, circles) and control group (standard abutment, squares) across three visits: V1 (baseline), V2 (6 months) and V3 (12 months). Both groups exhibited a reduction in the distance from the implant shoulder to the fBIC over time. At 6 and 12 months, the groups showed comparable values, and no statistically significant intergroup or intragroup differences were observed throughout the follow-up period.

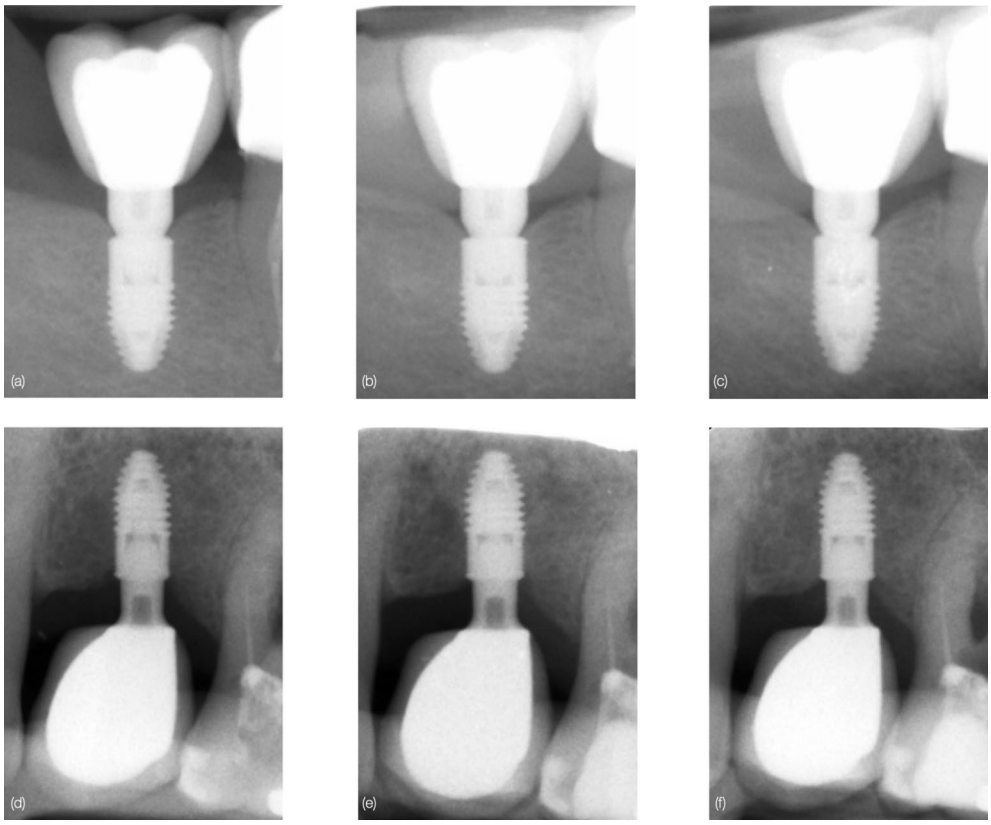

FIGURE 3 | Representative periapical radiographs of implants restored with standard (a–c) and narrow (d–f) abutments at baseline (a, d), 6 months (b, e) and 12 months (c, f) after prosthesis placement. Radiographic assessment of the distance from the implant shoulder to the first bone-to-implant contact (fBIC) demonstrated minimal changes over time in both groups. From baseline to 12 months, the mean bone level reduction was 0.21 ± 0.34 mm in the standard abutment group and 0.16 ± 0.31 mm in the narrow abutment group. No statistically significant intergroup or intra-group differences were observed throughout the follow-up period.

TABLE 2 | Distance from the implant shoulder to the first bone-to-implant contact (fBIC) (mm) at the patient level.

	Abutment diameter 2.9 mm		Abutment diameter 4.1 mm		
	n	**Mean ± SD (mm)**	***n***	**Mean ± SD (mm)**	**Intergroup *p*-value**
Baseline	11	−0.33 ± 0.47	11	−0.40 ± 0.43	0.652
6 months	11	−0.27 ± 0.48	11	−0.21 ± 0.22	0.748
12 months	11	−0.17 ± 0.39	11	−0.19 ± 0.18	0.171
Change from baseline to 12 months	11	0.16 ± 0.31	11	0.21 ± 0.34	0.718
Intra-group *p*-value (baseline to 12 months)		0.120		0.071	

Note: Statistically significant differences were considered for $p < 0.05$. Negative sign indicates bone loss. Per-protocol analysis.

3.3 | Papilla Index

Regarding the papilla index (Jemt 1997), 6 months after prosthesis placement, 26.7% of the implants with narrow abutments showed complete mesial papilla fill (grade 3), compared to 0% in the standard abutment group. Furthermore, at this same visit, none of the implants in the test group showed a complete absence of mesial papilla (grade 0), whereas 15.4% of the implants in the control group exhibited this condition (Table 4). These differences were statistically significant ($p = 0.039$).

3.4 | Mechanical Complications

Regarding mechanical complications, no complications were recorded at the time of prosthesis placement. However, at 6 months, the control group had one case of retention loss and one case of

TABLE 3 | Clinical parameters at baseline, 6, and 12 months.

Clinical parameters	Group	Baseline		6 months		12 months	
		n	Mean ± SD	*n*	Mean ± SD	*n*	Mean ± SD
Probing depth (mm)	Abutment diameter 2.9 mm	11	2.23 ± 0.55	11	2.38 ± 0.65	11	2.29 ± 0.51
	Abutment diameter 4.1 mm	11	2.08 ± 0.14	11	2.41 ± 0.49	11	2.25 ± 0.37
Intergroup *p*-value			0.42		0.82		0.93
Recession (mm)	Abutment diameter 2.9 mm	11	0.01 ± 0.02	11	0.05 ± 0.17	11	0.03 ± 0.06
	Abutment diameter 4.1 mm	11	0.07 ± 0.25	11	0	11	0
Intergroup *p*-value			1.00		0.75		0.48
Bleeding on probing	Abutment diameter 2.9 mm	11	0	11	0.06 ± 0.11	11	0.02 ± 0.05
	Abutment diameter 4.1 mm	11	0	11	0.05 ± 0.11	11	0.07 ± 0.11
Intergroup *p*-value			0.74		0.74		0.40
Plaque index	Abutment diameter 2.9 mm	11	0	11	0	11	0.01 ± 0.05
	Abutment diameter 4.1 mm	11	0	11	0.09 ± 0.17	11	0.09 ± 0.20
Intergroup *p*-value			1.00		0.30		0.69

Note: Statistically significant differences were considered for $p < 0.05$. Per-protocol analysis.

TABLE 4 | The papilla index at the implant level.

		Mesial papilla						Distal papilla					
		Baseline		6 months		12 months		Baseline		6 months		12 months	
	Grade	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Abutment diameter 2.9 mm	0	7	46.7%	0	0%	1	6.7%	8	53.3%	4	26.7%	5	33.3%
	1	8	53.3%	8	53.3%	9	60%	6	40%	3	20%	3	20%
	2	0	0%	3	20%	3	20%	1	6.7%	5	33.3%	5	33.3%
	3	0	0%	4	26.7%	2	13.3%	0	0%	3	20%	2	13.3%
Abutment diameter 4.1 mm	0	6	46.2%	2	15.4%	4	30.8%	4	30.8%	4	30.8%	6	46.2%
	1	6	46.2%	7	53.8%	5	38.5%	7	53.8%	6	46.2%	3	23.1%
	2	1	7.7%	4	30.8%	3	23.1%	2	15.4%	3	23.1%	3	23.1%
	3	0	0%	0	0%	1	7.7%	0	0%	0	0%	1	7.7%
Intergroup *p*-value		0.448		**0.039***		0.350		0.442		0.136		0.851	

Note: Statistically significant differences were considered for $p < 0.05$. *Statistically significant differences between groups. Per-protocol analysis.

seal loss, while the test group had one case of retention loss. At 12 months, the test group experienced one case of seal loss and one prosthesis fracture (ceramic chipping), while the control group had one case of seal loss. No significant differences were found between the two groups for any of the mechanical complications evaluated at baseline, 6-month, and 12-month follow-up, $p \geq 0.05$ (Table 5).

3.5 | Biological Complications

Regarding mucositis, all patients exhibited peri-implant health at the time of prosthesis placement. At 6 months, mucositis was observed in two patients (18.2%) in the control group and in three patients (27.3%) in the test group. At 12 months, four patients (36.4%) in the control group and two patients (18.2%) in the test group presented with mucositis. No cases of peri-implantitis were detected in either group (Table 6).

3.6 | Patient-Reported Outcomes (PROs) and Professional Aesthetics

At 12 months after the placement of the definitive prosthesis, the mean overall satisfaction was 9.45 (0.93 SD) in the standard abutment group, compared to 9.18 (0.98 SD) in the narrow abutment group. Aesthetics were evaluated with a mean of 9.36 (1.03 SD) in the control group and 8.82 (1.78 SD) in

TABLE 5 | Mechanical complications at baseline, 6 months, and 12 months (VAS).

Mechanical complications	Group	Baseline		6 months		12 months	
		n	Yes (%)	*n*	Yes (%)	*n*	Yes (%)
Retention loss	Abutment diameter 2.9 mm	11	0 (0%)	11	1 (9.1%)	11	0 (0%)
	Abutment diameter 4.1 mm	11	0 (0%)	11	1 (9.1%)	11	0 (0%)
Intergroup *p*-value			n.c		1.00		n.c
Seal loss	Abutment diameter 2.9 mm	11	0 (0%)	11	0 (0%)	11	1 (9.1%)
	Abutment diameter 4.1 mm	11	0 (0%)	11	1 (9.1%)	11	1 (9.1%)
Intergroup *p*-value			n.c		1.00		1.00
Screw loosening	Abutment diameter 2.9 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
	Abutment diameter 4.1 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
Intergroup *p*-value			n.c		n.c		n.c
Abutment fracture	Abutment diameter 2.9 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
	Abutment diameter 4.1 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
Intergroup *p*-value			n.c		n.c		n.c
Prosthesis fracture	Abutment diameter 2.9 mm	11	0 (0%)	11	0 (0%)	11	1 (9.1%)
	Abutment diameter 4.1 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
Intergroup *p*-value			n.c		n.c		1.00
Phonetic complications	Abutment diameter 2.9 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
	Abutment diameter 4.1 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
Intergroup *p*-value			n.c		n.c		n.c
Implant fracture	Abutment diameter 2.9 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
	Abutment diameter 4.1 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
Intergroup *p*-value			n.c		n.c		n.c

Note: Statistically significant differences were considered for $p < 0.05$. Per-protocol analysis. n.c: Statistical testing was not applicable given that observations showed identical values in both study groups.

TABLE 6 | Biological complications at the patient level.

Biological complications	Group	Baseline		6 months		12 months	
		n	Yes (%)	*n*	Yes (%)	*n*	Yes (%)
MUCOSITIS	Abutment diameter 2.9 mm	11	0 (0%)	11	3 (27.3%)	11	2 (18.2%)
	Abutment diameter 4.1 mm	11	0 (0%)	11	2 (18.2%)	11	4 (36.4%)
Intergroup *p*-value			n.c		1.00		0.63
PERI-IMPLANTITIS	Abutment diameter 2.9 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
	Abutment diameter 4.1 mm	11	0 (0%)	11	0 (0%)	11	0 (0%)
Intergroup *p*-value			n.c		n.c		n.c

Note: Statistically significant differences were considered for $p < 0.05$. Per-protocol analysis. n.c: Statistical testing was not applicable given that observations showed identical values in both study groups.

the test group. At phonation level, the mean score was 9.55 (0.93 SD) in the control group and 9.45 (0.69 SD) in the test group. Masticatory function was evaluated with a mean of 9.64 (0.67 SD) in the control group and 9.45 (0.69 SD) in the test group. Comfort was evaluated with a mean of 9.64 (0.67 SD) in the control group and 9.45 (0.69 SD) in the test group. No significant differences were found between the two groups for any of the PROs evaluated at the time of definitive prosthesis placement, at 6-month and at 12-month follow-up, $p \geq 0.05$. Aesthetics was also evaluated by two professional examiners (L.M., L.N.), with no significant differences between the groups, $p \geq 0.05$ (Table 7).

TABLE 7 | Patient-reported outcomes (PROs) and professional aesthetics assessment at baseline, 6 months, and 12 months (VAS).

		Baseline		6 months		12 months	
Patient-reported outcomes	**Group**	***n***	**Mean ± SD**	***n***	**Mean ± SD**	***n***	**Mean ± SD**
Overall satisfaction	Abutment diameter 2.9 mm	11	9.73 ± 0.47	11	9.55 ± 0.69	11	9.18 ± 0.98
	Abutment diameter 4.1 mm	11	9.64 ± 0.67	11	9.64 ± 0.67	11	9.45 ± 0.93
Intergroup *p*-value			0.45		0.87		0.60
Aesthetics	Abutment diameter 2.9 mm	11	9.09 ± 0.94	11	9.09 ± 1.51	11	8.82 ± 1.78
	Abutment diameter 4.1 mm	11	9.64 ± 0.51	11	9.73 ± 0.65	11	9.36 ± 1.03
Intergroup *p*-value			0.29		0.38		0.45
Phonation	Abutment diameter 2.9 mm	11	9.55 ± 0.52	11	9.36 ± 0.81	11	9.45 ± 0.69
	Abutment diameter 4.1 mm	11	9.73 ± 0.47	11	9.73 ± 0.65	11	9.55 ± 0.93
Intergroup *p*-value			0.66		0.37		0.29
Masticatory function	Abutment diameter 2.9 mm	11	9.55 ± 0.52	11	9.55 ± 0.69	11	9.45 ± 0.69
	Abutment diameter 4.1 mm	11	9.64 ± 0.51	11	9.73 ± 0.65	11	9.64 ± 0.67
Intergroup *p*-value			1.00		0.52		0.61
Comfort	Abutment diameter 2.9 mm	11	9.36 ± 0.67	11	9.18 ± 1.25	11	9.45 ± 0.69
	Abutment diameter 4.1 mm	11	9.55 ± 0.69	11	9.73 ± 0.65	11	9.64 ± 0.67
Intergroup *p*-value			0.66		0.38		0.61
Professional aesthetics	Abutment diameter 2.9 mm	11	7.64 ± 1.03	11	7.82 ± 1.08	11	7.27 ± 0.91
	Abutment diameter 4.1 mm	11	8.64 ± 1.36	11	7.91 ± 1.04	11	7.45 ± 1.29
Intergroup *p*-value			0.63		0.19		0.19

Note: Statistically significant differences were considered for $p < 0.05$. Per-protocol analysis.

4 | Discussion

This randomised clinical trial aimed to assess the effect of narrow and standard diameter abutments on marginal bone levels 12 months after definitive prosthesis placement. The results showed no statistically significant differences in radiographic peri-implant marginal bone levels between narrow abutments (3 mm height, 2.9 mm diameter) and standard abutments (3 mm height, 4.1 mm diameter) during the first year after the placement of the definitive prosthesis. Additionally, no significant differences were observed between groups in terms of clinical parameters, patient-reported outcomes, professional aesthetic assessment, biological or mechanical complications over the 12-month period.

The results of the present study are in line with two previous studies that found no statistically significant differences in bone remodeling at 1 year between the use of a concave macro-grooved abutment and a standard abutment (Weinlander et al. 2011; Patil et al. 2014). Although the design of these abutments differs considerably from those in the present study, with the test group abutment featuring a groove (i.e., a narrow part at the implant-abutment interface) that widens in the more coronal portion, both standard and grooved abutments demonstrated similar clinical and radiographic responses at the implant level after a 1-year observation period (Weinlander et al. 2011; Patil et al. 2014). Additionally, another clinical trial with a 3-year follow-up found no differences in the clinical variables of probing depth, bleeding on probing, plaque index, and recession when comparing a convex and a concave abutment. These results are consistent with the findings of the present study (Koutouzis et al. 2023).

On the other hand, other studies did report statistically significant differences. For instance, Bernabeu-Mira et al. (2023) found in a recent clinical trial that cylindrical abutments result in less bone remodeling and lower peri-implant marginal bone loss compared to wide abutments, with these differences reaching statistical significance at the 1-year follow-up. Similarly, another clinical trial demonstrated that early marginal bone loss (at 6 months) was significantly lower in concave abutments than in wider abutments (Perez-Sayans et al. 2022).

Other factors that can influence crestal bone loss include, among others, microleakage (Larrucea et al. 2018, Serrano et al. 2022) and abutment height (Blanco et al. 2018; Pico et al. 2019). In this study, we used implants with zero microleakage (Larrucea et al. 2018), platform-switching connections, and an abutment height of 3 mm, with a torque force of ≥ 20 Ncm.

Additionally, in the present study, it was observed that 6 months after prosthesis placement, 26.7% of the implants in the test group exhibited complete mesial papilla fill compared to 0% in the control group ($p = 0.039$). Twelve months after prosthesis placement, the differences disappeared, with the test group

showing 13.3% of complete papilla fill compared to 7.7% in the control group. Weinlander et al. (2011) reported a higher Pink Esthetic Score (Furhauser et al. 2005) for the mesial papilla in the control group (conventional convex abutment) 6 months after prosthesis placement, which was statistically significant. A systematic review found that thicker peri-implant mucosa is significantly associated with the presence of papilla, leading to an increased papilla index, less mucosal recession, and higher patient satisfaction (Bienz et al. 2022).

As a limitation of our study, although both types of abutments demonstrated adequate clinical, radiographic, and mechanical responses, long-term follow-up is needed to fully assess their impact on peri-implant marginal bone level and to detect any potential mechanical or biological complications that may arise over time. Furthermore, six patients were excluded from the per-protocol analysis due to incomplete attendance at follow-up visits. Another limitation is the imbalanced distribution of implant diameters between the two groups, which may have introduced a confounding factor influencing the outcomes.

Further long-term studies comparing abutments of different diameters are required to confirm these findings and evaluate their clinical relevance over time.

5 | Conclusions

In conclusion, despite the study's limitations, no significant differences in marginal bone levels were found between bone-level implants with narrow abutments or standard abutments after 12 months of follow-up. Furthermore, no significant differences were observed in clinical variables, patient-reported outcomes, professional aesthetic assessment, or in the occurrence of mechanical and biological complications.

Author Contributions

Antonio Liñares: writing – original draft, writing – review and editing, conceptualization, investigation, data curation. **Lucía Maceiras:** formal analysis, project administration, data curation. **Lourdes Nóvoa:** methodology, validation, data curation. **Alejandro González:** writing – review and editing. **Borja Rodríguez:** writing – review and editing. **Pilar Batalla:** conceptualization, funding acquisition. **Yago Leira:** formal analysis, methodology. **Juan Blanco:** conceptualization, funding acquisition, writing – original draft, writing – review and editing, methodology, formal analysis, supervision, resources.

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Conflicts of Interest

Juan Blanco declares that he conducts grant research with Ticare (Mozo-Grau S.A., Valladolid, Spain) through the University of Santiago de Compostela. The rest of 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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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Appendix S1:** clr70005-sup-0001-AppendixS1.doc. **Appendix S2:** clr70005-sup-0002-AppendixS2.doc.