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Marginal changes at bone-level implants supporting fixed screw-retained partial implant prostheses with or without intermediate standardised abutments: 1-year results of a randomised controlled clinical trial

Lucía Maceiras[1] | Antonio Liñares[1,2] | Lourdes Nóvoa[1] | Pilar Batalla[1] | Santiago Mareque[1] | Javier Pérez[3] | Juan Blanco[1,2]

[1]Periodontology Unit, School of Medicine and Dentistry, University of Santiago de Compostela, Santiago de Compostela, Spain

[2]Medical-Surgical Odontology (OMEQUI) Research Group, Health Research Institute of Santiago de Compostela (IDIS), Santiago de Compostela, Spain

[3]Lab Technician, Oral Design, Lugo, Spain

Correspondence
Antonio Liñares, Periodontology Unit, School of Medicine and Dentistry, C/ Entrerrios S/N, University of Santiago de Compostela, Santiago de Compostela, Spain.
Email: antonio.linares@usc.es

Funding information
Ticare®, Mozo- Grau S.A., Valladolid, Spain

Abstract

Objective: To compare marginal changes at bone-level implants restored with screw-retained implant prosthesis with or without intermediate standardised abutments, after 1 year of follow-up.

Materials and Methods: Thirty-six partially edentulous patients received 72 implants. Each patient received 2 implants and a 2- to 4-unit screw-retained implant-prosthesis. The test group received implants consisting of a screw-retained prosthesis connected directly to the implant shoulder, while the prostheses in the control group were connected through a 3-mm standardised intermediate abutment. Clinical and radiological data were recorded at baseline and at 3, 6 and 12 months in follow-up visits.

Results: At 12 months, the marginal bone loss was 0.17 ± 0.24 mm for the test group (19 patients) and 0.09 ± 0.15 mm for the control group (17 patients), with no statistically significant differences ($p > .05$). The mean probing pocket depth was 2.96 mm ± 0.46 for the test group and 2.86 ± 0.62 mm for the control group. The test and control groups showed bleeding on probing levels of 18.86 ± 14.12% and 13.73 ± 17.66%, respectively. All patients scored below 25% on the plaque index levels.

Conclusions: Restoration of bone-level implants with fixed screw-retained partial prostheses with or without intermediate abutments presented similar radiographic and clinical outcomes after 1 year.

KEYWORDS
CAD/CAM prosthesis, direct prosthesis to implant, implant-abutment connection, interproximal bone changes, marginal bone loss

1 | INTRODUCTION

The maintenance of the biological interface between soft peri-implant tissues and the dental implant (Berglundh & Lindhe, 1996; Gargiulo et al., 1961) has played a key role in the stability of peri-implant bone tissue. This biological width is reported to be similar in size to that obtained in the healthy soft tissues around teeth (Berglundh et al., 2007; Tomasi et al., 2014). However, there are several factors inherent to the implant, rehabilitation and prosthetic abutments that can interrupt or alter this protective barrier.

In the past decades, authors have suggested that marginal bone loss might be dependent on various factors, including the characteristics of the implant neck surface (Peñarrocha et al., 2004), the implant-abutment interface (micro-gap) (Canullo et al., 2009; Farronato et al., 2012; Hermann et al., 1997, 2001; Hürzeler et al., 2007; Prosper et al., 2009) or the connection/disconnection of implant abutments (Alves et al., 2015). Connection/disconnection of implant abutments can interfere with the insertion of soft tissues, compromising the marginal bone level (Abrahamsson et al., 1997; Alves et al., 2015; Koutouzis et al., 2017; Molina et al., 2017; oh, 2018). Limiting these disconnections can improve the maintenance of the crestal bone around the implants. Other factors such as the implant-abutment interface (micro-gap) (Ericsson et al., 1995), micro-movements (Canullo et al., 2010) and bacterial filtration (Broggini et al., 2016; Canullo et al., 2010, 2015) can cause an apical migration of the biological width, protecting the bone from irritation. Platform-switching connections have shown to displace the implant-abutment interface horizontally towards the centre of the platform, improving the "isolation" of the marginal bone (Atieh et al., 2010; Galindo-Moreno et al., 2016; Lazzara & Porter, 2006; Zarandi & Novin, 2017). Furthermore, distancing the abutment-prosthesis interphase (micro-gap) from the implant shoulder in a vertical direction could favour the maintenance of the peri-implant bone level (Blanco et al., 2018; Nóvoa et al., 2017; Pico et al., 2019). These studies reported higher marginal bone loss when using short intermediate abutments (<2 mm in height) than when using longer abutments (>2 mm).

Recently, a number of studies have reported the importance of the emergence angle of the prosthesis in relation to the establishment of peri-implantitis. Wide emergence angles (>30°) were a significant risk factor for establishing peri-implantitis in bone-level implants with matching platform restorations (Katafuchi et al., 2018). In contrast, Hentenaar et al. (2020) reported that the emergence angle in the first 3 mm, measured from the implant platform on platform-switched bone-level implants, had no correlation with peri-implant health or marginal bone loss.

When comparing the concepts of platform-switching connections and the use of "long" intermediate abutments, there is a lack of evidence on whether it is more appropriate to place an intermediate abutment or to construct the fixed implant prosthesis directly on the implant shoulder in terms of platform-switching implant systems.

Therefore, the aim of the present study was to evaluate marginal changes at bone-level implants restored with screwed-retained fixed partial prosthesis with or without intermediate standardised abutments.

Clinical relevance

Scientific rationale for study

The presence of a standardised abutment between the fixed dental prosthesis and the implant has been recently recommended to preserve the marginal bone level and to prevent peri-implant disease. Standardised abutments between the implant and prosthesis are used to distance the micro-gap from the implant shoulder and thereby allow the formation of the biological space. However, there is a lack of evidence in the literature on bone-level implants with directly connected prostheses and their effect on marginal bone loss.

Principal findings

The results showed no differences in terms of interproximal marginal bone-level changes or periodontal parameters when a prosthesis was connected directly to the implant shoulder versus when a 3-mm high abutment was interposed.

Practical implications

The use of customised, one-piece fixed dental prosthesis directly connected to the implant shoulder in bone-level implants and screw-retained CAD/CAM dentures could be a viable clinical alternative.

2 | MATERIALS AND METHODS

This randomised clinical trial was performed at the Periodontology Unit (School of Dentistry) of the University of Santiago de Compostela, Spain. The study protocol was accepted by the local medical research ethical committee (*Comité de ética de la investigación con medicamentos de Galicia* [2019/193]) following the CONSORT 2010 guidelines. The clinical trial was registered at the U.S. National Institutes of Health (Clinicaltrials.gov: NCT04369170).

2.1 | Study population

All participants were selected from the patients treated in the Periodontology Unit of the University of Santiago de Compostela. All patients were recruited and treated between May and October 2019. Additionally, all participants signed an informed consent form and were treated in agreement with the Declaration of Helsinki.

2.2 | Recruitment criteria

The patients were selected based on the following inclusion criteria:

- >18 years of age.
- Plaque index lower than 25%.
- Absence of at least two adjacent teeth, with natural proximal teeth, excluding the anterior upper zone, allowing rehabilitation with screwed-retained fixed partial prostheses over two implants and 2–4 prosthetic units.
- Adequate bone quantity to place implants with diameters of 3.75 mm or 4.25 mm and lengths of 8, 10 and 11.5 mm, without any hard/soft tissue grafting procedures.
- Natural antagonist teeth or implants with fixed restorations.

Patients were excluded based on the following criteria:

- Systemic factors:
  - Long-term use of systemic medication that could interfere with bone metabolism or medical conditions that require prolonged use of steroids and/or medication that might interfere with bone metabolism.
  - History of leucocyte dysfunction and deficiency, immunodeficiency syndromes, renal failure or bone metabolic disorders such as osteoporosis.
  - Physical disabilities that interfere with proper oral hygiene.
  - Use of any medication or device under study for a period of 30 days prior to the implant surgery in the study.
  - Alcoholism or drug abuse.
  - Smoker of more than 10 cigarettes per day.
  - Conditions or circumstances that could prevent compliance with study participation or interfere with the analysis of the results, such as a history of non-compliance or lack of reliability.
- Local factors:
  - History of local radiotherapy.
  - Bruxism, considered according to clinical signs of tooth wear.
  - Mucosal diseases, such as oral lichen planus.
  - Untreated periodontitis.
  - Persistent intraoral infection (e.g., apical periodontitis and other untreated infectious lesions of endodontic origin).
  - Unhealed extraction sockets (less than 12 weeks post-extraction).
  - Rehabilitation is needed on the anterior sextant of the maxilla.

2.3 | Sample size

Changes in the peri-implant bone level at 12 months were considered the primary endpoint, and an estimated mean intergroup difference of 0.80 mm (Blanco et al., 2018) was used to calculate the test group size with a standard deviation (SD) of 0.715 (Nóvoa et al., 2017). This estimate, with an alpha risk of 5% and a statistical power of 85%, resulted in a sample size of 30 participants. Assuming a potential drop-out rate of 20%, 36 patients were targeted for inclusion.

2.4 | Pre-treatment

Each patient's medical history and clinical and radiographic data were recorded. All participants underwent radiographic and surgical splints and cone-beam computed tomography analysis. An individualised film holder was designed for each patient to store the reproducible and comparable radiographs. Once the patients agreed to participate in the study, they received a full-mouth prophylaxis, consisting of one session of oral hygiene instructions and supragingival and subgingival debridement.

2.5 | Surgical intervention

The surgical procedures were performed under local anaesthesia (lidocaine 20 mg/mL plus epinephrine 0.0125 mg/mL; Inibsa Dental) by two operators (AL, JB). A mid-crestal incision was performed to obtain at least 2 mm of keratinised tissue at the buccal implant sites. The soft tissue height of the mucosa was measured with a periodontal probe (15 mm; PCP-UNC 15, Hu-Friedy) after raising the buccal flap. Osteotomy was performed following the manufacturer's instructions. The implants used in this study were bone-level implants with a platform-switching connection and a tapered design (Ticare Inhex, Mozo-Grau, S.A.; Resorbable Blast Media RBM TC surface, moderately rough, R_a = 1.2–1.5 μ). The implant parameters were 3.75 and 4.25 mm in width and 8–11.5 mm in length. The implants were installed 2 mm below the crest, measured on the buccal side. All implants received a 2-mm high cover screw (Ticare Inhex, Mozo-Grau, S.A.) and the mucoperiosteal flaps were repositioned to allow submerged healing and sutured with Supramid 5/0 (Aragó; Figure 3). Photographs and radiological data were taken, and the patients were instructed to rinse twice a day with chlorhexidine 0.12% + 0.05% cetylpyridinium chloride (Perio-Aid) for 2 weeks. Anti-inflammatory drugs (ibuprofen 600 mg every 8 h for 4 days) and systemic antibiotics (amoxicillin 500 mg + clavulanic acid 125 mg/8 h for 7 days) were prescribed. Sutures were removed 7 days after the surgery.

2.6 | Second-stage surgery, randomisation and restorative procedures

After 8 weeks of submerged healing, second-stage surgery was performed by two blinded operators (AL and JB) to expose the implants. Definitive impressions with custom open impression trays were taken with a polyether material (Impregum Penta Soft, 3 M ESPE Dental Products). Impression posts (Ticare Inhex, Mozo-Grau, S.A.) were directly screwed to the implant shoulder in both groups, without splinting. Patients were randomly allocated at a 1:1 ratio (person in charge, LM) using a simple allocation system, employing

SPSS software, version 20.0 (SPSS Inc.) in two treatment groups as follows:

- Test group: implants restored with a customised one-piece screw-retained computer-aided design (CAD)/computer-aided manufacturing (CAM) fixed dental prosthesis (FDP) connected directly to the implants
- Control group: implants restored with a screw-retained, CAD/CAM FDP connected to a standardised intermediate 3-mm high abutment to the implant shoulder.

Random allocation was performed with a closed opaque envelope containing the code obtained from the randomisation list provided by the SPSS software. The content of the envelope was revealed after the definitive impression was taken and before the order to the dental technician was delivered. This resulted in 19 patients in the test group and 17 in the control group.

Transmucosal healing abutments were placed in both groups while the prostheses were manufactured (Ticare Inhex, Mozo-Grau, S.A.). All definitive prostheses were digitally designed and manufactured (CAD/CAM), and porcelain was fused to metal frameworks. Once the master cast was obtained from the definitive impressions, a DCM file was obtained with a lab scanner (D1000, 3Shape). The test group implants were scanned with original Ticare scanbodies directly connected to the implant analogues. For the control group implants, intermediate abutments were connected to the implant analogues with 30 N of torque. Next, the original Ticare scanbodies were connected to the intermediate abutments for the scanning. Digital software (Dental System, 3Shape) was used to design the prosthetic structures. This design involved the same emergence profile for the test group prostheses as for the control group and was sent as a file to the milling facility (Ticare Biocam, Mozo-Grau S.A.) where the superstructure was produced. The test group prostheses (connected directly to the implant shoulder with a purely internal connection, without any seating on the implant shoulder) were manufactured in a cobalt-chromium (Co–Cr) milled framework connected to implants by a non-engaging 11° morse-cone connection. These prostheses were connected to the implants with a final torque of 30 N. The control group received a standardised grade V titanium abutment, 10° tapered, with a non-engaging morse-cone connection. The definitive prostheses connected to the standardised abutment were manufactured in a Co–Cr milled framework and connected to the standardised abutment by an engaging 11° internal connection. Abutments in the control group were screwed with a torque of 30 N (connected to the implant shoulder with a purely internal connection, without any seating on the implant shoulder) while the definitive prostheses of this group were joined with a final torque of 20 N. Once the frameworks were received from the milling facility, conventional veneering protocols for porcelain fused to metal bridges were applied. The occlusion scheme selected for all prostheses was centric occlusion with no contact in eccentric movements. Thus, no testing of the framework or the crown's size and shape was performed. Four weeks after the definitive impressions, the prostheses were produced and installed as described above. This visit was considered the control appointment for the purposes of the study. All patients received oral hygiene instructions with the new prosthesis. During this visit, clinical and radiological data were recorded. These data were also obtained at 3, 6 and 12 months after the control visit. Figures 1 and 2 show a flowchart diagram and the CONSORT flow diagram of the study protocol. Figure 3 shows follow-up X-ray images of the test and control cases, and Figure 4 shows the clinical pictures of the same cases as shown in Figure 3.

2.7 | Main variables

2.7.1 | Radiographic evaluation

Changes on the marginal peri-implant bone level were evaluated using a standardised intraoral radiographic technique with a customised film holder for each patient (Rinn holder, silicone key). This technique was used on each visit, and periapical radiographs were taken using the long-cone paralleling technique. A phosphor plate X-ray (Durr Dental) and an X-ray tube (Planmeca) with the same setting for each patient were employed. Two independent and calibrated examiners (L.M., L.N.) measured the distance from the implant shoulder (IS) to the first bone-implant contact (BIC), both in the mesial and distal surfaces of the implant, to the nearest 0.1 mm, using IMAGE

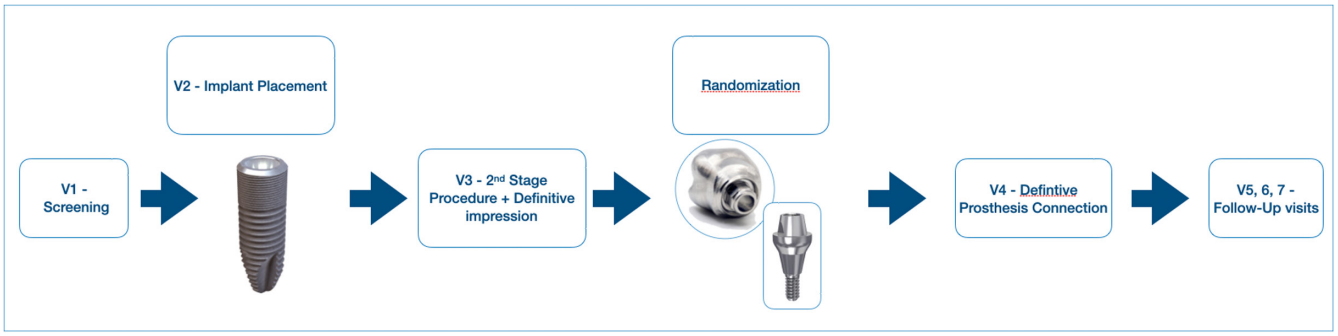
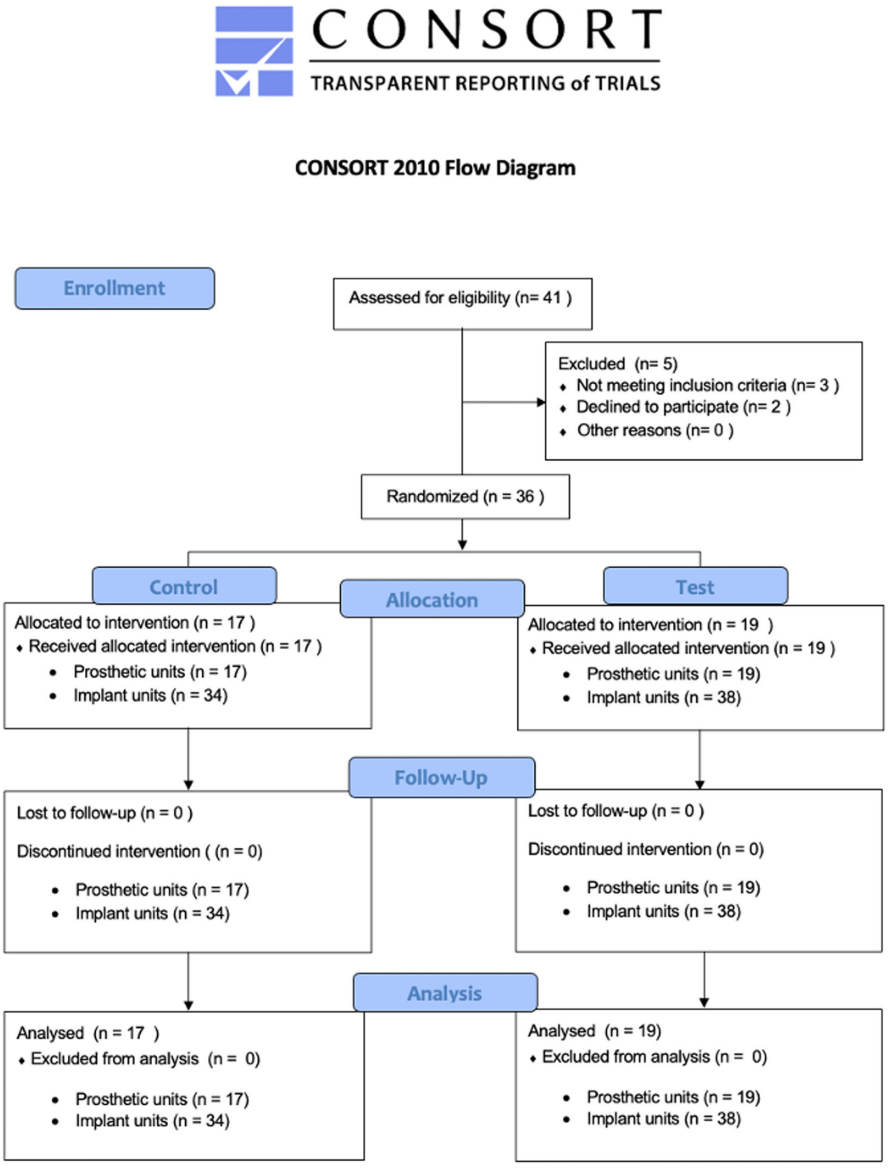


FIGURE 1 Flowchart diagram of the study protocol.

FIGURE 2 CONSORT guidelines flowchart.



J software (1.47V Wayne Rasband; National Institutes of Health). The mean of the two measures was calculated. All radiographs were scaled by the dental implant's height, which yielded a pixel/mm ratio. Changes in the interproximal peri-implant bone levels were calculated between definitive prosthesis connection (baseline), and at the 3, 6 and 12-month follow-ups after baseline (Figures 3 and 4).

2.7.2 | Clinical evaluation

Periodontal parameters such as probing pocket depth (PPD), plaque index (Mombelli, 1987) and bleeding on probing (BOP; Mombelli, 1987) were recorded for each implant at 6 location sites (mesio-buccal, mid-buccal, disto-buccal; mesio-lingual, mid-lingual and disto-lingual). Moreover, data regarding the implant surgery such as implant location, insertion torque (N), bone density (as assessed by the two expert surgeons according to Lekholm & Zarb, 1985), and gingival thickness were also recorded.

2.7.3 | Patient reported outcomes (PROs)

Patient-reported outcomes (PROs) were recorded using a numeric scale during the follow-up visits. Participants rated the following aspects from 0 (lowest) to 10 (highest): general satisfaction, aesthetics, comfort, phonetics and masticatory function (de Bruyn et al., 1997; Jokstad, 2018). Patients were classified according to their smoking status as smoker or non-smoker.

2.8 | Statistical analysis

The primary outcome measure was changes in the peri-implant marginal bone level (IS-BIC). Secondary outcomes included mean changes in PPD, BOP and PROs during the trial's follow-up. A reliability analysis was performed using the intraclass correlation coefficient with a two-way random effects model (absolute agreement). For the descriptive analysis of the variables, mean, standard

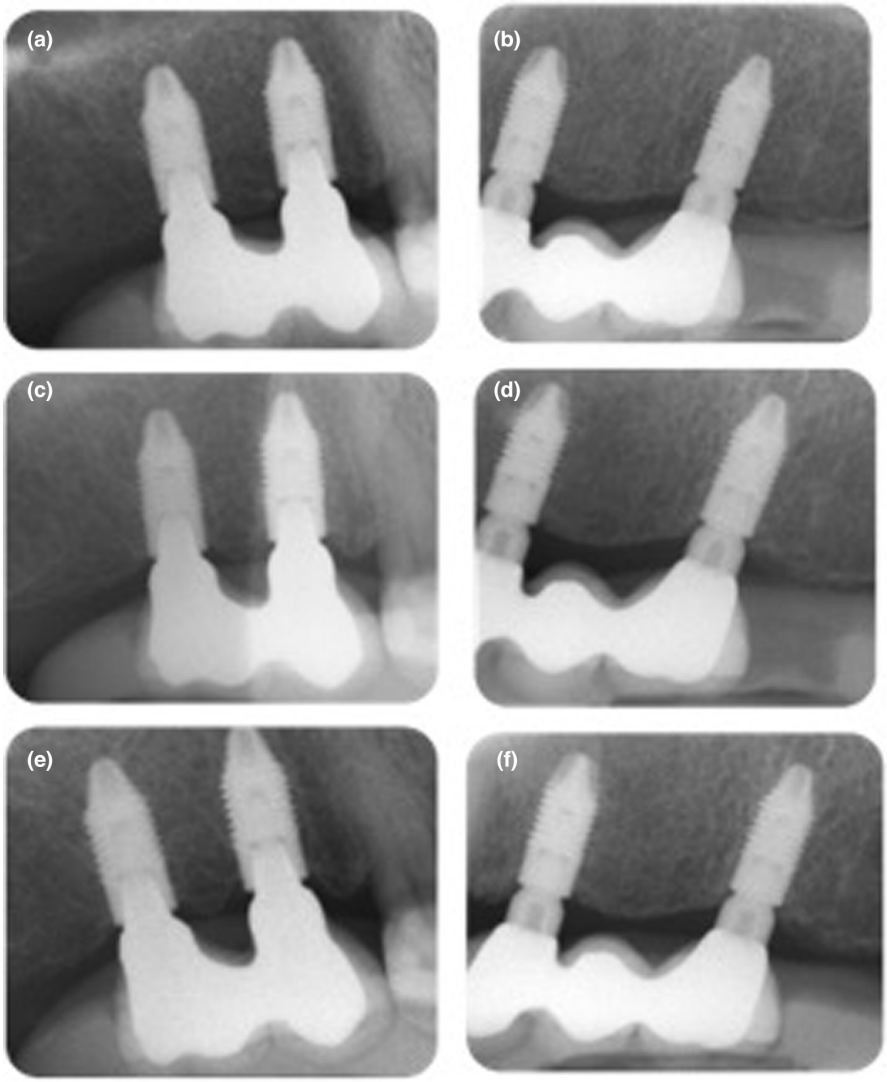


FIGURE 3 Follow-up periapical radiographs from test and control group. (a) Basal, test group; (b) basal, control group; (c) 6 months, test group; (d) 6 months, control group; (e) 12 months, test group; (f) 12 months, control group.

deviation and median values were calculated. To test the differences between the test and control groups, we used the analysis of variance of mixed design (mixed ANOVA) when repeated measurements of the main variable (IS-BIC) were performed on the patients. We also used the mixed ANOVA for the secondary variables. To observe the effect of gingival thickness and presence/absence of a pontic, we also used the mixed ANOVA, selecting subgroups within the primary endpoint and including other significant variables within the model. PROs at 12 months were compared between groups using Student's *t*-test. Results were considered statistically significant at $p < .05$. All analyses were performed using SPSS software.

3 | RESULTS

Thirty-six partially edentulous patients from the Periodontology Unit of the University of Santiago de Compostela were included in this study (Figure 1). Table 1 displays the included patients' demographic data, implant distribution, bone density, smoking habits and prosthesis design. None of the implants showed clinical sings of inflammation, pain or mobility and all patients completed the follow-up evaluation, resulting in a survival rate of 100%. Only two patients included in the study were smokers (<10 cigs/day; 5.5%).

3.1 | Radiographic evaluation of interproximal bone level

The reliability analysis provided an intraclass correlation coefficient of 0.96 (0.91–0.99), thereby demonstrating highly significant reproducibility between the examiners in the interproximal bone level variable.

The mean interproximal bone level at baseline was 0.13 mm ± 0.15 mm for the control group and 0.10 ± 0.13 mm for the test group. At the 12-month follow-up, the mean interproximal bone level was 0.09 ± 0.15 mm in the control group and 0.17 ± 0.24 mm in the test group (Table 2). There were no significant differences between the test and control groups [$F(1, 34) = 0.86$; $p > .05$; partial eta squared, 0.03 (Levene's Test of Equality of Error Variances, $p > .05$)]. There was no significant interaction between groups and visits in terms of peri-implant marginal bone level [intragroup analysis: $F(2.11, 71.68) = 1.99$; $p > .05$; partial eta squared, 0.06; Mauchly's Test

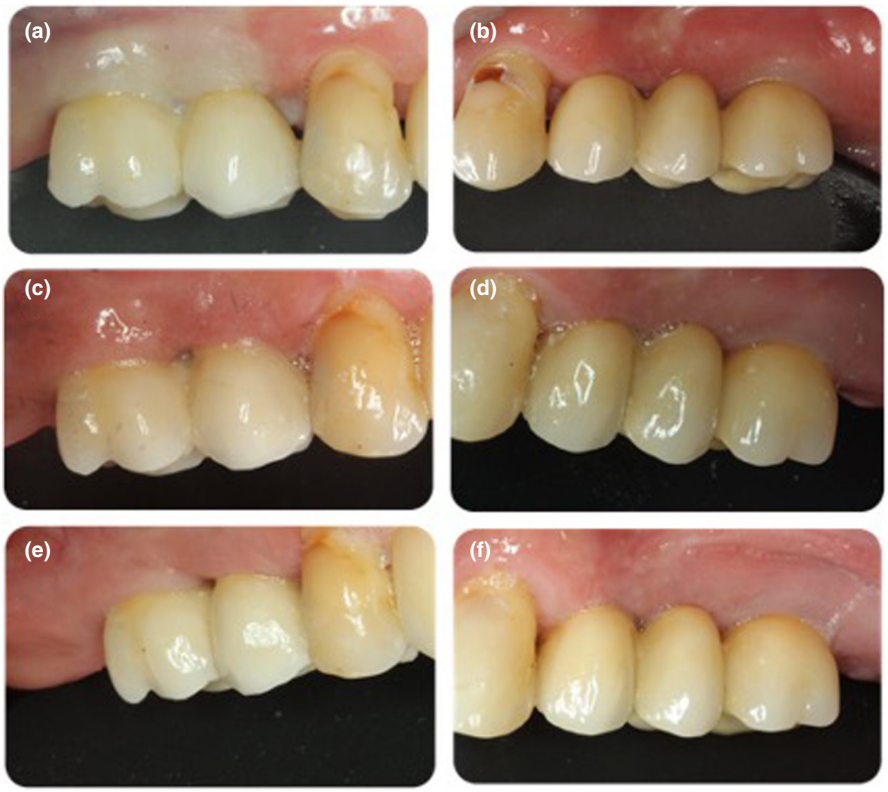


FIGURE 4 Follow-up clinical photographs from test and control group. (a) Basal, test group; (b) basal, control group; (c) 6 months, test group; (d) 6 months, control group; (e) 12 months, test group; (f) 12 months, control group.

of Sphericity, 0.05; partial eta squared = 0.07]. There was only one patient with marginal bone loss over 1 mm (1.52 mm at 3 months, 2.01 mm at 6 months and 1.89 mm at the 12-month follow-up). All other patients showed marginal bone loss of less than 1 mm in all follow-up visits. The frequency distribution is shown in Table 3.

3.2 | Clinical parameters

At baseline, the PPD for the control and test groups was 2.67 ± 0.35 mm and 2.52 ± 0.65 mm, respectively. The mean BOP score for the control and test groups was 12.25% ± 12.88% and 8.33% ± 17.12%, respectively. Twelve months after the connection of the definitive prosthesis, the control group showed a PPD of 2.86 ± 0.62 mm and a BOP score of 13.73% ± 17.66%, while the test group showed a PPD of 2.96 ± 0.46 mm and a BOP score of 18.86% ± 14.12%. There were no significant differences between groups, no significant interaction between PPD and visits, or between BOP factors and visits in the peri-implant marginal bone level in the intragroup analysis and no significant main effect for PPD and BOP factors in the intragroup analysis (Table 4). All patients were on a periodontal maintenance programme and scored below 25% in the plaque index in all follow-up visits (Table 4).

An adjusted analysis, including gingival thickness and presence/absence of a pontic in the model with mixed ANOVA, was performed. There was no significant interaction between groups and visits in the peri-implant marginal bone level in the group and gingival thickness variables and no significant differences between groups [F (1, 32) = 0.78; $p > .05$; partial eta squared, 0.01].

There was no significant interaction between groups and visits in peri-implant marginal bone level in the group and presence/absence of pontic variables and no significant differences between groups [F (1, 32) = 0.09; $p > .05$; partial eta squared, 0.01].

3.3 | Patient-reported outcomes (PROs)

In terms of PROs at 12 months after connecting the definitive prostheses, most patients included in this trial reported very high levels of satisfaction. The mean score for general satisfaction in the PROs was 9.42 (SD 0.87) for the test group and 9.53 (SD 0.96) for the control group ($p = .727$). The mean score for the aesthetic variable in the PROs was 9.16 (SD 1.19) for the test group and 9.0 (SD 1.37) for the control group ($p = .706$). The mean score for the comfort variable in the PROs was 9.16 (SD 1.26) for the test group and 9 (SD 1.37) for the control group ($p = .721$). The mean score for the phonetics variable in the PROs was 9.16 (SD 1.17) for the test group and 9.35 (SD 0.93) for the control group ($p = .586$). The mean score for masticatory function in the PROs was 9.16 (SD 1.34) for the test group and 9.18 (SD 1.01) for the control group ($p = .964$). There were no statistically significant differences between the groups in any of the variables compared.

4 | DISCUSSION

The aim of this clinical trial was to evaluate whether the use of a customised, one-piece, screw-retained, CAD/CAM, partial FDP, when

compared with an intermediate, standardised abutment, screw-retained, CAD-CAM FDP would lead to changes in the marginal interproximal bone level on bone-level implants 12 months after the connection. The results showed no significant differences in terms of interproximal marginal bone level changes when the customised one-piece FDP was used versus when a standard 3-mm high abutment was inserted. In terms of the periodontal parameters, the study showed no differences between the groups.

The present study showed no differences between direct-to-implant restorations and a standardised abutment connection, a finding that disagrees with the results of other recent studies in which less marginal bone loss was found on prostheses with standardised abutment rather than prostheses directly connected to implants (Göthberg et al., 2014, 2018; Hernández-Marcos et al., 2018; Serino & Hultin, 2019; Toia et al., 2019). The 5-year study by Göthberg was performed on implants with no platform-switching connections, and with an immediate loading protocol. This approach could have affected the results presented by the authors when compared to the present study. Nevertheless, the present investigation had a relatively short follow-up (1 year); consequently, longer follow-up assessments of the present investigation might show different results.

The study most similar to the present investigation (Toia et al., 2019) showed improved results at 1 year for the group with standardised abutments. However, the report mentions no abutment height data. A micro-misfit between the superstructure and implant is more likely at the implant level than at the abutment level, which could have affected the results of the aforementioned study. In the present investigation, however, the implants were installed 2 mm subcrestally, and it appears that in the Toia study, the implants were installed equicrestal in relation to the implant neck design (EV, OsseoSpeed EV Astra Tech Implant System, Dentsply Sirona Implants, Mölndal, Sweden) with a tilted profile. In fact, Blanco et al. (2018) reported that the vertical dimension of the transmucosal abutment is a factor associated with peri-implant marginal bone loss. Despite platform switching, greater peri-implant marginal bone loss was found when short, standardised abutments were used (Nóvoa et al., 2017). The use of 3-mm high abutments led to minimised vertical bone loss related to implant placement, results confirmed by a recent randomised clinical trial with a 1-year follow-up

TABLE 1 Demographic data and patient's characteristic.

	Control group ($n = 17$)	Test group ($n = 19$)
Age (mean [SD])	59.88 (1.63)	60.84 (1.33)
Gender (*n*, female/male)	3/14	6/13
Smokers (<10 cig/day)	1 (5.8%)	1 (5.2%)
No of implants	34	38
Gingival thickness (mean [SD]) (mm)	2.54 (0.62)	2.75 (1.22)
Bone density (per implant)	($n = 34$)	($n = 38$)
I	2 (5.8%)	7 (18.4%)
II	17 (50%)	14 (36.8%)
III	11 (32.3%)	13 (34.2%)
IV	4 (11.8%)	4 (10.5%)
Prosthesis location	($n = 17$)	($n = 19$)
Maxilla posterior	7	6
Mandible posterior	8	13
Mandible anterior	2	0
Prosthesis design	($n = 17$)	($n = 19$)
Presence of 1 Pontic	4 (23.5%)	4 (21.1%)
Presence of 2 Pontics	2 (11.8%)	0
Two splinted crowns	11 (64.7%)	15 (78.9%)

TABLE 3 Frecuency distribution of periimplant marginal bone loss.

Peri-implant marginal bone loss distribution		
	Control group	Test group
PBL (mm)	Cases ($n = 34$)	Cases ($n = 38$)
0–0.2	30 (88.23%)	27 (71.05%)
0.21–0.4	1 (2.94%)	6 (15.80%)
0.41–0.6	1 (2.94%)	4 (10.52%)
0.61–0.8	1 (2.94%)	0
0.81–1.0	1 (2.94%)	0
1.01–1.2	0	0
1.21–1.4	0	0
1.41–1.6	0	0
1.61–1.8	0	0
1.81–2.0	0	1 (2.63%)

TABLE 2 Periimplant marginal bone level: Distance from the implant shoulder to the first bone-to-implant contact (IS-BIC) (mm) during four visits in control and test group.

Descriptive statistics	Control group			Test group			
Visits	*N*	Mean (mm)	SD	*N*	Mean (mm)	SD	Between-groups
Baseline	17	0.13	0.15	19	0.10	0.13	No significant differences: $F(1, 34) = 0.86$; $p > .05$; Partial Eta Squared = 0.03
3 months	17	0.14	0.17	19	0.20	0.19	
6 months	17	0.13	0.15	19	0.22	0.25	
12 months	17	0.09	0.15	19	0.17	0.24	

TABLE 4 Clinical parameters during four visits in control and test group.

		Baseline		3 months		6 months		12 months	
	n	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Probing pocket depth (mm)[a]									
Control group	17	2.63	0.09	3.04	0.53	3.03	0.48	2.86	0.62
Test group	19	2.52	0.65	3.42	0.55	3.49	0.65	2.96	0.46
Bleeding on probing (%)[b]									
Control group	17	12.25	12.88	14.03	17.43	27.94	23.93	13.73	17.66
Test group	19	8.33	17.12	20.01	19.07	21.93	21.38	18.86	14.12
Plaque index (%)[c]									
Control group	17	0	0	8.3	3.5	21	8.9	13.8	6.5
Test group	19	0	0	3	1.5	4.3	2.9	0	0

Abbreviations: BOP, Bleeding on Probing (%); PI, Plaque Index (%); PPD, Probing Pocket Depth (mm).

[a]No significant differences between test group and control group $F(1, 34) = 1.81$; $p > .05$; Partial Eta Squared = 0.05.

[b]No significant differences between test group and control group $F(1, 34) = 0.28$; $p > .05$; Partial Eta Squared = 0.01.

[c]No significant differences between test group and control group $F(1, 34) = 5.77$; $p > .05$; Partial Eta Squared = 0.15.

(Pico et al., 2019). The use of long intermediate standard abutments (3-mm high) prevented the roughly 1 mm of extra marginal bone loss that occurred in the group in which shorter intermediate abutments were used (1 mm height).

The authors also recommended placing the implants subcrestally in cases with thin mucosa to prevent aesthetic complications; thereby ensuring the vertical biological width (Pico et al., 2019). The height of the peri-implant mucosa at surgery (after flap elevation at implant installation) in the present investigation was 2.54 ± 0.62 mm in the control group and 2.75 ± 1.22 mm in the test group. We considered that thin peri-implant mucosa is associated with greater marginal peri-implant bone loss (Lombardi et al., 2019; Pico et al., 2019) due to an insufficient vertical dimension for creating the biological space. These results agree with those presented by Linkevicius et al. (2009), who presented a relationship between thin (<2 mm) mucosa around implants and greater vertical bone loss. Thus, a supra or equicrestally placed implant surrounded by thin mucosa could lead to more peri-implant marginal bone loss.

The present investigation showed that most peri-implant marginal bone loss occurred during the first 3 months, agreeing with the results reported in the literature (Aimetti et al., 2015; Froum et al., 2018). This fact could be related to the establishment of the biological width space and consequent bone healing. Nevertheless, as shown in our results, there was one patient in the test group who displayed a marginal bone loss of 1.89 mm at the 12-month follow-up visit, which might be related to the fact that this patient was the only smoker in the test group.

Katafuchi et al. (2018) reported that an emergence angle profile greater than 30° was a significant risk factor for peri-implantitis for platform-matching bone-level implants. The authors also suggested that platform-switching implants will increase that risk even further due to the larger emergence angle. Hentenaar et al. (2020) found no correlation between the emergence angle and peri-implantitis in platform-switching bone-level implants. In addition, short abutments were used in both of the aforementioned studies, where the prosthetic crown started close to the implant shoulder.

Although the emergence angle was not a variable in the present investigation, we ensured that the prosthetic design of both groups was similar (test group: 22.34° ± 1.47; control group: 22.35° ± 1.52; no statistically significant differences between the groups).

When peri-implant marginal bone loss was compared as a function of demographic and clinical factors such as the presence/absence of pontics, position of the prosthesis and gingival thickness, there were no statistically significant differences in any of the follow-up visits. The statistically significant differences found in the smokers versus non-smokers could be biased due to the presence of two smokers (one in each group).

The presence of marginal microleakage due to the micro-gap is an important risk factor for peri-implant disease. Larrucea Verdugo et al. (2014) examined the in vitro presence of microleakage on both internal and external connection implants on the implant/abutment interface, concluding that Morse tapered internal connections tightened with 30 N of torque showed less microleakage than external connections. Moreover, the same group tested in vitro the same implants installed in the present investigation (Ticare Inhex, Mozo-Grau, S.A.), showing that at more than 20 N of torque no patency could be found in the implant/abutment micro-gap (Larrucea, 2018). These results confirmed the clinical data presented by Koo et al. (2012) and the results presented by Göthberg et al. (2014, 2018), given the authors used external connection implants. Thus, greater marginal bone loss could be expected in all of that study's groups.

All abutments and connections used in this study were original. Alonso-Pérez et al. (2018) showed that although there were no significant differences in terms of misfit, the original abutments showed the best accuracy for the components and smaller gaps between the crown and abutment. There were no statistically significant differences when static load was compared, but original components showed higher levels. These results were confirmed

by Tallarico et al. (2018) who reported significantly higher reverse torque and removal torque with original abutments. Moreover, non-original abutments showed significant micro-movements and a higher misfit, potentially causing micro-leakages. The authors therefore concluded that original abutments presented a lower incidence of mechanical failure and higher marginal accuracy.

Abrahamsson et al. (1998) analysed the influence of abutment material on peri-implant tissues by comparing titanium, aluminium oxide and gold alloy abutments. The results showed that titanium and aluminium oxide abutments had similar results, allowing the formation of a healthy mucosal attachment. However, gold and porcelain-fused-to-gold abutments showed a statistically higher marginal bone loss and more recession than the previous abutments. These results were subsequently confirmed by Welander et al. (2008). In a 2008 systematic review, Linkevicius and Apse (2008) showed that when zirconium was compared with titanium there were no differences in terms of the reaction of the peri-implant tissues. In this study, all prosthesis were made with a Co–Cr alloy, but the abutments of the control group were made of titanium. Kayikci and Ates (2021) tested the internal and external fit of 3-unit implant-supported fixed prosthetic substructures fabricated using CAD/CAM systems in an in vitro study. The authors observed no statistically significant differences between these two materials, and the internal and external fit found in the two study groups were within acceptable clinical limits.

This study has a number of limitations that should be considered. A 1-year follow-up is relatively short, and longer follow-ups are needed to evaluate the actual effect of the connection on marginal bone loss. Toia et al. (2022) showed that intergroup differences disappeared after a longer follow-up period, and the presence of an intermediate abutment could have limited clinical relevance. In this study, each participant received only a two implant-supported prosthesis, and implants were placed as parallel as possible by two experienced surgeons. However, it is feasible that a perfect fit between the superstructure and the implants is easier to reach at the abutment level than directly to the implants. More studies with fixed prostheses supported by more than 2 implant units (such as a full-arch prosthesis) are needed.

5 | CONCLUSIONS

Considering this study's limitations, we conclude that when using bone-level implants with internal connection and a submerged healing protocol, the CAD/CAM prosthesis directly connected to implants showed similar clinical parameters, PROs and marginal bone level changes at the 1-year follow-up to those in which standardised 3-mm high abutments were used.

AUTHOR CONTRIBUTIONS

Lucia Maceiras: Conceptualization (equal); data curation (equal); formal analysis (equal); methodology (equal); writing – original draft (equal). **Antonio Liñares:** Investigation (equal); methodology (supporting); supervision (supporting); writing – review and editing (supporting). **Lourdes Nóvoa:** Data curation (equal); formal analysis (equal); methodology (equal). **Pilar Batalla:** Funding acquisition (equal); project administration (equal); resources (equal). **Santiago Mareque:** Investigation (equal); supervision (equal). **Javier Pérez:** Resources (equal), Software (equal), Writing – Review & Editing (equal). **Juan Blanco-Carrión:** Funding acquisition (lead); investigation (lead); methodology (lead); project administration (lead); supervision (lead); validation (lead); writing – review and editing (lead).

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CONFLICT OF INTEREST STATEMENT

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.

ORCID

Lucía Maceiras https://orcid.org/0000-0001-5334-3232
Antonio Liñares https://orcid.org/0000-0003-1611-5884
Lourdes Nóvoa https://orcid.org/0000-0002-7843-5229
Pilar Batalla https://orcid.org/0000-0002-7661-1452
Santiago Mareque https://orcid.org/0000-0002-9308-9002
Juan Blanco https://orcid.org/0000-0001-9251-513X

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