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ORIGINAL ARTICLE

Titanium vs ceramic single dental implants in the anterior maxilla: A 12-month randomized clinical trial

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Abstract

Objective: The aim of this randomized clinical trial was to compare ceramic and titanium implants with respect to the esthetic and clinical parameters, and patient-reported outcome measures (PROMs).

Material and methods: Thirty patients received thirty implants (8–12 mm in length, 3.3 mm diameter, and a tissue level design) to replace single teeth in the anterior maxilla. Patients were randomly allocated to receive a ceramic or a titanium implant. Esthetic, clinical parameters, and PROMs were evaluated 18 months after surgery.

Results: At 12 months post-final loading, there were no significant differences between groups with respect to esthetics. Mean Index Crown Aesthetic score was 6.31 (95% C.I. 4.59–8.04) and 6.07 (95% C.I. 4.21–7.93) for ceramic and titanium implants, respectively. The pink esthetic score (PES) was 7.81 (95% C.I. 6.90–8.73) for ceramic implants and 7.86 (95% C.I. 7.11–8.60) for titanium implants, with no significant differences between groups. No statistically significant differences were found for any of the other clinical parameters and PROMs.

Conclusions: Monotype ceramic implants have proven to be a good treatment option in the upper anterior sector, showing favorable esthetic results, being comparable to titanium implants.

This clinical trial has been registered in clinical trials with the identifier CI_RCT_US16 and registration number NCT04707677. A retrospective registration of the clinical trial was carried out since registration was not mandatory on the date the study began.

KEYWORDS

dental implants, esthetics, humans, randomized controlled trial, zirconium

1 | INTRODUCTION

Dental implant treatment has proven to be a predictable option, with high survival and success rates in the long-term (Buser et al., 2012). However, these data are based on titanium implants. The use of this material in the esthetic zone may imply a risk of discoloration of peri-implant soft tissues, being able to observe a grayish-colored peri-implant soft tissue. (Pitta et al., 2020; Thoma et al., 2016), especially at sites with a thin phenotype. Perceivable differences in relation to the reflection of light have been observed between zirconia and titanium abutments, when the thickness of the mucosa is less than 2 mm (van Brakel et al., 2011). Moreover, patient's increasing demand for non-metallic restoration and the possible hypersensitivity reactions reported on titanium (Sivaraman et al., 2018) have led to a search for alternative materials.

Allergic reactions to titanium in oral implantology are very rare but signs such as erythema, urticaria, eczema, swelling, pain, necrosis, and bone loss due to titanium dental implants have been

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described in the literature (Kim et al., 2019; Müller & Valentine-Thon, 2006; Valentine-Thon et al., 2006). It is known that patients with a history of metal allergy have a higher risk of developing allergy to titanium implants (Chaturvedi, 2013). In a clinical study in 2008, 1,500 patients who received dental implants were examined to evaluate the presence of titanium allergy, and a 0.6% prevalence was observed in these patients (Sicilia et al., 2008).

In a 3-year retrospective study of ceramic implants in 2013, it was observed that these implants showed excellent biocompatibility with very positive esthetic results, but it was also observed that the surface treatment of these implants had to be significantly improved to achieve an osseointegration comparable to titanium implants. In addition, 12 implant fractures with a reduced diameter were reported (Gahlert et al., 2013). Thanks to the evolution of zirconia as a material for dental implants and its surface treatment, results have been improved. Recent studies have shown an excellent biocompatibility that allows a good integration of hard and soft tissues and excellent mechanical properties (Bormann et al., 2012; Depprich et al., 2008; Liñares et al., 2016; Roehling et al., 2019; Stadlinger et al., 2010). Similar results regarding removal torque have been observed, with reported values ranging from 12 to 98 Ncm for ceramic implants, and 42–74 Ncm for titanium implants (Gahlert et al., 2009; Kohal et al., 2004; Scarano et al., 2003; Sennerby et al., 2005). In fact, the ability of ceramic implants to withstand loading has been substantially improved, becoming comparable to that observed in titanium implants. It has been reported that the dynamic load significantly increases the fracture resistance of ceramic one-piece implants (Kohal et al., 2006). The percentages of BIC (bone-implant contact) of ceramic implants have proven to be very similar to those found in titanium implants, between 64% and 68% at 4 weeks after placement. In a minipig model (Liñares et al., 2016) comparing soft and hard tissue healing at tissue level titanium versus. ceramic implants showed at 8 weeks 85% of BIC% for titanium and ceramic implants with a SLA (sandblasting and acid-etched) and ZLA (zirconia sandblasted and acid-etched) surface, respectively. Moreover, the distance from implant shoulder to first bone-to-implant contact was similar in both groups. In terms of soft tissue healing, no difference in peri-implant mucosa height was found; however, the sulcular epithelium was significantly shorter for the ZrO2. In fact, another noteworthy aspect of ceramic implants is that they have demonstrated the ability to inhibit bacterial adhesion and a lower inflammatory response, which favors the integration of soft tissues (Liñares et al., 2016; Nickenig et al., 2012).

Thus, ceramic implants may represent a valuable alternative to titanium implants. However, not many clinical trials comparing zirconia and titanium implants are available yet.

In recent years, much attention has been focused on the esthetic aspect of peri-implant tissues, also defined as “pink esthetics.” This is due to the search for excellence in our treatments, at the same time, to an increase in the demand for esthetics by our patients. Although the perception of esthetics may be rather subjective, a series of parameters are considered to be important factors to achieving an esthetically pleasant result, such as the interproximal papilla, the level of the mucosa, and the contour and texture of the tissues. Different studies that analyze these parameters have compared the esthetics between titanium and zirconium abutments. In these analyzes, esthetics were evaluated through indices and scoring systems and they show how titanium abutments induce greater discoloration of the tissues than ceramic abutments. These results support the use of ceramic materials in cases of high esthetic demand (Carrillo de Albornoz et al., 2014; Jung et al., 2008; Pitta et al., 2020).

The aim of this randomized clinical trial was to compare the esthetic, clinical, and patient-reported outcome measures (PROMs) between ceramic and titanium implants in the anterior maxilla.

2 | MATERIAL and METHODS

2.1 | Study design and patient selection

The study was a double-blinded randomized controlled clinical trial (RCT), with a parallel design, comparing ceramic (test group) and titanium (control group) implants, for the replacement of a single-tooth in the anterior maxilla.

To calculate the sample size, a previous clinical study (Carrillo de Albornoz et al., 2014) was used in which titanium and ceramic abutments were compared. A sample size calculation was performed based on the changes on the Implant Crown Aesthetic index (ICAI), rendering a standard deviation of approximately 1.76. Considering a size effect of 3, power of 95% (Alfa risk 5%, Beta risk 5%). With this, we have obtained a sample size of 18 patients. However, considering the recommendation of the SPPSS program to assure normal assumption, the sample size should be 30 patients.

This study included 30 subjects (16 female) (Table 1 and Figure 1). The patients were selected among the individuals who attended to the Master of Periodontics at the University of Santiago de Compostela between January 2016 and March 2017. The study was carried out in compliance with the Helsinki Declaration and following the CONSORT guidelines (World Medical Association, 2013. The study protocol was approved by the Research Ethics Committee of Galicia (423/2015). All patients received detailed information about the trial both orally and through a written study information sheet.

Once the informed consent was signed, participating patients had to fulfill the following inclusion criteria:

- Periodontal and systemically healthy patients >18 years of age, with good plaque control (< 25%).
- Patients with a missing tooth in the anterior maxilla (from 1.3 to 2.3 both included) with the presence of adjacent natural dentition mesially and distally (single gap).
- A minimum of 4 months of healing after tooth extraction was required before implant insertion.
- Presence of ≥2mm of keratinized tissue.
- Simultaneous bone regeneration was allowed during surgery.

Reasons for exclusion were as follows:

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TABLE 1 Demographical and clinical parameter of study population and implant sites

	Ceramic implant *n* = 16		Titanium implant *n* = 14	
	n	%	*n*	%
Patient	16		14	
Age (y)	54.13		56.07	
Sex				
Male	4	25.0	10	71.42
Female	12	75.0	4	28.58
Smoking	0	0	5	35.71
Implant position				
Central incisor	7	43.75	2	14.28
Lateral incisor	8	50.0	10	71.48
Canine	1	6.25	2	14.28
Implant length				
8 mm	1	6.25	6	42.85
10 mm	3	18.75	6	42.9
12 mm	12	75.0	2	14.3
Bone Regeneration				
Yes	1	6.25	1	7.14

Note: p value statistically significant ≤0.05.
Abbreviations: %, percentage related to group; n, number; y, years.

- Intake of any medication or presence of any systemic disease that could affect bone metabolism.
- Pregnancy, or lactating women.
- Active periodontal disease
- Smoking >10 cig/day

During implant placement, patients were excluded if the implants were not properly placed, as indicated by the surgical stent, if there was lack of primary stability or if large bone regeneration was needed.

2.2 | Randomization

All patients were randomized and assigned to each of the study groups through a computer-generated randomization. The treatment was assigned by means of closed opaque envelopes containing the code derived from the random list. The envelope was opened after flaps had been raised and before to osteotomy.

2.3 | Surgical and restorative procedures

Prior to surgery, patients were instructed in oral hygiene techniques and received a complete oral examination. Intraoral X-ray and CBCT scan were carried out to assess bone dimensions for implant placement. The surgical treatment was performed under local anesthesia (Xilonibsa, Inibsa Laboratories, S.L.U.; 20 mg/ml + 0.0125 mg/ml solution for injection lidocaine hydrochloride+epinephrine). After intrasulcular and mid-crestal incisions, full thickness buccal and palatal flaps were raised. Subsequently, the implants were placed according to the manufacturer's instructions. In the test group, a Tissue Level ZLA Ceramic monotype implant was placed (Straumann PURE Ceramic implants; Narrow Diameter®; Institut Straumann) (Figure 2) while a Tissue Level SLA Titanium implant (Straumann Standard Plus Narrow Neck CrossFit®; Institut Straumann) was installed in the control group (Figure 3). Both implant types had a diameter of 3.3 mm in the intraosseous portion and 3.5 mm of shoulder diameter and a polished collar of 1.8 mm height. The length of the implants was 8, 10 and 12 mm and was chosen according to the patient's anatomy. Mucoperiosteal flaps were then sutured (GORE-TEX® V6, Gore & Associates, Inc), and primary closure around the healing abutment or the collar of the zirconium implant was obtained.

A post-surgical protocol with antibiotic and analgesics was implemented that consisted of the prescription of 500 mg of amoxicillin and 125 mg of clavulanic acid (Augmentine® 500 mg/125 mg, film-coated tablets; GlaxoSmithKline, France) three times a day for 7 days and 600 mg of Ibuprofen as required for pain relief (Neobrufen® 600 mg film-coated tablets; Abbot Spain). In addition, patients were instructed to rinse with 0.12% chlorhexidine+0.05% CPC (Perio·Aid®; Dentaid, S.L.) 15 ml, twice daily for 7 days.

Immediately after surgery, X-rays and implant level impressions were taken. Implants were provisionally restored 4 days later with a resin crown, without centric and non-centric occlusal contacts. The restorations were cemented in both study groups. In the titanium implants, a cementable straight angle 0° abutment was used (NNC Straumann abutment®, Institut Straumann, Basel, Switzerland). The sutures were removed at 7 days.

Eight weeks after implant placement, definitive impressions were taken with polyether impression material (Impregum™; 3 M España, S.L.) to make the final restoration. Twelve weeks after implant placement, the definitive prosthesis was placed and an individualized silicone key was made (Express™ Putty Soft; 3 M España, S.L.) and in this moment, the final crown was cemented with a provisional self-curing cement based on zinc oxide and eugenol (Temp-Bond™ Original; KaVo Kerr Group, Orange), which was maintained until its replacement by a definitive cement (3 M™ RelyX™ Unicem; 3 M Company) at 3 months (6 months after surgery). This moment was considered as the baseline, and the clinical, radiological, and esthetic variables were registered.

Follow-up visits were performed at 3, 6, 9, and 12 months after crown final cementation. The clinical, radiological, and esthetic parameters were registered at final crown cementation and at the 12-month follow-up. All patients followed a periodontal maintenance care program based on their individual needs.

2.4 | Outcome measures

The primary outcome was the Implant Crown Aesthetic Index (ICAI) (Meijer et al., 2005). Secondary outcomes were the pink esthetic

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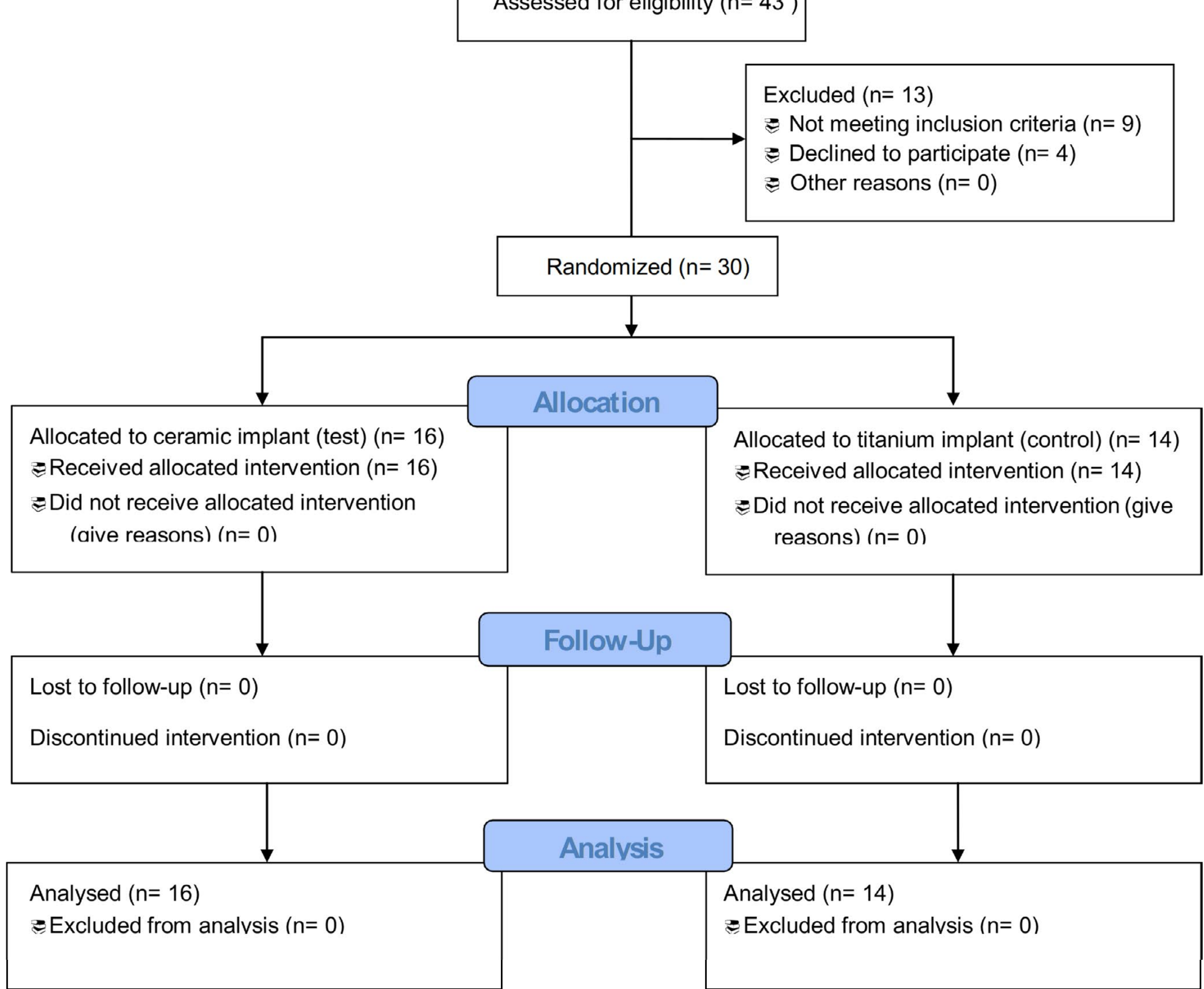

FIGURE 1 CONSORT Flow Diagram [Colour figure can be viewed at wileyonlinelibrary.com]

score (PES) (Belser et al., 2009), a Numeric Scale (NS) used to assess the overall esthetic outcome, clinical parameters, marginal bone levels, and PROMs.

2.4.1 | Esthetic variables

The primary outcome was the Implant Crown Aesthetic Index (ICAI). It consists of nine sections as follows: (a) mesiodistal dimension of the crown, (b) position of the incisal edge of the crown, (c) labial convexity of the crown, (d) color and translucency of the crown, (e) crown surface, (f) position of the gingival margin of the peri-implant mucosa, (g) position of the interdental papilla, (h) contour of the vestibular mucosa, and (i) color and surface of the vestibular mucosa. These sections were compared with the adjacent and contralateral tooth as a reference and assigned the following score: 0, excellent; 1 or 2 satisfactory; 3 or 4 moderate; 5 or more bad (Meijer et al., 2005).

2.4.2 | Evaluation of secondary outcomes

The pink esthetic score (PES) was used to evaluate the esthetic results of the soft-tissue peri-implant mucosa. This index includes the following variables: mesial papilla, distal papilla, vestibular mucosa curvature, vestibular mucosa level and convexity/color, and peri-implant soft tissue texture. Each of the parameters was assigned a score of 2, 1, or 0. The optimum conditions being the maximum score of 10 and a total score of 6 being considered acceptable (Belser et al., 2009).

In addition, a Numeric Scale (NS) was used to assess the overall esthetic outcome. Responses were classified using a ten-grade

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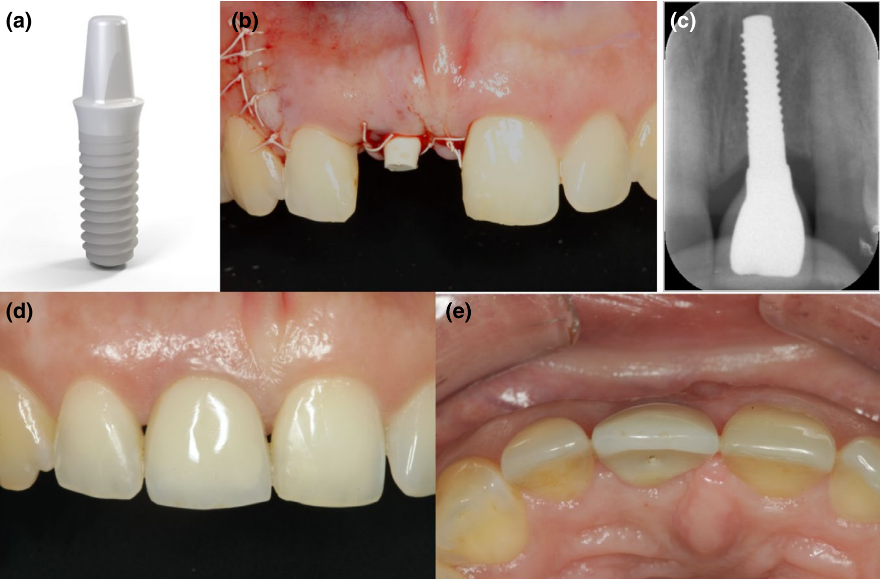

FIGURE 2 Zirconium implant used in this study (a), end of surgical procedure picture (b), X-ray after one year (c) and clinical picture at the final examination representing an implant-supported crown to replace a central maxillary incisor (11) in the test group (d, e) (Zirconium implants) [Colour figure can be viewed at wileyonlinelibrary.com]

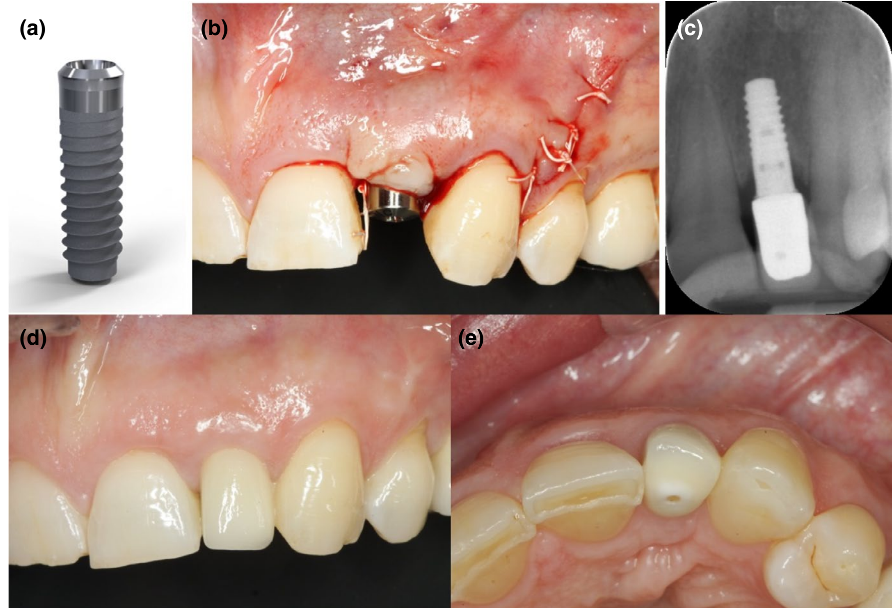

FIGURE 3 Titanium implant used in this study (a), end of surgical procedure picture (b), X-ray after one year and (c), clinical pictures at the final examination representing an implant-supported crown to replace a lateral maxillary incisor (22) in the control group (d, e) (Titanium implant) [Colour figure can be viewed at wileyonlinelibrary.com]

numeric scale, rated very negative to extremely positive (de Bruyn et al., 1997). This evaluation was performed by professionals.

Standardized photographs were used to assess the sections of each of these indexes. The camera was placed perpendicular to the vestibular surface of the crown and the photograph included the incisal edge of the restoration and at least 5 mm of soft tissue. In addition, occlusal photographs were taken to assess the vestibular convexity of the crown and the vestibular contour of the peri-implant mucosa. All photographs were taken with a digital camera (Canon 500D, Canon Inc), with a 100 mm macro (Canon Inc) and an annular flash (Canon MR14EX, Canon Inc).

Photographic measurements were performed by the same examiner (T.P.A) with an intra-class correlation coefficient greater than 90%. The examiner was blinded with respect to the implant treatment performed. Clinical measurements were done by another examiner (T.P.A), blinded to treatment assignment, with a correlation coefficient greater than 90%. Radiographic measurements were performed by a third examiner (R.H.P), previously calibrated with a set of X-rays that not included in the present study. Intraclass correlation coefficient was greater than 90% for the third examiner.

To assess the status of the implant at one year, a standard survival criterion was used, while success was interpreted as the presence of the restoration with the implant free of biological or technical complications. Biological complications were considered the presence of bleeding on probing (BOP) (peri-implant mucositis) with or without suppuration along with increases in probing pocket depth (PPD) and radiographic bone loss (peri-implantitis) (Schwarz et al., 2018).

The technical complications were considered (a) high (when restoration replacement was required); as well as fracture of the implant, fracture of the prosthesis, loss of suprastructures, (b) mild

TABLE 2 Frequency of distribution (percentage/absolute number related to group) of the implant crown esthetic index (ICAI) at 12 months after the placement of the definitive crown

	Ceramic implant *n* = 16			**Titanium implant *n* = 14**		
	No	**Slight**	**Major**	**No**	**Slight**	**Major**
Crown						
Mesiodistal dimension	1 (6.3)	15 (93.8)	0 (0.0)	2 (14.3)	12 (85.7)	0 (0.0)
Position incisal edge	4 (25.0)	12 (72.1)	0 (0.0)	6 (42.9)	8 (57.1)	0 (0.0)
Labial convexity	2 (12.5)	14 (87.5)	0 (0.0)	3 (21.4)	11 (78.5)	0 (0.0)
Color and translucency	5 (31.3)	11 (68.8)	0 (0.0)	7 (50.0)	6 (42.8)	1 (7.1)
Crown surface	6 (37.5)	10 (62.5)	0 (0.0)	5 (35.7)	9 (64.3)	0 (0.0)
Mucosa						
Position labial margin	10 (62.5)	5 (31.3)	1 (6.3)	7 (50.0)	7 (50.0)	0 (0.0)
Position papilla	4 (25.0)	12 (75.1)	0 (0.0)	5 (35.7)	9 (64.3)	0 (0.0)
Contour labial surface	11 (68.8)	4 (25.1)	1 (6.3)	9 (64.3)	5 (35.7)	0 (0.0)
Color and surface	13 (81.3)	3 (18.8)	0 (0.0)	9 (64.3)	5 (35.7)	0 (0.0)
Overall score	Ceramic implant n = 16			Titanium implant n = 14		
Poor esthetics	10 (62.5)			9 (64.3)		
Moderate	6 (37.5)			3 (21.4)		
Satisfactory	0 (0.0)			2 (14.3)		
Excellent	0 (0.0)			0 (0.0)		

Note: Intergroup comparison: chi-square test (**p* < .05). *n* (%). No, no deviation, slight, slight deviation, major, gross mismatch.

complications as fracture of the abutment, rupture of the prosthesis, and (c) minor complications, such as screw loss, loss of retention, need to cement again, loss of sealing (Lang et al., 2012).

Additionally, clinical variables were measured with a periodontal probe UNC-15 (Hu-Friedy®). Probing pocket depth (PPD) measured at 4 locations per implant and was defined as the distance from the peri-implant mucosal margin to the bottom of the peri-implant sulcus; bleeding on probing (BOP) (Mombelli et al., 1987) and plaque index (PI) (Mombelli et al., 1987).

Standardized radiographs were made and used to evaluate bone loss. The intraoral radiographs were performed using the long-cone paralleling technique. They were analyzed using a computer image analysis software (ImageJ, National Institutes of Health). Radiographs were calibrated using the diameter of the implant as a fixed reference. In this image analysis, the distance from the implant shoulder to the first bone-to-implant contact was measured. These measurements were made and are expressed without subtracting the 1.8 mm polished neck length of the implant. Mean values between mesial and distal sites were calculated for each implant. Mean values were calculated for each group, and differences between groups compared.

PROMs were used to evaluate patient satisfaction. Participants completed a questionnaire to assess their satisfaction with the treatment, which included esthetic appearance, phonetic skills, comfort, and overall satisfaction with the treatment. Patient's evaluations were classified using a ten-grade numeric scale (NS) rated very negative to extremely positive (de Bruyn et al., 1997).

2.5 | Statistical analysis

All data were collected in a database. Statistical analysis was performed using commercially available software IBM SPSS Statistics version 25 (IBM Corp). Outcome measures were described by means, SDs, *SEM*, medians, and minimum and maximum values. To determine the normality of data distribution, the Shapiro–Wilk test was used ($\alpha = 0.05$). Homogeneity of variance was confirmed by Levene's test ($p > .05$). The mean differences were considered statistically significant at $p \leq .05$ with a confidence interval of 95%. Depending on the distribution, various statistical tests were applied. In the case of parametric distribution, Student's *t* test was used to detect differences between groups; if not non-parametric, the Mann–Whitney U test was used.

3 | RESULTS

3.1 | Subjects and implants

Of the 43 screened patients, 9 did not meet the inclusion criteria, and 4 did not provide written consent. Therefore, a total of 30 patients were included, 16 in the test group and 14 in the control group. Implant placement took place between March 2016 and June 2017.

All patients were periodontally healthy. Implants were placed in twenty-five non-smoking patients and five smokers. All smokers

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TABLE 3 Frequency of distribution (percentage/absolute number related to group) of the pink esthetic score (PES) at 12 months after the placement of the definitive crown. Intergroup comparison: chi-square test (*p <.05). n (%)

	Ceramic implant $n = 16$			**Titanium implant $n = 14$**		
	Complete	**Incomplete**	**Absent**	**Complete**	**Incomplete**	**Absent**
Mesial papilla	6 (37.5)	10 (62.5)	0 (0.0)	7 (50.0)	7 (50.0)	0 (0.0)
Distal papilla	6 (37.5)	10 (62.5)	0 (0.0)	7 (50.0)	7 (50.0)	0 (0.0)
	No	**Minor**	**Major**	**No**	**Minor**	**Major**
PES						
Curvature of facial mucosa	10 (50.0)	5 (31.3)	1 (6.3)	4 (28.6)	10 (50.0)	0 (0.0)
Level of facial mucosa	13 (81.3)	2 (12.5)	1 (6.3)	9 (64.3)	5 (35.7)	0 (0.0)
Root convexity/soft tissue color and texture	1 (6.3)	0 (0.0)	15 (93.8)	1 (7.1)	0 (0.0)	13 (92.9)
Overall score	**Mean**	***SD***	**95% CI**	**Mean**	***SD***	**95% CI**
	7.81	1.72	6.9–8.73	7.86	1.29	7.11–8.6
VAS						
Esthetic	9.00 (7–10)			8.50 (6–10)		
PROMs						
Esthetic	10.00 (8–10)			9.50 (6–10)		
Speaking	10.00 (9–10)			10.00 (8–10)		
Comfort	10.00 (8–10)			10.00 (8–10)		
Chewing ability	10.00 (8–10)			10.00 (8–10)		
General satisfaction	10.00 (9–10)			10.00 (9–10)		

Note: No, no discrepancy, minor, minor discrepancy, major, major discrepancy. Mean, standard deviation (*SD*) and 95% confidence interval (CI) of the overall score of PES, intergroup comparison: *T* test. Medians, and minimum and maximum values of VAS and PROMs parameters, intergroup comparison: Mann–Whitney U test.

Abbreviations: PES, pink esthetic score; PROMs, patient-reported outcome measures;VAS, visual analog numeric scale.

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TABLE 4 Mean and standard deviation (*SD*) of the PPD and radiographic parameters at baseline and at 12 months after delivery of definitive restorations, intergroup comparison: *T* test

	Ceramic implant $n = 16$			Titanium implant $n = 14$			
	Mean	*SD*	95% CI	Mean	*SD*	95% CI	*p*
PPD baseline (mm)	2.84	0.64	2.5–3.18	3.1	0.68	2.71–3.5	0.28
PPD 12 months (mm)	2.75	0.5	2.48–3.01	3.16	0.45	2.89–3.42	0.15
MBL baseline (mm)	1.86	0.51	1.61–2.11	1.78	0.53	1.5–2.06	0.63
MBL 12 months (mm)	2.08	0.55	1.78–2.37	1.96	0.48	1.68–2.24	0.53

Note: p value statistically significant ≤0.05.
Abbreviations: MBL, marginal bone level; PPD, probing pocket depth.

were in the control group. Detailed patient and implant characteristics are provided in Table 1.

Bone regeneration was necessary in two cases, one in each group, due to the presence of a dehiscence or thickness <2 mm of the buccal bone. A xenograft (DBBM) was used (Geistlich Bio-Oss® Collagen; Geistlich Pharma AG), covered with an absorbable native bilayer collagen membrane (NBCM) (Geistlich Bio-Gide®; Geistlich Pharma AG).

There was no exclusion from the study of any patient due to implant misalignment, lack of primary stability or extensive bone regeneration during the surgical act of implant placement.

All of the 30 implants were available at the 12-month examination. Therefore, survival rate was 100% for both groups.

3.2 | Esthetic assessments

The results of the primary outcome, the ICAI score, are shown in Table 2. The overall score 12 months after crown placement was 6.31 (95% Confidence interval [C.I.] 4.59–8.04) and 6,07 (95% C.I. 4.21–7.93) for the test and control groups, respectively. Differences between groups were not statistically significant.

Table 3 shows the results of the esthetic analysis through the pink esthetic score (PES), the assessment through PROMs by patients and the NS in relation to overall esthetics evaluated by a dental professional. The PES showed an overall score at 12 months after definitive crown placement of 7.81 (95% C.I. 6.90–8.73) and 7.86 (95% C.I. 7.11–8.60) for the test and control group, respectively. There were no statistically significant differences between groups. The NS esthetic score was 8.88 (95% C.I. 8.49–9.26) and 8.36 (95% C.I. 7.78–8.94) for test and control group, respectively, without statistically significant differences between groups.

3.3 | Clinical and radiographic assessments

All clinical and radiographic parameters are summarized in Table 4. All surgical procedures healed uneventfully and all implants osseointegrated successfully. At the 9-month follow-up visit, a biological complication was observed in a patient in the test group, registering mean PPD of 6 mm and profuse BOP, accompanied by a mean of radiographic bone loss of 7.34 mm being therefore compatible with peri-implant disease (Schwarz et al., 2018). The patient received non-surgical (Liñares et al., 2019) and surgical treatment of peri-implantitis (Heitz-Mayfield et al., 2012). This patient in the test group remained in the sample. After treatment, inflammation was controlled and PPD reduced, at implant site, from a mean of 6.16 to 4.83 mm. After 12 months of follow-up, not only had the PPD been reduced, but there was also an improvement in BOP stopping the progression of bone loss. No technical complications were observed in any group throughout the study period.

The probing pocket depth (PPD) at the implant level was on average 3.16 mm (95% C.I. 2.89–3.42) and 2.75 mm (95% C.I. 2.48–3.01) for control and test group, respectively. In both groups, the plaque index (PI) was 0.01 (*SD* 0.06). The ceramic implants were associated with mean bleeding on probing (BOP) scores of 0.26 (*SD* 0.42) at 12 months. The corresponding values for the titanium implants were 0.05 (*SD* 0.10). There were no statistically significant differences between groups for PPD, PI, and BOP at the 12-month follow-up. Marginal bone levels (MBL) are summarized in Table 4. The ceramic implants were associated with a mean MBL of 2.08 mm (95% C.I. 1.78–2.37) at 12 months. The corresponding value for the titanium implants was 1.96 mm C.I. 1.68–2.24). The difference between the test and control was 0.11 (95% C.I. −0.51–0.27). T test revealed no significant intergroup differences ($p > .05$).

The overall survival and success rate was 100% and 96.6% at one year of follow-up.

4 | DISCUSSION

This clinical trial was designed to evaluate the esthetic, clinical, and radiological results of ceramic implants compared with titanium implants in the esthetic zone. Results from the present investigation showed no significant differences between groups in any of the studied variables, showing that ceramic implants may be a reliable alternative to titanium implants. Thus, results from the present study are in concordance with the previous results from different investigations (Hashim et al., 2016; Koller et al., 2020; Manzano et al., 2014; Osman et al., 2014; Wood & Warshaw, 2015).

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With regard to the esthetic evaluation and in relation to our main objective, the ICAI index (Meijer et al., 2005) was used since it is an index that assesses several important aspects of esthetic, evaluating both the implant-supported restoration, the peri-implant soft tissues and their integration into the dentition of the patient. It should not be forgotten that the parameters of the ideal esthetics in this type of rehabilitations are not yet correctly defined, so there is always a degree of subjectivity (Benic et al., 2012).

In the case of crown ICAI and referring to our results, we observe how in both groups the frequencies of distribution are very similar. However, focusing on mucosa ICAI we see how in the position of the gingival margin, the contour of the labial surface and the color and texture of this peri-implant tissue, the results are slightly better when a ceramic implant was placed. This affirms the excellent results observed in studies looking at the behavior of the soft tissues around zirconia (Blanco et al., 2016; Liñares et al., 2016; Nickenig et al., 2012).

In a study comparing ceramic versus titanium abutments found no statistically significant differences between groups also using the ICAI-crown score (Carrillo de Albornoz et al., 2014; Meijer et al., 2005). This group reported a total value for the ICAI index of 7.6 (*SD* 3.5) for zirconia abutments and 11.3 (*SD* 5.4) for titanium abutments. Taking into account that in our trial implants and not abutments are evaluated, the results that we obtain with respect to the final value of this index are more favorable in both groups, with an ICAI index of 6.31 (*SD* 3.24) and 6.07 (*SD* 3.22) for implants ceramics and titanium, respectively.

Also, in relation to the esthetic parameters, this study observed a pink esthetic score (PES) (Belser et al., 2009) value above the threshold of clinical acceptance set at a score of 6. Both groups presented a mean value above 7. Similar observations were reported in a clinical trial comparing titanium and ceramic two-piece implants (Koller et al., 2020; Payer et al., 2015) using a similar evaluation method (Fürhauser et al., 2005). For the ceramic and titanium groups they observed a PES of 11.11 (*SD* 1.27) and 11.56 (*SD* 1.01), respectively, after 80 months of follow-up.

With regard to MBL changes, results from the present investigation are consistent with findings from Payer et al. (2015) and Koller et al. (2020) showing no significant differences between ceramic and titanium implants. In the latter study, only tooth gaps up to three missing units were included in their study, similarly to our study, where only single-tooth gaps were included. On the contrary, Osman et al. (2014) found significant more bone loss for ceramic implants compared with titanium implants, when implants were used to support maxillary and mandibular overdentures, in a recent randomized clinical trial. When interpreting our results of marginal bone loss, the 1.8 mm dimension of the implant shoulder was not subtracted in both groups.

The present study has some limitations. The number of patients and the follow-up period (12 months) could be scarce when talking about success in implants, but we know from the existing literature how one-piece ceramic implants have survival rates mean values similar in 1 and 2 years, and marginal peri-implant bone loss after 1 year comparable with published data on titanium implants (Altuna et al., 2016; Gahlert et al., 2016).

It is known that the thickness of the peri-implant soft tissue, particularly at the most coronal area, may play a critical role on the functional and esthetic outcomes of implant therapy and this thickness is established as the limit below which there may be a risk of esthetic problems in relation to soft tissues, both recession and transparency of the underlying implant (Avila-Ortiz et al., 2020; Lin et al., 2013; Schwarz et al., 2018). In the in vitro study of Thoma et al. (2016) the association of vestibular soft tissue thickness after the placement of titanium and ceramic implants was studied and it was observed how with an average vestibular soft tissue thickness of 1.68 mm (*SD*: 0,91) discoloration of the mucosa occurs after placement of both types of implants; however, their results showed this discoloration was more pronounced with titanium compared with ceramic implants. Therefore, the potential of ceramic implants to improve esthetic outcomes may not be fully appreciated. One drawback of the tested ceramic implant, as one-piece implant, it only can be restored with cemented restorations, in contrast to the control implant which can be restored either cemented or screwed retained restorations. Thus, implant positioning of the present tested implant is more clinical demanding than the control one.

More research is still needed regarding the new emerging surface treatments on ceramic implants along with different implant designs, like two-piece implant designs. Nevertheless, more studies with a longer follow-up are required in order to assess long-term results.

5 | CONCLUSIONS

The results of this clinical trial show how ceramic implants present favorable esthetic results, both at the restoration level and with the integration of the peri-implant soft tissues, being similar to the adjacent and contralateral tooth. In addition to the clinical and radiological results, they are also comparable with conventional titanium implants, positioning themselves as a valuable treatment choice in this esthetic area.

AUTHOR CONTRIBUTIONS

Paula Andrea Ruiz Henao: Formal analysis (equal); Writing-original draft (equal). **Leticia Caneiro Queija:** Methodology (equal); Project administration (equal). **Santiago Mareque:** Investigation (equal); Supervision (equal); Writing-review & editing (equal). **Almudena Tasende Pereira:** Data curation (equal). **Antonio Liñares González:** Writing-review & editing (equal). **Juan Blanco-Carrión:** Conceptualization (equal); Funding acquisition (lead); Methodology (equal); Writing-review & editing (equal).

DATA AVAILABILITY STATEMENT

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

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