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Randomized controlled clinical trial comparing two dental implants with different neck configurations

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Abstract

Background: Peri-implant bone levels can vary according to the implant neck macro-design and the implant-abutment interface.

Purpose: To compare the changes in soft and hard tissues when using a one-piece implant with a machined collar (TG) versus a two-piece implant with a progressive platform widening and a platform switching connection (SP).

Material and methods: Partially edentulous patients willing to receive one or two implants in the posterior maxilla or mandible were randomized to the control (TG) or to the test group (SP). Final prostheses were delivered after 12 months. Radiographic measurements of interproximal bone levels (primary outcome) were assessed at implant loading and 1-year postloading. Clinical, patient related outcomes and adverse events were assessed at loading and after 6 and 12 months.

Results: Sixty-one implants were placed in 47 patients, 37 patients (18 in the TG group and 19 in the SP group), and 47 implants (23 TG and 24 SP) completed the 24-months follow up. At the patient level, a significantly greater bone resorption from baseline to implant loading was observed in the SP group (-0.42 ± 0.45 vs -0.07 ± 0.45; $P = .001$*), while from loading to the final visit, the TG group had significantly greater bone loss than the SP group (-0.26 ± 0.22 vs -0.11 ± 0.2; $P = .020$*). At 24 months after surgery, there were no significant differences between both groups (control: 0.33 ± 0.49 vs test: 0.53 ± 0.53; $P = .230$). Similarly, no significant differences were observed for the secondary outcomes.

Conclusions: Both types of implant reported high survival rates and similar bone level changes, clinical parameters, and patient related outcomes after 12 months of loading.

KEYWORDS
controlled clinical trial, dental implants, machined collar, platform switching

1 | INTRODUCTION

Although dental implants have shown a high predictability and long-term success,[1–4] peri-implant diseases are becoming an increasing problem that clinicians must learn to understand and prevent.[5–7] These diseases are characterized by a host inflammatory response to oral bacteria, including soft tissue inflammation with or without progressive loss of supporting bone beyond biological bone remodeling.[8] Different implant designs, configurations, as well as surgical and prosthetic protocols have been proposed with the aim of providing improved stability in the peri-implant tissues.[9] Among these, the implant neck configuration and the implant-abutment connection have attracted interest due to their possible influence in the preservation of the peri-implant hard and soft tissues.[9–11]

In regards to their design, implants can be classified in one-piece or two-piece. One-piece implants are comprised of an endosseous and a transmucosal component, with the implant–prosthetic interface located at increased distance from to the bone. This design has shown

highly predictable results,[12,13] including reduced bone loss and decreased inflammation of the peri-implant tissues.[14] This treatment approach, however, may present aesthetic limitations, since the polished supracrestal component can show through the peri-implant soft tissues or even be seen directly seen when placed supragingivally.[15]

In contrast, the two-piece implants consist of the implant being placed fully endosseous with its shoulder at bone level. The second piece (prosthetic components) are located transgingivally, thus allowing improved emergence profiles and better aesthetic outcomes.[16,17] These implant design, however, may suffer some degree of marginal bone loss at the time of abutment connection,[18,19] what may expose the most coronal aspect of the implant neck with a rougher micro-surface topography, which may provide a higher risk of bacterial colonization.

With the goal of reducing this likely marginal bone loss seen around two-piece implants at abutment connection, the concept of platform switching (PS) was introduced.[20,21] It is characterized by the utilization of a smaller diameter prosthetic component connected to a larger diameter implant platform.[22] It is hypothesized that this inward shift in the perimeter of the implant-abutment junction would allow the establishment of the biologic width more medially and thus marginal bone loss would be reduced.[23,24]

In spite of many scientific reports documenting these facts, there is a lack of controlled randomized clinical trials comparing the use of one-piece implants with a machined collar and a two-piece implants with a progressive platform widening and a platform switching connection.[11] It was, therefore, the aim of this study to assess whether a two-piece implant with a platform-switching concept would result in improved clinical, radiographic, and patient related outcomes when compared to a one-piece implant with a polished collar.

2 | MATERIALS AND METHODS

2.1 | Study design

The present study was designed as a randomized controlled clinical trial with a parallel group design. The proposed null hypothesis was that there would not be radiographic differences between the two-implant designs. Following approval from the local ethical committee, selected patients, previously screened for fulfilment of inclusion/exclusion criteria, were asked to comply with the prescribed treatment and the follow-up visits, as well as for the collection of relevant study data. When they agreed to participate by signing the approved informed consent, they were then included in the study.

2.2 | Subject population

Study patients were selected from those attending the Postgraduate Clinic in Periodontics, School of Dentistry, University Complutense of Madrid. The screening examination included the following:

- Cone-beam CT to determine the bone availability for dental implants.
- Clinical examination to evaluate the patient inclusion and exclusion criteria.

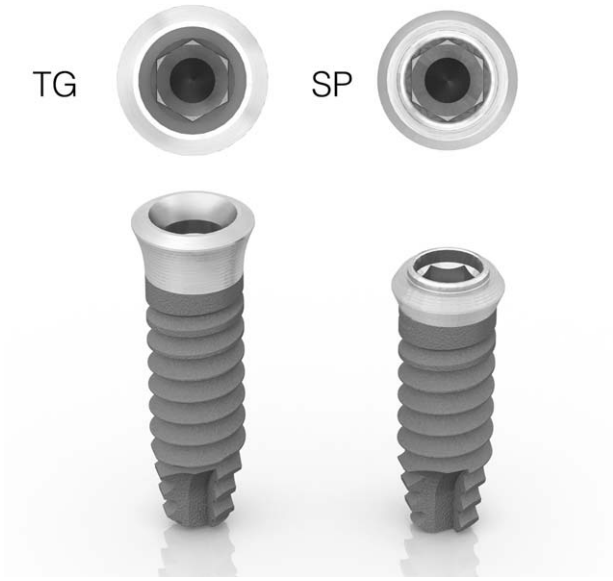

FIGURE 1 Sweden & Martina implants. One-piece implant (TG); two-piece implant (SP)

- Fabrication of surgical guides from waxed-up models.
- Standardized intraoral photographs for registering the baseline site status.

Patients were selected based on the following criteria,

2.2.1 | Inclusion criteria

- Male or female ≥20-years old.
- Presence of one or more adjacent missing teeth in the posterior maxilla or mandible (positions 4-7). A natural tooth had to be present mesially to the most proximal implant site, although free end situations were allowed.
- Adequate bone quality and quantity at the implant site to allow the insertion of Sweden and Martina Premium TG and SP implants SLR (Due Carrare, Padova, Italy), of diameters 3.8, 4.25, or 5 mm and lengths between 7 and 13 mm (Figure 1).
- Opposing dentition had to be natural teeth or implant supported fixed restorations.
- Once informed on the follow-up visits, the patient had to be willing to comply with the planned regimen.

2.2.2 | Exclusion criteria

The exclusion criteria were divided in systemic, local and surgical factors. In addition to the general contraindication for dental implants the following exclusion criteria were observed:

2.2.3 | Systemic exclusion criteria

- Medical conditions requiring prolonged use of steroids and/or with medications that could interfere with bone metabolism.
- History of leukocyte dysfunction and deficiencies.

- History of neoplastic disease requiring the use of radiation or chemotherapy.
- Patients with history of renal failure.
- Patients with metabolic bone disorders such as osteoporosis.
- History of uncontrolled endocrine disorders.
- Physical handicaps that would interfere with the ability to perform adequate oral hygiene.
- Use of any investigational drug or device within the 30-day period immediately prior to implant surgery on study day 0.
- Alcoholism or drug abuse.
- History of immunodeficiency syndromes.
- Patients who smoke >10 cigarettes per day or cigar equivalents.
- Conditions or circumstances, which in the opinion of the investigator, would avoid the completion of study participation, or interfere with analysis of study results, such as history of noncompliance or unreliability.

2.2.4 | Local exclusion criteria

- Untreated or active periodontitis defined as bleeding on probing (BOP) with probing depths (PD) greater than 5 mm assessed by means of a UNC-15 probe (Hu-Friedy. Chicago, IL)
- Mucosal diseases such as erosive lichen planus.
- History of local irradiation therapy.
- Inflammatory or developmental bone conditions that do not allow the placement of dental implants in the regions of interest.
- Unhealed extraction sites (less than 6-weeks postextraction of teeth in intended sites).
- Severe bruxism or clenching habits.
- Persistent intraoral infections such as active endodontic lessions, peri-coronaritis, or untreated caries.

2.2.5 | Exclusion criteria at surgery

- Lack of primary stability defined as <10 Ncm measured by hand torque wrench.
- Need of augmentation procedures in presence of dehiscences or fenestrations >3 mm.
- Unable to place the implant according to the prosthetic requirements.

Consecutive patients fulfilling the inclusion criteria following the implant site preparation were randomized to receive either an implant with a transgingival-machined collar of 2.2 mm (TG) or bone level implants with a progressive widening platform (SP). One independent investigator independent from those carrying out the screening performed the randomization sequence using random block sizes that were stratified according to tobacco. Allocation concealment was kept using opaque-sealed envelopes, which were opened by 1 investigator during surgery (immediately before the implant placement). In those cases, where patients required implants in more than one quadrant, the randomized quadrant was chosen by the following criteria: (1) quadrant where no augmentation was performed, (2) quadrant where the higher number of implants was needed, (3) quadrant number.

2.3 | Surgical procedures

Implant surgeries were performed under local anaesthesia by postgraduate students under the guidance of experienced instructors. Mucoperiosteal flaps were raised by means of crestal incisions and implants were inserted and placed either at bone level (SP) or at the limit of the machined collar (TG). Mesiodistally, implants were placed at least 1.5–2.0 mm from the adjacent natural tooth, and/or at a distance of 3.0 mm between two implants. Drilling was performed according to manufacturers recommendation. The differences in the osteotomy preparation lay in the use of the countersink bur, which was only used in the SP group in order to allow the seating of the expanded implant platform at the level of the osseous crest. In contrast, in the TG group the treated surface was completely submerged allowing the transgingival machined collar above the bone crest. Implant position was guided by the restorative needs and was registered in the CRFs. Primary stability was assessed by direct torque wrench testing. If implant dehiscence or fenestrations <3 mm were encountered a xenograft bone substitute (Sintlife 400-600 μ, 0.5 g; Sweden and Martina, Due Carrare, Padova, Italy) and a resorbable pericardium membrane (Bonetwo, Sweden and Martina, Due Carrare, Padova, Italy) were used.

Patients were instructed to brush the treated area with a surgical brush and to rinse twice a day with 0.15 mL of 0.12% Clorhexidine (Perio-Aid tratamiento, Dentaid SL, Barcelona, Spain), for 60 seconds until sutures were removed between 7 and 10 days postsurgery. Anti-inflammatory drugs were also prescribed as required by the patient (Ibuprofen 600 mg [CINFA S.A., Navarra, Spain], every 8 hours for 3 days).

2.4 | Restorative procedures

For both groups, healing caps were unscrewed and impressions were taken at the implant level with either an open or closed tray impression technique. Final prostheses were delivered 12 months after implant placement and screw tightening was performed at a torque of 40 Ncm.

Digital standardized periapical radiographs and clinical measurements were taken after definitive prosthesis installation. Finally, all patients received oral hygiene instructions and a professional prophylaxis using Teflon-coated ultrasonic scaler tips.

2.5 | Outcome variables

Two calibrated examiners performed the clinical assessments immediately after prosthesis installation and then 6 and 12 months after. Similarly, standardized digital periapical radiographs were taken after implant placement, after prosthesis installation and then at 12 months postloading (Figure 2). For the measurements of these main outcome variables, calibration of the examiners resulted in inter and intraexaminers reliability with more than 85% of agreement.

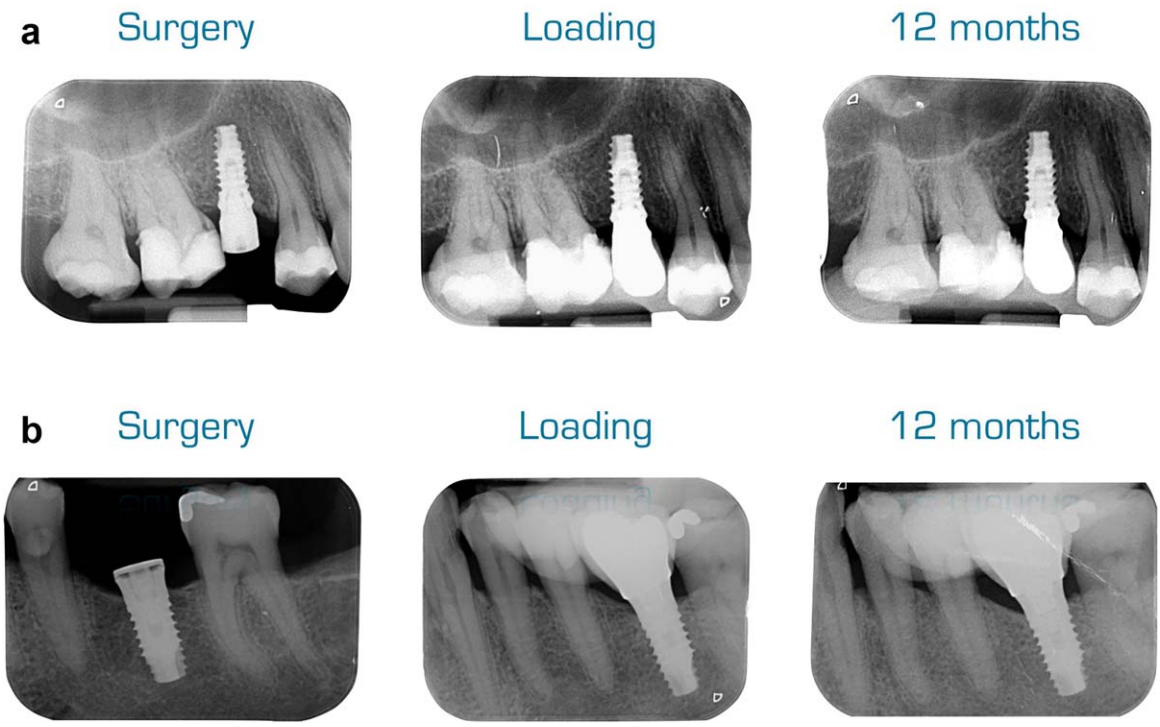

FIGURE 2 Example of clinical cases: radiographic evaluation

Each visit also included the evaluation of any change in the patient's dental or general history as well as patient's reported outcomes. All patient complaints or the advent of any complication, such as pain, paraesthesia, or peri-implant infection were recorded.

2.5.1 | Radiographic assessment

Changes in interproximal bone levels were recorded by measuring the distance from the implant shoulder to the first visible bone to implant contact (DIB: distance of implant to first bone contact) at the mesial and distal aspect of each implant. The standardization of the radiographs was achieved using a parallel technique with the aid of Rinn-Holders and individual silicon bite registrations. Two calibrated examiners executed all the measurements by means of computer image analysis software (Image J. National Institutes of Health [NIH], Bethesda, MD). Inter and Intraexaminer reliability was assessed by means of a calibrating session were 20 random radiographs were measured twice by both examiners (kappa values >0.8). The elimination of image distortions and the determination of the exact magnification were achieved by calibrating all images using the known distance between two implant threads and the length of the implants. For the TG implant 2.2 mm were subtracted from the linear measurement, corresponding to the machined collar.

2.5.2 | Clinical and aesthetic assessments

Clinical measurements were assessed on six sites per implant, using a manual periodontal probe (PCP UNC-15, Hu Friedy, Chicago, IL). The following parameters were registered: PD, keratinized tissue amount on the mid-buccal and mid-palatal/lingual sites, plaque index (PI) (±), BOP (±), and mobility of the implant.

Changes in soft tissue margins around implants and adjacent teeth were evaluated using a manual periodontal probe (PCP UNC-15, Hu Friedy, Chicago, IL) and registered with standardized photographs. The clinical crown length of the adjacent tooth (CLT: distance in mm from the occlusal aspect to the most apical site of the mucosal curvature) and the clinical crown length of the implant-supported crown (CLI: distance from the occlusal aspect of the implant prosthesis to the most apical site of the mucosal curvature) were recorded.

The Pink Esthetic Score[25] was used to assess the aesthetic outcome using seven parameters independently: mesial papilla, distal papilla, marginal tissue level, soft tissue contour, alveolar process, soft tissue color, and soft tissue texture.

2.5.3 | Patient reported outcomes measures

PROMS were assessed by means of a questionnaire comprising of five items: comfort, appearance, masticatory function, taste, and overall satisfaction. Patients were asked to rate these five aspects according to the following scale: very unsatisfied, unsatisfied, fair, satisfied, and very satisfied.

2.5.4 | Adverse events

The adverse events were classified as "implant or prosthesis related" or "non-implant related.". In regards to the first one, this included biological (ie, bone fracture, loss of osseointegration, chronic pain, and peri-implantitis as defined by the 7th European Workshop in Periodontology[26]) and mechanical complications (ie, fracture of devices such as crown or abutment, etc). As for the second one, this group included death or any life-threatening condition.

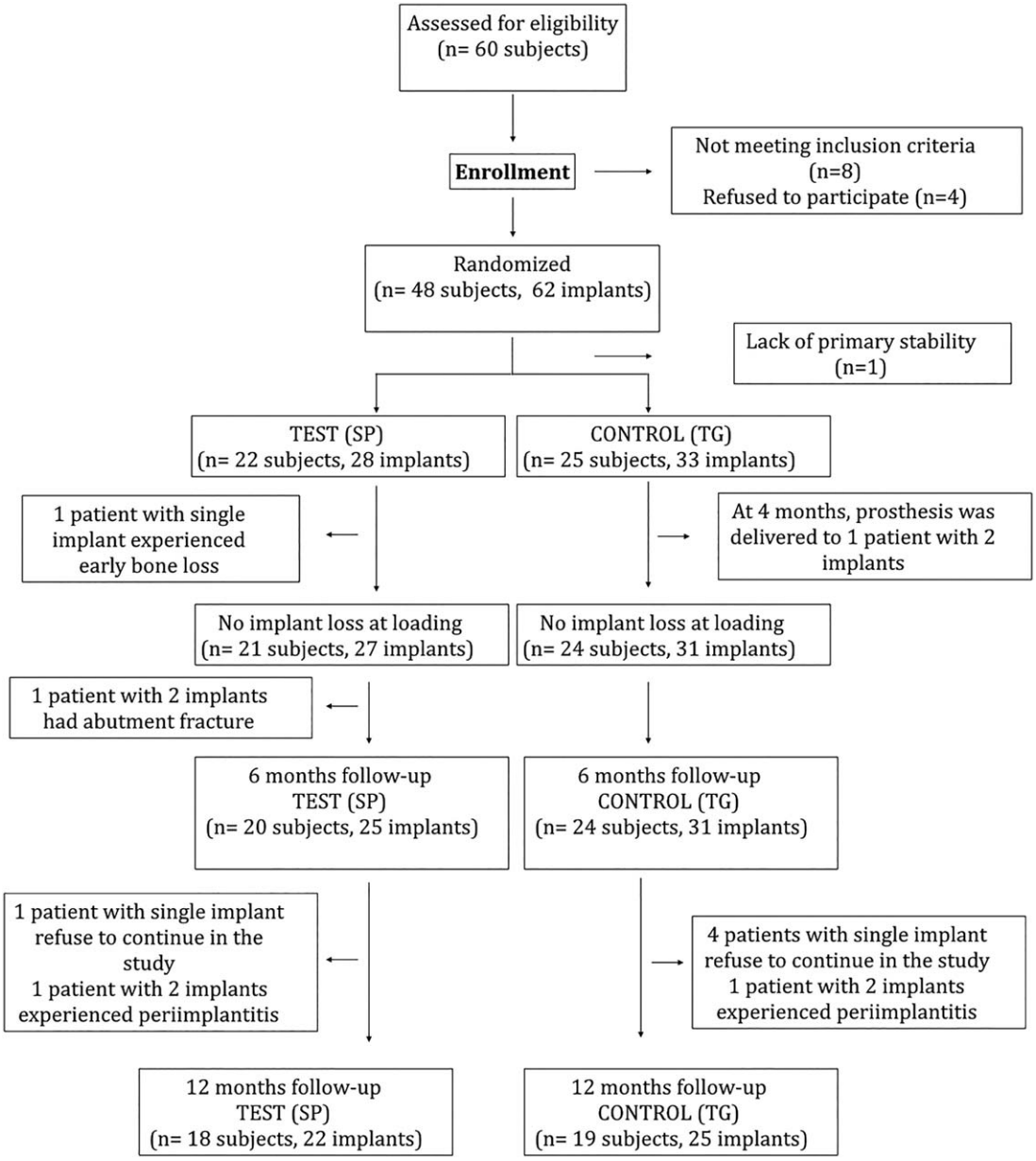

FIGURE 3 Study sample flow-chart

2.6 | Statistical analysis

A sample size calculation was performed to establish the minimum subjects included in the study. The criteria for significance was established as 5% for the type I error and 20% for the type II error. Taking into consideration a mean difference in bone levels of 0.20 mm with a standard deviation (SD) of 0.157[27] and assuming a 20% of likely drop-outs, a minimum of 44 subjects (22 per group) with a minimum of 44 implants were required.

Data normality was assessed using the Shapiro–Wilk Test and intra/intergroup comparisons were assessed using ANOVA. Chi-square test was assessed for the distribution of categorical variables such as gender; medication, tobacco, and implant position, while Mann–Whitney test was used for the crestal bone level changes. A two-sided value of $P \leq .05$ was considered to be statistical significant.

All data was analyzed at the subject level and one implant per patient was randomly chosen as test implant for the implant level analysis. The interproximal bone level changes were considered the main outcome measurement. As for this, the mean distance of the mesial and distal aspect was taken into consideration. For this outcome, the data was analyzed at the implant and subject level.

The statistical analysis was assessed with the aid of the software: SPSS V 21.0.0 (SPSS Inc., Chicago, IL).

3 | RESULTS

3.1 | Study population and follow up

Figure 3 reflects the flowchart of the study population. Patient recruitment was conducted from January 2013 to July 2013. Forty-eight

TABLE 1 Baseline demographic characteristics of the study sample

	Treatment group						
	Total ($n = 47$)		TG (Control, $n = 25$)		SP (Test, $n = 22$)		*P*-value
Sex (*n* and % subjects)							
Male	21	44.68%	14	66.67%	7	33.33%	.100
Female	26	55.32%	11	42.31%	15	57.69%	
Age (mean and SD)			57.72(11.9)		59.73(10.549)		.540
Smoking (*n* and %)							.560
Nonsmoker	36	76.60%	18	72.00%	18	81.81%	
Former smoker	1	2.12%	1	4.00%	0	0.00%	
Smoker <10 cigs/day	10	21.28%	6	24.00%	4	18.18%	
ASA classification (*n* and %)							.487
Type I	26	55.32%	13	52.00%	13	59.10%	
Type II	21	44.68%	12	48.00%	9	41.90%	
Number of implants placed			33		28		.680
Single units	33	70.21%	17	68.00%	16	72.72%	
Multiple units	14	29.79%	8	32.00%	6	27.28%	
Implants position							.870
Maxilla	30	49.18%	17	51.52%	13	46.42%	
Mandible	31	50.82%	16	48.48%	15	53.58%	
Implants position							.820
Premolars	26	42.62%	14	42.42%	12	42.85%	
Molars	35	57.38%	19	57.58%	16	57.15%	
Implant diameter							.750
3.8 mm	19	31.15%	12	36.36%	7	25.00%	
4.25 mm	24	39.34%	11	33.33%	13	46.43%	
5 mm	18	29.51%	10	30.30%	8	28.57%	
Implant length							.210
7 mm	6	9.84%	2	06.06%	4	14.28%	
8.5 mm	20	32.79%	8	24.24%	12	42.86%	
10 mm	21	34.43%	12	36.36	9	32.14%	
11.5 mm	11	18.03%	9	27.27%	2	07.14%	
13 mm	3	4.92%	2	06.06%	1	03.58%	

TG, transgingival; SP, switching platform; n, number of subjects or implants; SD, standard deviation; cigs, cigarettes.

patients were enrolled; nonetheless, one patient was excluded within the surgery due to lack of primary stability. A total of 47 patients and 61 implants were included in the study. One patient was excluded due to early bone loss before loading and one patient was lost because the prosthesis was delivered at 4 months after surgery. At 6 months postloading, one patient experienced a prosthetic abutment fracture, the implant had to be removed since the abutment could not be extracted. At 12 months, two patients experienced peri-implantitis and 5 patients did not show up for this visit (three refused to continue in the study and two were not able to continue due to medical conditions). The overall survival rate was 98.4% (100% in the TG group and 96.4% in the SP group).

3.2 | Demographic data and general health status

The sample included 21 (44.7%) men and 26 (55.3%) women with a mean age in the TG group of 57.7 and in the SP group 59.7. 55.3% of the subjects were systemically healthy and were classified as ASA type I patients, whereas 44.7% were classified as ASA type II due to the use of regular medication. The majority of the recruited patients (78%) had a previous history of periodontitis, but there were no differences between test and control groups. Furthermore, 10 patients (21.3%) reported being current smokers, 1 (2.1%) was a former smoker, and 36 (76.6%) had never smoked. There were no statistical significant differences between the groups at baseline in any of these variables (Table 1).

3.3 | Interventions

Twenty-five subjects (53.2%) and 33 implants were randomized to the control group (TG) and 22 (46.8%) subjects and 28 implants to the test group (SP). In the TG group, a total of 14 (42.4%) implants were placed in the premolar area and 19 (57.6%) on the molar area. In the SP group, a total of 12 (42.9%) implants were placed on the premolar area and 16 (57.1%) on the molar sites. Moreover, 30 (49.2%) implants were located in the maxilla and 31 (50.8%) in the mandible. Seventeen screw-retained single crown restorations were delivered in the TG group and 16 in the SP group, while 8 and 6 screw-retained implant

TABLE 2 Radiographic variables

	TG group		SP group		
Implant level	**Mean**	**SD**	**Mean**	**SD**	***P*-value**
DIB (mm)					
Loading	0.11	0.45	0.44	0.45	.003*
12 months	0.39	0.53	0.56	0.51	.23
DIB changes (mm) L - 12 m	−0.27	0.24	−0.12	0.19	.01*
Patient level					
DIB (mm)					
Loading	0.07	0.45	0.42	0.45	.001*
12 months	0.33	0.49	0.53	0.53	.23
DIB changes (mm) L - 12 m	−0.26	0.22	−0.11	0.2	.02*

DIB, distance implant shoulder—first bone to implant contact; SD, standard deviation; L, loading; *, statistically significant differences between groups ($P \leq .05$).

supported fixed partial dentures were delivered, respectively. With regards to the implant distribution, most of the implants presented a diameter of 3.8 mm and a length of 10 mm in the TG group and a diameter of 4.25 mm and length of 8.5 mm in the SP group (Table 1).

3.4 | Radiographic assessment (DIB)

3.4.1 | Implant-level analysis

The implant level analysis included a total of 47 implants (22 TG and 25 SP). In the TG group, the mean distances between the reference point and the marginal bone level was −0.11 mm (SD 0.45 mm) at loading and −0.39 mm (SD 0.53 mm) after 12 months. The corresponding values for the SP group were −0.44 mm (SD 0.45 mm) at loading, and −0.56mm (0.51 mm) 12 months later. The difference between the TG and the SP group at loading was statistically significant ($P = .003$).

In regards to the change of the bone level between loading and 12 months, the TG group experienced higher marginal bone loss, exhibiting a mean of −0.27 mm (SD 0.24 mm) lost compared to −0.12 mm (SD 0.19 mm) in the SP group. This difference was statistically significant ($P = .01$) (Table 2).

3.4.2 | Patient-level analysis

In the patient level analysis, one implant was randomly selected in cases of multiple unit restorations, corresponding to 18 implants in the TG group and 19 in the SP group.

The results were very similar at this level. In the TG group, the mean distances between the reference point and the marginal bone level was −0.07 mm (SD 0.45 mm) at loading and −0.33 mm (SD 0.49 mm) after 12 months. The corresponding values for the SP group were −0.42 mm (SD 0.45 mm) at loading, and −0.53 mm (0.53 mm) 12 months later. The differences between the TG and the SP group at loading were statistically significant ($P = .001$).

In regards to the change of the bone level between loading and 12 months; the TG group experienced higher marginal bone loss, exhibiting a mean of −0.26 mm (SD 0.22) lost compared to −0.11 mm (SD 0.2 mm) in the SP group. This difference was statistically significant ($P = .02$) (Table 2).

3.5 | Clinical and aesthetic assessments

3.5.1 | Probing depth

There were no statistically significant differences in probing depth at loading, 6 months and 12 months within or between groups. In the TG and SP groups, the mean PD at loading was 2.94 mm (SD 1.05 mm) and 2.95 mm (SD 0.62 mm), respectively. At 12 months, these measures were slightly increased to 3.17 mm (SD 0.70 mm) in the TG group and remained in 2.95 mm (SD 0.7 mm) in the SP group (Table 3).

3.5.2 | Plaque index

Both groups have a slight increment in the percentage of plaque. In the TG group, the percentage of positive sites increased from 17.61% to 27.7% at 12 months and in the SP group from 22% to 27.16%. However, there were not statistically significant differences within or between groups (Table 3).

3.5.3 | Bleeding on probing

The percentage of positive sites in the control group increased from 26.83% to 34.22%, at 12 months. In contrast, in the test group, these values were reduced from 25.37% to 23.26%. However, these differences were not statistically significant within or between groups (Table 3).

TABLE 3 Mean values for the different clinical outcomes

		TG group		SP group		
		Mean	**SD**	**Mean**	**SD**	***P*-value inter**
PD (mm)	Loading	2.94	1.05	2.95	0.62	.756
	6 months	3.17	0.70	3.05	0.78	
	12 months	3.17	0.70	2.95	0.70	
	P-value intra	.719		.768		
PI (%)	Loading	17.61	17.52	22.00	30.90	.714
	6 months	24.06	24.90	26.37	33.00	
	12 months	27.70	25.00	27.16	33.43	
	P-value intra	.341		.824		
BOP (%)	Loading	26.83	19.00	25.37	23.16	.570
	6 months	26.89	24.90	31.58	34.60	
	12 months	34.22	25.21	23.26	26.80	
	P-value intra	.392		.659		
KM (mm)	Loading	4.78	0.94	4.05	1.43	.221
	6 months	4.50	2.09	4.05	1.31	
	12 months	4.17	1.33	3.84	1.53	
	P-value intra	.104		.502		
CLI (mm)	Loading	8.72	1.40	8.58	1.98	.891
	6 months	9.28	1.48	9.37	2.00	
	12 months	8.72	1.48	9.00	2.08	
	P-value intra	.021*		.105		

TG, transgingival; SP, switching platform; PD, pocket depth; PI, plaque index; BOP, bleeding on probing; KM, keratinized mucosa width; CLI, crown length of the implant; SD, standard deviation; *, statistically significant ($P \leq .05$).

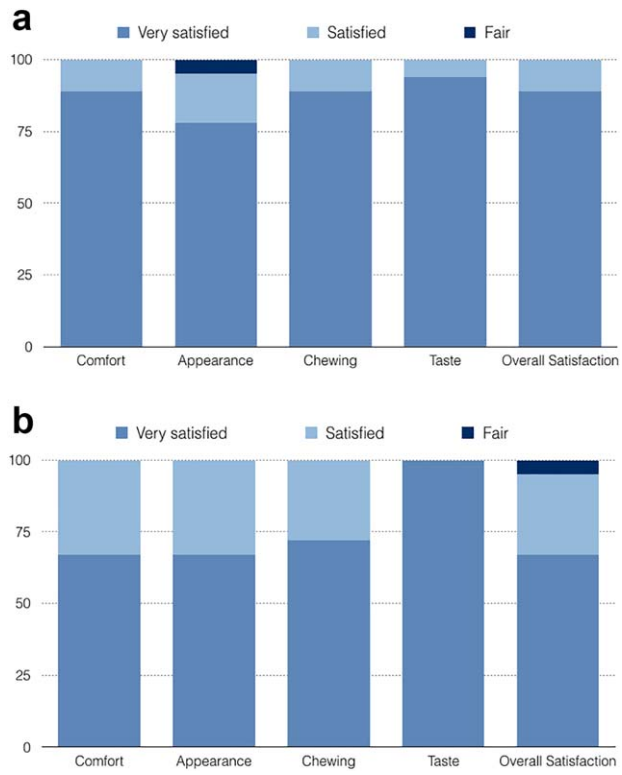

FIGURE 4 Patient related outcome measurements at 12 months (PROM's)

3.5.4 | Keratinized mucosa

There was a slight reduction of keratinized tissue from loading to 6 and to 12 months in both treatment groups, but these differences were not statistically significant for any of the comparisons (Table 3).

3.5.5 | Soft tissue margin

From baseline to 6 months, there was a slight increase in the CLI that was significant only in the TG group (from 8.72 to 9.28 mm in the TG group and from 8.58 to 9.37 mm in SP group). At the end of the study, there was a slight coronal displacement of the gingival margin in both groups, although no statistically significant differences between groups were found at any time point (Table 3). For the adjacent teeth, both the mesial and distal experienced a slight recession (<0.75 mm) and no differences were seen between groups.

3.5.6 | Pink esthetics score

The pink esthetics includes seven items and these parameters were evaluated separately. Most of the changes were found in the mesial and distal papilla, followed by the marginal tissue level. As for this last one, both groups experienced a slight worsening of the tissues. Furthermore, the soft tissue contour, the alveolar process, and the color seemed to remain more stable overtime in both groups. No SS differences were found between groups (Appendix Table A1).

3.5.7 | Patient reported outcomes measurements

Patients from both treatment groups showed a high degree of satisfaction with the treatment (Figure 4). No patient reported to be unsatisfied or very unsatisfied at any parameter. In general, the taste was the best-rated item and the appearance the least. However, there were no statistically significant differences between groups for any of the items evaluated.

3.5.8 | Technical complications

At 6 months postloading, one patient in the SP group experienced a prosthetic abutment fracture from one of the implants supporting a short-span bridge, which was not possible to remove. Three patients from the SP group presented crown mobility due to screw loosening at the 12 month follow up. In this situation, the screws were retightening and patients were recalled to check for the stability of the prosthesis.

4 | DISCUSSION

A high implant survival rate was found for both implant designs 24 months after placement (12 months after loading). The SP group experienced significantly higher marginal bone loss between placement and loading at both implant and patient levels when compared to the TG group (0.44 vs 0.11 mm at implant level). Between loading and 12 months, both the SP and TG groups experienced minor further crestal bone level changes (−0.12 and −0.27 mm at implant level, respectively). In the TG group, most of the bone level change occurred between loading and 1 year postloading while in the SG group most of the change occurred between implant placement and loading.

These observed crestal bone level changes are consistent with those reported in other clinical investigations using a similar design.[28–30] The comparison of one-piece versus two-piece standard implants using a split mouth study design did not find significant differences on changes in marginal bone levels, either at 1-year postloading[28] or at 3 years.[29] Similarly, using a parallel design RCT comparing one and two-piece implants, no significant differences were found at 12 months after loading.[30]

Different from the pervious reports, in this investigation we evaluated as test implants, two-piece implants with a platform switched connection. The use of this design has shown minimal bone loss over time in other clinical trials.[10,31,32] A recently published systematic review revealed significant reductions in crestal bone loss when platform switched implants were compared to regular platform implants (−0.41 mm 95% CI −0.52 to −0.29)[33] and long-term follow-up have also reported minimal bone loss over time.[34] The results reported in this study, however, have shown that one-piece implants were significantly superior in preventing crestal bone level changes between implant placement and loading when compared with the platform switched bone-level implants. This different behavior during implant healing may be explained by different factors:

First the demonstrated stability of the one-piece implant design, which has been widely reported in the literature and has demonstrated stable marginal bone levels 1 year after loading (0.1 mm)[28] 5 years after loading (0.32 mm)[35] and 10 years after loading (0.86 mm)[36] Experimental studies comparing one versus two piece implants explained the higher early (before loading) bone loss of the two piece implants by the

presence of a microgap at the implant to abutment connection[37–39] which was amenable for contamination, followed by inflammation, and marginal bone loss.[40] These differences in the bone level changes between placement and loading may also be explained by the consequences of abutment dis/reconnection. A recent RCT has shown that the connection and disconnection of the abutments (one dis/reconnection) led to greater bone loss when compared with the direct placement of definitive abutments at implant placement.[41] It can be hypothesized that the prosthetic maneuvers performed in the two-piece implants may have influenced bone levels more significantly, as the implant to abutment connection was closer to the bone.

Other factors that may explain the differences could be the different drilling protocols and differences in the final position of the implant in relation to the bone crest. SP implants needed additional burs to expand the coronal implant platform and thus allow a correct seating of the implant shoulder at the level of the bone crest. The submerged wide platform may have exerted excessive loading on the peri-implant bone, specially in cortical bone, leading to greater early bone loss.[42] Although the surgical protocol was aimed to place the SP implants leveled with the crestal bone and the TG implants leveled at the line separating the polished metal collar from the rough titanium, in situations of uneven residual ridges the metal polished collar in TG implants or the SP implant shoulder may have been submerged in order to avoid the exposure of rough titanium. The impact of the subcrestal position of these different implant designs may also have induced different crestal bone resorption patterns. In both implant designs, the subcrestal position may lead to greater bone loss,[43] although in PS implants the subcrestal position (1 mm) may prevent the exposure of rough titanium surface.[44]

In the present study, although both implant designs maintained crestal bone levels between loading and 1-year, TG implants demonstrated a significantly higher bone level change. These differences, however, although statistically significant, were of small magnitude (−0.12 and −0.27 mm) and probably irrelevant clinically. Although the implant to abutment connection is at a distance from the bone in TG implants and therefore, a higher mechanical stress under loading is expected with this implant design when compared to one-piece implants,[45] the possibility that this higher biomechanical load may be translated in more bone loss is unlikely. A more plausible explanation may be due to differences in plaque and bleeding scores between both groups once the definitive prosthesis were installed. The TG group presented slightly higher plaque levels and greater BOP, although these differences were not statistically significant.

With regards to soft tissue changes, both implant designs showed a slight decrease in the amount of keratinized mucosa (KM), although there were no differences between the two systems. In both treatment groups, the CLI seemed to increase at 6 months going back to baseline levels at 12 months. The minimal changes in crown height observed are consistent with those reported in a study with a similar methodology that compared one-piece and two-piece implants at one year of loading.[46]

At the end of the study, the plaque and bleeding scores reported were considered relatively high despite the efforts in motivating the patients on the importance of an adequate oral hygiene between the recall visits. This may have had an impact in the incidence of biological complications. The incidence of peri-implantitis was 4.25%, which is considered relatively high although smaller than what has been reported in a recent systematic review.[7] Nevertheless, the linear correlation existent between the years of loading and the incidence of the disease should be taken into account.

A possible explanation to the undesirable events may be that the population consisted mainly of patients with a history of periodontitis. These patients may exhibit significantly greater long-term probing pocket depth, peri-implant marginal bone loss, and incidence of peri-implantitis when compared with periodontally healthy subjects.[47,48] Moreover, plaque levels increased over the study period, which may have increased the risk for disease onset.[49]

The higher rate of technical complications seen in the SP group, in the form of abutment fracture and screw loosening, may be explained by the differences seen in the connection of the two systems used. While both had an internal hexagon, the TG implants had an additional 20° conical cone that may have provided increased stability and, therefore, resulted in fewer complications. Most of the available literature has focused on comparing the behavior of internal versus external connections.[50] Since there is no evidence comparing prosthetic complications of different implant designs, such as those used in this study, it is difficult to confirm or refute previous hypothesis. In vitro investigations have observed that conical connections provided greater resistance to deformation and fracture[51] and lower stress to the prosthesis and abutment complex.[52,53]

Although there was a high number of dropouts and patients lost during the study follow-up, the power of the study was not affected since additional number of patients and implants were included foreseeing this event. This fact may be due to the late delivery time of the final prosthesis, 12 months after implant surgery.

5 | CONCLUSION

Within the limitations of this study, it can be concluded that both implant designs resulted in high survival rates and similar bone level changes, clinical parameters, and patient related outcomes 12 months after loading (24 months after implant placement). The control implant design (TG), however, resulted in lesser marginal bone level changes during the healing phase before implant loading. This different behavior may not have consequences on the stability of peri-implant hard and soft tissues, but this fact, however, needs to be elucidated with future clinical research including longer-term evaluation times.

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CONFLICTS OF INTEREST

The authors declare to have no conflict of interests with the materials used in the present study.

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APPENDIX

TABLE A1 Pink aesthetic scores distribution for each item (%)

		0	1	2	*P*
Mesial papilla					
Baseline	TG	4.35	73.91	21.74	.670
	SP	4.17	62.50	33.33	
12 months	TG	26.09	60.87	13.04	.493
	SP	12.50	70.83	16.67	
Distal papilla					
Baseline	TG	5.26	84.21	10.53	.319
	SP	20	65	15	
12 months	TG	50	38.89	11.11	.569
	SP	33.33	55.56	11.11	
Marg tissue level					
Baseline	TG	0	17.39	82.61	.263
	SP	8.33	8.33	83.33	
12 months	TG	0	39.13	60.87	.393
	SP	4.17	25	70.83	
Soft tissue contour					
Baseline	TG	0	34.78	65.22	.464
	SP	0	25	75	
12 months	TG	0	34.78	65.22	.292
	SP	0	50	50	
Alveolar process					
Baseline	TG	0	56.52	43.48	.900
	SP	0	58.33	41.67	
12 months	TG	0	65.22	34.78	.846
	SP	0	62.50	37.50	
Soft tissue color					
Baseline	TG	0	0	100	.157
	SP	0	8.33	91.67	
12 months	TG	0	17.39	82.61	.638
	SP	0	12.50	87.50	
Soft tissue texture					
Baseline	TG	0	0	100	.157
	SP	0	8.33	91.67	
12 months	TG	0	17.39	82.61	.947
	SP	0	16.67%)	83.33	

TG, transgingival; SP, switching platform; *P*, *P*-value.