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Clinical and radiographic assessment of circular versus triangular cross-section neck implants in the posterior maxilla: Five-year follow-up of a randomized controlled trial

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Abstract

Objectives: Dental implants with a triangular neck design have been developed in order to maintain peri-implant bone. The primary aim of this randomized controlled trial (RCT) was to assess after 5 years the peri-implant bone stability and the peri-implant soft tissue conditions with this new triangular implant neck design compared to a conventional round neck implant design.

Material and Methods: This is a secondary evaluation of a RCT including 34 patients. Patients were recalled after 1, 3, and finally 5 years to assess implant survival and peri-implant bone levels using standardized radiographs. Peri-implant soft tissue health was also evaluated by recording probing depth, plaque index and Bleeding on Probing. Patient Reported Outcome Measures (PROMs) and the Pink Esthetic Score were also assessed.

Results: No implant loss occurred during the 5-year follow up period. The mean ± SD proximal bone remodeling after 5 years reached 0.38 ± 0.39 mm for the circular design and 0.29 ± 0.58 mm for the triangular design ($p = .49$). Peri-implant soft tissue health parameters and PROMs were found to be comparable. Altogether, 80% of implants presented peri-implant mucositis whereas one implant (4%) displayed sings of peri-implantitis.

Conclusion: The 5-year evaluation of the triangular neck implants showed similar results to the circular neck implants.

KEYWORDS
dental implants, hard tissue, implant design, RCT, soft tissue, stability

1 | INTRODUCTION

Dental implants have been used to replace missing teeth for over 50 years, however, new implant designs and features are continuously suggested in order to improve clinical outcomes and patient satisfaction. Implant designs and surface characteristics were suggested to influence peri-implant hard and soft tissue conditions and consequently influence the long-term success of dental implants (Chackartchi et al., 2019; Insua et al., 2017).

Recently, non-circular cross section implant designs were introduced by several companies in order to leave more space for bone apposition (Nevins et al., 2020), to allow a better force dissipation

in the region of the crestal bone (Zanatta et al., 2014) and potentially improve peri-implant bone stability when compared to classical round neck implant designs. Preclinical studies showed conflicting results: some studies suggested that triangular neck implants allow a greater thickness of peri-implant tissue while others did not find any differences in terms of buccal bone volume and soft tissues contours (Pérez-Albacete Martínez et al., 2018; Sanz-Martin et al., 2017).

According to some authors, triangular neck implant designs (Tri) allow the creation of gap between the osteotomy site and the implant surface, leading to a subsequent bone apposition (Nevins et al., 2020). Among the few clinical studies investigating the outcomes of Tri after 1 year, one retrospective study demonstrated a significant improvement of the Pink Esthetic Score (PES) as well as excellent hard and soft tissue preservation (D'Avenia et al., 2019) and a randomized controlled trial (RCT) observed better crestal bone level of implant placed in the anterior mandible with the Cir when compared to the conventional implant designs (Tokuc & Kan, 2021). On the other hand, the 1-year report of the present RCT did not find any difference between the control and the test group in terms of peri-implant bone changes, PES and patient satisfaction (Li Manni et al., 2020). Another RCT, demonstrated inferior primary stability of Cir when compared to classical round neck implants, however, secondary primary stability could be reached with both type of implants and the authors suggested that primary stability is not a critical factor for secondary stability and osseointegration (Eshkol-Yogev et al., 2019).

If this new implant design does not seem to significantly affect the early clinical outcomes, the available data remain rather limited and data longer than 1 year is not available. Medium and long-term outcomes of non-circular cross section implants remain unknown and clinical studies with a longer follow up are needed to recommend such implant designs in a daily practice.

The aim of this clinical study was to assess the 5-year clinical outcomes of triangular versus circular neck implants. Peri-implant bone remodeling, peri-implant health, PES, and patient reported outcome measures (PROMs) were evaluated after 1, 3 and 5 years.

2 | MATERIALS AND METHODS

2.1 | Study design

This is a follow-up study following a first one that has been initiated in 2015 and published in 2020 (Li Manni et al., 2020). The study was designed as a randomized controlled trial comparing two dental implants with different neck configurations: a conventional circular neck (C1, MIS Implants Technologies Ltd, Israel) versus a triangular cross section neck (V3, MIS Implants Technologies Ltd, Israel) (Figure 1). The study protocol was approved by the Ethical Committee of the University Hospital of the University of Liège, Belgium (file number: B707201423142). The study was registered on clinicaltrial.gov (file number: NCT02591706) and performed according to the CONSORT statement for transparent reporting of randomized clinical trials (http://www.consort-statement.org/). Patients needing replacement of a single hopeless tooth in the posterior maxilla (premolar or molar) and seeking implant therapy were enrolled between March 2015 and January 2016 in the Department of Periodontology and Oral Surgery at the University of Liege, Belgium. Three experienced surgeons (FL, GL, and ER) were involved in the surgical procedures. All clinical parameters and outcomes were recorded at implant placement (baseline), 1 year, 3 years and 5 years after the final restoration, respectively. The primary endpoint was the peri-implant bone change based on 2D intra oral X-rays from 1- to 5-year post-insertion. Our null-hypothesis was that there is no difference in peri-implant bone remodeling between test implants (triangular cross-section neck implant, Tri group) and control implants (conventional circular neck implant, Cir group). A power calculation showed that with at least 32 patients included in the study ($N = 16$ in each group), a difference (Δ) in peri-implant bone loss of at least 0.50 mm between the two types of implants could be evidenced with a power of 80% and a significance level of 5% using a two-sided unpaired t-test and assuming a standard deviation (SD) of bone losses of 0.50 mm. The final sample size was fixed at 34 patients to account for potential dropout during the study (Li Manni et al., 2020).

2.2 | Study population

The following inclusion criteria were used: good general health (ASA I, II), 12-week healing period after extraction or loss of tooth, at least 10 mm in the vertical dimension and 6 mm of bone in the buccolingual dimension (based on a CBCT), presence of at least 3 mm of keratinized mucosa at the implant site, aged >18 years old, cigarette smoking status of <10 cigarettes per day, and signed informed consent. Patients presenting signs of periodontitis had to be treated and be periodontally stable before inclusion. Exclusion criteria were as follows: use of bisphosphonate drugs intravenously, infection (local or systemic), uncontrolled diabetes, current breastfeeding, pregnancy, autoimmune disease that requires medical treatment, alcoholism, and immunodeficiency.

2.3 | Clinical procedures

2.3.1 | Pre-treatment evaluation

Prospective participants were screened for enrolment in the study. Those who complied with the inclusion criteria were enrolled in the study and were provided with written information concerning the study requirements and possible risks. Patients were examined clinically using a cone beam CT (CBCT) to ensure they complied with the requirements of the study.

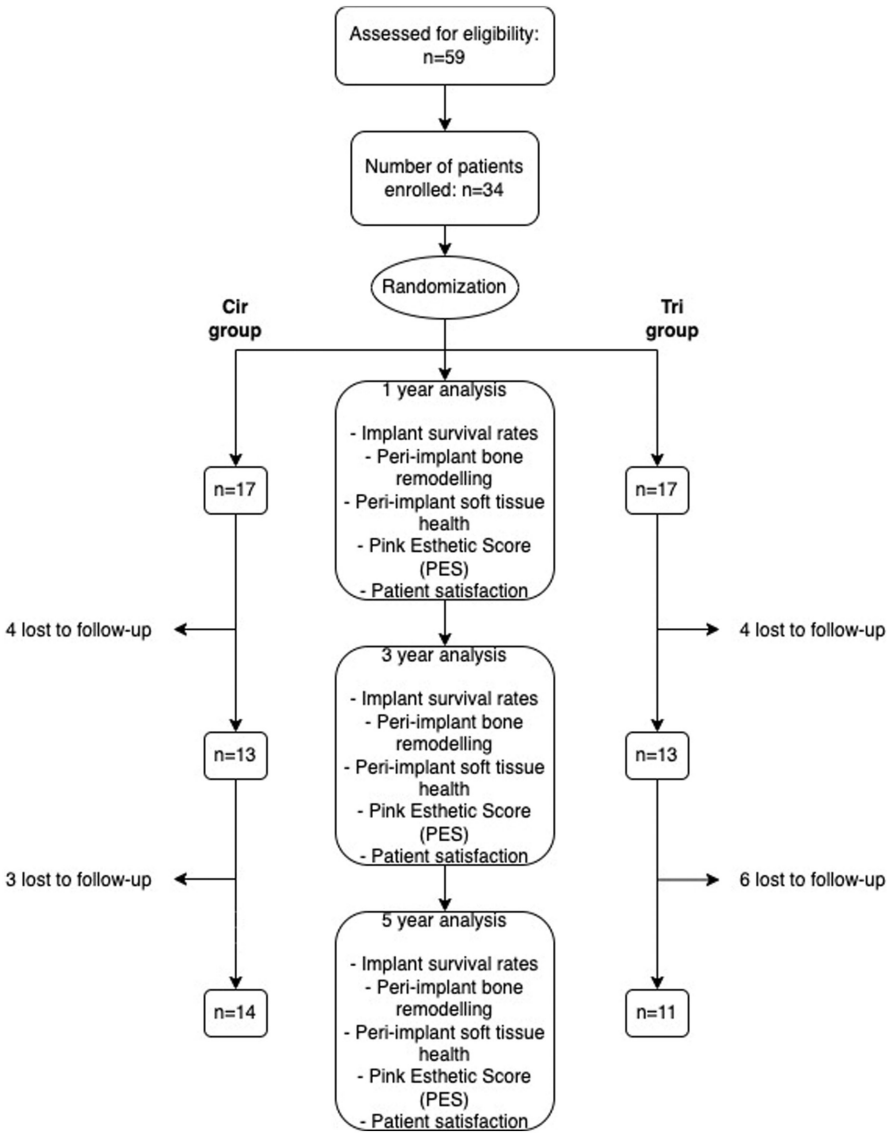

FIGURE 1 Study design. All parameters assessed and drop-outs at each follow-up visit.

2.3.2 | Surgical procedures

All subjects received pre-operative antibiotic (amoxicillin 2 g, or if allergic, clindamycin, 600 mg). After local anesthesia, a supra-crestal incision was made in the edentulous area and full thickness flaps were reflected to allow access to the site. The implantation procedure was carried out according to a standard surgical protocol and according to the manufacturers' protocol. Patients were randomly assigned to group Cir or Tri after flap opening using the software Splus version 8.1 (TIBCO Software Inc.) and treated similarly. They remained unaware of the type of implant received throughout the study. The implant stability (insertion torque) was measured using the wrench key and the surgeons did not exceed an insertion torque higher than 45 N cm. The implant neck was positioned at the crestal bone level or slightly infra bony (<1 mm). Transgingival healing abutments were placed for a period of 4 months. The area was sutured with thin nylon sutures for a primary passive fit closure. Immediately after surgery a calibrated CBCT was performed of the area of interest to assess baseline interproximal bone level and the buccal bone dimensions using a reduced field-of-view to cover the desired area using a voxel size of 0.2 mm and using a reduced field of view (Garib et al., 2014).

2.3.3 | Post-operative instructions and follow-up

Patients were instructed to rinse twice daily with an aqueous solution of 0.2% chlorhexidine. In addition, analgesics (400 mg Ibuprofen up to 4/d) were prescribed for the next 2 days according to individual needs. Patients were also instructed to refrain from mechanical plaque removal in the area of implantation for 1 week. The sutures were removed after 10 to 14 days. After a healing period of 4 months, patients received restoration with screw-retained crowns made of Zirconia framework veneered with cosmetic ceramic. The crowns were bonded in the lab on titanium bases with adhesive resin composites (RelyX Ultimate®; 3M) of various heights according to the trans-mucosal thickness. The follow-up visits were scheduled 1 year, 3 years, and finally 5 years after the final restoration. At each appointment, patients received instructions to improve their oral hygiene if needed. During

the entire follow-up period patients were referred to their general dentist for regular check-ups, no specific supportive periodontal care was considered in the context of the present trial.

2.4 | Data collection

In this follow-up evaluation, two blinded examiners performed all the radiographic and clinical assessments at 1 year, 3 years, and 5 years after final prosthesis installation. Each visit also included the evaluation of any change in the patient's dental or general history, PROMs, and the PES.

2.4.1 | Implant clinical outcomes

Implant survival was defined as the percentage of implants initially placed that was still present and not mobile at the follow-up visits. All patient complaints and complications, such as pain, paresthesia, or peri-implant infection, were recorded at each visit. At 1 year, 3 years, and 5 years after the implant loading, the peri-implant soft-tissue health was assessed based on BOP and modified bleeding index as described by Mombelli et al. (1987) et al was used to score the peri-implant inflammation. Additionally, probing pocket depth (PD) was collected at 3 and 5 years. Finally, full mouth plaque score (FMPS) described by O'Leary et al. (1972) was recorded at each timepoint.

2.4.2 | Radiographic assessments

The peri-implant bone levels were assessed on periapical radiography at 1, 3, and 5 years. The radiographies were performed using the paralleling technique and a personalized holder made with a putty silicone mold in order to consistently position the radiograph. The receptor-type was a phosphor plate. The linear distance between the implant shoulder of the bone level implants and the first bone to implant contact (DIB in mm) was measured at the mesial and distal aspects by two independent and calibrated examiners L.L and A.H. Before the radiographic assessment the two examiners (postgraduate student in periodontology) performed two calibration sessions at 1-week interval to evaluate the intra- and inter-reliability, after which resulting measurements were critically discussed. Thereafter the radiographs were calibrated using the known distance between the implants treads using the specific software Image FIJI (Image J; NIH) (Schindelin et al., 2012). This software corrects the radiographically projected distance by means of this known distance using the rule of proportion. With the same software and correction technique, the linear distance between the implant shoulder of the bone level implants and the first bone to implant contact (DIB, mm) was measured at the mesial and distal aspects. Final DIB values were recorded as the average of the obtained mesial and distal values (Figure 2).

2.4.3 | Pink esthetic score

The PES introduced by Fürhauser et al. (2005) was used to assess the peri-implant soft tissue esthetic directly after the prosthetic procedures at 1, 3, and 5 years after the final restoration A score of 2, 1, or 0 was assigned to each PES parameters, yielding a maximum score of 14.

2.4.4 | Patient-reported outcome measures

Patient-related data were recorded using a self-reporting visual analog scale questionnaire that employed a graduated scale of 0–10. The following parameter were collected at 1 week after the surgery, after 1, 3, and 5 years: (i) pain level at implant placement (1 = low to 10 = high), (ii) implant sensation compared with contralateral natural teeth (1 = not similar to 10 = very similar), (iii) general aesthetic result (1 = not satisfied to 10 = very satisfied), and (iv) implant aesthetic compared to contralateral natural teeth (1 = not similar to 10 = very similar). Additionally, the patients were asked if they would redo the treatment (1 = not at all to 10 = absolutely). The total score gives a maximum of 40 points.

2.4.5 | Peri-implant diseases classification

We classified peri-implant diseases using the 2017 World workshop definitions (Berglundh et al., 2018). Peri-implant mucositis was defined as presence of bleeding on gentle probing (and modified bleeding index 1, 2, 3). Peri-implantitis was defined as inflammation in the peri-implant mucosa and subsequent progressive loss of supporting bone. PD ≥6 mm and bone loss beyond crestal bone level changes resulting from initial bone remodeling at 1 year were considered as peri-implantitis.

2.4.6 | History of periodontitis

History of periodontitis was retrospectively investigated at the 5 years follow up in order to correlate this well-known risk factor (Karoussis et al., 2003) with development of peri-implantitis. History of periodontitis was identified based on the data collected during the study follow-up, based on patient reporting and on radiographic analysis. General bone loss higher that 20% without any local factors was considered as a history of periodontitis.

2.5 | Statistical analyses

Results were summarized as mean and standard deviation (SD), quartiles (median, Q1, Q3), and extremes (minimum, maximum) for quantitative variables and as frequency tables for categorical

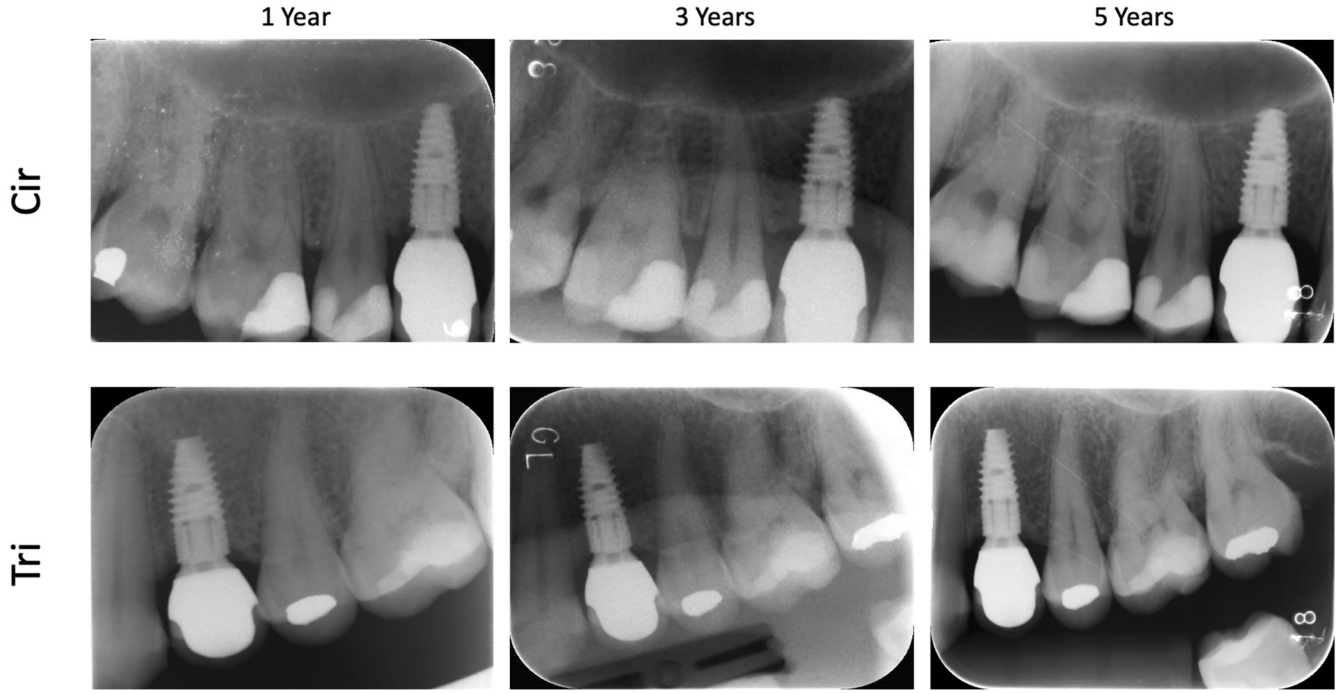

FIGURE 2 Standardized peri-apical radiograph. Both implant types showed stable peri-implant bone levels at 1, 3, and 5 years.

findings. Comparisons of change between two time points was evaluated by a paired Student *t*-test or by Wilcoxon signed rank test for quantitative variables, and by the McNemar test for categorical findings. Comparisons between groups were done using chi-square test for categorical findings and unpaired Student *t*-test or Kruskal–Wallis test for quantitative variables. The agreement between two quantitative variables are measured by Interclass Correlation Coefficient (ICC) with the confidence interval at 95%. For each measurement done by two examiners, we calculate the mean of both results. Results were considered significant at the 5% significance level ($p < .05$). Data were analyzed with SAS version 9.4 (SAS Institute).

3 | RESULTS

3.1 | Patient characteristics

All patients completed the 1-year follow-up study, however, eight patients failed to show at the 3-year follow-up and nine at the 5-year follow-up. Patients dropouts were found to be homogenous in both groups. Four patients displayed history of peri-implantitis and four patients were smokers. Patients demographics and implant characteristics were equally distributed in the test and control groups. The implant survival rate reached 100% for patients who presented over the full 5 years period. The outcome of the implant survival is unknown for the drop-out patients. The patient and implant related data are displayed in Table 1.

TABLE 1 Patient/implant-related characteristics.

	Cir	Tri	*p*-Value
Patient	*n* = 17	*n* = 17	
Age (years) Mean ± SD	45.7 ± 10.4	46.8 ± 11.3	.77
Gender			
Male	5	5	.99
Female	12	12	
Implant	*n* = 17	*n* = 17	
Length (mm)			
8 mm	6	3	.45
10 mm	6	9	
11.5 mm	5	5	
Diameter (mm)			
3.3	0	1	.94
3.75 (cir) – 3.9 (tri)	4	6	
4.2 (cir)-4.3 (tri)	10	7	
5	3	3	
Tooth type			
1st premolar	8	6	.60
2nd premolar	2	5	
1st molar	6	6	
2nd molar	1	0	
History of periodontitis			
Yes	2	2	1.00
No	15	15	
Smoking			
Yes	2	2	1.00
No	15	15	

3.2 | Radiographic outcomes

Global agreement for radiographical bone change measurements between the two examiners, assessed by the ICC and 95% confidence interval, was respectively 0.71 (95% CI: 0.55–0.84), 0.81 (95% CI: 0.69–0.91), and 0.85 (95% CI: 0.75–0.93) at 1, 3, and 5 years. The corresponding absolute observed differences were respectively 0.091 ± 0.31 mm, 0.055 ± 0.28 mm, and −0.082 ± 0.28 mm.

The mean Distance between the Implant shoulder and the Bone level (DIB—primary outcome) were stable from 1 to 5 years. They reached 0.39, 0.39, 0.38 and 0.27, 0.23, 0.29 mm respectively for the Tri and the Cir groups at 1, 3, and 5 years. No significant intergroup differences were observed at any of the timepoints.

One outlier was observed with bone loss exceeding 1 mm (DIB of 1.96 mm) associated with BoP in the control (Cir) group. That patient was identified with a history of periodontitis and active periodontal disease at the 5-year follow-up. However, over the whole study population, no statistical correlation could be found between DIB higher than 1 mm and history of periodontitis ($p = .15$). Detailed DIB values are displayed in Table 2.

3.3 | Clinical outcomes

Peri-implant health parameters (PI, BoP, and PD) were comparable between Cir and Tri groups at each timepoint. However, a significant increase in the Full Mouth Plaque Score (FMPS) and Bleeding on Probing (BoP) was found from 1 to 5 years. At 5 years, all implants (100%) in the Tri group presented sign of mucositis, including 63.6% of minor bleeding "spots" and 65% of the implants in the group Cir also presented signs of bleeding. Altogether, according to the definition of peri-implant diseases, at 5 years, the rate of mucositis yielded 80% and the rate of peri-implantitis 4%. Nevertheless at 5 years, all implants displayed probing pocket depth inferior to 6 mm. Detailed peri-implant health data is displayed in Table 3.

3.4 | Pink Esthetic Score

At each time point, intergroup results were comparable for the overall PES scores as well as for each sub-domain. However, regarding intragroup results over the follow-up period, a statistically significant decrease ($p = .046$) of the PES was observed from 1 to 5 years in the Tri group. The mean PES at 5 years reached 9.55 ± 2.58 and 9.64 ± 1.55 respectively in the Tri and the Cir groups. Detailed data regarding the PES are displayed in Table 3.

3.5 | Patient reported outcome measures

Patient satisfaction scores were high for each sub-domain (above 9 out of 10) and remained stable from 1 to 5 years. The detailed data are displayed in Table 4.

4 | DISCUSSION

The present study shows for the first-time 5-year clinical results on non-circular cross section implant designs. Over the 5-year follow up period, the results did not emphasize any significant difference between the groups; implant survival, peri-implant bone changes, peri-implant health as well as PROMs were comparable between Cir and Tri groups. From 1 to 5 years, peri-implant bone level changes were stable in both groups, however, FMPS and BOP increased significantly yielding a mucositis rate of 80% at 5 years.

4.1 | Peri-implant bone levels and peri-implant health

The overall peri-implant bone changes (primary outcomes) over 5 years were small and comparable in the two groups. Hence, the null hypothesis could not be rejected. The bone remodeling values found in the present study are consistent with the physiological bone remodeling

TABLE 2 Peri-implant bone remodeling (mm).

DIB (mm)				
	1 year (reference)	3 years	5 years	*p*-Value
Cir	0.27 ± 0.30	0.23 ± 0.43	0.29 ± 0.58	1.00
≤1 mm	17 (100%)	13 (100%)	14 (93.3%)	
>1 mm <4 mm	0	0	1 (6.7%)	
≥4 mm	0	0	0	
Tri	0.39 ± 0.45	0.39 ± 0.42	0.38 ± 0.39	1.00
≤1 mm	16 (94.1%)	14 (100%)	11 (100%)	
>1 mm <4 mm	1(5.9%)	0	0	
≥4 mm	0	0	0	
p-Value	1.00	1.00	1.00	

TABLE 3 Peri-implant soft-tissue health.

	Group	1 year (mean ± SD)	3 years (mean ± SD)	5 years (mean ± SD)	*p*-Value
FMPS (%)	Cir	6.35 ± 6.29	26.16 ± 21.00	30.00 ± 23.03	.0021*
	Tri	7.91 ± 8.31	15.28 ± 16.37	20.37 ± 15.04	.013*
	p-Value	.54	.17	.24	/
PI (%)	Cir	NA	18.18 ± 27.34	30.95 ± 32.59	.44
	Tri	NA	19.44 ± 25.46	19.70 ± 26.69	.63
	p-Value	NA	0.91	0.36	/
BoP (*n* (%))	Cir	❶: 12 (70.6) ❶: 5 (29.4) ❷: 0 (0) ❸: 0 (0)	❶: 10 (83.3) ❶: 2 (16.7) ❷: 0 (0) ❸: 0 (0)	❶: 5 (35.7) ❶: 5 (35.7) ❷: 4 (28.6) ❸: 0 (0)	
	Tri	❶: 14 (82.4) ❶: 3 (17.6) ❷: 0 (0) ❸: 0 (0)	❶: 8 (66.7) ❶: 3 (25) ❷: 1 (8.3) ❸: 0 (0)	❶: 0 (0) ❶: 7 (63.6) ❷: 4 (36.4) ❸: 0 (0)	
	p-Value	.42	.64	.08	/
PD (mm) (n(%))	Cir	NA	3.05 ± 0.704 <6 mm: 11 (100) >6 mm: 0 (0)	3.36 ± 0.531 <6 mm: 14 (100) >6 mm: 0 (0)	.25
	Tri	NA	2.88 ± 0.565 <6 mm: 12 (100) >6 mm: 0 (0)	3.32 ± 0.531 < 6 mm: 11 (100) > 6 mm: 0 (0)	.12
	p-Value	NA	.53	.83	/
PES/14	Cir	10.59 ± 2.06	12.18 ± 2.27	9.64 ± 1.55	.22
	Tri	11.18 ± 2.38	11.42 ± 2.50	9.55 ± 2.58	.046
	p-Value	.45	.45	.91	/

Abbreviations: BoP, bleeding on probing; FMPS, Full Mouth Plaque Score; NA, not available; PD, pocket depth; PES, Pink Esthetic Score; PI, Pocket Index.
*All *p*-values are based on the evolution of each category from 1 year to 5 years. If data for 1 year is missing, it is based on the evolution between 3 and 5 years.

described with conical connection platform switching implant design which seem to be superior to flat-flat connections to preserve crestal bone level at short to medium term follow-ups (Caricasulo et al., 2018).

A single implant (from the Tri group) showed a progressive bone loss associated to peri-implant inflammation, leading to an overall peri-implantitis rate of 4%.

The prevalence of peri-implant disease in the present trial is inferior to the data described in several systematic reviews (Schwarz et al., 2018). As reported in the literature the prevalence of peri-implantitis is 10% on the implant level and 20% on the patient level after a follow-up period of varying from 5 to 10 years (Mombelli et al., 2012). However, considering history of periodontitis as a risk factors peri-implantitis, it is worth noting that only 11,8% (4 of 34) the patients included in the present study displayed history of periodontitis based on our retrospective data collection and this may explain the low occurrence of peri-implantitis. As described by Karousis and coworkers, patients with history of periodontitis show lower survival at 10 years (90.5%), higher rates of peri-implantitis (25.8%) and lower success rates than in patients without a history of periodontitis (Karoussis et al., 2003). Additionally, the low number of smoking patients (11.7%), also known to be a risk factor for the development of peri-implantitis, may have an influence on the low rate of peri-implantitis (Karoussis et al., 2003; Schwarz et al., 2018).

Regarding the significant increase of bleeding on probing from 1 year to 5 years leading to a prevalence of mucositis of 80%, these findings are higher than the prevalence of 43% reported in systematic reviews (Roccuzzo et al., 2018). In this study, patients were followed-up by their general dentist and thus did not necessarily receive a regular supportive implant care program. A regular supportive peri-implant therapy with biofilm removal may have reduced this high mucositis occurrence. Therefore, a preventive strategy against the conversion of health to peri-implant mucositis and also against the progression of peri-implant mucositis to peri-implantitis (Heitz-Mayfield & Salvi, 2018; Schwarz et al., 2018) would be recommendable.

4.2 | PES

We used this score to assess peri-implant soft tissues in the posterior region which may be associate to a risk of bias. Even if the results were comparable in the two groups for each timepoint, a slight but significant decrease of the PES values was identified in the Tri group. This decrease may be attributed to the dropout and be related to the fact that not all the same patients were evaluated at the three timepoints.

4.3 | PROMs

De Bruyn et al. (2015) highlighted the urgent need of standardization of PROMs related to implant dentistry clinical trials (De Bruyn

TABLE 4 Patient-reported outcome measures (PROMs).

Variable		1 year		3 years		5 years		
		N	Mean ± SD	*N*	Mean ± SD	*N*	Mean ± SD	*p*-Value
Implant feeling like a natural tooth	Cir	17	9.06 ± 1.82	12	9.25 ± 0.97	14	9.79 ± 0.43	.30
	Tri	17	9.35 ± 1.5	12	9.58 ± 0.52	11	9.45 ± 0.93	.83
	p-Value	.61		.30		.25		/
General esthetic of the crown	Cir	17	9.71 ± 0.59	12	9.58 ± 0.67	14	9.57 ± 0.94	.69
	Tri	17	9.63 ± 0.86	12	9.67 ± 0.65	11	9.73 ± 0.47	.90
	p-Value	.82		.76		.62		/
Esthetic of the crown similar to a natural tooth	Cir	17	9.65 ± 0.6	12	9.42 ± 0.90	14	9.36 ± 1.15	.15
	Tri	17	9.53 ± 0.87	12	9.67 ± 0.78	11	9.45 ± 0.93	.58
	p-Value	.65		.47		.82		/
Redo the treatment?	Cir	17	10.00 ± 0	12	9.67 ± 0.78	14	9.79 ± 0.58	.12
	Tri	17	9.94 ± 0.24	12	9.75 ± 0.62	11	9.73 ± 0.65	.41
	p-Value	.32		.77		.81		/

Note: Pain level at implant placement 1 = low to 10 = high; implant sensation compared with contralateral natural teeth: 1 = not similar to 10 = very similar; general aesthetic result: 1 = not satisfied to 10 = very satisfied; implant aesthetic compared to contralateral natural teeth: 1 = not similar to 10 = very similar. Patients were also asked if they would redo the treatment: 1 = not at all to 10 = absolutely.

et al., 2015). The global PROM results indicate that patients were highly (>9/10) and equally satisfied within Cir and Tri group and this satisfaction level remained stable over the follow-up period. These results are not surprising as all implants were successful and no adverse event occurred. However, these PROMs data have to be interpreted cautiously, as the patient knew that they were included in a study, in which they had a potential interest.

4.4 | Limitations

It should be acknowledged that this report suffers from additional several limitations. This kind of radiographic assessments can lead to substantial errors (Schulze & d'Hoedt, 2001; Hollender & Rockler, 1980; Sewerin, 1990), however, several aspects were taken into consideration in order to increase the accuracy of the evaluation: two examiners performed the measurements, with an ICC of 0.81, personalized radiographic holders were used to standardized peri-apical radiographs and finally, each radiograph was calibrated using the known distance between implant treads.

Additionally, smoking status is known to influence marginal peri-implant bone remodeling (Afshari et al., 2022). The present study recorded the smoking conditions with the number of cigarettes per day while it is proven that the accumulative effect of cigarettes (packyears) can lead to higher risk of complication, thus would be more accurate to report the effect of smoking.

The relatively high drop-out rate at the 3- and 5-year timepoint is another limitation of the present study. However, long term studies are always at higher risk for patients dropouts.

5 | CONCLUSION

This 5-year follow up evaluation of the triangular neck implants designs did not show any significant difference when compared to the conventional circular neck implants in terms of implant survival, peri-implant bone changes, peri-implant health as well as PROMs. Peri-implant bone loss and occurrence of periodontitis were low (4%) while the prevalence of peri-implant mucositis was high (80%).

AUTHOR CONTRIBUTIONS

LLM, GL, and FL conceived the ideas; LLM, LL, and AH collected the data; AH, LS, and LL analyzed the data; AH and FL led the writing.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflicts of interest regarding the present study.

DATA AVAILABILITY STATEMENT

Research data are not shared due to privacy or ethical restrictions.

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