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Narrow diameter titanium–zirconium tissue-level implants supporting multi-unit FDPs in the anterior area: A 5-year prospective study

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Abstract

Background: Narrow diameter implants (NDIs) are used in cases of limited mesio-distal space, or if the alveolar ridge does not allow placement of a standard diameter implant.

Purpose: The aim of this prospective case series study is to present the 5-year clinical-, radiological-, and patient-reported outcome measures (PROMs) of patients with partial edentulism in the anterior area of the jaws requiring the placement of two narrow diameter implants to support a 3- or 4-unit fixed partial denture (FPD).

Materials and Methods: Thirty partially edentulous patients missing 3 or 4 adjacent teeth in the anterior area of the jaws were included in the study. Two titanium–zirconium tissue-level NDIs were placed in each patient in healed anterior sites (60 implants). A conventional loading protocol was performed to provide a FPD. Implant survival, success, marginal bone-level changes (MBL), clinical parameters, buccal bone stability with CBCT, adverse events and PROMs were recorded.

Results: The survival and success rates for the implants were 100%. The mean MBL (±SD) after prosthesis delivery, and 5-year follow-up (mean 58.8 months; range: 36–60) was 0.12 ± 0.22 and 0.52 ± 0.46 mm, respectively.

Decementation and screw loosening were the most frequent prosthetic complications, yielding a prosthetic survival and success rates of 100% and 80%, respectively. Patient satisfaction was high with a mean (±SD) score of 89.6 ± 15.1.

Conclusions: The use of tissue-level titanium–zirconium NDIs supporting splinted multi-unit FPDs in the anterior area seems to be a safe and predictable treatment option after a 5-year follow-up period.

KEYWORDS
biomedical and dental materials, dental implants, humans, narrow diameter, partial edentulism, patient-reported outcome measures, prospective studies, titanium–zirconium

1 | INTRODUCTION

Dental implants are a reliable option for the treatment of partial and total edentulism (Buser et al., 2012; Krebs et al., 2013; Lekholm et al., 2006). Occasionally, the available bone is not sufficient to place implants with a regular diameter and additional surgical bone regeneration techniques are necessary (Chiapasco et al., 2009; Jensen & Terheyden, 2009; Milinkovic & Cordaro, 2014). Narrow diameter implants (NDI) are an alternative treatment. A NDI is usually an implant of less than 3.5 mm in diameter, as defined by Klein and coworkers: Category 1: Implants with a diameter of <3 mm; Category 2: Implants with a diameter of 3 to <3.3 mm; Category 3: Implants with a diameter of 3.3–3.5 mm. (Klein et al., 2014). Implants in Category 1 have a survival rate of 94.7 ± 5%, usually with a one-piece design and are indicated in edentulous patients. Implants in Category 2 have a survival rate of 97.3 ± 5% and are used mainly in maxillary lateral incisors or mandibular incisors. Category 3 has a survival rate of 97.7 ± 2.3% and are described for all indications in the mouth (Schiegnitz & Al-Nawas, 2018). Although survival rates are high in this last category, the results usually include a mix of sites (anterior, posterior, maxilla, mandible) prosthesis designs (single crowns, FPDs and full-arch patients) and are not well described or not described at all.

Several studies describe the placement of NDIs with different designs in the posterior sectors. (Al-Aali et al., 2019; Altinci et al., 2016; El-Sheikh & Shihabuddin, 2014; Grandi et al., 2017; Shi et al., 2018). These articles describe their use in single and multiple prostheses and report high survival rates with few complications. From a systematic review, we can conclude that NDIs in posterior sectors can be used following some clinical recommendations, although it is based on short-term data (Assaf et al., 2015).

In the case of the anterior zone, the literature usually reports results for single crowns and there are few studies with results for FPDs (Galindo-Moreno et al., 2017; Parize et al., 2019). A retrospective study that includes anterior and posterior sectors rehabilitated with NDIs concludes that in both cases the implants worked equally well and with acceptable complication rates (Alrabiah et al., 2020). In a study in which mandibular incisors were replaced with single crowns or FPDs supported on tissue-level implants, the results were functionally and esthetically favorable (Cordaro et al., 2006). In 2016, Moráguez and coworkers reported on 10 splinted multi-unit FPDs that were used to replace the four maxillary incisors with tissue-level NDIs with a five-year follow-up period (Moráguez et al., 2017). Thus, the literature is scarce in the case of NDIs in the anterior area.

The main indications for NDIs are a reduced mesio-distal space (Cordaro et al., 2006; Polizzi et al., 1999), a narrow alveolar ridge (Allum et al., 2008) or little interradicular space (Davarpanah et al., 2000; Froum et al., 2007; Lee et al., 2013). On the other hand, the risk of potential mechanical failure has been reported in the literature (Wiskott et al., 1995). To overcome these limitations, titanium can be alloyed with other metals to improve its mechanical strength, like a titanium–zirconium alloy (Roxolid®) (Barter et al., 2012). This implant material is alloyed from 83% to 87% titanium and 13%–17% zirconium. Peri-implant bone formation and removal torque between titanium and Roxolid® has been shown to be similar or superior in experimental studies (Gottlow et al., 2012; Thoma et al., 2011). Biocompatibility of titanium–zirconium seems to be better than other metals and alloys containing aluminum or vanadium (Ikarashi et al., 2005; Steinemann, 1998). In the same way, a hydrophilic surface (SLActive®) with improved bone healing properties (Buser et al., 2004; Morton et al., 2010; Zollner et al., 2008) can be obtained.

Different randomized controlled clinical studies (Al-Nawas et al., 2012; de Souza et al., 2018; Ghazal et al., 2019; Ioannidis et al., 2015; Muller et al., 2015) and prospective studies (Akca et al., 2013; Al-Nawas et al., 2014; Barter et al., 2012; Chiapasco et al., 2012; Cordaro et al., 2013; Tolentino et al., 2014) have been conducted with high survival and success rates, comparable to standard diameter implants (Buser et al., 2012; Cochran et al., 2011). There are, however, no articles specifically describing the use of titanium–zirconium dental implants in partially edentulous patients in the anterior zone. The aim of our study is to assess the survival rate, among other clinical and radiological parameters, of narrow-diameter titanium–zirconium tissue-level implants with a hydrophilic surface supporting multi-unit FPDs. As secondary objectives, success rate, marginal bone loss (MBL), clinical parameters, biologic and technical complications, stability of the buccal wall and patient's satisfaction were investigated.

2 | MATERIALS AND METHODS

2.1 | Study design

This study was designed as a case series prospective clinical trial of a single cohort of patients with partial edentulism who attended to the University Dental Clinic (CUO) at Universitat Internacional de Catalunya (UIC), Barcelona, for oral rehabilitation. The study protocol was approved by the Clinical Research Ethics Committee (CEIC) of the Universitat Internacional de Catalunya with the code IMP-ECL-2012-01. This study was designed and carried out in accordance with the Declaration of Helsinki (World Medical Association, 2013), the Clinical investigation of medical devices for human subjects – Good clinical practice (UNE-EN ISO 14155:2020) and reported according to the STROBE guidelines (von Elm et al., 2007).

The trial was registered at ISRCTNregistry (ISRCTN23651018), and experimental procedures were performed from October 2012 until April 2016. Patients received information about the implant treatment and signed the UIC dental implant informed consent form. Additionally, the patients were informed verbally and in a printed form by means of a Patient Information Sheet on the advantages and disadvantages of participating in this study. Once the patients received the information and signed the specific research consent, they were given a copy of it to participate in the study. No study related interventions were performed prior to obtaining written consent from the patients.

2.2 | Study population

Thirty partially edentulous patients needing rehabilitation of three or four consecutive teeth from second premolar to second premolar were included in the study. A pre-operative assessment included a cast model analysis, intraoral and extraoral photographs, periapical and panoramic X-rays and a CBCT. All patients were recruited by the same calibrated investigator (P.A.) who enrolled them if they complied with the following inclusion and exclusion criteria:

a. Inclusion criteria: subjects should be at least 18 years old, having a healed alveolar ridge of at least 3 months after extraction and a ridge width between 3 and 6 mm. Buccal guided bone regeneration for a maximum of 3 mm dehiscence type defects and subepithelial connective tissue grafting could be allowed. Patients should be periodontally healthy and have an O'Leary plaque control of ≤25% at the time of surgery. Patients should not have any systemic condition, disease or metal allergies that may interfere with implant surgery.
b. Exclusion criteria: severe systemic condition, untreated periodontal disease, as well for subjects who had guided bone regeneration prior to implant placement.

Description of the timeline is presented in Figure 1.

2.3 | Surgical procedure for implant placement

Third year residents from the International Master of Oral Surgery (IMOS), and from the Master of Periodontology of the Universitat Internacional de Catalunya (Barcelona) performed all surgeries monitored by the same investigator (P.A.). All residents were specifically trained in the surgical protocol to place the implants.

Surgical guides were used to assure prosthetically driven implant positioning. Under local anesthesia (Articaine 1/100.000, Ultracain®), a full thickness flap was raised and two Straumann Roxolid® SLActive® Narrow Neck Crossfit (NNC) dental implants (Straumann Group AG) of 3.3 mm in diameter and between 10.0 and 14.0 mm in length were placed in each patient. Drilling sequence and placement were performed according to the manufacturer's recommendations. The insertion torque was checked by means of a torque wrench. The polished-rough neck interface was always submerged. When a partial dehiscence of the buccal wall, or a very thin buccal wall was detected (<1 mm), a 0 mm closure screw or a 2 mm healing abutment was placed, and a guided bone regeneration technique was performed by placing a xenograft (BioOss®, Geistlich Pharma AG) and a resorbable collagen membrane (Cytoplast RTM, Osteogenics Biomedical, Inc.). When there was a lack in the quantity (thickness) of the soft tissue in the esthetic area, a connective tissue graft from the premolar area of the palate was obtained and placed buccally, mainly for pontic enhancement.

If no regenerative procedure was necessary, 3- or 4.5 mm healing abutments were placed. Flaps were sutured with non-absorbable 4/0 suture (Ancladen Polyester green or PV Monofil, Ancladen). After the intervention, periapical radiographs were taken with the long cone technique and standardized positioners with a silicone bite registration. The patients received a temporary removable prosthesis during the healing period or a fixed tooth-supported temporary prosthesis. Amoxicillin 750 mg 1 every 8 h for 7 days, starting the intake 24 h before the intervention, as well as ibuprofen 600 mg every 8 h for 2 days and a 0.12% chlorhexidine mouthwash twice a day for 15 days were prescribed. In patients allergic to penicillin, clindamycin 300 mg every 8 h for 7 days was prescribed, starting the intake 24 h before the intervention.

Sutures were removed after 7 or 14 days, depending on whether a regenerative procedure had been done. After a variable period of healing (6–8 weeks), the secondary stability was confirmed by clinical tests (percussion and tightening of the healing abutments) and

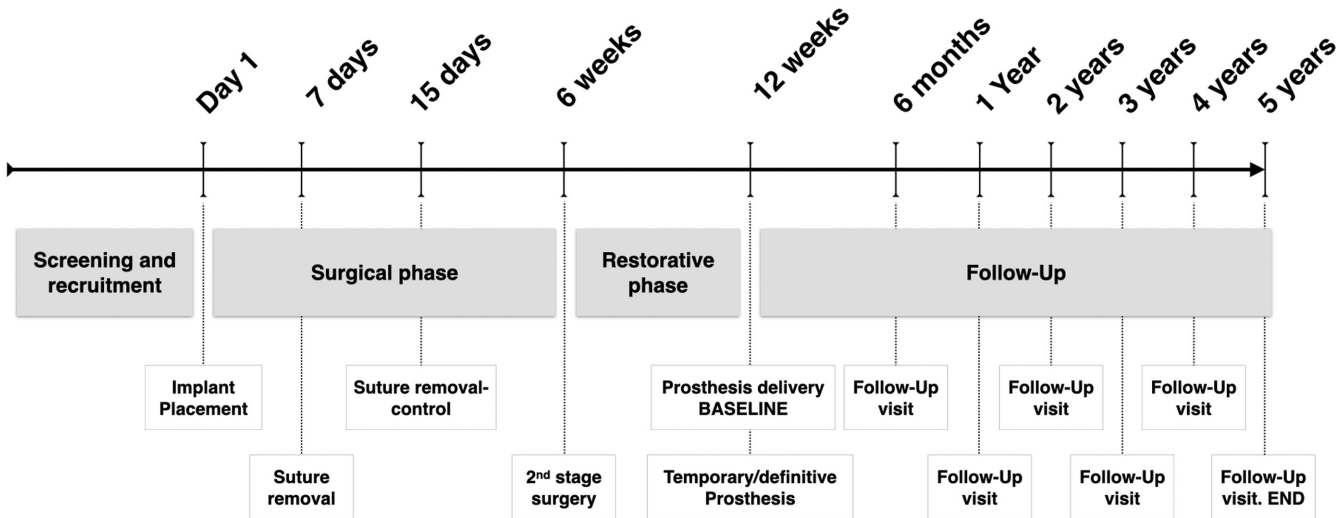

FIGURE 1 Timeline of the study from screening to the 5-year follow-up visit.

radiographs. Second-stage surgery was performed with local anesthesia after 6 weeks, if necessary, with a single incision technique in the crestal area or with a 3 mm-diameter soft tissue punch if there was an excess of keratinized tissue available. Patients were then referred for restorative treatment. Figure 2 shows the surgical sequence for a patient without guided bone regeneration.

2.4 | Restorative procedures

Clinical restorative procedures were carried out by second- or third-year residents of the Master of Restorative Dentistry (MORE), or by the International Master in Oral Surgery (IMOS) of the Universitat Internacional de Catalunya. The process for the preparation of the fixed partial denture (FPD) was similar for all patients: impression taking with an open tray and addition silicone, screwed aesthetic try-in test and prosthesis delivery, as illustrated in Figure 3. Passive fit was assessed radiologically and clinically at every step. Patients with high aesthetic demands underwent a preliminary phase with screwed provisional made of resin on two NNC temporary abutments (non-engaging) for bridge (Straumann Group AG). In the cases where the prosthesis was cemented, non-customized Ti-Al-Nb cementing abutments (Straumann Group AG) were used and a noble metal (Au-Pd) prosthesis was made with feldspathic ceramic veneer. In cases where the prosthesis was screw-retained, castable non-engaging gold abutments (Straumann Group AG) were used in conjunction with noble metal (Au-Pd) and with feldspathic ceramic veneering (Ivoclar-Vivadent SLU). A cleansable prosthesis design with ovate pontics was used in all cases. Emergence profile was designed as straight as possible. Ceramics were glazed and thoroughly polished. All laboratory procedures were carried out at the University Clinic's external lab (Odontècnic, SL, L'Hospitalet de Llobregat).

The final porcelain-fused-to-metal screw-retained prosthesis was placed with 35 Ncm torque. Access holes were sealed with PTFE tape and flowable composite (Charisma® Flow, Kulzer GmbH). In the case of cement-retained bridges, abutments were screwed with 35 Ncm torque. Abutment access holes were sealed with PTFE tape and flowable composite (Charisma® Flow, Kulzer GmbH). Prosthesis was cemented with a temporary cement (TempBond®, Kerr Corporation). One week after prosthesis placement was considered the baseline (BL) for future clinical and radiological measurements. All the patients were recalled for the 6 months, and 1-, 2-, 3-, 4- and 5-year examinations, coinciding with their maintenance appointment (minimum once a year). The same calibrated dentist (PA) performed all clinical and radiological follow-up visits.

2.5 | Outcome variables

2.5.1 | Implant survival and success

In this study, a surviving implant was considered to be functionally integrated at the time of assessment. Success criteria used in this study were the following (Karoussis et al., 2004):

1. Absence of mobility.
2. Absence of persistent subjective complaints (pain, foreign body sensation and/or dysesthesia).
3. No PPD > 5 mm.
4. No PPD = 5 mm and BoP.
5. Absence of a continuous radiolucency around the implant.
6. After the first year of service, the annual MBL should not exceed 0.2 mm.

2.5.2 | Prosthesis survival and success

Prosthesis survival was defined as the fixed dental prosthesis (FDP) remaining in situ with or without modification for the entire observation period. Prosthesis was considered successful if it was free of all complications during the study period (Pjetursson et al., 2012). Technical complications included screw loosening, screw fracture, porcelain chipping, decementation, implant fracture and abutment fracture.

2.5.3 | Marginal bone-level change

Radiographs were taken at the day of surgery, at the placement of the prosthesis, after 6 months and 1-, 2-, 3-, 4-, and 5-years to analyze the marginal bone-level change (MBL). To obtain standardized x-rays, a Digital Imaging Plate System (Carestream Health) and a digital developer CR7600 (Carestream Health) or VistaScan Mini (Dürr Dental AG) were used. On each X-ray, a 32 mm × 22 mm metal grid with copper lines arranged in 1 mm × 1 mm grid (Ace Surgical Supply Co.) was placed. An individualized bite registration was made for each patient with an addition silicone (Optosil®, Heraeus Kulzer GmbH & Co. KG) using the positioner (XCP®, Dentsply Rinn). This silicone key could be separated from the positioner, disinfected, and stored to repeat the same radiograph during follow-up in the same patient.

The digital radiographs were analyzed with ImageJ software (US National Institutes of Health) by a calibrated dentist (J.N.). The millimeter grid was used as a reference to perform the calibration. For the calibration, measurements were made on 10 radiographs twice in 24 h. The interclass correlation coefficient was greater than 90%. The interface between the polished neck and the rough surface was used as a reference, until the first contact with the bone. The polished neck of the Straumann NNC implant measures 1.8 mm. The mean MBL was calculated for each implant, by averaging the mesial and distal MBL. The changes in MBL from implant placement to prosthesis delivery, 6 months, 1-, 2-, 3-, 4- and 5-year examinations were calculated.

2.5.4 | Clinical parameters

The following variables were assessed at prosthesis placement, 6 months and 1-, 2-, 3-, 4- and 5-year examinations:

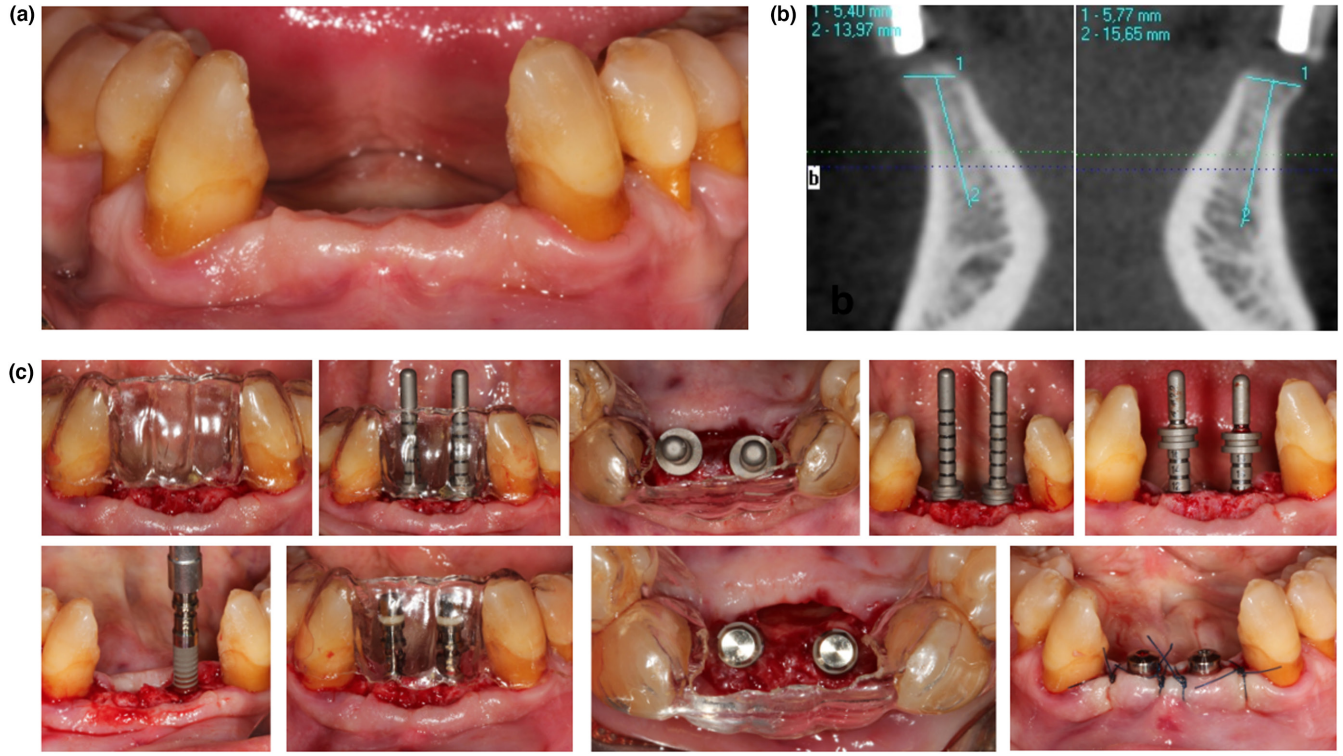

FIGURE 2 Surgery for implant placement. (a) Clinical situation. (b) Cone beam computed tomography (CBCT) and measurements corresponding to positions 3.2 and 4.2. (c) Implant site preparation and implant placement with a surgical guide.

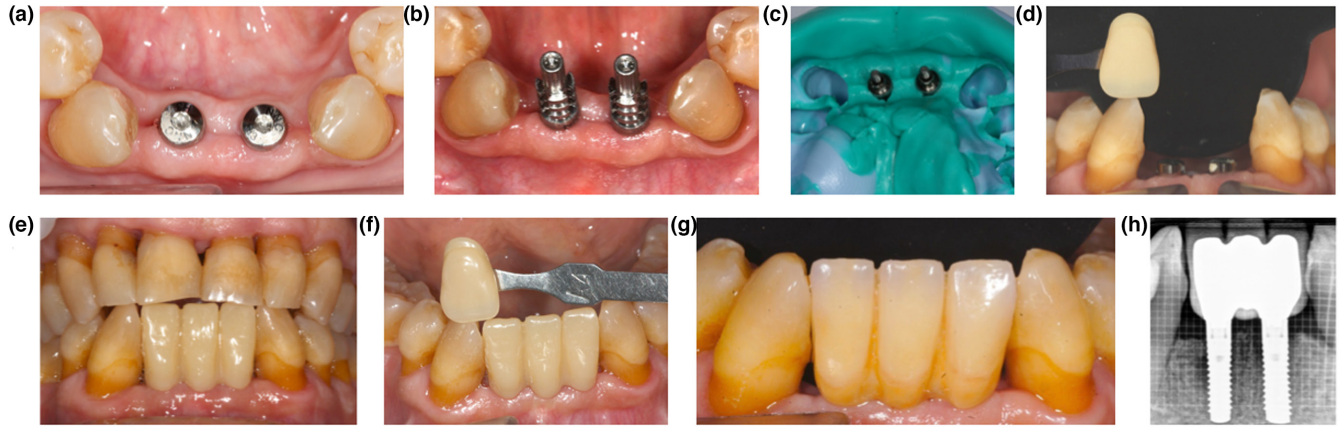

FIGURE 3 Step-by-step exemplary restorative procedure. (a) Initial situation. (b) Open tray impression abutments in place. (c) Open tray impression with addition silicone. (d) Color taking. (e) Screwed aesthetic try-in. (f) Color taking to improve aesthetic aspect of restoration. (g) Prosthesis delivery. (h) Standardized radiograph.

- Probing pocket depth (PD) at four sites per implant (mesial, distal, mid-vestibular and mid-palatal).
- Modified Plaque Index (PI) of Mombelli et al. (1987): was used to detect plaque around the implants. The following values are used: 0: plaque is not detected, value 1: plaque can be detected when passing a periodontal probe through the surface of the implant, value 2: plaque is detected by visual inspection and 3: abundant plaque.
- Modified Bleeding Index (BOP) of Mombelli et al. (1987): was used to detect bleeding. The values assigned are 0: absence of bleeding when using a probe, 1: isolated points of bleeding, 2: a continuous line of blood around the entire margin, 3: profuse bleeding.

PD, PI and BOP measurements were obtained with use of a manual periodontal probe (CP-15 UNC; Hu-Friedy).

2.5.5 | Stability of the buccal bone wall with cone beam computed tomography

Each patient included in the study received a CBCT (i-Cat, Imaging Sciences International Inc.) with parameters of 120 Kv, 5.125 mA and 3.6 s. of exposure, the day of the placement of the definitive prosthesis (Initial CBCT). After 12, 36 and 60 months, new CBCT's were performed.

Using the iCat Vision software (Imaging Sciences International Inc.), the measurements of these implants were made to evaluate the vestibular bone following the methodological procedure like the one described by other authors (Buser et al., 2013). Each implant was oriented and aligned in a perfect sagittal cut and parallel to the longitudinal axis of the implant. Knowing the length of the implant, it was measured from the apical to the polished neck-treated surface interface and it was assigned as L0. In the most vestibular area, 4 references were found: L0, L2, L4 and L6. L0 refers to the interface between the polished surface and the treated surface of the implant, L2 will be the point 2 mm apical to L0 following the longitudinal axis of the implant, L4 is the point 4 mm apical to L0 and L6 the point 6 mm apical to L0 both following the aforementioned axis. From L0, a perpendicular line to the axis of the implant will be traced until the outermost point of the visible vestibular table and the measurement will be recorded in millimeters. This measurement will be repeated for L2, L4 and L6. All measurements were carried out by two calibrated dentists (JN and PA), who were meeting before trial beginning to standardize measurements.

2.5.6 | Adverse events and complications

Adverse events (AE) and biological and technical complications were assessed and recorded at each study visit. Postoperative adverse events like postoperative pain, inflammation, edema, or infection were recorded. Biological complications were mucositis and periimplantitis. Mucositis was defined with the following criteria (Heitz-Mayfield & Salvi, 2018): The presence of bleeding on probing and or suppuration, with no additional bone loss following initial healing. Peri-implantitis was defined with the following criteria (Schwarz et al., 2018): Bleeding on probing and/or suppuration and marginal bone loss following initial healing. Technical complications included screw loosening, screw fracture, porcelain chipping, decementation, implant fracture and abutment fracture.

2.5.7 | Patient reported outcome measures

Patient reported outcome measures were assessed using a customized VAS questionnaire. On a 100 mm line, patients had to make a mark from "dissatisfied" to "very satisfied". The degree of satisfaction related with speaking, masticatory function, hygiene, esthetics, and general satisfaction were recorded at baseline and after 1, 2, 3, 4 and 5 years of function. The five questions included in the questionnaire were:

1. What is your level of satisfaction regarding speech?
2. What is your level of satisfaction regarding masticatory function?
3. What is your level of satisfaction in reference to hygiene?
4. What is your level of esthetic satisfaction?
5. What is your overall satisfaction level?

2.6 | Statistical analysis and sample size calculation

Statistical analysis was performed using the R 3.0.2 software (RFoundation for Statistical Computing). Descriptive analysis was applied for all the variables collected in the investigation: mean, standard deviation, minimum, maximum and median for the continuous and absolute and relative frequencies for the categorized ones.

A linear model has been estimated by generalized estimation equations (GEE) to evaluate changes in clinical and radiographic parameters over time. The effect of time is evaluated with a Wald Chi^2 statistic with Bonferroni correction for multiple comparisons. With this model, the intra-subject correlation inherent to the duplicity of implants within a patient is controlled. The level of significance used in the analysis was 5% ($\alpha = 0.05$).

A linear model has been estimated by generalized estimating equations (GEE) to evaluate changes at PD over time. Binary logistic models have been estimated for outcomes presence of PI and BOP (scores > 0) under GEE.

To detect a bone loss of 0.15 mm, considered clinically relevant, with a power of 80%, 34 implants (of 34 different patients) were required, assuming a standard deviation of 0.30 (Tolentino et al., 2015) and a confidence level of 95%. Given the multilevel design of the study (each patient will receive two implants), the previous sample size ($n = 34$) has to be corrected. Assuming a moderate intra-subject correlation ($\rho = 0.5$), the sample size increased to 51 implants. As the expected drop-out rate was 15%, a sample size of 30 patients with $n = 60$ implants was used.

3 | RESULTS

3.1 | Demography

A total number of 30 patients were operated between October 2012 and April 2016 for this prospective study (Patient flow diagram is illustrated on Figure 4). There were Twenty-one male (70%) and nine female (30%) patients with an average age of 57.8 years (SD 9.5). Two patients were smokers, and one was type II diabetic. 80% of patients lost their teeth due to periodontal disease. The rest of the patients lost their teeth due to decay or trauma, except one patient who had two implants placed in position 1.2 and 2.2 due to agenesia (Table 1).

3.2 | Surgery for implant placement

Sixty Ti–Zr implants were successfully placed. The average insertion torque was 30.8 Ncm (SD = 7.7). Thirteen patients (43.3%) received minor guided bone regeneration because of dehiscence defects or a thin buccal wall and 3 (10%) required soft tissue grafting for volume improvement in the pontics area (Table 2). Of the 13 implants that required GBR, second stage surgery was performed for 10 of them in a minimally invasive way and no sutures were used.

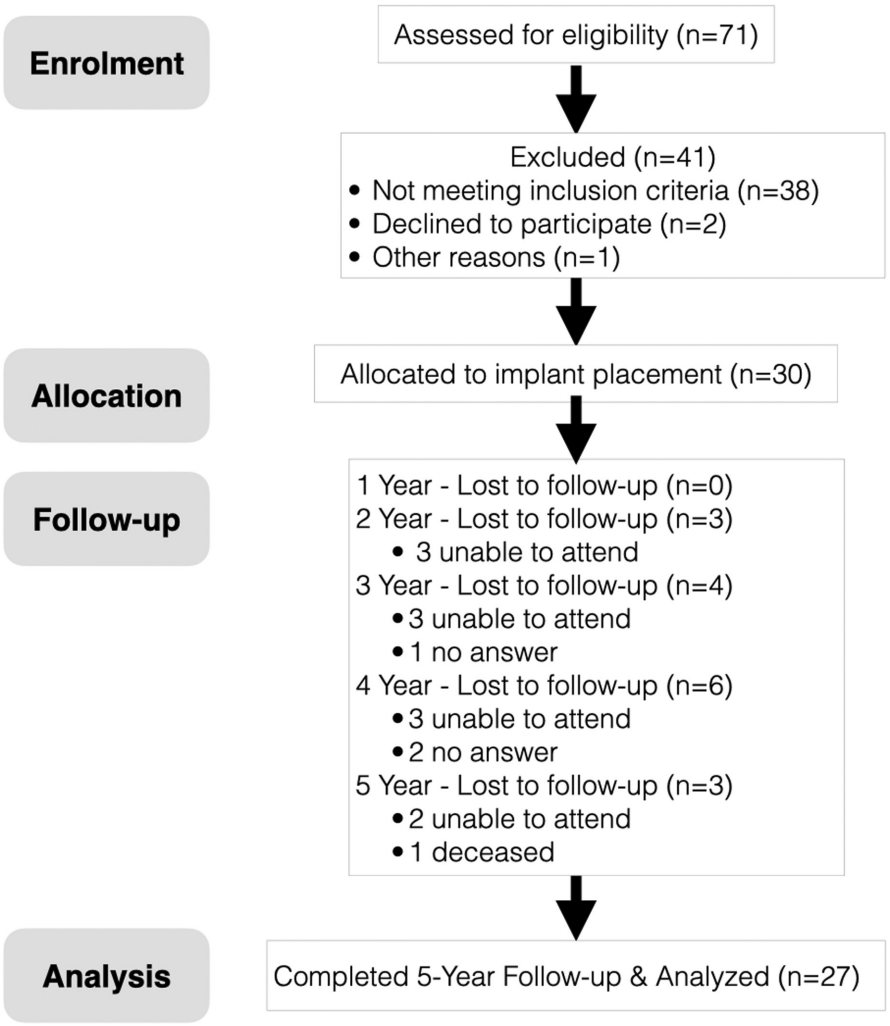

FIGURE 4 Patient flow diagram of the study.

3.3 | Survival and success of implants

All the patients attended the periodic check-ups at 7 and 15 days and between 6 and 8 weeks to assess the osseointegration and were referred for rehabilitation treatment. The 60 implants were functionally inserted and met the success criteria at 6 and 12 months, therefore the survival and success rates were 100%. During the 5-year period, three patients, representing six implants, dropped out of the study (Drop-out rate 10%). One patient died because of lung cancer during the study. The other two patients were handicapped and could not attend the University's Clinic and were on recall elsewhere. Twelve patients (40%) and 14 implants (23%) had peri-implant mucositis during the study, who were treated successfully with additional mechanical and chemical non-surgical therapy. The level of compliance with maintenance was correct for most of the patients. Consequently, 27 patients and 54 implants remained in the study for the final examination after 5 years of loading and yielded a survival rate of 100% at patient level (CI 95%, 87.2%–100%) and at implant level (CI 95%, 93.4%–100%). Success rates were 100% according to previously defined criteria.

3.4 | Marginal bone level (MBL)

At implant placement surgery, the mean (±SD) (median; IQR) MBL was 0.01 ± 0.03 mm (0; 0–0). At the time of placement of the prosthesis (BL), the MBL was 0.12 ± 0.22 mm (0; 0–0.13). Six months after the installation of the prosthesis, it was 0.20 ± 0.26 mm (0.10; 0–0.25). At 12 months, it was 0.24 ± 0.28 mm (0.15; 0.05–0.30). At prosthesis delivery, MBL was significantly increased compared to surgery ($p < .001$) After 5 years of follow-up, the mean MBL was 0.52 ± 0.46 mm (0.40; 0.20–0.60), with half of the implants presenting a value greater than 0.40 mm. These figures suggest an approximate annual rate of 0.1 mm MBL loss. There were no implants with a difference equal to or greater than 2 mm from baseline to 5 years of follow-up. There were four implants with a difference greater than 1 mm (7.4% of the total number of available implants at 5 years). These four implants were from four different patients. Therefore, there were four patients with one implant with a loss >1 mm, that is, 14.8% patients (out of a total of 27).

The progression of the bone loss is already evident even at the time of prosthesis placement and at the mesial and distal level (Figure 5 and Table 3).

TABLE 1 Patient demographics and reason for tooth loss.

	Number of patients	Percentage (%)
Gender		
Male	21	70
Female	9	30
Total	30	
Age		
Mean (SD)	57,8 (9,5)	
Range	33–72	
Reason for tooth loss for each implant site		
Periodontal disease	51	85
Infection	2	3.3
Agenesia	2	3.3
Trauma	2	3.3
Prostho	1	1.7
Unknown	2	3.3
Disease/Risk		
Smokers	4	
Diabetic	4	
HTA	4	
Penicillin allergy	1	
Hipo-/Hyperthyroidism	2	
Osteoporosis	1	
Other diseases/conditions	3	

3.5 | Rehabilitation results

Thirty multi-unit FPDs were delivered. Eighteen out of 30 patients had 3 or 4 missing mandibular incisors and the remaining 11 cases were missing maxillary incisors and one case missing a canine and incisors. Eight patients received 3-unit FPDs and 22 received 4-unit FPDs. Eighteen prostheses had no extensions, while three FPDs had one distal cantilever and nine had two distal cantilevers. Two FPDs were cemented using stock prefabricated abutments due to the position of the implants and the anatomy of the residual ridge. The rest of the patients received a screwed porcelain-fused-to-metal using original gold-cast abutments. Prosthesis was in place for 27 patients after the 5-year observation period, and therefore, the survival of the prosthesis was 100%.

3.6 | Clinical parameters

3.6.1 | Probing depth (PD)

At prosthesis delivery, the mean (±SD) (median; IQR) PD was 1.79 ± 0.76 mm (1.75 mm; 1.00–2.38). Six months after the installation of the prosthesis, it was 2.05 ± 0.75 mm (2; 1.50–2.63). At 12 months, it was 2.39 ± 0.86 mm (2.50 mm; 1.75–2.75). After 1 year, all the sites showed a statistically significant increase in PD with respect to baseline ($p < .001$).

TABLE 2 Description of implant sites, implant information and hard and soft tissue grafting needs.

	Maxilla (CI/LI/C)	24 (21/2/1)
Implant sites	**Mandible (CI/LI)**	**36 (4/32)**
Number of implants	Total	60
Bone quality per site *n* (%)	Type 1	7 (11.7%)
	Type 2	29 (48.3%)
	Type 3	24 (40%)
	Type 4	0
Insertion torque (Ncm)	Mean (SD)	30.8 (7.7)
	Range	20–45
Bone augmentation patients (%)	Yes	13 (43.3%)
	No	17 (56%)
Soft tissue grafting patients (%)	Yes	3 (10%)
	No	27 (90%)
Implant length (mm) *n* (%)	10	30 (50%)
	12	26 (43.3%)
	14	4 (6.7%)

Abbreviations: C, canines; CI, central incisors; LI, lateral incisors.

At 5 years, the mean (±SD) (median; IQR) PD was 3.30 ± 0.80 mm (3.25; 3.75), which is 84.3% more than at baseline. There are two distinct phases in the progression of PD. Until the 2nd year, it is an active phase of continuous elevation and beyond the 2nd year the PD measurement has stabilized. Probing depth details are presented in Table 3 and Figure 6.

3.6.2 | Plaque index (PI)

The plaque index (PI) tends to increase as the follow-up progresses, but without significant differences. Plaque index is presented in detail in Table 3 and Figure 7.

In total, 61.7% of implants had a plaque index (PI) score of 0, 30% had a PI of 1 and 8.3% had a PI of 2 at the time of loading. At 6 months, the PI values were 0 in 48.3%, 1 in 41.7%, 2 in 8.3% and 3 in 1.7% of the implants. At 12 months, PI values were 0 in 48.3%, 1 in 38.3%, 2 in 8.3% and 3 in 5% of patients. After 5 years, PI values were 0 in 46.3%, 1 in 37%, 2 in 13% and 3 in 3.7% of patients.

3.6.3 | Bleeding index (BOP)

In total, 58.3% of the implants had a bleeding index (BOP) of 0, 38.3% had a BOP of 1 and 3.3% had an index of 2 at the time of loading. After 6 months, 45% of the BOP values were 0, 50% were 1 and 5% were 2. At 12 months, 30% of the BOP values were 0, 58.3% were 1 and 11.7% were 2, representing a significant increase. After 5 years, 33.3% of the BOP values were 0, 57.4% were 1 and 9.3% were 2. Bleeding index details are presented in Table 3 and Figure 8.

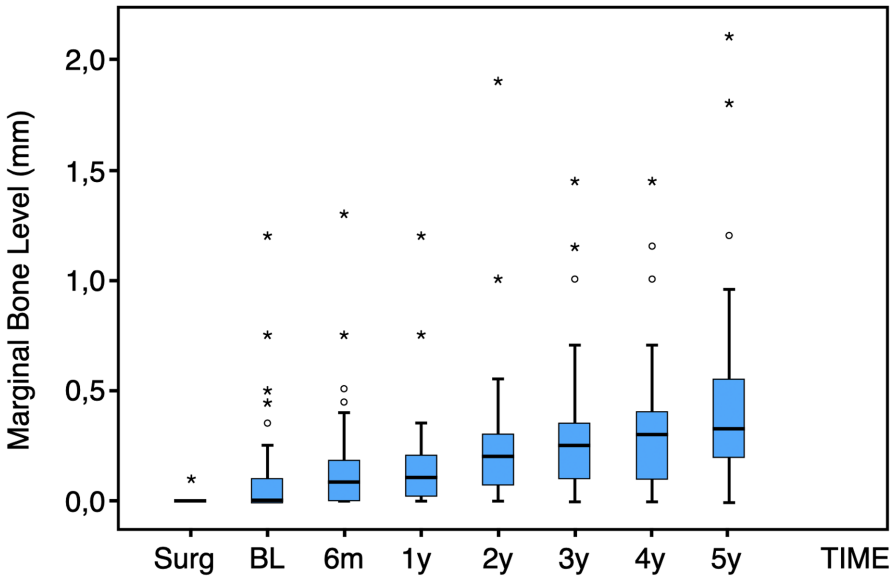

FIGURE 5 Marginal bone level (MBL) at different timepoints.

TABLE 3 Evolution of MBL and clinical parameters.

	Surgery	Prosthesis	6-months	1-year	2-year	3-year	4-year	5-year	*p*-Value
M MBL mean ± SD (median) in mm	0.01 ± 0.05 (0.00)	0.14 ± 0.27 (0.00) *p* = .124	0.20 ± 0.28 (0.10) ***p* = .003**[b]	0.22 ± 0.26 (0.15) ***p* < .001**[c]	0.32 ± 0.39 (0.20) ***p* < .001**[c]	0.32 ± 0.30 (0.20) ***p* < .001**[c]	0.34 ± 0.34 (0.20) ***p* < .001**[c]	0.42 ± 0.40 (0.20) ***p* < .001**[c]	***p* < .001**[c]
D MBL mean ± SD (median) in mm	0.00 ± 0.00 (0.00)	0.09 ± 0.20 (0.00) *p* = .057	0.20 ± 0.32 (0.10) ***p* < .001**[c]	0.25 ± 0.41 (0.15) ***p* < .001**[c]	0.28 ± 0.38 (0.20) ***p* < .001**[c]	0.35 ± 0.45 (0.20) ***p* < .001**[c]	0.36 ± 0.43 (0.20) ***p* < .001**[c]	0.60 ± 0.67 (0.40) ***p* < .001**[c]	***p* < .001**[c]
Mean MBL mean ± SD (median) in mm	0.01 ± 0.03 (0.00)	0.12 ± 0.22 (0.00) *p* = .067	0.20 ± 0.26 (0.10) ***p* < .001**[c]	0.24 ± 0.28 (0.15) ***p* < .001**[c]	0.30 ± 0.35 (0.20) ***p* < .001**[c]	0.34 ± 0.33 (0.20) ***p* < .001**[c]	0.35 ± 0.31 (0.30) ***p* < .001**[c]	0.52 ± 0.46 (0.40) ***p* < .001**[c]	***p* < .001**[c]
PD (mm)	–	1.79 ± 0.76 (1.75)	2.05 ± 0.75 (2.00) ***p* = .022**[a]	2.39 ± 0.86 (2.50) ***p* < .001**[c]	2.81 ± 0.70 (2.75) ***p* < .001**[c]	3.05 ± 0.77 (3.00) ***p* < .001**[c]	3.04 ± 0.58 (3.00) ***p* < .001**[c]	3.30 ± 0.80 (3.25) ***p* < .001**[c]	***p* < .001**
PI	Score 0	61.7%	48.3%	48.3%	55.6%	55.8%	54.2%	46.3%	
(%)	Score > 0	38.3%	51.7% *p* = 1.000	51.7% *p* = 1.000	44.4% *p* = 1.000	44.2% *p* = 1.000	45.8% *p* = 1.000	53.7% *p* = 1.000	*p* = .823
BOP	Score 0	58.3%	45%	30%	29.6%	34.6%	29.2%	33.3%	
(%)	Score > 0	41.7%	55% *p* = 1.000	70% ***p* = .024**[a]	70.4% *p* = .131	65.4% *p* = .662	70.8% *p* = .161	66.7% *p* = .996	***p* = .004**[b]

Note: Evolution of marginal bone-level changes (MBL): mean ± SD (median) in mm. Evolution of MBL: mean ± SD (median) in mm. Wald Chi^2 Test from the generalized estimating equations model (GEE) for the differences from surgery to the 5-year visit (with Bonferroni correction) and global changes (last column). Probing Depth (PD), mean ± SD (median) in mm; Plaque Index (PI), percentage of implants with Score 0; Score > 0; Bleeding Index (BOP), percentage of implants with Score 0; Score > 0. For dependent variables, the presence of PI (Score > 0) and BOP (> 0) over time, *p*-values estimated from a binary logistic regression model with GEE. For dependent variable PD over time, *p*-values estimated from a linear regression model with GEE. *p*-values at each timepoint for multiple comparisons compared to baseline. *p*-value in the last column for overall differences over time. *p*-values in bold were statistically significant ([a] $p > .05$, [b] $p > .01$, [c] $p > .001$).

3.7 | Stability of the buccal bone wall with cone beam computed tomography (CBCT)

Stability of the buccal bone measured with CBCT exhibited a significant decrease in measurements at L0 ($p = .030$) and L2 ($p = .015$), and less noticeable at L4 ($p = .201$) and L6 ($p = 104$). For L0, the decrease was only significant when the measurement at 5 years is compared to the baseline ($p = .025$). For L2, there was no significant decrease when the 5-year measurement was compared to baseline, although the decreasing serial *p*-values also suggested a progressive decrease. Table 4 and Figure 9 presents the buccal bone stability details.

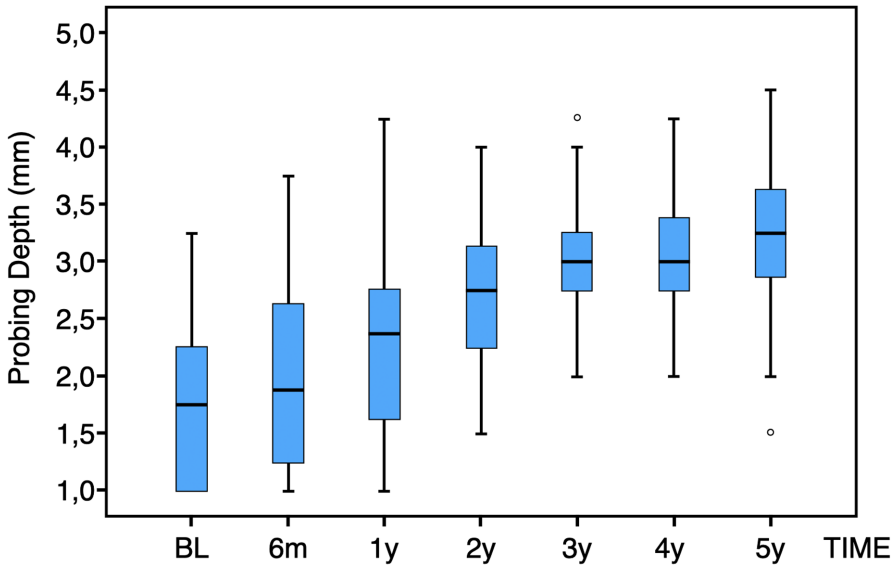

FIGURE 6 Probing depth results at different timepoints.

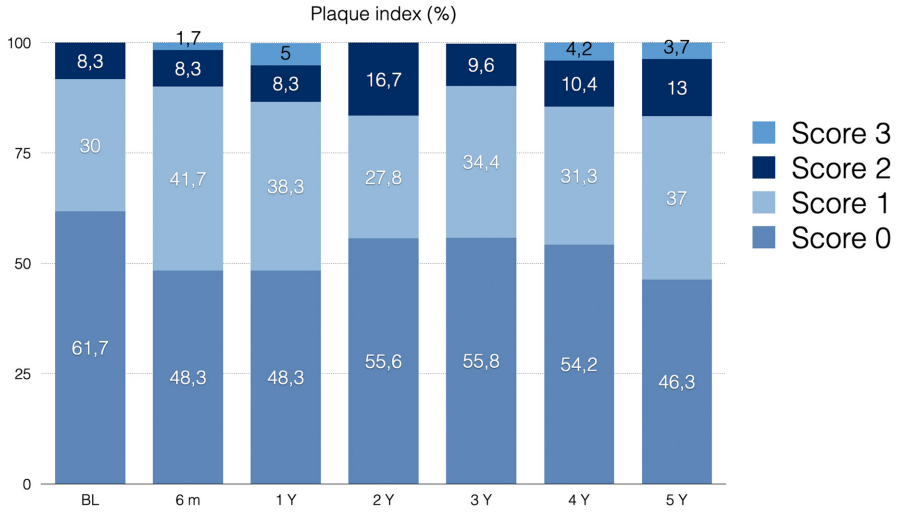

FIGURE 7 Plaque index results at different timepoints.

3.8 | Adverse events and complications

Most of the implants healed uneventfully, except two patients who presented with edema and postoperative inflammation. Both patients had received guided bone regeneration (GBR). In another patient, an episode of intense postoperative pain was recorded, in relation with a connective tissue graft obtained from the palate.

Twelve patients (40%) had mucositis (no marginal bone loss) during the study, who were treated successfully with additional non-surgical therapy. Events occurred after 24 months (2), 36 months (4), 48 months (4) and after 60 months (2).

During the study period, there were nine minor technical complications in 6 patients (20%). Decementation of the prosthesis occurred 22 and 58 months after loading in one patient with a 3-unit cantilevered prosthesis in the maxilla and after 36 months in a cemented 4-unit prosthesis of another patient (three events, two patients). Screw loosening occurred in two patients who had a maxillary 4-unit FPD with distal extensions after 5 and 20 months the first and after 11 and 44 months the second (four events, two patients). Fracture of a ceramic incisal edge (chipping) which required polishing occurred after 36 and 48 months in two patients with a 4-unit FPDs with extensions (two events, two patients). The prosthetic survival rate was 100% and the success rate was 80% according to previously defined criteria.

3.9 | Patient-reported outcome measures (PROMs)

The parameter general satisfaction of the patients was high: mean 89.6 ± 15.1 (median 95) at the last visit. Even so, there were four patients with very low scores (below 80) compared to the bulk of the sample. At 5 years, the mean of the esthetic parameter was 90.0 ± 15.8 (median of 96). These were the highest figures among the four aspects evaluated. The lowest scores were recorded with the hygiene parameter, with a mean score of 81.0 ± 21.0 (median of 92). The mean patient satisfaction of the different parameters (general, speech, hygiene, masticatory function, and esthetics) was 86.2 ± 16.5 (median of 91.4) at the last 5-year visit. There were no great variations throughout the follow-up, but an improvement in

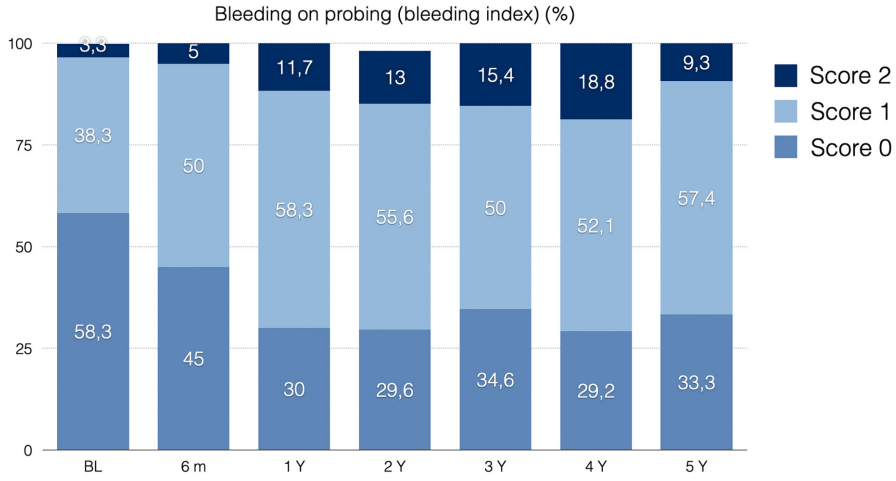

FIGURE 8 Bleeding index (bleeding on probing, BOP) results at different timepoints.

TABLE 4 Evolution of L (thickness of buccal wall, CBCT): mean ± SD (median) in mm.

	Baseline	1 year	3 years	5 years	
	Mean ± SD (median) in mm	Mean ± SD (median) in mm	Mean ± SD (median) in mm	Mean ± SD (median) in mm	*p*-Value
L0	1.18 ± 1	1.09 ± 0.92	0.90 ± 1.17	0.83 ± 1.00	**$p = .030$**
	(0.95)	(0.95)	(0.60)	(0.40)	
		$p = 1.000$	$p = .091$	**$p = .025$**	
L2	1.67 ± 1.14	1.46 ± 1.10	1.32 ± 1.19	1.37 ± 1.17	**$p = .015$**
	(1.24)	(1.24)	(1.20)	(1.20)	
		$p = .201$	$p = .128$	$p = .112$	
L4	1.95 ± 1.29	1.89 ± 1.31	1.81 ± 1.24	1.70 ± 1.12	$p = .201$
	(1.58)	(1.53)	(1.61)	(1.40)	
		$p = 1.000$	$p = 1.000$	$p = 0.371$	
L6	2.26 ± 1.51	2.12 ± 1.28	2.05 ± 1.33	1.89 ± 1.22	$p = .104$
	(1.82)	(1.80)	(1.77)	(1.85)	
		$p = 1.000$	$p = 1.000$	$p = .111$	

Note: Evolution of L0, L2, L4 and L6 (CBCT): mean ± SD (median) in mm. Wald Chi^2 test from the generalized estimation equations model (GEE) for the differences from baseline to the 5-year visit. Values in bold are statistically significant ($p < .05$)

the ease of hygiene from the 2nd year was appreciable at a descriptive level.

Evolution of Patient-reported outcome measures (PROMs) is described in detail in Table 5 and Figure 10.

4 | DISCUSSION

With the limitations of this study design and sample size, results suggest that narrow diameter titanium–zirconium tissue-level implants in partially edentulous patients are a predictable treatment option after 5 years. Implant survival and success rates were 100%, and the MBL was 0.52 ± 0.46 mm. These findings are comparable to the ones published in other studies with narrow diameter implants (Al-Nawas et al., 2012, 2015; Barter et al., 2012; Chiapasco et al., 2012; de Souza et al., 2018; Mühlemann et al., 2020; Muller et al., 2015; Tolentino et al., 2015) and standard diameter implants (Buser et al., 2012; Cochran et al., 2011).

Tissue-level implants have demonstrated high survival and success rates in long-term trials (Buser et al., 2012; Chappuis et al., 2013; Kim et al., 2018). This is the first study addressing the use of titanium–zirconium NDIs with a tissue-level design in partially edentulous patients in the anterior area of the jaws.

In a recent long-term study in a Swedish population, tissue-level implants had a lower incidence of periimplantitis than other implants with bone-level designs (Derks et al., 2016). In the present study, no peri-implantitis was diagnosed according to the clinical and radiological measurements and it is important to note that most of the patients of this study lost teeth due to periodontal disease. Mucositis was diagnosed and treated in 12 patients with nonsurgical therapy.

A CBCT was taken to evaluate the buccal bone thickness. In the most coronal part, an average of 0.83 ± 1 mm was obtained. In 19 out of 54 implants (35%), a cortical plate was not detected on the CBCT after 5 years. In these patients, no signs of clinical recession at implant sites were present. As reported in the literature (Gonzalez-Martin et al., 2016), if the cortical plate measures less than 1 mm, it

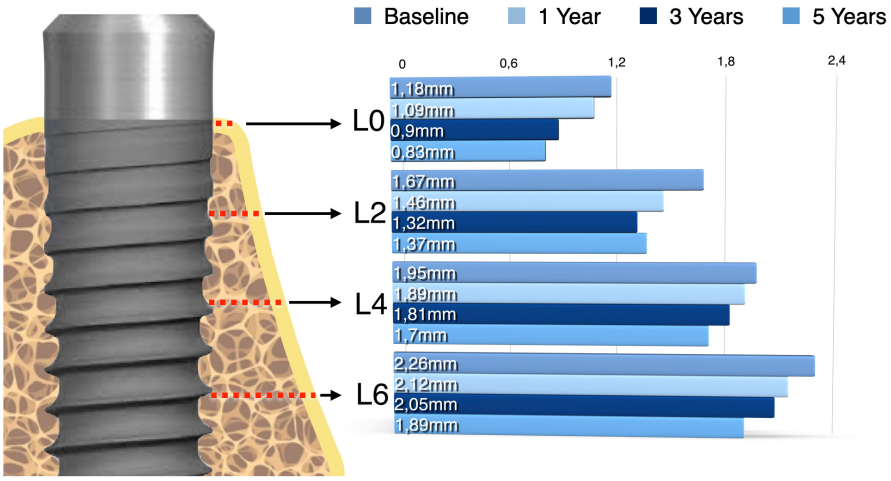

FIGURE 9 Thickness of the buccal wall measured with the cone beam computed tomography (CBCT) at prosthesis delivery (baseline) and after 1-, 3-, and 5-years for the different points of reference (L0, L2, L4, and L6). Implant drawing not to real scale.

is usually difficult to detect. In a study with immediate implants with a follow-up of 7 years, a control CBCT was taken. When the vestibular wall was not detected, they reported a clinical recession of 1 mm (Benic et al. 2012a). In another article, esthetic results were acceptable and stable when the buccal wall was thin or missing (Veltri et al., 2016).

Most of the implants in this study were placed in anterior areas (central and lateral incisors). According to the study protocol, first and second premolars could be included. It was very difficult to find posterior areas with less than 6 mm in width. We also found that the length of the partial edentulism required the placement of more than four teeth. Other patients had prior socket preservation or GBR performed and were excluded from the study. For the mentioned reasons, recruitment of patients extended in time more than expected.

In this study, 3- or 4-unit FPDs were installed to replace central and lateral maxillary incisors. In most of the cases (10), implants were installed in the central incisor position with an extension to the laterals. Several studies have tried to determine the best implant distribution for partial anterior edentulism. It is not clear whether implants should be located in lateral position, in the central position or unevenly distributed and usually is left as a clinician's choice. For some authors (Krennmair et al., 2011; Moráguez et al., 2017; Vailati & Belser, 2007), the best option would be to place two narrow implants in the lateral incisors, while for Vela-Nebot et al. (2011), the best option is to place the implants in the central incisors.

On the other side, eighteen 3- or 4-unit FPDs were installed to replace central and lateral mandibular incisors. The loss of mandibular incisors in patients with periodontal disease is often a complex treatment because of bone atrophy and represent both a surgical and restorative challenge. In a retrospective study, eight patients had two NDIs supporting three- or four-unit fixed partial dentures (FPDs) without cantilever to replace three or four mandibular incisors with very good esthetic outcomes (Cordaro et al., 2006).

Prosthesis survival according to the criteria described was also 100%. Studies reporting technical complications have been described for dental implants (Goodacre et al., 2003; Pjetursson et al., 2012; Sailer et al., 2018) and specifically for NDIs (Lee et al., 2013; Pieri et al., 2017). In this study, only minor complications, such as decementation or screw loosening, were described. The complications described in this study yield a prosthesis success rate of 80%. Complications in the present study (20%) are higher than the total number of complications found with metal ceramic FDPs (15.1%) in a recent systematic review (Sailer et al., 2018). In the present investigation, extensions were allowed and might have influenced prosthesis success, as it is also suggested in the literature (da Silva et al., 2018).

Standard diameter implants are recommended to support an FPD but the findings from the current study are not in accordance with the above concept as it suggests that NDIs may support an FPD, too. It seems that NDIs have a similar behavior compared to SDIs in single unit teeth (Ghazal et al., 2019). Conclusions in recent systematic reviews report that there were no differences between NDIs and standard diameter implants in terms of survival (Badaró et al., 2022; Cruz et al., 2021).

There are few randomized clinical trials or prospective studies on Ti-Zr tissue-level implants, and this trial is the only investigating partially edentulous patients in the anterior area in need of a FPD. Interest in Ti-Zr NDIs is increasing, and in recent years, three systematic reviews have been published on the topic (Altuna et al., 2016; Badran et al., 2017; Iegami et al., 2017). The main conclusions were that more studies are needed with longer follow-up periods. The cohort of patients of this study will add to the body of evidence available.

When performing dental implants, especially in the anterior maxilla, it would be of great interest to know for both clinicians and patients that there is a reliable and less invasive technique, that would be faster and that also will reduce economic costs of treatment. It is also important to note that implant survival and success rates seem to be better when inserted in native bone (Clementini et al., 2012). Regarding this question, in a 5-year retrospective study with patients who have received an implant with simultaneous lateral augmentation, it was concluded that one of the factors to avoid clinical recession was the use of narrower implants (Cairo et al., 2020). In another retrospective study, NDIs are compared to SDI with guided bone regeneration. Clinical results also suggest

TABLE 5 Evolution of patient satisfaction during the study: mean ± SD (median) in percentage.

	1-year	2-year	3-year	4-year	5-year	
	Mean ± SD (median) in mm	Mean ± SD (median) in mm	Mean ± SD (median) in mm	Mean ± SD (median) in mm	Mean ± SD (median) in mm	*p*-Value
General	92.6 ± 9.4 (96)	93.5 ± 5.9 (95)	94.2 ± 4.8 (93)	92.3 ± 8 (95.50)	89.6 ± 15.1 (95)	**$p = .682$**
Speech	91.8 ± 12.3 (96)	90.7 ± 9.4 (94)	90 ± 9.2 (93)	91.3 ± 8.2 (95)	84.9 ± 20.7 (92)	**$p = .486$**
Hygene	85.5 ± 11.9 (89)	83.8 ± 16.1 (87)	86.8 ± 12.8 (92)	87.9 ± 15 (94)	81 ± 21 (92)	**$p = .644$**
Esthetics	92.9 ± 8.7 (96)	93.9 ± 4 (95)	91.1 ± 10.4 (94)	90.3 ± 12.5 (95)	90 ± 15.8 (96)	**$p = 500$**
Masticatory Function	93.7 ± 6.2 (96.50)	90.9 ± 10.8 (95)	90.8 ± 7.9 (93)	91.5 ± 7 (94)	85.7 ± 21.8 (94)	**$p = .156$**

Note: Friedman test. Values in bold are not statistically significant ($p < .05$).

similar rates of survival and success, making NDIs placement a good option (Schiegnitz et al., 2021).

It should be noted that in 43% of the cases it was necessary to perform guided bone regeneration for dehiscence or fenestration. This percentage is similar to that reported by other authors (Al-Nawas et al., 2015; Chiapasco et al., 2012; Lambert et al., 2015).

Long-term studies are needed to prove that NDIs made of titanium–zirconium could be used as a routine basis in partially edentulous patients, avoiding the need for more advanced surgical procedures. Pommer et al. (2014) compared minimally invasive techniques, such as angled implants, short implants, or narrow implants, versus guided bone regeneration with high patient satisfaction.

In this study patient satisfaction was measured only after prosthesis delivery (BL) with a customized VAS scale and the mean patient satisfaction of the different parameters (general, speech, hygiene, masticatory function, and esthetics) was 86.2 ± 16.5 (median of 91.4). This satisfaction was comparable to the esthetic satisfaction score of 85.9% in a retrospective study (Al-Aali et al., 2019), but was lower than in other studies that reported rates of more than 90% (Krennmair et al., 2011; Moráguez et al., 2017). From the fourth year, there has been a drop in satisfaction values, probably due to the restricted operation of the university clinic during the COVID-19 pandemic, which may have negatively affected the results. The methods for assessing satisfaction have been different in all the studies, which may explain these differences.

This study has several limitations. Implants were placed in a university setting, which makes inclusion and exclusion criteria strict, compared to a private office. By having performed GBR or soft tissue augmentation procedures, we could have influenced the results of MBL or buccal bone stability. This could be one of the most important limitations for a cohort study, in which inclusion criteria should be even more strict. Another factor that could be considered a limitation is that implants were placed by unexperienced surgeons and prosthodontists and somehow could have affected results. Finally, no objective esthetic outcome measurement was possible, because there is a lack of a white and pink esthetic index for FPDs. It would be interesting to have one, as suggested in previous articles (Benic et al. 2012b), to compare with the patient's own esthetic satisfaction.

We can conclude that titanium–zirconium narrow diameter tissue-level implants with hydrophilic surface used to support a 3- to 4-unit FPDs in the anterior zone of both maxilla and mandible showed good clinical and radiological results after a follow-up of 5 years. Long-term controlled clinical trials with a larger sample size are necessary to further confirm this promising results.

AUTHOR CONTRIBUTIONS

Concept, design, data collection, analysis, drafting and critical revision of article.

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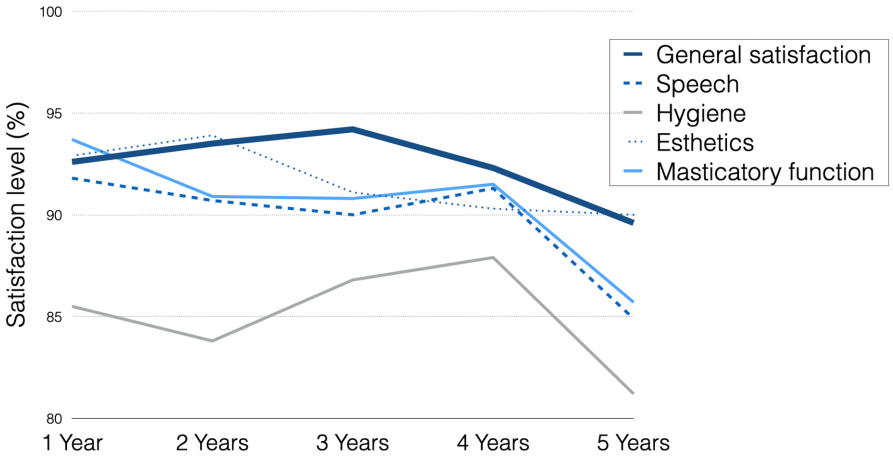

FIGURE 10 Evolution of patient satisfaction after 5 years.

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CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in ISRCTN at https://doi.org/10.1186/ISRCTN23651018, reference number 23651018.

ETHICS STATEMENT

Ethical approval was obtained to perform this clinical study. Patients received written and verbal information and signed an informed consent. The trial was registered at ISRCTNregistry (ISRCTN23651018).

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