KEY WORDS
Bone atrophy; Narrow-diameter implants; Bone resorption; Dental implants; Implant failure; Posterior mandible

Cohort study

NARROW-DIAMETER IMPLANTS SUPPORTING FIXED PROSTHESES IN THE POSTERIOR MANDIBLE: 5-YEAR REPORT ON A PROSPECTIVE SINGLE-COHORT STUDY

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PURPOSE. To assess the 5-year post-loading outcomes of narrow-diameter implants supporting fixed prostheses in the posterior mandible of patients with horizontal bone atrophy.

MATERIALS AND METHODS. A total of 42 partially edentulous patients who needed a fixed implant-supported prosthesis in a posterior mandible presenting a thin alveolar crest were enrolled in this study. One hundred and twenty-four narrow-diameter implants (2.75 and 3.25 mm) were placed and splinted with a fixed prosthesis. One implant was required to replace each missing tooth. Patients were followed-up for a period of 5 years. Outcomes considered were: implant failures, any complications, and marginal bone level changes.

RESULTS. Of the 42 patients, three dropouts were recorded (3/42, 7.1%). At the 5-year follow-up, five implants had failed in 4 patients: two 2.75 mm diameter implants and three 3.25 mm diameter implants. The implant survival rate was 90.5% at the patient level and 95.9% at the implant level. Peri-implant bone resorption was 0.47 mm (95% CI: 0.29; 0.65) one year after loading and 1.19 mm (95% CI: 0.81; 1.58) five years after loading. The marginal bone level changes were not significantly different between the two diameters used (P = 0.579). Of the 42 patients, eight (19.04%) experienced complications during the follow up.

CONCLUSIONS. Five years after loading, both narrow-diameter implants (2.75 to 3.25 mm) placed in posterior mandibles showed high survival and low complication rates, so can be considered a valid alternative to horizontal bone augmentation. However, longer follow-ups on a larger sample are needed.

CONFLICT OF INTEREST STATEMENT. Tommaso Grandi serves as a consultant for J Dental Care, Modena, Italy. However, this study was completely self-financed, and no funding was either sought or obtained, not even in the form of free material.

INTRODUCTION

Osseointegrated dental implants are the solution most widely used for the rehabilitation of masticatory and aesthetic function in partially or completely edentulous patients. The two main factors that influence implant insertion are the geometry and volume of alveolar bone, in particular atrophy of the alveolar crest with reduced bone width and height; this is often observed in patients after periodontitis, prolonged use of a removable denture, trauma and malformations[1].

In cases of reduced bone volumes, bone augmentation surgery is considered the best treatment solution to allow the placement of a dental implant[2]. However, despite the numerous

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surgical techniques developed to augment bone horizontally and vertically, there remain potential drawbacks to such procedures, including prolonged healing time, additional cost, and risk of postoperative pain, haemorrhage, nerve damage and increased surgical morbidity, especially in medically compromised patients[2-6].

In some cases, a potential alternative to horizontal bone augmentation surgery in the rehabilitation of narrow alveolar ridge is the use of reduced diameter implants, i.e., those of less than 3.75 mm[3]. The definition of a narrow-diameter implant (NDI) is still controversial, but broadly speaking NDIs have a diameter of between 3 to 3.4 mm, whereas those with diameters of 3.75 to 4 mm and 5 to 6 mm are classified as "standard" (SDI) and "wide" (WDI) implants, respectively[7].

When the buccolingual dimension is reduced and the width of available bone is less than 5 mm, the placement of a "standard" or a "wide" implant may lead to the exposure of implant threads, which could compromise the final outcome in terms of bone stability and aesthetics[8]. However, NDIs are mostly recommended to replace maxillary lateral incisors and mandibular incisors[9,10], and for use in clinical situations with reduced volume of interradicular bone or mesio-distal space of less than 6 mm[11], and have not been designed for the replacement of premolars and molars. Indeed, several published clinical studies have reported high success rates associated with NDIs positioned in area of the lower and upper lateral incisors, while there is limited evidence focusing on the long-term results of NDIs used for the rehabilitation of posterior jaws[8].

In fact, placement of NDIs in the posterior maxilla and mandible is commonly avoided due to prosthetic and biomechanical considerations. Specifically, the emergence profile of posterior teeth is rarely harmonious with a narrow implant neck[12], and posterior teeth sustain higher loads than the anterior teeth[13], meaning that there is the risk of fatigue fracture and subsequent failure of dental implants in the posterior region[14].

Though it is challenging to rehabilitate posterior regions of the jaws with reduced bone quantity without the use of complex reconstruction techniques, it would be desirable in certain cases for the reasons listed above. Hence, the aim of this prospective cohort study was to evaluate the clinical outcomes of two narrow-diameter implants (diameters 2.75 and 3.25 mm) supporting fixed prostheses in patients with insufficient bone ridge thickness for placing standard-diameter implants in the posterior mandible. This paper presents the 5-year post-loading data of a study whose 1-year results have previously been reported[15]. It is reported in line with the STROBE statement for improving the quality of observational studies (http://www.strobe-statement.org).

MATERIALS AND METHODS

The present prospective study was conducted at a private practice (Tommaso Grandi Dental Clinic, Modena) in Italy. A total of 42 patients with a mean age of 61.3 years (range 49-73) with partial edentulism in the posterior mandible (premolar/molar areas) requiring one multiple-tooth implant-supported restoration (2-, 3- or 4-unit prosthesis) and having a residual bone height of at least 8 mm and a thickness of at least 4 mm were included in this study. All subjects were 18 years or older and able to sign an informed consent form.

Preoperative periapical X-rays and CT scans were initially used to quantify the amount of bone present.

Exclusion criteria were:

- General contraindications to implant surgery;
- Irradiation in the head and neck area;
- Previous or ongoing treatment with intravenous aminobisphosphonates;

- Poor oral hygiene and motivation;
- Untreated periodontitis;
- Uncontrolled diabetes;
- Pregnancy or lactation;
- Substance abuse;
- Lack of opposing occluding dentition in the area designated for implant placement;
- Acute or chronic infection at the site designated for implant placement;
- Referral for implant placement alone (i.e., unavailable for monitoring at the treatment centre).

All subjects received full explanation and signed informed written consent before undergoing the treatment. All surgical and prosthetic interventions were performed by one operator (TG) in a private dental practice. Before the intervention, the patients underwent at least one session of oral hygiene instructions, and professionally delivered debridement if required. Antibiotic prophylaxis was achieved via 1 g of amoxicillin and clavulanic acid (Augmentin, Roche, Milan, Italy) taken every 12 h from the day before surgery to the sixth post-surgical day. In patients allergic to penicillin, clarithromycin (Klacid, Abbott, Rome, Italy) 500 mg was given 1 h before the intervention and 250 mg twice a day for one week.

On the day of surgery, patients were treated under local anaesthesia. Full-thickness crestal flaps were raised with minimal extension to reduce patient discomfort. Implant sites were prepared using the procedure recommended by the implant manufacturer (J Dental Care, Modena, Italy). The narrow-diameter implants used were JDIcon Ultra S and JDEvolution S grade 5 tapered titanium implants (J Dental Care) with respective diameters of 2.75 and 3.25 mm, each featuring internal connection and SLA-treated surface (sandblasted with large grits and acid etched). The implants were placed in the bone without any fenestration/dehiscence, and each implant neck was positioned at crestal level.

The operator was free to decide the length (8, 10, 11.5, and 13 mm) and diameter (2.75 and 3.25 mm) of implants, according to the clinical indications. One study implant for each missing tooth was placed.

Healing abutments were attached, and implants were left to heal unsubmerged. Interrupted sutures were placed using a synthetic monofilament thread (Vycril, Ethicon, Johnson & Johnson, Somerville, NJ, USA), and were removed after 10 days. After three months, all implants were loaded directly with definitive screw-retained or cemented partial fixed prostheses.

Primary outcome measures were the following.

- Implant failure: implant mobility or stable implants removed due to progressive marginal bone loss or infection. The stability of each implant was assessed by tightening the abutment screw manually with a wrench delivering a torque of 20 Ncm. Implant stability assessment was performed at delivery of definitive crowns (3 months after implant placement). After the definitive crowns were fitted, these were not removed to assess the clinical mobility of individual implants.
- Complications: any biological or prosthetic complication occurring at the implant site during the entire follow-up period. Examples of biological complications were:
  - Peri-implant mucositis (heavily inflamed soft tissue without bone loss) and peri-implantitis (presence of periodontal pockets ≥5 mm and bleeding on probing, with simultaneous presence of marginal bone loss), as assessed using a manual periodontal probe (Colorvue, Hu-Friedy, Milan, Italy);
  - Presence of fistulas;
  - Anaesthesia or paraesthesia (temporary or permanent);
  - Abnormal or prolonged pain after implant insertion;

Mechanical complications, including fracture or loosening of prosthodontic components, assessed clinically and radiographically.

The secondary outcome measure was peri-implant marginal bone level changes, as evaluated on intraoral radiographs taken with the paralleling technique at implant placement, and at 1 year and 5 years after loading. Specifically, radiographs were conventional, digitized in JPG format and converted to TIFF format with 600 dpi resolution, and peri-implant marginal bone levels were measured by means of Image J 1.42 software (National Institute of Mental Health, MD, USA), calibrated for every single image using the known implant diameter. Measurements of the mesial and distal crestal bone levels adjacent to each implant were made to the nearest 0.01 mm. The measurements were taken parallel to the implant axis. The most coronal margin of the implant collar and the most coronal point of bone-to-implant contact were considered as reference points for the linear measurements.
Statistical analysis was performed by a medical doctor (Giovanni Grandi) with expertise in dental biostatistics, using the statistical package StatView (version 5.01.98, SAS Institute Inc., Cary, NC, USA). The significance threshold was set at $P < 0.05$. The patient was the statistical unit of the analysis. Marginal bone levels were averaged at patient level and, for comparative purposes, for each of the two different treatment groups (2.75- and 3.25 mm-diameter implants). Differences in patient means for continuous outcomes were compared between groups via t-testing. Within-group comparison was performed via t-test for paired data. Student's t test was used to evaluate differences in bone resorption between the two study groups.

RESULTS

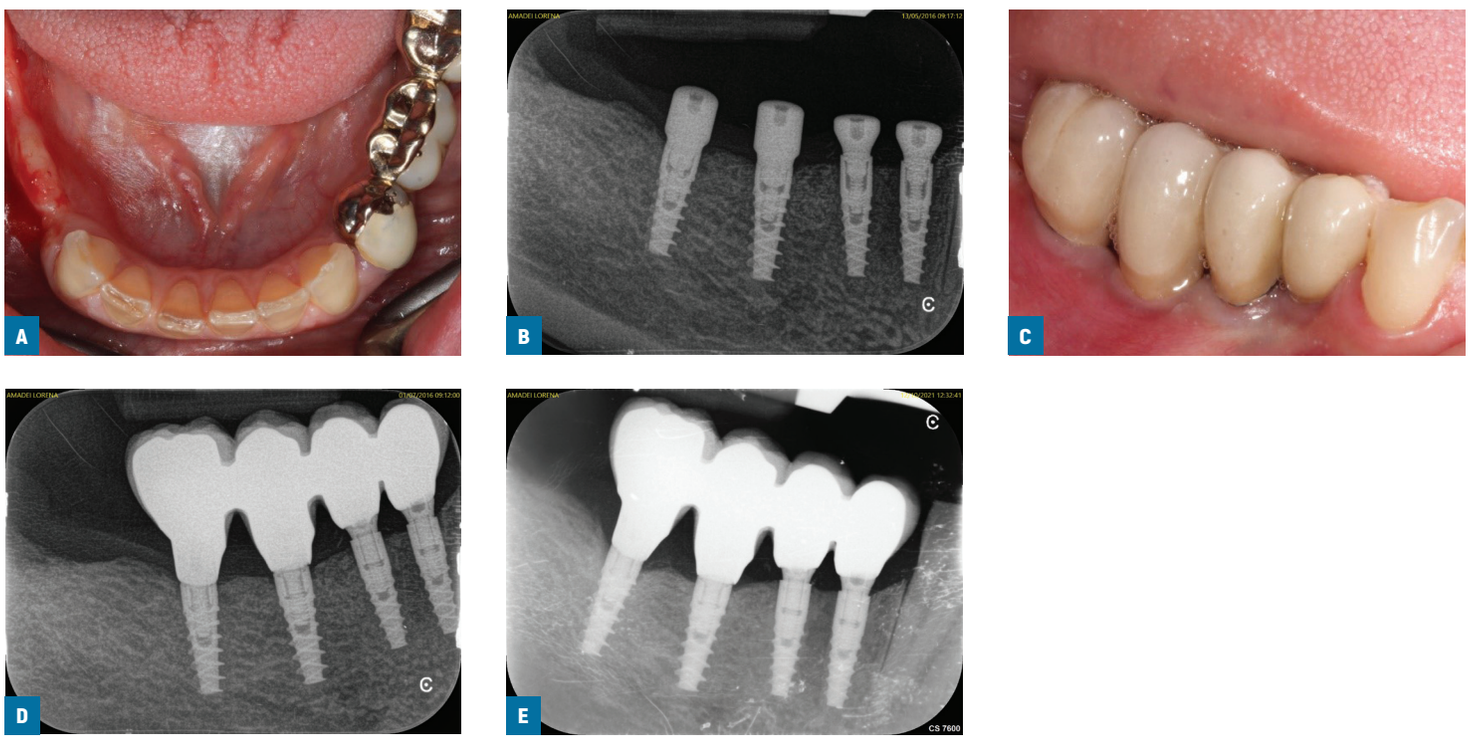
Forty-eight patients were initially screened for eligibility, but six subjects were not included for the following reasons: five patients (10.4%) were hesitant to receive implant treatment, and one patient (2.1%) was on intravenous aminobisphosphonates. Forty-two patients were therefore consecutively enrolled in the trial. All patients were treated according to the allocated intervention. Three dropouts were recorded (3/42, 7.1%), specifically:

- One patient died after 4 years;
- Two patients did not attend the 5-year follow-up because they had moved to another city.

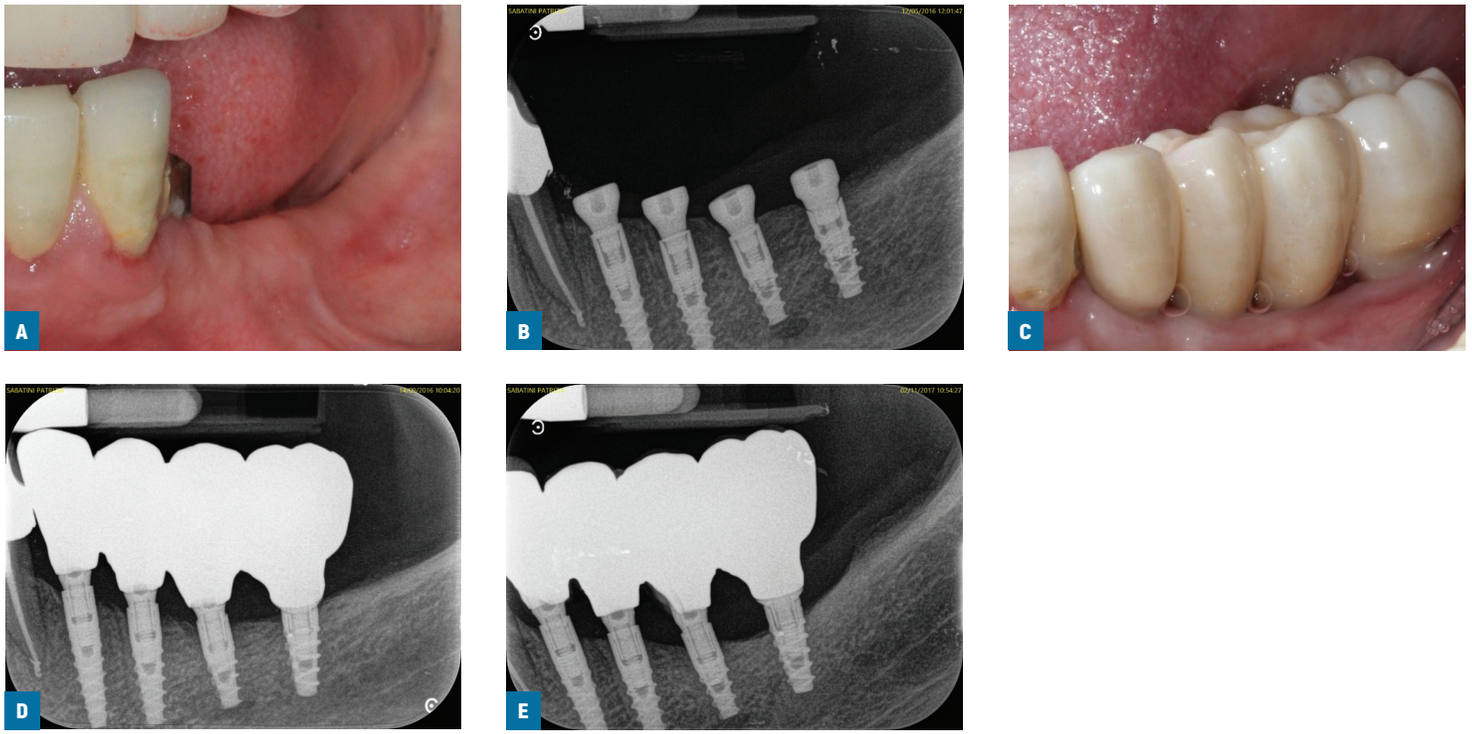
Patients were recruited and operated on from October 2014 to January 2016. The follow-up for all patients was 5 years post-loading (last follow-up: January 2021).
One hundred and twenty-four narrow-diameter implants (2.75 and 3.25 mm) were inserted in a total of 42 subjects. The main patient features at baseline are reported in **TABLE 1**, and **FIGS. 1** and **2** show clinical views and periapical radiographs from two patients involved in the study. Patients were generally healthy, though 19 patients (45.2%) had medication-controlled hypertension and 11 (26.2%) had controlled type 2 diabetes. The mean age of the patients at the time of surgery was 61.3 years (range 49-73).
All values for seating torque, and length and diameter of the inserted implants are reported in **TABLE 2**. The distribution of implant positions in the two implant diameter groups is reported in **FIGURE 3**. Measurements of insertion torque were averaged at patient level and then at group level; the average insertion torque was 46.6 Ncm (SD 11.8). Pain and discomfort from the surgical procedure appeared to be within the norm for flapped implant placement. No incidence of abnormal bleeding or ecchymosis were observed. The following outcomes were recorded at 5 years post-loading.

TABLE 1 CHARACTERISTICS OF THE SUBJECTS INCLUDED IN THE STUDY

Number of patients	42
Males (%)	18 (42.9%)
Females (%)	24 (57.1%)
Mean age at insertion (range)	62.6 (49-73)
Smokers (less than 10 cigarettes/day)	28.6%
Diseases in history: Controlled diabetes type 2 Hypertension	 11 (26.2%) 45.2%
Site of insertion: Premolar Molar	 81 (65.3%) 43 (34.7%)
Complete opposing maxillary dentition Opposing fixed rehabilitation and natural teeth Opposing removable prosthesis and natural teeth	7 (16.7%) 26 (61.9%) 9 (21.4 %)



FIGS. 1A-E: ***Case 1.*** *Example case 1: preoperative view of a partial edentulism in posterior mandible (A); baseline periapical x-ray (B); buccal view of the final metal ceramic restoration (C); periapical x-ray at 1 year post-loading (D); periapical x-ray at 5 years post-loading (E).*



FIGS. 2A-E: ***Case 2.*** *Example case 2: preoperative view (A); baseline periapical x-ray (B); buccal view of the final monolithic zirconia restoration (C); periapical x-ray at 1 year post-loading (D); periapical x-ray at 5 years post-loading (E).*

TABLE 2 DIMENSIONS (DIAMETER AND LENGTH) AND FINAL SEATING TORQUE OF THE IMPLANTS INSERTED (N = 124)

LENGTH (MM)	
8	18 (14.5%)
10	56 (45.2%)
11.5	43 (34.7%)
13	7 (5.6%)
DIAMETER (MM)	
2.75	69 (55.6%)
3.25	55 (44,4%)
INSERTION TORQUE (NCM)	
30	21 (16.9%)
35	16 (12.9%)
40	10 (8.1%)
45	11 (8.9%)
50	32 (25.8%)
55	7 (5.6%)
60	16 (12.9%)
65	5 (4.1%)
70	6 (4.8%)

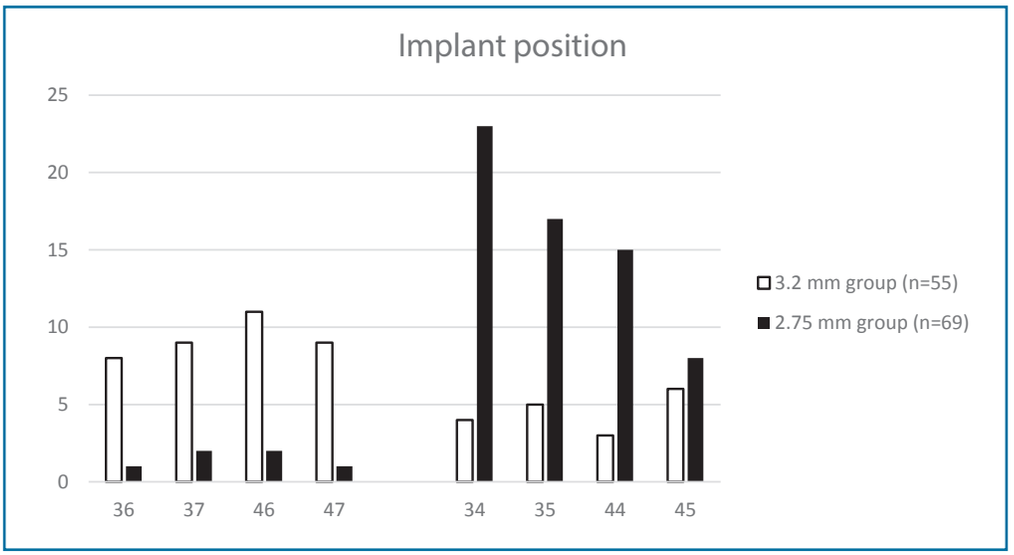


FIG. 3: *Distribution of implant positions in the two implant diameter groups.*

Implant failures

Five implants were lost in four out of the 42 patients, meaning that the survival rate was 95.9%. Specifically, two 2.75 mm-diameter implants and one 3.25 mm-diameter implant failed in three patients, each of whom displayed postoperative pain, oedema, and signs of infection with pus. These cases were all female smokers whose dental implants became mobile three weeks after placement and were successfully replaced after four months. A further two 3.25 mm diameter implants failed in one female non-smoker, who was affected by peri-implantitis; her implants became mobile 2 years after placement and were not replaced.

Complications

Eight patients (19.04%) experienced one complication each during the follow up:

- Three patients lost an implant, displayed post-operative pain and pus, and implants were removed 3 weeks after their placement;
- One patient lost two implants, which were affected by peri-implantitis and failed 2 years after loading;
- Three patients experienced one episode of peri-implant mucositis 3 years after loading, and were treated with non-surgical debridement of the affected implants;
- One patient's metal-ceramic prosthesis chipped 4 years after loading and was repaired in the laboratory.

Marginal bone level changes

The radiographic data are summarized in **TABLES 3** and **4**. The group had lost statistically significant marginal peri-implant bone at one year (–0.47; 95% CI: –0.29; –0.65, P <0.0001) and five years after loading (-1.19; 95% CI: -0.81; -1.58; P <0.0001). There were no differences in marginal bone level changes between the two diameters used, i.e., 2.75 and 3.25 mm (P = 0.579; **TABLE 4**).

TABLE 3 COMPARISON OF MEAN BONE LEVELS (MEANS ± SD) AT DIFFERENT TIME-POINTS (BASELINE, 1 YEAR, 5 YEARS) AT PATIENT LEVEL

		Time interval	
Follow-up	**Mean bone level (mm) (n = 42)**	**0-1 years (95% CI) (n = 42)**	**0-5 years (95% CI) (n = 39)**
Baseline	0.01 ± 0.06	-0.47 (-0.29; -0.65)	-1.19 (-0.81; -1.58)
1 year	0.48 ± 0.29	P <0.0001	P <0.0001
5 years	1.20 ± 0.38		

TABLE 4 COMPARISON OF MEAN BONE LEVELS (MEANS ± SD) AT DIFFERENT TIME-POINTS (BASELINE, 1 YEAR AND 5 YEARS) WITH DIFFERENT DIAMETER NDIS (2.75 MM AND 3.25 MM)

Diameter 2.75 mm				
Time-point	**Mean bone level changes (n = 69)**	**0-1 years (95% CI) (n =6 7)**	**0-5 years (95% CI) (n = 67)**	**Inter-group P**
Baseline	0.02 ± 0.07	-0.47 (-0.19: 0.75)	-1.16 (-0.81: 1.51)	P = 0.689
1 year	0.49 ± 0.30	Intra-group P	Intra-group P	
5 years	1.18 ± 0.37	P <0.0001	P <0.0001	
Diameter 3.25 mm				
Time-point	**Mean bone level changes (n = 55)**	**0-12 months (95% CI) (n = 54)**	**0-60 months (95% CI) (n = 52)**	**Inter-group P**
Baseline	0.00 ± 0.11	-0.48 (-0.15: 0.81)	-1.21 (-0.81: 1.61)	P = 0.579
1 year	0.48 ± 0.33	Intra-group P	Intra-group P	
5 years	1.21 ± 0.39	P <0.0001	P<0.0001	

DISCUSSION

Narrow-diameter implants are commonly placed when ridges are narrow or in cases of limited mesiodistal space between the anterior teeth. Several authors[16-20] have come to the conclusion that NDIs and SDIs, when used appropriately, give comparable survival rates, and marginal bone loss (MBL) within the parameters of success. In fact, Javed and Romanos reported that the role of implant diameter in long-term survival of dental implants is secondary, while a more crucial role is played by a well-designed surgical protocol, achieving primary stability during implant insertion, and maintenance of good oral hygiene over time[21].

Indeed, our success rates indicate that NDIs could be a less invasive alternative to bone augmentation. Using narrow implants reduces the possibilities of bone dehiscence during site preparation. Moreover, there is less risk of the bone overheating because of the reduced width of both the implants and drills[22]. Bearing in mind that patients generally prefer minimally invasive treatments to bone augmentation surgery[23], NDIs could be considered a valid option.

However, this solution has often been avoided in the posterior mandible due to prosthetic and biomechanical considerations, in particular the fact that the highest bite force is concentrated in the molar area[24]. Hence, only few clinical trials evaluating survival or success rate of NDIs used for implant-supported prosthetic rehabilitation of the posterior jaws are available. In a cohort study, Shi et al. evaluated the 8-year post-loading outcomes in terms of implant survival, complications, modified plaque index (MPI), peri-implant probing depth (PPD), percentage of bleeding on probing (BOP%), marginal bone loss (MBL) and patient satisfaction of 98 NDIs placed in the posterior jaws of 67 patients. High survival rates (97.1% at implant level and 98.7% at patient level), high patient satisfaction (89.2% were satisfied with the aesthetics of the restorations and 84.6% were satisfied with the function of the restorations), and acceptable complication rates (veneer chipping rates were 19.4% at patient level) and marginal bone loss (average MBL was 1.19 mm at implant level and 1.15 mm at patient level)[25] were reported.

In one randomized controlled trial, Esposito et al. compared the outcomes of immediately loaded 3 mm-diameter implants inserted in 23 patients *versus* 4 mm-diameter implants inserted 6 months after horizontal bone augmentation in 22 patients. One year post-loading, the difference in peri-implant bone loss between the two groups (mean difference = 0.38 mm) was significant, and one year after loading, patients treated with the narrower implants displayed better outcomes[6]. De Souza et al. also compared NDIs and SDIs placed in the posterior jaws, in a 3-year split-mouth randomized controlled trial. They found implant success rates and prosthesis success rates for NDIs and SDIs of 95% and 100% and 90% and 95%, respectively[26].

High survival and success rates for NDIs placed in posterior jaws have also been reported in other studies, specifically 100% survival rates in both a 2-year follow-up study by Chiapasco et al.[27] and a 1-year follow-up study by Tolentino et al.[28], and a 95.1% survival rate in an 11-year retrospective follow-up study by Malò et al.[29]. In a retrospective study with follow-up ranging from 2 to 6 years, Alrabiah et al. compared the clinical and radiographic outcomes, complications and patient satisfaction after the positioning of NDIs in the anterior and posterior jaws. Complication rates for NDIs in the posterior region were noted to be significantly higher than those for NDIs in the anterior region (P = 0.041), but NDIs in the anterior and posterior jaws functioned equally well as far as peri-implant soft and hard tissue health were concerned, and both provided reasonable complication rates and acceptable patient satisfaction[30].

In the cohort study reported here, all implants (diameters 2.75 and 3.25 mm) were placed in posterior areas having insufficient bone ridge thickness for placing standard-diameter implants to support partially fixed prostheses. The implant survival rate five years post-loading was 95.9%, the number of complications was low, and the implants lost an average of 1.19 mm of peri-implant bone. These findings are similar to those observed for other implant systems used under similar clinical conditions. It should be noted that outcomes were evaluated in real clinical conditions and patient inclusion criteria were rather broad, so we would expect similar results in other patients with similar characteristics treated similarly by other clinicians. Nevertheless, we would suggest splinting 2.75- and 3.25 mm-diameter implants under the same prosthesis, and placing one implant for each missing tooth. Indeed, placement of NDI implants supporting single molar crowns is generally not recommended, and splinting multiple implants has been reported to minimize the lateral forces, enhance force distribution, and reduce the stress on the implants[31]; splinting of NDI implants would theoretically protect the implants from excessive loading, and could thereby prevent implant/abutment screw fracture. Reduction in occlusal table and cusp inclines could also be advisable to minimize off-axis forces.

The main limitations of the present study are that the sample was small and not randomized. Hence, randomized controlled trials with a larger sample size are needed to confirm its findings. Moreover, a 5-year follow-up is not sufficient to draw definitive conclusions about the predictability of the treatment tested. Longer follow-ups are needed, since it may that NDI failure rates increase over time due to fracture or reduced bone–implant contact. Another limitation of the present study was that NDIs were tested only in mandibles, and since maxillae and mandibles differ in their bone density, there could be different outcomes when NDIs are placed in the maxillary arch.

CONCLUSIONS

Five years after loading, narrow-diameter implants (2.75 and 3.25 mm) supporting partially fixed prostheses displayed high survival and low complication rates when placed in posterior mandibles having thin bone ridges. Clinicians could therefore consider this treatment option a valid alternative to horizontal bone augmentation, if confirmed by randomized trials on larger samples with longer follow-up periods.

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