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Clinical Oral Implants Research / Volume 29, Issue 1

ORIGINAL ARTICLE | Free Access

Narrow- and regular-diameter implants in the posterior region of the jaws to support single crowns: A 3-year split-mouth randomized clinical trial

André Barbisan de Souza, Flávia Sukekava, Livia Tolentino
... See all authors »

First published: 09 October 2017
https://doi.org/10.1111/clr.13076
Cited by: 3

Abstract

Objectives

The objective of this 3-year split-mouth randomized controlled clinical study was to compare narrow-diameter implants (NDIs) to regular-diameter implants (RDIs) in the posterior region of the jaws (premolars and molars) in regards to (i) the marginal bone level (MBL) and (ii) implant and prosthesis survival and success rates.

Material and Methods

A total of 22 patients were included in the study. Each patient received at least one implant of each diameter (Ø3.3 and Ø4.1 mm), placed either in the maxilla or mandible to support single crowns. A total 44 implants (22 NDIs and 22 RDIs) were placed and included in the study. Twenty-one implants were placed in the premolar, whereas 23 were placed in molar areas. Radiographic evaluations to access the

MBL were performed immediately after implant placement, 1 and 3 years after implant loading. Peri-implant clinical variables including probing pocket depth (PPD) and bleeding on probing (BoP) were obtained after crown delivery, 1 and 3 years after loading. Furthermore, the survival and success rates of the implants and prosthesis were also evaluated.

Results

Twenty patients were able to complete the study. There was no statistically significant difference regarding MBL between groups at implant placement (p = .084), 1-year (p = .794) and 3-year (p = .598) time intervals. The mean peri-implant bone loss at 3-year follow-up was −0.58 ± 0.39 mm (95% CI: −0.751 to −0.409) and −0.53 ± 0.46 mm (95% CI: −0.731 to −0.329) for NDIs and RDIs, respectively. BoP was present at 15% and 10% of NDIs and RDIs, respectively, at 3-year follow-up. PPD >5 mm was observed in 5% and 0% of the implants of NDIs and RDIs, respectively, at 3-year follow-up. At the 3-year examination, the implant success rates were in the NDIs and RDIs sites, respectively, 95% and 100%. The corresponding values for prosthesis success rates were 90% for NDIs and 95% for RDIs.

Conclusion

The present study demonstrated that NDIs placed to support single crowns in the posterior region did not differ to RDIs in regards to MBL, implant survival, and success rates.

1 INTRODUCTION

In the last decades, implant dentistry underwent several changes promoted by the great improvement in biomaterial and techniques. The different types of implant treatment surface increased the bone-to-implant contact significantly (Buser, Nydegger, Hirt, Cochran, & Nolte, 1998) while the development of new titanium alloys increased considerably the tensile strength of the fixtures (Altuna et al., 2016; Joshi et al., 2013; Yamazoe, Nakagawa, Matono, Takeuchi, & Ishikawa, 2007). Narrow-diameter implants (NDIs)

were initially designed for reduced mesio-distal edentulous areas, such as upper lateral incisors and lower incisors. Nowadays, according to the literature, they are recommend also for (i) narrow ridges; (ii) avoiding bone graft procedures; and (iii) rehabilitating elderly population with less invasive and low-cost treatments (Klein, Schiegnitz, & Al-Nawas, 2014; Maiorana et al., 2015; Sierra-Sánchez, Martínez-González, García-Sala Bonmatí, Mañes-Ferrer, & Brotons-Oliver, 2014; Sohrabi, Mushantat, Esfandiari, & Feine,2012; Yaltirik, Gökçen-Röhlig, Ozer, & Evlioglu, 2011).

Several studies have shown that NDIs can be used to replace anterior and premolar teeth, exhibiting comparable long-term survival rates to regular-diameter implants (RDIs) (Arisan, Bolukbasi, Ersanli, & Ozdemir, 2010; Barter, Stone, & Bragger, 2012, Benic et al., 2013). The high survival rates of NDIs (Veltri, Ferrari, & Balleri, 2008; Vigolo, Givani, Majzoub, & Cordioli, 2004; Zinsli, Sägesser, Mericske, & Mericske-Stern, 2004) encouraged their use also in the posterior region, aiming to prevent bone augmentation procedures (Papadimitriou,

Friedland, Gannam, Salari, & Gallucci, 2015). Short-term prospective studies have reported that the survival and success rates of NDIs replacing posterior teeth seem to be similar to RDIs (Maló & Araújo Nobre, 2011; Tolentino et al., 2014).

Two recent systematic reviews evaluated the predictability of NDIs in posterior region (Assaf, Saad, Daas, Abdallah, & Abdallah, 2015; Javed & Romanos, 2015). Both review articles reported that NDIs may be valid an alternative to RDIs in the rehabilitation of posterior areas to support fixed bridges. However, only very few short-term prospective comparative clinical trials were performed to evaluate the use of NDIs to support single crowns in the molar and premolar sites (De Souza Tolentino, Garcez-Filho, Tormena, Lima, & Araújo, 2014; Tolentino et al., 2014). Thus, the aim of the present randomized clinical study was to compare the (i) marginal bone level (MBL), (ii) implant survival and success rates, and (iii) prosthesis success rates of NDIs and RDIs implants placed in the posterior region of the jaws to support single crowns after 3 years of load. The null hypothesis was that there was a difference in MBL between NDIs and RDIs.

2 MATERIAL AND METHODS

2.1 Patient selection

This clinical trial was approved by the Ethic Committee for Research in Humans at Federal University of Sergipe, Brazil, and all patients signed a written informed consent before taking part in the study. Twenty-two systemically healthy patients (10 males and 12 females) with a mean age of 59.2 years were scheduled for at least two single-unit prosthetic rehabilitation supported by one implant in the posterior region of the jaws.

The inclusion criteria for all participants were as follows: (i) to sign the informed consent agreeing to participate in the study; (ii) age ≥18 years old; (iii) require two implants in either the posterior maxilla or mandible (premolar [PM] or molar [M] areas) to be restored with a single crown and; (iv) to exhibit an alveolar ridge 5–6 mm wide. The exclusion criteria were the following: (i) previous guided bone regeneration at implant site; (ii) presence of untreated periodontitis in any teeth; (iii) presence of soft and/or hard tissues pathology that would require previous surgical procedure (e.g., cyst and granuloma); (iv) use of any drug that could affect bone metabolism; (v) tobacco abuse (>10 cigarettes/day); (vi) presence of immunocompromising conditions (HIV-positive, or under therapy with immunosuppressive drugs); (vii) pregnancy; (viii) presence of parafunctional habits and/or maxillo-mandibular discrepancies, and (ix) history of radiotherapy treatment on the head/neck region.

2.2 Study design

The patients were assigned to receive one NDI (Ø3.3 mm) and one RDI (Ø4.1 mm). Grade IV pure titanium, Straumann® Tissue Level Standard Plus implants with SLA surface and 4.8 mm platform diameter (Straumann® Dental Implant System, Basel, Switzerland). Thus, 22 patients received one implant of each diameter in the maxilla or in the mandible. The region of the implants' installation was randomly assigned following simple randomization procedures (computerized random numbers). Subsequently, the implants were distributed for each experimental site using a sealed envelope containing the implant diameter to be placed that was opened at the time of the surgery.

The surgical procedures, medical prescription, period of healing, and prosthetic rehabilitation were previously described at Tolentino et al. (2014) and De Souza Tolentino et al. (2014) as well as the same operator performed all surgical procedures and another operator performed all prosthetic rehabilitation. The patients were included in peri-implant maintenance regimen, which consisted of oral hygiene instruction and professional plaque control that took place every 6 months after the prosthetic rehabilitation had been delivered.

2.3 Primary outcome

The primary outcome measurement was the peri-implant MBL. Periapical radiographs were performed immediately after implant placement, 1 and 3 years after loading (Figure 1). All periapical radiographs were taken by an experienced technician in radiology using a standardized X-ray film, a film holder, and paralleling technique with the same equipment (Planmeca ProMax Planmeca, Helsinque, Finland). After processing, the radiographic film was scanned (Photo Scanner HP Scanjet G4050, Palo Alto, CA, USA) to obtain a digitalized image in which the measurements were performed. At mesial and distal aspects of each implant, the distance between the SLA surface to the first bone-implant contact was measured with the aid of a computer program (Image J®, National Institutes of Health, Maryland, USA), and an average data were obtained for each fixture.

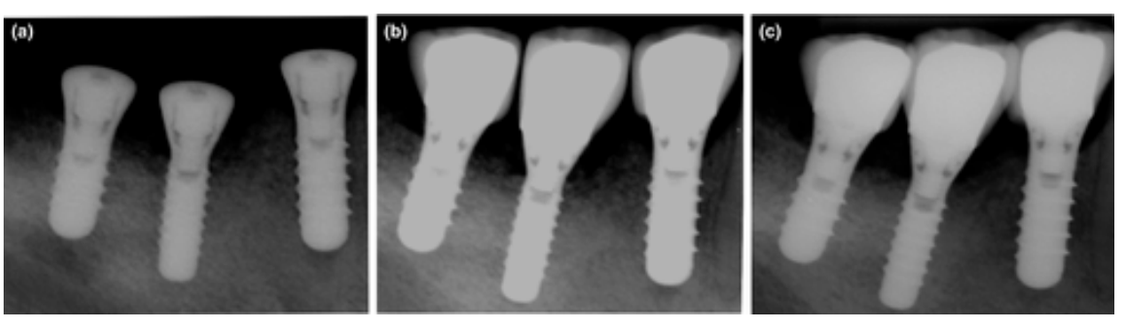

Figure 1

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Radiographic images of RDI at #46 and NDI at

#45 at (a) baseline, (b) 1 year, and (c) 3 years after loading

2.4 Secondary outcomes

The secondary outcomes measurements were the implant success and survival rates and implant-supported prosthesis success rate. Following the same clinical protocol described previously by Tolentino et al. (2014) and De Souza Tolentino et al. (2014), implant survival was defined as the implant being still in place during re-evaluation appointments. Implant success was defined as absence of (i) persistent pain, foreign body sensation, and/or dysesthesia; (ii) recurrent peri-implant infection with suppuration (S); (iii) implant mobility (M); (iv) continuous radiolucency around the implant; (v) probing pocket depth (PPD) ≥5 mm associated with bleeding on probing (BoP) as described by Karoussis et al. (2003). A manual periodontal probe (UNC periodontal probe; Hu-Friedy®, Chicago, USA) was used to evaluate presence or absence of (i) peri-implant S, (ii) BoP, and (iii) PPD. Furthermore, the percentage of visible bacterial plaque present on the different crown aspects was also determined. All variables described above were measured at the four implants aspects (mesial, distal, buccal, and lingual) at 6 weeks after restoration, 12 and 36 months after loading. A calibrated examiner who was not involved in the surgical procedure performed all measurements.

The prosthesis success was evaluated according to Pjetursson, Thoma, Jung, Zwahlen and Zembic (2012) was defined as (i) absence of prosthesis (crown or abutment) M and (ii) lack of necessity of prosthesis repair at 1- and 3-year follow-up examination.

2.5 Calibration

Calibration of the clinical and radiographic examinations was performed to ensure consistent evaluation of the implant sites. Intraobserver error was determined by measuring soft tissue characteristics (PPD and BoP) and measuring bone marginal level around 10 implants, five of each group, on others patients randomly chosen. Each measurement was performed twice over 2 days, with an interval of at least 24 hr, in patients not included in this clinical protocol. The intraclass correlation coefficient between examiners was 0.9.

2.6 Statistical analysis

The sample size was calculated using an equivalence trial test based on the primary outcome MBL at 3-year follow-up (Sealed Envelope Ltd. 2012 [Online]). A MBL difference of 0.5 mm between groups and a standard deviation of 0.5 mm with a power (1-beta) of 80% and significance level in 5% were established. A number of 18 patients for each experimental group were necessary to find no difference between the two treatment modalities. Due the split-mouth design, 22 patients were recruited expecting possible dropouts. To demonstrate that both treatment modalities were equivalent, the confidence interval of the difference in the MBL between groups had to be within the range of 0.5 mm.

Descriptive analyses with mean values and standard deviation (*SD*) or frequency distribution (%) were calculated for each variable. The patient was considered the statistical unit. Shapiro–Wilk normality test was applied and Wilcoxon test was used for comparison of MBL between groups (BioEstat 5.0 Software; Sociedade Civil Mamirau/MCT—CNPq, Belem, Brazil). The mean difference of MBL between baseline and 1-year follow-up and between 1- and 3-year follow-up was calculated with a confidence level of 95%. The peri-implant clinical parameters BoP, PPD >5 mm, suppuration (S), and implant mobility (M) as well as implant survival and success rates were described in percentage. A level of significance of 5% was considered as statistically significant.

3 RESULTS

A total of 44 implants were placed (22 RDIs and 22 NDIs) in 22 patients, 12 males and 10 females with a mean age of 53.4 years. In terms of implant distribution by region, in the NDIS, 13 premolars and 9 molars were placed, whereas in the RDIS, 8 premolars and 14 molars were placed. The region and jaw of implant placement of both groups are described in details at Table 1. All patients healed uneventfully. The implants ranged from 6 to 12 mm in length. All subjects completed the 1-year follow-up. However, at 3-year follow-up, there was a dropout of two patients, thus, a total of 20 patients and 40 implants were evaluated at this time point.

Table 1. Distribution of implant position, implant length (mm), and prosthesis complication in each patient of NDI and RDI groups at 3-year follow-up

Patient	Implant position	Length	Prosthesis complication	Dropout
1 RDI	45	10		
NDI	35	8		
2 RDI	46	10		
NDI	37	8		

3 RDI	34	10	
NDI	45	10	
4 RDI	16	8	Screw loosening
NDI	27	8	Screw loosening
5 RDI	45	10	
NDI	46	10	
6 RDI	15	8	
NDI	25	10	
7 RDI	25	8	
NDI	46	10	
8 RDI	46	8	
NDI	45	8	

9 RDI	26	10		
NDI	36	8		
10 RDI	46	8	Screw loosening	
NDI	44	8		
11 RDI	46	10		
NDI	14	10		
12 RDI	24	10		Lost to follow-up
NDI	26	8		
13 RDI	36	10		
NDI	15	10		

14 RDI	14	8	Veneer chipping
	35	6	
NDI			
15 RDI	46	8	
	36	8	
NDI			
16 RDI	24	8	
	27	8	
NDI			
17 RDI	45	8	
	46	8	
NDI			
18 RDI	45	10	
	46	12	
NDI			

19 RDI	15	8	Discontinue
NDI	26	8	
20 RDI	14	10	
NDI	17	8	
21 RDI	15	10	
NDI	46	10	
22 RDI	46	10	
NDI	16	8	

NDI, narrow-diameter implants; RDIs, regular-diameter implants.

[a] Patient discontinued for nontrial-related reasons.

At the end of the 1- and 3-year follow-up periods, cumulative implant survival rates of 100% were observed for both groups. At the end of the 1-year follow-up, implant success rates were 100% for both groups. At 3-year follow-up the implant success rate for RDIs was 100%, whereas for NDIs was 95% (one implant presented PPD ≥5 mm associated with BoP and S). The prosthesis success rates at 1-year follow-up were 95.4% for NDIs and 100% for RDIs. At 3-year follow-up, the corresponding values were 90% for NDIs and 95% for RDIs. The reasons of prosthesis failures were minor veneer chipping and screws loosening, as described in Table 1. For the crowns that presented veneer chipping, chairside repair was possible for all of them. The area of chipping was polished, and occlusion was adjusted without compromising the crown.

The mean MBL values of both groups are described at Table 2. At baseline, the MBL was +0.14 ± 0.16 mm (95% CI: 0.074 to 0.200) for NDIs and +0.06 ± 0.09 mm (95% CI: 0.023 to 0.097) for

RDIs (p = .084); at 1-year follow-up were −0.49 ± 0.27 mm (95% CI: −0.600 to −0.380) for NDIs and −0.42 ± 0.24 mm (95% CI: −0.520 to −0.320) for RDIs (p = .794) and at 3-year follow-up, the values were −0.58 ± 0.39 mm (95% CI: −0.751 to −0.409) for NDIs and −0.53 ± 0.46 mm (95% CI: −0.731 to −0.329) for RDIs (p = .598). The difference of mean MBL from baseline to 1-year follow-up was 0.38 ± 0.26 mm (95% CI: 0.272 to 0.488) for NDIs and 0.44 ± 0.36 mm (95% CI: 0.290 to 0.590) for RDIs (p = . 684) and between 1 and 3 years was 0.17 ± 0.09 mm (95% CI: 0.131 to 0.209) for NDIs and 0.12 ± 0.10 mm (95% CI: 0.077 to 0.163) for RDIs (p = .265). The MBL difference between groups at 3-year follow-up was 0.05 ± 0.44 (95% CI: −0.142 to 0.242). The CI of the difference between groups at 3 year was within the predefined range of 0.5 mm, demonstrating equivalence between groups. The MBL difference between baselines to 3-year follow-up in each patient is illustrated at Figure 2.

Table 2. Peri-implant bone level of NDI and RDI groups at baseline, 1- and 3-year follow-up

Follow-up	NDIs			
	Mean ± *SD*	Median	CI	Mean ± *SD*
Baseline	0.14 ± 0.16	0.00	0.074 to 0.200	0.06 ± 0.09
1 year	−0.49 ± 0.27	−0.52	−0.600 to −0.380	−0.42 ± 0.24
3 years	−0.58 ± 0.39	−0.65	−0.751 to −0.409	−0.53 ± 0.46

SD, standard deviation; NDI, narrow-diameter implants; RDIs, regular-diameter implants.

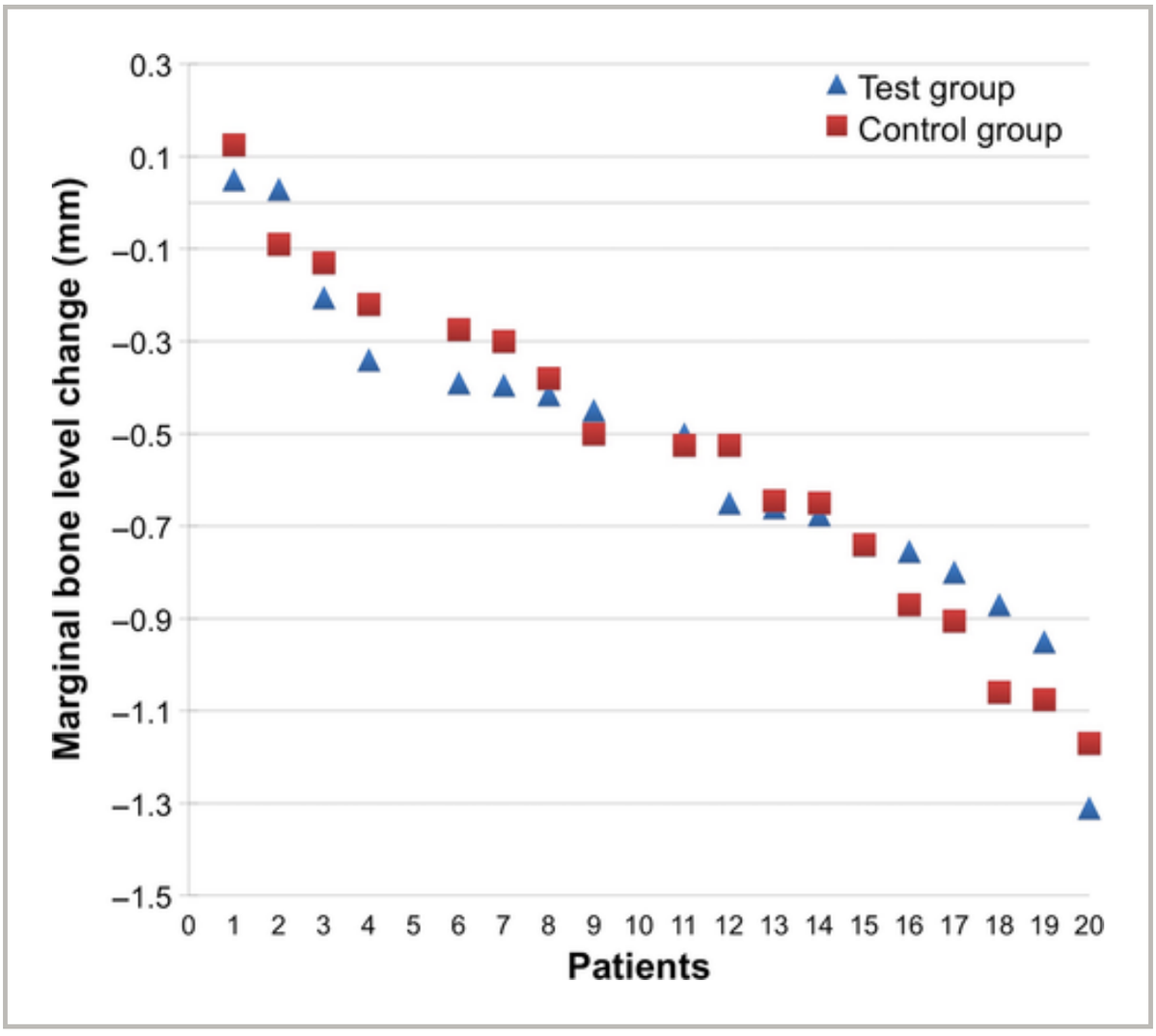

Figure 2

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Scatter plot demonstrating the difference of marginal bone level between baseline and 3-year follow-up at NDI and RDI groups

The percentage of implants with presence of BoP, peri-implant S, PPD >5 mm, and implant M at 1- and 3-year follow-up are described in Table 3. At 1-year follow-up, BoP was observed in 6% and 9% of NDIs and RDIs, respectively; whereas at 3-year follow-up, 15% and 10% of implants presented BoP in NDIs and RDIs, respectively. PPD >5mm was observed only in implants of NDIs with corresponding percentages of 4.5% at 1% and 5% at 3-year follow-up. None implants of both groups exhibited S at 1 or 3-year evaluation.

Table 3. Number and percentage of implants with presence of BoP, PPD >5 mm, S, and implant M at NDI and RDI groups at 1- and 3-year follow-up

Parameters	1-year follow-up		3-year follow-up	
	NDIs	RDIs	NDIs	RDIs
BoP	2 (9%)	2 (9%)	3 (15%)	2 (10%)
PPD >5 mm	1 (4.5%)	0 (0%)	1 (5%)	0 (0%)
S	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Mob	0 (0%)	0 (0%)	0 (0%)	0 (0%)

BoP, bleeding on probing; PPD, probing pocket depth; S, suppuration; M, mobility; NDI, narrow-diameter implants; RDIs, regular-diameter implants.

4 DISCUSSION

The present prospective randomized clinical trial assessed the use of NDIs and RDIs placed in the posterior region of the jaws to support single crowns after 3 years of load. The statistical analysis did not find differences in the primary outcome MBL. In addition, comparable outcomes were found between groups regarding the secondary variables implant survival and success rates. Furthermore, it was also demonstrated that the values of various clinical parameters as PPD, BoP, and S were comparable between the different experimental implant sites.

The implant cumulative survival rates and implant success rates for both groups were markedly high at the 3-year follow-up. Similar results were found in other clinical trials with long-term follow-up (Maló & Araújo Nobre, 2011; Romeo et al., 2006; Zinsli et al., 2004). The implants success and survival rates were evaluated by Klein et al. (2014) in a systematic review comparing NDIs (3.3–3.5 mm diameters) and RDIs in 16 clinical studies following specific the inclusion/exclusion criteria. Survival rates of NDIs ranged from 89% to 100%, and success rates varied from 91% to 98%. In addition, a meta-analysis was conducted and showed no statistically significant difference in implant survival rates compared to standard implants (Klein et al., 2014). In a literature review, Sohrabi et al. (2012)