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ORIGINAL ARTICLE

Randomised study for the 1-year crestal bone maintenance around modified diameter implants with different loading protocols: a radiographic evaluation

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Abstract This study evaluated by standardised digitised periapical radiography the crestal bone maintenance around modified diameter internal hex implants with variable thread design and narrow neck loaded with different procedures. Forty implants were placed in 25 patients. Twenty implants were conventionally loaded, 20 ones immediately loaded. Radiographs were taken with a customised bite record and processed with software. Measurements of bone from the fixture–abutment junction to mesial and distal marginal bone levels were made. Student's *t* test statistical analysis was adopted. Baseline data were variable; at 1-year follow-up, there were no significant differences for marginal bone loss between immediately and conventionally loaded maxillary implants (p=0.1031), whilst there were slight significant differences between immediately and conventionally loaded implants in the mandible (p=0.0141). Crestal bone maintenance around conventionally and immediately loaded modified diameter implants was similar, with slight significant differences in mandible where a lower marginal bone loss was observed.

Keywords Bone maintenance · Diagnostic imaging · Dental implants · Radiograph · Randomised study · Loading protocols

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Introduction

An enhancing number of clinical [1, 2] and experimental [3–6] publications reported successful early and immediate loading protocols. The clinical long-term success of implant-supported restorations depends, in part, on a stable connection between the prosthetic restoration and the implant body. Overloading has been identified as a primary factor behind dental implant failure [7]. The peak bone stresses normally appear in the marginal bone. The anchorage strength is maximised if the implant is given a design that minimises the peak bone stress caused by a standardised load. Then, stress paths on prosthetic structures and bone tissue are not only caused by occlusal loads but can be also related to inappropriate clinical practice or manufacturing defects, as in the case of stress induced by misfit for implant-supported prosthesis [8]. The amount and distribution of stress in the bone tissue may lead to marginal bone loss, thus affecting the osseointegration process and prosthesis load-bearing capacity. With immediate loading, initial marginal bone remodelling resulted to have mean value between 0.8 and 1.5 mm [9–11]. Different implant–abutment interfaces imply that the functional load is distributed in different ways upon the implant [12]. The abutment size has significant influence on the stress distribution in bone because of different load transfer mechanisms at the implant–abutment interface [13]. However, it was found that bone resorption could be reduced when the abutments are smaller than the diameter of the implant body (platform switching) [14–17]. In the case of the internal hex implant, the contact condition with friction between abutment and implant in the tapered joints and at abutment neck reduced the effect of bending caused by horizontal component of inclined load [13]. Some authors showed that tapered, roughened-surface implants immediately restored were as prosthodontically and aesthet-

ically successful as conventionally restored two-stage implants during 1-year follow-up observations [18]. Others observed that standard-design implants may provide levels of biologic stability similar to a tapered, self-tapping implant design in immediate placement protocols [19]. However, it needs to evidence that the majority of dental implants have not been designed for differing bone morphologies. Current literature on the clinical performance of the scalloped dental implant is limited. Wöhrle [20] demonstrated that the scalloped dental implant is designed to biologically guide and facilitate interproximal bone remodelling during healing and to maintain bone height and papillae during functional loading. Therefore, enhanced interproximal tissue preservation from scalloped implant designs may lead to more predictable aesthetic dental implant restorations in the anterior maxilla [21, 22]. A radiographic and clinical evaluation of 16 two-piece scalloped implants and nine one-piece scalloped implants revealed enhanced interproximal bone levels versus a non-scalloped conventional flat-top implant design [23]. It has been observed that a scalloped implant design allowed the preservation of the interproximal bony lamella with stable bone levels during 27 months of observation period [24]. In the case of immediately loaded multiple implants, the splinting could reduce the occlusal load transfer more effectively than single implants [25]. Splinting of multiple implants with a temporary bridge decreases the micromotion at the implant–bone interface and prevents implant failure [26, 27]. The cross-arch stabilisation has been demonstrated to be beneficial to the achievement and the maintenance of osseointegration in clinical and in vivo studies [25, 28]. The temporary prosthesis should not be peaked or removed during the healing period to avoid unnecessary movement [29].

The aim of this study was to evaluate by a computerised digital intraoral radiography system the peri-implant bone remodelling around conventionally and immediately loaded modified diameter implants.

Materials and methods

Patient selection

In order to evaluate the peri-implant bone remodelling around conventionally and immediately loaded modified diameter implants, all the patients scheduled for fixed implant-supported rehabilitations were asked to participate to the study provided that they fulfilled the following inclusion criteria: partial edentulism in posterior areas with residual alveolar width sufficient to place implants with 4.2-mm minimum diameter and 10-mm minimum length; sufficient primary stability as judged clinically and insertion torque of 35 N. For a complete pre-surgical evaluation, a computed tomography (CT) scan examination, a wax-up and a surgical template were performed for each implant site.

Exclusion criteria were the following: natural teeth adjacent to surgical area affected by untreated periodontal and endodontic infections, peri-implant bone defects requiring bone augmentation and absence of opposing occlusion. Additional exclusion criteria were: poor oral hygiene, smoking, parafunctional habits, severe maxillomandibular space discrepancies, any drug use (included biphosphonates) or alcohol abuse. All the patients were informed regarding the study and signed a written consent form.

The study protocol, approved by the Ethical Committee for Human and Animal Studies of the School of Medicine, University of Chieti, included 25 good health patients who were treated with the placement of 20 in the mandible and 20 in the maxilla. The titanium implants used in this study were grade II titanium dental implants approved for human use and are modified diameter internal hex implant with variable thread design and narrow neck (SFB screw internal hex implant, Alpha Bio Ltd., Israel). The implant surface was sandblasted and acid-etched. The implant features of the fixtures used in the study and the jaw position are displayed in Table 1. Each patient received one to three implants to support a single crown or two- to three-unit fixed partial dentures. Multiple implants were connected to each other.

Surgical protocol

All patients underwent the same surgical protocol. All the subjects adopted an antimicrobial prophylaxis with mouthrinses of 0.12% chlorexidine 1-min rinse before surgery and three times a day for the following 10 days (Dentosan 0.12%, Johnson &Johnson, USA) and antibiotics 2 g per day of clavulanic acid and amoxicillin for 3 days starting 1 h before surgery (Augmentin, Glaxo SmithKleine, Italy).

Local anaesthesia was induced by infiltration with articaine/epinephrine (Ecocain 20 mg/ml, Molteni Dental, Italy). Crestal incisions were made with maximum effort to maintain intact the periodontal tissues of adjacent teeth, and vertical release incisions were made only if necessary to obtain a better visibility. A full-thickness flap was reflected buccally and lingually to expose the alveolar ridge of implant site. The preparation of the recipient site was performed following the instructions of implant manufacturer under abundant saline solution irrigation. After a pre-surgical evaluation with a CT scan examination, a wax-up and a surgical template, all the implants were placed through the last apical half to compact bone with a driver mounted on an handpiece with an insertion torque of at least 35 N and low speed (50 rpm). No bone grafting was needed. Closure of the flap was obtained without tension using 3.0 silk sutures (Ethicon Silk 3.0, Ethicon, USA).

Table 1 Size and position of implants used in the study

Implant diameter (mm)	Implant length (mm)	UJCL	UJIL	LJCL	LJIL
		No. of implants and position	No. of implants and position	No. of implants and position	No. of implants and position
4.2	10	–	–	–	–
	11.5	–	–	3 (1 2nd P, 1 1st M, 1 2nd M)	1 (1 1st P)
	13	–	2 (1 1st P, 1 2nd P)	1 (1 2nd P)	3 (3 1st P)
	16	–	1 (1 LI)	1 (1 1st M)	–
5.0	10	3 (2 1st M, 1 1st P)	–	3 (3 1st M)	–
	11.5	1 (1 2nd M)	–	1 (1 2nd P)	1 (1 1st M)
	13	2 (1 2nd P,1 C)	–	–	2 (2 2n P)
	16	–	4 (4 CI)	1 (1 C)	1 (1 C)
6.0	10	2 (2 1st M)	–	–	–
	11.5	1 (1 2nd M)	3 (3 1st M)	–	2 (2 1st M)
	13	1 (1 2nd M)	–	–	–
				–	
Total		10	10	10	

UJCL upper jaw (maxilla) conventional loading, *UJIL* upper jaw (maxilla) immediate loading, *LJCL* lower jaw (mandible) conventional loading, LJIL lower jaw (mandible) immediate loading, *M* molar, *P* premolar, *C* canine, *LI* lateral incisor, *CI* central incisor

Patients were instructed to have a liquid or semi-liquid diet for the first 3 days and then gradually return to a normal diet. Painkiller medications were prescribed and adopted by the patient when needed (Aulin, nimesulide 100 mg, Roche SPA, Italy). Sutures were removed 7 days after surgery.

Prosthetic protocol

According to the consensus statement of Cochran et al. [30] about recommended clinical procedures regarding loading protocols for endosseous dental implants, ten implants inserted in the upper jaw were conventionally loaded and received provisional restorations 6 months after the surgical phase was completed, whilst the remaining ten implants were immediately loaded and received provisional restorations the same day of implant surgery. Ten implants inserted in the lower jaw were conventionally loaded and received provisional restorations after 3 months of the surgical phase, whilst the remaining ten implants were immediately loaded and received provisional restorations the same day of implant surgery.

Uncovering of implants restored with conventional loading was performed with a full-thickness flap with the maximum effort to preserve a band of keratinised tissue on both sides of the implant site.

For implants that were immediately loaded, titanium standard straight abutments for cement retention were inserted immediately, and direct impression was made with vinylsiloxane material in standard trays.

For implants conventionally loaded, transfer copings were connected and a pickup impression was performed with custom-made trays.

Straight abutments for cement retention or UCLA-type abutments when needed were used and provisional restorations made from self-curing composite resin (Protemp;3M ESPE, USA) were delivered. Multiple implants were connected to each other. An insertion torque of all the abutments to the implants of 35 N/cm was obtained with a torque wrench device. All the restorations were designed with contact in maximum intercuspal position or centric relation whilst working and balancing contacts were removed.

Criteria for success and follow-up examinations

The following conditions were considered for implant success at baseline and at 12 months and recorded by a previously calibrated and masked investigator for each implant: absence of fixture mobility, suppuration, pain, infection and paresthesia, absence of peri-implant radiopacity/radiolucency and bone loss lower than 1.5 mm at 12-month radiographic exam, bleeding on probing (BOP) (recorded as present or absent) and occlusion [31]. Five patients, each showing two natural teeth (single and multi-rooted) with probing depths >5 mm on at least one aspect of each tooth, were used for calibration. The examiner evaluated the patients on two separate occasions, 48 h apart. Calibration was accepted if the two measurements at baseline and at 48 h were similar to the millimetre at >90% level. At 12 months, peri-implant probing depth was

recorded with a millimetre-calibrated periodontal probe (PCP-UNC 15, Hu-Friedy, Chicago, IL, USA) to the nearest millimetre. The measurements were registered for each implant on vestibular, oral and central points of proximal site and the average calculated.

All the patients were placed under a strict plaque control regimen until complete soft tissue healing was obtained and were recalled at 1, 3, 6, 9 and 12 months after prosthetic loading.

Radiographic assessment

Radiographic evaluation was performed by a previously calibrated and masked investigator.

Standardised periapical radiographs were taken using a customised bite record fabricated with acrylic resin on a Rinn XCP Ring positioner (Dentsply, Constanz, Germany) and a beam guiding rod to allow parallelisation between the X-ray tube and the film and standardise all the radiographs. The radiographs were performed with a dental X-ray machine (TM 2002 Planmeca Proline CC, Planmeca Group Helsinki, Finland) equipped with a long tube that operated at 70 Kw/ 7.5 mA and were developed in an automatic developer under standardised conditions. In both the groups, radiographs were taken at baseline and 1, 6 and 12 months after prosthetic loading. The radiographs, set on a cephalometric unit in a darkroom, were acquired and converted in digital images with a camera and saved into a computer memory in TIFF format. Later, each image was processed with specific software (Scion Image Beta 4.03 for Windows XP, Scion Ltd., USA) and displayed on a high-resolution monitor. A computer-assisted calibration was made on the mesial and distal sides of each implant measuring the known distance between two threads. This calibration allowed a correct measurement even if there was a slight deviation of the central beam and a consequent magnification of the image.

The following reference points were assessed on each image: fixture–abutment junction, threads and first contact of the crestal bone with the implant on both the mesial and distal sides. This made possible, with the known values for implant diameter and length, making linear measurements of remaining peri-implant bone measured from the mesial and distal marginal bone levels and the fixture–abutment junction. The linear measurements were made by a trackball-driven cursor on a digitised image of the implant on the monitor magnified ten times. The amount of bone change over the baseline to 12 months after implant placement was calculated for all implants (Figs. 1, 2, 3, 4 and 5).

Statistical evaluation

In order to evaluate the minimal number necessary for statistical evaluation, the sample size was calculated by a public domain online software (Raosoft http://www.raosoft.com/samplesize.html). Two computer-generated restricted randomisation lists were made. The randomisation codes (1 or 2) were enclosed in sequentially numbered identical sealed envelopes that were opened at the moment of the surgery to choose between conventional and immediate loading.

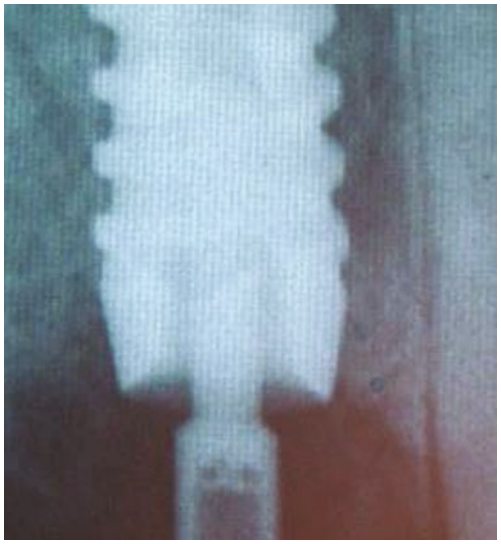


Fig. 1 Implant placed in the upper jaw and immediately loaded: baseline periapical radiograph

The author that made the statistics was kept blind and performed all the analysis without knowing the assignment group of the patients. The statistical analysis was performed with a commercially available statistical programme (SPSS® 13.0, SPSS, Chicago, IL, USA). Mean values and standard deviations (mean±SD) for the clinical variables were expressed in millimetres and were calculated based on the implant as the statistical unit. Differences between baseline clinical data and those recorded at 1-year follow-up were analysed using the paired Student's *t* test. Confidence interval was set at 95% mean for all measurements. Statistically significant differences were set at $p<0.01$.

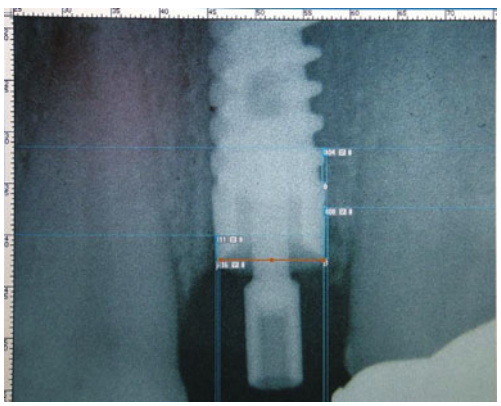


Fig. 2 Linear measurements were made from mesial and distal aspects of implant–abutment junction to the more coronal bone implant visible on the screen (baseline)

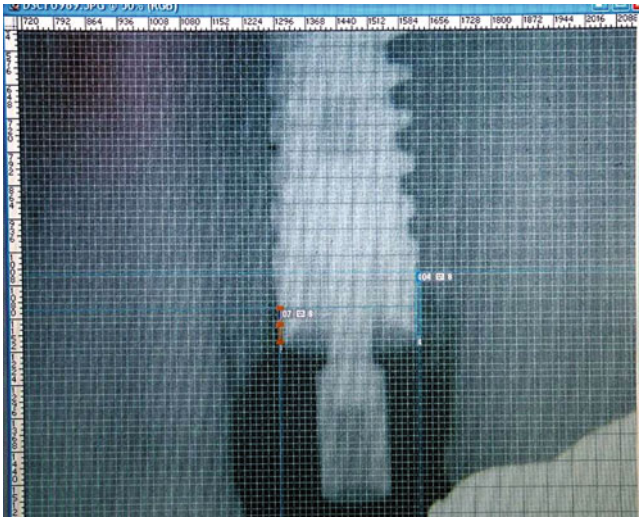


Fig. 3 Linear measurements (12-month follow-up)

Results

Clinical observations

Twenty-five consecutive patients were treated with the placement of 40 modified diameter implants immediately or conventionally loaded. All the patients joined the study until the end and no dropout was observed.

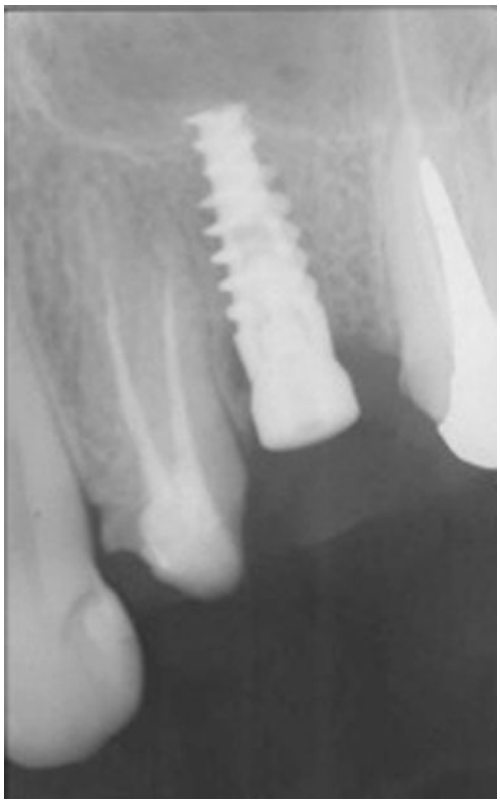


Fig. 4 Implant placed in the upper jaw and loaded 6 months after the surgical phase: baseline periapical radiograph

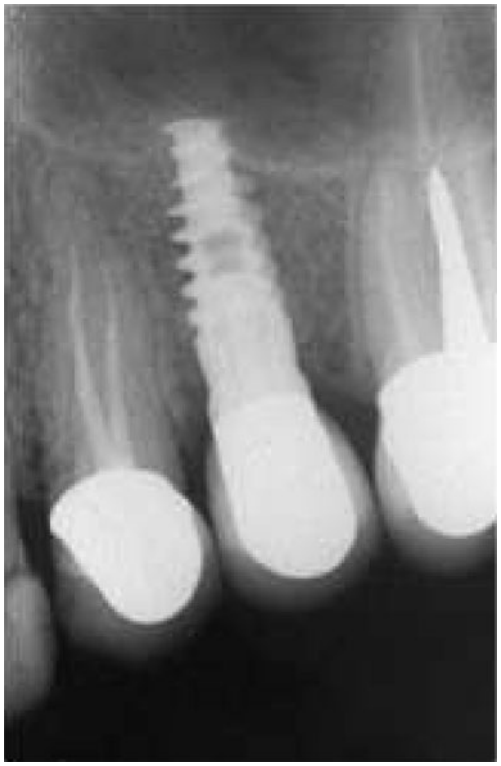


Fig. 5 Implant placed in the upper jaw and loaded 6 months after the surgical phase: periapical radiograph at 12-month follow-up

Peri-implant status was assessed by means of probing depth and bleeding on probing recordings.

The average peri-implant probing values were all normal and not deeper than 4 mm.

Although a careful plaque control regimen was performed during the entire study, a slight peri-implant inflammation was detected, and positive BOP values were sometimes observed. No implant was lost and all the fixtures placed fulfilled the aforementioned evaluated requirements for success. (Table 2)

Therefore, the cumulative success rate after 1 year was of 100% for both test and control groups.

Radiographic results

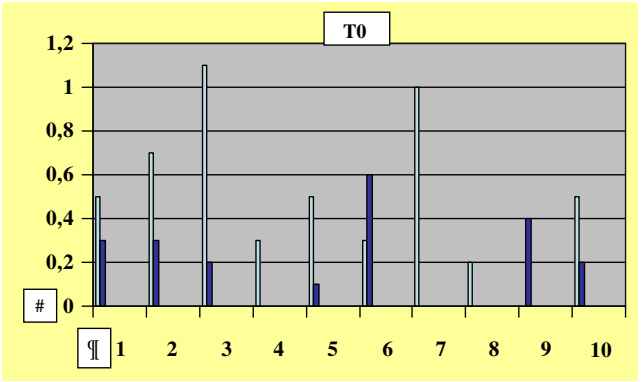
Maxilla

The baseline data regarding implants restored with conventional loading showed different values for each fixture probably because of the variable placement level of each implant with respect to the crestal bone level; the mean baseline marginal loss was 0.36 mm (SD ± 0.314 mm; Fig. 6). The values observed after 12 months of prostheses delivery describe the bone changes determined by functional loading. The mean marginal bone loss was 0.43 mm (SD ± 0.246 mm; 95% CI 0.320–0.550; Fig. 7). The baseline data regarding implants restored with an immedi-

Table 2 Clinical measurements and crestal bone maintenance in each group

Treatment procedure	Conventional loading	Conventional loading	Conventional loading	Conventional loading	Conventional loading	Immediate loading	Immediate loading	Immediate loading	Immediate loading	Immediate loading	Immediate loading
Follow-up period	Mean marginal bone loss±SD (mm)	Average probing depth±SD (mm) mesiofacial	Average probing depth±SD (mm) facial	Average probing depth±SD (mm) distofacial	Average probing depth±SD (mm) lingual	Percentage of positive sites at BOP assessment	Mean marginal bone loss±SD (mm)	Average probing depth±SD (mm)	Average probing depth±SD (mm) facial	Average probing depth±SD (mm) distofacial	Average probing depth±SD (mm) lingual	Percentage of positive sites at BOP assessment
Baseline (maxilla)	0.36 ± 0.314	NA	NA	NA	NA	NA	0.53 ± 0.347	NA	NA	NA	NA	NA
12 months (maxilla)	0.43 ± 0.246	3.03 ± 0.81	2.53 ± 0.41	3.06 ± 0.83	2.64 ± 0.56	5.3	0.34 ± 0.185	2.84 ± 0.82	2.03 ± 0.75	2.75 ± 0.45	2.53 ± 0.38	4.7
Baseline (mandible)	0.40 ± 0.239	NA	NA	NA	NA	NA	0.54 ± 0.287	NA	NA	NA	NA	NA
12 months (mandible)	0.33 ± 0.172	2.97 ± 0.67	2.39 ± 0.34	3.06 ± 0.43	2.87 ± 0.23	6.1	0.53 ± 0.258	2.75 ± 0.57	3.09 ± 0.67	2.39 ± 0.67	3.36 ± 0.23	5.5

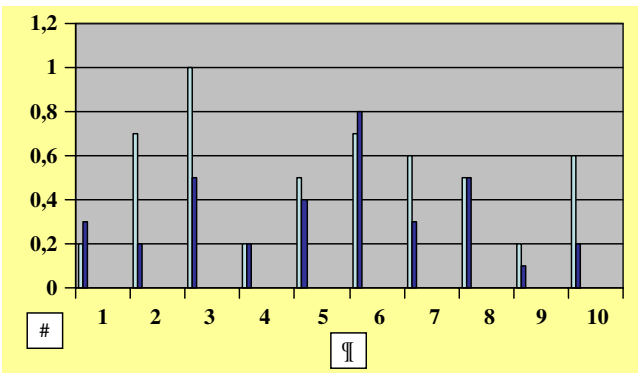
SD standard deviation, *NA* not assessed



¶= implants;
#= mean marginal bone loss
• = mesial aspect
• = distal aspect
CI: Interval of confidence
SD: Standard deviation

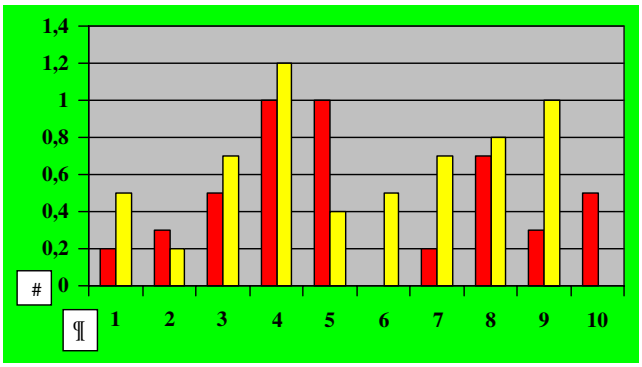
Fig. 6 Crestal bone maintenance around maxillary implants conventionally loaded (baseline); mean marginal bone loss, 0.36 mm (SD ± 0.314 mm; 95% CI 0.213–0.507)

ate loading procedure showed also different values for each fixture probably because of the aforementioned reasons for conventional loading. The mean baseline marginal loss was 0.53 mm (SD ± 0.347 mm; 95% CI 0.373–0.697; Fig. 8). Moreover, it was possible to observe again that at 1-year follow-up, there was a minimal bone remodelling with a marginal loss of 0.34 mm (SD ± 0.185 mm; 95% CI 0.257–0.426; Fig. 9). Comparing the values obtained after 1 year of prosthetic loading in both the groups (conventional and immediate procedures), there were no significant differences (p=0.1031).



¶= implants;
#= mean marginal bone loss
• = mesial aspect
• = distal aspect
CI: Interval of confidence
SD: Standard deviation

Fig. 7 Crestal bone maintenance around maxillary implants conventionally loaded (12 months); mean marginal bone loss, 0.43 mm (SD ± 0.246 mm; 95% CI 0.320–0.550)

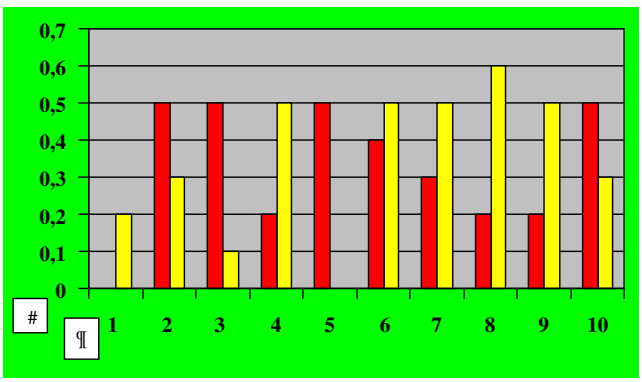


¶= implants;
#= mean marginal bone loss
• = mesial
◦ = distal
CI: Interval of confidence
SD: Standard deviation

Fig. 8 Crestal bone maintenance around maxillary implants immediately loaded (baseline); mean marginal bone loss0.53 mm (SD± 0.347 mm; 95% CI 0.373–0.697)

Mandible

The baseline data regarding implants restored with conventional loading procedure showed different values for each fixture probably because of the reasons mentioned for implants placed in maxilla; the mean baseline marginal loss was 0.40 mm (SD ± 0.239 mm; 95% CI 0.293–0.517; Fig. 10). The crestal bone maintenance after 1 year of functional loading was very good and the mean baseline marginal loss was of 0.33 mm (SD ± 0.172 mm; 95% CI 0.249–0.410; Fig. 11). The baseline data regarding implants restored with an immediate loading procedure showed also in this case different values for each fixture probably



¶= implants;
#= mean marginal bone loss
• = mesial
◦ = distal
CI: Interval of confidence
SD: Standard deviation

Fig. 9 Crestal bone maintenance around maxillary implants immediately loaded (12 months); mean marginal bone loss, 0.34 mm (SD± 0.185 mm; 95% CI 0.257–0.426)

because of the aforementioned reasons; the mean baseline marginal loss was 0.54 mm (SD ± 0.287 mm; 95% CI 0.406–0.674; Fig. 12); the mean marginal loss 1 year after prosthesis delivery was 0.53 mm (SD ± 0.258 mm; 95% CI 0.409–0.651; Fig. 13). Comparing the values obtained after 1 year of functional loading in both the groups (conventional and immediate loading), there were slight significant differences (p=0.0141).

Discussion

The purpose of the present study was to compare by standardised periapical radiographs the crestal bone maintenance around modified diameter implants conventionally and immediately loaded. With regard to implants placed in maxilla, the mean peri-implant bone loss after 1 year was 0.43 mm for conventionally loaded implants and 0.34 for immediately loaded implants. Significant differences were observed between the two groups after 1 year of functional loading (p=0.1031). Therefore, the immediate loading procedure did not affect negatively the crestal bone maintenance. With regard to implants placed in the mandible, the mean peri-implant bone loss was 0.33 mm for conventionally loaded implants and 0.53 for immediately loaded implants.

Slight significant differences were observed between the two groups after 1 year of functional loading (p=0.0141).

All the values of peri-implant bone loss observed in the present case series are lower than most of those described in literature for both conventional and immediate loading procedures [32–43].

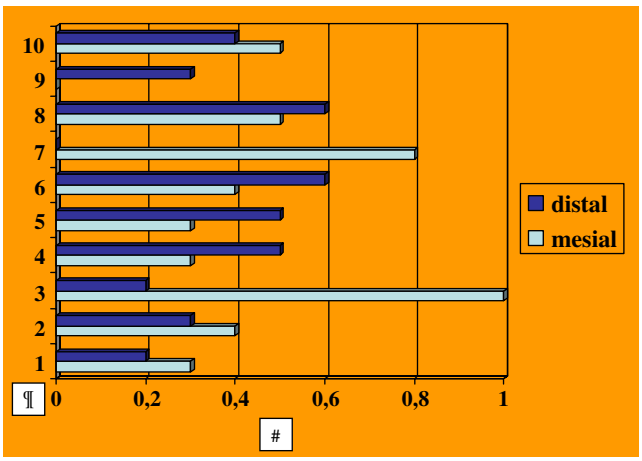


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Fig. 10 Crestal bone maintenance around mandibular implants conventionally loaded (baseline); mean marginal bone loss, 0.40 mm (SD±0.239 mm; 95% CI 0.293–0.517)

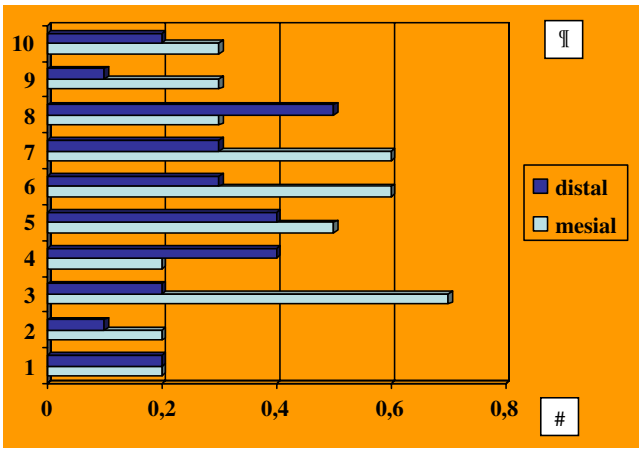

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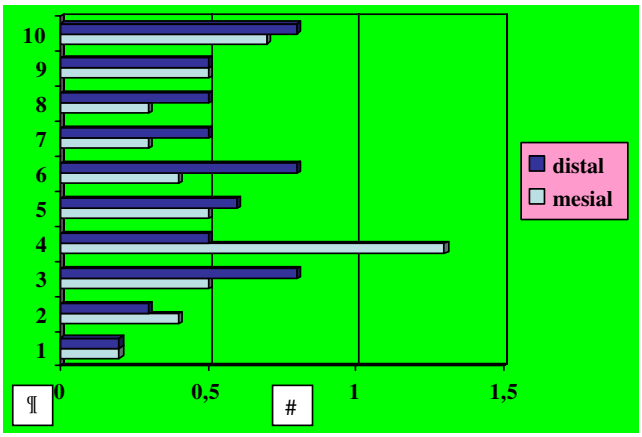
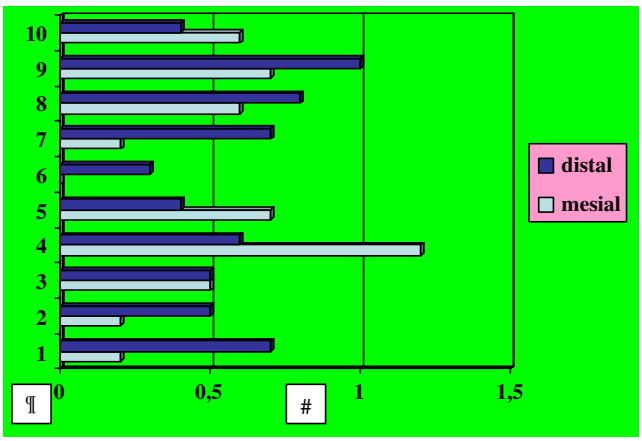
Fig. 11 Crestal bone maintenance around mandibular implants conventionally loaded (12 months); mean marginal bone loss, 0.33 mm (SD±0.172 mm; 95% CI 0.249–0.410)



¶ = implants;
# = mean marginal bone loss
CI: Interval of confidence
SD: Standard deviation

Fig. 13 Crestal bone maintenance around mandibular implants immediately loaded (12 months); mean marginal bone loss, 0.53 mm (SD±0.258 mm; 95% CI 0.409–0.651)

In accord to our results, other authors observed marginal bone loss in the first year to be slightly greater for implants placed in the maxilla than for those in the mandible. These data could be explained by the fact that there could be differences in the remodelling capacity and rate between maxillary and mandibular bone, the former being more vascularised and with more remodelling potential in the healing phase after implant placement [44]. Moreover, the mandible crestal bone could be easier to assess by periapical radiographs because of a higher mineralisation rate if compared to the maxilla. The high percentages of success of these case series could be explained by the short period of observation and the limited number of patients followed. In conclusion, when comparing crestal bone maintenance around immediately and conventionally loaded implants, it is possible to state that peri-implant bone loss after 12 months is similar.



¶ = implants;
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CI: Interval of confidence
SD: Standard deviation

Fig. 12 Crestal bone maintenance around mandibular implants immediately loaded (baseline); mean marginal bone loss, 0.54 mm (SD±0.287 mm; 95% CI 0.406–0.674)

Conclusions

Within the limited data from this study, it is possible to state that crestal bone maintenance processes around conventionally and immediately loaded implants are similar and no significant differences are expected to happen. The observations of the following case series showed a better crestal bone maintenance for implants placed in the mandible and immediately loaded. At the moment, the reasons for this observation could be only speculated and further investigations are needed.

Conflict of interest The authors declare to not have conflict of interest.

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