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An alternative solution for mandible rehabilitation: fixed full arch prosthesis on short implants: a randomized cohort study

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ABSTRACT

Aim The aim of this study was to evaluate a surgical/prosthetic protocol for the rehabilitation of edentulous mandible with four short implants and a metal-free fixed prosthesis.
Materials and methords Study design: ten patients with mandibular edentulism were enlisted into the study. Four short implants (4x5 mm) were inserted. After four months, the implants were uncovered and a metal-free prosthesis was designed using a substructure made from a fiber-reinforced composite (Trinia TM, Bicon LLC, Boston, MA) and denture teeth. Follow-up visits were scheduled at 6, 12, 24, and 36 months after prosthetic loading.
Results At the end of follow-up, an implant success rate of 95% was recorded. No significant effect over time on mean bone level variation (expressed as percentage of variation compared to baseline value) was observed, with an average bone loss of -0,47 mm ± 0.64 mm. In addition, no worsening of periodontal indexes examined and prosthetic complications were noted. Parameters of patient perception examined revealed a good level of satisfaction (score range 6-9, out of a 0-10 score scale).
Conclusions These data highlight the potential of the technique as an alternative solution to limit additional preprotesic surgery and to perform atraumatic and conservative treatment in case of atrophic jaws .

KEYWORD Fiber Reinforced Composite; Mandible edentulism; Short implant.

INTRODUCTION

Dental implants represent an effective method for the rehabilitation of edentulous patients (1-3). However, the ideal placement for dental implants could be constrained by a limited availability of bone. In such cases, the placement of traditional screw type long fixtures requires additional bone augmentation procedures (4-6). An alternative treatment is the "All On Four" treatment concept (7). This procedure overcomes anatomical limitations by using tilted screw type traditional long implants. Nonetheless, despite initial good results, some authors have questioned the paucity of long-term studies (5 years or more) that could reveal undetermined complications (8). The use of short implants could be a valid alternative in cases of atrophic bone, especially if compared to bone augmentation procedures performed at posterior atrophic jaw level (9). Short implants could give a faster and cost effective treatment and a lower post-surgical morbidity (10). According to Telleman et al., we define "short implant" a fixture long less than 10 mm (11). Many studies have investigated short implants for the rehabilitation of edentulous patients (12). In a retrospective cohort study conducted on 57 (5x5mm), 154 (6x5mm), and 199 (5x8 mm) implants, there were no statistically significant differences in the success rate of short implants (97.6%) and short implants (95.2%) (13). Other authors demonstrated that short implant rehabilitation could be effective and comparable to the use of standard-length implants (9,14). In addition to the data on short implants, there is evidence that the use of fiber-reinforced resinous materials would reduce the transmission of masticatory-occlusal stress on the implant-bone junction (15-17). Erkmen et al. (2011) has shown *in vitro* that the use of these materials for the construction of prosthetic structures results in a different distribution of stress at the bone-implant and implant-support junctures, suggesting that this phenomenon is acting positively on maintaining peri-implant bone (18). In fact, bone preservation is the first requirement to ensure long-term success of the

prosthetic implant treatment and this is even more crucial in cases of bone atrophy. Thus in this study, we aimed at evaluating the clinical characteristics of fixed implant-prosthetic rehabilitations of the edentulous mandible, supported by four short implants (4x5 mm, Bicon LLC, Boston, MA) and a metal-free fixed prosthesis made of fiber reinforced composite (FRC) (Trinia™, Bicon LLC, Boston, MA). This solution could avoid the need of bone augmentation procedures and the use of tilted implants, leading to a more conservative, fast and atraumatic treatment in case of bone atrophy. Forty implants were inserted in a cohort of ten patients and marginal bone level variation, clinical periodontal indices, patient perception and distal extension (cantilever) were evaluated during a three-year follow-up.

MATERIALS AND METHODS

Patient selection

The study sample of this prospective, single cohort study consisted of ten volunteers in care at the UOC Oral Surgery Department of Dental Sciences, Dental Clinic "Sapienza" University of Rome (Italy). The mean age of the sample was 61.1 years (range 42–80). The study was performed in accordance with the Helsinky Declaration and approved by the local ethics committee. An anamnestic questionnaire was submitted to patients to evidence the presence of diseases possibly affecting the outcome of the study, such as cardiovascular, endocrine, pulmonary, renal, hepatic diseases. Patients who received organ transplant or had tumor disease were excluded.

Inclusion criteria

Inclusion criteria were the following: patients in good general health as assessed by laboratory routine screening tests; edentulous mandible with classes IV-V of Cawood and Howell (19), but with sufficient height and thickness (minimum 6 mm height and 5 mm thick) for the insertion of short implants. Evaluation of mandibular anatomy and bone volume was carried through clinical examination and first and second level radiographic examination (orthopantomography and CT-scan).

Exclusion criteria

Exclusion criteria were: lack of informed consent, inability to give informed consent, age under 18 years old, age over 80 years old, uncontrolled diabetes (target HbA1c <6.5%), heavy smokers (more than ten cigarettes per day), chewing tobacco, alcohol, periodontal disease not treated at the level of the opposing bite, increased risk of bacterial endocarditis, rheumatic diseases, previous bisphosphonates or interferon treatment, chronic therapy with glucocorticoids, pregnancy, lack of compliance, physical disability that interferes with oral hygiene and patients who took part in drug trials in the last thirty days.

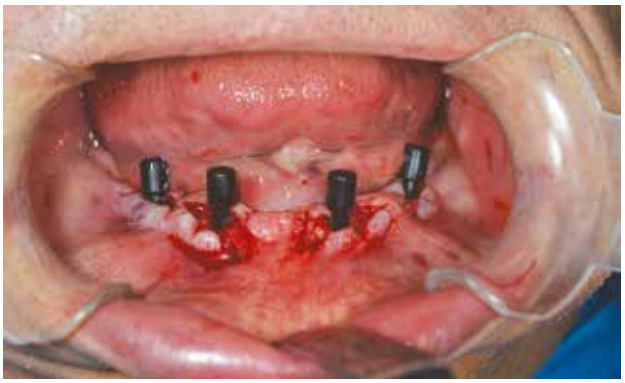

FIG. 1 Intraoral placement of implants.

Implants and prosthesis

Forty implants were inserted in ten patients, four males and six females. Eight patients had in the opposing dentition a total denture while two had their natural teeth. Patients received four short implants (Bicon LLC, Boston, Massachusetts, USA), 4 mm in diameter and 5 mm in height to support the fixed prosthesis. The implant is characterized by a plateau design, a crestal module with pure locking taper connection, sloping shoulder, abutment hemispheric profile and calcium phosphate surface treatment. The implants and abutments of the system are made of the titanium alloy Ti6Al4V. The prosthesis substructure is made of Trinia® (Bicon LLC, Boston, Massachusetts, USA) made up of interlaced multidirectional, multilayered fiberglass, immersed in a matrix of epoxy resin (FRC). It is supplied in milling blocks (pre-cured) for the CAD/CAM (computer-aided design/computer-aided manufacturing) technique. The substructure was completed by denture teeth made of composite material.

Surgical protocol

The surgery involved the insertion of four short implants for each patient. Implants were placed at position of 4.6, 4.3, 3.3, 3.6 using a template (Fig. 1). The preparation of the implant site was made by using a surgical guide. The first pilot drill works under irrigation, followed by atraumatic drills rotating at a speed of 50 rpm, without irrigation. The size of the last reamer was equal to the size of the implant and the implant was placed under pressure, line to line, from 1 to 3 mm below the bone (sub-crestal).

The bone harvested from the osteotomy during site preparation was positioned between the cortical bone of the surgical alveolus and the implant, above the implant shoulder.

All surgeries were performed by the same surgeon.

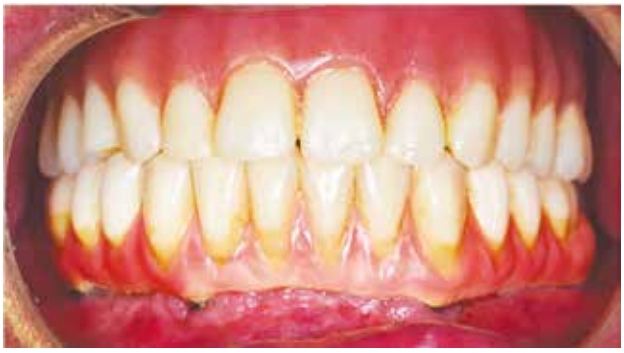

FIG. 2 Framework placed in function.

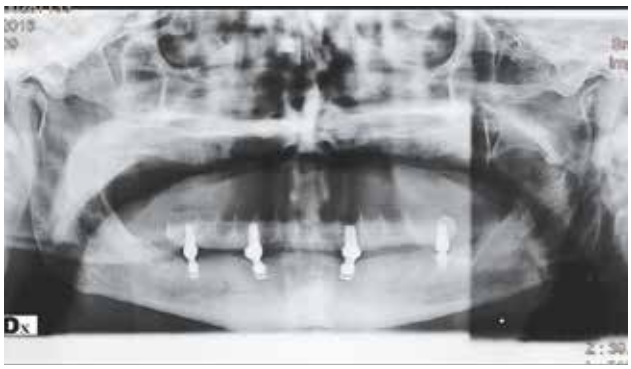

FIG.3 Radiographic evaluation.

Prosthetic protocol

After three months, implants were surgically exposed and the healing abutments were applied. Two weeks later, a full arch impression of the implants and the opposing teeth was taken. A siliconic material A-type (addition) was used (Elite HD, Zhermack). When ready, the milled abutments were connected to the implants using a template to achieve the correct orientation. The prosthesis was cemented using a temporary luting agent (Temp Bond NE, Kerr) (Fig. 2). Then, the control of the occlusion was performed. All prostheses were made by the same laboratory technician.

Follow-up

Follow-up visits were scheduled at 6, 12, 24, and 36 months after prosthetic loading, at the UOC Oral Surgery Department of Dental Sciences, Dental Clinic "Sapienza" at the University of Rome (Italy).

Evaluations

The evaluations made at baseline (prosthesis insertion) were compared with those recorded at 6, 12, 24, 36 months of follow-up.

Marginal bone level variation

Marginal bone level was recorded after the implant-abutment connection. Marginal bone level was defined as the maximum distance from the implant-abutment junction (IAJ) on the implant side to the marginal bone. Two mesial and distal sites were measured for each implant. Mesial and distal bone levels were measured directly on X-ray film (orthopantomography) using a millimeter ruler and the measurements were calibrated to the known size of the implant (Fig. 3). A positive value was assigned if bone was over the IAJ while a negative value if bone was below IAJ. The zero score was given when bone level was at IAJ. Thus, negative values express bone loss while positive values express bone gain. Only the vertical marginal bone level was measured; the horizontal level was ignored. One calibrated examiner recorded the mesial and distal aspects of each implant. Mesial and distal measurements were subsequently averaged to determine mean implant bone level variation. Marginal bone level variation (expressed as %) was measured at the four implant sites during the follow-up. Variation is meant as bone loss/gain as compared to the baseline (prosthesis cementation) reference value (which becomes zero).

Periodontal indices

At each follow-up visit, a clinical evaluation was carried out in order to record pocket depth (PD), te O'Leary plaque index (PI), and bleeding on probing (BOP) around implants. PD was measured with a CP12 probe on six sites: three vestibular (mesial, vestibular, distal) and three lingual (mesial, lingual, distal). The values, expressed in millimeters, were used to achieve the mean PD value for each patient. PI was measured on six sites around each implant (24 sites examined on each patient). Data are expressed as percentage of plaque sites (%PI) (Number of tooth surfaces with plaque/total number of sites examined x100). BOP was also measured on six sites around each implant (24 sites examined on each patient). Data are expressed as percentage of bleeding sites (%BOP) (Number of bleeding sites/total number of sites examined x100).

Patient perception

Patient perception was assessed by means of a questionnaire asking the subject to mark a score between zero and ten, for the following categories: level of satisfaction; evaluation of the prosthetic procedure; comfort; aesthetics; bite force; hygiene; phonetics; and stability of the implant. The questionnaire was administered at each follow-up visit.

Distal extension (cantilever)

The distal extension (cantilever) of each prosthesis was evaluated. The millimetric value was recorded through a millimeter ruler starting from the last hole present in the prosthesis structure, distally, each side.

Durability of the prosthesis and prosthetic complications

Particular attention was given to record every prosthetic complication during function.

Statistical analysis

Data on % of bone variation, PD, PI and BOP were analyzed by ANOVA for repeated measures, containing one repeated factor (time). Comparisons between bone variation at each follw-up visit were evaluated by one-way ANOVA test. Data on questionnaires were analyzed by descriptive statistics.
Statistical analysis was performed using the Statview software from SAS Institute. The level of statistical significance was set at $p < 0.05$.

RESULTS

Implant success rate

Two out forty implants in two different patients were lost before the prosthetic phase (lack of osseointegration). The success rate was therefore 95%. The lost implants were immediately replaced and osseointegration was thus obtained. The two patients and their implants were still included in the study because the failure was not due to the prosthetic rehabilitation but most probably to surgery.

Marginal bone level variation

Mean bone level variation (expressed as percentage of variation compared to the baseline value) of the ten patients measured at the four sites at follow-ups are reported in figure 4. ANOVA for repeated measure showed no significant effects over time on bone level at sites 4.6 (p=0.116), 4.3 (p=0.083), 3.6 (p=0.097) and 3.3 (p=0.118). The percentages of bone variations of each implant were also compared at each follow-up (6, 12, 24, 36 months), to evaluate whether the implant sites had different values of bone variation. The results are summarized in Table 1. One way ANOVA did not show significant differences among the implants at six months (p=0.448), one year (p=0.766), two years (p=0.70) and three year (p=0.681) follow up.

Clinical periodontal indices

Clinical periodontal indices were recorded at six months, and after 12, 24, 36 months after prosthesis insertion. The values at six months represent the baseline score as implants were inserted in edentulous mandibles.

- Probing depth (PD): Mean probing depth values are shown in Figure 5. The average PD at three-year follow up was 1.6 mm. Repeated measurements at ANOVA showed no significant effect over time (p=0.06).
- O'Leary plaque index (PI): O'Leary plaque index values expressed as percentage (PI%) after six months, one, two, and three years after prosthesis insertion are also shown in Figure 5. The average PI at the last follow up was 14.4%. Repeated measurements at ANOVA showed no significant effect over time (p=0.69).
- Bleeding on probing (BOP): Percentage of bleeding

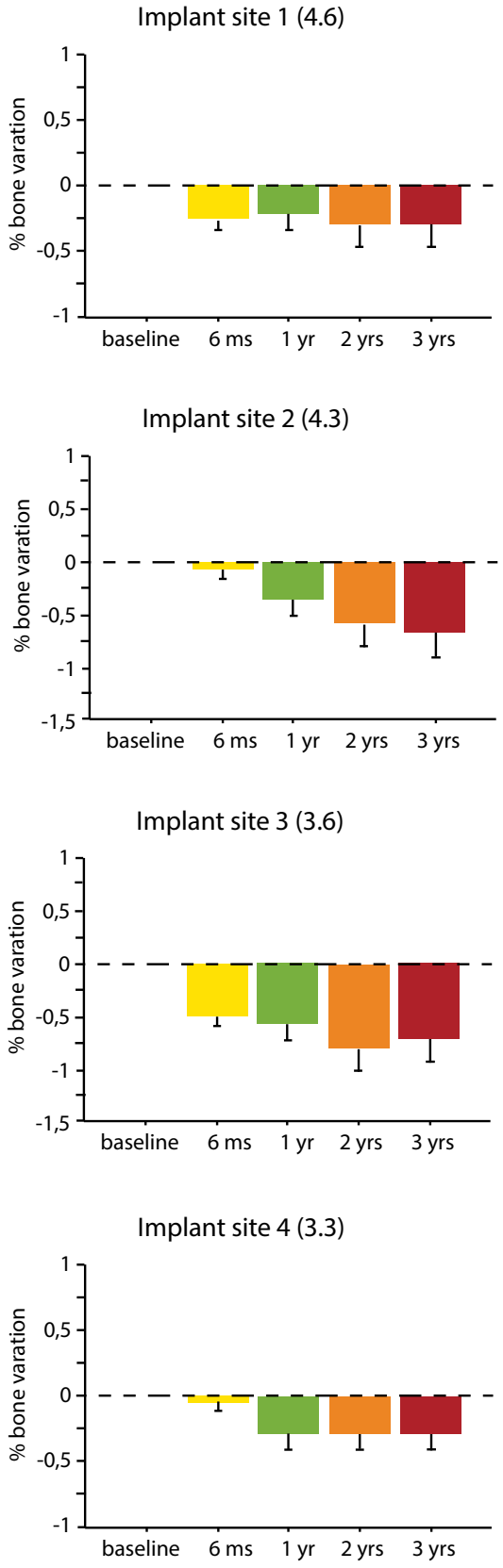

FIG. 4 Percentage of bone level variation on implant sites at follow-up visits (ms=months.)

Implant site (teeth)	Follow-ups			
	Six months	One year	Two years	Three years
1 (4.6)	-0.26±0.07	-0.21±0.11	-0.30±0.16	-0.28±0.18
2 (4.3)	-0.02±0.14	-0.36±0.2	-0.53±0.31	-0.70±0.42
3 (3.6)	-0.42±0.28	-0.49±0.2	-0.68±0.30	-0.55±0.23
4 (3.3)	-0.05±0.21	-0.33±0.19	-0.33±0.19	-0.33±0.18

Data are mean±SD.

TABLE 1 Marginal bone level variation (%) measured at the four implant sites during follow-up visits. Variation is meant as bone loss/gain as compared to the baseline value (which becomes zero). Negative values express bone loss; positive values express bone gain.

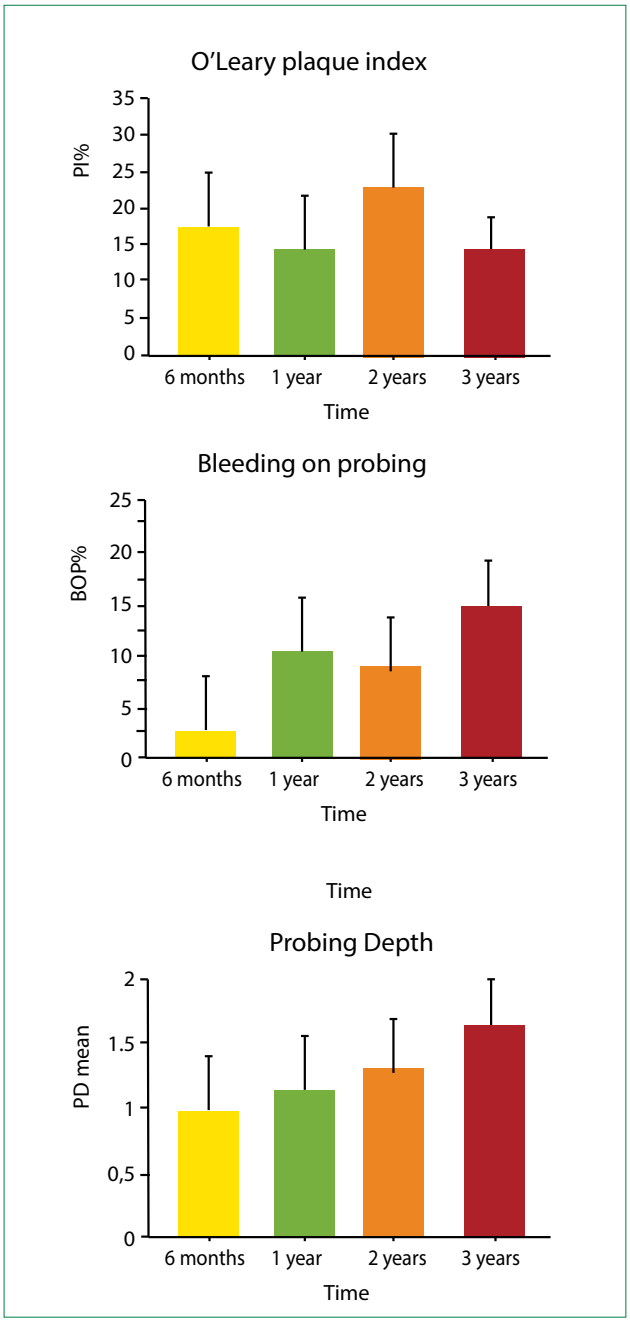

FIG. 5 Periodontal indices at follow-up visits.

on probing are also reported in Figure 5. The mean BOP value after 36 months was 16%. Again no significant effecta were found over time (p=0.125).

Patients perception

Data on patients perception are shown in Table 2. The highest scores were obtained for phonetics, aesthetics, and implant stability (mean score values >9). For level of satisfaction, comfort, and bite force, the mean score values were still high (>8). We observed a decreasing score over time for the evaluation of the prosthetic procedure (from 8 to 7) and hygiene (from 8 to 6).

Distal extension (cantilever)

Distal extension of prosthesis: the mean value of distal extension (cantilever) was of 8.8 mm.

Durability of the prosthesis and prosthetic complications

No fractures or chipping of the manufact were observed.

DISCUSSION

Although there are many techniques to overcome the problems of complex prosthetic implant rehabilitation of atrophic mandibles, so far, the literature has not shown which technique is the most efficient and has the most predictable results (4,5). Short implants appear to be a good alternative to traditional implants used after pre-implant surgery because they use a less invasive and complex procedure (6). Thus they could have a great potential in the rehabilitation of atrophic jaws (20). This study was performed to evaluate a surgical/prosthetic protocol for the rehabilitation of the edentulous mandible with four short implants and a metal-free fixed prosthesis. Forty implants were inserted in a cohort of ten patients and marginal bone level variation, clinical periodontal indices, patient perception and distal extension (cantilever) were evaluated during a three-year follow-up. The results showed an implant rate success of 95%. In addition, we recorded no significant bone level loss (expressed as percentage of variation compared to baseline values) during follow-up visits.

Questions	Scores			
	Six months	One year	Two years	Three years
Level of satisfaction	8.66±3.26	8.83±2.85	8.83±2.85	8.16±2.99
Evaluation of the prosthetic procedure	8.0±3.63	8.16±2.23	8.0±3.63	7.167±3.43
Comfort	8.5±2.34	8.66±2.06	8.66±2.06	8.66±2.06
Aesthetics	9.66±0.81	9.66±0.81	9.66±0.81	9.33±1.03
Bite force	8.5±2.34	8.66±2.06	8.5±2.34	8.5±2.34
Hygiene	8.16±2.23	7.5±1.87	6.66±3.07	6.66±3.07
Phonetics	10±0	10±0	10±0	9.66±0.81
Implant stability	9.5±0.83	9.5±0.83	9.5±0.83	9.5±0.83

TABLE 2 Data on patient perception assessed by a questionnaire where the subject marked a score between zero and ten. Data are the mean±standard deviation.

Properties	Unit
Flexural Strength	393 MPa
Flexural Strain at Max Stress	2.7 %
Flexural Modulus of Elasticity	18.8 GPa
Tensile Strength	169 MPa
Compression Strength (Parallel)	347 MPa
Compression Strength (Perpendicular)	339 MPa
Charpy Impact	26 KJ/m^2
Rockwell Hardness (R-Scale)	125 HRR
Barcol Hardness	63
Shore Hardness	92.5
Density / Specific Gravity	1.68 g/cm^3
Water Absorption	0.03%
Fracture Toughness	9.7 MPa m$^{1/2}$
Short Beam Shear	49 N/mm^2

TABLE 3 Physical and mechanical properties of Trinia TM (www.trinia.com).

Periodontal indices recorded also showed no significant changes over time and no prosthetic complications were noticed. Lastly, patient perception, recorded with the use of a questionnaire, showed a high level of satisfaction for the parameters phonetics, aesthetic, and implant stability (mean score values >9). For level of satisfaction, comfort, and bite force, the mean score values were still high (>8). We observed a decreasing score over time for the parameters of evaluation of the prosthetic procedure (from 8 to 7) and hygiene (from 8 to 6). In agreement with the literature, we considered a wide range of success criteria.

Success is measured, not only by the absence of symptoms and the stability of the marginal bone (21,22), but also for the functional integrity and aesthetics of the peri-implant mucosa, the absence of peri-implant inflammation, optimal prosthetic aesthetics, and the degree of patient satisfaction (23-25). The peri-implant bone level remained stable, with an average bone loss at three years of -0.47 mm ± 0.64 mm (in the four sites examined), which is much lower than the 2 mm of MBL regarded as normal during the first year of load (23).

The probing depth is an important and reliable diagnostic parameter when monitoring the health of peri-implant tissue (26). The average PD was 1.6 mm, indicating a good peri-implant health (27). A BOP value of 16% is low compared to that indicated in the literature (28-31). Lindhe et al., in the Consensus Report of the Sixth European Workshop on Periodontology in 2008, reported that peri-implant mucositis occurs in 80% of subjects (and 50% of sites) (26). Since poor oral hygiene is one of the possible risk factors for periimplant mucositis (26), we are carrying out a stricter program of follow-up on oral hygiene.

The keys of these results are, in our opinion, due to the two materials used: implants and prosthesis. The macro-design of implant fixtures ensures bone healing with direct osteogenesis and haversian bone formation (32-34). The sloping shoulder morphology at the crestal level (35) and the subcrestal placement (36) help the maintenance of the crestal bone. The pure conical connection between fixture and support would reduce bacterial contamination (37). The other characteristic of our study was the use of a prosthesis fabricated with a FRC structure (Trinia®). According to some authors, this type of material confers elasticity and resistance to the prosthesis. In fact, the use of a fiber-reinforced resinous material would reduce the transmission of masticatory-occlusal stress on the implant-bone junction (15-17), due to the fact that FRC has a lower flexural modulus than metal alloys (38), thus absorbing the energy of clenching forces. This phenomenon could positively act on maintaining peri-implant bone (18). It is important to note how by this study, it could be pointed out

that this biological advantage does not affect the clinical performance of the prosthesis. The physical characteristics of the material (Table 3) allowed to face the mean distal cantilever of 8.8 mm without any prosthetic complication. A further advantage may stem from the absence of metal and consequently its possible related side effects on the human body (39-43). Thus Trinia® is more biocompatible than metal alloys.

CONCLUSION

In conclusion, this study shows that the use of short plateau-implants and a FRC prosthesis appears to be a valid alternative to traditional implants, since this technique guarantees a less expensive, simple and minimally invasive surgery, with a reduction in morbidity and complications, and a faster post-operative recovery time.

Conflict of interest

Authors declare no conflict of interest.
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