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Clinical evaluation of an implant maintenance protocol for the prevention of peri-implant diseases in patients treated with immediately loaded full-arch rehabilitations

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Abstract: *Objective:* The aim of this prospective study was to assess the outcomes of an implant maintenance protocol for implants supporting a full-arch rehabilitation. *Materials and methods:* Sixty-one patients (28 women and 33 men) treated with immediately loaded full-arch rehabilitation, both mandibular and maxillary, supported by a combination of two tilted and two axial implants, were included in the study. Patients were scheduled for follow-up visits every 6 months for +2 years, then yearly up to 4 years. Each patient received professional oral hygiene treatment and detailed oral hygiene instructions. During each visit, modified plaque index, bleeding index and probing depth were assessed. The presence of peri-implant tissue inflammation was also evaluated. *Results:* Mean observation time, considering both mandible and maxilla, was 18.3 months ranging from 6 months to 5 years. Both plaque and bleeding indexes frequency decreased over time. Probing depth was stable (2.46 ± 0.5 mm at 4 years). Only three implants were lost due to peri-implantitis (1.4% at 12 months), whereas the incidence of peri-implant mucositis was less than 10% in each considered period. *Conclusions:* The adoption of a systematic hygienic protocol is effective in keeping low the incidence of peri-implant mucositis as well as in controlling plaque accumulation and clinical attachment loss.

Key words: immediate loading; implant maintenance; peri-implant mucositis; peri-implantitis; tilted implants

Introduction

Implant therapy is a consolidated procedure for full and partial rehabilitation of edentulous arches. Surgical and prosthetic protocols constantly improved over the years to reduce adverse side effects and to increase patients' satisfaction.

The use of a combination of tilted and straight implants supporting an immediately loaded full-arch prosthesis is an effective and safe procedure to rehabilitate full edentulous atrophic arches, avoiding grafting procedures and other invasive techniques (1–4).

Tilted implants were proved to be effective as support of fixed prosthesis (5–12) and did not present patterns of bone resorption different from those of straight ones (2, 12).

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According to the Consensus Statement of the 6th European Workshop of Periodontology, implant failures could be categorized as early and late, depending on onset time (13). Early failures usually occurred following surgical intraoperative infection or immediately after prosthetic load because of occlusal overload, whereas late ones were usually caused by peri-implant infection (14).

Infections of peri-implant tissues were classified as peri-implant mucositis, which is a reversible inflammation of peri-implant mucosa without bone resorption and peri-implantitis, which is an irreversible bone resorption process (15).

Zitzmann and Berglundh (16) showed that these pathologies are relatively frequent with a prevalence varying from 50% (17) to 90% (18) of implants (8–10 years) for mucositis and 28%–56% of patients and 12%–43% of implants for peri-implantitis. This incidence was recently confirmed in a retrospective study, which detected peri-implant mucositis in 39.4% of subjects and 27.3% of implants and peri-implantitis in 47.1% of subjects and 36.6% of implants (mean follow-up time: 8.4 years) (19).

Many clinical parameters are useful to evaluate the status of peri-implant mucosa and to diagnose tissue inflammation around implants early. Probing depth, bleeding on probing, plaque accumulation and radiographs are useful devices and techniques to evaluate symptoms of inflammation preventing the occurrence of peri-implantitis through adequate treatment protocols (20).

The aim of this prospective study was to evaluate clinical parameters such as probing depth, bleeding and plaque accumulation in patients treated with a full-arch prosthesis supported by a combination of straight and tilted implants according to an immediate loading protocol.

Study population and methodology

The Review Board of the IRCCS Istituto Ortopedico Galeazzi approved the study in 2009 (number 3026).

This study was conducted according to the principles embodied in the Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2000 (21). Sixty-one patients (28 women and 33 men; mean age: 54.2 years) with full-arch rehabilitation supported by a combination of two tilted and two straight implants, 47 in mandible and 14 in maxilla, were recruited from 2003 to 2009 at the Research Center in Oral Implantology at IRCCS Istituto Ortopedico Galeazzi in Milan considering the following inclusion criteria:

1 All patients must be systemically healthy (ASA-1, ASA-2) and able to use oral hygiene devices.

2 All patients must be treated with a full-arch rehabilitation supported by tilted and straight implants.

3 The compliance of patients must be high.

A total of 244 implants (188 in mandible and 56 in maxilla) were included in this prospective study.

Eighteen patients were smokers with a mean daily consumption of 8.6 cigarettes while 12 patients were heavy smokers (daily consumption ≥10 cigarettes). Every patient signed an informed consent form.

Clinical parameters

Each patient was called for a follow-up visit every 6 months for 2 years and then yearly. During each visit, two professional dental hygienists with more than 5 years of experience assessed the plaque index independently. The presence of acute peri-implant infection was also registered. Periapical radiographs were taken at baseline at 6 months and then yearly. A periodontal probe was used for clinical examination on four surfaces of each implant (mesial, distal, vestibular and palatal/lingual). Bleeding scores varied from 0 to 3: 0) no bleeding; 1) bleeding on probing without redness and swallowing; 2) bleeding on probing, redness and swallowing; 3) spontaneous bleeding. Plaque scores were 0: no plaque accumulation; 1) plaque accumulation revealed using a probe; 2) moderate accumulation of visible plaque/calculus; 3) high accumulation of visible plaque/calculus.

When peri-implant mucositis (bleeding index ≥2) and peri-implantitis (bleeding index ≥2, probing depth ≥4 mm) were registered, adequate treatment protocols were adopted. In case of peri-implant mucositis, patients were invited to use chlorhexidine 0.2% mouthwash twice a day for 10 days and then they were re-evaluated. In case of peri-implantitis, patients underwent antimicrobial treatment with local delivery of chlorhexidine 1% followed by surgical treatment to remove inflammatory tissue and decontaminate implant surface.

Probing depth was measured using a plastic probe (Colorvue® Hu-Friedy®, Rotterdam, Belgium with University of North Carolina markings) with a probing force of 0.25 N (22, 23).

Professional oral hygiene protocol

Every patient attended supportive treatment at implant level performed by a professional dental hygienist. For reasons of the peculiar characteristics of the prosthesis, the combined use of powered and manual devices was necessary in the debridement of implant neck and prosthetic surfaces. Manual teflon curettes were used to remove calculus from implant necks, while powered brushes were used for plaque removal on prosthesis surfaces. The use of interdental floss was necessary to complete the removal of plaque and calculus on mesial and distal surface of tilted implants necks.

Oral hygiene instructions and devices

Patients were instructed to use devices as indicated in Table 1. Before surgery, a full-mouth supragingival and subgingival scaling was performed and the importance of the maintenance protocol was explained to obtain a full compliance by the patients. Patients who did not agree to follow the protocol were excluded. Immediately after surgery, patients were instructed to use only chlorhexidine mouthwashes and

Table 1. **Oral hygiene devices**

Time	Devices
Before surgery	Chlorhexidine 0.2%; a 1-min mouthwash twice a day for 3 days
After surgery	Chlorhexidine 0.2%; a 1-min mouthwash three times a day for 3 days
Provisional restoration	Chlorhexidine 0.2%; a 1-min mouthwash twice a day for 7 days Soft bristles toothbrush only on prosthetic surfaces or teeth*
2 weeks from provisional restoration	Soft or medium bristles toothbrush only on prosthetic surfaces or teeth* Small diameter plastic-coated soft bristles interdental brush
1 month from provisional restoration	Soft or medium bristles toothbrush only on prosthetic surfaces or teeth* Medium diameter plastic-coated soft bristles interdental brush Spongy interdental floss
3 months from provisional restoration	Soft or medium bristles toothbrush only on prosthetic surfaces or teeth* Medium-wide diameter plastic-coated soft bristles interdental brush Spongy interdental floss
Definitive restoration	Soft or medium bristles toothbrush only on prosthetic surfaces or teeth* Small-medium diameter plastic-coated soft bristles interdental brush Spongy interdental floss
After definitive restoration	Soft or medium bristles toothbrush only on prosthetic surfaces or teeth* Small-medium diameter plastic-coated soft bristles interdental brush Spongy interdental floss

*Powered toothbrushes could also be used only with soft bristles.

spray. After the placement of provisional restoration, the use of manual or powered toothbrushes was limited to prosthetic surfaces. Two weeks after the positioning of provisional restoration, the use of soft bristled, plastic-coated interdental brushes or spongy interdental floss was limited to implant neck surfaces and the apical surface of the prosthesis. Patients were instructed on the use of spongy interdental floss and interdental brushes of different dimensions respecting a healing period for soft tissues. Two weeks after surgery, an interdental brush of smaller size was adopted, to fit with the provisional restoration. Later on, due to the formation of a wider gap between prosthesis and mucosa after soft tissue healing during the first month after surgery, interdental brushes of greater size were adopted. Definitive prosthesis was placed 3–4 months after surgery following complete healing of soft and hard tissues. The size of interdental brush had to be reduced to achieve a better fit with the new prosthesis. The efficacy of using oral hygiene devices was controlled in every follow-up visit.

Statistical analysis

Pearson's chi-square test was used to compare plaque and bleeding indexes between upright and tilted implants at each timeframe. Paired *t*-test was used to evaluate probing depth of tilted and upright implants. Unpaired *t*-test was used to compare probing depth at different timeframe values (significance $P < 0.05$). Confidence intervals ($\alpha = 0.05$) were calculated for probing depth measurements at each follow-up.

Results

The number of implants at different follow-up visits is shown in Table 2. Mean observation time was 18.3 months considering mandible and maxilla (18.6 months for mandibular restorations and 17.3 months for maxillary restorations) ranging from 6 months to 5 years. All implants were placed following the surgical and prosthetic protocol described above (Figs 1–5).

Data regarding the computerized examination of peri-implant bone level changes from periapical radiographs were reported previously (1, 2).

The prevalences of peri-implant mucositis and peri-implantitis are shown in Table 3; with the exception of the last follow-up

Table 2. **Number of implants evaluated at each follow-up visit**

	Mandible	Maxilla	Total
6 months	188	56	244
12 months	176	40	216
18 months	132	36	168
24 months	104	32	136
36 months	80	32	112
48 months	32	0	32
60 months	16	0	16

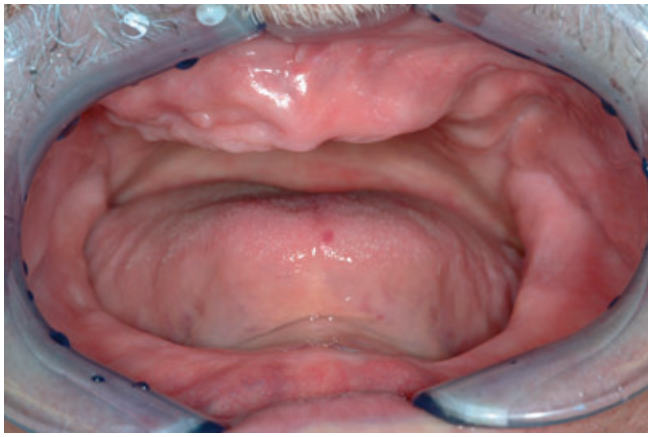

Fig. 1. Preoperative vision of the severely atrophic mandible.

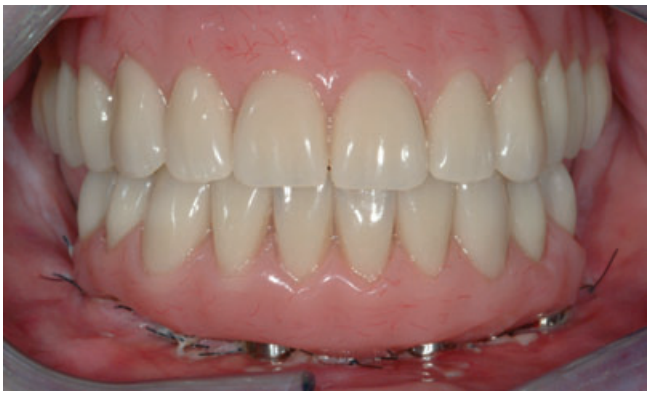

Fig. 2. Postoperative vision with the fixed provisional prosthesis in the mandible and a removable full prosthesis in the upper jaw (48 h after surgery).

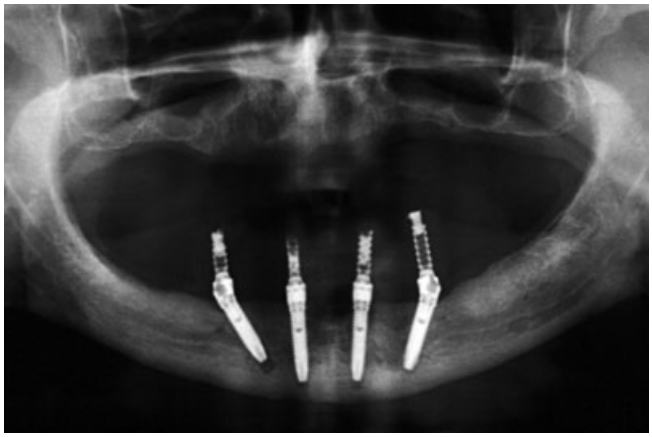

Fig. 3. Orthopantomography after placement of provisional restoration.

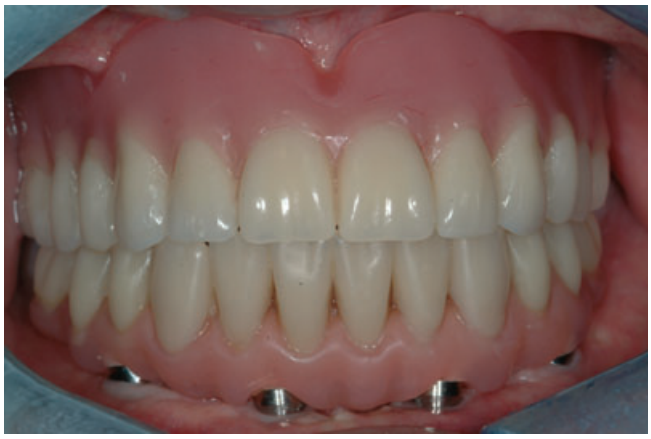

Fig. 4. Definitive restoration 2 years after surgery.

period, it was always less than 10%. Only three axial implants in two patients were considered unsuccessful due to peri-implantitis. One was in a 50-year-old non-smoking female patient after 3 years of loading and two in a 60-year-old non-smoking male patient after 18 months.

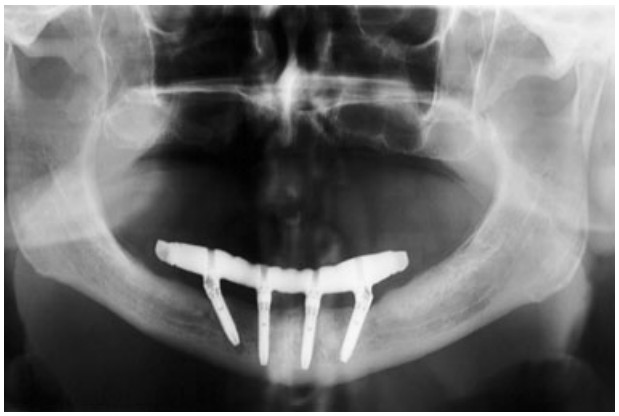

Fig. 5. Orthopantomography 2 years after surgery.

Table 3. **Incidence of peri-implant infections**

	Functioning implants	Mucositis (%) (at least 1 site affected)	Peri-implantitis (%) (at least 1 site affected)
0–6 months	244	12 (4.9)	0 (0)
6–12 months	216	8 (3.7)	3 (1.4)
12–18 months	165	13 (7.7)	0 (0)
18–24 months	133	4 (2.9)	0 (0)
24–36 months	109	7 (6.3)	0 (0)
36–48 months	29	2 (6.9)	0 (0

Table 4 shows frequencies of plaque and bleeding indexes at different timeframes.

Higher plaque levels were reported in the first follow-up visit 6 months after surgery (9.7% with code 2 and 29.2% with code 3). During the subsequent follow-up visit, there was an increase in the proportion of both lower levels (codes 0 and 1) of plaque accumulation. Code 0 (no plaque accumulation) frequency was 58.3% at 6 months, 74.3% at 12 months then growing up to 85.6% at 36 months and 88.5% at 48 months (Fig. 6). There was a statistically significant ($P < 0.05$) difference between 12 and 6 months ($P = 0.0015$), between 24 and 18 months ($P = 0.0163$), and between 48 and 36 months ($P < 0.0001$).

No bleeding was reported in 88.2% of sites at 6 months, 94.2% at 12 months, 78.6% at 18 months, 80.1% at 24 months, 90% at 36 months and 100% of sites at 48 months. A statistically significant reduction ($P < 0.05$) of bleeding index frequencies was found between 6 and 12 months ($P = 0.0011$), and between 18 and 24 months ($P = 0.0013$) (Fig. 7).

Statistically significant differences ($P < 0.05$) between tilted and upright implants were found only in plaque accumulation at 6, 12, 18 and 48 months.

The evaluation of probing depth revealed no increase over time even at the last follow-up visit at 4 years (2.46 ± 0.5 mm; 95% CI: 2.37-2.55) (Table 5) and no differences were observed between upright and tilted implants.

Table 4. **Plaque and bleeding indexes frequency (% of sites)**

	6 months	12 months	18 months	24 months	36 months	48 months
Plaque index						
0	569 (58.3)	642 (74.3)	483 (71.9)	377 (69.3)	384 (85.6)	113 (88.5)
1	27 (2.8)	59 (6.8)	84 (12.5)	136 (25)	31 (6.9)	9 (7.3)
2	95 (9.7)	63 (7.3)	90 (13.4)	22 (4)	11 (2.5)	1 (1)
3	285 (29.2)	100 (11.6)	15 (2.2)	9 (1.7)	22 (5)	4 (3.2)
Bleeding index						
0	861 (88.2)	814 (94.2)	528 (78.6)	436 (80.1)	403 (90)	(128) 100
1	13 (1.4)	14 (1.6)	111 (16.5)	108 (19.9)	31 (6.9)	0
2	102 (10.4)	31 (3.6)	33 (4.9)	0 (0)	11 (2.5)	0
3	0 (0)	5 (0.6)	0 (0)	0 (0)	3 (0.6)	0

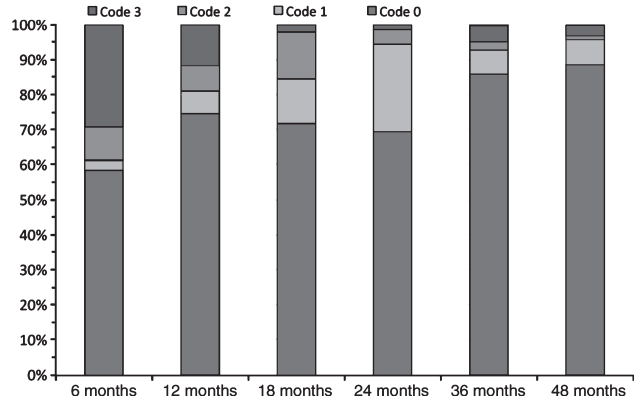

Fig. 6. Plaque index frequency.

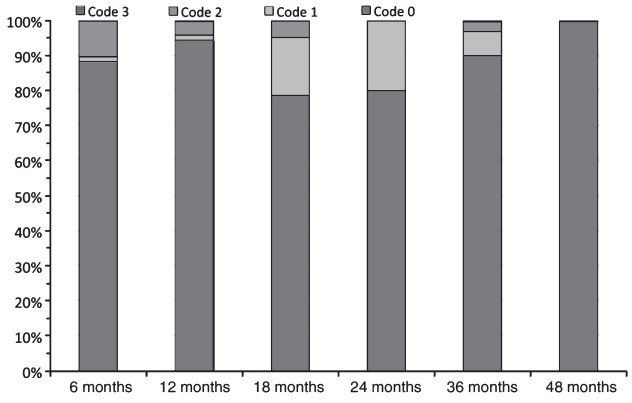

Fig. 7. Bleeding index frequency.

Table 5. **Probing depth expressed in mm (mean ± SD)**

	6 months	12 months	18 months	24 months	36 months	48 months
Probing depth (mm)	2.20 ± 0.87 (95% CI: 2.02–2.38)	2.31 ± 0.25 (95% CI: 2.21–2.41)	2.54 ± 0.42 (95% CI: 2.40–2.68)	2.44 ± 0.31 (95% CI: 2.32–2.55)	2.66 ± 0.49 (95% CI: 2.53–2.78)	2.46 ± 0.5 (95% CI: 2.37–2.55)

CI, confidence interval.

No statistically significant difference was found between smokers and non-smokers for plaque and bleeding index and in probing depth measures.

Discussion

There is scarce literature dealing with implant maintenance protocols or treatments to reduce the incidence of peri-implant inflammatory diseases (24).

Immediate loading protocol implies the presence of a prosthesis during peri-implant soft tissues healing. As described in a recent animal study (25), at first, the space between implant neck and soft tissue is filled by coagulum, then it is infiltrated and degraded by neutrophils during the first 2 weeks after surgery. At this stage, no complete formation of epithelial or connective tissue seal could be found. The formation of a mature barrier epithelium occurs after 6–8 weeks. These processes and histological characteristics of peri-implant soft tissues (26) cause a higher susceptibility to microbial insult than periodontal tissues. Other authors had also underlined that the reduced vascularization and the absence of crevicular fluid could be important factors in determining this susceptibility (27). It was also described that bacteria associated with periodontitis and peri-implantitis could colonize peri-implant pockets within a week and their number appeared to reach a stable level after 3 months (28).

An ideal implant supportive therapy should consider particular aspects of the implant treatment as loading time, peculiar characteristics of peri-implant disease and peri-implant mucosa and prosthetic shape and materials.

Considering prevention and treatment of periodontal disease, there is evidence that reduced recall periods and professional scaling and polishing were useful in periodontal maintenance (29). Also, the use of domiciliary oral hygiene

devices as toothbrushes, interdental brushes and flosses was demonstrated to be useful in reducing gingival inflammation (30–32).

Evaluating implant therapy, a similar consideration was recently made by Serino and Ström who found a clear correlation between some local and clinical parameters and peri-implantitis in partially edentulous patients (33). In this study, oral hygiene access and plaque control, measured using a plaque and bleeding index, were considered important factors in the development of peri-implant inflammatory disease. The authors also underlined the importance of proper oral hygiene instructions to patients rehabilitated with dental implants.

The aim of this study was to evaluate an implant maintenance protocol applied to an immediate loading full arch restoration. First, the steady decrease in plaque levels after the placement of definitive restoration suggests the improved ability of patients in plaque removal over time and the correct indication of oral hygiene devices and manoeuvres by the dental hygienist. A higher plaque index was observed on lingual surfaces and it could be due to the particular conformation of the prosthesis and to objective difficulties in reaching those surfaces using only interdental brushes. Considering all surfaces, plaque index was not different between tilted and axial implants. Bleeding index, which is a typical marker of inflammation, was low at every follow-up visit and it could be hypothesized that this was due to an optimal plaque control. The stability of probing depth in time confirmed the healthy status of the mucosa, being associated with the control of marginal inflammation.

Considering the present data and the efficacy of the proposed protocol relative to full-arch rehabilitations, such indications could be important also in single-tooth or partial restoration because of the similarities in soft tissue healing pattern.

Only three cases of peri-implantitis were observed in two patients and required surgical treatment to debride contaminated implant surface without implant removal. Peri-implant mucositis was also observed and successfully treated with complete symptom remission in 10 days. No association with smoking status was found, although smoking could have masked symptoms of peri-implant mucositis because of the effect of reducing vascularization of soft tissues (34, 35).

Data extrapolated from this study confirm that the described protocol was useful to prevent peri-implant inflammatory disease and to reduce plaque accumulation and bleeding on probing.

The absence of a control and the relatively low sample size at later follow-up visits were the main limitations of this study. Further randomized controlled trials are needed to validate this protocol.

Conflict of interest

All the authors declare no financial support.

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