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Oral rehabilitation with implant-supported fixed partial dentures in periodontitis-susceptible subjects

A 5-year prospective study

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Abstract

Background: Comparatively few studies with at least 5 years of follow-up are available that describe the use of implants in prosthetic rehabilitation of partially edentulous patients. Randomized, controlled clinical studies that evaluated the effect of different surface designs of screw-shaped implants on the outcome of treatment are also sparse.

Objective: To determine, in a prospective randomized, controlled clinical trial, the outcome of restorative therapy in periodontitis-susceptible patients who, following basic periodontal therapy, had been restored with implants with either a machined- or a rough-surface topography.

Material and Methods: Fifty-one subjects (mean age, 59.5 years), 20 males and 31 females who, following treatment of moderate-to-advanced chronic periodontitis, required implant therapy for prosthetic rehabilitation were recruited. Seventeen of the patients were current smokers. Following the active treatment, all subjects were included in an individually designed maintenance program. A total of 56 fixed partial dentures (FPDs) and a total of 149 screw-shaped, and self-tapping implants (Astra Tech® implants) – 83 in the maxilla and 66 in the mandible – were installed in a two-stage procedure. Each patient received a minimum of two implants and by randomization every second implant that was installed had been designed with a machined surface and the remaining with a roughened Tioblast® surface. Abutment connection was performed 3–6 months after implant installation. Clinical and radiographical examinations were performed following FPD connection and once a year during a 5-year follow-up period. The analysis of peri-implant bone-level alterations was performed on subject, FPD and implant levels.

Results: Four patients and four FPDs were lost to the 5 years of monitoring. One implant (machined surface) did not properly integrate (early failure), and was removed at the time of abutment connection. Three implants were lost during function and a further eight implants could not be accounted for at the 5-year follow-up examination. The overall failure rate at 5 years was 5.9% (subject level), 5.3% (FPD level) and 2.7% (implant level). Radiographic signs of loss of osseointegration were not found at any of the implants during the 5-year observation period. During the first year in function there was on average 0.33 (SD, 0.61) mm loss of peri-implant marginal bone on the subject and FPD levels and 0.31 (0.81) mm on the implant level. During the subsequent 4 years, the peri-implant bone-level alterations were small. The calculated annual change in peri-implant bone level was -0.02 (0.15) on subject and FPD levels and -0.03 (0.20) on the implant level. Thus, the mean total bone-level change over the 5-year interval amounted to 0.41 mm on all three levels of analysis. In the interval between baseline and 5 years, the machined and the Tioblast® implants lost on average 0.33 and 0.48 mm, respectively ($p > 0.05$).

Conclusion: The present randomized, controlled clinical trial that included partially edentulous periodontitis-susceptible subjects demonstrated that bone loss (i) during the first year of function as well as annually thereafter was small and (ii) did not vary between implants with machined- or rough-surface designs.

Key words: bone loss; clinical; dental implants; radiology; smoking; surfaces

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A large number of longitudinal studies have been presented that describe the use of endosseous implants for prosthetic rehabilitation of partially edentulous patients. The outcome of implant therapy in this group of patients was evaluated in both prospective and retrospective studies that were recently reviewed by Esposito et al. (1998), van Steenberghe et al. (1999) and Berglundh et al. (2002). In the systematic review presented by Berglundh et al. (2002) on implants placed in partially dentate patients, only 14 clinical trials were identified that had at least 5 years of follow-up. The overall outcome of treatment in these studies was considered to be good; only about 2.5% of all implants were lost before loading and about 3% were lost during function for a variety reasons such as peri-implantitis, progressive bone loss and implant fracture.

Only few clinical studies have been presented that describe the outcome of restorative therapy with fixed partial dentures (FPDs) supported by implants in partially edentulous patients in whom different implant systems and/or different surface modifications of the implants were analyzed.

The original implant of the Astra-Tech® System (Astra Tech, Mölndal, Sweden) was designed with a machined (turned) surface (e.g. Arvidson et al. 1992, Gotfredsen et al. 1993) that was subsequently modified to a rougher surface texture. This was accomplished by blasting the endosseous part of the implant with particles made of titanium. Animal studies disclosed that implants with this modified surface exhibited more bone-to-implant contact and higher removal torque values as compared with implants with the original surface (Ericsson et al. 1994, Gotfredsen et al. 1995).

Karlsson et al. (1998) and Gotfredsen & Karlsson (2001) in a prospective randomized, controlled multicenter study restored 50 partially dentate patients with 52 FPDs placed on 133 Astra Tech® implants. Each FPD was supported by at least one machined- and one rough-surfaced implant. The authors concluded that the implants used had a high survival rate and exhibited only small amounts of marginal bone loss during the 5 years of observation. Further, no difference in treatment outcome could be found between implants with different surface texture. van Steenberghe et al. (2000) compared the Astra Tech® Tioblast implant (rough surface) with the Mark II implant (machined surface) of the Brånemark® System (Nobel Biocare, Gothenburg, Sweden) for the rehabilitation of 18 partially edentulous patients. The clinical trial that included 19 jaws was designed as a split-mouth study and was randomized for the jaw in which the different implant systems were applied. No significant difference between the two systems could be observed during the 2 years of observation regarding probing pocket depth (PPD) or change in the marginal bone level. The marginal bone-level change that occurred at Astra Tech® implants – with a Tioblast® surface – and at Mark II implants (Brånemark System) – with a machined surface – was also evaluated by Engquist et al. (2002). Sixty-six patients with edentulous jaws were randomly assigned to treatment with Astra Tech® ($n = 184$) or Brånemark implants ($n = 187$). The marginal bone level was determined radiographically immediately following fixture installation, at abutment connection, at delivery of the prosthesis (baseline) and at 1- and 3-year follow-up examinations. The authors concluded that the survival rate was high and that the mean bone-level change (loss) for the two types of implants was small and did not differ between systems. Thus, between baseline and 3 years, the marginal bone loss in the maxilla and in the mandible amounted to between 0.1 and 0.2 mm.

Only few studies have been published on the prognosis of implant therapy in patients with varying degrees of periodontal tissue breakdown (e.g. Nevins & Langer 1995, Ellegaard et al. 1997, Brocard et al. 2000). The findings reported were interpreted to document that a high degree of success can be obtained with implant therapy also in properly treated and well-maintained periodontitis-susceptible subjects. In a recent publication, Hardt et al. (2002) described the outcome of implant therapy in relation to the amount of periodontal bone loss that had occurred at remaining teeth prior to fixture installation. Ninety-seven partially edentulous patients with a total of 346 Brånemark implants in the posterior maxilla were included in a retrospective study. The degree of radiographic marginal bone loss at the remaining teeth was first determined, and age-related bone loss scores (ArB score) calculated. The two end quartiles of the subject sample, based on ArB scores, defined subjects as being non-periodontitis or periodontitis susceptible. Implant loss and radiographic bone-level change that occurred during a 5-year period were analyzed. It was observed that longitudinal bone loss around implants ''is correlated with previous experience of loss of periodontal bone support'', i.e. that a periodontitis-susceptible individual may exhibit a higher degree of implant failure than a non-periodontitis patient.

The aim of the present prospective randomized, controlled clinical trial was to study the outcome of restorative therapy in periodontitis-susceptible patients who following basic periodontal therapy had been restored with implants with either a machined- or a rough-surface topography.

Material and Methods

The subject sample was recruited from a pool of otherwise healthy partially dentate patients who during a 3-year period had been referred to the Department of Periodontology, Göteborg University, for treatment of moderate-to-advanced chronic periodontitis.

A careful dental/periodontal examination was performed including assessment of plaque, gingivitis, PPD and radiographic bone loss at all remaining teeth (Nyman & Lindhe 2003). All patients received comprehensive periodontal therapy, which included careful oral hygiene instructions combined with non-surgical and surgical pocket therapy, and were thereafter included in an individually designed supportive periodontal therapy (SPT) program (Lang et al. 2003).

All subjects who following the completion of active periodontal treatment were in need of oral prosthetic rehabilitation that would require implant placement were invited to take part in the study. The following conditions were reasons for excluding a subject from participating in the study:

Local: inadequate self-performed plaque control, insufficient bone volume at the recipient sites, i.e. need for ridge augmentation or sinus lift procedures.

General: uncontrolled diabetes, hemophilia, metabolic bone disorder, history of renal failure, radiation treatment to the head or neck region, current chemotherapy and pregnancy.

The study protocol was reviewed and approved by the ethics committee at the Sahlgrenska Academy, Göteborg Uni-

Table 1. Characteristics of the patient sample ($n = 51$)

gender (male/female)	20/31
smokers/non-smokers	17/34
age (years)	59.5 (9.7)
no. of remaining teeth	18.5 (3.9)
periodontal bone level	43.9% (7.4)

Mean values (SD).

Table 2. Distribution of placed implants ($n = 149$) according to position in the jaws

	Implant position in the jaw							
	1	2	3	4	5	6	7	total
maxilla	3	8	10	26	21	12	3	83
mandible	0	0	2	15	19	20	10	66

Table 3. Distribution of placed implants according to length and jaw

Implant length (mm)	Maxilla	Mandible	Total (%)
8	2	11	13 (8%)
9	6	8	14 (9%)
11	21	20	41 (28%)
13	21	12	33 (22%)
15	20	10	30 (20%)
17	13	4	17 (12%)
19	0	1	1 (1%)
Total	83	66	149 (100%)

Table 4. Distribution of FPDs ($n = 56$) according to number of supporting implants and units

No. of implants	FPD extension (no. of units)					
	2	3	4	5	6	7
2	2	16	4			
3		15	9	6	2	
4					1	1

FPD, fixed partial denture.

versity. Written informed consent was obtained from 51 subjects who met the inclusion criteria.

Of the participants (Table 1), 20 were males and 31 females. The mean age of the patients at the time of recruitment was 59.5 years (SD, 9.7; range, 36–80 years). Seventeen of the patients were current smokers. The mean number of remaining teeth was 18.5 (3.9).

Periodontal bone level (*PBL*): Prior to implant installation, panoramic radiographs were obtained from each patient. The height of the periodontal bone (PBL) present at all remaining teeth was assessed according to the method described by Björn (1969) and by an examiner not involved in the clinical trial. The ruler used for the bone-level assessments was divided into 10 portions; portion 1 indicated that the marginal bone was located in the apical 10% of the tooth while portion 10 indicated the tip of the crown. The mean PBL value (%) was calculated for each patient. The mean overall PBL score for the sample was 43.9% (7.4).

Implant treatment

The surgical treatment was performed under local anesthesia by two periodontists (J. W. and J. L.), and according to the manufacturer's manual. A crestal incision was used and full thickness flaps were elevated to expose the bone. After implant installation, the flaps were closed with interrupted sutures. The patient received 2 g of penicillin (Kåvepenin®; Astra Läkemedel AB, Södertälje, Sweden) 1 h prior to surgery and 1 g twice daily for 7 days. The sutures were removed after 7–10 days.

The bone quantity and quality characteristics were assessed in conjunction with implant installation according to the criteria proposed by Lekholm & Zarb (1985). Most recipient sites exhibited pronounced bone resorption (scores B and C) and had a bone quality equivalent to score 2 or 3. As a rule, the insertion depth of the implants was even to the proximal bone level, which frequently resulted in some bone dehiscence at the facial and/or oral aspects of the implants, because of reduced buccofacial bone dimension. No attempts for bone augmentation in dehiscence sites were made.

One hundred and forty-nine screw-shaped and self-tapping Astra implants (Astra Tech® Dental Implant System, Mölndal, Sweden) – 83 in the maxilla and 66 in the mandible – were installed and cover screws placed (Table 2). A total of 47 implants were placed in the maxillary premolar region and 15 in the molar region. The corresponding numbers in the mandible were 34 (premolar region) and 30 (molar region). All implants had a diameter of 3.5 mm while the length varied between 8 and 19 mm (Table 3). Seventy percent ($n = 104$) of the implants were between 11 and 15 mm long, 17% were $\leqslant 9$ mm and 13% were $\geqslant 17$ mm. Each patient received a minimum of two implants, and by randomization every second implant that was installed had been designed with a *machined* surface and the remaining with a roughened Tioblast® surface. The randomization code for the single patient was made available for the operator first after he had completed preparation of the recipient sites.

Abutment connection was performed in a second-stage surgical procedure 3 months (mandible) or 6 months (maxilla) after implant installation. Standard, Uni-abutments® (Astra Tech® Dental Implant System) of varying length were used.

The prosthetic treatment was performed by three prosthodontists and followed the manual provided by the manufacturer. The final, screw-retained FPD was completed and delivered about 4 weeks after abutment connection. All FPDs were designed with the occlusal surface in porcelain. Careful oral hygiene instructions with emphasis on how to clean the implants were given to all patients in conjunction with the installation of the FPDs.

Table 4 presents the number of FPDs that were inserted, the number of crown units of the FPDs as well as the number of supporting implants. Twenty-two FPDs were supported by two implants each, 32 FPDs were placed on three implants, and two FPDs on four implants. Twenty-eight (50%) out of the 56 FPDs were designed with a distal cantilever unit.

Maintenance treatment

All patients were throughout the period of monitoring, enrolled in an individually designed SPT program (Lang & Lindhe 2003) that called for examination of the teeth, the implants and the surrounding soft tissues once every 4–6 months. Sites that showed bleeding following probing (BoP positive) were carefully instrumented and polished by use of rubber cups and low abrasive polishing pastes. In addition, the loading on the implant-supported prosthesis was carefully evaluated at annual follow-up examinations and adjustments were made when indicated.

Clinical examinations

At the baseline examination (i.e. delivery of the FPDs) and at the annual re-examinations the following clinical

parameters were recorded: pain from implant region, presence of plaque (mesial, distal, buccal and lingual surfaces), probing depth and BoP (probing pressure, 0.25 N) at four sites of each implant (mesial, distal, buccal and lingual units) and width of keratinized mucosa (buccal units).

Radiographic examinations

Postoperative radiographic examinations were performed at FPD installation and at the annual follow-up examinations. Standardized radiographs, with the film (Kodak Ektaspeed Plus, Eastman Kodak Co., Rochester, NY, USA) kept parallel and the X-ray beam (Heliodent MD, 60 kV, 7 mA, Siemens AG, Bensheim, Germany) perpendicular to the implant, were taken using an individually – for each implant or pairs of implants – fabricated film holder (Have-Super-Bite, Hawe-Neos Dental, Genilino, Switzerland). The film holder was attached to the occlusal surface of the suprastructure using an impression material (Optosil®P, Bayer Dental, Leverbusen, Germany).

Two experienced radiologists (A. E. and K. G.) working together performed the evaluation of the radiographs. For each implant, the radiograph was evaluated regarding (i) marginal bone height and changes over time, as well as (ii) the bone–implant contact zone to detect loss of osseointegration. The marginal bone height and bone-level change over time was assessed at the mesial and distal surface of each implant by measuring the distance between a reference point of the implant (Fig. 1) and the *bone-to-implant contact* level with use of a magnifying lens ($\times$ 7). Further, signs of problems correlated to the mechanical components of the implant system were noted.

The error of the radiographic assessment was determined through double recordings at one randomly selected implant from each patient representing the 5-year follow-up examination. The mean difference between the two readings was 0.04 mm (SD, 0.33).

Data analysis

The data analysis was performed according to intent to treat and hence all available data were included in the analyses representing the various time intervals. For description of the data, mean values, SDs and cumulative frequencies were calculated. The efficacy variables were implant survival and peri-implant bone-level change. Clinical data were considered as descriptors. The peri-implant bone-level data were analyzed on a subject level, FPD level as well as on implant level.

All statistical analyses were performed with the subject as the statistical unit. Intra-individual comparison was performed with regard to type of implants (machined versus Tioblast®) by the use of *t*-test for paired samples. All other statistical analyses were carried out by the use of two-sample *t*-test. Multiple regression models were formulated in order to analyze interactions between various confounding variables on bone-level alterations. A *p*-value of <0.05 was considered as statistically significant.

Results

Table 5 presents the number of patients, FPDs and implants at the time of implant installation, at FPD insertion (baseline) and at the five annual follow-up examinations. Four patients and four FPDs were lost to the 5 years follow-up examination. One implant (machined surface) did not properly integrate (early failure) and was removed at the second-stage surgery. The loss of the implant, however, did not result in an altered extension of the planned FPD.

Three implants were lost during function (one was explanted after 2 years and two after 4 years in function because of implant fracture, Fig. 2) and eight implants could not be accounted for at the 5-year follow-up examination because three patients had died (six implants/three FPDs) and one had discontinued maintenance therapy and failed to appear for the scheduled annual re-examination (two implants/one FPD). In all three cases that experienced implant fracture, the FPD was supported by two implants only, and consequently the FPD also was lost. Thus, the overall

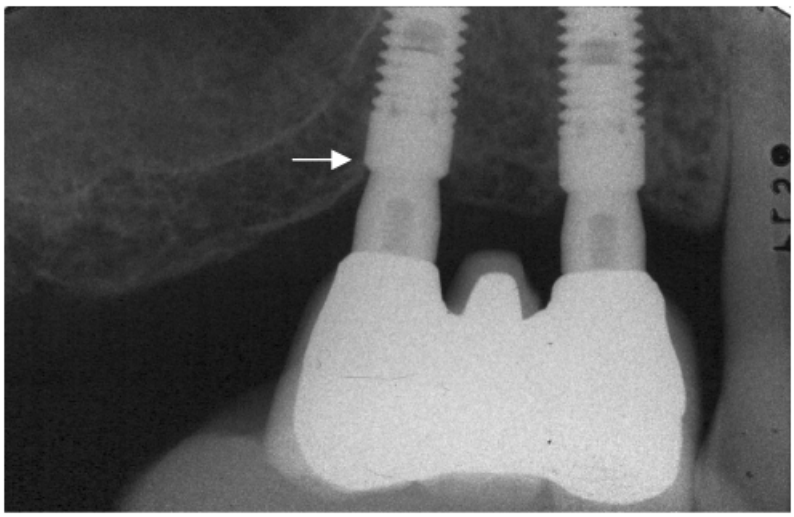

Fig. 1. Radiograph illustrating the reference point on the implant used in the assessment of the bone-to-implant contact level.

Table 5. Number of patients, FPDs and implants at the various examination intervals

	No. of patients	No. of FPDs	No. of implants	Reason for loss of implants to follow-up		
				explanted	drop-out	deceased patient
Implant placement	51	—	149			
FPD connection	51	56	148	1		
Follow-up (years)						
1	51	56	148			
2	50	55	145	1	2	
3	49	54	144			1
4	47	52	139			5
5	47	52	137	2		

FPD, fixed partial denture.

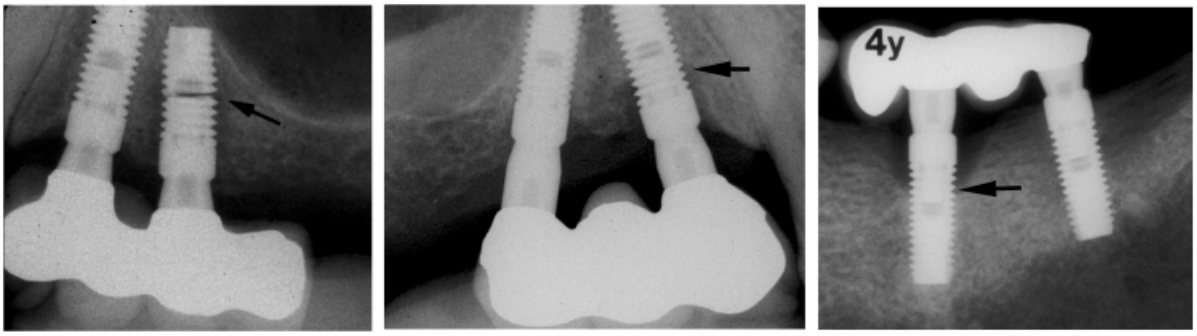

Fig. 2. Radiographs of the three cases that experienced implant fracture. The arrow indicates the fractured implant. (a) Fracture of the most distal implant after 2 years in function. (b) Fracture of the mesial implant after 4 years in function in a patient who was diagnosed as a bruxer. (c) Fracture of the implant after 4 years in function. The crown screw in the distal implant had been loose for several months.

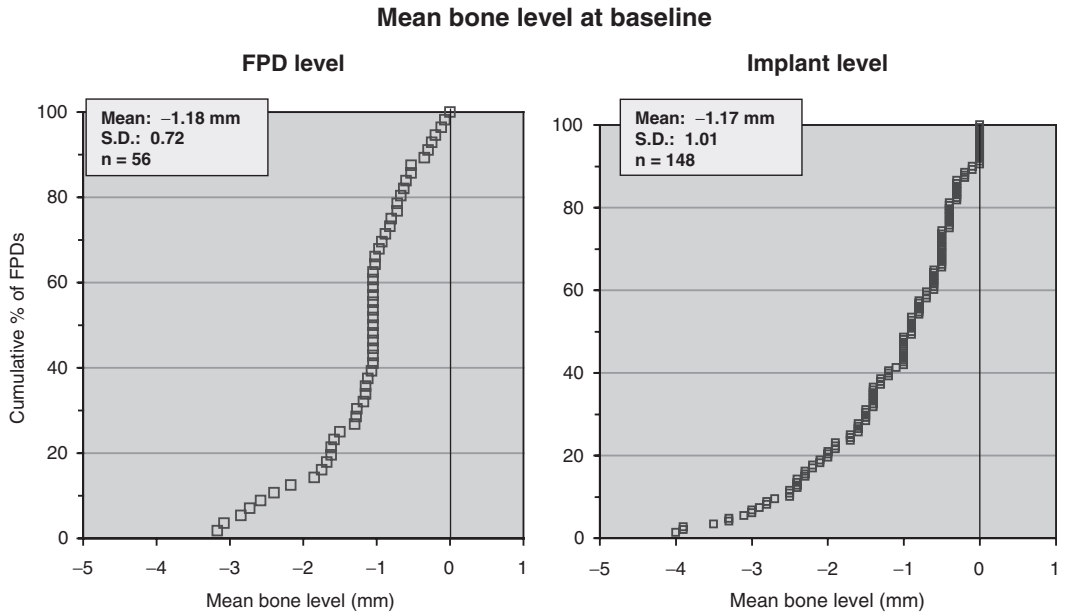

Fig. 3. Cumulative distribution of fixed partial dentures (FPDs) and implants according to mean peri-implant bone level at the time of insertion of the FPDs (baseline).

failure rate at 5 years was 5.9% (subject level), 5.3% (FPD level) and 2.7% (implant level). If the subject who was lost to follow-up after the first year is included, the failure rates were 7.8%, 7.1% and 4.0% for subject, FPD and implant levels, respectively.

Prosthetic complications

Besides the loss of three FPDs due to implant fracture, a total of six incidences of reparable prosthetic complications occurred during the 5-year observation period. In three patients, screws that attached the FPD to the implant lost retention and in three subjects minor porcelain fractures were observed.

Clinical findings

At the 5-year examination interval 5.3% (SD, 16.5) of all implant surfaces harbored plaque (Table 6), 5% (10.6) of the peri-implant sites bled on probing and the mean probing depth was 3.1 mm (0.8). Close to 80% of all peri-implant sites had a probing depth of $\leqslant 3$ mm and only 5.3% had a PPD value of $\geqslant 6$ mm. The mean width of the keratinized mucosa at the buccal aspect of the implants was 1.9 mm (1.3), with 19% of the sites showing < 1 mm, 25% 1 mm and 56% $\geqslant 2$ mm of keratinized mucosa.

Table 6. Clinical conditions at 5 years (subject level; $n = 51$)

Plaque score	5.3% (16.5)
Bleeding sites	5.0% (10.6)
PPD (mm)	3.1 mm (0.8)
$\leqslant 3$	79.8% (26.1)
4–5	14.9% (20.7)
$\geqslant 6$	5.3% (13.8)
Keratinized mucosa – width (buccal aspect)	1.9 mm (1.3)

Mean values (standard deviation).
PPD, probing pocket depth.

Radiographic findings

For all implants, radiographs were available and readable at all examination intervals. Radiographic signs of loss of osseointegration were not found at any of the implants during the 5-year observation period.

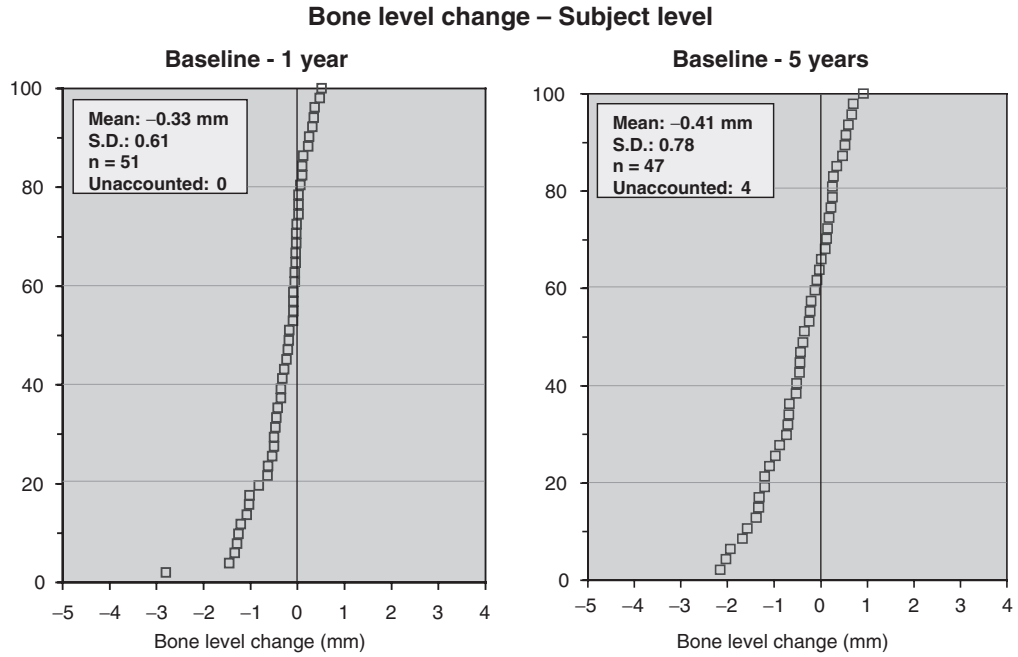

Fig. 4. Cumulative distribution of the subjects according to mean peri-implant bone-level change between baseline and 1 and 5 years, respectively.

Table 7. Mean bone-level change (SD) from the time of FPD connection (baseline)

	Subject level		FPD level		Implant level	
	n	bone-level change	*n*	bone-level change	*n*	bone-level change
Baseline to						
1 year	51	− 0.33 (0.61)	56	− 0.33 (0.61)	148	− 0.31 (0.81)
2 years	50	− 0.25 (0.64)	55	− 0.25 (0.63)	145	− 0.23 (0.84)
3 years	49	− 0.35 (0.76)	54	− 0.34 (0.75)	144	− 0.33 (1.02)
4 years	47	− 0.41 (0.76)	52	− 0.40 (0.75)	139	− 0.39 (1.04)
5 years	47	− 0.41 (0.78)	52	− 0.41 (0.76)	137	− 0.41 (1.01)

FPD, fixed partial denture.

Fig. 3 presents the frequency distribution at baseline of the peri-implant bone level of the 56 FPDs and 148 implants. The *bone-to-implant contact level* was located on average 1.18 mm (FPD level) and 1.17 mm (implant level) apical of the reference point on the implant. Only about 10% of the implants were judged to have the *bone-to-implant contact level* at the edge of the implant. At 66% (FPD level) and 42% (implant level) the marginal bone level was found to be $\geqslant$1 mm apical of the reference point on the implant.

Overall bone-level alterations

The mean peri-implant bone-level change that occurred during the 5 years of monitoring is described in Table 7 on the subject, the FPD and the implant level. During the first year in function there was on an average 0.33 (0.61) mm of marginal peri-implant bone loss on the subject and FPD levels and 0.31 (0.81) mm on the implant level. During the subsequent 4 years, the peri-implant bone-level alterations were small. The calculated annual change in peri-implant bone level was − 0.02 (0.15) on subject and FPD levels and − 0.03 (0.20) on the implant level. Thus, the mean total bone-level change over the 5-year interval amounted to 0.41 mm on all three levels of analysis.

Figs 4 (subject level), 5 (FPD level) and 6 (implant level) present the cumulative % of subject/FPDs/implants that exhibited varying amounts of bone-level change during the 5 years of observation. Between baseline and year 1, no subjects or FPDs were lost and no implants were explanted. During this interval 28% of the subjects, 30% of the FPDs and 45% of the implants had not experienced any bone loss. The proportion of implants that exhibited 1 mm peri-implant bone-level reduction was less than 20%. The number of subjects, FPDs and implants that displayed >2 mm bone loss was one (subject and FPD levels) and eight (implant level).

Between baseline and 5 years, four subjects were lost to follow-up, three FPDs were removed and finally three implants were explanted and eight could not be accounted for (Figs 4–6). Thirty-six percent of the subjects, 46% of the FPDs and 45% of the implants showed no bone-level reduction. Further, during the 5-year interval 23% of subjects, 20% of FPDs and 29% of implants exhibited a bone-level reduction that was $\geqslant$1 mm. The number of subjects, FPDs and implants that displayed >2 mm bone loss after 5 years was two (subjects and FPD levels) and 15 (implant level).

Machined versus Tioblast® surfaces

The mean bone-level change that took place during the 5 years of monitoring at implants with a machined (M) and implants with a Tioblast® (T) surface is reported in Table 8 and Fig. 7. Out of 73 M implants, two were explanted and

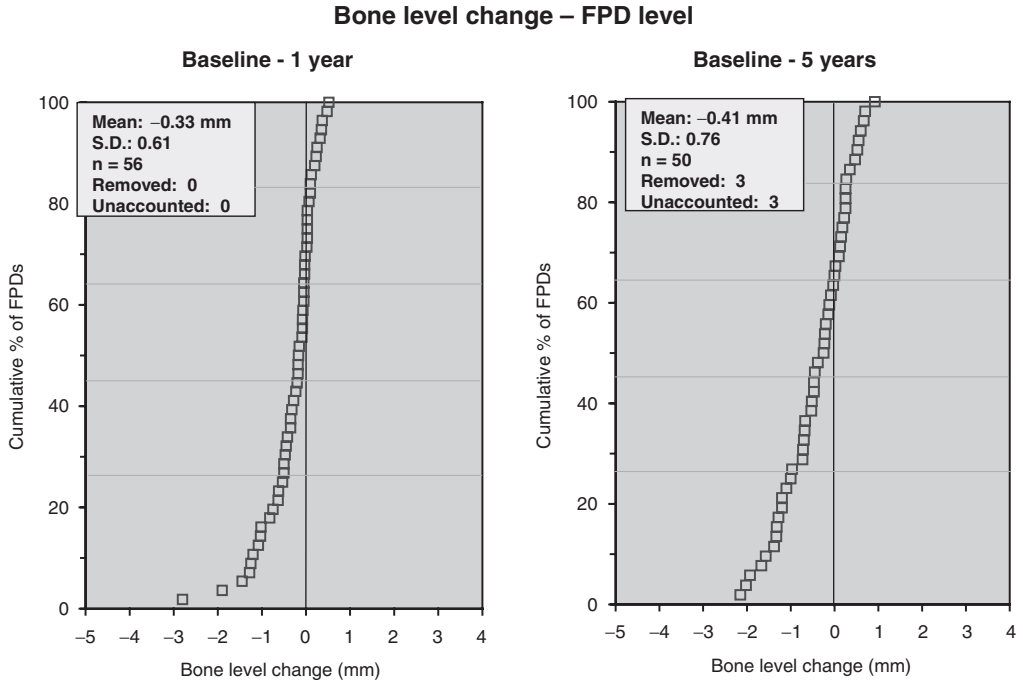

Fig. 5. Cumulative distribution of the fixed parital dentures (FPDs) according to mean peri-implant bone-level change between baseline and 1 and 5 years, respectively.

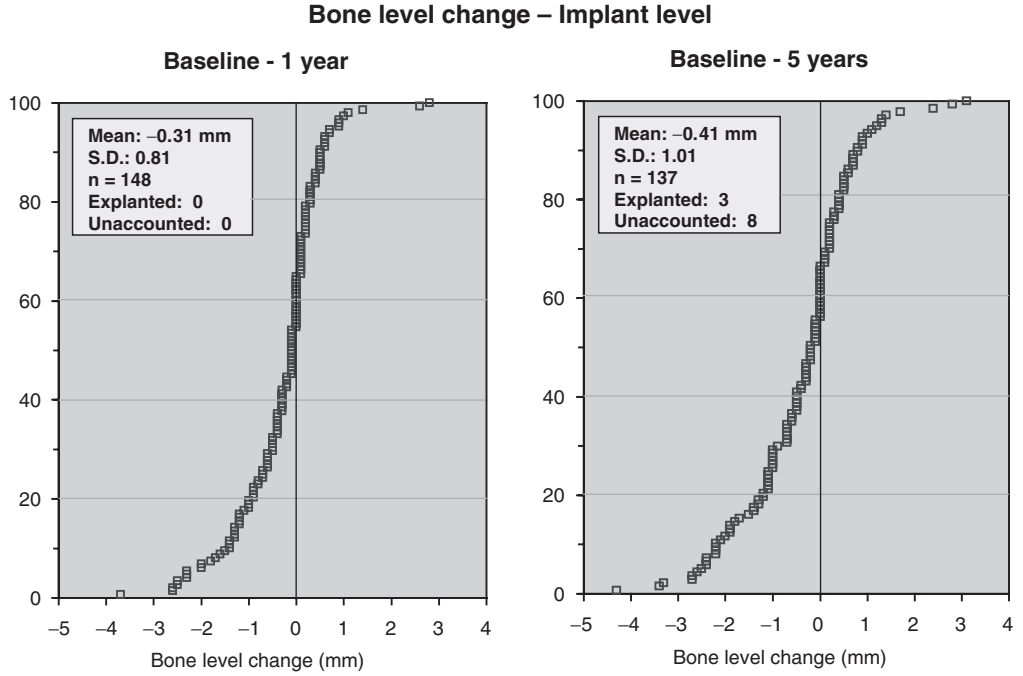

Fig. 6. Cumulative distribution of the implants according to mean peri-implant bone-level change between baseline and 1 and 5 years, respectively.

four could not be accounted for, while one out of 75 T implants was explanted and four were lost to follow-up. In the interval between baseline and year 1 (Table 8) the M implants lost on average 0.29 mm of bone height while the corresponding figure for the T implants was 0.33 mm ($p > 0.05$). In the interval between baseline and 5 years, the M and the T implants lost on average 0.33 and 0.48 mm, respectively ($p > 0.05$). Hence, the calculated annual bone loss after the first year in function was 0.01 mm for the M and 0.04 mm for the T implants. Forty-one percent of the T implants exhibited no bone loss at 5 years, whereas the corresponding figure for the M implants was 46%.

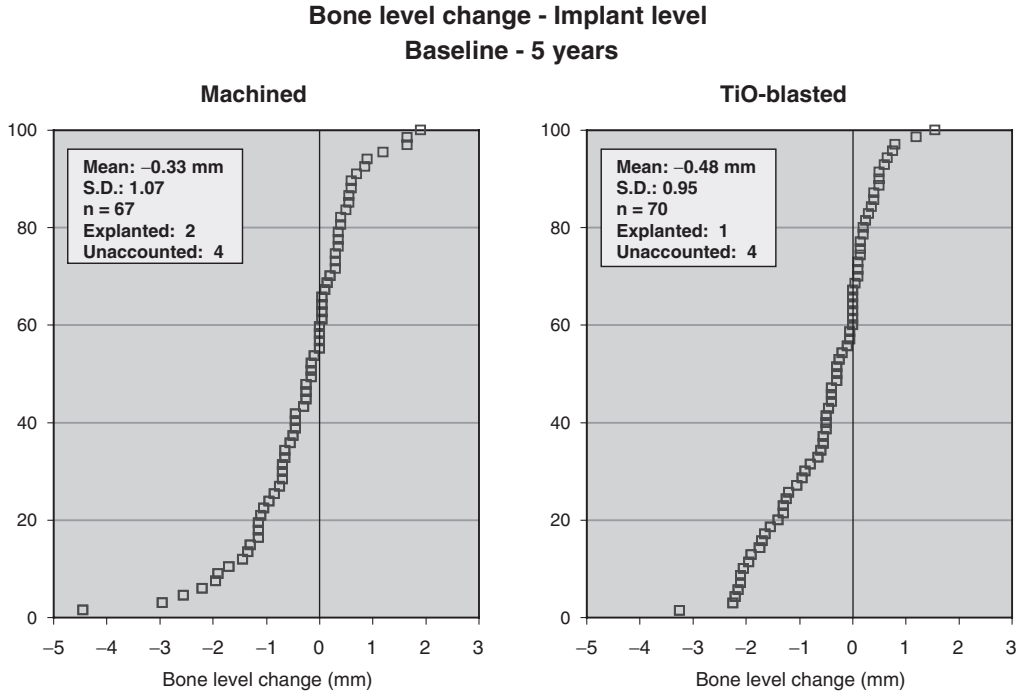

Fig. 7. Cumulative distribution of machined and Tioblast® implants according to mean peri-implant bone-level change during 5 years.

Table 8. Mean bone-level change (SD) from baseline to 5 years with regard to type of implant surface (implant level; $n = 148$).

	Machined		TiO-blasted	
	n	bone-level change	*n*	bone-level change
Baseline to				
1 year	73	– 0.29 (0.85)	75	– 0.33 (0.78)
2 years	71	– 0.22 (0.90)	74	– 0.28 (0.78)
3 years	71	– 0.27 (1.10)	73	– 0.40 (0.95)
4 years	69	– 0.32 (1.09)	70	– 0.46 (0.99)
5 years	67	– 0.33 (1.07)	70	– 0.48 (0.95)

Table 9. Mean bone-level change (SD) from baseline to 5 years with regard to jaw (FPD level; $n = 56$)

	Maxilla		Mandible	
	n	bone-level change	*n*	bone-level change
Baseline to				
1 year	31	– 0.42 (0.75)	25	– 0.22 (0.37)
2 years	30	– 0.35 (0.74)	25	– 0.12 (0.44)
3 years	29	– 0.52 (0.85)	25	– 0.14 (0.55)
4 years	29	– 0.60 (0.82)	23	– 0.16 (0.57)
5 years	28	– 0.61 (0.82)	22	– 0.15 (0.60)

FPD, fixed partial denture.

Implants in the maxilla versus mandible

The bone-level change (FPD level) that occurred between baseline and 5 years was more pronounced in the maxilla than in the mandible (Table 9 and Fig. 8). Thus, in this interval there was a mean loss of bone in the 28 remaining FPDs in the upper jaw (two were removed and one was unaccounted) that amounted to 0.61 mm (0.82) while the corresponding figure for the remaining 22 FPDs (one was removed and two were unaccounted) in the mandible was 0.15 mm (0.60). This difference was statistically significant ($p = 0.028$). Thirty-eight percent of the FPDs in the maxilla showed a mean bone loss of $\geqslant 1$ mm compared with 9% for the FPDs placed in the mandible.

Smokers versus non-smokers

Table 10 describes the amount of peri-implant bone-level change that occurred in non-smokers and smokers. Both in the interval between baseline and 1 year, and baseline and 5 years smokers exhibited more bone loss than non-smokers (0.41 versus 0.30 and 0.76 versus 0.22 mm, respectively). The difference in bone-level alteration in baseline to 5-year interval between non-smokers and smokers was statistically significant ($p = 0.022$). A mean bone loss of $\geqslant 1$ mm was observed in 44% of the smokers compared with 13% in the group of non-smokers (Fig. 9).

The multivariate analysis, having bone-level change at 5 years as dependent variable and smoking habits and jaw of treatment as explanatory variables, revealed a significant effect of the combined variables ($p = 0.023$, $R^2 = 0.14$); however, none of the in-

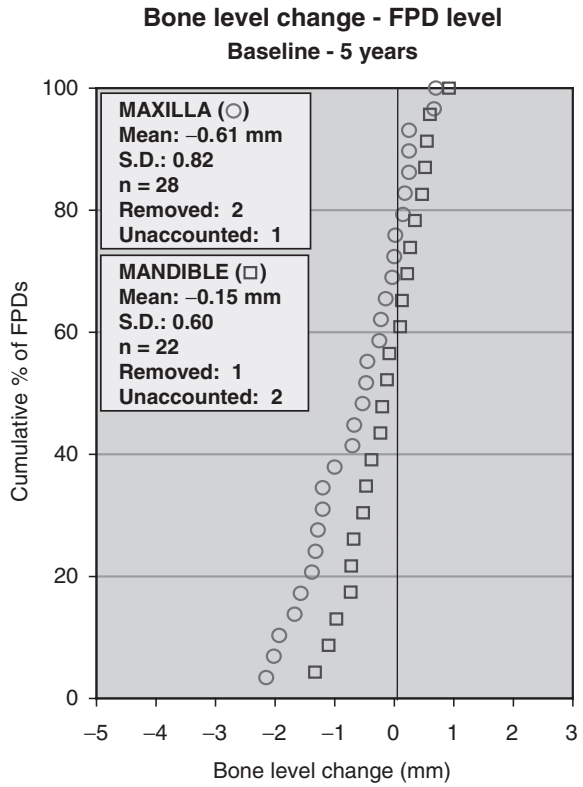

Fig. 8. Cumulative distribution of the fixed partial dentures (FPDs) in the maxilla and mandible, respectively, according to mean peri-implant bone-level change during 5 years.

Table 10. Mean bone-level change (SD) from the time of FPD installation (baseline) with regard to smoking habits (subject level; $n = 51$)

	Non-smokers		Smokers	
	n	bone-level change	*n*	bone-level change
Baseline to				
1 year	34	− 0.30 (0.51)	17	− 0.41 (0.78)
2 years	33	− 0.16 (0.56)	17	− 0.44 (0.76)
3 years	32	− 0.17 (0.65)	17	− 0.68 (0.85)
4 years	31	− 0.23 (0.67)	16	− 0.76 (0.82)
5 years	31	− 0.22 (0.69)	16	− 0.76 (0.84)

dividual explanatory variables reached statistical significance in the model. The proportion of restored maxillary jaws was 76% in smokers compared with 46% in non-smokers.

Discussion

The results of the present randomized, controlled clinical trial demonstrated that bone loss during the first year of function, as well as annually thereafter, was small and did not vary between implants with machined- or rough-surface designs. In fact, about 78% of the implants with a machined surface and about 73% of the implants with a Tioblast® surface exhibited < 1 mm bone loss during the 5 years of function (Fig. 6). In all respects, this observation is in agreement with previous findings (Gotfredsen et al. 1995, van Steenberghe et al. 2000, Engquist et al. 2002) from clinical trials including the use of Astra Tech® implants. It may be concluded, therefore, that provided the implants are submerged during healing periods of 3–6 months prior to loading (Brånemark et al. 1977), the surface design of the fixture has no obvious influence on bone-level change during function.

It was documented in animal studies that implants with a rough surface following healing and osseointegration exhibited greater bone-to-implant contact and better removal torque values than implants with a smooth surface (for review see Cochran 1996, 2000). Further, Cochran (2000) in a series of clinical trials showed that implants with a roughened SLA surface (ITI® System; Straumann, Waldenburg, Switzerland) could be predictably restored and loaded already after 6 weeks of healing. It remains to be documented in clinical studies, whether implants with a rough surface are superior to machined-surfaced implants in terms of early loading.

The overall failure rate at 5 years in the present study was 5.9% on the subject level, 5.3% on the FPD level and 2.7% on the implant level. These failure rates are low or similar to data describing treatment outcome in partially edentulous subjects (e.g. Jemt & Lekholm 1993, Nevins & Langer 1993, 1995, Lekholm et al. 1994, 1998, Ellegaard et al. 1997, Lindh et al. 1998, Bahat 2000, Behneke et al. 2000, Yi et al. 2000, Brägger et al. 2001, Gotfredsen & Karlsson 2001, Quirynen et al. 2001) and confirm the concept that implants can be used with great success in the occlusal rehabilitation in this type of patients.

The current subject sample included patients who had been treated for moderate-to-advanced chronic periodontitis (Fig. 10). Prior to as well as after implant placement and prosthetic rehabilitation, all subjects were enrolled in a careful maintenance program based on self-performed plaque control and needs-related professional tooth and implant cleaning. In this well-maintained group of patients, the annual amount of bone-level change was small (0.02 mm/year during the final 4 years), the implant survival rate was high (97.3%) and only 15 implants (11%) had suffered > 2 mm bone loss during the 5-year interval. In a similar group of periodontitis-susceptible patients, with implant-supported FPDs in the posterior maxilla, who were not included in a plaque control program during maintenance (Hardt et al. 2002), the implant failure rate (5 years) was 8% and 62% of the implants exhibited a mean bone loss (5 years) of $\geqslant 2$ mm. Taken together, the findings of the current study and the observations presented by Hardt et al. (2002) clearly demonstrate that in periodontitis-susceptible patients supportive therapy is a *sine qua non* for the long-term success of implant therapy.

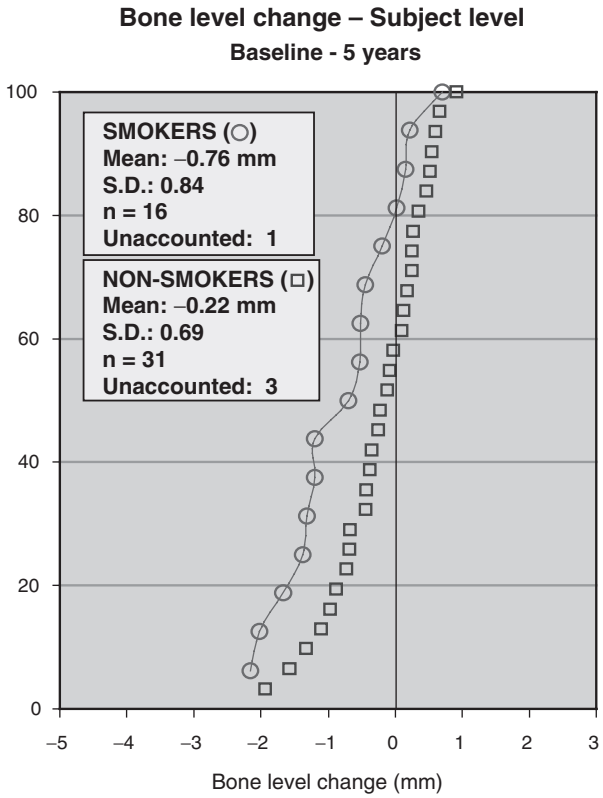

Fig. 9. Cumulative distribution of smokers and non-smokers according to mean peri-implant bone-level change during 5 years.

During the 5 years of function, 6.5% of the FPDs in the maxilla (two FPDs were removed) and 8% in the mandible (one FPD was removed and one was not accounted for) were classified as ''failures''. This proportion of ''failures'' is in agreement with data previously reported from a large number of prospective and retrospective studies describing the outcome of implant therapy in partially edentulous patients (for review see Esposito et al. 1998). Further, the clinical trials that included FPDs supported by Brånemark implants with varying time in function (1 month to 9 years), documented that implants in the maxilla and the mandible exhibited similar failure rates. In the present study it was observed, however, that the amount of peri-implant bone loss that occurred during the 5 years was significantly greater at implants placed in the maxilla (− 0.61 mm) than in the mandible (− 0.15 mm). This finding is not in agreement with peri-implant bone loss data previously reported from FPDs in partially edentulous subjects. Thus, Naert et al. (1992) and Lekholm et al. (1994, 1999) observed that the amount of bone loss that occurred at Brånemark implants after 6 and 10 years in the maxilla and in the mandible was similar. Further, Gotfredsen & Karlsson (2001) stated that the overall mean marginal bone loss at Astra Tech® implants that had occurred after 5 years of function varied between 0.21 mm (machined) and 0.51 mm (Tioblast®) in the maxilla and 0.22 and 0.52 mm in the mandible.

In the present sample of patients with moderate-to-advanced chronic periodontitis, the extraction of one or several periodontitis-involved teeth had resulted in marked buccal and lingual/palatal resorption of the bone plates at the edentulous site and the occurrence of a thin ridge. During surgery, the implants were inserted so that the marginal portion of the fixture was even with the marginal bone level at the mesial and distal surface. Especially in the maxilla, implant placement at a site with a reduced buccal, palatal dimension frequently resulted in the establishment of bone dehiscences of varying dimension at the facial and/or palatal aspects of the implants. There are reasons to suggest that over time this uneven outline of the marginal bone around the implants in the maxilla was leveled out by bone remodeling processes and a reduction of the bone height at the proximal surfaces. Such an explanation is in agreement with findings reported by Carmagnola et al. (1999) who, in a dog model, studied bone tissue reactions around implant placed in a compromised mandible. Following tooth extraction, the buccal bone plate was resected and a narrow ridge established. After 8 months of healing, implants were placed in the compromised site so that their lingual surfaces were invested in bone while about 4–5 mm of their buccal portion remained exposed. During the process of healing and during 4 months of function marked modeling and remodeling of the bone tissue around the implants took place. At the buccal surfaces some regrowth of bone occurred while at the lingual surfaces there was a substantial resorption of bone. As a result, the marginal level of osseointegration tended to become similar at all four aspects of the implants. Thus, the greater amount of peri-implant bone loss that occurred at the mesial and distal surfaces of the implants in the maxilla of the present sample than in the mandible may be explained by local anatomical features rather than by differences between the jaws regarding bone quality and force distribution during function.

Data presented in Table 10 and Fig. 9 illustrate that the amount of peri-implant bone loss that occurred in smokers during the 5-year interval was more pronounced than the corresponding change in non-smokers. During the first year of function, the peri-implant bone-level change was similar in the two categories of subjects, but in the second and third year smokers suffered increasing amounts of hard-tissue loss while in non-smokers the bone level remained almost unchanged. The finding that peri-implant bone loss in the smokers was significantly greater than in the non-smokers is in general agreement with previous findings (for review see Bain 2003). The conclusion that smokers over time may suffer more peri-impant bone loss than non-smokers must, however, be interpreted with caution. Firstly, the data in the literature that support this conclusion are based on treatments that have utilized implants with a machined surface. Secondly, the multivariate analysis performed in the current study revealed that the two variables *jaw of treatment* and *smoking* taken together had a significant effect on bone loss that occurred during the 5 years. However, none of

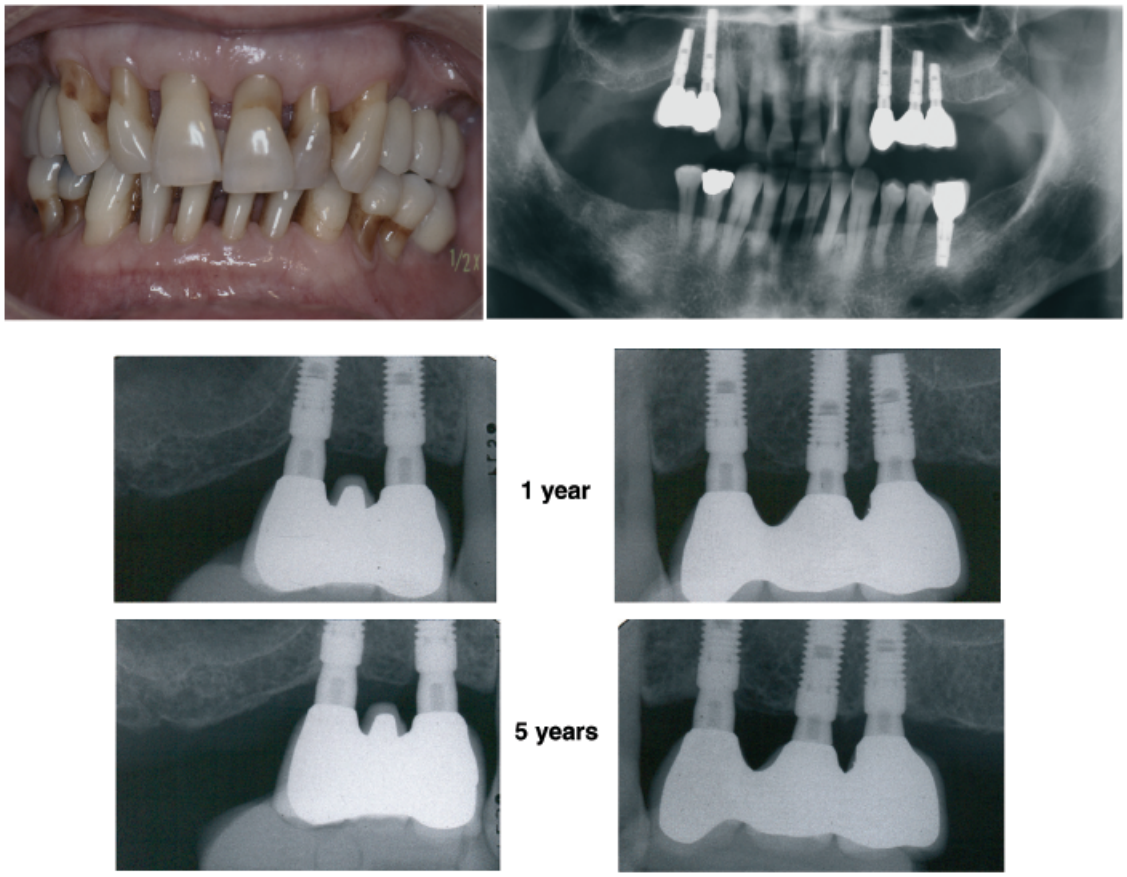

Fig. 10. Clinical and radiographic illustrations of one of a case with a mean periodontal bone level of 36%. The patient showed maintained peri-implant bone level over the 5 years of follow-up.

the two individual variables reached statistical significance in the model. In this context, it should be realized that 76% of all FPDs in smokers were placed in the maxilla while only 46% of the FPDs in non-smokers were placed this location.

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